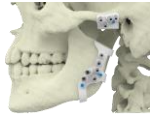


Xilloc Total Mandibular Joint

Instruction for Use - ENGLISH



**Implant: Titanium –
Zirconia - UHMWPE**



**Guides: Polyamide –
Titanium**

1 Device description

The Xilloc Total Mandibular Joint is an implantable medical device intended for the replacement of a uni- and/or bilateral mandibular joint.

The Total Mandibular Joint is designed and constructed with specific characteristics (e.g., size, shape, material) as prescribed by a healthcare provider for a specified patient. It is typically manufactured from a three-dimensional (3-D) CAD model based on computed tomography (CT) images. The Total Mandibular Joint is comprised of a mandibular component, a disc, and a glenoid fossa component and are manufactured out of Titanium, Zirconia and UHMWPE.

The system also includes:

- TMJ fixation instruments and screws. The TMJ is specifically designed for the use of these instruments and screws.
- Surgical Guides to predrill the fixation holes and to cut the condylar head.
- Anatomical Models, produced from a CT-scan of the patient's mandible and maxilla, which are intended to be used by the surgeon as an anatomical reference in planning and performing the implantation of the Total Mandibular Joint implant.

The implant does not contain any added factors to enhance bone ingrowth. The principle of operation is to replace the mandibular joint with a Total Mandibular Joint implant.

2 Clinical benefits

The following performance/benefits to the patient are intended to be achieved with the Xilloc Total Mandibular Joint:

- The Xilloc Total Mandibular Joint is manufactured to replace the patient's defective mandibular joint in such a way that no intraoperative adjustments are required to the implant and a functionally satisfying result is obtained.
- The Xilloc Total Mandibular Joint will result in good functional outcomes.

- The Xilloc Total Mandibular Joint results in movability improvement of the temporomandibular joint and improvements in quality of life.

3 Intended purpose

Xilloc Total Mandibular Joint is intended for temporo-mandibular joint replacement, for treatment of patients whose present conditions, in the surgeon's opinion, cannot be treated satisfactorily using other treatment methods. Total Mandibular Joint implants are used for reconstruction of the temporo-mandibular joint movements. It is intended to be used by (CMF, TMJ) surgeons with good knowledge of the specific operative technique, in a standard operating environment. The surgical guides are intended to guide the drill/saw/instruments onto the mandibular and fossa bone surfaces.

4 Indications

The Xilloc Total Mandibular Joint is intended to be used for the reconstruction of the temporomandibular joint. It is indicated for patients with one or more of the following conditions:

- Disfunction of temporo-mandibular joint
- Ankylosis
- Tumor
- Multiple operations to the temporo-mandibular joint
- Auto-immune disease
- end-stage degenerative joint disease
- recurrent ankylosis
- congenital disorders affecting the TMJ
- condylar loss due to neoplasia or trauma
- revision of a failed alloplastic or autogenous reconstruction

Mandibular movement is impaired for most of these patients, due to anatomical changes or surgically caused scarification. This often results in pain, difficulties in speech, and impaired oral function.

5 Contraindications

This device is contraindicated under any of the following conditions:

- Active or suspected infections and sepsis in or about the implantation site
- 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.

6 Potential adverse effects

As with any major surgical procedure, there are risks involved in total mandibular joint surgery. Potential risks identified with the use of this system include, but are not limited to:

- Poor bone formation, osteoporosis, osteolysis, osteomyelitis, inhibited revascularization
- Wound-related complications (e.g., wound dehiscence)
- Infection (superficial, deep, systemic, abscess formation)
- Cardio-/vascular related complications (e.g., bleeding, hematoma).
- Seizures
- Seroma formation
- Muscle atrophy
- Reduced vigilance
- Step/fissure formation
- Pain, discomfort, abnormal sensation, or palpability due to the presence of the implant
- Wrong implantation
- Generation of particle debris during surgical procedure
- Increased fibrous tissue response around the implant
- Implant exposure
- Implant fracture
- Implant migration
- Implant loosening
- Inadequate implant fitting
- Unsatisfactory aesthetic outcome
- Allergic reaction to materials

If an adverse effect occurs, healthcare professionals and/or the patient are obligated by law to inform the manufacturer and the National Healthcare authority/Medicine Agency of the patient's home country.

7 Warnings and precautions

Intended users

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.

Improper selection, placement, positioning, and fixation of the surgical guide and implant can cause a subsequent undesirable result. The surgeon must be thoroughly knowledgeable not only of the medical and surgical aspects of the surgical guide and implant but also the mechanical properties of the implants. As well the surgeon must have read and understood the surgical technique.

Patient education

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. 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 replacement of the temporo-mandibular joint and its function. They are intended or designed for full or partial load bearing equal to those of a healthy temporomandibular joint. 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 about surgical risks and the possible adverse effects. It is unlikely for the implant to migrate in the treatment of temporo-mandibular joint replacement. This is because the implant must always be fixed to the bone with locking-screws. Implants are subject to repeated stress in use, which can result in fatigue fracture. If the healing of a bone is delayed, unsuccessful or incomplete, the implant may migrate.

