FISH™ DEVICE

FEMORAL INTRODUCER SHEATH & HEMOSTASIS DEVICE

INSTRUCTIONS FOR USE
Read instructions before use.

Caution:
"Federal law restricts this device for use by or on the order of a physician (or allied healthcare professionals authorized by or under the direction of such physicians) who have been trained by an authorized representative of MIR, Inc. in the use of the FISH™ Device."

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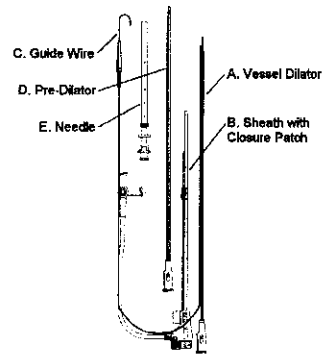

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SYSTEM COMPONENTS / DESCRIPTION

The Femoral Introducer Sheath and Hemostasis Device (FISH™ DEVICE) facilitates percutaneous entry of an intravascular device and aids in reducing time to hemostasis and ambulation for femoral arterial access. French sizes of the FISH™ Device are indicated by color coding. Listed below are the three available French sizes and their corresponding color.

FRENCH		COLOR
5	(1.65 mm)	Gray
6	(2.0 mm)	Green
8	(2.7 mm)	Blue

Vessel Dilator
The vessel dilator atraumatically transitions the guidewire to the sheath through a tapered tip which opens the tissue from the skin to the vessel below.

Guide Wire
The guidewire is provided to maintain access to the vessel upon removal of the needle and during the insertion of the FISH™ Device.

Pre-Dilator
The pre-dilator opens the hole of the entry tract to facilitate easy entry of the sheath and closure patch.

Needle
The needle provides access to the vessel, serves as a pathway for the guidewire and has markers placed on the outside for measurement of the vessel depth which aids in placement of the closure patch.

INDICATIONS
The Femoral Introducer Sheath and Hemostasis device (FISH™ Device) is intended for hemostatic closure of femoral artery access sites. The system is indicated for use in reducing time to hemostasis and time to ambulation in patients who have undergone diagnostic procedures using 5, 6, or 8 French procedural sheaths.

CONTRAINDICATIONS

This product should not be used in patients who have a known sensitivity or allergy to porcine derived material or resorbable sutures.

WARNINGS

- Do not use with Lipiodol contrast media, Ethiodol*, or contrast media that includes components of these agents.
- Do not leave the FISH™ Device in the artery for prolonged periods of time (>24 hrs.) without an obturator or catheter assisting and supporting the cannula wall.
- The FISH™ Device is for one use only. The function and/or performance of the device may be destroyed by reusing, resterilizing, or cleaning the device. Additionally, adverse patient reactions may result. MIR will not be responsible for any damages or expenses that may result from reusing the FISH™ Device.
- If the package of the FISH™ Device is damaged, stained, or appears tampered with/opened prior to use do not use.
- Do not autoclave. The catheter sheath and its components may be damaged by exposure to temperatures above 54° C (130° F).
- Do not expose device to organic solvents.

*Ethiodol is a trademark of Guerbet S. A.

PRECAUTIONS

- Prior to use, make sure the French size is correct for the catheter to be used.
- When the FISH™ Device is used, the entire procedure should occur aseptically.
- A power injector should not be used through the 3-way stopcock or the side tube.
- Note expiration date on the device, and do not use the device if it is labeled as being expired.
- Store FISH™ devices in a dark, cool, dry place. Avoid humidity and direct sunlight.
- Use of the FISH System in diagnostic patients has not been evaluated in patients receiving glycoprotein IIb/IIIa inhibitors.
- Do not use the FISH™ Device if the puncture is made through the posterior wall of the femoral artery or if there are multiple punctures as such punctures may result in a retroperitoneal hematoma.

Special Patient Populations

The safety and effectiveness of the FISH™ Device has not been established in the following patient populations:

- Patients who are pregnant or lactating
- Patients who are <18 or > 80 years of age
- Patients with bleeding diathesis or known hypercoagulable disorders
- Patients with bleeding or platelet disorders
- Patients having Von Willebrand's disease

- Patients having uncontrolled hypertension (systolic BP > 180 mmHg)
- Patients having auto-immune disorders
- Patients having vascular grafts at the puncture site
- Patients receiving glycoprotein IIb/IIIa inhibitors
- Patients with: Pseudoaneurysm, AV fistula, intraluminal thrombus, or arterial dissection present in the ipsilateral femoral artery prior to arterial closure.
- Patients having intra-procedural bleeding around the access site.
- Patients having a palpable ipsilateral hematoma of any size observed during the catheterization procedure.
- Patients developing absent pedal pulses in the ipsilateral lower extremity during the catheterization procedure
- Patients needing a procedure requiring an introducer sheath size of > 8F or < 4F
- Patients having arterial closure site depth > 7.5 cm
- Patients having ACT > 400 seconds at time of sheath removal

Adverse Effects of the Device on Health

The FISH System was evaluated in a randomized controlled clinical investigation involving 206 diagnostic patients enrolled at 8 United States clinical sites; 139 subjects (67%) received the FISH device and 67 subjects received (33%) the control, Manual Compression (MC). Prior to enrollment of randomized patients, each site enrolled non-randomized roll-in patients for training purposes. There were a total of 19 roll-in patients in the diagnostic study.

