

MAGNEZIX^{M3}

THE IMPLANT OF TOMORROW

SPECIAL PROPERTIES - UNIQUE BENEFITS: MAGNEZIX®

Intelligent innovations for a better life.
www.syntellix.com

 SYNTELLIX

STABILITY, RESORBABILITY AND OSTEOCONDUCTIVITY DEFINE A NEW STANDARD OF IMPLANTS!

Similar stability to comparable titanium implants.



Up to 5 times higher stability than polymer pins.

Metallic and biotransformable.

Osteoconductive.

Reduced risk of infection.

No remaining foreign material.

Practically no radiological artefacts.

Suitable for diagnostics in MRI and CT.

Free of aluminium, nickel, chromium and cobalt.

Excellent biocompatibility, no known allergies.

Reduced risk of stress shielding.



THE GAME CHANGER AND INNOVATION LEADER: MAGNEZIX®

Worldwide innovation leader

Most implants in the field of orthopedic surgery are made of non-resorbable materials such as steel or titanium which permanently remain in the body or have to be removed in a second surgery. These permanent implants can cause stress shielding, provoke inflammatory or foreign body reactions. In order to minimize these problems, resorbable, yet stable implants have become subject of extensive research. While there were many approaches to design a material that provides both adequate mechanical and degradation properties combined with excellent biocompatibility, MAGNEZIX® hit the market as **the globally first biotransformable metallic implant material** approved for human use.

Inventing new technologies

There were good reasons to think about using magnesium in orthopedic surgery:

1. An implant consisting of a magnesium based alloy would initially be **as strong as a traditional bone implant** made of steel or titanium and would, additionally, gradually dissolve.
2. It would show **very good biocompatibility, strong osteogenic potential and infect inhibiting effects.**

The challenge was to develop the right magnesium-based alloy suitable for osteosynthesis. The MAGNEZIX® alloy is based on the MgYREZr system and shows excellent values of strength properties (yield strength > 260 MPa, tensile strength > 290 MPa) and is free of known allergenic elements. Additionally, adapted casting, powdermetallurgical and extrusion processes significantly enhance the unique properties of the final product.

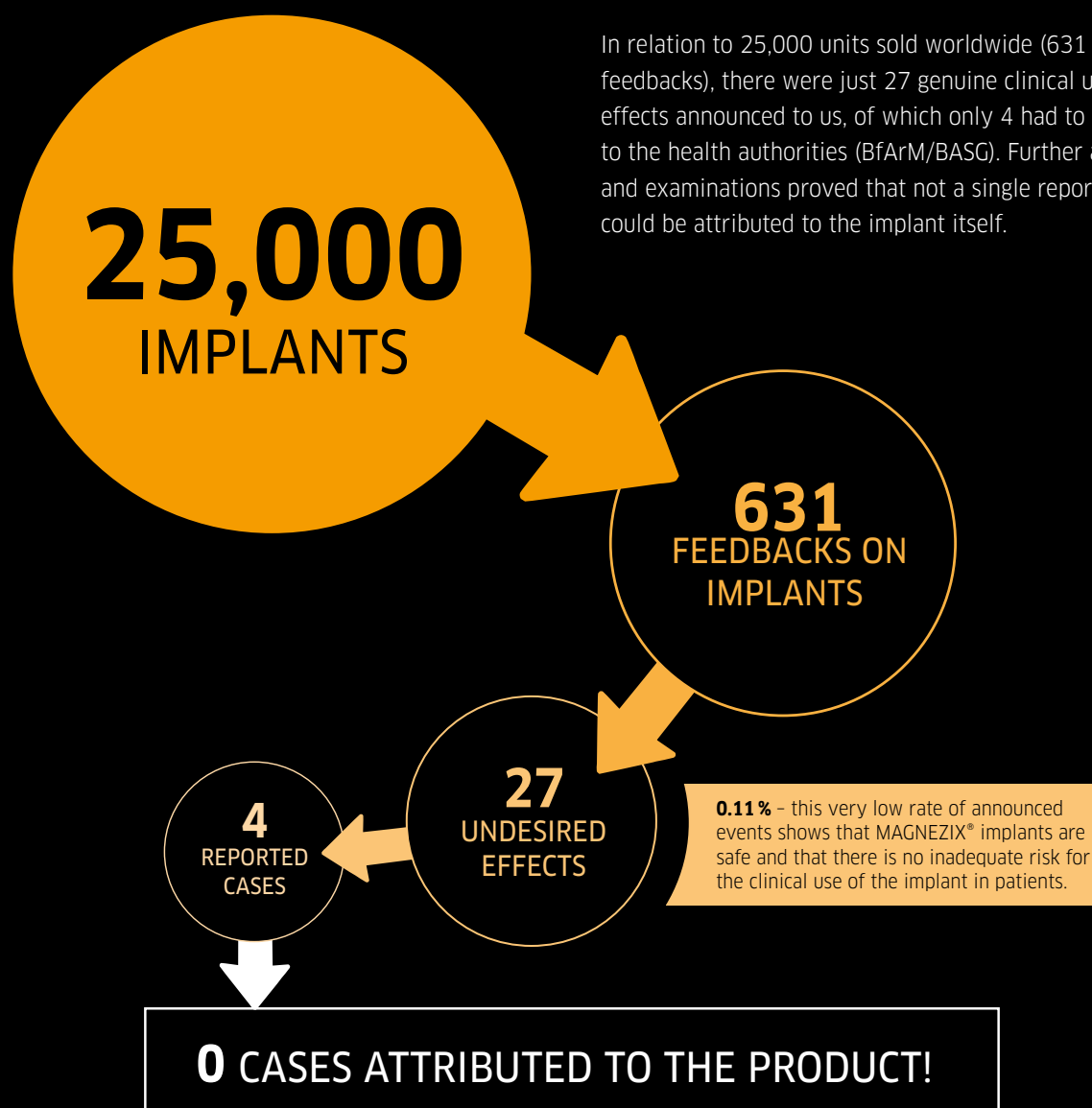
Progress requires change

The implementation of this innovation has not only led to a vast range of new possibilities, but also had and still has to deal with prejudices and reservation. In the end, every innovation requires reconsideration and every state-of-the-art product once was new and uncommon!



CE approval for MAGNEZIX® compression screws (CS) was granted in 2013, for the first time enabling the clinical use of a degradable bio-metal in Europe. In 2015 and 2016, new screw sizes and the MAGNEZIX® Pin broadened the CE-approved portfolio.

IN THOUSANDS OF SURGERIES NOT A SINGLE UNWANTED RESULT WAS ATTRIBUTED TO THE PRODUCT!*



In relation to 25,000 units sold worldwide (631 received feedbacks), there were just 27 genuine clinical undesirable effects announced to us, of which only 4 had to be reported to the health authorities (BfArM/BASG). Further analysis and examinations proved that not a single reported case could be attributed to the implant itself.

*All mentioned events seem to have been caused by the applicants' learning curve for the proper use and normal clinical course of the implant. Not a single case could be attributed to the product itself or its material.
Under no circumstances the product can be regarded more risky than comparable products which are already in wide spread use worldwide.

MAGNEZIX[®] IS AN INNOVATION WITH PROVEN BENEFITS!

Being a natural material, magnesium is subject to a biological degradation process!

When using magnesium implants for the first time, surgeons are not used to some **degradation-related appearances** they see in conventional X-rays. First, on postoperative radiographs, a MAGNEZIX[®] implant is not as dense as a titanium or steel implant. Second, during radiological control, the phenomenon of radiolucency may temporarily occur around the implant. This is a general phenomenon of the degradation processes of magnesium and therefore also associated with MAGNEZIX[®]: While the material dissolves, there is a natural loss of mass and weight. Also, magnesium releases small quantities of hydrogen gas which will be resorbed over time. Due to the osteoconductive capacity of MAGNEZIX[®], osteoclasts and osteoblasts will appear, helping to enable the process of bone remodeling, and osteoid (non-mineralized bone matrix) is formed.

Although sometimes visually inconvenient, **the described phenomenon of radiolucent zones around the implant is only short-term, does not effect bone healing and disappears by itself.** Experiences from laboratory testing, animal studies and the clinical use so far prove that the screw disappears within around 12 months and is replaced after 3 years at the latest by endogenous tissue that corresponds most closely to bone tissue.

The development of degradation byproducts in the dissolving process of magnesium seemed to be a critical factor for a long time. By optimizing the production process and the specific alloy composition of **MAGNEZIX[®], this issue was consequently reduced to a minimum level.**

It is recommended to include the phenomenon of potential radiolucency in the operating room note/ discharge note, pointing out that it does not have any clinically relevant influence on the healing process. This will inform the caregivers involved in the follow-up treatment about the special aspects of the implants' dissolving process.

Scaphoid fracture



post-op



follow-up after 6 weeks



follow-up after 18 weeks



Post-op X-ray a. p.



6 months after surgery a. p.

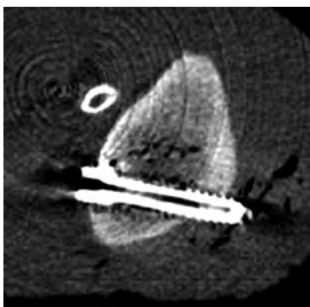
MAGNEZIX® implants provide an ideal stability since their mechanical properties are very close to those of cortical bone!

MAGNEZIX® implants were designed to gain a primary stability as in implants made of steel or titan and a load capacity which is 5 times higher compared to polymerbased pins.

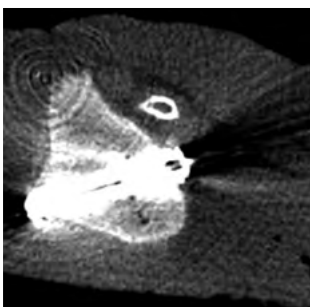
During the healing process, these magnesium implants naturally loose their original shape. In some cases they even appear as if they were broken, seen in image based diagnostic procedures. This phenomenon does not result from a lack of primary stability but is due to the fact that they are degrading as intended while the healing bone obtains the ability to bear higher load capacities (see X-rays on the left side).

