MAGNEZIX® CS 2.0 2.7/3.2

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® CS

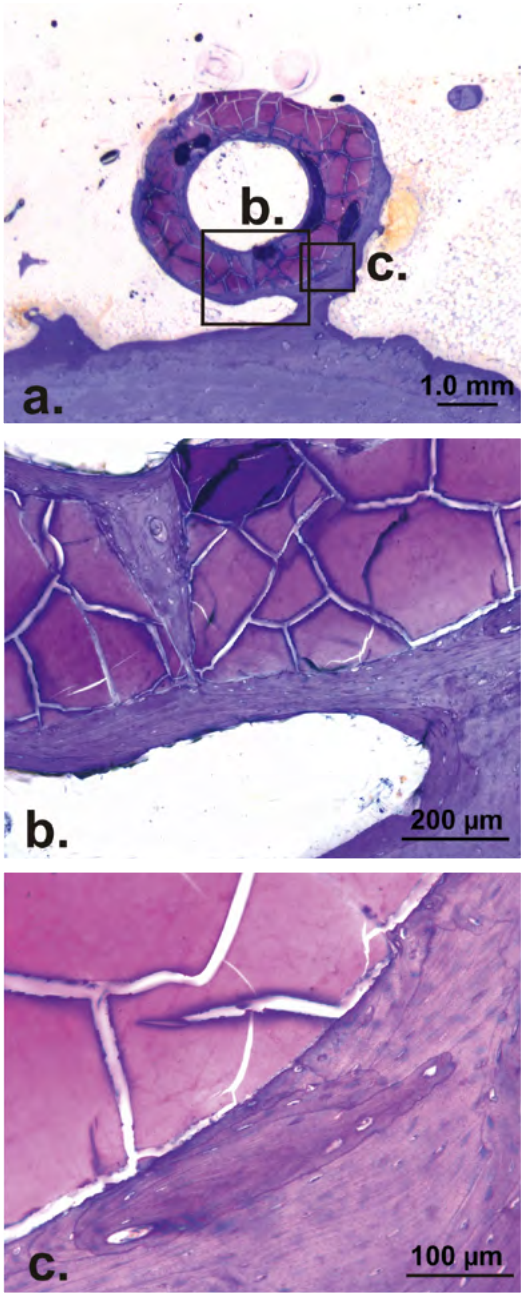
MAGNEZIX® is a trademark for CE-certified implants manufactured from the world's first transformable material consisting of a magnesium alloy (MgYREZr) for medical applications.
The biomechanical properties are very similar to those of human bone. MAGNEZIX® is completely degraded in the body and is replaced 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 and transformation 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 in an animal study verified full and complete transformation of the metallic implant after a 12-month implant period. Studies demonstrated new bone formation with direct implant contact and presence of osteoblasts and osteoclasts.



INTENDED USE

The MAGNEZIX® CS is a bioabsorbable compression screw that is used to restore the bone continuity after fractures and osteotomies (osteosynthe-sis) as well as for treatment of pseudarthroses. Specifically, the MAGNEZIX® CS 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 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 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 2.0, 2.7, 3.2:
- intra- and extraarticular fractures of small bones and bony fragments
- arthrodeses, osteotomies and pseudarthroses of small bones and joints
- small bony ligament and tendon ruptures
- similar indications

MAGNEZIX® CS 2.0:
- phalangeal and metacarpal bones
- processus styloideus radii et ulnae
- capitulum humeri and caput radii
- osteochondrosis dissecans
- similar indications

MAGNEZIX® CS 2.7, 3.2:
- carpal, metacarpal, tarsal and metatarsal bones
- processus styloideus radii et ulnae
- capitulum humeri and caput radii
- epicondylus humeri
- hallux valgus corrections
- similar indications

