



MAGNEZIX^{M3}
CS^C 4.8
Product Information

Intelligent innovations for a better life.



INTRODUCTION	03
THE MAGNEZIX® MATERIAL	03
INTENDED USE	04
INDICATIONS	04
CONTRAINDICATIONS	04

ADVANTAGES AND FEATURES	06
HINTS	06
WARNINGS	06
BIOABSORBABLE MAGNESIUM ALLOY	06

SURGICAL TECHNIQUE	08
---------------------------------	-----------

ORDERING INFORMATION	16
-----------------------------------	-----------

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 MAGNEZIX® MATERIAL

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.

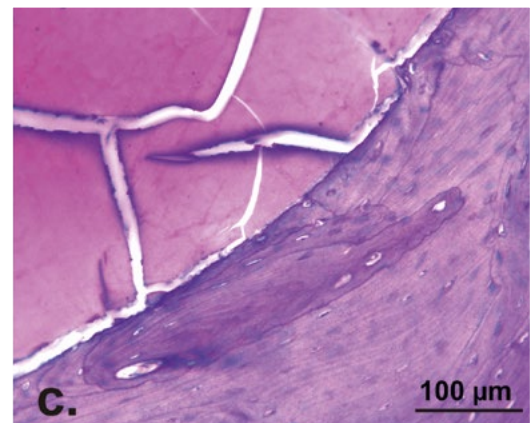
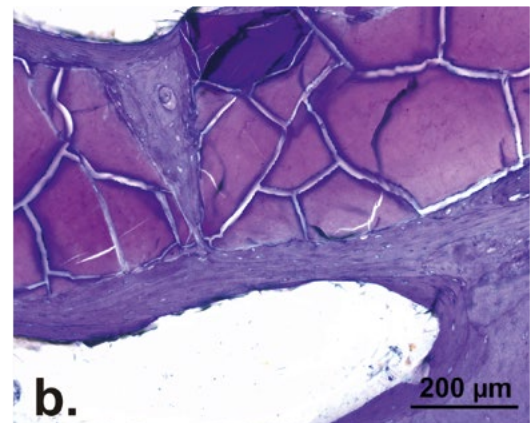
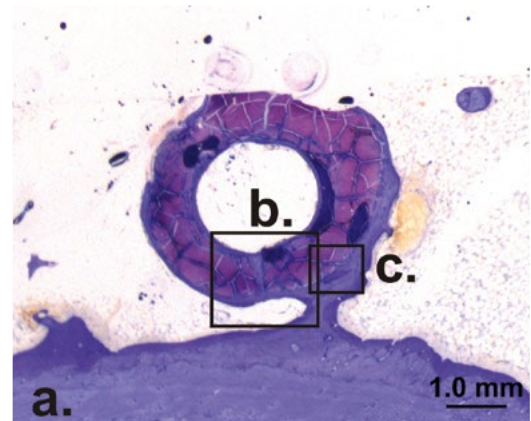
The mechanical properties are very similar to those of human bone. MAGNEZIX® gradually transforms within the body and is replaced by endogenous tissue. Experimental studies also confirm that magnesium has an osteoconductive¹ effect and tends to inhibit infection².

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.³
- 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).⁴
- The MAGNEZIX® CS^c has a highly innovative surface finish.⁵ The transformation is therefore postoperatively delayed in the first months.

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, Köneker 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.
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^c 4.8

INTENDED USE

MAGNEZIX® CS^c 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^c 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^c 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^c 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^c 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).

