

# Patient Consent for Cement augmentation – Vertebroplasty Kyphoplasty



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

Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

Physician: **Dr. Amit Bhandarkar**

The planned procedure:

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

After careful consideration, I have decided to undergo surgery to try to lessen my present pain. I authorize Dr. Bhandarkar and any assistants as may be selected and supervised by him to perform my surgery. I understand that Amit W Bhandarkar M.D. is my doctor and that he will participate in and supervise my hospital and surgical care. I understand that, in his absence, other designated physicians and/or assistants might be involved in my follow-up care. I acknowledge and understand that the above procedure or treatment has been explained to me (sometimes referred to as the patient) in layman's terms. This information is given to me so that I can make an informed decision about having cement augmentation of my vertebral body either by doing Kyphoplasty or Vertebroplasty. I also acknowledge that I had the opportunity to ask for clarifications and all my questions have been answered to my utmost satisfaction.

Kyphoplasty is a procedure that treats thoracic or lumbar vertebral compression fractures (collapsed vertebra). This is done by placing a large needle through the skin into the collapsed vertebrae under X-ray guidance. A cavity is then created inside of the vertebrae through the needle, which is then filled with biological cement in order to decrease the symptoms associated with the fracture.

**Benefits:** The benefits of Kyphoplasty/ Cement augmentation include complete or partial resolution of symptoms, improved quality of life, and preservation of neurologic function. These benefits cannot be guaranteed and only you can decide if the benefits are worth the risk.

**Alternative Managements:** The alternative management modalities for this procedure are physical therapy, pain management using medications or injections, spinal fusion, and expectant management with no treatment at all.

I understand that alternative methods of treating my condition(s) exist. They have been considered and discussed, but at the present time, my choice is to proceed with a percutaneous cement augmentation procedure. If I choose not to have the procedure, I have been informed that my prognosis (my future medical condition) is still fair.

## Expected outcomes

I understand that the goal of the procedure is not to cure or completely eliminate my chronic pain. The goal of the procedure is to try 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 cement augmentation 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 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.

I understand I may receive conscious sedation based on the nature of the procedure.

**Drug Reactions:** Unexpected allergies, lack of proper response to medications or illness caused by the prescribed drugs are possibilities. It is important for you to inform your physician and your anesthesiologist or certified registered nurse anesthetist of any problem you or your family have had with reactions to drugs and which medications you have taken in the past six months, including over-the-counter drugs, especially aspirin.

**Injury to Other Organs:** Because of the closeness of other organs to the area being operated on, there may be injury to other organs. The stress of surgery or the procedure may also harm other organ systems of the body.

7) Risks Specific to this Procedure:., potentially serious risk from allergic reactions to the cement material, and the need for further surgery.

## Nerve, spinal cord complications

Any spine surgery comes with the risk of damaging the nerves or spinal cord. The risks associated with this surgery include, but are not limited to, leakage of cement into the spinal canal causing damage to the spinal cord or nerve roots, leading to increased pain or other neurologic problems such as loss of bowel/bladder function, sexual dysfunction, weakness or paralysis, numbness. There is also risk of direct spinal cord or nerve damage by the needle.

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## Other Spine related complication

Transitional syndrome is when a spine segment causes extra stress and load to be transferred to the discs and bones above or below the cement augmentation. The added wear and tear can eventually degenerate the adjacent level and cause pain.

## 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 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 and 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 severity of the pre-existing problems (particularly severe heart and lung problems) and with the occurrence of postoperative medical complications.

## Cement embolization

In some cases, the cement may embolize (travel to) the lung which may need further treatment in the form of anticoagulation or in the form of embolectomy.

## 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 disease 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:

There are many more complications that could occur but they occur so infrequently that are not listed or discussed.

## 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 potentially reduce the severity of complications if they do occur.

## General complication prevention strategies: Pre-op

Reduce pre-operative anemia by taking oral iron supplements. This can reduce the need for blood transfusions/replacement.

Maintain good blood sugar control if you are diabetic. Elevated blood sugar can increase your risks 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 to aid in healing 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.

## 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 breast feeding 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 opportunity to discuss this issue with Dr. Bhandarkar (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, Codeine, Demerol, etc.) can be addicting. Medications will be provided on a temporary basis to suppress the pain associated with surgery. However, narcotics will not be prescribed for long-term use.

## Devices

Implants, devices and/or 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 or not 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.

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I understand that during the course of the procedure or treatment 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 in the course of my treatment. I consent to and authorize the persons described herein to perform such additional procedures and treatments, as they deem necessary or appropriate.

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.

## 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**. I understand that there can be no guarantees on a 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 Cement augmentation 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. 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)

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

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Witness' Printed Name/Signature/ Date and Time:

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