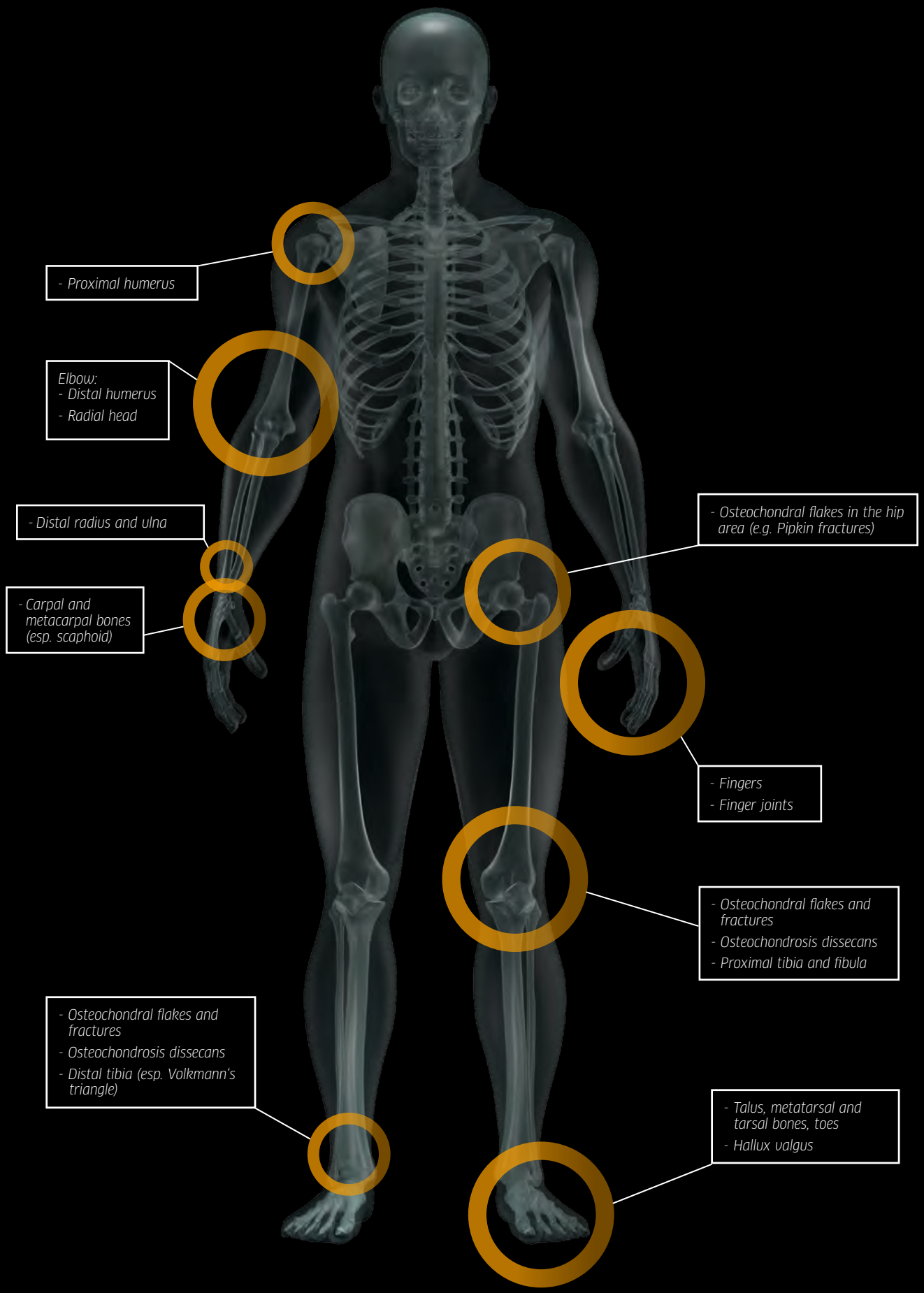
CONTRAINDICATIONS

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
- load-bearing stable osteosynthesis
- arthrodeses of medium to large joints
- applications on the spinal column

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

EXAMPLARY 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.

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 Tx[1] (ISO 10664 – x) design. The advantages of this ISO standardized technology are:

- Enlarged contact area
- Improved self-retaining mechanism
- Improved torque transmission

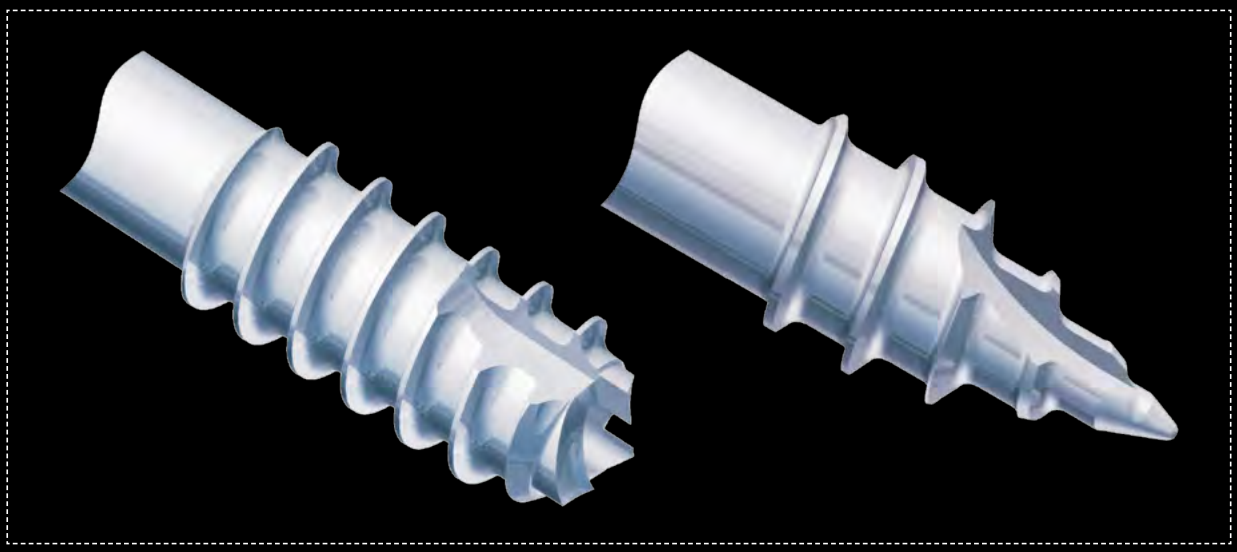
HINTS

In isolated cases, 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, 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 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.

[1] MAGNEZIX® CS 2.0: T4-drive (ISO 10664 – 4)
MAGNEZIX® CS 2.7: T7-drive (ISO 10664 – 7)
MAGNEZIX® CS 3.2: T8-drive (ISO 10664 – 8)



SURGICAL TECHNIQUE

MAGNEZIX® CS 2.0 – STEP BY STEP

Prior to implanting a MAGNEZIX® CS 2.0 screw it is necessary to ensure repositioning and temporary stabilization of the fracture or the osteotomy.

Although the MAGNEZIX® CS 2.0 screw has a self-cutting tip, a pilot hole must always be pre-drilled. The pilot hole also allows precise selection of the correct screw length.

Step 1: Drilling the pilot hole
Position the double drill guide through the soft tissue to the bone. Insert the drill bit through the double drill guide and into the bone, possibly monitoring with the image intensifier until it is at the required depth.

Important
If no pilot hole is drilled, the precise screw length cannot be correctly determined. Pre-drilling with an incorrect alignment can lead to malfunction of the screw.

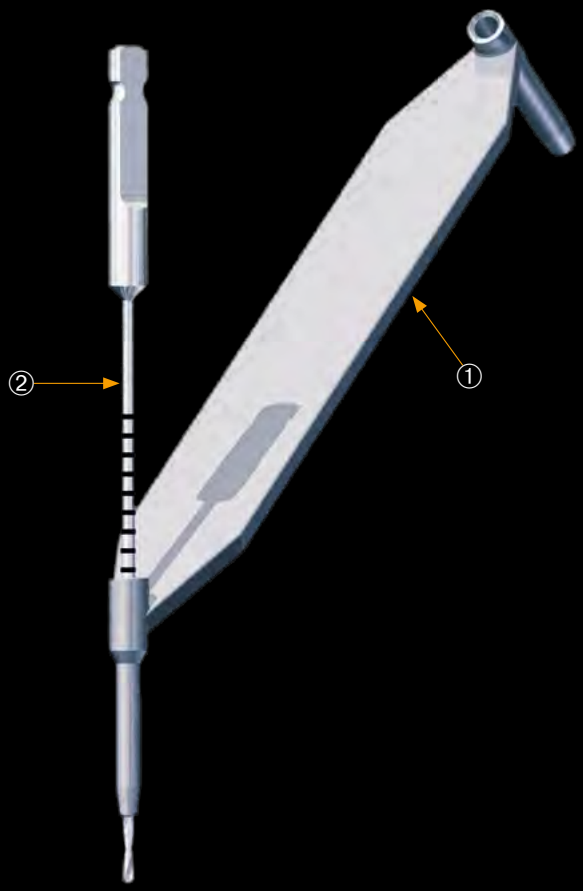
Instruments used:
① 9020.033 Double Drill Guide, Ø 2.2/1.5 mm
② 9020.020 Drill Bit, Ø 1.5 mm