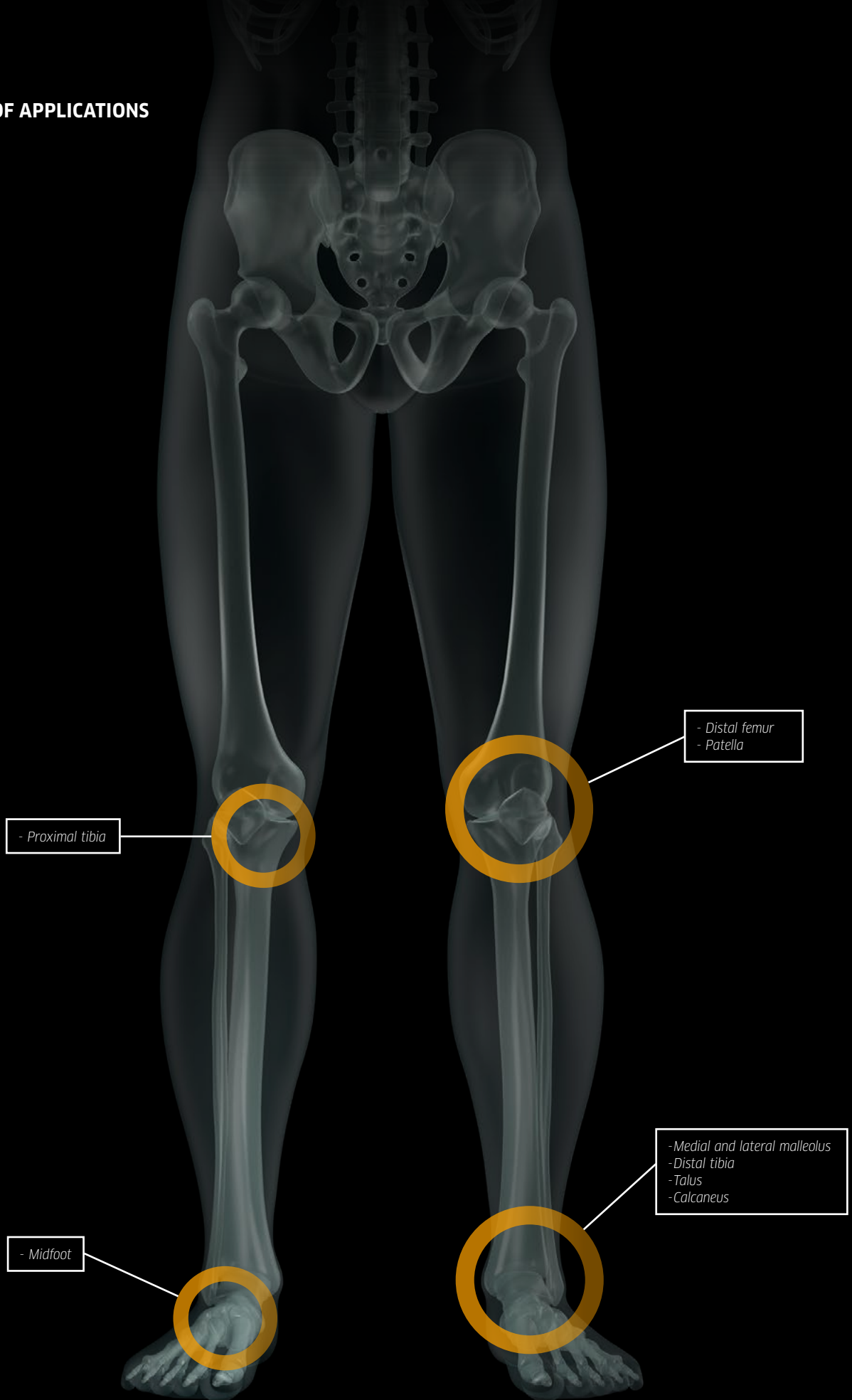
Absolute contraindications:

- 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



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^c 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 counter-sinking of the screw head.

