

**The CardioSEAL<sup>?</sup> STARFlex<sup>?</sup> Septal Occlusion System with Qwik Load<sup>?</sup>  
 Instructions For Use for Transcatheter PFO Closure  
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# CardioSEAL STARFlex Septal Occlusion System with QwikLoad

## Instructions for Use

Caution : Federal law (USA) restricts this device to sale by or on the order of a physician.

### 1. PRODUCT DESCRIPTION

The CardioSEAL STARFlex Septal Occlusion System consists of two primary components:

- ?? The STARFlex Occluder, a permanent implant, which is constructed of a metal (MP35N) framework to which polyester fabric is attached, and
- ?? The Delivery Catheter, a coaxial polyurethane catheter designed specifically to facilitate attachment, loading, delivery and deployment of the STARFlex to the defect.

The occluder is available in sizes 23mm, 28mm, and 33mm.

### 2. INDICATIONS FOR USE

The CardioSEAL STARFlex Septal Occlusion System with QwikLoad is indicated for closure of patent foramen ovale (PFO) in patients at risk for a recurrent cryptogenic stroke or transient ischemic attack (TIA) due to presumed paradoxical embolism through a PFO and, who are poor candidates for surgery or conventional drug therapy.

### 3. CONTRAINDICATIONS

Patients with thrombus at or near the intended site of implant, or documented evidence of venous thrombus in the vessels through which access to the defect is gained unless the patient is protected with other embolic protection devices such as a vena cava filter.

Active endocarditis, or other infections producing a bacteremia.

Patients whose vasculature, through which access to the defect is gained, is inadequate to accommodate a 10F delivery sheath.

Patients whose defect is too small to allow the 10 F sheath to cross the defect.

Anatomy in which the STARFlex size or position required would interfere with other intracardiac or intravascular structures, such as valves or pulmonary veins.

Patients who are unable to take Aspirin, Heparin, Coumadin, or other anticoagulants.

Patients with an intra-cardiac mass or vegetation.

### 4. WARNINGS

This device should only be used by those physicians trained in transcatheter defect closure techniques.

Physicians attempting to recover an embolized device should be limited to those that have completed appropriate device retrieval technique training.

Embolized STARFlex devices may disrupt critical cardiac functions and should be removed. Physicians must be prepared to deal with urgent requirements to extract or move embolized devices that result in critical hemodynamic compromise.

Embolized devices should not be withdrawn through intracardiac structures unless they have been adequately collapsed within a sheath. Devices that are not adequately collapsed within a sheath may entangle valvular or other cardiac structures.

Defect location relative to important cardiac structures must be carefully considered in determining which size device to implant, and suitability for the patient for implant. Device placement should only be considered when the operator is confident that post deployment device position will be of adequate distance from critical structures.

Do not attempt to repair or reuse damaged product. Do not reuse or resterilize product. Return to manufacturer.

STARFlex implants should only be performed at hospitals where cardiovascular surgery can be urgently performed.

Transient hemodynamic compromise may be encountered during device placement, which may require fluid replacement or other medications as determined by the physician.

## **5. PRECAUTIONS**

### **5.1 STARFlex – Handling Precautions**

Do not use the system if, during loading of the STARFlex, difficulty is encountered in transferring the STARFlex into the loader or from the loader into the delivery sheath.

Do not modify the delivery catheter or STARFlex. Modification may result in damage that can result in complications such as embolism, framework fracture, failure to release, and improper seating at the target defect.

### **5.2 STARFlex – Sizing Precautions**

The use of a compliant balloon catheter to determine defect localization is recommended.

Accurate defect sizing is critical to STARFlex size selection. Defect sizing methods, such as contrast angiography, echocardiography and / or balloon sizing should be considered as procedural alternatives. The defect and surrounding structures should be fully examined in multiple planes to assure proper sizing of the STARFlex, and suitability for receiving an implant without interfering with other critical cardiac structures.

