TMJ Fossa-Eminence and Condylar Prosthesis System

Instructions for Use

For total reconstruction (arthroplasty) of the temporomandibular joint

**Stock TMJ Fossa-Eminence Prosthesis System**

RIGHT SIDE (REF: FER-01 through FER-44)

LEFT SIDE (REF: FEL-01 through FEL-44)

**Patient-Specific TMJ Fossa-Eminence Prosthesis System**

(REF: CFER and CFEL)

**Stock TMJ Condylar Prosthesis System**

LEFT SIDE or RIGHT SIDE

(REF: R/L-MCP-45, R/L-MCP-50, R/L-MCP-55)

**Patient-Specific TMJ Condylar Prosthesis System**

(REF: CRMCP and CLMCP)

1. **DEVICE DESCRIPTION**

   **The TMJ Fossa-Eminence Prosthesis System**

   The TMJ Fossa-Eminence Prosthesis is designed to provide a thin, rigid, well-fitting prosthetic covering for the articulating surface of the temporal bone. The articular surface of the implant is highly polished to minimize friction in joint movement.

   The prosthesis and the fixation screws are manufactured from surgical cobalt-chromium-molybdenum alloy (ASTM F75 for prostheses and ASTM F1537 for screws). These devices are intended for permanent implant and are for single use only.

   All components in the TMJ Fossa-Eminence Prosthesis System, including individual prostheses, drills, burs and screws are sterilized by gamma-irradiation or e-beam irradiation (25-40 kGy), and are packaged in individual double-peek PETG and Tyvek containers.

   Additional **NON-STERILE** Stock TMJ Fossa-Eminence Trial Sizers and Instruments accompany the TMJ Fossa-Eminence Prosthesis System and are essential for its use. The Stock TMJ Fossa-Eminence Trial Sizers and Instruments tray contains trial sizers for each size of implant, TMJ Fossa-Eminence Prosthesis Holders, and screwdrivers.

   **The TMJ Condylar Prosthesis System**

   The TMJ Condylar Prosthesis, which is intended to be used with the TMJ Fossa-Eminence Prosthesis for total joint reconstruction, is designed to replace the articular surface of the mandibular condyle.

   The TMJ Condylar Prosthesis is designed to seat against the TMJ Fossa-Eminence Prosthesis and to be secured to the ramus of the mandible with cobalt-chrome alloy screws. The TMJ Condylar Prosthesis is manufactured in three lengths, and is designed to be used on either the RIGHT SIDE or LEFT SIDE. The entire TMJ Condylar Prosthesis and the fixation screws, are manufactured from surgical cobalt-chromium-molybdenum alloy (ASTM F75 for prostheses and ASTM F1537 for screws). These devices are intended for permanent implant and are for single use only.

   All components in the Condylar Prosthesis System, including individual prosthesis, drills, burs and screws are sterilized by gamma-irradiation or e-beam irradiation (25-40 kGy), and are packaged in individual double-peek PETG and Tyvek containers.

   Additional Stock TMJ Condylar Trial Sizers accompany this TMJ Condylar Prosthesis System and are essential for its use. The Stock TMJ Condylar Trial Sizers is comprised of sterile disposable trial sizer components for each size of implant, as well as a sizing template. The **NON-STERILE** instrument tray contains screwdrivers and holders. (The instruments may be packaged with the Stock TMJ Fossa-Eminence Trial Sizers and Instruments tray.)

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   **European Authorized Representative (“E.A.R.”)**

   **Caution:** United States Federal Law restricts this device to sale by or on the order of a physician or dentist.
2. INTENDED USE/INDICATIONS
The TMJ Fossa-Eminence and Condylar Prosthesis System is intended for use in treatment of severe temporomandibular joint disease. The TMJ Condylar Prosthesis is intended for use in conjunction with the TMJ Fossa-Eminence Prosthesis whenever total joint reconstruction is necessary due to:

- 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.

3. CONTRAINDICATIONS
The TMJ Fossa-Eminence and Condylar Prosthesis System should not be used for patients with one or more of the following conditions:

- Infection or malignancy in the head or neck region,
- Known allergy to any of the components of the system,
- Ability to exert significant post-operative masticatory muscle hyperfunction (clenching or grinding), which may lead to overload and fracture of the device or loosening of the screws.

