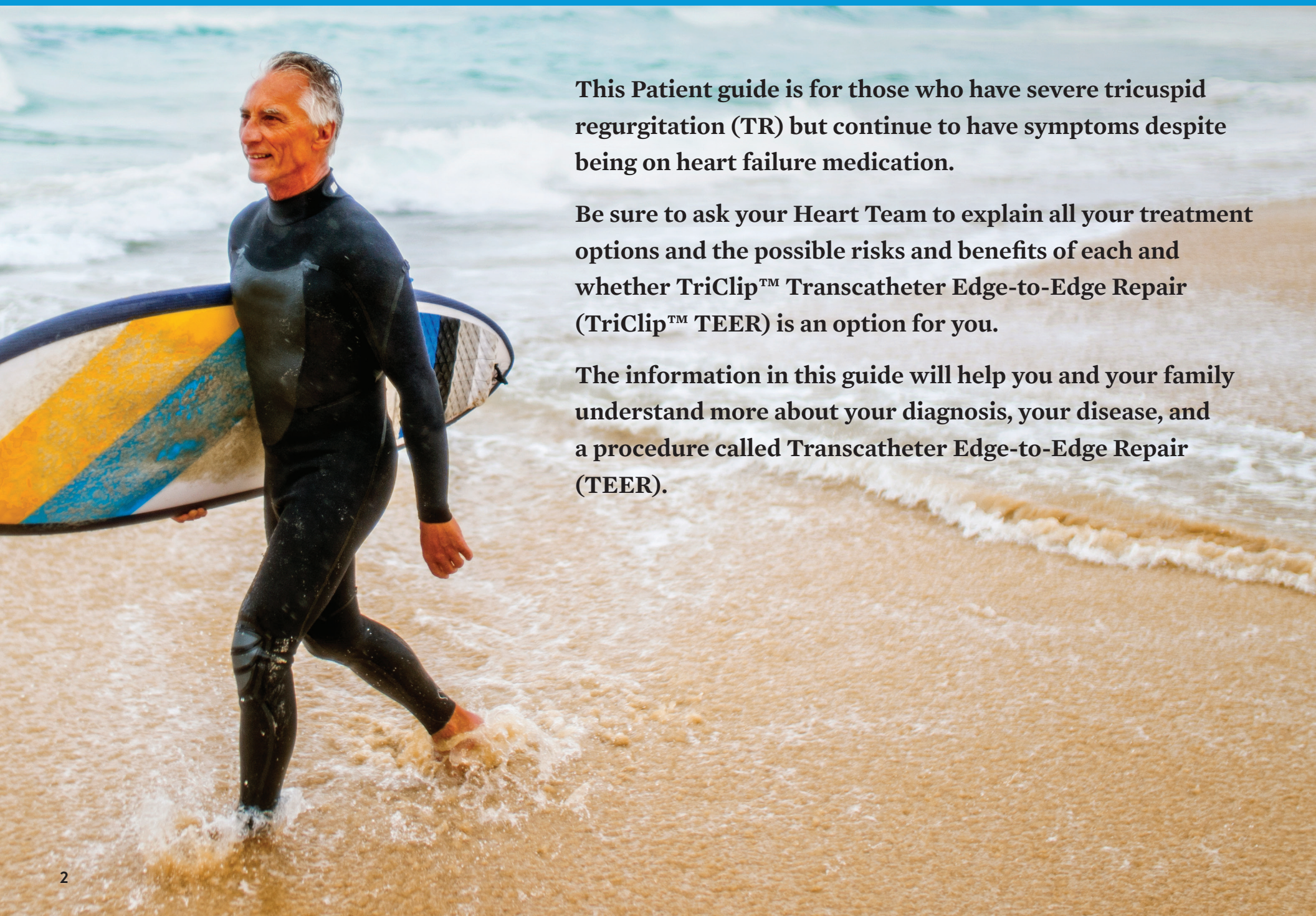


Abbott Transcatheter Tricuspid Valve Repair System

A GUIDE FOR PATIENTS WITH TRICUSPID REGURGITATION

TRICLIP™ Transcatheter Edge-To-Edge
Repair System





This Patient guide is for those who have severe tricuspid regurgitation (TR) but continue to have symptoms despite being on heart failure medication.

Be sure to ask your Heart Team to explain all your treatment options and the possible risks and benefits of each and whether TriClip™ Transcatheter Edge-to-Edge Repair (TriClip™ TEER) is an option for you.