The anatomic area surrounding the target defect should have sufficient contiguous structure to support the STARFlex.

### **5.3 STARFlex – Procedural Precautions**

Patients should be fully heparinized throughout the procedure using adequate dosing so as to keep the ACT greater than 200 sec.

Antibiotic therapy periprocedurally is recommended to reduce the risk of perioperative infection.

The use of Transesophageal Echocardiography (TEE) or Intra Cardiac Echocardiography (ICE) should be considered as a potential aid in placing the STARFlex Occluder.

Placement of the STARFlex requires the use of fluoroscopic X-ray guidance. The risk of increased x-ray exposure for patients who are pregnant must be weighed against the potential benefits of the technique.

Malpositioned STARFlex devices may interfere with cardiac, vascular or valvular structures. Physicians should consider removing malpositioned devices in these patients, or moving the implant to a non - obstructive position within the vasculature for subsequent removal via catheter or surgical techniques.

## 5.4 STARFlex – Post Implant Precautions

The time course of endothelialization of the device is unknown. Patients should receive appropriate endocarditis prophylaxis for the six months following implantation. The decision to continue prophylactic treatment after six months is subject to physician judgment.

Patients should be treated with antiplatelet/anticoagulation therapy, such as Aspirin (see Section 8 Clinical Studies for the dosage used in the High-Risk Study) for six-months following implant. The decision to continue medical treatment beyond six months is subject to physician judgment.

The STARFlex device is non-ferromagnetic. Independent studies in a 1.5 Tesla magnetic field demonstrated no movement of the STARFlex. However, MRI image quality may be compromised in the area of the implant.

## 6. ADVERSE EVENTS

### 6.1 Observed Adverse Events

Adverse events that were categorized as serious or moderately serious and were definitely, probably or possibly related to the device, implantation or catheterization procedure are summarized in Table 1.

**Table 1 – Serious and Moderately Serious Adverse Events<sup>1</sup>**

	Percent [95% Confidence Interval]	Number of Patients
<b>Device -Related</b>		
Atrial Fibrillation	6.1% [1.3%, 16.9%]	3
Thrombus w/ Transient Neurological Symptoms	2.0% [0.1%, 10.9%]	1
Palpitations	4.1% [0.5%, 14.0%]	2
SVT	2.0% [0.1%, 10.9%]	1
<b>Implantation-Related</b>		
Air embolism	2.0% [0.1%, 10.9%]	1
<b>Catheterization-Related</b>		
Catheter induced arrhythmia	4.1% [0.5%, 14.0%]	2
Retroperitoneal hematoma	2.0% [0.1%, 10.9%]	1
Vomiting	4.1% [0.5%, 14.0%]	2

1. Table includes all serious and moderately serious adverse events that were definitely, probably or possibly related to the device, implantation or catheterization procedure

Device arm fractures were observed in 7 of the 49 devices (14%). No fracture related adverse events occurred.

## 6.2 Potential Adverse Events

Placement of the STARFlex involves using standard interventional cardiac catheterization techniques. Complications commonly associated with these procedures include, but are not limited to:

- ?? Air Embolus
- ?? Allergic dye reaction
- ?? Anesthesia reactions
- ?? Apnea
- ?? Arrhythmia
- ?? Death
- ?? Fever
- ?? Headache / Migraines
- ?? Hematoma and/or Pseudoaneurysm including blood loss requiring transfusion
- ?? Hypertension; Hypotension
- ?? Infection including Endocarditis
- ?? Perforation of Vessel or Myocardium
- ?? Stroke / Transient Ischemic Attack
- ?? Thromboembolic events
- ?? Valvular regurgitation.

## 6.3 Observed Device Malfunctions

One device was discarded after it was collapsed into the loader (but prior to insertion in delivery catheter) when it was observed that one of the device arms was bent. Loading technique is the suspected cause.

