

MAGNEZIX^{M3}
IFSC
Product Information

Intelligent innovations for a better life.



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 implants 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).

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THE MAGNEZIX® MATERIAL

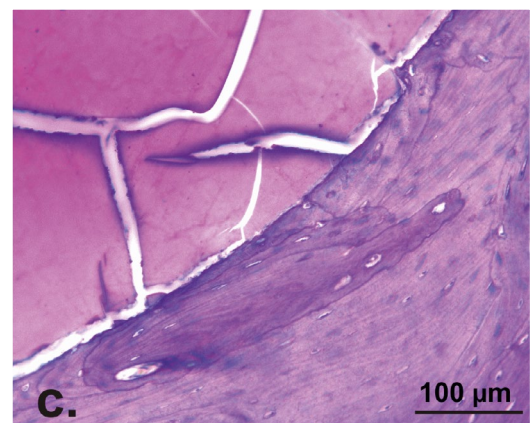
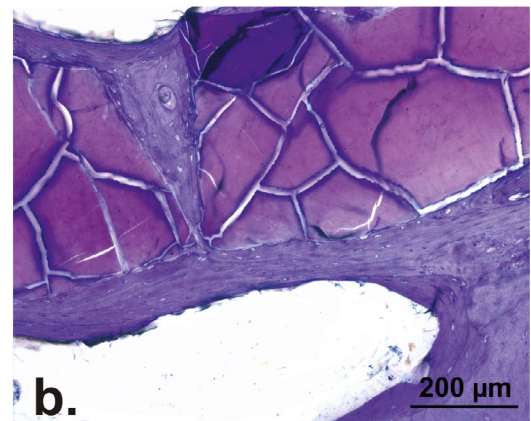
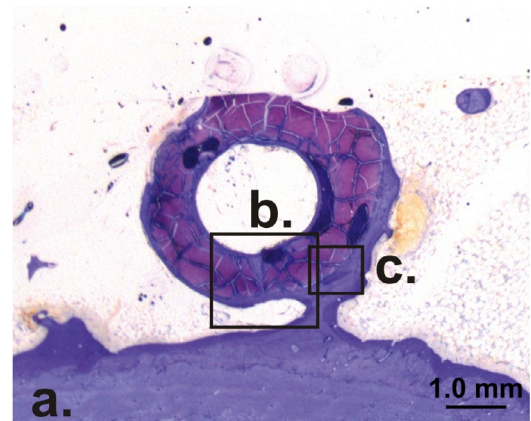
MAGNEZIX® is a trademark for the world's first bioabsorbable material consisting of a magnesium alloy (MgYREZr) for medical applications.

The biomechanical properties are very similar to those of human bone. MAGNEZIX® gradually transforms within the human body and is replaced by endogenous tissue. Experimental studies also confirm that magnesium has an osteoconductive¹ effect and tends to inhibit infection.²

Advantages for users and patients

- There is 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 already transformed implant zones.
- The use of MAGNEZIX® implants does not lead to so-called "stress shielding" (bone atrophy due to shielding from load) due to the bone-like mechanical properties.³
- In terms of application, MAGNEZIX® implants hardly differ from conventional implants. This is ensured by the adapted design, which takes the material and the transformation properties into account.
- MAGNEZIX® implants are radiologically visible, MRI-conditional and only generate minimal artifacts (see also the IFU).⁴
- The MAGNEZIX® IFS^c has a highly innovative surface finish.⁵ The transformation is therefore postoperatively delayed in the first months.

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.



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.

⁵ Ceramised MAGNEZIX® products are marked using a superscript "C" in connection with the product acronym.

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

MAGNEZIX® IFS^c

INTENDED USE

The MAGNEZIX® IFS^c is a bioabsorbable interference screw that is used in cruciate ligament reconstruction for fixation of soft tissue- or bone-tendon grafts in a press-fit technique. The implant is designed for single use.

