**INSTRUCTIONS FOR USE**

Read instructions before use.

Caution:

*Federal law restricts this device to 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 MI, Inc. in the use of the FISH™ Device.*

**CONTENTS:**

- Introducer Sheath with Closure Patch
- Vessel Dilator
- Guide Wire

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**SYSTEM COMPONENTS / DESCRIPTION**

A. Introducer Sheath with Closure Patch

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 indicated by color coding. Listed below are the two available French sizes and their corresponding color:

<table>
<thead>
<tr>
<th>FRENCH</th>
<th>COLOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 (2.3 mm)</td>
<td>Green</td>
</tr>
<tr>
<td>8 (2.7 mm)</td>
<td>Orange</td>
</tr>
</tbody>
</table>

B. Vessel Dilator

The vessel dilator atraumatically transitions the guide wire to the introducer sheath through a tapered tip, which opens the tissue from the skin to the vessel below.

C. Guide Wire

The guide wire is provided to maintain access to the vessel upon removal of an 18 or 21 gauge introducer needle during the insertion of the FISH™ Device.

**INDICATIONS**

The Femoral Introducer Sheath and Hemostasis device (FISH™ Device) is intended for hemostatic closure of the 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, 7, 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. Morris Innovative, Inc. will not be responsible for any damages or expenses that may result for 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 introducer sheath and its components may be damaged by exposure to temperatures above 54°C (130°F).
- Do not expose device to organic solvents.

*Thiokol 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 to 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 uncontrolled hypertension (systolic BP > 180mmHg)
- Patients having auto-immune disorders
- Patients having vascular grafts at the puncture site
- Patients receiving glycoprotein IIb/IIIa inhibitors
- Patients having a palpable ipsilateral hematoma of any size observed during the catheterization procedure
- Patients having arterial closure site depth > 7.5cm
- Patients having ACT > 400 seconds at the time of FISH™ device.

**Adverse Effects of the Device on Health**

The FISH™ System was evaluated in a randomized controlled clinical investigation involving 206 diagnostic patients enrolled at 5 United States clinical sites: 129 subjects (67%) received the FISH™ Device and 77 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 18 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 diagnostic 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.
Clinical Studies
The FISH closure device was studied in an open-label, randomized, multi-center clinical trial which enrolled 287 diagnostic and interventional patients. This United States based trial evaluated the FISH device to manual compression. The study included both diagnostic (N=206) and interventional (N=81) patients requiring a procedure with and without a 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 randomized. There were a total of 28 roll-in patients combined in the diagnostic and interventional study. The patients were randomized on a 2:1 randomization scheme (FISH™ device vs. manual compression). Of the 285 diagnostic patients enrolled in the study, 138 received the FISH™ device and 67 received manual compression.

This study included 8 U.S. sites and enrolled patients between January 2004 and June 2006. There were a total of 40 investigators who 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 days. The study included patients who were undergoing diagnostic or therapeutic coronary or peripheral procedures 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 6%. 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%.

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

<table>
<thead>
<tr>
<th>Randomized Subjects</th>
<th>N = 285</th>
<th>FISH Device (n=138)</th>
<th>Manual Comp. (n=67)</th>
<th><strong>p-value</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cumulative Major Complications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Access site related bleeding requiring transfusion</td>
<td>8.9%</td>
<td>6.0%</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>Non-infectious infection</td>
<td>0.9%</td>
<td>0</td>
<td>0.1319</td>
<td></td>
</tr>
<tr>
<td>Access site related pseudoaneurysm</td>
<td>0.0%</td>
<td>0</td>
<td>0.7218</td>
<td></td>
</tr>
<tr>
<td>Permanent access site related nerve injury</td>
<td>0.0%</td>
<td>0</td>
<td>0.7218</td>
<td></td>
</tr>
<tr>
<td>Access site related effective requiring IV antibiotics and or extended hospitalization</td>
<td>0.0%</td>
<td>0</td>
<td>0.7218</td>
<td></td>
</tr>
<tr>
<td><strong>Cumulative Minor Complications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Access site related hemorrhage</td>
<td>0.0%</td>
<td>0</td>
<td>0.7218</td>
<td></td>
</tr>
<tr>
<td>Perforated pseudoaneurysm treated with balloon-guided trans-catheter embolization</td>
<td>0.0%</td>
<td>0</td>
<td>0.7218</td>
<td></td>
</tr>
<tr>
<td>Perforated pseudoaneurysm treated with balloon-guided stent or stent graft</td>
<td>0.0%</td>
<td>0</td>
<td>0.7218</td>
<td></td>
</tr>
<tr>
<td>Access site related nerve injury</td>
<td>0.0%</td>
<td>0</td>
<td>0.7218</td>
<td></td>
</tr>
<tr>
<td><strong>Device Success</strong></td>
<td>99.5%</td>
<td>99.5%</td>
<td>0.7218</td>
<td></td>
</tr>
<tr>
<td><strong>Procedure Success</strong></td>
<td>99.5%</td>
<td>99.5%</td>
<td>0.7218</td>
<td></td>
</tr>
</tbody>
</table>

