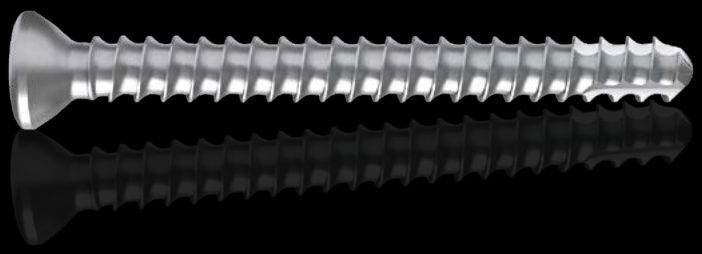


MAGNEZIX M3

CBS

Product information

Intelligent innovations for a better life.

SYNTELLIX

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.

MAGNEZIX® CBS

THE MATERIAL MAGNEZIX®

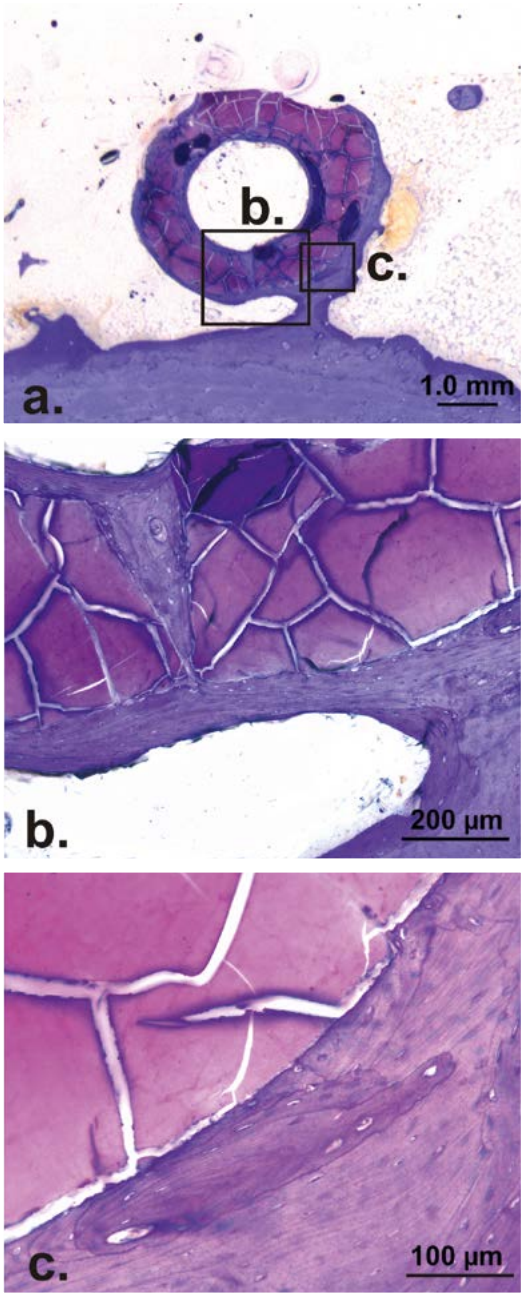
MAGNEZIX® is a trademark for CE-certified implants manufactured from the world's first transformable material consisting of a magnesium alloy (MgYREZr) for medical applications.
The biomechanical properties are very similar to those of human bone. MAGNEZIX® is completely degraded in the body and is replaced 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]

[1] Zreiqat et al.: Mechanisms of magnesium-stimulated adhesion of osteoblastic cells to commonly used orthopaedic implants. J Biomed Mater Res 2002 Nov;62(2):175-84.
[2] Robinson DA, Griffith RW, Shechtman D, Evans RB, Conzemius MG: In vitro antibacterial properties of magnesium metal against Escherichia coli, Pseudomonas aeruginosa and Staphylococcus aureus, Acta Biomaterialia 6 (2010) 1869-1877.
[3] Witte F, Hort N, Vogt C, Cohen S, Kainer KU, Willumeit R, Feyerabend F: Degradable biomaterials based on magnesium corrosion. Current Opinion in Solid State and Materials Science 12 (2008) 63-72.
[4] Sonnow L, Könneker S, Vogt PM, Wacker F, von Falck C: Biodegradable magnesium Herbert screw – image quality and artefacts with radiography, CT and MRI. BMC Medical Imaging (2017) 17:16.

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.



Waizy H, Diekmann J, Weizbauer A et al. (2013) In vivo study of a biodegradable orthopedic screw (MgYREZr-alloy) in a rabbit model for up to 12 months. J Biomater Appl 28 (5), 667-75.