The information in this guide will help you and your family understand more about your diagnosis, your disease, and a procedure called Transcatheter Edge-to-Edge Repair (TEER).

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Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutrition and branded generic medicines. Abbott serves patients in more than 160 countries.

The Abbott TriClip™ System is designed to repair and restore the tricuspid valve without open heart surgery and help reduce or eliminate tricuspid regurgitation.

WHAT IS TRICUSPID REGURGITATION?

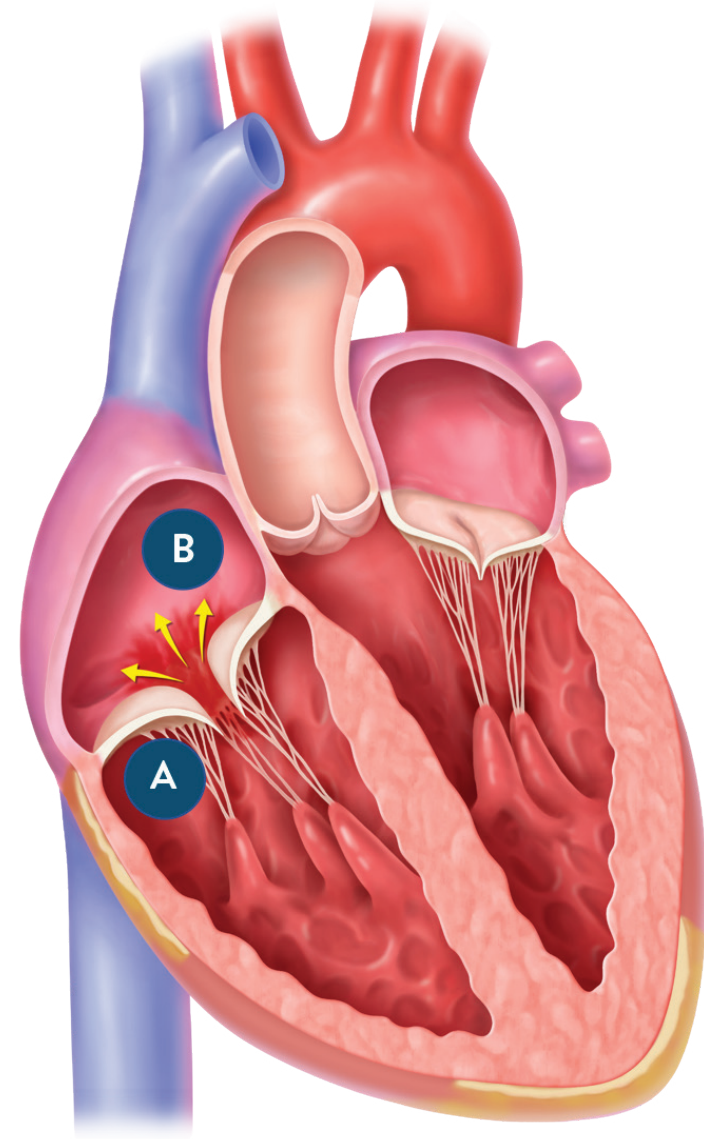
Tricuspid Regurgitation (TR) occurs when the tricuspid valve on the right side of the heart does not close properly and, as a result, blood flows backward from the lower chamber (right ventricle) into the upper chamber (right atrium) making the heart work harder to move blood through the body.

This typically occurs because:

- The right lower chamber becomes bigger and pulls the muscles connected to the valve leaflets (flaps), causing them to spread apart.
- The right upper chamber becomes bigger, causing the tricuspid valve annulus (a ring-shaped structure between the right lower chamber and right upper chamber) to become bigger.
- The leaflets are damaged.

TR worsens with time. It often does not cause signs or symptoms until the disease is severe. With TR, you may have shortness of breath or feel weak. It may also cause abnormal heart beats or swelling in your abdomen, ankles, neck, or feet. These symptoms can seriously affect your quality of life.

Heart With Tricuspid Regurgitation



A The tricuspid valve does not close properly due to an enlarged heart chamber or an issue with the valve's leaflets.

B As a result, blood leaks backward into the upper chamber (right atrium) instead of being pushed to the lungs.





Medication

Your doctor may prescribe certain medications to help reduce some of your symptoms. However, they may not be adequate to treat your TR symptoms.

