



PATIENT-FITTED TEMPOROMANDIBULAR JOINT RECONSTRUCTION PROSTHESIS SYSTEM PRODUCT INSERT INFORMATION

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 and F1341).

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 latex materials.

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:

- 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 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.

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Warnings Specific to TMJ Implant Components

TMJ implant components are provided **CLEAN AND NON-STERILE** and no additional cleaning prior to sterilization is needed.

TMJ implant components are intended to be repackaged and sterilized utilizing ethylene oxide (EtO) gas sterilization. (See the section titled **STERILIZATION INSTRUCTIONS FOR TMJ IMPLANT COMPONENTS** elsewhere in this product insert.)

DO NOT STEAM STERILIZE THE GLENOID FOSSA COMPONENT AS THE HIGH TEMPERATURE MAY DAMAGE THE PLASTIC PORTION OF THE IMPLANT.

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 implant components are intended to be implanted in matched pairs as provided by TMJ Concepts. Safety and efficacy have not been established for the use of other manufacturers' components, including screws, with these devices.

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.

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

PRECAUTIONS
General

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.

Precaution Specific to Anatomical Bone Models

The bone model contains fragile features. Handle with care.

PRODUCT INSERT INFORMATIONPrecautions 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.

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.

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

- Heterotopic bone formation (this is patient dependent and not device-related)
- Design complications (components loosened, became dislocated, or did not fit correctly)
- Patient requested removal of the implant with no clinical indications
- Post-operative infections
- Material failures (component breakage)

Other adverse events could 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. These complications include but are not limited to:

- Infection
- Post-operative pain, swelling, bruising, jaw muscle spasm, or hematoma formation
- Chronic or recurring pain
- Peripheral neuropathies
- Loss of joint mobility due to the development of adhesions, heterotopic bone, or ankylosis
- 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
- Dental malocclusion requiring bite adjustment, orthodontia, or reoperation
- Resorption or erosion of the glenoid fossa, mandible, or surrounding tissues
- Foreign body or allergic reaction to implant components
- Wear, displacement, breakage, or loosening of implant components
- Deleterious effects to the contralateral joint when implant placed unilaterally

CLINICAL DATA

A total of 347 patients have received the TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis. One study evaluated 215 patients (365 joints) implanted by 16 surgeons and another study evaluated the remaining 132 patients (218 joints). In these studies, data is not available for each patient at every evaluation time point. Long term information is available for a subset of patients.

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

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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. 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.

Effectiveness was evaluated in a subset analysis of 195 joints placed in 111 patients by 2 surgeons for whom detailed information was available at 2 or more years post-implantation. Of these 111 patients, there were 95 patients who had data at 3 years or beyond, but all those who did not have complete data at baseline, 1, 2, and 3 years were dropped from the statistical analysis. There were 34 patients who had complete data for pain and function and 33 patients who had complete data for diet and maximum interincisal opening (MIO).

Pain Measurements over Time for 34 Patients
(scale: 0mm = "no pain" to 55mm = "severest pain")

Month	Mean (mm)	S.D.(mm)
0	42.4	11.9
12	16.3	13.2
24	21.9	14.9
36	21.1	13.9

Function Measurements over Time for 34 Patients
(scale: 0mm = "no loss" to 55mm = "cannot function")

Month	Mean (mm)	S.D. (mm)
0	38.1	14.9
12	16.9	13.0
24	19.4	14.7
36	18.6	10.2

Diet Measurements over Time for 33 Patients
(scale: 0mm = "no restriction" to 55mm = "liquids only")

Month	Mean (mm)	S.D. (mm)
0	35.2	15.6
12	13.2	11.2
24	17.1	14.3
36	20.5	13.4

MIO Measurements over Time for 33 Patients

Month	Mean (mm)	S.D. (mm)
0	24.8	11.6
12	32.8	7.6
24	33.4	7.4
36	34.1	7.0

Statistical analyses of these cohorts of patients with complete data showed significant decrease in pain, increase in function, decrease in diet restrictions, and increase in maximum interincisal opening. The data from the 215 patients in the largest study and the 111 patient subset from the two sites showed similar trends. The analyzed cohorts represented approximately 10% of all the patients who have been implanted with the device.

Adverse events are presented for the 111 patient subset in the tables below. The device removal rate due to device-related failure or complication was 2.6%. Adverse events which did not result in device removal occurred in 25.6% of the devices, and one quarter of these were for device-related reasons. These types of adverse events and the rate at which they occurred 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.