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

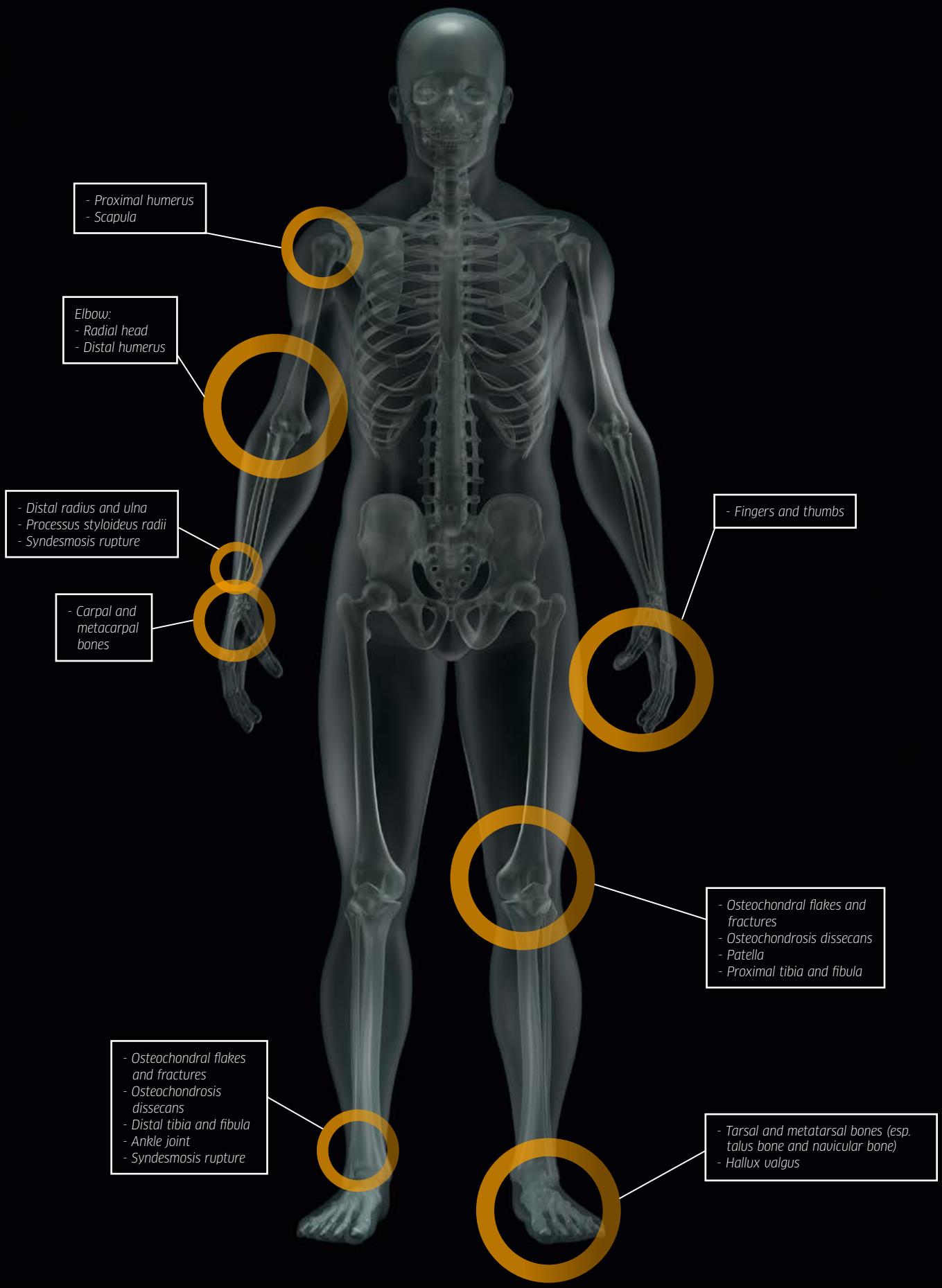
CONTRAINDICATIONS

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



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.

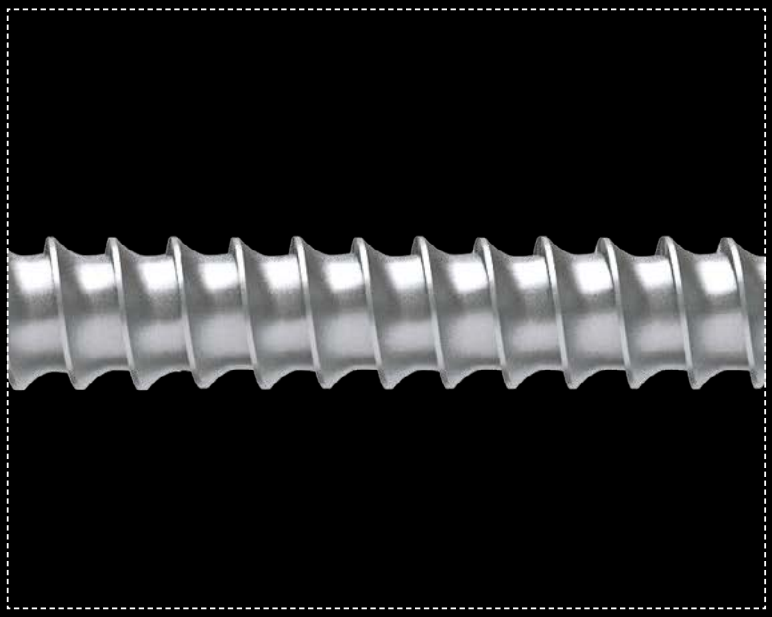
Screw tip
The additionally existing chip flutes improve the thread quality and ease the screwing-in. However, a precutting of the thread in cortical bone is required.

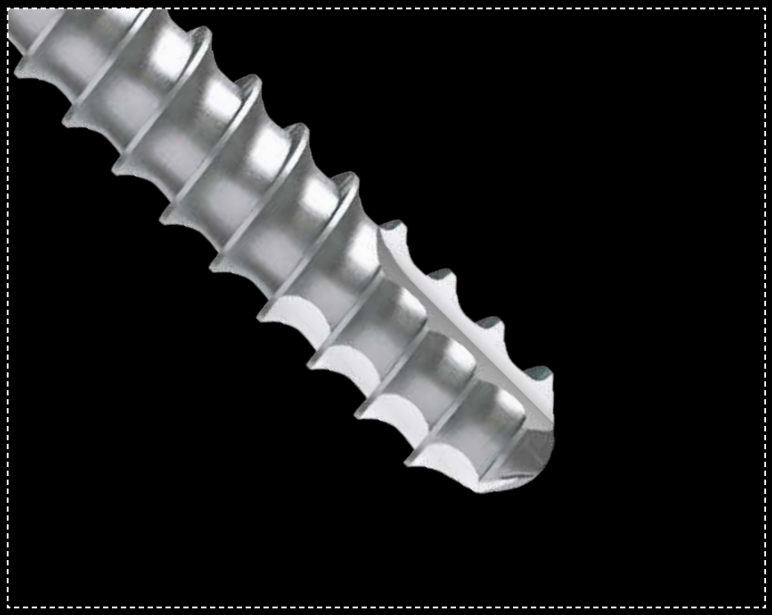
HINTS

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.





