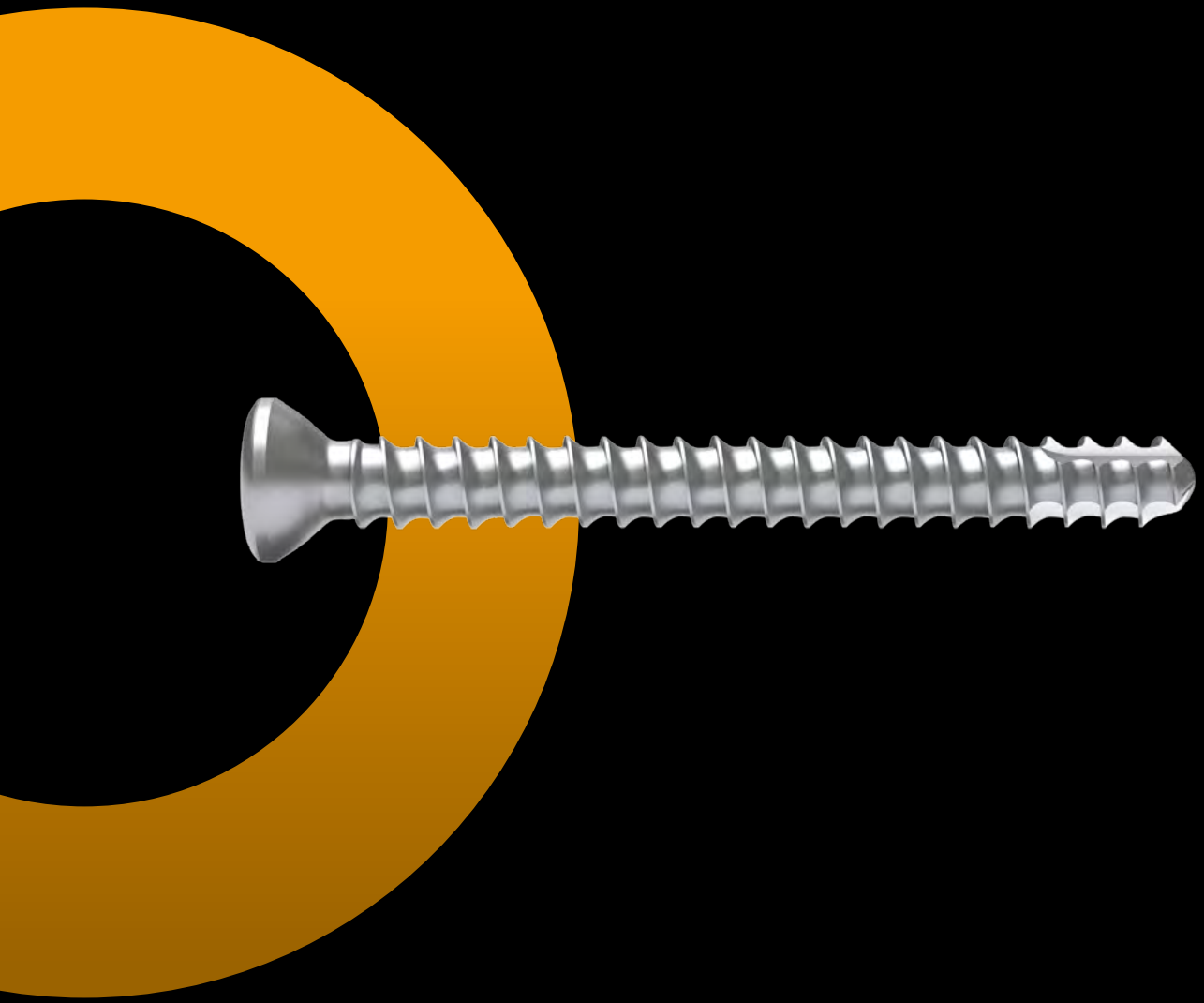
MAGNEZIX®

STABLE, TRANSFORMABLE, UNIVERSALLY APPLICABLE

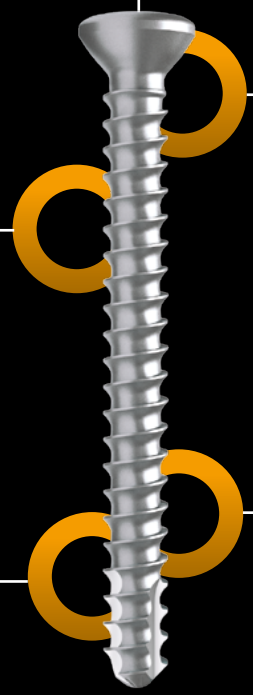
THE NEW MAGNEZIX® CBS OFFERS NEW ADVANTAGES!