4. WARNINGS

Read All Accompanying Labeling
Prior to use, the surgeon must read the entire Instructions for Use and device labeling.

General Warning
The TMJ Fossa-Eminence and Condylar Prosthesis System is intended for total joint reconstruction. The TMJ Condylar prosthesis must be implanted in conjunction with a TMJ Fossa-Eminence prosthesis manufactured by TMJ Medical.

Warnings Specific to Prostheses, Screws, Drills, Burs and TMJ Condylar Trial Sizers
All TMJ Fossa-Eminence and Condylar Prostheses, screws, drills, burs and TMJ Condylar Trial Sizers are provided STERILE. Inspect the sealed sterile package before opening. Do not use if package and/or seal is broken or damaged. Do not re-sterilize.

The surface of the devices must remain clean and free of debris prior to implantation. The implants must be handled only with talc-free gloves to avoid introduction of talc into the implantation site.

The prostheses must be protected from scratching or bending prior to and during surgical implantation, as such damage may cause weakening or fatigue of the metal or fracture of the device.

Warnings Specific to Reusable Instruments
Prior to use, the Stock TMJ Fossa-Eminence Trial Sizers and Instruments must be sterilized in their respective containers in accordance with hospital standards for steam sterilization (refer to Section 9). These containers include the Stock TMJ Fossa-Eminence Trial Sizers, TMJ Fossa-Eminence Prosthesis Holders, and screwdrivers.

Warnings Regarding Significant Forces
Patients undergoing local or general anesthesia, prolonged dental therapy, extraction of teeth, or those patients using mechanical devices which create abnormal forces within the joint need to be alerted to possible injury to the joint or prosthesis due to those unusual forces.

Dynamic fatigue tests were conducted on the TMJ Fossa-Eminence and Condylar Prosthesis System with a force applied vertically to the TMJ Fossa-Eminence Prosthesis. Fatigue run-out strength to 10 million cycles was found to be 130lbf. Physicians and dentists should carefully consider the results of these fatigue tests when patients present with particular anatomical considerations or unusual masticatory forces.

Warnings Regarding Suspected Hypersensitivity or Metal Allergy
Patients with suspected sensitivity to metals, such as nickel, should undergo appropriate testing for sensitivity to cobalt-chromium-molybdenum alloy. Upon request, TMJ Medical will supply a sample of this alloy and/or the chemical composition for pre-operative allergy testing. The device should not be used in patients who test positive for cobalt-chromium-molybdenum alloy sensitivity.

Warnings When Longer Screws Are Necessary
Occasionally, longer screws will be necessary to engage bone. It is important that the surgeon exercise great care to prevent injury to deeper vital structures. Care must be exercised not to penetrate or impinge on any adjacent structures such as auditory structure, middle cranial fossa, facial nerve, middle meningeal artery, or any neuro/vascular structures.
Warnings When Excising Bone

When performing an excision of bone in the area of the normal glenoid fossa and condyle, especially in cases of bony ankylosis, the surgeon must exercise great care to avoid penetration into the middle cranial fossa, the auditory canal, or other vital structures.

Warnings Regarding Reuse

The TMJ Fossa-Eminence and Condylar Prosthesis Systems are labeled for single-use only, meaning the prostheses and screws are intended to be used once for a single patient. The reuse of this device could pose a risk to the patient including but not limited to prosthesis loosening, foreign body reaction, allergic reaction, infection, device fracture, changes to the contralateral joint, improper fit/placement, and/or joint dislocation.

5. PRECAUTIONS

General Precautions

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.

There are instances when this technique is not recommended due to prior surgical procedures and the need to place prostheses in less than optimal angles and positions, or in cases where systemic medical disease would contraindicate this implant procedure in the view of the operating surgeon. The operating surgeon must make this evaluation. It is the surgeon’s responsibility to determine the need for patient-specific implants given anatomical considerations or unusual masticatory forces in a given patient.

Precautions Specific to Prostheses, Screws, and Drills

The TMJ Prosthesis Systems must be secured only through the use of the drills and screws supplied by TMJ Medical. The screws and drills provided with the TMJ Prosthesis Systems have been specifically selected by size to ensure correct fixation when used as directed. Any use of substitute drill bits or screws not supplied by TMJ Medical may result in less than optimal long-term results and may adversely affect the performance of the prothetic device.

