



MAGNEZIX^{M3}

Pin Product information

Intelligent innovations for a better life.

 SYNTELLIX

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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-sterilised. These implants should be discarded.
When other metal implants made of steel, titanium, cobalt-chromium alloys or similar metal alloys are implanted at the same time, it is important to note the following: metal implants that are not made from MAGNEZIX® must not be in direct contact with a MAGNEZIX® implant for an extended period; such contact may only be temporary during the period of the operation. Direct contact means that the implants physically touch one another.

The cover illustration is a CAD image. It is not an accurate representation of the actual implant.

MAGNEZIX® Pin

THE MAGNEZIX® MATERIAL

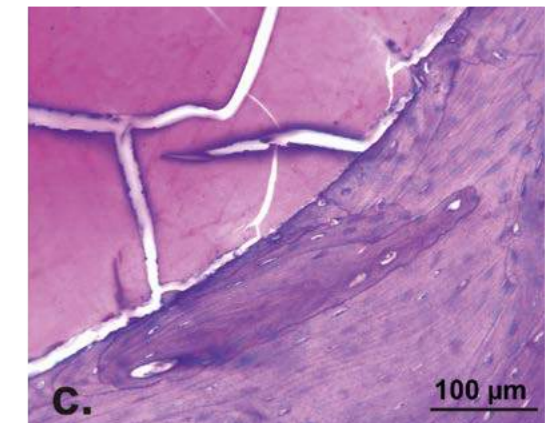
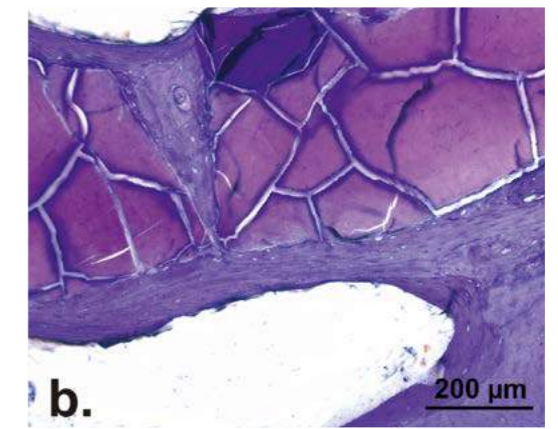
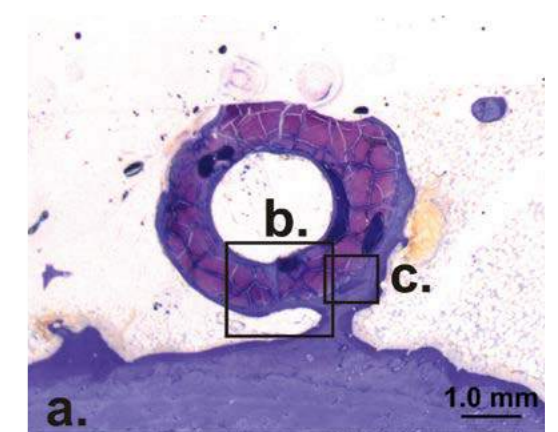
MAGNEZIX® is the name of the world's first bioabsorbable material that consists of a metal alloy and has been awarded the CE medical devices mark for medical applications in Europe.

MAGNEZIX® is a magnesium-based alloy, and despite having metallic properties, it completely degrades within the body and is replaced by endogenous tissue. The biomechanical properties of MAGNEZIX® are very similar to those of human bone. Some studies have also shown that magnesium alloys exhibit osteoconductive¹ properties.

Advantages for users and patients

- Complete absorption of the implant makes subsequent metal removal unnecessary.
- The mechanical properties are significantly better than with conventional resorbable implants.
- There is a complete homogeneous conversion of the implant to the patient's endogenous tissue.
- 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.
- In terms of application, MAGNEZIX® implants hardly differ from conventional implants. This is ensured by the adapted design, which takes the material properties and bioabsorption properties into account.
- MAGNEZIX® implants are radiologically visible, MRI-proof and only generate minimal artifacts (see also the IFU regarding this).

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.



© MHH Orthopaedic Clinic

¹ Revell et al.: The effect of magnesium ions on bone bonding to hydroxyapatite coating on titanium alloy implants. Key Eng Mater 2004;254-256:447-50.
Liu et al.: Magnesium directly stimulates osteoblast proliferation. J Bone Miner Res 1988;3:104.
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.

