INSTRUCTIONS FOR USE FOR:

GORE HELEX SEPTAL OCCLUDER

NOTICE FOR USE WITHIN THE UNITED STATES
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

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

1.0 BRIEF DEVICE DESCRIPTION

The GORE HELEX Septal Occluder is comprised of an implantable prosthesis and a catheter delivery system.
The Occluder is composed of expanded polytetrafluoroethylene (ePTFE) patch material with hydrophilic coating, supported by a nickel-titanium (nitinol) super-elastic wire frame. When fully deployed, the Occluder takes on a double disc shape that bridges, and over time occludes, the septal defect to stop the shunting of blood between the right and left atrium (Figure 1). The double disc nominal diameters range from 15 to 35 mm when fully deployed (a complete list of available sizes may be found in **Table 1**). The delivery system consists of three co-axial components: a 9 Fr delivery catheter, a 6 Fr control catheter, and a mandrel
The control catheter is equipped with a retrieval cord to reposition and retrieve the Occluder (Figure 2).
The GORE HELEX Septal Occluder functions by covering the defect and adjacent tissue with the ePTFE patch supported by the wire frame. Immediately after deployment, it remains in position across the defect with the aid of the mild tension created by the wire frame and the blood pressure that pushes the ePTFE patch against the atrial septum. The ePTFE patch is microporous and will become attached to the atrial septum by cellular penetration through the membrane micropores. Over time, the process of tissue attachment to the ePTFE patch will maintain the Occluder in position and create a permanent defect closure.

FIGURE 1: GORE HELEX Septal Occluder

FIGURE 1a: Left Atrial View

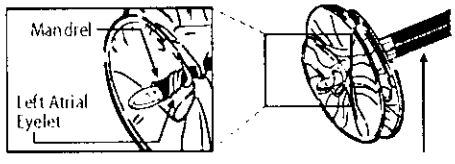


FIGURE 1b: Right Atrial View

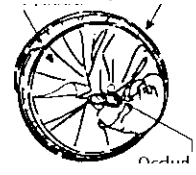
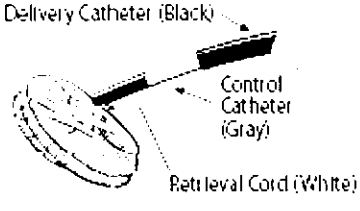
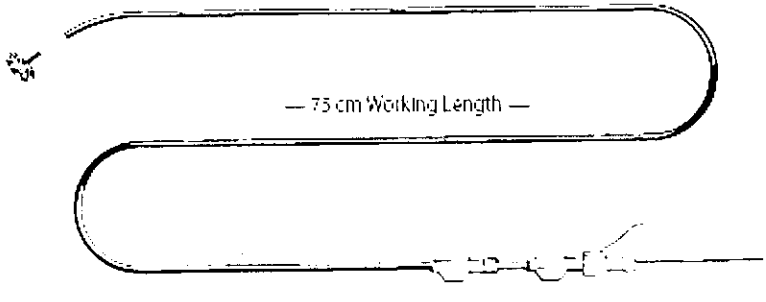


FIGURE 2: GORE HELEX Delivery System





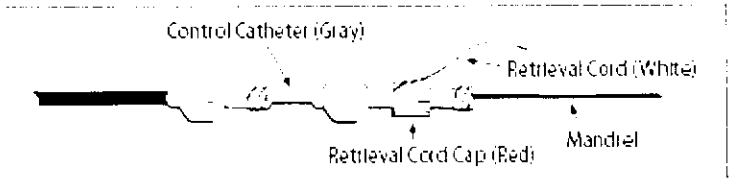


TABLE 1
Available GORE HELEX Septal Occluder Diameters

NOMINAL SIZE
15 mm
20 mm
25 mm
30 mm
35 mm

2.0 INDICATIONS/INTENDED USE

The GORE HELEX Septal Occluder is a permanently implanted prosthesis indicated for the percutaneous, transcatheter closure of *ostium secundum* atrial septal defects (ASDs).

3.0 CONTRAINDICATIONS

The GORE HELEX Septal Occluder is contraindicated for use in:

- Patients with extensive congenital cardiac anomalies which can only be adequately repaired by cardiac surgery.
- Patients unable to take anti-platelet or anticoagulant preventative medications such as aspirin, heparin, or warfarin.
- Anatomy where the GORE HELEX Septal Occluder size or position would interfere with other intracardiac or intravascular structures such as cardiac valves or pulmonary veins.
- 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.
- Patients whose vasculature is inadequate to accommodate a 9 Fr delivery sheath.
- Any patient known to have intracardiac thrombi.

4.0 WARNINGS

- The GORE HELEX Septal Occluder is not recommended for defects that measure larger than 18 mm.
- The GORE HELEX Septal Occluder is not recommended for patients with a septal thickness of greater than 8 mm in the area of the Occluder placement.
- The GORE HELEX Septal Occluder is not recommended for patients known to have multiple defects that would require placement of more than one device.
- The GORE HELEX 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 (examples include *sinus venosus* ASD and *ostium primum* ASD), or fenestrated Fontan.
- The GORE HELEX Septal Occluder is not recommended for, and has not been studied in, patients with significant atrial septal aneurysm.
- Regarding device deployment:
    - The defect and atrial chamber size should be evaluated by TEE and/or color flow Doppler measurement to confirm that 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 care cardiac structures or the free wall of the atria.
    - The defect should be evaluated to ensure there is an adequate rim to retain the device in ≥75% of the circumference of the defect.
    - The selected Occluder diameter should be at least two times the diameter of the defect (i.e., a 2:1 ratio of device diameter-to-defect diameter). Deploying the Occluder in cases where the Occluder diameter-to-defect diameter ratio is below 2:1 increases the risk of unsuccessful device placement and device embolization.
    - An Occluder that pulls through the defect during disc confirmation may be too small and should be removed and replaced with a larger size.
- Embolized devices must be removed. Embolized devices should not be withdrawn through intracardiac structures unless they have been adequately collapsed within a sheath.

- If successful deployment cannot be achieved after 2 attempts, an alternative treatment for ASD closure is recommended. Consideration should be given to the patient's total exposure to radiation if prolonged or multiple attempts are required for the placement of the GORE HELEX Septal Occluder.
- The GORE HELEX Septal Occluder should only be used by physicians trained in its use, and in transcatheter defect closure techniques. The procedure should be performed only at facilities where surgical expertise is available.
- Patients allergic to nickel may suffer an allergic reaction to this device.

5.0 PRECAUTIONS

5.1 Handling

- The GORE HELEX Septal Occluder is intended for single use only. An unlocked and removed Occluder cannot be reused.
- Inspect the package before opening. If seal is broken, contents may not be sterile.
- Inspect the product prior to use in the patient. Do not use if the product has been damaged.
- Do not use after the labeled "use by" (expiration) date.
- Do not resterilize.

