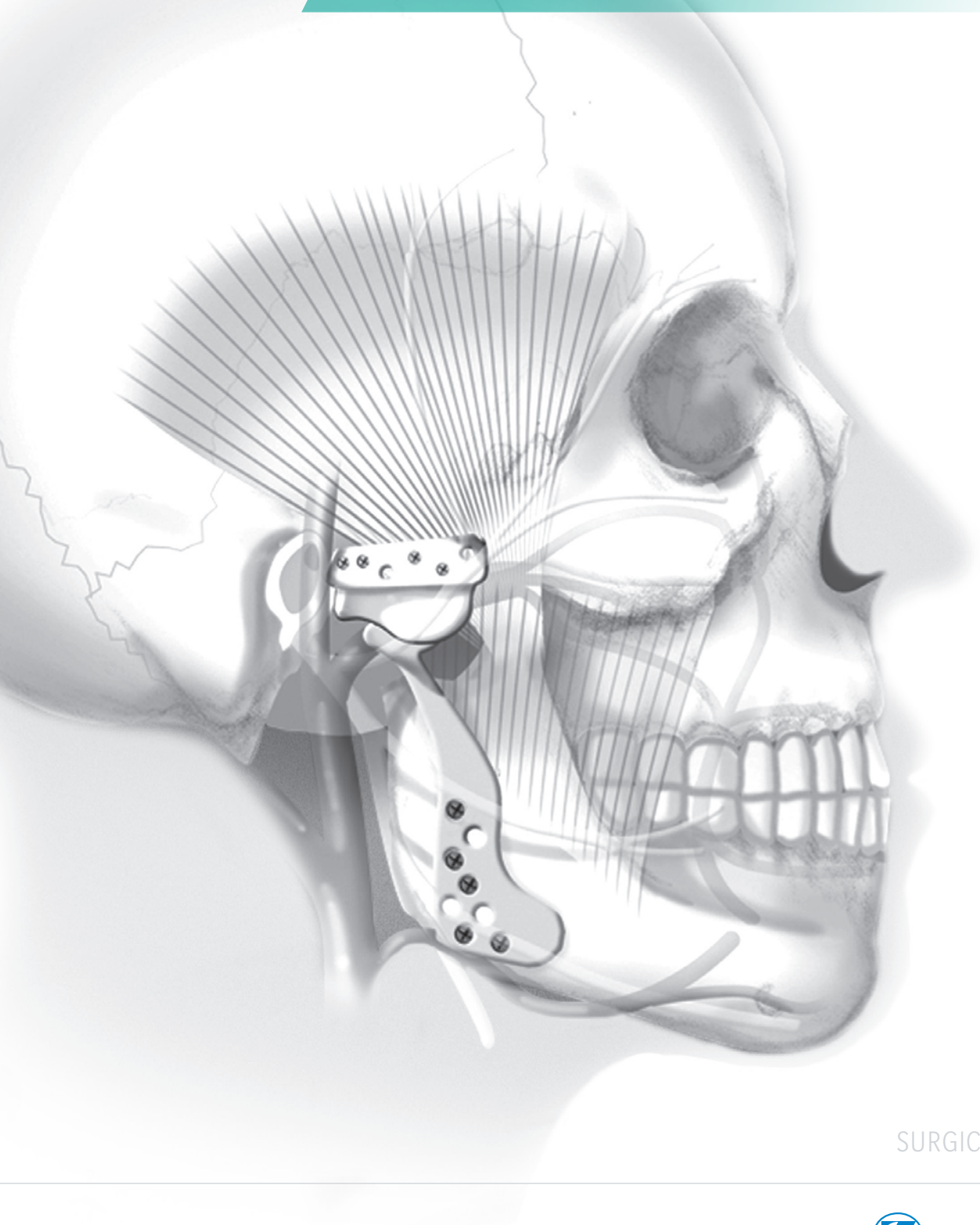
TMJ

Joint Replacement System



SURGICAL TECHNIQUE

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TMJ Joint Replacement System

The anatomy, function and pathology of the temporomandibular joint is clearly the most complex of all the articulations in the human body. The history of alloplastic temporomandibular joint reconstruction has been characterized by multiple failures based on inappropriate design, lack of attention to biomechanical principles, and inattention to the exceptional wisdom of the orthopaedic experience.

Between 1992 and 1995, the design and testing phase of the Zimmer Biomet total mandibular joint replacement system was completed. In the ten year clinical trial (from 1995 to 2005), over 400 prosthesis have been implanted with a patient success rate of over 96%.The current indications for alloplastic joint reconstruction include:

- 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

The Zimmer Biomet total mandibular joint replacement system received FDA approval in September of 2005.