It should be noted that MAGNEZIX® CS implants follow a **magnesium-specific design** which cannot be directly compared to titanium screws one to one (e.g. in terms of diameters). Thus, compared to titanium screws, it is recommended to use the next bigger MAGNEZIX® screw diameter in most cases.

The fact of using a self-cutting yet not a self-drilling screw should be considered as well. In some rare cases, the head of the screw had broken due to inadequate skipping of pre-drilling of either the cancellous or the cortical bone or both. For screws with **self-tapping tips, pre-drilling over the desired screw length is mandatory**, facilitating the subsequent tightening of the screw and reducing the rotation of small bone fragments.



MAGNEZIX® CS:
Minor interference signals in CT



Titanium:
Major interference signals in CT

MAGNEZIX® implants are suitable for MRI and CT diagnosis!

The metallic MAGNEZIX® implants are **suitable for MRI and CT diagnostics**.

Noise is greatly reduced and the implants only generate very few artefacts.

In addition, unlike conventional screws made of steel and titanium, implants made of MAGNEZIX® do not generate any noticeable temperature increases during common MRI scanning. This helps to considerably improve the analysis of images by surgeons and radiologists.

If X-rays are taken in order to intraoperatively evaluate implant positioning by means of fluoroscopy, the irradiated area should be **free of any other implants, guide wires, instruments etc.** Foreign materials in the irradiated field can raise the X-ray dosage, leading to inadequate exposure of MAGNEZIX® implants (**effect of „overexposure“**). The effect of overexposure can be reduced by **modification of the intensity of radiation**.

Degrading magnesium has osteogenic properties and reduces the risk of infections!

Magnesium is a biologically active material and can **support the healing process**. Both, *in vitro* and *in vivo* studies have shown excellent cell compatibility and distinct osteoconductive properties of magnesium alloys. *In vitro* trials with MAGNEZIX® have demonstrated a **high proliferation rate of human osteoblasts** and a stimulation of vitality.

Magnesium degrades via a corrosion process that creates a basic environment close to the implant, **inhibiting bacterial growth**. Furthermore, the presence of released hydrogen (or hydrogen ions) is described to be particularly advantageous in the human organism regarding cell and tissue protection. **Hydrogen, in this context, acts as an antioxidant** which selectively binds and defuses DNA-changing hydroxyl radicals or peroxi nitrides. These positive effects, proven for pure magnesium, can be strongly anticipated for MAGNEZIX®. Additionally, in order to minimize the risk of infection, all MAGNEZIX® implants are individually sterile packaged.

Supporting the healing process¹

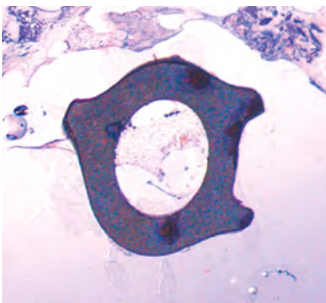
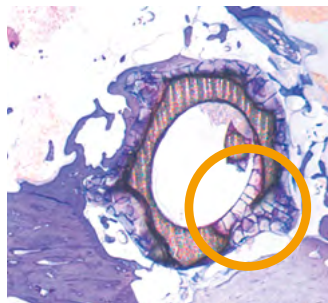
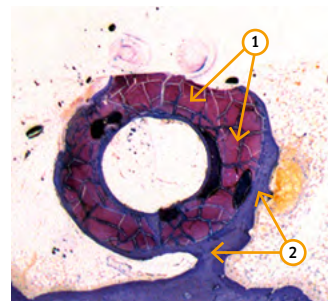


Image of histological examination show **outline of implanted screw** (from above) after surgery.



After three months you can see that **the screw is partially degraded** (in circle).



After 12 months the **screw has fully degraded**: it has been replaced by a potassium compound (1) with ingrowth of new bone (2).

MAGNEZIX® implants are free of nickel and aluminum and do not provoke any known allergies!

Magnesium itself has a **very good and proven biocompatibility**, which – amongst others – results from the high daily need of humans for the element magnesium. Within bone, it is easily available for resorption. This way, a magnesium implant that degrades within the bone can become a **source of essential magnesium ions**.

Since magnesium is a natural material essential for the body, generally it is very unlikely to provoke allergies. One advantage of MAGNEZIX® in this context is that it consists of more than 90% magnesium. **It contains no nickel, cobalt, chromium or aluminium elements**, which are all under suspicion to cause severe diseases. In summary, there are absolutely **no allergies or foreign body reactions known for MAGNEZIX® implants!**

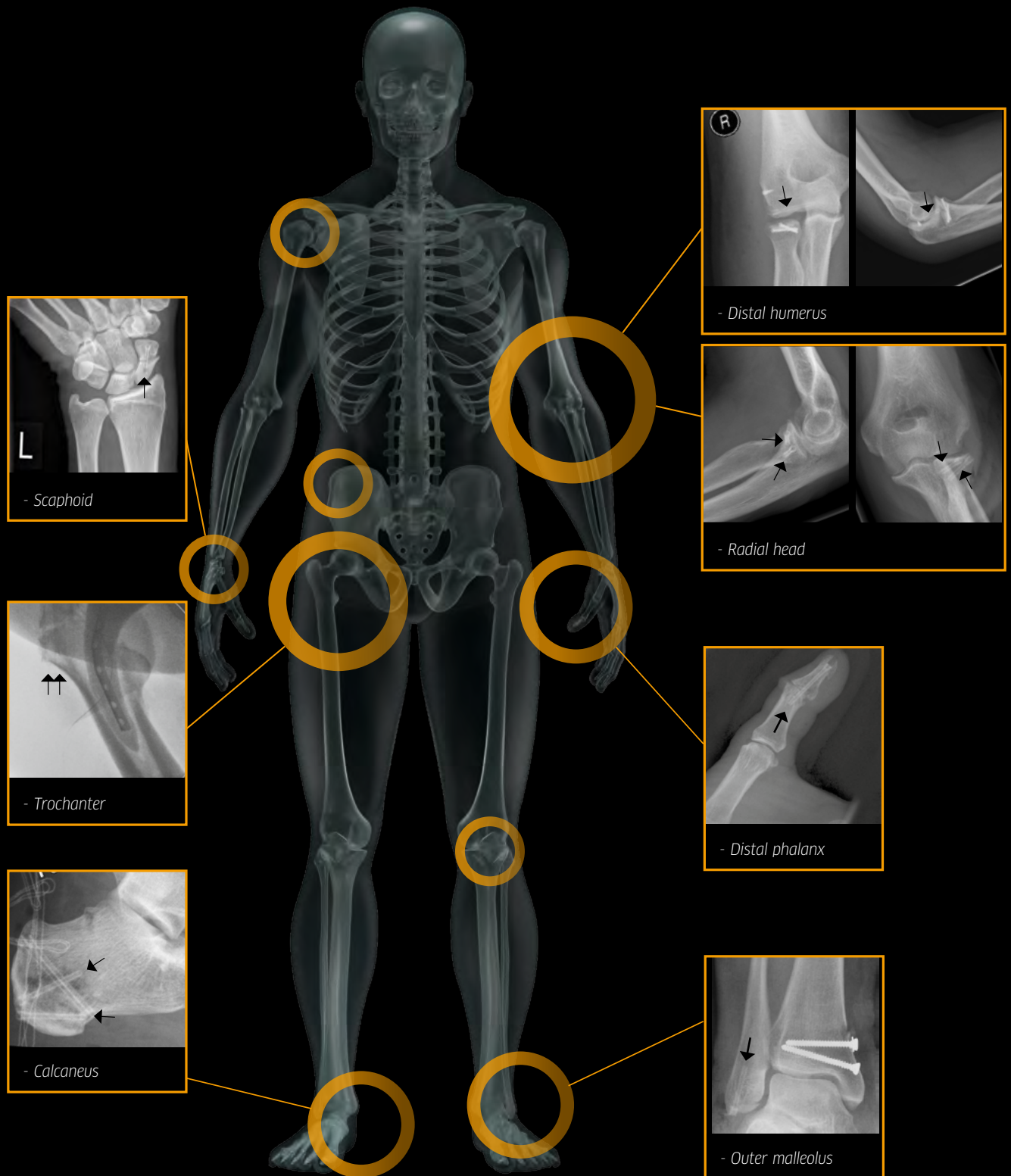
¹ Source: Waizy H, Diekmann J, Weizbauer A et al. (2014). In vivo study of a biodegradable orthopedic screw (MgYREZr-alloy) in a rabbit model for up to 12 months. J Biomater Appl 28 (5), 667-75.

MAGNEZIX® MEETS ALL CRITERIA OF AN IDEAL IMPLANT!

	TITANIUM	STEEL	POLYMERS	MAGNEZIX®
Degradation	No	No	1-6 years, beginning immediately	1-2 years, beginning immediately
Loss of stability half-value period	Only fatigue	Only fatigue	10-50 % after 12 weeks	App. 50 % after 12 weeks
Young's modulus (bone: 12-25 GPa)	105 GPa (5 times higher)	193 GPa (10 times higher)	4 GPa (lower)	47 GPa (2 times higher - ideal)
Tensile strength (bone: 150 MPa)	539 MPa	275-520 MPa	10-150 MPa	> 290 MPa
Biocompatibility	Gold standard	Foreign body reactions known	Foreign body reactions known	Good, proven with ISO 10993-1
Degradation products	No resorption	No resorption	Not finally checked	Biocompatible and bio-absorbable oxides and hydroxides, hydrogen gas
Radiology (CT, X-ray, MRI)	Good visible, partially with artefacts	Good visible, extensive artefacts	No artefacts, partially not visible	Low artefacts, visible with X-ray

MAGNEZIX® has mechanical stability values which are far above the values of those bioresorbable materials previously available. The mechanical properties of the MAGNEZIX® alloy, determined after the final extrusion process, result in yield strength properties higher than 260 MPa, tensile strength properties higher than 290 MPa and elongation to failure properties higher than 8 %. With a Young's Modulus of 47 GPa, **the biomechanical properties of MAGNEZIX® are very close to those of human bone.** The good bone-like stress-strain ratio effectively counteracts stress shielding effects that can result in loss of bone density (osteopenia). Consequently, the significant higher elasticity compared to steel or titanium implants implies micro-movement in the fracture zone leading to better healing conditions.