Surgical Valve Intervention

During open heart surgery the doctor opens your chest to repair (with bands, a ring, or stitches) or replace (with an artificial valve) the damaged valve. Tricuspid valve surgery is often performed with a heart valve procedure on the left side of your heart. During surgery, you are connected to a heart-lung machine that temporarily does the work of your heart and keeps the blood flowing throughout your body. After surgery, you are expected to stay in the hospital for a week or more, followed by a period of recovery.

Transcatheter Valve Replacement

During a transcatheter tricuspid valve replacement procedure, the doctor replaces your leaky tricuspid valve with an artificial valve without open heart surgery, using a delivery catheter (a tube-like device).

What is the Best Treatment for you?

A team of doctors will evaluate you for all treatment options. They will consider the following factors to decide the most appropriate treatment option for you:

- Your medical history
- Your age
- Your current health status
- Your ability to undergo a surgical or transcatheter procedure and recover from it
- The overall condition of your heart

What Are the Benefits of the TriClip™ Procedure?

Potential benefits may include:

- Reduced TR
- Improved heart function (e.g. reversal of heart enlargement and ability for the heart to pump blood more efficiently)
- Improved quality of life (e.g. ability to enjoy hobbies, perform household chores, and visit friends and family)*
- Relief of symptoms (e.g. decreased swelling of the legs, ankles, and feet, less fatigue, and less shortness of breath)*
- Shorter recovery time compared to surgery

* The degree of improvement will depend on your medical status before undergoing the TriClip Procedure.

TRICLIP™ TRANSCATHETER EDGE-TO-EDGE REPAIR (TRICLIP™ TEER)

During a transcatheter tricuspid valve repair procedure, the doctor places one or more clips (shown on the next page) to repair your valve.

Compared to surgery, a transcatheter repair is less invasive and you are expected to have less pain, a shorter hospital stay, and a shorter recovery time.

THE TRICLIP™ SYSTEM

Designed to repair your tricuspid valve and reduce or eliminate tricuspid regurgitation

The TriClip™ System is part of the latest technology from Abbott. The TriClip™ Implant is a small device (see picture below) that is implanted through a catheter (a thin tube), without the need for open-heart surgery. The TriClip System reduces TR by clipping the leaflets (the flaps) of the tricuspid valve together, resulting in the reduction or prevention of backward flow of blood from the right ventricle into the right atrium. The Implant is made with metal alloys and is covered in a polyester fabric that is commonly used in cardiovascular implants.

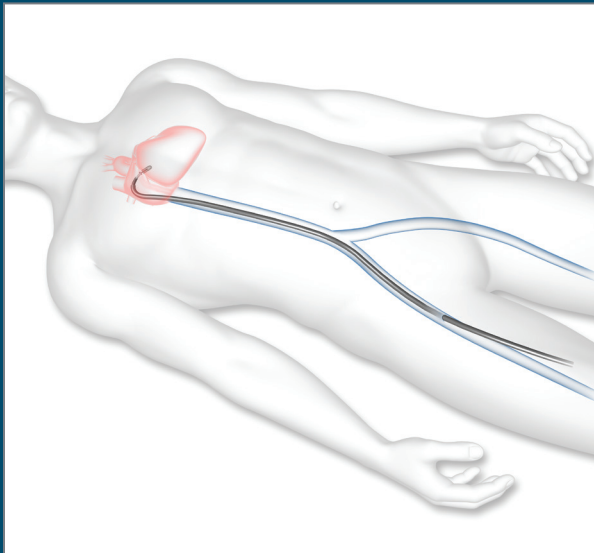


WHAT HAPPENS DURING THE TRICLIP™ PROCEDURE?

This section describes what happens during a transcatheter tricuspid valve repair procedure and is intended as a general overview. Your experience may be different. Please ask your doctor for more information about what you should expect if you have any questions.

