# Clinical Evaluation Report

*in accordance with*

## Medical Device Regulation 2017/745 (MDR)

*and*

*MEDDEV 2.7/1 Rev. 4 for the*

## MBST Magnetic Resonance Technology

### Statement of Confidentiality

## Approval

The following individuals confirm that they agree with the content of this report:

| Name | Function, Role | Date, Signature |
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## Change Record

| Version | Approved | Author | Changes |
|---|---|---|---|
| n.a. | 14.02.2019 | Prof. Dr. Christian Melzer | Initial Version |
| n.a. | 13.02.2020 | Prof. Dr. Christian Melzer | describe changes |
| 1.0 | 23.11.2020 | Daniela Penn | Amendments according to MDR and MEDDEV 2.7/1 Rev. 4 requirements |

# Content

# Definitions and Abbreviations

Document specific abbreviations/definitions:

| Term | Description |
|---|---|
| BfArM | Bundesinstitut für Arzneimittel und Medizinprodukte |
| CER | Clinical Evaluation Report |
| FDA | Food and Drug Administration |
| GBCA | Gadolinium-based contrast agents |
| GSPR | General safety and performance requirements |
| IFU | Instructions for Use |
| kHz | Kiloherz |
| MEDDEV | Medical Device Guideline |
| MDD | Medical Device Directive 93/42/EEC |
| MDR | Medical Device Regulation (EU) 2017/745 |
| MRI | Magnetic resonance imaging |
| mT | Millitesla |
| n. a. | not available/applicable |
| NMR | Nuclear Magnetic Resonance |
| OCD | Osteochondritis dissecans |
| PEMF | Pulsating magnetic fields |
| PMS | Post Market Surveillance |

| Term | Description |
|---|---|
| PMCF | Post-Market Clinical Follow-up |
| STK | Safety-related recurrent technical inspection |
| TU | Treatment unit |
| VAS | Visual Analogue Scale |

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# 1 Executive Summary

This clinical evaluation assesses the performance and safety of the MBST Magnetzic Resonance Technology System (MBST) (class IIa devices) manufactured by MedTec Medizintechnik GmbH. They are active medical devices with external power supply. The MBST is used to treat painful, degenerative and/or pathological changes in the musculoskeletal system.

This new version of this clinical evaluation of the MBST was performed on the basis of clinical data pertaining to the evaluated devices.

Detailed information about documents and papers that have been used for this clinical evaluation report is enclosed in the literature references, reference documents, and literature (sections 17-19).

The Medical Device Regulation 2017/745 (MDR), Article 61, and MEDDEV 2.7/1 Rev. 4 have been considered for the preparation of this clinical evaluation report.

The literature search was conducted on PubMed with focus on the intended use, indications, and product claims (such as technical and procedural success of the devices, etc.).

All publications and literature from previous clinical evaluation reports (CER) have been included and evaluated. A new literature search has been conducted to cover the period 2020 since the last CER. In total, no further publications have been found.

All of the claimed indications have been covered and confirmed with clinical data on the literature route of this clinical evaluation and coming from clinical investigations conducted with the medical devices.

Adequate clinical performance of MBST was confirmed in all papers. In all applications and procedures, no side effects or complications occurred. This was confirmed by clinical data, and data obtained from adverse event databases.

Furthermore, the analysis of the Post-Market Surveillance (PMS) data of MedTec Medizintechnik GmbH revealed no results for the evaluated medical devices.

In conclusion, the results of risk management, clinical literature review, and post-market experience confirm its safety and performance of the evaluated medical devices.

Identified, reviewed, assessed and analyzed clinical data were evaluated adequately to provide evidence of conformity of the evaluated medical devices with the MDR.

Based on the risk analysis, benefits to healthcare professionals and patients outweigh the potential risks. The overall residual design and manufacturing risks, as well as the risk/benefit ratio of the devices (section 12) are fully acceptable.

# 2 Clinical Evaluation History

The MBST Magnetic Resonance Technology has been evaluated in previous clinical evaluation reports (CER) in the past. The last ones were issued in 2019 and in February 2020:

- 2019-2_CER_Scientific_Evaluation_of_MBST-Therapy_Melzer-Kullich_GB (reference: R1)
- 400431-V1.0_Clinical_Evaluation_Report_2020_GB (Reference: R2)

This CER evaluates the clinical performance, safety and the clinical benefit of the MBST Magnetic Resonance Technology according to the MDR requirements. It supersedes the previous clinical evaluations and is deemed to be version 1.0.

This CER is based on clinical data pertaining to the evaluated device. Clinical investigations have been conducted and are currently conducted and planned with the device under evaluation. The relevant literature search results of the previous CERs are included herein and, in addition, another literature search is conducted for the period between January 2020 and November 2020 since the last one is dated 02/2020.

The safety database search is conducted for an unlimited period of time since there is no search in the previous CERs and this is a new version 1.0 according to the MDR requirements.

# 3 Purpose of this Document

## 3.1 Scope

The clinical evaluation of medical devices is an essential element of the conformity assessment for CE marking of medical devices. According to Medical Device Regulation (EU) 2017/745) (MDR), Annex XIV Part A, the evaluation of clinical performance and safety must be based on 'clinical data' and is required for all medical device classes. This clinical evaluation report (CER) and the clinical data on which it is based, verifies the clinical safety and performance of the following device:

| | |
|---|---|
| **Product Name** | MBST Magnetic Resonance Technology Systems (in the following referred to as MBST Magnetic Resonance Technology – MBST) |
| **Product Image** |  <br>Image example: ARTHRO- SPIN-FLEX<br>A detailed description of all product variants can be found in section 4.5. |

| | |
|---|---|
| **Product Models** | • MBST® OpenSystem350 / MBST® OpenSystem700<br>• MBST® OsteoSystem (ODM)<br>• MBST® ProMobil<br>• MBST® ArthroSpin Flex<br>• MBST® ArthroSpin Lift<br>• MBST® OsteoSpin<br>all including indication-specific therapy cards |
| **Classification** | Class IIa and rule 9 according to annex VIII MDR |
| **Software Versions** | See reference R11 |
| **Manufacturer(s)** | MedTec Medizintechnik GmbH<br>Sportparkstr. 9<br>D-35578 Wetzlar<br>Germany |

**Table 1: Medical device under evaluation**

With the review of identified clinical data it is demonstrated that:

- the device in question achieves its intended performance during normal conditions of use and
- is suitable and effective for the intended use as specified by the manufacturer,
- the known and foreseeable risks and any adverse effects are minimized and acceptable when weighted against the benefits of the intended performance,
- any claims made about the device's performance and safety are supported by suitable evidence.

The CER is part of the demonstration of conformity with the General Safety and Performance Requirements, MDR, Annex I and, therefore, part of the technical documentation.

## 3.2 New Conclusions derived from PMCF

Currently, further studies are in progress and planning. In detail, these are as follows:

1 Dr. med. Mazin Al Janabi, Dr. med. Rakshinda Mujeeb, Mediclinic Middle East, Dubai, UAE: MBST Magnetic Resonance Therapy in Osteoporosis The study has a double-blind, placebo-controlled and randomised setting and includes 60 patients.

2 PD. Dr. Bibiane Steinecker-Frohnwieser, Univ.-Doz. Dr. Werner Kullich Sonderkrankenanstalt Rehabilitationszentrum Groebming of the pension insurance company Austria: Magnetic resonance for reduced bone density, bone degeneration in leg amputees; placebo-controlled study with 140 patients

Following this CER, a PMCF Plan according to the MDR requirements will be compiled.

# 4 Product Description

## 4.1 Intended Use

The MBST® Magnetic Resonance Therapy System is used to treat painful, degenerative and/or pathological changes in the musculoskeletal system.

In principle, all patients who have been diagnosed with a typical indication for MBST treatment (see treatment zones and typical indications) may be treated with such treatment as long as a preliminary examination by a specialist (doctor) establishes that there are no known contraindications for them.

The MBST device exclusively is intended for usage in professional treatment centers/facilities. Furthermore, the device is permitted to be operated by professional, qualified personnel only. Before starting first treatment, the operator has to pass a user training by a manufacturer's authorised employee successfully, which shall be documented.

The series of treatment recommended by the manufacturer consists of a defined number of sessions of therapy each lasting 60 minutes. Only one therapy session should ever be performed per day with the recommended treatment duration and a treatment unit.

(References: R3)

## 4.2 Indications

With the exception of MBST OsteoSystem (ODM) and MBST OsteoSpin, all other therapy device variants can only be used for treatment of one part of the body at the time.

The possible treatment zones of MBST devices result from the device-specific construction. In this way, patients of almost any age and height can be treated efficiently. The treatment zone is defined in an individual therapy plan before the start of therapy. The plan must take into consideration the medical prescription stating the indication (including diagnosis and main symptoms) and the aim of the therapy as well as the diagnostic findings. The procedure is adapted to the patient's reaction. This applies in particular with regard to the positioning of the patient as well as the duration and scope of treatment.

The treatment zones depending on the therapy device are defined as follows:

- ArthroSpin Flex and OpenSystem 700 are treatment couches for the treatment areas shoulder, torso, spine, intervertebral discs, hip, leg, double knee. The extraordinary design and the open construction offer a lot of free space for the patients. Thanks to the variable entry or the positioning system, physically handicapped patients as well as obese and claustrophobic patients can also be treated.
- ArthroSpin Lift and OpenSystem350 are treatment units for the treatment zones arm, elbow, hand, fingers, leg, knee, foot and toes. The mobile magnetic resonance unit can be

used variably. The patient takes a seat in the treatment chair and the arm or leg that shall be treated can be optimally positioned.
- OsteoSystem and OsteoSpin are treatment couches with a treatment field covering the whole body.
- ProMobil is a flexible magnetic resonance treatment system for the treatment zones spine, torso, arm, shoulder, elbow, hand, fingers, leg, hip, knee, foot and toes. The mobile magnetic resonance control unit and up to 2 magnetic resonance applicators allow treatment of the respective treatment zones. In addition, a large-scale applicator can be order as accessory.

Thereof, the following indications result:

The range of treatable indications includes, among others, the following conditions and associated pain:

- Degenerative bone and joint conditions such as osteoarthritis, cartilage damage, degenerative osteoarthritis, chondropathy, partial treatment of osteoporosis (whole-body treatment is only possible with OsteoSystem and OsteoSpin)
- Injuries of joints
- Bone fractures
- Tendopathy
- Injuries of muscles, tendons and ligaments

(References: R3)

## 4.3 Contraindications

In normal therapeutic conditions, the MBST magnetic resonance therapy devices pose no acute or chronic health risks. However, an increasing number of patients has active implants. Even though no specific cases have become known, it cannot generally be ruled out that functional disorders of the implants may occur during the therapy or that undesirable effects in or on the body (e.g., sensation of heat) may show in connection with an MBST treatment which in the worst case might cause damage or serious injury to individual patients. Therefore, every patient has to be questioned about possible contraindications before the start of a treatment.

An MBST therapy must not be applicated if the following conditions are present:

- Implanted infusion, pain or insuline pumps or
- Cochlear implants or any other implanted neurostimulators etc. that come into the active treatment field or are in immediate proximity of the treatment zone: it cannot generally be ruled out that the high-frequency pulses used might induce a short-term weak current flow in these electrical conductors in individual cases (depending on the material, its geometry, biological characteristics of the patient, frequency and position of the implant in relation to the treatment field).
- However, modern pacemaker units and also the electrodes (probes) are designed in such a way nowadays that they are not negatively impacted or even damaged by the magnetic field in the MRI system and also do not overheat. Various types of pacemakers are available at the

moment which are classified as suitable for MRI resp. suitable for MRI to a certain extent. In these cases, they are no contraindication. In cases of heart valve prosthesis, an MBST therapy is usually possible depending on the type and function of the prosthesis.

- In order to assess whether an MBST therapy can be carried out despite a medical implant of a pacemaker or defibrillator system (e. g., ICD systems), the manufacturer is dependent on information about the material used (especially name and number of models, information about MRI suitability). In these cases, the manufacturer of said medical implants must have confirmed that contact with a magnetic field does not have a negative impact on their functioning. Otherwise, it cannot be ruled out that the medical implants may be damaged during the treatment or that interactions with the electromagnetic fields of the therapy system may cause damages to the patient.

In case of doubt, patients with ferromagnetic foreign objects (e. g. shards of metal or vascular clips made of ferromagnetic material) that come into the active treatment field should also be advised against treatment.

Negative effects of magnetic resonance therapy during pregnancy have not yet become known. An imaging MRI which uses a much higher field strength is usually possible in the case of pregnant women. However, since possible effects of an NMR therapy on pregnancy have not yet been sufficiently investigated, pregnant women should not be treated with MBST magnetic resonance therapy simply for reasons of safety.

In the case of patients with one of the following pre-existing conditions, the treating specialist should be consulted before the start of treatment in order to determine any potential relative contraindications for an MBST therapy in an interdisciplinary decision for this individual case, taking into account the indication and the appropriate safety measures.

- Cardiac diseases, cardiac arrythmias,
- Tumors in the treatment zone, leukemia
- HIV infection
- Bacterial infections
- Active rheumatic episode

A therapy may still be possible after strict benefit-risk balance by the treating physician, for example if the relevant pre-existing condition is not within the intended treatment zone (the recommended distance is 40 cm around the treatment field) or if the expected benefit of the therapy outweighs potential risks.

MBST therapy does not affect the fitness to drive and to operate machinery. Interactions with other therapeutic measures are currently unknown. There is no age limit.

The contraindications and precautions listed above also apply to personnel/operators and, if applicable, independent third parties to which the listed points apply, provided that they are within a range of 40 cm of the active treatment area and one or more of the contraindications described above are applicable.

(References: R3)

## 4.4 Precautions and Warnings

Compliance with the precautions and warnings in the instructions for use (IFU) of the medical devices ensures the safe use and application. (References: R3)

In the following, the precautions and warnings for the MBST devices are detailed. (References: R3)

The IFUs for ArthroSpin Flex and ArthroSpin Lift as well as for OsteoSpin use alerts and attention remarks. They are detailed in the following:

**Attention!**

Dangers from non-compliance with these instructions for use:

Failure to comply with information in these instructions for use may result in a potentially hazardous situation for the patients, the operator or the product itself. Failure to comply with the information and notes in these instructions for use – or even parts thereof – may give rise to the following hazards in particular:

➢ failure of important product features, thus leading to an inefficient therapy or even complete nonappearance of therapy success

➢ Possible danger to persons due to mechanical, electrical or other influences – in all forms and with all consequences.

NEVER leave children and any accompanying animals unattended near our therapy device, regardless of whether it is in operation or not.

The cushion of the treatment unit should not be used to store or transport things on it. While moving/relocating the therapy device, there should be nothing on the cushion, as these parts may fall off during transport and get damaged, or possibly even cause injury if they fall on the feet of the operator or other people nearby.

The contraindications and precautions listed above also apply to personnel/operators and, if applicable, independent third parties to which the listed points apply, provided that they are within a range of 40 cm of the active treatment area and one or more of the contraindications described above are applicable.

The therapy device can only manage one active treatment at a time! This means that it is NOT possible to treat another patient while a treatment is paused and then resume the treatment of the first patient from the time of the interruption.

Please advise patient never to put hands in the existing gaps. There is a risk of injury from getting them caught while opening and closing MBST® OsteoSpin. / Please keep in mind at all times that there is a permanent risk of injury from pinching/clamping of the fingers between the brake arm and the housing of the vertical pillar and point out to the patient or anyone else in the treatment room, never to place their fingers/hands near or in the present gap.

When moving the device, make sure that no persons stand in the way of the wheels, as their feet could get caught under the device wheels (danger of foot injury/crushing) and that no obstacles are rolled over as much as possible (e.g., risk of cable pinching/damage). There should also be no small, pointed objects on the floor, which can get stuck in the wheels and block their mobility or locking mechanism.

When moving the device, please make sure that there are no objects on the cushion of the treatment unit, as these can fall down and break. These would also pose a risk of injury to the operator or nearby persons if heavy and/or sharp objects fall from the cushion onto someone's feet.

When adjusting the height of the treatment unit, please keep in mind that there is a risk of injury from crushing/pinching fingers/hands in the guide area or brush gap for the height adjustment of the treatment unit, and also advise the patients to never insert the fingers/hands into the present brush gap.

When moving the treatment cushion, please do not grasp into the guide rail on the underside of the sliding unit but use only the laterally mounted handhold to adjust the cushion position, as otherwise there is a risk of squeezing your fingers.

When fixing the treatment cushion in a vertical position, take extra care to tighten the rotary knob sufficiently, so that the cushion cannot accidentally slip down from its position. In this case, there may be a risk of injury from crushing/pinching an underlying foot. Please also inform the patients about this potential risk so that he/she does not position his/her foot directly under the applicator unit.

Please ensure that no liquids and/or detergents leak into the device, as this could cause malfunctions or total failure of the device.

**Alert!**

When moving/shifting/positioning the two applicators, make sure that hands and/or feet do not get into the guide area (brush gap) of the applicators, otherwise there is a risk of injury from get them caught.

Never insert foreign objects into the unit. This poses a safety risk, can damage the therapy device, and could also lead to malfunctions or a life-threatening electric shock. Please also inform patients and other people in the treatment room.

Damaged mains cables can cause smouldering fires or deliver a potentially fatal electric shock and must not be used any further.

Since the MBST is a “Medical Electrical Device” (abbreviated to “ME device”) of the protection class I, exclusive connection of the device to an electrical grid with a functioning protective earth conductor (PE) to prevent the risk of an electric shock has to be ensured!

Please always observe the safety instructions (chapter 2), especially those concerning electrical safety for operators and patients during putting into operation as well as usage later on. / Make sure that you always follow the safety instructions in Section 2 – especially with regard to

electrical safety for users and patients – when putting the device into operation and later on, when using the device.

If the device is connected to the mains supply using a multiple socket (see page 10), the degree of electrical safety achieved no longer corresponds to the results tested by the manufacturer and can thus possibly lead to an increased safety risk.

When moving/shifting/positioning the two applicators, make sure that hands and/or feet do not get into the guide area (brush gap) of the applicators, otherwise there is a risk of injury from get them caught. Please also advise the patient never to put his hands in the existing brush gap for the guide rails of the applicator unit.

Before cleaning the MBST device, always disconnect it completely from the mains supply by unplugging the mains plug to avoid the risk of electric shock.

In the event of failure, disconnect the device immediately and completely from the mains supply by pulling out the mains connection and contact your customer service. Repairs of parts of the MBST may only be carried out by trained specialists.

The device or the lying surface may only be opened by competent, qualified personnel authorized by the manufacturer (service technicians), as other proceeding can pose the danger of electric shock from high-voltage parts inside the housing.

The IFUs for ODM and OpenSystem350/700 use **warning** remarks. They are detailed in the following:

Patients with:

- Heart diseases / Cardiac arrhythmia
- Tumors in the treatment area
- Leukemia
- Human immunodeficiency virus
- Bacterial inflammation
- Coasting phase rheumatism

may only be treated with the MBST and may only be in the immediate vicinity of the MBST applicator when active, pending a consultation by the active doctor. Applicator when active, pending a prior consultation with the acting doctor. The prohibitions and warnings also apply to personnel and/or third parties with active implants who are equally at risk.

This group of people must observe a minimum clearance of 40 cm around the MBST applicator.

Warning: To avoid the risk of electric shock, the device must only be connected to supply mains fitted with a protective earth conductor. Do not connect the mains cable to a multiple-socket outlet.

Avoid routing cables across the foot-traffic areas. There is a risk of tripping over and the cables can be damaged! Do not connect the mains cable to a multiple-socket outlet.

Never leave children and accompanying animal unsupervised in near the MBST-Therapy-System.

During the treatment, don't move around with the MBST. There is a risk to tilt or to trip and the cables can be tangled.

When positioning the patient using the mobile couch of the MBST, make sure that hands and feet are kept clear of the guide area of the couch at all times; there is a risk of fingers or toes becoming trapped.

The operator/patient must not be in simultaneous physical contact with the MBST®-System and other live components/devices outside the MBST system. This is because a short circuit with external components/devices could cause the current to flow through the patient or the operator. The operator must also avoid touching the patient and the MBST system simultaneously or other live components/devices outside the MBST-System simultaneously.

Always remove the power plug before undertaking any cleaning operations to the control unit!

Ensure that the control unit is not operational when you are cleaning the applicator!

Remove the mains plug before changing the fuses.

## 4.5 Product Overview

The MBST Magnetic Resonance Therapy Systems are a group of devices which are characterized by the fact that they are all based on the same technology and that the performance parameters which are achieved in the treatment zone and can affect a patient are comparable for all device variants (radio frequency strength: max. 1W in resonance, radio frequency range: 14–18 kHz; magnetic field strength: max. 1 micro-Tesla (directly at the casing of the applicators or max. 3–4mT directly at the coil).

The static values of the magnetic fields are only about 1 order of magnitude above earth's natural magnetic field and about 2 to 3 orders of magnitude below the field strength of NMR devices. The dynamic characteristics of the magnetic fields are also smaller by orders of magnitude than those of imaging NMR devices.

For all devices listed above, the underlying physical active principle is absolutely identical, and the field-generating character of the individual product variants does not differ at all. Only the volume of the generated resonance field and thus of the treatment field differs between the respective device variants. This is due on the one hand to the size and arrangement of the applicators and on the other hand to the electrical performance parameters required for this which are permanently preset in the respective control unit. In some circumstances, the space available in the user's practice may be a deciding factor for choosing a certain device variant.

Thus, the individual devices differ mainly in the shape and design of the treatment unit and consequentially in the size of the maximum achievable treatment field and thus in the body parts that can be treated with the respective device variant.

These different variants are detailed in the following section.

## 4.6 Product Variations/Configurations

### 4.6.1 ArthroSpin Flex

The medical device consists of several individual components which on its own are not a medical device, but only become one trough their combination. The two applicators A + B including the sweep coils, the RF applicator - which is located below the lying surface - and the lying surface itself are classified as applied parts (AP).

All individual components belonging to the complete medical device MBST® ArhroSpin Flex are listed below:

| **MBST® ARTHRO·SPIN·FLEX** | **[complete device]** |
|---|---|
| MBST® ARTHRO·SPIN·FLEX control device | [control unit] |
| MBST® ARTHRO·SPIN·FLEX applicator A | [applicator with operating element] |
| MBST® ARTHRO·SPIN·FLEX applicator B | [applicator without operating element] |
| MBST® ARTHRO·SPIN·FLEX applicator RF | [RF applicator] |
| MBST® ARTHRO·SPIN·FLEX treatment couch, consisting of: | [complete component] |
| MBST® ARTHRO·SPIN·FLEX aluminum frame | [part of the treatment couch] |
| MBST® ARTHRO·SPIN·FLEX lying surface | [part of the treatment couch] |
| MBST® ARTHRO·SPIN·FLEX complete casing | [part of the treatment couch] |
| MBST® ARTHRO·SPIN·FLEX connection cable | [electrical connection between components] |
| MBST® ARTHRO·SPIN·FLEX mains cable_XX | [suitable for country-specific power grid] |

**Table 2: Individual components ArthroSpin Flex**

### Overview


| | |
|---|---|
| **A** | MBST® ARTHRO·SPIN·FLEX treatment couch (Behandlungsliege) |
| **B** | MBST® ARTHRO·SPIN·FLEX lying surface (Liegefläche) |
| **C** | Applikatorbeleuchtung (blau): pulsierende Beleuchtung für Behandlungszone |
| **D** | MBST® ARTHRO·SPIN·FLEX Sweep-Applikatoren A und B |
| **E** | MBST® ARTHRO·SPIN·FLEX Display |
| **F** | Führungsbereich der Applikatoren A+B |

**Figure 1: Overview of ArthroSpin Flex and glossary**

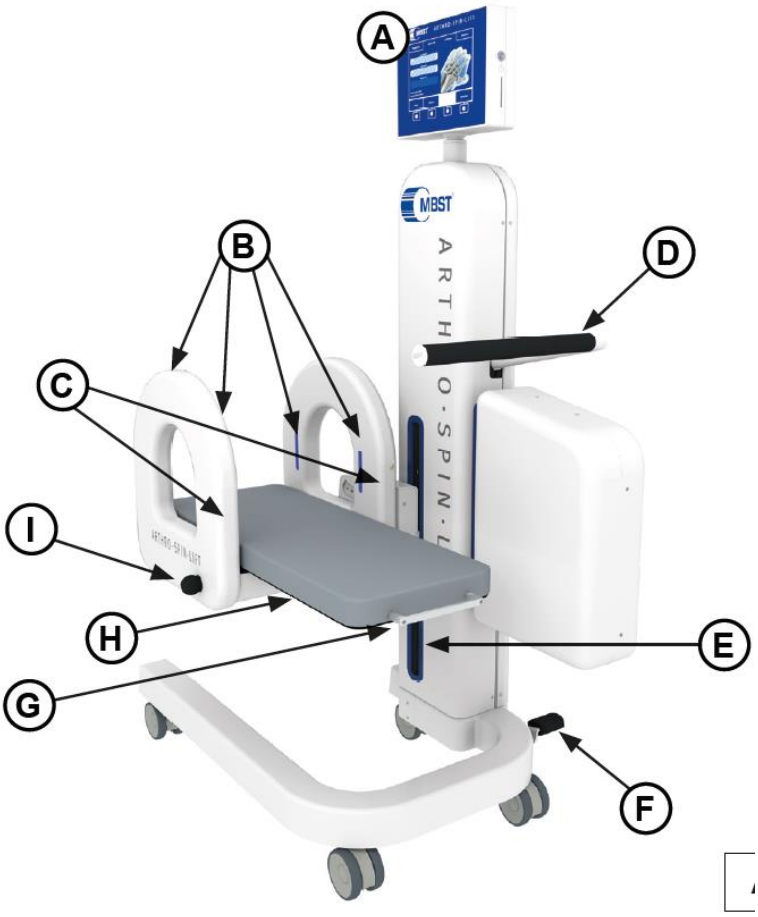
## Technical Specification

| | |
|---|---|
| **Maße (LxBxH) und Gewichte:** | |
| Gesamtsystem: | 2100x1004x1094 mm; ca. 140 kg |
| Steuergerät: | 285x330x98 mm; ca. 4 kg |
| Applikator A + Bedienelement: | 700x85x870 mm; ca. 15,5 kg |
| Applikator B: | 700x85x870 mm; ca. 15 kg |
| Behandlungsliege: | 2100x760x520 mm; ca. 105 kg |
| max. Patientengewicht: | 180 kg |
| **Elektrische Daten Steuergerät:** | |
| Schutzklasse: | Klasse I |
| IP-Schutzgrad: | IP 20 |
| Betriebsart: | Dauerbetrieb |
| Spannungsversorgung: | 100 V~ (AC) bis 240 V~ (AC) / 50–60 Hz |
| Leistungsaufnahme: | max. 250 VA |
| Netzsicherungen Steuergerät: | T 4,0 AL, 250 V (2 Stück) |
| Radiofrequenzleistung: | max. 1 W bei Resonanz |
| Steuerungsprogramme: | max. 256, Einstellung über Behandlungs-karte |
| Repetitionsrate: | max. 32, Einstellung über Behandlungs-karte |
| Behandlungsdauer: | max. 100 min (üblich 60 min) je Therapie-einheit |
| **Elektrische Daten Anwendungsteile (Applikator A+B sowie RF; Liegefläche)** | |
| IP-Schutzgrad: | IP 21 |
| Anwendungsteil: | Typ BF |
| Repetitionsrate: | 1 – 50 Hz, Einstellung über Behandlungs-karte |
| Radiofrequenz: | 16 kHz |
| Radiofrequenzbereich: | 14 – 17,5 kHz |
| Magnetfeldstärke: | 0,4 mT (Behandlungszone); max. 3 mT (Gehäusefront) |
| **Elektrische Daten Behandlungsliege** | |
| IP-Schutzgrad: | IP 21 |
| Netzsicherung Hauptschalter: EIN/AUS | T 2,5 AL, 250 V (2 Stück) |