INDICATIONS

The indications for MAGNEZIX® IFS^c implants are orthopedic reconstructive procedures for interference fixation of soft tissue- or bone-tendon-bone grafts to 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® IFS^c can be used as an interference screw as part of cruciate ligament reconstructions to secure soft tissue- or bone-tendon grafts in tibia or femur using the press-fit technique.

CONTRAINDICATIONS

MAGNEZIX® IFS^c 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
- confirmation or suspected septic infectious surgical site
- application in the area of the epiphyseal plates
- infection
- arthritis

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

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.

Surface design

The top layer of MAGNEZIX® IFS^c implants is converted into a dense, porous and strongly adherent magnesium-based oxide film. This surface finish acts as a protective layer and is fully bioabsorbable. A significant reduction in the degradation progress is achieved to maintain the desired integrity of the implant for an extended period of time.

Superior stability

Optimized mechanical properties reduce the risk of screw breakage during implant insertion. Material strength allows for screw insertion without tapping.

Secure insertion

The hexagonal recess design ensures optimal torque transmission. A self-retaining mechanism is implemented to facilitate safe and stable screw insertion.

Head geometry

Universal screw head design allows for use in tibial and femoral transplant fixation.

Optimized thread design

The rounded thread geometry ensures graft protection during screw insertion. Excellent fixation is provided for both soft tissue- and bone-tendon transplants.

HINTS

In isolated cases, temporary radiolucencies may be observed around the implant.

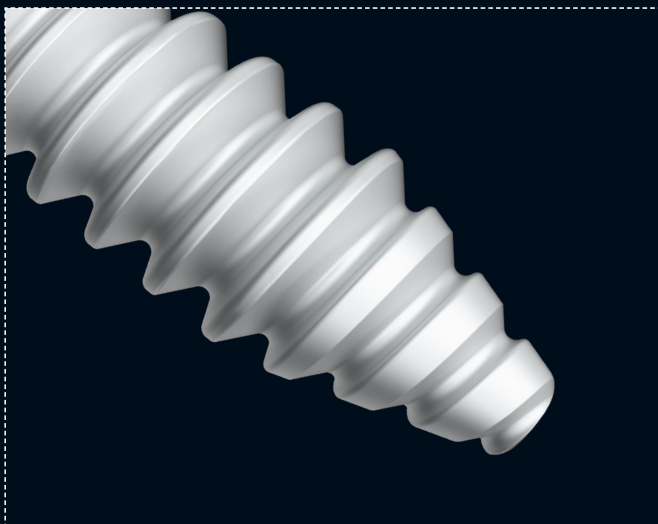
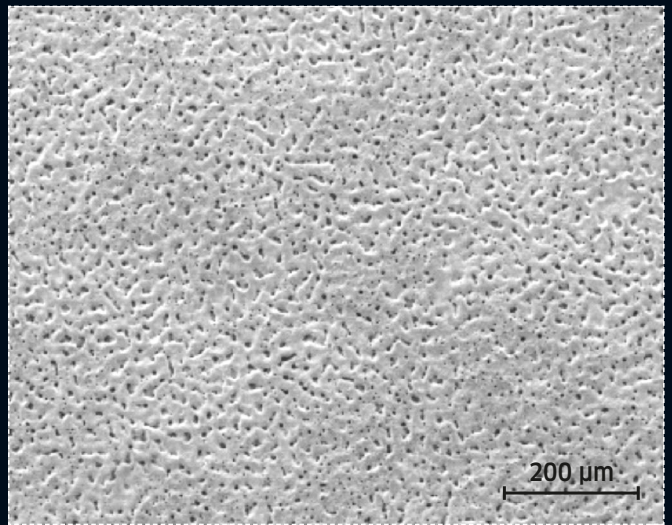
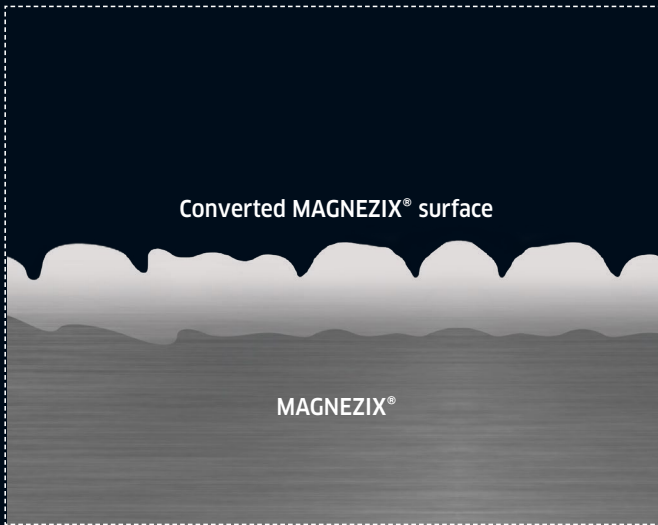
It is recommended to mention this phenomenon in the operative report and physician's letter, pointing out that, based on present knowledge, this does not have any relevant influence on the process of healing. This will inform the caregivers involved in the follow-up treatment of the special aspects of 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 implants 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.



