MAGNEZIX

UNDERSTANDING INNOVATIONS

A CLOSER LOOK AT THE SPECIAL PROPERTIES OF MAGNEZIX®

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

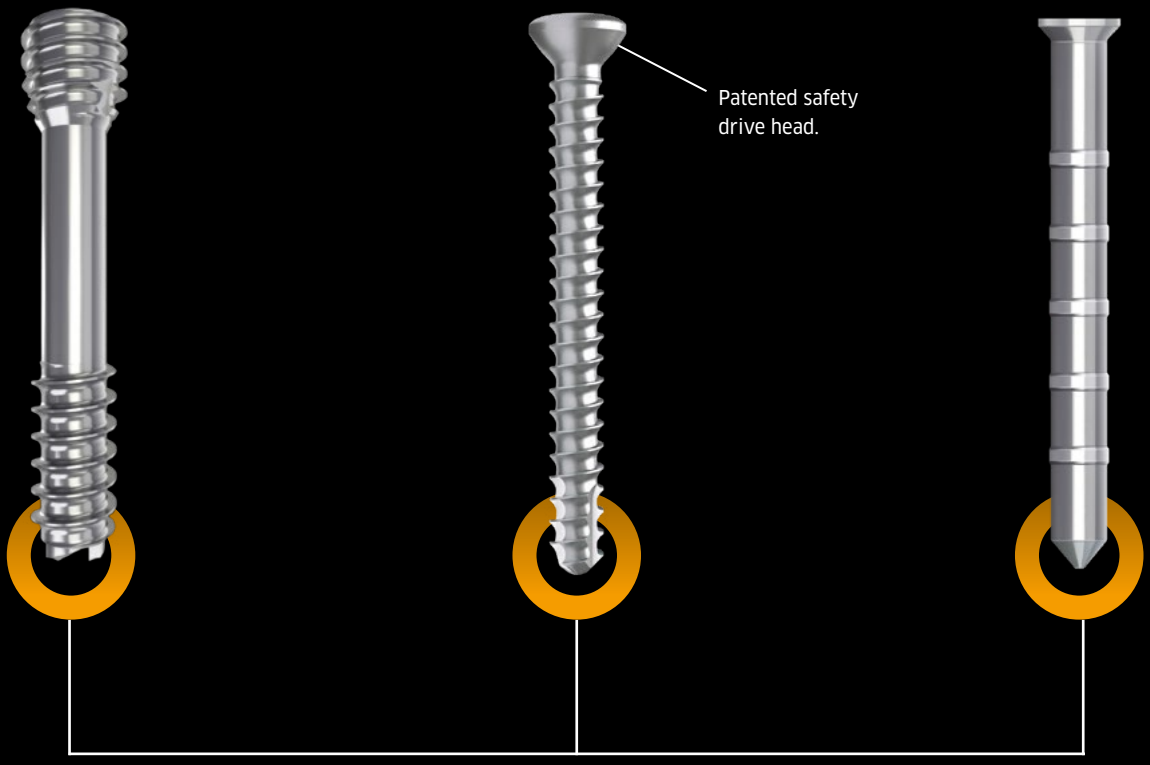
SYNTELLIX

STABILITY, TRANSFORMABILITY AND OSTEOCONDUCTIVITY DEFINE THE NEW STANDARD OF IMPLANTS!

Similar stability to comparable titanium implants.

Greater stability than PLA/PGA implants.

Up to 5 times higher stability than polymer pins.



Metallic and bioabsorbable.
Osteoconductive.
Reduced risk of infection.

No remaining foreign material.
Stable and elastic, reduced risk of stress shielding.

Practically no radiological artefacts.
Suitable for diagnostics in MRI and CT.

Free of aluminium, nickel, chromium and cobalt.
Excellent biocompatibility, no known allergies.

SUSTAINABILITY AWARD 2018
STEP AWARD Branchensieger Tech 2017
GERMAN MEDICAL AWARD Gewinner 2017
TOP 100 Innovator of the year 2017
INDUSTRIE PREIS 2017 FINALIST
cdgw Preisträger 2016 Deutscher Zukunftspreis Gesundheitswirtschaft
EUROPEAN INNOVATION PARTNERSHIP on Active and Healthy Ageing INNOVATIVE SOLUTION
TOP 100 Top-Innovator 2015 & 2016
INNOVATIONSPREIS DER DEUTSCHEN WIRTSCHAFT Sieger 2012/13

THE GAME CHANGER AND INNOVATION LEADER: MAGNEZIX®

Worldwide innovation leader

Most implants in the field of orthopedic surgery are made of non-resorbable materials such as steel or titanium which permanently remain in the body or have to be removed in a second surgery. Both entail risks for the patients. In addition to functional limitations, permanent implants can provoke stress shielding, inflammatory or foreign body reactions. The removal can cause eg. nerve and vascular lesions.

In order to minimize these problems, resorbable, yet stable implants have become subject of extensive research. While there were many approaches to design a material that provides both adequate mechanical and degradation properties combined with excellent biocompatibility, MAGNEZIX® hit the market as **the globally first transformable metallic implant material** approved for human use.