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.

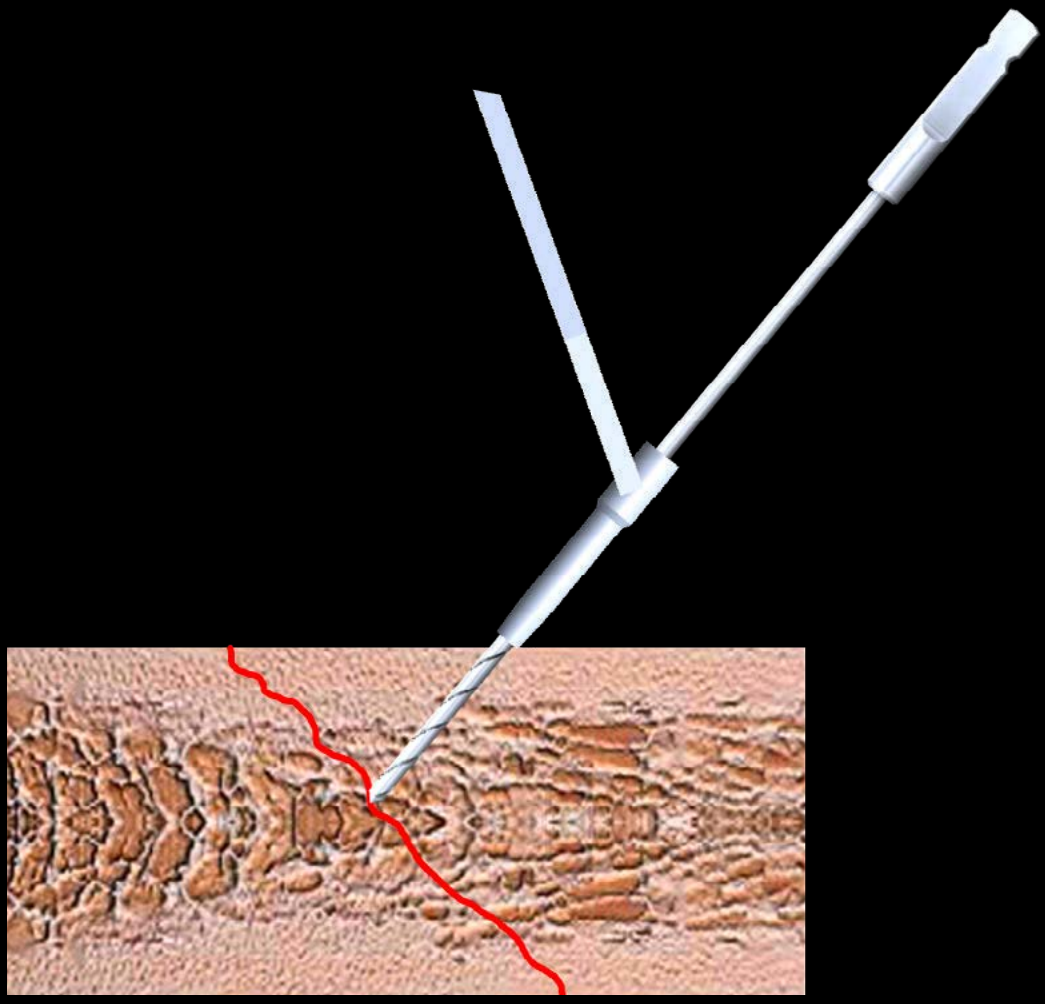
Instruments used

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.

