MAGNEZIX

CS^C 4.8

Product Information

Intelligent innovations for a better life.
CAUTION

This product description is not sufficient for immediate use of instruments or implants. Induction training by an authorised person must be carried out prior to use of these instruments and implants.

Implants that have been removed from the sterile packaging and not used must not be re-sterilized and have to be discarded.

When using other makes of implant at the same time, it is important to note that steel, titanium and cobalt-chromium alloys in the surgical site must not be in direct contact with a MAGNEZIX® implant for an extended period (physical contact between implants).
MAGNEZIX® is a trademark for CE-certified implants manufactured from the world’s first transformable material consisting of a magnesium alloy (MgYREZr) for medical applications.

The mechanical properties are very similar to those of human bone. MAGNEZIX® gradually transforms within the body and is replaced by endogenous tissue. Experimental studies also confirm that magnesium has an osteoconductive effect and tends to inhibit infection.

Advantages for users and patients

- There is a complete homogeneous conversion (transformation) of the implant to the patient’s endogenous tissue.
- This complete transformation of the implant makes subsequent metal removal unnecessary.
- The mechanical properties are significantly better than those of conventional resorbable implants.
- Histological investigations show bone formation at the surface of the implant, as well as bone growth into the implant zones already transformed.
- The use of MAGNEZIX® implants does not lead to so-called “stress shielding” (bone atrophy due to shielding from load) due to the bone-like mechanical properties.
- In terms of application, MAGNEZIX® implants hardly differ from conventional implants. This is ensured by the adapted design, which takes the material and transformation properties into account.
- MAGNEZIX® implants are radiologically visible, MRI-conditional and only generate minimal artifacts (see also the IFU regarding this).
- The MAGNEZIX® C5 has a highly innovative surface finish. The transformation is therefore postoperatively delayed in the first months.

5 Ceramised MAGNEZIX® products are marked using a superscript “C” in connection with the product acronym.

Histological evaluations of an animal study have shown complete conversion of the metal implant after a 12-month implantation period. Evidence was produced of bone formation with direct implant contact, as well as the presence of osteoblasts and osteoclasts.
**MAGNEZIX® CS<sup>C</sup> 4.8**

**INTENDED USE**

MAGNEZIX® CS<sup>C</sup> 4.8 is a bioabsorbable compression screw that is used to restore the bone continuity after fractures and osteotomies (osteosynthesis) as well as for treatment of pseudarthroses. Specifically, the MAGNEZIX® CS<sup>C</sup> 4.8 is intended to achieve anatomical retention of bone sections that have been joined together by surgical splinting following prior reduction until the bone has healed. The implant is designed for single use.

**INDICATIONS**

The indications for MAGNEZIX® CS<sup>C</sup> 4.8 implants are reconstruction procedures after fractures and malalignment in the human skeleton. The surgeon must determine the degree of injury and the scope of the required surgical procedure and then select the correct surgical procedure and the appropriate implant. This is particularly important when using bioabsorbable MAGNEZIX® implants. The surgeon is always responsible for the decision to use these implants.

Depending on the chosen size, the MAGNEZIX® CS<sup>C</sup> can be used as a bone screw for children, adolescents or adults for adaptation-capable or exercise-capable fixation of bones and bony fragments.

**MAGNEZIX® CS<sup>C</sup>-4.8:**
- intra- and extraarticular fractures of small and medium-sized bones and bony fragments
- arthrodeses, osteotomies and pseudarthroses of small and medium-sized bones and small joints
- and similar indications at
  - distal tibia
  - calcaneus, talus and metatarsus
- re-fixiation of bony fragments also on
  - distal femur
  - proximal tibia

**CONTRAINDICATIONS**

MAGNEZIX® implants are contraindicated (absolute contraindication) in specific clinical situations or they should only be planned and used after careful consideration (relative contraindication).