Inventing new technologies

There were good reasons to think about using magnesium in orthopedic surgery:

1. An implant consisting of a magnesium-based alloy would initially be **as strong as a traditional bone implant** made of steel or titanium and would, additionally, gradually dissolve.
2. It would show **very good biocompatibility, strong osteogenic potential and infect inhibiting effects.**

The challenge was to develop the right - strong yet elastic - magnesium-based alloy suitable for osteosynthesis. The MAGNEZIX® alloy is based on the MgYREZr system and shows excellent values of strength properties (yield strength > 260 MPa, tensile strength > 290 MPa) and is free of aluminum and of known allergenic elements like cobalt, chrome, and nickel.

CE

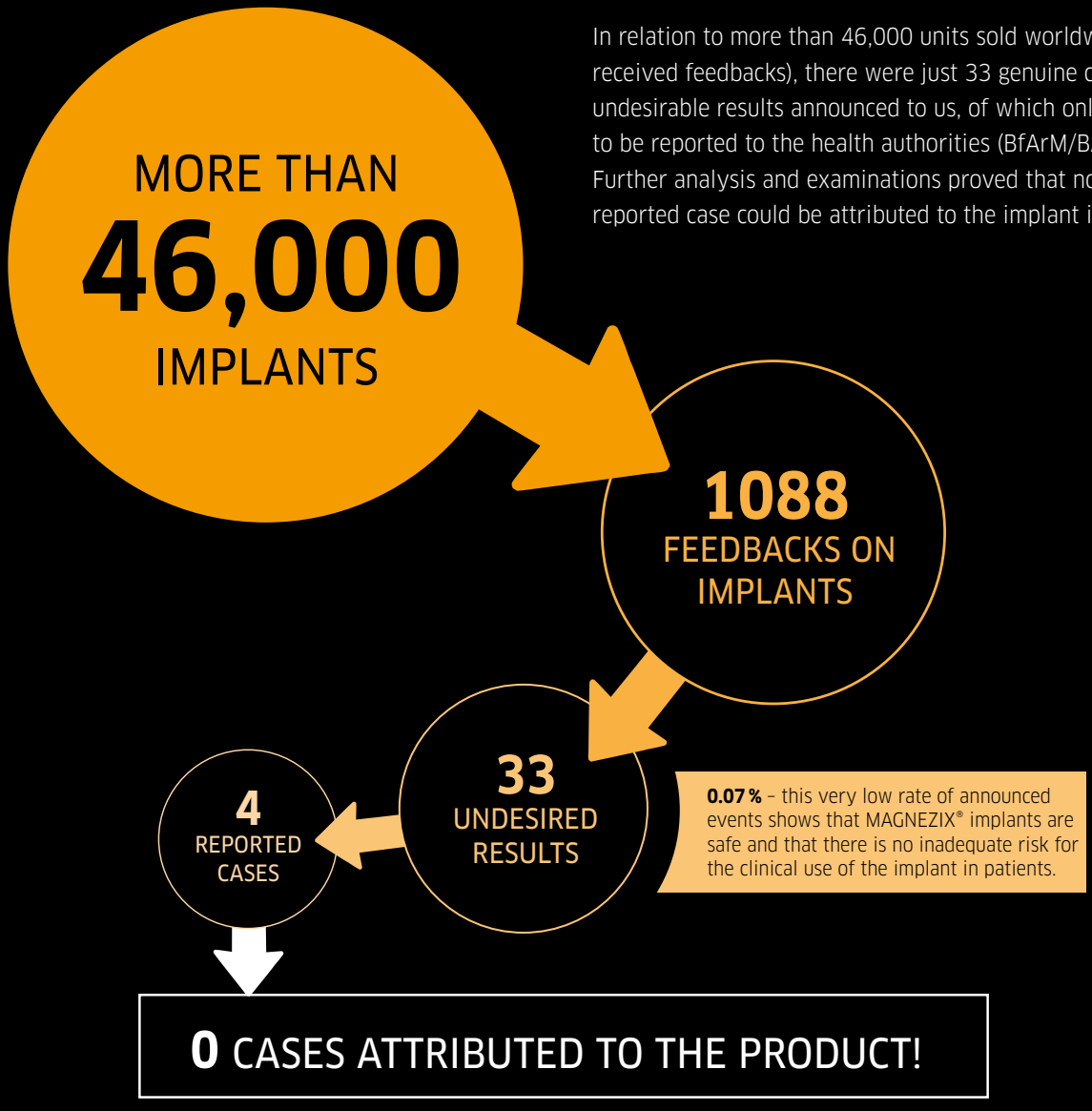
CE approval was granted in 2013 for MAGNEZIX® compression screws (CS), enabling the first clinical use of a self-dissolving metallic screw in Europe. In 2016 and 2017 the CE-certified MAGNEZIX® product portfolio was expanded to include the Pin and the CBS cortical bone screw.

Progress requires change

The implementation of this innovation has not only led to a vast range of new possibilities, but also had and still has to deal with reservation. In the end, every innovation requires reconsideration and every state-of-the-art product once was new and uncommon!

