TMJ CONCEPTS

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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.

S U R G I C A L P R E P A R A T I O N M A N U A L

Process Overview----------Page 1

CT Scan Instructions----------Page 2

Model Preparation Instructions ----------Page 3

Surgical Technique----------Page 4

Product Insert Information----------Page 9

PROCESS OVERVIEW

Welcome to the TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis System. This implant is unique from other systems in that its use involves a cooperative effort between the surgeon and TMJ Concepts. These implants are not off-the-shelf standard components, and each set of devices are jointly developed by TMJ Concepts and the implanting surgeon to address the unique anatomy and surgical planning for each patient.

Below is an outline of the complete process for using this system. The cycle length from initial order to device implantation varies, but the typical minimum is in the 6 to 8 week time frame. As this is a cooperative effort, it is very important that the surgeon and his office staff expedite their role to enable us to provide the devices in a timely manner.

In planning for the use of this system, please take into account the time frames indicated below. Note that roughly half the cycle time is spent on completion of the CT scan and the surgeon/TMJ Concepts design interactions.

1	**Order**	Patient is preapproved for the TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis by the surgeon's office and a TMJ Implant Order Form is mailed or faxed to TMJ Concepts.	Week 0
2	**CT**	Patient is scanned per the TMJ Concepts CT protocol. Scan data is sent to model vendor. **See page 2 for important instructions.**	Week 1
3	**Model**	CT scan data is evaluated and a single-piece or a two-piece (disarticulated) model is made per the surgeon's requirements.	
4	**Model Review**	Model is forwarded to the surgeon for review and preparation and then returned to TMJ Concepts. **See page 3 for important instructions.**	Week 2
5	**Design**	Implant designs are created to fit the surgeon prepared model.	
6	**Design Review**	Implant designs are sent to the surgeon for review and approval and then returned to TMJ Concepts.	Week 3
7	**Manufacturing**	Implants are manufactured per the surgeon-approved designs.	
8	**Shipment**	Implants, fixation screws, and instruments as necessary are shipped to the surgeon’s hospital.	Week 6
9	**Surgery**	Surgeon implants the Patient-Fitted TMJ Reconstruction Prostheses. **See the Surgical Technique on page 4 for important information.**	Week 7

CT SCAN INSTRUCTIONS

Patients must be scanned per the TMJ Concepts CT protocol.

The quality of the scan data is an important factor when designing patient-fitted implants. Motion during the scan can render it unusable.

Evaluate each patient prior to ordering their CT scan. Determine whether a one-piece or two-piece (disarticulated) anatomical bone model is to be produced for the particular case and inform TMJ Concepts of your plans.

ONE-PIECE MODELS

- Scan patients in the desired occlusion whenever possible. A one-piece model is preferred because it eliminates the difficulties that are involved in establishing the correct occlusion with a two-piece model.
- For patients who can achieve good occlusion, instruct them as appropriate to ensure that the desired occlusion is scanned. Patients who cannot maintain the desired occlusion for the scan should be placed in IMF if possible.

TWO-PIECE MODELS

- Patients with poor occlusion, open bites, asymmetry, etc., will typically require production of a two-piece model which will require the desired occlusion to be set later by the surgeon.
- Whenever possible, have these patients scanned in an open mouth position as this will aid in the production of the bone model and will yield a more accurate representation of the teeth.
- Specify your requirements on the CT scan order. Bite splints or similar devices can be used to hold patients' teeth apart and prevent motion during the scan.

Once the scan is complete, the CT data should be sent overnight to the model vendor.

FIRST-STAGE SURGERIES

Patients with existing metallic implants or severe bony ankylosis should have a first-stage surgery for implant removal, debridement, and preparation for the TMJ Concepts implants as appropriate. When performing a first-stage surgery, attention should be paid to the following items.

- Verify that the condylar resection level provides adequate space for the TMJ Concepts implants. Removal of an additional small amount of mandibular bone may still be required. In general, the resection should angle slightly posteriorly and inferiorly from the sigmoid notch to allow adequate room for the implant components. In some cases, an "L" shaped resection may be necessary to achieve adequate clearance anteriorly at the fossa eminence. There should be an overall gap of approximately 13mm between the base of a patient’s fossa and the mandibular resection.
- Review the lateral edges of condylar resection for any remaining lateral flair. If significant flair remains, flattening or beveling the flair along the lateral edge is recommended.
- Remodeling along the margins of mandibular implant components is common. After removal of a mandibular implant, be sure that any remodeling along the implant margins is smoothed down to provide an adequate surface for placement of the new implant.
- Check the fossa for undesirable remodeling and remove any such features. Remove any sharp prominences of bone that exist, and verify that there is adequate depth medially for the fossa implant. 20mm from the zygomatic process is recommended. Creating an adequate surface for placement of the new fossa component during the first stage surgery will eliminate the need to do so on the model and the potential difficulties that may be encountered when attempting to reproduce this recontouring on the patient at the time of device implantation.