Intelligent innovations for a better life.
www.syntellix.com

SYNTELLIX

The advantages are clear to see – at a glance



Unique safety drive head.

Metallic and transformable.

Osteoconductive.

Reduced infection risk.

Suitable for MRI and CT diagnostics.

Virtually no radiological artifacts.

Higher stability than PLA/PGA implants.

Avoids stress shielding.

No foreign materials remain.

No cobalt, chromium, nickel or aluminium.

Excellent biocompatibility, no known allergies.

EUROPEAN INNOVATION PARTNERSHIP on Active and Healthy Ageing
INNOVATIVE SOLUTION

cdgw Preisträger 2016 Deutscher Zukunftspreis Gesundheitswirtschaft

TOP 100 top100.de Top-Innovator 2015 & 2016

INNOVATIONSPREIS DER DEUTSCHEN WIRTSCHAFT Sieger 2012/13

MAGNEZIX

MAGNEZIX® CBS

UNIQUE ADVANTAGES, REMARKABLY VERSATILE

MAGNEZIX®, the advanced alternative to titanium and polymer materials, is now available as a cortical bone screw.
MAGNEZIX® CBS offers the ideal combination of a remarkably versatile implant together with the proven benefits of the MAGNEZIX® material. It is in particular the outstanding stability of the MAGNEZIX® CBS screw compared with regular PLA cortical screws which opens the door to a broad spectrum of application options.

Acknowledged MAGNEZIX® benefits:

Stability: MAGNEZIX® CBS is much more stable than polymer implants and clearly superior to conventional resorbable devices.

Osteoconductivity: MAGNEZIX® CBS promotes bone growth and is not only degraded but actually transforms into endogenous bone tissue.

Infection inhibiting: While magnesium degrades it creates an alkaline, anti-bacterial milieu.

Compatibility: MAGNEZIX® offers outstanding biocompatibility and the alloy's components are not causing any known allergies (it is completely free of nickel, chromium, cobalt and aluminium components).

CE

CE approval was granted in 2013 for MAGNEZIX® compression screws, enabling the first clinical use of a self-dissolving biometallic screw in Europe. In 2016 and 2017 the CE-certified MAGNEZIX® product portfolio was expanded to include the Pin and the CBS cortical bone screw.