IN THOUSANDS OF SURGERIES NOT A SINGLE UNWANTED RESULT WAS ATTRIBUTED TO THE PRODUCT!*

In relation to more than 46,000 units sold worldwide (1088 received feedbacks), there were just 33 genuine clinical undesirable results announced to us, of which only 4 had to be reported to the health authorities (BfArM/BASG). Further analysis and examinations proved that not a single reported case could be attributed to the implant itself.



*All mentioned events seem to have been caused by the applicants' learning curve for the proper use and normal clinical course of the implant. Not a single case could be attributed to the product itself or its material.
Under no circumstances the product can be regarded more risky than comparable products which are already in wide spread use worldwide.

Source: Official vigilance data Syntellix AG, July 2018

MAGNEZIX® IS AN INNOVATION WITH PROVEN BENEFITS!

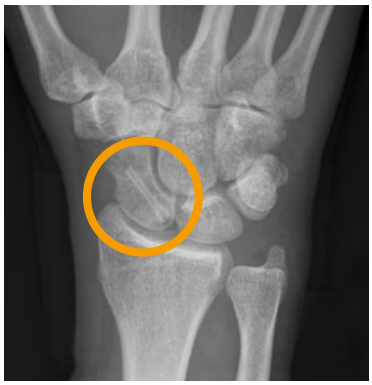
BEING A NATURAL MATERIAL, MAGNESIUM IS SUBJECT TO A DEGRADATION PROCESS!

When using magnesium implants for the first time, surgeons are not used to some **degradation-related appearances** they see in conventional X-rays. First, on postoperative radiographs, a MAGNEZIX® implant is not as dense as a titanium or steel implant. Second, during radiological control, the phenomenon of radiolucency may temporarily occur around the implant. This is a general phenomenon of the degradation process of magnesium and therefore also associated MAGNEZIX®: While the material dissolves, there is a natural loss of mass and weight. Also, magnesium releases small quantities of hydrogen gas which will be resorbed over time. Osteoclasts and osteoblasts will appear due to the osteoconductive capacity of MAGNEZIX®, helping to enable the process of bone remodeling, and an osteoid (non mineralized bone matrix) is formed.

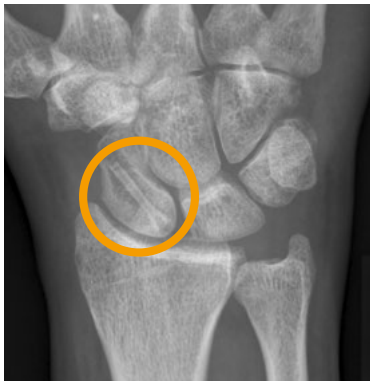
Although sometimes visually inconvenient, **the described phenomenon of radiolucent zones around the implant is only short-term, does not affect bone healing and disappears by itself.**[1] Experiences from laboratory testing, animal studies and the clinical use so far prove that the implant disappears within around 12 months and is replaced after 3 years at the latest by endogenous tissue that corresponds most closely to bone tissue. The development of degradation byproducts in the degradation process of magnesium seemed to be a critical factor for a long time, whose influence, however, **was reduced to a minimum level** by the particular production process and the specific alloy composition of MAGNEZIX®.

It is recommended to include the phenomenon of potential radiolucency in the operating room note/discharge note, pointing out that it does not have any clinically relevant influence on the healing process. This will inform the caregivers involved in the follow-up treatment about the special aspects of the implants' dissolving process.

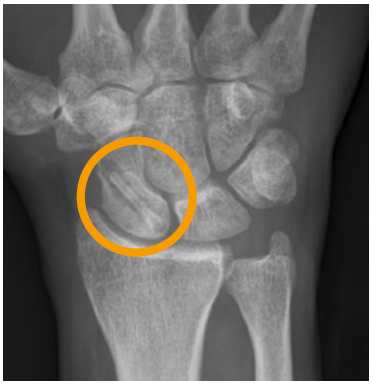
Scaphoid fracture



Post-op.

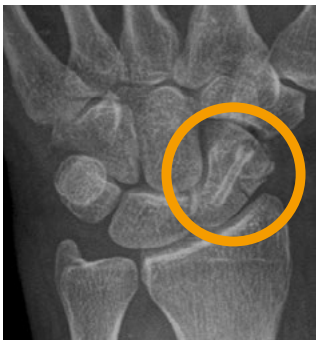


Follow-up after 4 weeks, around the shaft and tip of the implant a radiolucent zone is recognizable.

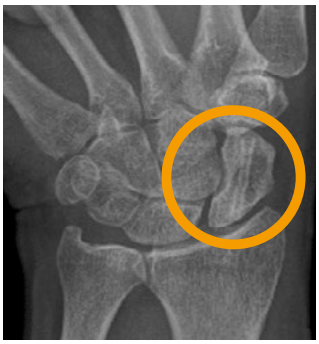


Follow-up after 8 weeks, the radiolucent zone noticeably regresses and has no effect on the cli-nical healing result of the patient.

[1] Source: Plaass C., et al. (2018): Bioabsorbable magnesium versus standard titanium compression screws for fixation of distal metatarsal osteotomies – 3 year results of a randomized clinical trial. Journal of Orthopaedic Science 23 (2), pp. 321-327.



