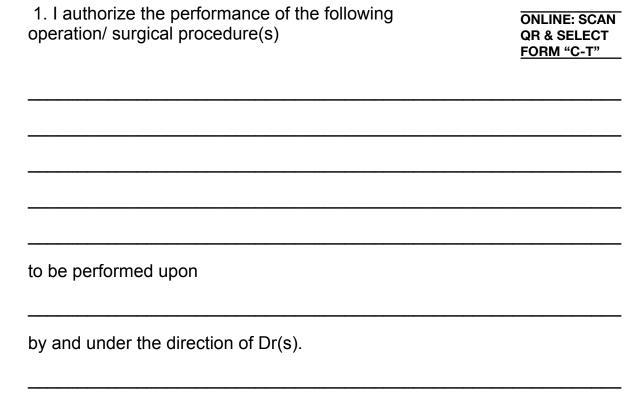


Form "C-T" Consent for Osia Implant

(309) 663-4368

CONSENT FOR SURGERY / OPERATION / PROCEDURE(S)



2. My physician(s) has fully explained to me the condition requiring treatment and the nature, purpose, risk and benefits of the operation(s) / procedure(s), possible alternative methods of treatment, including non-treatment, and the possibility of complications. Supplementary and reinforcing information has been made available at DoctorLansford.com. I was given the opportunity to ask questions and any such questions were answered to my satisfaction. No guarantee or assurance has been given by anyone as to the results that may be obtained. I am aware that the practice of medicine and surgery is not an exact science.

- 3. Surgical operations and special diagnostic or therapeutic procedures all involve RISKS OF COMPLICATIONS, SERIOUS INJURY, OR DEATH, from both known and unknown causes. Therefore, except in cases of emergency or exceptional circumstances, these operations and procedures will not be performed unless I have had an opportunity to discuss them with my physician. I have the right to consent to or refuse a proposed operation or special procedure.
- 4. My consent is given with the understanding that any operation or procedure, including anesthesia, involves risks and hazards.

Risks of surgery, in general, include, but are not limited to:

- Injury to anatomic structures near the surgical site is possible.
- Infection can occur, requiring antibiotics and further treatment.
- Bleeding could occur and may require a return to the operating room and/or blood transfusion(s). Bleeding is more common if you have been taking blood thinning drugs such as warfarin (Coumadin), clopidogrel (Plavix), dipyridamole (Persantine), rivaroxaban (Xarelto), aspirin or aspirin-like drugs, including ibuprofen (Advil, Motrin), naproxen (Aleve), and others, or if your blood does not clot normally. Bleeding is more common with high blood pressure.
- Small areas of the lung can collapse, a condition known as <u>atelectasis</u>, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
- Risk of wound infection, chest infection, heart and lung complications, and thrombosis (blood clots) is increased in individuals who smoke, have diabetes, or who have poor nutritional status.
- A heart attack (myocardial infarction) could occur due to the strain on the heart.
- A stroke (cerebrovascular accident) could occur.
- Blood clot in a vein (venous thrombosis) causing pain and swelling could occur. In rare cases part of the clot may break off and go to the lungs (pulmonary embolism).
- Damage to teeth or dental restoration is possible.
- <u>Urinary retention</u> after surgery may occur.
- Death as a result of this procedure is possible.

Additional procedure-specific risks include, but are not limited to:

- Nerves may be injured during dissection, which may cause numbness, muscle weakness, or pain in the area of the affected nerve(s). This may be permanent.
- Infection of the fluid around the brain (meningitis)
- Poor or no hearing benefit, including inconsistent benefit
- Leakage of fluid from around the brain, perhaps requiring another operation
- Device infection, movement and/or malfunction
- Possible need for implant removal
- After Osia implantation, you may undergo Magnetic Resonance Imaging (MRI)
 provided that the magnet used during imaging is 1.5 Tesla or less and that you
 use the MRI Cochlear MRI kit. Alternatively, if you have your implant surgically
 removed, there is no restriction related to Osia that would prevent you from
 undertaking an MRI.
- Electrocautery use during future medical procedures may render the implant nonfunctional. Informing a surgeon or proceduralist about the presence of a Osia implant is the patient's responsibility.
- 5. I consent to the performance of operations or other procedures in addition to or different from those now contemplated whether or not arising from presently unforeseen conditions, including the implantation of medical devices, which the above named physician(s) or his/her associate(s) or assistant(s) may consider necessary or advisable in the course of the operation.
- 6. I understand the risks, benefits, and alternatives to the type and method of anesthesia or sedation recommended, and I consent to the administration of such anesthesia as may be considered necessary or advisable by the physician(s) for this surgery / procedure.
- 7. I consent to the taking of photographs or video recordings that document conditions, treatments or procedures and understand that such images may be used for medical, research, professional certification, or teaching purposes. I understand that I am not allowed to take pictures or make video or audio recordings of my care, other patients, facility employees, providers, or students.
- 8. I consent to the presence of observers in the operating room, such as students, medical residents, medical equipment representatives, or other appropriate parties approved by my surgeon(s).
- 9. I consent to the disposal of any human tissue or body part which may be removed during the surgery / procedure(s).