*Success rate derived from clinical study conducted for system approval

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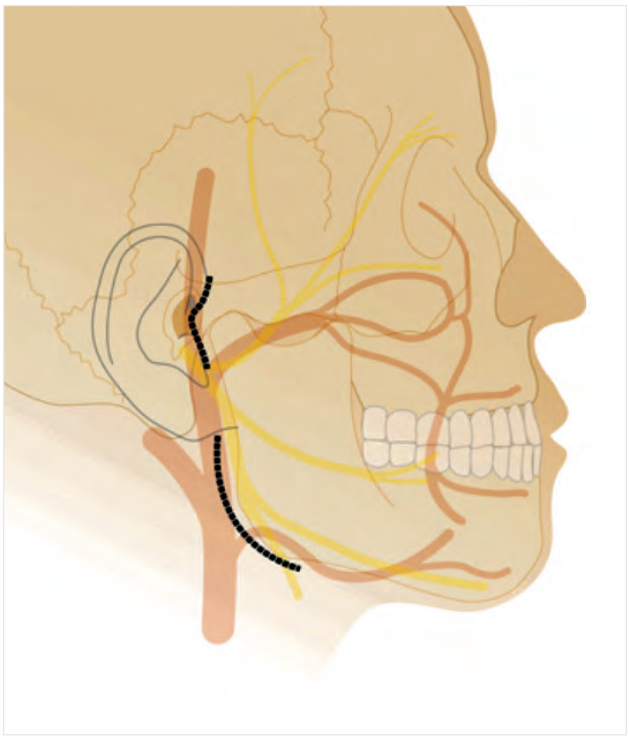
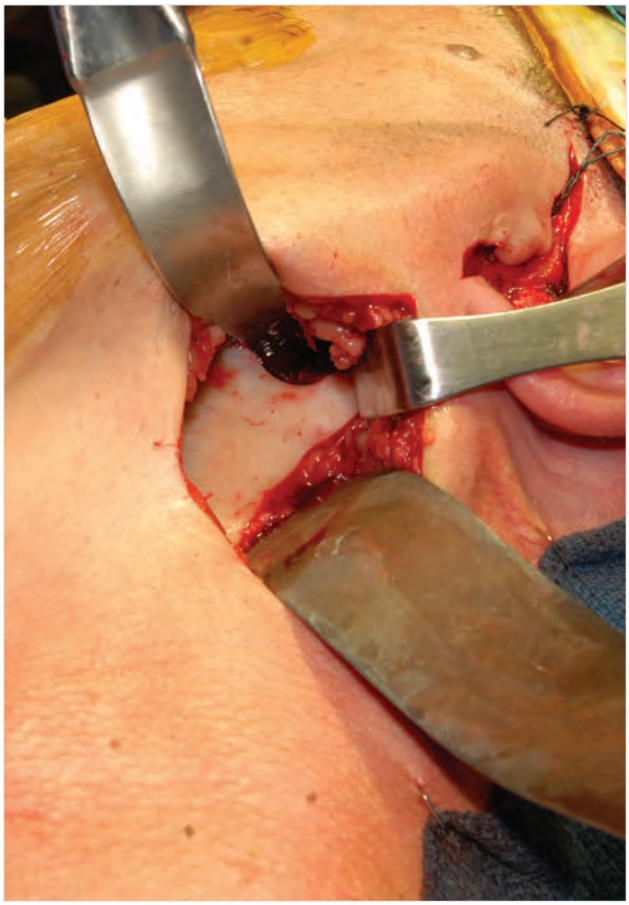
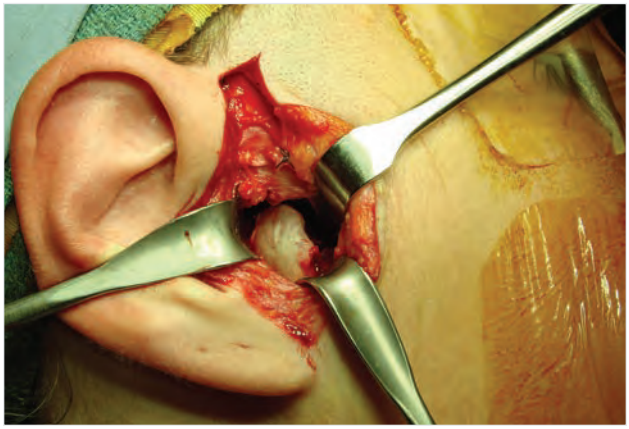
Step 1:
Exposure of the Ramus

The total mandibular joint replacement prosthesis is placed through a combination of an endaural incision and a posterior mandibular incision. It is important to complete the dissections for both the superior and inferior incisions before the osteotomies are performed to allow for optimal visualization and control of he orrhage from branches of the external carotid should it occur during the procedure.