Post-op X-ray.

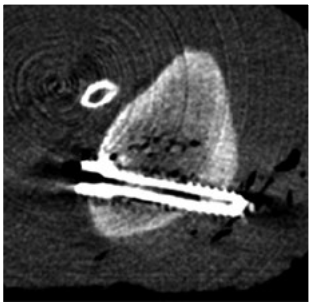


6 months after surgery.

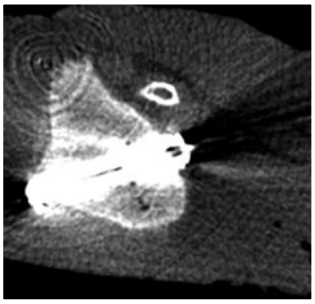
MAGNEZIX® IMPLANTS PROVIDE AN IDEAL COMBINATION OF STABILITY AND ELASTICITY SINCE THEIR MECHANICAL PROPERTIES ARE VERY CLOSE TO THOSE OF CORTICAL BONE!

MAGNEZIX® implants are designed to ensure a **primary stability like common screws made of steel or titan** (MAGNEZIX® CS and CBS) and a load capacity which is up to **5 times higher compared to ordinary polymer-based pins (MAGNEZIX® Pin).** During the healing process, magnesium implants naturally loose their original shape. In some cases, they even appear to be broken in diagnostic imaging. However, this phenomenon does not result from a lack of primary stability; it is rather due to the fact that with time, magnesium implants **degrade as intended** while the bone heals and recovers its ability to bear a higher load capacity (see X-rays on the left side).

It should be noted that MAGNEZIX® CS implants follow a **magnesium-specific design** which cannot be directly compared to titanium screws one to one (e.g. in terms of diameters). Thus, compared to titanium screws, it is recommended to use the next larger MAGNEZIX® screw diameter in most cases.
The fact of using a self-cutting, yet not a self-drilling screw should be considered as well. In some rare cases, the head of the screw broke during the insertion process due to the inadequate skipping of the mandatory pre-drilling of either the cancellous or the cortical bone, or both. For screws with **self-tapping tips, pre-drilling over the desired screw length is crucial,** facilitating the subsequent tightening of the screw and reducing the rotation of small bone fragments.



MAGNEZIX® CS:
Minor interference signals in CT



Titanium:
Major interference signals in CT

MAGNEZIX® IMPLANTS ARE SUITABLE FOR MRI AND CT DIAGNOSIS!

The metallic MAGNEZIX® implants are **suitable for MRI and CT diagnostics.** Noise is greatly reduced and the implants generate very few artefacts. In addition, unlike conventional screws made of steel and titanium, implants made of MAGNEZIX® do not generate any noticeable temperature increases during common MRI scanning. This improves considerably postoperative imaging for surgeons and radiologists.

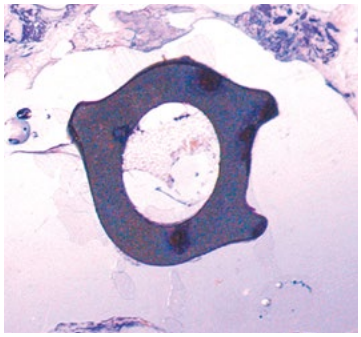
If X-rays are taken in order to evaluate intraoperatively the position of the implant by means of fluoroscopy, the irradiated area should be **free of any other implants,** guide wires, instruments etc. Foreign materials in the irradiated field can raise the X-ray dosage, leading to inadequate exposure of MAGNEZIX® implants **(effect of „overexposure“)**. The effect of overexposure can be reduced by **modifying the intensity of radiation.**

Source of CT images: Hannover Medical School, Institute for Diagnostics and Interventional Radiology

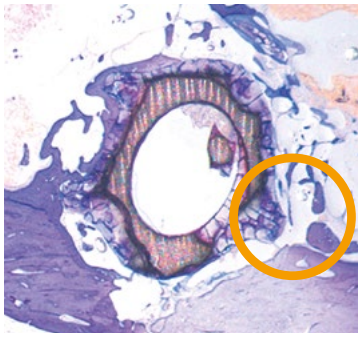
DEGRADING MAGNESIUM HAS OSTEOGENIC PROPERTIES AND REDUCES THE RISK OF INFECTIONS!

Magnesium is a biologically active material and can **support the healing process.** Both, *in vitro* and *in vivo* studies have shown excellent cell compatibility and distinct osteoconductive properties of magnesium alloys. *In vitro* trials with MAGNEZIX® have demonstrated a **high vitality of human osteoblasts.**
Magnesium degrades via a corrosion process which creates a basic (alkaline) environment in the direct surroundings of the implant, **thus inhibiting bacterial growth.** Furthermore, the presence of released hydrogen (or hydrogen ions) is described to be particularly advantageous in the human organism regarding cell and tissue protection. **Hydrogen, in this context, acts as an antioxidant** which selectively binds and defuses DNA-changing hydroxyl radicals or peroxid nitrides.
These positive effects, proven for pure magnesium, can be strongly anticipated for MAGNEZIX® (> 90 % Mg content). Additionally, in order to minimize the risk of infection, all MAGNEZIX® implants are individually sterile packaged.

