Objectives The aim of this study was to assess the feasibility, safety, and preliminary efficacy of a novel percutaneous left ventricular partitioning device (VPD) in patients with chronic heart failure (HF) and a prior anterior myocardial infarction.

Background Anterior myocardial infarction is frequently followed by left ventricular remodeling, HF, and increased long-term morbidity and mortality.

Methods Thirty-nine patients were enrolled in a multinational, nonrandomized, longitudinal investigation. The primary end point was an assessment of safety, defined as the successful delivery and deployment of the VPD and absence of device-related major adverse cardiac events over 6 months. Secondary (exploratory) efficacy end points included changes in hemodynamics and functional status and were assessed serially throughout the study.

Results Ventricular partitioning device placement was not attempted in 5 (13%) of 39 subjects. The device was safely and successfully implanted in 31 (91%) of the remaining 34 patients or 79% of all enrolled patients. The 6-month rate of device-related major adverse cardiac event occurred in 5 (13%) of 39 enrolled subjects and 5 (15%) of 34 treated subjects, with 1 additional event occurring between 6 and 12 months. For patients discharged with the device to 12 months (n = 28), New York Heart Association class (2.5 ± 0.6 to 1.3 ± 0.6, \( P < .001 \)) and quality-of-life scores (38.6 ± 6.1 to 28.4 ± 4.4, \( P < .002 \)) improved significantly; however, the 6-minute hall walk distance (358.5 ± 20.4 m to 374.7 ± 25.6 m, \( P \) nonsignificant) only trended toward improvement.

Conclusions The left VPD appears to be relatively safe and potentially effective in the treatment for patients with HF and a prior anterior myocardial infarction. However, these limited results suggest the need for further evaluation in a larger randomized controlled trial. (Am Heart J 2012;163:812-820.e1.)
disease is the most common cause of chronic HF, and the presence of a prior AMI portends a very poor prognosis compared with those with a nonischemic etiology of HF.\textsuperscript{3,4} Therapies that attenuate or reverse pathologic LV remodeling have been shown to improve functional status and outcomes in patients with HF, including those with post-AMI LV systolic dysfunction.\textsuperscript{5-10} The mechanisms by which these therapies promote reverse remodeling are varied; however, a hallmark of pathologic remodeling is progressive LV dilation due to increased wall stress. Consequently, a mechanical reduction in LV volume that lowers wall stress might be expected to promote a further reduction in LV volume over time, resulting in improved patient symptoms and outcomes. In general, surgical studies of LV volume reduction have supported but not proven this hypothesis\textsuperscript{11-14}; yet, several limitations in these surgical approaches to LV volume reduction exist. We evaluated, for the first time, a novel percutaneous device (the PARACHUTE; Cardiokinetix, Inc, Menlo Park, CA) that partitions the dysfunctional portion of the LV from the functioning portion of the LV in patients with chronic HF and a prior anterior AMI.

**Methods**

**Study population**

Between October 2005 and June 2009, 39 patients were enrolled at 12 sites in the United States and Europe. In the protocol, patients were defined as enrolled if they had signed a consent form, undergone baseline evaluation, and progressed as far as having a 14F or 16F sheath placed in the femoral artery for final in-laboratory assessment of eligibility. Participants were required to be at least 18 years old, have antero-apical akinesis (or dyskinesis) due to myocardial infarction (MI), and an LV ejection fraction of ≤40%, with a diagnosis of New York Heart Association (NYHA) classes II to IV HF on stable doses of standard HF medical therapy\textsuperscript{15} for at least 3 months before enrollment. Patients with myocardial ischemia requiring revascularization within 60 days, those with revascularization or cardiac resynchronization therapy within 60 days, and those with significant valve disease were excluded. Detailed inclusion and exclusion criteria are presented in the online Appendix. All sites obtained approval from an institutional review board or ethics committee before study commencement, and written informed consent was obtained for all subjects at the appropriate time before involvement in the study.

