METALLIC AND BIOABSORBABLE
TAKE A NEW LOOK AT IMPLANTS
Metallic and bioabsorbable.
Osteoconductive.
Reduced risk of infection.
No known allergies or foreign body reactions.
Nickel- and aluminium-free.

Similar stability to titanium.
Avoids stress shielding.
No second operation necessary to remove hardware.

Virtually no radiological artifacts.
Suitable for MRI and CT diagnostics.

The advantages are obvious – an overview
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 properties

<table>
<thead>
<tr>
<th>Material</th>
<th>Tensile/compressive strength (MPa)</th>
<th>Modulus of elasticity (GPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERAMICS ZrO₂</td>
<td>1.500</td>
<td>0</td>
</tr>
<tr>
<td>SURGICAL COBALT-CHROMIUM ALLOY CoCr</td>
<td>1.000</td>
<td>0</td>
</tr>
<tr>
<td>SURGICAL TITANIUM ALLOY Ti</td>
<td>0.500</td>
<td>0</td>
</tr>
<tr>
<td>SURGICAL STEEL ALLOY Fe</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>MAGNESIUM Mg</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>BONE</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Controlled degradation process (schematic)

- **Permanent implant**
- **Bioabsorbable Magnezix® implant**
- **Healing bone**
- **Necessary load-bearing strength**

Time

Stability

Functional phase

Absorption phase
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.

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!
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.

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.

Source of CT and MRI images: Hannover Medical School, Institute for Diagnostics and Interventional Radiology.
THE IMPLANTS

PRODUCT OVERVIEW

MAGNEZIX® CS compression screws are available in a range of dimensions and are suitable as bone screws for children, juveniles and adults for the fixation of bones and bone fragments.

<table>
<thead>
<tr>
<th>IMPLANT</th>
<th>DIMENSIONS</th>
<th>LENGTHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAGNEZIX® CS 2.0</td>
<td>Diameter 2.0 mm</td>
<td>8 to 24 mm (in 2-mm steps), non-cannulated</td>
</tr>
<tr>
<td></td>
<td>Head diameter 2.5 mm</td>
<td></td>
</tr>
<tr>
<td>MAGNEZIX® CS 2.7</td>
<td>Diameter 2.7 mm</td>
<td>10 to 34 mm (in 2-mm steps), cannulated</td>
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<td></td>
<td>Head diameter 3.5 mm</td>
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<td></td>
<td>Guide wire 1.0 mm</td>
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<tr>
<td>MAGNEZIX® CS 3.2</td>
<td>Diameter 3.2 mm</td>
<td>10 to 40 mm (in 2-mm steps), cannulated</td>
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<td></td>
<td>Head diameter 4.0 mm</td>
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<tr>
<td></td>
<td>Guide wire 1.2 mm</td>
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<tr>
<td>MAGNEZIX® CS 4.8</td>
<td>Diameter 4.8 mm</td>
<td>14 to 50 mm (in 2-mm steps)</td>
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<td></td>
<td>Head diameter 5.7 mm</td>
<td>55 to 70 mm (in 5-mm steps), cannulated</td>
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<tr>
<td></td>
<td>Guide wire 1.8 mm</td>
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</tr>
</tbody>
</table>
ADDITIONAL REFERENCES

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

Degradationsverhalten bioabsorbierbarer Magnesium-Implantate bei distalen Metatarsale-1-Osteotomien im MRT.
Fuss & Sprunggelenk (in press)

Früheregebnisse von distalen Metatarsale-1-Osteotomien bei Hallux valgus unter Verwendung eines biodegradierbaren Magnesium-Implantates. Fuss & Sprunggelenk (in press)

Magnesium and its alloys as orthopedic biomaterials: A review.
In: Biomaterials 27 (9), S. 1728-1734.

In vivo study of a biodegradable orthopedic screw (MgYREZr-alloy) in a rabbit model for up to 12 months.

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.

Mechanisms of magnesium-stimulated adhesion of osteoblastic cells to commonly used orthopaedic implants.
Implants are manufactured in Germany in cooperation with Königsee Implantate GmbH.

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