



# A Guide to Treating Your Tricuspid Regurgitation

**TriClip**<sup>™</sup>

Transcatheter Edge-to-Edge Repair



**Abbott**

**THIS BELONGS TO:**

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Dear Patient,

Our mission at Abbott is to restore people’s health and improve their quality of life. We are delighted that you have taken the first steps toward treating your tricuspid regurgitation with transcatheter edge-to-edge repair (TEER).

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

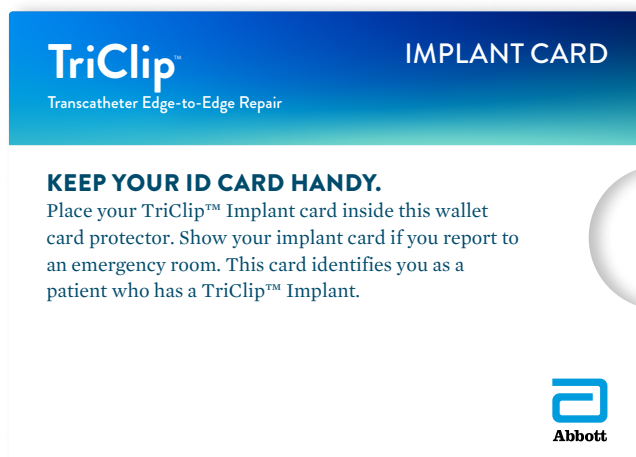
Please take the time to review the information found in this guide, as well as share it with your loved ones and friends. If you have any additional questions, please reach out to the healthcare professionals in your local Heart Team.

We wish you all the best and good health!



Lars Sondergaard,  
Chief Medical Officer

## YOUR IMPLANT CARD



# APPOINTMENTS

## MY TRICLIP™ PROCEDURE IS SCHEDULED:

Date/time: \_\_\_\_\_

Location: \_\_\_\_\_

Arrival Time: \_\_\_\_\_

## MY \_\_\_\_\_ FOLLOW-UP VISIT IS SCHEDULED:

Date/time: \_\_\_\_\_

Location: \_\_\_\_\_

Arrival Time: \_\_\_\_\_

## MY \_\_\_\_\_ FOLLOW-UP VISIT IS SCHEDULED:

Date/time: \_\_\_\_\_

Location: \_\_\_\_\_

Arrival Time: \_\_\_\_\_

## MY \_\_\_\_\_ FOLLOW-UP VISIT IS SCHEDULED:

Date/time: \_\_\_\_\_

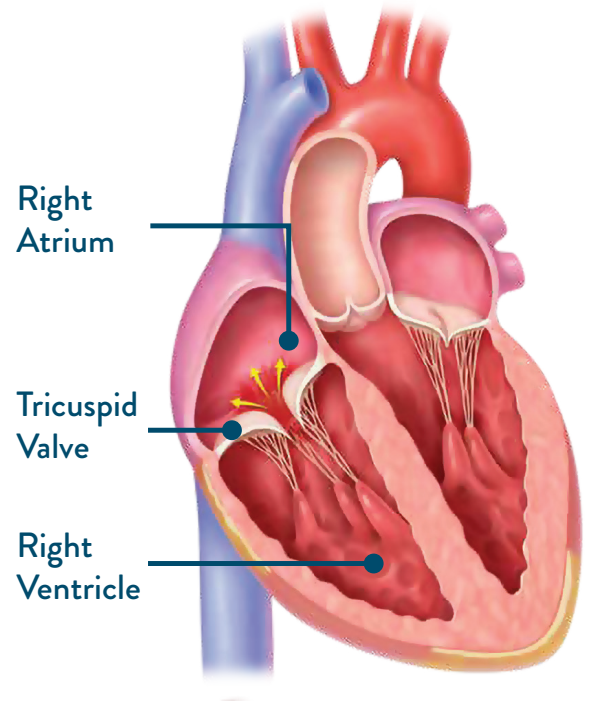
Location: \_\_\_\_\_

Arrival Time: \_\_\_\_\_

# WHAT IS TRICUSPID REGURGITATION?

Tricuspid Regurgitation (TR) is a condition affecting the tricuspid valve and occurs when the tricuspid valve fails to close completely, allowing the blood to leak backward into the upper chamber of the heart (right atrium).