TMJ BONE MODEL PREPARATION INSTRUCTIONS

CARE AND HANDLING INSTRUCTIONS

- The bone model contains fragile features. Handle with care.
- Do not use black permanent markers when marking on the model.
- Use dental acrylic, epoxy, or other rigid bonding material when it is necessary to set the occlusion on the model.
- Retain the original packaging for return shipment to TMJ Concepts.

SURGEON MODEL PREPARATION INSTRUCTIONS

Each patient bone model will require unique preparation based on the patient's clinical status. The following instructions are intended to be a general guide for preparation of the bone model prior to implant design. Surgeon preparation of the model is required to allow adequate room for the implants and to verify or set the planned occlusion.

Occlusion

In cases where the patients have been scanned in IMF or are in otherwise good occlusion at the time of the CT scan, you will receive the bone model as a single piece. For these single-piece models, it is still important to review the occlusal relationship to verify that it is in the desired position.

In cases where the occlusion needs to be established, you will receive the bone model with the mandible separated from the remainder of the model. Prior to setting the occlusion, it is important to confirm the modeling of the teeth. It is common for the patient's dental work to significantly alter the modeling of the teeth due to the interference of metal with the scanning process. It is recommended that the teeth be compared to dental impressions or a bite model and that the bone model be modified to account for any discrepancies. Use dental acrylic, epoxy, or other rigid bonding material when setting the occlusion on the model.

Mandibular Resections

Once the occlusion has been verified or set, the condylar resections may be made. In some cases, the resections may need to occur prior to setting the occlusion. For patients with existing condylar resections from prior procedures, the removal of an additional small amount of mandibular bone may still be required. In general, the resection should angle slightly posteriorly and inferiorly from the sigmoid notch to allow adequate room for the implant components. In some cases, an "L" shaped resection may be necessary to achieve adequate clearance anteriorly at the fossa eminence. We recommend a minimum gap of 3mm between the anterior lip of the fossa component and the mandibular resection. There should be a minimum gap of approximately 13mm between the base of a patient's fossa and the mandibular resection. The required gap can vary from patient to patient due to anatomical differences. After making the resections, review the lateral edges for any remaining lateral flair. If significant flair remains, flattening or beveling the flair along the lateral edge is recommended. Record the amount of bone resected for intraoperative reference.

Mandibular Preparation

Patients who have had previous implants or bone grafts may require some amount of lateral mandibular resurfacing to smooth an area in preparation for the mandibular implant component. Areas of concern will be marked in red for your reference during model preparation. It is important when smoothing lateral mandibular bone to be sure that any existing screw holes are not lost. It is recommended to deepen existing holes so that they will still be present after smoothing. This will allow future screw holes to be placed so as to avoid these locations. It is very important to consider whether or not resurfacing the lateral mandible is necessary. Reproducing lateral mandibular contouring intraoperatively can be very difficult due to limited surgical exposure.

Fossae Preparation

Patients who have had previous implants, bone grafts, or ankylosis may require some amount of fossae recontouring to remove prominences which have developed in or near the fossae. Areas of concern will be marked in red for your reference during model preparation. While it is not always necessary to remove these features, they may, at times, pose difficulties in the implant manufacturing process, compromise fossa component seating, and/or not allow adequate room in the joint space for the implant components.

RETURN SHIPMENT TO TMJ CONCEPTS

Once the preparation has been completed, please promptly return the bone model to TMJ Concepts via an overnight carrier. We recommend that you use the original TMJ Concepts packaging for return shipment. If you have any questions regarding the model preparation, please contact one of the TMJ Concepts design engineers.

SURGICAL TECHNIQUE

The following is one possible surgical technique for implantation of TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis. It is the surgeon's responsibility to become familiar with the surgical techniques for implantation of these devices through study of relevant publications, consultation with experienced associates, and attending relevant training courses.

