

IMPORTANT INFORMATION FOR THE ATTENDING PHYSICIAN

REDNESS, SWELLINGS, ALLERGIES

MAGNEZIX® implants have an excellent and proven biocompatibility. Magnesium (Mg) is an **essential element for the metabolism and basic body functions**. The recommended daily dietary intake is about 375 to 500 mg. In comparison, a MAGNEZIX® implant contains approximately 150 mg of magnesium, which is released very slowly during the degradation process. Therefore, even with several implants inserted, a magnesium overdose can be excluded.

In fact, a magnesium implant such as MAGNEZIX®, which degrades in the bone, can even serve as a **source of essential magnesium ions**. Since the majority of the body's magnesium supply is stored in the bones, the absorption is easily possible.

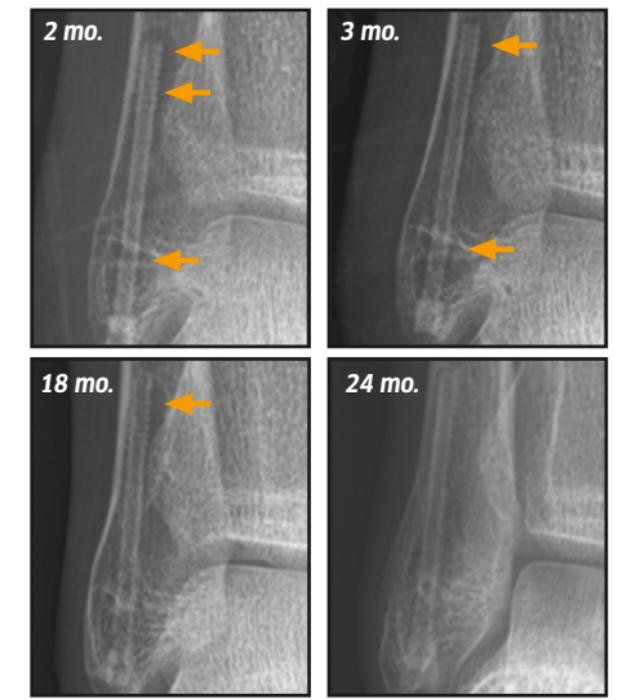
Redness and swelling in the surgical region can occur, as well as with other implants, in response to the surgery performed, but they are not material-specific and disappear after a short time.

No allergies are known for the components of the alloy.

RADIOLUCENCY PHENOMENA

In postoperative radiographic imaging, **temporary radiolucent zones around the implant may become visible** in some cases. These are due to the nature of the degradation process of magnesium implants and are a **short-term phenomenon**. They have **no negative effect on bone healing** and **disappear by themselves**. The release of by-products during the absorption process of magnesium has long been a critical factor that has been **reduced to a minimum level** by the optimized production process and the special alloy composition of MAGNEZIX®.

Results from laboratory tests, animal studies and clinical applications to date demonstrate the remodelling of a MAGNEZIX® implant within a period of 12-36 months. After three years, the former implant is replaced by endogenous tissue, which corresponds to the radiological endogenously formed bone tissue.



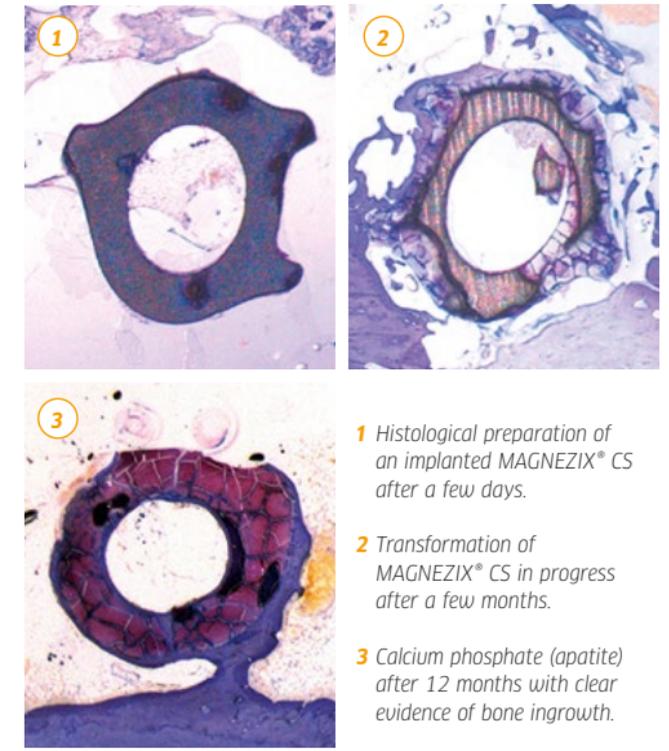
Lateral malleolar fracture (Weber type A) Fixation with MAGNEZIX® CS 3.2, until 24 months post-op. The radiolucent zone regresses at each subsequent follow-up and has no effect on the clinical healing result of the patient.

