

**CONSENT FOR TEMPOROMANDIBULAR JOINT RECONSTRUCTION WITH A
CUSTOM-FITTED TOTAL TMJ RECONSTRUCTION PROSTHESIS**

Page 1 of 4

Patient's Name

Date

Please initial each paragraph after reading. If you have any questions, please ask your doctor BEFORE initialing.

You have the right to be informed about your dental/medical condition and the recommended treatment so that you can make an informed decision whether to undergo the procedure. This disclosure is not meant to alarm you, but is rather an effort to properly inform you so that you may give or withhold your consent. By signing this consent, you are acknowledging that you are aware of the nature of the problem; the indications for the treatment proposed; the benefits, risks and likely complications; the possible alternatives to treatment for your particular circumstances, and that you have had an opportunity to have all of your questions about the treatment answered. Your signature indicates you are informed to your satisfaction.

____ 1. I authorize Dr. _____ and other associates and assistants directed by him/her to treat my condition diagnosed as _____

____ 2. The procedure planned to treat the condition noted above has been explained to me and I understand it to be: Total replacement of my (left) (right) jaw joint(s) using the _____ total temporomandibular joint (TMJ) reconstruction prosthesis (artificial joint).

TMJ reconstruction prostheses are artificial jaw joints usually made of a combination of titanium, chrome-cobalt molybdenum metal alloy or stainless steel metal, and polyethylene plastic or other synthetic materials compatible with human tissue. The fossa (socket) is attached to the zygomatic arch (cheek bone) with metal screws; the condyle (ball), which moves against the fossa (socket) during jaw function, is screwed into the ramus of the mandible (lower jaw bone).

____ 3. I have been informed of possible alternative forms of treatment (if any), including: _____

____ 4. Dr. _____ has explained that the chronic, badly-deteriorated condition of my TMJ(s) has made it necessary to perform this complex surgical procedure and, because of the seriousness of my condition, the TMJ reconstruction procedure cannot be considered an absolute solution for my TMJ problems. Although total joint reconstruction usually leads to improved function, I understand that this procedure may not allow me to regain full or even measurably improved function of my jaws, and that it may not reduce all of my pain or discomfort. This may be especially true because it may not be entirely possible to eliminate or adequately reduce underlying causes of my TMJ problems, such as clenching and grinding of my teeth, muscle spasms, and my individual reactions to external stress. I am aware that the results also depend on how well I follow postoperative rehabilitation and exercise programs, recommended changes in diet, etc.

**CONSENT FOR TEMPOROMANDIBULAR JOINT RECONSTRUCTION WITH A
CUSTOM-FITTED TOTAL TMJ RECONSTRUCTION PROSTHESIS**

Page 2 of 4

- _____ 5. Dr. _____ has explained to me that the potential for success of my joint surgery depends upon many factors, including my overall physical condition at the time of treatment, the condition and degree of disease/damage to my TMJ(s) at the time of implantation of the reconstruction prosthesis, my body's acceptance of the implant(s), and possible tissue reactions sometimes referred to as "foreign body reactions" around the implant and within associated regional lymph nodes. Other significant factors are: the degree to which underlying causes of my disease respond to pre- and post-operative management.
- _____ 6. It has been explained to me that there are certain potential risks and side effects of the proposed surgery, some of which may be serious. They include, but are not limited to:
- _____ A. Facial and jaw swelling after surgery, usually lasting several days.
 - _____ B. Temporary or permanent facial muscle weakness resulting from motor nerve stretching, bruising or injury during surgery. A common resulting problem is inability to wrinkle the brow, raise the eyebrow, or gain tight eyelid closure on the operated side.
 - _____ C. Allergic reaction to any medications given during the course of treatment.
 - _____ D. Numbness (temporary or permanent) of certain areas of the skin in the region of the jaw joint and sometimes in more remote areas of the face or scalp.
 - _____ E. Scarring of the incision lines that, if objectionable, may require later revision.
 - _____ F. Bruising and discoloration of the skin around eyes, ears and jaw.
 - _____ G. Ear problems, including inflammation of the ear canal, middle and inner ear infection, perforation of the eardrum and temporary or permanent hearing loss, ringing in the ears and/or equilibrium problems.
 - _____ H. Malocclusion: change in bite, possibly requiring further treatment.
 - _____ I. Development of adhesions (scarring) or ankylosis (bone fusion) within the joint space that may cause continued jaw dysfunction and decreased range of jaw movement, difficulty chewing and pain that may require additional treatment.
 - _____ J. Worsening of present TMJ symptoms that may require additional treatment.
 - _____ K. Post-operative infection, including osteomyelitis (bone infection) that may require additional treatment.
 - _____ L. Further degenerative joint changes, including in the un-operated joint.
 - _____ M. Rejection of the implant, allergic reaction, foreign-body reaction, wear, displacement, breakage or loosening of implant parts.
 - _____ N. Formation of hypertrophic bone (reactive bone) resulting in joint pain and/or immobility requiring additional treatment.
 - _____ O. Post-operative or future treatment including, but not limited to: physical therapy, bite splint therapy, restorative or reconstructive dentistry, orthodontics, orthognathic (jaw repositioning) surgery, and further reconstructive joint surgery, including removal of the implant.
 - _____ P. Other: _____