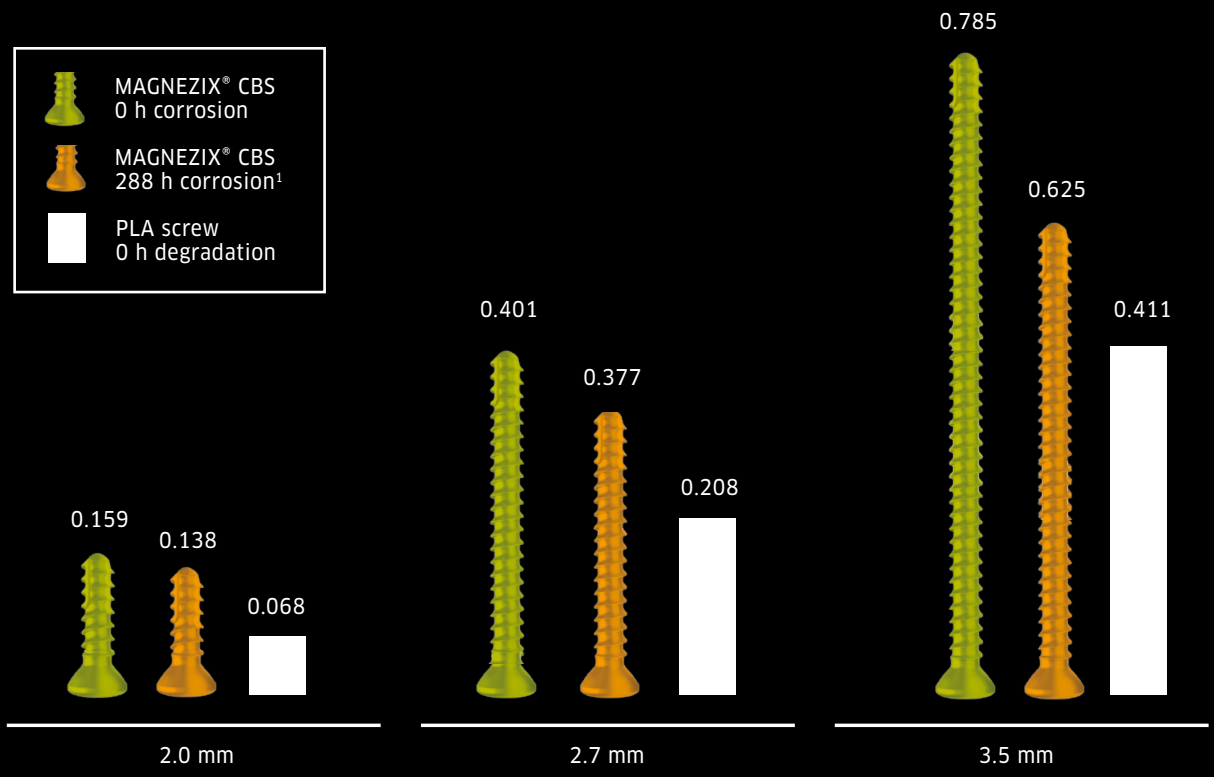
GET TO KNOW **THE ADVANTAGES!**

The better implant:
The metal MAGNEZIX® CBS is not only **considerably more stable than cortical screws made of PLA/PGA** but is actually transformed by the body into bone. A definite advantage for users and patients.

OUTSTANDING STRENGTH

MAGNEZIX® CBS COMES FIRST IN THE TORSION TEST

Max. torsion [Nm]: MAGNEZIX® CBS versus PLA cortical screw



Mechanical tests in accordance with ASTM F2502/F543 | certified test laboratory | corrosion medium PBS at 37 °C | Material: Sawbone grade 40

[1] 288 hours corrosion in vitro correspond to approx. 80 days in vivo (values can differ on a case-by-case basis depending on patient and implant position).

Like all other MAGNEZIX® products, **the CBS has more load capacity and is more stable than comparable polymer implants.** For example, a corroded CBS offers higher torsional force than a non-degraded PLA screw of the same diameter. These **definite advantages** are also very **persuasive** for day-to-day OP activities!

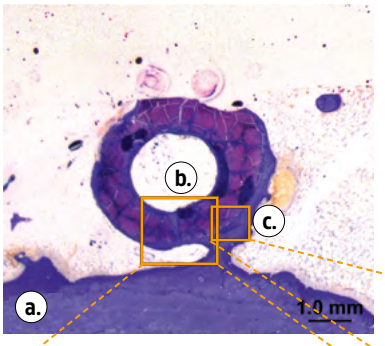
MAGNEZIX®: THE MATERIAL

REVOLUTIONARY AND FUTURE-PROOF

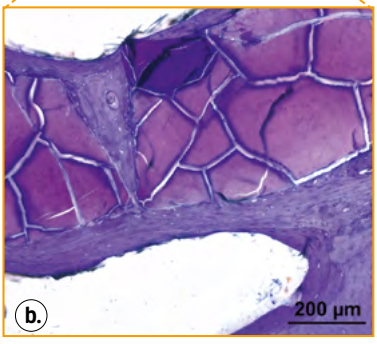
MAGNEZIX® is the name of a **magnesium-based alloy (more than 90 % magnesium)** which, while offering metallic properties, is completely transformed within the body and is replaced by **endogenous tissue.** The biomechanical properties of MAGNEZIX® are very similar to that of human bone.

A number of studies also show that **magnesium alloys have osteoconductive properties[2],** too. The degradation of magnesium is a corrosion process which also creates an anti-bacterial alkaline milieu in the immediate vicinity of the implant. As a result, MAGNEZIX® (comprising more than 90 % magnesium) is anticipated to have **anti-infectious properties[3].**
Furthermore, MAGNEZIX® implants are both radiologically visible as well as being MRI conditional and only generate minimal artifacts (see also the instructions for use).

