INSTRUCTIONS FOR USE FOR: GORE® CARDIOFORM Septal Occluder

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DESCRIPTION
The GORE® CARDIOFORM Septal Occluder consists of an implantable Occluder and a Delivery System. The Occluder is comprised of a platinum-filled nickel-titanium (Nitinol) wire frame covered with expanded polytetrafluoroethylene (ePTFE). The ePTFE includes a hydrophilic surface treatment to facilitate echocardiographic imaging of the Occluder and surrounding tissue during implantation. When fully deployed, the Occluder assumes a double-disc configuration to prevent shunting of blood between the right and left atria. The Delivery System consists of a 75 cm working length 10 Fr outer diameter Delivery Catheter that is coupled to a Handle. The Handle facilitates loading, deployment, and locking of the Occluder. The Handle also allows repositioning and retrieval of the Occluder via the Retrieval Cord, if necessary.

The Occluder is available in diameters of 15, 20, 25, and 30 mm. The Occluder is delivered using conventional catheter delivery techniques and may be delivered with the aid of a 0.035” guidewire (or smaller), if desired.

INDICATIONS / INTENDED USE
The GORE® CARDIOFORM Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of ostium secundum atrial septal defects (ASDs).

CONTRAINDICATIONS
The GORE® CARDIOFORM Septal Occluder is contraindicated for use in patients:

• Unable to take anti-platelet or anticoagulant medications such as aspirin, heparin, or warfarin.
• With anatomy where the GORE® CARDIOFORM Septal Occluder size or position would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins.
• With active endocarditis, or other infections producing bacteremia, or patients with known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement.
• With known intracardiac thrombi.
WARNINGS

- The GORE® CARDIOFORM Septal Occluder is not recommended for, and has not been studied in, patients with other anatomical types of ASDs that are eccentrically located on the septum (e.g., sinus venous ASD and ostium primum ASD), or fenestrated Fontan.
- The GORE® CARDIOFORM Septal Occluder has not been studied in patients with multiple defects requiring placement of more than one device.
- The GORE® CARDIOFORM Septal Occluder is not recommended for defects larger than 17 mm.
- Regarding device sizing:
  - The defect and atrial chamber size should be evaluated by Transesophageal (TEE) or Intracardiac Echo (ICE) with color flow Doppler measurement to determine if there is adequate space to accommodate the selected occluder size without impinging on adjacent cardiac structures (e.g., A-V valves, ostia of the pulmonary veins, coronary sinus, or other critical features). There must be adequate room in the atrial chambers to allow the right and left atrial discs to lie flat against the septum with disc spacing equal to the septal thickness, and without interference with critical cardiac structures or the free wall of the atria.
  - An occluder that pulls through the defect after disc conformation may be too small and should be removed and replaced with a larger size.

- Embolized devices must be removed. An embolized device should not be withdrawn through intracardiac structures unless the occluder has been adequately collapsed within a sheath.
- The GORE® CARDIOFORM Septal Occluder should be used only by physicians trained in its use, and in transcatheter defect closure techniques.
- Patients allergic to nickel may suffer an allergic reaction to this device. Certain allergic reactions can be serious; patients should be instructed to notify their physicians immediately if they suspect they are experiencing an allergic reaction such as difficulty breathing or inflammation of the face or throat. Some patients may also develop an allergy to nickel if this device is implanted.

PRECAUTIONS

Handling

- The GORE® CARDIOFORM Septal Occluder is intended for single use only. An attempt to recover and reinsert an unused occluder is not recommended. Gore does not have data regarding reuse of this device. Reuse may cause device failure or procedural complications including device damage, compromised device biocompatibility, and device contamination. Reuse may result in infection, serious injury, or patient death.
- Do not use after the labeled “use by” (expiration) date.
- Inspect the product prior to use in the patient. Do not use if the product is damaged.
- Do not use for the labeled “use by” (expiration) date.
- Do not resterilize.