5.2 Procedural

- Patients should be heparinized sufficiently to maintain an Active Clotting Time (ACT) of greater than 200 seconds throughout the procedure.
- The GORE HELEX Septal Occluder should only be used in conjunction with appropriate imaging techniques to assess the septal anatomy and to visualize the wire frame. These techniques include multiplanar TEE (Transesophageal Echo) and ICE (Intracardiac Echo), both with color flow Doppler, and fluoroscopy with real-time image magnification.
- Do not rotate the delivery system components with respect to each other. This may result in retrieval cord entanglement or unwinding of the retrieval cord from the right atrial eyelet.
- Retrieval equipment such as large diameter sheaths, loop snares, and retrieval baskets should be available for emergency or elective removal of the Occluder.
- There must be adequate room in the atrial chamber to allow the right and left atrial discs to lie flat against the atrial septum, without interference with critical cardiac structures, or the free wall of the atria.
- Removal of an Occluder should be considered if:
  - the lock fails to capture all three eyelets
  - the Occluder will not come to rest in a planar position opposing the septal tissue
  - the selected Occluder is too small and allows excessive shunting
  - excessive friction is encountered when the control catheter is removed
  - there is impingement on adjacent cardiac structures

5.3 Post-Implant

- Patients should take appropriate prophylactic antibiotic therapy consistent with the physician's routine procedures following device implantation.
- Patients should be treated with antiplatelet therapy, such as aspirin or clopidogrel bisulfate, for 6 months post-implant. During the Pivotal and Continued Access clinical trials, 66.7% of device patients received antiplatelet medications and 1.1% received anticoagulants for up to 6 months post procedure, refer to table 10. The decision to continue antiplatelet therapy beyond 6 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, and at 1, 6, and 12 months after occluder placement to assess defect closure.
- Fluoroscopy examination without contrast is recommended at 12 months post-procedure for patients with a 35 mm device with attention directed towards possible wire frame fractures.

6.0 ADVERSE EVENTS

6.1 Clinical Summary

The GORE HELEX Septal Occluder was evaluated in a feasibility study (two center, single arm), a pivotal study (multi-center, non-randomized), and a continued access study (multi-center, single arm, prospective). The feasibility study included 51 subjects treated with the device. The pivotal study compared the device to surgical closure of *ostium secundum* atrial septal defects. Investigators were required to complete 3 device training cases. The pivotal study included 119 non-training subjects treated with the device and 128 subjects treated with surgical closure. The continued access study included 113 non-training subjects treated with the device as of December 15, 2005, of which 77 subjects completed the 12-month follow-up evaluation.

These subjects form the basis of the observed adverse event data reported in the following section. An independent Data Safety Monitoring Board (DSMB) reviewed all reported adverse events to determine device/procedure relationship and event severity (major or minor). An event was considered major if it required reintervention, readmission to the hospital or resulted in permanent damage or deficit. For the GORE HELEX Septal Occluder studies, reintervention was defined as chronic medical, and acute surgical or interventional cardiology therapies.

6.2 Deaths

There was one post-operative death in the surgical control treatment arm of the pivotal study. This subject died of complications related to post-pericardiotomy syndrome on Day 10 post surgery. No deaths have been reported in the device subjects in the feasibility, pivotal, and continued access studies.

6.3 Observed Adverse Events

Major adverse events reported through the 12-month follow-up for the feasibility, pivotal and continued access studies are presented in **Table 2**.

Table 2
Number of Subjects with Successful Device Delivery by Category of Major Adverse Events
GORE HELEX Septal Occluder Studies
Events Reported Through 12-Month Follow-up

		Pivotal Study			
	Feasibility Study	Device Arm	Surgery Arm	Difference (95% CI)[1]	Continued Access Study
Subjects Evaluable for Safety	**51**	**119**	**128**		**77**
Deaths (Any Cause)	**0**	**0**	**1 (0.8%)**	**-0.8% (-2.4%, 0.8%)**	**0**
Subjects With One or More Major Adverse Events	**2 (3.9%)**	**7 (5.9%)**	**14 (10.9%)**	**-5.1% (-12.1%, 1.9%)**	**3 (3.9%)**
Cardiac	**1 (2.0%)**	**2 (1.7%)**	**10 (7.8%)**	**-6.1% (-11.5%, -0.8%)**	**2 (2.6%)**
Arrhythmia	1 (2.0%)	0	0		0
Bleeding (treatment required)	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Device Embolization (post- procedure)[2]	0	2 (1.7%)	na	na	2 (2.6%)
Pulmonary Edema	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Post-Pericardiotomy Syndrome	na	na	8 (6.3%)	na	na
Integument (Skin)	**0**	**1 (0.8%)**	**0**	**0.8% (-0.8%, 2.4%)**	**0**
Allergic reaction	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Neurologic	**1 (2.0%)**	**2 (1.7%)**	**0**	**1.7% (-0.6%, 3.9%)**	**0**
Migraine (new)	0	2 (1.7%)	0	1.7% (-0.6%, 3.9%)	0
Paresthesia	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Seizure	1 (2.0%)	0	0		0
Pulmonary (Respiratory)	**0**	**0**	**1 (0.8%)**	**-0.8% (-2.4%, 0.8%)**	**0**
Stridor	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Vascular	**0**	**1 (0.8%)**	**1 (0.8%)**	**0.1% (-2.2%, 2.3%)**	**0**
Hemorrhage (treatment or intervention required)	0	1 (0.8%)	1 (0.8%)	0.1% (-2.2%, 2.3%)	0
Wound	**0**	**0**	**2 (1.6%)**	**-1.6% (-3.8%, 0.7%)**	**0**
Hernia	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Scarring or scar related	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Device (HELEX Septal Occluder)	**0**	**3 (2.5%)**	**na**	na	**1 (1.3%)**
Allergic reaction	0	1 (0.8%)	na	na	0
Device size inappropriate	0	2 (1.7%)	na	na	0
Device removal due to fracture	0	0	na	na	1 (1.3%)
Other	**0**	**0**	**1 (0.8%)**	**-0.8% (-2.4%, 0.8%)**	**0**
Anemia	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0

NOTE: Analysis includes all Feasibility subjects, nontraining Pivotal subjects, and Continued Access subjects enrolled and evaluated through 12 month follow-up as of database closure on 12/15/05.

na – not applicable
[1] Differences between Pivotal device and surgery groups and associated 95% confidence intervals
[2] The 4 embolized devices were removed by transcatheter technique

Minor adverse events reported through the 12-month follow-up for the Feasibility, Pivotal and Continued Access studies are presented in Table 3.

Table 3
Number of Subjects with Successful Device Delivery by Category of Minor Adverse Events
GORE HELEX Septal Occluder Studies
Events Reported Through 12-Month Follow-up

