Patient Consent for Anterior Cervical Discectomy and Fusion (ACDF)

*DO NOT SIGN THIS FORM UNTIL YOU HAVE READ IT AND FULLY UNDERSTAND ITS CONTENTS*

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date of Birth: \_\_\_\_\_\_\_\_\_\_\_

Physician: ***Dr Amit Bhandarkar/ Dr \_\_\_\_\_\_\_\_\_\_\_\_\_\_***

The planned procedure: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Diagnosis: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

After careful consideration, I have decided to undergo surgery to try to lessen my chronic pain. I authorize Dr. Amit Bhandarkar and any assistants he may select and supervise to perform my surgery. I understand that Amit Bhandarkar, M.D., is my doctor and will participate in and manage my hospital and surgical care. I know that, in his absence, other designated physicians and assistants might be involved in my follow-up care. I acknowledge and understand that the above procedure or treatment has been explained in layman’s terms. This information is given to me so that I can make an informed decision about having anterior approach cervical discectomy and fusion (ACDF) to treat my chronic neck pain. I also acknowledge that I had the opportunity to ask for clarifications, and all my questions have been answered satisfactorily.

***Anterior Cervical discectomy and fusion*** is a surgery to remove a damaged or diseased disc in the neck and then insert a spacer/bone graft to create a fusion of the vertebrae (spinal bones) above and below the diseased disc. This is performed through a small incision in the front of the neck. The neck muscles, trachea, and esophagus are gently moved to the side to gain access to the disc and spinal bones. Once the disc is removed, a spacer/ bone graft is inserted to provide height and stability to the disc space. Your body will heal around this spacer, creating a fusion of the vertebrae above and below. Small metal plates and screws are placed to stabilize the spinal bones during the fusion process. These plates and screws do not have to be removed.

***Expected outcomes.***

I understand that the goal of the procedure is not to cure or eliminate my chronic pain. The goal of the procedure is to try to decompress the nerves/spinal cord to reduce my pain to a more tolerable level.

I understand that even with the best efforts and with the most competent care, there is no guarantee that the procedure will result in any improvement.

I understand that treating chronic pain is a difficult task. Sometimes, great efforts are spent with minimal or no positive results. Sometimes, treatments can paradoxically result in temporary or permanent worsening of the condition. Of course, every effort is made to avoid such circumstances.

***Risks/Complications***

I understand that, even though most of the time, anterior cervical surgery is performed safely and with minimal side effects, some risks do exist. They include but are not limited to the following:

***Anesthesia:***

Risks of cardiac arrest/failure, pulmonary failure, stroke and/or death. I consent to the administration of anesthesia by the hospital’s anesthesia team. They will explain the anesthetic procedure, risks, and possible complications to me separately.

Positioning myself in certain positions may cause positioning-related complications, which may involve nerve paralysis, skin sores, tape, and traction-related sores.

***Nerve spinal cord complications***

Any spine surgery risks damaging the nerves or spinal cord, which can cause numbness or even paralysis. However, the most common cause of persistent pain after surgery is irreversible nerve damage from the disc herniation itself. Some disc herniations may permanently damage a nerve, making it unresponsive to surgery. In these cases, [spinal cord stimulation](https://mayfieldclinic.com/PE-STIM.HTM) or other treatments may provide relief.

***Other Spine related complications***

Instability may occur after decompression, which might need fixation with instrumentation at the same time or subsequently by a different surgery.

Adjacent-level syndrome occurs when a spinal fusion transfers extra stress and load to the discs and bones above or below the fusion. The added wear and tear can eventually degenerate the adjacent level and cause symptoms due to nerve root/spinal cord compression that may require surgery.

***Wound complications and infection:***

The risk of infection increases with the length and complexity of the operation, as well as with other risk factors (for example, diabetes, poor nutrition, advanced age, pulmonary or cardiac disease). Infection can be limited to the wound or the implanted hardware or spread to the nervous system (meningitis) and/or the blood (sepsis).

Superficial (skin) infection which could result in need for additional antibiotics or possibly further surgery.