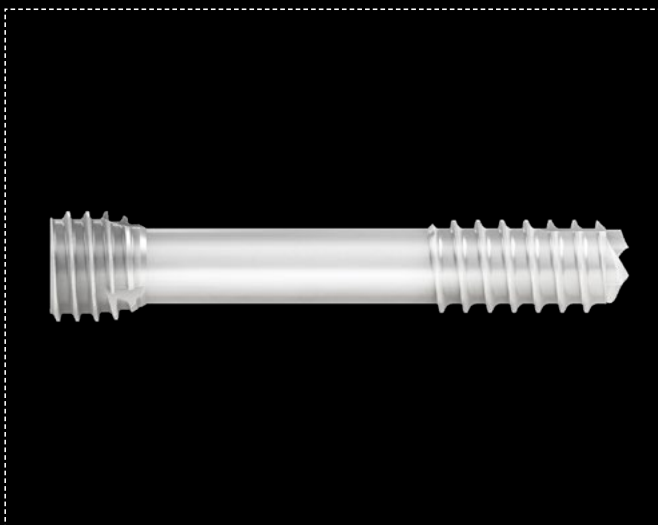
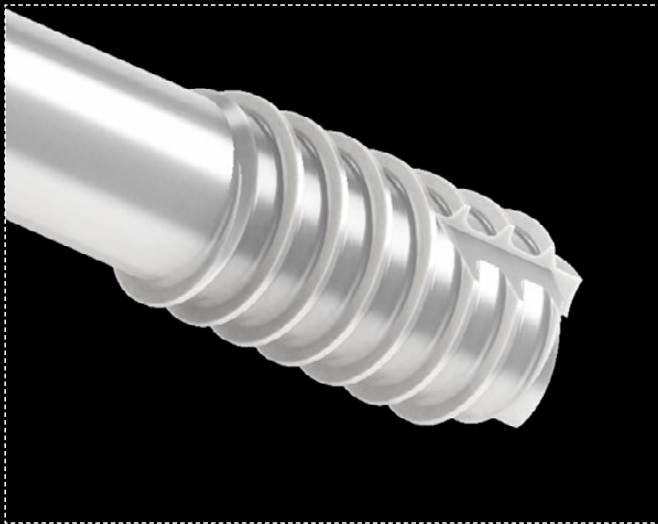
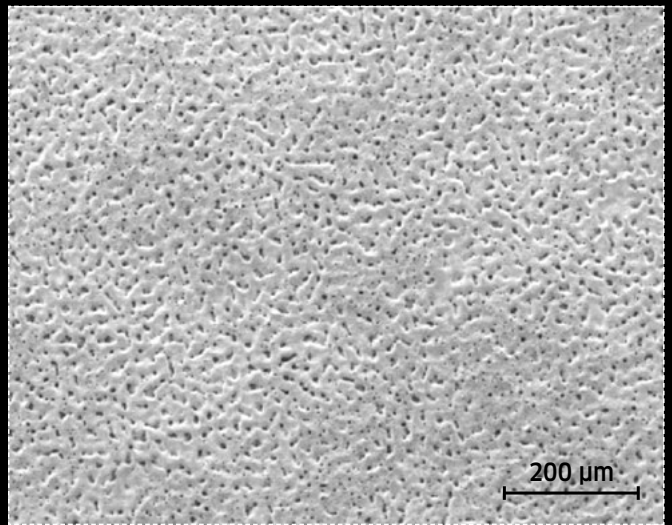
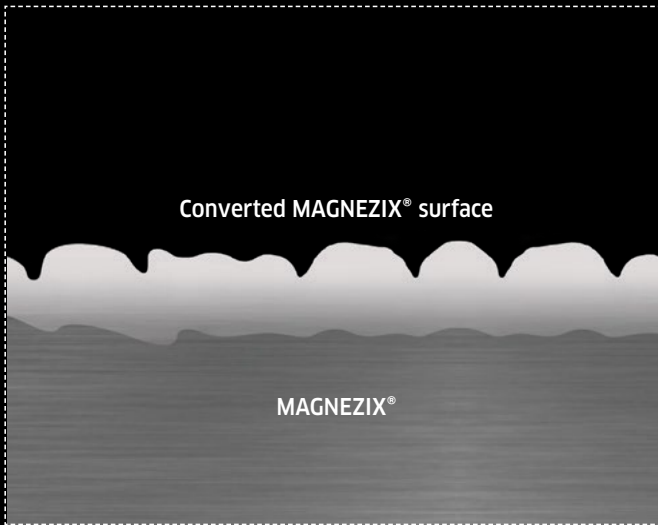
Different thread pitches

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:

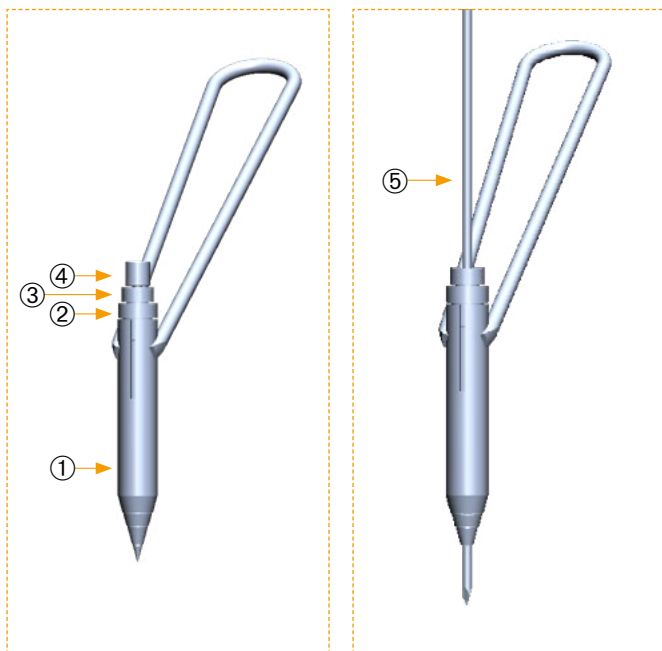
- enlarged contact area
- improved self-retaining mechanism
- improved torque transmission



