INSTRUCTIONS FOR USE

A retro-mandibular incision is utilized to gain exposure to the ramus. Expose ramus as high as possible. A pre-auricular incision is utilized to gain exposure to the condylar head and fossa. The condylar ahead is exposed through the preauricular incision. The condylar head is resected at the level of the sigmoid notch.

The fossa is cleaned and surface irregularities are removed. The Fossa component is placed and stability is checked. There should be no rocking or titling of the component. The fossa component is removed and the ultra-high molecular weight polyethylene bearing is inserted into the fossa component. The assembled prosthesis is placed back into position.

The ramus component is placed through the retro-mandibular incision and fit is checked. It is important to place the component so as to avoid the mandibular nerve. Sponges are packed into both incisions and the mouth is isolated. The patient is placed in maxillomandibular fixation (wire teeth together) so proper positioning of the implants and mouth can be obtained. Return to incisions to fixed prosthetic components.

The Fossa is fixed with four 2.0mm x 6 to 10mm screws. The ramus component is fixed next with 2.5mm, 2.7mm or 3.0mm screws. Incisions are closed in a normal layered fashion. The maxillomandibular fixation is removed and the patient is checked for ROM and occlusions.

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OrthoTiN

TMJ TEMPOROMANDIBULAR JOINT REPLACEMENT SYSTEM

Instructions For Use

ORTHOTIN TMJ TEMPOROMANDIBULAR JOINT REPLACEMENT SYSTEM

DESCRIPTION

The OrthoTin Temporomandibular Joint Replacement consists of the following components. a Titanium-Nitride coated Titanium alloy ramus and a metal backed UHMVVPE bearing fossa component both of which are secured to the bone with screws.

RAMUS COMPONENT

The Ramus component 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 (UHMVVPE) wear and in corrosion resistance and biocompatibility.

FOSSA COMPONENT

The Fossa is manufactured from Ti-6Al-4V alloy. It contains a customized surface for bone contact and a female dovetail slot for an ultra-high molecular weight polyethylene (UHMVVPE) bearing which articulates with the condylar head of the ramus component. The bearing is mechanically fixed to the fossa via a press fit dovetail

STERILIZATION

Steam autoclave (most heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended. Autoclaves should comply with the requirements of, and be validated, maintenance and checked in accordance with EN285/EN 13060, EN ISO17665, and ANSI AAMI ST79.

OrthoTiN Instruments shall be sterilized in the mounting condition as stored on the tray, i.e. if the brackets or recessions in the tray are designed to accommodate multi-component instruments in their assembled state, there is no need to disassemble these instruments for sterilization.
The process parameters shown below are validated and recommended by OrthoTiN for sterilization:

USA METHOD

Moist heat sterilization Cycle Pre-Vacuum (Pre-Vac): Temperature: 270°F (132°C); Exposure Time l: 4 minutes; Pressure 2: 15 PSIA; Drying Time 2: 30 minutes (minimum, in chamber); Cool Time: 60 minutes (minimum, at room temperature).

OUTSIDE USA

Method Moist heat sterilization according to EN ISO 17665 Cycle Saturated steam with fractional forced air removal; Exposure Time l: 4 minutes. Exposure time can be extended to 18 minutes to comply recommendation from World Health Organization (WHO), Koch Institute (RKI) etc. OrthoTiN medical devices are able to sustain sterilization cycles; Temperature: 132-137°C (270-277°F); Drying Time 2 recommended: 30 minutes (minimum, in chamber). **Please note** that according EN ISO 17665 the final responsibility for validation of sterilization techniques and equipment lies directly with the hospital. To ensure optimal processing all cycles and methods should be validated for different sterilization chambers, wrapping methods and/or various load configurations.

ALTERNATIVE (e.g UK, NL)

Method Moist heat sterilization according to EN ISO 17665 Cycle Saturated steam with fractional forced air removal; Exposure Time 3 minutes. Exposure time can be extended to 18 minutes to comply with the recommendation from World Health Organization (WHO), Robert Koch Institute (RKI) etc. OrthoTiN medical devices are able to sustain such sterilization cycles Temperature 134°C-138°C (273°F-280°F) Drying Time recommended: 30 minutes (minimum, in chamber)

STORAGE BEFORE USE

After sterilization, please store the medical devices in the sterilization packaging in a dry and dust-free place. The shelf life is depending on the sterile barrier employed, storage manner, environmental and handling conditions. A maximum shelf life for sterilized medical devices before use should be defined by each health care facility.

INDICATIONS FOR USE

The OrthoTiN Temporomandibular Joint is intended for reconstruction of painful and/or severely disabled TMJ joints resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, or previously failed prosthesis.

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.

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.

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.