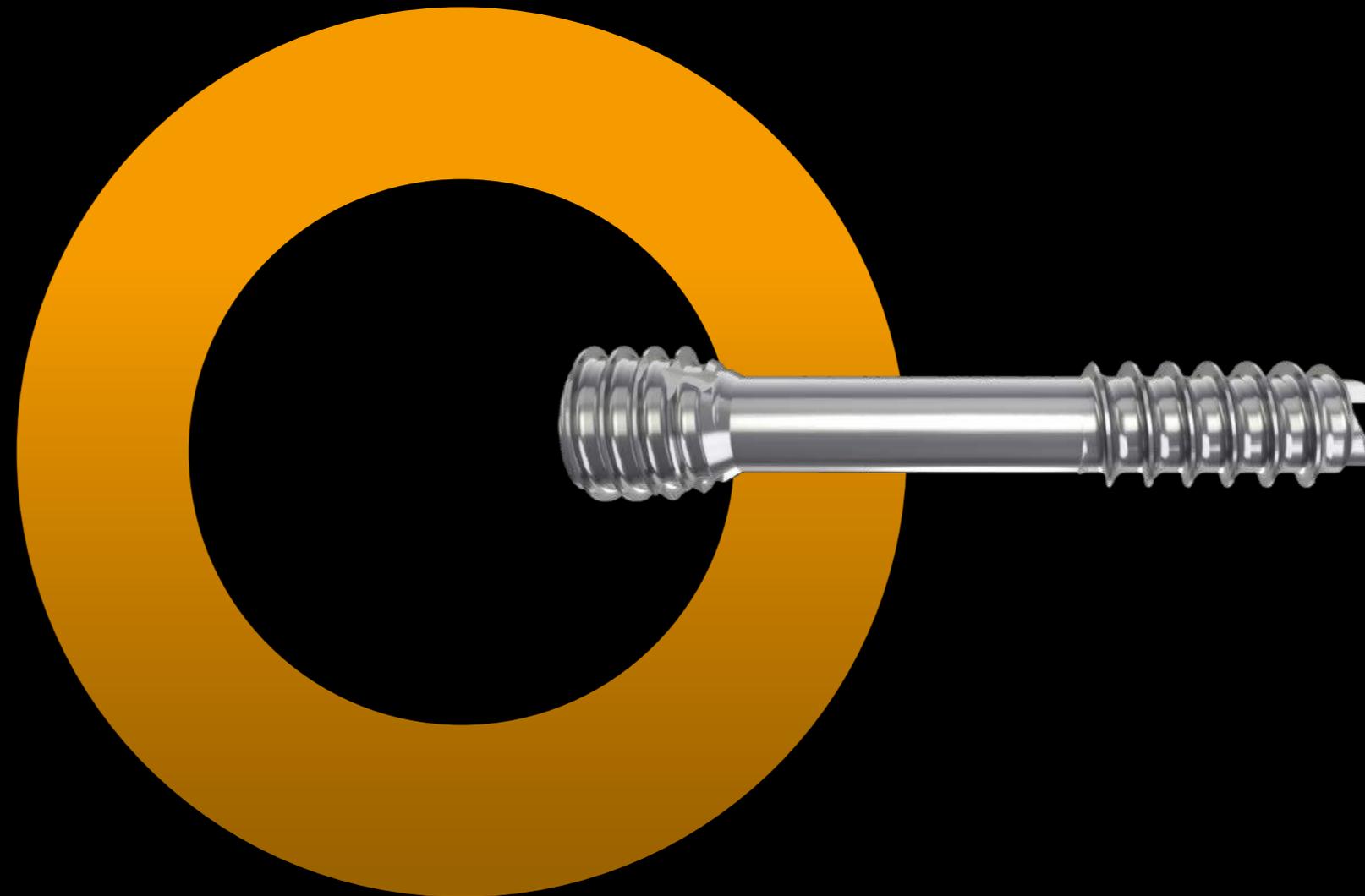


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MAGNEZIX^{M3}

METALLIC AND BIOABSORBABLE

TAKE A NEW LOOK AT IMPLANTS



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

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

 SYNTELLIX

The advantages are obvious - **an overview**

Virtually no radiological artifacts.