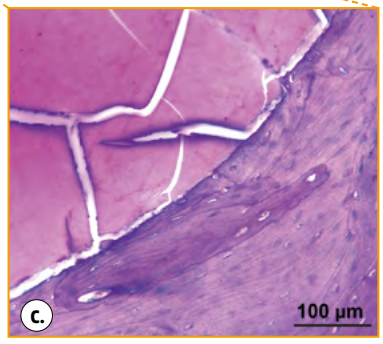
Metal transforms into bone



Overview A: *Histological evaluations of an animal study show complete transformation of the metal implant after a 12 month implant period.*



Section B: *The new bone formation (osteoid) at the surface of the degraded implant is histologically verified.*



Section C: *The presence of osteoclasts and osteoblasts characterises the bone transformation process.*

[2] 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.

[3] Robinson et al.: In vitro antibacterial properties of magnesium metal against Escherichia coli, Pseudomonas aeruginosa and Staphylococcus aureus, Acta Biomaterialia 6 (2010): 1869-1877.

INDICATIONS

NEW, WIDER APPLICATION RANGE

The MAGNEZIX® CBS cortical bone screw is suitable, depending upon the chosen size, as a bone screw (lag screw, position screw) for children, adolescents and adults for adaptation-capable or exercise-capable fixation of bones and bone fragments, for example:

MAGNEZIX® CBS 2.0, 2.7, 3.5:

- Intra- and extra-articular fractures of small bones and bone fragments
- Arthrodeses, osteotomies or pseudarthroses of small bones and joints
- Small bony ligament and tendon ruptures
- Osteochondral fractures and dissecates
- Similar indications

MAGNEZIX® CBS 2.0:

- Phalangeal and metacarpal bones
- Osteochondrosis dissecans
- Similar indications

MAGNEZIX® CBS 2.7 and 3.5:

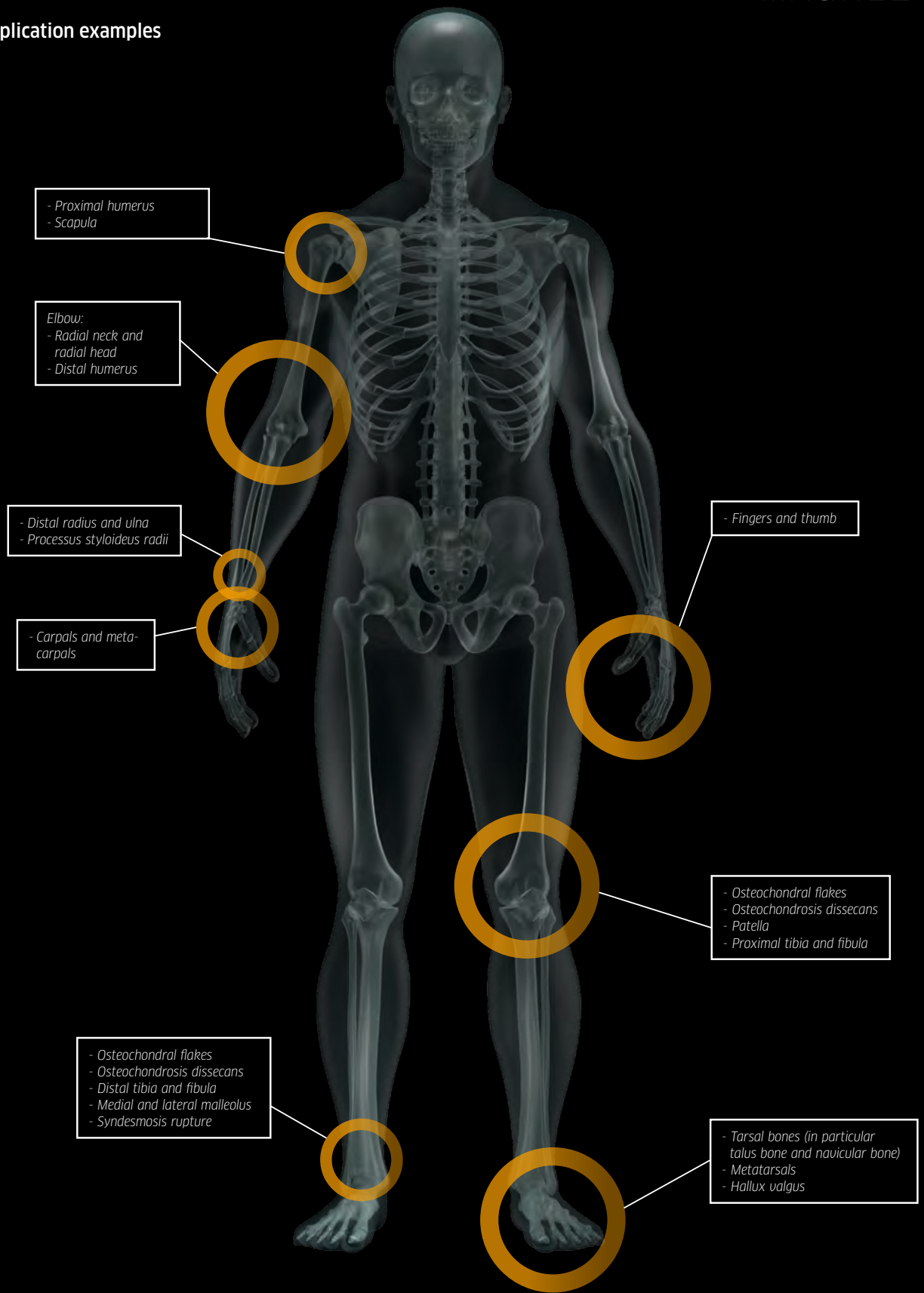
- Carpal, metacarpal, tarsal and metatarsal bones
- Epicondylus humeri
- Metaphyseal fractures of small and medium-sized bones and bone fragments
- Similar indications