Procedure

- The GORE® CARDIOFORM Septal Occluder should only be used in patients whose vasculature is adequate to accommodate a 10 Fr delivery sheath (or 12 Fr delivery sheath when a guidewire is used).
- Retrieval equipment such as large diameter sheaths, loop snares, and retrieval forceps should be available for emergency or elective removal of the occluder.
- An Activated Clotting Time (ACT) greater than 200 seconds should be maintained throughout the procedure.
- The GORE® CARDIOFORM Septal Occluder should be used only in conjunction with appropriate angiographic techniques to assess the septal anatomy and to visualize the wire frame.
- If successful deployment cannot be achieved after three attempts, an alternative device or treatment for ASD closure is recommended. Consideration should be given to the patient’s total exposure to radiation and anesthesia if prolonged or multiple attempts are required for the placement of the GORE® CARDIOFORM Septal Occluder.
- Expansion of an occluder disc may occur in the periprocedural time period. If there is uncertainty that an expanded device remains locked, fluoroscopic examination is recommended in order to identify if the Lock Loop captures all three eyelets.
- Removal of the Occluder should be considered if:
  - The Lock Loop does not capture all three eyelets
  - The Occluder will not come to rest in a planar position apposing the septal tissue
  - The selected Occluder allows excessive shunting
- An unlocked and removed occluder cannot be reused. Gore does not have data regarding reuse of this device. Reuse may cause device failure or procedural complications including device damage, compromised device biocompatibility, and device contamination. Reuse may result in infection, serious injury, or patient death.
- The GORE® CARDIOFORM Septal Occluder is not recommended for defects larger than 17 mm.
- Regarding device sizing:
  - An occluder that pulls through the defect after disc conformation may be too small and should be removed and replaced with a larger size.

Post Procedure

- Patients should take appropriate prophylactic antibiotic therapy consistent with the physician’s routine procedures following device implantation.
- Patients should be treated with antiplatelet therapy for six months post-implant. The decision to continue antiplatelet therapy beyond six months is at the discretion of the physician.
- In patients sensitive to antiplatelet therapy, alternative therapies, such as anticoagulants, should be considered.
- Patients should be advised to avoid strenuous physical activity for a period of at least two weeks after occluder placement.
- Patients should have Transthoracic Echocardiographic (TTE) exams prior to discharge, at 6, 12, and 24 months after occluder placement to assess disc closure. Attention should be given to the stability of the device on the atrial septum during these assessments, as a lack of device stability may be indicative of device frame fracture. In some instances where device stability is questionable, fluoroscopic examination without contrast is recommended in order to identify and assess wire frame fractures.

- Consideration should be given to the patient’s total exposure to radiation and anesthesia if prolonged or multiple attempts are required for the placement of the GORE® CARDIOFORM Septal Occluder.
- Expanded an occluder disc may occur in the periprocedural time period. If there is uncertainty that an expanded device remains locked, fluoroscopic examination is recommended in order to identify if the Lock Loop captures all three eyelets.
- Removal of the Occluder should be considered if:
  - The Lock Loop does not capture all three eyelets
  - The Occluder will not come to rest in a planar position apposing the septal tissue
  - The selected Occluder allows excessive shunting
- There is impingement on adjacent cardiac structures
Adverse Events
Clinical Summary
The GORE® CARDIOFORM Septal Occluder was evaluated in a multi-center, non-randomized Pivotal Study that included 50 subjects. An Independent Data Reviewer provided external oversight and review of subject safety data, including evaluation of all reported adverse events for accuracy of event coding, seriousness, and relationship to the device. An event was considered a Serious Adverse Event if it led to death or serious deterioration in health that resulted in a life threatening illness or injury or in permanent impairment. Device Events, a type of Serious Adverse Event, were defined as any post-procedure embolization, post-procedural device removal, or any other reintervention to the septal defect.

Deaths
No deaths have been reported in study subjects.