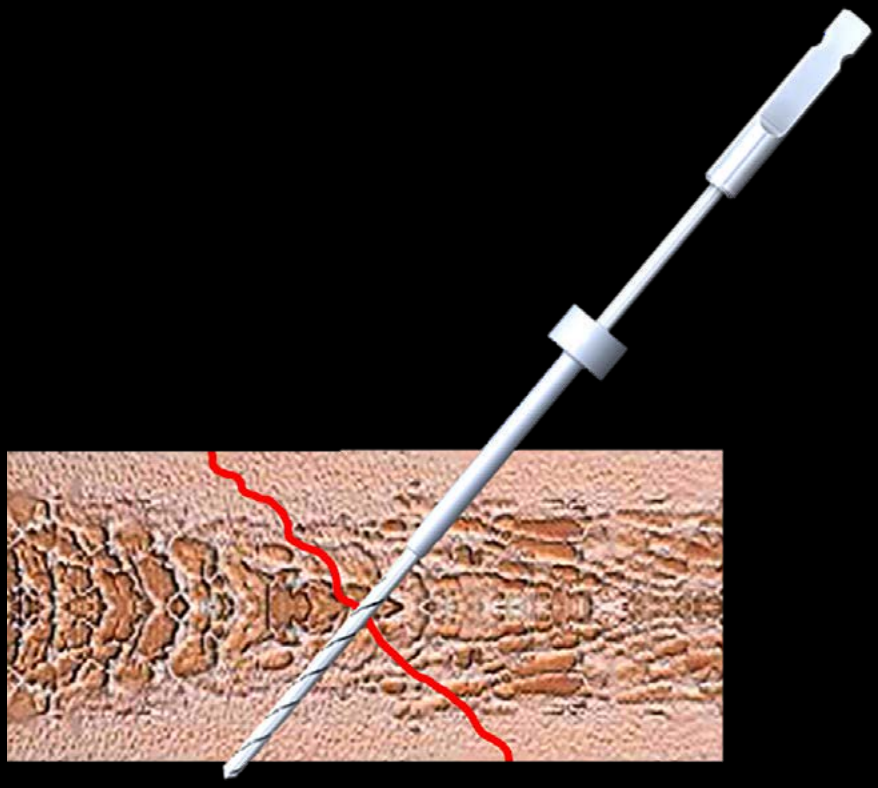
Instruments used

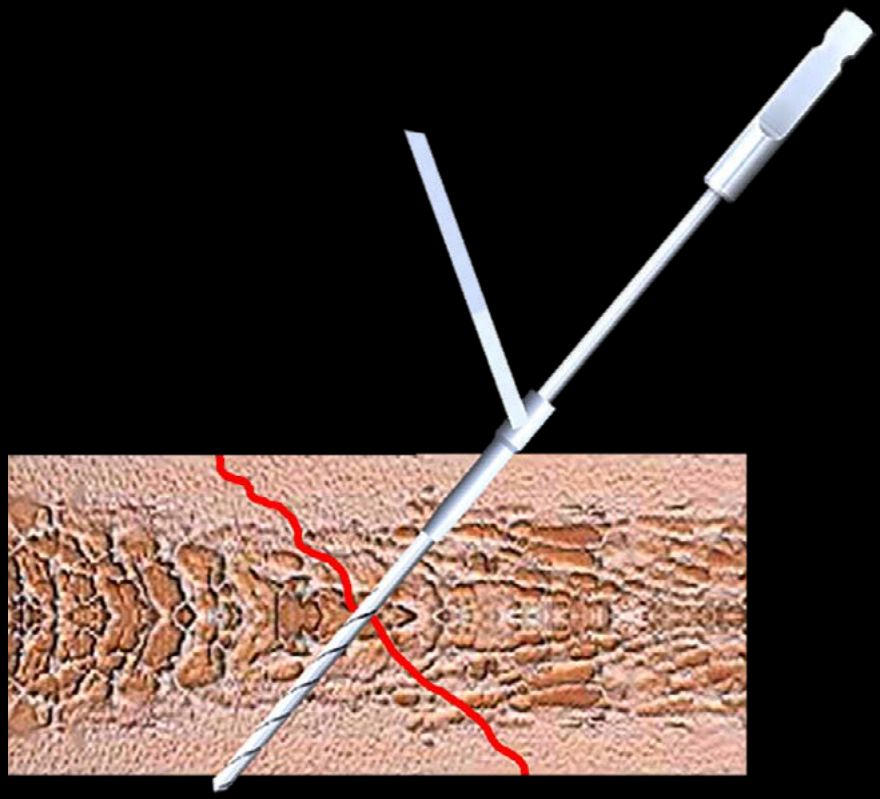
For MAGNEZIX® CBS 2.0:
9115.020 Drill bit Ø 1.5
9115.033 Double drill guide Ø 1.5/2.0

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

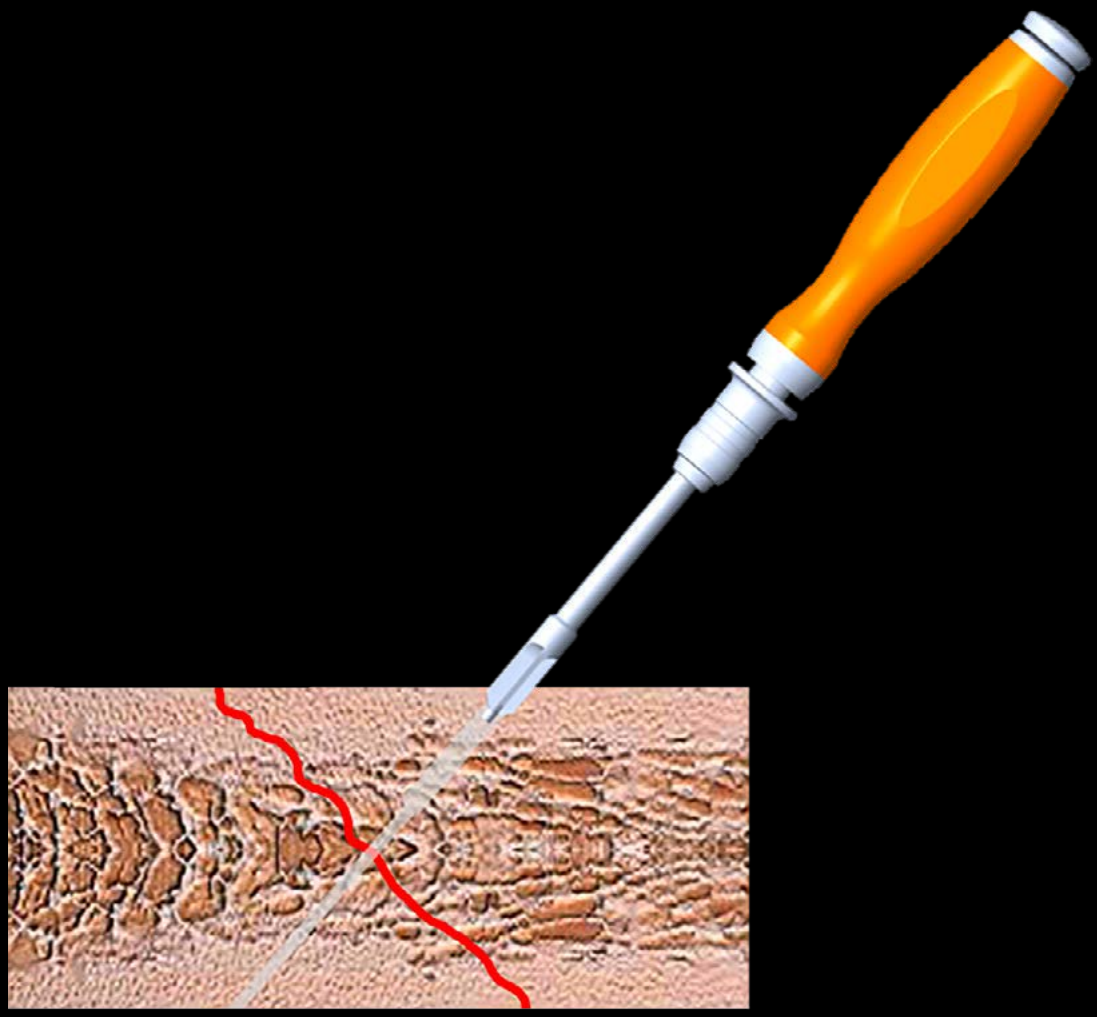
For MAGNEZIX® CBS 2.0:

