THIS SCREW TURNS INTO BONE

THE INTELLIGENT IMPLANT

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

Distributed in the UK by

ATHRODAX HEALTHCARE INTERNATIONAL LTD

MAGNEZIX

Patient Information
MAGNEZIX® CS - THE IMPLANT WHICH MAKES HEADLINES
DEAR PATIENT,

You will be undergoing an operation soon in which an implant will be used. In the past, these implants, in this case screws, were made of steel or titanium which remains in the body as a foreign material and can cause problems and possibly require a second operation to remove the metal. This represents additional risks for you as a patient and can be a source of considerable stress.

Thanks to medical advancements it is now possible to treat injuries on tendons, ligaments and bones using materials which are fully absorbed by the body, which degrade in a controlled fashion and are actually converted into body tissue. This is why your doctor has recommended the use of an innovative, bioabsorbable (self-degrading) implant: the MAGNEZIX® CS.

This compression screw is made of magnesium and is unique because it uses an alloy which while being much more stable than other resorbable implants is nonetheless fully absorbed into the body and actually converts into bone. We have prepared this brochure to give you detailed information about the properties of this innovative implant, about the material it is made of and also to answer frequently asked questions.
WHAT IS MAGNEZIX®?

Metal that turns into bone. You think that’s impossible? We can prove it - it really does work! MAGNEZIX® is more than an innovative material, it is a medical sensation. MAGNEZIX® is a magnesium-based alloy which has metallic properties and a similar stability to steel and titanium but which is completely absorbed by the body and converted into bone tissue.

Compared with conventional metal implants, the material properties of MAGNEZIX® match those of human bone and are the new benchmark in bone surgery.

This is the material we use to make MAGNEZIX® CS implants.

HOW SAFE IS MAGNEZIX® CS?

MAGNEZIX® CS implants are Class III medical devices, which means they must satisfy the highest safety requirements and the strictest safety and quality specifications. The implants we make are tested by the TÜV and approved for Europe (CE certificate). MAGNEZIX® CS also satisfies the extremely high approval standards of the internationally renowned HSA (Health Sciences Authority) in Singapore.

MAGNEZIX® has now been approved in 40 countries world-wide (as of July 2015) and has already been used several thousand times. MAGNEZIX® CS implants are safe and are top quality “made in Germany”. All of our products are manufactured exclusively in Germany.
CONVINCING ARGUMENTS – MAGNEZIX® AT A GLANCE:

• MAGNEZIX® is the world’s first approved implant made of a magnesium alloy.

• The bone-similar properties help prevent bone loss during the immobilisation period.

• During magnesium degradation a bactericidal, anti-infectious environment is formed.

• MAGNEZIX® CS implants stimulate bone growth and are converted into the body’s own bone tissue.

• There are no known allergies or foreign body reactions.

• The controlled degradation of MAGNEZIX® means a second operation to remove the “hardware” is unnecessary and no foreign material stays in the body.
WHERE CAN MAGNEZIX® CS BE USED?

The application areas for which MAGNEZIX® CS are suitable are operations which require the bone to be stabilised for a certain period using an implant. Depending upon the size of the screw, MAGNEZIX® CS can be used to fixate small to medium-sized bones and bone fragments, for example:

- Immobilisation of bone fractures
- Corrections of malpositions – e.g. Hallux valgus (bunion) surgery
- Corrections of false joints (pseudoarthroses)
- Joint stiffening
- Torn ligaments and tendons
- Flaking of cartilage from joint surfaces

The most frequent operation performed so far is the correction of (often very painful) Hallux valgus (or bunion) and treatment of the scaphoid bone in the hand. But the screws have also been successfully used at other locations such as the radius bone, the hip and the ankle.

THE IMPLANTS

MAGNEZIX® CS 2.0

MAGNEZIX® CS 2.7

MAGNEZIX® CS 3.2

MAGNEZIX® CS 4.8

Renderings enlarged.
Examples

- Fractures of the upper arm/shoulder
- Distal radius
- Scaphoid bone fracture
- Fractures of the metacarpal and carpal bones
- Finger fractures
- Radius
- Distal upper arm
- Cartilage/bone injuries in the knee
- Fractures of metatarsal and tarsal bones
- Bunion operations (Hallux valgus)
STABILITY ALONE IS NOT ENOUGH – THE IDEAL IMPLANT CAN DO MORE.

MAGNEZIX stimulates bone growth

Image of histological examination show outline of implanted screw (from above) after surgery.

After three months you can see that the screw is partially degraded (in circle).

After 12 months the screw has fully degraded: it has been replaced by a potassium compound (1) with ingrowth of new bone (2).
WHAT'S SO SPECIAL ABOUT MAGNEZIX® CS?

Magnesium has osteoconductive properties\(^1\), which means it actively stimulates bone growth and therefore helps the healing process. MAGNEZIX® implants are gradually dissolved in the body in a controlled fashion so that the new, healing bone gradually grows in place and can take more weight.

The degradation of the screw is a corrosion process which helps create a bactericidal environment in the immediate vicinity of the implant. This means MAGNEZIX® can help prevent infections. MAGNEZIX® has stability characteristics which go far beyond the values of previously available bioresorbable materials and is slightly higher than that of hard bone. This means MAGNEZIX® helps prevent loss of bone during immobilisation.

We know that you as a patient don’t like the idea of having a piece of metal permanently left in your body after surgery. But would also prefer not having an operation to remove that metal because you are aware of the risk of infection and also want to remain mobile. MAGNEZIX® CS offers some definite advantages for you.

WHAT ARE YOUR ADVANTAGES AS A PATIENT?

The use of MAGNEZIX® means there is no need to remove any metal, because it does not remain in your body as a foreign material. Which means you have:

• Less risk (of infection, anaesthetic)
• Less pain
• Less stress
• Less time lost (sick days, days off work).

---


HERE ARE SOME FREQUENTLY ASKED QUESTIONS

Thousands of patients have already been successfully treated with MAGNEZIX® CS. Many questions have been asked and answered. These are the foremost frequently asked questions:

Are MAGNEZIX® implants a burden for the body?
No, these screws are 90% magnesium, so a MAGNEZIX® CS 3.2 (20 mm long) screw contains about 150 mg of magnesium. This is about the same as in three large bottles of mineral water and is absolutely negligible compared with the total amount of magnesium in your body, especially since the screw actually degrades over a longer time period.

What happens to the products of degradation of MAGNEZIX® implants?
MAGNEZIX® implants are degraded over a number of intermediate steps to form body-own bone tissue. MAGNEZIX® CS degradation products are metabolised in the body and/or are eliminated through the kidneys.

Are MAGNEZIX® implants suitable for children and juveniles?
Yes, because in the case of juvenile patients in particular, removing the implant is generally crucial to allow undisturbed, continued growth. This is why this patient group benefits in particular from a self-degrading MAGNEZIX® CS.
Scaphoid fracture

The x-rays show treatment of typical indications in the foot and the hand with MAGNEZIX® CS.

Hallux valgus correction: MAGNEZIX® CS and titanium in a comparison

Before the operation.

MAGNEZIX® CS after one year: the outlines of the implant converted into bone are still recognisable.

Titanium after one year: conventional implants are clearly visible as foreign bodies.
This brochure is intended as information only, and is not a substitute for consultation with your treating doctor/orthopaedic surgeon.