TR worsens over 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, and limit your ability to complete simple day-to-day tasks.



## WHAT ARE THE SYMPTOMS?



FEELING WEAK



ABNORMAL HEARTBEATS



SHORTNESS OF BREATH



SWELLING IN ABDOMEN,  
ANKLES, NECK, OR FEET

# WHAT ARE THE TREATMENT OPTIONS?



## 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.



## TRANSCATHETER EDGE-TO-EDGE REPAIR (TEER)

TriClip™ TEER is a minimally invasive treatment to repair your leaking tricuspid valve using an implanted clip, delivered through a catheter (a tube-like device).



## TRANSCATHETER VALVE REPLACEMENT

If your tricuspid valve cannot be repaired, your doctor may recommend valve replacement with an artificial (prosthetic) valve. During a transcatheter tricuspid valve replacement procedure, the doctor replaces your leaky tricuspid valve with an artificial valve, delivered through a catheter (a tube-like device).



## TRICUSPID VALVE SURGERY

If your tricuspid valve cannot be repaired or replaced, your doctor may recommend open heart surgery to repair (with bands, a ring, or stitches) or replace the damaged valve with an artificial valve. 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, and you may stay in the hospital for a week or more.



DISCUSS ALL TREATMENT OPTIONS WITH YOUR DOCTOR.

Your doctor can describe the risks and benefits and help you decide which option is right for you.

# THE TRICLIP™ PROCEDURE

## DESIGNED TO REPAIR YOUR TRICUSPID VALVE AND REDUCE TR

TriClip™ Therapy is a simple procedure to fix your tricuspid valve. Doctors access the tricuspid valve with a catheter that is guided through a vein in your leg to reach your heart. A small implant is attached to your tricuspid valve to help it close more completely. This helps restore normal blood flow through your heart.

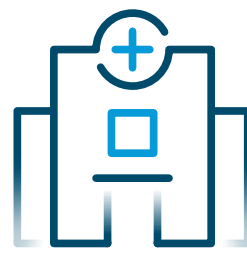
Tricuspid valve repair with the TriClip™ Implant is a safe, effective, and well-studied procedure. Highlights include:



**MINIMALLY  
INVASIVE**



**QUICK  
PROCEDURE**



**SHORT  
HOSPITAL STAY**

## TriClip™

Transcatheter Edge-to-Edge Repair

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™ Implant is  
about the size of a dime.**



## WHAT IS THE BEST TREATMENT FOR YOU?

A team of doctors will evaluate you for all treatment options and will consider the following factors when deciding the most appropriate treatment:

- Your age, medical history, and 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:** Reversal of heart enlargement and ability for the heart to pump blood more efficiently
- **Improved quality of life:** Ability to enjoy hobbies, perform household chores, and visit friends and family\*
- **Relief of symptoms:** Decreased swelling of the legs, ankles, and feet, less fatigue, and less shortness of breath\*
- Shorter recovery time compared to surgery

## WHAT DOES IMPROVED QUALITY OF LIFE MEAN TO YOU?\*

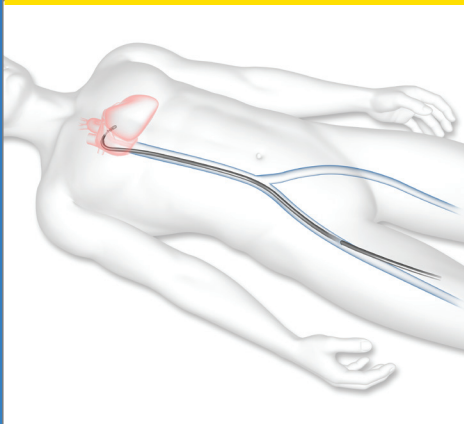
- Rejoining family and friends on day-to-day outings
- Sleeping more comfortably at night
- Reduced swelling to wear regular shoes again