- 10. I consent to pathological review of any tissue removed by the surgeon as he deems clinically appropriate. Examination of the tissue will then be performed and a report will be issued.
- 11. If complications arise, I agree to be admitted to the hospital of my surgeon's choice.
- 12. I have been advised that there is a possibility of damage to teeth during surgery and administration of anesthesia, particularly if the teeth are weak, loose, decayed or artificial, and I waive any claim for damage to teeth as a result thereof.
- 13. I understand that, unless instructed otherwise, I am required to have a responsible adult accompany me after my surgery / procedure(s) and that I will be released to that person's custody, and must rely upon him/her for my return home and supervision, as instructed.
- 14. I understand that if I am pregnant, or if there is the possibility that I may be pregnant, I must inform the surgeon and medical staff immediately since the scheduled surgery / procedure(s) could cause harm to my (unborn) child or myself.
- 15. If I am not the patient, I represent that I have the authority of the patient whom, because of age or other legal disability, is unable to consent to the matters above. I represent that (a) I have the full right to consent to the matters above; (b) I agree to release, indemnify, and hold harmless the surgical facility, its employees, agents, medical staff, partners, and affiliates from any liability or cost arising out of my lack of adequate authority to provide the consent set forth herein.
- 16. I understand that Illinois Administrative Code, Title 77, Chapter 1, Section 697.120, permits the facility to perform a blood test for HIV (the AIDS virus) on any patient during whose treatment a health care professional sustains a puncture, mucous membrane or open wound exposure to a patient's blood or other bodily fluids. A test for Hepatitis B and C may also be drawn.

17. I have not had anything to eat or drink since	
---	--

18. Advance Directives – Living Will – Health Care Proxy

I understand that Advance Directives and Living Wills are NOT honored at a surgery center or clinic, and in the event of an emergency or life threatening

situation, advanced cardiac life support will be initiated and patients will be transported to a facility providing a	_
[] I have provided the medical staff with my Adva Will/Health Care Proxy.	nce Directive/Living
[] I have an Advance Directive/Living Will/Health not provide it to the medical staff.	Care Proxy but did
[] I do not have an Advance Directive/Living Will/	Health Care Proxy.
[] I wish to have information on how I can obtain Living Will/Health Care Proxy.	an Advance Directive
MY SIGNATURE BELOW CONSTITUTES MY ACKNO	OWLEDGMENT THAT
1. I have read, understand and agree to the foreg	going;
The proposed surgery / procedure(s) have bee explained to me and that I have all of the infor	-
3. I hereby give my authorization and consent, ar	nd;
 All blank spaces on this document have either crossed off if they do not apply prior to my sign 	-
SIGNED	DATE & TIME
WITNESS	DATE & TIME
AUTNICOS DEL ATIONICI UD TO DATIENT	-
WITNESS' RELATIONSHIP TO PATIENT	

SURGEON'S ATTESTATION: Prior to the procedure, I discussed the condition requiring treatment and the nature, purpose, risks, and benefits of the operation(s), surgery/procedure(s), possible alternative methods of

Osia Implant Consent Page 5 of 6

	treatment, including non-treatment, and the possibility of complications with my patient or the patient's authorized representatives. I provided my patient or his/her representative with the opportunity to ask questions and answered all questions to their apparent satisfaction. I have reviewed the surgical consent form and verified that the planned surgery/procedure is accurate. Surgeon's initials:
	TRANSLATOR'S STATEMENT, IF APPLICABLE: I have verbally translated this consent into (applicable language) for the benefit of the patient or his/her authorized representative who understands said language better than English. To the best of my ability, I believe the patient or his/her representative understands these statements, as witnessed by their signature on the consent form.
	Translator's initials:
You may find more information at <u>DoctorLansford.com</u>	

Osia Implant Consent Page 6 of 6