

AXIUM™ PRIME DETACHABLE COIL EXTRA SOFT

IN-SERVICE PRESENTATION

THE FOLLOWING IS INTENDED AS A SUMMARY OF THE DIRECTIONS FOR USE. REFER TO THE IFU FOR COMPLETE INSTRUCTIONS FOR USE.

AXIUM™ PRIME DETACHABLE COIL AND AXIUM™ I.D. (INSTANT DETACHER) INSTRUCTIONS FOR USE PN 70902-001 REV 03/15



Medtronic
Further, Together

DEVICE DESCRIPTION AND COMPATIBILITY

- The Axiu™ Prime detachable coil (extra soft) consists of a platinum embolization coil attached to a composite implant delivery pusher with a radiopaque positioning marker and a hand-held Instant Detacher (I.D.), which, when activated, detaches the coil from the delivery pusher tip.
- I.D. (Instant Detacher) is sold separately.
- The following devices are used with the Axiu™ Prime detachable coil (extra soft):
 - Micro catheter with a minimum inside diameter of 0.0165" -0.017" with two marker bands
 - Axiu™ I.D. (Instant Detacher)

PREPARATION: CONTINUOUS SALINE FLUSH AND FITTINGS

- It is advised to maintain a continuous saline flush between the:
 - Femoral sheath and the guiding catheter
 - Micro catheter and guiding catheter
 - Micro catheter and implant delivery pusher and the Axium™ Prime coil (extra soft)
- Check all fittings so that air is not introduced into guiding catheter or micro catheter during continuous flush.

PREPARATION: INSPECTING THE COIL SYSTEM

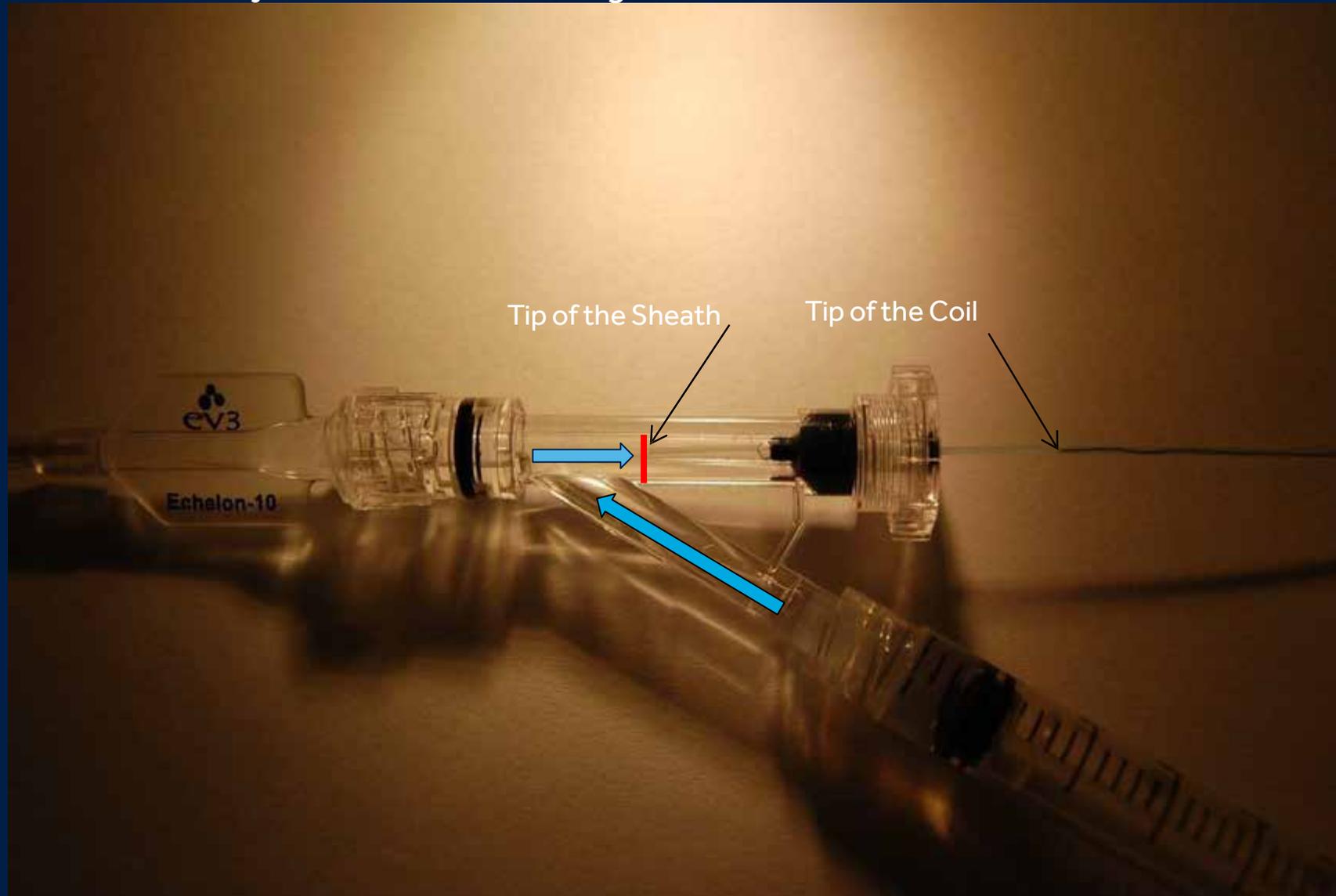
- Visually inspect the Axium™ Prime detachable coil (extra soft) and implant delivery pusher for irregularities.
- If irregularities exist, replace with a new Axium™ Prime detachable coil (extra soft)