IMPLANT DEFORMATION AND "BREAKAGE"

MAGNEZIX® implants provide **primary stability like screws made of titanium** and up to 5x **higher load capacity compared to polymer-based implants**.

During the healing process, magnesium implants naturally lose their original shape. In some cases they even appear to be "broken" in diagnostic imaging. This phenomenon is due to the fact that they reabsorb as intended, while the healing bone regains the ability to bear higher loads.

A not yet mineralized bone matrix (osteoid) is formed by osteoclasts and osteoblasts which are responsible for bone remodeling (osteoconductive properties of magnesium). Therefore, it is an indispensable step in the degradation process of magnesium implants.



- 1 Histological preparation of an implanted MAGNEZIX® CS after a few days.
- 2 Transformation of MAGNEZIX® CS in progress after a few months.
- 3 Calcium phosphate (apatite) after 12 months with clear evidence of bone ingrowth.

This implant pass is only for supplemental information of the patient and the attending physician. It does not replace the doctor's letter/discharge report.

Syntellix AG
Aegidientorplatz 2a
30159 Hannover
Germany

T +49 511 270 413 50
F +49 511 270 413 79

info@syntellix.com
www.syntellix.com

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

Misprints and errors are reserved.

IMPLANT PASS

MAGNEZIX® CS | Pin | CBS | StarFuse® | CS^c

M 7041.001.004 12/19

DEAR PATIENT,

You've had surgery recently. And instead of using steel or titanium screws that remain in the body as foreign material, which may cause problems and for which a second metal removal surgery may be required, your treating surgeon has recommended an innovative, bioabsorbable (self-dissolving) MAGNEZIX® implant to help you reduce those risks and to avoid additional burdens.

These **magnesium-based implants** are unique in the world because they are made of metal, so that they are significantly more stable than other resorbable implants, yet they completely dissolve in the body and turn into bone. For a proper follow-up treatment of your procedure, we have created this pass for you.

DEAR COLLEAGUES,

Your patient has been surgically treated with a metallic, absorbable magnesium-based implant. Compared to conventional implants, they have some special features that need to be considered. To help you with the optimal follow-up care, you will find the most important information in this implant passport.

With best regards,
Yours



Prof. Dr. med. Martin H. Kirschner
Member of the Executive Board/CTO

PATIENT

Mr. Ms.

FIRST NAME

LAST NAME

DATE OF BIRTH

FOLLOW-UP APPOINTMENTS

_____ Wk./ Mo. post-op on:  _____

_____ Wk./ Mo. post-op on:  _____

_____ Wk./ Mo. post-op on:  _____

_____ Wk./ Mo. post-op on:  _____

SURGERY

DATE OF SURGERY

UPPER EXTREMITY

Shoulder Upper arm Forearm Hand

LOWER EXTREMITY

Upper leg Knee Lower leg Foot

TORSO

Hip Pelvis

OTHER

INDICATION/COMMENTS

NOTES

SURGEON

HOSPITAL/CLINIC STAMP

MAGNEZIX® IMPLANT



CS CS^c 4.8 Pin CBS StarFuse® IFSC^c

LOT/LABEL (NUMBER, IMPLANT DESIGNATION)