TMJ

Joint Replacement System

ZIMMER BIOMET

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An Innovative Implant for Total Joint Replacement

Your progress. Our promise.™ A leading innovator in musculoskeletal healthcare, Zimmer Biomet provides end-to-end patient solutions.

The Total TMJ Replacement System is a temporomandibular joint prosthesis. It incorporates 30 years of orthopedic total joint experience into the design and materials used in this system.

The Total TMJ replacement system has been manufactured and clinically used since July 1995 under an approved investigational device exemption (IDE) from the FDA. The clinical study yielded a 96% patient success rate.* For complete information, we invite you to contact us or visit zimmerbiomet.com today.

*Success rate derived from clinical study conducted for system approval.

System Components

Mandibular Components

The mandibular (condylar) prosthesis is designed to replace the articular surface of the mandibular condyle. The mandibular prosthesis is offered in 3 sizes (45mm, 50mm, and 55mm) designated left and right. The mandibular prosthesis is offered in 3 styles (standard, offset, and narrow) to fit a diverse range of mandibular sizes and shapes. The mandibular prosthesis is made of Cobalt Chromium Alloy. The undersurface of the prosthesis is coated with titanium plasma spray for increased bony integration to the mandibular prosthesis.

Fossa Prosthesis

The fossa prosthesis is designed to replace the articulating surface of the temporomandibular joint comprised of the glenoid fossa and the articular eminence of the temporal bone. The fossa prosthesis is made of Arcom® Ultra High Molecular Weight Polyethylene (UHMWPE). UHMWPE is the same material used effectively in total hip and knee surgery for over 30 years. The fossa prosthesis is offered in 3 sizes (small, medium, and large) in which all sizes are freely interchangeable with every size and style of the mandibular prosthesis. The spherical head of the mandibular prosthesis is designed similar to the spherical radius of the fossa prosthesis allowing for excellent articulation of the joint.

Fossa and Mandibular Screws

The system screws are made of 6AL/4V titanium. The screws are self-retaining and self-tapping to facilitate ease of insertion.The fossa screws (2.0mm) are specially designed to fit the fossa prosthesis. The fossa screws have a flat screw head to ensure a proper fit onto the fossa prosthesis and to create an extremely low-profile implant. The mandibular prosthesis screws (2.7mm) have a spherical radius on the head of the screw to mate with the counter sink in the screw holes of the mandibular prosthesis resulting in a low-profile implant.

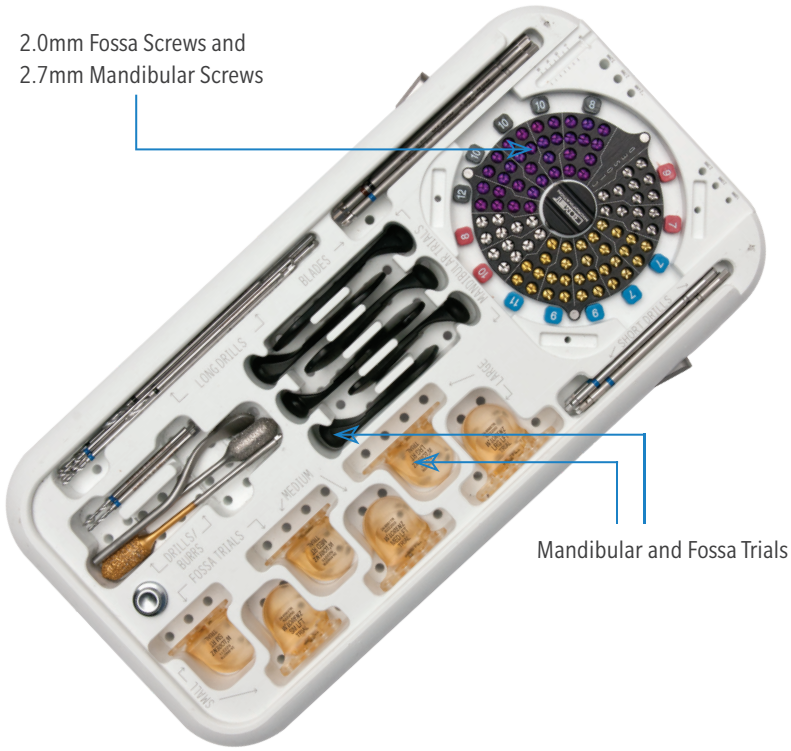
Mandibular Implant, Standard

(Underside view on left)

