MAGNEZIX®

StarFuse®

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 have not been 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

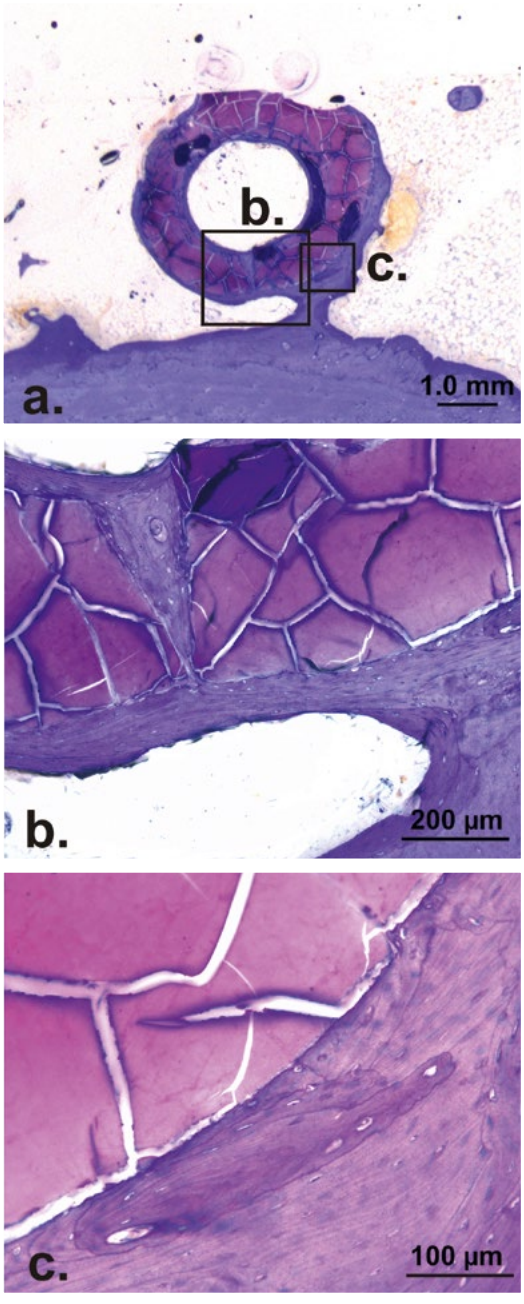
MAGNEZIX® is a trademark for CE-certified implants manufactured from the world's first bioabsorbable material consisting of a magnesium alloy (MgYREZr) for medical applications.

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 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 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 (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]

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.



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Waizy et al: In vivo study of a biodegradable orthopedic screw (MgYREZr-alloy) in a rabbit model for up to 12 months. Journal of Biomaterials Applications Vol 28, Issue 5, pp. 667-675.

[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.

MAGNEZIX® StarFuse®

INTENDED USE

The MAGNEZIX® StarFuse® is a bioabsorbable intramedullary arthrodesis implant that is intended for adaptation-capable or exercise-capable fixation of small bone reconstruction limited to interphalangeal fusion of the lesser toes. The implant is designed for single use.

INDICATIONS

The indications for MAGNEZIX® StarFuse® implants are small bone reconstruction procedures after malalignment in the human skeleton. The surgeon must determine the degree of the deformity 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 and angulation, the MAGNEZIX® StarFuse® can be used for adaptation-capable or exercise-capable fixation of osteotomies and reconstruction procedures limited to interphalangeal arthrodesis of the lesser toes.

CONTRAINDICATIONS

MAGNEZIX® StarFuse® implants are contraindicated in specific clinical situations or they should only be planned and used after careful consideration.

Absolute contraindications:

- PAOD (peripheral arterial occlusive disease)
- insufficient or avascular bone mass for anchorage of the implant
- confirmation or suspected septic infectious surgical site
- load-bearing stable osteosynthesis
- arthrodeses of medium-sized and large joints

Relative contraindications:

- options for conservative treatment
- no options for adequate postoperative treatment (e.g. temporary strain relief)
- application in the area of the epiphyseal plates
- uncooperative patient or patient with restricted intellectual capacity
- alcohol, nicotine and/or drug abuse
- poor skin/soft tissue conditions
- osteoporosis
- acute sepsis
- epilepsy

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.