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 3



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

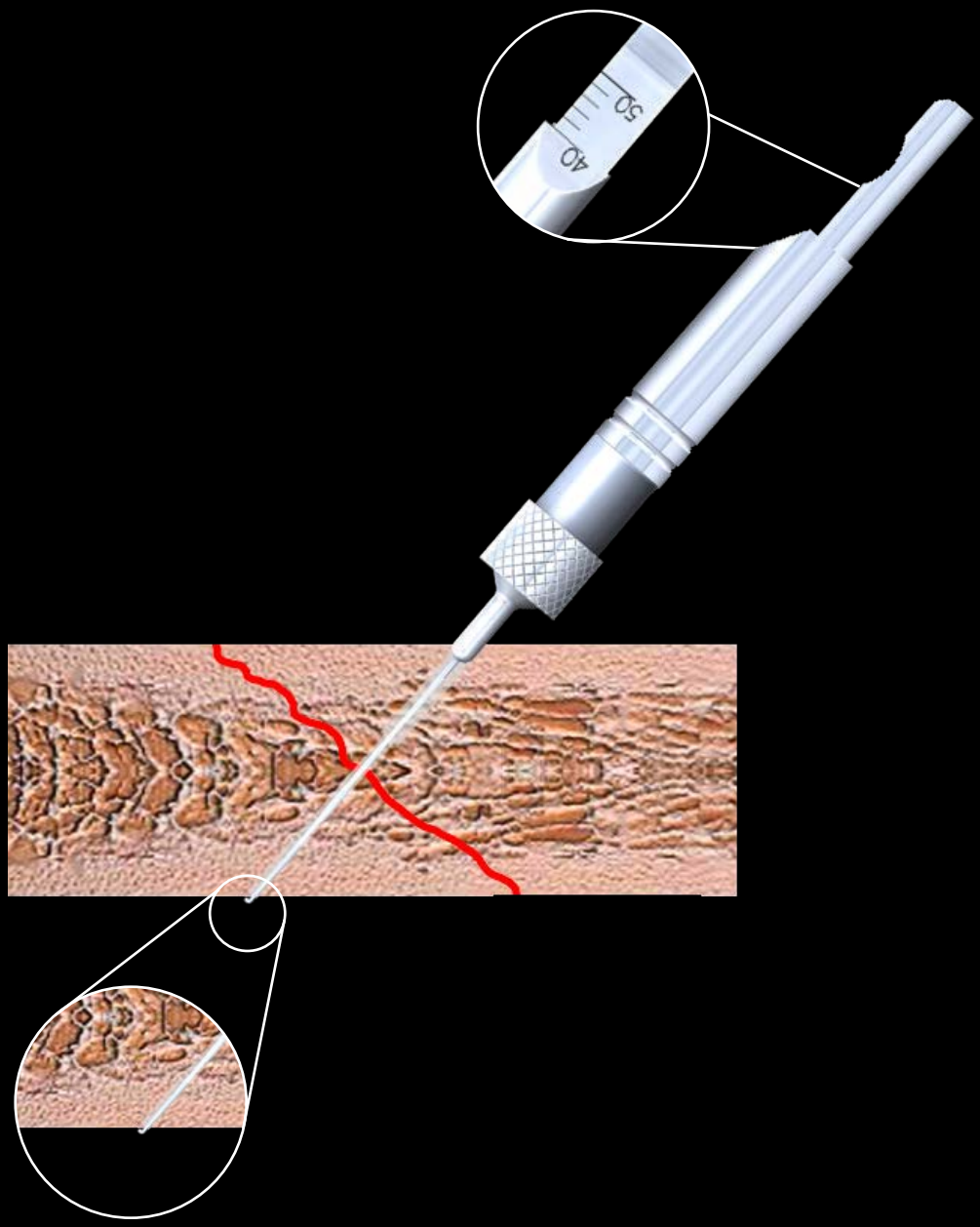
The length can only be correctly determined when the tip hook of the depth gauge is correctly positioned on the back side of the far cortical side.

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 lefthand 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