## 7. CLINICAL STUDIES

### 7.1 Study Design/Objective

The multi-center clinical trial conducted by Children's Hospital, Boston, Massachusetts, is a prospective, non-randomized trial studying the use of the STARFlex? Septal Occlusion system to close a variety of hemodynamically significant defects. The risks of surgical closure for the patients enrolled in this trial were considered sufficient to justify the known and potentially unknown risks of transcatheter closure with the STARFlex device. The study (referred to as the High-risk study) is ongoing and is summarized below. Data from patients undergoing PFO closure were extracted from this study.

### 7.2 Patient Entry

Patients were eligible for enrollment in the High Risk Study if they had a defect(s) of sufficient size to require closure, but were considered to be at high risk for surgical closure, due to either complex medical or cardiac disease. An independent peer review group determined whether a patient should be enrolled into the trial based on the following criteria:

- ?? the patient had a type of defect that was technically difficult or impossible to close surgically, such that the surgical risks were sufficient to justify the known and potential unknown risks of the device, or

?? the patient's overall medical condition was such that the surgical risks were sufficient to justify the known and potential unknown risks of the device.

### **7.3 Methods**

After enrollment, patients underwent cardiac catheterization. Position and size of the defect were confirmed by angiography. A hemodynamic assessment was performed pre-implant, and after test occlusion of the defect with a balloon. When these data suggested that the defect contributed to unfavorable hemodynamics and was feasible for transcatheter closure, device placement proceeded. Patients received aspirin, 1mg/kg/day, rounded to the nearest half tablet of 80 mg size, for at least six months following the procedure. Patients were seen for follow up assessments at 1, 6, 12 and 24 months.

### **7.4 Results**

At the time the PFO data was analyzed, 49 patients were enrolled in the study for closure of a PFO with a STARFlex device. Enrollment occurred at four investigational sites. All but one patient had a prior neurological event as their indication for device closure (98%).

Device placement was successful, using a single device at a single procedure, in all 49 patients (100%).

The cohort included patients with significant comorbid illness, including significant pre-procedure arrhythmias (16%), elevated pulmonary vascular resistance (16%) and significant non-cardiac medical illness (43%). Twenty-four (49%) of the patients were males and 25 (51%) were females. The age of the patients ranged from 2.0 years to 72.6 years, with a median age of 39.1 years.

The primary efficacy outcome was defined as a reduction of embolic risk as demonstrated by complete PFO closure by echocardiography at most recent follow-up. The secondary efficacy outcomes were the occurrence of potential embolic neurological events after device implantation, and, an improvement in oxygen saturation in those patients with fixed right-to-left shunt prior to implant.

During the follow-up period (median 6.5 months, range 1 day to 21.2 months), 43 of 44 patients (98%, 95% C.I. [88%, 100%]) with echocardiographic assessment of residual flow had reduction of their risk of embolic events, as evidenced by documented complete closure of their PFO. The remaining patient had trivial residual flow.

There were no patient deaths, device embolizations or strokes during the follow-up period.

Four patients experienced transient neurological symptoms during the follow-up period, only one of which was consistent with TIA. Resultant device explant occurred in 1 of the 4. The device was explanted surgically approximately one month after implant in a patient with a history of CVA and atrial ectopy, who experienced episodes of atrial fibrillation and transient left sided weakness. At explant, clot was found to be adherent to the device and also to the atrial myocardium, remote from the device.

Ten of the 49 patients had documented fixed right-to-left shunt prior to implant. In these 10 patients, median oxygen saturation improved from 88% prior to implantation to 98.5% at most recent follow-up ( $p=0.02$ ). No patient experienced a decrease in oxygen saturation.

Baseline demographics, principal effectiveness measures and principal safety measures are summarized in Table 2.