		Pivotal Study			
	Feasibility Study	Device Arm	Surgery Arm	Difference (95% CI)[1]	Continued Access Study
Subjects Evaluable for Safety	**51**	**119**	**128**		**77**
Subjects With One or More Minor Adverse Events	**19 (37.3%)**	**34 (28.6%)**	**36 (28.1%)**	**0.4% (-10.9%, 11.8%)**	**21 (27.3%)**
Cardiac	**7 (13.7%)**	**14 (11.8%)**	**26 (20.3%)**	**-8.5% (-17.8%, 0.7%)**	**2 (2.6%)**
Arrhythmia	3 (5.9%)	10 (8.4%)	5 (3.9%)	4.5% (-1.5%, 10.5%)	2 (2.6%)
Chest Pain	1 (2.0%)	2 (1.7%)	0	1.7% (-0.6%, 3.9%)	0
Embolus - air	1 (2.0%)	0	2 (1.6%)	-1.6% (-3.8%, 0.7%)	0
Hemopericardium	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Hypotension	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Palpitations	1 (2.0%)	0	0		0
Pericardial effusion	1 (2.0%)	1 (0.8%)	5 (3.9%)	-3.1% (-6.9%, 0.8%)	0
Pneumopericardium	0	0	3 (2.3%)	-2.3% (-5.1%, 0.4%)	0
Post-Pericardiotomy Syndrome	na	na	10 (7.8%)	na	na
Syncope	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Vaso-vagal reaction	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Integument	**0**	**0**	**0**		**1 (1.3%)**
Abrasion	0	0	0		1 (1.3%)
Neurologic	**7 (13.7%)**	**8 (6.7%)**	**0**	**6.7% (2.3%, 11.1%)**	**7 (9.1%)**
Dizziness	2 (3.9%)	0	0		0
Headache	4 (7.8%)	5 (4.2%)	0	4.2% (0.7%, 7.7%)	7 (9.1%)
Migraine (new)	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Paresthesia	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Visual field disturbance or defect	1 (2.0%)	2 (1.7%)	0	1.7% (-0.6%, 3.9%)	0
Pulmonary (Respiratory)	**0**	**1 (0.8%)**	**8 (6.3%)**	**-5.4% (-10.1%, -0.7%)**	**1 (1.3%)**
Atelectasis	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Congestion	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Dyspnea	0	0	0		1 (1.3%)
Pleural effusion (not requiring drainage)	0	0	3 (2.3%)	-2.3% (-5.1%, 0.4%)	0
Pneumothorax	0	0	4 (3.1%)	-3.1% (-6.3%, 0.0%)	0
Pneumonia	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Renal & Uro-Genital	**0**	**1 (0.8%)**	**0**	**0.8% (-0.8%, 2.4%)**	**0**
Urinary retention	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Anesthesia	**1 (2.0%)**	**3 (2.5%)**	**1 (0.8%)**	**1.7% (-1.4%, 4.9%)**	**5 (6.5%)**
Abdominal Pain	0	0	0		1 (1.3%)
Corneal abrasion	0	0	0		1 (1.3%)
Emesis	0	1 (0.8%)	1 (0.8%)	0.1% (-2.2%, 2.3%)	1 (1.3%)
Nausea	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Nausea with emesis	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	3 (3.9%)
Paresthesia	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Sore throat	1 (2.0%)	0	0		0
Drug-Related	**5 (9.8%)**	**6 (5.0%)**	**2 (1.6%)**	**3.5% (-1.0%, 7.9%)**	**4 (5.2%)**
Allergic response	1 (2.0%)	0	2 (1.6%)	-1.6% (-3.8%, 0.7%)	0
Bruising / Ecchymosis	2 (3.9%)	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	1 (1.3%)
Gastric irritation	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Nosebleed	1 (2.0%)	4 (3.4%)	0	3.4% (0.2%, 6.5%)	3 (3.9%)
Rectal Bleeding	1 (2.0%)	0	0		0
Wound	**2 (3.9%)**	**1 (0.8%)**	**4 (3.1%)**	**-2.3% (-5.8%, 1.3%)**	**1 (1.3%)**
Access site bleeding	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Access site pain	1 (2.0%)	0	0		0
Hematoma (not requiring treatment or intervention)	1 (2.0%)	0	0		1 (1.3%)
Scarring or scar related	0	0	2 (1.6%)	-1.6% (-3.8%, 0.7%)	0

		Pivotal Study			
	Feasibility Study	Device Arm	Surgery Arm	Difference (95% CI)[†]	Continued Access Study
Suture related	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Sternal wire	na	na	1 (0.8%)		na
Delivery System	**2 (3.9%)**	**1 (0.8%)**	na	na	**0**
Mandrel Kink	1 (2.0%)	0	na	na	0
Retrieval cord break	1 (2.0%)	0	na	na	0
Retrieval cord detachment	0	1 (0.8%)	na	na	0
Device (HELEX Septal Occluder)	**3 (5.9%)**	**6 (5.0%)**	**na**	na	**5 (6.5%)**
Fracture-wire frame	3 (5.9%)	6 (5.0%)	na	na	5 (6.5%)
Non-Investigational Device Related	**0**	**0**	**0**		**1 (1.3%)**
Contrast reaction	0	0	0		1 (1.3%)

NOTE: Analysis includes all Feasibility subjects, nontraining Pivotal subjects, and Continued Access subjects enrolled and evaluated through 12 month follow-up as of database closure on 12/15/05.

na – not applicable
[†] Differences between Pivotal device and surgery groups and associated 95% confidence intervals

6.4 Potential Device or Procedure-Related Adverse Events

Adverse Events associated with the use of the GORE HELEX Septal Occluder may include, but are not limited to:

- Repeat procedure to the target ASD
- Post-procedure device embolization
- New arrhythmia post-procedure
- Surgical intervention for device failure or ineffectiveness
- Access site complications requiring surgery, interventional procedure, transfusion, or prescription medication
- Neurological problems resulting in permanent deficit
- Thrombosis or thromboembolic event resulting in clinical sequelae
- Permanent loss of arterial pulse
- Perforation of a cardiovascular structure by the device
- Device fracture resulting in clinical sequelae or surgical intervention
- Pericardial tamponade
- Cardiac arrest
- Renal failure
- Sepsis
- Pneumothorax requiring chest tube evacuation
- Significant pleural or pericardial effusion requiring drainage
- Significant bleeding
- Endocarditis
- Death

7.0 CLINICAL STUDIES

7.1 Feasibility Study

The GORE HELEX Septal Occluder was evaluated in a single arm, prospective feasibility study intended to provide an initial evaluation of the safety and performance of the GORE HELEX Septal Occluder for closure of *ostium secundum* atrial septal defects (ASDs). Two U.S. sites participated in the study and enrolled 63 subjects. The median subject age was 11 years (range: 6 months to 65 years) and 65% of the subjects were female. The median estimated defect size was 12 mm (range: 4.5 to 20 mm). In subjects with a delivery attempt (n=59), the median stretched defect size was 18 mm (range 6 to 26 mm).

The GORE HELEX Septal Occluder was successfully implanted in 86.4% (51/59) of subjects with a delivery attempt. Subjects with a successful device delivery were followed for 12 months. No deaths, device embolizations, thrombus on the device, or erosions requiring surgery were reported through the 12-month follow-up. There were no repeat procedures to the target ASD in the study population.

Of subjects evaluated for 12-month ASD closure by independent echocardiography core laboratory review, 94.6% (35/37) had a successful defect closure (complete occlusion or clinically insignificant leak). Clinically significant leaks were present in two subjects (5.4%) at the 12-month follow-up evaluation. Clinical success, a composite of safety (no major AE or repeat procedure) and efficacy (clinical closure at 12 months), was achieved in 89.5% of subjects (34/38) available for evaluation.

Table 4
GORE HELEX Septal Occluder Feasibility Study
Principal Safety and Effectiveness Results

	Feasibility
Technical Success[1]	51 / 59 (86.4%)
Clinical Closure Success[2]	
Pre-Discharge	49/51 (96.1%)
6 Months	30/31 (96.8%)
12 Months	35/37 (94.6%)
Principal Safety Measures	
Major Adverse Events 12 Months	2/51 (3.9%)
Minor Adverse Events 12 Months	19/51 (37.3%)
Survival at 365 Days (K-M)	100%
Composite Clinical Success 12 Months[3]	34/38 (89.5%)

[1] Technical Success defined as successful delivery of the device
[2] Clinical Closure Success defined as defect that is either Completely Occluded or Clinically Insignificant Leak. Leak status was evaluated by the investigational sites at pre-discharge and 6 months and by the echocardiography core laboratory at 12 months
[3] Composite Clinical Success defined as no major adverse event or repeated procedure and clinical closure success at 12 months

7.2 Purpose - Pivotal and Continued Access Studies

The purpose of the pivotal study was to evaluate the safety and effectiveness of the GORE HELEX Septal Occluder for the closure of *ostium secundum* atrial septal defects. The purpose of the continued access study was to evaluate design modifications to the GORE HELEX Septal Occluder. The design modifications incorporated into the GORE HELEX Septal Occluder were implemented based on investigator input and feedback given during the feasibility and pivotal trials.