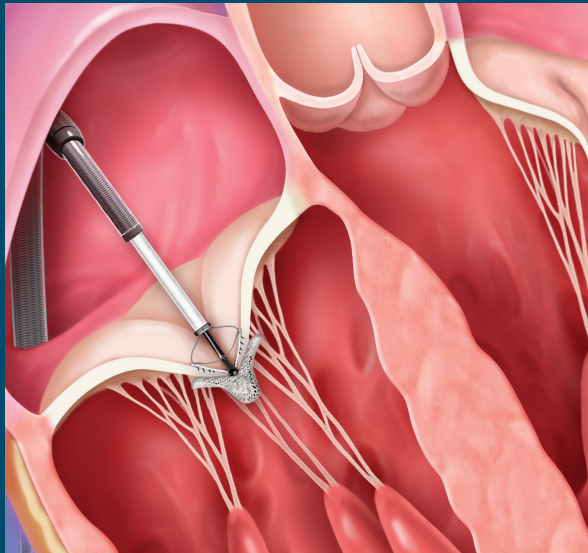


ON AVERAGE, A TRICLIP PROCEDURE LASTS ABOUT 2 HOURS



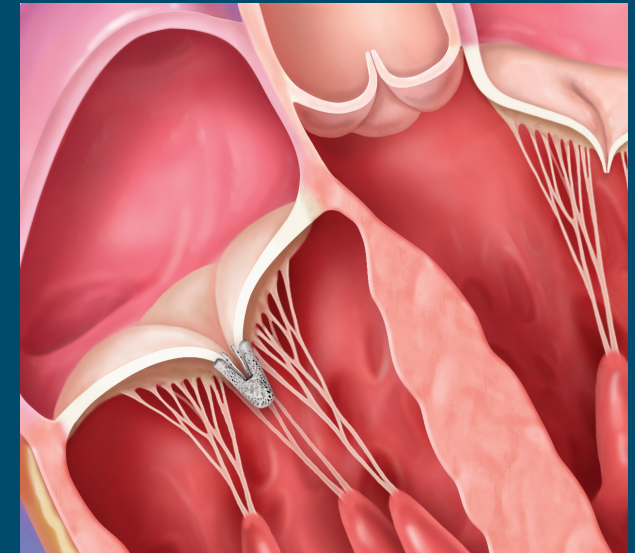
1

Your doctor will make a small puncture in your groin to access your vein and insert a delivery system catheter to reach your heart.



2

The device will be advanced through the vein to the diseased tricuspid valve and positioned in the appropriate location within your heart.



3

One or more TriClip™ Implants will be deployed to reduce your TR.



What happens after the TriClip™ Procedure?

After your procedure, you may spend on average 1-2 days in the hospital. The recovery time may differ among patients.


Before you leave the hospital, your doctor will discuss next steps with you. They will give you specific instructions to help you with your recovery. It is important to carefully follow your doctor's directions, especially if you need to take any medications.

Follow-up Visits

Regular check-ups with your doctor are very important. You will be released to the care of your cardiologist or family doctor, and you may be asked to return for follow-up visits per your doctor's directions. It's important that you call or see your doctor whenever you have questions or concerns about your health.

Your Abbott Implant Card

As you leave the hospital, you will receive an Implant card, which has information about your TriClip™ Implant. Please share this card with all members of your healthcare team, including your dentist. It is important to share your Implant card before any medical, dental, or MRI (magnetic resonance imaging) procedures. If you need an MRI, inform your doctor that you have an Abbott TriClip Implant.

 **Abbott** Sample Implant Identification Card

Patient Name: _____

Implant Date: _____

Device LOT#: _____

Implanting Physician: _____

Physician Phone: _____

Abbott Medical, 177 County Road B East, St. Paul, MN 55117 USA
TEL: +1 855 478 5833 FAX: +1 651 756 5833
Outside USA TEL: +1 855 478 5833 Outside USA FAX: +1 651 765 5833
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English
(continued on reverse)

**Please carry this card at all times.
Show it to any medical personnel
who may be treating you.**



This person is implanted with a metal implant attached to the leaflets of the tricuspid valve and can be safely scanned only under very specific conditions. Scanning under different conditions may result in severe injury or device malfunction. Full MRI safety information is available in the MRI Safety Information section of the Instructions for use which can be obtained at efu.abbott or by calling +1 855 478 5833.

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For more information on your Implant card, please go to Abbott.com

CLINICAL DATA

The safety and effectiveness of the TriClip™ System was studied in a clinical trial that enrolled over 600 patients. These patients had symptoms from severe TR despite being on heart failure medication. The table below shows the risk of complications that were seen in patients following tricuspid valve repair with the TriClip System through 1 year.

