

**TMJ CONCEPTS**

2233 Knoll Drive
Ventura, CA 93003
USA

(805) 650-3391 Phone
(805) 650-3392 Fax
www.TMJConcepts.com

**STERILE IMPLANT****PRODUCT INSERT****PATIENT-FITTED TEMPOROMANDIBULAR JOINT
RECONSTRUCTION PROSTHESIS SYSTEM****CAUTION**

United States Federal Law restricts this device to sale by or on the order of a physician.

DESCRIPTION

The Patient-Fitted Temporomandibular (TMJ) Reconstruction Prosthesis is comprised of a mandibular component and a glenoid fossa component that have been customized for the patient identified on the front of the product insert.

The system also includes TMJ Fixation Screws, TMJ Fixation Instruments, and an Anatomical Bone Model.

All prosthesis materials comply with the indicated ASTM surgical implant standards.

The TMJ implant mandibular component is comprised of a condylar head fabricated from cobalt-chromium-molybdenum alloy (ASTM F1537) and a mandibular body fabricated from titanium 6Al-4V ELI alloy (ASTM F136).

The TMJ implant glenoid fossa component is comprised of a fossa bearing fabricated from ultra-high-molecular-weight polyethylene (ASTM F648) and a mesh backing fabricated from unalloyed titanium (ASTM F67).

The TMJ Fixation Screws are fabricated from titanium 6Al-4V ELI alloy (ASTM F136) and are specifically designed for use in the fixation of Patient-Fitted TMJ Reconstruction Prostheses.

The TMJ Fixation Instruments are specifically designed for use in the implantation of Patient-Fitted TMJ Reconstruction Prostheses and TMJ Fixation Screws. Pilot drills are labeled for single use, and all other instrumentation is labeled as reusable. For a list of the instrumentation, see the table at the end of the WARNINGS section.

The Anatomical Bone Model is produced from a CT scan of the patient's mandible and maxilla and is intended to be used by the surgeon as an anatomical reference in planning and performing the implantation of Patient-Fitted TMJ Reconstruction Prostheses.

These products and their packaging contain no natural rubber latex.

INDICATIONS FOR USE

The TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis System 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:

- Inflammatory arthritis involving the temporomandibular joint not responsive to other modalities of treatment
- Recurrent fibrous and/or bony ankylosis not responsive to other modalities of treatment
- Failed tissue graft
- Failed alloplastic joint reconstruction
- Loss of vertical mandibular height and/or occlusal relationship due to bone resorption, trauma, developmental abnormality, or pathologic lesion

CONTRAINDICATIONS

The TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis System should not be used for patients with one or more of the following conditions:



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- Active or suspected infections in or about the implantation site
- Uncontrollable masticatory muscle hyperfunction (clenching or grinding) which may lead to overload and loosening of screws
- Known allergy to any of the component materials

WARNINGS

General

Do not use product from damaged or open packaging.

Warnings Specific to TMJ Implant Components

TMJ implant components are provided **CLEAN AND STERILE** and require no additional processing prior to implantation.

If it becomes necessary to resterilize a TMJ implant component, refer to the section titled RESTERILIZATION INSTRUCTIONS FOR TMJ IMPLANT COMPONENTS elsewhere in this product insert.

DO NOT STEAM STERILIZE THE GLENOID FOSSA COMPONENT AS DAMAGE TO THE PLASTIC PORTION MAY OCCUR.

TMJ implant components are designed to accommodate a patient's unique anatomy and their implanting surgeon's pre-operative plans using an anatomical bone model produced from a CT scan. These pre-operative plans include establishing the patient's desired occlusal setting either on the patient prior to their CT scan or on their bone model after it has been produced and may also include modifying the anatomical contours of the model. It is very important that the surgeon accurately reproduce the patient's planned occlusal setting and any anatomical contouring at the time of implantation in order to achieve the intended placement of the implant components.

Bone cement or other grouting agents should not be used when implanting these devices. Safety and efficacy have not been established for the use of bone cement or other grouting agents with these implants.

TMJ Concepts implant components are intended to be implanted in mating sets consisting of a mandibular component and a glenoid fossa component. Safety and efficacy have not been established for the use of other manufacturers' components, including screws, with these devices.