There was one (1) death reported during the randomized investigation, which was not device-related. This patient was randomized to the FISH device.

Closure method related adverse events seen in the clinical study were:

- Hematoma
- Bleeding Requiring Transfusion
- Pseudoaneurysm Requiring Thrombin Injection

Potential complications of allergic reaction, adhesion formation, infection or abscess, foreign body reaction, wound dehiscence, or vessel occlusion were not seen. The following table (Table 1) shows the adverse events from the diagnostic clinical study.

Table 1 - Major and Minor Complications through 30 Days – Diagnostic ITT Patients

Cumulative Major and Minor Complications - Blackwelder Test for Equivalence					
Randomized Subjects N = 206	FISH Device (n=139)		Manual Comp. (n=67)		p-value **
	% of Patients 95% CI *	No. of Events	% of Patients 95% CI *	No. of Events	
Combined Major Complications	**0.72%** (0.02%, 3.94%)	1	**0%** (0.0%, 5.36%)	0	**<0.0001**
Access-site related bleeding requiring transfusion	0.72% (0.01%, 2.88%)	1	0 (0.0%, 3.42%)	0	<0.0001
New ischemia in ipsilateral leg	0 (0.0%, --)	0	0 (0.0%, --)	0	--
Vascular surgical repair, US-guided compression, transcatheter embolization, or stent graft	0 (0.0%, --)	0	0 (0.0%, --)	0	--
Surgery for access-site related nerve injury	0 (0.0%, --)	0	0 (0.0%, --)	0	--
Permanent access-site related nerve injury	0 (0.0%, --)	0	0 (0.0%, --)	0	--
Access-site related infection requiring IV antibiotics and/or extended hospitalization	0 (0.0%, --)	0	0 (0.0%, --)	0	--
Combined Minor Complications	**2.88%** (0.79%, 7.20%)	4	**1.49%** (0.04%, 8.04%)	1	**0.039**
Access-site related hematoma > 6cm	2.16% (0.45%, 6.18%)	3	1.49% (0.04%, 8.04%)	1	0.012
Pseudoaneurysm treated with ultrasound-guided thrombin injection	0.72% (0.13%, 3.73%)	1	0% (0.02%, 5.14%)	0	<0.0001
Pseudoaneurysm treated with ultrasound-guided fibrin adhesive injection	0 (0.0%, --)	0	0 (0.0%, --)	0	--
Non-treated pseudoaneurysm (documented by ultrasound)	0 (0.0%, --)	0	0 (0.0%, --)	0	--
Non-treated AV fistula (documented by ultrasound)	0 (0.0%, --)	0	0 (0.0%, --)	0	--
Device Success***	99% 137/139	--	--	--	--
Procedure Success****	100% 139/139	--	100% 67/67	--	--

* Exact 95% confidence interval based on Clopper-Pearson method
** Blackwelder's test with an equivalent limit of 0.05. The significance level of 0.041 was used for the interim analysis (p-value was not calculated if AE rates were 0 for both treatment groups)
***Device Success – the ability to achieve hemostasis without major adverse events or the use of mechanical compression and within the allotted time (60 minutes).
**** Procedure Success – the ability to establish hemostasis in a given subject within any time period using any method.

Table 1 shows that the overall MACE rates were 0.72% and 0.0% for FISH device and control group, respectively. The overall Minor Adverse Events rates were 2.88% and 1.5 % for the FISH device and control group respectively.

Clinical Studies

The FISH closure device was studied in an open-label, randomized, multi-center clinical trial which enrolled 297 diagnostic and intervential patients. This United States based trial evaluated the FISH device to manual compression. The study included both diagnostic (N=206) and interventional (N=91) patients requiring a procedure with an 8 Fr or smaller sheath size. The study of interventional patients with the FISH™ device is currently ongoing. Data

from the interventional study is not discussed here. Each investigator had the opportunity to enroll up to 2 roll-in patients which were non randomized patients. There were a total of 28 roll-in patients combined in the diagnostic and interventional study. The patients were randomized on a 2 to 1 randomization scheme (FISH device vs. Manual Compression). Of the 206 diagnostic patients enrolled in the study, 139 received the FISH™ device and 67 received manual compression.

This study included 8 U.S. sites and enrolled patients between January 2004 and June of 2006. There were a total of 40 investigators which enrolled patients for the study.

All patients enrolled in the study provided a signed written informed consent and agreed to return for a follow-up evaluation at 30±5 days. The study included patients who were undergoing diagnostic or therapeutic coronary or peripheral procedure performed percutaneously via the common femoral artery. The candidates were required to meet general inclusion and exclusion criteria. The patients did not require a femoral artery angiogram prior to placement of the FISH device.

The null hypothesis for safety was that the experimental device had a major adverse event rate that exceeded that of the control by a delta of 5%. The alternative hypothesis was that the experimental device has a primary safety endpoint rate less than that of the control or exceeding that of the control by no more than the delta 5%.