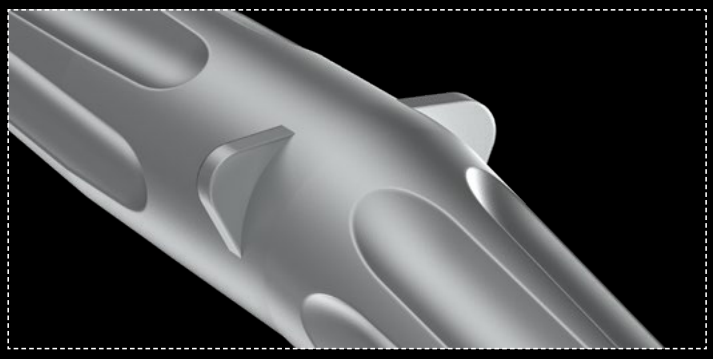
Increased stability
The mechanical properties of MAGNEZIX® implants are significantly better than those of conventional resorbable implants.

Radiologic visibility
MAGNEZIX® implants are radiologically visible and generate significantly less imaging artifacts compared with titanium or steel implants[5]. This allows a good level of control of implant position as well as bone consolidation.

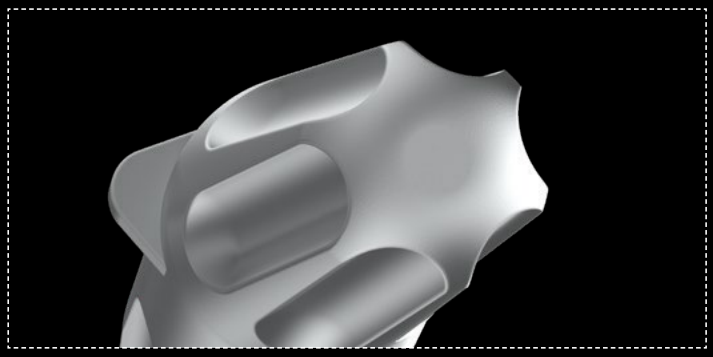
Implant removal
In case the biodegradation process is advanced, the implant can be drilled out with a conventional drill bit. Special instruments are not required.

Patient satisfaction
Intramedullary implant design eliminates discomfort associated with external pins.

[5] 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.

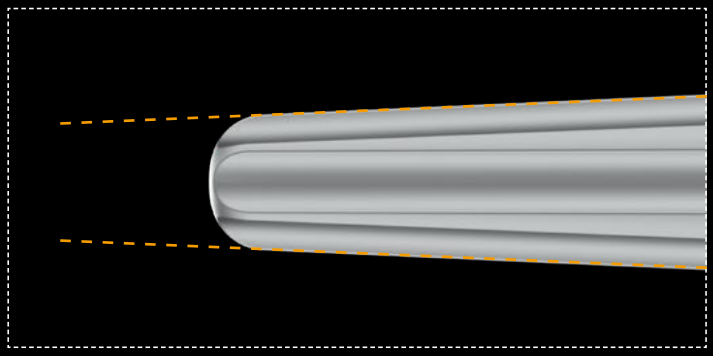


Patented wing design
Two small-sized wings act as a mechanical stop during insertion and following reduction of the more distal phalanx. This innovative design feature ensures stable axial implant positioning.