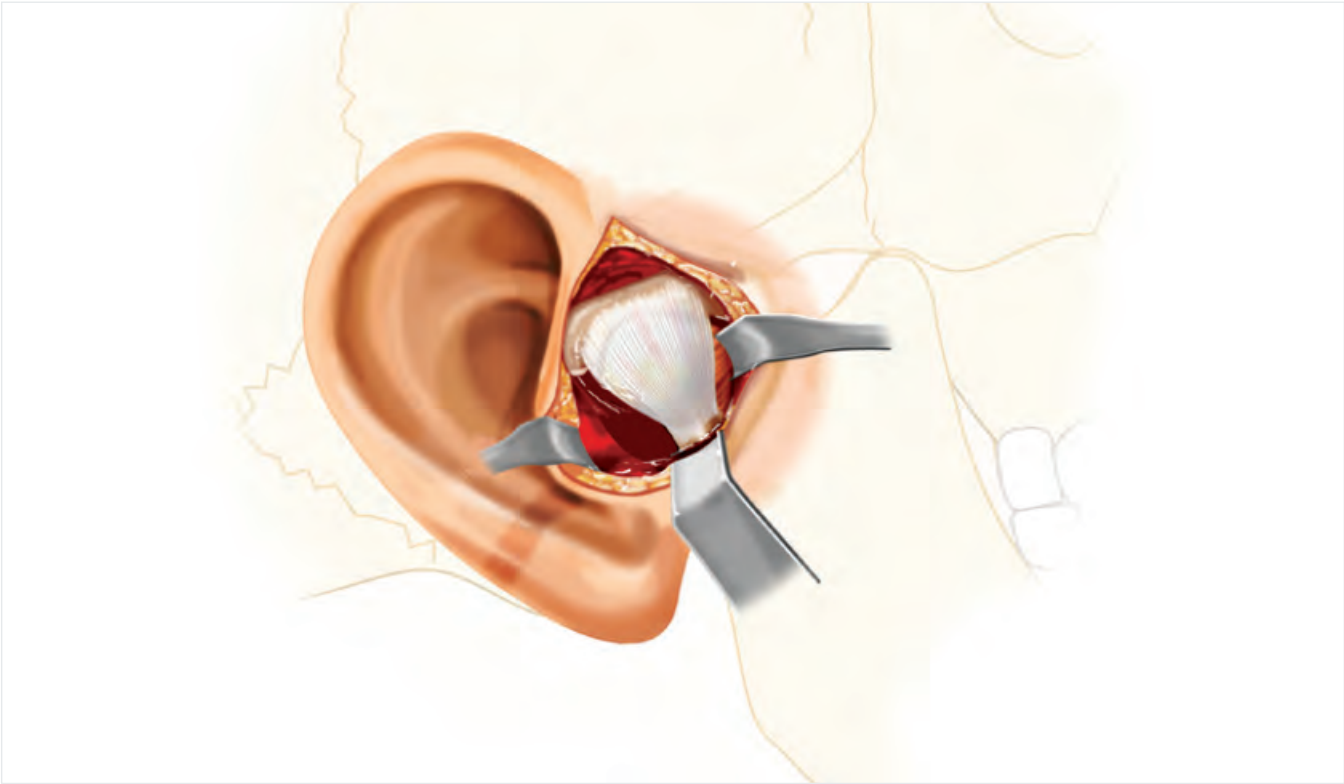






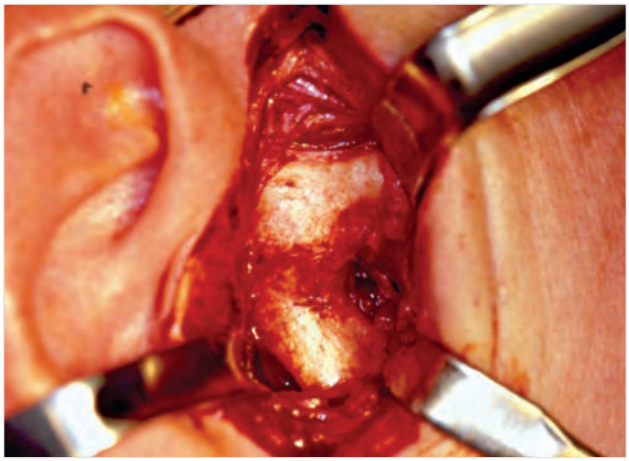
Step 2:
Exposure of the Zygomatic Arch

Dissection is carried down to the posterior root of the zygomatic arch to keep the dissection as far posteriorly as possible to avoid any damage to the branches of the facial nerve.



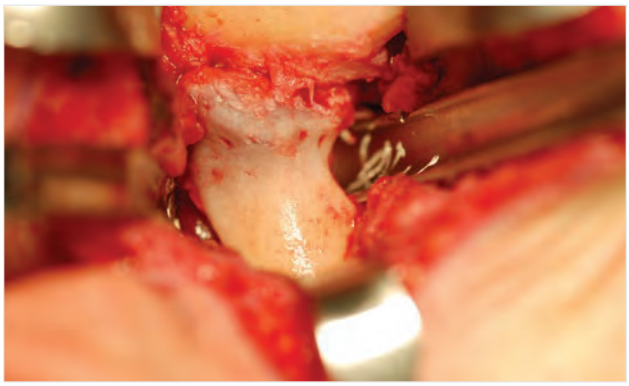
Step 3:
Exposure of the Entire Joint

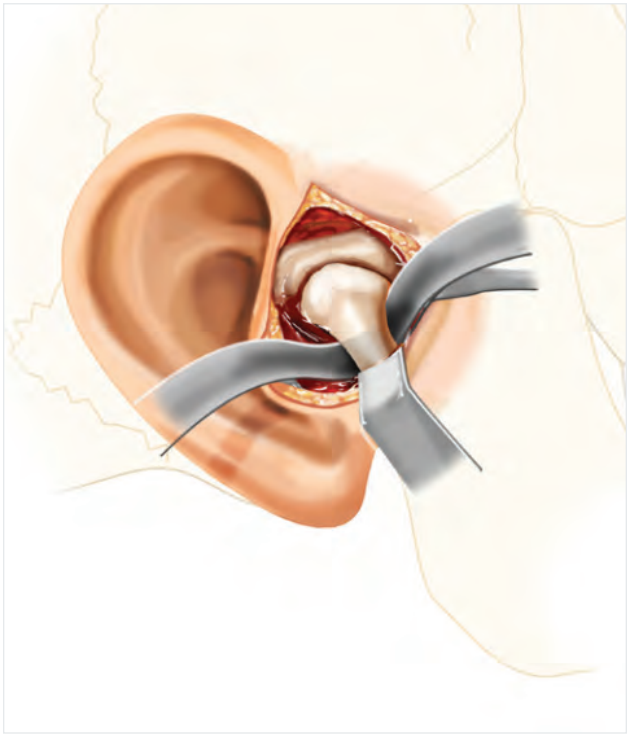
Condylar retractors are used to isolate the neck of the condyle to avoid damage to the internal maxillary artery and its branches.

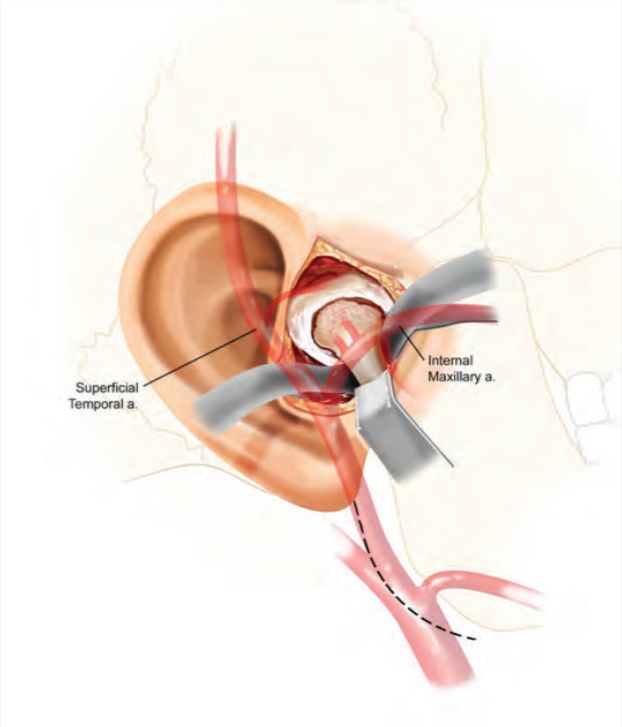


Step 4:
PDQ Retractors to Prepare for Osteotomy

With a combination of condylar retractors and a specifically designed condylar neck retractor (PDQ Retractor), the condyle is isolated in preparation for the two-step osteotomy.