**Table 3: Technical Specification ArthroSpin Flex**

### 4.6.2 ArthroSpin Lift

#### Overview




| | |
|---|---|
| **A** | MBST® ARTHRO·SPIN·LIFT Bedienelement mit Display |
| **B** | Applikatorbeleuchtung (blau): pulsierende Beleuchtung für Behandlungszone |
| **C** | Applikatoreinheit |
| **D** | Bremshebel zum Arretieren/Verschieben des MBST®ARTHRO·SPIN·LIFT |
| **E** | Führungsbereich zum vertikalen Verschieben der Behandlungseinheit |
| **F** | Fußpedal zum vertikalen Positionieren der Behandlungseinheit |
| **G** | Griff zum Verschieben/Positionieren des Behandlungspolsters |
| **H** | Drehknopf zum horizontalen Verschieben des Polsters zwischen den Applikatoren (nicht sichtbar, befindet sich an der Unterseite des Polsters) |
| **I** | Zugknopf zum Kippen der Behandlungseinheit |

**Figure 2: Overview of ArthroSpin Lift and glossary**

## Technical Specification

| | |
|---|---|
| **Maße (LxBxH) und Gewichte:** | |
| Gesamtsystem: | 1200x790x1755 mm; ca. 135kg |
| Steuergerät: | 330x285x98 mm; ca. 4,4kg |
| Bedienelement: | 320x87x410 mm; ca. 6,6kg |
| Applikator-/Behandlungseinheit: | 895x450x495 mm; ca. 27kg |
| Zentralsäule mit Rollenfuß: | 1200x685x1723 mm; ca. 97kg |
| max. Gewichtsbelastung der Behandlungseinheit (kalkuliert mit einem max. Patientengewicht von 160 kg): | 30 kg |
| **Elektrische Daten Steuergerät:** | |
| Schutzklasse: | Klasse I |
| IP-Schutzgrad: | IP 20 |
| Betriebsart: | Dauerbetrieb |
| Spannungsversorgung: | 100 V~ (AC) bis 240 V~ (AC) / 50–60 Hz |
| Leistungsaufnahme: | max. 100 VA |
| Netzsicherungen Steuergerät: | T 4,0 AL, 250 V (2 Stück) |
| Radiofrequenzleistung: | max. 1 W bei Resonanz |
| Steuerungsprogramme: | max. 256, Einstellung über Behandlungskarte |
| Repetitionsrate: | max. 32, Einstellung über Behandlungskarte |
| Behandlungsdauer: | max. 100 min (üblich 60 min) je Therapieeinheit |
| **Elektrische Daten Applikator-/Behandlungseinheit** | |
| IP-Schutzgrad: | IP 21 |
| Anwendungsteil: | Typ BF |
| Repetitionsrate: | 1 – 51 Hz, Einstellung über Behandlungskarte |
| Radiofrequenz: | 16 kHz |
| Radiofrequenzbereich: | 14 – 17,5 kHz |
| Magnetfeldstärke: | 0,4mT (Behandlungszone); max. 4mT (Spule) |

**Table 4: Technical Specification ArthroSpin Lift**

### 4.6.3 OsteoSystem (ODM)

#### Overview


| | |
|---|---|
| **1** | Control unit |
| **2** | Treatment couch |
| **3** | Pulsating blue light at the side of the bed |
| **4** | Treatment zone 3 of Applicator “A1” |
| **5** | Treatment zone 2 of Applicator “A1” |
| **6** | Treatment zone 1 of Applicator “A1” |

**Figure 3: Overview of OsteoSystem (ODM) and glossary**

## Technical Specification

| | |
|---|---|
| **Measurements and weights** | |
| Control unit: | 370 mm x 270 mm x 140 mm, approx. 3.2 kg |
| Applicator: | 1.960 mm x 630 mm x 110 mm, approx. 46 kg |
| Treatment bench: | 2000 mm x 680 mm x 680 mm, approx. 63 kg |
| **Electrical data** | |
| **Control unit** | |
| - Protection class: | Class II |
| - Operation type: | Continuous use |
| - IP degrees of protection: | IP22 |
| - Power supply: | 115 V~ (AC)… 240 V~ (AC) / 50 Hz …60 Hz |
| - Power consumption: | max. 90W |
| - Fuse: | 2 x T 1,0 AL 250V |
| - Radio frequency: | max. 1 W at resonance |
| - Monitoring programs: | max. 16, employment using Treatment Card |
| - Energy pulse rate: | max. 32, employment using Treatment Card |
| - Treatment period: | max. 100 min. (typically 60 min.) per treatment unit |
| **Applied Part** | **Applicator** |
| - Applied component: | Type BF |
| - Frequency range: | 1 Hz - 50 Hz, employment using Treatment Card |
| - Frequency: | 15 kHz |
| - Frequency range: | 14 kHz – 16,5 kHz |
| - Magnetic field: | 0,3 mT, max. 3 mT |
| **Expected life cycle:** | 5 years |
| **Environmental conditions** | |
| **Operation** | |
| - Temperature range: | +5 °C to +40 °C |
| - Relative humidity: | 35 % to 80 %, no condensation |
| - Air pressure: | 750 mbar (hPa) to 1030 mbar (hPa)<br>Not higher than 2000 m above sea level |
| **Storage and transportation** | **Control unit and Applicator** |
| - Temperature range: | -10 °C to +50 °C |
| - Relative humidity: | 10 % to 90 %, no condensation |
| - Air pressure: | 500 mbar (hPa) to 1060 mbar (hPa) |

**Table 5: Technical Specification OsteoSystem (ODM)**

## 4.6.4 OpenSystem350 and OpenSystem700

### Overview


| | |
|---|---|
| **1** | Treatment couch |
| **2** | LED Light (blue) *pulsating light for the treatment zone* |
| **3** | LED Light (green) *Kernspin- indicator- light* |
| **4** | Switch *for the blue pulsating light (LED)* |
| **5** | Test badge "Technical Safety Control" |
| **6** | Sticker *Q-Test* |
| **7** | Connector socket (connection cable-control unit) |
| **8** | Example type plate |

**Figure 4: Overview of OsteoSystem700 and glossary**


| | |
|---|---|
| **9** | Treatment trolley |
| **10** | Switch *for the blue pulsating light (LED)* |
| **11** | LED Light (blue) *pulsating light for the treatment zone* |
| **12** | LED Light (green) *Kernspin- indicator- light* |
| **13** | Sticker *Q Test* |
| **14** | Test badge "Technical Safety Control" |
| **15** | Connector socket (connection cable-control unit) |
| **16** | Example type plate |

**Figure 5: Overview of OsteoSystem350 and glossary**

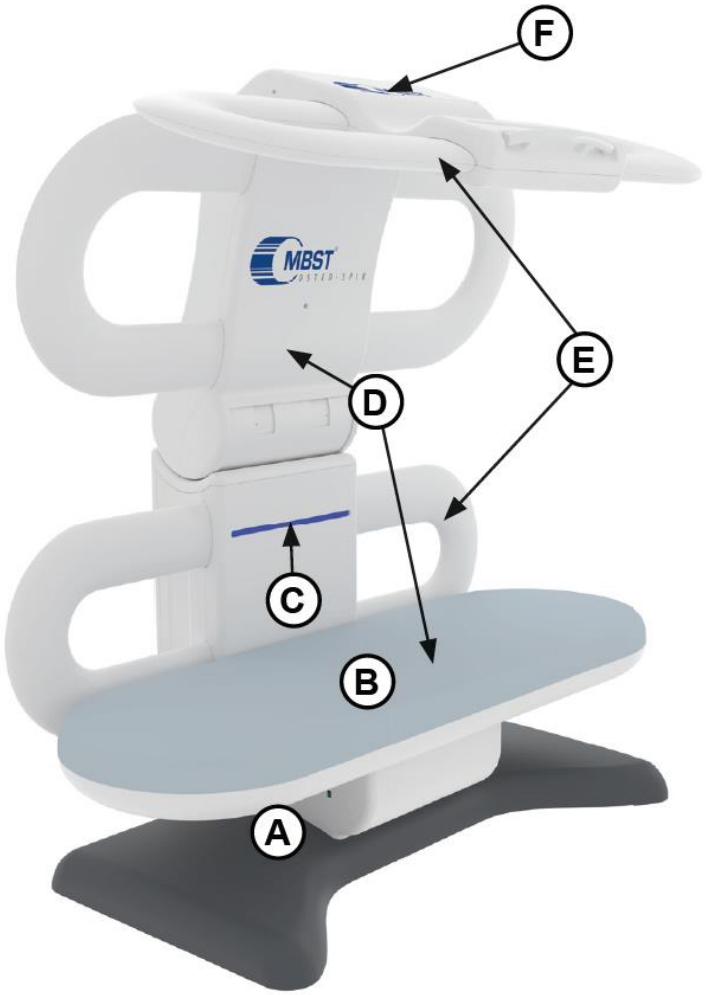
## Technical Specification

| | |
|---|---|
| **Measures and weights** | |
| Control unit: | 370 mm x 155 mm x 320 mm, approx. 5.5 kg |
| Applicator Type 350 OS: | 410 mm x 470 mm x 320 mm, approx. 7 kg |
| Applicator Type 700 OS: | 810 mm x 770 mm x 630 mm, approx. 35 kg |
| Treatment Cart: | 690 mm x 740 mm x 445 mm, ca. 24 kg |
| Treatment Couch: | 725 mm x 720 mm x 2000 mm, approx. 115 kg |
| **Electrical data** | |
| **Control unit** | |
| - Protection class: | Class I |
| - IP degrees of protection: | IP21 |
| - Operation type: | Continuous use |
| - Power supply: | 100 V~ (AC)… 240 V~ (AC) / 50 Hz …60 Hz |
| - Power consumption: | OpenSystem 350: max 65W<br>OpenSystem 700: max.120W |
| - Fuse: | T 1,6 AL , 250V (2x) |
| - Radio frequency: | max. 1 Watt with resonance |
| - Monitoring programs: | max. 16, employment using Treatment Card |
| - Energy pulse rate: | max. 32, employment using Treatment Card |
| - Treatment period: | max. 100 min. (typically 60 min.) per treatment unit |
| **Applied Part** | **Applicator** |
| - IP degrees of protection: | IP51 |
| - Applied component: | Type BF |
| - Frequency: | 16 kHz |
| - Magnetic field: | 0.4 mT (Treatment Zone), max. 3 mT (case front) |
| **Applicator 350 open** | |
| - Energy pulse rate: | 1 Hz – 50 Hz, employment using Treatment Card |
| - Frequency range: | 15 kHz - 18 kHz |
| **Applicator 700 open** | |
| - Energy pulse rate: | 1 Hz – 80 Hz, employment using Treatment Card |
| - Frequency range: | 14 kHz - 17 kHz |
| **Expected life cycle:** | 5 years |
| **Environmental conditions** | |
| **Operation** | |
| - Temperature range: | +5 °C to +40 °C |
| - Relative humidity: | 35 % to 80 %, no condensation |
| - Air pressure: | 750 mbar (hPa) to 1030 mbar (hPa)<br>Not higher than 2000 m above sea level |
| **Storage and transportation** | **Control unit and Applicator** |
| - Temperature range: | -10 °C to +50 °C |
| - Relative humidity: | 10 % to 90 %, no condensation |
| - Air pressure: | 500 mbar (hPa) to 1060 mbar (hPa) |

**Table 6: Technical Specification OpenSystem350/700**

### 4.6.5 OsteoSpin

#### Overview




| | |
|---|---|
| **A** | MBST® OSTEO·SPIN treatment couch (Behandlungsliege) |
| **B** | MBST® OSTEO·SPIN lying surface (Liegefläche) |
| **C** | Applikatorbeleuchtung (blau): pulsierende Beleuchtung für Behandlungszone |
| **D** | MBST® OSTEO·SPIN Radiofrequenz-Applikatoren A und B |
| **E** | MBST® OSTEO·SPIN Sweep-Applikatoren A und B |
| **F** | MBST® OSTEO·SPIN Display |

**Figure 6: Overview OsteoSpin**

## Technical Specification

| | |
|---|---|
| **Maße (LxBxH) und Gewichte:** | |
| Applikator geschlossen: | 2200x1231x1390 mm |
| Applikator 45° geöffnet | 2200x1544x1924 mm |
| Applikator 60° geöffnet | 2200x1463x2093 mm |
| Applikator 75° geöffnet | 2200x1295x2213 mm |
| Höhe Liegefläche über Boden: | 560 mm |
| Größe Liegefläche: | 2200x740 mm |
| Max. Patientenmaße/-gewicht: | 210 kg |
| Systemgewicht: | ca. 400 kg |
| **Elektrische Daten Gesamtsystem und Steuergerät:** | |
| Schutzklasse: | Klasse I |
| IP-Schutzgrad Steuergerät: | IP 20 |
| IP-Schutzgrad Gesamtsystem: | IP 21 |
| Betriebsart: | Dauerbetrieb |
| Spannungsversorgung: | 100 V~ (AC) – 240 V~ (AC) / 50–60 Hz |
| Leistungsaufnahme: | max. 280 VA |
| Netzsicherungen Steuergerät: | T 4,0 AL, 250 V (2 Stück) |
| Netzsicherung Gesamtsystem: | T 2,5 AL, 250 V (2 Stück) |
| Radiofrequenzleistung: | max. 1 W bei Resonanz |
| **Elektrische Daten Anwendungsteile (Applikator A+B, Applikator RF A+B)** | |
| Anwendungsteil: | Typ BF |
| Repetitionsrate: | 1 – 50 Hz, Einstellung über Behandlungskarte |
| Radiofrequenz: | 14,5 kHz |
| Radiofrequenzbereich: | 13,5 – 16 kHz |
| Magnetfeldstärke: | ca. 0,33 – 0,4 mT (Behandlungszone); max. 3 mT (Gehäusefront) |
| **Umgebungsbedingungen im Betrieb:** | |
| Temperaturbereich: | +5°C bis +40°C |
| Relative Luftfeuchtigkeit: | 30 – 80%, nicht kondensierend |
| Luftdruck: | 750 hPa – 1060 hPa (nicht höher als 2000 m ü.NN) |

**Table 7: Technical Specification OsteoSpin**

### 4.6.6 ProMobil

#### Overview


| | |
|---|---|
| **A** | MBST® PRO·MOBIL Steuergerät |
| **B** | MBST® PRO·MOBIL kleine Applikatoren |
| **C** | MBST® PRO·MOBIL großflächiger Applikator |
| **D** | Trolley zum Transport |
| **E** | Netzkabel |
| **F** | Verlängerung Anschlussleitung großflächiger Applikator |

**Figure 7: ProMobil**

| | |
|---|---|
| **Maße (LxBxH) und Gewichte:** | |
| Steuergerät: | 300x160x320 mm; ca. 5 kg |
| Applikator, klein: | 430x255x20 mm; ca. 1,5 kg |
| Applikator, großflächig: | 440x640x40 mm; ca. 6 kg |
| Gesamtgewicht Koffer: | 480x750x290 mm; ca. 23 kg |
| **Elektrische Daten Steuergerät:** | |
| Schutzklasse: | Klasse II |
| IP-Schutzgrad: | IP 22 |
| Betriebsart: | Dauerbetrieb |
| Spannungsversorgung: | 100 V~ (AC) bis 240 V~ (AC) / 50–60 Hz |
| Leistungsaufnahme: | max. 35 W |
| Netzsicherungen Steuergerät: | T 1,6 AL, 250 V (2 Stück) |
| Radiofrequenzleistung: | max. 1 W bei Resonanz |
| **Elektrische Daten Anwendungsteile (Applikator)** | |
| IP-Schutzgrad: | IP 51 |
| Anwendungsteil: | Typ BF |
| Repetitionsrate: | 1 – 80 Hz (in 32 Stufen) |
| Radiofrequenz: | ca. 16 kHz |
| Radiofrequenzbereich: | 14,5 – 18 kHz |
| Magnetfeldstärke: | 0,4 mT (typ.); max. 3 mT |
| **Umgebungsbedingungen im Betrieb:** | |
| Temperaturbereich: | +5°C bis +40°C |
| Relative Luftfeuchtigkeit: | 30 – 80%, nicht kondensierend 750 |
| Luftdruck: | hPa – 1030 hPa (nicht höher als 2000 m ü.NN) |
| **Umgebungsbedingungen für Lagerung /Transport** | |
| Temperaturbereich: | -10°C bis +50°C |
| Relative Luftfeuchtigkeit: | 10 – 90 %, nicht kondensierend |
| Luftdruck: | 500 hPa – 1060 hPa |
| **Erwartete Betriebslebensdauer:** | **10 Jahre** |

**Table 8: Technical Specification ProMobil**

## 4.7 Application

The application of the evaluated medical devices is described in detail in the respective IFU (Reference: R3).

In the following, information on application and use are presented as an overview:

Based on study data as well as practical experiences of physicians and specialists, duration of treatment with MBST magnetic resonance therapy is:

- Duration of therapy is determined by the treating physician depending on severity of damage and indication.
- Recommended treatment units (TU/hours of treatment) depending on severity of damage and indication:
  - Osteoarthritis, early stages = 5 TU, advanced stages = 7/9 TU
  - Refreshing therapy osteoarthritis = 3 TU
  - Acute injuries muscles, ligaments, tendons = 5 TU
  - Chronic conditions muscles, tendons = 7 TU, ligaments = 9 TU
  - Osseous structures, bones, intervertebral discs = 9 TU
  - Osteoporosis, whole-body treatment = 10 TU

All therapy units should take place on consecutive days. A break during the weekend is possible.

Initial examination and diagnosis by the treating and diagnosing specialist may require an additional report by the radiologist.

Other necessary tools for diagnostics: anamnesis, MRI, CT, ultrasound or X-rax images or DXA measurements.

**Required presence of the physician**

- Evaluation and monitoring during every treatment unit
- Supervision of correct patient positioning
- Supervision and observance of therapy-related contraindication (in some circumstances bacterial infections in the treatment zone, electronic implants, tumors etc.)
- Starting the treatment device with the therapy software chip card
- Control of proper functional sequence and functioning of the magnetic field in the treatment system (structure of field)
- Control of magnetic spin indicator
- Evaluation of the grade of the disease by a specialist using MRI, CT or X-ray images, the medical diagnostic report of the radiologist or the measured values of DXA procedure
- Comprehensive medical consultation including recommendation and information about the condition and the possibilities of the active principle of magnetic resonance method including indications and contra- indications
- Determination and definition of the tissue-specific therapy software chip card (number of treatment units and type of therapy software chip card)
- Planning and coordination of course of treatment
- Execution and supervision of correct course of treatment
- Explanation, control and evaluation of assessment scores (pain, functioning, effectivity) to monitor the success of treatment that shall be filled in for every patient at 4, if possible 5 points in time (before and after therapy as well as 3, 6 and if possible 12 months after therapy)

**Procedure of a MBST magnetic resonance therapy**

The scientifically based MBST magnetic resonance therapy is only applicated in certified MBST treatment centers by general practitioners, specialists or therapists with successfully accomplished further training. Individual consulting and thorough diagnostics in the MBST treatment center are the basis for a successful MBST therapy.

Your MBST treatment is ordered at MedTec Medizintechnik GmbH by the treating physician only after an appropriate diagnosis.

**The indication is the basis for a therapy**

In accordance with the description of symptoms, thorough diagnostics and observance of possible contraindications, the treating physician in a MBST treatment center informs the patient if MBST magnetic resonance therapy is a treatment option for your complaints. The patient will get detailed information during the consultation. The tissue respective indication specific therapy card is ordered for the patient personally according to the indication.

**Therapy options**

The patient can choose between several therapy options for treatment for a certain disease or injury. In this case, possible benefit and damage, such as side effects or downtimes, need to be considered carefully. It is ideal to consult a doctor in an MBST treatment center who can support the patient in evaluating the information and making the decision for further proceedings.

**Course of therapy**

After the patient has made the decision for a MBST magnetic resonance therapy, the MBST treatment center orders the MBST therapy card specified for the condition or injury at MedTec Medizintechnik GmbH. There, the treatment data is loaded onto a coded MBST therapy card which is then send to the MBST treatment center.

The treatment data is transferred directly from the therapy card to the MBST therapy device which guarantees an optimal treatment. The medical staff helps the patient to take up a position in or on the MBST therapy device so that the body part to be treated is placed ideally within the treatment field.

With the start of the therapy unit, the MBST therapy device establishes magnetic resonance conditions with the tissue and then begins the targeted energy transfer. Most patients do not notice any sensations during the therapy. Some describe a light feeling of warmth or a slight tingling.

Each treatment session lasts for 60 minutes. Meanwhile, the patient can relax and for instance listen to music, read a book or even sleep. A MBST treatment series consists of five to ten treatment units. Depending on the diagnosis and extent of damage, different MBST therapy devices are used.

Reference: https://www.mbst.de/english/procedure-of-MBST-therapy.php

**Cleaning**

The MBST is NOT suitable for sterilization.

However, for hygienic reasons, the device must be cleaned after installation, after each maintenance/repair/STK (by the service technician) as well as before and after each treatment (by the operator).

Only clean the device with a soft, lint-free cloth so that the surfaces do not get scratched during cleaning. Persistent dirt can also be cleaned like this and the basis for germ formation is withdrawn. For thorough cleaning of the treatment unit, a moist cloth with a commercially available, all-purpose cleaner may be used.

For surface disinfection, a hospital-grade surface disinfectant can be used. Consult the instructions for the detergent before use to make sure that it does not attack the surfaces and to learn how it should be used.

**Disposal**

***Disposal of packing material***

Please dispose of the packaging materials of the MBST® OSTEO·SPIN in accordance with local regulations and laws, if possible, recycling, unless it has already been removed by the service technician.

***Disposal of empty therapy cards***

Do NOT dispose of used/empty therapy cards as domestic waste. When a therapy is completed or if there are no more treatment units left on a therapy card, please send the empty card back to your contractual partner or directly to MedTec Medizintechnik GmbH. In order to protect the environment and save valuable resources, the MBST therapy cards will be formatted, reprogrammed and thus used several times.

***Disposal of the treatment device***

When the MBST reaches the end of its product life cycle, contact your contractual partner or MedTec Medizintechnik GmbH directly to organize the return or an environment-friendly recycling or disposal of the device in accordance with the applicable local regulations and laws.

To avoid transmitting any sources of infection to third parties, please clean and disinfect your therapy device thoroughly before return/disposal.

Should you need further detailed help and information on recycling or environmental-friendly disposal, please do not hesitate to contact the manufacturer.

Please also clean and disinfect the MBST and, in case of applicators, the applicator prior to their disposal.

## 4.8 Compatibilities with other Devices

Compatibility with other devices is not given by means of interfaces since the MBST Magnetic Resonance Technology Systems are all stand-alone devices.

# 5 Context and Focus of the Clinical Evaluation

In addition to the state of the art data and technical as well as medical background information in the previous CERs, another literature search for the following two state of the art sections has been conducted (see section 8 and [A1], literature search protocol) in order to find reviews, meta-analyses, and guidelines to show the technical and medical state of magnetic resonance therapy and therapeutic applications of magnetic fields. Especially, publications with focus on other therapeutic applications with magnetic fields are included in these state-of-the-art sections.

## 5.1 State of the Art – Technology

In the use of magnetic fields for therapeutical purposes, one must always distinguish between:

a) static magnetic fields
b) dynamic, pulsating magnetic fields
c) magnetic resonance effects based on the larmor frequency of protons

Since the effects of these three types of application to living biological cell systems are very different, it is important to caution against confusion or merging – as it is often done in popular and lay media – and to point out the fundamental differences.

Ad a) The importance of static magnetic fields in nature is well described in literature and is not subject of this clinical evaluation report. To what extent these findings can be used for therapeutic purposes is still unknown.

Ad b) The importance of pulsating magnetic fields is discussed in literature in two ways. On the one hand, there is a well-founded presumption that mobile communication exposes persons to magnetic fields, the effects of which cannot yet be conclusively estimated. For example, a double-blind, placebo-controlled, randomized clinical trial showed a significant effect on electrical brain activity in humans (Reiser et al., 1995).

On the other hand, the effects on living tissue of pulsating magnetic fields have been investigated in many studies with the aim of determining a possible therapeutical usage. Also, in this case, single successful experiments are reported that mainly showed an effect on a cellular basis, but these cannot be generalized due to heterogeneous test designs using a wide range of frequencies for treatment of diverse indications.

A comparison with the MBST method evaluated in this report is not possible at all.

Ad c) However, usage of the principle of magnetic spin resonance based on the well-known magnetic resonance imaging using both static and dynamic magnetic fields for therapeutical purposes is – scientifically speaking – still quite new. This may be partly due to the fact that this technology was developed just a few years ago. These are the therapy devices offered under the name MBST technology.

With regard to the underlying principle, this technology for stimulating a special magnetic spin resonance of protons and its usage in said therapy device, it can be referenced to the expert opinion of Prof. Dr. Jakob, University of Wuerzburg.

This evaluation clearly shows that these therapy devices indeed have the declared properties with regard to the stimulation of special magnetic spin resonance (Jakob, 2005). Thus, they differ from a purely technical point of view in the most significant way from conventional therapy devices which are based on one of the other two forms of application of magnetic fields (static or pulsating). The technological invention concerns a device for magnetic resonance therapy by means of which magnetic resonance can be achieved in the target tissue by sweeping a magnetic field, which extends as homogeneously as possible throughout the treatment volume, and simultaneously irradiating an alternating magnetic field perpendicular to it, at least when the sweep field decreases.