It is strongly recommended that at least four (4) screws be used where practical to achieve firm fixation of the TMJ Fossa-Eminence Prosthesis. NOTE: Use only the supplied 2.0mm or 2.3mm screws to ensure correct fixation, and to ensure compatibility of the metals.

It is strongly recommended that at least six (6) screws for the TMJ Condylar Prosthesis be used, where practical, to achieve firm fixation of the TMJ Condylar Prosthesis. Care must be taken to secure at least 3 screws in the topmost holes, where practical. NOTE: Use only the supplied 2.7mm or 3.0mm screws to ensure correct fixation, and to ensure compatibility of the metals.

Caution should be used so as not to force the screw in place with too much pressure as the screw head could fracture.

Precautions Specific to Prosthesis Fit

It is recommended that the head of the TMJ Condylar Prosthesis be placed into the prosthetic glenoid fossa portion of the TMJ Fossa-Eminence Prosthesis with all interposing soft tissue removed. The TMJ Condylar Prosthesis articulating surface should preferably be centered in the fossa and should not contact the screws of the TMJ Fossa-Eminence Prosthesis.

6. ADVERSE REACTIONS

Potential adverse events and complications associated with temporomandibular joint surgery and reconstruction may require further treatment and include but are not limited to the following. These adverse events are categorized in descending order by frequency and severity observed in the prospective clinical study. A statistical comparison of the rates of events was made for those that occurred for at least 10% of the subjects in either the partial joint or total joint (refer to 1-084) reconstruction groups.

While the findings of the study indicate that proper use of this device reduces patient pain and improves patient quality-of-life, the number of patients lost to follow-up prior to study completion was sufficient to limit the study’s ability to offer conclusive scientific information about the device’s long-term performance.

Moderate Adverse Event (meaning discomfort sufficient to cause interference with usual activity or to affect clinical status)

- Pain (30.8%)
- Neurological deficit/dysfunction (11.5%)
- Swelling (11.5%)

Mild Adverse Event (meaning awareness of a sign or symptom but easily tolerated)

- Pain (57.7%)
- Edema (43.6%)
- Soreness (26.9%)
- Neurological deficit/dysfunction (29.5%)
- Muscle spasm (21.8%)
- Decrease/Loss of Range of Motion (20.5%)
- Myalgia (20.5%)
- Headache (18.0%)
- Weakness (17.9%)
- Muscle rigidity (17.9%)
- Numbness (12.8%)
• Nausea (11.5%)
• Infection (11.5%)
• Swelling (10.3%)
• Surgical procedure (10.3%)
• Joint disorder (3.8%)

Other adverse events could occur following placement of this prosthesis system. The incidence of the adverse events may be related to the patient’s previous surgical history, prior medical conditions, or their on-going temporomandibular joint disease.

• Implant loosening due to poor bone quality and/or ankylosis.
• Foreign body reaction due to metal sensitivity
• Allergic reaction to implant materials
• Infection due to the patients challenged immune system
• Device fracture due to unauthorized implant modification, trauma, and/or excessive load (i.e. extreme clenching)
• Chronic pain due to disease progression
• Subsequent fibrosis due to multiple joint surgeries and/or disorders on the TM joint.
• Subsequent adhesions or ankylosis due to multiple joint surgeries and/or disorders on the TM joint.

7. CLINICAL DATA
A prospective clinical study was performed with these prostheses. The primary objective of this study was to demonstrate that the TMJ Fossa-Eminence Prosthesis used with a TMJ Condylar Prosthesis significantly reduced TMJ pain. The primary hypothesis being that at 36 months post implant of a TMJ Fossa-Eminence used alone, or with a TMJ Condylar Prosthesis, subjects on average will have experienced a consistent and persistent reduction in perceived pain of 4.5 cm on a 10 cm scale.

An additional objective was to demonstrate that the TMJ Fossa-Eminence Prosthesis used with a TMJ Condylar Prosthesis demonstrates improvement in interincisal opening. The secondary hypothesis being that those subjects who entered the study because of interincisal opening (≤ 15 mm) will be judged a success if they had a 5 mm or greater increase in their opening at 18 months.