**Absolute contraindications:**
- insufficient or avascular bone mass for anchorage of the implant, except osteochondral fractures and dissecates
- confirmation or suspected septic infectious surgical site
- application in the area of the epiphyseal plates
- load-bearing stable osteosynthesis
- arthrodeses of medium to large joints
- applications on the spinal column
- radioscaphoid and/or midcarpal arthrosis

**Relative contraindications:**
- options for conservative treatment
- no options for adequate postoperative treatment (e.g. temporary strain relief)
- uncooperative patient or patient with restricted intellectual capacity
- alcohol, nicotine and/or drug abuse
- poor skin/soft tissue conditions
- osteoporosis
- acute sepsis
- epilepsy
EXAMPLES OF APPLICATIONS

- Medial and lateral malleolus
- Distal tibia
- Talus
- Calcaneus
- Distal femur
- Patella
- Midfoot
- Proximal tibia
**ADVANTAGES AND FEATURES**

**HINTS**

In isolated cases, temporary radiolucencies may be observed around the implant. It is recommended to mention this phenomenon in the operative report and physician’s letter, pointing out that, based on present knowledge, this does not have any relevant influence on the process of healing. This will inform the caregivers involved in the follow-up treatment of the special aspects of the radiological healing process.

Since MAGNEZIX® implants are degraded completely in the body in the course of time and are replaced by endogenous tissue, they do not have to be removed.

**WARNINGS**

When using other makes of implant at the same time, it is important to note that steel, titanium and cobalt-chromium alloys (or similar alloys) in the surgical site must not be in direct contact with a MAGNEZIX® implant for an extended period (physical contact between implants).

Since the implants are intended for single use only, re-use of MAGNEZIX® implants constitutes gross negligence. It may lead to increased risk of infection and especially loss of implant stability. Re-sterilisation will have an unpredictable impact on the product.

**BIOABSORBABLE MAGNESIUM ALLOY**

Use of MAGNEZIX® implants makes any subsequent implant removal unnecessary, and moreover supports the osseous healing process. MAGNEZIX® is biocompatible and bioabsorbable.

**Surface design**

The top layer of MAGNEZIX® CS implants is converted into a dense, porous and strongly adherent magnesium-based oxide film. This surface finish acts as a protective layer and is fully bioabsorbable. A significant reduction in the degradation progress is achieved to maintain the desired integrity of the implant for an extended range of indications.

**Self-tapping screw tip**

The self-tapping properties of the screw tip reduce the operation time and simplify the surgical application technique.

**Cannulated screw**

The screw is cannulated (hollow) to allow controlled positioning of the screw using the guide wire. This feature supports minimal invasive surgery.

**Self-tapping head thread**

The self-tapping design of the screw head simplifies insertion and countersinking of the screw head.

**Different thread pitches**

The threads of the head and the shaft have different thread pitches. This adapted design of the screw generates compressive forces and supports the intended inter-fragmentary compression.

**Self-holding screwdriver**

The drive of the screw head is of T15 (ISO 10664–15) design. The advantages of this ISO standardized technology are:

- enlarged contact area
- improved self-retaining mechanism
- improved torque transmission
Prior to implanting a MAGNEZIX® CS 4.8 screw it is necessary to ensure repositioning and temporary stabilization of the fracture or the osteotomy. The drill guide system is inserted through a stab incision through the soft tissue to the bone.

**STEP 1: POSITIONING THE GUIDE WIRE**

Position the guide wire through the drill guide system after removing the trocar, if necessary monitor using image intensification, until it is in the required position.

**Important**

The guide wire is inserted a few millimeters longer than the later selected screw. This prevents the guide wire from being completely drilled off during the subsequent drilling process and removed with the cannulated drill bit. Avoid excess force when inserting the guide wire. Excess force will bend the guide wire and may hinder subsequent reaming or insertion of the screw.

**Instruments used:**

1. 9048.030 Protection Sleeve, Ø 5.0 mm
2. 9048.031 Drill Sleeve, Ø 5.0/4.0 mm
3. 9048.032 Drill Sleeve, Ø 4.0/1.9 mm
4. 9048.033 Trocar, Ø 1.8 mm
5. 9048.043 Guide Wire Ø 1.7 mm, with trocar tip, length 150 mm
   or
5. 9048.044 Guide Wire Ø 1.7 mm, with threaded tip, length 150 mm
**STEP 2: DETERMINATION OF SCREW LENGTH**

The length of the screw is determined by sliding the measuring device over the guide wire to the bone. The end of the guide wire, visible in the scale of the measuring device, indicates the length of the screw to be used (22 mm in the figure).