7.3 Patient Selection

7.3.1 Pivotal Study

The pivotal study enrolled 143 non-training subjects in the device treatment arm and 128 subjects in the surgical control arm at 14 clinical sites within the U.S. Investigators who did not participate in the feasibility study were required to complete 3 device training cases. Fifty subjects were enrolled as training cases and these subjects were excluded from the primary endpoint analyses.

Enrolled patients had echocardiographic evidence of an *ostium secundum* atrial septal defect and right heart volume overload (or as indicated by a Q_P:Q_S ratio of ≥ 1.5:1 for the device treatment arm). Patients enrolled in the device treatment arm had a defect size of 22 mm or less as measured by balloon sizing and an adequate rim to retain the device present in ≥75% of the circumference of the defect. Patients enrolled in the surgical control arm had surgical intervention within 12 months of IRB approval for the study, a minimum body weight of 8kg at the time of surgery, and a pre-operative, non-anesthesized echocardiogram performed within 6 months of the ASD surgery date. Exclusion criteria included:

- Patient had concurrent cardiac defect(s) that were associated with potentially significant morbidity or mortality that could elevate morbidity/mortality beyond what is common for ASD or that is expected to require surgical treatment within 2 years for the device treatment group or 5 years for the surgical control group.
- Patient had systemic or inherited conditions that would significantly increase patient risk of major morbidity and mortality during the term of the study.
- Patient had an uncontrolled arrhythmia.
- Patient had history of stroke.
- Patient was pregnant or lactating.
- Patient had contraindication to antiplatelet therapy (device treatment arm).
- Patient had a pulmonary artery systolic pressure greater than half the systemic systolic arterial pressure unless the indexed pulmonary artery resistance was <5 Woods units (device treatment arm).
- Patient had significant atrial septal aneurysm (device treatment arm).
- Patient had multiple defects that would require placement of >1 device (device treatment arm).
- Patient had an atrial septum >8mm thick (device treatment arm).
- Patient had an attempted transcatheter septal defect closure device placement within 1 month of surgery (surgical control arm).
- Patient had significant pulmonary hypertension at the time of surgery (surgical control arm).
- Patient had already completed a routine 12-month post-operative evaluation (surgical control arm).

7.3.2 Continued Access Study

The continued access study enrolled 156 non-training subjects at 13 clinical sites within the U.S as of December 15, 2005. Investigators who did not participate in the feasibility and pivotal studies were required to complete 3 device training cases and these cases were excluded from the primary analyses. Enrolled subjects met the same inclusion and exclusion criteria as the pivotal study subjects.

7.4 Demographics

The median age of the 143 subjects enrolled in the device treatment arm of the pivotal study was 6.5 years (range: 1.4 to 72.4 years) and 65.7% of the subjects were female. The median estimated defect size was 10 mm (range: 1.3 to 25 mm) and in subjects with a delivery attempt (n=134), the median stretched defect size was 14 mm (range 5 to 24 mm).

The median age of the 128 subjects enrolled in the surgical control arm of the pivotal study was 4.7 years (range: 0.6 to 70.4 years), and 63.3% of the subjects were female. The median estimated defect size was 15 mm (range: 1.5 to 42 mm).

The median age of the 156 non-training subjects enrolled in the continued access study was 5.5 years (range: 0.8 to 51.4 years) and 66.0% of the subjects were female. The median estimated defect size was 10 mm (range: 1.7 to 20.0 mm). In subjects with a delivery attempt (n=129), the median stretched defect size was 14 mm (range: 4 to 22 mm).

Table 5
GORE HELEX Septal Occluder Studies
Subject Demographics

	Pivotal Study			
	Device Arm	Surgery Arm	Difference (95% CI)[1]	Continued Access Study
Number of Subjects	143	128		156
Gender				
Male	49 (34.3%)	47 (36.7%)	-2.5% (-13.9%, 9.0%)	53 (34.0%)
Female	94 (65.7%)	81 (63.3%)	2.5% (-9.0%, 13.9%)	103 (66.0%)
Subject Ethnicity				
White or Caucasian	95 (66.4%)	84 (65.6%)	0.8% (-10.5%, 12.1%)	106 (67.9%)
Black or African American	15 (10.5%)	9 (7.0%)	3.5% (-3.2%, 10.2%)	9 (5.8%)
Hispanic or Latino	26 (18.2%)	23 (18.0%)	0.2% (-9.0%, 9.4%)	20 (12.8%)
Asian	3 (2.1%)	7 (5.5%)	-3.4% (-8.0%, 1.2%)	5 (3.2%)
Other	3 (2.1%)	3 (2.3%)	-0.2% (-3.8%, 3.3%)	9 (5.8%)
Unknown	1 (0.7%)	2 (1.6%)	-0.9% (-3.4%, 1.7%)	7 (4.5%)
Subject Age (years)				
n	143	128		156
Mean (Std Dev)	12.4 (14.0)	9.2 (12.2)	3.2 (0.1, 6.4)	8.2 (8.3)
Median	6.5	4.7		5.5
Range	(1.4, 72.4)	(0.6, 70.4)		(0.8, 51.4)
Weight (kg)				
n	143	128		156
Mean (Std Dev)	35.6 (26.0)	27.5 (22.4)	8.2 (2.3, 14.0)	27.9 (20.5)
Median	23.0	17.5		19.0
Range	(9.2, 132.5)	(8.3, 135.0)		(6.9, 105.5)
Body Surface Area (BSA)				
n	143	128		156
Mean (Std Dev)	1.08 (0.51)	0.91 (0.46)	0.2 (0.1, 0.3)	0.92 (0.44)
Median	0.89	0.72		0.77
Range	(0.32, 2.61)	(0.38, 2.01)		(0.33, 2.07)
Estimated ASD Size (mm)				
n	141	124		155
Mean (Std Dev)	10.7 (3.8)	15.5 (6.3)	-4.8 (-6.1, -3.6)	10.0 (3.2)
Median	10.0	15.0		10.0
Range	(1.3, 25.0)	(1.5, 42.0)		(1.7, 20.0)

NOTE: Analysis includes all nontraining Pivotal subjects and Continued Access subjects enrolled and evaluated through 12 month follow-up as of database closure on 12/15/05

[1] Differences between Pivotal device and surgery groups and associated 95% confidence intervals