Null Hypothesis

MIR FISH (%MACE) > Manual Compression (%MACE) + 5% delta

Alternative Hypothesis

MIR FISH (%MACE) < Manual Compression (%MACE) + 5% delta

For the diagnostic patients, the FISH device demonstrated safety with a total adverse event rate of 0.7% (1/139) versus the control 0.0% (0/67). The one event for the FISH device was a site related bleeding requiring transfusion. These rates for MACE in the diagnostic patients were found to be equivalent ($p < 0.0001$) under the experimental conditions outlined prospectively in the investigational plan.

The minor adverse event rate was low for both the FISH device (2.9%) and the control (1.5%), the tests for equivalence showed these to be equal (p=0.039). The events for the device include 3 hematomas > 6 cm and 1 pseudoaneurysm. For the control there was one hematoma > 6cm. During the course of this clinical trial there was one patient death (1 FISH, 0 Manual Compression). The death was <u>not related</u> to the use of the device.

There were no Unanticipated Access Site Related Adverse Events.

Effectiveness Results

In all effectiveness endpoints the FISH device proved superior in diagnostic patients compared to the control manual compression. The median time for hemostasis in the FISH patients was 6 minutes versus 17 minutes for the control group manual compression. The median time for ambulation for the FISH device was 2.0 hours for the FISH group versus 4.2 hours for the control. The median time to eligible discharge for the FISH device was 2.3 hours versus 4.5 hours for the control manual compression. The median time to discharge was 3.0 hours for the FISH patients versus 4.9 hours for the control group manual compression. The following table (Table 2) shows the effectiveness results.

Table 2 - Diagnostic Procedures: Primary Effectiveness Results ITT

Primary Effectiveness			
Time to Hemostasis (Minutes)	**FISH™**	**Manual Compression**	**p-value**
N	139	67	< 0.0001
Mean (SD)	9.4 (8.7)	17.2 (6.7)	
Median	**6**	**17**	
Min – Max	2 - 75	7 – 55	
Time to Ambulation (Hours)	**FISH™**	**Manual Compression**	**p-value**
N	131	65	<0.0001
Mean (SD)	2.6 (2.5)	4.3 (1.0)	
Median	**2.0**	**4.2**	
Min – Max	0.9 – 19.6	1.3 – 7.3	
Secondary Effectiveness			
Time to Eligible Discharge (Hours)	**FISH™**	**Manual Compression**	**p-value**
N	130	65	<0.0001
Mean (SD)	3.1 (3.3)	5.5 (4.0)	
Median	**2.3**	**4.5**	
Min – Max	1 – 22.4	1.5 - 24.2	
Time to Discharge (Hours)	**FISH™**	**Manual Compression**	**p-value**
N	127	65	<0.0001
Mean (SD)	16.2 (43.1)	24.9 (53.1)	
Median	**3.0**	**4.9**	
Min – Max	1.5 - 263	3.4 – 217.9	
Equivalence Study At 30 Days			
Discomfort (Subjective Scale 0-10)	**FISH™**	**Manual Compression**	**p-value**
N	138	67	--
Mean (SD)	0.51 (1.5)	0.21 (1.0)	
Median	**0**	**0**	
Min – Max	0 - 8	0 – 6	

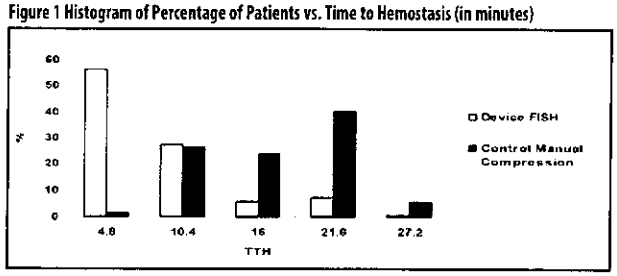
The effectiveness calculations were based on the Wilcoxon Two-Sample Test using a normal approximation and two-sided criteria ($Pr > Z < .0001$).

The results of the statistical analyses demonstrate that the FISH™ device is superior to Manual Compression in terms of effectiveness measures for vascular hemostasis, ambulation, eligible discharge, discharge and equivalent relative to discomfort subjectively measured at 30 days post procedure. The FISH device has demonstrated safety through its low incidence of complications in diagnostic patients when compared to manual compression.

Effectiveness Endpoints

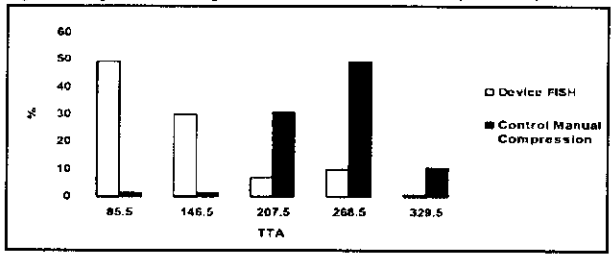
• Time to Hemostasis (TTH) was measured from the time of sheath pull to the time the patient achieved hemostasis. For this study, the time of hemostasis was defined as "Absence of oozing blood that is readily treated by light compression methods (e.g. sandbags, pressure dressing, light manual pressure)" The study was designed to demonstrate TTH superiority as compared to the control therapy.

