



StarClose SE

Vascular Closure System



 **Abbott**
A Promise for Life

<https://www.cardiovascular.abbott/int/en/hcp/products/peripheral-intervention/vessel-closure/starclose-se-vascular-closure-system/ordering.html>

StarClose SE Overview

Indications

Diagnostic and Interventional

5-6F

Early Ambulation Indication

Diagnostic patients may ambulate and be eligible for discharge as soon as possible after device placement

Contraindication

Patients with known hypersensitivities to nickel-titanium

MRI Conditional

Patients can safely undergo MRI immediately following implantation

RE-ACCESS/RE-CLOSE¹

¹ See IFU information which provides bench data on multiple repunctures and reclosures

Starclose SE Video

[Click for Video](#)



Objectives

StarClose SE Overview

- System Components

- Key Functions of each Component

- Deployment

- Troubleshooting

- Recognition and Resolution



StarClose SE Overview



StarClose SE Vascular Closure System

StarClose SE
Vascular Closure System

Secure

- 360° circumferential clip closure
- Secure Closure – Close, Challenge and Confirm on the table gives you the close you can trust
- Early ambulation – RISE Study median time to ambulation was 6.25 minutes¹

Easy

- Advanced design for greater stability and ease of use
- Numbered windows and numbered steps provides visual guidance for step completion
- Four clicks to close

Extravascular

- Designed not to impact lumen diameter or distal blood flow
- Proprietary nitinol design – nothing remains inside the artery



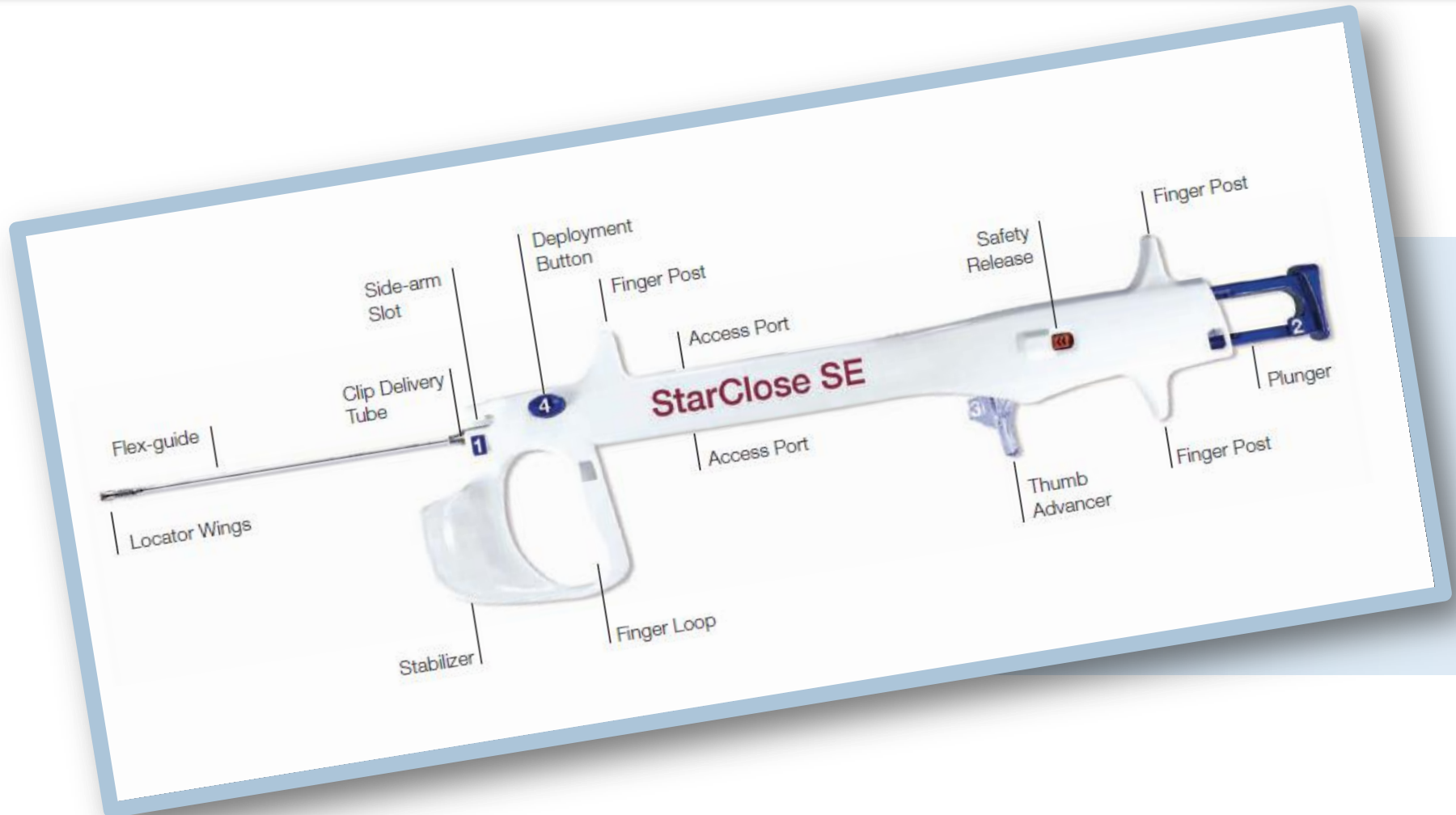
Photographs taken by and are on file at Abbott Vascular.
Tests performed by and data on file at Abbott Vascular