**Important**
From the measured length at least 2 mm to 4 mm must be subtracted so that the guide wire is not removed during pre-drilling as described in step 1. The maximum length of the screw must therefore not exceed 20 mm. Only the original guide wires guarantee correct measurement.

**Instruments used:**
- 9048.042 Measuring Device for Guide Wire Ø 1.7 mm, Guide Wire length 150 mm

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**STEP 3: PRE-DRILLING**

For screws with self-tapping tips, pre-drilling over the desired screw lengths is mandatory. At this point, the cannulated drill bit is directed by the underlying guide wire. This facilitates the subsequent tightening of the screw and prevents the rotation of small bone fragments. The drill bit calibration allows the drill depth reached to be read at the top end of the drill sleeve. The fine ring marks correspond to 2 mm steps (up to 50 mm) or 5 mm steps (50-70 mm). The dominant ring marks indicate 10 mm drill steps.

**Important**
At least the last 2 mm to 4 mm up to the guide wire tip must not be drilled, so that the guide wire remains in the bone. Slowly pull the drill bit out vertically from the drill sleeve while slowly turning in a forward direction so as to leave the guide wire in position.

**Instruments used:**
- 9048.030 Protection Sleeve, Ø 5.0 mm
- 9048.031 Drill Sleeve, Ø 5.0/4.0 mm
- 9048.020 Drill Bit Ø 4.0/1.9 mm, cannulated, length 160/135 mm, for Quick Coupling
STEP 4: COUNTERSINKING

In order to simplify insertion of the screw head, the head side of the intended implant position is now reamed using the countersink with the guide wire still in place.

**Important**

If the screw is positioned perpendicular to the bone surface, countersinking to the first ring marking (RM 1) is required in order to achieve adequate countersinking of the screw head.

If the screw is positioned at an angle of 45° to the bone surface, countersinking to the second ring marking (RM 2) is required in order to achieve adequate countersinking of the screw head.

The countersink is pulled vertically out of the drill sleeve while still slowly turning in the forward direction so as to leave the guide wire in position.

**Instruments used:**

1. 9048.030 Protection Sleeve, Ø 5.0 mm
2. 9048.021 Countersink Ø 5.0/1.9 mm, cannulated, for Quick Coupling
STEP 5: INSERTION OF THE SCREW

This is now followed by the tightening of the MAGNEZIX® CS 4.8 over the underlying guide wire in the length previously determined in step 2. This should always be done without a power tool.

Important
Take care to ensure that the guide wire was not damaged during steps 1 through 4. A damaged guide wire may result in the MAGNEZIX® CS 4.8 not ending up fully screwed in. In this case the guide wire must be removed before insertion of the screw.

Bear in mind that the shaft thread could pull out of the distal bone fragment if the induced compression forces are excessive when screwing-in the screw.

If the selected screw is too short the shaft thread might cross the fracture or osteotomy gap. If this situation results no compression will be generated. Therefore, to ensure the correct position of the threaded shaft it is recommended to check the position using an image intensifier.

If one finds the thread crossing the fracture or osteotomy gap the screw must be removed and a longer screw has to be selected in order to generate compression. When doing this and in the case of a hard (dense) bone situation, it might be necessary to repeat the pre-drilling process as described in step 3 to further deepen the pre-drilled pilot hole for the selected screw with an adequate length.

When the screw is in its final position the guide wire is removed.

Instruments used:
③ 9099.003 Screwdriver Handle, for quick coupling
④ 9048.015 Screwdriver Blade T15, self-holding, with Quick Coupling optional
    9048.030 Protection Sleeve, Ø 5.0 mm
**MAGNEZIX® CS® 4.8 IMPLANTS**

All implants are individually sterile packaged. It is not possible to re-sterilize the implants.

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### INSTRUMENTS MAGNEZIX® CS® 4.8

The figures are not to scale.

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<td>Cleaning Stylet Ø 1.85 mm, for Ø 1.8 mm cannulated instruments</td>
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METALLIC AND TRANSFORMABLE. 
STABLE AND ELASTIC. 
A MEDICAL SENSATION. 
MAGNEZIX®
Implants are manufactured in Germany in cooperation with Königsee Implantate GmbH.