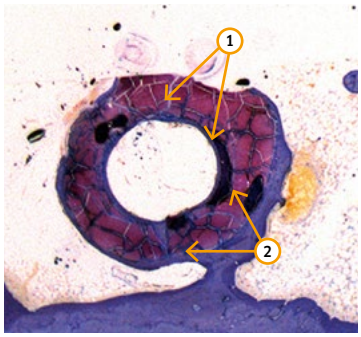
Supporting the healing process[2]



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



Transformation of MAGNEZIX® CS in progress after a few months.



MAGNEZIX® CS conversion into calcium phosphate (1) after 12 months with clear evidence of bone ingrowth (2).

MAGNEZIX® IMPLANTS ARE FREE OF NICKEL AND ALUMINIUM AND DO NOT PROVOKE ANY KNOWN ALLERGIES!

Magnesium itself has **good biocompatibility,** which – amongst others – results from the high daily need of humans for the element magnesium. Magnesium (Mg) is an **important mineral for the physiological metabolism and basic functions,** and the recommended daily dietary intake is about 375 to 500 mg. MAGNEZIX® implants, which consist of more than 90 % of Mg, have a **very good proven biocompatibility.** On average, such an implant contains approximately 150 mg of magnesium, which is released very slowly during the degradation process – even with several implants inserted, an overdosing or other harmful effects can be excluded. Quite the contrary, within the bones are well 50 % of the body's total stock of magnesium easily available for resorption. This way, a magnesium implant that degrades within the bone can become a **source of essential magnesium ions.** Since magnesium is a natural material which is essential for proper bodily functions, it it very unliekely to provoke allergies. One advantage of MAGNEZIX® is that **it contains no nickel, cobalt, chromium or aluminium elements,** which are all under suspicion to cause severe diseases.

In summary, there are absolutely **no allergies known for MAGNEZIX® implants!**

[2] Source: Waizy H, Diekmann J, Weizbauer A et al. (2014). In vivo study of a biodegradable orthopedic screw (MgYREZr-alloy) in a rabbit model for up to 12 months. J Biomater Appl 28 (5), 667-75.

THE EXPERIENCE OF OUR USERS IS THE BEST REFERENCE!

PATIENTS/IMPLANTS	INDICATIONS	PERIOD OF TIME	AUTHOR/SOURCE	COUNTRY
19-year-old female patient	Lateral malleolar fracture	2 years	Acar et al., Cureus, April 2018 (Case Report)	Turkey
200 patients	Hallux Valgus	October 2014 to June 2016 (magnesium cohorts), January 2013 to August 2014 (titanium cohorts)	Klauser, Foot Ankle Surg, February 2018 (Article)	Germany
11 patients	Medial malleolar (MM) fracture	Februrary 2015 to August 2016	Kose et al., Archives of Orthopaedic and Trauma Surgery, February 2018 (Case Report)	Turkey
26 patients	Hallux valgus	March 2010 to July 2011	Plaass et al., Journal of Orthopaedic Science, November 2017 (Article)	Germany
17,000 implants in 20 countries	Multiple	Since market entry in 2013	Kirschner/Seitz, Wehrmedizin und Wehrpharmazie 2/16, June 2016 (Article)	Over 20 different countries
25 feet with hallux valgus deformity (15 left, 10 right)	Hallux valgus	March 2015 to April 2016	Thevendran, June 2016 (Presentation)	Singapore
20 female patients	Hallux valgus	April 2015 to April 2016	Juutilainen, April 2016 (White paper)	Finland
4 patients	Scaphoid fractures	September 2015 to April 2016	Schächinger, 57th DAH Symposium, April 2016 (Presentation)	Germany

DESCRIPTION/RESULTS

Successful and complete fracture union in a young adult **without any clinical complications.** MAGNEZIX® bioabsorbable screws offer a clear advantage over conventional metallic implants for the fracture fixation – **there is no need to remove implant after bone union.** The **bioabsorbability** of MAGNEZIX® implants was **proven without implant failure** or re-displacement of the fracture. When using MAGNEZIX® implants, a **temporary radiolucent zone** surrounding the implant was observed in post-operative imaging, however, the radiolucency **did not affect the healing process of the bone.** The American Orthopaedic Foot & Ankle Society (AOFAS) gave a score of **100 points** after the final 24-months postoperative examination.

