

STABILITY WITHOUT COMPROMISES

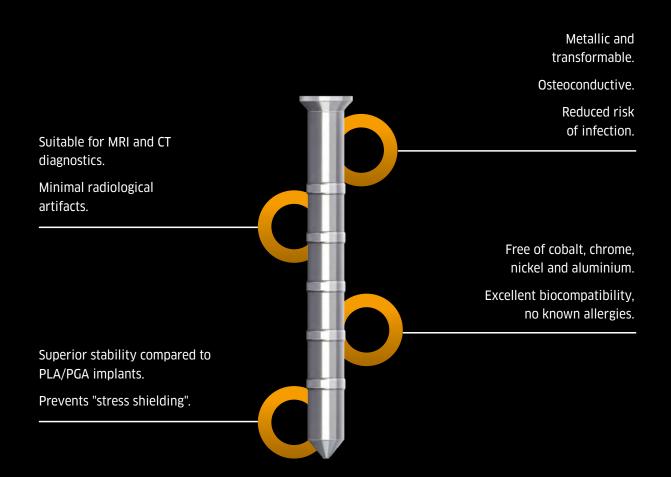
MAGNEZIX® PIN: AT FIRST METAL - THEN BONE







The benefits at a glance













MAGNEZIX[®] Pin

KEEPS ITS PROMISES

Innovation has no end: MAGNEZIX[®], the world's unique material for metal implants **that are both stable and transformable**, is now also available as a pin!

No more compromises: The metallic MAGNEZIX[®] Pins are mechanically stable and therefore **much more resilient** than conventional polymer implants. However, unlike normal metal screws or wires, **they do not need to be removed** – instead, they degrade completely within the body and are replaced by endogenous tissue.

The ideal solution: MAGNEZIX[®] implants are suitable for all indications that require temporary but **secure fixation** of the bone, but for which remaining material or a surgical removal of the metal following the healing process is not desirable. The MAG-NEZIX[®] Pin therefore opens up a broader spectrum of indications – particularly for **trauma and sports surgery**.

CE

MAGNEZIX[®] [ma'gneziks]: A magnesium alloy (Mg content > 90%) with unique stability properties and material of the world's first approved bioabsorbable metal implants.

MAGNEZIX® Pins offer you:

Stability: MAGNEZIX[®] Pins offer significantly greater stability than polymer pins.

Transformation: MAGNEZIX[®] Pins transform in the body and will be replaced by endogenous bone tissue.

Osteoconductivity: MAGNEZIX[®] implants stimulate bone growth.

Inhibition of infection: When magnesium degrades, an alkaline, anti-bacterial environment is created.

Tolerance: The components of the alloy are not known to cause any allergic reactions.

A WORLD FIRST!

The MAGNEZIX® principle

First healing, then dissolving! MAGNEZIX[®] Pins combine *metallic stability and transformation,* setting new standards for traumatology and sports surgery.

SUPERIOR STABILITY

UP TO 5 TIMES MORE STABLE THAN POLYMER PINS (E.G. PLA)

Setting new standards: MAGNEZIX® Pins boast mechanical stability values far superior to those of previously available bioresorbable materials. Both initially and during the degradation process, MAGNEZIX® Pins offer considerably greater stability than comparable PLA pins and even those with larger dimensions. That means superior stability that is sure to impress during day-to-day surgery. Not only this, MAGNEZIX® can offer you and your patients even more benefits: osteoconductivity, inhibition of infection and very high tolerance levels.

DESIGN AND FUNCTION

SOPHISTICATED DETAILS FROM THE HEAD TO THE TIP



Head design

The flat design of the MAGNEZIX[®] Pin head enables the bone fragment to be repositioned with a high degree of stability and the pin head to be completely countersunk.



Axially stabilising shaft design

The symmetrically positioned collars on the pin shaft result in the compression of the free bone fragment during impaction of the implant. In addition, they increase the axial positioning precision of the implant.

