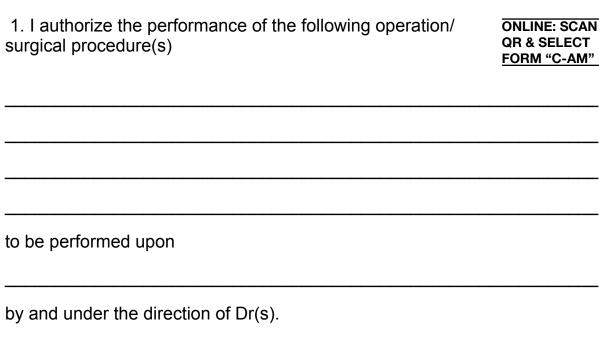


Form "C-AM" Consent for Inspire implant

(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).
- <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:

- Stimulation lead tethering may occur in which the wire connecting the tongue to the generator in the chest pulls tight with certain head movements
- Injury to the <u>marginal mandibular nerve</u>, which moves the lower lip, on the operative side. This may be partial or complete, and temporary or permanent.

- Injury to the <u>lingual nerve</u>, which may cause an <u>alteration of taste</u> and/or numbness of the tongue on the operative side.
- Injury to the hypoglossal.nerve, which can cause impairment in movement of the tongue. This may be partial or complete, and temporary or permanent.
- Injury to the <u>brachial plexus</u>, which may cause arm sensation and/or movement problems on the operative side.
- Failure to place stimulation lead cuff around nerve that moves the tongue (the hypoglossal nerve), in which case, the device would not function without revision surgery.
- Inappropriate lead connection with generator, in which case, the device would not function without revision surgery.
- Collapsed lung (pneumothorax) may arise from a hole in the surface of the lung. Air then leaks from the lung, causing the lung to collapse. The lung may come back up itself, or a tube may need to be put into the chest through the skin to remove the air from around the lung. This may need a longer hospital stay.
- · Blood vessel damage
- Hematoma, which is a collection of blood under the skin and may require drainage.
- Infection involving the device, which may require removal of the device.
- Intolerance of the device.
- 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 requiring hospitalization 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. <u>Advance Directives – Living Will – Health Care Proxy</u>
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 in every instance and patients will be transported to a facility providing a higher level of care.
[] I have provided the medical staff with my Advance Directive/Living Will/Health Care Proxy.
[] I have an Advance Directive/Living Will/Health Care Proxy but did not provide it to the medical staff.
[] I do not have an Advance Directive/Living Will/Health Care Proxy.
[] I wish to have information on how I can obtain an Advance Directive Living Will/Health Care Proxy.
MY SIGNATURE BELOW CONSTITUTES MY ACKNOWLEDGMENT THAT
1. I have read, understand and agree to the foregoing;

- 2. The proposed surgery / procedure(s) have been satisfactorily explained to me and that I have all of the information that I desire;
- 3. I hereby give my authorization and consent, and;

4. All blank spaces on this document have either be off if they do not apply prior to my signing.	een completed or crossed
SIGNED	DATE & TIME
WITNESS	DATE & TIME
WITNESS' RELATIONSHIP TO PATIENT	
SURGEON'S ATTESTATION: Prior to the procedur condition requiring treatment and the nature, purporthe operation(s), surgery/procedure(s), possible alternatment, including non-treatment, and the possible my patient or the patient's authorized representative or his/her representative with the opportunity to ask answered all questions to their apparent satisfaction surgical consent form and verified that the planned accurate. Surgeon's initials:	se, risks, and benefits of ernative methods of lity of complications with es. I provided my patient questions and n. I have reviewed the
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 (if applicable):	
u may find more information at <u>DoctorLansford.com</u>	

Inspire Implant Consent Page 6 of 6