Figure 1 Histogram of Percentage of Patients vs. Time to Hemostasis (in minutes)



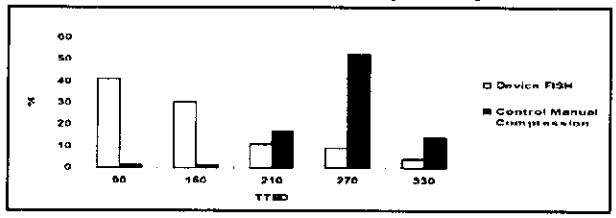
• Time to Ambulation (TTA) – this was measured from the time of sheath removal to the time when the patient stood at the bedside and walked at least 20 feet without evidence of re-bleeding. The study was designed to demonstrate TTA superiority as compared to the control therapy.

Figure 2 Histogram of Percentage of Patients vs. Time to Ambulation (in minutes)



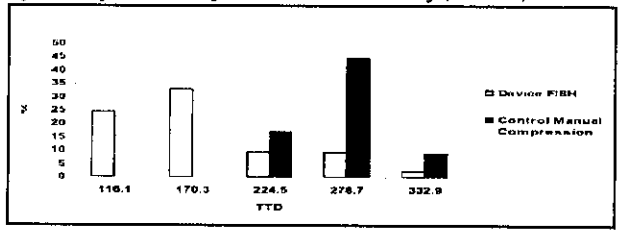
• Time to Eligible Discharge (TTED) – this was measured from the time of sheath pull to the time when the patient was deemed eligible for discharge from the hospital based only on the condition of the access site. The study was designed to demonstrate TTED superiority as compared to the control therapy.

Figure 3 Histogram of Percentage of Patients vs. Time to Eligible Discharge (in minutes)

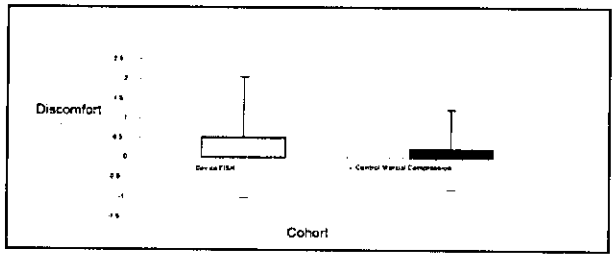


• Time to Discharge (TTD) – this was measured from time of sheath removal to the time the patient was discharged. The study was designed to demonstrate TTD superiority as compared to the control therapy.

Figure 4 Histogram of Percentage of Patients vs. Time to Discharge (in minutes)



• Patient Discomfort - All patients were subjectively asked at the 30 day follow up to rate their site related discomfort from 0 to 10, with 0 being no pain and 10 being the worst pain imaginable. The results from this subjective study showed the device to be equal to the control.



PROCEDURE SUCCESS RATE

Procedure Success Rate (defined as the number of patients in which hemostasis was achieved with freedom from major complications vs. the number attempted). This includes hemostasis which was achieved using adjunctive compression (such adjunctive compression is typically for ≤ 5 minutes).

Device failure was defined as an instance in which hemostasis could not be achieved using the FISH™ Device within an allotted time (60 minutes) or with Manual Compression (Control) – that is when additional means such as a fem-stop or a mechanical compression clamp were required to achieve hemostasis. Four cases of device failure were reported – all but one were interventional subjects.

CONCLUSIONS DRAWN FROM STUDIES

Based on the results from the clinical, in vivo and in vitro studies there is valid scientific evidence and reasonable assurance that the FISH™ Device is safe and effective when used in accordance with the instructions for use.

The FISH™ Device has demonstrated safety through its low incidence of complications in diagnostic patients when compared to manual compression. The FISH™ Device has demonstrated effectiveness by achieving hemostasis and ambulation earlier than the control group manual compression.

RECOMMENDED PROCEDURE

The procedures and techniques presented in these instructions are not representative of all acceptable protocols. Additionally, they are not meant to replace or override the physician's judgment in treating a patient. The procedure listed below involves four processes: 1.) inserting the needle, 2.) placing the patch, 3.) advancing the sheath and 4.) removing the sheath.

Needle Insertion

1. Using controlled sterile technique, remove the FISH™ Device and its contents from the package.
2. Remove air from the FISH™ Device by flushing it with a suitable isotonic solution.
3. Insert the vessel dilator through the introducer hemostasis valve. At the hub, snap it into place. Flush the dilator with a suitable isotonic solution.
4. CAUTION: After the dilator is in the sheath do not attempt to remove the dilator or it may displace the release wire allowing the patch to be independent prematurely.
5. Using aseptic technique, introduce the cannula of the needle into the vessel (Figure 1).

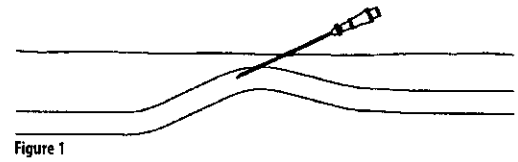


Figure 1

6. Securing the needle by holding it in place, insert the flexible end of the guide wire through the needle and into the vessel. In the case that a J tip is used, slide the guide wire introducer over the J in order to straighten it before insertion. Advance the guide wire to the proper depth (Figure 2).

