

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.

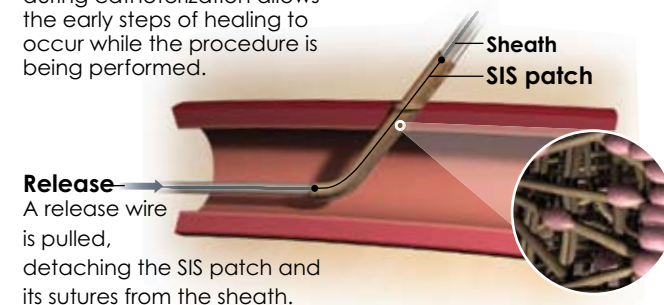
Why is the FISH™ Device being used on me?

Your physician chose to use the FISH™ Device in 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 30 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:

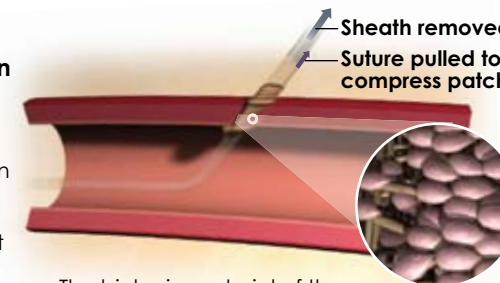
Positioning

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.



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.



FISH

FEMORAL INTRODUCER
SHEATH & HEMOSTASIS
DEVICE

Healed. Not scarred.

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.

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 angiograms 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 cells 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.

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.

Please indicate FISH™ Device placement site, date, deployment time and ambulation time on label. Attach label to patient's chart.

FISH™
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SHEATH & HEMOSTASIS
DEVICE

INSERTED: RIGHT LEFT (check one)
Femoral Artery

Date: _____

Deployment time: _____

Ambulation Time: _____

Deployed By: _____

Lot Number: _____

Attach label to top of sterile FISH™ Device dressing site.

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