Step 2: Determination of screw length
The length of the screw is determined by means of the depth gauge to determine the depth of the pre-drilled pilot hole in the bone (18 mm in the figure).

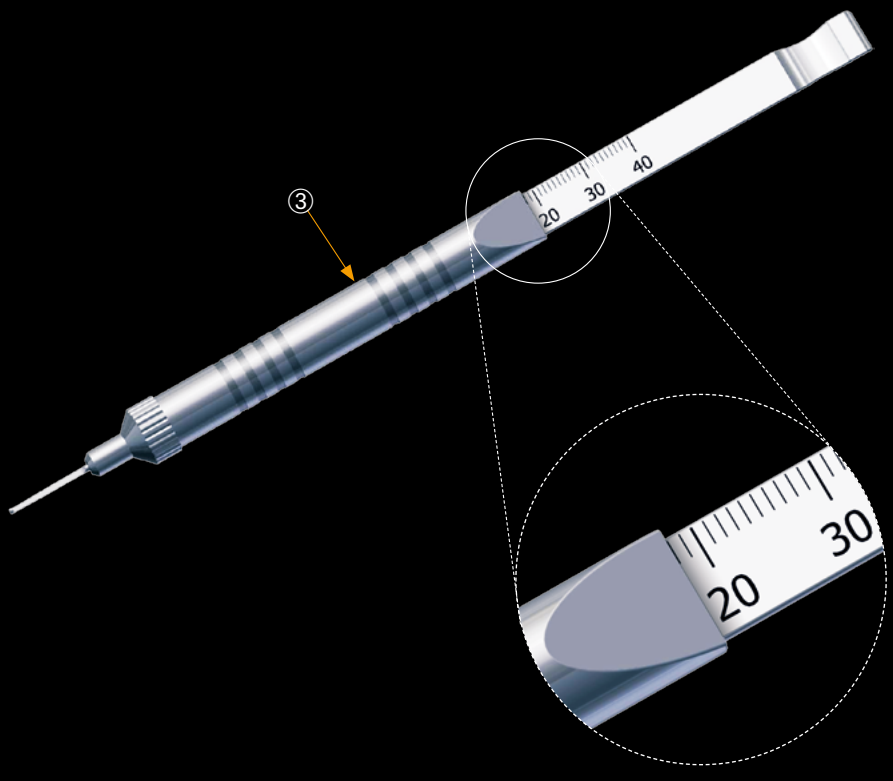
Important
When selecting the length of the screw one has to ensure proper compression of the fracture gap.

Instruments used:
③ 9020.042 Depth Gauge for screws

STEP 1



STEP 2



Step 3: Countersinking
In order to simplify insertion of the screw head the head-side of the intended implant position is now reamed using the countersink.

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.

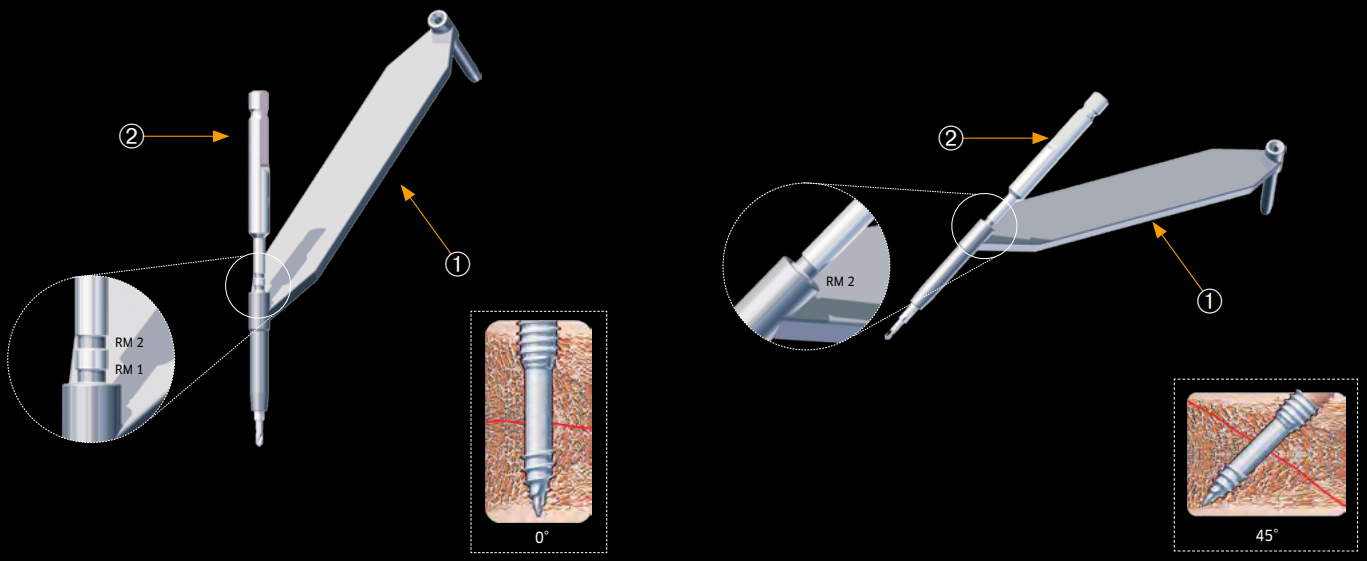
Instruments used:
① 9020.033 Double Drill Guide, Ø 2.2/1.5 mm
② 9020.021 Countersink Ø 2.2/1.5 mm, for quick coupling

Step 4: Inserting the screw
The MAGNEZIX® CS 2.0 of the previously determined length (step 2) is now screwed into place.