SAGE Publications Ltd. Alle Rechte vorbehalten 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, 03.01.2013

INTENDED USE

The MAGNEZIX® Pin is a bioabsorbable 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 bioabsorbable 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 dissecates

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).

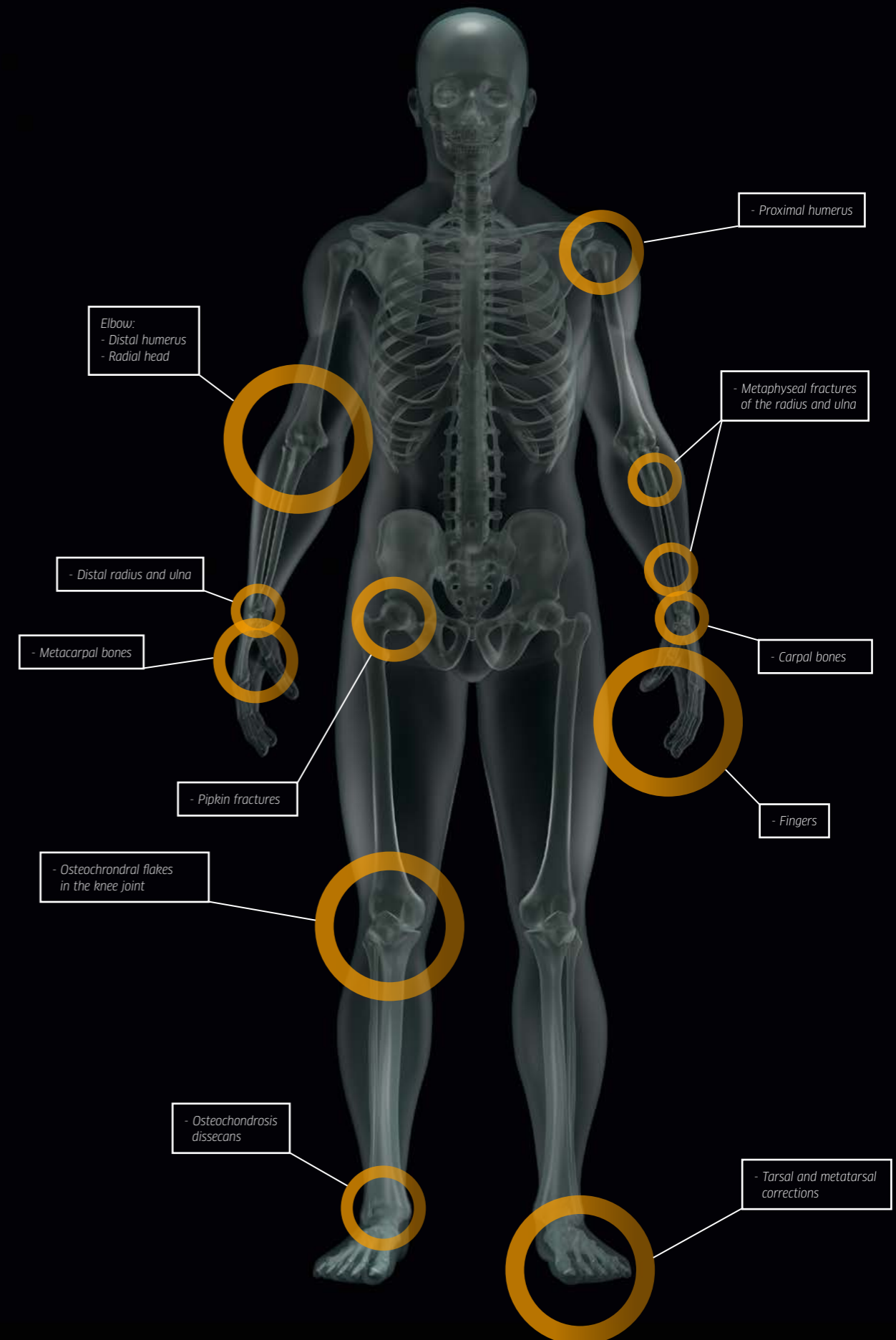
Absolute Contraindications:

- 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)

EXAMPLES OF APPLICATIONS



ADVANTAGES AND FEATURES

BIOABSORBABLE MAGNESIUM ALLOY

Use of MAGNEZIX® implants makes any subsequent implant removal unnecessary, and moreover, it supports the osseous healing process. MAGNEZIX® is bioabsorbable, 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