The field strength of the sweep field is between 0.3 and 3 mT with alternating field frequency of 10 to 100 kHz. The maximum strength of the alternating field is preferably between 0.1 and 3 mT. The coils are preferably mainly in Helmholtz configuration and thus generate an essentially homogeneous field, crossways along the couch.

In addition, the MBST system uses Adiabatic Fast Passage (AFP) for magnetization which compensates for the effective inhomogeneity of the necessary static basic magnetic field B0.

Thus, the technology has unique characteristics. Scientific studies on the therapeutic efficacy of magnetic resonance therapy, both in vivo and in vitro, are available in large numbers and will be presented below.

(Reference: R2)

**Therapeutic magnetic resonance**

The physical effect of magnetic resonance is also used in MRI diagnostics. It is based on a highly developed technology also known as magnetic resonance imaging (MRI).

**Principles of MRI**

Magnetic resonance imaging (MRI) is based on different properties of human tissue in a (strong) magnetic field. In particular, the occurrence of Hydrogen nuclei in human tissue is exploited for image generation. They can be considered as small dipole magnets aligning themselves either parallel or anti-parallel along a strong external magnetic field. While aligned in that field, the Hydrogen protons (a Hydrogen nucleus only consists of one proton) spin arbitrarily around the axis of the field. There is a slight difference in the number of parallel and anti-parallel aligned protons (see following figure on the left):

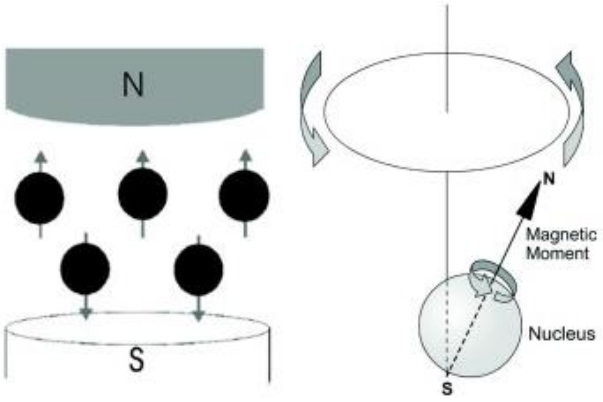



**Figure 8: Left: The protons are aligned according to the external magnetic field. Some protons are aligned parallel to the magnetic field, while others are aligned anti-parallel. Right: Spin and precession of the protons. Next to their self-rotation (spin), they perform an additional precession movement around the direction of the magnetic field.**

In MRI a strong magnetic field is applied over the subject that is to be scanned. Unpaired protons, mostly those in the nuclei of the hydrogen atoms that form part of water molecules, precess about the magnetic field direction at the Larmor frequency *w*, an angular frequency that is related to the strength of the magnetic field *B* that point by the gyromagnetic ratio γ. This precession is analogous to that of a spinning top in the gravity field.

In contrast to the transfer principle based on ions of magnetic field therapy, magnetic resonance technology achieves the energy transfer into the organism at the very effective proton level of the hydrogen atoms. Basic conditions for magnetic resonance are a homogeneous static basic magnetic field, the sweep field and an additional radio frequency field. This signal (reflection or echo) is used to create the image. In this way, the entire body can be permeated without contact or side effects.

C conventional MRI devices require very large amounts of energy to generate the magnetic field of 0.3 to 4 tesla necessary for the signal processing in image production.

Since the human body consists of 70–80% water, it is the optimal way to transfer energy into the body in resonance, i. e., almost without losses, and in another resonance to the target location of the damaged tissue. The physical effect of magnetic resonance makes it possible to stimulate proton spins in living tissue in order to use them for energy transport (temporary storage of energy in the protons of the hydrogen atomic nuclei) so that they in turn emit a measurable signal.

(Reference: R2)

The energy transmitted by the resonance system (B0 and RF field) by means of the protons of the hydrogen atoms into the tissue is precisely controlled by the cell resonance effect into the still living, damaged cells of the tissue and here stimulates regeneration.

**Course of the therapeutic use of magnetic resonance technology**

In MBST magnetic resonance therapy, a magnetic field is generated that prompts the hydrogen protons to align themselves according to the field lines. However, the generated field is many

times weaker than that of an MRI. The reason is that MBST magnetic resonance technology only targets specific tissues and not all tissue structures in the target area. For example, MBST therapy sequences only stimulate hydrogen protons in tissues that are in resonance. These are the receivers of the energy transfer. In this way, various processes can be triggered and the metabolism of the cells can be influenced. Scientific data indicate that MBST magnetic resonance technology may stimulate various biophysical processes and trigger anti-inflammatory and pain-relieving effects.

**Advantages of MRI and MBST compared to CT, ultrasound or x-rays**

MRI is one of the most modern, safe and gentle methods to detect pathological changes inside the body without the use of the burden of x-rays. With modern MRI scanners, location, extent and cause of a particular disease can be displayed much better than with conventional procedures such as x-ray examinations or ultrasound.

(Reference: R2)

**Standards to be applied:**

| | |
|---|---|
| DIN EN ISO 13485 | Medizinprodukte QM- Systeme Anforderungen für regulatorische Zwecke |
| DIN EN ISO 10993-1 | Biologische Beurteilung von Medizinprodukten Teil 1 Beurteilung Risiko |
| DIN EN ISO 14971 | Anwendung des Risikomanagements auf Medizinprodukte |
| DIN EN ISO 15223-1 | Aufschriften von Medizinprodukten und Symbole |
| EN 60529 | Schutzarten von Gehäusen |
| EN 60601-1 | Medizinische Elektrische Geräte Allgemeine Festlegung für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale Edition 3.1 |
| EN 60601-1-2 | Medizinische Elektrische Geräte Allgemeine Festlegung für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale Ergänzung EMV |
| EN 60601-1-6 | Medizinische Elektrische Geräte Allgemeine Festlegung für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale Gebrauchstauglichkeit |
| EN 60601-1-11 | Medizinische Elektrische Geräte Allgemeine Festlegung für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale häusliche Umgebung |
| EN 60601-1-12 | Medizinische Elektrische Geräte Allgemeine Festlegung für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale El. Geräte Umgebung Notfalleinsatz |
| EN 62304 | Medizingeräte Software Lebenszyklus |
| IEC 62366-1 | Medizinprodukte - Teil 1 Anwendung der Gebrauchstauglichkeit auf Medizinprodukte |
| RoHS EU2011-65- E | Richtlinie zur Beschränkung gefährlicher Stoffe |
| ISO TR 80002-2 | Medical device Software. Validierung von SW für M |

ISO/IEC 7816-9 Identification cards — Integrated circuit cards — Part 9: Commands for card management

## 5.2 State of the Art – Medical

### Degenerative diseases and injuries of the musculoskeletal system

Several guidelines referring to degenerative diseases and injuries of the musculoskeletal system recommend almost the same therapy options. The following table lists the most important guidelines and the recommended therapy for the respective disease/condition.

| Guideline | Disease/condition | Recommended therapy options |
|---|---|---|
| Neurotraumatologie und Erkrankungen von Wirbelsäule und Nervenwurzel<br>Beschleunigungstrauma der Halswirbelsäule, AWMF-Registernum m er: 030/095<br>https://dgn.org/wp-content/uploads/2013/01/030-095l_S1_Beschleuningstrauma_der_HWS_2012_verlaengert.pdf | Acceleration trauma of the cervical spine | • Conservative<br>• Analgesia<br>• Administration of medicinal products<br>• Local heat or cold<br>• Massage<br>• Electrotherapy<br>• Physiotherapy |
| "S2k-Leitlinie Koxarthrose<br>AWMF-Registernummer: 033-001<br>https://www.awmf.org/uploads/tx_szleitlinien/033-001l_S2k_Koxarthrose_2019-07_1.pdf" | Coxarthrosis | • Conservative (medicinal products /non- medicinal products)<br>• Surgical |
| "S2k-Leitlinie<br>Gonarthrose<br>Federführende Fachgesellschaft DGOOC<br>AWMF Registernummer: 033-004<br>https://www.awmf.org/uploads/tx_szleitlinien/033- | Gonarthrosis | • Medicinal products<br>• Conservative:<br>  ○ Physiotherapy<br>  ○ Physical therapy including electrotherapy<br>  ○ Ergotherapy |

| | | |
|---|---|---|
| 004l_S2k_Gonarthrose_2018-01_1-verlaengert.pdf" | | |
| "S2k-Leitlinie „Rehabilitation nach traumatischen Frakturen der<br>Brust- und Lendenwirbelsäule ohne neurologische Ausfälle“<br>AWMF – Registernummer: 033 - 043<br>Version vom März 2016<br>https://www.awmf.org/uploads/tx_szleitlinien/033-043l_S2k_Rehabilitation_Frakturen_Brustwirbelsaeule_Lendenwirbelsaeule_2017-04.pdf" | Trauma fractures | 7.2. pain therapy 97.3. physiotherapy / remedial gymnastics / remedial gymnastics on the apparatus / remedial gymnastics in the exercise pool 107.4. sports therapy / medical training therapy 117.5. physical therapy 127.5.1 massage 127.5. 2 Thermotherapy / Cold / Heat Therapy 127.5.3 Electrotherapy 137.5.4 Hydrotherapy / Balneotherapy 137.6 Ergotherapy 137.7 Orthoses 147.8 Health Education and Information 157.9 Pain Psychotherapy / Psychological Trauma Therapy |
| "Leitlinie zur konservativen, operativen und rehabilitativen<br>Versorgung bei Bandscheibenvorfällen mit radikulärer<br>Symptomatik<br>S2k Leitlinie der Deutschen Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC), der Sektion Wirbelsäule der Deutschen Gesellschaft für Orthopädie und Unfallchirurgie (DGOU), der Deutschen Gesellschaft für Neurochirurgie (DGNC) und der Deutschen Wirbelsäulengesellschaft (DWG).<br>Federführung: Greitemann, B., Schmidt, R. (Ansprechpartner)<br>AWMF-Registernummer: 033-048 | Slipped disc | Medicinal products<br>Non-medicinal:<br>Acupuncture<br>Psychological Pain Therapy Behavioral Therapy Relaxation Procedures (Progressive Muscle Relaxation)<br>Exercise Therapy Physiotherapy<br>Physiotherapy<br>Back School<br>Manual Therapy<br>Physical Therapy Equipment Supported Traction<br>Electrotherapy<br>Ultrasound<br>Massage<br>Thermotherapy Ergotherapy |

| | | |
|---|---|---|
| https://www.awmf.org/uploads/tx_szleitlinien/033-051l_S2k_Spezifischer_Kreuzschmerz_2018-02.pdf" | | |
| "S2k-Leitlinie<br>Spezifischer Kreuzschmerz<br>AWMF Registernummer: 033-051<br>Stand vom Dezember 2017<br>https://www.awmf.org/uploads/tx_szleitlinien/033-051l_S2k_Spezifischer_Kreuzschmerz_2018-02.pdf" | Back pain | Percutaneous neurotomy (e.g., using radiofrequency therapy) may be considered in patients with a persistent facet syndrome.<br>If the symptomatology is conservative or interventional therapy refractory, theindication for surgery should be considered.<br>Non-surgically symptomatic drug and physical-therapeutic procedures and the local interspinous injection of local anesthetics with cortisone can be used.<br>Despite the relatively low evidence of long-term success for drug therapy, physiotherapy, orthoses and injections, a conservative therapy attempt should first be attempted in the absence of a neurological deficit or immobilizing pain with accompanying success control. |
| Prophylaxe, Diagnostik und Therapie der<br>OSTEOPOROSE<br>bei postmenopausalen Frauen und bei Männern<br>Leitlinie des Dachverbands der Deutschsprachigen<br>Wissenschaftlichen Osteologischen Gesellschaften e.V. 2017<br>- LangfassungAWMF-Register-Nr.: 183/001<br>https://www.awmf.org/uploads/tx_szleitlinien/183-001l_S3_Osteoporose- | Osteoporosis | Medicinal products or<br>TREATMENT OF PAIN AND FUNCTIONAL LIMITATIONS<br>10.6.1 Conservative therapy for acute stable osteoporotic<br>Vertebral body fractures<br>10.6.1.1 Mobilization<br>10.6.1.2 Pain therapy<br>10.6.1.3 Orthoses<br>10.6.2 Rehabilitation, self-help groups<br>10.6.3 Kyphoplasty and Vertebroplasty [DVO Guideline 2017]. |

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|---|---|---|
| Prophylaxe-Diagnostik-Therapie_2019-02.pdf | | |
| Aurich, M., Albrecht, D., Angele, P., Becher, C., Fickert, S., Fritz, J., … Walther, M. (2016). Behandlung osteochondraler Läsionen des Sprunggelenks: Empfehlungen der Arbeitsgemeinschaft Klinische Geweberegeneration der DGOU. Zeitschrift Für Orthopädie Und Unfallchirurgie, 155(01), 92–99. doi:10.1055/s-0042-116330 | osteochondral lesions of the ankle joints | Non-operative treatment shows good results for selected indications in children and adolescents, especially in early stages of osteochondritis dissecans (OCD). However, surgical treatment is usually indicated in adolescents and adults, depending on the size and location of the lesion. Various arthroscopic and open procedures are frequently employed, including reattachment of the fragment, local debridement of the lesion with fragment removal and curettage of the lesion, bone marrow-stimulation by microfracture or microdrilling (antegrade or retrograde), and autologous matrix-induced chondrogenesis.<br>For larger defects or as salvage procedure, osteochondral cylinder transplantation or matrix-induced autologous chondrocyte transplantation are recommended. |

**Table 9: Guidelines for indications**

Another NICE guideline is under development:

Magnetic resonance therapy for knee osteoarthritis

In development [GID-IPG10159]

Expected publication date: TBC (source: https://www.nice.org.uk/guidance/indevelopment/gid-ipg10159)

### Former treatment options for diseases of the musculoskeletal system

The generally known medical conservative treatment options for degenerative diseases are very limited. So far, no procedures for effective and long-lasting treatment of musculoskeletal disorders are known.

Almost all recognized forms of treatment in the medical field focus on the consequenses but are no causal treatment of the symptoms as is the magnetic resonance therapy. Not to mention the extensive lists of side effects for numerous widely administered drugs.

Since usually treatments for osteoarthritis – these are

1) Painkillers (mostly NSAIDs) and

2) intra-articular administration of corticoids or hyaluronic acid – only aim at the symptoms but not at the causes, all of them ultimately lead to expensive artificial joint implantation.

Even these are usually worn out after 10–15 years and have to be replaced which becomes increasingly difficult with each revision. For total endoprostheses, it is now common knowledge that 50% of patients are not satisfied with the result of a joint replacement surgery.

(Reference: R2)

**Physical therapy**

The aim of the therapeutic use of physical methods is the restoration of the impaired balance on a cellular and molecular level. The fact that the therapeutic application of physical methods is not invasive is an enormous advantage. It can generally be achieved in two different ways.

- First option, electric energy is applied directly to the body, for example in the use of tens devices. It is surprising for laypeople that enormous changes in brain activity can be achieved with the help of electrodes resp. the application of very small amounts of energy to the peripheral nerve. A lot helps a lot is not always the guideline to follow (example: electroshocks in the treatment of depression).
- Second option, electric energy is applied indirectly to the body using the principle of magnetism. There are also examples of application where a large amount is transmitted by induction as in the case of transcranial magnetic stimulation (TMS) for the treatment of depression (also known as “soft electroshock”).

The fact that even small amounts of energy have an influence on electrochemical processes within the body is now undisputed and has been proven in numerous scientific tests and studies about the efficacy of magnetic resonance application.

In the past, the problem with the therapeutic application of smaller amounts of energy was partly due to the fact that the knowledge about biophysical processes at molecular level which are to be influenced was still insufficient.

Therefore, it was inevitable that in therapeutic application a great deal of experiments was initially carried out using simple pulsating magnetic fields (PEMF technology) (especially field strengths, signal patterns and different frequencies) without a scientifically justifiable basis for the use of these parameters. It is not surprising that in the past, therapeutic success and a general acceptance of “magnetic field therapy”, as documented in Prof. Krone’s report (Krone et al. 1996), could not be achieved although minimal effects of special frequencies and the transport of energy via ions, which are known to exist in living organisms as charge carriers only in very small numbers, could not be ruled out.

Another disadvantage is the extremely high dissipation factor of this PEMF technology, only very small amounts of the available energy can be transferred into the ions of the body.

This changed fundamentally with the introduction of the imaging method based on magnetic resonance (MRI).

The results of observations of diagnostic magnetic resonance imaging (magnetic resonance tomography, MRI) now led directly to therapeutical usage in the form of highly effective magnetic resonance therapy systems (MBST magnetic resonance therapy or MBST therapeutic magnetic resonance). Both, magnetic resonance imaging and magnetic resonance therapy, use the same technology, the physical phenomenon of magnetic resonance of hydrogen protons and the different relaxation times of different tissue types.

The transfer of energy and the resulting therapeutical effect is achieved via the protons of hydrogen atoms in human or animal tissue which are present in large numbers due to the body's very high content of water. This was confirmed in an evaluation by the University of Wuerzburg. (Jakob, 2005)

Following this, magnetic resonance therapy cannot be compared to or equated with conventional magnetic field therapies.

The use of a special frequency, the larmor frequency, which is used for stimulation in resonance of the protons of the hydrogen atoms for therapeutic purposes is absolutely new and unique and therefore patented worldwide with numerous patents.

Radio frequency and modulated special low frequencies are radiated using a technically complex control unit and a connected highly complex system of air coils with a static basic magnetic field, thus causing the loss-free energy transfer in resonance via the stimulated protons.

(Reference: R2)

**Regenerative medicine**

Regenerative medicine is the restoration of cells, tissues or organs whose functions are impaired. This is achieved by stimulating the body's own regeneration and repair processes or by biological replacement in the form of living cells or tissues cultivated in the laboratory. The objective is to restore the healthy and functional original condition of an affected tissue instead of replacing and repairing it temporarily.

In the 19th century, when research showed that the cause of disease can often be found in the cells, scientists began to decipher the processes of regeneration. In recent decades, research and medical technology have developed rapidly changing regenerative medicine fundamentally. We know now that even specialized cells are not fixed building blocks of the body, but changeable structures whose behavior can be influenced and reprogrammed. Focusing on the body's ability to regenerate could help to solve many pressing problems in medical care. Not least for this reason, a promising future is predicted for regenerative medicine.

(Reference: R2)

**Molecular biophysical stimulation**

Living organisms are a highly complex biological system which follows cybernetic regularities. The healthy respective normal state of this biological system is determined by a balance in the processes of regeneration and degeneration. It is usually defined as a disease if changes respective disorders occur within this system that diverge from the norm. Disturbances of this equilibrium can not only be detected on several levels with the help of scientific methods –

biophysical or biochemical – but can also be corrected in many cases. This applies equally to the whole-body and organ level as well as to the cellular and molecular level. The basis, however, is a preferably exact and comprehensive understanding of molecular, chemical cellular and physical processes including their inter- dependencies. Regarding correction of the disorder, usually a distinction is made between causal and symptomatic therapy. The number of available causal therapies is still very limited as most disease processes have not yet been understood sufficiently. Therefore, in most cases symptomatic therapies must be used. These are usually based on medical experience and still make up the majority of medical practice. Unfortunately, medical doctrines are still predominant which in parts would have to be modified following new study results.

One of these outdated opinions is that cartilage tissue and cartilage cells could not at all or hardly be regenerated, even though evidence of the contrary has been produced over 20 years ago.

Another insupportable and incorrect assertion, which is still discussed often, is that magnetic resonance can only be generated with extremely strong magnetic fields (more than 0.5 tesla). Scientific tests and expert evaluations showed that magnetic resonance can be generated even with a magnetic field of the same strength as earth's static magnetic field.

This is important insofar as the desired approach called "evidence-based medicine" is not even applicable to all long-established treatment strategies. The therapeutic practice of the individual physician is still predominantly determined by his experiences. The therapeutic approach still derives mainly from interventions in chemical processes and much less from modulations through physical processes. This has historical reasons, as plant extracts, whose medical function comes from their chemical substances, have been used successfully for thousands of years. The use of physical principles could naturally only be attempted after natural scientific connections at the molecular and cellular level had been discovered. Only after the discovery of the electrical processes in the living body, research was able to investigate their significance and propose corrective measures for the treatment of disorders. Exactly this therapeutic alternative of biophysical findings regarding electrical processes is the subject of the here discussed therapeutic procedure with its extensively confirmed causal efficacy free of side effects.

Another reason is the lobby of the pharmaceutical industry which tries to dominate the health care market with ever new expensive drugs and promises. Under these conditions, it is very difficult to take hold in the healthcare market with new, innovative therapies that are effective, causal and inexpensive for the social system in the long term.

(Reference: R2)

**Hypothetical active principle**

The molecular basis of electric activity in individual cells is bound to the presence of ion channels in the cell membrane (which separates the interior from the exterior of a cell). These ion channels are formed by large protein structures (protein molecules) which, due to their configuration, allow very selective ions to pass through the membrane or exclude them from the passage.

In contrast to the generally known current coming from the socket, the charge carriers in living tissue are ions and not electrons. Ions are negatively or positively charged atoms like K+, Na+, Ca++, Cl- but also H+ (protons). So called proton channels in the latter case. Recent research in this field made it possible to assign biological functions to the different channels which are among others distinguished by their conductivity. For example, it was possible to establish a connection between the proton channels and the receptor for vanilla acid. This receptor is important in pain transmission (Hellwig et al., 2004).

A change in the passage of protons through these channels due to changes in the energy level of protons (caused by resonance) would clearly affect the experience of pain. The importance of proton channels, fast transport of protons, energy-transmitting membrane proteins and enzymes is clarified by recent research (e. g. Pomes/Roux, 2002; Miloshevsky/Jordan, 2004). An explanation of pain reduction caused by a successful therapy with MBST tech- nology is therefore based on quantum mechanics.

(Reference: R2)

**Course of the diagnostic use of magnetic resonance technology**

When a radio wave pulse is switched off, the hydrogen protons return to their energetic state of equilibrium, i.e., back to the position determined by the magnetic field. The time required for this process is called relaxation time. Part of the energy that the hydrogen protons have absorbed is then released and this is measured from outside the body. Since the water content of the different tissues in the body varies (content of water in bone tissue, for example, is lower than in cartilage), the tissues contain different amounts of hydrogen protons. Due to the different relaxation times of the different tissue types, MRI technology can represent these differences in the form of image contrasts. From the data of the measured signals and with the help of special mathematical methods, the computer generates an image in different shades of grey. By changing the measurement settings, the presentation of certain types of tissue can be highlighted or softened, depending on the tissue that shall be examined. (FDA, 2017)

**Benefits**

An MRI scanner can be used to take images of any part of the body (e.g., head, joints, abdomen, legs, etc.), in any imaging direction. MRI provides better soft tissue contrast than CT and can differentiate better between fat, water, muscle, and other soft tissue than CT (CT is usually better at imaging bones). These images provide information to physicians and can be useful in diagnosing a wide variety of diseases and conditions. (FDA, 2017)

**Risks**

MR images are made without using any ionizing radiation, so patients are not exposed to the harmful effects of ionizing radiation. But while there are no known health hazards from temporary exposure to the MR environment, the MR environment involves a strong, static magnetic field, a magnetic field that changes with time (pulsed gradient field), and radiofrequency energy, each of which carry specific safety concerns:

- The strong, static magnetic field will attract magnetic objects (from small items such as keys and cell phones, to large, heavy items such as oxygen tanks and floor buffers) and

may cause damage to the scanner or injury to the patient or medical professionals if those objects become projectiles. Careful screening of people and objects entering the MR environment is critical to ensure nothing enters the magnet area that may become a projectile.

- The magnetic fields that change with time create loud knocking noises which may harm hearing if adequate ear protection is not used. They may also cause peripheral muscle or nerve stimulation that may feel like a twitching sensation.
- The radiofrequency energy used during the MRI scan could lead to heating of the body. The potential for heating is greater during long MRI examinations.

The use of gadolinium-based contrast agents (GBCAs) also carries some risk, including side effects such as allergic reactions to the contrast agent. See GBCAs for more information.

Some patients find the inside of the MRI scanner to be uncomfortably small and may experience claustrophobia. Imaging in an open MRI scanner may be an option for some patients, but not all MRI systems can perform all examinations, so the patient should discuss these options with the physician. Anti-anxious medication might be necessary to reduce claustrophobia.

To produce good quality images, patients must generally remain very still throughout the entire MRI procedure. Infants, small children, and other patients who are unable to lay still may need to be sedated or anesthetized for the procedure. Sedation and anesthesia carry risks not specific to the MRI procedure, such as slowed or difficult breathing, and low blood pressure.

(FDA, 2017)

However, an important question remains unanswered: Where is the wear and tear of the joint replacement deposited? What are the long-term negative consequences for the patient?

In contrast to all known forms of treatment, with the exception of the often unsatisfactory systemically effective agents such as glucosamine, magnetic resonance therapy targets degenerative joint changes causally at the cellular level.

The regeneration of cartilage or bone tissue significantly alleviates or even eliminates long-term pain and function, and mobility are restored.

(Reference: R2)

**Ostheoarthritis**

Arthrotic changes of the musculoskeletal system are a very big problem for health systems and one of the highest cost factors due to their enormous prevalence. The age structure rises and the conditions of private and working environment are constantly becoming more negative so that degenerative changes in joint and bone structures, osteoarthritis, spinal disorders and osteoporosis are increasing heavily.

Until 2000, the medical doctrine prevailed that cartilage tissue could not be regenerated once damaged. This has been shown to be inaccurate based on the findings in cell research.

The counterevidence was supported by the results of, among others, studies using magnetic resonance therapy devices.

A large number of scientific examinations following internationally accepted regulations showed that magnetic resonance fields can trigger verifiable regenerative processes in living tissue.

(Reference: R2)

**Therapeutic efficacy in the treatment of osteoporosis as well as metabolic and circulatory disorders of the bone**

Osteoporosis is a pathological, painful condition of the body that is characterized by a reduction of bone mass compared to the age and gender relevant norm. It is diagnosed with the help of various procedures, on the one hand with quantitative tomography (QCT) and on the other hand with the low-radiation DXA procedure, whose technology and measured values are internationally recognized.

(Reference: R2)

**Indication back pain – low back pain – degenerative changes of the spine, ruptured or herniated intervertebral discs**

Chronic back pain is very common and causes considerable psychosocial and health economic costs. The cervical and lumbosacral regions are usually affected. Low back pain is often associated with functional deficits/disabilities.