Mandibular Implant, Narrow

(Available in 45mm and 50mm)

Fossa Prosthesis



Items not to scale

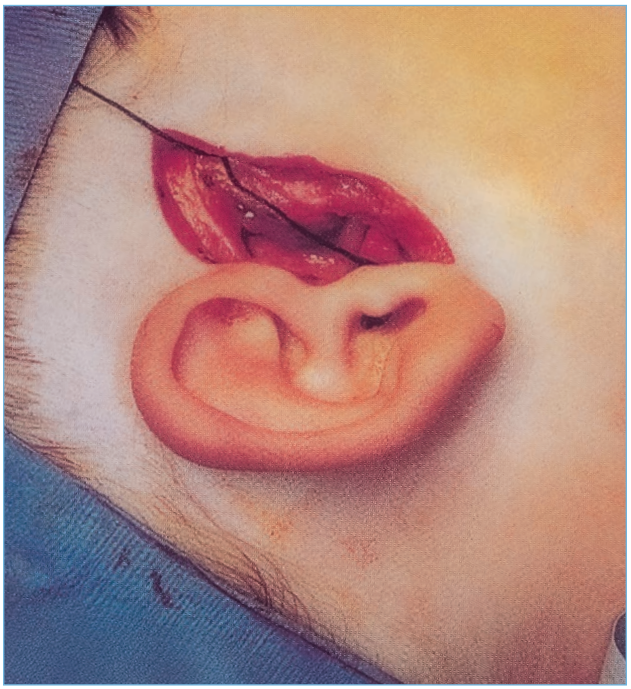
Surgical Technique

Pre-Operative

After satisfactory induction of general nasotracheal anesthesia, the patient is prepped and draped in the usual manner. Twenty-six and twenty-four gauge stainless steel wires are used to place Ivy loop fixation wires in both the maxilla and the mandible, so that during the critical time of condylar prosthesis screw placement, the patient can be placed in inter-maxillary fixation.