System Components

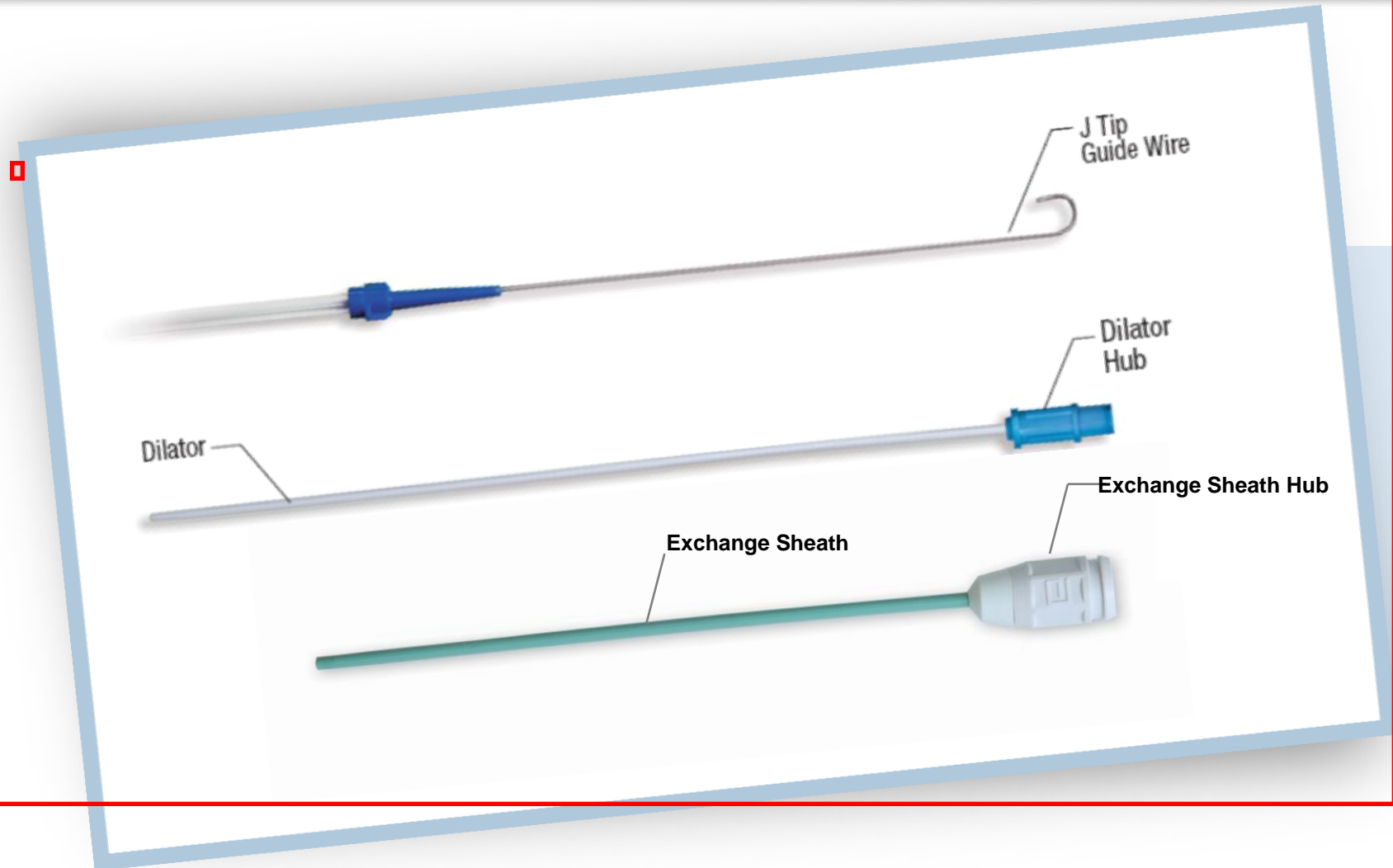


StarClose SE Components



System Components Exchange System

StarClose SE
Vascular Closure System



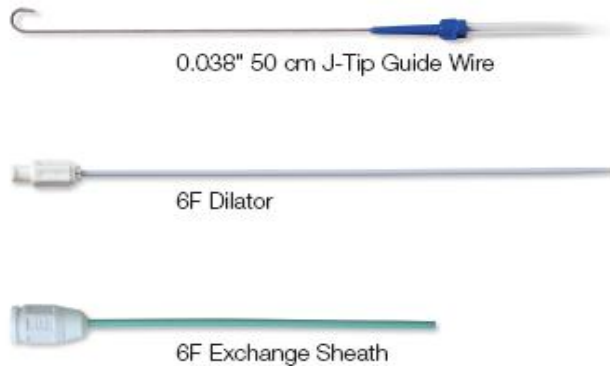


Key Functions



System Components Exchange System

Allows introduction
of Clip Applier



Exchange Sheath

- PTFE
- Tube 6F
- 11 cm length
- Splits longitudinally & radially

Dilator

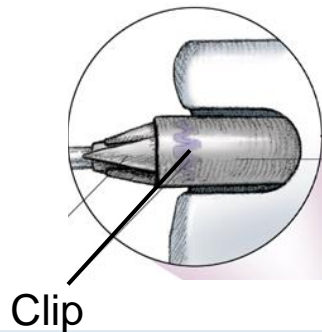
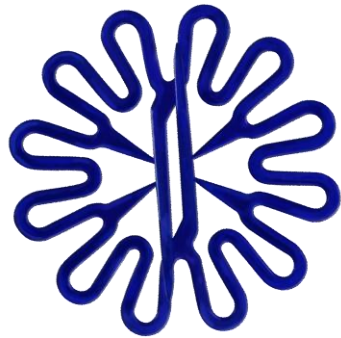
- Hub
- 6F