The prevalence of chronic, non-specific low back pain is constantly on the rise in all industrialized countries. Beside patients' impairment at work and in everyday activities, consequential treatment costs and loss of work also cause high socio-economic expenses for the general public.

The vertebral joints with articular surfaces on the *processus articulares* can cause considerable pain when affected by degenerative arthrotic changes. Following wear and loss of their function as mechanical stabilizers and load distributors by the degeneration and reduction of the height of the intervertebral discs, pathological shifts, shear movements and tilting become possible which affect the entire motion segment.

In the region of the posterior pillar of the spinal column, overstressing and degeneration or osteoarthritis of the vertebral arch joints occur.

Such arthritic processes of the spine are called spondylarthrosis or facet joint syndrome. Here, too, the characteristics of osteoarthrosis are a narrowing of the joint line, sclerosis and edge serration that is visible in x-rays.

These changes in the vertebral joints cause pain, muscle tension and vertebral blockage with myofascial pains at the tendon/ligament attachments.

(Reference: R2)

**Therapeutic efficacy in cases of chronic specific back pain**

Chronic back pain is a major problem in the population. In many cases, treatment can only be symptomatically. In practice, therefore, physiotherapeutic measures are often supplemented with additional forms of therapy.

Changes of voltage in collagen structures due to mechanical changes of stress cause the transport of electrical signals in and out of tissue structures and thus have a positive effect on the metabolic situation.

Studies show the stimulating influence of magnetic resonance therapy on the proliferation of chondrocytes and osteoblasts and suggest a regeneration of cartilage-like structures.

The results of the study were published in 2005 and 2006 in a lecture and in 2 publications in internationally recognized peer-reviewed journals.

Chronic low back pain is primarily a consequence of segmental dysfunction and muscle pain, usually associated with degenerative or post-traumatic changes in the affected part of the spine. The clinical examination is therefore very important and was performed on all patients included in the study.

Waddell's signs were taken into consideration: sensitivity to light pressure, pressure pain, compression pain of the lumbar spine under axial stress, pain during rotation of lumbar spine, pain when lifting the stretched leg, local muscle weakness, sensitivity disorders when lifting the stretched leg, non-verbal communication of pain. Mobility was assessed using the finger-to-floor distance test and the Schober index. Vertebral and paravertebral structures in palpation were examined, followed by a segmental functional examination and an examination of the hips and statics. The clinical examination was supported by radiological and computer tomographic examination methods.

Kullich et al. compared the effects of a complementary application of MBST therapy of 1 hour per day in combination with physiotherapy in a double-blind, placebo-controlled randomized study design.

The findings were presented aforehand in a lecture at the annual conference of the Austrian Society for Rheumatology and Rehabilitation in Vienna. The results of 62 patients (30 with MBST treatment, 32 with only physiotherapy and placebo treatment) show a clear, statistically significant superiority of the combination therapy compared to only physiotherapy with placebo treatment in almost all parameters such as the Visual Analogue Scale or the Oswestry disability score both 1 week after the beginning of therapy and after 3 months (Kullich et al., 2006).

(Reference: R2)

## 5.3 Device Technology and Development History

Specialized medical technological devices have been developed for the therapeutic application of magnetic resonance which can generate low-energy therapeutic magnetic resonance effects.

**The regenerative approach of MBST therapy**

Leland R. Kaiser coined the term regenerative medicine in 1992. According to his definition, it is the gentle renewal and replacement of tissue that no longer fulfils its function. This should be done by gentle adjustment and repair. Therefore, one of the most important goals of regenerative medicine is to use the body's own powers to treat or even cure diseases. This developed into a new branch of research worldwide.

With the current state of medicine, many diseases can be treated, but in many cases, they cannot really be cured. This is particularly true for age-related conditions. As a consequence of better nutrition and developments in medicine, the general population is getting older and older. However, the human body is not always prepared for this and, depending on age and state of health, cells often die, and functions of organs diminish.

**Regenerative medicine**

Regenerative medicine aims to restore diseased tissue and its functionality, primarily by using the body's self-healing powers.

In order to be able to enjoy the increasingly high age people reach, innovative solutions are needed, especially in the health sector. The enormous potential of the regenerative approach in medicine can already be seen in theory and in some research areas.

However, this is not so easy to implement, because it takes a long time for innovative treatment approaches to find their way into general medical care and high investments are necessary.

But more and more patients want to use innovative therapies. On the other hand, the health care system, e.g., in Germany tries to cut costs – an attitude which complicates the introduction of innovative medicine. For example, it took 20 years before stem cell transplantation was accepted as a standard therapy for blood cancer patients. Only after another ten years, this form of treatment was accepted and paid for by health insurances.

MBST magnetic resonance therapy has to struggle with the same hurdles. So far there are over 200 studies, academic publications or lectures. We are continuously working on further research results and are implementing them into new MBST therapies for the benefit of our patients, despite the complex and cost-intensive approval procedures.

MBST magnetic resonance therapy also uses the research approach of regenerating instead of, for example, repairing surgically. The aim is to use the self-healing powers of the human body in order to treat injuries or diseases sustainably and gently and to enable patients to achieve a significantly higher quality of life – without costly and risky operations or other invasive interventions in the body. MBST magnetic resonance therapy also does not include any medication or painkillers that can have unpleasant or severe side effects.

**From MRI to MBST therapy**

It was not until 1977 that R. Damian succeeded in creating the first image of the human body. The resolution was not yet sufficient for diagnostic use and the recording times were still several hours. In 1981, for the first-time tumor tissue could be distinguished from healthy tissue. MRI was increasingly accepted clinically, among other things because of its advantages, e.g. the high soft tissue contrast and the lack of radiation exposure. In the early stages of MRI, patients often had to be examined many times. After frequent magnetic resonance imaging examinations, many Patients with joint problems reported – initially inexplicable to physicians – that their complaints had improved.

Axel Muntermann, the developer of therapeutic magnetic resonance, also became aware of these results. Together with physicians, biologists and physicists, he finally came to the conclusion that

it might be the phenomenon of magnetic resonance that triggered this positive effect. Based on this, the MBST treatment systems, which use the same physcial principle as the MRI device – magnetic resonance – were developed in several years of work.

**Differences between the MBST magnetic resonance therapy system and magnetic resonance imaging (MRI)**

The biggest difference is the use for diagnostic or for therapeutic purposes. In addition, the MBST magnetic resonance therapy system is characterized by the open design of the therapy devices. This means that patients do not have to fear suffering from claustrophobia during MBST treatment. They can relax and listen to music, read or even sleep.

The patented MBST magnetic resonance technology also requires no special premises and uses magnetic fields that are not nearly as strong as those of MRI. MedTec has succeeded in using the so-called Adiabatic Fast Passage to generate resonance conditions even at low magnetic field strengths. Therefore, contraindications for MRI do not necessarily apply to MBST therapy.

Depending on the treatment zone, ring-shaped, open or flat applicators are used for energy transfer.

The size of the magnetic resonance field is in the range of 0.4 mT which is a fraction of the field a magnetic resonance tomograph uses in MRI and cannot exceed a maximal value of 4 mT due to technological restrictions.

To prevent mistakes in the operation of the device, the treatment process was automatized, starting is done easily and error-free by means of a special start button.

Prior to the start of treatment, tissue-specific treatment data specified for the indication is automatically loaded into the control unit via a smart card reader unit. For each indication, the correct, study-based, tissue-specifically programmed therapy chip card is required. Duration of treatment is one hour and is applicated daily. During this time, different tissue-specific program sequences are processed.

Depending on the indication, a series of treatments consists of 7 to 10 therapy units. The devices can be used for a wide variety of clinical indications.

The first MBST Magnetic Resonance Technology Systems have been developed in 1998.

The following figure shows the brand history and milestones:

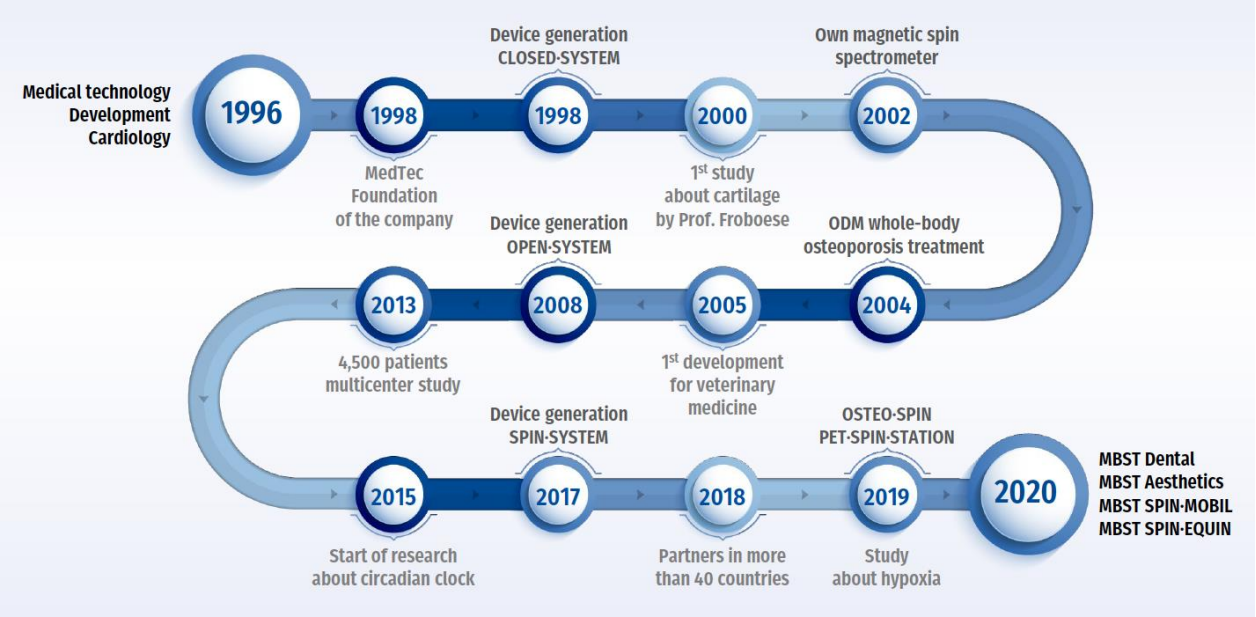


**Figure 9: Development and milestones**

## Developmental stages:

1st generation of therapeutic magnetic resonance, series CLOSED·SYSTEM

- Ring system with permanent magnets
- Magnetic resonance field with a volume of approximately 1 l for the model CS300 and 10 l for the model CS600

The Closed Systems are no more manufactured since 2014/2015. There are still approximately 50 devices on the market and therapy cards are still available for them.

2nd generation of therapeutic magnetic resonance, series OPEN·SYSTEM

- Electrical generation of the static basic field B0
- Fast Adiabatic Passage, FAP
- The transition from the device generation CLOSED·SYSTEM (ring systems with permanent magnets) to OPEN·SYSTEM (open systems) was only possible with the invention of Fast Adiabatic Passage. This greatly increases homogeneity of the basic magnetic field.
- The volume of the magnetic resonance field was increased by the factor 10, i.e., approx. 30 l for the model OS350 and 150 l for the model OS700.
- Thus, the success rate of treatment could be increased considerably (due to minimization respective prevention of errors in patient positioning).

3rd generation of therapeutic magnetic resonance, series SPIN·SYSTEM

- Completely new therapy systems with expanded range of treatment zones
- Basis for 4 new patents
- Fast Adiabatic Passage, FAP

- Electronic testing and monitoring of magnetic resonance field regarding quality, size and effectivity
- Possibility to pause therapy
- Improved compensation for metal parts in the treatment room
- Optimized and enlarged magnetic resonance treatment field with expanded fields of application and a significantly higher rate of success
- Optimal and comfortable execution of all treatment options

OS350 is a successor device to the CS300 and the ASL is a successor to the OS350.

OS700 is a successor of the CS600 and the ASF is a successor of the OS700.

In the scope of the verification all of the required technical tests have been performed. These are part of the technical documentation of the medical device.

## 5.4 General Safety and Performance Requirements (GSPR)

Medical devices must comply with the applicable general safety and performance requirements (GSPR) according to Annex I of the MDR, taking into account the intended use of the device. The safety and performance requirements, which must be supported by relevant clinical data according to the CEP (Reference: R4), are listed below.

| No. | GSPR | Evidence of Conformity | References to Supporting Documents / Comments |
|---|---|---|---|
| 1. | Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. | EN 60601-1<br>EN 60601-1-2<br>EN 60601-1-6<br>ISO 14971<br>EN 62366<br>EN 62304<br>EN 62353<br><br><br><br>ISO 100993-1 | Test report EN 60601-1<br>EMC test report<br>Patient ergonomics<br>Risk management file<br>Usability<br>Software documentation<br>Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment<br>Biocompatibility information |
| 5. | In eliminating or reducing risks related to use error, the manufacturer shall:<br>(a) reduce as far as possible the risks related to the ergonomic features of the device and the | ISO 14971<br>EN 62366 | Risk management file<br>Usability |

| No. | GSPR | Evidence of Conformity | References to Supporting Documents / Comments |
|---|---|---|---|
| | environment in which the device is intended to be used (design for patient safety), and<br>(b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users). | | |
| 6. | The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions. | EN 60601-1<br>EN 60601-1-2<br>EN 60601-1-6<br>ISO 14971<br>EN 62366<br>EN 62353 | Test report EN 60601-1<br>EMC test report<br>Patient ergonomics<br>Risk management file<br>Usability<br>Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment |
| 8. | All known and foreseeable risks, and any undesirable side-effects, shall be minimized and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use. | ISO 14971 | Risk management file |

**Table 10: General safety and performance requirements (GSPR) for the device**

## 5.5 Preclinical Testing

Preclinical testing has been performed for the MBST Magnetic Resonance Technology Systems. The medical devices thus meet all of the general safety and performance requirements according to Appendix I of the Medical Device Regulation.

### Usability (EN 62366)

Since the medical devices are on the market and no changes have been made, a usability engineering file of unknown provenance was compiled for each device of the complete product family except for MBST® OsteoSpin to confirm usability engineering activities of a legacy user interface according to Annex C (User Interface of Unknown Provenance – UOUP) of IEC 62366-1:2015. The confirmation relies on the available documentation and information and considers

risk assessment as part of the risk analysis. In 2017, for MBST® OsteoSpin a retrospective validation and summative usability test has been conducted. The test was passed, the validation was successful.

(References: R10)

**Electrical safety (EN 60601-1)**

Electrical safety has been tested for all evaluated MBST Magnetic Resonance Technology Systems since they are active medical devices. Gap analysis have been performed and only the current standards have been applied. The devices have passed the tests and are electrically safe.

(References: R14)

**Electromagnetic compliance (EN 60601-1-2)**

Also, electromagnetic compliance has been tested and passed for all evaluated devices. The tests are all documented and part of the technical documentation. All MBST Magnetic Resonance Technology Systems are electromagnetically compatible.

(References: R15)

**Biocompatibility (ISO 10993-1)**

The evaluated devices are only in contact with the skin for a short duration (< 24 hours) according to DIN EN ISI 10993-1. The maximal treatment time is 1 hour/day.

All required biocompatibility tests have been performed. The material being in contact with the skin are all biocompatible according to DIN EN ISO 10993-1.

(References: R12)

**Software verification (ISO 62304)**

The software system is split on two different hardware platforms. These are:

- Control unit with the board ControlVerst V2.0 Rev.2
- MBST-HMI

There is a main software component for each hardware platform, which is divided into further software components. A division of the software components into software units can be void here, since the entire software was classified as safety class A.

All tests have been performed and the software development is compliant with ISO 62304.

(References: R13)

## 5.6 Marketing History

The evaluated medical devices are available on the EU market and CE-marked. Six variations are available:

- MBST® OpenSystem350 / MBST® OpenSystem700
- MBST® OsteoSystem (ODM)

- MBST® ProMobil
- MBST® ArthroSpin Flex
- MBST® ArthroSpin Lift
- MBST® OsteoSpin

The first-generation Closed systems have been the first devices being CE-marked. They have been on the market since 1998 and are no more manufactured since 2014/2015.

Since 01/2005, the sales figures are recorded in a new system and since then, 1,737 devices and 175,061 therapy cards have been sold all around the globe (Europe, Asia): (Reference: R9)

| | Sale/piece | |
|---|---|---|
| **Device** | **Devices count** | **Therapy card** |
| OSTEO·SPIN | 6 | 434 |
| ARTHRO·SPIN·FLEX | 128 | 16.083 |
| ARTHRO·SPIN·LIFT | 82 | 4.150 |
| OPEN·SYSTEM·700 | 323 | 55.987 |
| OPEN·SYSTEM·350 | 211 | 25.407 |
| CLOSED·SYSTEM·600 | 197 | 23.608 |
| CLOSED·SYSTEM·300 | 200 | 25.369 |
| OSTEO·SYSTEM·1 | 126 | 4.349 |
| PRO·MOBIL | 347 | 15.668 |
| SPIN·REPAIR | 37 | 979 |
| PRO·ION | 2 | 51 |
| PET·SPIN·STATION | 5 | 154 |
| PRO·VET·STATION | 26 | 1.197 |
| PRO·VET·MOBIL | 47 | 856 |
| Democard (red label) | - | 456 |
| Testcard (blue label) | - | 28 |
| Servicecard (yellow label) | - | 28 |
| Other | - | 257 |
| **Total** | **1.737** | **175.061** |

**Table 11: Devices/therapy cards sold since 2005**

## 5.7 Risks related to the Medical Device

A risk analysis according to ISO 14971 has been performed for the MBST Magnetic Resonance Technology Systems. (References: R5, R6)

### Analysis of Clinical Hazards

The following side effects that are generally observed with MRI and magnetic resonance applications in general and which are described in the literature (see sections 5.1 and 5.2 regarding state of the art):

MR images are made without using any ionizing radiation, so patients are not exposed to the harmful effects of ionizing radiation. But while there are no known health hazards from temporary exposure to the MR environment, the MR environment involves a strong, static magnetic field, a magnetic field that changes with time (pulsed gradient field), and radiofrequency energy, each of which carry specific safety concerns:

The strong, static magnetic field will attract magnetic objects (from small items such as keys and cell phones, to large, heavy items such as oxygen tanks and floor buffers) and may cause damage to the scanner or injury to the patient or medical professionals if those objects become projectiles. Careful screening of people and objects entering the MR environment is critical to ensure nothing enters the magnet area that may become a projectile.

The magnetic fields that change with time create loud knocking noises which may harm hearing if adequate ear protection is not used. They may also cause peripheral muscle or nerve stimulation that may feel like a twitching sensation.

The radiofrequency energy used during the MRI scan could lead to heating of the body. The potential for heating is greater during long MRI examinations.

The use of gadolinium-based contrast agents (GBCAs) also carries some risk, including side effects such as allergic reactions to the contrast agent.

Side effects associated specifically with the MBST devices are:

- Skin burns, irritation
- Injuries
- Electric shock
- High temperature sensation
- Cardiac problems

Clinical hazards that have to be evaluated:

- Energetic hazards
- Mechanical hazards
- Hazards due to material properties, e.g., biological, chemical substances and environmental influences
- Hazards arising from operation
- Hazards due to malfunction
- Hazards due to information
- Hazards due to foreseeable misuse
- Hazards in production/during shipment/downstream phases

**Implemented Risk Control Measures**

Risk control measures were defined and implemented according to Reference R5.

Implemented risk control measures are largely based on the compliance with applicable harmonized standards. Additionally, the following technical control and surveillance measures were implemented and successfully verified for effectiveness:

- Validation
- Constructive actions
- Application of standards such as EN 60601-1
- System tests
- STK tests

Furthermore, hazards associated with use errors related to the device-user interface were reduced to an acceptable risk level by:

- descriptions in the instructions for use
- user trainings

After implementation of these risk control measures the residual risk was assessed again. Remaining individual risks and overall residual risks are assessed in the Risk Management Report (Reference R6). Section 12 Risk/Benefit Assessment provides an in-depth discussion of the risk/benefit profile.

## 5.8 Clinical Safety and Performance Claims

This clinical evaluation aims to demonstrate the performance and safety of the medical devices under evaluation. Essential performance and safety requirements have been defined for these medical devices that shall be substantiated with relevant data in this clinical evaluation. Reference: https://www.mbst.de/uebersicht-ueber-die-mbst-therapiegeraete.php and product brochures.

**Performance claims:**

- Low-maintenance due to durable components designed for continuous use
- Newly developed magnetic resonance applicators that generate a homogeneous treatment field
- No exposure to radiation (Radio frequency coil (RF field with 14–17.5 kHz), FAP effective magnetic field: B0 = 0.33–0.40 mT, defined magnetic resonance field volume)
- The module controls and regulates strength and quality of the magnetic resonance field during the therapy session to guarantee optimum treatment conditions.
- Control unit (electrical protection class I) with switching power supply
- Sweep coils (static and variable field)

**Safety claims:**

- The non-copyable MBST therapy cards are encrypted according to EMV standard for maximum security.
- Surface is resistant to impacts, scratches and abrasions, easy to clean and to disinfect.
- The material complies with the medical product regulation DIN EN ISO 10993-5+10 and is biocompatible.

## 5.9 Benefits related to the Medical Device

The clinical benefit of the evaluated medical device results from the performance and safety claims above:

- Non-invasive procedure
- Causal form of therapy

- Uncomplicated form of treatment for diseases of the musculoskeletal system for which no essential form of treatment is available (e. g. finger joint arthrosis, spondylarthrosis, polyarthrosis, metabolic or circulatory disorders of the bone, osteoporosis, etc.)
- Short duration (5, 7, 9 or 10 hours of treatment depending on stage and type of disease)
- Delaying surgery or accelerating regeneration after necessary surgery
- In case of surgical interventions such as cartilage smoothing, the causal active principle at cellular level may be used to build up cartilage
- In the case of intervertebral disc problems and herniated discs, surgery and the resulting scar tissue may be prevented
- Sustainable and long-lasting therapy effect of 4.5 years and more
- Painless and silent

# 6 Consideration of Equivalence

The evaluated MBST Magnetic Resonance Therapy System included in this clinical evaluation already bears the CE mark and the devices are marketed worldwide since 1998 (see section 5.3). The devices have long-term clinical experience and are based on long-standing, well-characterized technologies and materials. Many clinical investigations have been conducted with the devices themselves.

Therefore, clinical data pertaining to the medical devices under evaluation is available and will be evaluated in section 8. Therefore, the identification of equivalent devices is not deemed to be necessary for demonstrating safety and effectiveness performance of the evaluated MBST Magnetic Resonance Therapy System. The focus also in future PMCF activities (please refer to section 12) will be based on clinical data pertaining to the MBST Magnetic Resonance Therapy System itself.

# 7 Choice of Clinical Data

## 7.1 Clinical Data

Relevant clinical data to prove that the MBST Magnetic Resonance Technology Systems achieve their intended performance during normal conditions of use, for the indications as described in this clinical evaluation report, results from:

### 7.1.1 Literature search

The use and application of the evaluated medical device in the scope of the intended use is described in section 4.1. The literature search in PubMed to identify the safety and performance of the evaluated medical devices is deemed to be sufficient. The literature review and the corresponding results are documented in section 8.

The evaluation of MBST is based on a comprehensive research of literature at monthly intervals. For this purpose, established databases for scientific literature are used and the relevant results are taken into account. Naturally, such a keyword search also leads to a large number of

irrelevant search results, which can be excluded in the present evaluation. The most common reason is that these publications are not about the therapy procedure examined herein or a comparable technology.

The search is carried out regularly and new results are included. Depending on the findings and other relevant new information, a summarizing assessment of new data is carried out at least once a year in the context of the CER. The listed data was last compiled on the basis of searches in February 2020. Now, it is compiled again and, thus, reflects the state of the databases at that point of time of version 1.0 according to the MDR requirements.

### 7.1.2 Clinical Experience

#### Internal Clinical Experience

In section 9.1, the internal clinical experience data including the PMS data resulting from the manufacturer's PMS system are summarized and evaluated.

#### Safety Databases

Retrospectively, the data of clinical experiences are analyzed and evaluated. All results are documented in section 0 of this CER. The following databases were searched with focus on medical device alerts, recommendations and recalls related to the evaluated devices:

a) **MHRA** (Medicines and Healthcare products Regulatory Agency): Executive agency of the Department of Health, Great Britain. Responsible for ensuring performance and safety of medicines and medical devices. Start: 03/2003 Source: www.mhra.gov.uk
b) **Swissmedic**: Swiss agency for the authorization and supervision of therapeutic products. Provides a recall list of medical devices. Start: 01/2002. Source: www.swissmedic.ch
c) **BfArM** (Bundesinstitut für Arzneimittel und Medizinprodukte): Federal institute for drugs and medical devices in Germany, operating under the Federal Ministry of Health. Ensures the central collection of manufacturer´s field corrective actions and recommendations by the BfArM. Started in 06/1994. Sources: www.bfarm.de

Since the MBST magnetic resonance technology is not yet available in the USA and is, thus, not listed at the FDA this database can, therefore, be neglected for the present evaluation.

# 8 Literature Review

Evaluation of clinical data is a prerequisite for compliance with the MDR and the European Commission Guideline MEDDEV 2.7/1 Rev. 4 (June 2016) (Clinical Evaluation: A guide for manufacturers and notified bodies).

The above listed regulatory documents ensure that:

- patient benefits outweigh the risks,
- clinical performance claims are upheld, and
- any undesirable side-effects constitute an acceptable risk when weighed against the intended performances.

The requirements provide that the data, by which compliance is demonstrated, may be based on either the results of clinical investigations or a critical review of scientific literature or a combination of both. If available, also market experience of the same or similar devices shall be taken into consideration.

The objective of the literature search is to systematically assess risks and benefits associated with the use of the MBST Magnetic Resonance Technology Systems in compliance with the European guidance document MEDDEV 2.7/1 Rev. 4. Furthermore, it shall provide analysis of available published and unpublished clinical data to determine its suitability for demonstration of safety and performance of the device, and to establish conformity with the General Safety and Performance Requirements (GSPRs) of the MDR.

This is why further data was provided by the manufacturer on request and included. Some of this is unpublished for different reasons. The studies from 2002 and 2003 were conducted as a prospective study shortly after the development of MBST therapy and were only presented at congresses. 3 others, Oliva, 2014, Budny, 2015 and Thöni, 2019 are master or doctoral theses that have only been published in the university.

An article, Egg, 2017, has not yet been published, but has been accepted for publication by a peer-reviewed journal. As it is highly relevant for the current state of knowledge about MBST nuclear magnetic resonance technology, a lecture manuscript with similar content has been included.

Other studies are also included which were published but could not be found in the databases used. They shall nevertheless be used here as they are indispensable for a comprehensive picture of MBST magnetic resonance therapy.