Serious Adverse Events
No Serious Adverse Events, including Device Events, were observed in any study subjects through the 6-month follow-up.

Non-Serious Adverse Events
Non-Serious Adverse Events reported through the 6-month follow-up for Pivotal Study subjects and determined to be potentially or definitely related to the implant procedure or to the device are presented in Table 1.

Table 1. Subjects with Non-Serious Adverse Events Through 6 Months – Pivotal Study

<table>
<thead>
<tr>
<th>Subjects Evaluable for Safety</th>
<th>50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects With One or More Non-Serious Adverse Events</td>
<td>12 (24.0%)</td>
</tr>
<tr>
<td>Anesthesia or Procedural</td>
<td>8 (16.0%)</td>
</tr>
<tr>
<td>Incision site complication</td>
<td>4 (8.0%)</td>
</tr>
<tr>
<td>Anesthesia complication</td>
<td>3 (6.0%)</td>
</tr>
<tr>
<td>Procedural pain</td>
<td>2 (4.0%)</td>
</tr>
<tr>
<td>Nervous System</td>
<td>2 (4.0%)</td>
</tr>
<tr>
<td>Burning sensation</td>
<td>1 (2.0%)</td>
</tr>
<tr>
<td>Migraine</td>
<td>1 (2.0%)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (6.0%)</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal</td>
<td>2 (4.0%)</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>1 (2.0%)</td>
</tr>
</tbody>
</table>

POTENTIAL DEVICE OR PROCEDURE-RELATED ADVERSE EVENTS
Adverse Events associated with the use of the Occluder may include, but are not limited to:

- Repeat procedure to the septal defect
- Device embolization
- New arrhythmia requiring treatment
- Intervention for device failure or ineffectiveness
- Access site complications requiring surgery, interventional procedure, transfusion, or prescription medication
- Thrombus or thromboembolic event resulting in clinical sequelae
- Perforation of a cardiovascular structure by the device
- Device fracture resulting in clinical sequelae or surgical intervention
- Occluder disc expansion resulting in clinical sequelae or intervention
- Air embolism
- Myocardial infarction
- Pericardial tamponade
- Cardiac arrest
- Renal failure
- Sepsis
- Significant pleural or pericardial effusion requiring drainage
- Significant bleeding
- Endocarditis
- Headache or migraine
- TIA or stroke
- Death

CLINICAL STUDIES
The GORE® CARDIOFORM Septal Occluder was evaluated for safety and effectiveness in a multicenter, non-randomized Pivotal Study with 50 subjects enrolled for closure of ostium secundum atrial septal defects.

Design
Patient Selection
Subjects enrolled in the Pivotal Study were required to have an ostium secundum atrial septal defect with evidence of right heart volume overload. Subjects were eligible for enrollment if their defect measured ≤ 17 mm in diameter by stop-flow balloon sizing and had adequate septal rims to successfully retain the occluder. Exclusion criteria included:

- Significant known pre-existing electrophysiologic, structural cardiovascular defect, or other comorbidities that could elevate morbidity / mortality beyond what is common for ASD or would be expected to require surgical treatment within three years of device placement.
- Systemic or inherited conditions that would significantly increase subject risk of major morbidity and mortality during the term of the study.
- Anatomy where the size or position of the occluder would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins.
- Active endocarditis, other infections producing bacteremia, or known sepsis within one month of planned implantation, or any other infection that could not be treated successfully prior to device placement.
- One or more known intracardiac thrombi.
- Uncontrolled anemia.
- History of stroke resulting in a significant morbidity or disability.
- Pregnant or lactating at time of enrollment.
- Contraindication to antplatelet therapy.
• Pulmonary artery systolic pressure greater than half the systemic systolic arterial pressure unless the indexed pulmonary arteriolar resistance was < 5 Woods units.
• Multiple defects based on screening imaging and stop-flow balloon sizing that would require placement of more than one device. Subjects provided informed consent prior to enrollment. No training cases were required by study investigators prior to enrollment in the Pivotal Study.