Gently immerse the Axium™ Prime detachable coil (extra soft) and its detachment zone in heparinized saline. While still immersed in the heparinized saline, point the introducer sheath vertically into saline and gently retract the distal tip of the coil into the introducer sheath.

BACK FLUSH--STEP 1*:

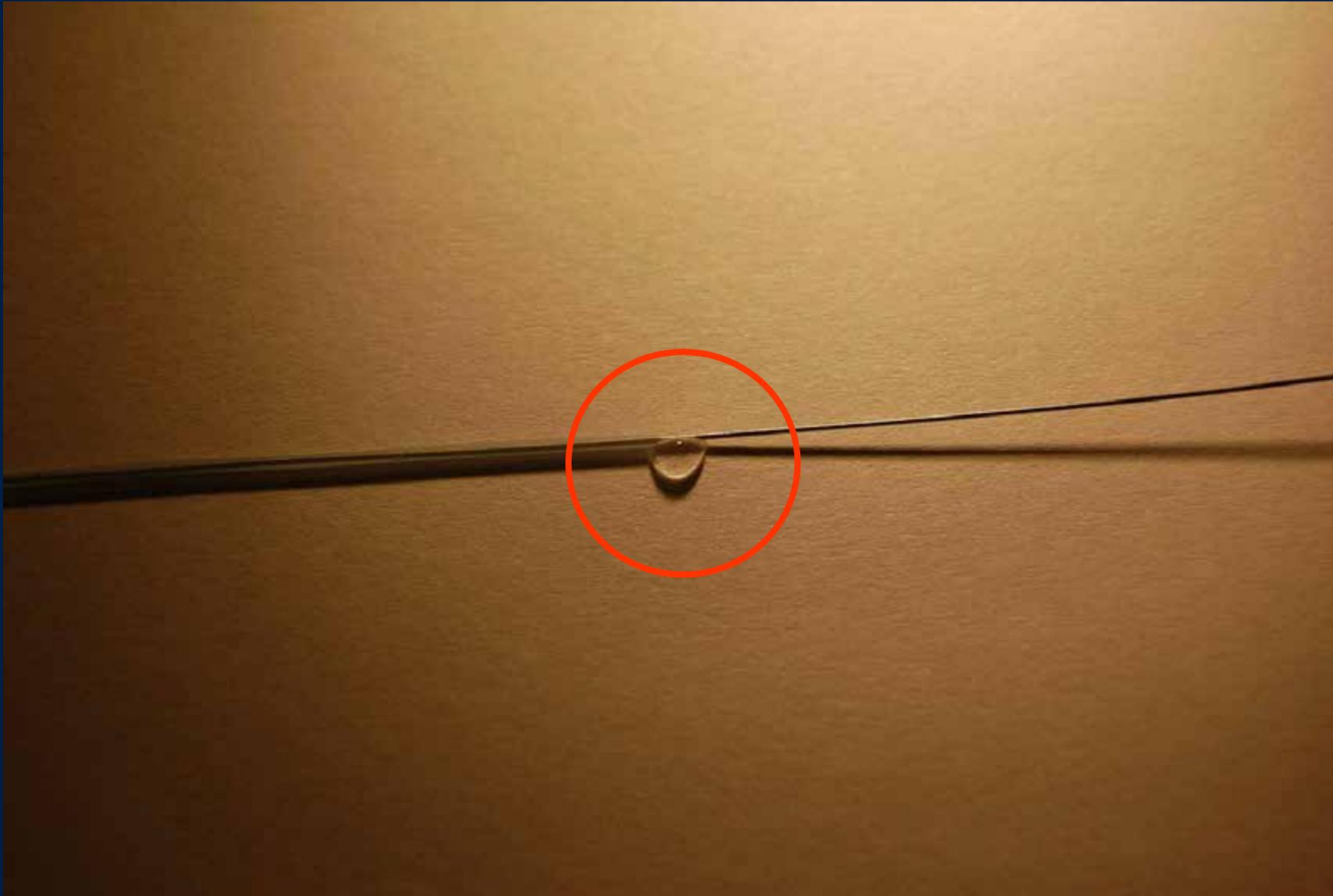
Insert the sheath into the Y connector. Position the tip of the sheath right before the junction (red mark). Tighten the hemostatic valve. Back flush.