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

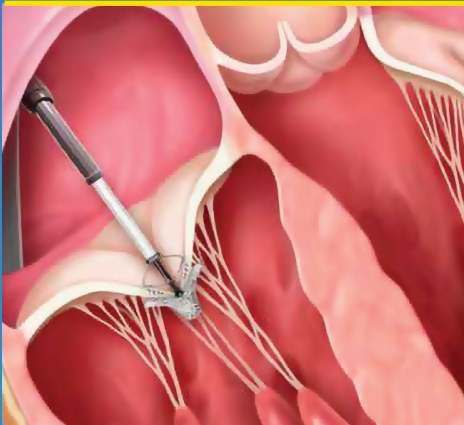


# WHAT HAPPENS DURING THE PROCEDURE?

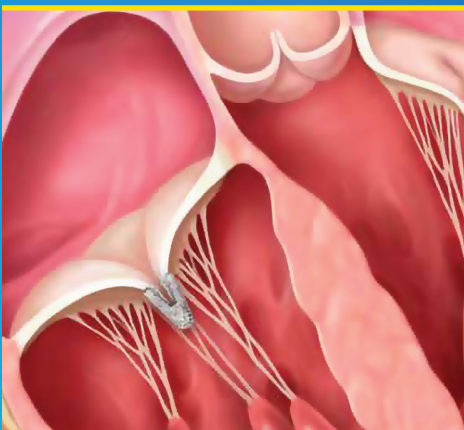
The following steps provide a general overview of the TriClip™ Procedure — your experience may be different. Your doctor will explain the procedure to you and can provide you with specific details and answer any questions you may have.



- 1** Your doctor will make a small puncture in your groin to access your vein and insert a catheter to reach your heart.



- 2** The Implant 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 tricuspid regurgitation.

# AFTER THE PROCEDURE

## WHAT HAPPENS AFTER THE TRICLIP™ PROCEDURE?

Clinical data from patients who underwent the TriClip™ Procedure demonstrate an immediate reduction of tricuspid regurgitation.

After your procedure, you may spend on average 1–2 days in the hospital. Most patients are discharged right to their homes.

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.

## HOW LONG BEFORE I FEEL THE EFFECTS OF THE TRICLIP™ PROCEDURE?


You should experience significant improvement in your symptoms of tricuspid regurgitation and quality of life soon after your procedure. It is important to discuss what to expect following the procedure with your Structural Heart Team.

## 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 your Implant card with all members of your healthcare team, and before any medical, dental, or MRI (magnetic resonance imaging) procedures.

	TriClip™ System Patient Implant Card
Patient Name:	_____
Implant Date:	_____
Device LOT#:	_____
Implanting Physician:	_____
Physician Phone:	_____
<small>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: +1 651 756 5833 ™ Indicates a trademark of the Abbott group of companies.</small>	
<small>(continued on reverse)</small>	

IT'S GOOD TO BE BACK HOME,  
BUT REMEMBER TO TAKE TIME  
TO RECOVER.



# RECOVERING AFTER YOUR PROCEDURE

You should be back to your baseline activity at 1-2 weeks. Your doctor will provide more detailed instructions about when you can return to normal activities. For now, be sure that you are familiar with these important recovery tips.

## TEND TO YOUR ACCESS SITE

### Keep your access site dry for the first 24 hours

- Avoid soaking the area, you are likely able to take a shower
- Avoid perfumes, lotions, etc.

### If bruising around the access site suddenly gets bigger or harder:

- Call your doctor immediately
- If any bleeding occurs, or if symptoms worsen, you may need to seek emergency medical treatment.



**Call for help if you experience any of the below symptoms.  
Contact your doctor or emergency services.**

- 1 You experience an increase in shortness of breath or sudden chest pain that doesn't go away with rest or medication**
- 2 You feel dizzy, very tired or faint, or have a fever**
- 3 You have weight gain greater than 2lbs overnight**
- 4 You cannot keep taking your medications because of side effects, such as rash, bleeding, or upset stomach**
- 5 The access site is bleeding, becomes swollen, red, painful or has yellow or green discharge**

# PRE-PROCEDURE TESTS

Your doctor may order some of the tests below.

