BRONSON

Affix Patient Label	
Patient Name:	Date of Birth:

Informed Consent: Vertebral Augmentation

This information is given to you so that you can make an informed decision about having a **vertebroplasty or a kyphoplasty.** This procedure is most often done with moderate sedation or anesthesia.

Reason and Purpose of this Procedure:

A compression fracture occurs when the vertebral body collapses on itself due to osteoporosis (bone thinning), disease (such as cancer), or trauma.

- A **vertebroplasty** is a procedure done to reduce the pain associated with vertebral compression fractures. The doctor will insert a needle into the fractured bone using X-ray guidance and inject bone cement to stabilize the bone fragments.
- A **balloon kyphoplasty** is a minimally invasive treatment similar to a vertebroplasty. Using X-ray guidance, orthopedic balloons gently lift the bone fragments to return them to the correct position.

The procedure usually takes less than one hour for each fracture treated. You may need to stay in the hospital overnight.

Benefits of this Procedure:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Less back pain.
- Better quality of life.
- Better movement.
- Improved ability to perform everyday activities.

General Risks of Procedures:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

- Small areas of the lungs may collapse. This would increase the risk of infection. This may need antibiotics and breathing treatments.
- Clots may form in the legs, with pain and swelling. These are called DVTs or deep vein thrombosis. Rarely, part of the clot may break off and go to the lungs. This can be fatal.
- A strain on the heart or a stroke.
- Bleeding may occur. If excessive you may need a blood transfusion.
- Reaction to the anesthetic. The most common reactions are nausea and vomiting. In rare cases, death may occur. This procedure can be done with moderate sedation or general anesthesia, The anesthesiologist or radiologist will discuss this with you.

Risks of this Procedure:

The risks of a kyphoplasty/vertebroplasty are directly related to the severity of the condition.

- **Fracture.** Lying on your stomach during the procedure may cause bones weakened by osteoporosis to break.
- **Infection.** Infection may occur in the wound, near the surface or deep in the tissues. This may include the bone. You may need antibiotics or more treatment.
- **Migration (movement) of cement.** The cement is very quick drying. In rare cases the cement may leak out of the fracture site and into the spinal canal. This may cause pain and numbness. You may need more surgery if this occurs.
- **Pulmonary embolism.** Rarely, cement may leak and travel to the lungs. This can cause a blockage. You may have trouble breathing, a fast heart rate, and problems with circulation. This could be fatal. You may need medicine and more surgery.
- **Injury to a nerve,** the spinal cord, or adjacent organs.

Potential Radiation Risks:

- **Any exposure to radiation may cause a slightly higher risk for cancer later in life.** This risk is low.
- **Skin rashes. Skin rashes may lead to breakdown of skin and possibly severe sores.** This is rare.
- **Hair loss. This does not happen to everyone.** This can be temporary or permanent.
- **It is possible we may have to use higher doses of radiation.** If we do, we will tell you.
- **If you see changes with your skin, you should report them to your doctor.**

Risks Associated with Smoking:

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Associated with Obesity:

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Specific to You:

_____

_____

_____

_____

Alternative Treatments:

Other choices:

- Pain management (medications).
- Physical or occupational therapy.
- Spine surgery.
- Do nothing. You can decide not to have the procedure.

If you Choose not to have this Treatment:

- Your doctor can discuss the alternatives treatments with you.

Information on Moderate Sedation:

You will be given medicine in an IV to relax you. This medicine will also make you more comfortable. This is called "moderate sedation". You will feel sleepy. You may even sleep through parts of your procedure. We will monitor your heart rate and your blood pressure. We will also monitor your oxygen level.

If your heart rate, blood pressure or oxygen levels fall outside the normal range, we may give medications to reverse the sedation. We may be unable to reverse the sedation. We may need to support your breathing.

Even if you have a NO CODE status:

- You may need intubation to support your breathing.
- You may need medications to support your blood pressure.

We will re-evaluate your medical treatment plan and your NO CODE status when sedation has cleared your body.

Benefits of Moderate Sedation:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Less pain during the procedure.
- Less anxiety or worry.
- Decreasing your memory of the procedure.

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Risks of Moderate Sedation:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect. The list includes:

- Decreased breathing during the procedure and dropping oxygen levels. To help you breathe, a tube may be placed into the mouth or nose and into the trachea to help you breathe.
- Allergic reactions: nausea & vomiting, swelling, rash.
- Vomit material getting into the lungs.
- A drop in blood pressure. This needs fluids or medicine to increase blood pressure.
- Heart rhythm changes that may require medicines to treat.
- Not enough sedation or analgesia resulting in pain or discomfort.

Your physical and mental ability may not be back to normal right away. You should not drive or make important decisions for at least 24 hours after the procedure.

General Information:

During this procedure, the doctor may need to perform more or different procedures than I agreed to.

During the procedure, the doctor may need to do more tests or treatment.

Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.

Students, technical salespeople, and other staff may be present during the procedure. My doctor will supervise them.

Pictures and videos may be taken during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected.

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By signing this form, I agree:

- I have read this form or had it explained to me in words I can understand.
- I understand its contents.
- I have had time to speak with the doctor. My questions have been answered.
- I want to have this procedure: ☐ **Vertebroplasty at level(s):** _____
  ☐ **Kyphoplasty at level(s):** _____
- I understand that my doctor may ask a partner to do the procedure.
- I understand that other doctors, including medical residents or other staff may help with the procedure. The tasks will be based on their skill level. My doctor will supervise them.

Provider: This patient may require a type and screen or type and cross prior to procedure. If so, please obtain consent for blood/products.

Patient Signature: _____ Date: _____ Time: _____

Relationship: ☐ Patient ☐ Closest relative (relationship) _____ **☐ Guardian/POA Healthcare**

Reason patient is unable to sign: _____

Interpreter's Statement: I have interpreted the doctor's explanation of the consent form to the patient, a parent, closest relative or legal guardian.

Interpreter's Signature: _____ ID #: _____ Date: _____ Time: _____

Telephone Consent ONLY: *(One witness signature MUST be from a registered nurse (RN) or provider)*

1st Witness Signature: _____ 2nd Witness Signature: _____ Date: _____ Time: _____

For Provider Use ONLY:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Provider signature: _____ Date: _____ Time: _____

Teach Back:

Patient shows understanding by stating in his or her own words:

_____ Reason(s) for the treatment/procedure: _____

_____ Area(s) of the body that will be affected: _____

_____ Benefit(s) of the procedure: _____

_____ Risk(s) of the procedure: _____

_____ Alternative(s) to the procedure: _____

OR

_____ Patient elects not to proceed: _____ Date: _____ Time: _____
(Patient signature)

Validated/Witness: _____ Date: _____ Time: _____