

# HEAL-IST

CLINICAL TRIAL



## PATIENT INFORMATION GUIDE

A Clinical Trial for People with  
Inappropriate Sinus Tachycardia (IST)

HEAL-IST Is Sponsored by AtriCure, Inc.  
[www.AtriCure.com](http://www.AtriCure.com) +1 (866) 349-2342



**THIS BROCHURE  
DESCRIBES A  
CLINICAL TRIAL USING  
AN INVESTIGATIONAL  
THERAPY TO TREAT  
INAPPROPRIATE SINUS  
TACHYCARDIA (IST).  
YOU AND YOUR  
DOCTOR CAN DECIDE  
IF YOUR ENROLLMENT  
IN THIS TRIAL MAY BE  
RIGHT FOR YOU.**

# ABOUT INAPPROPRIATE SINUS TACHYCARDIA

IST is a complex condition that occurs in otherwise healthy younger people. It results in a rapid heartbeat of over 100 bpm, even at rest.

IST may cause symptoms such as:

- ☐ Palpitations — fluttering or pounding sensations in your chest<sup>1</sup>
- ☐ Chest discomfort<sup>2</sup>
- ☐ Weakness, dizziness, lightheadedness, or fainting<sup>3</sup>
- ☐ Shortness of breath<sup>3</sup>
- ☐ Fatigue<sup>1</sup>
- ☐ Certain mental health issues such as anxiety<sup>1</sup>
- ☐ Exaggerated response to exercise or stress<sup>4</sup>

All of these symptoms can affect your day-to-day life and can also diminish your quality of life. Currently, there are no proven, effective Food and Drug Administration (FDA)-approved therapies for IST. Doctors usually recommend exercise, as well as some or all of the following options:

## MEDICATIONS TO LOWER THE HEART RATE

The primary treatments for IST are drugs to try to control the heart rate.

## THERAPIES FOR SYMPTOMS

Other medications cause sodium to be retained in the body, and this may help with symptoms. Pressure stockings may possibly help prevent blood pooling in the legs.

## SURGERY

Surgery may or may not be a good option for some patients, depending on their health. Only your doctor can advise you on the appropriate treatment.

# CONVENTIONAL ABLATION PROCEDURE USED FOR IST

In some cases, heart doctors have used ablation, which uses heat to create scars, or lesions, on the heart tissue. This conventional type of ablation modifies or destroys the part of the heart called the sinoatrial (SA) node. It is the area where the heartbeat originates in the heart. Because the SA node no longer functions, or doesn't function as well, the person often needs a pacemaker to keep the heart beating properly. However, there are other negative side effects. The procedure's effectiveness also has not been proven.

## SINOATRIAL (SA) NODE

The SA node is the small area of the heart where the heart's electrical impulses begin, causing the heart to beat as the heart's chambers contract. The SA node causes the atria (upper chambers) to contract first; then the ventricles (lower chambers) contract. Someone with IST has abnormal stimulation, causing the heart to beat inappropriately fast.

# NEW HYBRID ABLATION PROCEDURE FOR IST

There is a new type of ablation procedure, now being tested in a clinical trial named HEAL-IST. A heart doctor uses ablation to modify small areas outside and sometimes inside the heart. The goal is to stop the rapid heart rhythm from IST by creating lesions on the heart surface.

It's important to note that this Hybrid Ablation procedure is designed to spare the natural function of the SA node. In fact it is called a **hybrid sinus node sparing ablation procedure**. When the heart can beat properly on its own, there would be no need for a pacemaker.

# HEAL-IST CLINICAL TRIAL FOR INAPPROPRIATE SINUS TACHYCARDIA

## PURPOSE

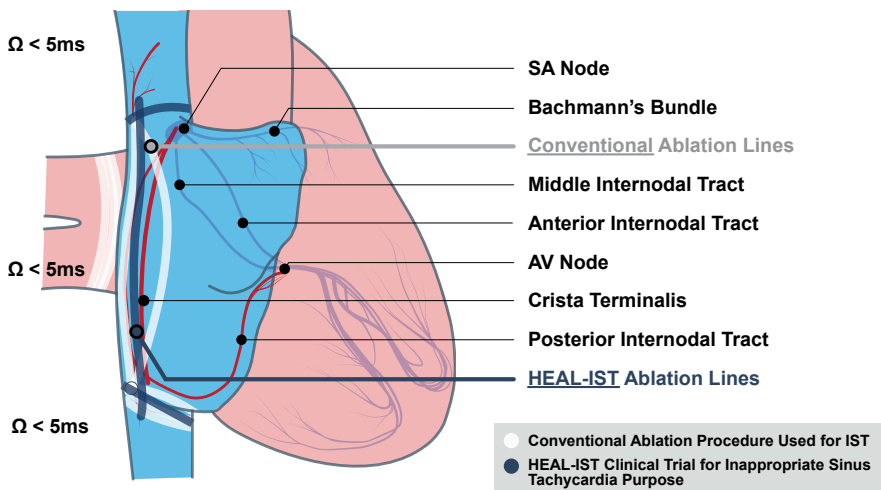
The purpose of this trial is to learn more about the safety and effectiveness of a hybrid sinus node sparing ablation procedure to treat IST. The heart doctor will create scars, or lesions, in parts of the heart to stop the IST from causing symptoms.