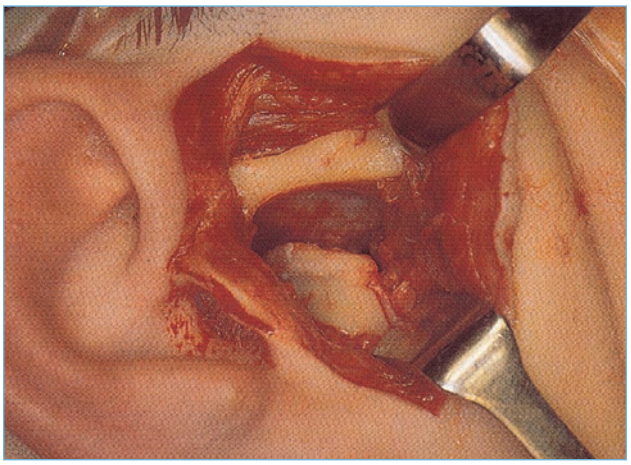
1. Incisions

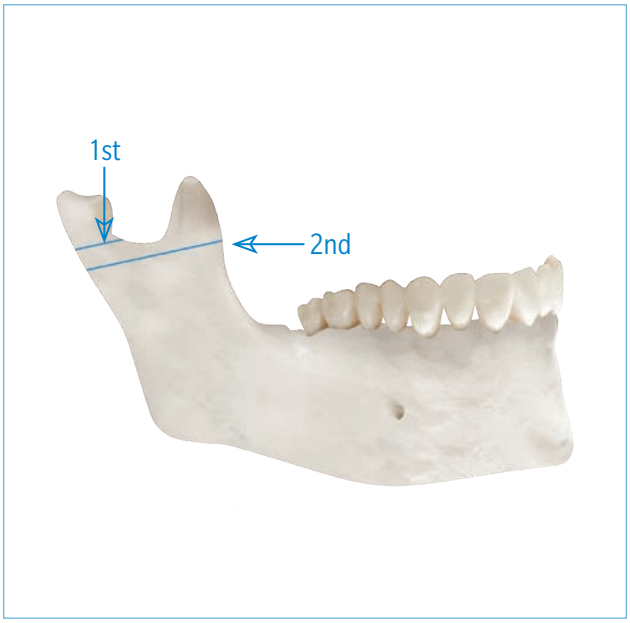
A standard endaural incision is made with dissection along the tragal cartilage down to the joint space itself, avoiding any damage to the upper trunk of the facial nerve. The root of the zygoma is identified and periosteum is stripped off to expose the zygoma. The dissection is then carried down to expose the capsule of the joint. A modified posterior mandibular incision is then made approximately two finger breadths below, and posterior to, the angle of the mandible. This is truly a retro-mandibular incision, which allows better visualization of the entire ramus and also permits rapid access to the terminal branch of the external carotid if any troublesome hemorrhage is encountered from the internal maxillary artery during the condylectomy. Dissection is carried through to the subcutaneous tissue until the marginal mandibular branch of the facial nerve is identified and retracted superiorly. Dissection is then carried in a plane between the anterior border of the sterno-cleidomastoid muscle and the submandibular gland. The facial artery and vein can be ligated at this time and then the aponeurosis between the masseter and pterygoid muscle is identified and incised. After stripping off the masseter muscle, the surgeon should be able to have full visualization of the lateral ramus up to the neck of the condyle.



2. Exposure of the Joint

Attention is then directed back to the joint itself where an incision is made along the posterior root of the zygoma and a full-thickness mucoperiosteal flap is elevated to expose the entire lateral surface of the glenoid fossa and the capsule of the joint itself. The neck of the condyle is isolated with condylar retractors and a two step condylectomy is performed.





3. Performing the Osteotomy

A 1mm fissure burr is first used to make a traditional condylectomy cut at the level of the sigmoid notch. After the condyle is removed, the angle of the mandible is grasped securely with bone holding forceps and the ramus is pushed superiorly so that more of the superior ramal stump is visualized in the endaural exposure. This allows the second osteotomy to be performed, which is approximately 5mm below the sigmoid notch and can include the coronoid to be removed in a single section osteotomy. This is necessary to accommodate the thickness of the glenoid fossa implant.

4. Preparing for the Fossa Prosthesis

A specially designed, large diamond burr or reciprocating diamond rasp can be used to flatten the articular eminence. This removes the majority of the variability in the glenoid fossa. The end of the burr has a radial shape, which matches the medial radial surface of the fossa component.

5. Occlusion Placement

Surgical wounds are now packed with antibiotic-soaked sponges. (Irrigant for the entire case is antibiotic infused solution). The surgeon now re-enters the oral cavity and places the patient in the optimum desired occlusion with secure twenty-six and twenty-four gauge inter-maxillary wires. IMF screws can also be used as an alternative.

Surgical Technique

6. Sizing and Implantation of the Fossa Prosthesis

The surgeon changes his/her gown and gloves to place the fossa implant. The fossa trial (sizer) can now be used to assess the initial fit of the prosthesis, with the goal to have a tripod stable fit of the fossa with minimal dead space. At this point, the surgeon can determine which of the three sizes of the fossa prosthesis would best allow a minimum of four 2.0mm zygomatic screws to be placed. The difference between sizes is strictly in the flange area for screw placement options. The articular surface is identical between sizes. It is extremely important to reduce the bone on the medial surface of the glenoid fossa adequately enough to allow proper seating of the medial edge of the fossa prosthesis. This ensures that the fossa is positioned so that it is approximately parallel to the Frankfurt-Horizontal line, and it avoids an anterior-posterior or medio-lateral tilt to the implant. Once the proper fit is achieved, two 2.0mm screws are used for the initial fixation, followed by a minimum of two additional 2.0mm screws.