Adverse Events Requiring Device Removal				
Category	Patients (n=111)		Joints (n=195)	
	No.	%	No.	%
Device removal due to failure or complication	5*	4.5%	5*	2.6%
Patient requested removal of implant with no clinical indications (category is not device-related)	4	3.6%	8	7.2%
Total adverse events requiring device removal	9	8.1%	13	6.7%
Subtotal device-related adverse events requiring device removal	5*	4.5%	5*	2.6%

* 4 of these 5 devices were removed for mandibular component loosening that was related to early implant designs. Changes to quantity and placement of screw holes in mandibular components reduced the incidence of implant loosening.

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Adverse Events Not Requiring Device Removal				
Category	Patients (n=111)		Joints (n=195)	
	No.	%	No.	%
Improper fit	3	2.7%	5	2.6%
Dislocation	1	0.9%	2	1.0%
Post-operative infection	3	2.7%	3	1.5%
Other	2	1.8%	2	1.0%
Heterotopic bone formation (category is not device-related)	20	18.0%	38	19.5%
Total adverse events not requiring device removal	29	26.1%	50	25.6%
Subtotal device-related adverse events not requiring device removal	9	8.1%	12	6.2%

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.

STERILIZATION INSTRUCTIONS FOR THE TMJ IMPLANT COMPONENTS

The TMJ implant components are intended to be sterilized in double Tyvek/film or paper/film peel pouches utilizing ethylene oxide (ETO) gas sterilization. They must be removed from their original non-sterile packaging and repackaged appropriately at the hospital.

The following sterilization cycle has been shown to produce terminally sterile product with a sterility assurance level of 10^{-6} and residual levels below FDA proposed limits. Other similar cycles may be used but have not been evaluated. It is the responsibility of the customer to demonstrate the appropriateness of the sterilization cycle used should it vary from the following:

Gas Concentration:	600mg/L \pm 50mg/L
Temperature:	130°F \pm 5°F (55°C \pm 3°C)
Exposure Time:	4 hours (240 minutes) \pm 15 minutes
Humidity:	30% to 80% RH
Air Washes:	3 cycles
Aeration:	12 hours minimum @ 130°F \pm 5°F

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 @ 270-275°F (133-135°C)



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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 @ 270-275°F (133-135°C)

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.

Are You Considering Total Temporomandibular Joint Replacement?

INFORMATION FOR THE PATIENT



Your surgeon has asked you to consider total temporomandibular joint (TMJ) reconstruction because your TMJ has become compromised or damaged resulting in pain and/or loss of jaw function.

This pamphlet is intended to provide you with information about your TMJ condition, about the risks and potential complications associated with TMJ surgery, and about the *TMJ Concepts* Patient-Fitted TMJ Reconstruction Prosthesis so that you may make an educated decision as to whether or not to undergo treatment with this implant.

Much of the information included in this brochure is general and should only be considered as an aid to your surgeon's explanation of your specific problem. Please address your clinical questions to your surgeon as you make your final decision. Also, *TMJ Concepts* is available to address inquiries related to implant design and manufacture.

WHAT MAKES UP MY TMJ?

The TMJ can be considered a ball-in-socket joint. The ball (condyle) is a part of the lower jaw (mandible). The socket (fossa) is part of the skull (Figure 1). These two parts come together to form the moveable joint that you can feel when you place your fingers over the skin in front of your ears as you open and close your mouth.