Important
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 1 to further deepen the pre-drilled pilot hole for the selected screw with an adequate length.

Instruments used:
③ 6020.104 Screwdriver T4, One-Piece Handle
Optional:
6020.204 Screwdriver T4, Multi-Part Handle

STEP 3



STEP 4

SURGICAL TECHNIQUE

MAGNEZIX® CS 2.7/3.2 – STEP BY STEP

Prior to implanting a MAGNEZIX® CS 2.7/3.2 screw it is necessary to ensure repositioning and temporary stabilization of the fracture or the osteotomy.

Step 1: Positioning the guide wire
Position the guide wire through the double drill guide with fitted drill guide, 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:

For MAGNEZIX® CS 2.7
① 9027.033 Double drill Guide, Ø 3.1/2.2 mm
② 9027.034 Drill Guide, Ø 2.2/1.1 mm
③ 9027.040 Guide Wire Ø 1.0 mm, with trocar tip, length 100 mm
or
③ 9027.041 Guide Wire Ø 1.0 mm, with threaded tip, length 100 mm

For MAGNEZIX® CS 3.2
① 9032.033 Double Drill Guide, Ø 3.5/2.5 mm
② 9032.034 Drill Guide, Ø 2.5/1.3 mm
③ 9032.040 Guide Wire Ø 1.2 mm, with trocar tip, length 150 mm
or
③ 9032.041 Guide Wire Ø 1.2 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.

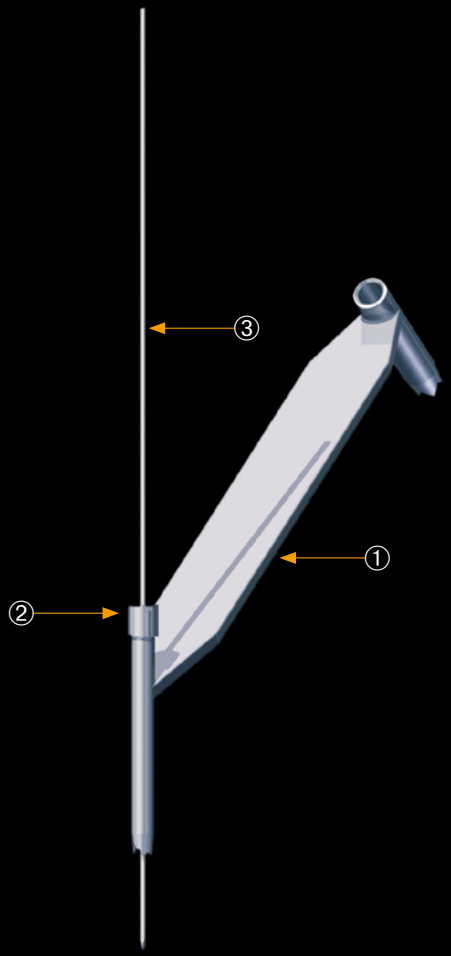
Important
From the measured length at least 2 mm to 4 mm must be substracted so that the guide wire is not removed during pre-drilling as described in step 1. The maximum length of the screw must therefore not exceed 20 mm.
Only the original guide wires guarantee correct measurement.

Instruments used:

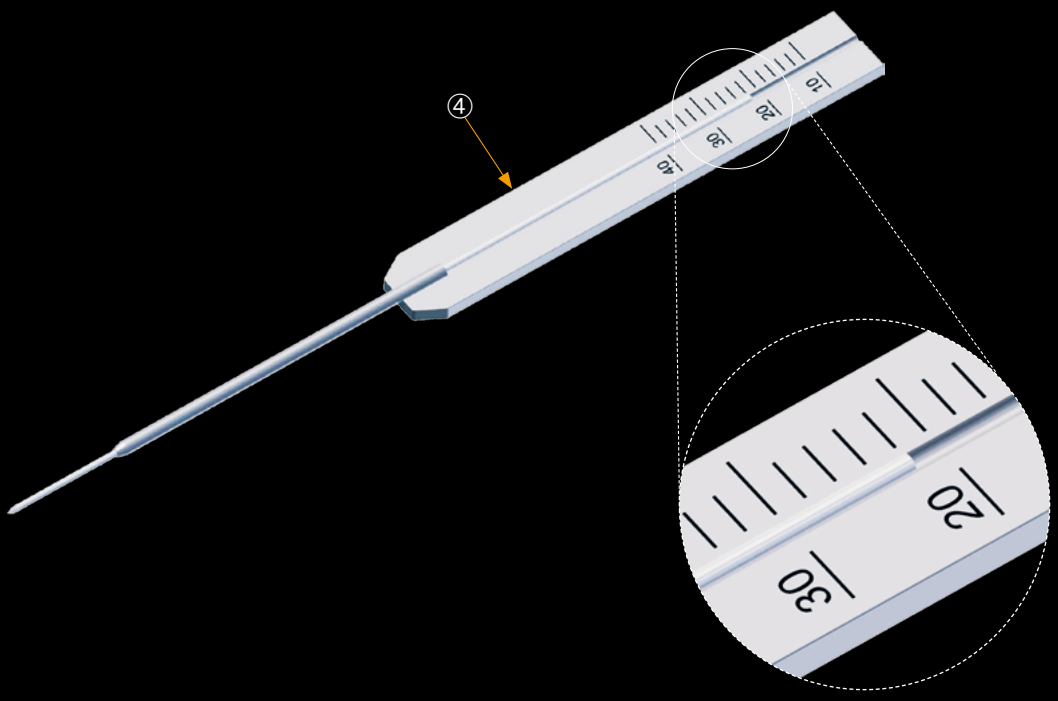
For MAGNEZIX® CS 2.7
④ 9027.042 Measuring Device for Guide Wires Ø 1.0 mm, Guide Wire length 100 mm

For MAGNEZIX® CS 3.2
④ 9032.042 Measuring Device for Guide Wires Ø 1.2 mm, Guide Wire length 150 mm

STEP 1



STEP 2



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 guide. The fine ring marks indicate 2 mm steps, 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 double drill guide while slowly turning in a forward direction so as to leave the guide wire in position.