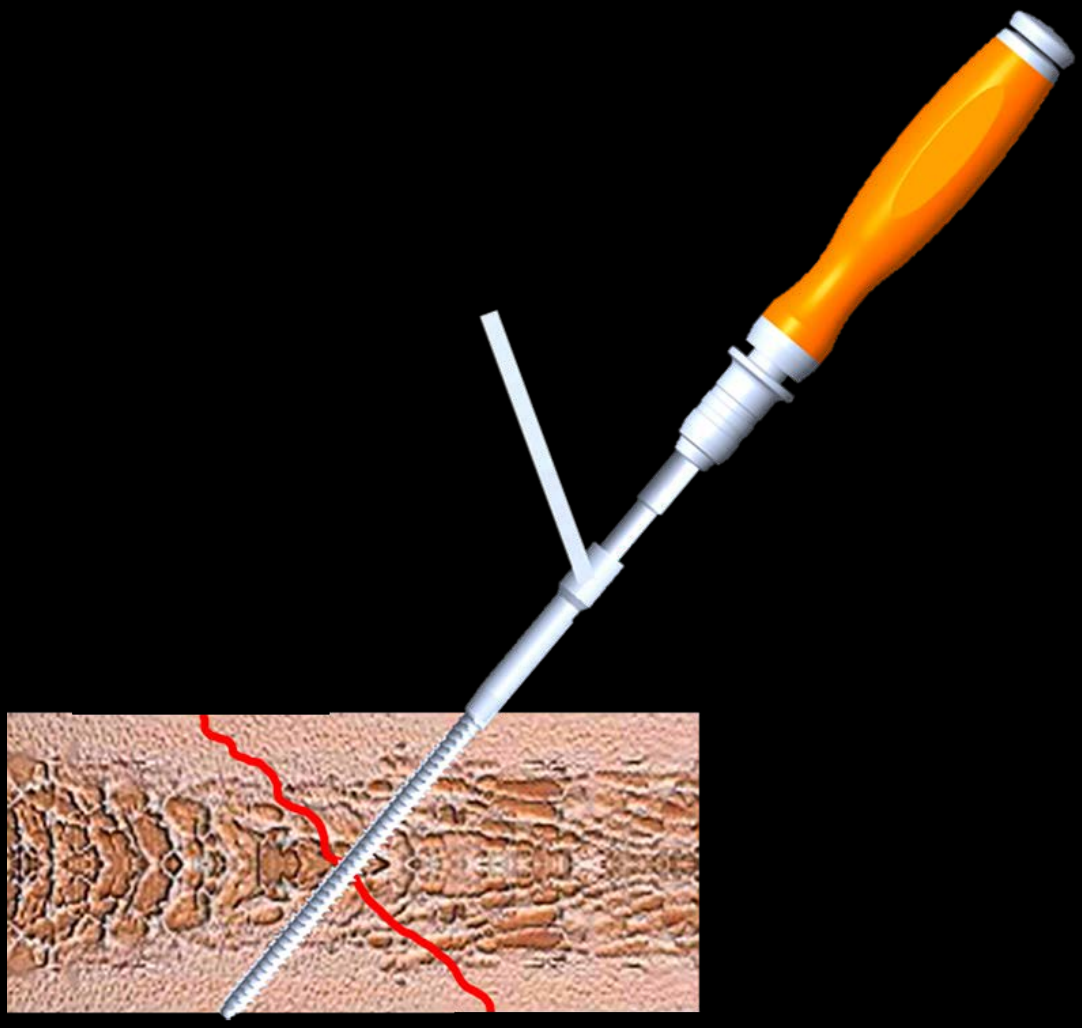
For MAGNEZIX® CBS 2.7:

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

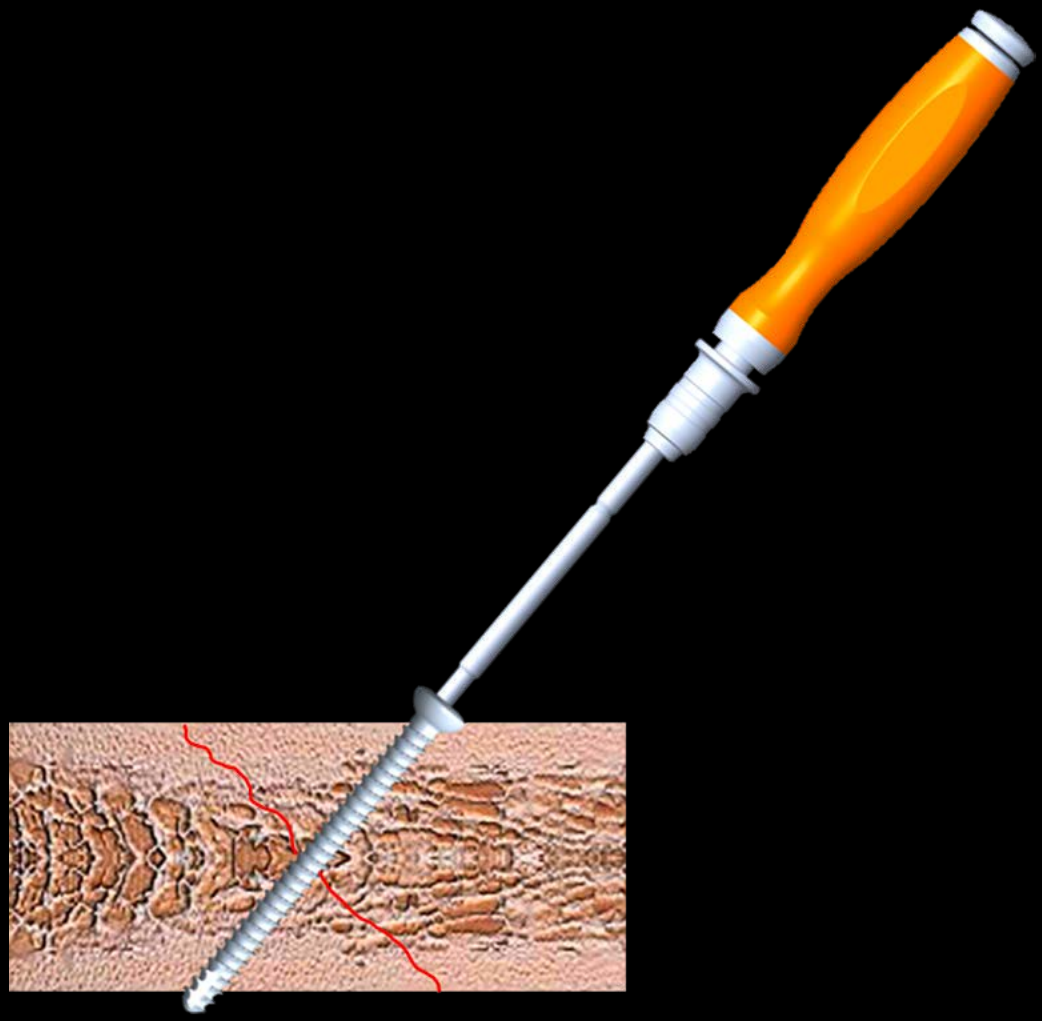
For MAGNEZIX® CBS 2.7:

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:

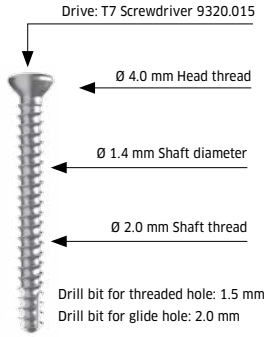
9335.015 Screwdriver blade T10
9099.004 Small screwdriver handle with quick coupling
9335.016 Holding sleeve CBS 3.5

STEP 6



IMPLANTS* MAGNEZIX® CBS

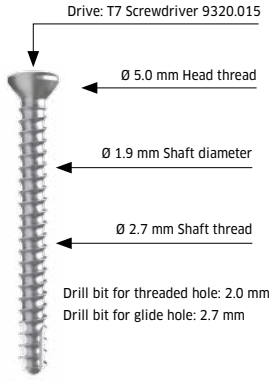
MAGNEZIX® CBS 2.0



Head height is 1.9 mm.

Art. No.	length [mm]
1320.006	6
1320.008	8
1320.010	10
1320.012	12
1320.014	14
1320.016	16
1320.018	18
1320.020	20

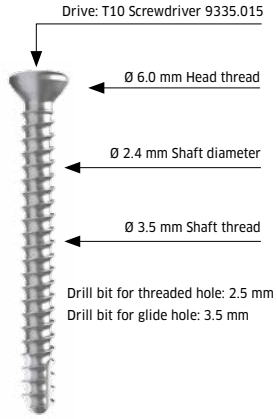
MAGNEZIX® CBS 2.7



Head height is 2.3 mm.

Art. No.	length [mm]
1327.006	6
1327.008	8
1327.010	10
1327.012	12
1327.014	14
1327.016	16
1327.018	18
1327.020	20
1327.022	22
1327.024	24
1327.026	26
1327.028	28
1327.030	30

MAGNEZIX® CBS 3.5



Head height is 2.6 mm.

Art. No.	length [mm]
1335.008	8
1335.010	10
1335.012	12
1335.014	14
1335.016	16
1335.018	18
1335.020	20
1335.022	22
1335.024	24
1335.026	26
1335.028	28
1335.030	30
1335.032	32
1335.034	34
1335.036	36
1335.038	38
1335.040	40