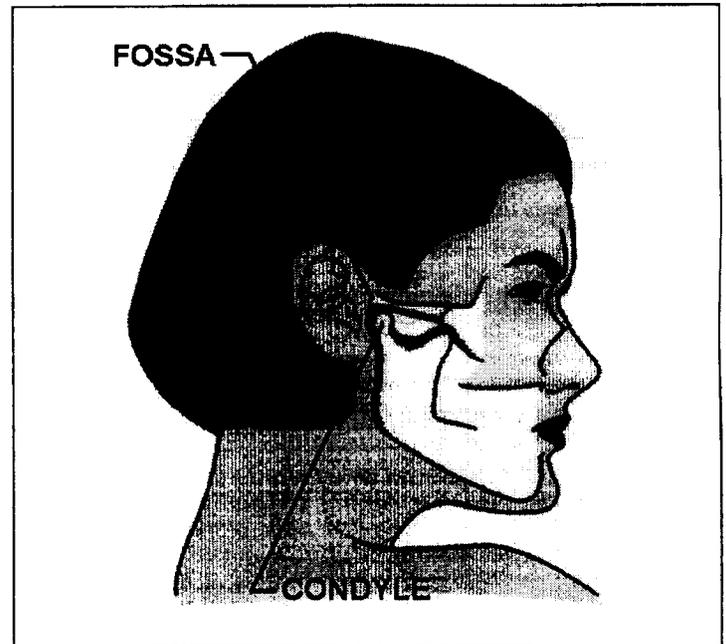


Figure 1

WHEN MIGHT I BENEFIT FROM THIS IMPLANT?

You may benefit from this implant if you suffer from one of the following conditions.

- Inflammatory arthritis (such as rheumatoid arthritis) of the TMJs not responsive to other treatment
- Immobility of the joints (fibrous and/or bony ankylosis) not responsive to other treatment
- Failed TMJ reconstructions using body tissue such as bone, muscle, or cartilage
- Failed TMJ reconstructions using joints or other implants made from man-made materials
- Loss of correct jaw position due to bone loss (resorption), trauma, developmental abnormality, or tumor

WHEN SHOULD THIS IMPLANT NOT BE USED?

This implant should not be used if you have one of the following conditions.

- Active or suspected infections in or near the TMJs
- Uncontrolled clenching or grinding of teeth which may lead to overload or loosening of attachment screws
- Any mental or neuromuscular disorder that may cause the limitations and precautions for the use of this implant to be ignored
- Known allergy to any of the implant materials

If any of these conditions apply to you, speak to your surgeon.

WHAT MATERIALS ARE IN THIS IMPLANT?

The components of this implant (Figure 2) are made with the same types of materials used for decades in orthopedic surgery to successfully reconstruct knees, hips, shoulders, elbows, and other joints of the body.

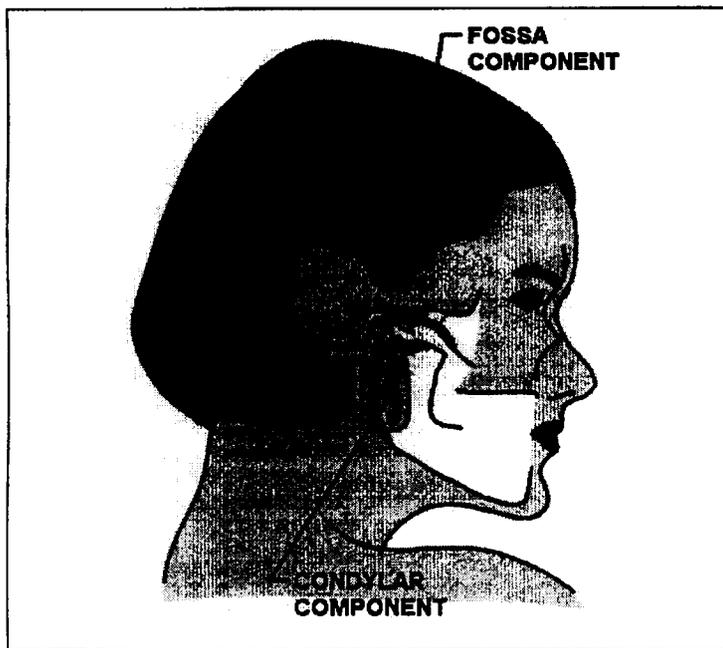


Figure 2

The condylar component has a metal condyle made from cobalt-chromium-molybdenum. This is attached to a metal implant body made from titanium alloy. This component is anchored to the lower jaw with titanium alloy screws.

The fossa component has a durable medical-grade plastic surface made from ultra-high-molecular-weight polyethylene (also known as UHMWPE). This is attached to a metal backing made from pure titanium. This component is anchored to the skull with titanium alloy screws.

HOW ARE THESE IMPLANTS MADE?

Each set of components is made to fit the unique shapes of your skull and lower jaw and to address your surgeon's specific plans for your TMJ surgery. This is done using an anatomical bone model of your TMJ anatomy.

The following steps are required to make these implants:

- The surgeon orders implants from *TMJ Concepts*.
- The patient undergoes a CT scan of their TMJs.
- The scan is used to make an anatomical bone model.
- The model is forwarded to the surgeon for evaluation and surgical planning modifications.
- The model is returned to *TMJ Concepts* for design of the patient-fitted TMJ implant components.
- The model and implant designs are sent to the surgeon for review and approval.
- Once approved, the implant components are made and sent to the surgeon's hospital for implantation.

