Important Safety Information

TRICLIP™ G5 SYSTEM

Rx ONLY **INDICATIONS**

The TriClip™ G5 System is indicated for improving quality of life and functional status in patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy, who are at intermediate or greater risk for surgery and in whom transcatheter edge-to-edge valve repair is clinically appropriate and is expected to reduce tricuspid regurgitation severity to moderate or less, as determined by a multidisciplinary heart team.

CONTRAINDICATIONS

The TriClip™ G5 System is contraindicated for use in patients with the following conditions:

- Intolerance, including allergy or untreatable hypersensitivity, to procedural anticoagulation
- Untreatable hypersensitivity to Implant components (nickel-titanium alloy, cobalt-chromium alloy)
- Active endocarditis or other active infection of the tricuspid valve

WARNINGS

- The TriClip™ Steerable Guide Catheter and TriClip™ G5 Delivery System are designed, intended, and distributed for single use only. Cleaning, re-sterilization and / or reuse may result in infection, malfunction of the device and other serious injury or death.
- The Stabilizer, Lift, and Support Plate are non-sterile and must be cleaned, disinfected, and/or sterilized prior to each use. Follow the cleaning, disinfection, and sterilization instructions provided with these accessories.
- The devices should be handled using standard sterile technique to prevent infection.
- Do not use the devices if the “Use by” date specified on the package has elapsed.
- Do not use the devices if the package is damaged or the packing seal is broken.
- Inspect all reusable accessories prior to use. Do not use if the devices are damaged or mishandled.
- Read all instructions carefully. Use universal precautions for biohazards and sharps while handling the TriClip™ G5 System to avoid user injury.
- Failure to prepare the device as stated in these instructions and failure to handle the device with care might result in damage to the device coating, which may lead to additional intervention or serious adverse events.
- Failure to follow these instructions, warnings and precautions may lead to device damage, user injury, or patient injury including:
  - Failure to deliver the TriClip™ G5 Implant to the intended site
  - Difficulty or failure to retrieve TriClip™ G5 System components

PRECAUTIONS

- The TriClip™ G5 System should be implanted with sterile techniques using fluoroscopy and transesophageal echocardiography in a facility with immediate access to cardiovascular surgery.
- Echocardiographic images should be carefully assessed to ensure they are of adequate quality to allow successful implantation of the TriClip™ G5 Implant.
- The TriClip™ G5 Procedure should be considered with caution in patients with rheumatic disease who have significant leaflet thickening and small annular dimensions considering the risk of iatrogenic tricuspid stenosis.
- Patients with pre-existing cardiac leads should be assessed to ensure placement of the TriClip™ Implant is possible.
- The safety and effectiveness of the TriClip™ G5 System has not been established in the following patient populations:
  - Pregnant or lactating women
  - Pediatric patients less than 18 years old
  - Patients with systolic pulmonary artery pressure (sPAP) >70 mmHg or fixed pre-capillary pulmonary hypertension as assessed by right heart catheterization (RHC)
  - Patients with severe uncontrolled hypertension defined as systolic blood pressure (SBP) ≥180 mmHg and/or diastolic blood pressure (DBP) ≥110 mm Hg)

POTENTIAL ADVERSE EVENTS

The following events have been identified as possible complications of the TriClip™ G5 Procedure.

- Allergic reactions or hypersensitivity to latex, contrast agent, anaesthesia, device materials and drug reactions to anticoagulation, or antiplatelet drugs
- Additional treatment / surgery from device-related complications
- Bleeding
- Blood disorders (including coagulopathy, hemolysis, and Heparin Induced Thrombocytopenia (HIT))

- Cardiac arrhythmias (including conduction disorders, atrial arrhythmias, ventricular arrhythmias)
- Cardiac ischemic conditions (including myocardial infarction, myocardial ischemia, unstable angina, and stable angina)
- Cardiac perforation
- Cardiac tamponade
- Chest pain
- Death
- Dyspnea
- Edema
- Embolization (device or components of the device)
- Endocarditis
- Fever or hyperthermia
- Fluoroscopy and Transesophageal echocardiogram (TEE) -related complications:
  - Skin injury or tissue changes due to exposure to ionizing radiation
  - Esophageal irritation
  - Esophageal perforation
  - Gastrointestinal bleeding
- Hypotension / hypertension
- Infection including:
  - Septicemia
- Nausea or vomiting
- Pain
- Pericardial effusion
- Stroke / cerebrovascular accident (CVA) and transient ischemic attack (TIA)
- System organ failure:
  - Cardio-respiratory arrest
  - Worsening heart failure
  - Pulmonary congestion
  - Respiratory dysfunction or failure or atelectasis
  - Renal insufficiency or failure
  - Shock (including cardiogenic and anaphylactic)
- Thrombosis
- Tricuspid valve complications, which may complicate or prevent later surgical repair, including:
  - Chordal entanglement / rupture
  - Single leaflet device attachment (SLDA)
  - Dislodgement of previously implanted devices
  - Tissue damage
  - Tricuspid valve stenosis
  - Worsening, persistent or residual regurgitation
- Vascular access complications which may require additional intervention, including:
  - Wound dehiscence,
  - Bleeding of the access site
  - Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation (rupture), vascular occlusion
  - Embolism (air, thrombus)
  - Peripheral nerve injury
- Venous thrombosis (including deep vein thrombosis) and thromboembolism (including pulmonary embolism)