J Tip Guide Wire

- 0.038" diameter
- 50 cm length

Not to be used as a procedural sheath

The Clip



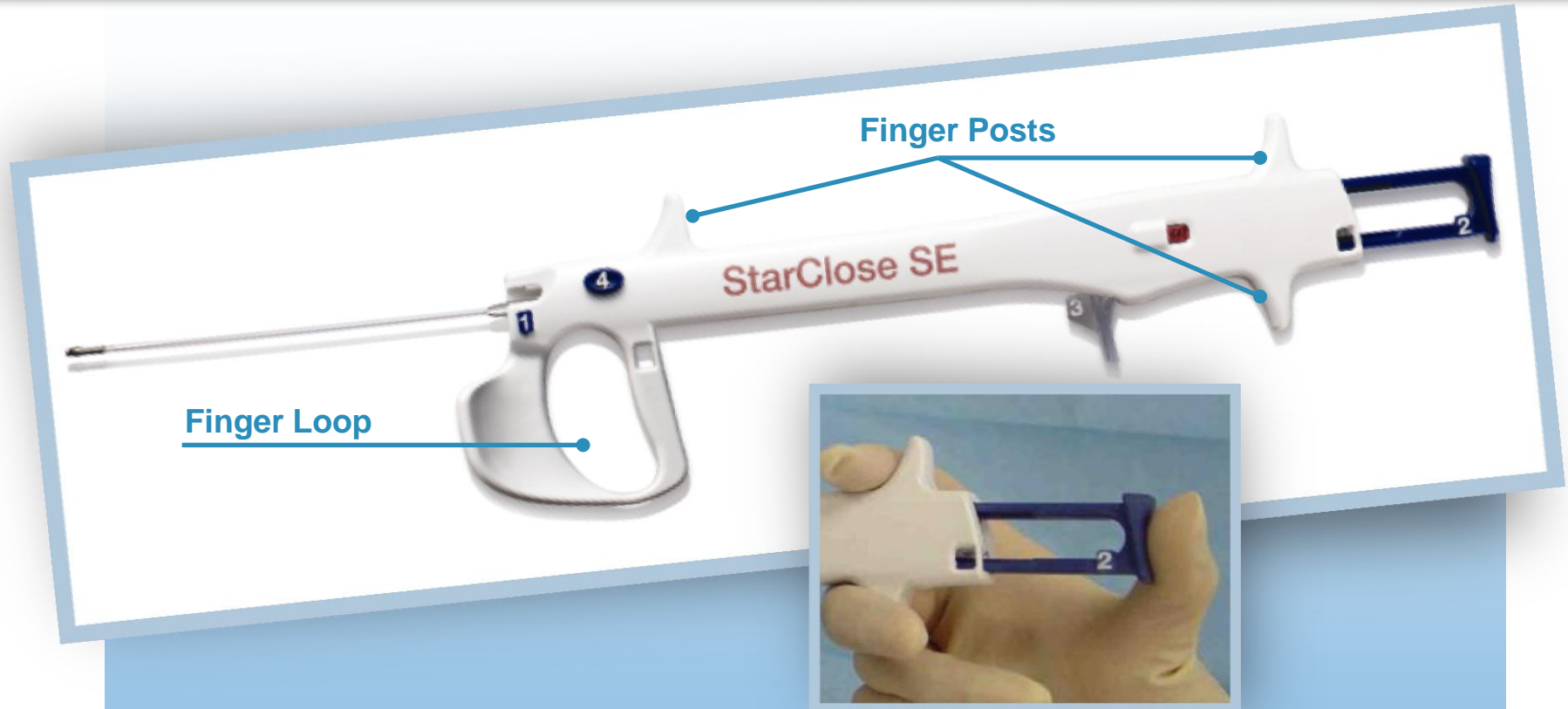
Provides Extravascular Arterial Closure

Nitinol (56% Nickel, 44% Titanium)

- 4 mm diameter
- 0.2 mm (0.008") thick

Housed inside Clip Delivery Tube

Finger Post and Finger Loop



Allows Operator to Stabilize Device During Procedure

Stabilizer



Stabilizer

Contoured to natural grip with left hand
Stabilizes Clip Applier at ~45° angle



Allows Operator to Stabilize Device During Procedure

Side-arm Slot—Step 1



- Number 1
(Visual Cue for Click 1)
- Allows visual confirmation of sheath engagement
- Audible “Click” when locked

Engages Sheath Hub onto Clip Applicator

Plunger—Step 2

Deploys Vessel Locator Wings

Initial Sheath split above skin level

**Advances Clip Delivery Tube and
Thumb Advancer 2.54 cm**

- Number 2 (Visual Cue for Step /Click 2)
- When fully depressed, “2” completely visible in window
- Audible “Click”



Locator Wings



- Nitinol - 4 flexible wings
- 5 mm overall diameter
- Retracts completely after clip deployment

Provides Tactile Feedback for Device Positioning in Artery

Thumb Advancer—Step 3

Advances Clip Delivery Tube
Delivers Clip to top of arteriotomy
Splits the Exchange Sheath

- Number 3 (Visual Cue for Click 3)
- Can ONLY be advanced with fully depressed Plunger (Step 2)
- When fully advanced, “3” completely visible and locked in window
- Audible “Click”



Deployment Button—Step 4



- Number 4 (Visual Cue for Click 4)
- Oval-shaped
- Audible “Click”
- Retracts Locator Wings
- Activates spring mechanism for Clip deployment
- Can **ONLY** be activated when Thumb Advancer is fully advanced i.e. “3” is completely visible in the window (Click 3)