PREPARATION OF THE PATIENT FOR SURGERY

1. The patient should be directed to thoroughly wash and rinse their hair the night before the surgery with a mild shampoo and avoid the use of hair spray or styling gels the day of surgery.
2. Patients are started pre-incision and kept on a broad spectrum IV antibiotic (e.g., Ancef 1g) during the hospital course followed by one week of oral antibiotic (e.g., Cephradine 500mg) therapy. Antiinflammatory steroid therapy to minimize edema may be started pre-incision and continued post-operatively as with other reconstruction or orthognathic surgery.
3. Arch bars should be applied prior to draping. Retain all non-sterile instruments, suction, and wires on a separate Mayo stand for use later.
4. After the patient is anesthetized and the airway secured, any hair that could become involved in the surgical field should be carefully arranged and/or parted to facilitate the incision of the skin. If the hair is to be shaved, care should be taken to avoid cutting or nicking of the skin in the area of the surgical incision.
5. The auditory canal(s) and tympanic membrane(s) should be inspected with an otoscope to ensure there is no pre-operative infection and to document any pre-surgical pathology.
6. Occlude the external auditory canal on the surgical side. A cotton pledget moistened with sterile mineral oil can be utilized.
7. The surgical incision sites should be prepared and isolated so that there is no loose hair appearing in the surgical fields. After shaving the hair to above the ear, pull the remaining hair away from the pre-auricular and surrounding areas and up toward the crown of the head. Using foam tape, wrap the head circumferentially (forehead--above the ear--occiput) so that the hair is under the tape and off the skin over the pre-auricular incision site(s).
8. In unilateral cases, a plastic adhesive isolation drape (e.g., 1010) should be applied from the contralateral submental area to the ipsilateral temporal area to isolate the mouth from the surgical fields. This drape allows access to the oral cavity while providing for sterility of the implantation sites during application of IMF wires later in the procedure.
9. In bilateral cases, first seal the mouth with a plastic adhesive occlusive dressing (e.g., Tegaderm, Opsite). Then to isolate the nose and endotracheal tube, use a plastic adhesive isolation drape (e.g., 1010) on each side of the face. Place each drape vertically anterior to the planned pre-auricular and retromandibular/submandibular incision sites. Fold them together sterilely over the nose and endotracheal tube and seal with Steri-Strips.

SURGICAL APPROACHES

The surgical approaches for the placement of the TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis are the classic preauricular and submandibular approaches to the mandible. The preauricular approach has been modified to include the Al-Kyatt and Bramley modifications (Br J Oral Surg 17:91-103, 1979-80).

Due to the prior surgical procedures most of these patients have undergone, the classic anatomy described in the techniques presented below will be distorted or nonexistent. Therefore, the surgeon is advised that modifications of these techniques will be required based on the conditions found at each surgery.

In some cases, especially those involving ankylosis, the surgeon may elect to use a hemi-coronal or bi-coronal incision to approach the fossa. These incisions provide good access to the anterior aspect of the zygoma and the coronoid process in complex cases.

PREAURICULAR INCISION

1. Find the crease between the helix and the preauricular skin and mark a line from the top of the helix to the lobe. In previously operated patients, use the scar to make this incision. In patients with multiple scars, excise the scarred tissue with the initial incision and revise the scar at closure. The superior aspect of the incision should be extended anteriorly and superiorly 4cm at a 45 degree angle to the zygomatic process of the temporal bone.
2. Inject a vasoconstrictor (e.g., 1:200,000 epinephrine solution) along the line to be incised to decrease bleeding. Wait for its effect (3 minutes).
3. Apply traction to each end of the incision line with single-ended skin hooks.
4. With a #15 blade, incise the skin and subcutaneous tissue along the incision line.
5. At the superior aspect of the incision, spread the tissue with a curved mosquito hemostat to find the superficial layer of the temporalis fascia. This is the very obvious tough, shiny, white, sinewy appearing dense tissue.
6. Once this layer has been found, slide the hemostat inferiorly along the top of this fascia to the area of the zygomatic arch.
7. Deepen the remainder of the incision to this plane using dissecting scissors remembering to stay close to the auricular cartilage posteriorly in the avascular plane. In the multiply operated patient, this is more difficult due to the scar tissue. Care must be taken to avoid cutting or nicking the auricular cartilage to avoid a post-operative chondritis.
8. Using blunt retractors, retract the skin flaps. Care must be taken to avoid penetration of the parotid capsule at the inferior aspect of the incision as this may lead to persistent bleeding.
9. At the tragus, in previously unoperated patients, just above the parotideomasseteric fascia, is the tragal ligament beneath which are found the auriculotemporal nerve and the transverse facial artery, both of which can be sacrificed.
10. Once the parotideomasseteric and superficial temporal fascias have been exposed, make an incision approximately 2cm long at a 45 degree angle through the superficial layer of the temporalis fascia. The deep temporal vein crosses the zygomatic process of the temporal bone and can be cauterized at this point to avoid persistent bleeding. Extend this fascial incision across the posterior aspect of the temporal bone inferiorly along the posterior aspect of the condyloid process.
11. Reflect this fascial flap anteriorly along the zygomatic process of the temporal bone exposing the lateral aspect of the fossa and the articular tubercle. Care must be taken not to tear this tissue as branches of the facial nerve course through it in this area. Electrocautery and retraction should also be done in a judicious manner to avoid injury to these nerves as well. In the multiply operated patient, this step is made more difficult due to scar tissue. This flap may have to be elevated with the assistance of dissecting scissors cutting the scar tissue away from the temporalis muscle above the zygomatic process of the temporal bone as the flap is elevated. To assist in determining the anterior extent of dissection, refer to the anatomical bone model that should be available in the operating room. **Sterilizing the anatomical bone model and handling during surgery in the sterile field is specifically not recommended.**
12. The fossa can be entered through the superior aspect of the capsule if present. If there is an articular disc, it can be seen as the fossa is entered.
13. With a Freer periosteal elevator, separate the capsular tissue from the lateral aspect of the condyle and make a vertical incision through that tissue directly over the instrument, opening this tissue to expose the lateral aspect of the condyle and condyloid process. This step is also made more difficult in the multiply operated patient due to scar tissue.
14. The condylar resection can be performed at this point if desired. If the remnant of the condyle or condyloid process is too small to be seen, felt, or reached from the preauricular incision, proceed to the submandibular incision and dissect up to the fossa area from below along the posterior mandibular ramus to find the bone for resection.
15. Control all bleeding, irrigate, and pack the area with moist gauze, and direct attention to the submandibular incision.