TRICLIP™ TRANSCATHETER EDGE-TO-EDGE REPAIR (TRICLIP™ TEER) WITH THE TRICLIP™ G4 SYSTEM	RISK WITHIN 30 DAYS	RISK WITHIN 1 YEAR
Major Complications		
Death from any cause	1 out of 100	9 out of 100
Death from heart related cause	1 out of 100	6 out of 100
Stroke	1 out of 100	2 out of 100
Tricuspid valve surgery	1 out of 100	2 out of 100
Tricuspid valve intervention	2 out of 100	2 out of 100
Hospitalization for heart failure	4 out of 100	15 out of 100
Transient ischemic attack	0 out of 100	1 out of 100
Cardiac shock	0 out of 100	0 out of 100
Permanent pacemaker implant	1 out of 100	3 out of 100
Heart attack (myocardial infarction)	0 out of 100	
New onset renal failure	1 out of 100	
Major bleeding	5 out of 100	
Cardiac surgery for TriClip related adverse event	0 out of 100	
Endocarditis (infection of a heart valve) requiring surgery	0 out of 100	

CLINICAL DATA

The main benefit patients experienced in the clinical study was an improved quality of life as measured by the Kansas City Cardiomyopathy Questionnaire. This is a survey used by doctors and researchers to understand how heart disease affects a person's quality of life. It asks questions about symptoms like shortness of breath, fatigue, and chest pain, as well as how heart disease impacts daily activities and overall well-being. An improvement of 5 points in this survey is a small but meaningful change, and an improvement of 15 points is considered to be a moderate to large improvement in health status.

The table below shows the probability that patients in the clinical study experienced an improvement in KCCQ score by at least 15 points. Patients who have good baseline quality of life may not experience further improvement in quality of life with the TriClip™ G4 System. Patients on average are unlikely to experience any survival benefit or a reduced rate of heart failure-related hospitalization compared to treatment with medical therapy alone.

TRICLIP™ TRANSCATHETER EDGE-TO-EDGE REPAIR (TRICLIP™ TEER) WITH THE TRICLIP™ G4 SYSTEM	PATIENTS TREATED WITH TRICLIP + MEDICAL THERAPY	PATIENTS TREATED WITH MEDICAL THERAPY
Probability of experiencing an improvement in KCCQ-OS by at least ≥ 15 points at 12 months	1 out of 2	1 out of 4

PRECAUTIONS

- If you have a diseased valve or a heart pacemaker, your doctor will carefully assess if TriClip™ therapy is appropriate for you.
- Patients who have had a TriClip™ Procedure should receive antibiotic medication before any medical or dental procedure to lessen the chance of infection.
- The TriClip™ System has not been tested in pregnant or lactating women, children or infants.

THE TRICLIP™ SYSTEM CANNOT BE USED IN PEOPLE WHO:

- Have an active infection in the heart
- Have an untreatable allergy to nickel-titanium or cobalt chromium alloys or blood thinning medications



As with any medical procedure, there is a possibility of complications. The most serious risks of the TriClip™ Procedure include:

- **Death**
- **Stroke:** A condition in which decreased blood flow to the brain can result in brain damage and may cause severe disability
- **Transient ischemic attack:** Stroke symptoms that last only a few minutes
- **Major vascular complications:** Damage to a major blood vessel that may require surgery
- **Life threatening bleeding event:** a major bleeding event that requires a blood transfusion

Additional potential risks associated with the procedure include:

- Heart attack
- Worsening heart failure
- Failure of your heart to pump enough blood to the body organs
- Foreign particles (air, blood clot, or device material) floating in the bloodstream or attached to a blood vessel, that may cause blockage in blood flow
- Infection in your heart, blood, or other areas
- Injury to your blood vessels or heart which may require additional surgery or other intervention
- Blocking, tightening, narrowing, or bulging of a blood vessel
- Trouble or inability to breathe
- Swelling caused by fluid build-up
- Irregular heartbeat
- Abnormally high or low blood pressure
- Pain
- A wound that does not close or heal properly
- Fever
- Incorrect positioning, inability to implant, or movement of the TriClip™ G4 Implant
- Continuing tricuspid regurgitation through the tricuspid valve
- Blocking, narrowing, or injury to the tricuspid valve
- Additional treatment or surgery
- Nausea or vomiting
- Chest pain
- Throat irritation
- Injury or narrowing of the throat
- Worsening kidney function or kidney failure
- Blood disorders
- Skin injury or tissue changes due to exposure to radiation
- Allergic reactions
- Lung failure
- Nerve damage caused by compression of the nerves, injury to the nerve or interruption of blood supply to the nerves

CONTACT INFORMATION

For more information on the
TriClip™ Procedure, please
contact Abbott:

Toll-free phone in the USA:
1-800-544-1664

Email Address:
SHcustomerservice@Abbott.com

Mail:
Abbott
177 County Road B East
St. Paul, MN 55117



CAUTION : Product(s) intended for use by or under the direction of a physician. Prior to use, reference to the Instructions for Use, inside the product carton (when available), at eifu.abbott or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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