VARIOUS APPLICATIONS – ONE SIMILARITY: NO REMAINING OF FOREIGN MATERIAL!



THIS SCREW TURNS INTO BONE

MAGNEZIX® CS

Intended Use

MAGNEZIX® CS biotransformable compression screws serve the purpose of re-establishing bone continuity after fractures and osteotomies (osteosynthesis) as well as for treatment of pseudarthroses (re-osteotomies). The objective when using the MAGNEZIX® CS device is specifically anatomic retention by way of surgical splinting of assembled bone fractions after prior repositioning until bony healing. The implants are designed for single use only.

Indications

The indications for MAGNEZIX® CS implants are reconstructive procedures after fractures, malpositions and/or other pathological bone alterations of the human skeleton. The surgeon must in all cases determine the extent of the injuries or the bony alterations and the scope of the necessary surgical intervention and select the appropriate operating procedure and the appropriate implant. This applies in particular when using biotransformable MAGNEZIX® implants. The surgeon is always responsible for the decision to use the implant.

According to its respective dimension, MAGNEZIX® CS can be used for adaption- and exercise-stable fixation of bones and bone fragments in children, adolescents and adult persons. Relevant medical literature and guidelines must be observed when determining the dimensions of screws to be used.

The MAGNEZIX® CS is for example suitable for the following:

- Intra-articular and extra-articular fractures of small to medium-sized bones and bony fragments
- Arthrodeses, osteotomias and pseudarthroses of small to medium-sized bones and small joints
- Small bony avulsions of ligaments and tendons

Including:

- Phalanges, metacarpalia
- Processus styloideus radii et ulnae
- Capitulum and caput radii
- Osteochondrosis dissecans
- Carpalia, metacarpalia, tarsalia and metatarsalia
- Epicondylus humeri
- Hallux-valgus-corrections

Among others:

- Distal tibia
- Calcaneus, talus and metatarsus

Re-fixation of bony fragments for example:

- Proximal humerus
- Distal femur
- Proximal tibia

CONTRAINDICATIONS

In specific clinical situations the use of MAGNEZIX® implants may be prohibited (absolute contraindication) or use may be planned subject to certain considerations (relative contraindication).

Absolute contraindications

- Insufficient bone substance to anchor the implant → Evidence or suspicion of septic-infectious operating area
- Known allergies and/or known foreign body reactions
- Application in the area of the epiphyseal plates
- Load-stable osteosyntheses
- Arthrodeses of medium-sized and large joints
- Use in the spinal column

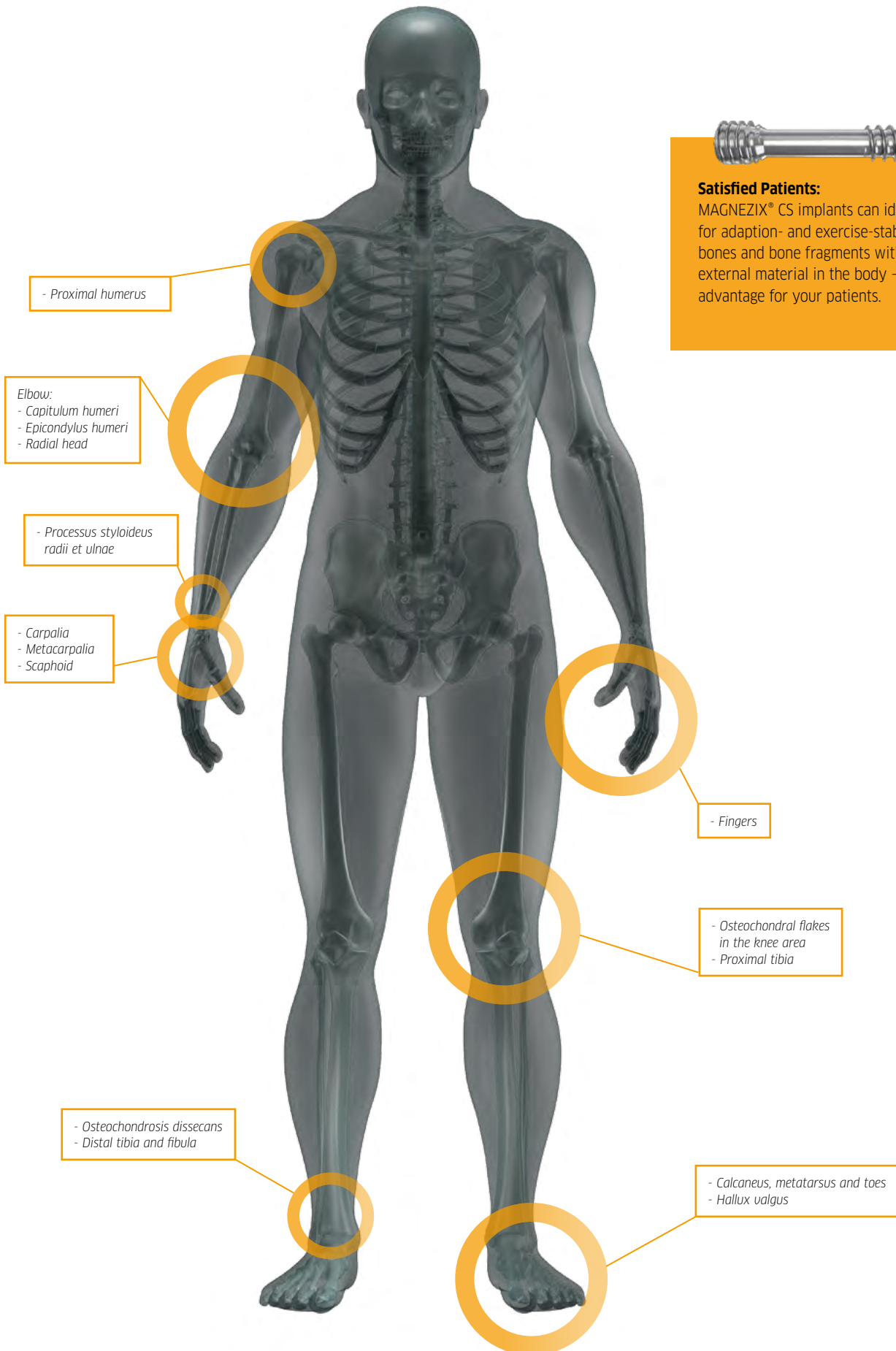
Relative contraindications

- Options for conservative treatment
- Acute sepsis
- Osteoporosis
- Alcohol and/or drug misuse
- Epilepsy
- Limited skin/soft tissue conditions
- Non co-operative patient or limited mental state of patient
- No possibility for providing adequate post-operative follow-up (e.g. temporary load relief)



Satisfied Patients:

MAGNEZIX[®] CS implants can ideally be used for adaption- and exercise-stable fixation of bones and bone fragments without leaving external material in the body - an outstanding advantage for your patients.

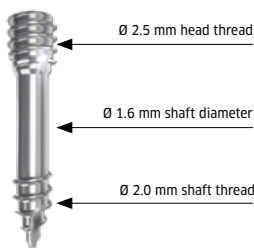
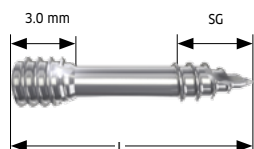


MAGNEZIX® CS

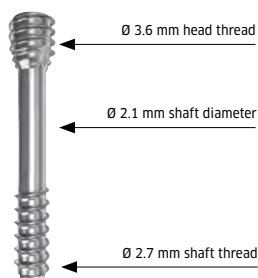
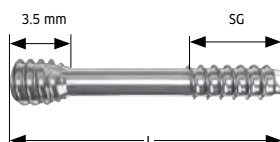
PRODUCT OVERVIEW

DIMENSIONS

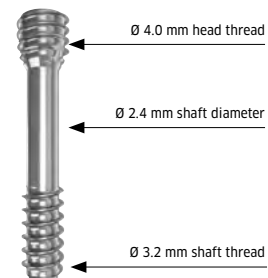
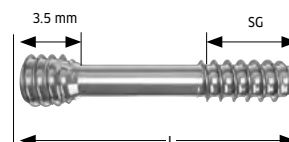
MAGNEZIX® CS 2.0



MAGNEZIX® CS 2.7



MAGNEZIX® CS 3.2



Art. No.	Threaded shaft length [mm] SG	Screw length [mm] L
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

Art. No.	Threaded shaft length [mm] SG	Screw length [mm] L
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

Art. No.	Threaded shaft length [mm] SG	Screw length [mm] L
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

ADVANTAGES AND FEATURES

MAGNEZIX[®] CS IMPLANTS



Biotransformable magnesium alloy

The use of MAGNEZIX[®] makes subsequent removal of the implant obsolete: furthermore MAGNEZIX[®] promotes the bone healing process. MAGNEZIX[®] is biotransformable, biocompatible and non-toxic in a biological environment.

The use of the innovative MAGNEZIX[®] metal alloy allows the screw to be implanted using standard techniques.



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 head of the screw is of T4/T7/T8 (ISO 10664-4/7/8) design. The advantages of this ISO standardized technology are:

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

Warnings

In the case of concurrent use of third party implants it must be borne in mind that steel, titanium and cobalt-chromium alloys may not remain in direct contact with a MAGNEZIX[®] implant at the intervention site (i.e. no physical contact of implants). Since the implants are designed for single use only, reuse of MAGNEZIX[®] implant devices is grossly negligent and can result in an increased risk of infection and loss in implant stability. In general, re-sterilization alters the implant's functionality in an unpredictable way.

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 predrilled. 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.

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.

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.