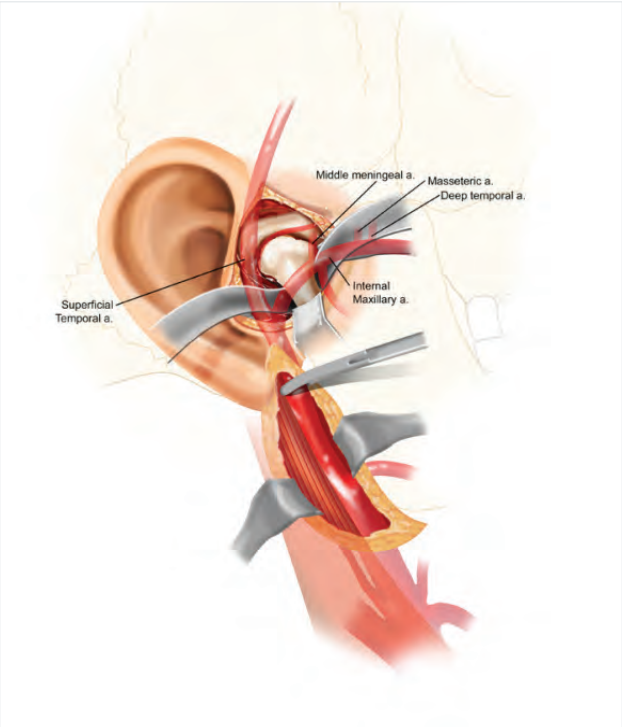






Step 5:
Dissection Medial to Condylar Neck

The superficial temporal artery is ligated as part of the initial dissection down to the root of the zygoma. Adequate dissection of the soft tissue medial to the neck of the condyle is important to avoid hemorrhage from the internal maxillary artery and the branches most commonly involved with hemorrhage during temporomandibular joint surgery (middle meningeal artery and deep temporal artery). This is especially important in the multiple operated patient where scarring and fibrosis may bring these vessels in closer proximity to the osteotomy cuts.