**Table 2 - Baseline Demographics, Principal Effectiveness Measures, & Principal Safety Measures**

Patient Demographics			
Age (years)	median [range]	39.1 [2.0, 72.6]	
Gender			
Female		25 (51%)	
Male		24 (49%)	
Patient Enrollment (number of patients)			
Enrolled		49	
Occluder(s) Implanted		49	
Single Procedure		49	
Principal Effectiveness Measures (n=49)			
	Percent [95% C.I.]		Number of Patients
Technical Success <sup>1</sup>	100% [92.7%, 100%]		49
Procedural Success <sup>2</sup>	97.7% [88.0%, 99.9%]		43
Secondary Efficacy Outcomes <sup>3</sup>			
-Stroke	0% [0.0%, 7.3%]		0
-TIA	2.0% [0.1%, 10.9%]		1
-Other Transient Neurological Symptoms	6.1% [1.3%, 16.9%]		3
	Median O <sub>2</sub> Saturation	p-value	
Pre-implant oxygen saturation	88%		9
Post-implant oxygen saturation <sup>4</sup>	98.5%	0.02	8
Principal Safety Measures (n=49)			
	Percent [95% C.I.]		Number of Patients
Serious & Moderately Serious Adverse Events <sup>5</sup>			
Device Related	14.3% [5.9%, 27.2%]		7
Procedure Related <sup>6</sup>	12.2% [4.6%, 24.8%]		6
Device Fractures <sup>7</sup>	14.3% [5.9%, 27.2%]		7

1. Technical success - successful deployment of implant.

2. Procedural success - primary efficacy outcome defined as reduction of embolic risk as demonstrated by complete closure by echocardiography at most recent follow -up. Among the 49 patients, follow -up echocardiography was available on 44 patients.

3. Secondary efficacy outcome defined as the occurrence of potential embolic neurological event after device implantation.

4. Secondary efficacy outcome defined as an improvement in oxygen saturation at most recent follow -up in patients with fixed right-to-left shunt prior to implant. Ten of the 49 patients fall under this category. One of the 10 did not have a baseline oxygen saturation value recorded, but this patient was on oxygen prior to device implant. Follow -up oxygen saturation rates were available on 8 patients.

5. Includes all serious and moderately serious adverse events that were definitely, probably or possibly related to the device, implantation or catheterization procedure.

6. Includes implantation and catheterization procedure related adverse events.

7. Device arm fractures were observed in 7 of 49 implants. No fracture related adverse events occurred.

## **8. HOW SUPPLIED**

The occluder and delivery system are packaged separately and are supplied sterile. Product is sterilized with ethylene oxide.

## **9. DIRECTIONS FOR USE**

### **9.1 Detailed Product Description**

The CardioSEAL STARFlex Septal Occlusion System consists of two primary components.

The STARFlex (Occluder) is comprised of a metal alloy (MP35N) framework to which polyester fabric material has been attached. From the center of the STARFlex, a small wire with a pin at its end extrudes out at approximately 90 degrees to the plane of the device. The centering spring, designed to align the implant centrally within the defect, is attached on the inside surface of each umbrella. The STARFlex is attached to sutures through a loading funnel. The loader should always be connected via sutures to the side of the STARFlex opposite the side from which the pin wire extrudes.

The delivery catheter is comprised of a coaxial catheter shaft through which a spring guide travels, connected to a solid control rod. At the proximal end of the control rod, a control handle is connected to an inner control wire, which courses through the spring guide to the distal end of the catheter shaft, where it terminates within a small tubular sleeve. The control wire terminates at the distal end in a pin, for attachment to its mate on the STARFlex. When retracted, the pin slides inside the sleeve. Retraction on the control rod moves the inner control wire coaxially within the catheter shaft. Refer to figure 1 for an illustration of the delivery system and STARFlex.