*While our IFU does not require a back flush, it is customary in many laboratories to use a back-flush technique while using embolic coils

BACK FLUSH STEP 2*:

Check for drop of saline at the proximal end of the sheath.



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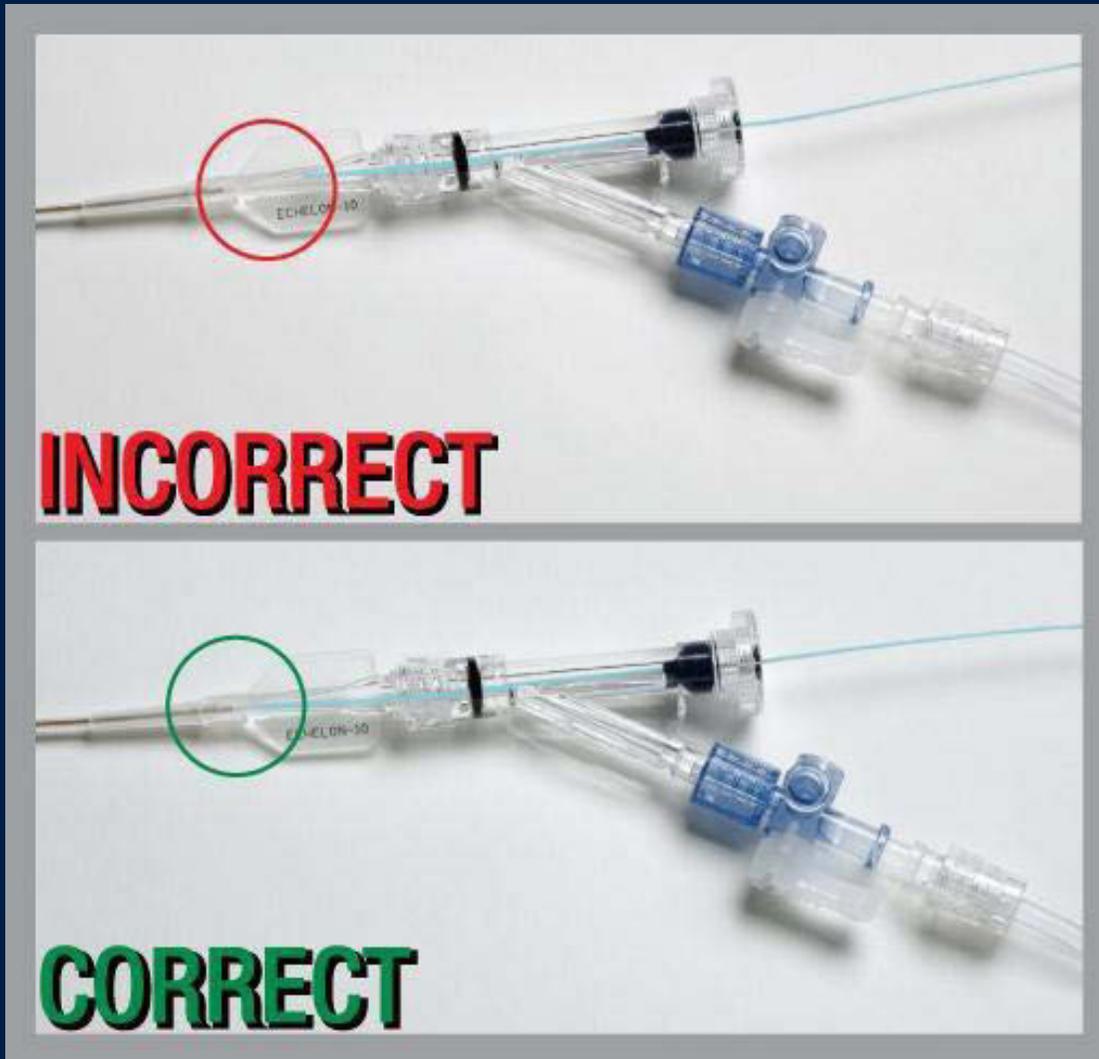
BACK FLUSH STEP 3*:

Open the hemostatic valve. Seat the sheath distally inside the micro catheter hub. Tighten the hemostatic valve. Load the coil.