Instruments used:

For MAGNEZIX® CS 2.7
① 9027.033 Double Drill Guide, Ø 3.1/2.2 mm
② 9027.020 Drill Bit Ø 2.2/1.1 mm, cannulated, length 100/75 mm, for quick coupling

For MAGNEZIX® CS 3.2
① 9032.033 Double Drill Guide, Ø 3.5/2.5 mm
② 9032.020 Drill Bit Ø 2.5/1.3 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.

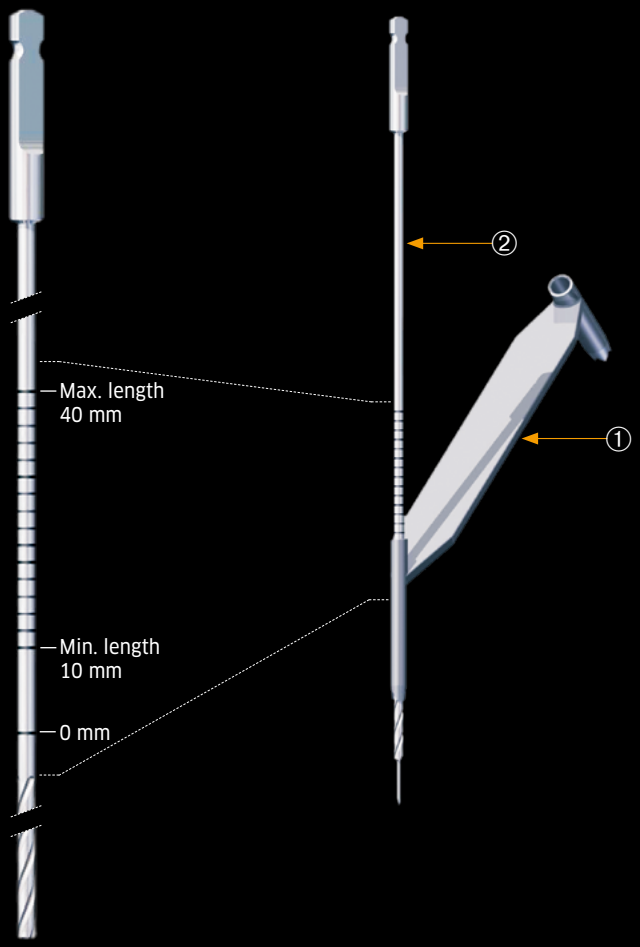
Important
If the screw is positioned perpendicular to the bone surface, countersinking to the first ring marking (RM 1) is required in order to achieve adequate countersinking of the screw head.
If the screw is positioned at an angle of 45° to the bone surface, countersinking to the second ring marking (RM 2) is required in order to achieve adequate countersinking of the screw head.
The countersink is pulled vertically out of the drill guide while still slowly turning in the forward direction so as to leave the guide wire in position.

Instruments used:

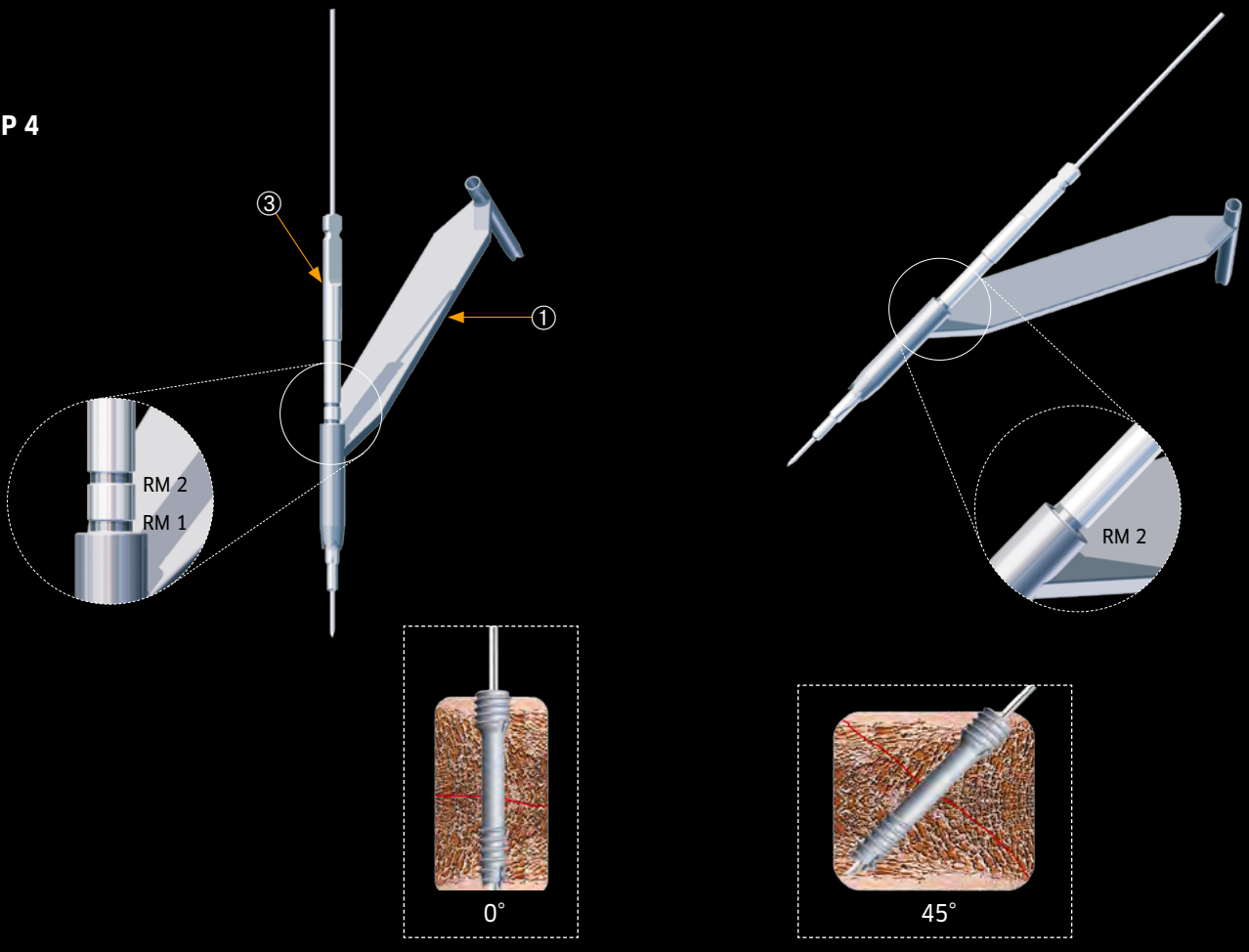
For MAGNEZIX® CS 2.7
① 9027.033 Double Drill Guide, Ø 3.1/2.2 mm
③ 9027.021 Countersink Ø 3.1/1.1 mm, cannulated, for quick coupling