## 8.1 Sources of Data

Chosen source for the literature search is PubMed (database MEDLINE). Compiled by the United States National Library of Medicine (NLM), MEDLINE is available on the Internet and searchable via PubMed. MEDLINE facilitates evidence-based medicine. Most systematic review articles published nowadays are built on extensive searches of MEDLINE.

Source: www.ncbi.nlm.nih.gov/pubmed

## 8.2 Database Search Strategy

The search is conducted in English and online via PubMed. Defined search categories are listed in the table below:

| No. | Search Category | Search Terms |
|---|---|---|
| **1** | **Medical application/intended use** | |
| **1.1** | The MBST® Magnetic Resonance Therapy System is used to treat | (“magnetic resonance therapy” OR MRI) AND pain AND “musculoskeletal system” |

| No. | Search Category | Search Terms |
|---|---|---|
| **1.2** | painful, degenerative and/or pathological changes in the musculoskeletal system. | ("magnetic resonance therapy" OR MRI) AND ("degenerative change" OR "pathological change") AND "musculoskeletal system" |
| **2** | **Indications** | |
| **2.1** | Nuclear Magnetic Resonance Therapy, osteoarthritis | ("magnetic resonance therapy" OR MRI) AND osteoarthritis |
| **2.2** | Nuclear Magnetic Resonance Therapy, gonarthrosis | ("magnetic resonance therapy" OR MRI) AND gonarthrosis |
| **2.3** | Nuclear Magnetic Resonance Therapy, osteoporosis | ("magnetic resonance therapy" OR MRI) AND osteoporosis |
| **2.4** | Nuclear Magnetic Resonance Therapy, degenerative bone and joint conditions | ("magnetic resonance therapy" OR MRI) AND degenerative AND (joint OR bone) |
| **2.5** | Nuclear Magnetic Resonance Therapy, injuries of joints | ("magnetic resonance therapy" OR MRI) AND injury AND joint |
| **2.6** | Nuclear Magnetic Resonance Therapy, bone fractures | ("magnetic resonance therapy" OR MRI) AND "bone fracture" |
| **2.7** | Nuclear Magnetic Resonance Therapy, tendopathy | ("magnetic resonance therapy" OR MRI) AND tendopathy |
| **2.8** | Nuclear Magnetic Resonance Therapy, injuries of muscles, tendons and ligaments | ("magnetic resonance therapy" OR MRI) AND injury AND (muscle OR tendon OR ligament) |
| **3** | **Evaluated medical devices** | |
| **3.1** | MBST | MBST OR (MBST AND "magnetic resonance") |
| **4** | **Guidelines (publication type)** | ("magnetic resonance therapy" OR MRI) AND pain |

**Table 12: Search categories**

General exclusion criteria are the following:

- publications not available as full texts,
- publications with only a conference abstract available,
- publications with no abstract available,
- studies/reports with a different intended use from MBST, as they are out of scope of the equivalence,
- studies/reports with different indications from MBST as they are out of scope of the equivalence,
- books – are not available in-house for review.

Publications written in a language other than English or German are excluded following the analysis of the abstract if the abstract shows no relevance for the clinical evaluation. If the abstract shows such a relevance for the clinical evaluation, the full text of the publication written in another language shall be translated and evaluated accordingly.

## 8.3 Selection Criteria

The literature appraisal is done in terms of relevance, quality and clinical significance:

**Relevance**

Publications with the following content are relevant for the clinical evaluation of MBST in general:

- Publications with focus on clinical data pertaining to the evaluated within the intended use,
- Publications with focus on the same indications and evaluating a therapeutic or other effect of MBST magnetic resonance technology – positive or negaive – on cells and/or tissue,
- Publications with focus on product claims.

Publications with the following content are generally not relevant for the clinical evaluation of the MBST:

- Publications not within the scope of the intended use
- Publications with focus on other indications
- Publications with focus on history reports about MR/MRI
- Publications with focus on the application itself
- Publications with focus on patient information
- Publications with focus on training of physicians/qualified staff
- Publications with focus on other medical devices not being the evaluated one
- Publications on the therapeutic use of simple magnetic field therapies such as pulsating signal therapy
- Publications on the use of magnetic resonance for diagnostics as in MRI
- Publications not evaluating any therapeutic effects of the technology

**Quality**

The appraisal regarding the quality of the literature is done according to the medical level of evidence[1]:

| Level | Method |
|---|---|
| Level 1 | Systematic review of randomized controlled trials |

[1] Based on `*Oxford Centre for Evidence-Based Medicine, "The Oxford 2011 Levels of Evidence", http://www.cebm.net

| Level | Method |
|---|---|
| Level 2 | Randomized controlled trials (includes quasi-randomized processes such as alternate allocation.) |
| Level 3 | Non-randomized controlled trials (includes prospective studies with predetermined eligibility criteria and outcome measures.) |
| Level 4 | Observational studies with controls (includes retrospective, interrupted times series, case-control studies, cohort studies with controls, and health service research service adjusting for likely confounding variables.) |
| *Level 5* | Observational studies without controls, expert opinions (includes cohort studies, case series and case studies without controls.) |

**Table 13: Evidence levels**

Independently of this categorization, scientific literature including experimental studies without human subjects, monographs as well as guidelines of respected societies might be included in the evaluation if meaningful.

**Journal Impact Factor**

The Journal Impact Factor (JIF) of the respective scientific journal is indicated.

**Clinical Significance**

Significance of a publication in terms of this clinical evaluation's focus on clinical safety and performance is divided into three categories:

- Potentially relevant [PR]
- Relevant [R]
- Not relevant [NR]

## 8.4 Literature Search Results

### 8.4.1 Previous Literature Searches

For previous CERs exhaustive literature searches have been conducted. (References: R1, R2)

The following criteria for the assessment of found data have been applied:

In accordance with this table, all search results are also classified regarding their usefulness for the evaluation of the performance and safety of the medical device. The weighting of the individual references is based on the equivalence criteria in column 3.

Level 1 data means references that are mostly classified 1 (A1, I1, P1, R1) and not classified 3 in any category.

Level 2 data means references that are mostly classified 2 (A2, I2, P2, R2) and have a maximum of one topic classi- fied 3 if another topic is classified 1.

Level 3 data means references that are classified 3 (A3, I3, P3, R3) at least twice or three times if the classification in another heading is 1.

Level 4 data means references that are only classified 3.

Level 1 > Level 2 > Level 3 > Level 4

| **Assessment criteria** | **Description** | | **Classification** |
|---|---|---|---|
| Respective use | The device is used for the same purpose (e. g., same type of usage) | A1<br>A2<br>A3 | Same purpose<br>Small deviation<br>Large deviation |
| Respective indication | The same tissue or same body part is examined | I1<br>I2<br>I3 | Same indication<br>Small deviation (e. g. same symptoms in another body part<br>Large deviation (e. g. other tissue, other indication) |
| Respective target group | Data is collected from a representative group of patients (e. g. age, severity of condition) | P1<br>P2<br>P3 | Homogeneous group<br>Group with small deviations<br>Heterogenous group |
| Acceptable data collection | Search results/studies/publications include enough information to allow rational and objective evaluation | D1<br>D2<br>D3 | High data quality<br>Small deficiencies (e. g. small number of cases < 50 but homogenous group)<br>Insufficient data (e. g. small number of cases, inhomogenous group or different conditions) |

**Table 14: Assessment criteria for the suitability of found data**

| References | Criterion use | Criterion indication | Criterion target group | Criterion data quality | Level of weighting |
|---|---|---|---|---|---|
| **Osteoarthritis** | | | | | |
| Auerbach/Melzer, 2003 | A1 | I1 | P1 | D2 | L1 |
| Brockamp, 2009 | A1 | I3 | P3 | D2 | L3 |
| Fagerer/Kullich, 2007 | A1 | I1 | P1 | D2 | L1 |
| Froböse et al., 2000 | A1 | I1 | P1 | D2 | L1 |
| Jansen et al., 2011 | A1 | I3 | P3 | D3 | L3 |
| Kullich/Ausserwinkler, 2008 | A1 | I1 | P1 | D2 | L1 |
| Kullich et al., 2013 | A1 | I1 | P1 | D1 | L1 |
| Levers et al., 2011 | A1 | I1 | P1 | D2 | L1 |
| Steinecker-Frohnwieser et al., 2017 | A1 | I2 | NN | D1 | L1 |
| Temiz-Artmann et al., 2005 | A1 | I2 | NN | D1 | L1 |
| Klapsch, 2002 | A1 | I2 | P1 | D2 | L2 |
| Gökşen et al., 2016 | A3 | I2 | P2 | D3 | L3 |
| Barker, 2010? | A3 | I1 | NN | NN | NN |
| Mucha et al., 2017 | A1 | I3 | P3 | D3 | L3 |
| Mueller et al., 2015 | A1 | I3 | P3 | D3 | L3 |
| **Intervertebral discs** | | | | | |
| Kullich et al., 2013 | A1 | I1 | P1 | D1 | L1 |
| Kullich/Schwann/Machreich/ Ausserwinkler, 2006 | A1 | I1 | P1 | D1 | L1 |

| | | | | | |
|---|---|---|---|---|---|
| Kullich/Schwann/Walcher/ Machreich, 2006 | A1 | I1 | P1 | D1 | L1 |
| Salfinger et al., 2015 | A1 | I1 | P1 | D2 | L1 |
| Salomonowitz, 2011 | A1 | I1 | P2 | D2 | L2 |
| Levchenko et al. 2017 | A1 | I1 | P2 | D1 | L1 |
| **Osteo/bone** | | | | | |
| Krpan/Kullich, 2017 | A1 | I1 | P1 | D1 | L1 |
| Temiz-Artmann et al., 2005 | A1 | I2 | NN | D1 | L1 |
| Handschuh/Melzer, 2008 | A1 | I1 | P2 | D2 | L2 |
| Klapsch, 2003 | A1 | I1 | P2 | D2 | L2 |
| Overbeck et al., 2003 | A1 | I1 | P2 | D2 | L2 |
| Krpan et al., 2015 | A1 | I1 | P1 | D1 | L1 |
| Kullich et al., 2016 | A1 | I1 | P1 | D1 | L1 |

**Table 15: Evaluation of the relevance of the data found in relation to the total number of search results found**

The table above only classifies studies as articles, expert opinions etc. usually do not bring statistically meaningful results. Some titles are excluded from the relevance assessment because they deal with basic research on the application and technology of MBST magnetic resonance therapy. As this naturally applies equally to all indications, it makes no sense to include them here, but of course they are highly relevant for the evaluation.

The literature search for the last CER in 02/2020 resulted in 1 more publication: Levchenko et al. 2017.

These results have been analysed in the previous CERs. All in vitro studies are now excluded and the remaining relevant publications are analysed in section 8.7.1 in this CER.

Excluded publications from the table above due to not being relevant as being in vitro:

Temiz-Artmann et al., 2005

Gökşen et al., 2016

Barker, 2010

Mucha et al., 2017

Mueller et al., 2015

Brockamp, 2009

Jansen et al., 2011

Steinecker-Frohnwieser et al., 2017

Temiz-Artmann et al., 2005

### 8.4.2 Current Literature Search

A current literature search was done according to defined data sources and search terms (see section 8.2) in order to update the previous CER from 02/2020 for the version 1.0 according to the MDR requirements.

- Person conducting literature search: Daniela Penn
- Date of the literature search: 17.11.2020
- Period of the literature search: 01/2020 – 11/2020
- Used medium: online, PubMed (MEDLINE) via Endnote

The criteria (search terms/key words) listed in Table 10 have been applied.

Please refer to the literature search protocol [A1] in the annex for the detailed results of the literature search.

## 8.5 Appraisal of potentially relevant Publications

All relevant publications of the previous CERs have been included into this current CER. They are analyzed in section 9.1.

After cross-check and screening of the search results of the current literature search, 74 publications have been considered as potentially relevant (PR). They were selected after application of exclusion criteria and aspects regarding general relevance for the context of the clinical evaluation (table 2 in the Literature Search Protocol [A1]). The abstracts of the 74 publications have been read and appraised regarding the context of the clinical evaluation (Table 2 in the Literature Search Protocol [A1]).

Following the reading of the abstracts, none of the 74 potentially relevant publications (abstracts) have been read as full texts and, thereof, none have been appraised as relevant for the context of the clinical evaluation for the MBST [Table 3; A1]. One publication (guideline) has been found and analyzed in view of the state-of-the-art section.

# 9. Summary of Literature Analyses

## 9.1 Summary of Previous Literature Analyses

The previously conducted literature searches have been analyzed in the respective CERs. (References: R1, R2). The relevant publications referring to the evaluation of the clinical

performance and safety of the evaluated MBST Magnetic Resonance Technology Systems and being according to the MDR requirements are documented in this section in order to provide a complete and exhaustive clinical data overview for the version 1.0 of this CER.

As mentioned in section 8.4.1, this summary includes clinical data from the literature searches but also unpublished data or data pertaining to the manufacturer. The literature references are listed in section 18.

The review and evaluation of the magnetic resonance therapy (MBST) was based on the documents provided by MedTec Medizintechnik GmbH, Wetzlar, in the form of numerous studies conducted and published in vivo and in vitro, publications in peer-reviewed journals, posters and lectures at international conferences as well as expert opinions in the human and veterinary field.

As has been shown by numerous research groups on the basis of very extensive preclinical experiments, clinical studies and studies carried out according to international standards on both cell cultures and animals, there is no doubt that the special fields in the context of the application of MBST trigger biological effects like an influence on cell metabolism which cannot be explained with sham or placebo effects.

### 9.1.1 Performance

**Influence on osteoarthritic symptomatology**

After a biological effect of magnetic resonance therapy at the cellular and organic level could be demonstrated, the question of therapeutic usability arises. In contrast to a general effect on biological systems, the focus here shall be on the efficacy in the treatment of certain indications. Following numerous reports on the efficacy of pulsating magnetic fields in orthopedic indications, Kroesche and Breitgraf (1998) carried out a prospective study of the application of MBST therapy for multiple joint complaints in 30 patients.

Since more than one joint was affected in some patients, a total of 44 treatments were performed. Gonarthrosis was documented in 27 patients. The assessment was based on a 6-stage analogue scale for sensitivity, pain frequency, pain intensity, restriction of movement, change of bending angle in the knee joint, swelling, over- heating, redness and discomfort.

***Results***

6 weeks after therapy, 20 patients (66.6%) showed an improvement, 8 patients (26.7%) showed no improvement, and 2 patients (6.7%) showed a deterioration. 5 patients had a follow-up treatment with an identical setting, 3 of which showed an improvement.

Taking into consideration that this study was carried out under real world conditions, the result is remarkable, especially since no negative effects, no side effects or other impairments apart from an occasional feeling of warmth or a tingling were apparent.

Looking at the overall results including follow-up treatments, 76.7% of the treated patients experienced an improvement in at least one treated joint, 70% of the patients had an improvement in all treated joints. According to the authors, this proves that MBST therapy is an effective and innovative treatment for osteoarthritic disorders. (Breitgraf et al., 1998)

**MBST magnetic resonance therapy – Effects in the tissue**

An observational study by Dr. Klapsch, Spittal an der Drau, Austria, came to a similarly positive conclusion. The results were presented at the 27th annual conference of the Austrian Orthopedic Society in Graz (Klapsch, 2003) In this study, predominantly knees and ankle joints were treated with 5-hour therapy cycles (34/11) and 9-hour therapy cycles (52/7). Subjective satisfaction of the patients, pain levels at rest and stress as well as joint function and effects on body tissue were assessed.

Very good to good results were achieved in 70% of the patients with short treatment and 73.5% of the patients with long (9 hours) treatment. (Klapsch, 2003; Klapsch, 2002)

**Regeneration of cartilage structures in cases of gonarthrosis**

The available literature includes a publication by Prof. Dr. Froboese, University of Cologne (Froboese et al., 2000) about the application of the above-mentioned magnetic resonance therapy on 14 patients with gonarthrosis.

The success of the treatment was demonstrated by means of a technically highly optimized tomographic method with color images which is also based on magnetic resonance. The field size of the MRI scanner was 1 tesla.

All patients had diagnosed cartilage defects, some very serious (Wirth 2 to 3) before the start of treatment.

The MRI images of the knee joint were taken before and 3 months after MBS therapy. The subsequent cartilage quantification and visual presentation of the positive adjustments of the cartilage structures of the knee joint showed a highly significant increase (increase in volume was more than 30%) in thickness, volume and area of the cartilage structures. Mean density of the cartilage structures of patella and tibia was compared before and after treatment with magnetic resonance therapy. Statistically, highly significant differences between the values before and after treatment value were recorded for both structures.

Of course, the question of a controlled test design always arises when presenting such results. It should be noted that a visual representation of an MRI image is real, i.e., a momentary, real, controlled state and thus free of placebo.

Taking into account that the results of the measurements provided a clear approximation to the values of healthy people, a relatively high value must be attributed to the study, especially as the authors believe that equivalent successes were a complete novelty and had not yet been observed. (Froböse et al., 2000)

**MBST therapy in the treatment of gonarthrosis**

Prospective study of the effect of magnetic resonance therapy in conservative treatment of gonarthrosis: Further evidence of the efficacy of was reported by Auerbach and colleagues of the Waldkrankenhaus Bad Dueben – an orthopedic clinic – and presented at the German Orthopedic Congress in Berlin (Auerbach et al., 2005).

60 patients with arthroscopically verified cartilage damage were treated with a therapy device of MedTec Medizin- technik GmbH, Wetzlar, for 1-hour treatments on 5 consecutive days. The success of the treatment was objectified by means of several internationally recognized analogue scales and questionnaires.

***Results***

- Assessment of efficacy in 59 patients immediately and 2 and 6 months after treatment. For all criteria (7 in total), a statistically significant improvement compared to the previous value could be recorded. Pain, joint stiffness as well as joint functions had improved. 6–15% of the patients reported improvements directly after the treatment, 19–27% after 2 months and up to 32–40% after 6 months, depending on the parameters.
- The success of the treatment was also clearly visible in a further assessment 12 months after completion of the therapy. After this period of time, placebo effects are no longer to be expected. This time frame is remarkable because it must be concluded that magnetic resonance therapy has initiated long-term structural regeneration processes that may result from changes in protein synthesis (see section on preclinical effects).

(Auerbach et al., 2003)

**Functional improvement in hand and finger polyarthrosis by therapeutic usage of magnetic resonance**

Due to the limited treatment options for hand and finger joint arthrosis, there is a need for the evaluation of new therapeutic principles. Magnetic resonance may stimulate repair processes in the cartilage and influence pain signal transduction cascades. Thus, therapeutic effects on osteoarthritis are possible.

Latest publications on wrist arthrosis urgently demand the evaluation and examination of new therapeutic strategies in clinically controlled studies. This demand is met with the magnetic resonance therapy.

Osteoarthritis of wrists and finger joints is the main cause of impairment in everyday activities. Main symptoms of finger osteoarthritis are a feeling of tension and stiffness in early stages, stress-dependent pain, increased pain in cold and damp weather, swelling and redness of the joints, restrictions in flexibility, tense muscles due to compensatory relieve postures, loss of function. (Kullich et al., 2008)

To date, not all pathogenetic processes are known so therapy consists in fighting symptoms or surgical interventions. This is why therapy concepts which follow new ways to improve pain-related handicaps in the treatment of wrist and finger joint osteoarthritis are of great interest. One of these new concepts is therapeutic magnetic resonance (KSRT). Cells can react to magnetic resonance of hydrogen protons with a functional or structural change.

Everyday activities such as finger functioning, dressing as well as hand functioning for personal care and house- hold activities, “hold a cup” or “open a lock” are well recorded with the QUABA score.

The effect of magnetic resonance treatment on 70 patients with osteoarthritis of the wrist or finger joints was examined in a double-blind, randomized, placebo-controlled study over a period of 6 months (length of treatment series: 9 x 1 hour).

The study design included patients with clinically and radiologically diagnosed finger joint osteoarthritis according to the criteria of the American College of Rheumatology (ACR). Medial age of patients was 69 ± 8 years. Assignment to one of 2 groups was performed randomly and double-blind: group I (n = 35) with active magnetic resonance therapy and group II (n = 35) placebo group without activated magnetic resonance field.

Blinded software chip cards for the control unit of the magnetic resonance therapy system guaranteed double- blind randomization. The therapy system used was a device from MedTec Medizintechnik GmbH, Wetzlar, Germany (magnetic resonance therapy, Key 1B, type MBST 300). Therapy duration was 1 hour daily on 9 consecutive days (total duration of therapy = 9 hours).

In order to measure the effect of magnetic resonance therapy and to make statements about the progression of the finger joint osteoarthritis, the following tools for outcome measurement were used: Visual analogue scale (VAS) for peak, stress and pain at rest; the clinically functional handscore according to QUABA for assessing hand function and disability for the criteria:

1. Dressing (pull on stockings; button blouse/shirt),
2. Personal care (wash and comb hair; dry with a towel),
3. Household activities (cut with scissors; open cans with a mechanic opener),
4. Manual everyday activities (grasp single coins from a wallet; hold a soft plastic cup filled with water, open or close the front door lock; write with a pen).

Measurement dates were day 0, day 10 and day 180.

***Results***

Pain intensity could be significantly reduced by magnetic resonance therapy but not in the placebo group. Peak pain, stress pain and pain at rest improved after the application of KSRT but not under placebo. During the active magnetic resonance therapy and the follow-up after 6 months, pain frequency could continuously be significantly reduced.

In the control group with placebo treatment, however, there was a steady and after 6 months even significant increase in pain frequency ($p < 0.005$).

Hand functioning improved distinctly after treatment with active magnetic resonance as the highly significant increase of the QUABA overall score shows.

Even 6 months later, this significant improvement was still noticeable ($p < 0.00001$).

In the placebo group with inactive magnetic resonance on the other hand, QUABA values of hand functioning did not improve after placebo treatment. In contrast to the group with active magnetic resonance treatment, the values of this group deteriorated significantly after 6 months. Both therapy groups did not differ statistically on day 0 but after 6 months, the group with active magnetic resonance therapy had a significantly higher QUABA score than the placebo group. Similarly, good results in the active magnetic resonance group and a deterioration in the placebo group could also be observed for QUABA score subcriteria dressing, personal care, household

activities, manual dexterity. In both groups, not a single adverse effect was recorded during treatment with magnetic resonance therapy system.

***Summary***

Due to the limited number of available therapy options for hand and finger joint osteoarthritis, there is a need for the evaluation of new therapeutic principles. Magnetic resonance therapy is a new effective treatment for hand and finger joint osteoarthritis. Everyday functionality such as finger function when "dressing" as well as hand functioning in personal care and household activities, "holding a cup" or "opening a lock" are well recorded using QUABA score. Our study shows that these finger functions as well as stress pain were improved after 6 months in patients treated with KSRT but not after placebo treatment. Here, a significantly reduced hand functioning with an increase in pain within 6 months could be observed. A proliferation of volume and density of cartilage in osteo- arthritis of the knee joint following therapeutic application of magnetic resonance treatment was already computertomographically demonstrated a few years ago. Stamm et al. recommend choosing daily activities and pain as well as mobility and stiffness as variables for clinical outcome measurement. Studies by Kjeken et al. show that about half of the patients with finger joint osteoarthritis have problems with opening bottles and wringing out clothes because the strength of their grip is reduced by more than 40% and the limited mobility of the hands is painful. Our examinations show that finger functioning in manual everyday activities is improved sustainably for several months and pain is reduced after treatment with magnetic resonance. This clearly recommends magnetic resonance therapy as a new treatment option for osteoarthritis of the finger and wrist joints. (Kullich et al., 2008)

**Multicentric data of more than 4,500 patients shows long-term effect of magnetic resonance therapy for osteoarthritis treatment**

***Introduction***

In this study, treatment data for a technical medical device was evaluated in an unusually large group of 4,518 treated patients over a period of 10 years. Data was recorded and evaluated multicentrically for various types of arthrosis at follow-up evaluation dates of 10 days, 3 months, 6 months and 12 months after magnetic resonance therapy treatment using internationally recognized pain questionnaires and score sheets.

The non-surgical MBST therapy tries to delay or even reverse the course of disease. Non-drug treatments for osteoarthritis are often based on relieving the joint to reduce symptoms (Rannou/Poiraudeau, 2010).

In patients with chronic non-specific low back pain, there is no clear indication for surgical intervention. There- fore, depending on the pain situation, therapy is usually medication or physiotherapy. The indication low back pain shall be evaluated later in another section.

***Methodology***

In this large-scale study, pain at rest, stress pain and peak pain recorded with Visual Analogue Scale VAS were chosen as criteria for assessment of the therapeutic effect. For further evaluation of the clinical success, validated indices for functioning were used which are well suited for long-

term documentation of osteoarthritis and record disability, functional deficits and impairments in everyday activities in addition to pain condition.

- Lequesne functional scores were used for the indications gon- and coxarthrosis (Lequesne, 1991; Lequesne/ Mery et al., 1987). The score sheets developed for gon- and coxarthrosis by Lequesne (1987, 1990, 1991) for recording symptoms and physical functional handicaps are often recommended for use at the end of studies evaluating symptom-oriented therapies (Stucki et al., 1996). The Lequesne Index is an internationally well established tool for self-assessment. Time investment is short and the sensitivity to change is excellent.
- The score sheet of Mazur et al. (1979) was used to assess osteoarthritis of the ankle joint.
- Back function was assessed using the Oswestry back disability questionnaire by Fairbank et al. (1980).

The evaluation included the reports of 4,518 patients (gonarthrosis n = 2770; coxarthrosis n = 673; osteoarthritis of the ankle joint n = 420; low back pain n = 655). Medial age of the patients was 62.4 ± 12.9 years (gonarthrosis), 64.6 ± 10.7 years (coxarthrosis), 58.6 years ± 15.3 years (osteoarthritis of the ankle joint), 62.8 ± 14.1 years (low back pain).

***Gonarthrosis***

The largest number of evaluated records covers knee joint arthrosis. 41.9% of gonarthrosis patients were male, 58.1% female. It is noticeable that the highest percentages of overweight (45.8%) and obese (22.2%) persons were observed in cases of gonarthrosis. Only 32% of the patients surveyed were of normal weight with a BMI below 25.

During the course of the 1-year follow-up, peak pain, stress pain and pain at rest were on average continuously reduced. Already directly after the MBST treatment series, patients reported reduced pain scores on VAS scale. The improvement further intensified after 3, 6 and 12 months and did not rise to baseline levels again. For all 3 types of pain, the pain was significantly reduced at all 4 evaluation dates with a significance level of $p < 0{,}00001$. The frequency of pain in the knee joint also decreased significantly for all 3 types of pain with a remarkable low incidence of pain 6 and 12 months after MBST therapy. On a 10-part scale, stress pain decreased from a score of about 6 (= often) to about 4 (= little), the frequency of peak pain was reduced to “very little” (= 3) and the pain at rest to “rare” or “very rare”.