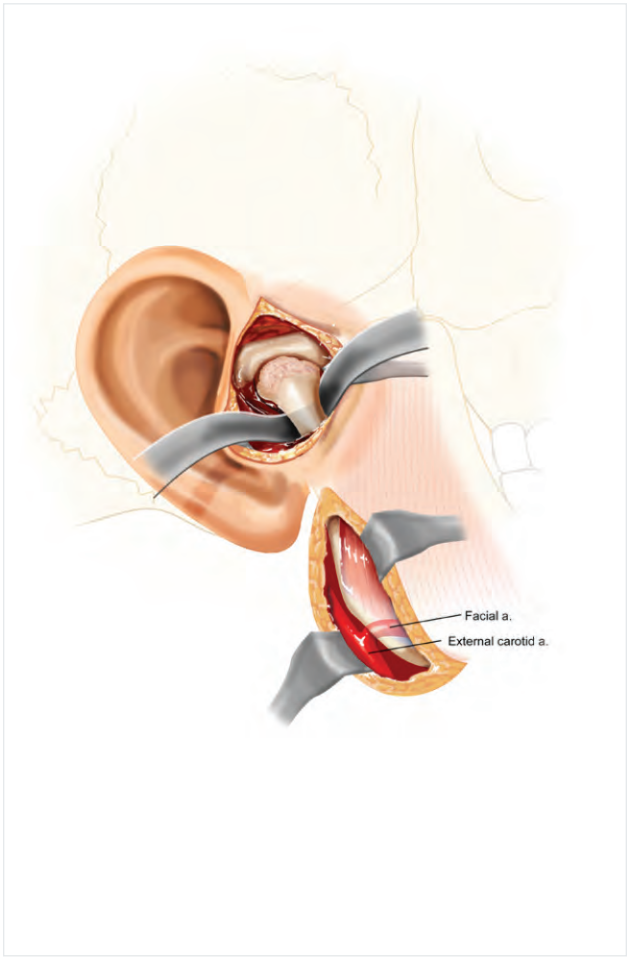


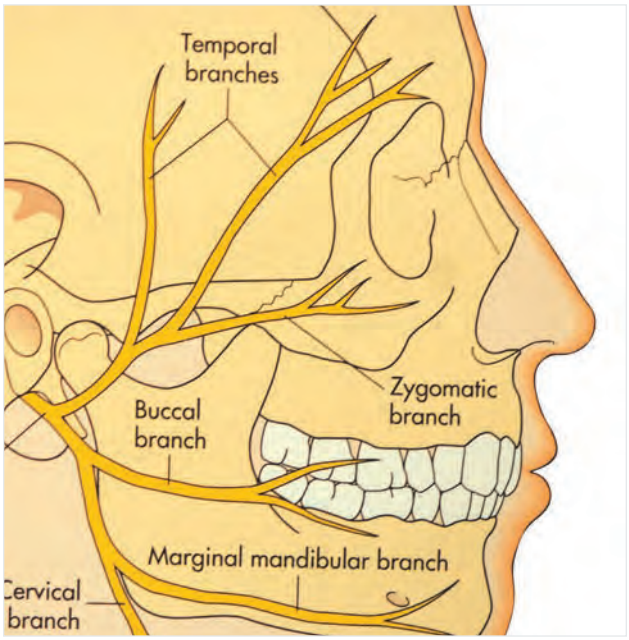
Step 6:
Ramal Exposure

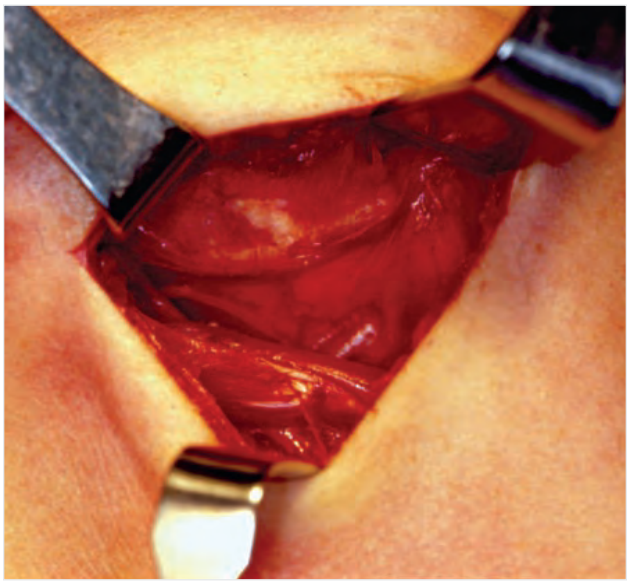
The posterior mandibular incision is largely a vertical plane of dissection anterior to the sternocleidomastoid muscle. This gives greater visualization of the entire ramus for placement of the condylar prosthesis and allows rapid access to the upper portion of the external carotid in case it is necessary to ligate that vessel to control hemorrhage on the medial surface of the condylar neck and superior ramus. Ligation of the external carotid, above the posterior auricular branch and below the transverse facial, has been shown to be more efficacious in decreasing flow to the internal maxillary artery and its branches compared to ligation at the bifurcation of the common carotid.

Step 7:
Dissecting Around the Mandibular Branch of the Facial Nerve

The posterior mandibular incision maximizes the visibility of the lateral ramus. The marginal mandibular branch of the facial nerve should be retracted superiorly in this dissection.





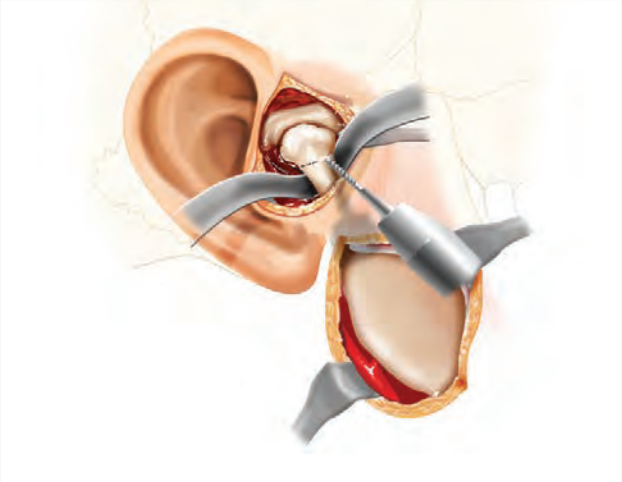


Step 8:
Masseter Reflection

Once the aponeurosis between the masseter and the medial pterygoid has been identified, a scalpel is used to incise through the aponeurosis anteriorly from the ante-gonial notch and posteriorly approximately one-third of the length of the posterior ramus.

Step 9:
Ramal Exposure

A periosteal elevator is used to cleanly strip the masseter muscle at its aponeurotic insertion to avoid incising muscle fibers and causing undue hemorrhage.