PLA/PGA comparative dimensions regarding stability

MAGNEZIX® CBS diameter	2.7	3.5	4.0
2.0			
2.7			
3.5			

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

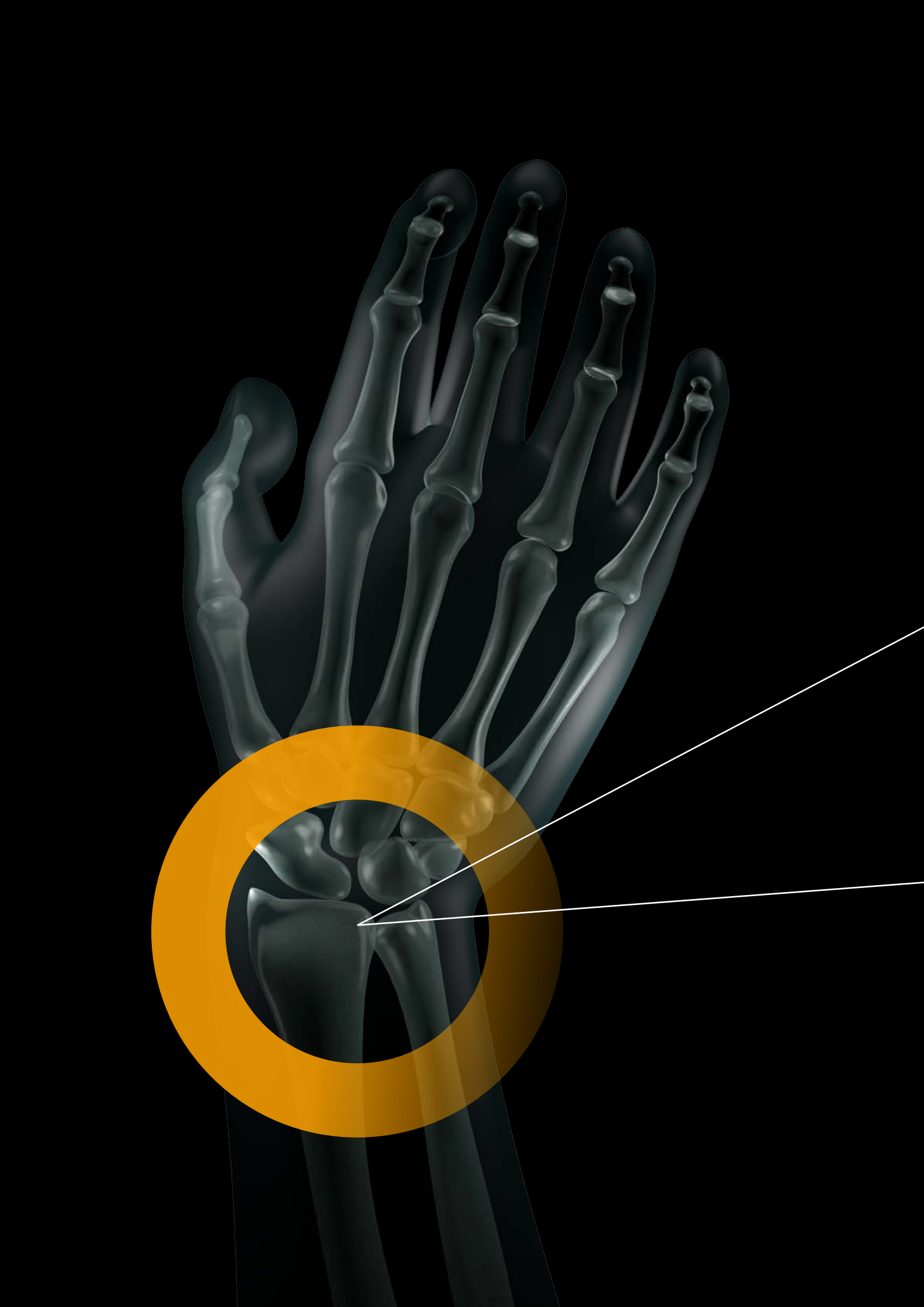
INSTRUMENTS** MAGNEZIX® CBS

Art. No.	Description
9115.020	Drill bit Ø 1.5 mm, Length 115/90 mm, for quick coupling
9120.020	Drill bit Ø 2.0 mm, Length 115/90 mm, for quick coupling
9127.020	Drill bit Ø 2.7 mm, Length 115/90 mm, for quick coupling
9325.020	Drill bit Ø 2.5 mm, Length 115/90 mm, for quick coupling
9335.020	Drill bit Ø 3.5 mm, Length 115/90 mm, for quick coupling
9320.021	Countersink CBS Ø 2.0, for quick coupling
9327.021	Countersink CBS Ø 2.7/3,5, for quick coupling
9320.022	Tap CBS Ø 2.0, for quick coupling
9327.022	Tap CBS Ø 2.7, for quick coupling
9335.022	Tap CBS Ø 3.5, for quick coupling
9115.033	Double drill guide, Ø 1.5/2.0 mm
9327.033	Double drill guide, Ø 2.0/2.7 mm
9335.033	Double drill guide, Ø 2.7/3.5 mm
9327.034	Insert drill sleeve Ø 2.7/2.0
9335.034	Insert drill sleeve Ø 3.5/2.5
9300.045	Depth gauge for MAGNEZIX® CBS
9320.015	Screwdriver blade T7, for quick coupling
9335.015	Screwdriver blade T10, for quick coupling
9320.016	Holding sleeve CBS Ø 2.0, for 9320.015
9327.016	Holding sleeve CBS Ø 2.7, for 9320.015
9335.016	Holding sleeve CBS Ø 3.5, for 9335.015
9099.004	Small screwdriver handle with quick coupling

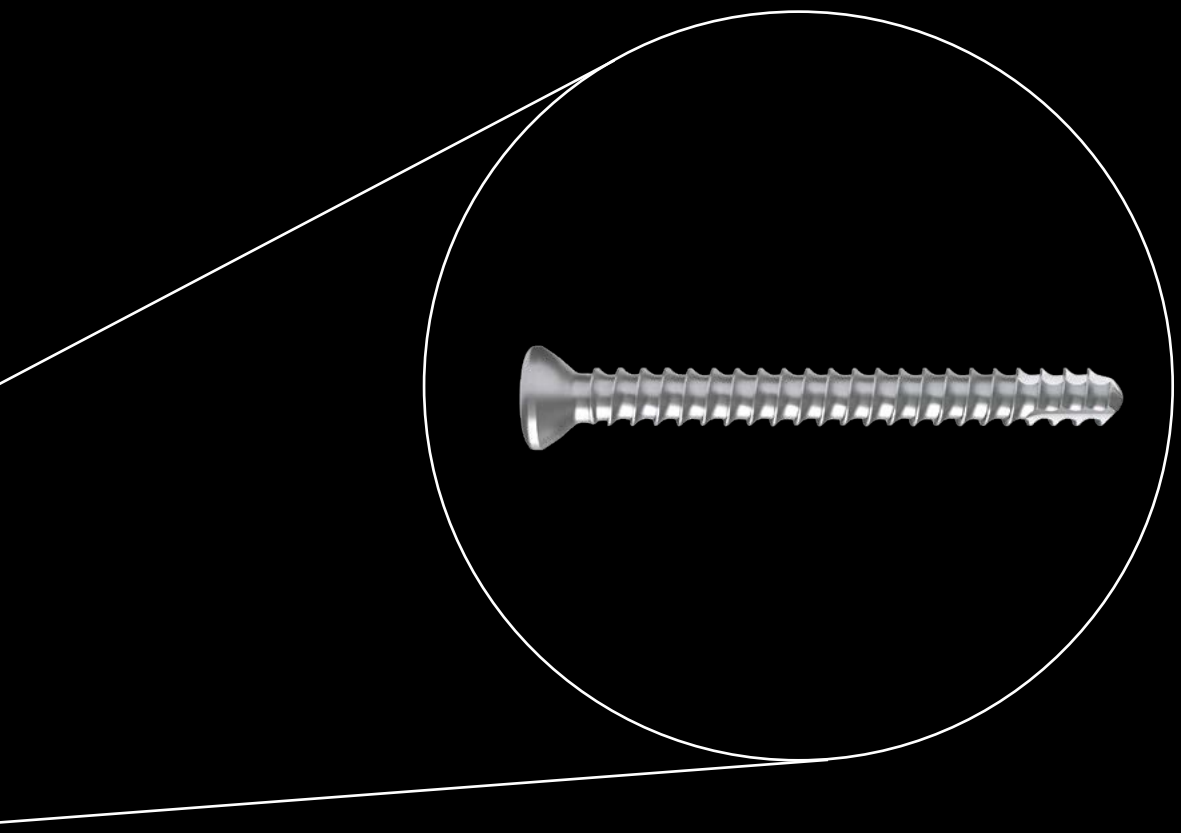
Not shown:

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®



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INNOVATIONSPREIS DER DEUTSCHEN WIRTSCHAFT
Sieger 2012/13

Presented by:

Syntellix AG
Aegidientorplatz 2a
30159 Hannover
Germany

T +49 511 270 413 50
F +49 511 270 413 79

info@syntellix.com
www.syntellix.com

Implants are manufactured in Germany in cooperation with Königsee Implantate GmbH.

CE 0197

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