For MAGNEZIX® CS 3.2
① 9032.033 Double Drill Guide, Ø 3.5/2.5 mm
③ 9032.021 Countersink Ø 3.5/1.3 mm, cannulated, for quick coupling

STEP 3



STEP 4



Step 5: Insertion of the screw
This is now followed by the tightening of the MAGNEZIX® CS over the underlying guide wire in the length previously determined in step 2.

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 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:

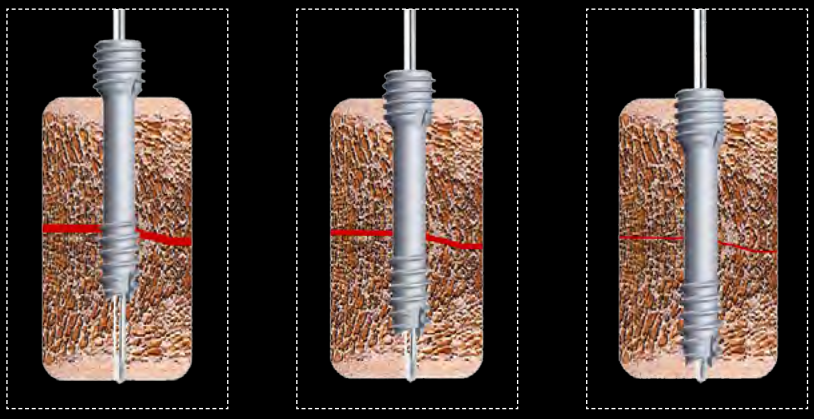
For MAGNEZIX® CS 2.7

①	6027.108	Screwdriver T7, One-Piece Handle, Ø 1.1 mm cannulated
	9027.033	Double Drill Guide, Ø 3.1/2.2 mm
	Optional:	
	6027.208	Screwdriver T7, Multi-Part Handle, Ø 1.1 mm cannulated

For MAGNEZIX® CS 3.2

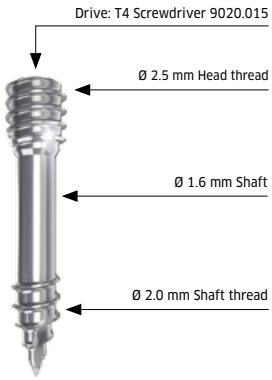
①	6032.108	Screwdriver T8, One-Piece Handle, Ø 1.3 mm cannulated
	9032.033	Double Drill Guide, Ø 3.5/2.5 mm
	Optional:	
	6032.208	Screwdriver T8, Multi-Part Handle, Ø 1.3 mm cannulated

STEP 5



IMPLANTS* MAGNEZIX® CS

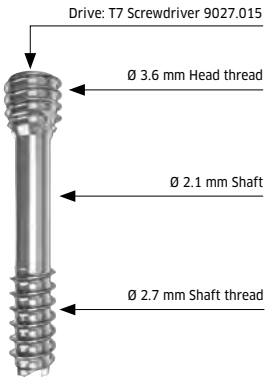
MAGNEZIX® CS 2.0



Head height is 3.0 mm.

Art. No.	Threaded shaft length (mm)	Screw length (mm)
1020.008	4	8
1020.010	4	10
1020.012	4	12
1020.014	5	14
1020.016	5	16
1020.018	5	18
1020.020	6	20
1020.022	6	22
1020.024	6	24

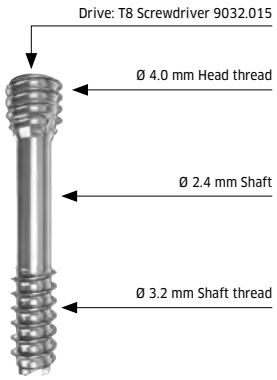
MAGNEZIX® CS 2.7



Head height is 3.5 mm.

Art. No.	Threaded shaft length (mm)	Screw length (mm)
1027.010	4	10
1027.012	5	12
1027.014	5	14
1027.016	7	16
1027.018	7	18
1027.020	7	20
1027.022	7	22
1027.024	7	24
1027.026	7	26
1027.028	7	28
1027.030	7	30
1027.032	9	32
1027.034	9	34

MAGNEZIX® CS 3.2



Head height is 3.5 mm.

