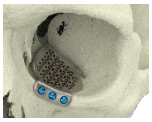
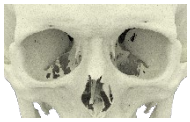
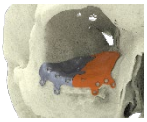
**Orbital Floors - ENGLISH**



**Implant**



**Anatomical Model**



**Implant Complex**

## Instructions for use

### 1 Symbols

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

| | | | |
|---|---|---|---|
| | Do not reuse | | Do not re-sterilize |
| | Caution, consult accompanying documents. | | Use by date |
| | Consult instructions for use. | NON STERILE | Non-sterile |
| REF | Catalogue number | LOT | Batch code |
| | Do not use if package is damaged. | | Manufacturer |
| MD | Medical Device | | Keep dry. |
| | Manufacturing Date | | Double sterile barrier system |
| MR | MR Safe | | Patient Information Website |
| | Keep away from sunlight. | | Health care centre or doctor |
| QTY | Quantity of devices | | Patient Identification |
| 31 | Implantation date | # | Patient number |
| STERILE VH2O2 | | Sterilized using vaporized hydrogen peroxide | |

*Table 1: Explanation Symbols*

### 2 Description

These instructions for use do not include all of the information necessary for use of the products. Additional, case-specific information can be found in the respective documents (“MedX – Design Steps” "Surgical Guidelines", " Compliance Statement Custom Made Devices"), which are supplied with each case and can be viewed online on the MedX portal in the case overview.

Xilloc Patient-Specific Orbital Floor Implants are individually engineered for patient-specific use according to surgeon specifications. Pre-planning dictates customized Implant decisions.

Orbital Floor Implants are intended for orbital floor reconstructions or augmentation for treatment of patients whose present conditions, in the surgeon’s opinion, cannot be treated satisfactorily using other treatment methods. Orbital Floor Implants are intended for the use in cranio-maxillofacial surgery, trauma and reconstructive surgery.

The implant is static and does not contain any added factors to enhance bone ingrowth. The implant is surgically implanted and fixed in place with titanium non-locking screws. All Xilloc Orbital Floor Implants have been designed based on the recipe of the operating surgeon and have been approved by the operating surgeon prior to manufacture of the Orbital Floor Implants.

Patient Orbital Floor Implants originate from a patient CT scan. With surgeon input, Xilloc’s biomedical designers provide a customized reconstruction solution.

Implant design includes predictive screw holes that are uniquely placed to avoid contact with sensitive anatomy (i.e., nerves, roots). Digital models of anatomy are used to further mitigate unwanted screw contact during planning phases.

### 3 Materials

Orbital Floor Implants are either from Ti6Al4V *(Titanium 6 Aluminium 4 Vanadium) or* PEEK *(Poly Ether Ether Ketone)*

Surgical Guides are made from PA2200 (Polyamide/Nylon 12) and or Ti6Al4V *(Titanium 6 Aluminium 4 Vanadium)*, Anatomical Models are made from PA2200 (Polyamide/ Nylon 12)

### 4 Indications

Orbital Floor Implants are intended for the use in cranio-maxillofacial surgery, trauma and reconstructive surgery in:

- Orbital floor fractures
- Medial orbital wall fractures
- Combined orbital floor and medial wall fractures
- Revision procedures where other treatments or devices have failed

### 4.1 Contraindications

This device is contraindicated under any of the following conditions:

- Active infection and sepsis
- Degenerative bone disease which would render the device or the treatment unjustifiable

- Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation
- Patients with limited blood supply, insufficient quantity or quality of bone, insufficient soft tissue quantity or quality, or latent infection
- Distant foci of infection which can spread to the implant site
- Uncooperative patients or patients with neurologic or psychiatric/psychologic dysfunction who are incapable or unwilling to follow postoperative instructions.

### 4.2 Instructions for clinical use

- Read these instructions for use in their entirety before beginning surgery. Also read the individual "surgery guidelines"- that accompany each specific case.
- Confirm the Xilloc Orbital Floor Implant product label for: patient ID and expiration date.
- Make the patient aware of the Instructions For Patient on the patient information website. www.xilloc.com/ifp.
- Confirm the Xilloc Orbital Floor Implant intact double pouch sterility barrier before beginning surgery or opening the Xilloc Orbital Floor packaging.
- The Xilloc Orbital Floor Implant is manufactured to fit the patient's defect site. Check if fixation screws are provided.
- The number of fixation screws should be determined by the operating surgeon based on the size and shape of the implant.
- Surgical Guides may be used to prepare the implant site with pre planned cutting planes and drill holes.
- The fixation screws are installed through the holes in the implant. Holes may be predrilled trough the use of Surgical Guides.
- 1.5 mm screws are to be use for the fixation of the Implant. Unless agreed otherwise during preoperative planning in MedX.
- Determine the appropriate screws to be used as indicated within the Surgery Guidelines.
- Open the sterile package containing the device corresponding to the procedure being performed.
- It is not allowed to drill in or adapt the implant during surgery.
- Fill in the required details on the Implant Card en provide this to the patient.