### **9.2 STARFlex Size Selection and Inspection**

Selection of an appropriately sized STARFlex should be based upon measuring the PFO size through the use of a sizing balloon (stretched defect diameter – SDD), procedural angiography, Intracardiac, and/or Transesophageal echocardiography, unless the size of the defect is known from the medical record. It is recommended that the STARFlex to Stretched Defect Diameter ratio (O:SDD) be 1.7-2.0:1, and that the area containing the target defect be large enough to allow the STARFlex to fully deploy. The defect and surrounding structures should be fully examined in multiple planes to assure proper device size selection. If an atrial septal aneurysm is present, the physician should consider selecting a STARFlex occluder of sufficient size to occlude the PFO and cover the area of aneurysmal tissue so as to stabilize septal motion.

The Right Femoral Vein is recommended for vascular access. Infrequently, the right femoral artery can be used for access. Closure of a PFO via subclavian or internal jugular artery is not recommended due to the extreme sheath curvature required from these anatomical locations.

A 10F or 11F, 75cm long, hemostasis control introducer sheath with NIH type curve is recommended for STARFlex delivery, depending on device size selected. Generally, while all implants will fit adequately in a 10F sheath, the 11F sheath will provide less friction during deployment. Sheath curve shape may need modification based on individual patient conditions and defect location. As the use of long sheaths represents a potential risk of air embolus, care should be taken to insure adequate irrigation and 'backfilling' of the sheath with saline during removal of the dilator and during all sheath manipulations in order to avoid air entry.

A 14F or 16F short introducer sheath may be placed coaxially over the long introducer sheath prior to long sheath insertion if the physician believes the circumstances of the case raise the potential for device retrieval after attempted placement.

Prior to use, inspect the delivery system and STARFlex for signs of damage, such as kinks or bends in delivery wire or framework of the STARFlex. Check for secure attachment of the fabric to the framework.

Manipulate the delivery system and actuate the control handle to ensure that the attach release pin exits and retracts into the sleeve, and that the control handle locking stem appropriately interfaces with the white locking tab on the pin wire control handle.

### **9.3 Preparation for Delivery**

*NOTE:* Attachment and loading of the STARFlex into the delivery catheter should not occur until

- a. the defect has been determined to be of appropriate size and position to accommodate the STARFlex, and
- b. access to the defect with an appropriate French size and length introducer sheath has been obtained.

### **9.4 General Description of the STARFlex Occluder and Delivery System with Qwik load adaptation**

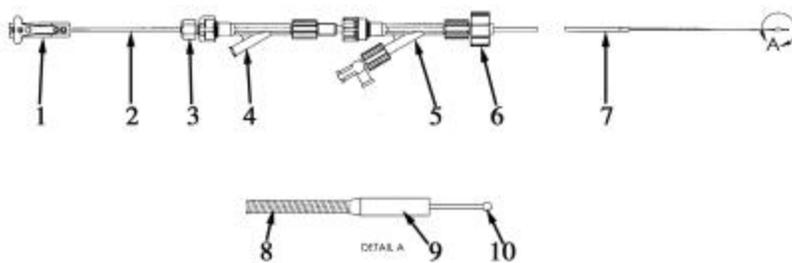
The CardioSEAL STARFlex Septal Occlusion System incorporates a loading system, called QwikLoad<sup>®</sup> that serves to transfer the loaded STARFlex into the delivery sheath. The QwikLoad Assembly is comprised of a Funnel Pod that directs the Occluder into a tubular section called the Funnel Pod Tube. The Funnel Pod Tube is protected by a clear Outer Jacket that acts as a stop to prevent the occluder from being pulled out the end. The Funnel Pod has luer threads on the outer rim for connection to the Irrigation Troughy on the delivery catheter to facilitate irrigation of the Occluder prior to insertion in the sheath. See Figure 1 for a diagram of the Occluder and associated nomenclature.