Deploys Clip, Collapses and Retracts
Locator Wings Nearly Simultaneously

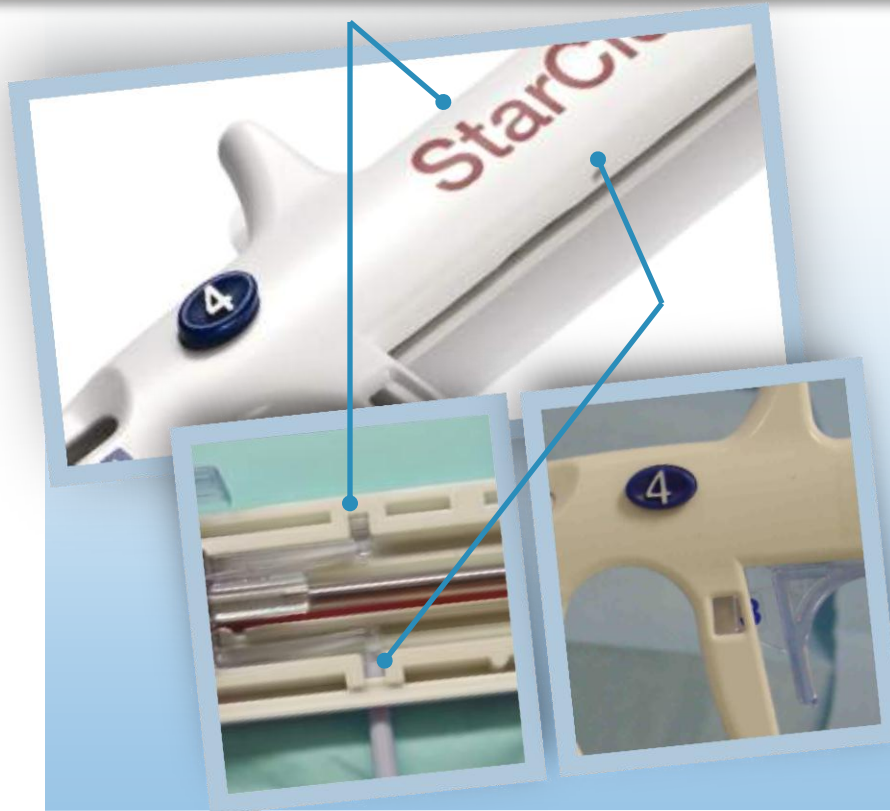
Safety Release

- Allows early termination of procedure prior to clip deployment or before “3” locks in window
- Red-colored
- Use fingernail to **slide forward in direction of arrows**
- Audible “Click”
- “2” exits window
- Partially recessed to prevent accidental release



Collapses and Retracts Locator Wings

Access Ports



- Utilized after Clip is deployed or after Step 3 when Thumb Advancer is locked
- Openings on the medial and lateral sides, i.e. 2 ports, approximate to product logo
- Insert Dilator (or 18-Gauge Thin-wall Needle) in ports to unlock, one at a time
- Audible “Click” after insertion in each port
- Thumb Advancer is unlocked when the “3” exits the window

Retract the Thumb Advancer back

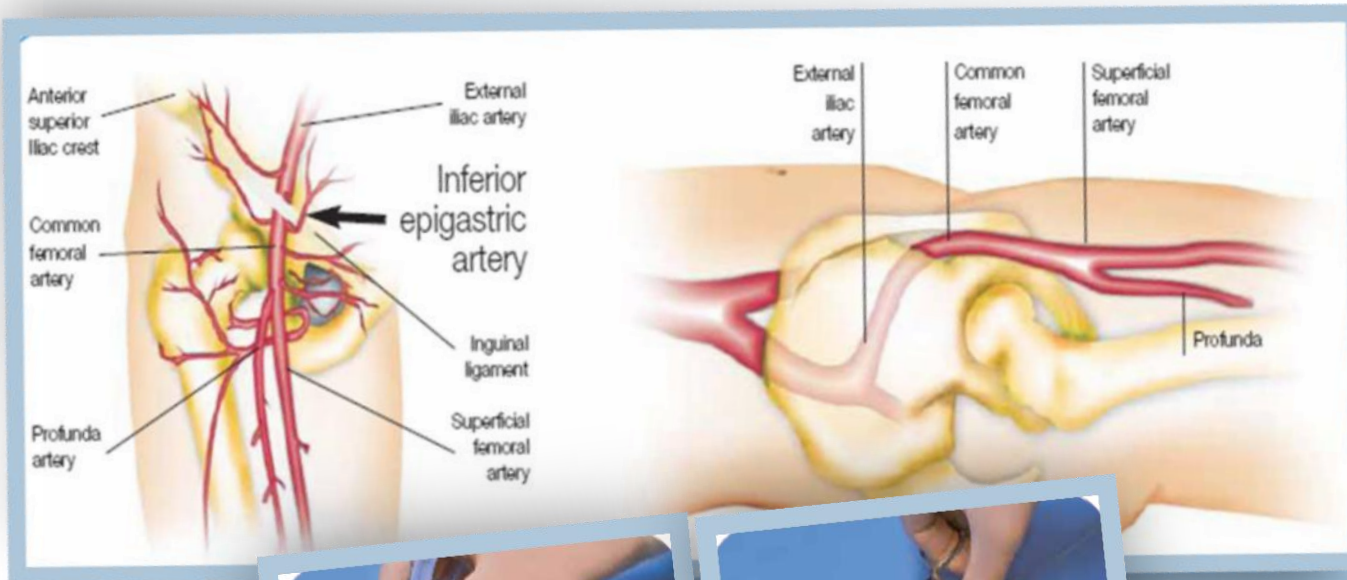
**Releases Thumb Advancer Locking Mechanism
Allows Retraction of Clip Delivery Tube**