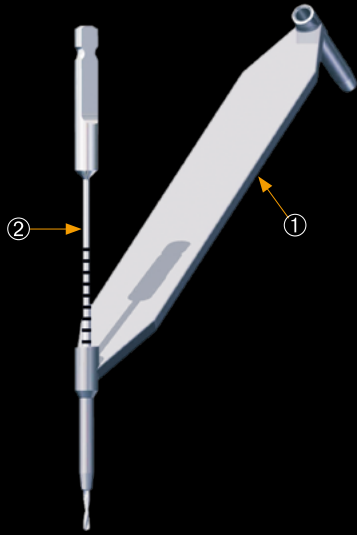
Step 4: Inserting the screw

The MAGNEZIX® Compression Screw 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 when screwing-in the screw are excessive. 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.

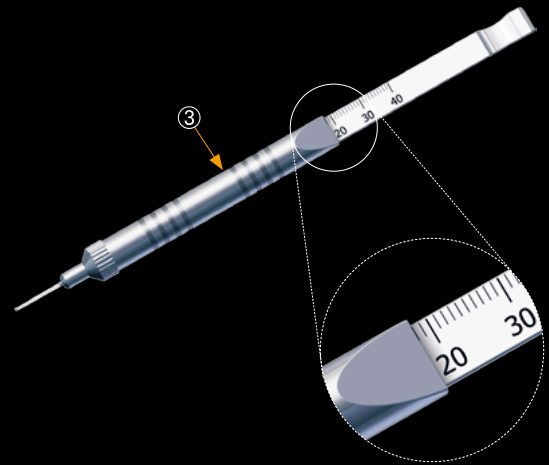
STEP 1



Instruments used:

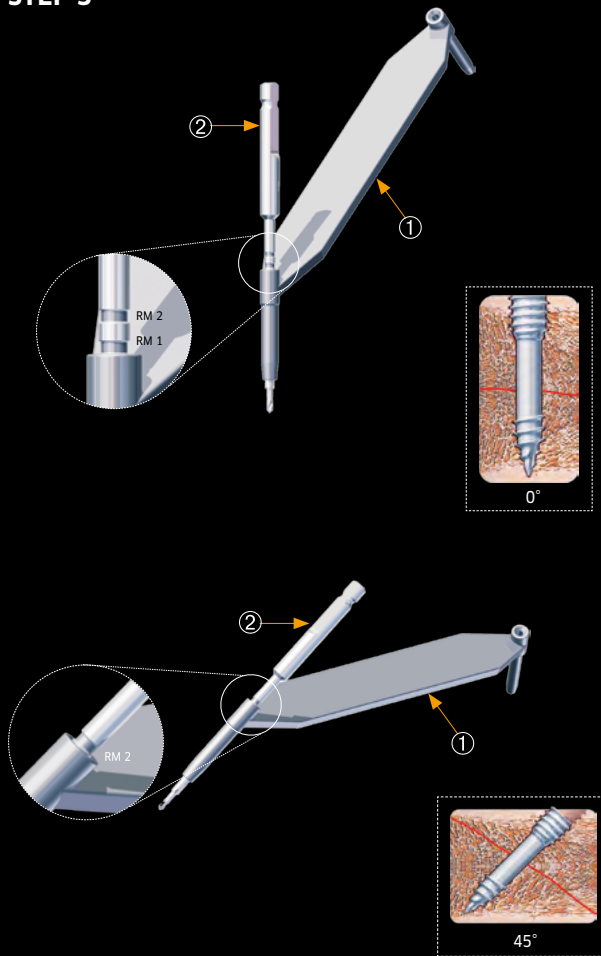
- ① 9020.033 Double Drill Guide, Ø 2.2/1.5 mm
- ② 9020.020 Drill Bit, Ø 1.5 mm

STEP 2



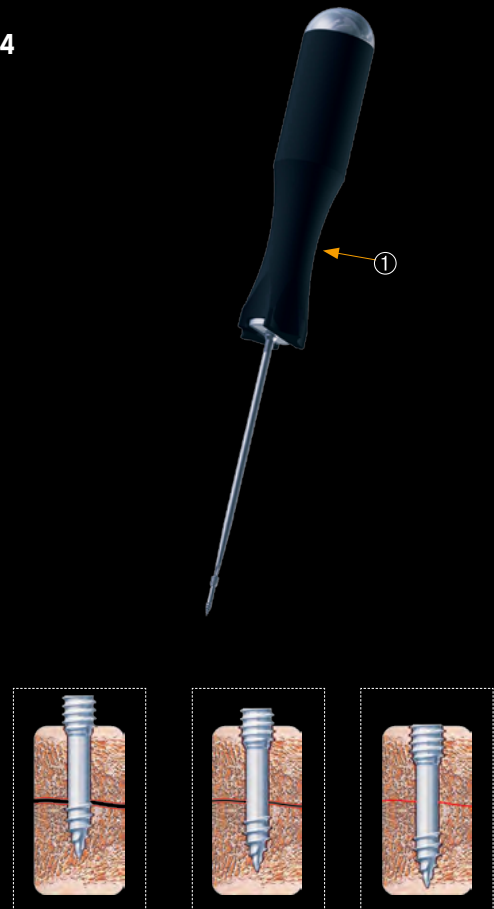
- ③ 9020.042 Depth Gauge for screws

STEP 3



- 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



- ① 6020.104 Screwdriver T4, One-Piece Handle | **Optional:**
6020.204 Screwdriver T4, Multi-Part Handle

SURGICAL TECHNIQUE

MAGNEZIX® CS 2.7 AND 3.2 – STEP BY STEP

Prior to implanting a MAGNEZIX® CS 2.7 or 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: 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.

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: Only the original guide wires guarantee correct measurement.

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: It is crucial to only drill to the tip of the guide wire. 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.

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.

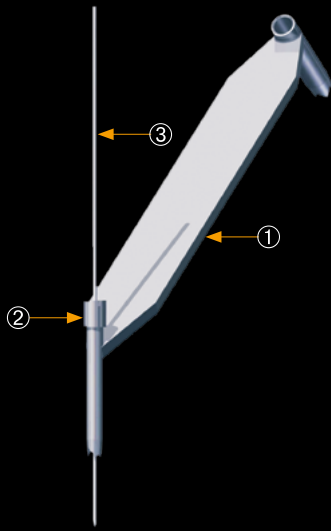
Important: If the screw is positioned perpendicular to the bone surface, countersinking to the first ring marking (RM 1) is required in order to achieve adequate countersinking of the screw head. If the screw is positioned at an angle of 45° to the bone surface, countersinking to the second ring marking (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.

Step 5: Insertion of the screw

This is now followed by the tightening of the MAGNEZIX® Compression Screw 2.7/3.2 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® Compression Screw 2.7/3.2 to not end up fully turned 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 when screwing-in the screw are excessive. 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.

STEP 1



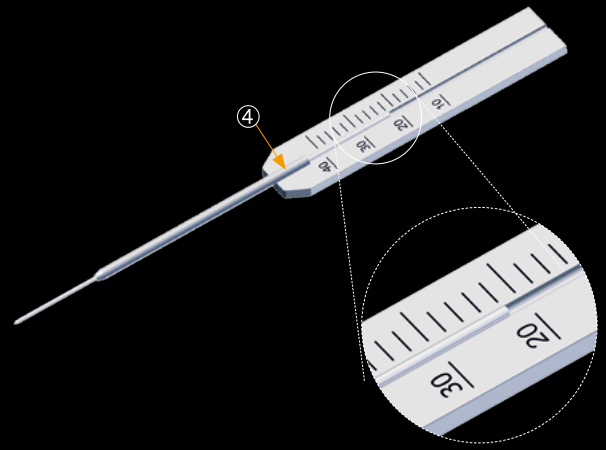
Instruments used for 2.7:

- 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

Instruments used for 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

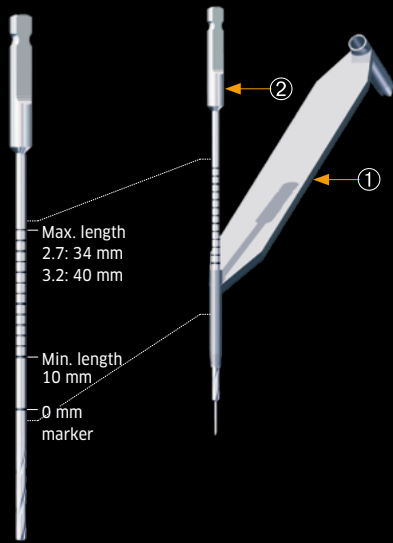
STEP 2



- ④ 9027.042 Measuring Device for Guide Wires Ø 1.0 mm, Guide Wire length 100 mm

- ④ 9032.042 Measuring Device for Guide Wires Ø 1.2 mm, Guide Wire length 150 mm

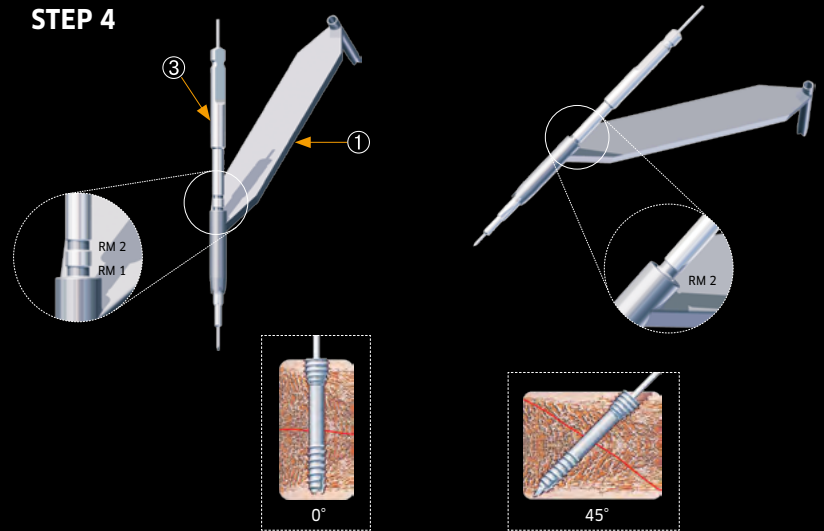
STEP 3



- 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

- 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

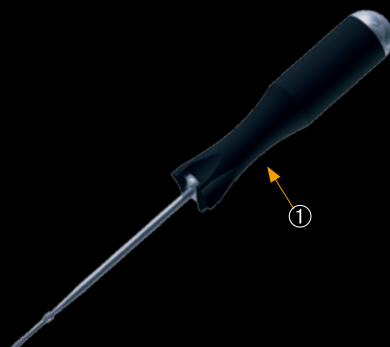
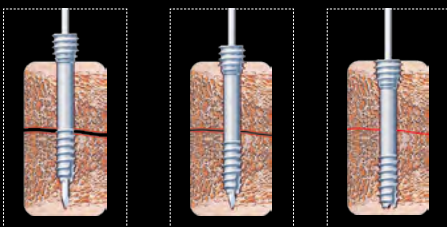
STEP 4