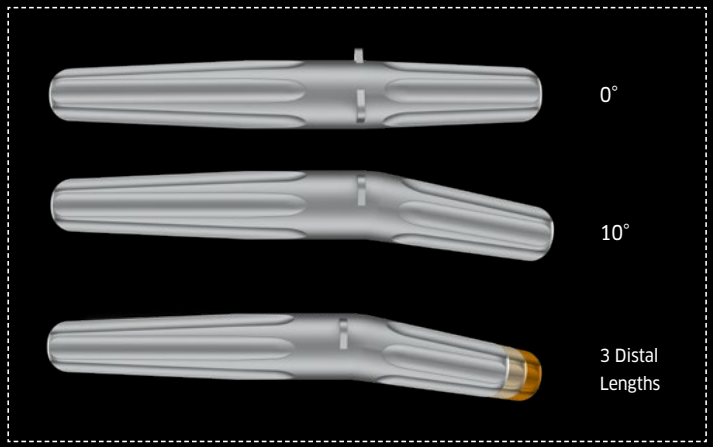


Star-shaped profile
Deep cutting longitudinal flutes guarantee proper rotational stability for optimal fixation.

Blunt ends
The blunt end design ensures secure implant position via reducing the risk of axial implant displacement.



Tapered design
The conical shape of the proximal and distal end allows fast and easy insertion. This design aspect further achieves proper intra-medullar press-fit anchoring.



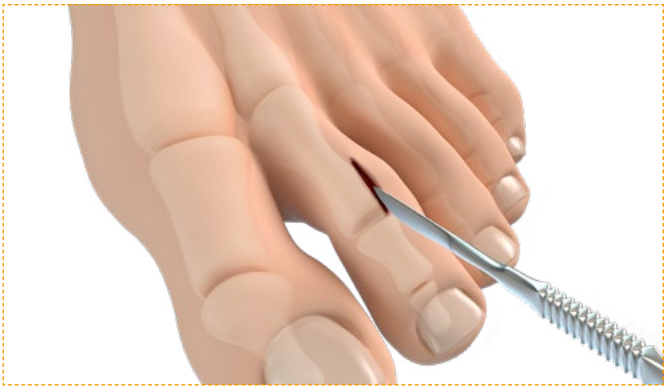
Multiple sizes
The implants are available in two angles, 0° and 10°, with three different distal lengths each.

SURGICAL TECHNIQUE PIP ARTHRODESIS

The following surgical technique demonstrates one possible procedure for the use of MAGNEZIX® StarFuse® and serves as an example of how to handle implant and instruments. All handling instructions also apply to other techniques in which MAGNEZIX® StarFuse® can be used.

ACCESS AND JOINT SURFACE PREPARATION

① The proximal interphalangeal joint is approached through a longitudinal or transverse access. Resection of articular surfaces of the proximal phalanx (P1) and middle phalanx (P2) according to usual techniques. The use of the calcar reamer is recommended to obtain a flat bone surface. Subchondral bone should be preserved as much as possible.



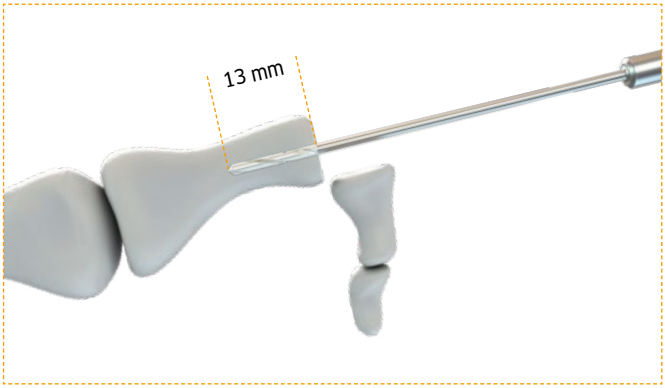
Choosing the implant

The appropriate implant is selected based on the patient's toe morphology. The implant length is determined corresponding to the size and quality of the bone. Angulations of 0° (neutral design) and 10° are available. The implant is chosen according to the plantar flexion desired.