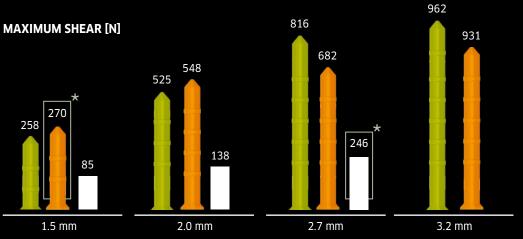


Design of the pin tip

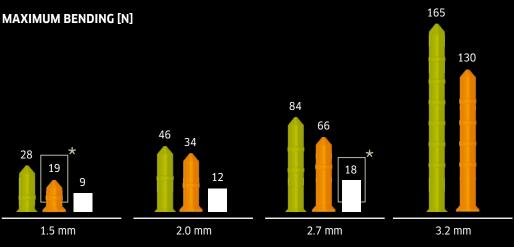
The tip design of the MAGNEZIX[®] Pin displaces cancellous bone, thereby compressing the implant bed and facilitating positioning.



Comparative stability values



(Tested in accordance with ASTM F1044-05 | ASTM F2502-11 | Load rate 5 mm/min)

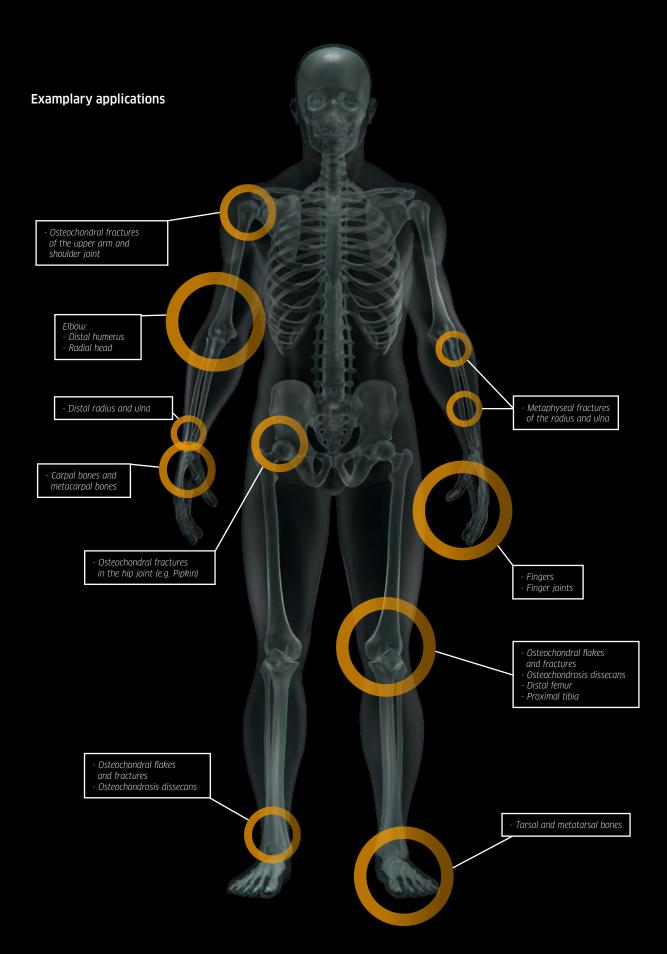


(Tested in accordance with ASTM F1264-14 | ASTM F2502-11 | Load rate 5 mm/min)



IMPRESSING STABILITY!

Not only initially, but also when corroded, even the smallest MAGNEZIX® Pin 1.5 offers significantly better stability than a larger, non-degraded PLA pin with a diameter of 2.7 mm.





INDICATIONS

A MULTITUDE OF TRAUMATOLOGY APPLICATIONS

MAGNEZIX® implants are ideally suited for indications in acute medicine or sports medicine that require secure fixation of the bone with no foreign material remaining in the body - a clear advantage for you and your patients.

The indications for MAGNEZIX[®] Pins are reconstructive procedures following fractures and misalignment of the human skeleton, 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 Indications for MAGNEZIX® Pin 2.0 include:
- Osteochondral fractures and dissecates

Indications for MAGNEZIX® Pin 1.5 include:

- Phalangeal and metacarpal bones
- Osteochondrosis dissecans

- Carpal, metacarpal, tarsal and metatarsal bones
- Ulnar and radial styloid processes
- Capitulum of the humerus and radial head

Indications for MAGNEZIX® Pin 2.7 and 3.2 include:

- Pipkin fractures
- Metaphyseal fractures of the radius and ulna



MAGNEZIX[®] implants stimulate **bone growth**, support the **healing process** and help to avoid unnecessary sick days and risks, as no foreign material that could cause problems and requires removal remains within the body.