Deployment Technique



Pre-Procedural



Perform nick and spread

Procedure Preparation

Click 1

Exchange Sheath to Device Engagement



1. Position

- Place device on patient's body
- (Left hand) Hold base of sheath hub
- (Right hand) Insert Flex Guide with device logo facing upward or 12 o'clock

2. Engage

- Lock Sheath Hub to device

3. Verify

- Audible "Click"
- Gently pull on Hub

Click 2 Locator Wing Deployment



1. Position

- (Left thumb) On Stabilizer
- (Right hand) Syringe grip on Plunger
- Device coaxial to tissue tract
- Retract device 3 to 4 cm because of initial sheath split

2. Engage

- (Right thumb) Depress Plunger
- Keep the Flex Guide straight

3. Verify

- Audible “Click”
- “2” in window
- Initial Sheath split above skin level

Advancement of the Thumb Advancer



1. Position

- (Left thumb) on Stabilizer
- (Right hand) Syringe grip on Thumb Advancer
- **Maintain device coaxial to tissue tract**
- Retract device with right hand until slight resistance is felt
- Keep device stable with left hand always on the Stabilizer and patient
- Hold device to maintain apposition

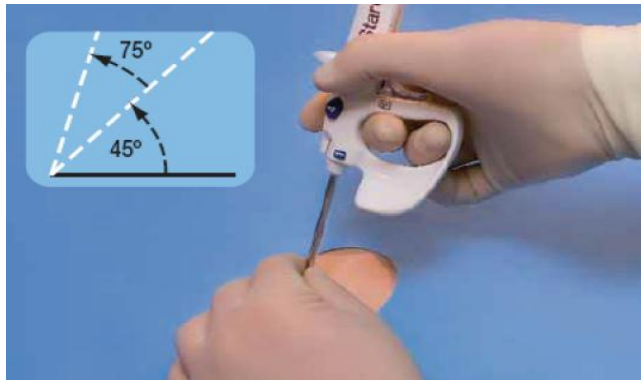
2. Engage

- Use your right thumb pad to advance Thumb Advancer

3. Verify

- Audible “Click”
- “3” in window

Click 4 Clip Deployment



1. Position

- (Right hand) Stabilize device
- (Left hand) Support Clip Delivery Tube close to the skin
- Raise to 60° to 75° angle
- Gently push down and rest on the artery

2. Engage

- Maintain slight downward pressure
- (Right Thumb) Depress Deployment Button
- Hold for 2 to 3 seconds before removing device

3. Verify

- Audible “Click”
- (Left hand) Apply counter-traction on skin site
- (Right hand) Remove device
- Challenge and confirm the close



Troubleshooting



StarClose SE Troubleshooting

Inadequate Nick and Spread

Carving

Difficult to Remove Device

- Use of Access Ports
- Use of Safety Release

Clip Misfires

Ooze Management

Obese Patients

Early Termination Options

Inadequate Skin Nick & Spread



What will the operator see?

- Puckering of skin or Clip Delivery Tube does not advance easily beneath the skin
- Clip may be deployed on the skin or in the tissue track below the skin

What will the operator feel?

- Resistance while advancing the Thumb Advancer

Why did it happen?

- Inadequate skin nick & tissue spread

What not to do?

- Use scalpel to widen skin incision to avoid cutting the sheath
- Retract and re-advance Thumb Advancer

Inadequate Skin Nick & Spread



What to do?

- Do not complete step 3
- Pull back the Thumb Advancer
- Slide the Safety Release forward to retract the Locator Wings
- Terminate procedure

How to prevent?

- **5 to 7 mm** skin nick and use a hemostat to spread the tissue through all the layers of the skin **prior** to device deployment

Carving



What will the operator feel?

- Excessive resistance while depressing the Plunger (Click 2) or advancing the Thumb Advancer (Click 3)

What will the operator see?

- The Plunger or Thumb Advancer may not advance fully into the window
- Prior to advancing Thumb Advancer or upon removal of device, the shaft or Flex Guide will be shredded/carved



Carving

Why did it happen?

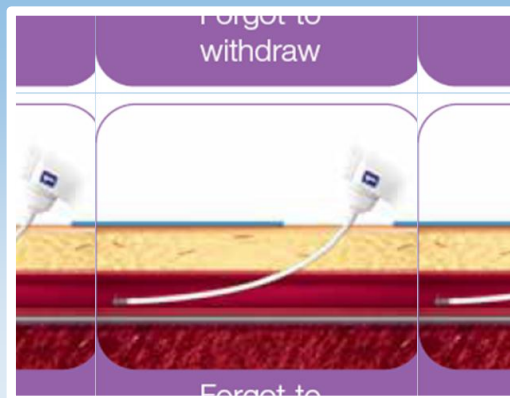
- User did not keep the Flex Guide straight and at a 45° angle while depressing Plunger (Click 2) or while advancing the Thumb Advancer (Click 3)
- If an angle is created in the Flex Guide during the advancement of the Clip Delivery Tube, the Clip Delivery Tube will burrow into the Flex Guide



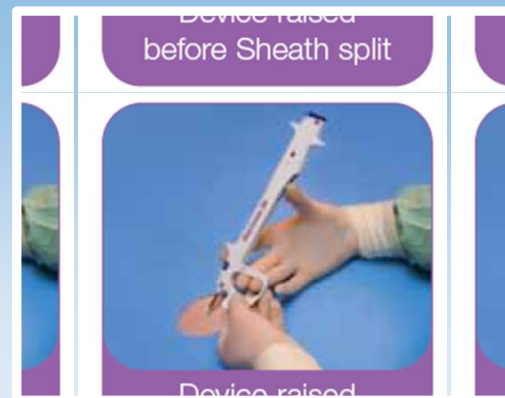
Carving

What may cause a bend in Flex-guide?

