



Affix Patient Label

Patient Name:

Date of Birth:

Informed Consent For Pediatric

24 hour PH/Impedance Probe Study with Impedance Probe Insertion, With/Without Sedation

This information is given to you so that you can make an informed decision about your child having **24 hour PH Impedance Probe Study**.

Reason and Purpose of the Procedure:

This test measures a child's acid reflux. It tells the doctor how much reflux your child has and how severe it is in a 24 hour period.

Your child will receive a numbing gel in their nose, and some medicine to help them relax. A thin flexible tube is inserted into the nostril and moved into the esophagus. This tube will be withdrawn and a very thin and flexible tube will be placed into the nostril. It will be moved to an exact location in the esophagus. The tube is secured to the nose and connected to a recorder. Your child will carry it on a strap and wear it overnight.

Benefits of this Procedure:

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

- Helps the doctor diagnose conditions that are not reflux and prescribe the correct treatment.
- Helps the doctor choose the right medicine.
- Helps the doctor decide if surgery is needed.

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:

- **Perforation.** This is small hole or puncture. Your child may need surgery to repair.
- **Pain.** The probe can cause irritation after insertion. Your child may need pain medication.

Information on Moderate Sedation:

Your child will be given medicine in an IV to relax him/her. This medicine will also make your child more comfortable. This is called "moderate sedation". Your child will feel sleepy. He/she may sleep through parts of the procedure. We will monitor your child's heart rate and blood pressure. We will also monitor their oxygen level. If your child's heart rate, blood pressure or oxygen levels fall outside the normal range, we may give medications to reverse the sedation. We may not be able to reverse the sedation. We may need to support their breathing. Even if your child has a NO CODE status, they

- may need intubation to support their breathing.
- may need medications to support their blood pressure.

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



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General Risks of this Procedure:

- 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.
- Bleeding may occur. If excessive your child may need a blood transfusion.
- Reaction to the anesthetic. The most common reactions are nausea and vomiting. In rare cases, death may occur. The anesthesiologist will discuss this.

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 Your Child:

Alternative Treatments:

Other choices:

- Medicines. There are several different types of medications.
- Diet changes. Avoiding certain foods as well as specific positions after eating can help.
- Do nothing. You can decide not to have the procedure.

If You Choose Not to Have this Treatment:

- Erosion of the esophagus. This is due to continued acid exposure from the stomach.
- Pain and discomfort. Acid may continue to irritate the upper stomach and esophagus.

General Information:

- During the procedure your child’s doctor may need to perform more or different procedures than I agree to.
- During the procedure your child’s 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 child’s doctor will supervise them.
- Pictures and videos may be done during the procedure. These may be added to my child’s medical record. These may be published for teaching purposes. My child’s 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 my child’s doctor. My questions have been answered.
 - I want my child to have this procedure: **24 hour PH/Impedance probe study with Impedance probe insertion with/without sedation:**
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- I understand that my child’s doctor may ask a partner to do the surgery.
 - I understand that other doctors, including medical residents or other staff may help with procedure. The tasks will be based on their skill level. My child’s 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.

Parent Signature _____ Date: _____ Time: _____

Relationship: Parent 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 parent has agreed to procedure.

Provider signature: _____ Date: _____ Time: _____

Teach Back

Parent 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

____ Parent elects not to proceed: _____ (parent signature)

Validated/Witness: _____ Date: _____ Time: _____