SURGICAL TECHNIQUE

ANTERIOR CRUCIAL LIGAMENT (ACL)



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

Prior to implanting a MAGNEZIX® IFS^c it is necessary to perform several usual surgical steps that are not implant-related.

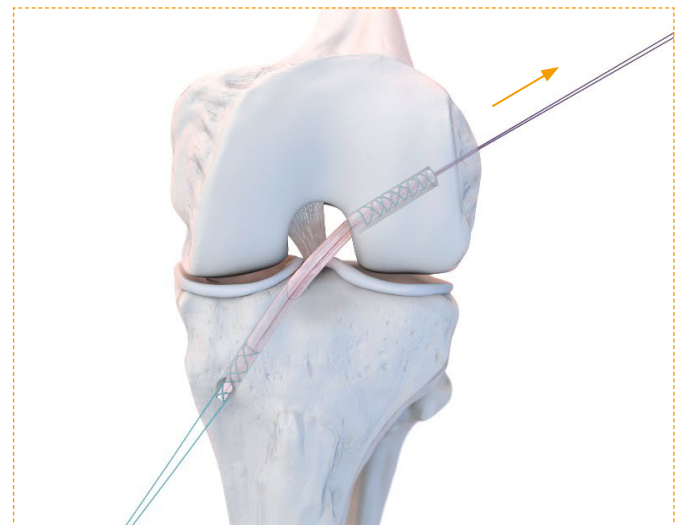
These include:

- graft harvesting, preparation and sizing
- femoral and tibial tunnel preparation
- implant sizing

NOTE: The use of common procedure-related instruments and corresponding techniques are not addressed within this document.

INTRODUCING THE GRAFT

The graft is introduced into the tibial and femoral tunnel and positioned according to usual techniques.



FEMORAL FIXATION

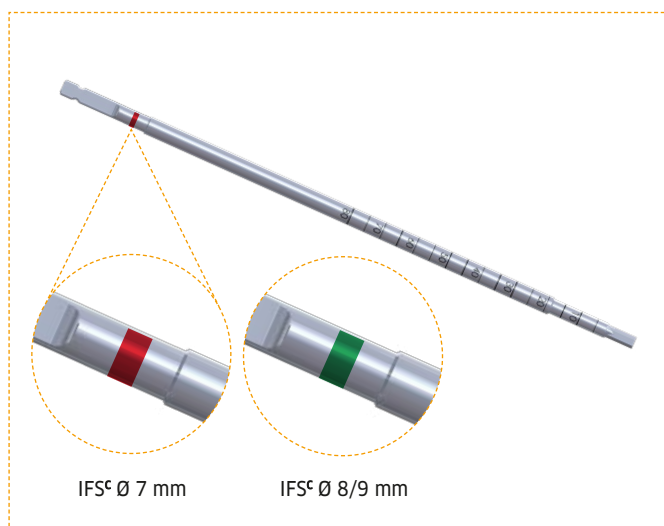
① Tunnel notching (optional)

The tunnel notcher is used for creating a groove into the wall of the bone tunnel. Therefore, the instrument is inserted until the fin is buried. The resulting vacant pathway facilitates guide wire placement and enhances precise screw insertion.