* Exact 95% confidence interval based on Clopper-Pearson method
** Blackwater's test with an equivalent limit of 0.05. The significance level of 0.041 was used for the interim analysis.
*** Device Success – the ability to achieve hemostasis without major adverse events of the use of mechanical compression and within the allotted time (30 minutes).
**** Procedure Success – the ability to establish hemostasis in a given subject within any time period using any method.

Table 2 – Diagnostic Procedures: Primary Effectiveness Results ITT

<table>
<thead>
<tr>
<th>Event</th>
<th>FISH™</th>
<th>Manual Compression</th>
<th><strong>p-value</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to Hemostasis (Minutes)</td>
<td>8.9 (6.05)</td>
<td>17.2 (9.17)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Time to Ambulation (Hours)</td>
<td>2.0</td>
<td>4.2</td>
<td>0.0451</td>
</tr>
<tr>
<td>Time to Eligible Discharge (Hours)</td>
<td>2.3</td>
<td>4.5</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

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. 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.

Effectiveness Endpoints
- Time to Hemostasis (TH) was measured from the time of introducer 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. sandbag, pressure dressing, light manual pressure”). The study was designed to demonstrate TH superiority as compared to the control therapy.
- Time to Ambulation (TA) – this was measured from the time of introducer sheath removal to the time when the patient sat at the bedside and walked at least 20 feet without evidence of re-bleeding. The study was designed to demonstrate TA superiority as compared to the control therapy.
- Time to Eligible Discharge (TED) – this was measured from the time of introducer 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 TED superiority as compared to the control therapy.
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 sheath.
4. Using controlled technique, introduce the cannula of the needle into the vessel (Figure 1).
5. Remove air from the FISH® Device by flushing it with a suitable isotonic solution.

Advancement

1. With the release wire removed, the introducer sheath must be advanced into working position (with hub touching the skin), which releases the patch inside the artery. Observing no movement of the compression tab and suture during introducer sheath advancement is an indication of proper patch placement (Figure 6).

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 earlier than the control group manual compression.

RECOMMENDED PROCEDURE

The procedures and their 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 introducer sheath, and 4) removing the introducer sheath.

NOTE: The introducer needle is not included in the kit, so a sterile 18 or 21 gauge needs to be provided by the user according to preference.

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

Figure 3

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

Patch Placement

1. Place the FISH® Device over the guide wire (Figure 3). A release 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 3

2. Keeping the seam portion of the cuff facing down toward the skin and the "numbers" on the introducer sheath hub (Figure 4) facing up, VERY SLOWLY advance the assembly through the tissue and into the vessel. There are two methods for confirming proper patch placement.
   a. The user may feel the positive stop or resistance of the cuff (A Figure 4) as it approached the artery wall.
   b. Leave the side port of the introducer sheath open to visualize blood back.

Figure 4

3. Once proper patch placement is achieved, stop advancing the introducer sheath.

Figure 4

CAUTION: At this point if the device needs to be retrieved, grasp all of the sutures along with introducer sheath and remove over guide wire.