Warnings Specific to Anatomical Bone Models

The bone model is provided **CLEAN AND NON-STERILE** and **IS NOT INTENDED TO BE STERILIZED**. No sterilization processes have been demonstrated to produce adequate bone model sterility assurance levels. Sterilization processes may have detrimental effects on the accuracy and integrity of the model.

Implants should not be placed in contact with bone model surfaces nor should the model be introduced into the sterile field at the time of surgery due to the possibility of contamination from residual substances on the model.

Warnings Specific to Screws and Instruments

TMJ Fixation Screws are provided **CLEAN AND NON-STERILE** and require no additional cleaning prior to sterilization.

Single Use TMJ Fixation Instruments (see table below) are provided **CLEAN AND NON-STERILE** and require no additional cleaning prior to sterilization.

Reusable TMJ Fixation Instruments (see table below) are provided **CLEAN AND NON-STERILE** and should be cleaned and sterilized prior to each use.

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INSTRUMENTATION		
Part Number	Description	Use
60-0100	Quick-Connect Instrument Handle	Reusable
60-0110	Driver Blade	Reusable
60-0120	Implant Stabilizer	Reusable
60-0130	Mandibular Forceps	Reusable
60-0200	Fossa Seating Tool	Reusable
60-0300	Drill Guide	Reusable
60-0420	Pilot Drill for 2.0mm Screws	Single Use
60-0423	Pilot Drill for 2.3mm Screws	Single Use
60-0500	Sterilization Case Lid	Reusable
60-0510	Sterilization Case Screw Base	Reusable
60-0520	Sterilization Case Instrument Base	Reusable

PRECAUTIONSGeneral

It is the responsibility of each surgeon using this product to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedures and the potential complications that may occur in each specific case. The benefits of the surgical procedure may deteriorate over time and no longer meet the patient's or surgeon's expectations necessitating additional or alternative procedures to be performed. Revision implant surgery is not uncommon, therefore the surgeon must balance many considerations to achieve the best long term result for each patient.

Patients should be advised of the limitations of the implant and instructed to adjust their activities accordingly.

Special attention should be paid to patient selection. Careful evaluation should be made of patients with disorders that might interfere with their ability to comply with the limitations and precautions necessary to achieve beneficial outcome from this implant.

Precautions Specific to TMJ Implant Components

These implants contain 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.

Precaution Specific to Anatomical Bone Models

The bone model contains fragile features. Handle with care.

Precautions Specific to Screws

Always place screws into proper locations in the sterilization case for sterilization.

Screws should only be handled with blunt, smooth-surfaced instruments to avoid damage. Instruments with teeth, serrations, or sharp edges should not be used.

Precautions Specific to Instruments

A surgical technique describing the use of the instruments 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.



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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.

ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Adverse events can occur following placement of this implant and may require further treatment. The occurrence of a complication may be related to or influenced by the previous surgical history or prior medical conditions of the patient.

Adverse events reported in the clinical use of TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis are as follows (in descending order of frequency):

- Infection
- Operative difficulties
- Chronic or recurring pain and/or swelling
- Dental malocclusion requiring bite adjustment, orthodontia, or reoperation
- Loss of joint mobility due to the development of adhesions (scar tissue), heterotopic bone, or ankylosis
- Dislocation of implant components
- Wear, displacement, breakage, or loosening of implant components
- Resorption or erosion of the glenoid fossa or mandible
- Perforation or dehiscence of surrounding tissues
- Foreign body or allergic reaction to implant components
- Ear problems, including inflammation of the ear canal, middle or inner ear infections, perforation of the ear drum, temporary or permanent hearing loss, ringing in the ears, and equilibrium or eustachian tube problems

Other complications may occur and include but are not limited to:

- Post-operative pain, swelling, bruising, jaw muscle spasm, or hematoma formation
- Peripheral neuropathies
- Deleterious effects to the contralateral joint when implant placed unilaterally

CLINICAL DATA

A total of 279 patients (465 joints) were enrolled in a post-approval study in which clinical data was collected both pre-operatively (month 0) and post-operatively at various follow-up intervals out to 5 years (month 60). Based on previous clinical studies of TMJ patients, it was anticipated that a large number would become lost to follow up. It was desired to have a cohort of at least 100 patients remaining at the 5-year evaluation time point, therefore a significantly larger number of patients were enrolled in the study. Clinical data was obtained out to 5 years on a final cohort of 128 patients (204 joints).

