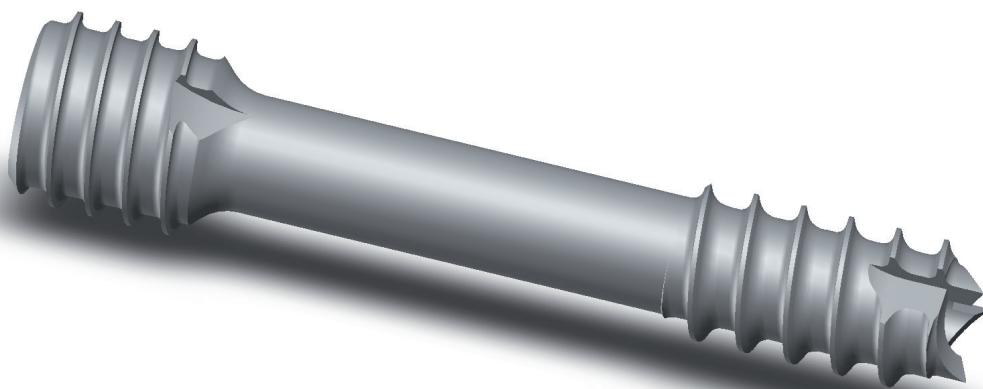


MAGNEZIX^{Mg}

Compression Screw 3.2

Bioabsorbable



∴ Product information

 **CAUTION**

The current product description is not sufficient for the immediate application of instruments and implants. Instructional training by an authorised person must be carried out prior to the application of these instruments and implants.

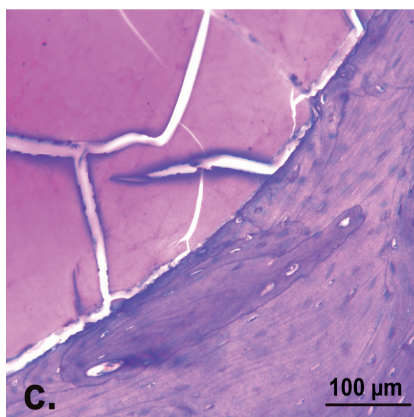
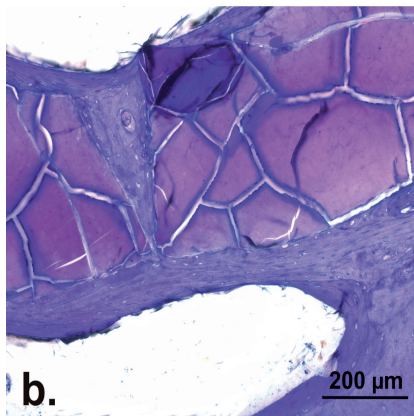
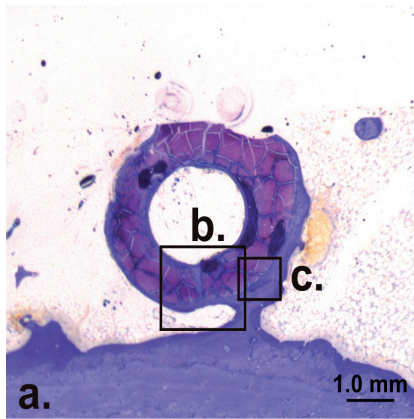
Implants, which have been removed from the sterile packaging and not used, must not be re-sterilised. These implants should be discarded.

Please note the following with regard to concurrent implantation of other metallic implants made from steel, titanium, chrome-cobalt alloys or similar metal alloys:

Metallic implants, which are not made from MAGNEZIX[®], may not be in direct permanent contact with a MAGNEZIX[®] implant; such contact may only be temporary during the period of the operation. Direct contact means that the implants physically touch.

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

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Histological evaluations of an animal study have shown complete transformation of the metallic implant after a 12-month implantation period. Bone formation with direct implant contact, as well as the presence of osteoblasts and osteoclasts, was demonstrable. SAGE Publications Ltd, All rights reserved © 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, 03.01.2013

MAGNEZIX^{Mg}

MAGNEZIX® the name of the world's first absorbable metal alloy which obtained the CE marking of Medical Devices for medical applications within Europe.

MAGNEZIX® is a magnesium based alloy, and despite having metallic properties, it completely degrades within the body and is replaced by the body's own tissue. The biomechanical properties of MAGNEZIX® are very similar to those of human bone. Some studies have also shown that MAGNEZIX® exhibits osteoconductive properties.