PROXIMAL PHALANX (P1) – INTRA MEDULLAR PREPARATION

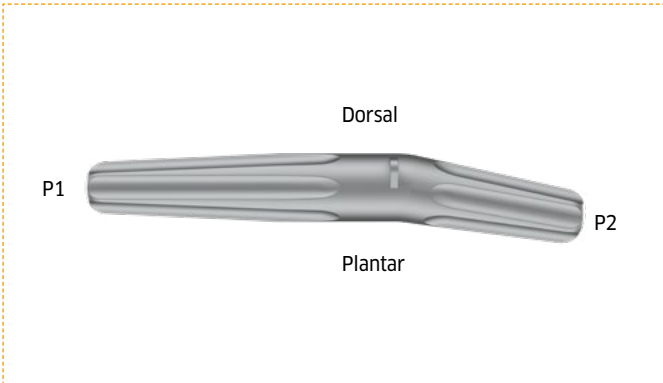
② **Pre-drilling**

Use the drill bit to create a central hole in the cancellous bone. Insert the drill along the central axis of P1 until the flutes are buried.



③ **Proximal punch**

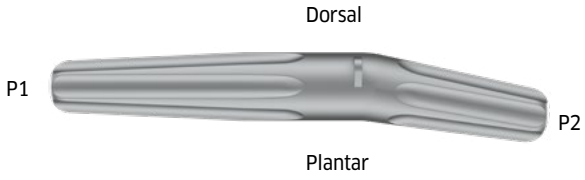
Further insert and fully seat the proximal punch into P1 up to its shoulder contacts the resection margin. Instruments should be kept on axis during application. **Note:** The punches are labelled with “PROXIMAL” for use in P1 and “DISTAL” for use in P2.



MIDDLE PHALANX (P2) – INTRA MEDULLAR PREPARATION

④ **Distal punch**

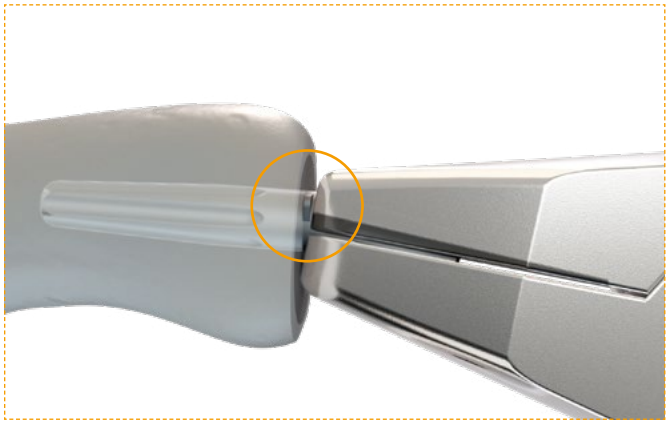
Insert and fully seat the distal punch into P2 up to the depth stop.