Table 6
GORE HELEX Septal Occluder Studies
Subject Medical History

	Pivotal Study			
	Device Arm	Surgery Arm	Difference (95% CI)[1]	Continued Access Study
Subjects Enrolled	143	128		156
General Medical History				
Previous Cardiac Surgery	8 (5.6%)	4 (3.1%)	2.5% (-2.4%, 7.3%)	7 (4.5%)
ECG Abnormalities	72 (50.3%)	89 (69.5%)	-19.2% (-30.6%, -7.7%)	91 (58.3%)
Cardiac Arrhythmia(s)	12 (8.4%)	3 (2.3%)	6.0% (0.8%, 11.3%)	4 (2.6%)
Chromosomal Abnormalities	4 (2.8%)	7 (5.5%)	-2.7% (-7.4%, 2.1%)	12 (7.7%)
Emotional or Psychiatric Problems	5 (3.5%)	0 (0.0%)	3.5% (0.5%, 6.5%)	6 (3.8%)
Epilepsy	0 (0.0%)	0 (0.0%)	0.0% (0.0%, 0.0%)	1 (0.6%)
Failure to Thrive	1 (0.7%)	5 (3.9%)	-3.2% (-6.8%, 0.4%)	8 (5.1%)
Migraines	3 (2.1%)	1 (0.8%)	1.3% (-1.5%, 4.1%)	1 (0.6%)
Neurological Deficits/Symptoms	7 (4.9%)	5 (3.9%)	1.0% (-3.9%, 5.9%)	9 (5.8%)
Other (non-ASD) Cardiac Disease	15 (10.5%)	5 (3.9%)	6.6% (0.5%, 12.6%)	18 (11.5%)
Other Vascular Disease	2 (1.4%)	1 (0.8%)	0.6% (-1.8%, 3.1%)	2 (1.3%)
Pre-Term Baby	6 (4.2%)	8 (6.3%)	-2.1% (-7.4%, 3.3%)	12 (7.7%)
Respiratory Difficulties	14 (9.8%)	13 (10.2%)	-0.4% (-7.5%, 6.8%)	18 (11.5%)
Hepatitis	0 (0.0%)	0 (0.0%)		0 (0.0%)
Other	29 (20.3%)	43 (33.6%)	-13.3% (-23.8%, -2.8%)	68 (43.6%)
Current Medication Pre-procedure				
Anti-arrhythmic	7 (4.9%)	2 (1.6%)	3.3% (-0.8%, 7.5%)	0 (0.0%)
Anti-coagulant	2 (1.4%)	0 (0.0%)	1.4% (-0.5%, 3.3%)	1 (0.6%)
Anti-hypertensive	4 (2.8%)	2 (1.6%)	1.2% (-2.2%, 4.7%)	0 (0.0%)
Anti-platelet	10 (7.0%)	2 (1.6%)	5.4% (0.7%, 10.1%)	13 (8.3%)
Diuretic	5 (3.5%)	5 (3.9%)	-0.4% (-4.9%, 4.1%)	3 (1.9%)
Other	36 (25.2%)	29 (22.7%)	2.5% (-7.6%, 12.7%)	42 (26.9%)

NOTE: Analysis includes all nontraining Pivotal subjects and Continued Access subjects enrolled and evaluated through 12 month follow-up as of database closure on 12/15/05.
[1] Differences between Pivotal device and surgery groups and associated 95% confidence intervals

7.4 Design

7.4.1 Pivotal Study

The Multicenter Pivotal Study of the GORE HELEX Septal Occluder was a non-randomized, controlled trial comparing safety and efficacy outcomes of the GORE HELEX Septal Occluder with traditional (open) surgical repair of atrial septal defects.

The primary study endpoint was clinical success, a composite evaluation of safety and efficacy, which was evaluated at 12 months post-procedure. Clinical success was defined as: 1) A residual defect classified as either completely occluded or clinically insignificant leak as determined by echocardiography core lab assessment; 2) No repeat procedure to the target ASD; and 3) No major device- or procedure-related adverse events. The study was designed to demonstrate that the clinical success rate of the GORE HELEX Septal Occluder was not inferior to the clinical success rate for surgical closure of ASDs.

Additional safety endpoints included the proportion of subjects experiencing one or more major and minor device-related and/or procedure-related adverse events through 12 months post-procedure. Additional efficacy endpoints included delivery (technical) success, defined as successful deployment and accurate placement of the GORE HELEX Septal Occluder to the target ASD, and treatment efficacy, defined as the proportion of subjects with a final residual defect assessment of clinically successful closure (completely occluded or clinically insignificant leak).

7.4.2 Continued Access Study

The continued access study was a prospective, single-arm trial intended to evaluate design modifications to the GORE HELEX Septal Occluder . The design modifications incorporated into the GORE HELEX Septal Occluder were implemented based on investigator input and feedback given during the feasibility and pivotal trials. The continued access study endpoints were the same as those of the pivotal study and were evaluated at 12 months.

7.5 Method

7.5.1 Pivotal Study - Device Treatment Arm

For patients enrolled in the device treatment arm of the pivotal study, dimensional verification and characterization of the ASD and surrounding cardiac structures were performed per the investigator's standard methods. An initial static measurement of the septal defect was obtained during echocardiographic visualization. A second measurement was taken utilizing a balloon to gently stretch the defect and measure the balloon's waist (narrowest portion of the balloon), and the balloon stretched defect size was used to determine the optimal size of the GORE HELEX Septal Occluder per IFU recommendations. Fluoroscopic and echocardiographic guidance were used throughout the procedure for placement of, and at the completion of each procedure to assess the status of, the GORE HELEX Occluder.

There was no requirement for prior therapy or medical management. All subjects were placed on the investigator's choice of antiplatelet therapy for 6 months following implantation of the GORE HELEX Septal Occluder, 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 the residual defect status by TTE, were performed at hospital discharge, and at 1, 6, and 12 months post-procedure. If the TTE was inconclusive, a TEE or angiography may have been performed. At the 6 and 12 month follow-up visits, fluoroscopic examinations were performed to assess device integrity.

7.5.2 Pivotal Study - Surgical Control Arm

Investigators identified surgical control subjects at their respective sites who had undergone an open-heart surgical ASD closure within 12 months of IRB approval of the pivotal study, and who also met the inclusion/exclusion criteria for the control arm. Open-heart surgical ASD repair was performed per the investigator's standard procedure, and was achieved by suturing the defect edges or by implantation of autologous or synthetic patch materials over the defect.

Subjects were placed on antiplatelet therapy and prophylactic, post-procedure antibiotic therapy at the investigator's discretion and consistent with investigator's standard method.

Follow-up evaluations, which included a physical exam, ECG, and an assessment of the residual defect status by TTE, were performed at hospital discharge and at 12 months. If the TTE was inconclusive, a TEE or angiography may have been performed.

7.5.3 Continued Access Study

The methodology and follow-up of the continued access study was the same as that of the device treatment arm of the pivotal study.

7.6 Results

7.6.1 Pivotal Study - Device Treatment Arm

The GORE HELEX Septal Occluder was successfully implanted in 88.1% (119/135) of subjects with a delivery attempt. No deaths, device-related thrombus, perforations, or erosions requiring surgery were reported. Major adverse events were reported in 5.9% of subjects with a successful delivery through the 12-month follow-up. Clinically successful closure (complete occlusion or clinically insignificant leak), as determined by echocardiographic core laboratory review, was achieved in 98.1% of subjects evaluated at 12 months post-procedure. The primary clinical success endpoint was achieved in 91.7% of subjects evaluated.

7.6.2 Pivotal Study - Surgical Control Arm

Major adverse events were reported in 10.9% of control subjects. One death resulting from complications of post-pericardiotomy syndrome was reported. Clinically successful closure, as determined by echocardiographic core laboratory review, was achieved in 100% of subjects evaluated at 12 months post-procedure. Clinical success was achieved in 83.7% of subjects evaluated.