In addition to the reduction of pain, the functional handicaps assessed with Lequesne index were significantly improved.

The Lequesne Osteoarthritis index consists of 3 sections with a total of 10 questions. In addition to the overall score, these 10 questions were also assessed with relation to complaints, walking and functioning and the 3 sections were calculated statistically. In the same way as the overall score, all 3 subsections of the Lequesne index improved significantly. Most noticeable is the highly significant reduction in functional handicap and in pain and discomfort ($p < 0.000001$). The number of patients with gonarthrosis who had no complaints at night increased from baseline 39% to 72% 12 months after magnetic resonance therapy.

The group without pain while walking also increased from 23.5% to 48.2%. Remarkably good improvements with high percentages were recorded especially regarding climbing stairs,

walking on uneven ground, kneeling and walking distance 6 to 12 months after magnetic resonance therapy. 31.9% of patients with knee joint osteoarthritis were able to kneel or squat without any difficulty 1 year after the therapy. Before, this had only been possible for 14.9% of the 2,770 patients.

The correlation analysis showed significant correlations between pain and functional limitations in patients with gonarthrosis with respect to the changes within 1 year after an MBST treatment series. Thus, for example, the reduction of the stress pain as described above correlated clearly with the complaints during walking recorded using Lequesne index ($r = 0.42$; $p < 0.000001$).

Another example is the correlation between the decrease in intensity of peak pain within 12 months and an improved ability to “squat down” ($r = 0.38$; $p < 0.000001$) or “go down the stairs” ($r = 0.40$; $p < 0.000001$).

It should be noted that significant improvements in the degree of movement could be observed after only 3 months. These increases in flexion and extension were even higher after 6 and 12 months.

The analysis of the collected data with regard to the Body Mass Index (BMI) is also interesting. In the case of obesity with a BMI > 30, a significantly higher Lequesne global index could be demonstrated at all times of measurement. This also applies to the subsections pain/complaints, walking distance and functional handi- caps. 1 year after magnetic resonance therapy, the initially significantly higher pain in obese patients, regarding both intensity and frequency of pain, did not differ from the values of normal weight gonarthrosis patients with a BMI < 25.

***Coxarthrosis***

The application of a series of magnetic resonance treatments showed a definite overall improvement in pain and functioning in the group of patients with hip joint arthrosis. It is interesting to note that these improvements could still be observed 1 year after the therapy. Stress pain improved from a medial VAS score of 4.6 ± 2.4, which stands for strong pain, to a value of 3.3 ± 2.1. Intensity of peak pain also decreased significantly from 5.2 ± 2.7 to 3.1 ± 2.9 after 1 year.

Calculation of the percental change in each individual patient, based on the baseline value of peak pain, shows on average a clear increase in the percentage of coxarthrosis patients with reduced peak pain from 18.9% at 3 months to 27.7% at 6 months to 34.5% at 12 months.

Improvement was also noticeable for pain at rest ($p < 0.000001$) where the value after 1 year, VAS 1.4 ± 1.7, differed significantly from the baseline value of 2.8 ± 2.5.

Based on the improvement of each individual patient, the level of improvement for pain at rest after 1 year was 42.8% with regard to intensity and 36.3% with regard to frequency. With the decrease in pain intensity, a significant reduc- tion in the 10-part scale of pain frequency with regard to peak pain, stress pain and pain at rest was observed in the course of 1 year after magnetic resonance therapy. Peak pain and stress pain correlated significantly with the overall score of the Lequesne index ($r = 0.33$ resp. $r = 0.34$; $p < 0.01$) but also with functional handicaps ($r = 0.34$, $p < 0.01$).

These changes also explain the improvement in sleep quality recorded in the Lequesne index. The overall score of the Lequesne index for the recording of symptoms and physical functional impairments in the case of coxarthrosis decreased significantly an average of 7.14 ($p < 0.000001$) to 4.58 in the course of the 1-year follow-up period. This is also confirmed by the distribution-independent medial value which dropped from 7.0 to 4.0.

In addition to the Lequesne overall score, which comprises the values assessed in 10 questions in 3 sections, the sections on pain/complaints, walking and functioning were also statistically evaluated individually for hip joint arthrosis. Especially the values for complaints improved highly significantly ($p < 0.000001$) from baseline. The func- tional handicaps were also significantly lower than before treatment 3–12 months after magnetic resonance therapy.

Regarding the percental distribution of the individual questions, it is noticeable that almost half of the patients, 47.5%, reported no problems with walking after 1 year. At baseline, this was only possible for about 20% of the patients. Before treatment, 21.9% reported that they were only able to put on stockings with considerable effort resp. great difficulties. 12 months after the therapy, this handicap existed in only 12.1% of the patients. 13 patients had not even been able at all to put on their stockings themselves before therapeutic application because they could not bend the leg in the hip so far forward.

After 1 year, none of the patients reported this kind of handicap. More than half of the patients with hip joint arthrosis (53.5%) were able to put on their stockings themselves without difficulties. All patients were also able to get into and out of a car after 1 year, nobody had great difficulties and only 4% of them had to make a lot of effort. Parallel to the lower rate of functional handicaps and reduced pain, the percentage of patients who were able to walk up/downstairs without difficulties was doubled after 12 months (59.6%).

Rank correlation analysis following Spearman (which allows an exact examination also in case of a non-standard distribution of measured values) of changes between baseline and 12 months after KSRT showed distinct, significant correlations between the intensity of coxarthrosis pain and the Lequesne index which assesses functioning ($p < 0.01 – p < 0.001$).

Osteoarthritis of the hip is often one-sided and predominantly of secondary etiology. As the disease progresses, the possible walking distance shortens increasingly together with a characteristic limping. The examinations show that patients with coxarthrosis experienced a clear improvement of the restricted walking distance after magnetic resonance therapy while the discomfort of walking was reduced at the same time.

### *Osteoarthritis of the ankle joints*

For the patients with painful arthritic degenerations of the ankle joint included in the survey, a clear significant reduction in the intensity of stress pain but also with regard to peak and rest pain could be achieved right after magnetic resonance therapy.

The improvement, calculated from the changes of each individual patient with ankle joint arthrosis, averaged 46.7% for peak pain, 47.0% for stress pain and 40.4% for pain at rest 1 year after the therapy series. Pain reductions of about 37–40% were already observed 3–6 months after magnetic resonance therapy.

Frequency of pain also showed a statistically significant ($p < 0.000001$) decreasing tendency from score values around 6 = often/daily over 4 = little to 2 = rarely/1x per month.

The score calculated following to Mazur averaged 51.8 (median: 53.0) points with pain being the leading symptom. In the 12-month follow-up, the survey showed a continuous increase over 63.5 (median: 70.0) points 3 months after magnetic resonance therapy up to 69.3 (median: 75.0).

The complaints in the upper ankle joint caused clear restrictions due to limping, especially with regard to walking distance and stair climbing. All of these parameters were significantly improved after 12 months ($p < 0.01$ for stair climbing to $p < 0.000001$ for walking distance).

These observations show a clear improvement in the functioning of the upper ankle joint after therapeutic magnetic resonance.

With regard to functioning, it should also be noted that after just 6–8 weeks the walking distance, which is a good indicator of an improvement regarding the ankle joint, had improved considerably with further increases over the entire observation period of 1 year. At the same time, other parameters such as climbing stairs, walking uphill, standing on tiptoe improved and the use of walking aids was reduced significantly.

The statistical analysis proves these observations with correlations in intensity of peak pain with the overall score following Mazur ($r = 0.46$; $p < 0.003$), walking up and down stairs ($p < 0.02$ – $p < 0.002$) as well as walking distance ($r = 0.40$; $p < 0.01$). Clearly, a significant formal correlation between the increase in the walking distance and walking up and downhill could be proven ($r = 0.68$ or $r = 0.60$; $p < 0.00001$ or $p < 0.000001$).

A Finnish study (Karjalainen et al., 2003) describes a negative influence of a high BMI on the success of therapies for low back pain. This observation is confirmed by our examinations since the effects on pain after the application of magnetic resonance therapy are lower in patients with a high BMI than with normal weight patients, especially after 12 months. Also, back function was significantly better after 1 year in patients with normal weight (BMI < 25) than in those with obesity (BMI > 30). In contrast, the effects of magnetic resonance therapy did not differ for normal weight and obese patients in the case of osteoarthritis of the ankle joint, gonarthrosis and coxarthrosis.

***Summary***

The presented improvements in pain and functioning in knee and hip joint arthrosis after KSRT treatment can also be valued positively for fatigue which occurs in about half of the patients. This connection was recently described by a Dutch study group in an examination of 231 patients with gon- and coxarthrosis (Snijders et al., 2011).

As is the case in other joints, osteoarthritis of the upper ankle joint is associated with cartilage degeneration, increased abrasion and a narrowing of the joint line. Similar to progression of the other kinds of osteoarthritis, the symptoms in the ankle joint appear more frequent and the exercise capacity decreases in the course of the disease. Further damage is caused by inflammatory reactions in the joint. Due to the osteoarthrosis of the ankle joint and associated functional handicaps, the quality of life of the affected person decreases continuously.

***Conclusion***

The data gained in an observation period of almost 10 years clearly shows that the application of therapeutic magnetic resonance for degenerative rheumatic diseases can result in lasting improvement in the experiencing of pain and impairments due to functional deficits in everyday activities.

From a cost-benefit point of view, the statistical analyses carried out show that the application of magnetic resonance therapy in the treatment of degenerative rheumatic diseases, in particular osteoarthritis, is an economical additional therapy resp. alternative treatment due to its long-term effects and thus makes a highly significant contribution to the health economy.

(Kullich et al., 2013; Stritzinger et al., 2013)

**Usage of magnetic resonance as new therapy option for gonarthrosis**

Further studies by the authors of the Ludwig Boltzmann Department in Saalfelden and Groebming (Austria) with a small group of 32 patients showed a good pain-reducing effect of magnetic resonance therapy. For knee osteo- arthritis even for only 5 therapy units but the effect shows a slightly decreasing tendency after 6 months. Experience shows that 7 to 9 units are more advantageous for sustainability.

If the restriction of activities of daily life is reduced in accordance with the intensity of the pain as recorded in the Visual Analogue Scale, which could be demonstrated for the therapy with KSRT in several thousand patients, an overall assessment of the long-term course of the disease becomes possible.

(Fagerer et al., 2007)

**Analysis of the long-term effects of MBST magnetic resonance therapy for gonarthrosis**

The results of the study are based on questionnaires on pain condition and restrictions in everyday life of 39 patients suffering from gonarthrosis who were treated with MBST magnetic resonance therapy up to 4 years before. Patient data includes information on their state of health directly before and after the therapy, as well as 6 months after the therapy and at the time of the current survey. MBST treatment was 9 treatment sessions of 60 minutes each on consecutive working days. The survey was carried out by means of an anonymous patient questionnaire for self-assessment of the course of the disease which recorded frequency and intensity of spontaneous peak pain, mean stress pain and pain at rest as well as the Lequesne index for knee diseases. While the information on pain frequency and intensity is recorded directly via a numerical analogue scale from 0 (no pain) to 10 (permanent pain resp. strongest imaginable pain), the Lequesne index was determined indirectly by means of a multiple-choice survey on restrictions in everyday activities such as climbing the stairs.

An overview of the study shows that for all areas examined – pain intensity, pain frequency and Lequesne index – all levels have been shifted to lower values. The result is thus an improvement of the general state of health after MBST therapy. A comparison of the distribution of pain and Lequesne levels before and after the therapy shows a significant increase in the percentage of patients with no or little pain. Similar values can be observed regarding intensity and frequency

of pain. The percentage of patients in the range of lower points (0–1) increases from 50–60% to 85% for pain at rest, from 10% to 40–55% for moderate stress pain and from 15% to 40% for spontaneous peak pain. At the same time, the percentage of patients with severe pain (>5), which was in some levels more than 60% before therapy, is reduced to a maximum of 15%. The Lequesne index also shows a shift to lower values after magnetic resonance therapy. In this context, the number of patients with low or no handicaps increases from approx. 30% to 45%.

The results of the study showed that MBST can have a very positive and sustainable influence on the impairments in everyday activities assessed by the Lequesne index as well as on intensity and frequency of pain. The temporal development of pain implies that the healing process takes at least 1 year but that patients' symptoms often subside significantly after only 6 months so that overstressing the regenerating cartilage tissue during this period can have a negative effect on the healing process. The generally significant reduction of pain at rest indicates that the regeneration process of degenerated cartilage tissue that is activated by MBST therapy first affects pain at rest which usually only occurs at an advanced stage as a result of a high degree of cartilage degeneration. Analysis of the reduction of pain intensity shows that the extent of the decrease does not generally correlate with the corres- ponding value before treatment but is also influenced by additional factors such as gender, age and physical activity. In contrast, a clear correlation can be observed between the frequency of pain before therapy and the level of pain reduction. A higher value in pain before treatment correlates with a greater reduction in the frequency of pain. Patients with higher stages of osteoarthritis and/or more active forms can therefore benefit more. The gender-specific comparison shows that the therapy has a more positive effect in female patients despite similar initial values in the areas of pain intensity and the Lequesne index. It is possible that an increase in bone density, which is also stimulated by the therapy and which tends to be low and steadily decreasing in women at least after the menopause, is probably more noticeable and leads to a stronger subjective experience of pain reduction. Analysing age structure, the study shows that there is a much more pronounced reduction of impairments and a more significant decrease in intensity and frequency of pain in the group of elderly patients. A possible cause might be the higher age and thus state of retirement of this group of patients who, as a result, are not exposed to the physical stress of working life and more severe everyday stress. It is also possible that a concomitant effect on osteoporosis, which is frequent in this age, occurs.

The data regarding sports activity shows a slightly higher decrease in mean stress pain and peak pain in the active group, although the level of pain remains above that of inactive patients after treatment. Regarding pain at rest, however, a much more positive effect could be observed in inactive patients so that these tend to achieve a better overall therapy success. Therefore, a positive influence of sports activities is neither recognizable regarding restrictions of everyday life nor pain condition. A possible reason could be that even when practising sports that are regarded as easy on the joints, wrong performance or misconception of the individual limit of stress can have a negative effect on the cartilage tissue. The study showed that MBST magnetic resonance therapy can achieve a significant success in the treatment of osteoarthritis and that the regeneration process is not yet complete even years later. Patients obviously feel better for years after a therapy. Further and mostly more expensive treatments are often rendered unnecessary. It is noticeable that a significant improvement of condition is especially common in

elderly patients with an advanced stage of osteoarthritis. In many cases, total endoprothetic joint replacement can be delayed for years or even avoided. Hardly any other conservative method of treatment with similar results is known to date.

(Van Laack et al., 2011)

**Indication sports and accidental injuries**

One study examined the successes of the therapy in sports and accidental injuries. For some time now, another method has been used to treat various injuries in handball players: magnetic resonance therapy (MBST). 85% of the patients benefit from the therapy with effects that sometimes last for several years. Based on the active principle, it is an alternative option that can be used for various sports injuries: to accelerate the healing process (MRI-controlled) in addition to rehabilitative measures and to restore performance more quickly.

Among others, the following diagnoses could be treated with good or very good success: therapy-resistant fracture of the sesamoid metacarpal bone, bone marrow edema acromion after contusion, non-dislocated fracture MTF V, retropatellary, femoral cartilage damage in IM rupture, internal ligament fracture of the knee joint, partial rupture of the anterior cruciate ligament, bone marrow edema/bone bruise tibia, muscle bundle rupture M. rectus abdominis, ruptured muscle fiber M. iliopsoas, rupture Musculus teres major. Generally, several target structures (bones, muscles, cartilage/joint, tendons/ligaments) can be treated by means of the differentiated, standardised treatment schemes.

The very good efficacy of magnetic resonance therapy shall be illustrated in two case studies of muscular injuries in handball players.

1) Injury: rupture of muscle fiber musculus iliopsoas on November 1, 2015 during match, conservative treatment

Treatment: 7 treatment units MBST muscle (November 11, 2015 – November 18, 2015)

Therapy/rehabilitation: physiotherapy, general condtioning and stress build-up (among others exercise bath, training therapy), from week 4 in combination with handball-specific build-up training 1x/day, control MRI on December 8, 2015

Result: ability to compete after 6 weeks, free of complaints under full stress, no follow-up injury or relapse

2) Injury: rupture of M. obliquus internal abdominis, partial rupture of M. obliquus externus on February 2, 2015 during training, conservative treatment

Treatment: 7 treatment units MBST muscle (February 11, 2015 – February 19, 2015)

Therapy/rehabilitation: physiotherapy, general conditioning and functional therapy with continuious stress build-up (among others exercise bath, training therapy), after 4 weeks of complete freedom of complaints in combination with handball-specific build-up training, control MRI on March 3, 2015

Result: Ability to compete after 5.5 weeks, free of complaints under full stress, no relapse or follow-up injury

***Conclusion***

Both the individual application and in particular the combination of methods such as cryolight therapy, ESWT and magnetic resonance therapy (MBST) can further develop and optimize the treatment of muscle injuries. In addition to the factor time, the focus is always on avoiding relapses and injuries that are more or less directly connected with the treated muscle injury. This is one of the most important arguments from the point of view of sports medicine for a long-term successful return to competition.

(Toussaint, 2016)

**Osteoporosis**

Prospective study on the effectiveness of MBST magnetic resonance therapy for whole-body treatment of osteoporosis

This indication was examined by an observation of application by the specialists Overbeck, Gerhardt and Urban (Overbeck et al., 2004). The examination that was carried out in three medical practices and one treatment centre provides concrete indices for the useful application of magnetic resonance therapy for the indication osteoporosis. A total of 27 patients with diagnosed osteoporosis and existing results of bone density measurement were treated. The therapy series consisted of 10 treatments of 1 hour each. Following therapy, 4 bone density measurements were carried out within a period of 6 months: before the therapy, approx. 6 weeks, 3 months and 6 months after the beginning of the therapy. The therapy was generally characterized as painless, free of side effects and gentle. The evaluation of 21 patients, whose data could be recorded completely, showed highly significant improvements in condition of pain, pain frequency and bone density compared to the initial measurement.

Even though bone density was determined using two different measurement methods, an overall assessment was made possible by breaking down evaluation to individual patients. For this indication, the absence of a placebo or control group or evaluation against an alternative treatment has no negative effects on the results since osteo- porosis does not improve without therapy. The success achieved with magnetic resonance therapy therefore speaks for itself even if they were initially only gained within the scope of an observation of application. Since – as already mentioned – physicians still primarily use their experiences for orientation, the enthusiasm of the authors at the end of the report is quite understandable: “The MBST magnetic resonance therapy is impressive because of its high efficacy and the absence of known side effects. Following our results, bone density and thus stability under MBST magnetic resonance therapy increases faster than with any other therapy known to date.” (Overbeck et al., 2003)

**MBST magnetic resonance therapy as possible non-drug therapy for osteoporosis**

A small-scale study on osteoporosis was conducted at the Justus Liebig University Giessen to determine whether MBST magnetic resonance therapy is an effective treatment for this disease.

***Results***

A considerable improvement in pain intensity and pain severity could be found. Similarly, a highly significant increase of up to 55% bone density and mineral salt content was observed within 22 to 120 days.

The author concludes that the magnetic resonance method in osteoporosis treatment is an extraordinary and very fast-acting treatment method. (Grumbrecht, 2003)

**Prospective study on the efficacy of whole-body treatment with MBST magnetic resonance therapy as a possible non-drug therapy for osteoporosis**

In the case of osteoporosis, bone mass per volume unit is reduced in comparison to the age and gender standard values. It is a pathological condition that can be separated from the physiological decline of bone mass in older age in which the structure of the bone substance does not significantly deviate from the norm. Osteoporosis can occur generally and localized. The general form is the most common metabolic osteopathy that is mostly prevalent in the female sex and here predominantly postmenopausal. But osteoporosis can also occur premenopausally, in males and adolescents, even in children. The prevalence of manifest osteoporosis is estimated to be around 5 million in Germany.

After very positive experiences in osteoarthritis treatment, it was of interest to examine whether magnetic resonance therapy is similarly effective in osteoporosis.

A total of 15 female volunteers took part in an initial scientific survey. Mean age was 65 years (49–78 years). The patients were treated with 10 MBST sessions of 1 hour each in the whole-body treatment field. Prior to treatment, the patients filled in a questionnaire including an individual assessment of pain on a 10-point scale. In addition, the volunteers agreed to regular blood sampling and urine tests which were used to determine the course of various bone metabolism parameters, e. g. calcitonin IS or desoxypyridinoline. Before, during and after treatment, only vitamin D tablets were administered to the patients. An additional therapy with bisphosphonates was excluded. Before and after the first treatment, a QCT to determine bone density was made by an independent radiological institute.

***Results***

- There was no significant change in the concentration of certain metabolic parameters, especially not of calcitonin and parathormone.
- Pain intensity was improved markedly by an average of 5 points. At the end of the treatment, all patients assessed their pain severity at least 8 points better than before treatment. Pain frequency had also decreased significantly (improvement by 4 resp. 7 points).
- The measured QCT values showed an increase in mean bone density from 88 +/-37 to 90+/-28 mg/cm3 calcium hydroxylapatite which is equivalent to a mean percentage increase of 12%. An average increase of 28.2% in mineralization was observed in 9 patients and a maximum decrease of 16% was recorded in 6 patients.
- Time between the first and second QCT was 44 days on average (min. 22, max. 119 days). A longer time between the density measurement and the end of therapy had a positive influence on bone density. This might suggest a long-term effect.

- The determined Z- and T-values showed a dramatic increase of up to 54.75% in some cases, but this can be attributed to the fact that the WHO corrected the reference values downwards during the survey and the radiological institute used these new reference values for most of the second measurements. Therefore, the determined T- and Z-values cannot be used methodically!

***Summary***

In summary, the author concludes that the therapeutic effects of magnetic resonance therapy cannot be explained by metabolic stimulation, the regenerative effects are probably much more complex and multifactorial. However, subjective pain sensation in advanced osteoporosis was significantly improved, an effect which is already known from osteoarthritis therapy with MBST.

The results obtained from the scientific survey should be taken as incentive for further clinical and radiologically controlled studies, in particular studies over a longer course of time, maybe with repeated applications, and they should be planned with the aim of confirming the promising initial results obtained so far. (Klapsch, 2003)

**Treatment of Osteoporosis with MBST magnetic resonance therapy**

The aim of this study by the Orthopedic Clinic in Bad Dueben, Germany, was to find proof of the influence of magnetic resonance therapy on bone mineralization content.

In the period between January 2004 and March 2006, a total of 54 patients were treated with MBST magnetic resonance whole-body treatment for osteoporosis. All patients had a bone density in the range of osteopenia or manifest osteoporosis before the start of therapy. For this purpose, a QCT (Quantitative Computed Tomography) measurement of the lumbar spine was performed in a radiological practice. Control measurements were carried out under standardized comparative conditions 6 months after treatment. In addition, the standardized examination of the patients was carried out following the “osteology checklist” (anamnesis, clinical examination, laboratory, risk profile, primary diseases, e. g. osteomalacia, history of an osteoporotic fracture, medication).

Patients who had already suffered vertebral body fractures related to osteoporosis or who were treated with teriparatide were not included in the study due to the risk of a falsification of bone density measurements. Patients taking bisphosphonates or selective estrogen receptor modulators were assessed separately. In addition to magnetic resonance therapy, a basic therapy with calcium and vitamin D3 was administered as well as hydrogenation prior to treatment with about 2 liters of liquid. The treatment was carried out on 10 consecutive weekdays with a 2-day break (interruption by weekend) always at the same time of day on a standard whole-body magnetic resonance therapy couch (ODM) of the company Medtec Medizintechnik, Wetzlar. Treatment duration was 10 units of 1 hour. Assessment dates: before the start of therapy, after the end of therapy, 3 months and 6 months after the end of therapy. Scores: modified Fairbank Score, Roland-Morris-Score, Osteoporosis Quality of Life Questionnaire and the Numerical Analogue Scale to determine peak pain, pain at rest and permanent pain. The bone mineralization content was determined by QCT before and 6 months after therapy.

Mean bone density of the patients (bone mineralization content in mg/ml, measured with QCT at the lumbar spine) was 97.5 mg/ml (SD: 16.9) before the start of magnetic resonance therapy. After 6 months, mean bone mineralization content had increased to 100.2 mg/ml ($p < 0.05$, SD: 15.8). There was no significant difference in bone mineralization content after 6 months in the 14 patients under continuous therapy with bisphosphonates and SERM. The Osteoporosis Quality of Life Questionnaire records pain, impairments on activities of daily life, household activities, exercise, leisure time and social activities, perception of general health and mood. Thus, it is a good indicator of the general condition of the patients. No significant differences could be found in measurements during therapy and shortly afterwards. But correlating with the increase in mineral content of bones, however, it was possible to observe a significant reduction in symptoms over the course of 6 months. Similar results could be found for the modified Fairbank Score and Roland-Morris Score. The most significant indicator of pain is an evaluation with the Numerical Analogue Scale for the determination of peak pain, pain at rest and permanent pain. Pain at rest did not change during therapy or shortly afterwards. All 3 types of pain showed a significant reduction after 3 or 6 months.

The 27 patients included in the study showed a significant increase in bone mineralization content 6 months after therapy. It is also noteworthy that in the 14 patients under long-term medication with bisphosphonates and SERMs, no significant change in bone density could be detected after 6 months. It can be assumed that the reason for this is the stabilizing effect of bisphosphonates and SERMs on the bone structure. No side effects of MBST magnetic resonance therapy could be found in the activity scores (OIQÖQ, Fairbank, Roland-Morris). The only exception to this is a short-term increase in pain during and after therapy. The cause of the increase in pain remains unclear. Presumably, it is an expression of the physical response (activation of bone metabolism) to the therapy.

MBST magnetic resonance therapy is an innovative, free of side effects and easy-to-use therapy that, in combi- nation with a basic therapy with calcium and vitamin D3, at least for a while stabilises orincreases bone density, reduces the patient's complaints and improves his general condition. It has no influence on the bone density of patients with a long-term drug therapy with bisphosphonates and SERMs. Comparing the costs of long- term medication for osteoporosis with the one-time-only costs of MBST magnetic resonance therapy shows another interesting therapeutic approach. Since there are no long-term results or comparable studies as yet, the long-term effect resp. the benefit of conservative osteoporosis therapy remains to be seen. (Handschuh et al., 2008)

**Therapeutic application of magnetic resonance in osteoporosis**

The aim of a study in Croatia was an examination of the long-term effects of the therapeutic application of magnetic resonance imaging (KSRT) on bone density parameters in patients with osteoporosis.