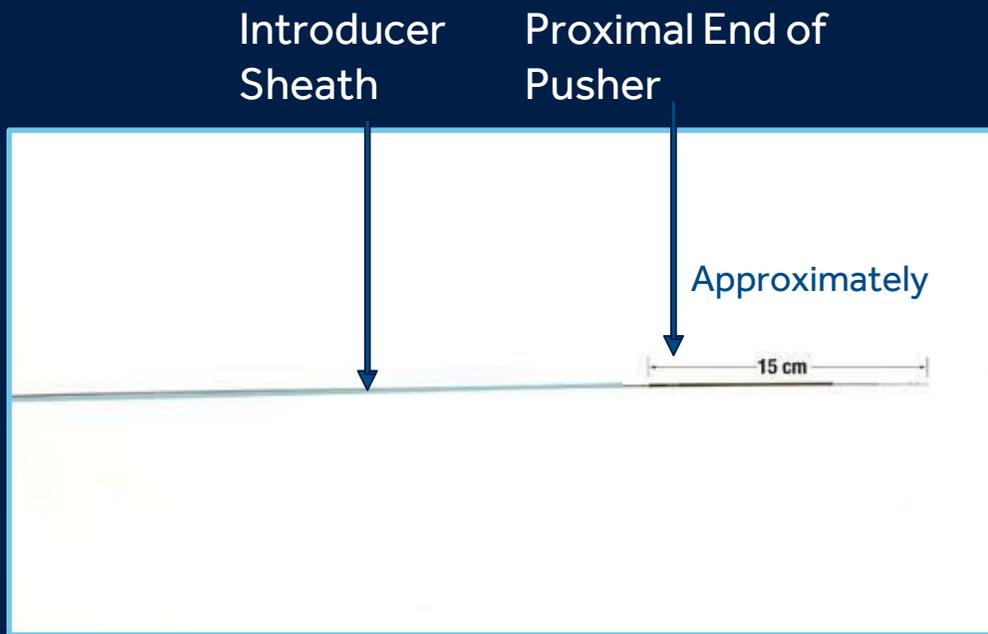
*While our IFU does not require a back flush, it is customary in many laboratories to use a back-flush technique while using embolic coils

DELIVERY:



Insert the introducer sheath into the hub of the micro catheter until it is fully seated. Tighten the valve and advance the coil with smooth, continuous 1-2 cm strokes.

