



Affix Patient Label

Patient Name:

DOB:

Informed Consent Disc Aspiration and Biopsy

This information is given to you so that you can make an informed decision about having a CT or **fluoroscopy guided needle aspiration biopsy** of an intervertebral disc space with a biopsy of nearby bone if needed

Aspiration biopsy location: _____

Disc spaces are located in between the vertebral bodies (spinal bones) in the spine. Sometimes infection can occur in the disc space and in the spinal bone next to the disc space. If an infection occurs, it is important to determine the type of infection. This will allow your doctor to use the best treatment for the infection. In some cases, degenerative disc disease or a tumor can look similar to infection. This test can help your doctor know if there is an infection or not.

The radiologist will use X-ray fluoroscopy or computed tomography (CT scan), to guide placement of a needle into the abnormal disc space. Small samples of tissue or fluid will be removed. These will be sent to the laboratory to test for infection. In some cases, a sample of bone will be removed through the needle. This may also be tested for infection or will be sent to the pathologist to examine.

Medication to numb your skin will be injected at the needle insertion site. You will be given some intravenous relaxing medication and pain medicine during the procedure. For most patients, the procedure is well tolerated. Some patients will have moderate discomfort during the procedure.

Reason and Purpose of the Procedure

- To determine if there is a disc space infection and try to make a specific diagnosis.

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.

- Help your doctor decide how to treat you.
- Diagnose the type of infection.
- Make your recovery more rapid.

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

- **Inconclusive results:** Even when infection is present, it is often not possible to make a specific diagnosis by a needle aspiration. The information is considered to be so important that the aspiration and biopsy is still considered to be worth performing.
- **Rare serious complications include the following:**
 - **Injury to a spinal nerve:** This could cause permanent numbness or weakness.
 - **Injury to the lining of the spinal canal:** This could result in leak of spinal fluid which could cause a headache. This could require surgery to repair. This could cause spinal meningitis.
 - **Bleeding into the spinal canal:** This could compress the spinal cord or nerves. This could require emergency surgery to drain the blood and release the compression. Paralysis or nerve damage could occur.

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- **Injury to an artery supplying the spinal cord:** This could result in paralysis.
- **Death.**

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**

General Risks of Procedures

- **Bleeding:** In rare cases you may need a blood transfusion or emergency procedure to stop bleeding.
- **Infection:** Could occur in the skin, soft tissue under the skin or at the internal biopsy site. These infections are rare. You may need antibiotics.
- **Complications from sedation medicine:** You may have low blood pressure. You may have breathing problems including slow breathing and choking on vomit (aspiration). If you are sedated you will be monitored by a nurse and given oxygen to breath.

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.

Alternative Treatments

Other choices:

- Do nothing. You can decide not to have the procedure.
- Open surgical biopsy under general anesthesia.

If You Choose Not to Have this Treatment

- Your doctor may find it more difficult or not possible to effectively treat your problem.

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.
- Pictures and videos may be done 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: **Needle Biopsy of:** _____
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- 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 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 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: _____