- 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

- 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 5

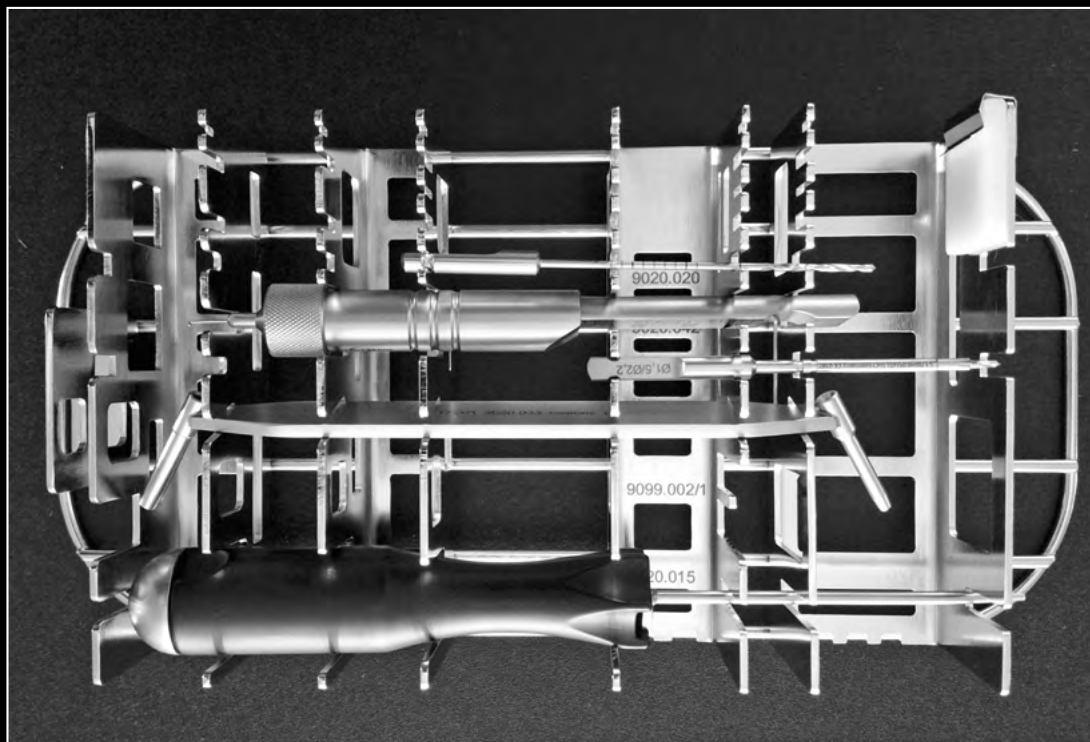


- ① 6027.107 Screwdriver T7, One-Piece Handle, Ø 1.1 mm cannulated | **Optional:** 6027.207 Screwdriver T7, Multi-Part Handle, Ø 1.1 mm cannulated
- 9027.033 Double Drill Guide, Ø 3.1/2.2 mm

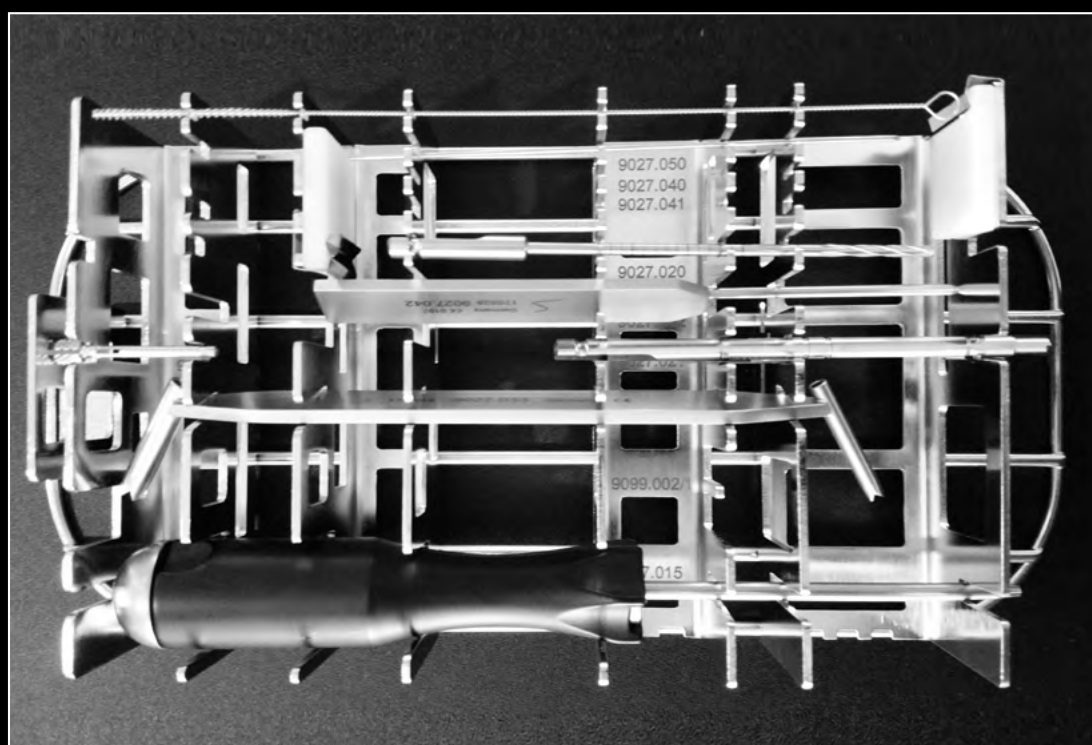
- ① 6032.108 Screwdriver T8, One-Piece Handle, Ø 1.3 mm cannulated | **Optional:** 6032.208 Screwdriver T8, Multi-Part Handle, Ø 1.3 mm cannulated
- 9032.033 Double Drill Guide, Ø 3.5/2.5 mm

MAGNEZIX® CS 2.0, 2.7, 3.2

OVERVIEW INSTRUMENTS AND TRAY



MAGNEZIX® CS 2.0



MAGNEZIX® CS 2.7 (SIMILAR TO CS 3.2)

INSTRUMENTS* MAGNEZIX® CS

PRODUCT OVERVIEW

Art. No.	Description
6020.104	Screwdriver T4, One-Piece Handle, consisting of:
	9099.001 One-Piece Handle for Screwdriver, 9020.015 Screwdriver Blade T4
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
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
6020.204	Screwdriver T4, Multi-Part Handle, consisting of:
	9099.002 Multi-Part Handle for Screwdriver, 9020.015 Screwdriver Blade T4
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
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
9099.003	Screwdriver Handle for quick coupling
9048.015	Screwdriver Blade T15, self-holding, for quick coupling
9020.020	Drill Bit Ø 1.5 mm, Length 88/63 mm, for Schnellkupplung
9027.020	Drill Bit Ø 2.2/1.1 mm, cannulated, Length 100/75 mm, for quick coupling
9032.020	Drill Bit Ø 2.5/1.3 mm, cannulated, Length 160/135 mm, for quick coupling
9048.020	Drill Bit Ø 4.0/1.9 mm, cannulated, Length 160/135 mm, for quick coupling
9020.021	Countersink Ø 2.2/1.5 mm, cannulated, for quick coupling
9027.021	Countersink Ø 3.1/1.1 mm, cannulated, for quick coupling
9032.021	Countersink Ø 3.5/1.3 mm, cannulated, for quick coupling
9048.021	Countersink Ø 5.0/1.9 mm, cannulated, for quick coupling
9020.033	Double Drill Guide, Ø 2.2/1.5 mm
9027.033	Double Drill Guide, Ø 3.1/2.2 mm
9032.033	Double Drill Guide, Ø 3.5/2.5 mm
9020.042	Depth Gauge for screws
9027.042	Measuring Device, for Guide Wire Ø 1.0 mm, Guide Wire length 100 mm
9032.042	Measuring Device, for Guide Wire Ø 1.2 mm, Guide Wire length 150 mm
9048.042	Measuring Device, for Guide Wire Ø 1.8 mm, Guide Wire length 150 mm
9027.034	Drill Sleeve, Ø 2.2/1.1 mm
9032.034	Drill Sleeve, Ø 2.5/1.3 mm
9048.032	Drill Sleeve, Ø 4.0/1.9 mm
9048.031	Drill Sleeve, Ø 5.0/4.0 mm
9027.040	Guide Wire Ø 1.0 mm, with trocar tip, Length 100 mm, (do not reuse)
9032.040	Guide Wire Ø 1.2 mm, with trocar tip, Length 150 mm, (do not reuse)
9048.040	Guide Wire Ø 1.8 mm, with trocar tip, Length 150 mm, (do not reuse)
9027.041	Guide Wire Ø 1.0 mm, with threaded tip, Length 100 mm, (do not reuse)
9032.041	Guide Wire Ø 1.2 mm, with threaded tip, Length 150 mm, (do not reuse)
9048.041	Guide Wire Ø 1.8 mm, with threaded tip, Length 150 mm, (do not reuse)
9027.050	Cleaning Stylet Ø 1.05 mm, for Ø 1.1 mm, cannulated instruments
9032.050	Cleaning Stylet Ø 1.25 mm, for Ø 1.3 mm, cannulated instruments
9048.050	Cleaning Stylet Ø 1.85 mm, for Ø 1.8 mm, cannulated instruments
9048.030	Protection Sleeve, Ø 5.0 mm
9048.033	Trokar, Ø 1.8 mm

Not shown:				Sterilizing Tray without contents		Lid for Sterilizing Tray	
Ø 2.0 mm	8020.001	Ø 3.2 mm	8032.001	Ø 2.0 mm	8020.002	Ø 3.2 mm	8032.002
Ø 2.7 mm	8027.001	Ø 4.8 mm	8048.001	Ø 2.7 mm	8027.002	Ø 4.8 mm	8048.002

* The figures are not to scale.