## THOSE ENROLLED

The people in the trial must be diagnosed with IST. They have also been treated — for instance, with medications — yet the treatment has not been successful, or it has caused too many side effects. As a result, the symptoms of IST continue to be a problem.

## LESIONS ON THE OUTSIDE OF THE HEART

The heart doctor creates lesions on the outside of the heart in certain areas: (1) superior vena cava; (2) crista terminalis; and (3) inferior vena cava.



## MAPPING SHOWS HEART RHYTHM ACTIVITY INSIDE THE HEART

The doctor will do mapping of the heart, creating a detailed, 3-D map. The map shows precisely where the heartbeat begins and where the rhythm moves through the tissues of the heart. The map guides the doctor regarding:

- ☐ Where to create lesions on the outside of the heart
- ☐ Where lesions might also be placed inside the heart—only if needed—to help stop IST





## **COSTS AND COMPENSATION FOR THE HEAL-IST CLINICAL TRIAL**

### **COSTS ARE COVERED**

All costs of the procedure will be billed to the patient's health insurance. If any tests or procedures (required by the HEAL-IST clinical trial) are not covered by the person's insurance, those costs will be covered by AtriCure, Inc. AtriCure is the company sponsoring the HEAL-IST clinical trial.

### **EXPENSES ARE PAID**

People in the trial are paid for the costs of time and travel. They will be paid as long as they go to each scheduled visit. The exact amount will be discussed during the initial patient visit.

## **BENEFITS AND RISKS OF THE HEAL-IST CLINICAL TRIAL**

Insights gained from this trial may benefit other people with IST.

The trial doctor and/or research staff will discuss risks with each person at the screening visit.



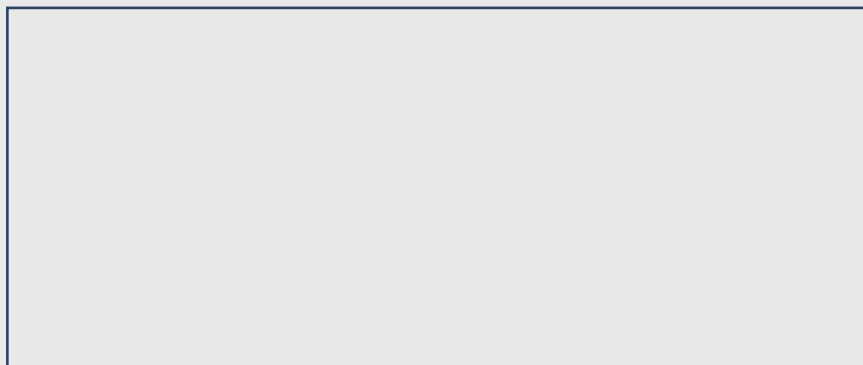
## ARE YOU A CANDIDATE FOR THE HEAL-IST CLINICAL TRIAL?

You may qualify for the HEAL-IST Clinical Trial if all of the following apply to you:

- ☐ You are between 18 and 75 years of age
- ☐ You have been diagnosed with IST
- ☐ You are willing and able to receive all the trial-related procedures and go to the scheduled follow-up visits over a 2-year period of time
- ☐ You are willing to provide written informed consent

Your trial doctor or research staff will discuss the full list of inclusion criteria with you.

**If you have questions about this trial, or you want more information, contact:**



**Caution:** Investigational therapy. Limited by federal (or United States) law to investigational use.

AtriCure — delivering best-in-class solutions to treat even the most complex cases.

#### **References**

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AtriCure, Inc. of Mason, Ohio,  
is the sponsor of the HEAL-IST Clinical Trial.  
7555 Innovation Way, Mason, Ohio 45040 USA  
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