THE MAGNEZIX® MATERIAL

REVOLUTIONARY AND PIONEERING

While metal implants that convert to bone may at first seem like fantasy, this has become a reality for medicine following years of research into materials.

Specifically, MAGNEZIX[®] is a magnesium-based alloy (more than 90% Mg content), which, despite its metallic properties, completely degrades within the body and is replaced by endogenous tissue. The biomechanical properties of MAGNEZIX[®] closely resemble those of human bone.

Some studies have also shown that **magnesium-based alloys exhibit osteoconductive² properties.** As magnesium is degraded by means of corrosion, an alkaline, anti-bacterial environment is also created in the immediate vicinity of the implant. For this reason, MAGNEZIX[®] (> 90 % Mg) can be expected to exhibit **anti-infective properties.**

Advantages for users and patients:

- The mechanical properties (e.g. bending, tension, torsion) are significantly better than those of conventional resorbable implants.
- Fully conversion of the implant to endogenous tissue makes subsequent removal of the metal unnecessary.
- Histological investigations show bone formation at the surface of the implant, as well as bone growth in the implant areas where resorption has already taken place.

- The favorable elasticitiy (Young's modulus) of MAGNEZIX[®] implants helps to prevent "stress shielding".
- There are barely any differences in application between MAGNEZIX[®] implants and conventional implants made of steel or titanium.
- MAGNEZIX[®] implants are radiologically visible, conditionally MRI-proof and only generate minimal artifacts.
- Cost savings as MAGNEZIX[®] eliminates the need to prepare/plan and perform an implant removal.

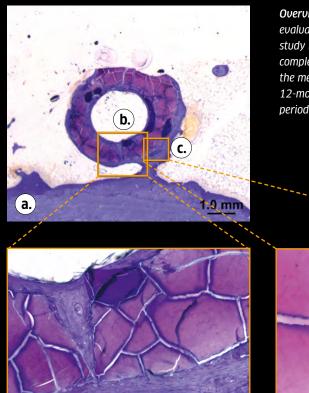
² Revell et al.: The effect of magnesium ions on bone bonding to hydroxyapatite coating on titanium alloy implants. Key Eng Mater 2004:254-256:447-50.

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.

Liu et al.: Magnesium directly stimulates osteoblast proliferation. J Bone Miner Res 1988;3:104.



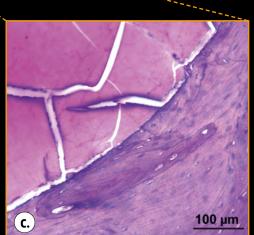
Supporting the healing process



Section b: Formation of new bone (osteoid) on the surface of the degraded implant has been histologically demonstrated.

(b.)

Overview a: Histological evaluations of an animal study have shown complete conversion of the metal implant after a 12-month implantation period.



Section c: The presence of osteoclasts and osteoblasts characterises the bone conversion process.

Diagrams: SAGE Publications Ltd. All rights reserved. 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

200 µm

THE IMPLANTS

PRODUCT OVERVIEW

Depending on size, the MAGNEZIX[®] Pin can be used as a bone pin for children, adolescents or adults for the adaptation-stable or exercise-stable fixation of bones, bone fragments or osteochondral fragments for areas that are only subjected to minor loads.

PIN	DIMENSIONS		LENGTHS
MAGNEZIX [®] Pin 1.5	Diameter	1.5 mm	8 to 30 mm
	Head diameter	2.5 mm	(in 2-mm increments)
MAGNEZIX® Pin 2.0	Diameter	2.0 mm	8 to 40 mm
	Head diameter	3.0 mm	(in 2-mm increments)
MAGNEZIX* Pin 2.7	Diameter	2.7 mm	12 to 50 mm
	Head diameter	4.0 mm	(in 2-mm increments)
MAGNEZIX* Pin 3.2	Diameter	3.2 mm	12 to 50 mm
	Head diameter	5.0 mm	(in 2-mm increments)