DELIVERY:



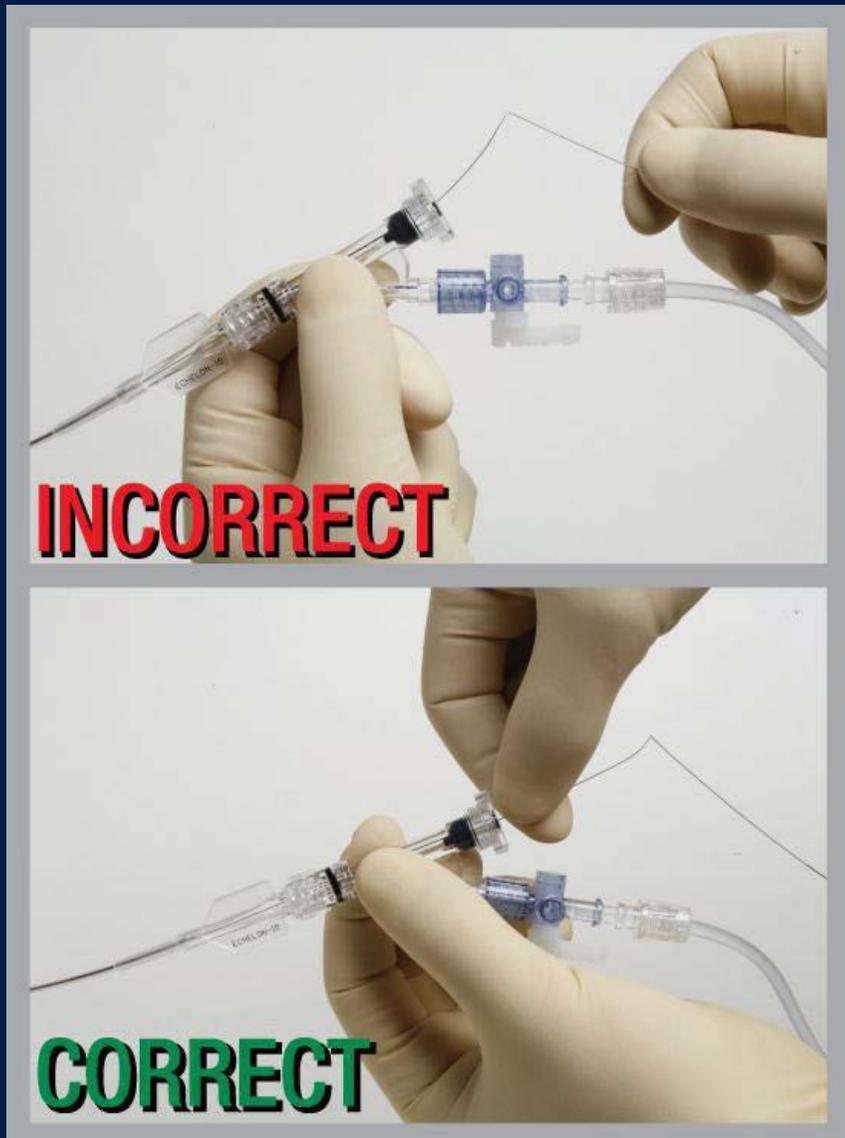
Continue to advance the coil through the sheath until approximately 15 cm of the pusher remains proximal to the sheath. Do not attempt to advance the entire implant pusher into the introducer sheath. Doing so may cause kinking in the proximal pusher.