### 4.3 Possible adverse effects and complications

- Poor bone formation, bone necrosis osteoporosis, osteolysis, osteomyelitis, inhibited revascularisation, or infection can cause the device to loosen.
- Sensitivity to device materials, or allergic reaction to a foreign body.
- Pain, discomfort, abnormal sensation, or palpability due to the presence of the implant.
- Increased fibrous tissue response around the fracture site and/or the implant.
- Inadequate healing.
- Non-union or delayed union, which may lead to breakage of the implant.
- Migration, bending, fracture or loosening of the implant.
- Decrease in bone density due to stress shielding.
- Generation of particle debris during surgical procedure
- Inappropriate use of screws or drill bits
- Poor joint mechanics

Apart from these adverse effects there are always possible complications associated with any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant. If an adverse effect occurs, healthcare professionals and/or the patient are obligated by law to inform the manufacturer and patient's home country's National Healthcare authority/Medicine Agency.

- While rare, implantation of foreign materials may result in sensitivity reactions.
- Peripheral neuropathies have been reported in conjunction with surgical procedures involving implantation of various types of Implants. Subclinical nerve damage occurs more frequently, usually as a result of surgical exposure/trauma.
- Implants can loosen or migrate due to loss of fixation or trauma.
- Infection can lead to failure of the procedure.

Intraoperative and early postoperative complications can include:

- fracture of the implant,
- fracture of bone or soft tissue damage,
- extrusion of the implant,
- dehiscence of the incision,
- prominence or disfigurement at the implant site
- infection.

Late postoperative complications can include:
- fracture of the device due to traumatic injury,
- loosening or migration due to loss of fixation or trauma, and prominence or disfigurement over time at or near the implant site.

## 5 Warnings

- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
- It is unlikely for the implant to migrate in the treatment of an Orbital Floor. This is because the implant must always be fixed rigidly to the orbital/zygomatic bone with screws.
- Implants are subject to repeated stress in use, which can result in fatigue fracture.
- Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws.
- If the healing of a bone graft is delayed, unsuccessful or incomplete, the implant may migrate or fracture.

- Patient-dependent factors such as each patient's activity level and adherence to loading instructions have an effect on the attachment and/or migration of the implant.
- The surgeon must be thoroughly knowledgeable not only of the medical and surgical aspects of the implant but also the mechanical properties of the implants.
- Correct placement of the implant is of great importance. Improper placement may harm surrounding tissues, for example the muscles. The skin above the implant must be in good condition before surgery and incision above the implant should be avoided.
- Correct handling of the implants is extremely important. The implants should not be shaped or bent. Bending, scratches and notches add to the risk of particle release and implant breakage.
- The manufacturer does not allow cutting of the Implant, because this may result in the Implant breaking and particles being released from the Implant.
- Implants can loosen, fracture, migrate, or cause pain. If there is need for implant removal, the implants can be removed. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Adequate postoperative management should follow implant removal.
- Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful treatment. Patients with senility, mental illness, alcoholism, or drug abuse may be at higher risk of device failure since these patients may ignore instructions and activity restrictions.
- The patient is to be made fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, load bearing or an accident directed to the device.
- Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants.
- The patient is to be made aware and warned of general surgical risks, complications, possible adverse effects, and to follow the instructions of the treating physician.
- The patient is to be advised of the need to come in for regular postoperative follow-up examinations for as long as they are necessary to ensure recovery.

These implants are used for augmenting and reconstruction of the orbital floors. While these Implants are generally successful in attaining these goals, they cannot be expected to replace normal healthy bone or withstand the unsupported stress placed upon the device by full load bearing. Do not use these devices for replacement of bone within articulating surfaces. Patients who engage in contact sports or other activities that risk facial injury are to be warned that facial injury may lead to damage of the implant and a subsequent failure of treatment. The patient is to be warned that the device does not replace normal healthy bone and that traumatic injury could necessitate surgical treatment. The patient must be advised of surgical risks and the possible adverse effects. THIS DEVICE HAS BEEN DESIGNED TO FIT THE DEFECT EXISTING AT THE TIME OF THE CT SCAN AND IMPLANT FABRICATION. CHANGES IN THE PATIENT'S ANATOMY OCCURRING AFTER THE CT SCAN AS WELL AS THE USE OF THE IMPLANT AFTER SUCH CHANGES MAY RESULT IN A SUBOPTIMAL FIT WITHIN THE DEFECT.