ADVANTAGES FOR USERS AND PATIENTS

- ❖ Complete absorption of the implant makes subsequent metal removal obsolete.
- ❖ The mechanical properties are significantly better than conventional absorbable implants.
- ❖ There is a complete homogeneous conversion of the implant to the patient's own body tissue .
- ❖ Histological investigations show bone formation at the surface of the implant, as well as bone growth incorporated into the already-resorbed zones of the implant.
- ❖ 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 made of steel or titanium. This is ensured by the adapted design, which takes the material and bioabsorbable properties into account.
- ❖ MAGNEZIX® implants are radiologically visible, MRI-proof and do not generate artefacts.

INDICATIONS

MAGNEZIX® CS 3.2 can be used for the fixation of small bones and bone fragments:

- ❖ Intra-and extra-articular fractures
- ❖ Pseudarthrosis
- ❖ Arthrodesis
- ❖ Bunionectomies and osteotomies

These include, for example:

- ❖ Carpal and metacarpal bones
- ❖ Tarsal and metatarsal bones
- ❖ Tarsometatarsal and metatarsophalangeal arthrodesis
- ❖ Ulnar and radial styloid processes
- ❖ Radial head and capitulum
- ❖ Hallux valgus corrections

CONTRAINDICATIONS

- ❖ Active sepsis
- ❖ Known allergies and/or possible foreign body intolerance to the applicable product or the material
- ❖ Physiologically or psychologically unsuitable patient
- ❖ Unsuitable skin, bone or neurovascular status
- ❖ Insufficient or inadequate bone mass for anchoring the implant
- ❖ Existing option of conservative treatment

PRECAUTIONS

Handling of sterile packagings

MAGNEZIX® implants must be stored in their protective packaging. This packaging must only be opened immediately before use. Packaging must be examined for damage before the use of a sterile implant, as it may otherwise compromise the sterility.

Re-sterilisation is not possible

The implant must be discarded if the protective packaging shows any damage, or if the protective packaging has been opened without the implant then being used.

MAGNEZIX® implants may not be used after the printed expiration date.

Concomitant usage of foreign implants

Please note the following during concomitant usage of other metallic implants made of steel, titanium, chrome-cobalt alloys or similar metallic alloys:

Metallic implants, which are not made from MAGNEZIX®, may not be in direct permanent contact with a MAGNEZIX® implant; such contact may only be temporary during the period of the operation. Direct contact means that the implants physically touch.

ABSORBABLE MAGNESIUM ALLOY

MAGNEZIX® makes any subsequent implant removal obsolete, and moreover, it supports the osseous healing process. MAGNEZIX® is absorbable, biocompatible and non-toxic within a biological environment. The screw can be introduced in the usual way due to the MAGNEZIX® innovative absorbable metallic alloy.

Self Tapping screw tip

The self tapping properties of the screw tip reduces operating time and simplifies the surgical technique.

Cannulated screw

The cannulation of the screw allows for controlled positioning of the screw with the guide wire. This supports a minimally invasive technique.

Self tapping threaded head

The self tapping threaded head facilitates both the tightening and the countersinking of the screw head.

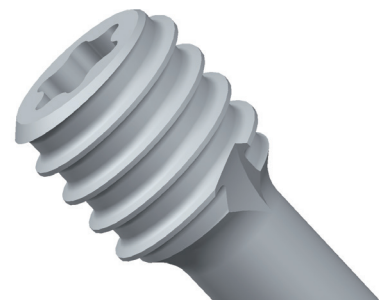
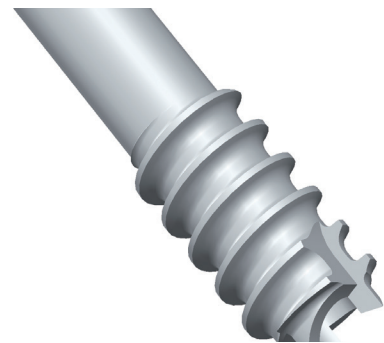
Various thread pitches

Threaded heads and threaded shafts exhibit different gradients. This creates a compression effect of the screw and leads to the desired inter-fragmentary compression.

Self-holding screwdriver

The screw head is equipped with an ISR - 8 (hexalobular socket ISO 10664-8). The advantages of this ISO-standardised propulsion technology are:

- ❖ Increased contact area
- ❖ Improved self-locking mechanism
- ❖ Increased torque transmission



SURGICAL TECHNIQUE

MAGNEZIX® CS – STEP BY STEP

Before stabilisation with a MAGNEZIX® CS 3.2 can be performed, repositioning and temporary stabilisation of the fracture or osteotomy must have been carried out.

Step 1: Positioning the guide wire

Positioning the guide wire to the desired location using image intensifier monitoring through the tissue protection sleeve with both established drill sleeves.

It should be noted

that the excessive application of force should be avoided during the insertion of the guide wire. This would otherwise bend the guide wire and impede any subsequent over-drilling or tightening of the screw.