- Operator pushes device forward while splitting Sheath instead of maintaining tactile feedback against arterial wall
- Operator raises (changes) angle of device to tissue tract while splitting Sheath
 - Keep sheath at 45° until “3” is locked in the window
- Operator not holding the device in-line with tissue tract to maintain straight Flex Guide which can result from relaxing the device or moving the device medial or lateral



Forgot to
withdraw



Device raised
before Sheath
split

Carving

What not to do?

- Continue to force Plunger or Thumb Advancer against resistance
- Rock or twist the device

What to do if Plunger “Step 2” is not fully advanced?

- Terminate procedure
 1. Retract the Plunger
 2. Back up Thumb Advancer
 3. Remove the device and apply counter traction

Carving

What to do if Thumb Advancer is not fully advanced?

- **Terminate procedure**
 1. Retract the Thumb Advancer
 2. Slide the Safety Release (Number 2 exits window)
 3. Remove the device and apply counter traction

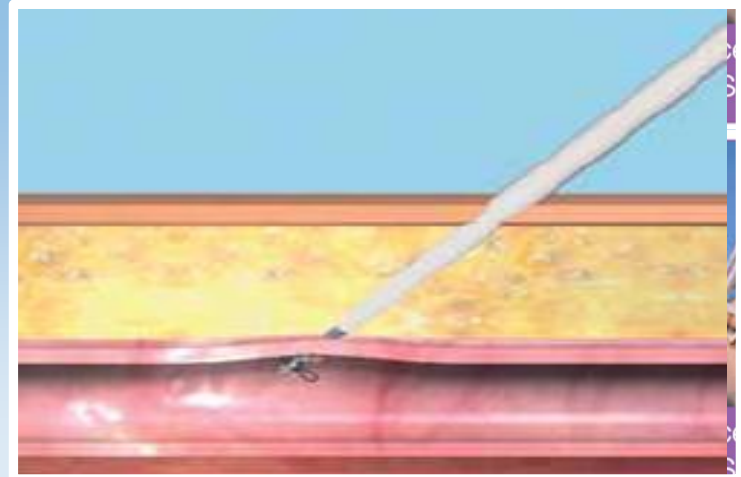
What to do if Thumb Advancer is fully advanced (Number 3 is in window)?

- **Terminate the procedure**
 1. Insert dilator or 18 gauge needle into each Access Port (Number 3 exits the window)
 2. Slide the Thumb Advancer back
 3. Remove the device and apply counter traction

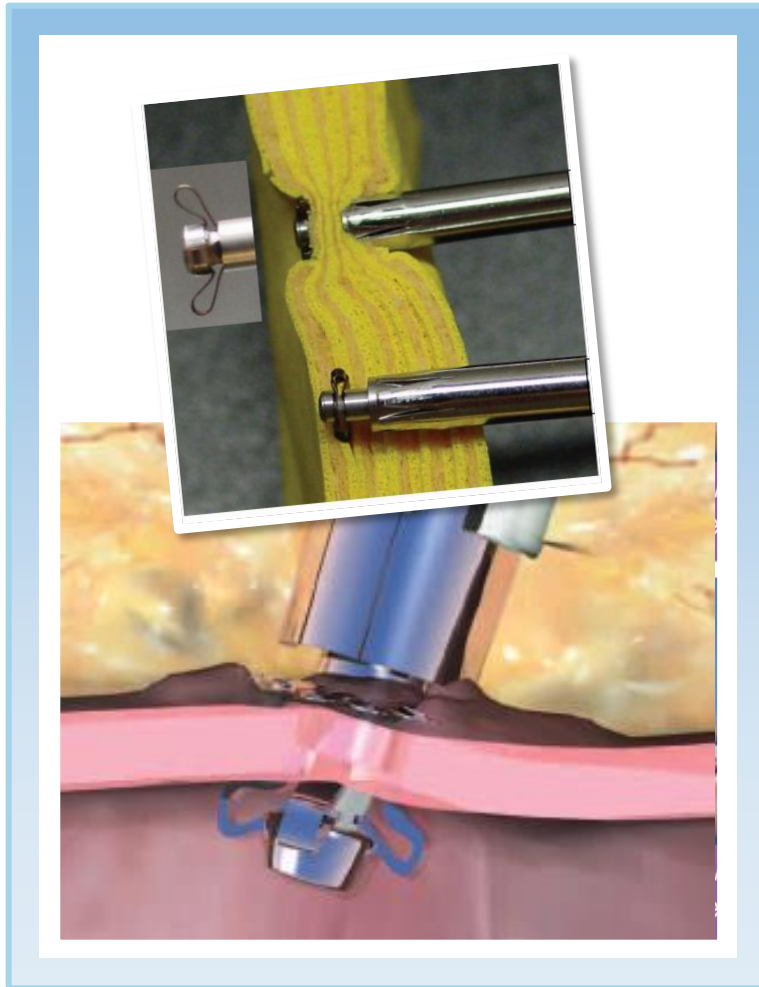
Carving

How to prevent?