② Guide wire insertion

A nitinol guide wire is introduced between the tunnel wall and graft at the desired screw location.

CAUTION: Nitinol consists of nickel as major alloying element. A nitinol wire should not be used in patients that are prone to allergic or sensitivity reactions caused by nickel.



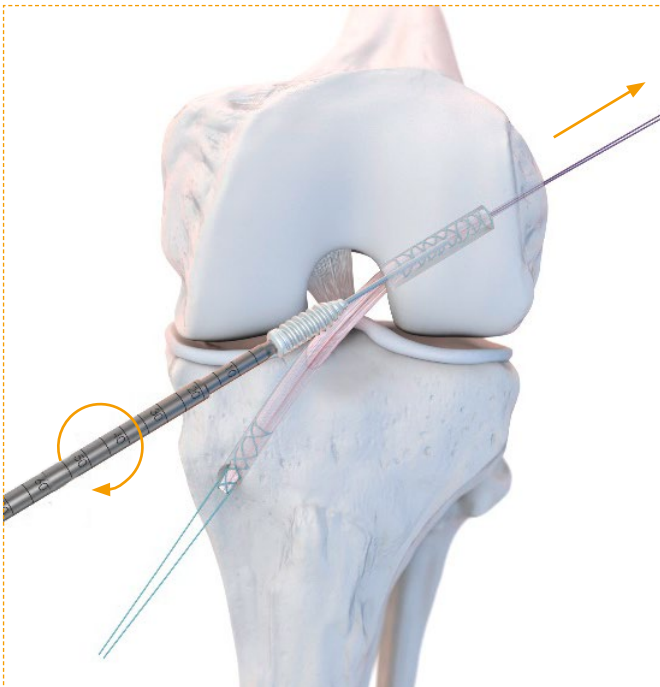
③ Choosing the implant

The appropriate screw dimension is chosen based on graft and tunnel size as well as bone quality.

Colour-coded screwdriver blades are explicitly only to be used for the corresponding screw size:

- IFS^c Ø 7 mm: Screwdriver Blade Hex 3.0 mm (red)
- IFS^c Ø 8 or 9 mm: Screwdriver Blade Hex 3.5 mm (green)

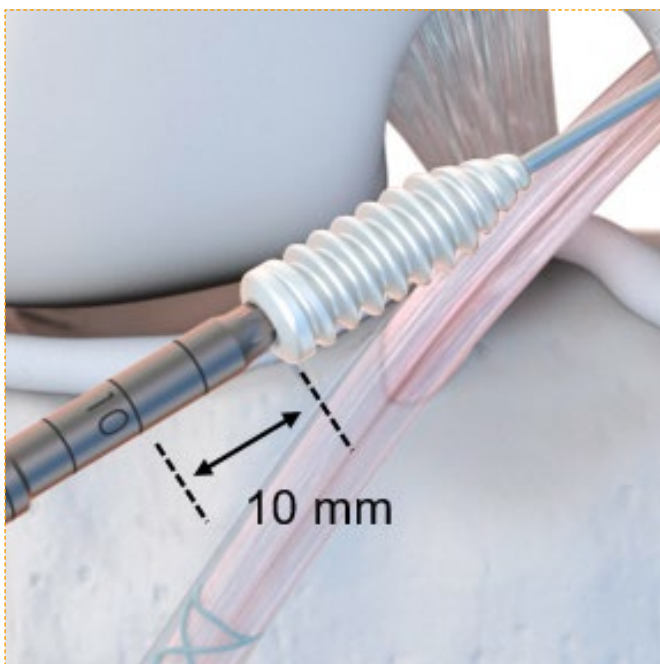
NOTE: Push the screw firmly towards the screwdriver blade to achieve secure self-retaining purchase.