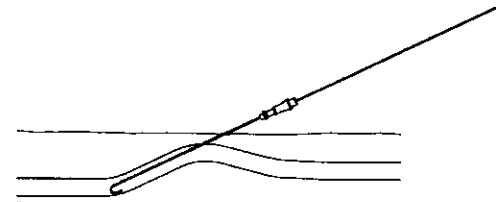


Figure 2

7. Set the needle depth gauge at skin level. (Figure 3).

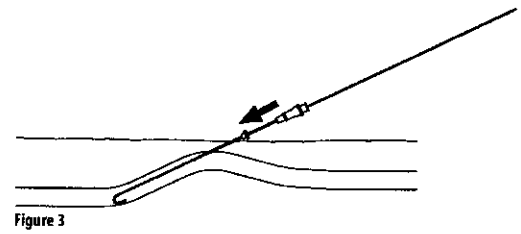


Figure 3

8. Withdraw the needle while holding the guide wire in place. Apply pressure to the puncture site until the introducer is inserted.

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9. An optional pre-dilation step may be done at this point. If this step is taken, thread the pre-dilator over the guide wire. Remove the pre-dilator from the guide wire before placing the FISH™ Device (Figure 4).

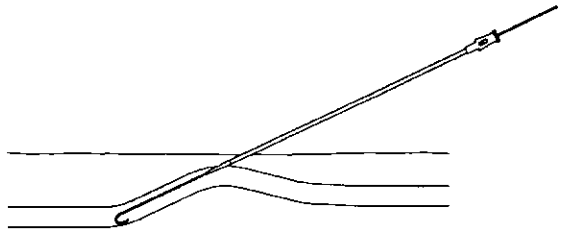

Figure 4

Patch Placement

1. Place the FISH™ Device into the vessel over the guide wire. A retaining wire that travels from within the proximal hub to the tip of the patch will hold the patch until it is placed in the vessel wall (Figure 5).

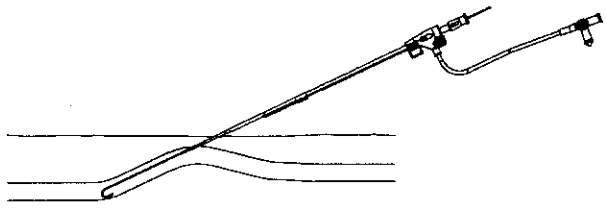

Figure 5

2. Keeping the seam portion of the sleeve and the flush tube positioned down towards the skin, advance the assembly through the tissue and into the vessel (Figure 6).

   NOTE: The sleeve has a tapered front end for ease of insertion. Keeping the seam down will allow this taper to minimize the force on the vessel.

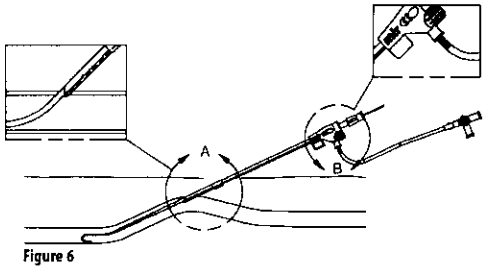

Figure 6

There are three methods for confirming proper patch placement:

   A. Advance the sheath an additional 1.5 to 2 cm after the sleeve has entered the tip of the vessel.
   B. Advance the sheath to the same depth mark as indicated on the needle depth gauge.
   C. Leave the side port of the sheath open to visualize flash back, then advance the sheath an additional 1.5 to 2 cm.

3. The user will feel a slight increase in pressure as the tip of the sleeve enters the vessel. As the sleeve positive stop reaches the vessel wall, there will be a large increase in pressure. At this point, stop advancing.
4. CAUTION: After the patch is in the vessel do not attempt to remove the patch or sheath without first pulling the release wire located on the sheath hub (Figure 7).
5. Pull the release wire (Figure 7).

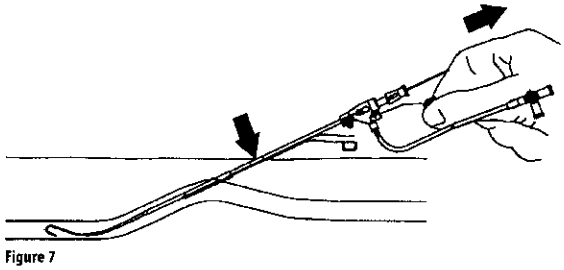

Figure 7

Advancement

1. With the release wire removed, the sheath becomes independent of the patch and can be advanced further into working position (Figure 8).