Procedure and Follow-up
Dimensional verification and characterization of the ASD, interatrial septum, and surrounding cardiac structures were performed during the implant procedure. The measurement of ASD size was taken utilizing the stop-flow technique (a balloon was placed across the defect and slowly expanded until it filled the defect space and blood flow through the defect was prevented). The measurement of the balloon’s waist (i.e. the narrowest portion) was recorded as the defect diameter and used to determine the appropriate size GORE® CARDIOFORM Septal Occluder. Fluoroscopic and echocardiographic guidance were used throughout the procedure for placement and assessment of the GORE® CARDIOFORM Septal Occluder. All subjects were placed on the investigator’s choice of antiplatelet therapy for six months following device implantation, and on prophylactic, post-procedure antibiotic therapy consistent with the investigator’s routine procedure. Follow-up evaluations, which included a physical exam, ECG, and an assessment of residual shunt status by echocardiography, were performed at hospital discharge, and at 1 and 6 months post-procedure. At the 6-month follow-up visit, fluoroscopic examination was performed to assess device integrity.

Endpoints
The primary endpoint for the study was Composite Clinical Success, evaluated at 6 months post-procedure. Composite Clinical Success was defined as: 1) Successful deployment and retention of a GORE® CARDIOFORM Septal Occluder, 2) No Serious Adverse Events during 30-day follow-up, 3) No Device Events through 6-month follow-up, and 4) Clinical closure success, where the defect was classified as either completely occluded or having a clinically insignificant shunt at the 6-month follow-up as determined by echocardiography core lab evaluation. An event was considered a Serious Adverse Event if it led to death or serious deterioration in health that resulted in a life threatening illness or injury or in permanent impairment. Device Events were defined as any post-procedure embolization, post-procedural device removal, or any other reintervention to the septal defect. Secondary endpoints evaluated specific safety and efficacy results in study subjects. Safety endpoints were defined as the proportion of subjects who experienced a Serious Adverse Event in the first 30 days or a Device Event through the 6-month follow-up. Technical Success was defined as successful deployment and retention of a GORE® CARDIOFORM Septal Occluder. Closure success endpoints were evaluated for those subjects with Technical Success. Procedure Success was defined as a residual shunt of ≤ 2 mm at the end of the implant procedure as measured by the investigational site. Closure Success was defined as a residual shunt ≤ 2 mm at 6-month follow-up as measured by the echocardiography core lab.

Results
Demographics and Defect Characteristics
Subject demographics at enrollment and defect characteristics assessed at the implant procedure by the investigational site are listed in Table 2. Subject medical history is shown in Table 3.
### Table 2. Subject Demographics and Defect Characteristics – Pivotal Study

<table>
<thead>
<tr>
<th>Number of Subjects</th>
<th>50</th>
</tr>
</thead>
</table>

#### Patient Demographics

<table>
<thead>
<tr>
<th>Gender</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Subjects</td>
<td>23 (46.0%)</td>
<td>27 (54.0%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race</th>
<th>Black or African American</th>
<th>White or Caucasian</th>
<th>Other Race</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Subjects</td>
<td>8 (16.0%)</td>
<td>39 (78.0%)</td>
<td>4 (8.0%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>N = 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (Std Dev)</td>
<td>19.7 (21.0)</td>
</tr>
<tr>
<td>Median</td>
<td>7.4</td>
</tr>
<tr>
<td>(Min, Max)</td>
<td>(3.4, 68.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Height (cm)</th>
<th>N = 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (Std Dev)</td>
<td>133.0 (33.6)</td>
</tr>
<tr>
<td>Median</td>
<td>121.5</td>
</tr>
<tr>
<td>(Min, Max)</td>
<td>(40.5, 188.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>N = 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (Std Dev)</td>
<td>45.1 (32.3)</td>
</tr>
<tr>
<td>Median</td>
<td>27.6</td>
</tr>
<tr>
<td>(Min, Max)</td>
<td>(11.9, 133.6)</td>
</tr>
</tbody>
</table>