Patients having failed metal implants in place may need to have them removed before the CT scan is performed. This is because metal often interferes with the scanning process. If existing implants are removed, your talking, eating, jaw opening, or other functioning may become temporarily impaired until your new implants are designed and implanted. Ask your surgeon what to expect in your particular case.

HOW ARE THESE COMPONENTS IMPLANTED?

The surgery used to implant these components is performed under general anesthesia in a hospital operating room. Two incisions are made. The condylar component is implanted through an incision below and behind the lower jaw. The fossa component is implanted through an incision in front of the ear (broken lines in Figure 3).

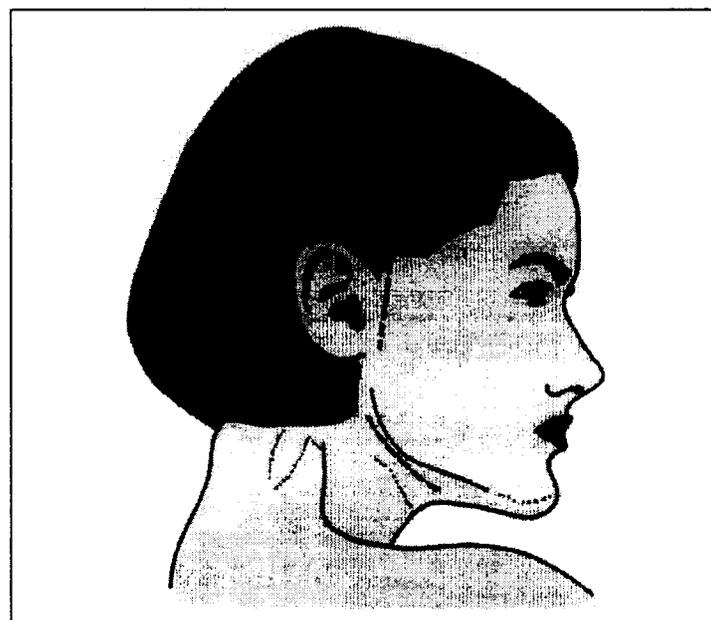


Figure 3

WHAT ARE POSSIBLE COMPLICATIONS?

Complications may occur following placement of these implants and may require further treatment. The occurrence of a complication may be related to or influenced by previous surgical history or prior medical conditions. These complications include but are not limited to:

- Continued or increased pain levels or worsening of other present TMJ symptoms
- Infection
- Facial and jaw swelling after surgery usually lasting several days
- Bruising and discoloration of the skin around the eyes, ears, and jaw
- Temporary or chronic jaw muscle spasm
- Temporary or permanent facial muscle weakness resulting from motor nerve injury during surgery (The most common problems are an inability to wrinkle the brow, raise the eyebrow, or fully close the eyelids.)
- Temporary or permanent numbness of certain areas of the skin in the region of the joint and sometimes in more remote areas of the face and scalp
- 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
- Loss of joint mobility due to the development of scar tissue (adhesions), heterotopic bone, or ankylosis
- Dental malocclusion (improper bite) requiring bite adjustment, orthodontia, or reoperation
- Resorption or erosion of the glenoid fossa, mandible, or surrounding tissues
- Foreign body reaction or allergic reaction to implant components
- Wear, displacement, breakage, or loosening of implant components
- Functional compromise of the opposite TMJ when only one joint is being reconstructed
- Allergic reaction to any of the medications given during or after the surgery
- Objectionable scarring of the incisions

WHAT OTHER TREATMENTS MIGHT I NEED?

Due to the complex nature of your TMJ problem or to the occurrence of a complication, you may require additional treatments including but not limited to:

- Extended physical therapy
- Bite splint therapy
- Restorative or reconstructive dentistry
- Orthodontia (dental braces)
- Orthognathic surgery (jaw repositioning surgery)
- Further reconstructive TMJ surgery

WHAT CAN I EXPECT FOLLOWING SURGERY?

In the immediate post-operative period, your surgeon will provide you with the appropriate medication and care required for your recovery.

In order to establish the proper relationship between the upper and lower jaws, your teeth are wired together during surgery. Depending on your specific circumstances, these fixation wires may temporarily be left in place following surgery.