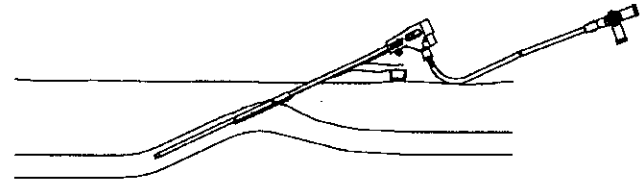

Figure 8

2. After the sheath is in working position detach the dilator from the hub and withdraw both the guide wire and dilator.
3. CAUTION: The sheath tip can become damaged if the dilator is removed prior to the sheath being fully advanced to the working position.
4. Before placement of wires or catheters through the sheath aspirate and flush from the side port to remove any potential air. To aid in the prevention of thrombus a heparinized saline drip via the side port should be considered.
5. To introduce a selected catheter into the hemostatic hub use one of the following methods:

   A. Straighten the catheter by hand and insert by holding as close to the tip as possible.

   or

   B. Insert a guide wire into the sheath hub then load the catheter onto the wire.

   NOTE: Hold the sheath hub in place when inserting, positioning, or removing a catheter. There is a suture collar that may be used to temporarily stabilize the sheath.

   NOTE: If the hemostasis valve leaks, insert and remove the tip of the vessel dilator into the valve.

   NOTE: If measuring right arterial pressure and/or determining cardiac output by thermodilution methods, discontinue infusion through the side port to prevent errors in measurement, reconnect after measurements are taken.

   If exchanging a catheter, slowly remove the catheter from the introducer hub and repeat the insertion process.

Sheath Removal

1. Before removing the sheath, pull the suture compression tab about one inch. (Suture compression tab is located on the sheath hub next to the flush port tube.) (Figure 9)

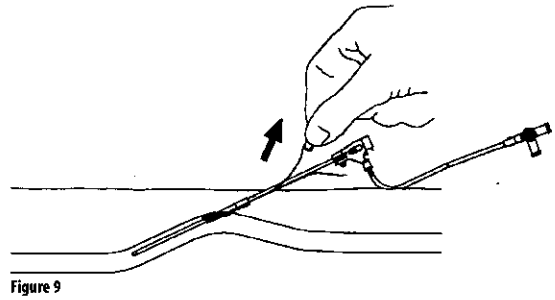

Figure 9

2. To remove the introducer, place firm downward pressure at the site and slowly remove the sheath (Figure 10).

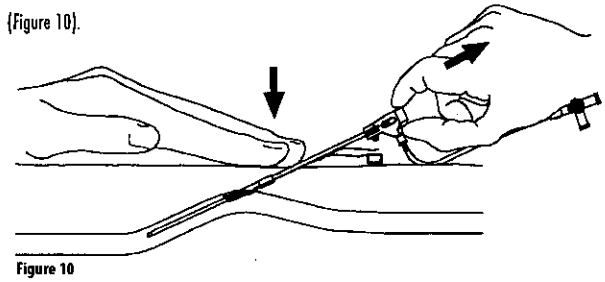

Figure 10

NOTE: Insure the safety sutures are out of the way and that they do not get pulled during sheath removal.

3. Lightly pull the tabbed suture until resistance is felt while maintaining downward pressure at the insertion site (Figure 11).

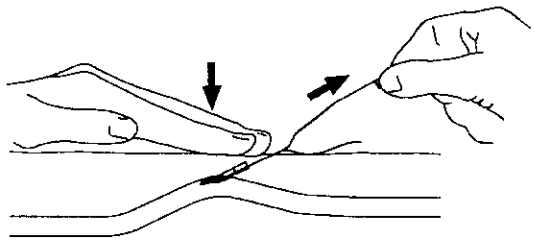

Figure 11

4. If the vessel does not attain immediate hemostasis, place manual compression on the vessel to aid the device in closing the flow from the vessel.
5. Using minimal tension, cut the safety sutures after insuring flow is not obstructed (Figure 12). (Check Pedal Pulses)

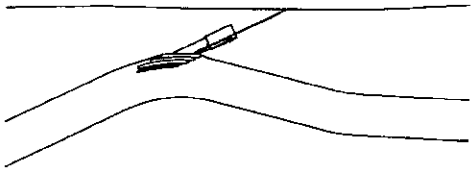

Figure 12

6. Treat puncture site appropriately to minimize the risk of infection.

Removal of Both FISH™ and Patch Instructions

If the operator believes the FISH™ Device is misplaced or out of position or needs to be exchanged for a larger French size, the following steps should be taken:

A. Insert guide wire into the sheath.

B. Pull the release wire on the FISH™ sheath to free SIS patch from sheath.

C. With the guide wire in place, remove the sheath. The patch may now be removed over the guide wire by pulling both the compression and tabbed sutures simultaneously.

Repuncture

If an additional procedure is required within 30 days, please access the opposite femoral artery (preferred) or access 2 cm above the current FISH™ Device access site. The device has an intra arterial sleeve and an extra-vascular positioning cuff.

Site Care

Patients receiving the FISH ™ Device should avoid bathing in a tub, swimming or sitting in a hot tub for 3 days post procedure, however patients may shower, pat site dry and apply clean dressing.

Sterility

The FISH™ Device and its components are provided sterile and non-pyrogenic in its unopened, undamaged packaging. The contents are sterilized with ethylene oxide and are intended for single use only. Do not resterilize. The device and components are latex free. Store in a cool dry place.

