



Affix Patient Label

Patient Name:

DOB:

Informed Consent for Sacroplasty

This information is given to you so that you can make an informed decision about having a **Sacroplasty**.

Reason and Purpose of the Procedure

Sacroplasty is a procedure done to reduce the pain associated with sacral fractures. The doctor will insert a needle into the fractured bone using X-ray guidance and inject bone cement to stabilize the bone fragments.

The procedure is usually done under local anesthesia with sedation but general anesthesia can be used. Your doctor will decide which is best for you. The procedure usually takes one to two hours. 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 pelvic pain.
- Better quality of life.
- Better movement.
- Improved ability to perform everyday activities.

Risks of Procedure

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.

Risks of this procedure

- **Fracture:** Lying on your stomach during the procedure may cause bones weakened by osteoporosis to break. You may need further surgery.
- **Infection:** Infection may occur in the wound, near the surface or deep in the tissues. This would usually be treated with antibiotics for a week or two. A bone infection could require antibiotics to suppress infection for many years. This is rare.
- **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 sacral nerve canals. 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.

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.

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General Risks of Procedure

- Small areas of the lungs may collapse. This would increase the risk of infection. This may need antibiotic 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 may occur.
- Bleeding may occur. If there is too much bleeding you may need a transfusion.
- Reaction to the anesthetic may occur. The most common reactions are nausea and vomiting. In rare cases, death may occur. The Anesthesiologist will discuss this with you.

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.
- Prolonged rest to allow fractures to heal.
- Do nothing. You can decide not to have the procedure.

If You Choose Not to Have this Treatment

Your doctor can discuss the alternative treatments with you

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 sales people and other staff may be present during the procedure. My doctor will supervise them.
- Radiology images will be obtained. They will be part of 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: **Sacroplasty** _____
- I understand that my doctor may ask a partner to do the surgery/procedure.
- I understand that other doctors, including medical residents or other staff may help with surgery. 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 surgery. IF so, please obtain consent for blood/product.

Patient Signature _____ Date: _____ Time: _____

Relationship: Patient Closest relative (relationship) _____ Guardian

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

Interpreter: _____ Date _____ Time _____

*Interpreter (if applicable)***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

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.

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: _____