7.6.3 Continued Access Study

The GORE HELEX Septal Occluder was successfully implanted in 85.6% of subjects with an attempt. No deaths, device-related thrombus, perforations, or erosions requiring surgery were reported. Major adverse events were reported in 3.9% of subjects with a successful delivery who have been evaluated through 12 months. Clinically successful closure, as determined by echocardiographic core laboratory review, was achieved in 98.0% of subjects who have been evaluated at 12 months post-procedure. The primary clinical success endpoint was achieved in 92.6% of subjects evaluated.

7.6.4 Tables of Safety and Effectiveness Results

The principal safety and effectiveness results through 12 months and the procedure outcomes for the pivotal and continued access studies are reported in **Tables 7 and 8**.

Table 7
GORE HELEX Septal Occluder Studies
Principal Safety and Effectiveness Results

	Pivotal Study			Continued Access Study
Study Outcomes	Device Arm	Surgery Arm	Difference (95% CI)[4]	
Technical Success[1]	119/135 (88.1%)	na	na	113 / 132 (85.6%)
Clinical Closure Success[2]				
Pre-Discharge	115/118 (97.5%)	123/123 (100%)	-2.5% (-5.4%, 0.3%)	110/112 (98.2%)
Month 6	99/101 (98.0%)	na	na	80/80 (100%)
Month 12	103/105 (98.1%)	82/82 (100%)	-1.9% (-4.5%, 0.7%)	50/51 (98.0%)
Principal Safety Measures				
Major Adverse Events 12 Months	7/119 (5.9%)	14/128 (10.9%)	-5.1% (-11.9%, 1.8%)	3/77 (3.9%)
Minor Adverse Events 12 Months	34/119 (28.6%)	36/128 (28.1%)	0.4% (-10.8%, 11.7%)	21/77 (27.3%)
Survival at 365 Days (K-M)	100%	99.1%		100%
Composite Clinical Success 12 Months[3]	100/109 (91.7%)	72/86 (83.7%)	8.0% (-1.3%, 17.4%)	50/54 (92.6%)

NOTE: Analysis includes non-training Pivotal subjects and non-training Continued Access subjects enrolled and evaluated through 12 month follow-up as of database closure on 12/15/05.
na – not applicable
[1] Technical Success defined as successful delivery of the device in subjects with a delivery attempted
[2] Clinical Closure Success defined as residual defect that is either Completely Occluded or Clinically Insignificant Leak. Leak status was evaluated by the investigational sites at pre-discharge and 6 months and by the echocardiography core laboratory at 12 months
[3] Composite Clinical Success defined as no major adverse event or repeated procedure and clinical closure success at 12 months
[4] Differences between Pivotal device and surgery groups and associated 95% confidence intervals

Table 8
GORE HELEX Septal Occluder Studies
Procedural Outcomes

	Pivotal Study			
	Device Arm	Surgery Arm	Difference (95% CI)[1]	Continued Access Study
Subjects with Delivery Attempt/Surgery	135	128		132
Total Time Under Fluoroscopy (minutes)				
n	134	na		127
Mean (Std Dev)	28 (21)			23 (16)
Median	22			19
Range	(6, 148)			(5, 116)
Total Time Under Anesthesia (minutes)				
n	133	128		125
Mean (Std Dev)	168 (63)	205 (43)	-37.1 (-50.3, -23.9)	157 (61)
Median	160	202		153
Range	(55, 360)	(30, 330)		(30, 380)
Days in Hospital for Procedure				
n	135	128		129
Mean (Std Dev)	1 (0)	3 (1)	-1.9 (-2.1, -1.7)	1 (0)
Median	1	3		1
Range	(0, 4)	(1, 9)		(0, 2)

NOTE: Analysis includes all nontraining Pivotal subjects and Continued Access subjects enrolled and evaluated through 12 month follow-up as of database closure on 12/15/05.
na – not applicable
[1] Differences between Pivotal device and surgery groups and associated 95% confidence intervals

Table 9 presents the number of devices attempted and number of those successfully delivered for each device size overall and by subject age at procedure for combined device subjects from the pivotal and continued access studies.

Table 9
GORE HELEX Septal Occluder Studies
Number of Devices Attempted and Successfully Delivered
By Device Size and Subject Age at Procedure

	HELEX 15 mm (N_S/N_A)[1]	HELEX 20 mm (N_S/N_A)[1]	HELEX 25 mm (N_S/N_A)[1]	HELEX 30 mm (N_S/N_A)[1]	HELEX 35 mm (N_S/N_A)[1]	Overall (N_S/N_A)[1]
Subject Age						
Infant (< 2 yrs)	1 / 1	3 / 4	2 / 5	0	0	6 / 10
Child (2-5 yrs)	5 / 5	21 / 35	53 / 100	27 / 64	4 / 12	110 / 216
Child (6-11 yrs)	3 / 4	10 / 12	15 / 24	23 / 41	4 / 12	55 / 93
Adolescent (12-20 yrs)	2 / 2	6 / 9	11 / 15	10 / 16	12 / 22	41 / 64
Adult (21+ yrs)	0	0	5 / 6	7 / 8	9 / 13	21 / 27
Overall	11 / 12	40 / 60	86 / 150	67 / 129	29 / 59	233 / 410

NOTE: Analysis includes non-training Pivotal device subjects and non-training Continued Access subjects enrolled and evaluated through 12 month follow-up as of database closure on 12/15/05.
[1] N_S = Number of successful device deliveries, N_A = number of devices attempted.

Table 10 presents the frequency of reported medications at follow-up visits for combined device subjects from the pivotal and continued access studies.

Table 10
GORE HELEX Septal Occluder Studies
Summary of Reported Medications for Device Subjects

	Pre-Procedure	Pre-Discharge	Six Months	Twelve Months
Medications				
Anti-Platelet	23/300 (7.8%)	200/231 (86.6%)	122/183 (66.7%)	14/177 (7.9%)
Anti-Arrhythmic	7/300 (2.3%)	6/231 (2.6%)	5/183 (2.7%)	4/177 (2.3%)
Anti-Hypertensive	4/300 (1.3%)	2/231 (0.9%)	3/183 (1.6%)	3/177 (1.7%)
Anti-Coagulant	3/300 (1%)	12/231 (5.2%)	2/183 (1.1%)	3/177 (1.7%)
Diuretic	8/300 (2.7%)	2/231 (0.9%)	2/183 (1.1%)	2/177 (1.1%)

NOTE: Analysis includes non-training Pivotal device subjects and non-training Continued Access subjects enrolled and evaluated through 12 month follow-up as of database closure on 12/15/05.

Table 11 presents a summary of procedural fluoroscopy time by device delivery success and number of devices attempted for combined device subjects from the pivotal and continued access studies.

Table 11
GORE HELEX Septal Occluder Studies
Summary of Procedural Fluoroscopy Times for Device Subjects

	N	Median (minutes)	Range (minutes)
Subjects with Successful Delivery	232	18.7	(5.3, 92.1)
One Device Attempted	161	15.7	(5.3, 46.6)
Two Devices Attempted	49	28.6	(9.8, 76.1)
Three or More Devices Attempted	22	40.0	(24.0, 92.1)
Subjects with Unsuccessful Delivery	35	36.2	(13.4, 148.0)
One Device Attempted	17	27.3	(13.4, 51.3)
Two Devices Attempted	9	34.9	(31.3, 56.2)
Three or More Devices Attempted	9	72.4	(41.5, 148.0)

NOTE: Analysis includes non-training Pivotal device subjects and non-training Continued Access subjects enrolled and evaluated through 12 month follow-up as of database closure on 12/15/05.