Pre-operative data and post-operative follow-up data were collected using a standardized data collection format. Subjective data related to pain, function of the lower jaw, and diet were obtained using a 55mm length visual analogue scale. The pain scale ranged from "no pain" at 0mm to "severest pain" at 55mm. The function scale ranged from "no loss" at 0mm to "cannot function" at 55mm. The diet scale ranged from "no restriction" at 0mm to "liquids only" at 55mm. Subjective data was also collected by asking each patient how their current quality of life compared to before they received their TMJ implants. Objective measurements of mandibular range of motion were made directly on the patients. These measurements, recorded in millimeters, included maximum interincisal opening and left and right excursion.

Results are shown for only the month 0 and month 60 evaluation time points as clinical data was not available for each patient at every intermediate follow-up interval. These

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clinical data show a statistically significant decrease in pain, increase in function, decrease in diet restrictions, and increase in maximum interincisal opening. A summary of the quality of life responses at month 60 is also shown.

Pain Measurement Improvement at 5 Years

(scale: 0mm = "no pain" to 55mm = "severest pain")

Month	Mean (mm)	S.D.(mm)
0	39.0	13.4
60	18.3	15.9

Function Measurement Improvement at 5 Years

(scale: 0mm = "no loss" to 55mm = "cannot function")

Month	Mean (mm)	S.D. (mm)
0	36.4	13.0
60	17.9	13.8

Diet Measurement Improvement at 5 Years

(scale: 0mm = "no restriction" to 55mm = "liquids only")

Month	Mean (mm)	S.D. (mm)
0	32.4	14.2
60	14.7	13.4

MIO Measurement Increase at 5 Years

Month	Mean (mm)	S.D. (mm)
0	25.0	11.2
60	33.4	9.2

Summary of Quality of Life Responses at 5 Years

How does your current quality of life compare to before you received your TMJ implants?

Response	Percentage of Patients
Much Better	52.3%
Better	25.8%
Same	7.8%
Worse	12.5%
Much Worse	1.6%

Several of the patients enrolled in the post-approval study that were not included in the final cohort of 128 patients had adverse events reported prior to their becoming lost to follow up or being removed from the study for another reason. The adverse event data presented below includes events reported for any of the 279 initially enrolled patients.

These types of adverse events and the rate at which they occurred as well as the quality of life responses shown above are not unexpected in this compromised patient population with many previous surgeries involving failed tissue grafts and/or failed implants from other manufacturers which may leave behind material particulates.

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Adverse Events Resulting in Additional Surgery				
Category	Patients (n=279)		Joints (n=465)	
	No.	%	No.	%
Chronic or recurring pain and/or swelling	4	1.4%	4	0.9%
Infection	3	1.1%	3	0.6%
Dislocation of implant components	2	0.7%	3	0.6%
Perforation or dehiscence of surrounding tissues	2	0.7%	2	0.4%
Loosening	2	0.7%	2	0.4%
Material sensitivity (reaction to implant components)	1	0.4%	2	0.4%
Malocclusion	1	0.4%	1	0.2%
Total	15	5.4%	17	3.7%

INSTRUCTIONS FOR USE

A detailed Surgical Preparation Manual is available which provides instructions for CT scanning patients, describes how to prepare the Anatomical Bone Model prior to implant design, and outlines one possible surgical technique for implantation.

It is the responsibility of the surgeon to become familiar with the surgical techniques for implantation of these devices through study of relevant publications, consultation with experienced associates, and training in procedures applicable to this particular implant.

Accepted surgical practice should be followed in post-operative care.

STERILITY OF TMJ IMPLANT COMPONENTS

The TMJ mandibular and glenoid fossa components are packaged in double Tyvek/film pouches and have been sterilized using an ethylene oxide gas cycle that has been shown to produce terminally sterile product with a sterility assurance level of 10^{-6} and residual levels below ANSI/AIMI/ISO 10993-7 limits and FDA proposed limits.

DO NOT USE COMPONENTS IN OPEN OR DAMAGED PACKAGING.**RESTERILIZATION INSTRUCTIONS FOR TMJ IMPLANT COMPONENTS**

In the event that a TMJ implant component needs to be resterilized, it may be returned to TMJ Concepts for repackaging and resterilization.

Alternatively, clean TMJ implant components may be repackaged into double Tyvek/film or paper/film peel pouches per standard hospital practice and resterilized using one of the ethylene oxide (EO) gas cycles listed below. It is recommended that the components be processed by themselves with no other products in the sterilization chamber. It is the responsibility of the customer to demonstrate the appropriateness of the sterilization cycle used should it vary from those listed.