SURGICAL TECHNIQUE

MAGNEZIX® CS^c 4.8 – STEP BY STEP

Prior to implanting a MAGNEZIX® CS^c 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

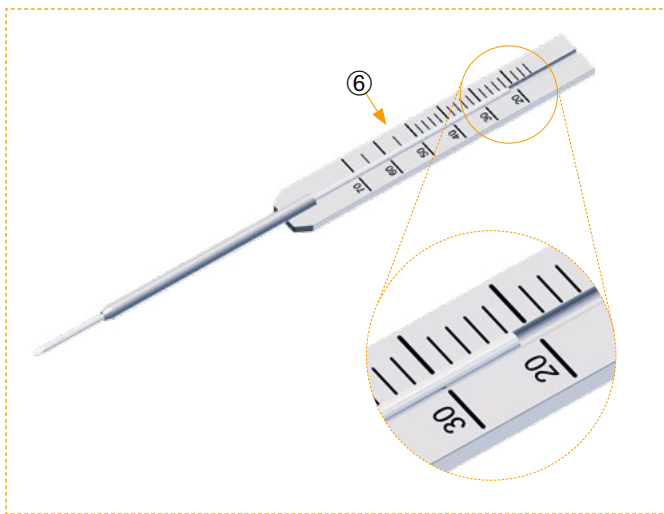
Position the guide wire through the drill guide system after removing the trocar, if necessary monitor using image intensification, until it is in the required position.

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

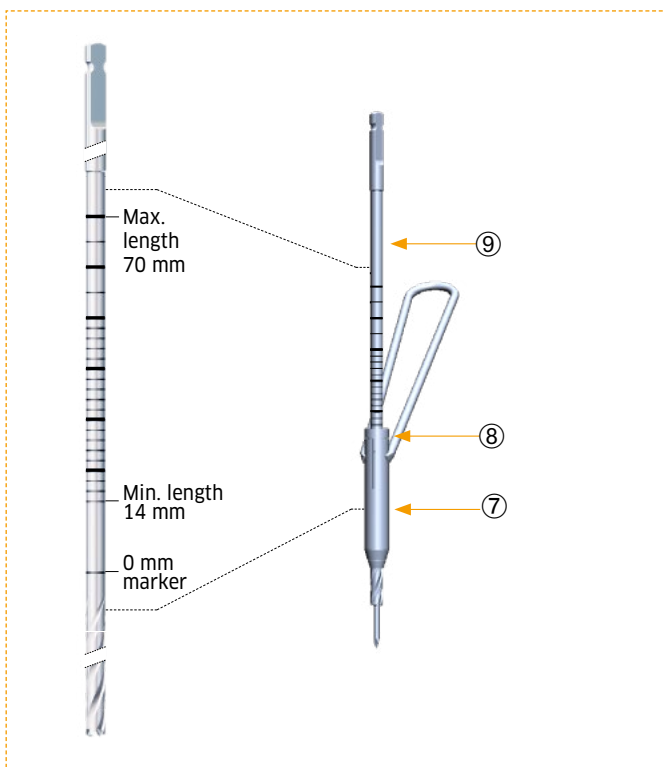
The length of the screw is determined by sliding the measuring device over the guide wire to the bone. The end of the guide wire, visible in the scale of the measuring device, indicates the length of the screw to be used (22 mm in the figure).

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:

- ⑥ 9048.042 Measuring Device for Guide Wire Ø 1.7 mm, Guide Wire length 150 mm



STEP 3: PRE-DRILLING

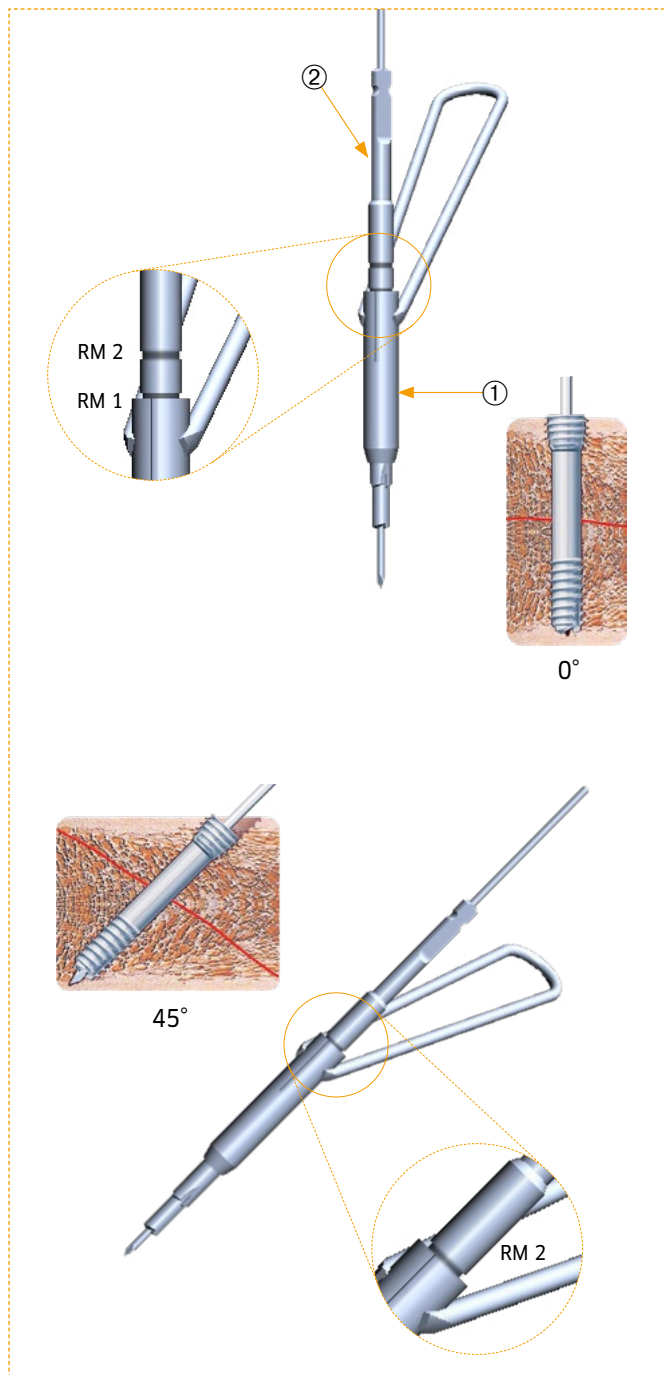
For screws with self-tapping tips, pre-drilling over the desired screw lengths is mandatory. At this point, the cannulated drill bit is directed by the underlying guide wire. This facilitates the subsequent tightening of the screw and prevents the rotation of small bone fragments. The drill bit calibration 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:

- ⑦ 9048.030 Protection Sleeve, Ø 5.0 mm
- ⑧ 9048.031 Drill Sleeve, Ø 5.0/4.0 mm
- ⑨ 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

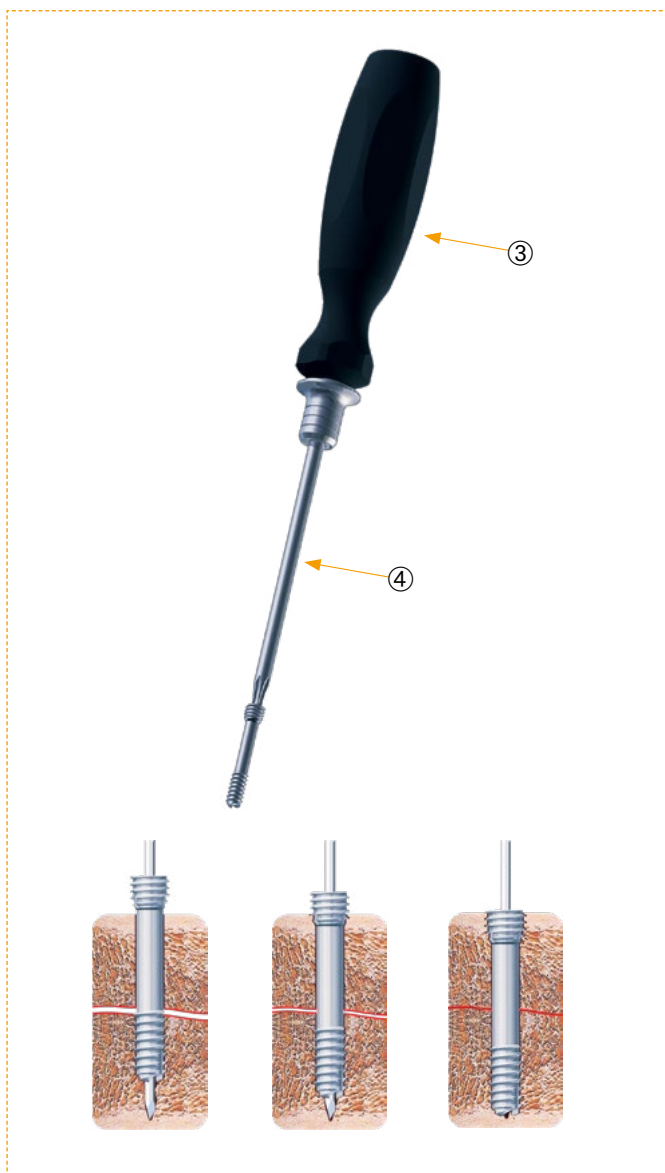
If the screw is positioned perpendicular to the bone surface, countersinking to the first ring marking (RM 1) is required in order to achieve adequate countersinking of the screw head.