UNIQUE IN THE WORLD!

MAGNEZIX® CBS combine **metal stability and transformation.** They set new benchmarks in orthopaedics, traumatology and sports surgery.

MAGNEZIX

Application examples



NO METAL REMOVAL NECESSARY

MAGNEZIX® WAIVES THE NEED FOR A SECOND OPERATION TO REMOVE METALWORK

Magnesium is a physiological element required by the human body which can support the healing process. During the course of healing, the MAGNEZIX® implant gradually degrades while the regenerating bone gradually gains in load-bearing capacity. **There is no need for a second operation to remove metalwork.** This saves costs and time and reduces risks.

Arguments for the removal of implants are fairly obvious:

- possible negative influence on bone growth
- functional restrictions due to the presence of implants
- irritation of joints, tendons, muscles, subcutis and skin
- possible allergies
- reduced elasticity, stress shielding of bones
- primary infections and later infections
- more difficult diagnostics and therapy conditions due to renewed fracture of the affected bone and/or the implant (due to accident or subsequently due to aging)
- limitations to diagnostics (CT, MRI)
- implant is a nuisance in prominent body locations
- higher patient expectations

Removal of metal represents higher levels of potential complications for surgeons:

- ➔ The intervention must be planned during implantation in order to allow simplified access if necessary.
- ➔ Technical complications, such as worn drives, can make removal considerably more difficult.
- ➔ Nerve and vessel lesions can be caused.
- ➔ May cause infections to bones and soft tissues as well as interfere in wound healing.
- ➔ Renewed fractures may occur (intraoperatively, postoperatively or at a breaking point).
- ➔ Increased scarring, possibly the need for scar correction.

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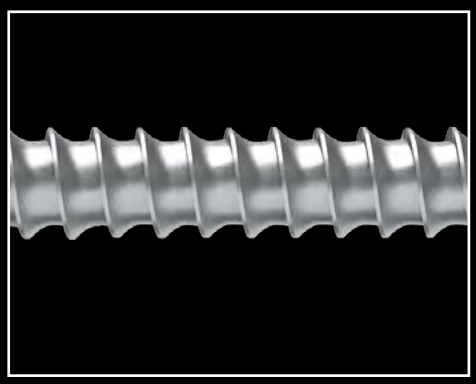
FUNCTIONAL DESIGN

ATTENTION TO DETAIL TO ENSURE YOUR SURGICAL SUCCESS



Unique, transformable magnesium alloy
Using MAGNEZIX® implants makes the need for later metal removal obsolete and also supports the bone's healing process. MAGNEZIX® is bioabsorbable and biocompatible.