Deep (below the skin) infection which could result in abscess formation, bone infection, or infection of the spinal cord or nerve roots that could result in paralysis and/or death. \*Deep infection would result in need for additional surgery(s) and might seriously jeopardize the expected result of the surgery. There may be a need for prolonged IV antibiotics. A severe infection might require the removal of the hardware, followed by a regimen of intravenous antibiotics.

Dehiscence or re-opening of the wound after closure can increase the risk for infection. The wound will need to be examined for treatment, including repeat surgical closure.

***Death***

This is an extremely rare occurrence, and its risks increase with age, with the severity of the pre-existing problems (particularly severe heart and lung problems), and with the occurrence of postoperative medical complications.

***Hoarseness and swallowing difficulties*.**

Most of the patients after anterior cervical decompression and fusion have transient swallowing discomfort/difficulty after surgery mostly due to swelling in the surgical area of the neck. This is mainly experienced while eating dry foods, bread, meat etc. A large majority of the patients do not have swallowing discomfort for more than a few weeks. In some, it may take longer. With very few, it may become a permanent issue**.**

In some cases, temporary hoarseness can occur. The recurrent laryngeal nerve, which controls the vocal cords, is affected during surgery. It may take several months for this nerve to recover. In rare cases (less than 1/250), hoarseness and swallowing problems may persist and need further treatment with an ear, nose, and throat specialist.

***Failure and malfunction of the device***

**Bone graft/Spacer migration occurs in** rare cases (1 to 2%). The bone graft can move from the correct position between the vertebrae soon after surgery. This is more likely to occur if hardware (plates and screws) is not used or if multiple vertebral levels are fused. If this happens, a second surgery may be necessary.

**Hardware failure/fracture** can occur when the metal screws and plates used to stabilize the spine move or break before the bones are completely fused. If this happens, a second surgery may be needed to fix or replace the hardware.

**Vertebrae failing to fuse (*Pseudo-arthrosis)***

 There are many reasons why bones do not fuse together. Common ones include smoking, osteoporosis, obesity, and malnutrition. Smoking is by far the greatest factor that can prevent fusion. Nicotine is a toxin that inhibits bone-growing cells. If you continue to smoke after your spinal surgery, you could undermine the fusion process.

***Damage to the visceral Structures***

This surgery is performed where the food pipe (esophagus) and windpipe (trachea taken to one side, and the major blood vessels are taken to one site. These significant structures are at risk for injury while doing surgery. Even though it is extremely rare, injury to these structures is very catastrophic and has very high chances of death or significant mortality. The other structures that may get injured are the apex of the lung, thoracic duct, and vertebral artery (the injury to which is also catastrophic).

***Blood Loss & replacement***

Blood loss during or after surgery can result in the need for blood transfusion or replacement.

Blood from the blood bank would be used and, although rare, can expose you to the risk of blood-borne diseases such as hepatitis and AIDS.

***General surgical complications:***

Atelectasis - mechanical pneumonia

Pulmonary embolus (blood clot in the lungs) which can lead to death.

Deep vein thrombophlebitis (blood clot in the leg).

Complications related to urinary catheter.

Urinary tract infection, sepsis/death.

Heart attack due to strain on the heart

Stroke or transient ischemic episodes (TIAs)

***Other potential complications:***

We talked about other risks of the surgery including but not limited to bleeding, hematoma changes in voice, and horners syndrome. We talked about neuromonitoring, Gardner wells tongs application and allograft use.

***Complication prevention:***

It is important for you to follow all the instructions provided to you by your surgeon and other care providers. Instructions are provided to assist you in your recovery and reduce the risks of surgical complications. Knowing the complications to be aware of and signs of potential complications help you to identify any problems early. Early discovery and intervention can reduce complications' severity if they do occur.

***General complication prevention strategies: Pre-op***

**Maintain good blood sugar** control if you are diabetic***.*** Elevated blood sugar can increase your risk for infection, impair your wound healing***,*** and increase the potential for organ failure, such as kidneys.

Maintain good nutritional status before your surgery***.*** This will help your immune system heal after surgery.

**Stop smoking*.*** Smoking can increase your risk of infection***.*** Smoking can increase your risk of blood clots***.*** Smoking can increase your risk of pneumonia***.*** Smoking can impair oxygen to your wound causing delayed or poor healing of the incision. Smoking can increase the risk of surgical failure by many folds.

