

Patient Information about the Heartsbreath Test

Humanitarian Device authorized by Federal law for use as an aid in the diagnosis of grade 3 heart transplant rejection in first year heart transplant recipients. The effectiveness of this device for this use has not been demonstrated.

Intended use/ Indications for use

The Heartsbreath test is indicated for use as an aid in the diagnosis of grade 3 heart transplant rejection in patients who have received heart transplants within the preceding year. The Heartsbreath test is intended to be used an adjunct to, and not as a substitute for, endomyocardial biopsy. The use of the device is limited to patients who have had endomyocardial biopsy within the previous month.

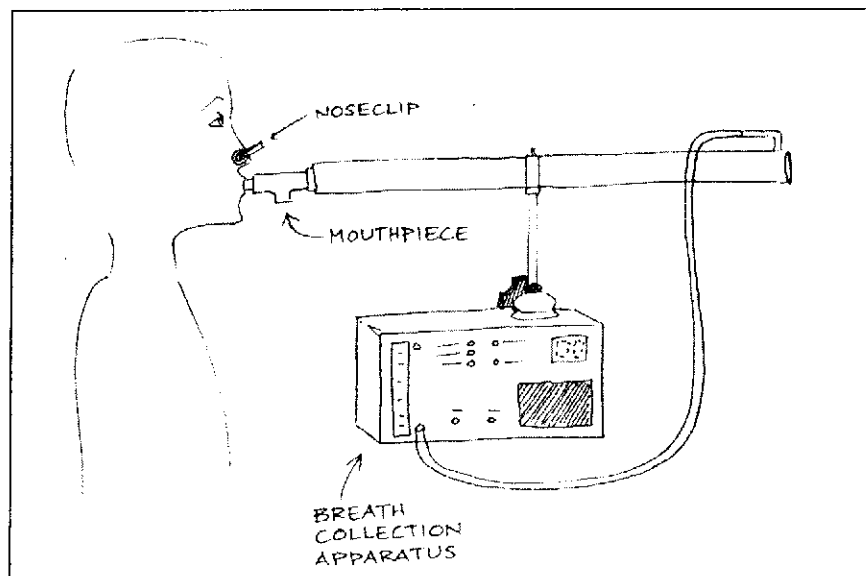
Heart transplant rejection

After a heart transplant, the body sometimes tries to get rid of the new heart. That is called heart transplant rejection, and it can be very dangerous. You are probably taking drugs to prevent heart transplant rejection, and your doctor needs to know whether these drugs are working properly. That is why your doctor does a heart biopsy (also known as an endomyocardial biopsy) by taking a small piece of your heart and then looking at it under a microscope. Doctors grade the heart transplant rejection by how severe it looks under the microscope: grade 0 is no rejection at all, grade 1 is mild rejection, grade 2 is moderate rejection, and grade 3 is severe rejection. Grade 4 is very severe rejection, but it is unusual nowadays. Generally, doctors only need to change your drugs if the biopsy shows grade 3 heart transplant rejection.

The Heartsbreath test measures chemicals in your breath which tell if you have grade 3 heart transplant rejection or no rejection at all. It is not used in place of a biopsy – your doctor uses the Heartsbreath test and the biopsy together, to judge whether you have grade 3 rejection. Your doctor cannot use the Heartsbreath test if you have not had a recent biopsy or if you have had your new heart for more than a year.

How the Heartsbreath test is used

The Heartsbreath instrument collects chemicals from your breath. This picture shows a person breathing into the Heartsbreath instrument (it is called a breath collection apparatus).



You will be asked to do the same thing as in the picture. You put on a nose clip so your breath passes through the mouthpiece of the Heartsbreath instrument. You breathe easily in and out through the mouthpiece for two minutes. The mouthpiece does not resist your breathing. You do not have to work hard – just breathe normally. Each patient uses a new mouthpiece. This helps you avoid exposure to germs from a previous patient.

After you have breathed into the Heartsbreath instrument, the lab tests the chemicals from your breath. The lab compares chemicals from your breath with chemicals from the breath of other transplant patients. Some of the other patients had grade 3 rejection, so the lab can tell your doctor whether the chemicals in your breath match those of other patients with grade 3 rejection. Your doctor compares your Heartsbreath results with your biopsy results to see whether the two tests agree with each other.

When the Heartsbreath test should not be used (Contraindications)

There are no known risks to breathing into the Heartsbreath instrument.

Preparing for the day of the test

- Do not eat after midnight before your test. If you do, the test results will not be useful. You may drink water, chew gum, and use toothpaste, mouthwash, and deodorant after midnight.
- Do not smoke or use other kinds of tobacco after midnight before your test. If you do, your test results will not be useful.
- Do not stop taking your prescribed medicines.

Checklist for the day of the test

- Have you smoked or used any tobacco products since midnight?
- Have you had anything to eat since midnight?
- If you have used tobacco products of any kind or consumed any food since midnight, you must inform the Heartsbreath technician.

Important Information about the Heartsbreath test

- The Heartsbreath test is not a substitute for endomyocardial biopsy – your doctor uses it only with a biopsy. Your doctor will use both tests together in combination, to help find out whether or not you are suffering from grade 3 heart transplant rejection.
- Breath collection is safe. There are no known risks to breathing into the Heartsbreath instrument. You will use a new mouthpiece, so there is no risk of germs from other patients.
- It is easy to breathe in and out of the Heartsbreath instrument, so the test is not uncomfortable.

Risks of the Heartsbreath test

- The Heartsbreath technician installs a clean mouthpiece for you. If the operator fails to do this, you may get germs from a previous patient.
- Your Heartsbreath test could be wrong and mislead your doctor if you may have different breath chemicals from other patients with the same amount of rejection.

Benefits of the Heartsbreath test

- The biopsy test can be wrong. If your biopsy test shows grade 3 transplant rejection, the Heartsbreath test can help you be sure it is right. Using the Heartsbreath test and your biopsy test together helps you get the correct treatment.

Postoperative care with the Heartsbreath test

Your doctor will get your Heartsbreath test results in about 2 days. Your result will be "positive", "negative", or "intermediate". An intermediate result will have a probability number.

- A negative Heartsbreath test and a negative biopsy means you probably do not have grade 3 rejection.
- A positive Heartsbreath test and positive biopsy means you probably do have grade 3 rejection.
- Any other result means you may or may not have grade 3 rejection.

Importance of the need to adhere to a care regimen

- You and your physician are partners in your care. Grade 3 heart transplant rejection is a hazardous and potentially life-threatening condition, so it is essential for you to work together with your physician to reach the correct diagnosis and to adhere to the plan of treatment that is prescribed for you.