- Improper selection, placement, positioning, and fixation of the Implant can cause a subsequent undesirable result. The surgeon is to be familiar with the implant and the surgical procedure prior to performing surgery.
- To prevent dehiscence at the incision site, a firm primary closure of the incision is required.
- Rapid remodeling of the orbital floor may cause the shape to change significantly between the time of the CT scan and the time implants are ready. The custom implant may no longer optimally fit the defect.
- Do not reuse Implants. While the device may appear clean and undamaged, a used implant may be contaminated as the material is highly absorbent. Discard any unused portion.

Caution: Law (EU) restricts this device to sale by or on the order of a physician.

## 6 Precautions

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been even momentarily placed in a different patient. Use a Xilloc Orbital Floor Implants only on the patient, for whom it is designed. Pay attention to the correct positioning of the Implant according to preoperative planning.

Instruments are available for each implant system to aid in the accurate implantation of internal fixation devices. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. It is recommended that all instruments be regularly inspected for wear and disfigurement.

Operating Surgeons and all personnel involved with handling these products are responsible for attaining appropriate education and training within the scope of the activities which they are involved in the handling and use of this product.

## 7 Accessories

- 3D-models of patient's Orbital Floors are called Anatomical Models. These can be used as tools to plan the surgery. The Anatomical Models are a non-sterile instrument.

- A Surgical Guide or a Surgical Guides set can be delivered as part of the order, if requested. This can be used as a tool transfer the digital bone resection plan onto the patient's bone in theatre. In case of a Surgical Guide that has been delivered at the same time, read their Instructions For Use before starting the operation. The Surgical Guide must never be implanted.
- If requested Xilloc can sell or supply a loaner fixation kit.
- The screwdriver, which has been designed, for a particular system of screws must always be used to be sure that proper screwdriver/screw head connection is achieved.
- Incorrect alignment or fit of the screwdriver to the screw head may increase the risk of damage to the implant or screwdriver.
- Excessive torque can cause the screw to fracture.
- Twist drills are labelled for single use only.
- When using twist drills, appropriate cooling is necessary to aid in the prevention of injury to bone, skin and tissue. It should be combined with low-speed drilling to prevent risks of bone demineralization, possible loosening of the bone screw and injury to the patient.
- The manufacturer's instructions for the hand piece used with the twist drill must be followed. The manufacturer of the hand piece may recommend proper speeds to avoid failures such as breakage of the twist drill.
- Excessive force may cause unusual stress conditions and result in breakage or fracture of the device.
- Breakage of twist drills may result in injury to the patient, the user, or third party.
- Drill guides and cannulas are provided to assist the operating surgeon in guiding the twist drill and to aid in the protection of the patient, user and third parties. Drill guides and cannulas should be properly irrigated to prevent risks of injury to the patient.

## 8 Sterility

- The Xilloc Orbital Floor implants can be supplied STERILE or NON-STERILE.
- Do not use the implant if the sterile packaging is damaged. Xilloc Orbital Floors Implants are sterilised using VH2O2.
- The Xilloc Surgical Guide can be supplied STERILE or NON-STERILE. Do not use the Surgical Guide if the sterile packaging is damaged. The Xilloc Surgical Guide is sterilised using VH2O2.
- The Anatomical Model is supplied NON-STERILE. Do not use the Anatomical Model within the sterile OR circle.

## 9 MR

XILLOC ORBITAL FLOOR IMPLANTS IN THE MAGNETIC RESONANCE (MR) ENVIRONMENT:

The PEEK Orbital Floor Implant alone is composed of a non-conducting, non-magnetic material containing Poly Ether Ether Ketone (PEEK). Xilloc has rationalized the non-clinical effects based on the scientifically relevant characteristics of the PEEK material in a Magnetic Resonance environment. The PEEK implant is determined to be MR Safe in accordance with EN 62570 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. MR Safe refers to an item that poses no known hazards in all MR environments.

For the Titanium Cranial Reconstruction Implant the effects of the MR environment have not been determined. This device has not been tested for heating or migration in the MR environment.

## 10 Recommended storage and handling conditions

The products shall be stored and handled with care. The primary and secondary packaging shall remain intact at all times. The products shall be stored and handled in an environment that is:

- dry and clean
- protected from direct sunlight
- not in close proximity of heat sources.

## 11 Manufacturer

Xilloc Medical Int B.V.
Urmonderbaan 22
6167RD Geleen
The Netherlands