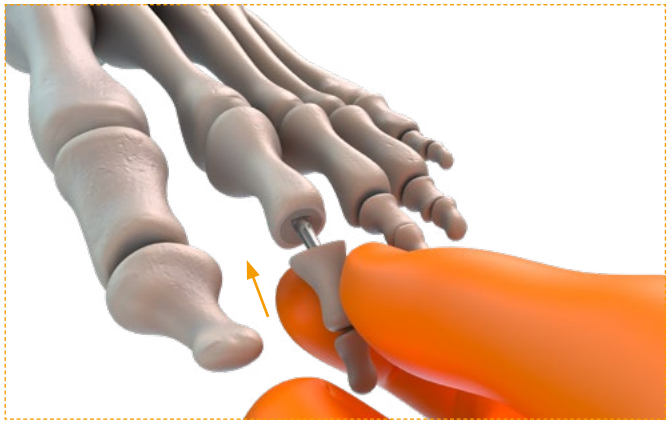
IMPLANT INSERTION

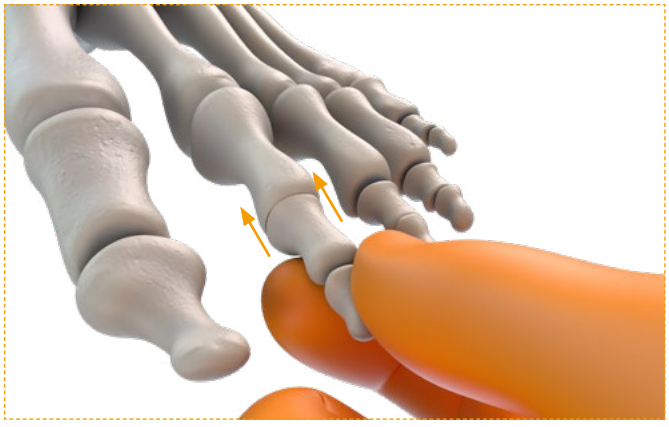
⑤ For implant insertion, the shorter (distal) part of the implant is secured within the jaws of the holding forceps. To prevent the implant from any potential damages, make sure that the wings are located outside the jaws. Thus, it is recommended to insert the implant while the holding forceps is closed.

⑥ The longer end of the implant is inserted into P1, up to the mechanical stop (realized by the wings) is reached. In case an angulated size is chosen, special care should be taken to ensure correct implant orientation.
Note: Deep cutting longitudinal flutes guarantee proper rotational stability. Care should be taken to avoid any rotational implant movements during and after insertion. These actions can negatively affect implant anchoring.

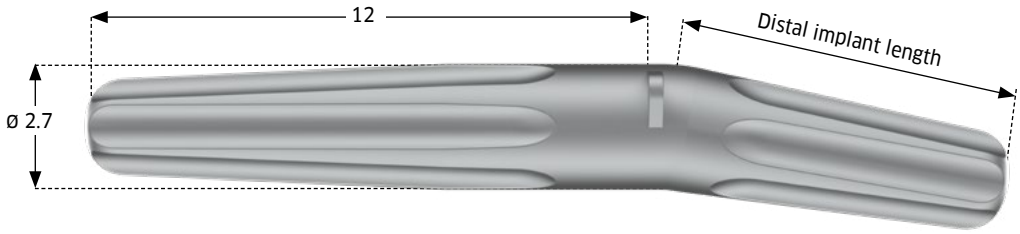


⑦ P2 is reduced over the distal part of the implant. Good bone contact is achieved by manual compression of the joint surfaces. To obtain good reconstruction results, the implant must be fully inserted into P1 and P2. Both wings should have direct contact to the adjacent resection surfaces.
Note: Potential gaps at the osteotomy site must be avoided to facilitate optimal bony fusion.





MAGNEZIX® StarFuse®

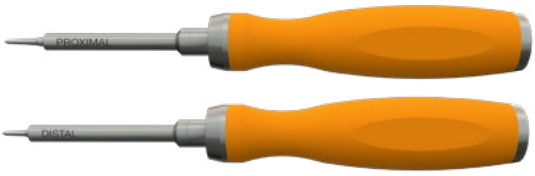


Item Number	Description	Proximal length [mm]	Distal length [mm]	Angle
1427.126.00	MAGNEZIX® StarFuse® Short 0°	12	6	0°
1427.126.10	MAGNEZIX® StarFuse® Short 10°	12	6	10°
1427.127.00	MAGNEZIX® StarFuse® Medium 0°	12	7	0°
1427.127.10	MAGNEZIX® StarFuse® Medium 10°	12	7	10°
1427.128.00	MAGNEZIX® StarFuse® Long 0°	12	8	0°
1427.128.10	MAGNEZIX® StarFuse® Long 10°	12	8	10°

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

INSTRUMENTS MAGNEZIX® StarFuse®

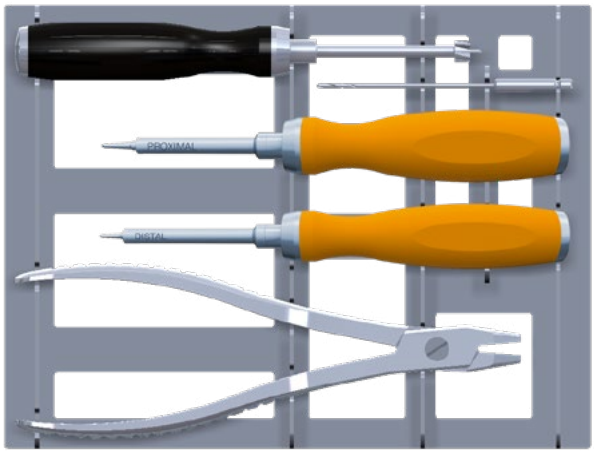
Art. No.	Description
9427.001	StarFuse® Calcar Reamer
9427.020	Drill Bit Ø 1.5 mm, length 85/60 mm, for Quick Coupling