- Maintain the angle of the tissue tract and keep the Flex Guide straight while depressing the Plunger (Click 2) and while advancing the Thumb Advancer (Click 3)
- Keep left thumb on the Stabilizer and left hand/finger on the patient for device stability



Difficult to Remove Device



What will the operator feel?

- Device is difficult to remove after Clip deployment (Click 4)

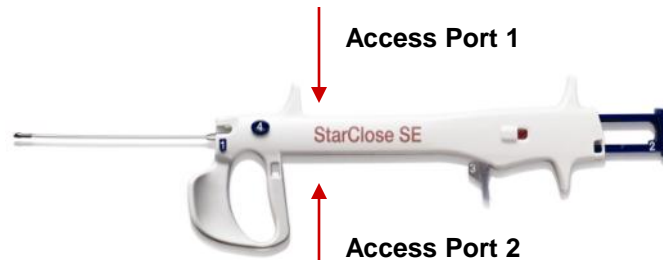
Why did it happen?

- Locator Wings unable to collapse due to inadequate nick and spread and compacted scar or fibrous tissue

OR

- Locator Wing collapsed, but short tines or long tines trapped behind distal ring

Difficult to Remove Device: Use of Access Ports



What not to do?

- Rock or twist the device

What to do?

Use of Access Ports Steps:

1. Unlock Thumb Advancer
 - Insert Dilator or 18 gauge needle into each Access Port, one at a time. Both must be disengaged.
 - Hear audible “Click” after each insertion
 - Number 3 exits window
 - **Retract Thumb Advancer**
2. Slide Safety Release
3. Remove device
 - Left hand apply counter-traction to skin site

Difficult Device Removal

How to prevent?

- **5 to 7 mm** skin nick and use a hemostat to spread the tissue through all the layers of the skin prior to device deployment
- Maintain angle of tissue tract during advancement of Thumb Advancer (Click 3) to prevent Carving



Clip Misfires

What will the operator see?

- Arterial bleeding
- Clip attached to distal end of the sheath

Why did it happen?

- Relaxing downward pressure or retraction of the device during clip deployment can result in incomplete tissue capture or clip deployment above the artery
- Failing to raise the device from 45° to 60-75° prior to clip deployment may result in incomplete tissue capture
- Device wasn't stabilized with the left hand during clip deployment

What to do?

- Remove device and hold pressure

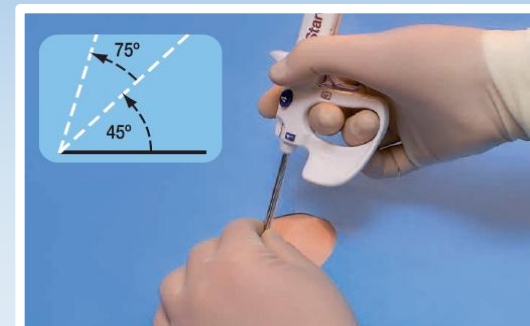
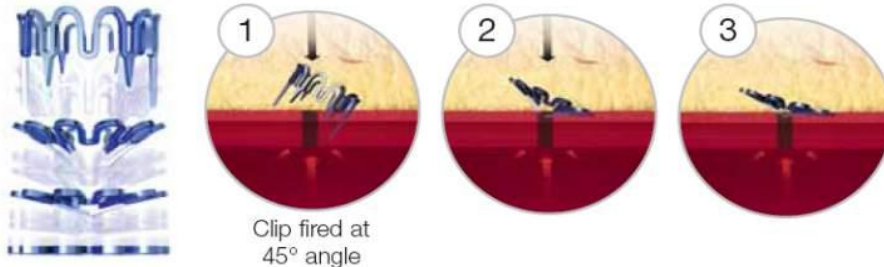
Clip Misfires

How to prevent?

- Raise the device from a 45° angle to 60-75° before clip deployment for complete tissue capture



Arterial bleeding - Incomplete tissue capture by Clip

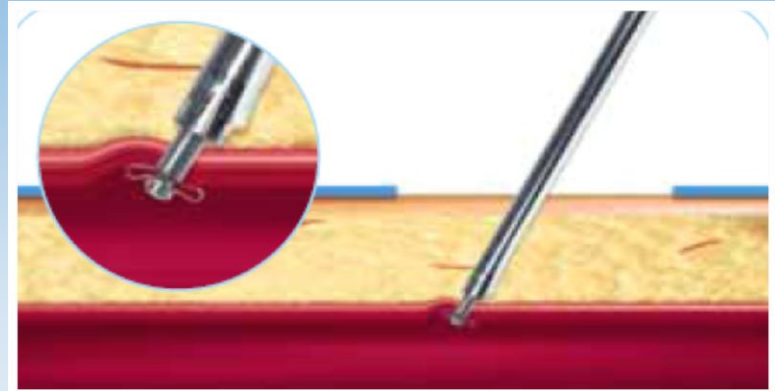


Clip Misfires

How to prevent?

- During clip deployment
 - Apply gentle downward pressure and hold/stabilize Clip Delivery Tube with left hand
 - Depress Deployment Button and hold for 2 to 3 seconds

Clip Deployment- Maintain contact with the artery during the clip deployment



Retraction during Clip deployment will result in the Clip deployment above the artery.

Oozing

What will the operator see?

- Blood seeping out from puncture site

Why does it happen?

- Loose sheath exchange during procedure
- Late skin incision after anticoagulants are administered
- Small vessel disruption in tissue tract
- Multiple punctures
- Use of anticoagulants and anti-platelet therapy
- Patient Considerations
 - High blood pressure
 - Inelastic arterial tissue
 - Delayed time time from scarred or fibrotic tissue



Oozing

How to prevent/reduce?