**Study design**

The PARACHUTE study was a prospective, single-arm, multicenter trial performed in the United States and Europe. Administratively, the study was run as 2 trials, 1 in the United States and 1 in Europe, but analyzed together because the eligibility criteria, study procedures, and end points were similar. The study was designed to assess the safety and feasibility of a novel ventricular partitioning device (VPD), described in detail below. After implantation of the device, clinical and echocardiographic follow-up was performed at 1, 3, 6, 9, 12, 24, 36, 48, and 60 months. Although the study design was to follow up patients to 60 months, the intent of this publication is to present the 12-month follow-up data (due to lack of sufficient data and power for analysis at the longer periods). Safety data were acquired continuously throughout the study. Titration of HF medications was permitted during the trial, and all patients were required to receive 12 months of aspirin and 6 months of clopidogrel post device implant. It was recommended that patients be placed on anticoagulation with warfarin for 3 months post device implant.

**Ventricular partitioning device**

**Device description and function.** The VPD, also known as the Parachute device, is a partitioning membrane deployed within the aneurysmal LV. This novel device partitions an enlarged, scarred ventricle into a dynamic and a static chamber. The static chamber is the portion of the LV volume that is distal to the device and is taken out of the circulation. Stresses placed on the partitioned myocardium and the forces previously transmitted to the apical segment are decreased both in diastole and systole, lessening the forces responsible for LV dilation. In addition to this regional unloading, the reduction in size of the dynamic chamber results in a decrease in the myocardial stress in the normal myocardium via Laplace law, providing a global unloading of the ventricle. In an ovine model, after device implantation, there was a significant reduction in LV volumes and corresponding improvement in LV systolic function.\textsuperscript{16}

**Device system components.** The system consists of three components: a) an Access System b) a Delivery System, and c) the VPD (Figure 1A, B, and C). The access system includes a guide catheter (14-16F) and a dilator, and their purpose is to provide access to the apical region of the LV. The delivery catheter has a central lumen that provides a channel for the torque shaft, at the distal end of which is a screw that engages the VPD. This catheter is used to deliver the collapsed VPD to the apex of the LV in preparation for deployment. The inner lumen on the torque shaft provides a channel for inflating and deflating a balloon located just proximal to the engagement screw. When inflated, the balloon is designed to push against the struts of the device, ensuring that the struts engage the tissue of the LV wall. The VPD is composed of a self-expanding nitinol frame, an expanded polytetrafluoroethylene (ePTFE) occlusive membrane, and a distal atrumatic (pebax polymer) foot. The nitinol frame is shaped like an umbrella with 16 struts. The tip of each strut ends in a 2-mm anchor. Upon expansion of the VPD by the delivery catheter balloon, these anchors engage the tissue, stabilize the device, and prevent dislodgment and migration after the device is detached from the delivery catheter. After the device is expanded, the occlusive membrane provides a barrier to seal off the static chamber on the distal side of the device. The distal atrumatic foot is radio-opaque and provides a contact point between the apex of the LV and the VPD. The expanded nominal diameter of the device used in the trial was either 75 or 85 mm.\textsuperscript{17}

**Study end points**

The primary end point of the PARACHUTE study was an assessment of safety, defined as the successful delivery and
deployment of this first in-man device and 6-month follow-up without the occurrence of major adverse cardiac events (MACEs) related to the investigational device as adjudicated by the Data Safety Monitoring Board.

Major adverse cardiac event was broadly defined for this trial to include cardiac death, emergent cardiac surgery, erosion of the device through the LV, cardiac tamponade, peripheral embolization (including stroke), new or worsening HF,
endocarditis or device infection, device migration or embolization, or placement of a mechanical support device. Secondary efficacy end points included hemodynamic measurements determined by echocardiography (LV volume indices, ejection fraction, and stroke volume [SV]) and functional parameters (change in 6-minute walk distance, NYHA functional class ranking, and quality of life assessed by the Minnesota Living With Heart Failure [MLWHF] quality score). New York Heart Association functional class was assessed by an independent blinded monitor at each site.

Statistical analysis

All values are reported as mean ± SEM or as medians with the interquartile range (25th-75th percentiles). Continuous variables were compared between baseline and 12-month time points using paired t test for subjects with complete sets of measurements (n = 28). Ordinal measurements were analyzed using Wilcoxon signed rank test. One-way analysis of variance (ANOVA) or Kruskal-Wallis 1-way ANOVA on ranks was used to compare variables between baseline, 6-month, and 12-month time points for all subjects and all measurements. All pairwise multiple comparison procedures were performed using Tukey test or Dunn method. All results were considered statistically significant when P < .05. The entire analysis was performed using SPSS Sigma Stat statistical software version 2.0 (SPSS, Chicago, IL).

