



FemoSeal[™]

Vascular Closure Device

ACTIVE
**VASCULAR
CLOSURE**

Now, by

TERUMO
INTERVENTIONAL
SYSTEMS



Button

Deploys inner disc and outer locking disc.

Safety Catch

Allows retraction of dilator and guidewire and prevents pre-deployment of button.

FAST, EFFECTIVE¹, EASY TO USE

- Effective and instant hemostasis with an easy to use deployment system.
- Significantly lower major bleeding frequency than the Abbott StarClose™ vascular closure device (FemoSeal bleeding frequency 76.9% lower than StarClose ($p < 0.05$)).¹

FULLY BIOABSORBABLE

- All components of FemoSeal™ vascular closure device are fully bioabsorbable: two fully bioabsorbable polymer discs held together by a bioabsorbable suture.
- FemoSeal has re-stick indications at the same puncture site after 90 days. If repuncture of the same femoral artery becomes necessary within 90 days, repuncture should be made at least 1 cm proximal to the previous FemoSeal™.²

RAPID HEMOSTASIS¹ AND EARLY AMBULATION

- Designed to achieve effective and instant hemostasis. Sealing femoral artery punctures following catheterization procedures promotes rapid ambulation with low vascular complication rates.¹
- The clinical evaluation shows that the FemoSeal median Time To Hemostasis (TTH) is 1 minute.⁴

1. SCAAR Registry 2009.

2. FemoSeal Instruction For Use.

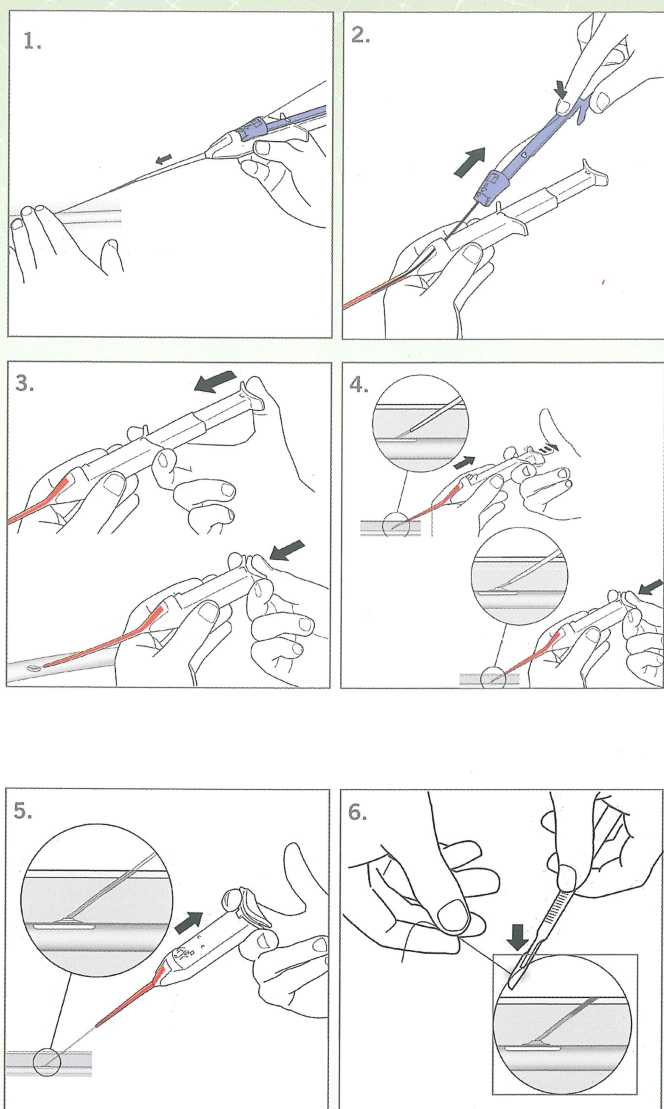
3. SCAAR Registry 2009.

4. Schulz-Schupke S, Helde S, Gewalt S, et al. Comparison of Vascular Closure Devices vs Manual Compression After Femoral Artery Puncture The ISAR-CLOSURE Randomized Clinical Trial. JAMA. 2014;312(19):1981-7.

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HOW TO USE



LOCATE THE ARTERY¹

- Thread the FemoSeal device over the guidewire and insert the sheath and dilator into the artery
- Detach the safety catch with dilator.

When the FemoSeal **safety catch** with dilator has been retracted a few centimeters (2-4cm), blood should appear in the proximal part of the sheath, verifying that the sheath is in the artery.

SEALING THE FEMORAL ARTERY

- Deploy the **inner disc** by pressing down the button completely in one continuous movement. Pull back on the FemoSeal device until the depressed button springs back.
- The **inner disc** establishes hemostasis. Maintain suture tension while deploying the outer locking disc. Deploy the disc by completely pressing down the button again.

VERIFYING HEMOSTASIS

- Remove the FemoSeal device. Verify hemostasis.
- After verification, cut the suture below skin level using a sterile instrument. Clean puncture site and apply a sterile dressing so that it can easily be observed during recovery.

ORDERING INFORMATION

Product code	French size	Guidewire diameter (in)
C11202	7	0.038

¹ Assess puncture site location by fluoroscopy

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