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® CSC 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® CSC 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.

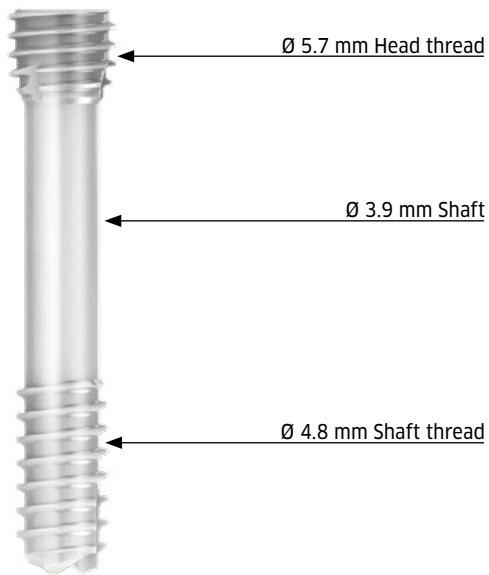
If one finds the thread crossing the fracture or osteotomy gap the screw must be removed and a longer screw has to be selected in order to generate compression. When doing this and in the case of a hard (dense) bone situation, it might be necessary to repeat the pre-drilling process as described in step 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^c 4.8 IMPLANTS



Art. Nr.	Shaft thread length SG [mm]	Screw length L [mm]
2048.014	6	14
2048.016	6	16
2048.018	6	18
2048.020	6	20
2048.022	8	22
2048.024	8	24
2048.026	8	26
2048.028	8	28
2048.030	10	30
2048.032	10	32
2048.034	10	34
2048.036	10	36
2048.038	14	38
2048.040	14	40
2048.042	14	42
2048.044	14	44
2048.046	14	46
2048.048	14	48
2048.050	14	50
2048.055	20	55
2048.060	20	60
2048.065	20	65
2048.070	20	70

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

INSTRUMENTS MAGNEZIX® CSC 4.8

	Art.-Nr.	Description
	9099.003	Screwdriver Handle with Quick Coupling
	9048.015	Screwdriver Blade T15, self-holding, for Quick Coupling
	9048.020	Drill Bit Ø 4.0/1.9 mm, cannulated, length 160/135 mm, for Quick Coupling
	9048.021	Countersink Ø 5.0/1.9 mm, cannulated, for Quick Coupling
	9048.030	Protection Sleeve, Ø 5.0 mm
	9048.031	Drill Sleeve, Ø 5.0/4.0 mm
	9048.032	Drill Sleeve, Ø 4.0/1.9 mm
	9048.033	Trocar, Ø 1.8 mm
	9048.043	Guide Wire Ø 1.7 mm, with trocar tip, length 150 mm
	9048.044	Guide Wire Ø 1.7 mm, with threaded tip, length 150 mm
	9048.042	Measuring Device, for Guide Wire Ø 1.7 mm, Guide Wire length 150 mm
	9048.050	Cleaning Stylet Ø 1.85 mm, for Ø 1.8 mm cannulated instruments
	8048.001	Sterilizing Tray for MAGNEZIX® CSC 4.8 mm, without contents
	8048.002	Lid for Sterilizing Tray for MAGNEZIX® CSC 4.8 mm

The figures are not to scale.



METALLIC AND TRANSFORMABLE.
STABLE AND ELASTIC.
A MEDICAL SENSATION.
MAGNEZIX®



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