Please do not use any marijuana or other substances and please discuss with your surgeon and anesthetist as it will have bearing on your health.

**Alternatives to Proposed Surgical Care:**

* Rest and anti-inflammatory medications
* Exercise/physical therapy/re-conditioning
* Spinal Bracing

I understand that alternative methods of treating my condition(s) exist. They have been considered and discussed, but at present, my choice is to proceed with an ACDF procedure. If I choose not to have the procedure, I have been informed of my prognosis.

***MRI after surgery***

Materials used in spinal hardware are typically non-magnetic meaning they are safe during MRI scan. However, your surgeon may recommend for some time for healing before you have an MRI. Check with your surgeon if another physician requests and MRI to ensure safety from dislodgement of hardware or re-opening of the wound.

***For women only***:

I represent to my physician that I am not pregnant nor am I breastfeeding at this time and understand that there are risks of sedation or of the procedure to an unborn child.

I also understand that controversy exists about the use of the stimulator during pregnancy. I have had the opportunity to discuss this issue. (applicable only when appropriate).

***Pain medications***

I understand that patients with pain problems occasionally require a great deal of narcotic medications to suppress their pain. These narcotic medications (e.g., Percocet, Norco, Codeine, Demerol, etc.) can be addicting. Medications will be provided for the first 2-6 weeks only to suppress the pain associated with surgery. However, narcotics will not be prescribed for long-term use by the surgeon’s clinic.

***Devices***

Implants, devices and pharmacologic agents may be used in a manner considered to be an “off-label use” by the FDA. “Off-label use” refers to using a drug, implant or device for a reason not specifically approved by the FDA. The decision of whether to use an implant, device or pharmacologic agent for an off-label use is a matter of medical judgment.

***Additional procedures***

I understand that the practice of medicine is not an exact science and that no guarantees or assurances have been made to me concerning the results of this procedure or treatment.  I understand that during the procedure or therapy described above it may be necessary or appropriate to perform additional procedures or treatments that are unforeseen or not known to be needed at the time this consent was given. It may also be necessary or appropriate to have diagnostic studies, tests, anesthesia, x-ray examinations and other procedures performed during my treatment. I consent to and authorize the persons described herein to perform such additional procedures and treatments as they deem necessary or appropriate.

The following additional procedures may be deemed necessary during surgery(including but not limited to:

1. Bone marrow aspiration
2. Bone graft harvesting
3. Placement of urinary catheters
4. Neuromonitoring – invasive
5. Surgery at additional levels adjacent to surgical level
6. Additional hardware placement

Depending on the patient’s diagnosis and the procedure or treatment to be performed, it may be necessary or appropriate for tissues and specimens to be removed from the patient’s body. I consent to the removal, testing, retention for scientific or teaching purpose, and disposal of such tissues and specimens within the discretion of the physician, facility or other healthcare provider.

***Photography***

I consent to the taking of photographs or the use of video recording equipment during the procedure for the purpose of medical education only.

***Summary***

I have been counseled regarding the nature of the condition for which surgery is proposed. I understand the alternative(s) to surgery. The basic steps of the proposed procedure, the advantages, disadvantages, risks, possible complications, and alternative treatments have been explained and discussed with me by **Dr Amit Bhandarkar or his associates**.  I understand that there can be no guarantees of a favorable surgical outcome or that a surgical complication will not occur. I understand that the proposed surgical procedure may not completely relieve all the pain I am experiencing and that the possibility exists that the pain I currently have could be the same or worse after the surgery.

I have carefully read/viewed the material on ACDF surgery given to me by Dr Amit Bhandarkar and I have had the opportunity to ask questions about the upcoming procedure. I have been given a copy of this consent if asked for, so that I can further review it at my leisure. If I have further questions or issues, I will contact Dr Amit Bhandarkar and/or his team.

Patient’s Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Giving Consent Date and Time (and relationship to the patient if person giving consent is not the patient)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If the person giving consent is not the patient, state the reason why the patient is unable to consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness’ Printed Name/Signature/ Date and Time:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Witness’ Signature Date Time \*Consent valid for 30 days from date of signature.*