

meets international safety and design standards such as (ISO 13485, ISO 5832-3, ISO 13356).

Instructions for patient

1 Symbols

Symbols may be used on the package label and implant card. The following table provides the definition of these symbols.






	Patient Information Website		Healthcare institution
	Implant Date		Patient Name
	Patient ID number. Product is intended for this patient only.		

Table 1: Explanation Implant Card Symbols

ENGLISH

Information about the implant

Custom Made Device

Please read the following information carefully.

If you have any questions or are not sure about the information provided below, ask your doctor.

You will or have received a patient implant card that holds important information about your implant. If you need medical assistance, show your card to the doctor at your health facility.

Further information can be found at the following website:

<https://ec.europa.eu/tools/eudamed>

(When European Database on Medical Devices is available)

What does the implant do?

- Improves the function and or aesthetics of the defected area.
- Reduce pain.

Who is the implant for?

Your custom-made device (Implant) is developed and produced specifically for your requirements and condition as diagnosed by your doctor.

What is the implant comprised of?

If you have any questions about your implant, ask your doctor. The material your implant is made of is stated on your Implant Card. Your implant is made of materials that have been used in implants for a long time. The implant

Material Name	Composition in weight %	ISO	Material Precaution
Titanium - Ti6Al4V	Titanium: 88.52-91 Aluminium: 5.5-6.75 Vanadium 3.5-4.5 Iron: 0.2 max Oxygen: 0.13 max Carbon: 0.08 max Nitrogen: 0.05 max Hydrogen: 0.015 max	5832-3	None
Zirconia - ZrO2 Z-700 E	ZrO2+HfO2+Y2O3a: max 99 Y2O3: 4,5 - 6 HfO2: max 5 Al2O3: max 0,5 Other oxides: max 0,5	13356	None

Implants are generally made from different materials. No implant is completely free of side effects when inserted in the human body. For appropriate applications, introducing these materials into the body is acceptable.

	PEEK - VESTAKEEP® i4 PL	Titanium - Ti6Al4V	UHMWPE - Chirulen® 1020	Zirconia - ZrO2 Z-700 E
<i>Cranial Reconstruction</i>	✓	✓		
<i>Facial Augmentation</i>	✓	✓		
<i>Orbital Floor</i>	✓	✓		
<i>Mandible Reconstruction</i>		✓		
<i>Le Fort reconstruction, I, II, III</i>		✓		
<i>Total Mandibular Joint Implants</i>		✓	✓	✓

Table 2: Implant Material Matrix

The implant can also include separate components designed to be implanted in, and replace parts of, the bones of the patient. The implants are implanted by your doctor during a surgery.

If you think or know that you are allergic to anything, tell your doctor in the consultations before the surgery. Also tell your doctor if you have any allergic reactions after surgery.

Can I undergo an MRI Scan?

MR stands for Magnetic Resonance Imaging.

Your implant is MR Conditional: This means it can undergo MR, but only under special conditions*.

Before having an MRI scan, you must:

- Discuss it with your doctor and MRI staff
- Show them your patient Implant Card before the scan. Your implant material is specified on this card.

*And if approved by your doctor

Your implant has not been tested on MR-Safety and compatibility. This means the following:

- No research was done on the safety and compatibility of this medical device in an MR environment.
- Your implant is not tested for heating or movement in an MR environment.
- The possibility of heating or movement may exist in an MR environment.
- Metal implants can cause MR imaging artefacts in an around the implant.

Before you undergo an MR scan you must:

- Consult this with your doctor and the MR personal.
- Show them your Implant Card before the scan is made.

Can I go through a security scanner at airports and other official buildings?

Your implant may cause an alarm at a security scanner. Show your patient Implant Card to security staff.

How often will I need to visit the doctor?

Your doctor will decide. This will depend on your individual situation, medical history and other medical conditions you have.

What should I do if I need help or advice?

You should always follow the information provided by your doctor and other medical staff. They will tell you what to do after the surgery. Your doctor will also tell you about the risks and possible complications:

- Advice for best recovery after surgery
- Warnings of the general risks related to your surgery and the implant
- Possible complications (side effects)

Contact your doctor if:

- You have questions about how the implant functions
- You are worried about your health after surgery
- You start to experience pain or swelling

What are the possible issues?

There may be issues that can shorten the life of the implant and lead to early replacement. They may include (but are not limited to this list):

- Peripheral neuropathies (nerve injuries)
- Infections
- Damage of surrounding soft tissues
- Wear (of the implant)
- Heterotopic bone formation (abnormal formation of bone within soft tissue)
- Hypersensitive reactions (exaggerated immune system response to implant material)
- Inflammatory reactions
- Osteolysis, resorption (progressive deterioration of the bone around the implant)
- Dislocation, subluxation and/or joint instability
- Vascular complications (complications to blood vessels)

- Corrosion of metal implants (breakdown of metal due to chemical reaction in the body)
- Loosening of components (loosening of the implant's fixation to the bone)
- Disassembly of implant components
- Implant breakage, damage
- Pain
- Poor function
- Bone fracture, perforation
- Impingement and altered range of motion
- Other complications associated with surgery in general, e.g., with medication, instruments used, blood and/or anaesthesia

How long will my implant last?

If the implant is used under normal conditions and if you follow the detailed instructions from your doctor, the implant can last for a certain lifetime during which it functions as intended in a human body. However, all implants may need replacement at some point.

Many factors could have an effect on how long your implant lasts. An implant might last longer or (considerably) shorter due to surgical and/or patient specific circumstances and characteristics.

Some factors are controlled by your doctor, such as:

- Selecting the proper implant for you
- The technique used during the surgery

You can control other factors, such as:

- Your health
- How active you are
- Lifestyle choices
- Your weight

But other factors cannot be controlled, such as:

- Your physical characteristics
- Any disease you might already have as well as its stage
- The condition of your bone
- The condition of muscles and / or tissue
- Infections
- Further surgeries

These factors can also change as you get older.

How do I care for my implant?

An implant is not the same as normal healthy bone. An implant has some limitations which you should take into account. These limitations can impact your lifestyle. An implant can break early if you put too much demand on it. An implant can also become damaged or loose if it is put under too much stress. It can fracture, dislocate and wear out, if it is put under too much stress.

Here are some reasons why your implant might fail early (but not limited to this list):

- Excessive forces placed on it
- Accident or fall
- Extreme movement
- Activity level
- Excessive weight
- Not following the recovery program

Does my implant have special operating instructions?

No, there are no special instructions apart from the virtual surgical plan that is shared by us with your doctor.

What should I do if I have a problem?

Report any suspected serious incident with your implant.

To do so, you can contact:

- Your doctor
- The manufacturer
- The local distributor
- The competent authority
- The ministry of health
- The local delegated agency

Manufacturer

Xilloc Medical Int B.V.

Urmonderbaan 22

6167RD Geleen

The Netherlands