OTHER MAGNEZIX® IMPLANTS

CS	DIMENSIONS		LENGTHS	CBS	DIMENSIONS		LENGTHS
MAGNEZIX° CS 2.0	Diameter Head diameter	2.0 mm 2.5 mm	8 to 24 mm (in 2-mm increments), non-cannulated	MAGNEZIX® CBS 2.0	Diameter Head diameter	2.0 mm 4.0 mm	6 to 20 mm (in 2-mm increments)
MAGNEZIX° CS 2.7	Diameter Head diameter Guide wire	2.7 mm 3.5 mm 1.0 mm	10 to 34 mm (in 2-mm increments), cannulated	MAGNEZIX [®] CBS 2.7	Diameter Head diameter	2.7 mm 5.0 mm	6 to 30 mm (in 2-mm increments)
MAGNEZIX° CS 3.2	Diameter Head diameter Guide wire	3.2 mm 4.0 mm 1.2 mm	10 to 40 mm (in 2-mm increments), cannulated	MAGNEZIX® CBS 3.5	Diameter Head diameter	3.5 mm 6.0 mm	8 to 40 mm (in 2-mm increments)

For further information, please contact our field team or write to us at: info@syntellix.com

ADDITIONAL LITERATURE AND STUDIES

Helling H.-J. | Prokop A. | Schmid H. U. | Nagel M. | Lilienthal J. | Rehm K. E. (2006):

Biodegradable implants versus standard metal fixation for displaced radial head fractures. A prospective, randomized, multicenter study. In: Journal of Shoulder and Elbow Surgery 15 (4), S. 479-485.

Plaass C. | Ettinger S. | Sonnow L. | Koenneker S. | Noll Y. | Weizbauer A. | Reifenrath J. | Claassen L. | Daniilidis K. | Stukenborg-Colsman C. | Windhagen H. (2016):

Early Results Using a Biodegradable Magnesium Screw for Modified Chevron Osteotomies. In: Journal of Orthopaedic Research, online - DOI: 10.1002/jor.23241.

Prokop A. | Chmielnicki M. (2013):

Versorgung von dislozierten Radiuskopffrakturen mit bioresorbierbaren Implantaten. In: Zeitschrift für Orthopädie und Unfallchirurgie 151 (6), S. 565-568.

Prokop A. | Jubel A. | Helling H. J. | Udomkaewkanjana C. | Brochhagen H. G. | Rehm K. E. (2002):

Neue biodegradable Polylactidimplantate (Polypin[®]-C) zur Therapie von Radiuskopffrakturen. In: Der Chirurg 73 (10), S. 997-1004.

Seitz J.-M. | Lucas A. | Kirschner M. H. (2016):

Magnesium-Based Compression Screws: A Novelty in the Clinical Use of Implants. In: Journal of The Minerals, Metals & Materials Society 68 (4), S. 1177-1182.

Sonnow L. | Könneker S. | Vogt P. M. | Wacker F. | von Falck C. (2017):

Biodegradable magnesium Herbert screw – image quality and artifacts with radiography, CT and MRI. In: BMC Medical Imaging 17(1):16, DOI: 10.1186/s12880-017-0187-7.

Tabaddor R. R. | Banffy M. B. | Andersen J. S. | McFeely E. | Ogunwole O. | Micheli L. J. | Kocher M. S. (2010):

Fixation of Juvenile Osteochondritis Dissecans Lesions of the Knee Using Poly 96L/4D-lactide Copolymer Bioabsorbable Implants. In: Journal of Pediatric Orthopaedics 30 (1), S: 14-20.

Waizy H. | Diekmann J. | Weizbauer A. | Reifenrath J. | Bartsch I. | Neubert V. et al. (2014):

In vivo study of a biodegradable orthopedic screw (MgYREZr-alloy) in a rabbit model for up to 12 months. In: Journal of Biomaterials Applications 28 (5), S. 667–675.

Waris E. | Ashammakhi N. | Kaarela O. | Raatikainen T. | Vasenius J. (2004):

Use of Bioabsorbable Osteofixation Devices in the Hand.

In: Journal of Hand Surgery 29 (6), S. 590-598.

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