In a sample of 200 patients, from which 100 patients were treated with MAGNEZIX® screws and 100 patients with titanium screws, there were **no significant differences** between magnesium-based screws and titanium screws in terms of **stability** and **wound healing.** However, MAGNEZIX® implants degrade over time and obviate the necessity of implant removal and, are therefore, **"clinically superior"** over conventional titanium screws. The use of MAGNEZIX® implants implies a **huge long-term reduction of costs.**

The use of MAGNEZIX® screws for the fixation of displaced MM fractures resulted in **excellent functional results** and a **safe and effective treatment** for the fracture fixation of **trauma cases.** Complete bone healing was achieved in all patients without complications. **Moderate radiolucent zones** around the implant **disappeared after 6-12 months postoperatively** and this phenomenon **did not cause any clinical symptom,** neither did it interfered negatively with the fracture healing process. The **headless design** of MAGNEZIX® CS screws offers **clear clinical advantages.**

The 3-year post-surgery results of the fixation of distal metatarsal osteotomies using MAGNEZIX® screws and standard titanium (Ti) screws prove that **MAGNEZIX® metallic screws offer the same high level of safety and efficiency than Ti-screws.** The study demonstrates **clear advantages of MAGNEZIX®** implants such as **bioabsorbability** and **less artifacts in radiologic imaging.** Among the patients treated with MAGNEZIX®, **no patient complained about pain,** swelling or inflamation. All patients in the MAGNEZIX® group were **satisfied** with the surgery and would **recommed it to others.**

By February 2016, 17,000 implants in 20 countries have been successfully placed on the market. **Clinically, positive results were achieved in almost every case of more than 7,000 implantations.**

MAGNEZIX® bioreabsorbable screws, when used in hallux valgus deformity correction, **are at least as good as conventional titanium alloy screws with regards to functional results and radiologic correction.** Bioreabsorbable implants, however, do not necessitate removal nor cause stress shielding. Socio-culturally, patients are much more receptive to having these implants.

The first 20 hallux valgus operations using MAGNEZIX® screws were uneventful. The preliminary results in this case are the same as compared to titanium or stainless steel screws. There were **no major problems during the healing period.** No deep infections were noticed and there was no need for a second operation. **There were no complications due to the used fixation material.** All patients were asked about subjective satisfaction of the operation, **all said that they would have the same operation if the other foot had to be operated in the future.** MAGNEZIX® screws should vanish in a few years. So there should be no need for hardware removal at any time. Altogether, MAGNEZIX® screws offer a good alternative for fixation of first metatarsal osteotomies.

Compared to compression screws made of titanium, when using the bio-degradable magnesium-based compression screw, there are no major differences concerning the operating technique or healing process and no clinical anomalies have been seen so far. Temporary radiolucencies during radiological control seem to be clinically ineffectual and have to be clearly differentiated to known radiolucencies (like osteolysis because of an infection or loosening).

MAGNEZIX® MEETS ALL CRITERIA OF AN IDEAL IMPLANT!

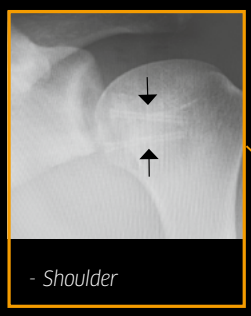
	TITANIUM	STEEL	POLYMERS (PLA/PGA)	MAGNEZIX©
Degradation (time in months)	No	No	3-18[3], beginning immediately	12-24, beginning immediately
Loss of stability half-value period	Only fatigue	Only fatigue	10-50 % after 12 weeks	App. 50 % after 12 weeks
Young`s modulus (bone: 12-25 GPa)	105 GPa (5 times higher)	193 GPa (10 times higher)	1.5-7[3] GPa (lower)	47 GPa (2 times higher)
Tensile strength (bone: 150 MPa)	539 MPa (4 times higher)	275-520 MPa (2-4 times higher)	21-100[4] MPa (lower)	> 290 MPa (2 times higher)
Biocompatibility	Gold standard	Foreign body reactions known	Foreign body reactions known[6,7]	Good, proven with ISO 10993-1
Degradation products	No resorption	No resorption	Not finally checked	Biocompatible and bio-absorbable oxides and hydroxides, hydrogen gas
Radiology (CT, X-ray, MRI)	Well visible, partially with artefacts	Well visible, extensive artefacts	No artefacts, partially not visible[7]	Low artefacts, visible with X-ray

MAGNEZIX® has mechanical stability values which are far above the values of those bioresorbable materials previously available.

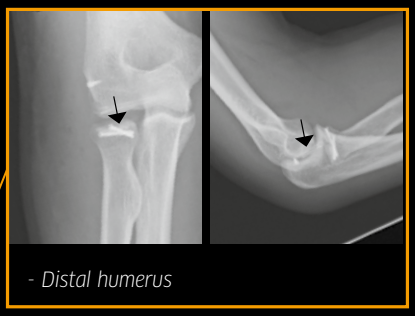
The mechanical properties of the MAGNEZIX® alloy, determined after the final extrusion process, result in yield strength properties higher than 260 MPa, tensile strength properties higher than 290 MPa and elongation to failure properties higher than 8 %. With a Young's Modulus of 47 GPa, **the biomechanical properties of MAGNEZIX® are very close to those of human bone.** The good bone-like stress-strain ratio effectively counteracts stress shielding effects that can result in loss of bone density (osteopenia). Likewise, micro-movements in the fracture zone can lead to better healing conditions.

Source:
[3] Tan L., Yu X., Wan P., Yang K. J. Mater. Sci. Technol. 2013, 29, 503.
[4] Thomas S., Alavi S., Sandeep K. P., Kalarikkal N. Polymers for packaging applications. Apple Academic Press, Toronto 2014.
[5] Suuronen R., Pohjonen T., Hietanen J., Lindqvist C. Oral Maxillofacial Surg. 1998, 56, 604.
[6] Rovinsky D., Nissen T., Otsuka N., Orthopedics 2001, 24, 177.
[7] Ernstberger T., Buchhorn G., Heidrich G. Neuroradiology 2009, 51, 525-529.