④ Implant insertion

While appropriate tension is maintained on the graft, the screw is introduced over the guide wire and fully inserted into the bone tunnel. Ensure that the instruments remain parallel to the bone tunnel during application. Pay attention to place the implant below the bone surface to avoid soft tissue irritation and screw protrusion.

Once the implant is in its final position, guide wire and screwdriver are removed.



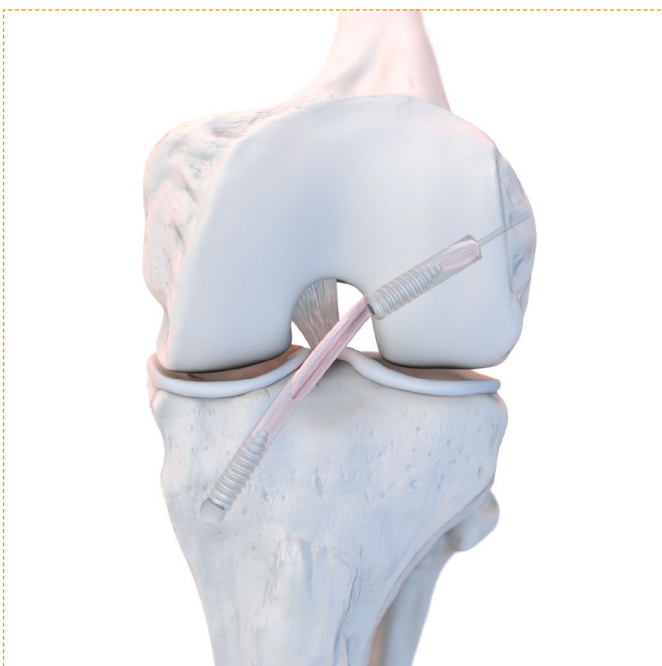
NOTE: The value indicated by the scale on the screwdriver blade refers to the distal end (rounded head) of the screw. To get information on the full insertion depth, the length of the chosen implant has to be added.



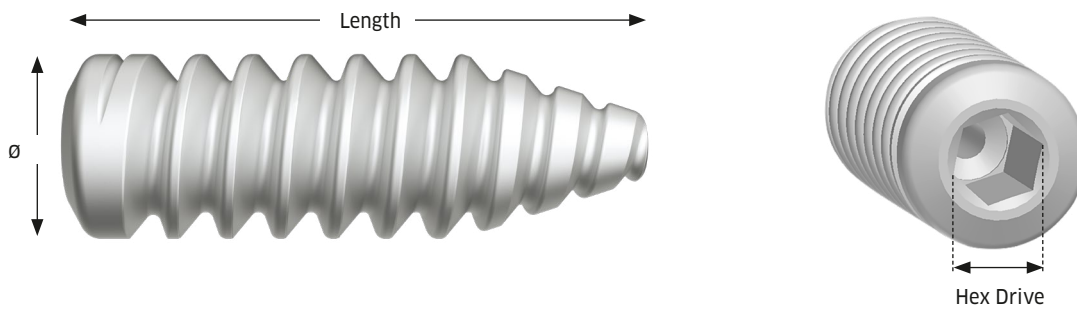
TIBIAL FIXATION

For screw fixation at the tibial side, repeat steps ① - ④.
Sufficient graft tension has to be maintained until the transplant is fully secured.

Any excess graft and suture is removed.