4. Pull the release wire completely out of the introducer sheath and discard (Purple cap marked #2) (Figure 5).

Figure 5

5. Detach the suture compression tab (#3) and place it anterior to the access site. The suture should be kept straight and in view of the operator (Figure 8).

Figure 8

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

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

Figure 5 Average and Standard Deviation of Patients Discomfort (Subjective Scale 0–10)
Compression

1. While applying pressure to keep introducer sheath in place, pull the compression tab about 5 inches on a line parallel to the introducer sheath and guide wire (Figure 7). The knots on the compression suture serve as a visual reference and will slide toward each other as the intravascular portion of the patch is cinched against the artery wall. The suture knots should be approximately 1.5 to 2.5 inches apart.

2. Cut sutures at a point below the skin level to avoid potential infection. If knots are closer than 1 inch, the cuff may have been placed inside of the artery and proper closure will not be possible. If this is the case, proceed with “Removal of Both FISH™ and Patch” instructions below.

Procedural (If using FISH only for closing, proceed to Introducer Sheath Removal below)

1. With the introducer sheath and patch in working position, detach the dilator from the hub and withdraw both the guide wire and dilator.

CAUTION: The introducer sheath tip can become damaged if the dilator is removed prior to the introducer sheath being fully advanced to the working position.

2. Before placement of wires or catheters through the introducer sheath, aspirate and flush from the side port to remove any potential air. To aid in the prevention of thrombus, heparinized saline drip via the side port should be considered.

3. 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 introducer sheath hub, then load the catheter onto the wire.

NOTE: If measuring right atrial pressure and/or determining cardiac output by thermodilution methods, the catheter should be appropriately placed.

NOTE: Once the introducer sheath is in working position, if the patch needs to be retrieved, first insert guide wire, remove the introducer sheath, and remove the patch by pulling sutures over the guide wire.

Introducer Sheath Removal

1. With the introducer sheath and patch in working position, detach the dilator from the hub and withdraw both the guide wire and dilator.

2. If the introducer sheath was not used as a procedural sheath, leave the introducer sheath in the patient for approximately 3-5 minutes to allow the SIS material to fully hydrate.

3. To remove the introducer sheath, place firm downward pressure at the site and slowly remove the introducer sheath (Figure 8).

4. Maintain firm pressure at the site as needed to allow the SIS plug to naturally fill the puncture site and attain hemostasis (Figure 9).

5. Ensure sutures are not visible; 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 introducer sheath

B. Pull the release wire on the introducer sheath to free the patch from introducer sheath

C. With the guide wire in place, remove the introducer 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 1 cm above the current FISH™ device access site. The device has an intra-arterial sleeve and an intra-vascular positioning cuff.

Suggested Aftercare

The following are the recommended times for aftercare and discharge for both non-heparinized and heparinized patients:

<table>
<thead>
<tr>
<th>30°-head of bed</th>
<th>Immediately</th>
<th>≤5000 U</th>
<th>≥6,000 U</th>
</tr>
</thead>
<tbody>
<tr>
<td>90°- side of bed</td>
<td>1 hr</td>
<td>1 hr</td>
<td>2 hrs</td>
</tr>
<tr>
<td>Ambulate</td>
<td>2 hrs</td>
<td>2 hrs</td>
<td>3 hrs</td>
</tr>
<tr>
<td>Discharge when stable</td>
<td>3 hrs after hemostasis</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 packaging. The contents are sterilized with ethylene oxide and are intended for single use only. Do not re-sterilize. The device and components are latex free. Store in a cool dry place.

How supplied

Femoral Introducer Sheath and Hemostasis Device

6 French Device List Number/ REF 16-06-05-5
Contains: Guide wire
6 French Introducer Sheath with Closure Patch
6 French Dilator

8 French Device List Number/ REF 18-08-05-5
Contains: Guide wire
8 French Introducer Sheath with Closure Patch
8 French Dilator

Graphic Symbols for Medical device Labeling

- **LOT**: Batch Code
- **DO NOT USE**: Do not use by or on the order of a physician
- **STERELEO**
- **LATEX FREE**

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Bloomington, IN 47403
Toll free Customer Service: 888.647.4465
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16-040, Rev. Al