7.7 Conclusions

The clinical success outcomes satisfied the primary, non-inferiority hypothesis for the pivotal study ($p<0.001$ using two-sample binomial proportions test with non-inferiority margin of 10%) and indicated that the clinical success rate of the GORE HELEX Septal Occluder is not inferior to surgical closure.

8.0 HOW SUPPLIED

The GORE HELEX Septal Occluder is supplied STERILE in a protective tray in one or more pouches. Provided that the integrity of the pouches is not compromised in any way, they will serve as an effective barrier until the "use by" (expiration) date printed on the box.

8.1 REQUIRED MATERIALS

- GORE HELEX Septal Occluder
- A large volume syringe
- Heparinized saline
- Y-adapter
- Sizing balloon
- 9 Fr or greater introducer sheath
- Sterile bowl

9.0 RECOMMENDED PROCEDURES

9.1 HANDLING THE PRODUCT

The GORE HELEX Septal Occluder is supplied sterile. Check the "use by" (expiration date) and the condition of the package. If there is no obvious damage to the package, all of the contents should be removed from the package in the cardiac catheterization facility in an aseptic manner and placed on a sterile field in preparation for inspection prior to use.

9.2 SIZING THE DEFECT AND SELECTING THE PROPER OCCLUDER SIZE

9.2.1 General recommendations

When sizing the atrial septal defect use ultrasound to measure the septal length in the 4-chamber and short axis views.
Measure the septal defect using the stretched defect balloon technique. Place a contrast filled, compliant balloon across the defect and gently inflate until shunting through the defect has stopped. At this point measure the stretched diameter of the defect using either ultrasound or calibrated biplane fluoroscopy.
When selecting the Occluder size for the defect, consider the following;

- **The Occluder size selected for the defect should achieve at least a 2:1 ratio.**
- To assure that there is adequate space to accommodate the disc within the atrial chambers the selected Occluder diameter should be no more than 90% of the measured septal length.
- The septal tissue margins surrounding the defect must be of sufficient size and integrity to prevent the disc prolapse through the defect and embolization.
- The GORE HELEX Septal Occluder is not recommended for defects larger than 18 mm.

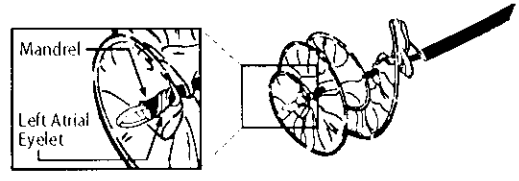
9.3 DEVICE PLACEMENT

1. Evaluate the defect and atrial chamber size by TEE or ICE with color flow Doppler measurement, confirming that 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).
2. Determine defect size using a sizing balloon across the defect.
3. Ensure there is an adequate rim to retain the Occluder in ≥75% of the circumference of the defect.
4. The recommended GORE HELEX Septal Occluder size should provide a 2:1 Occluder diameter-to-defect diameter ratio. **Deploying the Occluder in cases where the Occluder diameter-to-defect diameter ratio is below 2:1 increases the risk of device embolization and residual defects. An Occluder that pulls through the defect during disc conformation may be too small and should be removed and replaced with a larger size.**

9.4 OCCLUDER PREPARATION

1. Inspect the product for damage and ensure that the eyelets are engaged over the mandrel.

FIGURE 3



2. **Loading the Occluder into the black delivery catheter:** To reduce the chance of air entrapment in the delivery system, this step should be conducted with the Occluder submerged in a heparinized saline bath. Attach a y-adapter to the red retrieval cord cap and fill a large volume syringe with heparinized saline. Begin by flushing the control catheter, then, while continually flushing, advance the mandrel and draw back on the gray control catheter until the entire Occluder has been withdrawn into the black delivery catheter (Figures 4, 5, and 6). If the Occluder cannot be easily withdrawn into the delivery catheter the product

should not be used.

FIGURE 4

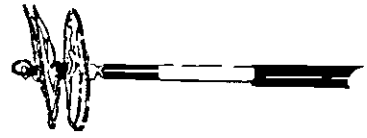


FIGURE 5

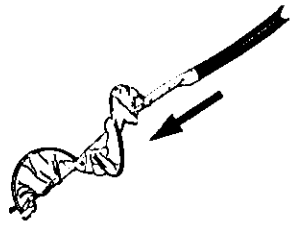
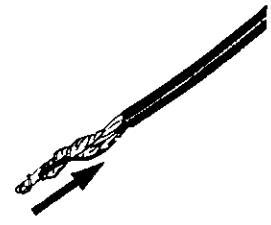


FIGURE 6



3. **Removing air from the delivery system:** After the Occluder has been loaded into the delivery catheter, continue to flush the delivery system through the y-adapter side port. Cover the tip of the black delivery catheter with a gloved fingertip and continue to flush until flushing media is observed at the hub of the delivery catheter.
4. Once the delivery system is flushed, ready for use, and placed within the introducer sheath, remove the y-adapter. **Verify that the red retrieval cord cap is securely attached to the gray control catheter.**

9.5 OCCLUDER DELIVERY

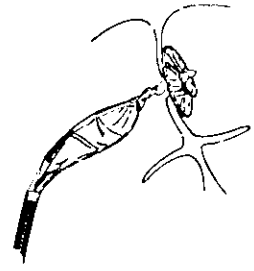
Throughout the procedure, the patient must be heparinized sufficiently to maintain an Activated Clotting Time (ACT) value of greater than 200 seconds.

1. Once the defect is confirmed and measured, insert the black delivery catheter through the introducer sheath and advance the catheter tip through the defect.
2. Confirm that the tip of the black delivery catheter is across the defect using TEE or ICE.
3. Deploy the left atrial disc of the GORE HELEX Septal Occluder into the left atrium by advancing (pushing) the gray control catheter, then retracting (pulling) the mandrel to form the Occluder. Repeat the "push-pull" method until the center (septal) eyelet of the Occluder has exited the tip of the black delivery catheter. **During deployment of the Left Atrial (L.A.) disc, care must be taken to prevent inadvertent lock release by ensuring that the left atrial eyelet is well outside (5 mm) the visible end of the black delivery catheter tip (Figure 7).**

FIGURE 7

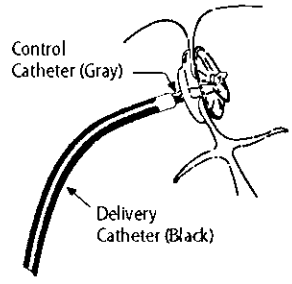
4. Once the left atrial disc is deployed, pull back on the delivery system until the Occluder is in contact with the septal wall. (Figure 8).
5. Confirm proper position using TEE or ICE. If the position is not correct, refer to the repositioning steps later in these instructions.

FIGURE 8



6. Deploy the right atrial disc of the Occluder into the right atrial chamber by first withdrawing the black delivery catheter away from the left atrial disc and septum by 2-3 cm. Form the right atrial disc by holding the mandrel and black delivery catheter in position and pushing the gray control catheter forward. Continue deployment until the tip of the gray control catheter has exited the black delivery catheter and both sides of the device have assumed opposing planar disc shapes (Figure 9).

