Translation sample EN-PT (Brazilian) by Hadriano M. Lacerda – hadriano101@icloud.com

SOURCE TEXT (en):

The BioVentrix PliCath HF System consists of implantable anchors, the delivery system, and accessories which are sterile and biocompatible. These devices are used in the reconfiguration of the abnormal cardiac geometry that is causing dysfunction by excluding a portion of the ventricular chamber. The PliCath HF System is supplied as five pre-packaged sterile kits which contain implantable components and a delivery system that is used to place and secure the implantable components. The implantable components are a series of titanium anchor pairs (Hinged and Locking) covered in polyester cloth.

Exclusion Criteria

- Calcified ventricular wall in the area of intended scar exclusion as verified by echocardiography or equivalent;
- Thrombus or intra-ventricular mass in the left atrium or ventricle as verified by echocardiography or equivalent;
  Cardiac Resynchronization Therapy (CRT) device placement ≤ 60 days prior to enrollment;
- Significant diastolic dysfunction, defined as a pseudo-normal Doppler filling pattern with E/A ratio>2;
- **Thin walled, paradoxically moving septal scar that would preclude successful support of the anchor pairs as evidenced by an MRI;**
- Cardiac valve disease (except mitral valve) which, in the opinion of the investigator, will require surgery;
- Intolerance or unwillingness to take warfarin;
- Functioning pacemaker leads in antero-apical RV, which, in the opinion of the investigator, would interfere with anchor placement;