7. Fitting the Mandibular Component

The mandibular trial (sizer) is used to assess whether a 45mm, 50mm, or 55mm prosthesis will be used. It is also used to determine whether an optional narrow component or offset component could be appropriate. There is unlimited size interchangeability between the mandibular components and the fossa components. The trial also allows the surgeon to determine whether the large diamond burr or rasp needs to be utilized to contour the lateral surface of the ramus so there is a flush fit of the mandibular component against the ramus. The specially designed diamond rasp can be also used to radius the edge of the resected ramus. The mandibular implant may not be bent in any way.

8. Range of Motion

Once the head of the permanent mandibular prosthesis is positioned in the mid portion of the glenoid fossa, two 2.7mm screws are placed temporarily to secure the prosthesis. When drilling the holes for the ramus prosthesis, it is important to approximate the position of the inferior alveolar nerve to avoid any damage while placing the screws. If desired, a drill guide is available to assist in drilling. Once the prosthesis is placed temporarily, and the wounds are covered with sterile drapes, the surgeon then goes back into the oral cavity and removes the intermaxillary fixation. The mandible should be put through a reasonable range of motion with an interincisal opening of 30 to 35mm to assess the mechanical functioning of the joint, and to look for any subluxation, dislocation, or mechanical obstruction. If there is any question that the patient has increased muscle tone under a light anesthetic, it may be necessary to request that the anesthesiologist administer a short acting muscle relaxant to make sure that there is proper mechanical joint function with a reasonable range of motion. If, under full muscle relaxation, there appears to be significant impairment to range of motion, it may be important to assess whether a coronoidectomy is necessary or whether further stripping of the soft tissue attachments would be appropriate. If the range of motion and the occlusion are satisfactory, the maxillary and mandibular fixation wires could be removed at that time and an occlusive dressing is placed over the oral cavity.

9. Final Screw Placement

The remaining screws are then placed with an average of 4-6 screws recommended for securing the mandibular component. The implant may not be bent and great care should be taken to avoid scratching or damaging the articular surface of the mandibular component.

Closure

The surgical wounds are then irrigated with antibiotic solution; the deep layers of the wounds are closed with 3-0 chromic, the subcutaneous layer is closed with 4-0 chromic, and the skin incisions are closed with 5-0 nylon. The pressure dressing is applied. At the end of the procedure, all of the fixation wires of the maxilla and mandible are removed, and the patient is extubated.

Rehabilitation and Follow Up

The day following surgery, a regimen of jaw exercises may be recommended and should be continued until maximum opening is achieved, or for at least six weeks. The post-operative evaluation form must be filled out at the prescribed follow-up intervals.

Ordering Information

Implants

FOSSA			TRIALS*	
Fossa	Left	Right	Left	Right
Small	24-6563	24-6562	24-6563TR	24-6562TR
Medium	24-6561	24-6560	24-6561TR	24-6560TR
Large	24-6565	24-6564	24-6565TR	24-6564TR
MANDIBULAR			**TRIALS***	
45mm	24-6546	24-6545	24-6546TR	24-6545TR
50mm	24-6551	24-6550	24-6551TR	24-6550TR
55mm	24-6556	24-6555	24-6556TR	24-6555TR
MANDIBULAR (Narrow)			**MANDIBULAR (Offset)**	
45mm	01-6546	01-6545	24-6646	24-6645
50mm	01-6551	01-6550	24-6651	24-6650

Add TI for Titanium Implants
Titanium Implants available for patients with nickel allergies * Trials are not implantable devices

Screws

FOSSA SCREWS		MANDIBULAR SCREWS	
X-Drive		HT X-Drive	
Part #	Description	Part #	Description
99-6577	2.0 x 7mm	91-2708	2.7 x 8mm
99-6579	2.0 x 9mm	91-2710	2.7 x 10mm
99-6581	2.0 x 11mm	91-2712	2.7 x 12mm
X-Drive Emergency		HT X-Drive Emergency	
99-6587	2.3 x 7mm	**99-9948**	3.2 x 8mm
99-6589	2.3 x 9mm	**99-9950**	3.2 x 10mm