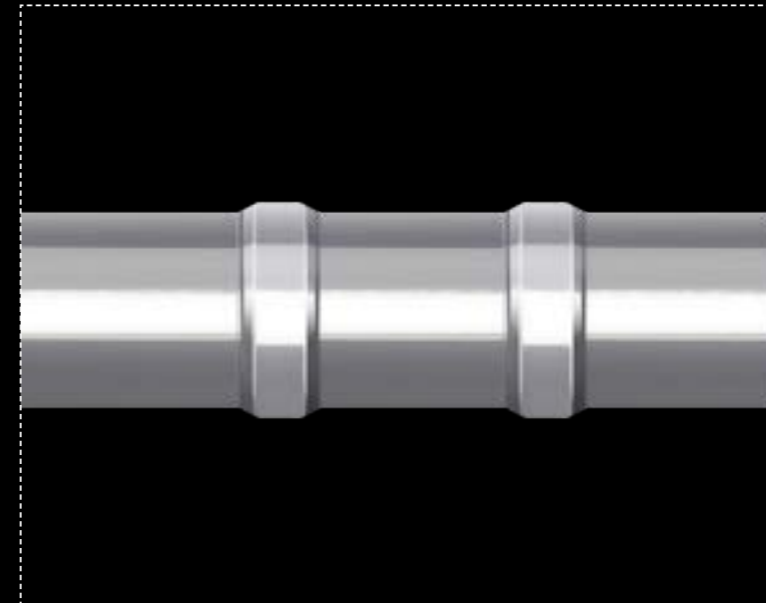
The tip design of the MAGNEZIX® Pin displaces cancellous bone and thus compresses the implant bed. The pin tip without any collars facilitates positioning of the MAGNEZIX® Pin in the pre-drilled implant bed.

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.

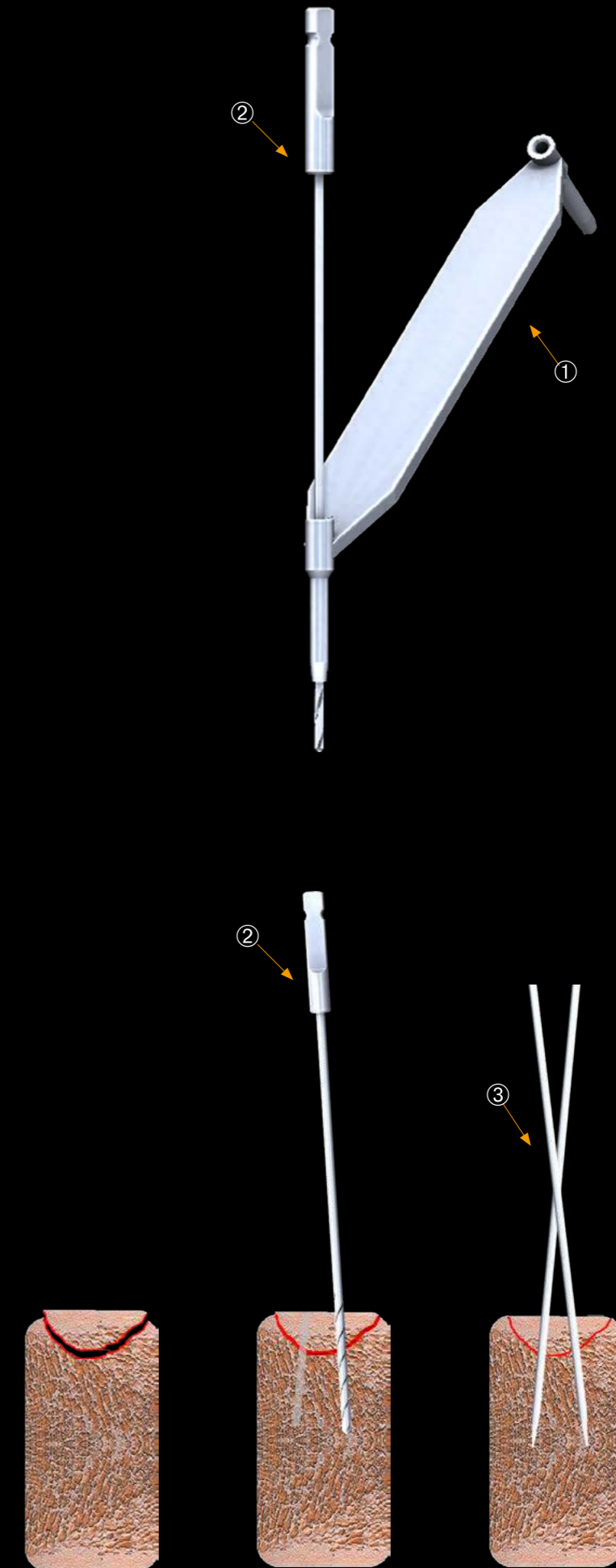
Instruments used

- ① 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
- 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
- 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 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

STEP 1



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.