FIGURE 9

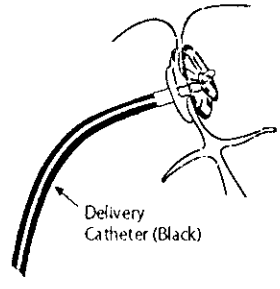


7. Confirm the position of the Occluder using TEE or ICE and assess for residual leak. The discs should appear planar and opposed to the septum with a space equal to the septal thickness. Again, if the position is not acceptable, refer to the repositioning steps later in these instructions.

9.6 OCCLUDER LOCK AND RELEASE

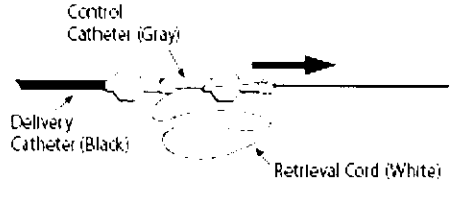
1. In preparation for lock release, advance the tip of the gray control catheter until it is in contact with the Occluder.
2. Confirm the position and alignment of the three eyelets and the Occluder.
3. Advance and position the tip of the black delivery catheter against the right atrial Occluder disc (Figure 10).

FIGURE 10



4. Unscrew the red retrieval cord cap and remove it from the delivery system.

FIGURE 11



5. While maintaining contact of the delivery catheter with the Occluder, withdraw the control catheter 1-2 cm (Figure 11) and return the control catheter to its original position against the Occluder. This step provides 1-2 cm of retrieval cord "slack" between the tip of the control catheter and the right atrial eyelet.
6. Pull the delivery catheter back 2-3 cm.
7. With the control catheter in contact with the Occluder, pull back on the mandrel until the lock is released inside the control catheter. If needed, the control catheter can be withdrawn to complete the release of the locking loop. **Do not withdraw the control catheter so far that the retrieval cord end is pulled inside the delivery catheter hub.**
8. Withdraw the mandrel and remove it completely from the delivery system.
9. At this step, the Occluder is still loosely attached to the gray control catheter by the retrieval cord. If the Occluder position is not acceptable, it may be removed by replacing the retrieval cord and red retrieval cord cap (refer to Step 2 of "Retrieving or Recapturing the GORE HELEX Septal Occluder") and unlocking the Occluder.
10. **With appropriate imaging, re-check the device position. Once the gray control catheter is withdrawn (in the next step), the Occluder cannot be retrieved using the delivery system.**
11. Place the tip of the black delivery catheter against the Occluder and remove the gray control catheter and retrieval cord from the delivery catheter lumen. This step eliminates the ability to retrieve the Occluder using the retrieval cord.

9.7 REPOSITIONING THE OCCLUDER

The Occluder can only be repositioned prior to lock release.

1. To reposition the atrial discs, reverse the deployment steps by advancing (pushing) the mandrel (Figure 5), then retracting (pulling) the gray control catheter (Figure 6). Repeat this reverse "push-pull" method until enough of the Occluder has been retrieved into the black delivery catheter to allow the Occluder to be safely manipulated. Reposition the black delivery catheter and then repeat the deployment steps as outlined above.

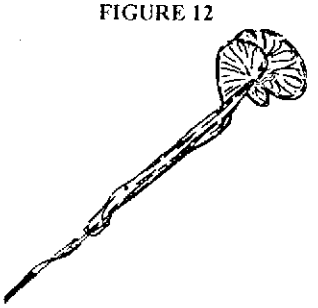
2. Prior to lock release, both the right atrial and the left atrial discs can be repositioned by using the reverse "push-pull" method.

9.8 RETRIEVING OR RECAPTURING THE GORE HELEX SEPTAL OCCLUDER

If the Occluder is retrieved, it should be disposed of, and a new Occluder should be used to complete the procedure.

1. If the lock is released and/or mandrel removed, and if the retrieval cord is still attached to the gray control catheter, the Occluder can be removed by pulling it into its linear form ("unlocking").
   - Tighten the retrieval cord and securely attach the red retrieval cord cap.
   - Position the black delivery catheter in the right atrium and withdraw the gray control catheter while observing the right atrial disc begin to return to its linear form ("unlocking") (Figure 12).
   - Provide sufficient space to allow the locking loop to straighten without contacting the black delivery catheter.

FIGURE 12



   - **Do not attempt to pull the device back into the black delivery catheter if excessive force is encountered.**
     - Important: Without the mandrel to support the wire frame, the operator must prevent catching the eyelets on the introducer sheath or delivery catheter tip. If an eyelet catches on the opening of the introducer sheath and the device is forcefully pulled inside the sheath tip, the retrieval cord may break or the wire frame may fracture.
     - Normal retrieval practices will bring 50-100% of the Occluder frame into the delivery catheter. If locked or unlocked portions of the occluder remain outside of the delivery catheter, withdraw the control catheter and delivery catheter together. If necessary, remove the introducer sheath and the Occluder together.
2. **Emergency recapture** In the event that the Occluder is malpositioned, embolized, or prematurely deployed, it can be recaptured with the aid of a loop snare. A long sheath (10 Fr or greater) positioned close to the device is recommended for recapture. Avoid pulling the unlocked device across valve tissue.

9.9 Multiple Attempts to Close An Atrial Septal Defect

- An initial placement of the Occluder may be considered to assess the Occluder efficacy or to assess the Occluder size, position, septal tissue integrity, and the defect spacing in the case of multi-fenestrated defects. Should the placement of an initial Occluder result in a residual defect that is clinically significant or if the Occluder appears unstable due to poor tissue integrity it is recommended that the Occluder be removed. If prolonged or multiple attempts at occluder placement are required, consideration should be given to minimize the patient's exposure to radiation (see **Table 11**). If the patient's septal anatomy is determined to be unsuitable for the GORE HELEX Septal Occluder, alternative treatment options such as other Occluder designs or surgical closure of the defect should be considered.
- If successful delivery cannot be achieved after 2 attempts, an alternate treatment for ASD closure is recommended.

10.0 POST-PROCEDURAL RECOMMENDATIONS

- Patients should take appropriate prophylactic antibiotic therapy consistent with the physician's routine procedures following device implantation.
- Patients should be treated with antiplatelet therapy, such as aspirin or clopidogrel bisulfate, for 6 months post-implant. The decision to continue antiplatelet therapy beyond 6 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, and at 1, 6, and 12 months after occluder placement to assess defect closure.
- Fluoroscopy examination without contrast is recommended at 12 months post-procedure for patients with a 35 mm device with attention directed toward possible wire frame fractures.

11.0 MRI INFORMATION

- *Through non-clinical testing, the GORE HELEX Septal Occluder has been shown to be MRI safe at field strengths of 3.0 Tesla or less and a maximum whole body averaged specific absorption rate (SAR) of 3.0w/kg for 15 minutes of MRI. The GORE HELEX Septal Occluder should not migrate in this MRI environment. Non-clinical testing has not been performed to rule out the possibility of device migration at field strengths higher than 3.0 Tesla.*

In this testing, the GORE HELEX Septal Occluder produced a temperature rise of less than or equal to 0.5 degrees C at a

maximum whole body averaged specific absorption rate (SAR) of 3.0 w/kg for 15 minutes of MRI.

MRI quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the GORE HELEX Septal Occluder.

8-10-06