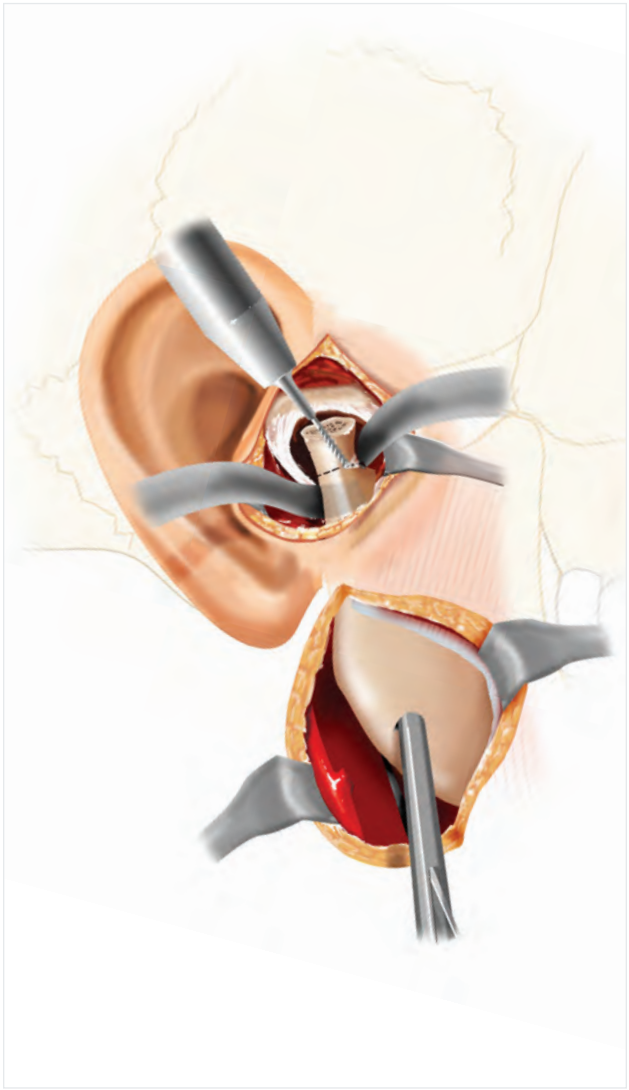


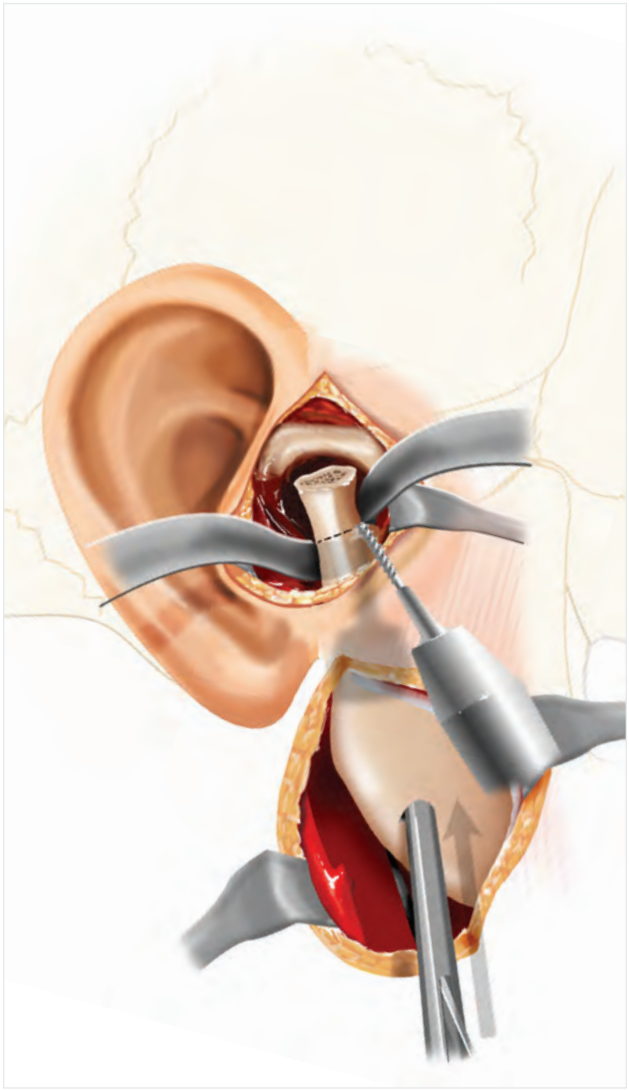
Step 10:
Begin Osteotomy with 1mm Fissure Burr

Once the lateral ramus is stripped from its masseteric insertion and temporalis insertion, if necessary, attention is directed back to the endaural incision for the first phase of the two-step osteotomy. A 1mm fissure bur is used to perform a standard condylectomy with appropriate protection from the condylar retractor

Step 11:
T-bar Osteotome to Finish Osteotomy

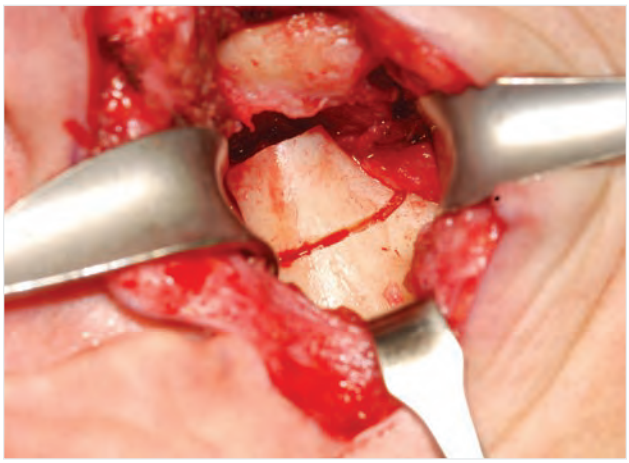
Approximately ninety percent of the osteotomy cut is performed with a 1mm fissure bur and the final portion of the medial cortical bone is separated with a T-bar osteotome to avoid vascular injury. The condyle is then removed with bone holding forceps after stripping the remnants of the external pterygoid muscle from the fovea of the condyle.