Art. No.	Threaded shaft length (mm)	Screw length (mm)
1032.010	4	10
1032.012	5	12
1032.014	5	14
1032.016	7	16
1032.018	7	18
1032.020	7	20
1032.022	7	22
1032.024	7	24
1032.026	7	26
1032.028	7	28
1032.030	7	30
1032.032	9	32
1032.034	9	34
1032.036	9	36
1032.038	9	38
1032.040	9	40

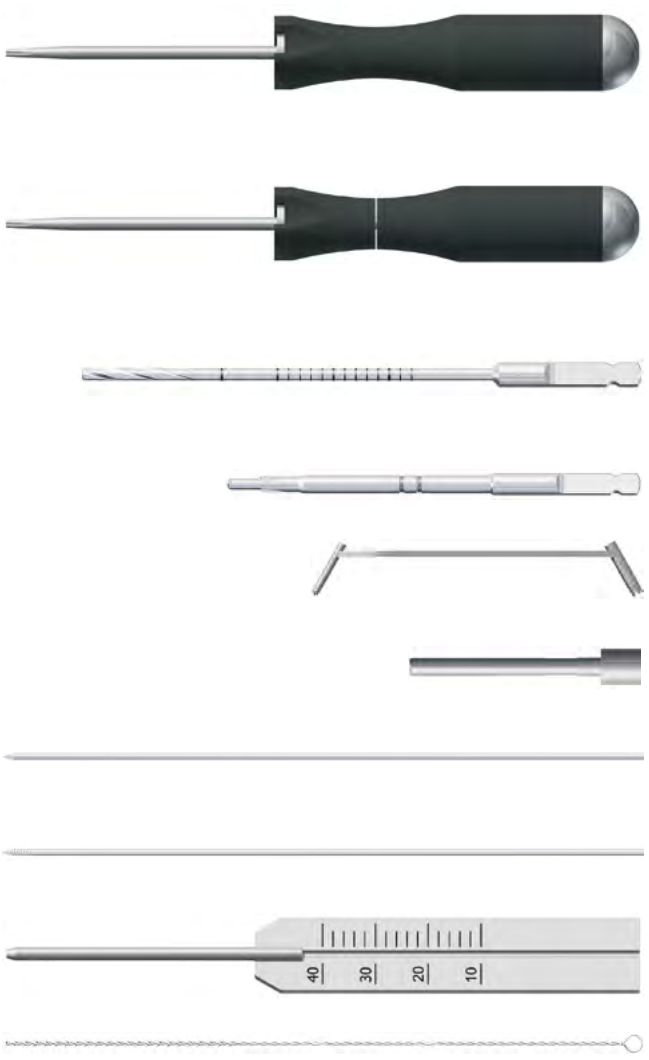
*All implants are individually packaged. It is not possible to re-sterilize the implants.

INSTRUMENTS** MAGNEZIX® CS 2.0

Art. No.	Description
6020.104	Screwdriver T4, One-Piece Handle, consisting of: 9099.001 One-Piece Handle for Screwdriver 9020.015 Screwdriver Blade T4
6020.204	Screwdriver T4, Multi-Part Handle, consisting of: 9099.002 Multi-Part Handle for Screwdriver 9020.015 Screwdriver Blade T4
9020.020	Drill Bit Ø 1.5 mm, length 88/63 mm, for quick coupling
9020.021	Countersink Ø 2.2/1.5 mm, for quick coupling
9020.033	Double Drill Guide, Ø 2.2/1.5 mm
9020.042	Measuring Device for Screws
Not shown:	
8020.001	Sterilization Tray for MAGNEZIX® CS Ø 2.0 mm, without contents
8020.002	Lid for Sterilization Tray for MAGNEZIX® CS Ø 2.0 mm

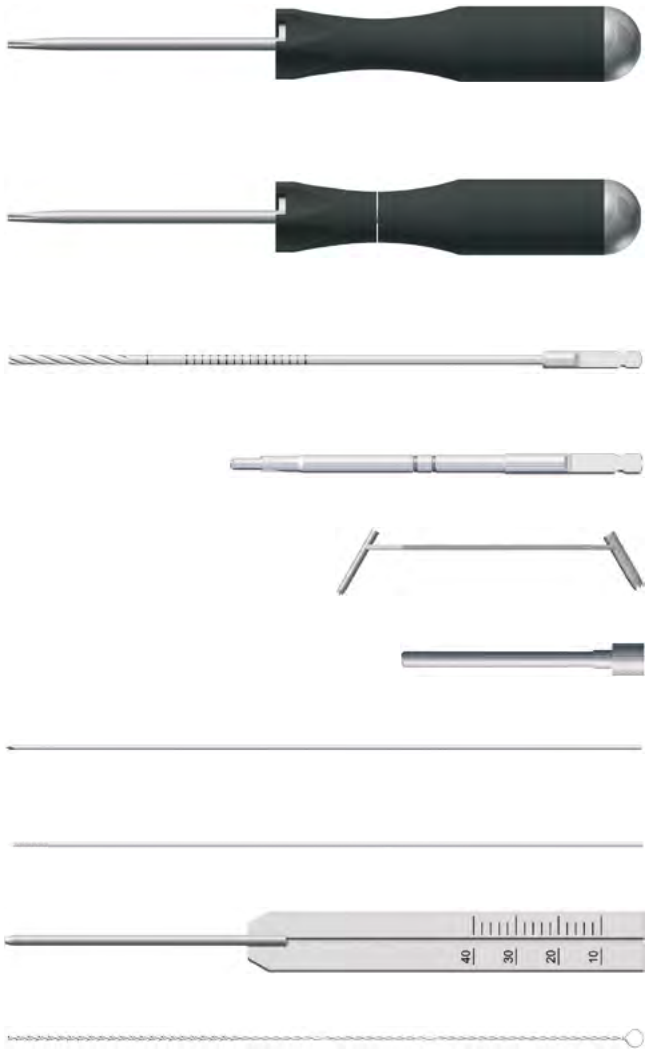
** The figures are not to scale. Instruments of the latest generation can have additional color coding

INSTRUMENTS* MAGNEZIX® CS 2.7



Art. No.	Description
6027.107	Screwdriver T7, One-Piece Handle Ø 1.1 mm cannulated, consisting of: 9099.001 One-Piece Handle for Screwdriver 9027.015 Screwdriver Blade T7
6027.207	Screwdriver T7, Multi-Part Handle Ø 1.1 mm cannulated, consisting of: 9099.002 Multi-Part Handle for Screwdriver 9027.015 Screwdriver Blade T7
9027.020	Drill Bit Ø 2.2/1.1 mm, cannulated, length 100/75 mm, for quick coupling
9027.021	Countersink Ø 3.1/1.1 mm, cannulated, for quick coupling
9027.033	Double Drill Guide, Ø 3.1/2.2 mm
9027.034	Drill Guide, Ø 2.2/1.1 mm
9027.040	Guide Wire Ø 1.0 mm, with trocar tip, length 100 mm
9027.041	Guide Wire Ø 1.0 mm, with threaded tip, length 100 mm
9027.042	Measuring Device, for Guide Wire Ø 1.0 mm, Guide Wire length 100 mm
9027.050	Cleaning Stylet Ø 1.05 mm, for Ø 1.1 mm cannulated instruments
Not shown:	
8027.001	Sterilization Tray for MAGNEZIX® CS Ø 2.7 mm, without contents
8027.002	Lid for Sterilization Tray, for MAGNEZIX® CS Ø 2.7 mm