Instruments used

- ❖ 9032.030 Protection Sleeve, Ø 6.0/4.0 mm
- ❖ 9032.031 Drill Sleeve, Ø 2.5/1.3 mm
- ❖ 9032.032 Drill Sleeve, Ø 4.0/2.5 mm
- ❖ 9032.040 Guide Wire Ø 1.2 mm, with trocar tip, length 150 mm

Or

- ❖ 9032.041 Guide Wire Ø 1.2 mm, with threaded tip, length 150 mm

Step 2:**Determination of screw length**

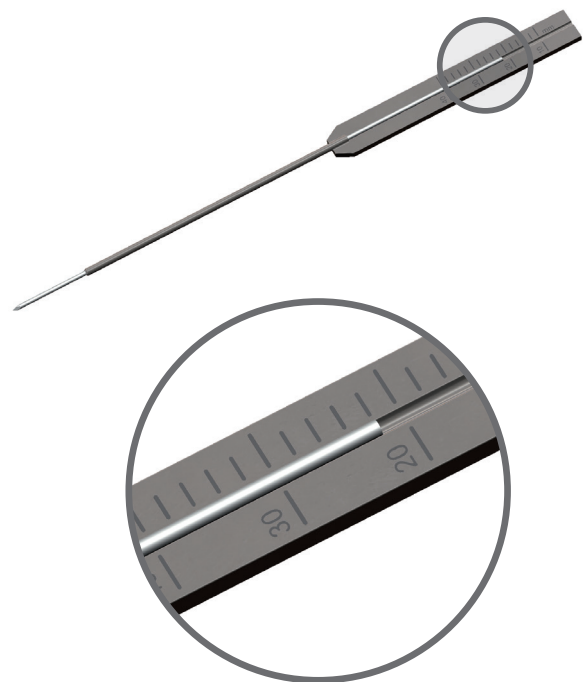
The measuring device should be pushed over the guide wire up to the bone in order to determine the length of the screw. The end of the guide wire – visible in the scale of the measuring device – determines the length of the subsequent screw (22 mm in the figure).

It should be noted

that only the use of the original guide wires will ensure the correct measurement.

Instruments used

- ❖ 9032.042 Direct Measuring Device for Guide Wire
Ø 1.2 mm, length 150 mm



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.

It should be noted

that drilling should only reach up to the guide wire tip. The drill should be withdrawn in a slow, forward-running vertical motion from the drill sleeve, so that the guide wire remains in its position.

Instruments used

- ❖ 9032.030 Protection Sleeve, Ø 6.0/4.0 mm
- ❖ 9032.032 Drill Sleeve, Ø 4.0/2.5 mm
- ❖ 9032.020 Drill Bit Ø 2.5 / 1.3 mm cannulated length 150 mm, 4-flute



Step 4: Countersinking

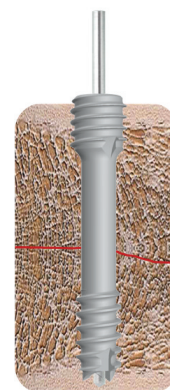
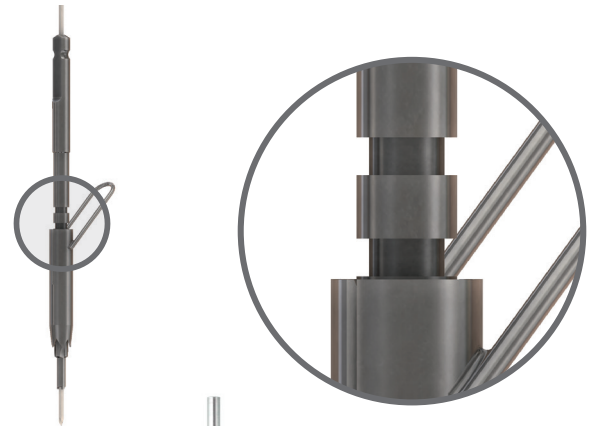
In order to facilitate the tightening of the screw head, the head-end implant sites should now be expanded with a countersink via the still-underlying guide wire.