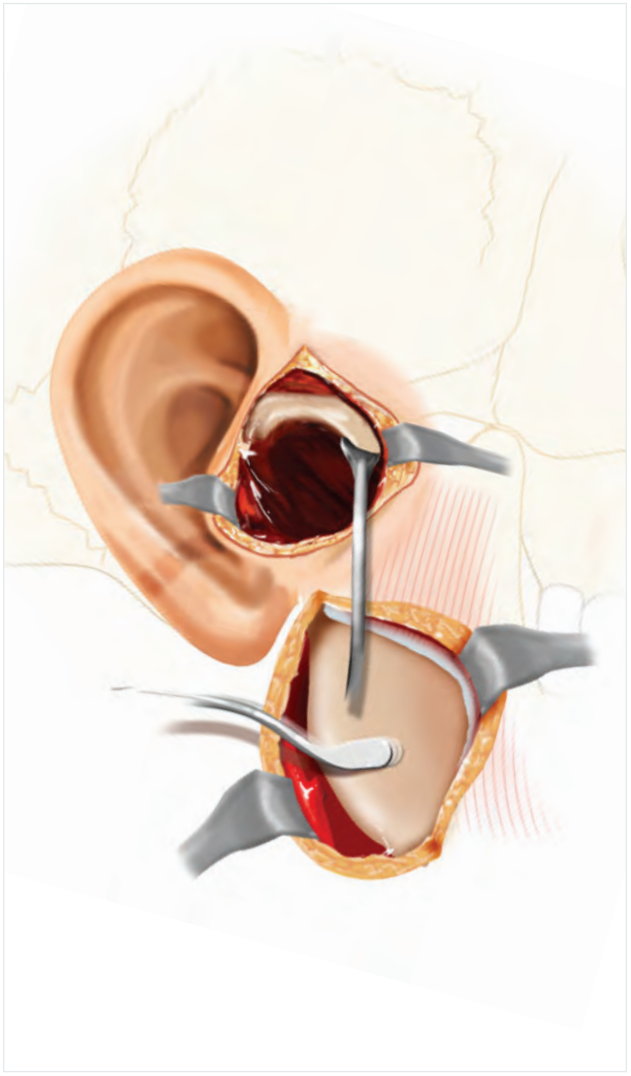
Step 12:
Two-Step Osteotomy - Phase II

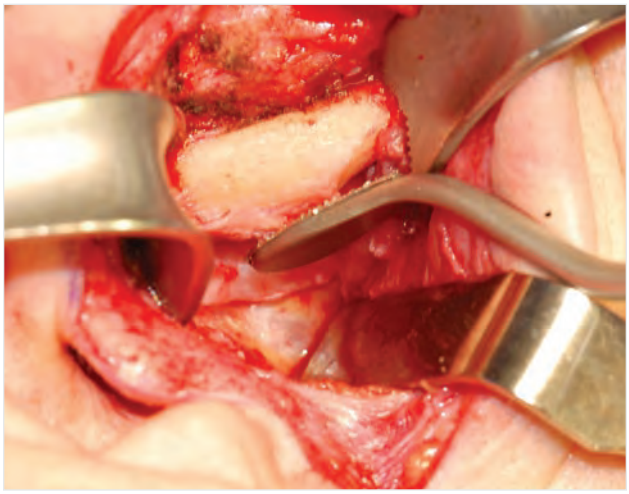
Specially designed bone holding forceps are used to maintain a secure purchase point on the inferior border of the mandible. The ramus is then pushed superiorly up into the space created by step one of the two-step osteotomy. This now allows better visualization of the lower portion of the condylar neck and superior ramus for performance of this second step osteotomy. Approximately 5 to 7mm of additional bone is now removed so the osteotomy cut is actually below the lowest point of the sigmoid notch. It is important to remove adequate bone to allow for the thickness of the polyethylene fossa implant. If adequate bone is not removed, then a superior portion of the condyle-ramus may impinge on the fossa prosthesis when the patient is placed in intermaxillary fixation. Again, the retractors are used to protect the medial tissues during the osteotomy.

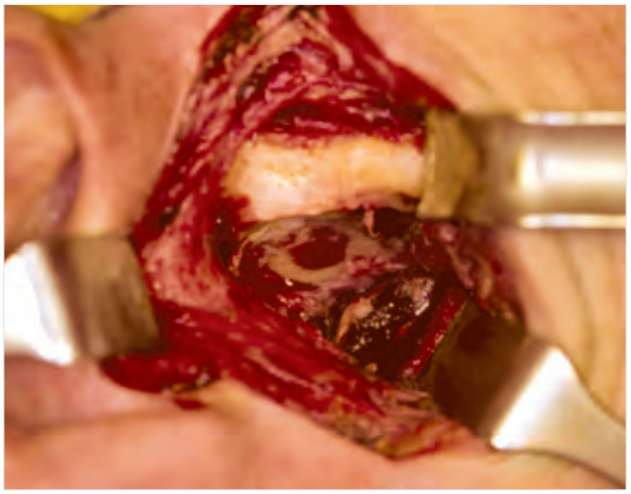


Step 13: Reciprocating Rasp Flattens Fossa Eminence

A coarse diamond reciprocating rasp has been designed to flatten the articular eminence to allow "tri-pod" stability of the fossa implant against the base of the skull. The same rasp can also be used to uniformly level the lateral ramus, especially in patients who have had a history of bruxism, where there may be a sharply defined ridge of cortical bone along the inferior border where the hypertrophic masseter muscle had attached.

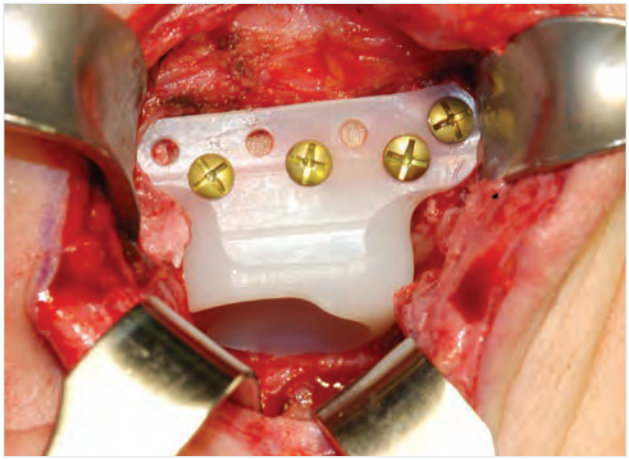






Step 14:
Sizing and Implantation of Fossa Component

With the use of the fossa templates, the appropriate size of the fossa implant is selected (small, medium, large). It is important to make sure that the fossa is approximately parallel to the Frankfurt horizontal line. "Tipping" the fossa anteriorly at an excessive angle could potentially lead to displacement of the condylar prosthesis during function. It is recommended to place the fossa prosthesis with two screws initially to make sure the mating between the fossa prosthesis and the condylar prosthesis is optimal before placing the recommended four screws.