MAGNEZIX® IFSC[©]



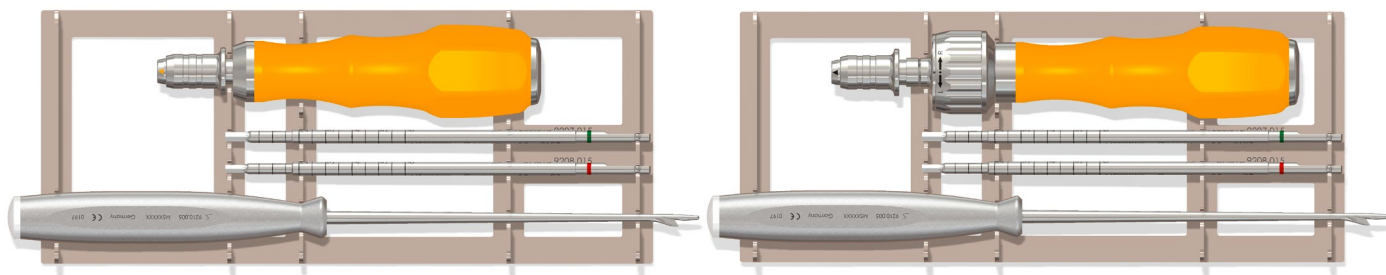
Item Number	Diameter [mm]	Length [mm]	Hex Drive [mm]
2207.020	7	20	3.0
2207.025	7	25	3.0
2207.030	7	30	3.0
2208.020	8	20	3.5
2208.025	8	25	3.5
2208.030	8	30	3.5
2209.025	9	25	3.5
2209.030	9	30	3.5

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

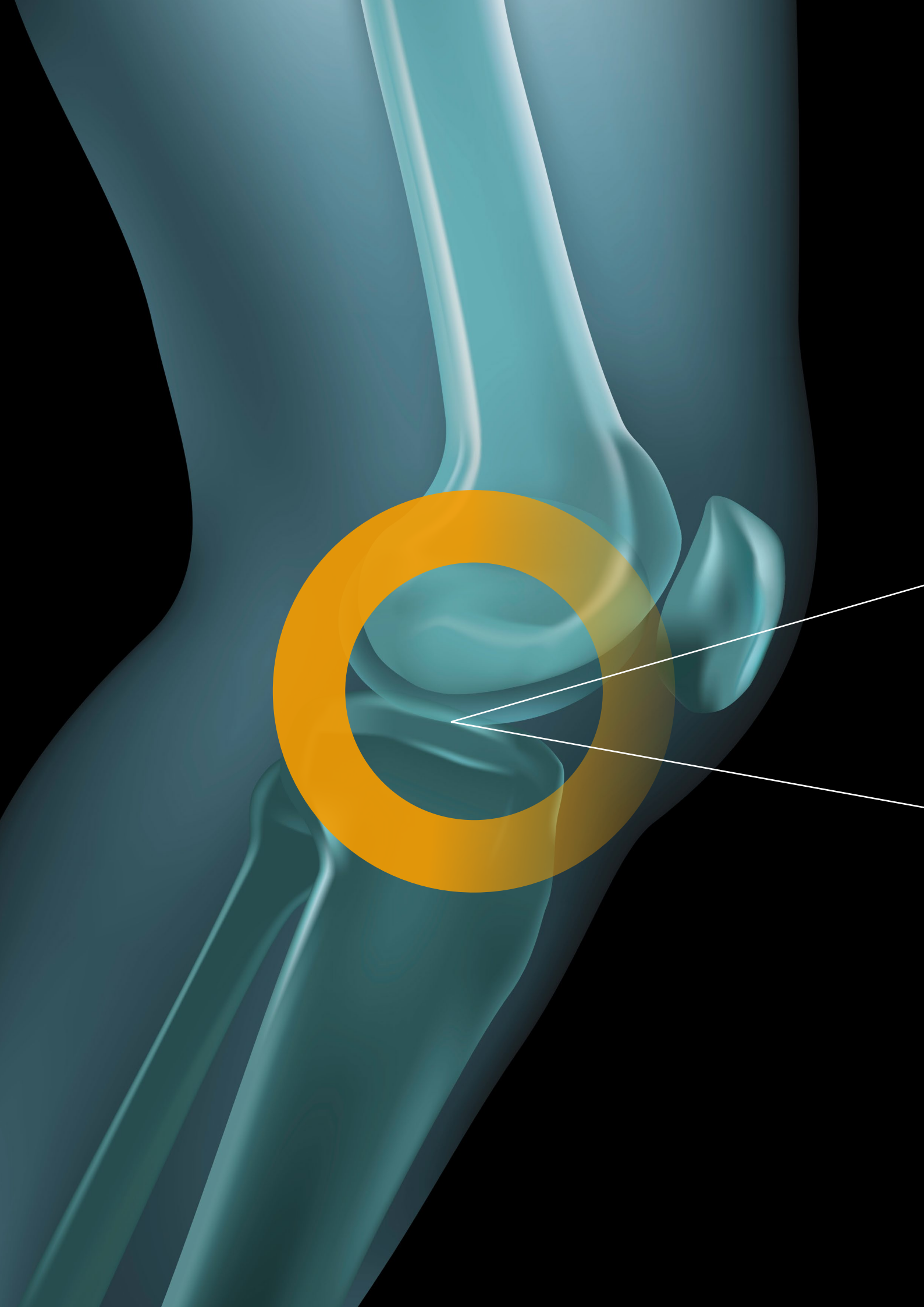
INSTRUMENTS MAGNEZIX® IFS[®]