- 5-7 mm skin nick and single spread with forceps
 - At the beginning of procedure or prior to administration of anticoagulants and antiplatelets

Ooze Management

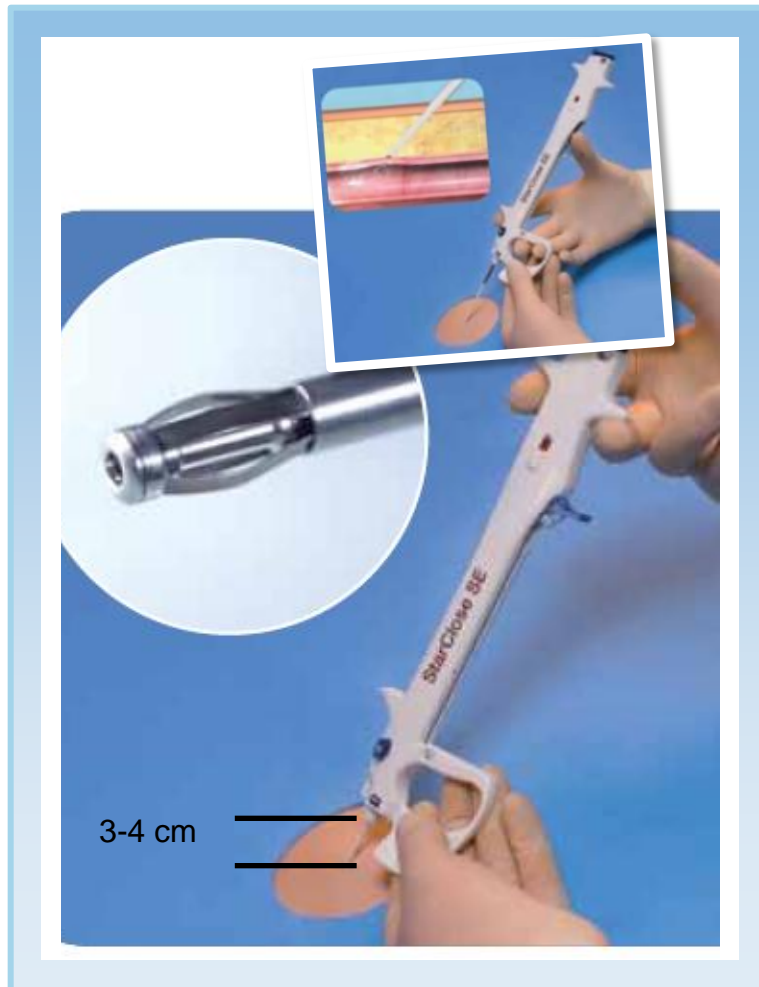
- Nick and spread early
- Bend patient's leg and express blood in the tissue tract
- Give time to revert back to original memory position (30 seconds to 2 minutes)

Oozing

Ooze Treatment Options

- Two 4x4 gauze tightly folded with biocclusive dressing
 - Apply in lab for interventional patients
- Moderate/venous/digital **pressure directly over the skin puncture site**
- 1% lidocaine with epinephrine 1:100,000 injected (lab) or topical application (floors or lab) over the skin track
- Hemostatic patch
- Pressure dressing

Obese Patients



Things to Consider:

- Prior to Click 2, 3-4 cm device retraction is recommended for visual verification of initial sheath splitting
- **The 3-4 cm device retraction may result in losing arterial access in obese patients**
- To maintain access, **split directly into the subcutaneous tract** (Click 2) then gently retract the device until you get tactile arterial feedback prior to completing (Click 3)
- Lift panniculus and/or push down on thigh to straighten out the tissue tract and keep Flex Guide straight



Troubleshooting

Early Procedure Termination Options



Safety Release vs. Access Ports Summary

Safety Release

When to use?

- Terminate procedure after Click 2 (after Locator Wing deployment)
- Terminate procedure before finishing Click 3 (before locking Thumb Advancer)

How to use?

1. Retract Thumb Advancer

- Slide Safety Release
- Number 2 exits window
- Retract Thumb Advancer

2. Remove device

- Left hand apply counter-traction

Access Ports

When to use?

- Terminate procedure after finishing Click 3 (after locking Thumb Advancer)
- Difficult to Remove Device

How to use?

1. Unlock Thumb Advancer

- Insert Dilator or 18 gauge needle into each Access Port, one at a time. Both must be disengaged.
- Hear an audible “Click” both times. Number 3 exits window.
- Retract Thumb Advancer

2. Slide Safety Release

3. Remove device

- Left hand apply counter-traction



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VC Global Training - Starclose SE

AP2939155-INT A

A

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Associated Products (product name(s) only): *** NONE *** (N)

Reference Documents

Document	Location
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Approval Signatures

Level	Role / Function	Name	Site	Signature	Date	Comments
1	Doc Control/Labeling	Cecilio, Janet	CA	Cecilio, Janet	11/8/2013 4:02:52 PM	
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2	Marketing	Chen, Charlene	CA	Chen, Charlene	11/11/2013 2:54:30 PM	
2	Marketing Com	Shpolyansky, Natalya	CA	Shpolyansky, Natalya	11/8/2013 4:22:13 PM	
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A	11/11/2013 8:56:00 PM	Purpose: Presentation to train new hires on the Starclose SE product for Vessel Closure therapy.; Geography: Global; Method of Distribution: By global training departments. In digital and hard copy.; Intended Audience: Internal employees and distributors.	349264	Cecilio, Janet