**Figure 1**

- |    |            |    |                 |
|----|------------|----|-----------------|
| 1. | Occluder   | 4. | Funnel Pod Tube |
| 2. | Suture     | 5. | Outer Jacket    |
| 3. | Funnel Pod | 6. | Suture button   |

The Delivery System with QwikLoad (Figure 2) is a coaxial catheter that facilitates attachment of the Occluder and transfer of the Occluder from the Funnel Pod to a previously placed and irrigated (10F minimum) sheath.



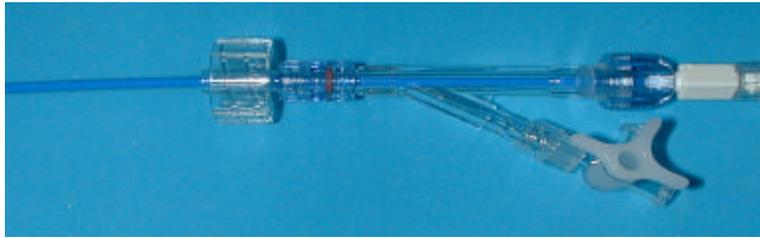
**Figure 2**

- |    |                         |     |                       |
|----|-------------------------|-----|-----------------------|
| 1. | Pin Wire Control Handle | 6.  | Irrigation Toughy Cap |
| 2. | Control Rod             | 7.  | Blue Catheter Shaft   |
| 3. | Locking Collar          | 8.  | Spring Guide          |
| 4. | Control Toughy          | 9.  | Sleeve                |
| 5. | Irrigation Toughy       | 10. | Pin Wire              |

## 9.5 Attachment and Loading of the Occluder to the Delivery System

Open and remove components from the Occluder and Delivery System packages and inspect for obvious signs of damage from shipment. If damage is suspected, do not use. Place the Occluder with Qwik Load Assembly into sterile saline for irrigation.

**Figure 3:** Recheck Irrigation Toughy on the blue delivery catheter shaft and, if loose, gently tighten to prevent it from slipping off the catheter and to keep it out of the way until required for irrigation later in the loading process.



**Figure 3**

Loosen the locking collar on the delivery system and fully extend the spring guide from the tip of the blue catheter shaft. This will facilitate irrigation of the delivery system and allow for easier attachment of the Occluder.

Irrigate the delivery system via the side port on the control toughy. Remember to tighten the locking collar around the control rod to facilitate downstream irrigation of the catheter shaft portion. Leave locking collar in the tightened position to fix relationship of blue catheter to spring guide.

Using the Pin Wire Control Handle, extrude the Pin Wire about 2-3 mm out from the sleeve.

**Figure 4:** Holding the Occluder, insert the Occluder pin into the sleeve of the delivery system, and then retract delivery system pin wire back into the sleeve using the Pin Wire Control Handle.



**Figure 4**

Lightly pivot the occluder to assure that pivoting mechanism is operating. The Occluder is now securely attached to the delivery system and ready for collapsing into the Qwik Load assembly.

#### **Loading of the Occluder**

Irrigate the Funnel Pod loader with the Irrigation Toughy with normal saline. DO NOT REMOVE LOADER JACKET.

**Figure 5:** While holding the blue catheter shaft steady, pull the suture button to draw the distal arms of the Occluder into a fully collapsed position.



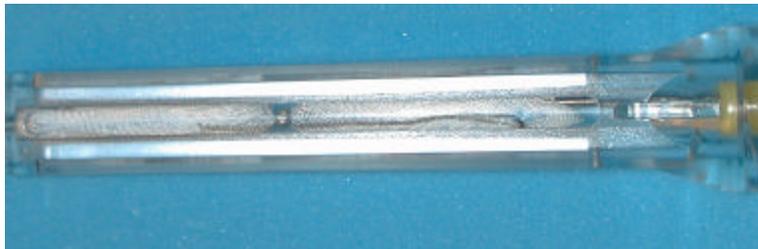
**Figure 5**

**Figure 6:** While holding light tension on both the suture button and the blue catheter, gently advance the Funnel Pod over the collapsed Occluder arms and then over the proximal arms.



