



TMJ CONCEPTS

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Overview of All-Ti Compassionate Use (CU) Program

Phase 1 – Items Needed to Obtain FDA Pre-Approval

Please provide the following documents that we will use to submit a Compassionate Use request to the FDA. FDA approval is expected within 4 to 6 weeks; however, this can vary and may affect implant lead times.

- TMJ Implant Order Form: Provide a TMJ Implant Order Form to get a case number assigned to your patient. Indicate “All-Ti Mandibular Component” in the lower right hand “NOTES” block.
- Letter from Primary TMJ Surgeon: The letter must include certain types of information from the requesting surgeon which are needed, at a minimum, to justify the FDA granting approval for compassionate use of the device. The surgeon’s evaluation of the patient should address each of the following questions:
 1. When did the patient present to the referring doctor and for what reason?
 2. What is the TMJ treatment history of the patient, history which has led the patient to now require a CU TMJ total replacement device?
 3. What current Quality of Life challenges is the patient facing which will be improved by the requested CU device?
 4. What information is revealed during your examination?
 5. Why does the patient require a patient-matched TMJ device, instead of a stock device?
 6. * Why does the patient require an all-titanium device?
 7. This information is expected to be typed on the professional letterhead of the requesting surgeon and signed by the requesting surgeon.
- “Second Opinion” Letter from Independent Physician: An independent assessment from an uninvolved physician (one that is not involved with the patient’s treatment or planned surgery and is not associated with the manufacturer) that supports the treatment plan requiring the compassionate use device. * Please refer to (6). The independent assessment can be executed by a colleague **who is not in the same office as the primary surgeon** and not by a subordinate e.g., fellow or resident.

Phase 2 – Items Needed to Ship Implants

After FDA pre-approval is obtained, it will be provided to you along with a Detailed Description of the All-Ti implants and an All-Titanium Informed Consent Form.

The following documents will be required prior to the shipment of implants:

- IRB Approval: Obtain IRB approval from your hospital per their requirements using the above provided documents. This information is expected to be typed on the IRB letterhead and signed by the IRB representative.
- Hospital Clearance: Obtain clearance from the institution, if required, in accordance with their policies. Many hospitals do not require “institutional clearance” above and beyond the IRB approval. If additional clearance is not required, a one-time letter from the physician or the hospital administration clarifying this fact is required. This information is expected to be typed and signed by the Hospital General Manager, Chief of Surgery and/or OR Risk Management/OR Executive Committee representative.
- All-Titanium Informed Consent Signed by Patient

Phase 3 – Post Surgery Report

TMJ Concepts shall submit a report to the FDA that includes the following:

- Follow-up Report: We will need a report/letter from you within one month of surgery that includes: (1) the date of surgery. (2) A description of how the device performed after surgery, including any problems with the use of the device. (3) A description of how the patient is faring, in terms of resolution of original problems (opening, pain, etc.) based on follow-up appointments within the one-month period. (4) A plan for long-term follow up of the patient by the surgeon who placed the implant and/or the patient’s referring dentist including further treatment and physical therapy, as appropriate.

This information is expected to be typed on the professional letterhead of the requesting surgeon and signed by the surgeon.