Suitable for MRI and CT diagnostics.

Similar stability to titanium.

Avoids stress shielding.

No second operation necessary to remove hardware.



Metallic and bioabsorbable.

Osteoconductive.

Reduced risk of infection.

No known allergies or foreign body reactions.

Nickel- and aluminium-free.

MAGNEZIX[®]

REVOLUTIONARY AND PIONEERING

Metal that turns into bone. You think that's impossible? We can prove it - it really does work! Innovative material **MAGNEZIX[®]** is the start of a medical revolution.

We have developed a metallic implant for osteosynthesis which has similar stability to screws made of steel or titanium but which degrades in a controlled fashion in the body and is replaced by the body's own bone tissue.



MAGNEZIX[®] is the first implant of its kind in the world to have CE and HSA approval, satisfying the highest safety standards. It offers doctors, patients and cost providers with unique advantages.



Syntellix AG is an internationally active medical technology company based in Germany specialised in the research, development and distribution of self-degrading metallic implants made of magnesium.

We have received many awards for our work: 2013 the "German industry innovation award" and in 2015 as the "Top Innovator" of the German Mittelstand

PROPERTIES

OSTEOCONDUCTIVE AND REDUCED RISK OF INFECTION

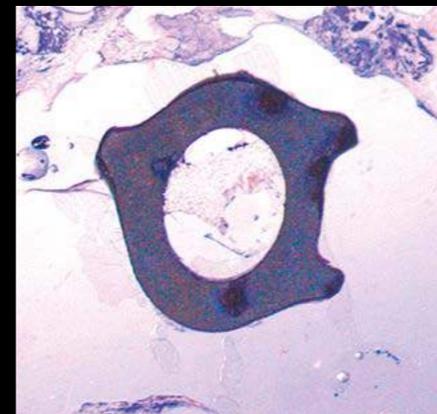
MAGNEZIX® has osteoconductive properties. Human osteoblasts have not only to great vitality in vitro but in addition they are stimulated in proliferation tests. The formation of new bone (osteoids) has been proven histologically at the surface of the degrading implant.

MAGNEZIX® implants help reduce the risk of infection because they are delivered as sterile devices. The degradation of the screw through corrosion further creates an alkaline bactericidal environment in the immediate vicinity of the implant such that MAGNEZIX® is anticipated to have anti-infectious properties.

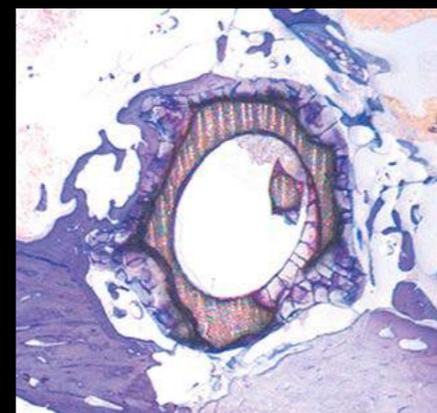
Right side

Histological sections show the implant's conversion process. The images show a cross-section of the cannulated MAGNEZIX® CS at various times post-OP.

Supporting the healing process



Histological preparation of an implanted MAGNEZIX® CS after a few days.