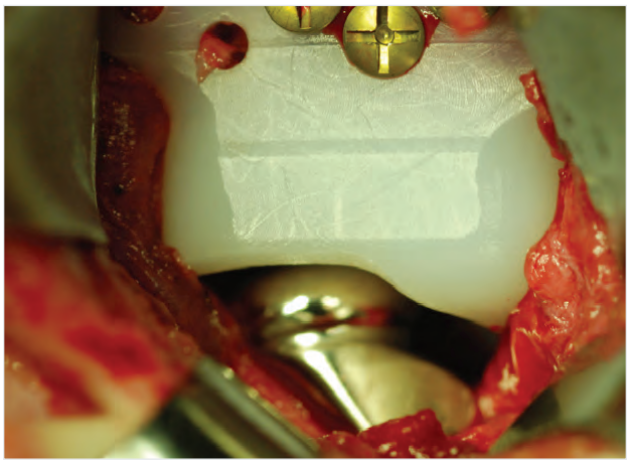
Step 15:
Inter-Maxillary Fixation

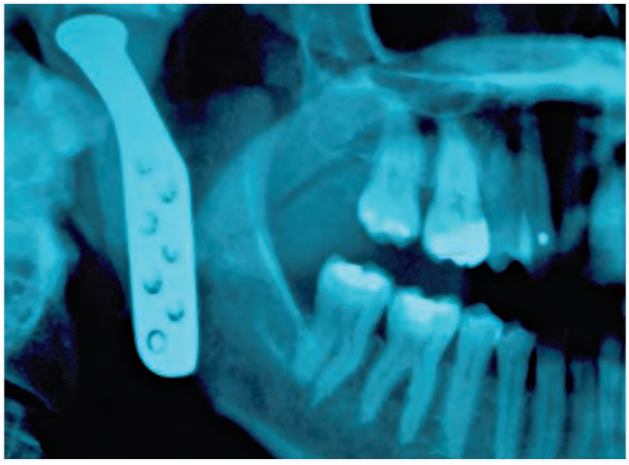
Prior to the extra-oral incisions, Erich arch bars or Ivy loops were placed to allow for intermaxillary fixation in the desired occlusion at this stage of the operation. Once the fossa prosthesis is placed, the wound should be covered with antibiotic-soaked sterile sponges, and the surgeon and assistant now enter the oral cavity to place the patient in rigid maxillary fixation. This is done with a separate set of instruments specifically for the intra-oral procedure. After the occlusion is secured, the surgical team should change their gowns and gloves to return to the extra-oral surgical dissections.

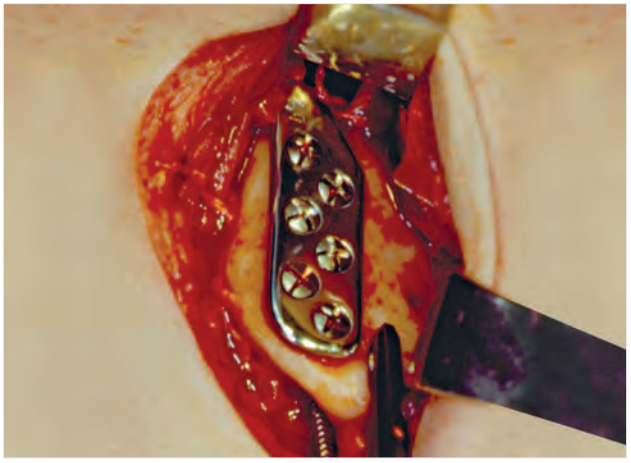
Step 16:
Fitting and Placement of the Mandibular Component

With the patient in intermaxillary fixation, a condylar prosthesis is now selected using the 45, 50 and 55mm templates. Either the narrow or standard design can be used depending on the adequacy of bone and defects from previous surgeries. As illustrated in Figure **16a**, it is extremely important to position the head of the condyle as far posteriorly as possible so that there can be some degree of "pseudo-translation" of the condylar head in the fossa as the patient opens to the expected range of 32 to 35mm. Positioning the condyle too far anteriorly in the closed position, as shown in the right portion of the illustration, could lead to dislocation of the condyle anterior of the fossa. Also note that the fossa is parallel to the Frankfurt horizontal plane and is not tipped anteriorly or superiorly.

Fig. 16a

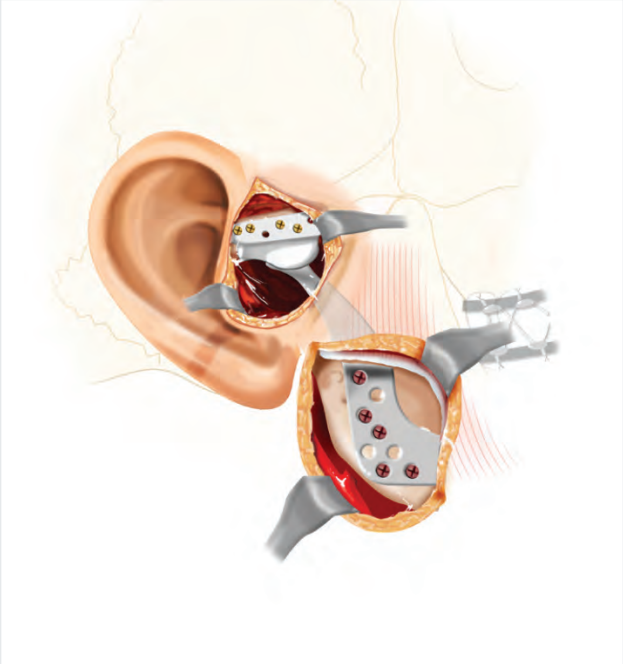






Step 17:
Final Screw Placement

The condylar prosthesis is placed with two 2.7mm screws and again the surgical incisions are covered, sterile drapes are placed over the wounds and the surgeon and the assistant now return to the oral cavity to remove the intermaxillary fixation wires to make sure that there is an acceptable range of motion of the prosthesis is without any evidence of anterior dislocation or mechanical obstruction. If the surgical team is satisfied with position of the implant at this time, they again change gowns and gloves and return to the surgical wounds for placement of the remainder of the ramal condylar implant screws (an average of 4-6 screws is recommended). The surgeon must note the position of the inferior alveolar nerve in order to place the screws either posterior or anterior to the neurovascular bundle. The standard design with the expanded "foot plate" was designed to allow some flexibility in screw placement. It is preferable to use the heavier bone along the inferior/ posterior ramus, if possible, for screw placement. The implant should not be bent and great care should be taken to avoid scratching or damaging the articular surface of the mandibular component.



Warnings and Precautions for use of the Total Mandibular Joint 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.

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