#### Defect Characteristics

<table>
<thead>
<tr>
<th>Stop Flow Balloon Defect Size (mm)</th>
<th>N=49</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (Std Dev)</td>
<td>11.9 (3.4)</td>
</tr>
<tr>
<td>Median</td>
<td>12.0</td>
</tr>
<tr>
<td>(Min, Max)</td>
<td>(5.7, 17)</td>
</tr>
</tbody>
</table>

Atrial Septal Aneurysm1 |
- Number of Subjects: 14.0% (7/50) |

Deficient Retroaortic Rim |
- Number of Subjects: 26.0% (13/50) |

Multiple Fenestrations |
- Number of Subjects: 20.0% (10/50) |

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1 Protrusion of the septum ≥ 10 mm from baseline in either direction or ≥ 15 mm total septal excursion
2 Measured as < 5 mm

### Table 3. Subject Medical History – Pivotal Study

<table>
<thead>
<tr>
<th>Number of Subjects</th>
<th>50</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Cardiac Arrhythmia</th>
<th>8 (16.0%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>5 (10.0%)</td>
</tr>
<tr>
<td>Migraines</td>
<td>8 (16.0%)</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>4 (8.0%)</td>
</tr>
<tr>
<td>Previous Cardiac Surgeries</td>
<td>2 (4.0%)</td>
</tr>
<tr>
<td>Non-ASD Cardiac Disorders</td>
<td>27 (54.0%)</td>
</tr>
<tr>
<td>Vascular Disorders</td>
<td>3 (6.0%)</td>
</tr>
<tr>
<td>History of Stroke and/or TIA</td>
<td>4 (8.0%)</td>
</tr>
<tr>
<td>Birth/Genetic Defects</td>
<td>9 (18.0%)</td>
</tr>
<tr>
<td>Neurological Disorders</td>
<td>7 (14.0%)</td>
</tr>
<tr>
<td>Pulmonary/Respiratory Disorders</td>
<td>14 (28.0%)</td>
</tr>
</tbody>
</table>

A wire frame fracture was observed in 9.3% (4/43) of subjects with fluoroscopic evaluation completed at 6 months. No fractures were associated with device instability or clinical sequelae.

### Procedure and Endpoint Outcomes

Primary, safety, and efficacy endpoint results are shown in Table 4. All subjects with an atrial septal aneurysm, multiple fenestrations or deficient retroaortic rim who received a GORE® CARDIOFORM Septal Occluder had complete clinical closure and no Serious Adverse Events at 6 months.
Table 4. Primary, Safety, and Efficacy Endpoints – Pivotal Study

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Endpoint</strong></td>
<td></td>
</tr>
<tr>
<td>Composite Clinical Success1</td>
<td>40/43 (93.0%)</td>
</tr>
<tr>
<td><strong>Safety Endpoints</strong></td>
<td></td>
</tr>
<tr>
<td>30-Day Serious Adverse Events</td>
<td>0.0% (0/50)</td>
</tr>
<tr>
<td>6-Month Serious Adverse Events</td>
<td>0.0% (0/50)</td>
</tr>
<tr>
<td>6-Month Device Events2</td>
<td>0.0% (0/50)</td>
</tr>
<tr>
<td><strong>Efficacy Endpoints</strong></td>
<td></td>
</tr>
<tr>
<td>Technical Success1</td>
<td>47/50 (94.0%)</td>
</tr>
<tr>
<td>Procedure Success2</td>
<td>46/47 (97.9%)</td>
</tr>
<tr>
<td>6-Month Closure Success2</td>
<td>43/45 (95.6%)</td>
</tr>
<tr>
<td>6-Month Clinical Closure Success3</td>
<td>40/40 (100%)</td>
</tr>
</tbody>
</table>