99-Singles, 01-5/pk

91-Singles, 95-5/pk

Instruments

PART #	DESCRIPTION
01-6505	TMJ Implant Container
01-6507	TMJ Instrument Case
01-7600	2.0/2.4mm Screwdriver Handle
01-7390	Green 1.5/2.0 Screwdriver Handle
24-1194	2.4/2.7mm X-Lock Blade, Short
24-1196	2.4/2.7mm X-Lock STD Blade
01-7694	2.0mm X-Lock Blade, Short
01-7696	2.0mm X-Lock STD Blade
24-6520	TMJ Double Ended Drill Guide
24-6610	1.5 x 50mm, 11mm Stop Twist Drill
24-6612	1.5 x 105mm, 11mm Stop Twist Drill
24-6614	2.0 x 70mm, 12mm Stop Twist Drill
24-6616	2.0 x 115mm, 12mm Stop Twist Drill
24-6618	2.2 x 70mm, 12mm Stop Twist Drill
24-6620	2.2 x 115mm, 12mm Stop Twist Drill
24-6526	TMJ Diamond Rasp
24-6530	TMJ Diamond Burr, Coarse (Gold)
24-6532	TMJ Diamond Burr, Medium
24-6534	TMJ Diamond Short Burr, Coarse*
24-6536	TMJ Diamond Short Burr, Medium*
ADDITIONAL INSTRUMENTATION	
24-6510	PDQ Zygoma Retractor
24-6512	PDQ Condylar Retractor
24-6514	PDQ Coronoid Retractor
01-0200	Condylar Stripper
01-0194	Posterior Condylar Retractor
27-0066	Dingman Bone Holding Forceps
01-0431	Dunn-Dautrey Spatula Osteotome
24-1110	Plate Holding Forceps
15-1150	Tray Rack System*
01-9095	Bone Plate Holding Forceps*

* Optional Instrumentation

Warnings and Precautions for Use of the Total TMJ Replacement

Caution
Federal Law (USA) restricts this device to sale, distribution, or use, by or on the order of a physician.

Description
The Total Temporomandibular Joint (TMJ) Replacement System is implanted in the jaw to functionally reconstruct a diseased and/or damaged temporomandibular joint. The Total TMJ Replacement System is a two-component system comprised of mandibular condyle and glenoid fossa components. Both components are available in multiple sizes as right and left side specific designs and are attached to the bone by screws. Included in the system are trials, instruments and instrument cases.

Materials
- Mandibular Component—Cobalt-Chromium-Molybdenum (Co-Cr-Mo) alloy with titanium alloy coating or Titanium (Ti-6Al-4V) alloy with titanium alloy coating
- Fossa Component—ultra high molecular weight polyethylene (UHMWPE)
- Screws—titanium alloy
- Trials: Mandibular—aluminum, Fossa—Radel® plastic
- Instruments: TMJ flat diamond rasp, TMJ diamond burrs, TMJ double-ended drill guide, retractors—stainless steel
- Instrument Case—stainless steel, silicone, Radel® plastic

Indications
The Total Temporomandibular Joint Replacement System is indicated for reconstruction of the temporomandibular joint. The reconstruction is necessary due to one of the following diagnoses:
- Arthritic conditions: osteoarthritis, traumatic arthritis, rheumatoid arthritis
- Ankylosis including but not limited to recurrent ankylosis with excessive heterotopic bone formation
- Revision procedures where other treatments have failed (e.g. alloplastic reconstruction, autogenous grafts)
- Avascular necrosis
- Multiply operated joints
- Fracture
- Functional deformity
- Benign neoplasms
- Malignancy (e.g. post-tumor excision)
- Degenerated or resorbed joints with severe anatomic discrepancies
- Developmental abnormality