**Figure 6**

**Figure 7:** Pull gently until resistance is felt when the collapsed Occluder reaches the end of the Funnel Pod Tube (visible through Outer Jacket).



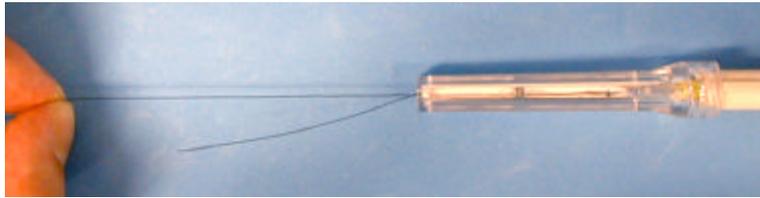
**Figure 7**

**Figure 8:** Loosen the locking collar on the delivery system and advance the blue catheter into the Funnel Pod Tube until the tip of the blue catheter is adjacent to the collapsed (or within 1mm) Occluder. Then, retighten locking collar.



**Figure 8**

**Figure 9:** Cut the Suture and remove and discard Suture and Suture Button.



**Figure 9**

**Figure 10:** Remove and discard Outer Jacket (attached by luer connection).



**Figure 10**

**Figure 11:** The Occluder should now be fully collapsed inside the Funnel Pod. Note how the blue catheter is adjacent to the Occluder.



**Figure 11**

**Figure 12:** Loosen the Irrigation Troughy and advance it over the blue catheter, connecting it securely to the Funnel Pod.



**Figure 12**

Irrigate the Funnel Pod thoroughly by attaching a syringe to the 3-way stopcock. First, loosen the toughy portion of the Irrigation Toughy and irrigate proximally toward the catheter hub. Tighten the toughy portion of Irrigation Toughy and irrigate distally through the Funnel Pod, which contains the collapsed Occluder. The Occluder is now ready to be transferred into the previously placed delivery sheath. *Re-irrigation of the delivery sheath prior to Occluder insertion is recommended; especially if the sheath has been inserted for some time prior to implant transfer.*

**Figure 13:** Insert the Funnel Pod Tube into the hub of the previously placed long sheath. Advance it (the Funnel Pod Tube) through the sheath hub and into the sheath, until resistance is met. The Occluder is now ready to be transferred into the sheath, which is in place through the defect.

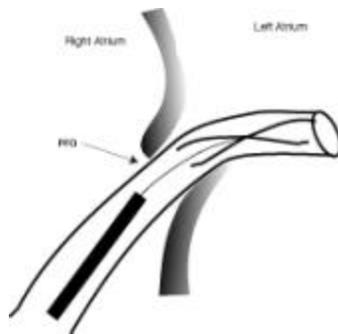


**Figure 13**

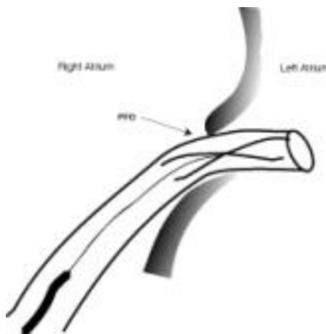
## 9.6 Insertion

**NOTE:** As previously discussed in Section C, Preparation, Note B, an introducer sheath of sufficient French size for the STARFlex and of adequate length to reach the PFO should have been placed via the venous system across the defect.

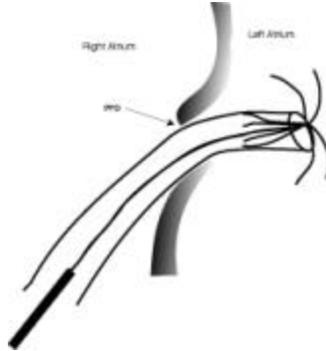
- 9.6.1 Reposition sheath across the defect so that the distal tip of the sheath is approximately 1cm into the distal side of the defect. Thoroughly irrigate the previously placed introducer sheath to minimize risk of air entry and air embolus.
- 9.6.2 Using the delivery catheter, advance the STARFlex into the sheath. The STARFlex will remain collapsed within the sheath. Continue to advance the STARFlex until it is within 1-2mm of the tip of the sheath.