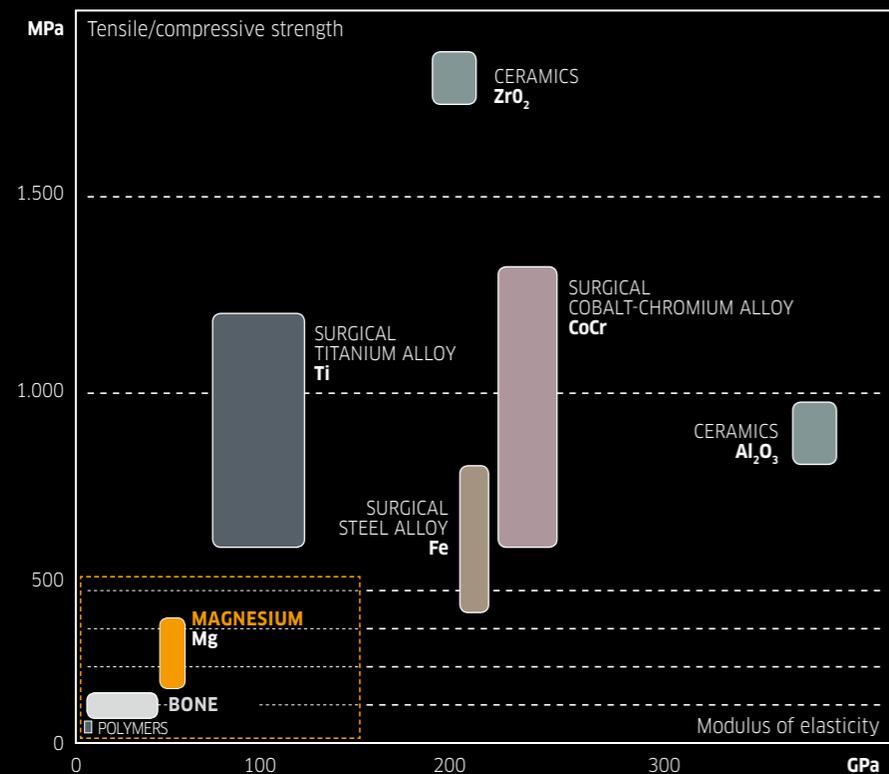


Conversion of MAGNEZIX® CS in progress after 3 months.



MAGNEZIX® CS conversion into calcium phosphate after 12 months with clear evidence of bone ingrowth.

Bone-like properties¹



PROPERTIES

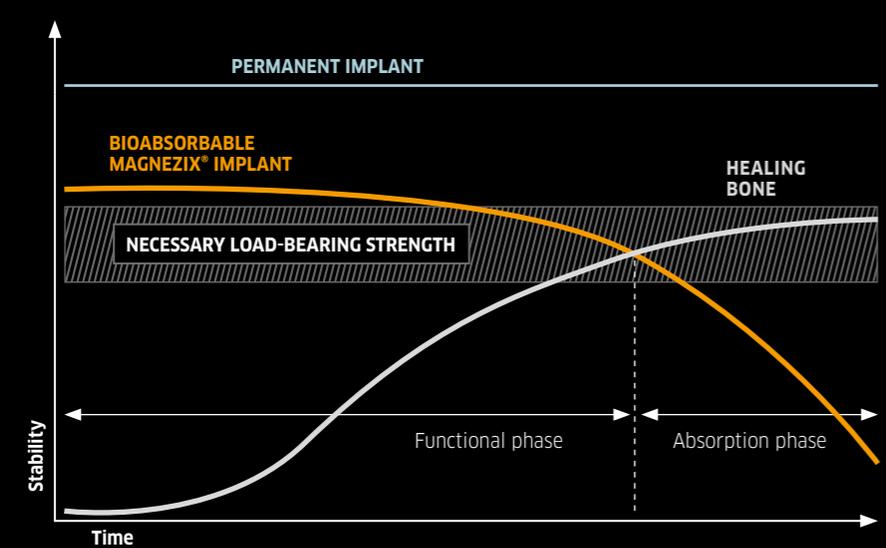
METALLIC AND BIOABSORBABLE

Stability alone is not enough - the ideal implant can do more.

MAGNEZIX[®] has mechanical stability values which are far above the values of those bioresorbable materials previously available. The good bone-like stress-strain ratio (modulus of elasticity) effectively counteracts stress shielding effects, which can result in loss of bone density (osteopenia).

MAGNEZIX[®] is based on a magnesium alloy with stable metallic properties. Over the course of time it is completely degraded in the body and is replaced by the body's own bone tissue.

Controlled degradation process (schematic)



¹Image based on: Wintermantel, E. (1996) Biocompatible materials and building methods. Published by Springer, Berlin

FEWER ARTIFACTS

A NEW DIMENSION IN DIAGNOSTIC IMAGING

MAGNEZIX[®] CS is a metallic implant. Nonetheless interference signals are greatly reduced both in computer tomography as well as MRI diagnostics - the implants generate very few artifacts. **This helps considerably improve the analysis of images by surgeons and radiologists.**

Unlike conventional screws made of steel and titanium, implants made of MAGNEZIX[®] do not generate any noticeable temperature increases during MRI.