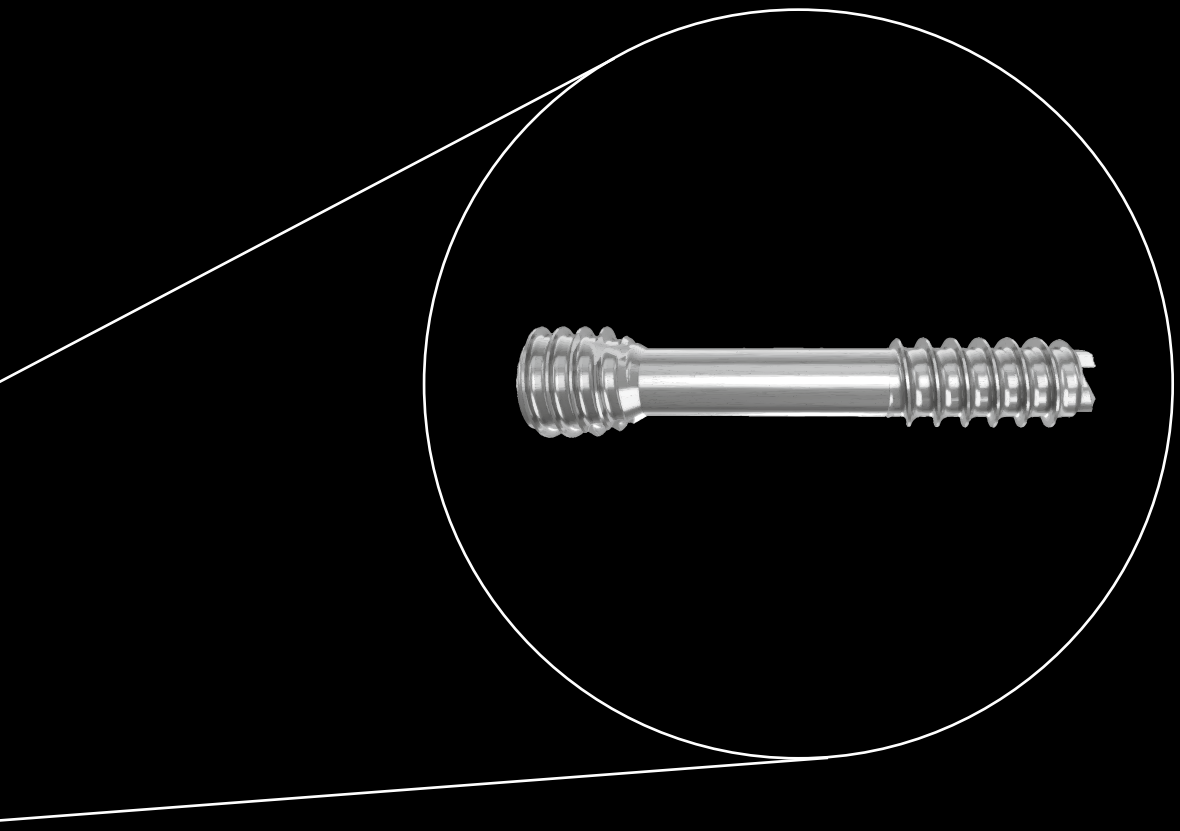
INSTRUMENTS* MAGNEZIX® CS 3.2



Art. No.	Description
6032.108	Screwdriver T8, One-Piece Handle Ø 1.3 mm cannulated, consisting of: 9099.001 One-Piece Handle for Screwdriver 9032.015 Screwdriver Blade T8
6032.208	Screwdriver T8, Multi-Part Handle Ø 1.3 mm cannulated, consisting of: 9099.002 Multi-Part Handle for Screwdriver 9032.015 Screwdriver Blade T8
9032.020	Drill Bit Ø 2.5/1.3 mm, cannulated, length 160/135 mm, for quick coupling
9032.021	Countersink Ø 3.5/1.3 mm, cannulated, for quick coupling
9032.033	Double Drill Guide, Ø 3.5/2.5 mm
9032.034	Drill Guide, Ø 2.5/1.3 mm,
9032.040	Guide Wire Ø 1.2 mm, with trocar tip, length 150 mm,
9032.041	Guide Wire Ø 1.2 mm, with threaded tip, length 150 mm,
9032.042	Measuring Device, for Guide Wire Ø 1.2 mm, Guide Wire length 150 mm
9032.050	Cleaning Stylet Ø 1.25 mm, for Ø 1.3 mm cannulated instruments
Not shown:	
8032.001	Sterilization Tray for MAGNEZIX® CS Ø 3.2 mm, without contents
8032.002	Lid for Sterilization Tray, for MAGNEZIX® CS Ø 3.2 mm

* The figures are not to scale. Instruments of the latest generation can have additional color coding.

METALLIC AND TRANSFORMABLE. A MEDICAL SENSATION. MAGNEZIX®



TOP 100 top100.de Innovator of the year 2017

INDUSTRIE PREIS 2017 FINALIST

EUROPEAN INNOVATION PARTNERSHIP on Active and Healthy Ageing

INNOVATIVE SOLUTION

cdgw Preisträger 2016 Deutscher Zukunftspreis Gesundheitswirtschaft

INNOVATIONSPREIS DER DEUTSCHEN WIRTSCHAFT Sieger 2012/13

Presented by:

SYNTELLIX

Syntellix AG
Aegidientorplatz 2a
30159 Hannover
Deutschland

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.

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