MAGNEZIX® CBS
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).

The cover illustration is a CAD image. It is not an accurate representation of the actual implant.
THE MATERIAL MAGNEZIX®

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 biomechanical properties are very similar to those of human bone. MAGNEZIX® is completely degraded in the body and is replaced by endogenous tissue. Experimental studies also confirm that magnesium has an osteoconductive\(^1\) effect and tends to inhibit infection.\(^2\)

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 with conventional resorbable implants.
- Histological investigations show bone formation at the surface of the implant, as well as bone growth into the implant zones already resorbed.
- The use of MAGNEZIX® implants does not lead to so-called “stress shielding” (degradation of bone tissue) due to the bone-like biomechanical properties.\(^3\)
- In terms of application, MAGNEZIX® implants hardly differ from conventional implants. This is ensured by the adapted design, which takes the material properties and bioabsorption properties into account.
- MAGNEZIX® implants are radiologically visible, MRI-conditional and only generate minimal artifacts (see also the IFU regarding this).\(^4\)

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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.
INTENDED USE

The MAGNEZIX® CBS is a bioabsorbable bone screw that is used to restore the bone continuity after fractures and osteotomies (osteosynthesis) as well as for treatment of pseudarthroses. Specifically, the MAGNEZIX® CBS 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 only.

INDICATIONS

The indications for MAGNEZIX® CBS implants are reconstruction procedures after fractures and malalignment in the human skeleton. The surgeon must determine the degree of injury or changes in the bone and the scope of the required surgical procedure and then select the correct surgical procedure and the correct implant. This is particularly important for the use of bioabsorbable MAGNEZIX® implants. The surgeon is always responsible for the decision to use these implants. Depending on the chosen size, the MAGNEZIX® CBS can be used as a bone screw for children, adolescents or adults for adaptation-capable or exercise-capable fixation of bones and bone fragments.

MAGNEZIX® CBS 2.0, 2.7, 3.5:
- Intra- and extra-articular fractures of small bones and bone fragments
- Arthrodeses, osteotomies or pseudarthroses of small bones and joints
- Small bony ligament and tendon ruptures
- Osteochondral fractures and dissecates
- Similar indications

MAGNEZIX® CBS 2.0:
- Phalangeal and metacarpal bones
- Osteochondrosis dissecans
- Similar indications

MAGNEZIX® CBS 2.7, 3.5:
- Carpal, metacarpal, tarsal and metatarsal bones
- Epicondylus humeri
- Metaphyseal fractures of small and medium-sized bones and bone fragments
- Similar indications

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
- Loadbearing stable osteosynthesis
- Arthrodeses of medium to large joints
- Applications on the spinal column
- Applications in combination with osteosyntheses plates, consisting of foreign material

Relative contraindications:
- Options for conservative treatment
- Acute sepsis
- Osteoporosis
- Alcohol, nicotine and/or drug abuse
- Epilepsy
- Poor skin/soft tissue conditions
- Uncooperative patient or patient with restricted intellectual capacity
- No options for adequate postoperative treatment (e.g. temporary strain relief)
EXEMPLARY APPLICATIONS

- Proximal humerus
- Scapula

Elbow:
- Radial head
- Distal humerus

- Distal radius and ulna
- Processus styloideus radii
- Syndesmosis rupture

Carpal and metacarpal bones

- Osteochondral flakes and fractures
- Osteochondrosis dissecans
- Patella
- Proximal tibia and fibula

- Osteochondral flakes and fractures
- Osteochondrosis dissecans
- Distal tibia and fibula
- Ankle joint
- Syndesmosis rupture

- Tarsal and metatarsal bones (esp. talus bone and navicular bone)
- Hallux valgus

- Tarsal and metatarsal bones

- Fingers and thumbs

- Radial head
- Distal humerus

- Proximal humerus
- Scapula
ADVANTAGES AND FEATURES

BIOABSORBABLE MAGNESIUM ALLOY

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

Head design
The head of the MAGNEZIX® CBS, with a typical cortical screw design, allows for stable repositioning of the bone fragment, with good compression characteristics.

Drive design
The special design of the TORX-based drive protects the implant in the shaft area from failure. The drive “slips” during the screwing-in operation if the torsional load is too high.

Thread design
The thread design, which is typical for cortical screws, produces a strong fixation in cortical bone. A dimension-dependent thread pitch supports the controlled compression of bone fragments.