A CLASS OF ITS OWN

MAGNEZIX® Pin

Intended Use

The MAGNEZIX® Pin is a biotransformable bone pin that is used to restore the bone continuity of bone fragments that are subjected to low loads and dimensionally stable after fractures, for the treatment of bony avulsion fractures, re-fixation of bone fragments and osteochondral fragments. Specifically, the MAGNEZIX® Pin 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® Pin 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 MAGNEZIX® implants. The surgeon always remains responsible for the decision to use these implants. Depending on the chosen size, the MAGNEZIX® Pin can be used as a bone pin for children, adolescents or adults for adaptation-capable or exercise-capable fixation of bones, bone fragments or osteochondral fragments for areas that are only subjected to minor loads. The relevant medical literature and corresponding guidelines of the professional associations must be observed when selecting the pin size that is going to be used.

MAGNEZIX® Pin 1.5, 2.0, 2.7, 3.2 for example:

- Intra-articular and extra-articular fractures of small bones and bone fragments
- Arthrodeses and osteotomies of small bones and joints
- Small osseous ligament and tendon ruptures
- Osteochondral fractures and dissections

MAGNEZIX® Pin 1.5 among others:

- Phalangeal and metacarpal bones
- Osteochondrosis dissecans

MAGNEZIX® Pin 2.0 among others:

- Carpal, metacarpal, tarsal and metatarsal bones
- Ulnar and radial styloid processes
- Radial head and capitulum

MAGNEZIX® Pin 2.7 and 3.2 among others:

- Pipkin fractures
- Metaphyseal fractures of the radius and ulna
- Hallux valgus corrections

CONTRAINDICATIONS

MAGNEZIX® implants are contraindicated (Absolute Contraindication) in specific clinical situations or they should only be planned after careful consideration (Relative Contraindication).

Absolute Contraindications:

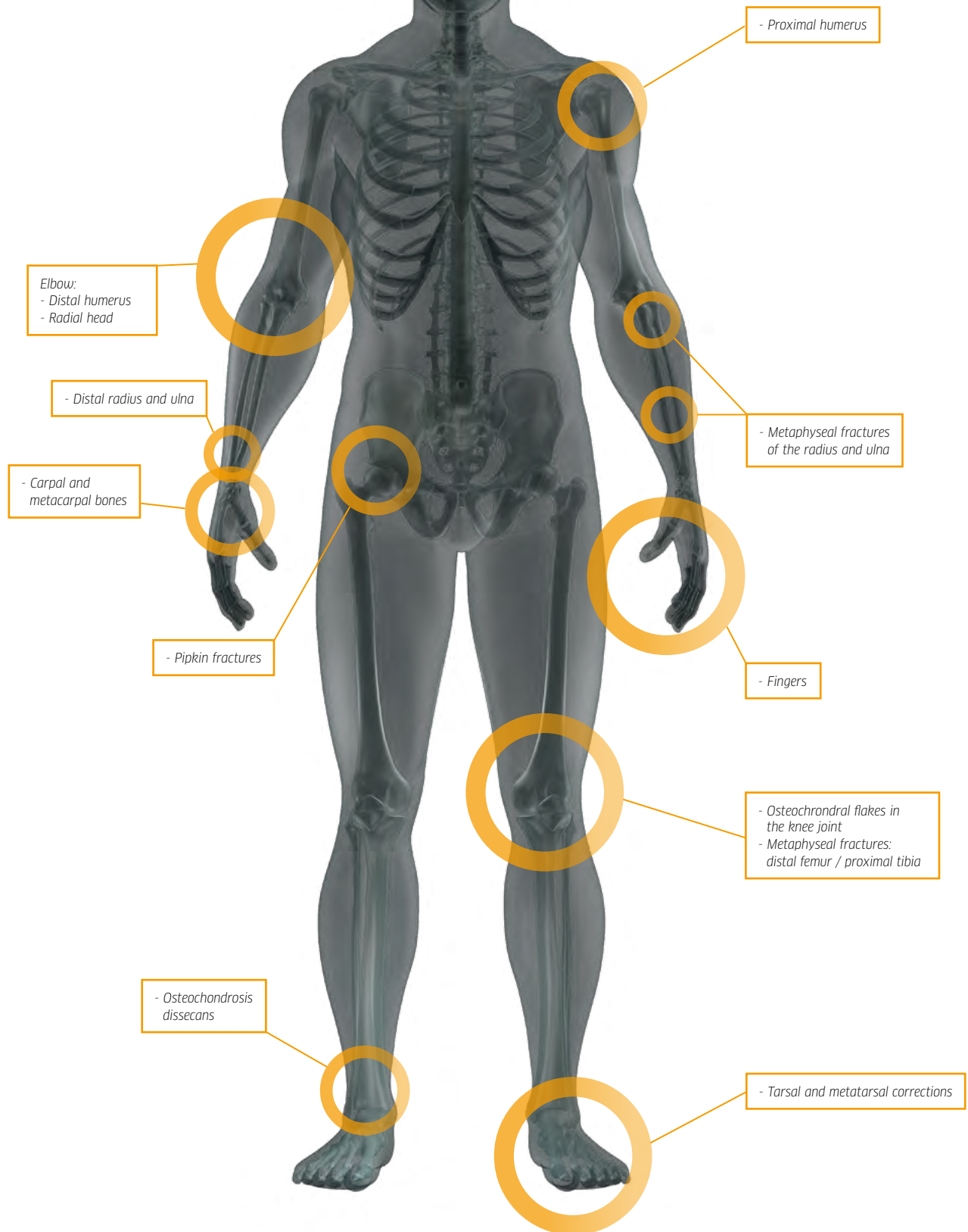
- Insufficient or avascular bone tissue for anchorage of the implant
- Confirmation or suspected septic infectious surgical site
- Application in the area of the epiphyseal plates
- Functionally stable osteosynthesis
- Arthrodeses of medium to large joints
- Applications on the spinal column

Relative Contraindications

- Options for conservative treatment
- Acute sepsis
- Osteoporosis
- Continuous stretching of tendons and ligaments with foreseeable secondary dislocation
- 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)



The **outstanding stability (5x higher compared to PLA/PGA implants)** of MAGNEZIX[®] Pins sets a whole new level for several indications in Traumatology and Sports surgery. Convince yourself!

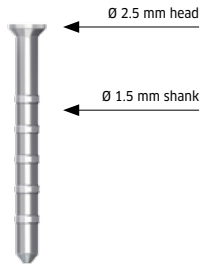


MAGNEZIX® Pin

PRODUCT OVERVIEW

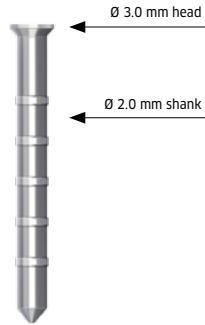
DIMENSIONS

MAGNEZIX® Pin 1.5



Head height is 1.0 mm.

MAGNEZIX® Pin 2.0



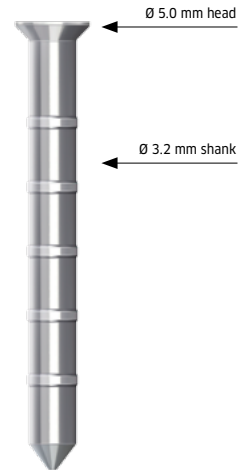
Head height is 1.0 mm.

MAGNEZIX® Pin 2.7



Head height is 1.1 mm.

MAGNEZIX® Pin 3.2



Head height is 1.3 mm.

Art. No.	Length [mm]
1115.008	8
1115.010	10
1115.012	12
1115.014	14
1115.016	16
1115.018	18
1115.020	20
1115.022	22
1115.024	24
1115.026	26
1115.028	28
1115.030	30

Art. No.	Length [mm]
1120.008	8
1120.010	10
1120.012	12
1120.014	14
1120.016	16
1120.018	18
1120.020	20
1120.022	22
1120.024	24
1120.026	26
1120.028	28
1120.030	30
1120.032	32
1120.034	34
1120.036	36
1120.038	38
1120.040	40

Art. No.	Length [mm]
1127.012	12
1127.014	14
1127.016	16
1127.018	18
1127.020	20
1127.022	22
1127.024	24
1127.026	26
1127.028	28
1127.030	30
1127.032	32
1127.034	34
1127.036	36
1127.038	38
1127.040	40
1127.042	42
1127.044	44
1127.046	46
1127.048	48
1127.050	50

Art. No.	Length [mm]
1132.012	12
1132.014	14
1132.016	16
1132.018	18
1132.020	20
1132.022	22
1132.024	24
1132.026	26
1132.028	28
1132.030	30
1132.032	32
1132.034	34
1132.036	36
1132.038	38
1132.040	40
1132.042	42
1132.044	44
1132.046	46
1132.048	48
1132.050	50

ADVANTAGES AND FEATURES

MAGNEZIX® PIN IMPLANTS



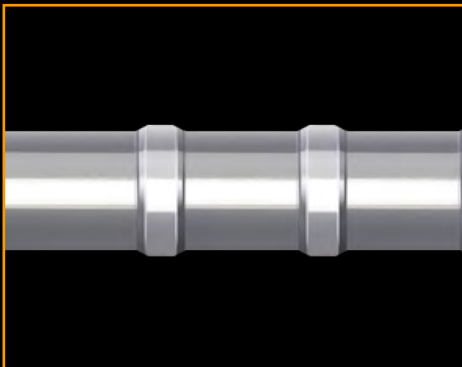
BIOTRANSFORMABLE MAGNESIUM ALLOY

Use of MAGNEZIX® implants makes any subsequent implant removal unnecessary, and moreover, it supports the osseous healing process. MAGNEZIX® is biotransformable, biocompatible and non-toxic within a biological environment.