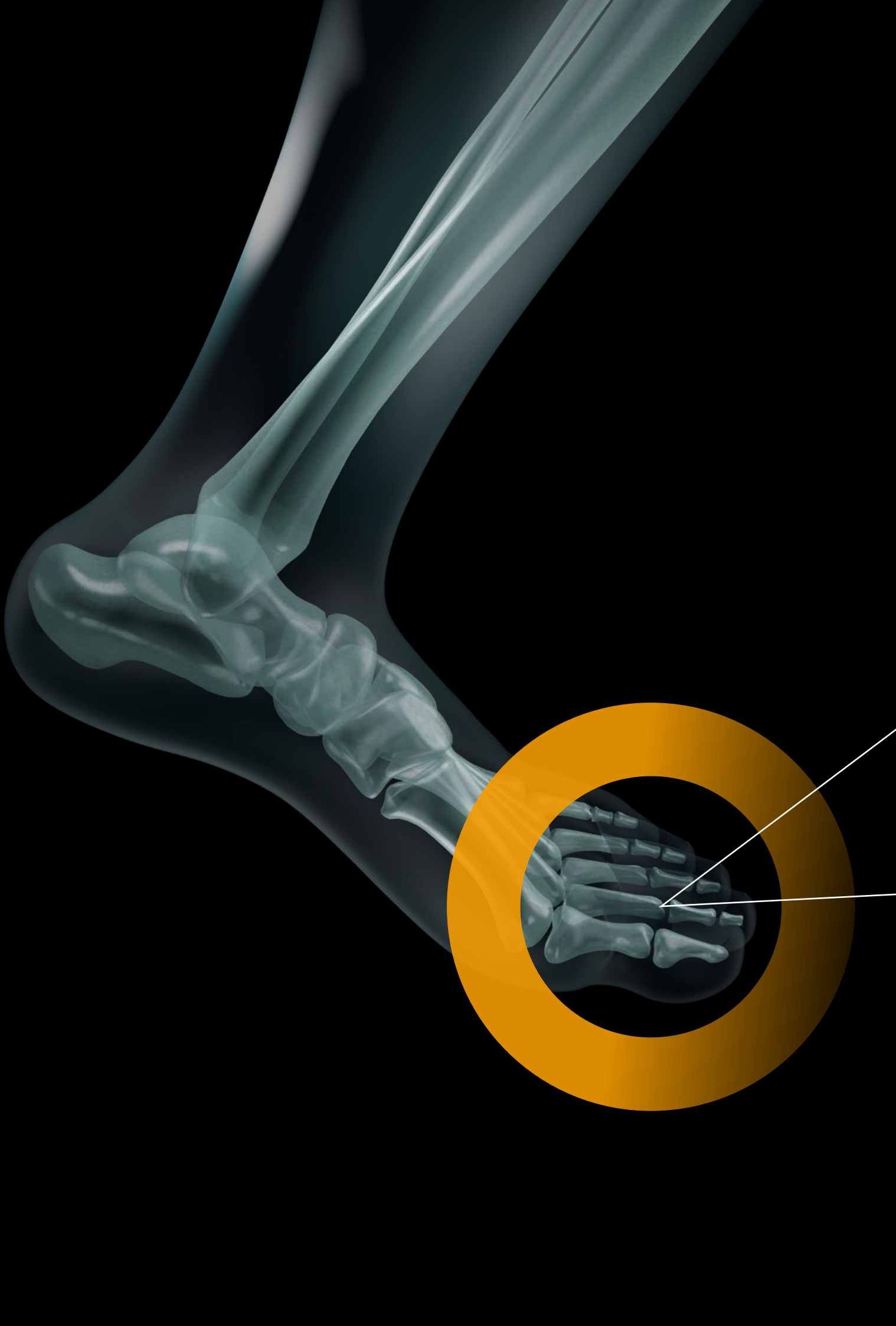
9427.003	Punch, proximal, with depth stop
9427.004	Punch, distal, with depth stop