Screw tip
The additionally existing chip flutes improve the thread quality and ease the screwing-in. However, a precutting of the thread in cortical bone is required.

HINTS

Occasionally, temporary radiolucencies may be observed around the implant.

It is recommended to mention this phenomenon in the operating room note/discharge note, pointing out that, based on present knowledge, it 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 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, reuse 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.
Advantages and Features
SURGICAL TECHNIQUE

MAGNEZIX® CBS – STEP BY STEP

Before a MAGNEZIX® CBS can be implanted as a lag screw, the fracture, the osteotomy or the bone fragment must be repositioned and temporarily stabilised. This can be done with e.g. reduction forceps with points. The temporary stabilisation is left until after the screw has been implanted.

The following operation steps of the standard lag screw technique ("glide hole first technique") apply for all MAGNEZIX® CBS dimensions, because the design of the instruments to be used is identical. However, the instruments differ in their dimensions.

Alternatively, of course the "thread hole first technique" can be used for all dimensions.

When selecting the MAGNEZIX® CBS dimension it must be kept in mind that, compared to titanium or steel screws, a larger dimension must be chosen to achieve similar stability. For the choice of a 2.0 mm cortical screw in titanium/steel, a MAGNEZIX® CBS 2.7 should be chosen.

Step 1: Drill near cortex for gliding hole
Positioning of the double drill guide through the soft tissue to the bone. Insertion of the drill bit through the double drill guide. Drilling of the near cortical bone side only.

Important
The lag screw must be positioned vertically and in the centre of the fracture line. In addition, make sure that the gliding hole passes through the fracture gap to ensure compression by the implant.

Instruments used

For MAGNEZIX® CBS 2.0:
9120.020  Drill bit Ø 2.0
9115.033  Double drill guide Ø 1.5/2.0

For MAGNEZIX® CBS 2.7:
9127.020  Drill bit Ø 2.7
9327.033  Double drill guide Ø 2.0/2.7

For MAGNEZIX® CBS 3.5:
9335.020  Drill bit Ø 3.5
9335.033  Double drill guide Ø 2.5/3.5
STEP 1
**Step 2: Drill far cortex for threaded hole**

Pre-drilling of the far cortex. Here, the required double drill guide or, if available, an insert drill sleeve is inserted into the drill hole of the near cortex to allow for an axially correct pre-drilling of the far cortical bone side.

**Important**

Only the use of the double drill guide or an insert drill sleeve ensures an axially correct drilling procedure.

**Instruments used**

**For MAGNEZIX® CBS 2.0:**
- 9115.020 Drill bit Ø 1.5
- 9115.033 Double drill guide Ø 1.5/2.0

**For MAGNEZIX® CBS 2.7:**
- 9120.020 Drill bit Ø 2.0
- 9327.033 Double drill guide Ø 2.0/2.7
- 9327.034 Insert drill sleeve Ø 2.7/2.0

**For MAGNEZIX® CBS 3.5:**
- 9325.020 Drill bit Ø 2.5
- 9335.033 Double drill guide Ø 2.5/3.5
- 9335.034 Insert drill sleeve Ø 3.5/2.5
STEP 2
Step 3: Countersink near cortex
If the screw head has to be countersunk, the head space must be prepared with the countersink tool in advance, before linear measurement of the pilot hole. This should always be done without a power tool.

Important
If the head space prepared is too deep and the cortical bone is very thin, the screw head will hardly have any support. As a result, it will no longer be possible to ensure sufficient compression. In contrast, if the head space prepared is too shallow, the protruding screw head may irritate or damage the adjacent tissue.

Instruments used

For MAGNEZIX® CBS 2.0:
- 9320.021 Countersink CBS 2.0
- 9099.004 Small screwdriver handle with quick coupling

For MAGNEZIX® CBS 2.7/3.5:
- 9327.021 Countersink CBS 2.7/3.5
- 9099.004 Small screwdriver handle with quick coupling
Step 4: Determine screw length
The screw length is determined with the depth gauge. The required length of the screw can be read off directly from the scale.

Important
The length can only be correctly determined when the tip hook of the depth gauge is correctly positioned on the back side of the far cortical side.
A measurement must always be performed before cutting the thread, otherwise the thread could be damaged.