This study was sponsored solely by CardioKinetix, Inc (Menlo Park, CA). The authors are solely responsible for the design and conduct of the study, all study analysis, the drafting and editing of the manuscript, and its final contents.

Results

VPD implant procedure data

Ventricular partitioning device placement was not attempted in 5 (13%) of the 39 patients primarily due to LV anatomical considerations that were identified during the diagnostic portion of the implant procedure. Of these 5 “non-attempts,” 4 occurred in the European portion of the trial before a change in protocol requiring cardiac computed tomographic (CT) scans before enrollment. In 1 European patient, the device was not implanted because the delivery system was too short. The system was subsequently modified to fit patients with larger anatomy. Another European subject had suboptimal 2-dimensional (2D) echocardiogram windows, which led to inaccurate estimates of ventricular size, and the procedure was aborted in the catheterization laboratory after LV angiogram was performed. Finally, in 2 European patients, there was severe apical deformity unrecognized by 2D echocardiogram, which led to the inability to place the footplate of the device safely into the apex of the LV (this also occurred in 1 US patient). Because of the European experience, the US protocol was amended to include a cardiac CT scan as part of the enrollment screening process. The cardiac CT scan improved the
accuracy of identifying the anatomy of the LV apex, the LV morphology (including “left moderator band”), and the LV size. It also helped identify severe calcification in the implant zone, which was responsible for a device migration during a European implant failure. All of these factors led to an improved implantation success rate in the US portion of the trial. In the lone US patient who was enrolled but not implanted, the device was not deployed because of difficulty in optimally positioning the foot of the VPD in the apex of the ventricle, which unfortunately was not adequately identified on CT scan.

As enrolled/not treated patients, these patients were followed up for 6 months as safety analysis only. Final subject disposition is outlined in Figure 2, and detailed demographic information, medical history, and medication use of the patients enrolled in the study are presented in Table I.

Primary end point: safety

The VPD was deployed in 34 (87%) of the 39 patients; this group was considered to have been “treated” since the VPD was released from the delivery catheter. Of these 34 patients, 1 US patient and 2 European patients had the device removed before discharge for the following reasons: (1) In patient 6, the device was surgically removed 15 days post implant as the patient was septic (subsequently found to be from a source other than the implant). (2) In patient 12, during implantation, the nitonal struts of the device could not anchor into a heavily calcified ventricular wall; thus, the device rotated on delivery and was removed surgically. Subsequently, a change in the protocol screening process was added to identify and exclude patients with calcified endocardium in the implant zone. (3) In patient 28, the device did not open completely and was removed via a percutaneous approach; consequently, the trial was temporarily

Figure 2

Disposition of enrolled patients.

39 Total Patients Enrolled

These study subjects were considered “enrolled” because a 14F or 16F sheath was placed in the femoral artery

5 Patients Not Treated

Severe apical deformation (n=3)
Delivery System too short (n=1)
LV too short for Implant (n=1)

34 Patients Treated

These study subjects were considered “treated” because the Implant was deployed in the left ventricle

3 Implants Removed
(Patients Followed for Safety)

Device migration (n=1)
Device migrated in calcified LV (n=1)
Unrelated sepsis (n=1)

31 Patients Discharged with Implant
stopped, and this was addressed via engineering modification of the device. Overall, of the 39 enrolled patients, a total of 31 patients were discharged with the device in place. Therefore, 79% of patients enrolled in the trial met the primary end point of successful delivery and deployment of the VPD. In those patients in whom deployment was attempted, it was completed successfully in 91%.

From implantation to 6 months, there were a total of 5 DSMB adjudicated MACE events (n = 39) either related to the device or possibly related to the device (Table II).