Reduction in Pain
Forty-two (42) out of 78 (53.8%) subjects have pain data through 36 months. Additionally, there were 5 subjects that recorded post 36 month pain data (recorded as 36+). The figure below presents the number of subjects that have pain data collected at each timed visit. The results show a 4.9 cm reduction in pain at 36 months.

Pain Reduction vs. Time

Whose Base-Line Opening was ≤15 mm

Improvement in Opening vs. Time
Whose Base-Line Opening was ≤15 mm

Interincisal Opening Data for Subjects whose Base-Line Interincisal Opening was < 15 mm
Eighteen total joint replacement subjects were admitted with an interincisal opening of ≤ 15 mm. The subjects showed an interincisal opening improvement of 16.8 mm within 18 months which exceeded the targeted 5 mm. Additionally, the subjects showed an 18.0 mm improvement at 36 months.

Notes: The time period “0” stands for a preoperative visit. All other time periods are months following implantation. To further explain the wide confidence interval at 36+ months, this is due to only 5 data points which were 0.0, 0.5, 2.4, 6.3 and 8.5.

Instructions for Use
Notes: The time period “0” represents a preoperative visit. All other time periods are months following implantation. There was no opening data collected at time period 30 months. The subjects were contacted via phone and interincisal opening was not measured.

8. INFORMATION FOR USE

General Instructions for Use

A detailed Surgical Manual and a CT Scanning Protocol is available upon request.

Perfect the Technique for Implantation

It is strongly recommended that the surgeon perfect the technique for implantation of the TMJ Fossa-Eminence and Condylar Prosthesis System. It is the responsibility of the surgeon to become familiar with the surgical techniques for implantation of these devices through attendance at surgical demonstration courses, use of instructional materials, consultation with experienced associates and manipulation of replica models.

TMJ Medical can provide names of individuals, independent from the company, with extensive experience for consultation prior to surgery. Additionally, instructional materials are available from TMJ Medical.

Placing the TMJ Fossa-Eminence Prosthesis

The normal preauricular or endaural incision and approach to the joint are accomplished. Exposure of the entire zygomatic process of temporal bone lateral to the joint is necessary to facilitate placement of the TMJ Fossa-Eminence Prosthesis.

When the joint is fully exposed try the TMJ Fossa-Eminence Trial Sizer for fit. Find the sizer that fits the bone most accurately with at least 3-point contact and allows the condyle to function smoothly, without dislocation of the joint and provides suitable stability. At this stage, check the occlusion very carefully. Ensure the occlusion remains as seen pre-operatively or as desired post-operatively. If not, determine why.

After selecting the proper sizer, check the number and record it for future reference. Select the same numbered prosthesis, which has been packaged sterile. Try it for accuracy of fit, proper occlusion, and mobility of the condyle.

It is strongly recommended that at least four (4) screws be used where practical to achieve firm prosthesis fixation. NOTE: Use only the supplied 2.0mm or 2.3mm screws to ensure correct fixation, and to ensure compatibility of the metals. Caution should be used so as not to force the screw in place with too much pressure as the screw head could fracture. Using the provided drills, drill hole slightly deeper than the length of the screw. When the implant has been secured in place, check again for proper jaw function and proper occlusion.

Placing the TMJ Condylar Prosthesis

Once the wound has been opened to expose the remaining natural condyle and the occlusion has been fixated, then remove enough condyle height to allow a Stock TMJ Condylar Trial Sizer with its 13mm head to be placed in position. The condylar trial sizer will allow you to determine which length of the Stock TMJ Condylar Prosthesis will most accurately fit the patient’s mandible.

When the correct condylar length has been determined by use of the condylar trial sizer, you are now ready to place the actual TMJ Condylar Prosthesis.

It is recommended that the head of the TMJ Condylar Prosthesis be placed into the prosthetic glenoid fossa portion of the TMJ Fossa-Eminence Prosthesis with all interposing soft tissue removed. The TMJ Condylar Prosthesis articulating surface should preferably be centered in the fossa and should not contact the screws of the TMJ Fossa-Eminence Prosthesis.