Instruments used
9300.045  Depth gauge for MAGNEZIX® CBS
STEP 4
Step 5: Tap
Cortical bone must be pre-cut, otherwise the implant or the drive in the screw head could be damaged. This should always be done without a power tool.

Important
The cutting process must be interrupted repeatedly by left hand rotations to break the cortical chip. The double drill guide protects the surrounding tissue while this is happening.

Instruments used

For MAGNEZIX® CBS 2.0:
9320.022 Tap CBS 2.0
9099.004 Small screwdriver handle with quick coupling
9115.033 Double drill guide Ø 1.5/2.0

For MAGNEZIX® CBS 2.7:
9327.022 Tap CBS 2.7
9099.004 Small screwdriver handle with quick coupling
9327.033 Double drill guide Ø 2.0/2.7

For MAGNEZIX® CBS 3.5:
9335.022 Tap CBS 3.5
9099.004 Small screwdriver handle with quick coupling
9335.033 Double drill guide Ø 2.5/3.5
STEP 5
Step 6: Insertion of the screw

The screw is then inserted through the gliding hole of the near cortical bone and screwed into the thread section of the far cortical bone side. This should always be done without a power tool. The fracture gap must be checked during the process to evaluate the degree of compression. If required, an optional holding sleeve can be used for this purpose. The holding sleeve encompasses the screw head securely and fixes it to the screwdriver blade.

Important

The repositioning aid must be loosened before completing the screwing-in process so that the screw compression can be evaluated. If too much compression is generated during the screwing-in process, the thread may pull out in the far fragment. If the chosen screw is too short, it is possible that the thread section in the far cortex will not be sufficient. As a result, it might not be possible to achieve enough compression. The position of the screw should therefore be checked with an image amplifier. A screw head that does not lie properly against the bone might not generate any compression. If the screw head is found not to be lying properly against the bone, the screw must be repositioned to generate compression. It should be kept in mind that it might be necessary to repeat the pre-drilling procedure (see step 2), the head room countersinking (see step 3) or the thread cutting (see step 5), possibly deeper, according to the length of the selected screw.

Instruments used

For MAGNEZIX® CBS 2.0:
9320.015 Screwdriver blade T7
9099.004 Small screwdriver handle with quick coupling
9320.016 Holding sleeve CBS 2.0

For MAGNEZIX® CBS 2.7:
9320.015 Screwdriver blade T7
9099.004 Small screwdriver handle with quick coupling
9327.016 Holding sleeve CBS 2.7

For MAGNEZIX® CBS 3.5:
9335.015 Screwdriver blade T10
9099.004 Small screwdriver handle with quick coupling
9335.016 Holding sleeve CBS 3.5
STEP 6
**Product Overview**

**IMPLANTS® MAGNEZIX® CBS**

**MAGNEZIX® CBS 2.0**
- Drive: T7 Screwdriver 9320.015
- Ø 4.0 mm Head thread
- Ø 1.4 mm Shaft diameter
- Ø 2.0 mm Shaft thread
- Drill bit for threaded hole: 1.5 mm
- Drill bit for glide hole: 2.0 mm
- Head height is 1.9 mm.

**MAGNEZIX® CBS 2.7**
- Drive: T7 Screwdriver 9320.015
- Ø 5.0 mm Head thread
- Ø 1.9 mm Shaft diameter
- Ø 2.7 mm Shaft thread
- Drill bit for threaded hole: 2.0 mm
- Drill bit for glide hole: 2.7 mm
- Head height is 2.3 mm.

**MAGNEZIX® CBS 3.5**
- Drive: T10 Screwdriver 9335.015
- Ø 6.0 mm Head thread
- Ø 2.4 mm Shaft diameter
- Ø 3.5 mm Shaft thread
- Drill bit for threaded hole: 2.5 mm
- Drill bit for glide hole: 3.5 mm
- Head height is 2.6 mm.

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**PLA/PGA comparative dimensions regarding stability**

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* All implants are individually sterile packaged. It is not possible to re-sterilize the implants.
## INSTRUMENTS** MAGNEZIX® CBS

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Not shown: 8300.001 Sterilizing tray CBS  
8300.002 Lid sterilizing tray CBS  
8300.003 Insert sterilizing tray CBS

** The figures are not to scale.
METALLIC AND TRANSFORMABLE. A MEDICAL SENSATION. MAGNEZIX®
Implants are manufactured in Germany in cooperation with Königsee Implantate GmbH.