**CONSENT FOR TEMPOROMANDIBULAR JOINT RECONSTRUCTION WITH A
CUSTOM-FITTED TOTAL TMJ RECONSTRUCTION PROSTHESIS**

Page 3 of 4

- ____ 7. Dr. _____ has informed me that patients who have already undergone prior TMJ surgery may have a higher risk of complications with less-than-ideal results.
- ____ 8. I understand all my treatment options, including the risks and benefits of each. I wish to proceed with the recommended treatment. I am aware that my current condition is serious and that there can be no promise or warranty of cure, and that my condition may return or worsen after this procedure.
- ____ 9. It has been explained in laymen's terms where and how the required surgical incisions will be made, and what steps are involved in reconstructing my TMJ(s) with this total temporomandibular joint reconstruction prosthesis. All questions have been answered to my satisfaction.
- ____ 10. I understand that Dr. _____ may discover different conditions during surgery that were not evident during clinical, x-ray or other diagnostic studies performed before surgery. These conditions may require additional or different procedures that were not anticipated prior to surgery, including modification of the implant. I authorize Dr. _____ to perform such additional procedures that are necessary and advisable in the exercise of his/her professional judgment.
- ____ 11. General anesthesia will be used for this surgery and I have been told of the risks, including bronchitis, pneumonia, hoarseness or voice changes, irregularities of heart beat, heart attack, stroke and death. I am aware of the importance of not having anything by mouth (including clear liquids **unless authorized by surgeon or anesthesiologist**) for **SIX (6) hours** prior to my anesthetic and that do **TO DO OTHERWISE MAY CAUSE LIFE-THREATENING COMPLICATIONS.**
- ____ 12. I realize the importance of providing true and accurate information about my health, especially concerning possible pregnancy, use of birth control pills, allergies, medications (including homeopathic and herbal remedies), and history of drug and/or alcohol abuse. If I misinform my doctor, I understand the consequences may be life-threatening or otherwise adversely effect the result of surgery. I have given a truthful medical and dental history, including all information that may affect this treatment.
- ____ 13. I agree to comply fully with recommendations by my doctor, realizing that lack of cooperation may result in a less-than-optimal result.
- ____ 14. I agree to use only those medications approved by my doctor and not to participate in contact sports, water sports or strenuous activity for six weeks following surgery.
- ____ 15. As with any joint replacement, it is not possible to guarantee how long a total joint implant will last in any particular patient. I realize I should not consider my TMJ implant(s) to be a lifetime replacement, and that the implant(s) may require removal and/or replacement at any time, or that additional joint reconstructive therapy may be required in the future.

**CONSENT FOR TEMPOROMANDIBULAR JOINT RECONSTRUCTION WITH A
CUSTOM-FITTED TOTAL TMJ RECONSTRUCTION PROSTHESIS**

Page 4 of 4

_____16. I understand that my doctor is not the seller of the implant device itself and makes no warranty or guarantee regarding success or failure of the implant or its attachments due to manufacturing defects.

CONSENT

I certify that I speak, read and write English and that all blanks were filled in prior to my initialing and signing this form. I have been given the opportunity to obtain a second opinion from a qualified professional regarding this proposed procedure.

By signing this form, I acknowledge that I have read it completely and understand the procedure to be performed, the risks, and the alternatives to surgery. I have had all of my questions answered to my satisfaction, was under no pressure to sign this form, and have made a voluntary choice to proceed with treatment.

Patient's (or Legal Guardian's) Signature

Date

Doctor's Signature

Date

Witness' Signature

Date