How Supplied

Femoral Introducer Sheath & Hemostasis Device

*21 gauge needle option will contain 0.018 guide wire

5 French Device List Number/REF 01-000-05 contains:
0.035 or 0.018 Guidewire
5 French Sheath with ECM patch
Pre-Dilator
5 French Dilator
18 or 21 Gauge Needle

6 French Device List Number/REF 01-000-06 contains:
0.035 or 0.018 Guidewire
6 French Sheath with ECM patch
Pre-Dilator
6 French Dilator
18 or 21 Gauge Needle

8 French Device List Number/REF 01-000-08 contains:
0.035 or 0.018 Guidewire
8 French Sheath with ECM patch
Pre-Dilator
8 French Dilator
18 or 21 Gauge Needle

Graphic Symbols for Medical Device Labeling

Batch Code

Do not reuse

Latex Free

Use by

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

Sterilized using Ethylene Oxide

CAUTION: Refer to accompanying Documents.

Distributed in the U.S. by MIR, Inc
907 W. Second Street
Toll free Customer Service:
888.647.4465
Bloomington, IN 47403
USA

Manufactured by MIR, Inc. under the following U.S. Patent: 6,790,220

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Glossary

Angiographic Procedure—A medical procedure used to diagnose and treat problems with blood vessels (arteries).

Angiogram (xray picture with dye) is done by placing a hollow tube (sheath) in a blood vessel and using xray contrast (dye) to look at the condition of the blood vessels.

Femoral Artery—A large blood vessel located in the groins of the human body. This artery is used to provide access into other blood vessels such as the blood vessels of the heart, kidneys and other areas of the body. Doctors like to use the femoral artery because it is large, easy to locate and provides a pathway to other blood vessels. The femoral artery is frequently used to perform angioplasms but other arteries like the brachial or radial arteries in the arm may also be used.

Closure Device—After an angiogram, the small hole made by the sheath or tube inserted into the blood vessel must be closed off to prevent loss of blood. There are several ways to do this: applying manual pressure with the hands, applying manual pressure with a clamp or using a closure device such as the FISH™ device.

Manual Compression—Using the hands to apply pressure to a blood vessel such as the femoral artery to prevent bleeding after an angiographic procedure.

Porcine—Comes from a pig.

Biotissue—Material that comes from living cells that is extracted in such a way to provide a structural framework but no actual living cells. This tissue helps to build new cells that are similar to the cell in the surrounding tissue.

Hemostasis—Stopping the flow of blood.

SIS—Small Intestinal Submucosa—The biotissue that makes up the FISH™ closure device patch is made from the small intestinal submucosa of pigs. This material is found between the inside lining and the muscle of the small intestine.

Resorbable Sutures—A type of suture (stitch) that does not need to be removed but rather is broken down and absorbed inside the body.

PATIENT INFORMATION BROCHURE

Potential Complications Associated with the Use of Closure Devices

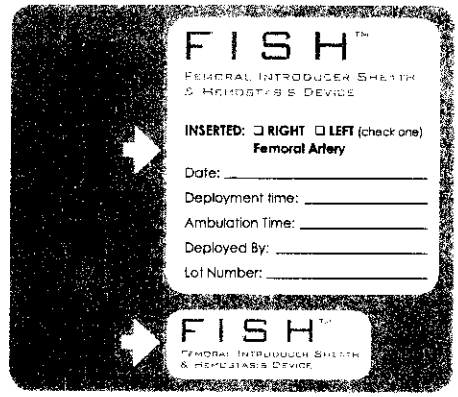
During any angiographic femoral artery procedure in which a closure device or manual compression is used, certain risks exist. The risks include but are not limited to the following:

- Pseudoaneurysm—Ballooning of the blood vessel
- Arterio-venous Fistula—Unintended connection between the artery and vein
- Pain/tenderness/bruising in the groin
- Vessel tear or disruption
- Puncture of the artery or vein
- Allergic reaction
- Undesired arterial occlusion—blockage of the artery
- Bleeding or hematoma
- Infection

Caution: Federal law restricts this device to use by or on the order of a physician.

Benefits of Using the FISH™ Device

The Femoral Introducer Sheath and Hemostasis (FISH™) Device is indicated for femoral artery closure, reducing time to hemostasis, time to ambulation and time to eligible discharge in patients requiring access of 5,6 or 8 French sheaths for endovascular diagnostic procedures.



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FISH™

Femoral Introducer Sheath & Hemostasis Device

(fold here)

FISH™
Femoral Introducer Sheath & Hemostasis Device

PATIENT INSTRUCTIONS:

Carry this card with you in your wallet for the next 30 days.

Immediately report persistent tenderness in the groin area; bleeding; swelling; wound drainage; numbness or burning in the leg; fever; or redness, warmth, bruising at the puncture site; or any other unusual observation at the puncture site to the physician listed on the reverse side of this card. If another procedure is necessary within 30 days of this one, inform the physician that you received a FISH™ Device and show this card to the physician.