	Art. No.	Description
	9207.015	Screwdriver Blade Hex 3.0 mm, cannulated, for Quick Coupling
	9208.015	Screwdriver Blade Hex 3.5 mm, cannulated, for Quick Coupling
	9099.005	Non-Ratcheting Screwdriver Handle IFS [®] , with Quick Coupling
	9210.005	Tunnel Notcher for IFS [®]
	9207.040	Nitinol Guide Wire Ø 1.1 mm, length 38.5 cm, non-sterile
	9099.006	Optional Instruments Ratcheting Screwdriver Handle IFS [®] , with Quick Coupling
	8200.001	Sterilizing Tray IFS [®] , without contents
	8200.002	Lid IFS [®]
	8200.003	Insert Sterilizing Tray IFS [®]

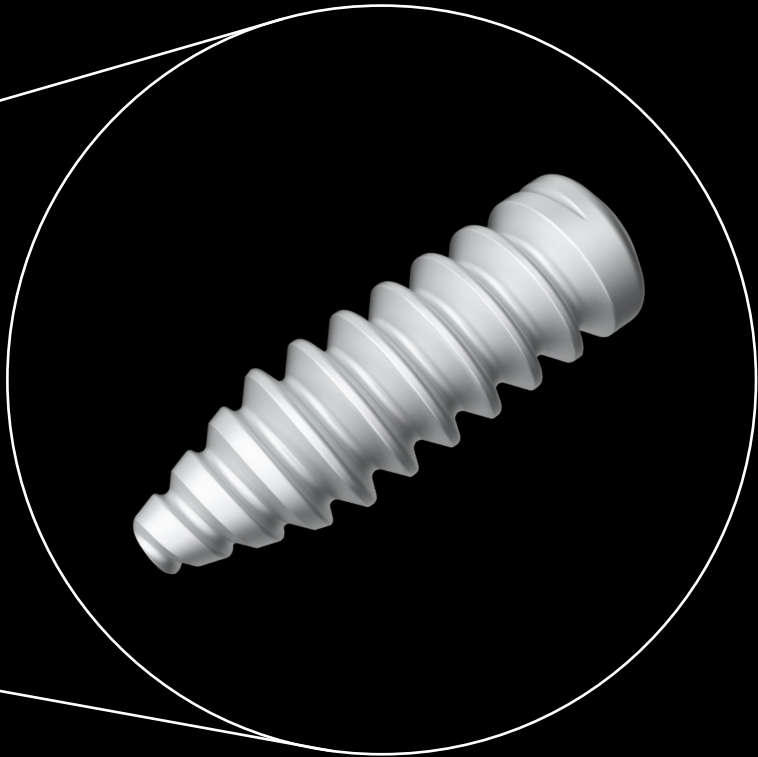
Tray configuration



The figures are not to scale.



METALLIC AND TRANSFORMABLE.
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A MEDICAL SENSATION.
MAGNEZIX®



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