ORTHOTiN

ORTHOTIN TMJ TEMPOROMANDIBULAR JOINT REPLACEMENT

DESCRIPTION

The OrthoTiN Temporomandibular Joint Replacement consists of the following patient-matched components; a Titanium-Nitride coated Titanium alloy ramus and a solid Titanium alloy fossa assembled with an UHMWPe bearing. Both components are secured to the bone with screws. The components are designed preoperatively, and the shape, position, and fixation of the components are reviewed and approved by the surgeon.

RAMUS COMPONENT

The ramus component is designed to mate to the mandibular bony surface. It is manufactured from Ti-6Al-4V alloy and coated with C-TiN-C ceramic coating. This coated material is superior to cobalt chromium alloy in both reducing ultra-high molecular weight polyethylene (UHMWPe) wear and in corrosion resistance and biocompatibility.

FOSSA COMPONENT

The fossa component is manufactured from Ti-6Al-4V alloy. It contains a customized surface for bone contact to the zygomatic arch. It is assembled with an ultra-high molecular weight polyethylene (UHMWPe) bearing which provides the articulating surface for the condylar head of the ramus component. The bearing is mechanically fixed to the fossa via locking tabs and a dovetail slot.

STERILIZATION

When sterile TMJ components are provided, they are sterilized by exposure to ethylene oxide with a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 14937 and AAMI TIR 56 Annex B.

STORAGE BEFORE USE

Please store the medical devices in their sterile packaging in a dry and dust-free place. The shelf life of the medical devices is two years.

INDICATIONS FOR USE

The OrthoTiN Temporomandibular Joint Replacement is intended for the reconstruction of painful and/or severely disabled TMJ joints resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis, ankylosis, avascular necrosis, failed tissue graft, previously failed prosthesis, or loss of vertical mandibular height and/or occlusal relationship due to bone resorption, trauma, developmental abnormality, or pathological lesion.

CONTRAINDICATIONS

1. Any active or suspected latent infection in or about the TMJ joint.
2. Mental or neuromuscular disorders which would create an unacceptable risk of prostheses instability, prostheses fixation failure, or complications in postoperative care.
3. Uncontrollable masticatory muscle hyperfunction (clenching or grinding) which may lead to overload and loosening of screws.
4. Known allergies to any of the component materials.

PRECAUTIONS

Before clinical use, the surgeon should be familiar with all aspects of the surgical procedure. Patients should be instructed in the limitations of the prosthesis and should be taught to govern their activities accordingly. Safe disposal of explants is to be taken to reduce the risk of infection or microbial hazards

WARNINGS

Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions and subsequent reduction in the performance and service of the prosthetic implants. Accepted practices should be followed meticulously in postoperative care and the patient should be made aware of the limitations of total joint reconstruction.

MR SAFETY

The OrthoTiN TMJ Replacement has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifacts in the MR environment. The safety of the OrthoTiN TMJ components in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

INSTRUCTIONS FOR USE

A retromandibular incision is utilized to gain exposure to the ramus. The ramus is exposed as high as possible for greater visualization of implant location and fit. A pre-auricular incision is utilized to gain exposure to the condylar head and fossa. The incision will expose the posterior root of the zygomatic arch and the affected condyle. The superficial temporal artery should

be ligated during the incision to expose the zygomatic arch.
The ramus cutting guide is inserted onto the ramal anatomy. A proper fit is ensured by verifying that the posterior margin of the guide makes full contact with the posterior ramus and mandibular angle. A 1.8 mm drill guide is inserted into both cutting guide sleeves to drill pilot holes. Place a 2.0 mm cortical screw in the guide sleeve and repeat the process for the second screw location to fix the guide in place. The cutting guide holes correspond to screw locations on the ramus implant (typically second from superior and most distal).
Resect the condylar head along the guide's reference level. Typically, a 10mm clearance between the zygomatic arch and the mandible is necessary for fossa insertion. Remove the cutting guide.
Elevate/Dissect the fossa floor and eminence for fossa implant placement on the bony structures including the lateral arch. The fossa component is placed, and stability is checked. There should be no rocking or tilting of the component.
The ramus component is placed through the retromandibular incision or through the pre-auricular incision. If needed, the ramus component can be placed first, then the fossa can be reinserted. The ramus component is placed on the anatomy per the design phase planned position and fit is checked.
Return to incisions to fixate the prosthetic components. Check fit of components. The condylar head of the ramus component should rest on the bearing posterior articular surface. The fossa is fixated with screws as per the pre-operative plan.
The ramus component is fixated with screws as per the pre-operative plan. As a final check, observe if the ramus condylar head is seated both superiorly and posteriorly on the bearing surface and that the ramus component is placed along the posterior edge of the ramal anatomy and examined for rocking. Any bony interference should be removed at this time.
Once, the ramus is in the positioning, the distal screw is fixated first. A second screw is inserted to immobilize the ramus into position. The occlusion is checked. Then, the incisions are again exposed, and the oral cavity is sealed off. The remaining ramus screws are fixated onto the anatomy. Close and seal the incisions.

In Case of Serious Incident

In the case that a serious incident occurs in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

CONTACT INFORMATION
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SYMBOL	SYMBOL TITLE	STANDARD REFERENCES
	Manufacturer	ISO 15223-1 Reference #5.1.1 FDA Recognition # 5-117 ISO 7000 Reference #3082 FDA Recognition # 5-103
	Date of Manufacture (m1/d1/y4)	ISO 15223-1 Reference #5.1.3 FDA Recognition # 5-117 ISO 7000 Reference #2497 FDA Recognition # 5-103
	Use-by Date (m1/d1/y4)	ISO 15223-1 Reference #5.1.4 FDA Recognition # 5-117 ISO 7000 Reference #2607 FDA Recognition # 5-103
LOT	Batch Number	ISO 15223-1 Reference #5.1.5 FDA Recognition # 5-117 ISO 7000 Reference #2492 FDA Recognition # 5-103
STERILE EO	Sterilized Using Ethylene Oxide	ISO 15223-1 Reference #5.2.3 FDA Recognition # 5-117 ISO 7000 Reference #2501 FDA Recognition # 5-103
MD	Medical Device	ISO 15223-1 Reference #5.7.7 FDA Recognition # 5-148
	Consult instructions for use	ISO 15223-1 Reference #5.4.3 FDA Recognition # 5-117 ISO 7000 Reference #1641 FDA Recognition # 5-103
	Do not re-use	ISO 15223-1 Reference #5.4.2 FDA Recognition # 5-117 ISO 7000 Reference #1051 FDA Recognition # 5-103
	Caution	ISO 15223-1 Reference #5.4.4 FDA Recognition # 5-117 ISO 7000 Reference #0434A FDA Recognition # 5-103
	Keep Away From Sunlight	ISO 15223-1 Reference #5.3.2 FDA Recognition # 5-117 ISO 7000 Reference #0624 FDA Recognition # 5-103
	Keep Dry	ISO 15223-1 Reference #5.3.4 FDA Recognition # 5-117 ISO 7000 Reference #0626 FDA Recognition # 5-103
	Do not use if package is damaged.	ISO 15223-1 Reference #5.2.8 FDA Recognition # 5-117 ISO 7000 Reference #2606 FDA Recognition # 5-103
MR	MR Conditional Compatibility	ASTM F2503-23 Reference #3.1.9 FDA Recognition # 8-602
CE 2803	European Conformity	Medical Device Regulation (MDR): (EU) 2017/745

Symbols Glossary

The OrthoTiN TMJ Replacement is not currently available for distribution in the United States.