

# The INNOVATE Trial for the BrioVAD® System

Evaluating a New Left  
Ventricular Assist Device  
(LVAD) for Heart Failure

## Left Ventricular Assist Devices

A left ventricular assist device (LVAD) is implanted in your chest. The LVAD helps pump blood to your body that your sick heart can't, allowing you the chance to live your life and do the activities you enjoy.

These devices consist of parts used inside and outside of your body:

### Inside

- Pump implanted in your chest during surgery

### Outside

- Controller and battery pack worn outside the body
- Driveline cable comes out of your body to connect the pump to the controller and battery pack

LVADs can help extend and improve the lives of people with advanced heart failure.



## The BrioVAD® System

The BrioVAD System is designed to reduce complications from treating advanced heart failure.

The BrioVAD System is different from other LVAD technology in many ways:



The pump uses advanced technology designed to minimize blood damage and potentially reduce blood clots



The smaller pump fits patients better

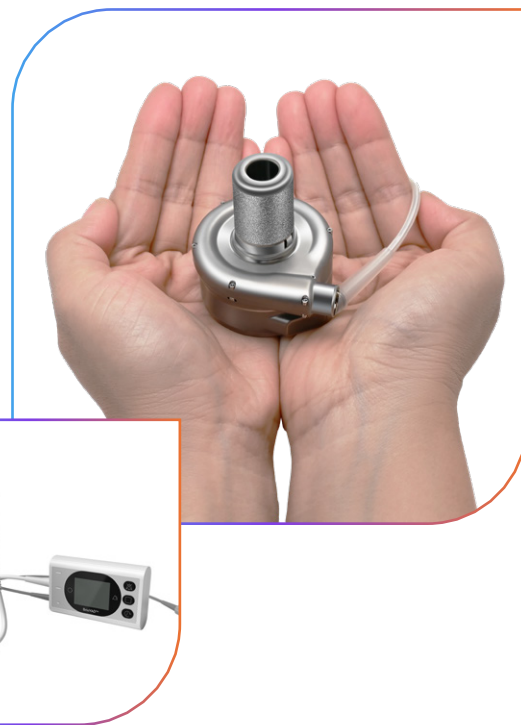


The controller and battery are lighter and designed with fewer connections



The driveline that connects the pump to the controller is flexible and smaller for better patient comfort and to potentially reduce infection where it exits the body

More than 300 patients outside the U.S. have received the BrioVAD pump being used in the INNOVATE Trial.

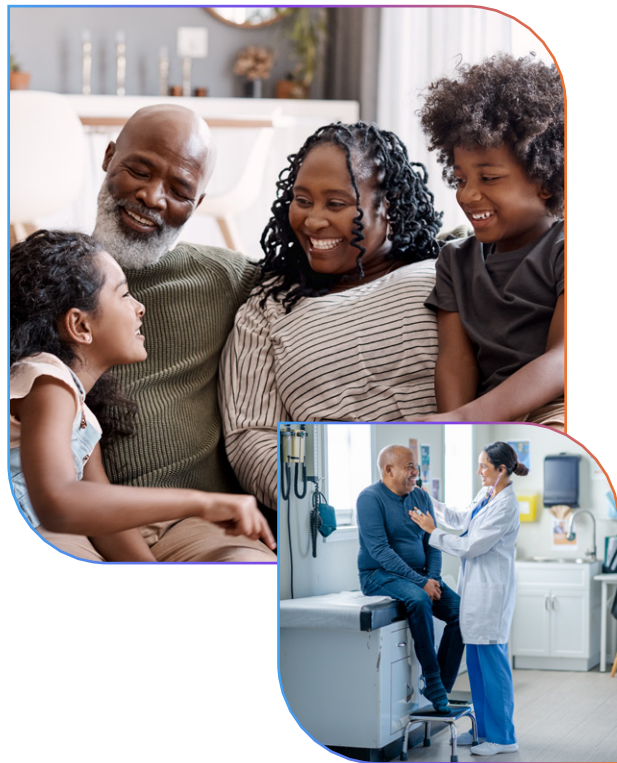


## The INNOVATE Trial

The INNOVATE Trial is evaluating how safe and effective a new LVAD is and if it works. The new LVAD is called the BrioVAD® System.

The INNOVATE Trial is enrolling about 800 patients at leading medical centers across the U.S. The trial will look at overall survival and if you have complications. It will also look at quality of life – or how you feel with the LVAD. The trial will also see if patients living with the BrioVAD System spend less time in the hospital.

The INNOVATE Trial is randomized. This means that participants will receive either the BrioVAD System or another LVAD. Participants have a 2 in 3 chance of receiving the new BrioVAD System.



## What to Expect in the INNOVATE Trial

Your heart failure care team will determine if you are eligible to be part of the INNOVATE Trial. They will likely perform a series of tests and evaluations to decide.

Participating in a clinical study such as the INNOVATE TRIAL offers you access to LVAD treatment and scheduled check-ups as part of the trial plan. This may result in more detailed evaluation of you and your advanced heart failure care. You will be evaluated at regular times: one, three, six, 12, 18 and 24 months after you receive your LVAD. At these check-ups, you will be asked to complete questionnaires, forms, lab testing, echocardiograms and physical examinations.

The same check-ups are required regardless of which LVAD you receive.

You may receive compensation for study check-ups that are not part of routine LVAD care.

## Why Participate in a Clinical Trial?

Development of new treatments depends on patient participation in clinical trials. The knowledge gained from the INNOVATE Trial will be used to help patients now and in the future, in your community and across the country.

*A complete review of risks will be covered in the consent form.*



If you would like more information about the INNOVATE Trial, please visit:  
[www.BrioHealthSolutions.com/INNOVATE](http://www.BrioHealthSolutions.com/INNOVATE)