PHYSICIAN INSTRUCTIONS:

This patient has received a FISH™ Vascular Closure Device. The Device completely remodels into host tissue within 30 days of placement. If an additional procedure is required within 30 days, please access the opposite femoral artery (preferred) or access 2 cm above the current FISH™ Device access site. The device has an intra-arterial sleeve and an extra-vascular positioning cuff. For additional information, please contact the physician noted on the reverse side. The FISH™ Device components are not made of latex. This product is MRI compatible.

NOTE TO PREPRESS:

1.) This gray area will be trimmed off.

2.) Dashed magenta lines indicates perforation. Please delete before printing.

3.) Client wants patient info card to have a vertical score down the middle so it can easily be folded in half and put in a wallet.

WHAT IS THE FISH™ DEVICE?

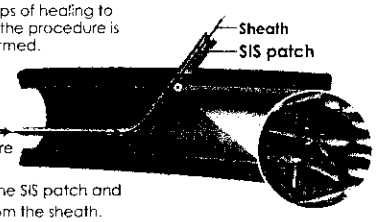
After femoral artery angiographic procedures, the femoral artery must be closed to prevent bleeding. You are scheduled to receive the Femoral Introducer Sheath and Hemostasis (FISH™) Device. The Fish™ Device is used to gain access into your femoral artery at the start of the procedure and then close the puncture site in your artery after your procedure. The FISH™ Device is a porcine biomaterial known as SIS (Small Intestinal Submucosa), which comes from pigs and will aid in healing your artery. A small amount of the SIS patch is placed inside the femoral artery and the rest of the patch sits just outside the artery under your skin—this creates a plug for the artery, stopping the flow of blood. The SIS will remain in place until the femoral artery is healed. The healing process takes about 30 days. The patch will not need to be removed. Instead, the SIS will remodel to resemble the cells of your blood vessel. The sutures used in the SIS patch will be resorbed. It is not unusual to feel a small pea-sized knot in the groin as the artery heals.

Why is the FISH™ Device being used on me?

Your physician chose to use the FISH™ Device to close the femoral artery instead of using manual compression (using the hands) or mechanical compression (using a device like a clamp.) Using these techniques, the femoral artery is closed by applying pressure directly to the artery for about 15 to 80 minutes followed by 2 to 6 hours of bed rest. By using the FISH™ Device, bleeding is controlled quickly so that you may get out of bed earlier. Typically, patients are able to get out of bed within about 60 minutes.

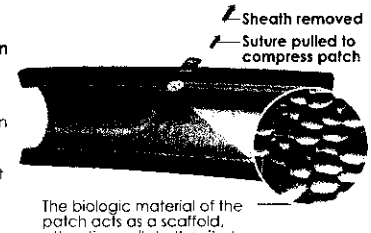
How the FISH™ Device works:

Positioning
The patch, fashioned from an extracellular matrix known as SIS, is attached to the sheath. The presence of SIS during catheterization allows the early steps of healing to occur while the procedure is being performed.



Release
A release wire is pulled, detaching the SIS patch and its sutures from the sheath.

Compression
After the sheath is removed, a compression suture is used to tighten the patch against the hole in the artery.



The biologic material of the patch acts as a scaffold, attracting cells to the site to remodel the artery wall.

Healing
The vessel wall is remodeled within 30 days.

What should I discuss with my doctor or nurse about the FISH™ Device?

CAUTION. If you have an allergy to pork or absorbable suture, please tell your doctor or nurse. If you have a vascular graft or have uncontrolled high blood pressure, circulation problems, bleeding or clotting conditions, auto-immune disease or are pregnant or lactating, please tell your doctor or nurse.

How should I care for my site after discharge?

Some bruising or discomfort is common following femoral artery procedures. You may feel a pea-sized knot under the skin and this is normal unless it causes undue discomfort.

- For the next several hours, if you need to cough, laugh or sneeze, place your hand over the site and apply light pressure.
- If any bleeding or swelling is seen around the site, apply direct pressure with your hand and contact your physician.
- Notify your doctor if you have any pain, numbness or burning at the site or in your flank, leg or back.
- Notify your doctor if you see any signs of infection or run a fever.
- If any of the FISH patch material or suture is visible outside the puncture site, do not pick at this—cover it with a clean, dry dressing and contact your doctor.
- Notify your doctor if you have any unusual symptoms.
- You may shower but do not sit in a bath tub, hot tub or swim for 3 days following this procedure. After you shower don't rub the area; simply pat area dry and apply a clean dressing.
- If you need another procedure involving your femoral artery within the next 30 days, ask your doctor to use the opposite leg or access the site 2 cm above the current puncture site. Refer to wallet card.

(tear here)

Patient Information Card

I have received the Femoral Introducer Sheath and Hemostasis (FISH) Device. A **FISH™** Device has been placed in my (circle one): RIGHT or LEFT femoral artery. If an additional procedure is required within 30 days, please access the opposite femoral artery (preferred) or access 2 cm above the FISH™ Device access site. Direct all inquiries to:

Institution: _____

Physician: _____

Phone #: _____

Date of Procedure: _____

NOTE TO PREPRESS:

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2.) Dashed magenta line indicates perforation. Please delete before printing.

3.) Client wants patient info card to have a vertical score down the middle so it can easily be folded in half and put in a wallet. This is indicated with the solid magenta line. Please delete before printing.