### Table I. Patient characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean ± SD (range), or n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic data</strong></td>
<td></td>
</tr>
<tr>
<td>Age, y</td>
<td>56.4 ± 9.6 (42-71)</td>
</tr>
<tr>
<td>Sex, male</td>
<td>34 (87%)</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>95.3 ± 22.23 (64-176)</td>
</tr>
<tr>
<td>Height, cm</td>
<td>174.6 ± 0.08 (162-188)</td>
</tr>
<tr>
<td>BMI</td>
<td>31.34 ± 7.4 (22.6-58.8)</td>
</tr>
<tr>
<td>Non-Hispanic or Latino</td>
<td>39 (100%)</td>
</tr>
<tr>
<td>White</td>
<td>39 (100%)</td>
</tr>
<tr>
<td><strong>Medical history data</strong></td>
<td></td>
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<tr>
<td>History of smoking</td>
<td>1.4 (36.8%)</td>
</tr>
<tr>
<td>History of stroke</td>
<td>4 (10.3%)</td>
</tr>
<tr>
<td>History of hypertension</td>
<td>23 (59.0%)</td>
</tr>
<tr>
<td>History of diabetes</td>
<td>15 (38.5%)</td>
</tr>
<tr>
<td>History of dyslipidemia</td>
<td>30 (76.9%)</td>
</tr>
<tr>
<td>Prior ICD implantation</td>
<td>18 (46.2%)</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>19 (48.7%)</td>
</tr>
<tr>
<td>Prior CRT</td>
<td>US: 4 (20%)</td>
</tr>
<tr>
<td>Prior CABG surgery</td>
<td>8 (20.5%)</td>
</tr>
<tr>
<td><strong>Medication use</strong></td>
<td></td>
</tr>
<tr>
<td>ACE inhibitor</td>
<td>35 (89.7%)</td>
</tr>
<tr>
<td>Angiotensin receptor blocker</td>
<td>3 (7.7%)</td>
</tr>
<tr>
<td>β-Blocker</td>
<td>39 (100%)</td>
</tr>
<tr>
<td>Loop diuretic</td>
<td>31 (79.5%)</td>
</tr>
<tr>
<td>Aldosterone antagonist</td>
<td>11 (28.2%)</td>
</tr>
</tbody>
</table>

BMI, Body mass index; ICD, implanted cardioverter/defibrillator; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft; ACE, angiotensin-converting enzyme.

* Missing data from 1 patient, n = 38.

Two US patients died before 6-month follow-up, although neither death was adjudicated by the DSMB as device related, and 1 US patient was transplanted between 6 and 12 months, adjudicated as not device related.

There were 2 cases of worsening HF, 2 device migrations during implant, and 1 device was surgically removed in a the aforementioned patient with sepsis. During long-term follow-up (6-24 months), no patients were lost to follow-up, and there was 1 stroke adjudicated as possibly device related; however, this event was not counted toward MACE, as it was outside the predefined end point (within 6 months of implant). Although there were no bleeding complications, worsening arrhythmias, nor device-related thrombus formation identified during follow-up, these were not identified as end points, and the data are inconclusive.

Taken together, successful delivery and deployment of the VPD implant through 6-month follow-up without the occurrence of MACE related to the investigational device were accomplished in 29 of the 39 patients enrolled, for an overall success rate of 74%.

### Table II. Device-related MACEs through 6 months (primary end point) to 24 months

<table>
<thead>
<tr>
<th>MACE category</th>
<th>Before discharge, n = 39</th>
<th>Discharge to 6 m, n = 37</th>
<th>6-12 m, n = 28</th>
<th>12-24 m, n = 28</th>
<th>Total (events)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rehospitalization for HF</td>
<td>2</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergent cardiac surgery</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device migration or embolization</td>
<td>2</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>6</td>
</tr>
</tbody>
</table>

* Two deaths from the time of implant to 6 months that were adjudicated by DSMB as nondevice related.
† After 6 months, only the 31 patients discharged with the device were followed up for secondary analysis and safety end points. One patient was transplanted between 6 and 12 months, 2 patient deaths (as above).
79.5 ± 3.6, P < .02, and 127.2 ± 4.2 vs 105.6 ± 3.1 vs 110.4 ± 4.6, P < .001). Ejection fraction (percentages) did not show significant difference between time end points (26.9 ± 1.4 vs 30.1 ± 1.3 vs 29.4 ± 1.4, P = .26) nor did SV (SV index, in milliliters per square meter) index (33.5 ± 1.6 vs 31.7 ± 1.6 vs 32.0 ± 1.8, P = .71).