SATISFIED PATIENTS

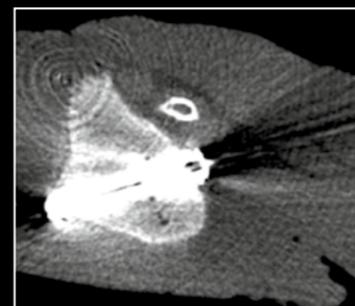
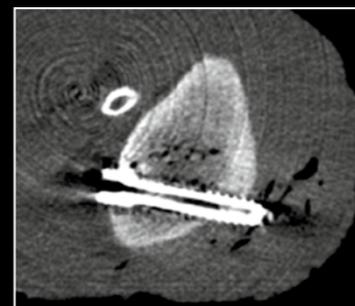
PROGRESS, WHICH PAYS OFF

Patients don't like the thought that after an operation there will be metal in their bodies permanently. But they also don't like having the metal removed because they are aware of the risk of infection and would like to stay mobile. The funding agencies are also backing Syntellix' efforts to avoid the need for a second operation and the associated costs.

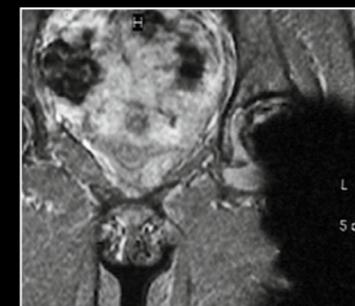
Patient satisfaction is high, and that is the talk of the town. You would be effectively creating your own USP in your region by offering patients the choice of innovative MAGNEZIX[®] technology - the use of MAGNEZIX[®] demonstrates that you are a front-runner, in tune with your patients' wishes!

Right side
Views of MAGNEZIX[®] CS compared with titanium in various imaging diagnostic methods (top)
The x-rays show examples of typical indications on feet and hands (bottom).

CT



MRI



MAGNEZIX[®] CS:
Minimal interference signals

Titanium:
Considerable interference signals

Hallux valgus correction



MAGNEZIX[®] CS after 6 weeks.

MAGNEZIX[®] CS after one year.

Titanium after one year.

Scaphoid fracture



MAGNEZIX[®] CS after 3 days.

MAGNEZIX[®] CS after 3 months.

During radiological control the phenomenon of lighter zones may temporarily occur around the implant. This is associated with the degradation processes of MAGNEZIX[®] and based on clinical experience to date is considered harmless.

THE IMPLANTS

PRODUCT OVERVIEW

According to its respective dimension, MAGNEZIX® CS can be used for adaption- and exercise-stable fixation of bones and bone fragments in children, adolescents and adult persons.

IMPLANT	DIMENSIONS	LENGTHS
MAGNEZIX® CS 2.0 	Diameter 2.0 mm Head diameter 2.5 mm	8 to 24 mm (in 2-mm steps), non-cannulated
MAGNEZIX® CS 2.7 	Diameter 2.7 mm Head diameter 3.5 mm Guide wire 1.0 mm	10 to 34 mm (in 2-mm steps), cannulated
MAGNEZIX® CS 3.2 	Diameter 3.2 mm Head diameter 4.0 mm Guide wire 1.2 mm	10 to 40 mm (in 2-mm steps), cannulated
MAGNEZIX® CS 4.8 	Diameter 4.8 mm Head diameter 5.7 mm Guide wire 1.8 mm	14 to 50 mm (in 2-mm steps), 55 to 70 mm (in 5-mm steps), cannulated

ADDITIONAL REFERENCES

Belenko L. | Könniker S. | Wacker F. | von Falck C. (2015):

Biodegradable magnesium Herbert screw in different modalities - image quality and artifacts. Poster presentation ECR 2015 / C-2339.

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), 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), 148-155

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), 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), 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, 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), 175-184.