It should be noted

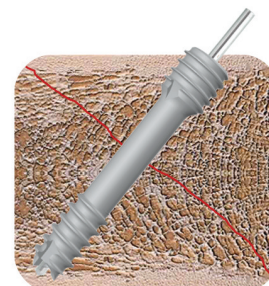
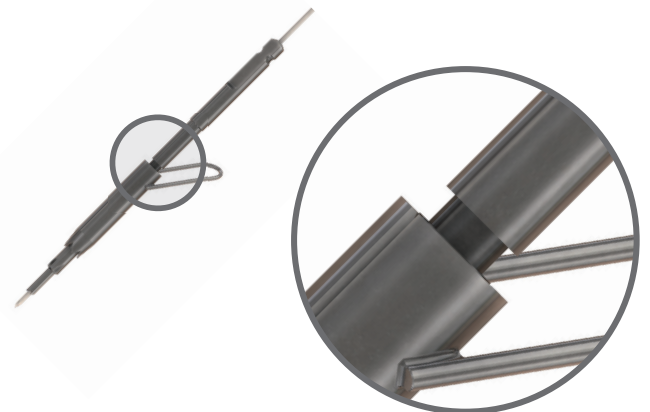
that, with perpendicular screw positioning onto the bone surface, it must only be milled until to the first ring markings in order to completely countersink the screw head. With a screw position of 45° onto the bone surface, it must be milled until the second ring marker for complete countersinking of the screw head. The countersink should be withdrawn in a slow, forward-running vertical motion from the drill sleeve, so that the guide wire still remains in its position.

Instruments used

- ❖ 9032.030 Protection Sleeve, Ø 6.0/4.0 mm
- ❖ 9032.021 Countersink Ø 3.5 / 1.3 mm, cannulated, for quick coupling



0°



45°



Step 5: Insertion of the screw

This is now followed by the tightening of the MAGNEZIX® Compression Screw 3.2 in the length specified previously in step 2 over the still-underlying guide wire.

It should be noted

that the guide wire has not been damaged during steps 1 through 4. A damaged guide wire may result in the MAGNEZIX® Compression Screw 3.2 not being tightened or screwed in completely. In this case, the guide wire must be removed before the screw can be tightened or screwed in.

If excessive compression is generated during the insertion of the screw, the threaded tip could pull out in the far fragment.

If the selected screw is too short, there may be a possibility of the threaded shaft crossing the fracture or osteotomy gap. In this case, no compression should be applied. The correct position of the threaded shaft should be verified using an image intensifier.

If it turns out that the thread crosses the fracture or osteotomy gap, the screw must be removed and replaced with a longer screw in order to generate compression. In this respect, it is necessary to keep in mind that the pre-drilling process (as described in step 3) for hard bone may possibly have to be repeated deeper once more, corresponding with the selected length of the screw.

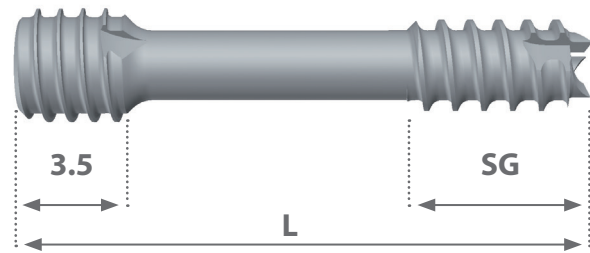
The guide wire should be removed once the screw is in position.

Instruments used

❖ 9032.010 Screwdriver ISR - 8,
self-holding, Ø 1.3 mm cannulated

optional

❖ 9032.030 Protection Sleeve, Ø 6.0 / 4.0 mm








MAGNEZIX® CS 3.2 IMPLANTS**MAGNEZIX® CS 3.2 mm**

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

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

** These screw lengths are not included
in the standard equipment.*

MAGNEZIX® CS 3.2 INSTRUMENTS

	❖ 9032.010	Screwdriver ISR - 8, self-holding, Ø 1.3 mm cannulated
	❖ 9032.020	Drill Bit Ø 2.5/1.3 mm cannulated length 150 mm, 4-flute, for quick coupling
	❖ 9032.021	Countersink Ø 3.5/1.3 mm, cannulated, for quick coupling
	❖ 9032.030	Protection Sleeve, Ø 6.0/4.0 mm
	9032.031	Drill Sleeve, Ø 2.5/1.3 mm
	9032.032	Drill Sleeve, Ø 4.0/2.5 mm
	❖ 9032.040	Guide Wire Ø 1.2 mm, with trocar tip, length 150 mm, (do not reuse)
	❖ 9032.041	Guide Wire Ø 1.2 mm, with threaded tip, length 150 mm, (do not reuse)
	❖ 9032.042	Direct Measuring Device for Guide Wires Ø 1.2 mm, length 150 mm
	❖ 9032.050	Cleaning Stylet Ø 1.25mm for Ø 1.3 mm cannulated Instruments

Illustrations of the instruments are not to scale.

Presented by:



Syntellix AG
Schiffgraben 11
30159 Hannover
Germany

Tel +49 511 270413-50
Fax +49 511 270413-79
info@syntellix.com
www.syntellix.com

Instruments and implants are manufactured in cooperation with Königsee Implants GmbH in Germany.