

CONSENT FOR TEMPOROMANDIBULAR JOINT RECONSTRUCTION WITH THE *TMJ CONCEPTS* PATIENT-FITTED TMJ RECONSTRUCTION PROSTHESIS

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You have the right to be informed about your condition and the recommended treatment so that you can make an informed decision whether or not to undergo the procedure, after knowing the risks and potential complications involved. 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.

We will make every effort to assure that you are fully informed and will strive to answer any and all questions you may have. **Remember, no question is unimportant!** It is your responsibility to ensure that you fully understand and are comfortable with the benefits, risks, and potential complications associated with the proposed surgery.

By signing this consent, you are acknowledging that we have been successful in making you aware of the nature of the problem, the necessity for the treatment proposed, the benefits, risks and likely complications, as well as the possible alternatives to that treatment for your particular circumstances, including the opportunity to have all of your questions about the treatment answered. Your signature indicates you are informed to your satisfaction.

Do not sign or initial until you are satisfied that you fully understand what you are signing and until all of your questions are answered to your satisfaction.

Patient Name: _____ Date: ____/____/____

- ____ 1. I authorize Dr. _____ and his staff to treat the condition diagnosed as:

- ____ 2. The procedure planned to treat the condition noted above has been explained to me and I understand it to be: _____

- ____ 3. I understand that the *TMJ Concepts* Temporomandibular Joint (TMJ) Reconstruction Prosthesis is fabricated with the aid of CT scan generated model of the patient's actual anatomy. The fossa (cup) is made of ultra-high-molecular-weight polyethylene (plastic) attached to a commercially pure titanium metal backing which is secured to the zygomatic arch (cheek bone) with titanium alloy screws. The condyle (ball), which moves against the fossa (cup) during jaw function, is made of cobalt-chromium-molybdenum metal alloy attached to a titanium alloy plate which is secured to the ramus of the mandible (lower jaw bone) with titanium alloy screws.
- ____ 4. I have been informed to my satisfaction of possible alternative forms of treatment (if any), including:

- ____ 5. 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 to my TMJ problems. Although the *TMJ Concepts* device has undergone preliminary *in vivo* tests and improved results are anticipated, I have been informed that this procedure may not allow me to regain full or even better function of my jaws and that it may not reduce my pain and 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 reaction to stress. I am aware that the results also depend upon how well I follow the post-operative rehabilitation and exercise program, recommended change in diet, etc.

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- ____ 6. 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 any 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 in the associated lymph nodes. Other significant factors are: the degree to which underlying causes of my disease may respond to pre-operative treatment or continue after surgery (i.e., clenching and grinding of teeth, jaw muscle spasm), how well I follow post-operative rehabilitation and exercise programs and otherwise cooperate with my surgeon's instructions, and whether or not I deal effectively with other contributing factors such as stress, diet, etc.
- ____ 7. Dr. _____ has informed me that patients who have already undergone prior TMJ surgeries have a higher risk of complications and less than ideal results.
- ____ 8. I understand all of my treatment options, including the risks and benefits of each. I wish to proceed with the treatment recommended in item #2. I am aware that my current condition is serious, that there can be no promise or warrantee of cure, and that my condition may return or worsen after this procedure.
- ____ 9. It has been explained to me in layman's terms where and how the required surgical incisions will be made and what steps are involved in reconstructing my TMJ with the *TMJ Concepts* Patient-Fitted TMJ Reconstruction Prosthesis. All questions have been answered to my satisfaction.
- ____ 10. I understand that Dr. _____ may find other or different conditions during the surgery which were not evident during clinical or radiographic examination or other diagnostic studies performed before surgery. These discovered conditions may require additional or different procedures that were not anticipated prior to surgery. Therefore, I consent to and authorize Dr. _____ to perform those procedures which are necessary and advisable in his/her professional judgement.
- ____ 11. It has been explained to me that there are certain potential risks and side effects of this 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 injury during surgery. The most common problem resulting is an inability to wrinkle the brow, raise the eyebrow, or gain tight closure of the eyelids.
 - ____ C. Allergic reaction to any of the medications given during or after the surgery.
 - ____ D. Numbness (temporary or permanent) of certain areas of the skin in the region of the joint and sometimes in more remote areas of the face and scalp.
 - ____ E. Objectionable scarring of the incision line, possibly requiring later revision.
 - ____ F. Bruising and discoloration of the skin around the eyes, jaw, and ear.
 - ____ G. Ear problems, including inflammation of the canal, middle or inner ear infections, perforation of the ear drum, temporary or permanent hearing loss, ringing in the ears, or equilibrium problems.
 - ____ H. Malocclusion (change in bite) after surgery requiring treatment.
 - ____ I. Post-operative development of adhesions or ankylosis within the joint space which may cause continued jaw dysfunction, decreased range of jaw movement, difficulty chewing, and pain requiring further treatment.
 - ____ J. Worsening of present TMJ symptoms which may require further treatment.
 - ____ K. Post-operative infection requiring additional treatment.
 - ____ L. Further degenerative joint changes and development of adhesions (scar tissue), joint arthritis (opposite joint in unilateral cases), or osteomyelitis of the jaw (bone infection).
 - ____ M. Foreign body reaction or allergic reaction and rejection of the implant, wear, displacement, breakage, or loosening of the implant parts.
 - ____ N. The formation of heterotopic bone (reactive bone) resulting in joint pain and/or mobility limitations requiring further surgical intervention.