103 patients aged 45–89 years with a definite diagnosis of osteoporosis and a reduced bone density (T-score below –2.5) were included in the study. All patients were treated with magnetic resonance osteoporosis therapy for 1 hour per day on 10 consecutive days (MBST ODM, MedTec, Germany). Before and 12 months after KSRT treatment, bone density was determined by DEXA

measurement. In addition, the bone turnover markers osteocalcin and bone cross-laps (ß-CTX; crosslinked telopeptides of collagen 1) were determined using commercial Elisa techniques.

Bone density and serum levels of osteocalcin increased statistically significantly from baseline to 12 months. ß-CTX remained stable.

Therapeutic application of magnetic resonance increases the parameters of bone density within 1 year after a treatment series (10 x 1h). Therefore, KSRT can be recommended as an alternative or additional therapy to medicinal therapy for osteoporosis patients. (Krpan et al., 2015: Non-pharmacological treatment of osteoporosis with Nuclear Magnetic Resonance Therapy (NMR-Therapy))

**A new concept of integrated holistic approach in treatment of chronic musculoskeletal diseases – the "BAR" method**

Another study under extended "BAR" conditions was carried out and published in the polyclinic K-CENTAR, Zagreb, Croatia under the lead of Prof. Dr. sc. Dalibor Krpan: the "BAR" method, a new concept in the treatment of chronic bone and joint diseases. An essential part of the concept is cell regeneration using magnetic resonance therapy.

The "BAR" treatment concept stands for: B – for Biomechanics, A – for analgesia and R – for regeneration.

It is an integrated, holistic therapy approach with a combination of methods to improve "biomechanics" which offers very good and regular biomechanical impulses and stimulates the regeneration of cartilage and bone formation very well. It relieves pain already during treatment, improves mobility and thus the quality of life. It also stimulates the regeneration of cartilage and bone formation.

Statistical analysis of clinical trials with patients with osteoarthritis who were treated with MBST magnetic resonance therapy shows several changes after an MBST cycle of 5 or 7 days:

- overall improvement of more than 60% up to 80%
- pain reduction to about 50%
- constant decrease of intensity and frequency of pain
- Maximum result for all achievement set in 8 weeks to 6 months after the therapy and lasted sustainably for 1 year. Osteoporosis treatment showed a significant increase of BMD of up to 35%, T-Score up to 33,9% and Z-Score up to 72,46%.

Based on clinical experiences, the results of scientific and clinical studies and a cost-benefit analysis, MBST can be recommended for usage under the following conditions:

1. MBST therapy once a year for all persons with an increased risk of osteoarthritis or osteoporosis in combination with regular exercise
2. MBST therapy of 5 or 7 days for all people with osteoarthritis once a year together with exercise and pain therapy
3. MBST program of 7 days twice a year in combination with physical and sometimes orthopaedic therapy of advanced osteoarthritis

4. 10 days MBST osteoporosis program in case of osteopenia, increased risk of osteoporosis or failure of pharmacotherapy

(Krpan, 2015: A new concept of integrated holistic approach in treatment of chronic musculoskeletal diseases The "BAR" method)

**Magnetic resonance therapy in osteoporosis reduces the risk of fractures in accidents/downfalls – case report study**

Despite the existence of various pharmacological treatments, the problem of osteoporosis has not yet been solved or reduced. Fractures, side effects of medication after long-term pharmacotherapy show a need for new treatment methods. Magnetic resonance therapy could be an alternative or supplement to pharmacotherapy. The aim of the case report study is to present clinical experiences with the application of NMRT in the treatment of osteoporosis based on a follow-up examination of the incidence of fractures.

For the examination of fractures, 450 patients (male n = 55, female n = 395) with a median age of 68.4 years were assessed on the basis of anamnesis and medical documentation. In a period of 5 years, all patients had been treated with MBST therapeutic magnetic resonance standard cycles of 10 days at the K-Centre (Policlinic / Centre for Osteoporosis and Other Bone and Joint Disorders, Director: Prim. Prof. Dr. med. D. Dalibor Krpan, Zagreb, Croatia). The data shows a reduction in the rate of fractures after NMRT for more than 1 year after an NMRT cycle of 10 days.

All patients suffered from osteoporosis which had been diagnosed via DEXA measurements (T-score less than –2.5). They were treated with a therapy series of MBST magnetic resonance therapy with the MBST osteo treatment couch (ODM device) from MedTec GmbH, Wetzlar, Germany (1-hour per day for 10 consecutive day).

Due to the fact that NMRT works with a time delay, the maximum effect is achieved after about 6 months. Time for assessment of fractures was determined as follows:

a) Less than 3 months after treatment
b) Between 3 months and 1 year after treatment
c) Between 1 and 2 years after treatment
d) More than 2 years after treatment

It is especially noteworthy that in 11 well-documented cases no fractures occurred even after severe trauma. Because they are very important proof of a therapeutic effect, these cases shall be described separately.

***Results***

e) Less than 3 months after treatment: 2 patients with fractures
f) Between 3 months and 1 year after treatment: no patient with fractures
g) Between 1 and 2 years after treatment: 2 patients with fractures
h) More than 2 years after treatment: 14 patients with fractures

In the period less than 3 months after NMR treatment (a), there are 2 patients with fractures. Both suffered a fracture of the forearm after a severe fall and both had had previous fractures and a very low BMD.

No fractures occurred within the period between 3 months and 1 year after NMR treatment (b).

Within the period between 1 year and 2 years after NMR treatment (c), there were 2 patients with fractures: one patient aged 80 years suffered a new compression fracture of L5. The fracture was only discovered on X-rays. The other 83-years old patient suffered a fracture of the forearm but had no fracture of the hip after a fall down the stairs. A large hematoma around the left hip clearly indicates severe trauma.

Within the period of more than 2 years after NMR treatment (d), there were 14 patients with fractures: 1 severe hip fracture trauma, 4 vertebral compression fractures and 9 fractures of the forearm. It is important to add that the lady with the hip fracture could be completely restored after TEP.

Very important proofs are patients who suffered a severe trauma but without a fracture. All of them had a low BMD before NMRT and 4 had previously suffered fractures.

***An overview of the examined patients***

Case 1: Patient, 82, fell several times after NMR treatment and suffered no fractures. She had a large hematoma around the hip twice but no fracture. The last time was 5 years after MBST treatment.

Case 2: Patient, 80, fell down when the bus stopped suddenly due to a traffic accident. He suffered a large hematoma but no fracture. The accident happened 1 and a half year after MBST treatment. A significant increase of BMD was found in the control DXA measurement.

Case 3: Patient, 87, stumbled in a hole in the ground and suffered a severe hematoma but no fracture. The fall happened more than a year after MBST. A significant increase of BMD was found in the control DXA measurement.

Case 4: Patient, 78, had a fall in the street, no fracture. It was 3 years after MBST treatment. No control DXA measurement was made.

Case 5: Patient, 75, was injured in a traffic accident 2 years after NMR treatment but had no fractures. No significant difference of BMD was found in the control DXA measurement.

Case 6: Patient, 80, had a fall in her house. She had a large hematoma at the hip but no fracture. The fall happened more than 2 years after MBST treatment.

Case 7: Patient, 75, was involved in a traffic accident and suffered various hematomas and bruises but no fracture. It happened 3 years after MBST treatment. A significant increase in BMD was found in the control DXA measurement.

Case 8: Patient, 78, had a fall in her house, she had no fracture. It happened more than 3 years after MBST treatment. Before MBST treatment, she had suffered fractures of the forearm and multiple vertebral fractures. A significant increase in BMD was found in the control DXA measurement.

Case 9: Patient, 85, fell in the street and had a large hematoma around the hip but no fracture. It happened more than 1 year after MBST treatment.

Case 10: Patient, 70, was injured in a car accident. She suffered a lot of bruises but no fractures. It happened more than 1 year after MBST treatment.

Case 11: Patient, 71, fell from a tree. He suffered many bruises and contusions but no fracture. It happened more than 2 years after MBST treatment.

Incidents like these are very common in the elderly population and the risk of falling increases with age and reduced physical ability: about one third of healthy people aged 65 or older and half of the over 80-year-olds fall at least once a year. Therefore, the authors are of the opinion that this case report study provides important information although the number of cases is rather small. All reported cases are well documented and show that MBST can be the new non-pharmaceutical method that can reduce the risk of fractures.

A thorough analysis shows that one of these patients, an 83-year-old woman who fell down the stairs, suffered no hip fracture even though she had fallen directly on the hip. A large hematoma on the hip was clear evidence of severe trauma. Other cases showed a reduction in risk of fractures even several years after MBST treatment.

it is possible that the 2 cases of fractures within the first 3 months of MBST treatment occurred due to the delayed onset of effect of MBST. This cannot be seen as an indicator of failed therapy.

There have been few studies regarding osteoporosis so far. These studies show that MBST is a therapy which targets the bones and stimulates bone formation and increases BMD values. The studies on MBST treatment for osteoporosis encourage expectations that MBST can be a useful alternative to or supplement of medical therapy in patients with osteoporosis. It is particularly important that MBST has no risk of side effects which makes it a suitable treatment within a strategy to prevent fractures in combination with exercise and vitamin D3. (Krpan et al., 2017)

**Back Pain**

Placebo-controlled, double-blind, randomized, mono-centric multipoint survey over a period of 3 months. 62 patients (36 men and 26 women aged 18–71 years, mean age = 48.1 years) with chronic low back pain. The multidisciplinary rehabilitation concept for all patients consisted of a standardized in-patient physiotherapy program combined with a series of treatments with 1 hour of therapy per day for 9 consecutive days in an MBST magnetic resonance therapy system.

Double-blind randomization into two groups was achieved using blinded computer chip cards.

1. Group I: magnetic resonance activated (active MBST group; n = 30)
2. Group II: magnetic resonance inactive (placebo group; n = 32)

Examinations were made at the beginning of the study (day 0) as well as 1 week and 3 months after treatment using the following parameters:

- 10-part Visual Analogue Scale (VAS),
- Oswestry-Low-Back-Pain-Disability Questionnaire following Fairbank et al. 1980,
- Roland & Morris Disability Survey

A standardized multidisciplinary therapy significantly improved the Roland-Morris (RM) overall score for chronic low back pain during a 3-week rehabilitation. RM overall score increased again after the therapy in both groups, placebo and MBST. But the value of the MBST group remained significantly below baseline. The Roland & Morris Disability Questionnaire showed that everyday activities could be improved by an additional MBST therapy.

Group I achieved a better result than group II in several parts of the Oswestry Disability Questionnaire (such as walking, sitting). This is also noticeable in the overall score of group I which showed a significantly better result than the placebo group with $p < 0.001$ at the measurement dates of 1 week and 3 months. The fact that there were major advantages in the part "personal care" should be of great importance for back pain patients. 73.7% of the group I patients reported an improvement after 3 months and 0% reported a deterioration.

The pain measurements (VAS) show a clear reduction of pain in both groups (MBST and placebo group) after only 1 week. 3 months after therapy, the peak pain in both groups was still significantly better. However, a significant reduction of stress pain after 3 months was only observed in the MBST group.

Due to its high prevalence, low back pain is of great importance for social medicine, causing considerable health economic costs. Standard for the evaluation of a therapeutical success is: back-specific functioning, pain, ability to work and patient's satisfaction.

Additional MBST can result in a sustainable improvement of the painful chronic low back pain. MBST is an interesting, easy-to-use treatment method that can be used as additional therapy in the rehabilitative treatment of low back pain. Positive effects over a period of 12 weeks were evident. Thus, MBST is an additional therapy method for the rehabilitation of patients with low back pain which significantly further improves the significant success of in-patient rehabilitation of disorders of the spine. Again, in this controlled study, no side effects of MBST therapy were observed. (Kullich et al., 2006)

**Prolonged success of rehabilitation treatment in case of low back pain after MBST therapy**

The high costs of treatment and frequent sick leave of patients with chronic low back pain as a result of the relative therapeutic refractory have an important social medical significance. In multidisciplinary rehabilitative approaches, we are nowadays looking for concepts that include new ways of improving pain-related disabilities. Back pain often becomes chronic because of different psychosocial factors and psychological stress with the feeling of not being able to cope with daily activities (among others in the job): Main aim is to interrupt the structural interconnection involved in back pain as quickly as possible by means of appropriate therapy measures to achieve a reduction of the impairment. Thus, the treatment of back pain should be multimodal, and this can be realized best in the context of in-patient rehabilitation.

Recently, a special form of magnetic resonance technology can be used, a therapy method with special and highly complex magnetic fields based on magnetic resonance frequency, known as MBST magnetic resonance therapy. The active principle is based on the well-known magnetic resonance tomographic diagnostic system.

The study included 62 patients (36 men, 26 women) aged 18 to 71 (mean age: 48.1 years) with low back pain who had been admitted to the special hospital for illnesses of the musculoskeletal system of the Saalfelden pension insurance institution for 3-week in-patient rehabilitation. The diagnoses of the patients with chronic low back pain were verified by a physician and by means of computer tomographic, radiological or magnetic resonance imaging (MRI) techniques. They included: chronic lumbar syndrome (chronic low back pain, disc protrusion, spondylarthrosis, condition after fractures of spinal columns) n = 52, discus prolapse n = 7, postlaminectomy syndrome after discus extraction n = 6, cervical syndrome n = 10 (partly combinations of several diagnoses).

The study was designed as placebo-controlled, double-blind, randomized, monocentric, multipointsurvey over a period of 3 months. All patients were treated with a standard in-patient multidisciplinary rehabilitation concept for spinal disorders including a standardized physiotherapeutic concept consisting of spinal gymnastics in water and on land, mechanotherapy, massages, parafango and medical baths. Electrotherapeutic applications and stan- ger baths on the affected spinal segments were avoided.

All patients were treated with a series of magnetic resonance therapy field for the affected part pf the spine in 1-hour therapy sessions for 5 consecutive days (total treatment duration = 5 hours).

The treatment device (magnetic resonance therapy system version KSRT-Key K1B, type MBST 600 KSRT; serial number 12100015) of MedTec Medizintechnik GmbH, D-35578 Wetzlar, Germany, works according to a new MBST therapy principle which brings the protons of the hydrogen atoms into resonance using magnetic resonance. The protons of the hydrogen atoms (hydrogen nuclei) align their polarity (spin axis) in the magnetic field following the field lines. The energy level of the hydrogen nuclei is influenced by defined frequency changes of the electro-magnetic field through coupled radio frequencies with modulated treatment sequences. The magnetic resonance transfers energy to the hydrogen protons which is then emitted highly effectively and in resonance into the surrounding tissue when the field direction changes.

In contrast to the conventional technique of pulsating electromagnetic fields (PEMF), MBST uses a command control unit with 12 separately controllable and independent coil systems which are arranged partly ortogonally, i. e., offset by 90°, to generate 3 three-dimensional treatment fields. Together with the permanent magnetic field, these generate a magnetic resonance field in the center of the coil system. The coded software chip cards were also used for double-blind randomization. The complex magnetic resonance treatment field was initiated by the control unit for half of the patients (= patient group with MBS therapy). In the other group of patients, no magnetic resonance field was generated (= patient group without additional MBS therapy = magnetic resonance placebo treatment).

After a comprehensive clinical examination at the start of the rehabilitation treatment and onset of the study (= day 0), the pain symptoms were recorded by means of a 10-part visual analogue scale (VAS) for a) peak pain, b) average pain during movement and c) pain at rest 1 week and 3 months after therapy. In order to assess the extent of disability caused by chronic low back pain, the Roland & Morris questionnaire for low back pain was used at the above-mentioned measurement times.

***Results***

In the context of in-patient rehabilitation, the Roland & Morris' overall score for low back pain improved significantly in all patients with low back pain after the 3-week rehabilitation period with the standardized multi- disciplinary rehabilitation program, both in the group with additional MBS therapy ($p < 0.00001$) as well as in rehabilitation patients without MBST ($p < 0.005$). It is noticeable that despite double-blind randomization, those patients with active MBST magnetic resonance therapy, starting from a higher average Roland & Morris score, improved more distinctly than the control group with values of 10.93 ± 4.42 compared to 6.37 ± 4.48. On average, both groups were practically identical after the 3-week rehabilitation with regard to the Roland & Morris score.

After 3 months, however, the Roland & Morris overall score in the group of patients without MBST therapy rose again in scores close to those of baseline and was then no longer significantly lower than baseline with a score of 10.07. In the group of patients who had received additional 5-hour MBST magnetic resonance therapy during in-patient rehabilitation, a significantly reduced Roland & Morris overall score (7.30; $p < 0.00001$) could still be documented after 3 months.

Particularly noticeable improvements in the MBST group were observed in question 18 regarding sleep disorders for which a significant ($p < 0.02$) improvement was observed after only 3 weeks which persisted even after 3 months. Also, in question 6 – "I lay down to rest more often because of my back" – the percentage of patients who answered "Yes" was reduced by half. It was also apparent that impairments in bending down and kneeling due to low back pain were significantly improved after 3 weeks ($p < 0.05$) and remained significantly reduced in an even higher percentage after 3 months ($p < 0.01$) while this impairment persisted unchanged in the control group. Further advantages for MBST treated patients were achieved in the time needed for dressing which is subject of the Roland & Morris Question 9.

Pain measurements with the 10-part visual analogue scale showed that during the 3-week in-patient rehabilitation pain could be significantly improved in both placebo and active MBST patient groups after only 1 week. This reduction in low back pain was partially still noticeable 3 months later. Using VAS, patients with low back pain assessed peak pain after 3 months at 5.3 resp. 5.1 which is significantly lower than before the 5-day treatment series (VAS 7.9 resp. 8.1). VAS-values of stress pain were significantly reduced after MBST even after 3 months but not under placebo. In general, all patients in the active MBST group rated MBST as pleasant and free of side effects and pain.

Lifetime prevalence of low back pain, i. e. the frequency of spinal pain in relation to the whole life, is reported to be 50–80%. This high incidence shows a high social-medical significance of low back pain due to the resulting impairments which cause considerable costs for the health economy.

Today's standard for the evaluation of therapy success is: back-specific functioning, pain, general health, ability to work and patient's contentment. The Roland & Morris questionnaire is a validated instrument for recording the functional status of patients with low back pain, also in a German language version. With the combination of a 10-part Visual Pain Scale (VAS) and the

Roland & Morris questionnaire, it is possible to measure the success of low back pain therapy regarding pain, disability and physical improvement.

The results show that the successes achieved with standardized physiotherapy during 3-week rehabilitation with significant improvements in function, measured using the Roland & Morris questionnaire for low back pain, are likely to last longer in those patients with additional MBST as was evident after 3 months. At that time, the overall Roland & Morris score was still significantly improved. In contrast to this, the rehabilitative effect of standardized physical therapy measures without MBS therapy is likely to be exhausted after 3 months since Roland & Morris score values of the placebo group were again on the level of baseline values at that time.

In many questions of the Roland & Morris scores, patients treated with active MBS therapy had a significant advantage over the group with standard therapy program and additional MBST placebo treatment. MBST treated patients were significantly less handicapped after 3 months in for example bending down and dressing than the placebo group.

Of special interest is the significant improvement of sleep disorders that were caused by low back pain which could be observed only a few days after the therapy. The patients treated with MBST could still benefit from an improved sleep quality even after 3 months. It should be noted that these patients also reported less pain-related periods of rest (Roland & Morris, question 6). The pain measurement (VAS) shows that a long-term positive improvement of the pain tolerance could be achieved in both groups. This significantly documents the success of the 3-week in-patient rehabilitation program. However, a clear advantage was observed in the group with active MBST therapy who reported a reduction of stress pain over the entire observation phase. This naturally suggests a structurally modifying effect which seems possible after 3 months. But the distinct improvement of stress pain after just 1 week of therapy indicates an additional fast triggering of other directly analgesic effects.

In general, MBST magnetic resonance therapy is seen as an additional, easy-to-use therapy procedure with very short therapy duration which can distinctly increase the therapeutic success of the rehabilitation of patients with low back pain without side effects. (Kullich et al., 2006)

**Impact of magnetic resonance therapy on sickness absence of patients with nerve root irritation following a lumbar disc problem**

The Orthopedic Hospital Speising, CEOPS, Department of Orthopedic Pain Therapy together with the Department of Radiodiagnostics of the Medical University of Vienna and the St. Poelten Regional Hospital carried out another study about complementary medical intervention using magnetic resonance therapy in patients with nerve root irritation due to a lumbar disc herniation. Evaluation parameters were: variance analyses, time effects, results related to medication groups ZP1 / ZP2, physical functions SF-36, Roland-Morris-Score, VAS scale, neuro-status, pain medication and rehabilitation as well as days of sick leave.

***Results***

Consistent significantly positive results have been observed in MBST treatment of herniated discs, especially in the lower lumbar spine. Those patients who were treated with an active field of magnetic resonance therapy device had significantly fewer days of sick leave.

Sick leave before therapy was 14.7 days, after therapy 5.8 days. In contrast, the number of sick leave days of patients in the control group was 7.6 days before therapy and 13.8 days after therapy. The authors: “the cost- effectiveness analysis showed that the direct costs of nuclear magnetic resonance therapy were compensated in varying degrees depending on the occupational group. For workers, 16.9 days of sick leave compensated for the direct and indirect costs of magnetic resonance therapy for workers, 11.4 days for salaried employees and 9.1 days for civil servants” (Salomonowitz et al. 2011).

By measuring the number of days of sick leave, the study was able to confirm that pain relief and thus a health economic benefit can be achieved by a relatively cheap, alternative technique. (Salomowitz et al., 2010; Salfinger et al., 2015)

**Effect of MBST magnetic resonance therapy on low back pain**

The assessment included 655 patients (247 men = 37.7%; 408 women = 62.3%) with chronic nonspecific back pain.

Therapeutic magnetic resonance had a definite influence on the symptom back pain in degenerative spinal diseases. Chronic pain in the spinal column was clearly reduced during the 1-year observation phase, both during daytime peaks as well as under stress and at rest.

The intensity of stress pain was remarkably reduced 1 year after magnetic resonance treatment. On average, it decreased from 5.01 to 2.86. At the same time, the distribution-independent mean value of peak pain decreased from baseline 6.0 to 2.5 after 12 months. Pain intensity at rest was also clearly and highly significantly ($p < 0.000001$) reduced with 1.96 on average (medial: 1.0) after 6 months and 1.91 (medial: 1.0) after 12 months compared with average baseline pain intensity of 3.2 (medial: 3.0).

The frequency of peak, stress and pain at rest in low back pain also decreased distinctly and significantly during the 12-month follow-up period ($p < 0.000001$).

Considering percental improvement in pain intensity of each individual spine patient, it becomes clear that the greatest reductions are observed 6 months after magnetic resonance therapy (peak pain –37.7%; stress pain

–32.4%; pain at rest –35.9%) but that they are only marginally lower after 12 months (–35.5%; –32.0%; –33.1%). This clearly demonstrates the sustainable effect of magnetic resonance therapy for chronic back pain.

Parallel to pain reduction, patients with spinal affections were able to perform everyday activities such as lifting, walking, sitting, standing and travelling more easily, especially in the period of 6 months to 1 year. The quality of sleep improved continuously and the ability to personal care was less impaired. These functional improvements are included in the Oswestry Disability Index. The overall score of Oswestry Disability Questionnaire showed a clear downward tendency both on average and in median. The change from 23.9 (median: 22.5) points baseline to

12.4 (median: 7.5) points in Oswestry after 12 months represents a clear improvement, which is usually seen from a difference of 10 points or more, statistical data processing showed a

significant decrease in the Oswestry dis- ability score ($p < 0.000001$). This reduction in impairments of activities resp. subjectively experienced handicaps has a very positive effect on the psychosocial influencing factors in the process of chronification of back pain.

When comparing obese and normal weight patients with back pain in relation to the sustainability of the effect of therapeutic magnetic resonance, it is noticeable that the effects are weaker in the case of obesity. A significant deterioration of all types of pain in terms of intensity and frequency after 12 months can be observed. These values are significantly different from the VAS measurement results of normal weight patients who reported the lowest pain scores after 1 year. This fact is also confirmed by the Oswestry Disability Index with significantly ($p < 0.000001$) better values for back functioning with normal weight (BMI < 25) compared to those with obesity (BMI > 30) 12 months after magnetic resonance therapy.

The chronicity of low back pain also includes individual, psychosocial and acquired risk factors such as changes in the boundaries of pain (pain memory), depression, obesity. Therefore, the data of normal weight and obese patients were compared in the evaluation. Any long-term pain-reducing treatment, such as in our case therapeutic magnetic resonance, is important to prevent a chronification of pain with negative effects on the pain memory. The data from this 10-year survey confirms the experiences of previous studies. The Oswestry disability questionnaire clearly shows functional improvements for everyday activities such as walking, sitting, lifting, travelling, personal care and quality of sleep after magnetic resonance treatment series. (Kullich, 2007)

**Case studies low back pain**

Further support of the efficacy of magnetic resonance therapy for back problems is provided by some very impressive case studies of MBST treatments of acute herniated discs, recorded in the form of MRI images prior to therapeutic application and 8 weeks after MBST treatment. They were presented by the osteopath Roland Opel at the conference for orthopedists, surgeons and sports physicians in Wetzlar in March 2017.

Male patient, 42, farmer

- The patient's first records date back to 2013.
- He complained of severe pain in the lumbar spine with paresthesia in both legs and had to take strong painkillers several times a day in order to cope with everyday life.
- Diagnosis was a herniated disc which was treated shortly after with 9 hours MBST.
- A second magnetic resonance therapy series with 10 treatment hours on the ODM whole-body treatment couch was completed soon after in 2014 because of severe osteoporotic changes of the spine.
- The patient has had no complaints since March 2014.

Male patient, 46, busdriver

- Pain in the area of the cervical spine with severe respiratory problems.
- Physiotherapy and manual therapy as well as the constant use of painkillers did not bring any relief.
- Diagnosis after x-ray: chest kyphosis.

- In the further course of differential diagnostics, an NPP in cervical spine vertebrae 3 was found.
- Treatment with 9 hours MBST.
- Free of complaints after the 7th treatment unit.
- The patient is still very satisfied until today, he has no problems with work and his hobby skiing.