1 Technical Success and 6-Month Clinical Closure Success without Serious Adverse Events through 30 days or Device Events through 6 months
2 Post-procedural device embolization, post-procedural device removal, or any reintervention to the septal defect
3 Successful delivery and retention of the device in subjects with a delivery attempted
4 Technical Success with completely occluded defect or residual shunt ≤ 2 mm at the completion of the implant procedure
5 Technical Success with completely occluded defect or residual shunt ≥ 2 mm at 6 months
6 Technical Success with completely occluded defect or clinically insignificant residual shunt at 6 months

HOW SUPPLIED

The GORE® CARDIOFORM Septal Occluder is supplied sterile in a protective tray and pouch. Provided that the integrity of the pouch is not compromised in any way, it will serve as an effective barrier until the “use by” (expiration) date printed on the box.

REQUIRED ACCESSORIES

- 10 Fr Introducer Sheath
- Heparinized saline
- Flushing syringe
- Stopcock
- Sizing balloon
- Sterile bowl for flushing catheter

OPTIONAL ACCESSORIES

- 0.035” / 0.89 mm guidewire, or smaller (if necessary for defect access)
- 12 Fr Introducer Sheath when a guidewire is utilized.

RECOMMENDED PROCEDURES

A. Sizing the Defect and Selecting the Proper Occluder Size

1. Use echocardiography to measure the septal length.
2. Measure the septal defect using fluoroscopy or echocardiography; the stop flow balloon technique is recommended, as described below:
   a. Place a contrast filled, compliant balloon across the defect and gently inflate until shunting through the defect has stopped.
   b. Measure the diameter of the defect using either echocardiography or calibrated fluoroscopy.
3. Select the appropriate occluder size for the defect, taking the following recommendations into consideration:
   - A minimum occluder to defect size ratio of 1.75:1 is recommended (reference Table 5). The defect size should be no greater than 17 mm. An occluder that pulls through the defect after disc conformation may be too small and should be removed and replaced with a larger size.
   - There must be adequate space to accommodate the discs within the atrial chambers. To assure that there is adequate space to accommodate the discs within the atrial chambers, the selected occluder diameter should be less than 90% of the measured septal length.
   - The septal tissue margins surrounding the defect must be of sufficient size and integrity to prevent disc prolapse through the defect and Occluder embolization.

Table 5: GORE® CARDIOFORM Septal Occluder Device Sizing

<table>
<thead>
<tr>
<th>Labeled Occluder Diameter (mm)</th>
<th>Maximum Recommended Defect Size Measured with Stop Flow Balloon Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>8.5</td>
</tr>
<tr>
<td>20</td>
<td>11</td>
</tr>
<tr>
<td>25</td>
<td>14</td>
</tr>
<tr>
<td>30</td>
<td>17</td>
</tr>
</tbody>
</table>

B. Access Site Preparation

1. Prepare the venous access site according to standard practice.
2. Place appropriately sized Introducer Sheath.

C. Occluder Preparation and Loading

1. Check the “use by” (expiration date) and the condition of the package.
2. Using aseptic technique, remove the sterile tray from the pouch, and remove the packaging tray lid.
3. Remove the device from the package and visually inspect the device for shipping damage. Ensure that the Retrieval Luer is tight.
4. Remove the Packaging Insert from the handle (Figure 3).
5. Loading and Flushing the Occluder:
   a. Submerge the Occluder and catheter tip in a heparinized saline bath during loading to reduce the chance of an entrapment in the delivery system.
   b. Fill a syringe with heparinized saline.
c. Attach the syringe to a stopcock and the Flush Port.

d. Flush the device until air no longer exits the tip of the Delivery Catheter.

e. When the initial flushing is completed, begin loading the Occluder by pushing the Slider up and then to the right until the Slider stops (Figure 4a).

f. Complete Occluder loading by pushing the Slider down and then to the right until it stops (Figure 4b).

g. Flush the device again until air no longer exits the tip of the Delivery Catheter.

h. If additional air removal is desired, it is recommended to deploy the Occluder (refer to Section E “Occluder Deployment”) and repeat steps d-g above.