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____ O. Post-operative and/or future treatments are not limited to, but may include: physical therapy, bite splint therapy, restorative or reconstructive dentistry, orthodontia, orthognathic surgery (jaw repositioning surgery), further reconstructive TMJ surgery.

____ P. Other: _____

- ____ 12. 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, or death. I am aware of the importance of not having anything by mouth (including clear liquids unless specifically authorized by the surgeon or anesthesiologist) after midnight on the day before surgery.
- ____ 13. I realize the importance of providing true and accurate information about my health, especially concerning possible pregnancy, allergies, medications, and history of drug and/or alcohol abuse. If I misinform my doctor, I understand the consequences may be life threatening or otherwise adversely affect the result of the surgery. I have given a truthful medical and dental history, including all problems, drug and/or alcohol use, and any other information that may affect this surgery.
- ____ 14. I agree to fully comply with the recommendations of my surgeon, realizing that lack of cooperation may result in less than an optimal result.
- ____ 15. I agree to use only those medications approved by my surgeon and not to participate in contact sports, water sports, and strenuous physical activity for six weeks following surgery.
- ____ 16. As with any joint reconstruction, it is not possible to guarantee how long the implant will last in any particular patient. I realize that I should not consider any TMJ implant to be a lifetime replacement and that it may require removal and/or replacement at any time or another form of TMJ reconstructive therapy may have to be performed.
- ____ 17. I certify that I speak, read and write English, that I fully understand this consent form for surgery, and that all the 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.

CONSENT

By signing this consent 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. I was under no pressure to sign this form and have made a voluntary choice to proceed with surgery.

Patient's, Parent's, or Guardian's Signature

Date

Surgeon's Signature

Date

Witness' Signature

Date

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AGREEMENT FOR SHARED RESPONSIBILITY FOR
CONTINUED CARE AND FOLLOW-UP

I acknowledge that my doctor has advised me of the necessity for return visits for the purpose of monitoring my progress with this implant system and that *TMJ Concepts* is required to report this information to the FDA at prescribed intervals. I understand that if I do not return for proper continuing care, my condition may progress to require more advanced treatment or further surgery or in rare cases may be life threatening.

I agree to comply with regularly scheduled examination appointments, understanding that I may choose a convenient appointment but not postpone care beyond a reasonable time.

I also understand that if I feel there are adverse changes in my symptoms or condition between scheduled visits, I should notify my doctor's office immediately

Patient's, Parent's, or Guardian's Signature

Date

Surgeon's Signature

Date

ACKNOWLEDGEMENT OF DEVICE TRACKING RESPONSIBILITY

I understand that *TMJ Concepts* is required by the FDA to keep track of me as long as I have these devices implanted so that I may be contacted if needed. I acknowledge and accept my responsibility to notify *TMJ Concepts* of any change in my name, address, or telephone number. I also agree to notify *TMJ Concepts* if and when I have these devices removed for any reason.

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Patient's, Parent's, or Guardian's Signature

Date