The proper placement of the condylar head into the TMJ Fossa-Eminence Prosthesis, assures that the head does not contact any screw heads during function. It is important to fix the TMJ Condylar Prosthesis to the ramus of the mandible with as many screws as possible. It is strongly recommended that at least six (6) screws be used, where practical, to achieve firm fixation of the TMJ Condylar Prosthesis. Care must be taken to secure at least 3 screws in the topmost holes, where practical. NOTE: Use only the supplied 2.7mm or 3.0mm screws to ensure correct fixation, and to ensure compatibility of the metals.

The flange direction of the TMJ Condylar Prosthesis is generally ideal when it parallels the posterior margin of the mandibular ramus.

If both sides of the mandible area are to be reconstructed, the contralateral side is operated in a similar fashion.

The mandible should now be mobilized and forced open, observing the maximum range of opening. Should mobility be limited, the surgeon should assess the possible need for coronoidectomies and/or relief of adhesions to the ramus. Observe the movement of the condylar head(s) to be sure that dislocation does not occur.

Additional Considerations

The placement of a fat graft around the implants at surgery may reduce the occurrence of subsequent adhesion or even ankylosis. For those patients susceptible to heterotopic bone formation, appropriate fat grafts and radiation therapy should be considered.
Post Surgery

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

After the joint reconstruction is completed, all instruments must be thoroughly cleaned, decontaminated, and sterilized in accordance with section 9.

9. CLEANING AND STERILIZATION

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Sterile Components Provided

Store within the range of 10 °C and to 32 °C (50 °F to 90 °F) and 20% to 80% relative humidity. The TMJ Condylar Prostheses, TMJ Condylar Trial Sizers, screws, drills and burs, and the TMJ Fossa-Eminence Prostheses, screws, drills and burs are all packaged sterile in double Tyvek/film or paper/film peel pouches utilizing gamma-irradiation or electron beam (e-beam) irradiation sterilization at levels of 25-40 kGy with a sterility assurance level (SAL) of 10^-6. Care must be taken to assure packaging remains undamaged to ensure sterility.

Cleaning Instructions for Reusable Components

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

Clean instruments before sterilization in the autoclave trays provided by TMJ Medical 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 wash the sizer templates and instrumentation with mild enzymatic detergent following the manufacturer’s instructions for use. Follow the detergent manufacturer’s recommendations for use dilution. Use enzymatic detergents (e.g. Enzol™) and warm/hot water prepared as recommended by the manufacturer. PH neutral detergents 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 > 12) are not recommended. Avoid exposure to acidic or alkaline solutions and solutions containing chlorides, bromides, or iodines.

Allow the devices to soak in a mild enzymatic detergent for a minimum of one minute. Use a soft bristle brush to manually clean the devices while immersed in the cleaning detergent, paying particular attention to crevices and other hard-to-clean areas. Clean the devices until all adherent visible soil is removed.

After washing, thoroughly rinse instruments for one minute under lukewarm clean, deionized or distilled water.

Inspect for cleanliness, especially in crevices or recesses. Check instruments thoroughly for damage, (i.e. chips, cracks, corrosion, surface wear, etc.) especially those 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.

Dry completely with a clean, soft cloth before sterilization.

Sterilization Instructions for Reusable Components

Reusable instruments, (e.g., the Stock Fossa-Eminence Trial Sizers, and the screwdrivers and holders), for both prostheses must be sterilized prior to surgical use and after cleaning post-surgically in their respective containers provided by TMJ Medical.

The following sterilization cycle has been shown to sterilize product to a sterility assurance level (SAL) of 10^-6. Other similar cycles may be used but have not been evaluated. It is the responsibility of the customer to demonstrate the appropriateness of the sterilization cycle used should it vary from the following:

- **Sterilizer Type:** Prevacuum Steam
- **Sterilization**
  - Preconditioning Pulses: 3
  - Minimum Temperature: 132 °C
  - Full Cycle Time: 4 minutes
  - Minimum Dry Time: 20 minutes
  - Maximum Load: 5 trays
  - Configuration: Minimum Load
  - Configuration: Sample Configuration
  - Wrapped

10. LIMITED WARRANTY

TMJ Medical 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.

Should you have any questions, please feel free to call us at 800.825.4865 or 303.277.1338.