Head design
The head of the MAGNEZIX® CBS, with a typical cortical screw design, allows for stable repositioning of the bone fragment, with good compression characteristics.

Drive design
The special design of the TORX-based drive protects the implant in the shaft area from failure. The drive "slips" during the screwing-in operation if the torsional load is too high.

Thread design
The thread design, which is typical for cortical screws, produces strong fixation in cortical bone. A dimension-dependent thread pitch supports the controlled compression of bone fragments.

Screw tip
The design features chip flutes to improve the thread quality and ease the screwing-in. However, a pre-cutting of the thread in cortical bone is required.

THE IMPLANTS

PRODUCT OVERVIEW

IMPLANT	DIMENSIONS		LENGTHS
MAGNEZIX® CBS 2.0 	**Diameter** **Head diameter**	2.0 mm 4.0 mm	6 to 20 mm (in 2-mm steps)
MAGNEZIX® CBS 2.7 	**Diameter** **Head diameter**	2.7 mm 5.0 mm	6 to 30 mm (in 2-mm steps)
MAGNEZIX® CBS 3.5 	**Diameter** **Head diameter**	3.5 mm 6.0 mm	8 to 40 mm (in 2-mm steps)

DIMENSIONS IN A STABILITY COMPARISON

PLA/PGA comparative dimensions regarding stability

MAGNEZIX® CBS diameter	2.7	3.5	4.0
 2.0			
2.7			
3.5			

ADDITIONAL MAGNEZIX® IMPLANTS

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

CS	DIMENSIONS		LENGTHS
MAGNEZIX® CS 2.0 	**Diameter** **Head diameter**	2.0 mm 2.5 mm	8 to 24 mm (in 2-mm steps), not cannulated
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 steps), cannulated
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 steps), cannulated

ADDITIONAL REFERENCES

Modrejewski C. | Plaass C. | Ettinger S. | Caldarone F. | Windhagen H. | Stukenborg-Colsman C. | von Falck C. | Belenko L. (2015):
Degradationsverhalten bioabsorbierbarer Magnesium-Implantate bei distalen Metatarsale-1-Osteotomien im MRT.
In: Fuß & Sprunggelenk 13 (3), S. 156–161.

Plaass C. | Modrejewski C. | Ettinger S. | Noll Y. | Claassen L. | Daniilidis K. | Belenko L. | Windhagen H. | Stukenborg-Colsman C. (2015):
Frühergebnisse von distalen Metatarsale-1-Osteotomien bei Hallux valgus unter Verwendung eines biodegradierbaren Magnesium-Implantates.
In: Fuß & Sprunggelenk 13 (3), S. 148–155.

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.

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.

Staiger M. P. | Pietak A. M. | Huadmai J. | Dias G. (2006):
Magnesium and its alloys as orthopedic biomaterials: A review.
In: Biomaterials 27 (9), S. 1728-1734.

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.

Windhagen H. | Radtke K. | Weizbauer A. | Diekmann J. | Noll Y. | Kreimeyer U. et al. (2013):
Biodegradable magnesium-based screw clinically equivalent to titanium screw in hallux valgus surgery:
short term results of the first prospective, randomized, controlled clinical pilot study.
In: BioMedical Engineering OnLine 12 (1), S. 1-10.

Zeng J. | Ren L. | Yuan Y. | Wang Y. et al. (2013):
Short-term effect of magnesium implantation on the osteomyelitis modeled animals induces by staphylococcus aureus.
In: Journal of Materials Science: Materials in Medicine 24, S. 2405–2416.

Zreiqat H. | Howlett C. R. | Zannettino A. | Evans P. | Schulze-Tanzil G. | Knabe C. et al. (2002):
Mechanisms of magnesium-stimulated adhesion of osteoblastic cells to commonly used orthopaedic implants.
In: Journal of Biomedical Materials Research 62(2), S. 175-184.

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Implants are manufactured in Germany
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