	<u>100% EO Gas Cycle</u>	<u>EO Gas Mixture Cycle</u>
Gas Concentration:	775 mg/L \pm 10%	600 \pm 50 mg/L
Temperature:	130 \pm 5°F (55 \pm 3°C)	130 \pm 5°F (55 \pm 3°C)
Exposure Time:	1 hour \pm 2 minutes	4 hours \pm 15 minutes
Humidity:	30% to 80% RH	30% to 80% RH
Air Wash:	30 minutes	3 cycles
Aeration:	12 hours minimum at 130 \pm 5°F	12 hours minimum at 130 \pm 5°F



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These cycles have been shown to produce terminally sterile product with a sterility assurance level of 10^{-6} and residual levels below ANSI/AIMI/ISO 10993-7 limits and FDA proposed limits when used on clean TMJ implant components.

DO NOT RESTERILIZE COMPONENTS THAT HAVE BEEN IMPLANTED OR HAVE BECOME CONTAMINATED WITH DEBRIS, RESIDUE, OR BODY FLUIDS. IN THESE INSTANCES, THE COMPONENTS SHOULD BE RETURNED TO TMJ CONCEPTS.

DO NOT STEAM STERILIZE THE GLENOID FOSSA COMPONENT AS DAMAGE TO THE PLASTIC PORTION MAY OCCUR.

STERILIZATION INSTRUCTIONS FOR SCREWS

The screws are intended for steam sterilization in the TMJ Fixation Hardware Sterilization Case provided by TMJ Concepts. The following sterilization cycle has been shown to produce terminally sterile product with a sterility assurance level of 10^{-6} . Other similar steam cycles may be used but have not been evaluated.

Wrapped or Unwrapped Prevacuum Steam Sterilization,
15 minutes at 270-275°F (133-135°C)

CLEANING INSTRUCTIONS FOR REUSABLE INSTRUMENTS

For your safety, be familiar with the procedures for handling contaminated materials at your facility prior to utilizing these instructions.

Clean instruments as soon as possible after use. Avoid allowing soiled instruments to dry. Immerse into or use towels dampened with deionized or distilled water to keep soiled instruments moist prior to cleaning.

Manually or mechanically wash with mild detergent following the detergent manufacturer's instructions for use. Avoid using extreme detergent concentration levels. Enzyme cleaners and warm/hot water may be used to aid in cleaning. pH neutral cleaners are recommended. If acidic or alkaline solutions are used, follow the manufacturer's recommendations for neutralizing the pH by rinsing with water or other neutralizing solution. Highly alkaline cleaners (pH \geq 12) used in some mechanical washers are not recommended. Avoid prolonged exposure to acidic or alkaline solutions and solutions containing chlorides, bromides, or iodine.

After washing, thoroughly rinse instruments with clean deionized or distilled water.

Use of water-soluble medical instrument lubricant is recommended for instruments with moving parts and/or intended to interfit with other instruments.

Dry completely before sterilization.

Inspect for cleanliness, especially in recesses. The effectiveness of the cleaning process may be evaluated by applying a 2% hydrogen peroxide solution. If the solution produces bubbles, repeat the washing process.

Check instruments thoroughly for damage, especially instruments with moving parts or interfits such as a quick-connect mechanism. Do not use instruments that have been damaged. Damaged instruments should be replaced before further use.

STERILIZATION INSTRUCTIONS FOR REUSABLE AND SINGLE USE INSTRUMENTS

The instruments are intended for steam sterilization in the TMJ Fixation Hardware Sterilization Case provided by TMJ Concepts. The following sterilization cycle has been shown to produce terminally sterile product with a sterility assurance level of 10^{-6} . Other similar steam cycles may be used but have not been evaluated.

Wrapped or Unwrapped Prevacuum Steam Sterilization,
15 minutes at 270-275°F (133-135°C)



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LIMITED WARRANTY

TMJ Concepts warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse, or improper handling of the product subsequent to receipt by the purchaser.

SYMBOL GLOSSARY



Do Not Re-use



Use-by Date (Expiration Date)



Part Number



Lot or Batch Code



Non-sterile



Sterilized Using Ethylene Oxide



Manufacturer



Date of Manufacture



Authorized Representative in the European Community

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