HEAD DESIGN

The flat designed head of the MAGNEZIX® Pin enables stable reduction of the bone fragment. Prominent protrusion of the implant involving possible damage to proximal structures can thus be avoided and the pin head can be completely countersunk.

In addition, a recess in the pin head improves positioning of the impactor and the impactor is prevented from slipping off the pin head during impaction.



AXIALLY STABILISING SHANK DESIGN

The symmetric collars on the pin shank result in compression of the free bone fragment during impaction of the implant. In addition, the collars increase the axial positioning precision of the implant and thus ensure reduction during the healing process.



DESIGN OF THE PIN TIP

The tip design of the MAGNEZIX® Pin displaces cancellous bone and thus compresses the implant bed. The pin tip without any collars facilitates positioning of the MAGNEZIX® Pin in the pre-drilled implant bed.

Hints

In isolated cases, temporary radiolucencies may be observed around the implant. It is recommended that the phenomenon of radiolucencies be included in the operating room note / discharge note, pointing out that based on present knowledge the phenomenon 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, there is never any need to remove them.

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® Pin implants constitutes gross negligence. It may lead to increased risk of infection and especially loss of implant stability. Re-sterilisation will have an incalculable impact on the product.

SURGICAL TECHNIQUE

MAGNEZIX® PIN – STEP BY STEP

Before implantation of a MAGNEZIX® Pin can be performed, reduction and temporary stabilisation of the fracture, osteotomy or bone fragment must have been carried out first. For this purpose the reduction wires in the respective pin size can also be used. The following surgical steps apply to all MAGNEZIX® Pin sizes because the design of the instruments to be used is identical. The instruments differ in terms of sizing though.

Step 1: Pre-drilling the pin bed

Position the double drill guide through the soft tissue up to the bone. Introduce the drill bit to the bone through the double drill guide. Drill to the required depth, under fluoroscopy if necessary. Alternatively, reduction and pre-drilling of the implant bed can also be performed with the reduction wires.

It should be noted: that without pre-drilling it is not possible to determine the suitable pin length properly. Incorrectly oriented pre-drilling can impair the function of the pin. If multiple pins are used, overall stability is increased by divergent or convergent positioning of the pins in relation to one another.

Step 2: Determination of pin length

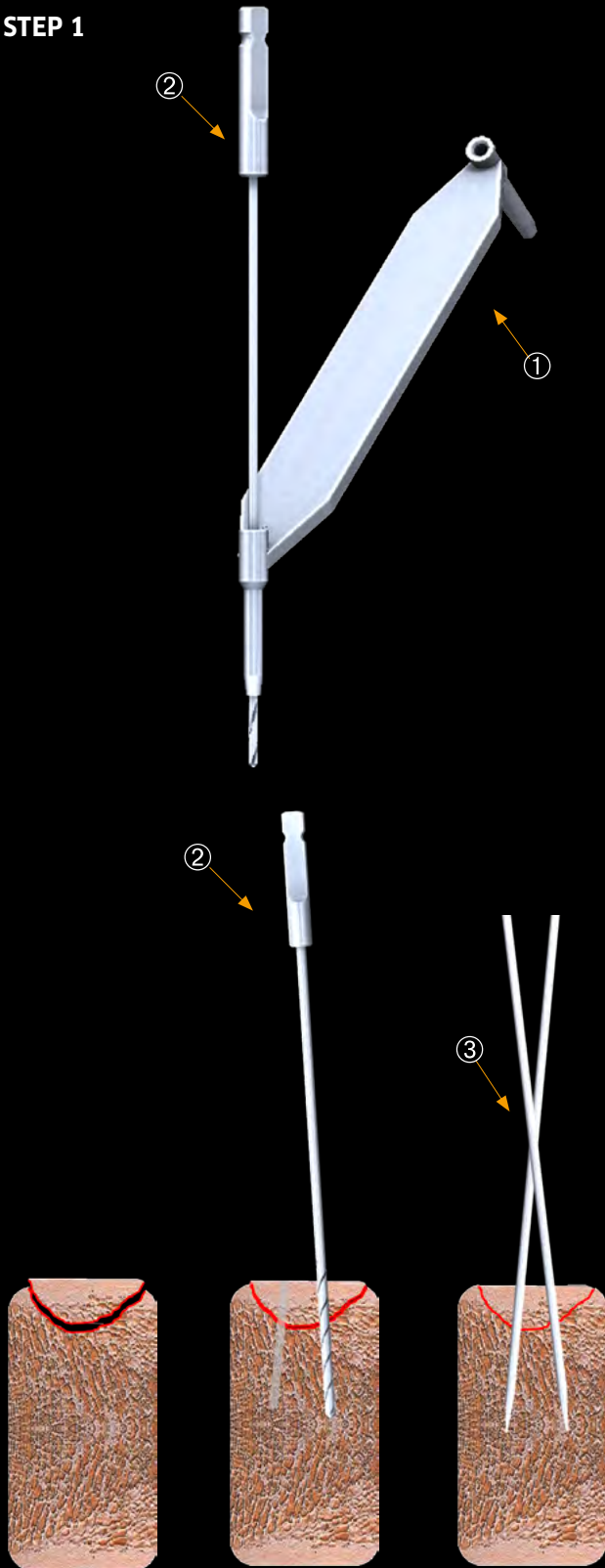
Pin length can be determined in two different ways.

Method 1: If reduction wires have been used for temporary stabilisation of the fracture situation, the measuring device is advanced up to the bone over the reduction wire. The end of the reduction wire, which is visible on the scale of the measuring device, determines the length of the pin to be used (34 mm in the figure).

Method 2: If temporary stabilisation of the fracture situation has been performed in a different way, to determine the length of the pin the depth of the drilled hole in the bone can be determined with the depth Gauge (34 mm in the figure).

It should be noted: that when selecting pin length the fracture gap has to be included. Also, with a measurement of 35 mm, for example, the next smaller pin with a length of 34 mm must be used. If the pin selected is too long, reduction of the bone fragment might be prevented. Specification of pin length refers to the total length of the implant including its head.

STEP 1



Instruments used for 1.5/2.0:

- ① 9115.033 Double Drill Guide, for MAGNEZIX® Pin Ø 1.5/2.0 mm
- ② 9115.020 Drill Bit Ø 1.5 mm, length 115/90 mm
- 9120.020 Drill Bit Ø 2.0 mm, length 115/90 mm

Optional:

- ③ 9115.040 Reduction Wire Ø 1.5 mm, spade point tip, length 100 mm
- 9120.040 Reduction Wire Ø 2.0 mm, spade point tip, length 100 mm

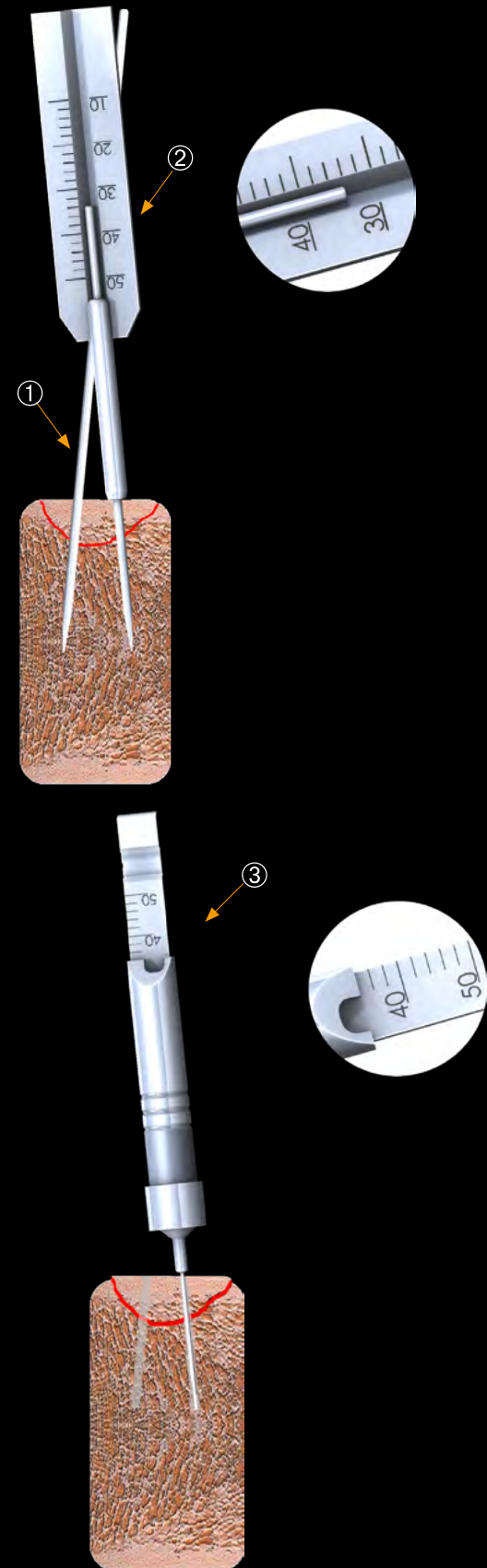
Instruments used for 2.7/3.2:

- ① 9127.033 Double Drill Guide, for MAGNEZIX® Pin
- ② 9127.020 Drill Bit Ø 2.7 mm, length 115/90 mm
- 9132.020 Drill Bit Ø 3.2 mm, length 115/90 mm

Optional:

- ③ 9127.040 Reduction Wire Ø 2.7 mm, spade point tip, length 100 mm
- 9132.040 Reduction Wire Ø 3.2 mm, spade point tip, length 100 mm

STEP 2



Instruments used for 1.5/2.0:

- ① 9115.040 Reduction Wire Ø 1.5 mm, spade point tip, length 100 mm
- 9120.040 Reduction Wire Ø 2.0 mm, spade point tip, length 100 mm

Instruments used for 2.7/3.2:

- ① 9127.040 Reduction Wire Ø 2.7 mm, spade point tip, length 100 mm
- 9132.040 Reduction Wire Ø 3.2 mm, spade point tip, length 10

- ② 9100.042 Measuring Device, for reduction wires up to Ø 3.2 mm, for length 100

Optional:

- ③ 9100.045 Depth Gauge for MAGNEZIX® Pin

Step 3: Impaction of the pin

Impaction of the pin is assisted by use of the impactor. The inner bolt of the impactor is removed and a MAGNEZIX® Pin is inserted into the impactor sleeve with the tip first. Then the bolt is reinserted and advanced until the tip of the pin becomes visible at the tip of the impactor. The tip of the MAGNEZIX® Pin can now be positioned in the pilot hole. With the aid of a hammer the pin is now carefully impacted into the pilot hole up to the desired position of the head.