The Occluder Lock should not be moved before or during Occluder loading or deployment. Partial or complete Occluder locking may prevent Occluder loading and deployment.

FIGURE 3: Packaging Insert Removal

FIGURE 4: Occluder Loading

FIGURE 4a: Initial Occluder Loading

FIGURE 4b: Completion of Occluder Loading

D. Occluder Delivery

1. If applicable, load the Delivery Catheter onto the guidewire by threading the guidewire into the lumen of the Delivery Catheter from the tip and out the Guidewire Slot (Figure 5).

2. While flushing the device, load the Delivery Catheter into the appropriately sized introducer sheath. Close the stopcock and remove the flushing syringe from the stopcock.

E. Occluder Deployment

1. Advance the Delivery Catheter across the atrial septum until the tip is positioned within the left atrium.

2. If a guidewire was utilized, remove the guidewire before attempting to deploy the Occluder.

3. Begin deploying the Occluder left disc by pushing the Slider to the left until it stops (Figure 6a).

4. Complete Occluder left disc deployment by pushing the Slider up and then to the left until a flat left disc has formed (Figure 6b). This step may be performed while simultaneously retracting the Delivery System to minimize advancement of the Occluder within the left atrial chamber.
5. Gently pull on the Handle to bring the left atrial disc onto the surface of the left atrial septum.

6. Deploy the right atrial disc by pushing the Slider to the left until it stops and then down. Confirm that the Slider has moved completely to the left and down position (Figure 6c). Failure to move the Slider completely to the left and down position may prevent Occluder locking.

7. Confirm that both left and right discs appear planar and apposed to the septum with septal tissue between the discs.

If the position is not correct, refer to Section G, "Reloading the Occluder". Note that the Occluder can only be Reloaded prior to Occluder Locking.

FIGURE 6: Occluder Deployment

FIGURE 6a: Initial Occluder Deployment

FIGURE 6b: Left Atrial Disc Deployment

FIGURE 6c: Right Atrial Disc Deployment

F. Occluder Locking and Delivery System Removal

1. Prior to Occluder locking, assess that the Occluder position and defect closure are acceptable and that the Delivery System is not exerting tension on the septum and Occluder.

2. Lock the Occluder by holding the Handle in a fixed position to prevent applying tension on the Occluder. Note that excessive compression of the handle may prevent Occluder locking. Next, squeeze and then slide the Occluder Lock decisively and with a consistent amount of force to the right (Figure 7). At the completion of Occluder locking, the Occluder is still attached to the Delivery System by the Retrieval Cord.

During the Occluder locking step, the Delivery Catheter moves proximally and may exert minimal tension on the introducer sheath. It is recommended to confirm adequate introducer sheath insertion prior to Occluder locking.

3. If the Occluder position is not acceptable, refer to Section H, "Removing the Occluder with the Retrieval Cord After Occluder Locking".

4. If the Occluder position is acceptable, hold the Handle in a fixed position, pull up on the red Retrieval Cord Lock (Figure 8a), disengage it from the Slider, and gently pull the Retrieval Cord Lock until the Retrieval Cord has been completely removed from the Handle (Figure 8b).

5. The Occluder is now released from the Delivery System and the Delivery System can be removed.

6. Once the Retrieval Cord is removed, the Occluder cannot be removed using the Delivery System, refer to Section I, "Recapture".
G. Reloading the Occluder Before Occluder Locking

1. Reload the Occluder by pushing the Slider up and then to the right until the desired portion of the Occluder discs is reloaded or until the Slider stops, if complete disc reloading is desired (Figure 4a).

2. If desired, complete Occluder reloading by pushing the Slider down and then to the right until it stops (Figure 4b). Ensure that the Delivery Catheter tip remains across the defect to maintain defect access.