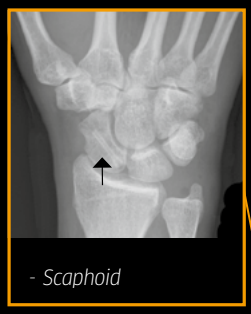
VARIOUS APPLICATIONS – ONE SIMILARITY: NO REMAINING OF FOREIGN MATERIAL!



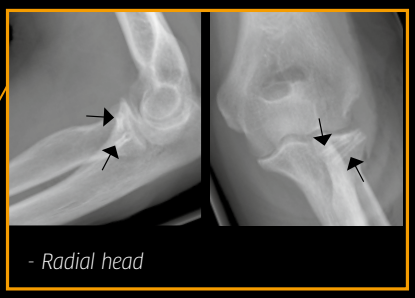
- Shoulder



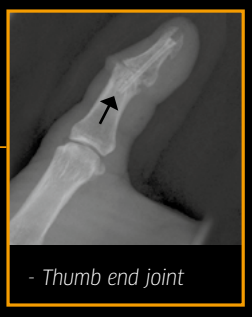
- Distal humerus



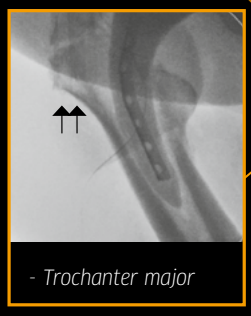
- Scaphoid



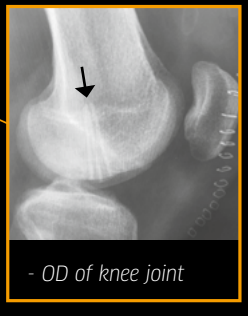
- Radial head



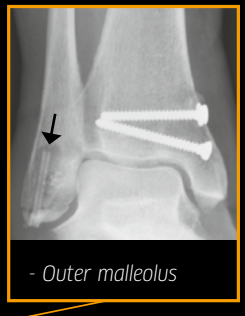
- Thumb end joint



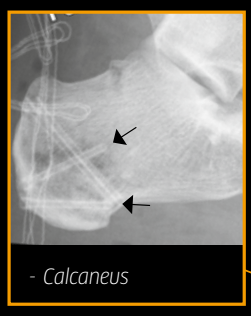
- Trochanter major



- OD of knee joint



- Outer malleolus



- Calcaneus

NO METAL REMOVAL NECESSARY

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

After a successful osteosynthetic treatment with conventional implants, the question of metal removal arises. Whether it is generally recognized (as in children and adolescents), or is medically necessary (e.g. due to clinical complaints) or even desired by the patient – it always requires a balance of potential advantages and disadvantages.

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)
- Disturbing implants on prominent parts of the body
- Increased expectations of patients

Removal of metal represents higher level 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 (intraoperativiely, or postoperatively at a breaking point).
- ➔ Increased scarring, possibly the need for scar correction.

MAGNEZIX® makes implant removal unnecessary.

MAGNEZIX® screws (CS, CBS) and Pins are designed to achieve a primary stability similar to that of steel or titanium, which is considerably higher than the strength of polymers.
In the course of healing, magnesium implants transform over time, while the regenerating bone gains in load bearing capacity. Studies have demonstrated excellent cell compatability and osteoconductive properties (new bone formation on the implant).