<input checked="" type="checkbox"/> Ordered	TEST	PURPOSE/EXPLANATION	<input checked="" type="checkbox"/> Completed
<input type="checkbox"/>	<b>Transthoracic Echocardiogram (TTE)</b>	An ultrasound of your heart which shows how your heart and valves are functioning	<input type="checkbox"/>
<input type="checkbox"/>	<b>Transesophageal Echocardiogram (TEE)</b>	An ultrasound of your heart, performed with sedation, which shows how your heart and valves are functioning. The probe is placed in your throat for closer images of your tricuspid valve	<input type="checkbox"/>
<input type="checkbox"/>	<b>Cardiac Assessment</b>	Your physician may order an invasive or non-invasive test to evaluate your heart anatomy and measure pressures within the heart	<input type="checkbox"/>
<input type="checkbox"/>	<b>Electrocardiogram (EKG/ECG)</b>	Evaluates the electrical rhythm of your heart	<input type="checkbox"/>
<input type="checkbox"/>	<b>6-Minute Walk Test</b>	Timed walk test done during the office visit to assess balance, mobility, and exercise capacity	<input type="checkbox"/>
<input type="checkbox"/>	<b>Kansas City Cardiomyopathy Questionnaire (KCCQ)</b>	A questionnaire to measure your quality of life	<input type="checkbox"/>
<input type="checkbox"/>	<b>Laboratory Tests</b>	Baseline blood work prior to procedure	<input type="checkbox"/>
<input type="checkbox"/>	<b>Chest X-Ray</b>	Non-invasive imaging to review any lung abnormalities	<input type="checkbox"/>
<input type="checkbox"/>	<b>Other</b>		<input type="checkbox"/>

# CONVERSATIONS WITH YOUR CLINICIAN

The following are some suggested questions as you discuss your treatment plan. Be sure to write down any questions you have and bring them to your scheduled appointments.

1. What are the benefits and risks of TriClip™ vs. surgery?

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2. Is there any type of access site care that will need to be managed?

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3. What type of sedation will be used for the procedure?

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4. How long will I be in the hospital? Will I go home or into rehab?

Will someone need to drive me home?

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5. After the procedure, are there medications that I need to take or will there be a change in my medications? What are my recovery instructions?

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6. What type of support should I arrange in advance for after I am discharged?

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7. When can I return to work/normal activities?

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# 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.

TRANSCATHETER EDGE-TO-EDGE REPAIR (TEER) WITH THE TRICLIP™ G4 SYSTEM	RISK WITHIN 30 DAYS	RISK WITHIN 1 YEAR
<b>Major Complications</b>		
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	Data collected at 30 days only, per clinical trial design*
Cardiac surgery for TriClip™ related adverse event	0 out of 100	
Endocarditis (infection of a heart valve) requiring surgery	0 out of 100	

\*These events were only tracked through 30 days to look for possible device or procedure related adverse events.



## QUALITY OF LIFE

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 a good baseline quality of life may not experience further improvement in quality of life with the TriClip™ 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.

<b>TRANSCATHETER EDGE-TO-EDGE REPAIR (TEER) WITH THE TRICLIP™ G4 SYSTEM</b>	<b>PATIENTS TREATED WITH TRICLIP™ + MEDICAL THERAPY</b>	<b>PATIENTS TREATED WITH MEDICAL THERAPY</b>
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.

### WHO SHOULD NOT HAVE THE PROCEDURE

**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

# RISKS

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™ 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

# RESOURCES FOR CAREGIVERS

As a caregiver, you have an important role to play in supporting the recovery of the patient. Below are things you should be considering both before and after the procedure.

1

## **Accompany the patient to their doctor's visits.**

If possible, join the patient on their visit to help ensure they bring their list of questions for the heart team, and that those questions are answered and written down. Bring your own list of questions, as well. A list of suggested questions is provided in the back of this guide.

2

## **Check that the patient has prepared their legal documents.**

If needed, work with the patient to make sure their legal documents are organized and ready before the procedure.

3

## **Help the patient pack for their hospital stay.**

It can be easy to forget a needed item—Prepare a packing list to help ensure everything is there for the patient to have a more comfortable stay.

4

## **Go over the discharge plan ahead of time.**

Once the patient is home, they may need additional support in many ways. They may need assistance taking their medicines and getting to follow-up doctor visits. They may also need help with their routine care and chores or errands around the home.

5

## **Watch over the patient's physical activity after their procedure.**

Make sure they are following the heart team's instructions.

6

## **Help the patient develop and maintain healthy eating habits.**

It's important to understand dietary changes recommended for the patient, and to help them create and stick to a well-balanced diet.



# NOTES

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# 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](mailto:SHcustomerservice@Abbott.com)

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

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