Post-implantation physical therapy is very important to achieving and maintaining optimum joint function. Your surgeon may recommend a jaw-exercising device for you. You must follow his instructions with regard to the use of that device in order to attain the maximum benefit from your surgery.

Your surgeon may also recommend that you work with a physical therapist for a period of time post-operatively. Each case may have a different regimen in this regard, but most important is the continuous motion of the new joint to attain and maintain motion and function.

WHAT ELSE CAN I EXPECT?

Your diet will start as liquid, pureed, or even solid foods. This will depend on what your surgeon recommends for your particular circumstances.

You may experience "noises" from your new implants that include squishing, squeaking, clicking, and popping. These noises are not usual but may occur in some cases.

You may also notice stuffiness and/or a ringing sensation in your ears for a few weeks after surgery. This should subside over time.

In order to implant these devices, certain muscles which assist in jaw function will have to be removed if they have not already been removed from a previous surgery. This removal will reduce your ability to move your jaw from side to side and forward and down. Some of this motion may be regained, however, with aggressive physical therapy.

This implant will not allow you to have "normal" jaw function. A patient with a hip or a knee reconstruction can not expect to be able to run in a race or participate in other sports that are strenuous on the legs. Similarly, a patient with a TMJ reconstruction should not expect to be able to eat hard, crunchy, or tacky foods without discomfort and risk of implant damage.

Long-term success with these joint prostheses may also be dependent on the physical demands placed on them. Excessive joint forces from grinding or "bruxing" teeth can lead to accelerated wear and fatigue resulting in early failure of this TMJ implant.

WILL MY PAIN BE REDUCED?

Unfortunately, the complete elimination of pain is not possible. Some patients may even experience more pain due to the additional surgery required to implant the devices. Even though many patients have experienced some relief from their symptoms, the amount of pain reduction will vary from patient to patient over time.

Patient data collected to date indicates that patients having undergone two or fewer previous surgeries experience less pain post-operatively than those patients having undergone larger numbers of prior operations.

HOW LONG WILL THIS RECONSTRUCTION LAST?

Despite the fact that these implants are fitted specifically to your anatomy, you should not expect them to last for a lifetime. While the expected life of a TMJ implant is difficult to estimate, it is finite and may significantly differ for each patient due to the diversity of conditions seen in TMJ reconstruction.

These components are made from man-made materials which are placed within the body for the potential restoration of jaw function and reduction of pain. However, due to the many biological, mechanical, and physiochemical factors which affect these devices, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

Scar tissue or unwanted bone may develop around the implant components over time and may cause a decrease in motion and function. If this occurs, additional surgery may become necessary to remove this scar tissue or bone. This does not usually require replacement of the implant components.

WHAT ARE THE ALTERNATIVES TO THIS TYPE OF RECONSTRUCTION?

Alternatives to this type of reconstruction include grafts of bone, soft tissue, or cartilage. The suitability of alternative treatments will depend on the condition of the bones, cartilage, disc, ligaments, muscles, nerves, and blood vessels in and around your TMJs. Your surgeon can discuss this aspect of your particular case with you.

HOW DO I CARE FOR AND PROTECT MY TMJ IMPLANTS?

- Inform your surgeon about other types of surgeries or dental procedures you intend to have after your TMJ reconstruction. He may want to prescribe antibiotics to decrease the possibility of infection that could jeopardize the success of your implants.
- Contact your surgeon if you have any problems related to your surgery or your TMJ implants.
- See your surgeon for prescribed follow-up visits. After the first year, it is important that you visit your surgeon for annual check-ups.
- Follow your surgeon's post-operative instructions, especially those related to physical therapy.
- Continue to take medications and to follow the diet as prescribed by your surgeon.
- Avoid hard, crunchy, or tacky foods.
- Refrain from chewing gum.
- Avoid contact sports.
- Never place yourself at physical risk that may result in damage to your TMJ implants.
- Refrain from water sports and general strenuous physical activity for six weeks following surgery.

WHAT OTHER RESPONSIBILITIES DO I HAVE?

- Request that your implants be returned to *TMJ Concepts* for analysis should they be removed for any reason.
- Notify *TMJ Concepts* if you change your address so that you can be contacted if necessary with information regarding your TMJ implant. *TMJ Concepts* is required by the FDA to be able to locate you should the need arise.

For more information contact:



TMJ Concepts

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