Instruments used

- ① 9100.042 Measuring Device, for reduction wires up to Ø 3.2 mm, for length 100 mm

Optional:

- ② 9100.045 Depth Gauge for MAGNEZIX® Pin

STEP 2



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.

Instruments used

- 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

STEP 3

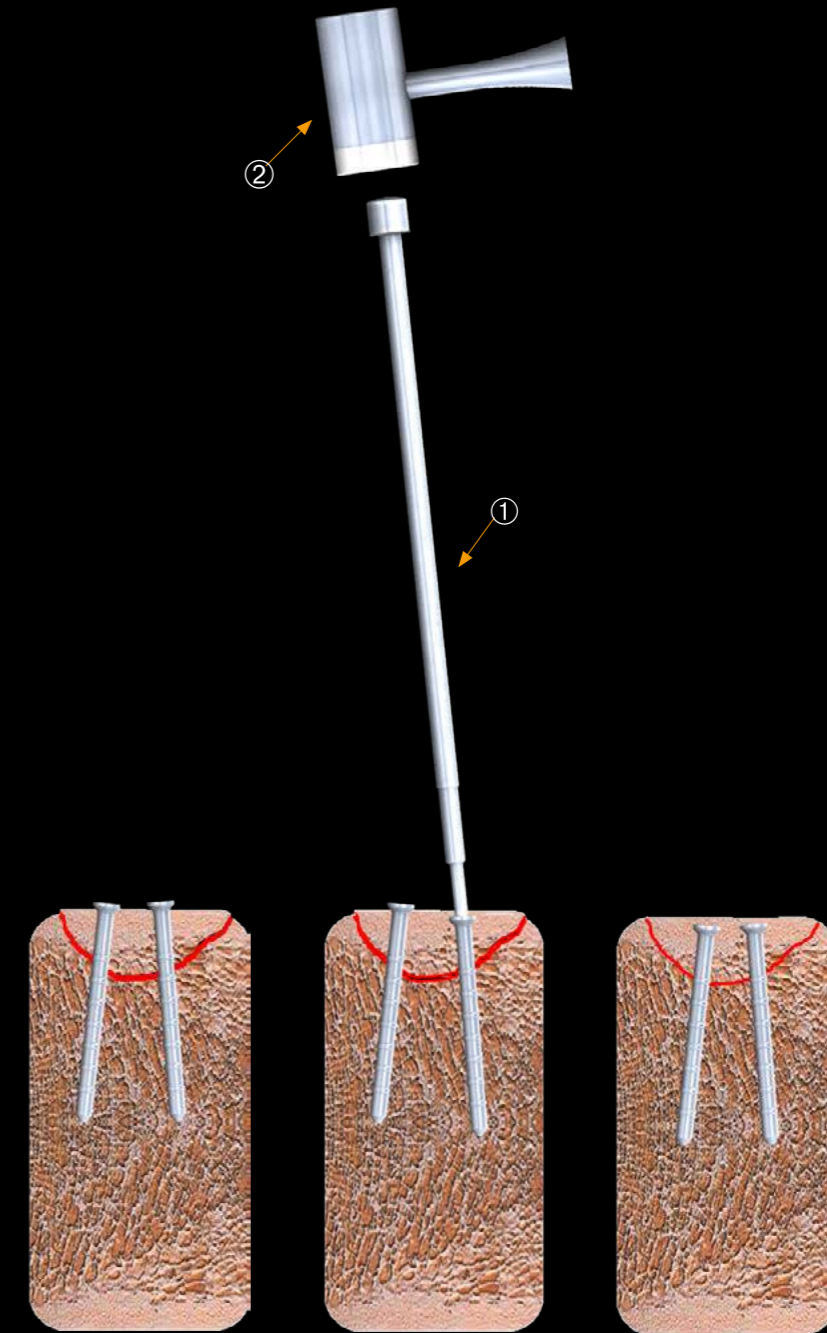


Step 4: Countersinking the pin (optional)

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.