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.

Make the patient aware of the Instructions For Patient on the patient information website. www.xilloc.com/ifp.

Packaging

Check for each component that the primary packaging is undamaged by visual inspection for breaches of packaging. The packaging should be intact upon receipt. Damaged or unintentionally opened sterile packages and products should not be used.

Use by date and Patient ID

Check for if the use-by-date is not expired and if the correct patient ID is present.

Fixation Instruments

Check if the correct fixation instruments and screws are available.

Single use

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 Total Mandibular Joint only on the patient, for whom it is designed. Pay attention to the correct positioning of the Implant according to preoperative planning.

<p>Implant fit</p> <p>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.</p>
<p>Implant handling</p> <p>Correct handling of the implant is extremely important. The implant contains articulating surfaces that may become damaged if mishandled. Any damage to these surfaces may affect the long-term performance of the implants. Avoid contact with the articular surfaces as much as possible. Implants should only be handled with blunt, smooth-surfaced instruments to avoid damage. Instruments with teeth, serrations, or sharp edges should not be used.</p> <p>The implant should not be shaped or bent. Bending, scratches and notches add to the risk of particle release and implant breakage.</p>
<p>Implant placement</p> <p>Correct placement of the implant is of great importance. Improper placement may harm surrounding tissues. The skin above the implant must be in good condition before surgery and incision above the implant should be avoided.</p>
<p>Instruments</p> <p>A surgical technique is available. The surgeon should be familiar with the application of the instruments prior to use. Specialty instruments should never be used to perform tasks for which they are not specifically designed. Misuse of an instrument may result not only in damage to the instrument but also trauma to the patient or operating room personnel. Avoid storing or transporting instruments in contact with one another as damage may occur. Use care in handling instruments with cutting edges, points, sharp corners, and hinges as they may cause injury and/or damage surgical gloves compromising sterility. Do not use instruments that have been damaged. Damaged instruments should be replaced before further use. Do not attempt to straighten bent instruments as this may compromise the strength of the instrument and lead to subsequent failure or injury.</p>
<p>Powered instruments</p> <p>Using a powered instrument for drilling an irrigation while drilling is recommended.</p>
<p>Instrument wear</p> <p>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.</p>
<p>Wound closure</p> <p>To prevent dehiscence at the incision site, a firm primary closure of the incision is required.</p>
<p>Disposal</p> <p>Dispose all components and materials according local regulations.</p>

8 Material specifications

The Total Mandibular Joint components are manufactured from medical grade Ti6Al4V (Titanium 6 Aluminum 4 Vanadium, ISO 5832-3), Zirconia (ZrO2 Z-700 E, ISO13356) UHMWPE Ultra High Molecular Weight Poly Ethylene, ISO11542-PE-UHMW QD, 2-2-2 ASTM).

9 Packaging

Packages for each of the components should be intact upon receipt. Damaged or unintentionally opened sterile packages and products should not be used and should be returned to Xilloc.

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 Combination devices

- 3D-models of patient’s skull are called Anatomical Models. These can be used as tools to plan the surgery. The Anatomical Models accompanying a Total Mandibular Joint are a sterile instrument.
- A Surgical Guide set is delivered as part of the order. These are used as a tool to transfer the virtual surgical drilling and resection plan onto the patient’s anatomy. In case of Surgical Guides that have been delivered with the Total Mandibular Joint Implant, read their Instructions For Use before starting the operation. The Surgical Guides must never be implanted.
- If requested, Xilloc can sell or supply a loaner fixation Instrument kit.

12 Sterilization

The Total Mandibular Joint implants are supplied STERILE.

Do not use the implant if the sterile packaging is damaged. Xilloc Total Mandibular Joint Implants are sterilized using VH2O2.

13 Product complaints

If the implant ever “malfunctioned” and/or may have caused or contributed to the death or serious injury of a patient, the manufacturer should be notified immediately by telephone or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the manufacturer is requested. Any serious incident that has occurred in relation to the device should also be reported to

the competent authority of the Member State in which the user and/or patient is established.

14 MR safety

The Xilloc Total Mandibular Joint Ti6Al4V (Titanium 6 Aluminum 4 Vanadium), ZrO₂ Z-700E (Zirconia) and UHMWPE (Ultra High Molecular Weight Polyethylene) has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Xilloc Total Mandibular Joint in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Fixation method has not been taken into account, used screws can contain additional MR safety information.

In all cases, the Healthcare Professional is responsible for the MR conditions, MR imaging quality and patient safety. Any safety issues or major image artefacts should be reported.

15 Explanation of harmonized and non-harmonized symbols

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

16 Manufacturer

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