ADDITIONAL REFERENCES

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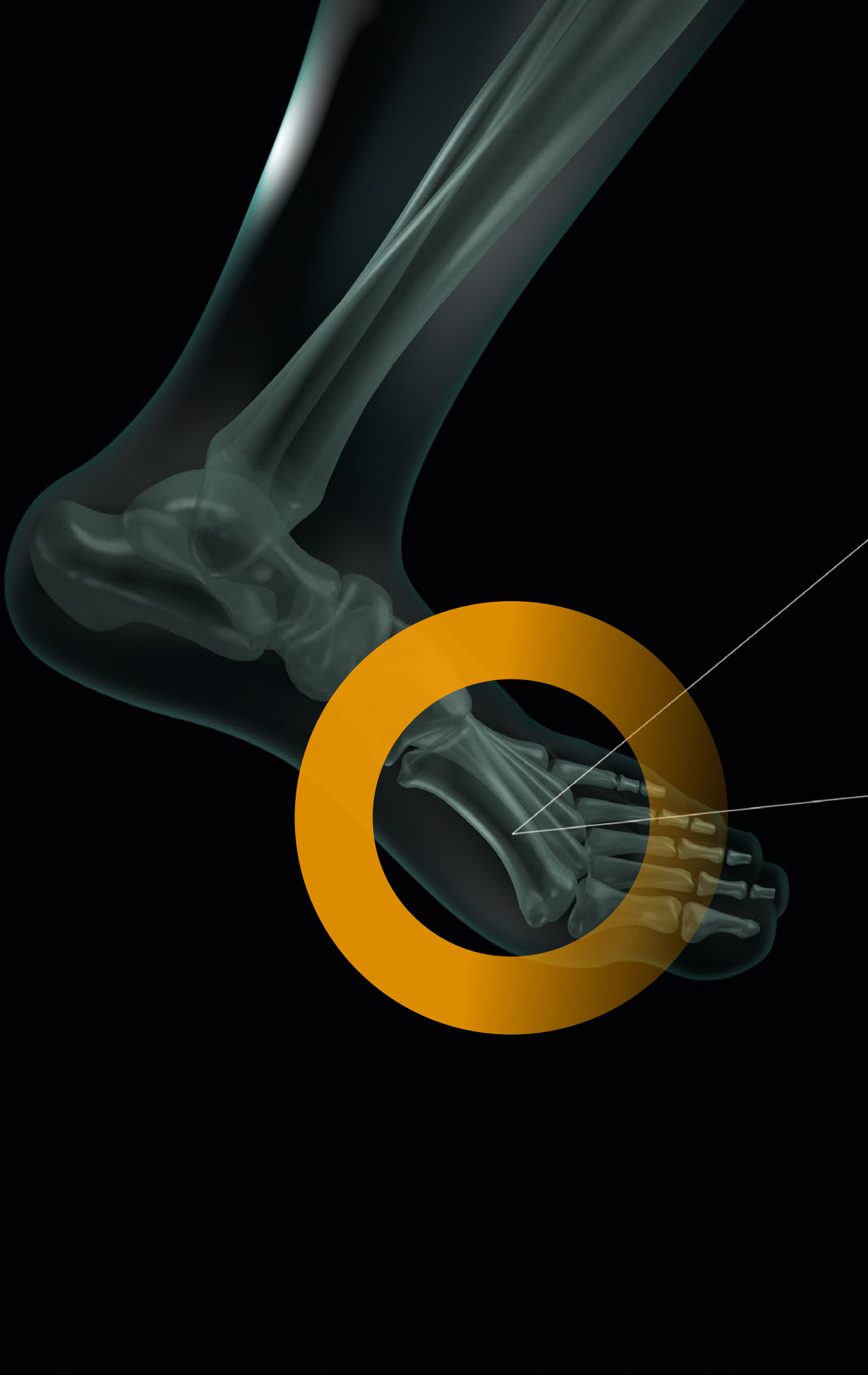

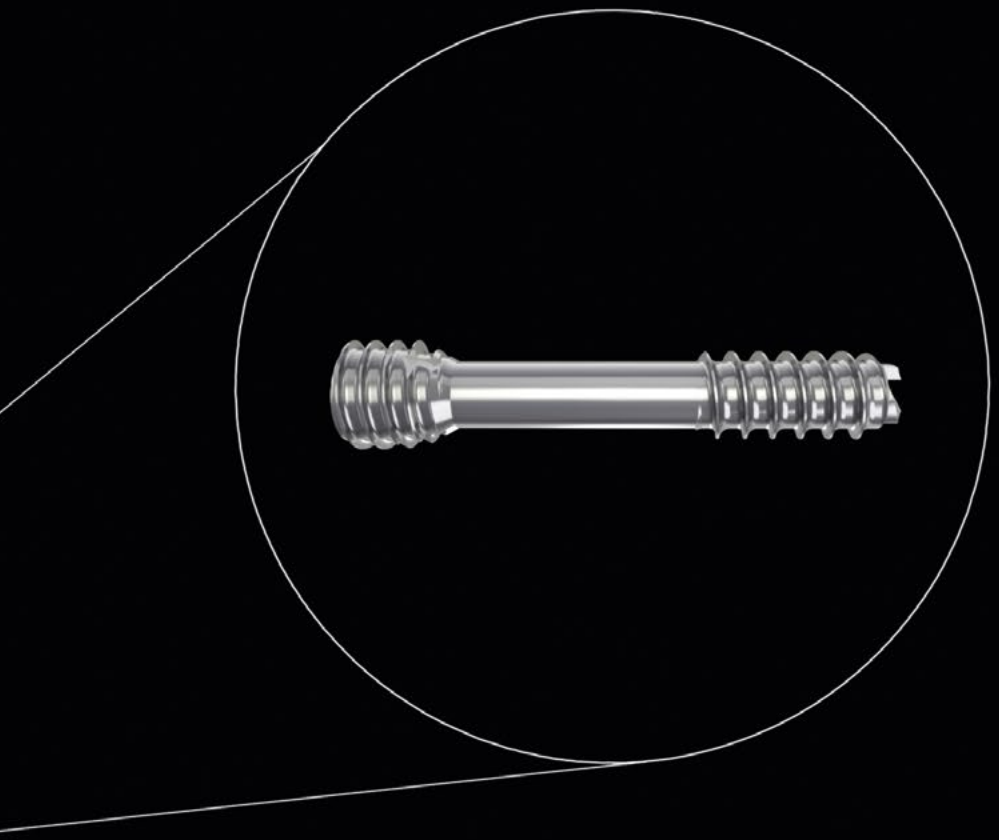

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