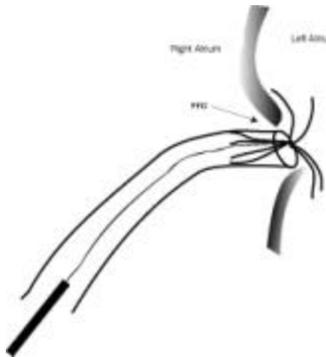
- 9.6.3 Recheck sheath tip position to verify location on distal side of defect. Holding the control rod steady to maintain the position of the Occluder at the tip of the sheath, loosen the locking collar and retract the delivery catheter off the guide wire approximately 10 cm.



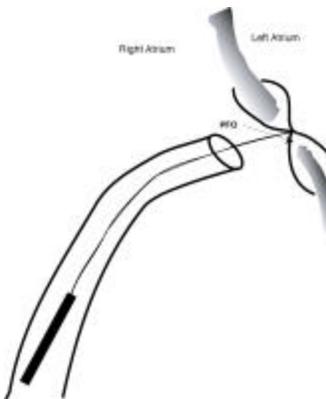
- 9.6.4 Holding the delivery catheter steady open distal set of STARFlex arms by retracting sheath off of the distal arms. Under fluoroscopy and Transesophageal echo, ascertain that all four distal STARFlex arms have fully deployed and are intact.



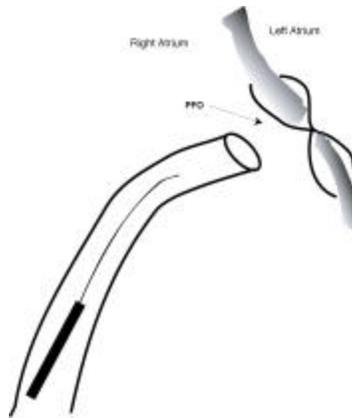
- 9.6.5 Holding the sheath and catheter steady, retract entire sheath – delivery catheter - STARFlex system until the distal STARFlex arms approximate or engage the distal wall of the defect.



- 9.6.6 Once approximated or engaged, retract STARFlex further to slightly flex the STARFlex arms. Retract sheath off of proximal STARFlex arms while maintaining position in the defect. This will release the proximal arms of the STARFlex to engage the proximal defect wall.



- 9.6.7 Allow delivery catheter and sheath to assume a neutral (i.e. no retraction) position and confirm correct placement of all arms on appropriate sides of the defect.
- 9.6.8 Once proper positioning is confirmed, advance the pin from the sleeve using the control handle at the proximal end of the delivery system. This will release the STARFlex from the delivery catheter. Use caution to avoid pushing the delivery catheter forward while releasing the catheter, in order to avoid inadvertent advancement of the entire implant into the left atrium



- 9.6.9 Remove delivery system from sheath.

## 10. PATIENT INFORMATION

The following counseling information should be provided to the patient:

- ?? Patients should be reminded of the importance of adhering to medication regimens as prescribed post implant.
- ?? If an MRI is required, the patient should inform MRI staff of the presence of the STARFlex occluder.
- ?? Patients should be encouraged to contact their physician if they have any questions or concerns.
- ?? A patient implant information card is included in the instructions for use with each implant. NMT Medical recommends that this card be completed by cath lab personnel and given to each patient for each implant received .
- ?? A patient brochure is available entitled: "Understanding embolic stroke and patent foramen ovale: Information for patient and families about non surgical, catheter based closure using the CardioSEAL STARFlex Occluder". Please contact NMT Medical for additional copies.