It should be noted: that the pin must not jam during impaction. Long pins in particular are protected by the inherent guiding action of the impactor from bending. Use of the impactor is therefore advisable.

The four impactors, which have different inside diameters, are colour-coded and are explicitly only to be used for the particular pin size. A wrong selection would mean that the pin is not guided properly or it could jam in the impactor.

Red: MAGNEZIX® Pin 1.5 mm

Yellow: MAGNEZIX® Pin 2.0 mm

Green: MAGNEZIX® Pin 2.7 mm

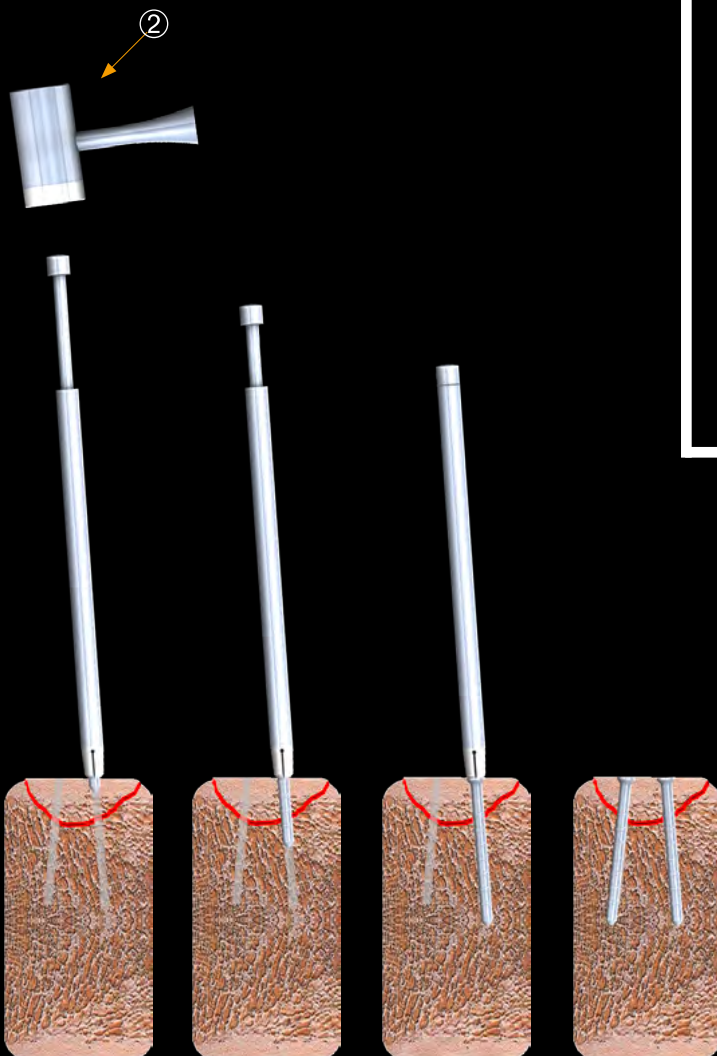
Blue: MAGNEZIX® Pin 3.2 mm

Note: If X-rays are taken in order to intraoperatively evaluate implant positioning by means of fluoroscopy, the irradiated area should be free of any other implants, guide wires, instruments etc. Foreign materials in the irradiated field can raise the X-ray dosage, leading to inadequate exposure of MAGNEZIX® implants (effect of „overexposure“). The effect of overexposure can be reduced by modification of the intensity of radiation.

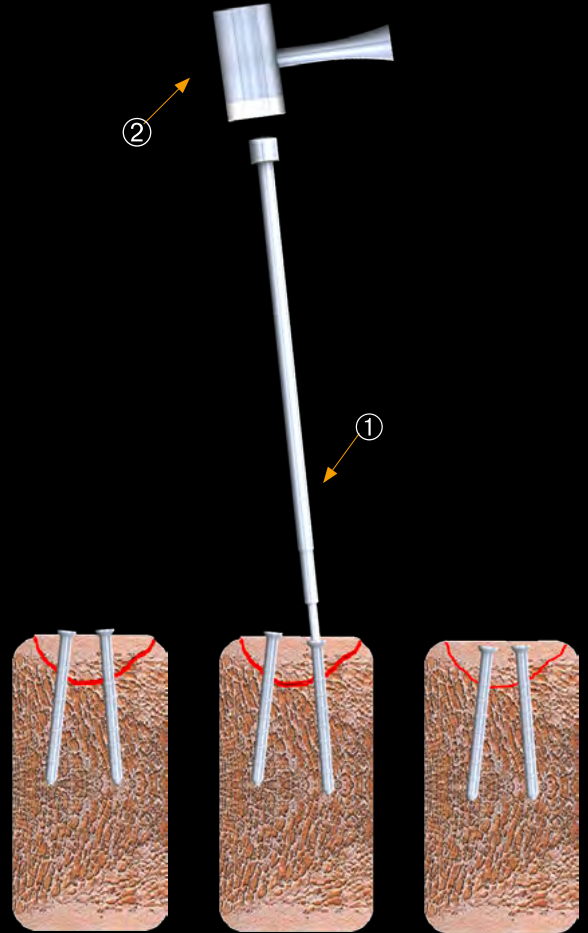
Step 4: Countersinking the pin (optional)

In some cases it is necessary to countersink the pin below the bone surface or subchondrally. For this purpose the bolt of the impactor can be used after introduction of the bone pin. Especially in this application the recess in the head of the pin is helpful when positioning the bolt of the impactor. In addition, this recess reduces the risk of the bolt slipping off the head of the MAGNEZIX® Pin.

STEP 3



STEP 4



- ① 9115.011 Impactor Insert for MAGNEZIX® Pin, Ø 1.5 mm
- 9120.011 Impactor Insert for MAGNEZIX® Pin, Ø 2.0 mm
- 9127.011 Impactor Insert for MAGNEZIX® Pin, Ø 2.7 mm
- 9132.011 Impactor Insert for MAGNEZIX® Pin, Ø 3.2 mm
- ② 9100.000 Hammer 230 g, with plastic insert















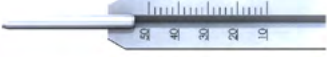

- ① 6115.010 Impactor for MAGNEZIX® Pin Ø 1.5 mm
- 6120.010 Impactor for MAGNEZIX® Pin Ø 2.0 mm
- 6127.010 Impactor for MAGNEZIX® Pin Ø 2.7 mm
- 6132.010 Impactor for MAGNEZIX® Pin Ø 3.2 mm
- ② 9100.000 Hammer 230 g, with plastic insert

MAGNEZIX® Pin 1.5, 2.0, 2.7, 3.2

OVERVIEW INSTRUMENTS AND TRAY



INSTRUMENTS** MAGNEZIX® Pin

Art. No.	Description
	6115.010 Impactor for MAGNEZIX® Pin Ø 1.5 mm, consisting of: 9115.010 Impactor Sleeve for MAGNEZIX® Pin Ø 1.5 9115.011 Impactor Insert for MAGNEZIX® Pin Ø 1.5 9115.012 Impactor Tip for MAGNEZIX® Pin Ø 1.5
	6120.010 Impactor for MAGNEZIX® Pin Ø 2.0 mm, consisting of: 9120.010 Impactor Sleeve for MAGNEZIX® Pin Ø 2.0 9120.011 Impactor Insert for MAGNEZIX® Pin Ø 2.0 9120.012 Impactor Tip for MAGNEZIX® Pin Ø 2.0
	6127.010 Impactor for MAGNEZIX® Pin Ø 2.7 mm, consisting of: 9120.010 Impactor Sleeve for MAGNEZIX® Pin Ø 2.7 9127.011 Impactor Insert for MAGNEZIX® Pin Ø 2.7 9127.012 Impactor Tip for MAGNEZIX® Pin Ø 2.7
	6132.010 Impactor for MAGNEZIX® Pin Ø 3.2 mm, consisting of: 9132.010 Impactor Sleeve for MAGNEZIX® Pin Ø 3.2 9132.011 Impactor Insert for MAGNEZIX® Pin Ø 3.2 9132.012 Impactor Tip for MAGNEZIX® Pin Ø 3.2
	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
	9132.020 Drill Bit Ø 3.2 mm, length 115/90 mm, for quick coupling
	9115.033 Double Drill Guide, for MAGNEZIX® Pin Ø 1.5/2.0 mm
	9127.033 Double Drill Guide, for MAGNEZIX® Pin Ø 2.7/3.2 mm
	9115.040 Reduction Wire Ø 1.5 mm, spade point tip, length 100 mm
	9120.040 Reduction Wire Ø 2.0 mm, spade point tip, length 100 mm
	9127.040 Reduction Wire Ø 2.7 mm, spade point tip, length 100 mm
	9132.040 Reduction Wire Ø 3.2 mm, spade point tip, length 100 mm
	9100.042 Measuring Device, for reduction wires, up to Ø 3.2 mm, for length 100 mm
	9100.045 Depth Gauge for MAGNEZIX® Pin

Not illustrated: 8100.001 Sterilizing Tray for MAGNEZIX® Pin, without contents
8100.002 Lid for Sterilizing Tray, for MAGNEZIX® Pin
9100.000 Hammer 230 g, with plastic insert, optional
9100.001 Plastic Insert, spare part

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

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