**Functional assessment.** As placebo effect cannot be excluded, the following results should be interpreted cautiously: NYHA class decreased significantly (P < .001) from median value at baseline NYHA class 3 to a median value NYHA class 1.5 at 12 months; MLWHF questionnaire score improved from 38.6 ± 5.1 at the baseline to a score of 28.4 ± 4.4 at 12 months (P < .002); 6-minute walk (in meters) was not significantly different between the baseline and 12 months (358.6 ± 20.4 vs 374.7 ± 25.7, P = .19), although the increase in the mean value indicated a trend toward improvement.

Using 1-way ANOVA to compare baseline, 6-month, and 12-month data, the NYHA class decreased significantly from median value at the baseline NYHA class 3 to median value at 6 months of NYHA class 1 and to median value at 12 months of NYHA class 1.5 (P < .001). The MLWHF questionnaire score median values did not statistically change (41 vs 13 vs 20.5) nor did 6-minute walk (in meters) (358.6 ± 20.4 vs 374.6 ± 22.9 vs 374.7 ± 25.7, P = .85); however, the differences in median and mean values may indicate the trend toward improvement. Of significance, titration of HF medications was permitted during the trial; however, patients had to be on stable doses of medications (with the exception of diuretics) for 3 months before enrollment.

**Discussion**

The results of this study demonstrate the feasibility and preliminary safety and efficacy of percutaneous LV partitioning in patients with HF with a prior anterior MI. The VPD was safely and successfully implanted in 31 (91%) of the 34 patients who were anatomically suitable for implantation and in 79% of all enrolled patients. Improved preimplantation anatomical screening, a wider variety of VPD sizes, the development of a second generation delivery device, and the continued experience of the operators are expected to improve this overall implantation success rate and decrease device-related MACE. For an invasive first-in-man study of a novel device, the safety of the implant procedure and of the VPD was reasonable; however, evaluation of a larger cohort to assess safety and efficacy is required.

This study also demonstrates the potential of percutaneous ventricular partitioning to improve measures of patient functional status and LV structure and function in patients with HF with a prior anterior MI. As expected, implantation of the VPD resulted in an immediate and sustained reduction in LV volumes and a trend toward improvement of the LV ejection fraction. These changes
were associated with improvements in NYHA functional class ranking, quality of life, and exercise capacity; however, conclusions regarding these end points cannot be drawn, as placebo effect cannot be excluded. Nonetheless, in aggregate, these observations provide proof of concept supporting the potential efficacy of the device in this patient population.

The natural history of ischemic HF of this type treated medically is associated with poor quality of life, frequent hospital admissions, and a mean survival of only 4.1 year,\(^1\) an annual mortality rate of 12% to 17%, mostly due to sudden cardiac death or LV failure.\(^2\) The onset and progression of LV dysfunction and HF leading to this poor quality of life and high mortality rate are due to AMI followed by progressive LV remodeling. Excluding the primary dysfunctional (akinet ic or dyskinetic) area of myocardium might thus be expected to improve this outcome.

This therapy differs from the surgical approach to LV volume reduction in multiple ways: (1) it is accomplished via a percutaneous approach, potentially reducing the risk of volume reduction associated with surgery in patients with advanced HF; (2) it is not intended for patients requiring a concomitant coronary revascularization procedure, differentiating the targeted population from that enrolled in most studies of surgical LV volume reduction;\(^3\) (3) the device is different than the autologous or artificial patch, which is sometimes used in surgical LV volume reduction. In this regard, the novel VPD is a complex LV partitioning membrane supported by a nitinol framework with an ePTFE membrane that results in restoration of elasticity and a more elliptical shaped LV than that seen with surgical LV volume reduction (Figure 4A and B).

There are several limitations of this study. First, the number of patients enrolled was small, thus precluding definitive conclusions about the safety and efficacy of the VPD and delivery system. The PARACHUTE study was designed as a pilot study, to support the conduct of a subsequent larger trial. In addition, the study was unblinded and uncontrolled, and the preliminary efficacy end points were lenient; thus, a placebo effect cannot be excluded. Finally, although the US trial sequentially followed the European trial, it took approximately 2 years for each trial to enroll a total of 39 patients, implying a limited and well-defined patient population.

In conclusion, this multicenter, nonrandomized trial supports the feasibility, safety, and potential clinical benefit of the novel VPD (Parachute device) in patients with HF and a prior anterior MI as well as the need for a larger, randomized controlled trial to better assess the clinical risks and benefits of this approach.