SUBMANDIBULAR INCISION

1. Mark a 6cm line along one of the skin creases, one finger-breath below the earlobe along the inferior and posterior aspect of the mandible.
2. Inject a vasoconstrictor (e.g., 1:200,000 epinephrine solution) along the line to be incised to decrease bleeding. Wait for its effect (3 minutes).
3. Apply traction to each end of the incision line with single-ended skin hooks.
4. With a #15 blade, incise the skin and subcutaneous tissue along the incision line down to the platysma.
5. Incise through this muscle, carefully testing for the marginal mandibular branch of the facial nerve.
6. The next layer encountered in the previously unoperated patient will be the superficial layer of the deep cervical fascia. Dissect carefully through this layer, testing for the marginal mandibular branch of the facial nerve.
7. Carefully dissect out the facial vein and artery, isolate them, and clamp, cut, and tie these vessels.
8. Identify and incise the pterygomasseteric sling and the periosteum at the inferior border of the mandible along the length of the incision, then using a periosteal elevator expose the whole lateral aspect of the ramus of the mandible, the coronoid process, and the sigmoid notch. Connect the preauricular dissection with this one by following the posterior border of the mandible up to the condyloid process resection. Passing the blunt end of a periosteal elevator from below up into the area of the resection will allow it to be seen in the fossa through the preauricular incision.

CONDYLAR RESECTION

1. As pre-operatively determined during the work-up of the anatomical bone model, resect the condyloid process. A template made prior to surgery from suture pack foil can be useful in determining the location of this cut.
2. Mark the position of the ramus cut and using a short-blade oscillating saw with copious irrigation separate the proximal segment containing the condyloid processes form the ramus.
3. Once the proximal condyloid process segment is separated, bring it lateral to the ramus with a Seldin elevator and remove.
4. Using a similar technique, the coronoid process may be resected at this time if desired.
5. Obtain hemostasis.
6. Perform the submandibular incision if not already completed.

FOSSA PREPARATION

1. The residual fossa must be thoroughly debrided of all soft tissue posteriorly to the tympanic plate, anteriorly to the remnant of the articular eminence of the temporal fossa, and medially to the medial ridge of the fossa where the medial capsule attaches superiorly to the temporal bone.
2. Reproduce any fossa contouring that was pre-operatively performed on the anatomical bone model.
3. Reference the fossa component outline on the anatomical bone model and expose the zygoma anteriorly as required to accept the lateral flange of the implant.

VERIFICATION OF IMPLANT FIT

1. At this point, the patient-fitted fossa component is tried into place. Care must be exercised so as not to scratch the plastic bearing surface with sharp instruments.
2. Seat the fossa component superiorly and medially with the fossa seating tool. The component must fit snugly without any rocking and the lateral flange should engage the zygomatic arch securely. **Failure to properly seat the fossa component could result in breakage.**
3. If there is any resistance or rocking noted, determine the impinging hard or soft tissue and relieve or remove it. The fossa component must fit passively in its intended position as indicated on the anatomical bone model.
4. **The fossa component should not be secured in place with screws until its location has been verified by trial placement of the mandibular component with the patient in IMF**.