Contraindications
- Active or chronic infection.
- Patient conditions where there is insufficient quantity or quality of bone to support the components.
- Systemic disease with increased susceptibility to infection.
- Patients with extensive perforations in the mandibular fossa and/or bony deficiencies in the articular eminence or zygomatic arch that would severely compromise support for the artificial fossa component.
- Partial TMJ joint reconstruction.
- Known allergic reaction to any materials used in the components. NOTE: Patients with known or suspected nickel sensitivity should not have Co-Cr-Mo devices implanted since this material contains nickel.
- Patients with mental or neurological conditions who are unwilling or unable to follow postoperative care instructions.
- Skeletally immature patients.
- Patients with severe hyper-functional habits (e.g. clenching, grinding etc.)
- Patients with a foreign body reaction due to previous implants.

Warnings
- Mandibular and fossa components are provided STERILE. DO NOT RESTERILIZE.
- Screws, trials, instruments and instrument cases are provided NON-STERILE. CLEAN AND STERILIZE BEFORE USE.
- DO NOT USE if there is a loss of sterility of the devices.
- DO NOT USE damaged implants and only use implants that are packaged in unopened or undamaged containers.
- DO NOT USE the individual components of this total system (e.g. mandibular components, fossa components, or screws) for partial joint reconstruction.
- 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.
- DO NOT USE IN CHILDREN. The Total TMJ Replacement was designed for skeletally mature patients.

Precautions
The device is limited to surgeons who are adequately trained in the use of the device through hands-on and educational course work. In all cases sound medical practice is to be followed and the surgeon must select the type of device appropriate for treatment.

The patient is to be warned that the system does not replace normal healthy bone in their TMJ and they may continue to have chronic pain and limited range of motion. The system can break or loosen as a result of stress, activity, or trauma. Patients with severe hyper-functional habits may have an undesirable outcome. The presence of existing mandibular and/or zygomatic arch screws or screw holes may compromise fixation. Note that placement of the implant in one joint only may result in harmful effects to the joint on the opposite side. Placement of the implant may produce an improper relationship between teeth surfaces that should contact during biting.

The patient is to be made aware of surgical risks and possible adverse effects prior to surgery and warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment. Specialized instruments/trials are designed for use with the Total TMJ Replacement System to aid in the accurate implantation of the components. DO NOT USE trials/instruments or cases that are disfigured, cracked, corroded, or otherwise damaged. Instruments/trials are subject to wear with normal usage and are susceptible to fracture when exposed to extensive use or excessive force. All trials/instruments and cases should be regularly inspected for wear or disfigurement. These should be disposed of appropriately.

Adverse Events
Adverse events that may occur following placement of the Total TMJ Replacement System are listed below. See Tables 7 and 8 located in the insert # 01-50-1000 for more detailed information on adverse events from the clinical trial.
- Removal of components(s) including, but not limited to the following:
  - implant changes caused by loading and/or wear
  - degenerative changes within the joint surfaces from disease or previous implants
  - implant materials producing particles or corroding
- Loosening or displacement with or without removal of the implant
- Infection (systemic or superficial)
- Foreign body or allergic reaction to implant components
- Fossa wear through
- Facial swelling and/or pain
- Facial nerve dysfunction
- Excision of tissue
- Heterotopic bone formation
- Neuroma formation
- Ear problems
- Dislocation

Patient Counseling Information
- Discussion of the following points is recommended prior to surgery.
- The importance of prompt medical attention if they experience unusual swelling in the area of the implant.
- The risks associated with a Total TMJ System (see Warnings and Adverse Events).
- Post-operative pain relief and return of function varies from patient to patient.
- Additional treatment may be required including but not limited to extended physical therapy, bite splint, dental braces, and/or orthognathic and reconstructive surgery.

Sterility
The Total Temporomandibular Joint Replacement System mandibular and fossa components are sterilized by exposure to a minimum of 25 kGy of gamma irradiation. DO NOT RESTERILIZE. Screws, trials, and the TMJ Instrument Case containing instruments are supplied non-sterile and should be wrapped with an FDA cleared sterilization wrap prior to steam sterilization in order to maintain sterility.

For more information on TMJ please contact us at:

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