**Acknowledgements**

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**Disclosures**

CardioKinetix, Inc (Menlo Park, CA) supported this study. Drs Mazzaferri, Jr; Abraham; Gradinac; and Sievert

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Figure 4

A, Angiogram of VPD with partitioning membrane supported by a nitinol framework with an ePTFE membrane that results in a more elliptical shaped LV. B, Computed tomographic scan VPD with partitioning membrane supported by a nitinol framework with an ePTFE membrane that results in a more elliptical shaped LV.
served as consultants for Cardiokinetix, Inc. Dr Nikolic is an employee of CardioKinetix, Inc.

References

Appendix

Inclusion criteria

1. Akinesis or dyskinesis due to MI limited to anteropapical region
2. Diagnosis of HF for a minimum of 6 months before enrollment
3. NYHA class at time of enrollment, either:
   - NYHA class III or IV—if predominant during the 3-month period before enrollment
   - NYHA class II—if diagnosed with NYHA class III or IV during 3-month period before enrollment and ≥1 hospitalization for HF during 12-month period before enrollment
4. Left ventricular ejection fraction ≤40% as measured by echocardiography
5. Left ventricle must have appropriate anatomy as measured by cardiac CT per the Parachute implant sizing criteria described in the device's Instructions For Use
6. Eligible for cardiac surgery
7. Between 18 and 74 years old (inclusive)
8. Receiving appropriate medical treatment of HF according to the American College of Cardiology/American Heart Association 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult during the 3 months before enrollment
9. Female patients with childbearing potential must have a negative pregnancy test (within 7 days of the procedure) and must agree not to attempt to become pregnant during the course of the study
10. Provide written informed consent
11. Agree to the protocol-required follow-up

Exclusion criteria

1. Myocardial ischemia requiring percutaneous coronary intervention or coronary artery bypass graft
2. Acute MI (see MI definition) within 60 days of enrollment or patients with suspected evolving MI at time of enrollment
3. Cardiogenic shock within 72 hours of enrollment
4. Revascularization procedure (percutaneous coronary intervention or coronary artery bypass graft) within 60 days of enrollment
5. Patient has received a CRT device within 60 days of enrollment
6. Patient diagnosed with significant valve disease (aortic insufficiency >1+; mitral regurgitation >2+), which may or may not require surgery
7. Patient has received an implanted cardioverter/defibrillator within 60 days of enrollment
8. Patient has received a pacemaker within 60 days of enrollment
9. History of aborted sudden cardiac death, if patient has not received an implanted cardioverter/defibrillator and has potentially lethal ventricular arrhythmia, ventricular tachycardia, or ventricular fibrillation
10. Patients with a history or a current diagnosis of either persistent or paroxysmal atrial fibrillation as well as patients who present with a contraindication to oral anticoagulant therapy
11. Aortic valve replacement or repair
12. Resting systolic blood pressure is >180 mm Hg or <90 mm Hg
13. Resting heart rate >120 beats/min
14. Cardiac CT or echocardiographic evidence of thrombus in the LV or left atrium
15. History of bleeding diathesis or a major coagulopathy (ie, platelet count <100,000 platelets per milliliter whole blood; partial thromboplastin time or prothrombin time >1.3 times control value)
16. Gastrointestinal bleed requiring transfusion within the past 3 months
17. Patient had a stroke within the past 6 months
18. Evidence of severe calcification in the Parachute Implant attachment zone
19. Evidence of a significant subaortic obstruction ("left moderator band") in the area of implant
20. History of Kawasaki disease
21. Patient has received a heart, lung, liver, and/or kidney transplant
22. Patient on dialysis or expected to require hemodialysis within 12 months
23. Patient has chronic liver disease
24. Patient has received intracardiac gene therapy or stem cell therapy
25. Creatinine >2.5 mg/dL or impaired renal function that places patient at risk for contrast-induced renal failure
26. Hypersensitivity to contrast media
27. Allergy or contraindication to clopidogrel or aspirin
28. Evidence of ongoing infection (fever with temperature >38°C and/or white blood cell >15,000)
29. Comorbidities associated with a life expectancy of <12 months or there are factors making echocardiogram and clinical follow-up difficult (no permanent address, etc.)
30. Patient is currently participating in another investigational device or drug research study for which the follow-up period is not complete.