5. Place the mandibular component on the ramus without the fossa component in position to ensure its independent fit. The mandibular component should fit passively in its intended position as indicated on the anatomical bone model if no pre-operative contouring of the ramus was performed. **Wait to perform any pre-operatively planned mandibular contouring until the patient is placed in IMF.**
6. There are some cases where the lateral ramus bone remodels in an unusual manner after a first-stage surgery, particularly after failed alloplasts and bone grafts. This trial placement will determine the amount of remodeled lateral bone that may have to be removed to allow the mandibular component to have maximal bone contact with the residual ramus. **Mandibular contouring should not be performed, however, until the patient is placed in IMF.**
7. For a bilateral case, irrigate and pack the incisions with moist gauze, and perform the incisions and implant trial reduction on the contralateral side.

FINAL IMPLANT FIXATION

1. Place the patient in tight IMF at the planned occlusion using 25 gauge box wires bilaterally posteriorly and anteriorly. Care must be taken not to contaminate the surgical sites during this procedure. It is recommended that the individual applying the IMF change their gown and gloves before returning to the sterile field. Care must also be taken that none of the instruments used intraorally find their way back to the sterile field. Having a separate Mayo stand with dedicated IMF instrumentation and suction precludes such problems.
2. Perform any pre-operatively planned mandibular contouring. **Remove bone conservatively with repeated trial placement of components to prevent unnecessary bone removal.**
3. Insert the fossa component and place into proper position using the fossa seating tool.
4. Once the fit of the fossa component has been confirmed, place the mandibular component through the submandibular incision. Articulate it with the fossa component and align it with the lateral surface of the mandible. **The fit of each component and the articulation is finalized by ensuring that the condylar head is centered on the fossa bearing in the M/L direction and seated against the bearing's posterior lip.** The mandibular component may be held flush against the ramus with the mandibular forceps. Use a Freer elevator to check for gapping along the perimeter of the mandibular component, particularly around the superior portion where visualization is limited. Gapping may indicate an insufficient condylar resection, inadequate mandibular contouring, or improper fossa component seating.
5. Once the fit of both components and their articulating relationship have been confirmed, fixate the fossa component with the mandibular implant removed using the predetermined size and length screws. The fossa component screws are placed using slow speed and copious irrigation to prevent devitalizing the bone. Use the fossa seating tool to stabilize the implant.
6. Hold the mandibular component in position with the mandibular forceps, check head position, and fixate using the predetermined size and length screws. The drill guide should be placed into each screw hole when drilling through the ramus for screw placement. Use slow speed and copious irrigation to prevent devitalizing the bone. The screws should be placed after each hole is drilled. A percutaneous technique may be necessary for anterior superior screw holes. Return to each screw and check that it is fully seated prior to proceeding.
7. For a bilateral case, repeat fixation of implant components on the contralateral side.
8. IMF is released and the mandible functioned. The joint components are directly observed to ensure proper movement with function. While the patient is in occlusion, the condylar head of each component should continue to be centered on the fossa bearing in the M/L direction and seated against the bearing's posterior lip.
9. Training elastics are placed for immediate post-operative comfort. Once again, care must be exercised so as not to cross contaminate the surgical sites from the oral cavity.
10. Both wounds are copiously irrigated and closed carefully in layers. A pressure dressing is applied and kept in place for 24 hours.

POST-OPERATIVE MANAGEMENT

1. Post-operative radiographs (panoramic and PA skull or PA cephalometric) are made to confirm position and alignment of the components and screws.
2. Arch bars or orthodontic appliances should remain in place while the use of training elastics is deemed necessary.
3. Limit early post-operative opening to avoid dislocation particularly in patients that have significant soft tissue laxity due to coronoidectomies and/or extensive dissection performed to regain opening or reposition mandible. The use of training elastics in the immediate post-operative period can reduce the potential for dislocation. Dislocation is typically only of concern for the first week post-operatively.
4. When it is considered that the potential for dislocation is low, the training elastics can be released when the pressure dressing is removed, and the patient can be started on a jaw-exercising device (e.g., Therabite). Should the patient require the assistance of a physical therapist to increase and maintain mandibular range of motion post-operatively, two to three visits per week for a minimum of 3 months is appropriate.
5. While the patient is using training elastics, the diet is restricted to full liquids. Once the training elastics are no longer being used, the patient should be encouraged to chew a soft diet and advance their diet as tolerated.

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).

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

<u>General</u>

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.

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.

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.

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 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.

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.

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

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)

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.