3. Refer to Section E, “Occluder Deployment” to re-deploy the Occluder.
   - If desired device placement cannot be achieved after multiple deployment attempts, consideration should be given to minimize the patient’s exposure to radiation and prolonged anesthesia time. If the patient’s septal anatomy is determined to be unsuitable for the GORE® CARDIOFORM Septal Occluder, alternative treatment options such as other devices or surgical closure of the defect should be considered.

H. Removing the Occluder with the Retrieval Cord After Occluder Locking

1. Unscrew the Retrieval Luer, hold the Delivery Catheter in place and withdraw the Handle until the Occluder has unlocked (Figure 9). This step requires that the Delivery Catheter is sufficiently spaced away from the Occluder to permit full extension of the Lock Loop.

2. Continue to withdraw the Handle to pull the entire Occluder into the Delivery Catheter. Do not use excessive force in an attempt to withdraw all of the Occluder into the Delivery Catheter. Doing so could cause the Retrieval Cord to break or result in Occluder damage.
   - The operator must ensure that the Occluder does not catch on the Delivery Catheter tip or introducer sheath. If the Lock Loop or eyelet catch and the Delivery System is forcibly retracted, the Retrieval Cord or Occluder frame is at risk of damage.

3. If necessary, remove the introducer sheath and Occluder together.
   - If the Occluder is removed, it should be disposed of and a new Occluder should be used.

Note that without a hemostatic valve at the Delivery Catheter proximal end, care should be taken to avoid air entry or blood loss if the Occluder is completely removed from the Delivery Catheter.
I. Recapture

1. In the event that the Occluder is malpositioned, embolized, or otherwise requires removal, it may be recaptured with the aid of a loop snare or other suitable means. A long sheath (11 Fr or greater) positioned close to the device is recommended for recapture.

2. Attempt to recapture the device by first snaring the left or right atrial eyelet to facilitate Occluder retraction into the sheath. If necessary, the loop snare may be placed around any portion of the Occluder frame.

3. Pull the Occluder into the long sheath using the snare. If a portion of the Occluder frame cannot be retracted into the long sheath, it may be necessary to remove the Occluder, loop snare, and long sheath as one unit. Do not use excessive force in an attempt to withdraw all of the Occluder into the long sheath. Doing so could result in Occluder damage.

4. Bring the recaptured Occluder into the sheath to avoid pulling the unlocked device across valve tissue.

MR CONDITIONAL

J. MRI Information

The GORE® CARDIOFORM Septal Occluder has been determined to be MR-conditional. Non-clinical testing demonstrated that the GORE® CARDIOFORM Septal Occluder is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field
- Static magnetic field of 3-Tesla or 1.5 Tesla
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less
- Maximum scanner displayed whole body averaged specific absorption rate (WB-SAR) of 3.0 W/kg for 15 minutes of scanning.

MRI-Related Heating
In non-clinical testing, the GORE® CARDIOFORM Septal Occluder produced the following temperature rise during MRI performed for 15 minutes of scanning (i.e., per pulse sequence) in 1.5-Tesla/64-MHz (Magnetom, Siemens Medical Solutions, Malvern, PA, Software Numaris/4, Version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner) and 3-Tesla/128-MHz (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR systems:

- Highest temperature change: +1.8°C

The MRI-related heating experiments for the GORE® CARDIOFORM Septal Occluder at 1.5-Tesla using a transmit / receive RF body coil at an MR system reported whole body averaged SAR of 2.9 W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.1 W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.3°C. The MRI-related heating experiments for the GORE® CARDIOFORM Septal Occluder at 3-Tesla using a transmit / receive RF body coil at an MR system reported whole body averaged SAR of 3.0 W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.8 W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C.

Multiple overlapping implants
MR- related heating effects with multiple overlapping GORE® CARDIOFORM Septal Occluder implants is unknown.

Artifact Information
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the GORE® CARDIOFORM Septal Occluder. There should be no overlap of fiducial imaging parameters to compensate for the presence of this device may be necessary.

Pulse Sequence
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