Female patient, 29, Bachelor in health management

- The young patient first consulted the practice due to massive seizure-like pain in 2014.
- Diagnosis showed a severe impairment of the right leg with numbness of the right foot.
- MBST treatment was completed (9 hours with a therapy card for intervertebral discs.
- The walking pattern improved continuously over the course of the therapy, together with a considerable reduction of pain.
- 2 days after the last treatment session, she started her annual holiday and took a flight to the Dominican Republic. She could enjoy this flight without any complaints.
- Later, her mother (49 years) was also treated with 9 hours MBST because of an NPP in the area of the cervical spine. She was also completely free of symptoms 3 weeks later.
- In 2016, her 21-year-old sister consulted the practice with an NPP in the range of C4 C5. She was also treated with a 9h therapy card for intervertebral discs. Also, in this case, there were no more complaints after 3 weeks.

Male patient, 57, self-employed

- Patient lives in Valencia, Spain.
- He had heard about the therapy from his sister who had already been treated successfully in the practice.
- Late in 2014, he was treated with a 9h therapy card for intervertebral discs on the magnetic resonance therapy couch.
- There were three NPPs in the area of L3 to L5.
- Already during the last treatment session, the patient was free of symptoms.
- In February 2017, an NPP in C2 C3 was treated with the same procedure. He was free of pain after 7 treatment sessions.

Final assessment by the osteopath and Master of chiropractics Opel

- “Due to my treatment successes and my experience with magnetic resonance therapy, I was able to notice that the intervertebral disc treatment cards are highly effective in the efficiency of the treatment of NPPs and significantly exceed the treatment success of the spinal hip and the spinal shoulder treatment cards.”
- “Personally, I know of no other treatment method that triggers such a rapid and highly significant therapeutic success so quickly and sustainably with the stimulated regenerative process.”
- “The success in the treatment of herniated discs, the efficacy, the very fast effect of magnetic resonance therapy and the long-term result cannot be surpassed.”

(Opel, 2017)

Of course, these case descriptions are only evidence level 5 in the sense of evidence-based science but the observations from daily practice impressively complement the results of placebo-controlled randomized studies.

**MBST as monotherapy for chronic dorsalgia**

The aim of the study is the analysis of the clinical effect of a monotherapy with therapeutic magnetic resonance on chronic pain syndromes caused by degenerative changes of the spine. 132 patients, male and female, were treated with 9 therapy units of MBST. MRI scans of the affected part of the spine as well as VAS before, directly after and 3, 6 and 12 months after therapy were used for the assessment of therapeutic efficacy. The objectively verifiable results of structural changes on the pathological deformations of the spine correlated with a significant reduction of pain at all control dates. Therefore, MBST is an effective non-invasive monotherapy for patients with chronic back pain caused by degenerative dorsopathy. (Levchenko et al., 2017)

### 9.1.2 Safety

The following safety risks have been identified in the literature and clinical investigations which have been conducted with the evaluated medical devices:

A possible damaging effect was also examined in cell cultures and could not be observed on the basis of the results.

Pain and harmful side effects have not become known to this day.

Seldom, short-term minor pain intensifications, which can be assessed as a generally known positive therapeutic reaction, or reactions in the form of a pleasant feeling of warmth or tingling may occur.

Finally, neither in the previous clinical evaluations and literature searches nor in this current one no publication indicated any complication related to the evaluated medical devices.

Therefore, the MBST intended to treat painful, degenerative and/or pathological changes in the musculoskeletal system have been safely applied.

## 9.2 Summary of Performance and Safety

Review of the available scientific material on the efficacy of MBST therapy showed a consistently very positive and stable picture.

Sufficiently clear data is available both in the pre-clinical and in the clinical field, i. e. was presented at scientific congresses or published in accepted journals, so that an evaluation of efficacy was unproblematic.

There can, therefore, be no doubt about the efficacy of the discussed therapy method with the application of magnetic resonance on human bone and cartilage cells, thus with a positive effect on various forms of osteoarthritis and bone metabolism (e.g., in cases of fractures or osteoporosis). Taking also into account that even today therapeutic practice is still oriented primarily on the experience of clinically active physicians in combination with publications

mainly in peer-reviewed scientific journals ("evidence-based medicine"), the available extensive material consisting of case studies, prospective studies, practice reports and controlled studies – double-blind, randomized and placebo-controlled or evaluated against a standard therapy – represents an extremely solid basis that cannot be doubted.

This clearly distinguishes the present form of therapy from other therapy attempts with, for example, static or simple pulsating magnetic fields whose therapeutic effect is discussed controversially due to the very heterogeneous experimental approach.

Since the technology described here is a completely new therapeutic approach, a comparison with previous experiences made in the field of magnetic field therapy is neither possible nor permissible. Overall, it can be concluded that proof of the therapeutic efficacy of MBST therapy has clearly been given.

A possible damaging effect was also examined in cell cultures and could not be observed on the basis of the results.

So far, a therapeutic, clinically relevant efficacy in patients with the following indications has been proven:

- Degenerative changes of the musculoskeletal system such as osteoarthritis and osteoporosis
- Disorders of growth, metabolism or circulation of the bone
- Degenerative and painful spinal conditions (for example low back pain)
- Injuries of muscles, tendons and ligaments
- Acute and chronic sports and accidental injuries
- Stimulation of verifiable regenerative processes in organs

Pain and harmful side effects have not become known to this day. Seldom, short-term minor pain intensifications, which can be assessed as a generally known positive therapeutic reaction, or reactions in the form of a pleasant feeling of warmth or tingling may occur.

On the symptomatic level, consistent reports about a reduction of pain exist. This can be explained against the background of recent scientific findings from basic research/electrophysiology with an influence of magnetic resonance on voltage-dependent Ca ion channels and a change in intracellular Ca2+ concentrations as a direct connection between ion channels and intracellular Ca in the transmission and processing of pain but also a change/regulation of pain-maintaining mitogen activated protein kinases under magnetic resonance therapy could be proven.

Therefore, the following claimed clinical benefits have been shown:

- The MBST magnetic resonance therapy is a non-invasive procedure versus other therapy options and represents a causal form of therapy.
- It is described as uncomplicated form of treatment for diseases of the musculoskeletal system for which no essential form of treatment is available (e. g. finger joint arthrosis, spondylarthrosis, polyarthrosis, metabolic or circulatory disorders of the bone, osteoporosis, etc.).
- The overall duration of the treatment is short: 5, 7, 9 or 10 hours of treatment depending on stage and type of disease.

- The application of the MBST Magnetic Resonance Therapy system results in delaying a surgery or in accelerating regeneration after a necessary surgery. In the case of intervertebral disc problems and herniated discs, surgery and the resulting scar tissue may be prevented.
- In case of surgical interventions such as cartilage smoothing, the causal active principle at cellular level may be used to build up cartilage.
- The therapy is sustainable and long-lasting with an effect of 4.5 years and more.
- The therapy is painless and silent.

Overall, it can be said that the data available provides proof of the therapeutic efficacy of MBST therapy in the scientific and medical sense.

In addition, all available scientific data shows that MBST magnetic resonance technology has a demonstrable influence on cells, i.e., on the fundamental biological organizational units that make up almost all known organisms. In this sense, it is definitely possible to transfer the principle of action from already examined cells to differentiated cells and, thus, other tissues. This is evident from the research results and scientific data obtained so far over the last 20 years of intensive research activity.

# 10 Clinical Experience Data

In order to identify safety-relevant events in connection with the medical devices under evaluation internal and external databases (MHRA, Swissmedic, and BfArM) were searched for an unlimited period on 18.11.2020. Since there are no equivalent or similar devices, only the evaluated devices are included in this search. Also the no more marketed Closed Systems are included in this search since they are still on the market and applied.

## 10.1 Post-Market Surveillance Data

The evaluated medical devices are on the market for several years. MedTec Medizintechnik GmbH has established a complaint management to ensure that products placed on the market do not endanger health, safety or any other aspect of protection of public interests. (Reference: R7) MedTec Medizintechnik GmbH has further established a functioning post-market surveillance system. The first MBST devices were developed and delivered in 1998, since then there have not been a single complaint from patients/users, incidents or recalls etc. Until October 2020, no clinically relevant reclamations have been recorded for the medical devices under evaluation. (Reference: R7)

The monitoring of medical device alerts, adverse events, and other safety notices did not give any indications to new or higher risks to the MBST for the patient, the operator or other persons.

In the observation period until October 2020 there were no incidents to be reported.

No need for applying any necessary corrective or preventive actions for the MBST could be identified in the considered time period.

## 10.2 Safety Database Search

### a) MHRA

A search regarding alerts and recalls has been carried out for the evaluated medical device. The following search terms have been used:

- MBST AND "magnetic resonance"
- MBST AND MedTec

No entries were found for the evaluated medical device.

### b) Swissmedic

A search regarding alerts and recalls has been carried out for the evaluated medical device. The following search terms have been used:

- MBST AND "magnetic resonance"
- MBST AND MedTec

No entries were found for the evaluated medical device.

### c) BfArM

A search regarding "Recalls" in the BfArm database has been carried out for the evaluated medical device. The following search terms have been used:

- MBST AND "magnetic resonance"
- MBST AND MedTec

No entries were found for the evaluated medical device.

# 11 Clinical Investigation Data

In addition to the literature searches, the clinical trial database clinicaltrials.gov was searched for further unpublished studies/clinical investigations on 18.11.2020.

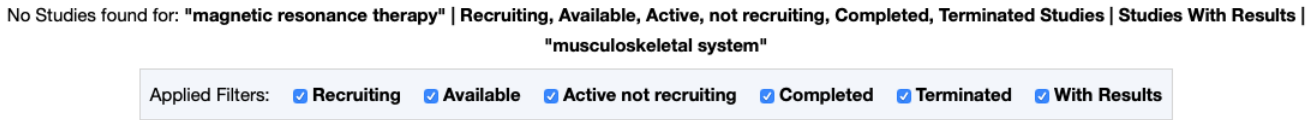


**Figure 10: clinicaltrial.gov search results**

Also, the search for "MBST" instead of "magnetic resonance therapy" revealed no results.

# 12 Risk-Benefit Assessment

The benefits and risks of a medical device can only be assessed in interrelation by "weighing any benefit to health from the use of the device against any probable risk of injury or illness from

such use"[2]. Hence, they are to be understood as relative terms: A balanced consideration based on valid scientific evidence in making risk and benefit determinations, including the critical issue of identifying benefits and residual risks is essential.

The benefits and residual risks of the MBST Magnetic Resonance Therapy System have been discussed in detail in the previous chapters and are summarized in the following table:

| **Benefits** | **Reference for benefit** | **Residual Risks** | **Reference for residual risks** |
|---|---|---|---|
| Non-invasive procedure | Section 9.1 | General application risk:<br>Skin burns, irritation | Section 5.7 |
| Causal form of therapy | Section 9.1 | General application risk:<br>Injuries | Section 5.7 |
| Uncomplicated form of treatment for diseases of the musculoskeletal system for which no essential form of treatment is available (e. g. finger joint arthrosis, spondylarthrosis, polyarthrosis, metabolic or circulatory disorders of the bone, osteoporosis, etc.) | Section 9.1 | General application risk:<br>High temperature sensation | Section 5.7 |
| Short duration (5, 7, 9 or 10 hours of treatment depending on stage and type of disease) | Section 9.1 | General application risk:<br>Cardiac problems | Section 5.7 |
| Delaying surgery or accelerating regeneration after necessary surgery | Section 9.1 | Product specific risks:<br>Electric shock | Section 5.7 |
| In case of surgical interventions such as | Section 9.1 | -- | -- |

[2] Guidance for Industry and Food and Drug Administration Staff, Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications, 2012

| Benefits | Reference for benefit | Residual Risks | Reference for residual risks |
|---|---|---|---|
| cartilage smoothing, the causal active principle at cellular level may be used to build up cartilage | | | |
| In the case of intervertebral disc problems and herniated discs, surgery and the resulting scar tissue may be prevented | Section 9.1 | -- | -- |
| Sustainable and long-lasting therapy effect of 4.5 years and more | Section 9.1 | -- | -- |
| Painless and silent | Section 9.1 | -- | -- |

**Table 16: Overview of benefits and residual risks**

The risks in connection with the application of the evaluated medical devices have been considered in detail in previous sections. All individual risks and the total risks have been assessed as acceptable after the implementation of respective risk control measures. Based on the moderate number of sold medical devices for many years and no reported and/or investigated incidents, complaints, problems, recalls, and/or adverse events during this time since 1998 (please refer to section 10), a safe application of the evaluated medical devices can be assumed.

Based on the findings from literature, clinical data as well as risk analysis it can be inferred that the probability of a patient experiencing a substantial benefit when using the MBST Magnetic Resonance Therapy System outweighs the probability of suffering harm due to a residual risk of the device significantly.

# 13 Post-Market-Surveillance Activities

The complaint management (please refer to section 10.1) and the PMS system of the manufacturer are deemed to be sufficient.

However, resulting from the risk-benefit assessment in section 12 above the following PMS and PMCF activities are recommended according to the upcoming MDR requirements:

**PMS activities:**

- Information on issues with the own products and processes, including information on serious incidents, and information received through safety reports and field safety corrective actions, as well as through records of non-serious incidents and data on any undesirable side-effects.
- Gathering and assessment of customer feedback
- Evaluation of in-house tests
- Analysis of trends, decide on the necessity of measures and implementing them
- Compilation of a PMS/PMCF plan
- Compilation of the PMS/PMCF report

**PMCF activities:**

In addition to the already mentioned completed assessments and studies, further studies are in progress and planning. In detail, these are as follows:

***Studies in progress***

1. Dr. med. Mazin Al Janabi, Dr. med. Rakshinda Mujeeb, Mediclinic Middle East, Dubai, UAE: MBST Magnetic Resonance Therapy in Osteoporosis: The study has a double-blind, placebo-controlled and randomised setting and includes 60 patients.
2. PD. Dr. Bibiane Steinecker-Frohnwieser, Univ.-Doz. Dr. Werner Kullich: Sonderkrankenanstalt Rehabilitationszentrum Groebming of the pension insurance company Austria: Magnetic resonance for reduced bone density, bone degeneration in leg amputees; placebo-controlled study with 140 patients

***Planned further studies***

1. Dr. Silvia Hayer, PD Dr. Bibiane Steinecker-Frohnwieser, Univ.-Doz. Dr. Werner Kullich: Pilot experiment: Prophylactic and therapeutic effects of nuclear magnetic resonance therapy on systemic bone mass and density in healthy, aged, and ovarectomized-mice; Medical University of Vienna, Internal Medicine III, Division of Rheumatology
   - The aim of the study is to investigate the effects of nuclear magnetic resonance therapy on systemic bone mass, bone density, cartilage structure and bone marrow composition in healthy, aged, osteoporotic and osteoarthritic mice.
2. PD Dr. Bibiane Steinecker-Frohnwieser, PD Dr. L. Weigl, Univ.-Doz. Dr. Werner Kullich: Influence of NMRT on the metabolism of different types of cells focusing on inflammation and pain Department for special anaesthesia, Medical University of Vienna:
   - Can NMRT incluence the inflammative process and pain mechanisms on general and independent of the cell type and thus prevent inflammations in connection with several disease? Does NMRT have a cell type- specific effect and can it modulate metabolism-based mechanisms that characterise the type of cells? Can NMRT treatment correct disease-induced wrong programming of these metabolis processes? Effect of NMRT on pain.

Furthermore, the evaluation included the reports of 4,518 patients (gonarthrosis n = 2770; coxarthrosis n = 673; osteoarthritis of the ankle joint n = 420; low back pain n = 655) continuous; further data is collected.

It can be transferred into a validated and monitored product registry which can be evaluated once/twice a year.

A respective PMS/PMCF plan will be compiled.

# 14 Conclusion

In addition to the previous literature searches, a new and comprehensive literature search was performed in the appropriate databases for scientific literature as well as in the relevant safety databases and databases for clinical trials (ClinicalTrials.gov, ClinicalTrials.eu) with respect to the evaluated device on 17 and 18 November 2020. The searches covered the period between 01/2020 and 11/2020 in case of the literature search and an unlimited period for the safety database and other database searches and, therefore, the complete product lifecycle with respect to the evaluated medical devices. The literature review reflects current medical practice and generally acknowledged state-of-the-art technology.

In addition, the previous literature search results of the former CERs have been taken into consideration as well.

The new literature search revealed no new relevant publications for the period between 01/2020 and 11/2020. The reason may be that the last CER was written in 02/2020 and no new publications regarding the evaluated medical device have been published since then.

However, the publications existing and resulting from the previous searches revealed all technical and procedural success of the equivalent devices used in the treatment of painful, degenerative and/or pathological changes in the musculoskeletal system. This is consistent with the results of the previous literature searches (R1 and R2).

It can furthermore be confirmed that all evaluated devices

- do not cause any undue safety concerns to either patient or healthcare professional; and
- the risks associated with the use of the devices are acceptable when outweighed against benefits to the patient.

Based on the risk analysis, potential benefits to healthcare professionals and patients outweigh the potential risks. The overall residual design and manufacturing risks, as well as the risk/benefit ratio of the device when used on subjects according to the manufacturer's instructions for use are fully acceptable.

No safety alerts or recalls related to the evaluated MBST were found on post-market surveillance safety databases.

There have been no differences in the principle of action depending on the MBST magnetic resonance therapy device or on the entire MBST magnetic resonance therapy system since the principle of action is guaranteed by the patented technology used in all MBST magnetic resonance therapy devices. This clearly shows that the MBST magnetic resonance therapy principle can be applied to tissue-specific indications that shall be treated.

In conclusion, the results of risk management, IFU, clinical literature review, and post-market experience with the evaluated devices confirm the clinical safety and performance of the evaluated MBST Magnetic Resonance Technology Systems.

The following clinically relevant parameters (CRP) defined in the Clinical Evaluation Plan (CEP, Reference: R8) have been demonstrated:

**Performance Parameters**

- Easy use
- Reduced duration of total therapy time
- Optimal treatment conditions
- Effectivity of treatment (e.g., less pain)
- No radiation

**Safety Parameters**

- Usability
- Electrical safety
- Biocompatibility
- Cleanability
- Device malfunctions per year
- Number of adverse events per year

Identified, reviewed, assessed and analyzed clinical data were evaluated adequately to provide evidence of conformity of the evaluated MBST with the MDR.

The medical safety and performance of the evaluated MBST was demonstrated with this clinical evaluation. The clinical evaluation report demonstrates that the evaluated devices comply with the General Safety and Performance Requirements of ANNEX I of the MDR.

# 15 Updates of the Clinical Evaluation Report

Due to the positive benefit-risk ratio of the MBST Magnetic Resonance Technology Systems as class IIa products and the application on the market for a few years with a moderate number of sold medical devices with no events occurred, the update of the Clinical Evaluation Report should be done in two years also in order to involve the results of currently conducted clinical investigations.

In case of a safety-relevant event resulting in an adverse event and/or an incident or event that must be reported to the competent authority or in case of safety-relevant modifications to the medical device with an effect on the risk management, the update is immediately done with relation to the respective event/modification.

# 16 Qualification and Experience of Evaluators

**Author: Daniela Penn**

Daniela Penn is Regulatory Affairs Manager, Quality Manager, Medical Writer, and Senior Clinical Affairs Manager with the following professional focus since 2005:

- Creation of diverse Technical Documentations (class I-III, including risk management, clinical evaluation, usability, essential requirements, PMS, instructions for use)
- Classification of devices, selection, and performance/coordination of a conformity assessment procedure
- National and international registration
- Creation of a quality management manual
- Quality policy and quality objectives
- Identification of processes and documentation in procedure instructions (e.g., development, production, supplier control, market surveillance, document guidance, internal audits, management evaluation, etc.)
- Description of the process interaction
- Internal audits, supplier audits

She has a Medical Writing Certificate and successfully passed the Regulatory Affairs Manager training for Medical Technology at the University Lubick in 2016.

Furthermore, she is an author of several different Clinical Evaluation Reports according to MEDDEV 2.7/1 Rev. 3 and Rev. 4 dealing with many different medical devices (Class I to III, active medical devices, not active medical devices, implants, etc.) and different indications (among others: oncology, cardiology, dermatology, orthopedics (including surgeries, invasive and non-invasive treatments), trauma surgery, dental medicine, disinfection and sterilization, etc.). She performed further training in trauma surgery and practical training in orthopedic surgery.

She conducts workshops, in-house seminars, internal seminars, and two-day seminars on clinical evaluation and related topics at the Johner Institut.

She also headed the CRO at the Johner Institut, where she was responsible for planning and conducting clinical trials for medical devices according to ISO 14155 until the end of August 2020. She holds a GCP certificate for MPG studies according to ISO 14155.

On 01.09.2020 the CRO division at the Johner Institut was outsourced to the independent GmbH medXteam, of which she is the managing director.

**Reviewer: Dr. Gisela Knopf**

After her license to practice Medicine in 1996, Dr. med. Gisela Knopf worked in several different fields such as Internal Medicine, Surgery, Orthopedics, Neurology, Urology, Psychotherapy. Having passed her specialists examination, she registered in the GP sector in 2011. In addition, she worked as a Medical Advisor by order of several Medical Companies since 2007 with focus on:

Medical advice and review/assessment of study data:

- Adverse events and concomitant medication coding

- Checks for non-compliance (e.g., in-/exclusion criteria, prohibited medication, etc.)
- Review of safety data
- Medical advice for study protocols

Since Mai 2018 she is working as medical advisor at Johner Institute GmbH and since September 2020 also at medXteam GmbH with a focus on

- Medical Review of Clinical evaluation reports for medical devices according to MEDDEV 2.7/1 revision 4 and MDD/MDR.
- Compliance with GCP-regulations, trainings of investigators and study personal
- Study design/compiling and review of clinical investigation documents such as Clinical Investigation Plan (CIP), Informed Constent, Investigator's Brochure, etc.

# 17 Reference Documents

| Reference | Document | Document name |
|---|---|---|
| R1 | CER 2019 | 2019-2_CER_Scientific_Evaluation_of_MBST-Therapy_Melzer-Kullich_GB |
| R2 | CER 2020 | 400431-V1.0_Clinical_Evaluation_Report_2020_GB |
| R3 | Instructions for Use | MBST_ArthroSpinFlex_Instruction for Use_V3.1_GB<br>Instruction for Use_ ASL_rev.3.1_2018-12-05<br>MBST_ODM1_V3_Instruction for use_V1.4_GB_F_2018-04-18<br>MBST_OS350+700_Instruction for Use-V2.3_GB-F<br>120319-V1.0_Instructions_for_Use_OSTEOSPIN_GB<br>ProMobil V2_Gebrauchsanweisung-V2.1-GB |
| R4 | General safety and performance requirements | Grundlegende Anforderungen MBST-Geräte_MDD |
| R5 | Risk Analysis | Risikoanalyse-MBST-Produkt |
| R6 | Risk Management Report | Risikomanagementbericht Osteo.Spin |

| Reference | Document | Document name |
|---|---|---|
| R7 | Post-Market Surveillance | Änderungs-_Marktüberwachung |
| R8 | Clinical Evaluation Plan (CEP) | Clinical-Evaluation-Plan-MBST_V1.0 |
| R9 | Sales figures | Verkaufszahlen_weltweit_18.11.2020 |
| R10 | Usability documentation | MBST®ARTHRO·SPIN·FLEX Gebrauchstauglichkeitsakte_rev 1<br>FB-09-6-Geb Gebrauchstauglichkeit OS 350-700-1<br>Gebrauchstauglichkeit OS 350-700-1<br>FB-09-6-Gebrauchstauglichkeitsakte OSP-rev-1.0<br>FB-09-6-Gebrauchstauglichkeitsakte ASL-rev-1.0<br>ArthroSpinLift_FB-736.1-3 Validierungsbericht Gebrauchstauglichkeit_rev.0_2017-12-12<br>Gebrauchstauglichkeit PM v2<br>Verification of the usability of the user-product interfaces_ASL<br>ArthroSpinFlex_FB-736.1-3 Validierungsbericht Gebrauchstauglichkeit_rev.0_2016-12-09<br>ASF_Verifizerung Benutzer-Produkt-Schnittstelle<br>Verifizierung Gebrauchstauglichkeit OS 350-700<br>OSP_Verifizerung Benutzer-Produkt-Schnittstelle_rev1.0<br>FB-736.1-3-Validierungsbericht Gebrauchstauglichkeit OSP-rev-0.0 |
| R11 | Software versions | SW-Versionen MBST Geräte |
| R12 | Biocompatibility tests | 160831_Biokompatibilität_AM50<br>180411_Biokompatibilität_AM50<br>Biologische Beurteilung OS350-700<br>Biokompatibilität<br>Leder-Skai Biologische Beurteilung |

| Reference | Document | Document name |
|---|---|---|
| | | Report on biological compatibility plastic cladding acc. to 10993-1_2018-09-26<br>Leder-Skai_Tundra_ Biologische Beurteilung |
| R13 | Software development and tests | MBST®ARTHRO·SPIN·FLEX Softwarelebenszyklus Rev.6<br>MBST®ARTHRO·SPIN·LIFT Softwarelebenszyklus_rev7<br>Designverifizierung Software Control_OS<br>FB-73.1-1 SW-Lebenszyklus 62304-2016 (Softwareverionen V3.x.x)<br>Designverifizierung Software Control_OSP_V1.0-99 Rev.1.0<br>MBST®OSTEO·SPIN Softwarelebenszyklus |
| R14 | Electrical safety | MBST®ARTHRO·SPIN·FLEX TRF 60601-1 3.1Ed___<br>ArthroSpinLift TRF 60601-1 3.1Ed<br>Gap Analysis 60601-1 3.0Ed zu 60601-1 3.1Ed_OS 350+OS 700<br>F21_10_Rev6_TRF 60601-1_OS350+OS700_rev2<br>Stand_FB-F21-17-TRF 60601-1-rev-1.0_deutsch_17.Jul.2019_12h_mit_4.0_Norm_weiter<br>F21_10_Rev6_TRF 60601-1_CS600V5 + CS300V4 (NMR)_rev0<br>F21_10_Rev6_TRF 60601-1_rev1<br>TRF 60601-1_ProMobil -V2-Rev 1.0 |
| R15 | Electromagnetic compatibility | EMC Test report ArthroSpinFlex<br>23803_30082017_ArthroSpinLift<br>23803_26022020_EMV_OpenSystem 700<br>01_EMC-Testprotokoll_23803_09012017_OsteoSpin<br>EMV_23803_19032015_ProMobil V2 und ProVetMobil-Applikator<br>23803_11022016_OsteoSystem1 |

# 18 Literature

Auerbach B, Melzer C. Prospektive Untersuchung der Wirksamkeit der MBST®-Kernspinresonanztherapie bei der Behandlung der Gonarthrose. Waldkrankenhaus Bad Dueben, 2003

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# 19 Appendices

| Appendices | Document name |
|---|---|
| A1: Literature Search Protocol | A1_Literature Search Protocol-MBST_V1.0 |
| A2: Author's declaration of interests | A2_Interessenserklärung-MBST |