9427.002	StarFuse® Holding Forceps

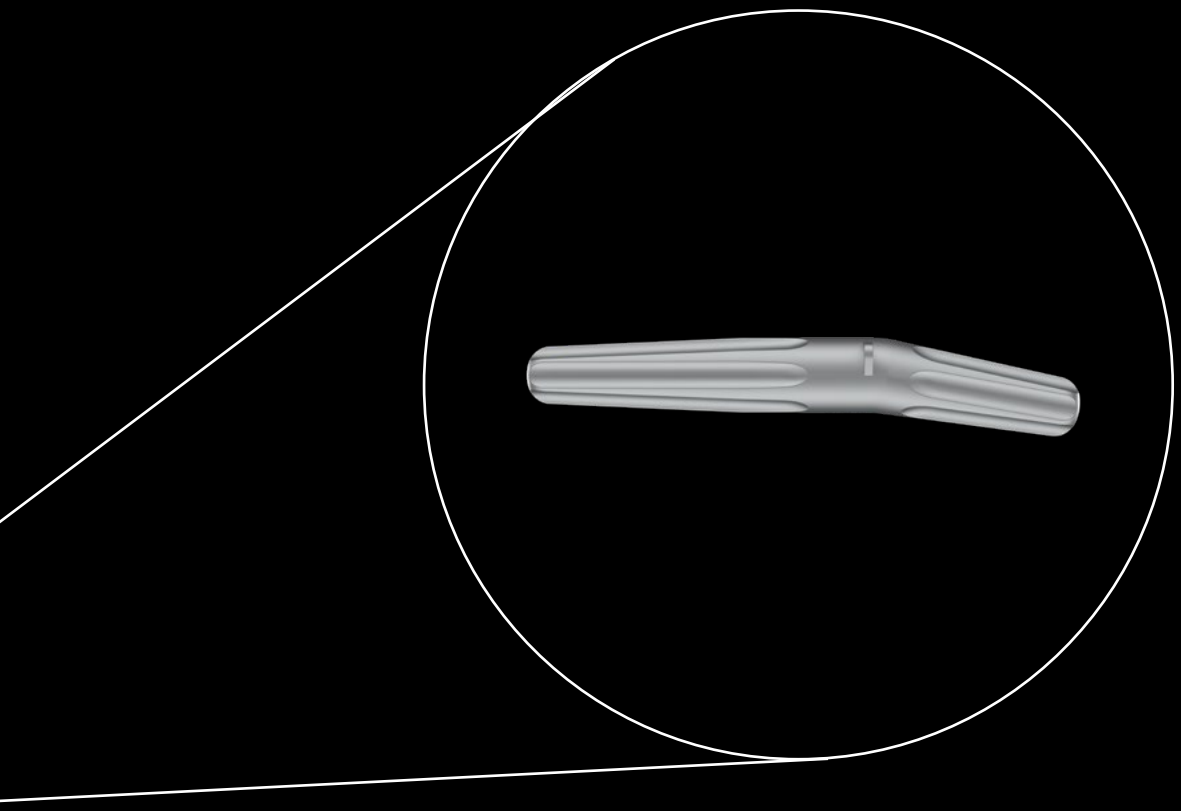
8400.001	Sterilization Tray for MAGNEZIX® StarFuse®, without contents
8400.002	Lid for Sterilization Tray for MAGNEZIX® StarFuse®
8400.003	Insert for Sterilizing Tray for MAGNEZIX® StarFuse®



The figures are not to scale.



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



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INNOVATIONSPREIS DER DEUTSCHEN WIRTSCHAFT Sieger 2012/13

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

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