Instruments used

- 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



IMPLANTS* MAGNEZIX® Pin

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

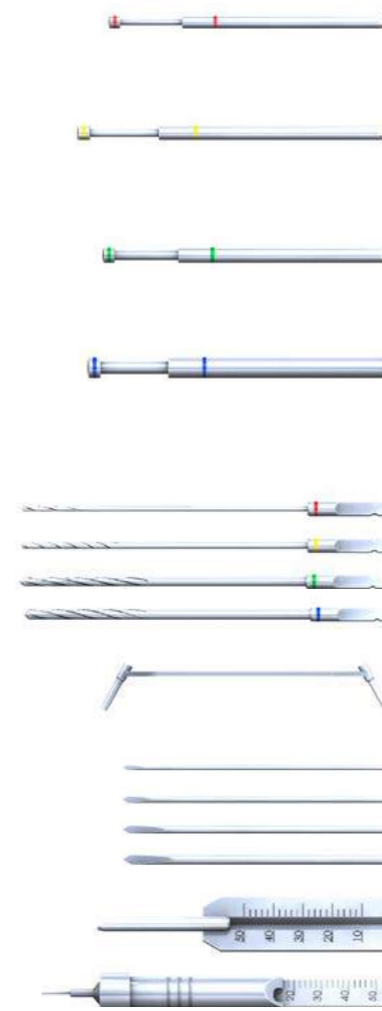
Art. No.	Length [mm]
1120.008	8
1120.010	10
1120.012	12
1120.014	14
1120.016	16
1120.018	18
1120.020	20
1120.022	22
1120.024	24
1120.026	26
1120.028	28
1120.030	30
1120.032	32
1120.034	34
1120.036	36
1120.038	38
1120.040	40

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

INSTRUMENTS** MAGNEZIX® Pin

Art. No. Description

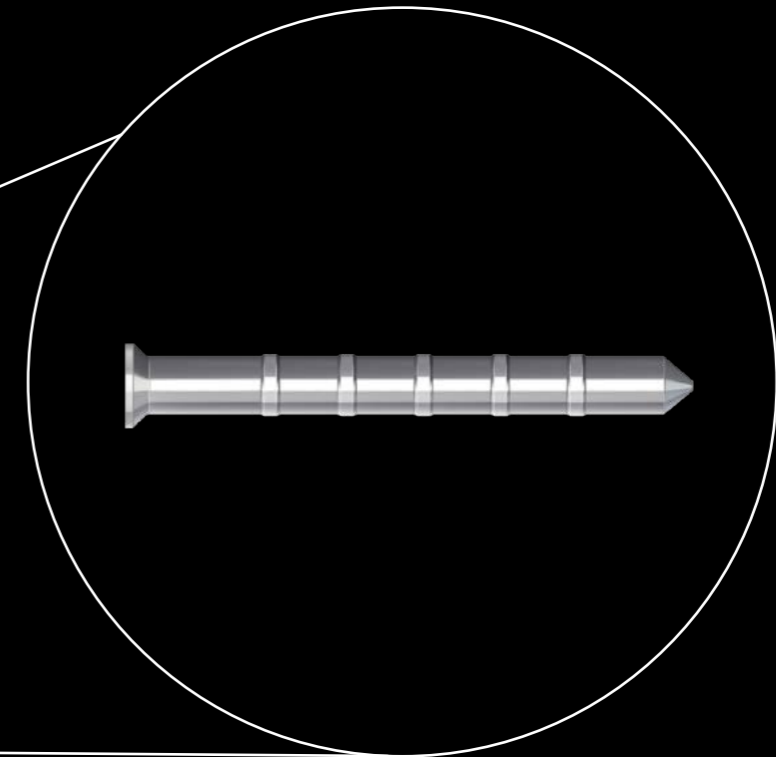


6115.010	Impactor for MAGNEZIX® Pin Ø 1.5 mm, consisting of: 9115.010 Impactor Sleeve for MAGNEZIX® Pin Ø 1.5 9115.011 Impactor Insert for MAGNEZIX® Pin Ø 1.5 9115.012 Impactor Tip for MAGNEZIX® Pin Ø 1.5
6120.010	Impactor for MAGNEZIX® Pin Ø 2.0 mm, consisting of: 9120.010 Impactor Sleeve for MAGNEZIX® 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

*All implants are individually wrapped and sterile. Re-sterilisation is not possible.

** Illustrations of the instruments are not to scale.

METALLICALLY STABLE
AND BIOABSORBABLE.
UNIQUE WORLDWIDE.
MAGNEZIX® Pin



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Implants are manufactured in collaboration with
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