DELIVERY:



Remove the sheath and continue to advance the coil. Activate fluoroscopy to confirm positioning of coil prior to advancing coil into aneurysm.

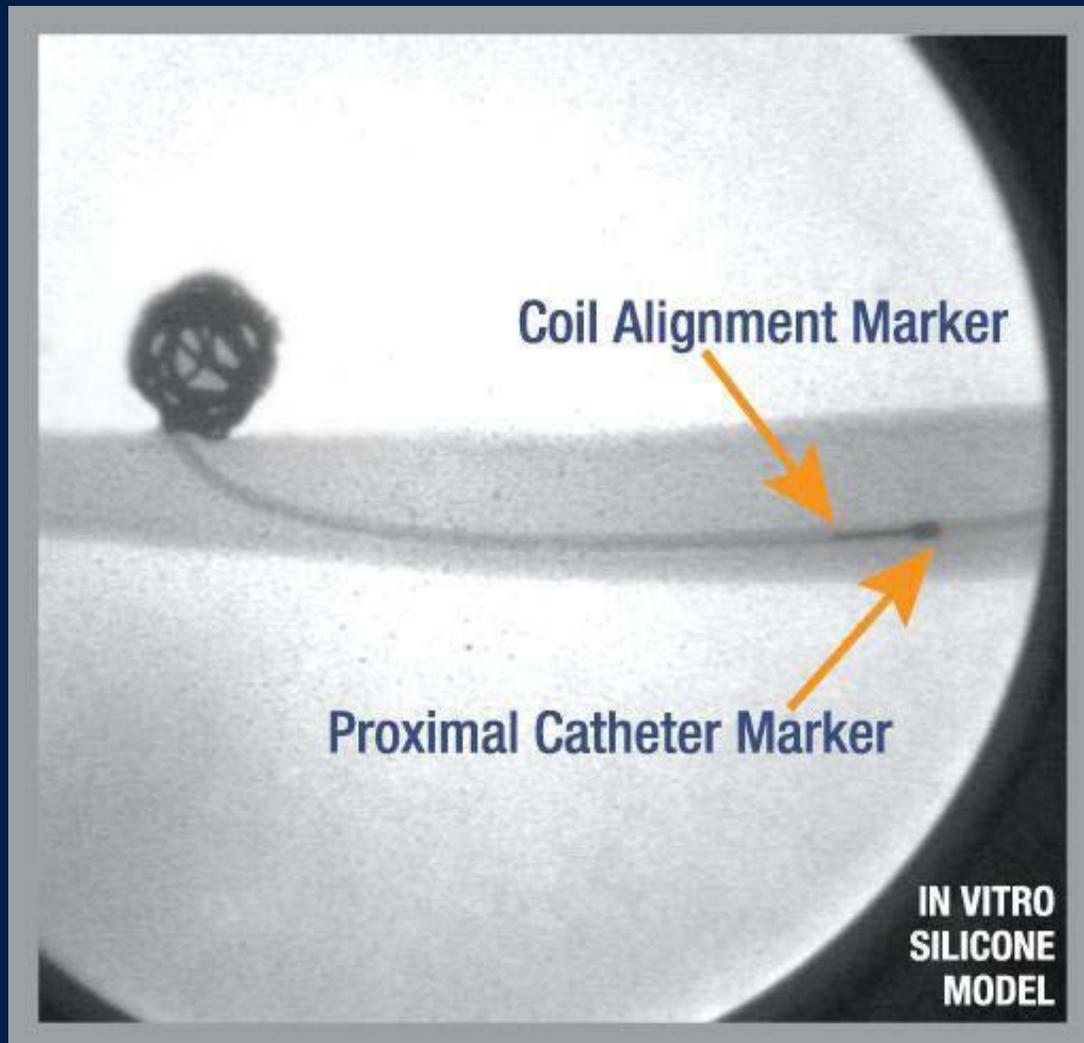
DELIVERY:



If the pusher is kinked, it is recommended to remove the pusher from the micro catheter and replace with a new Axium™ Prime coil (extra soft).

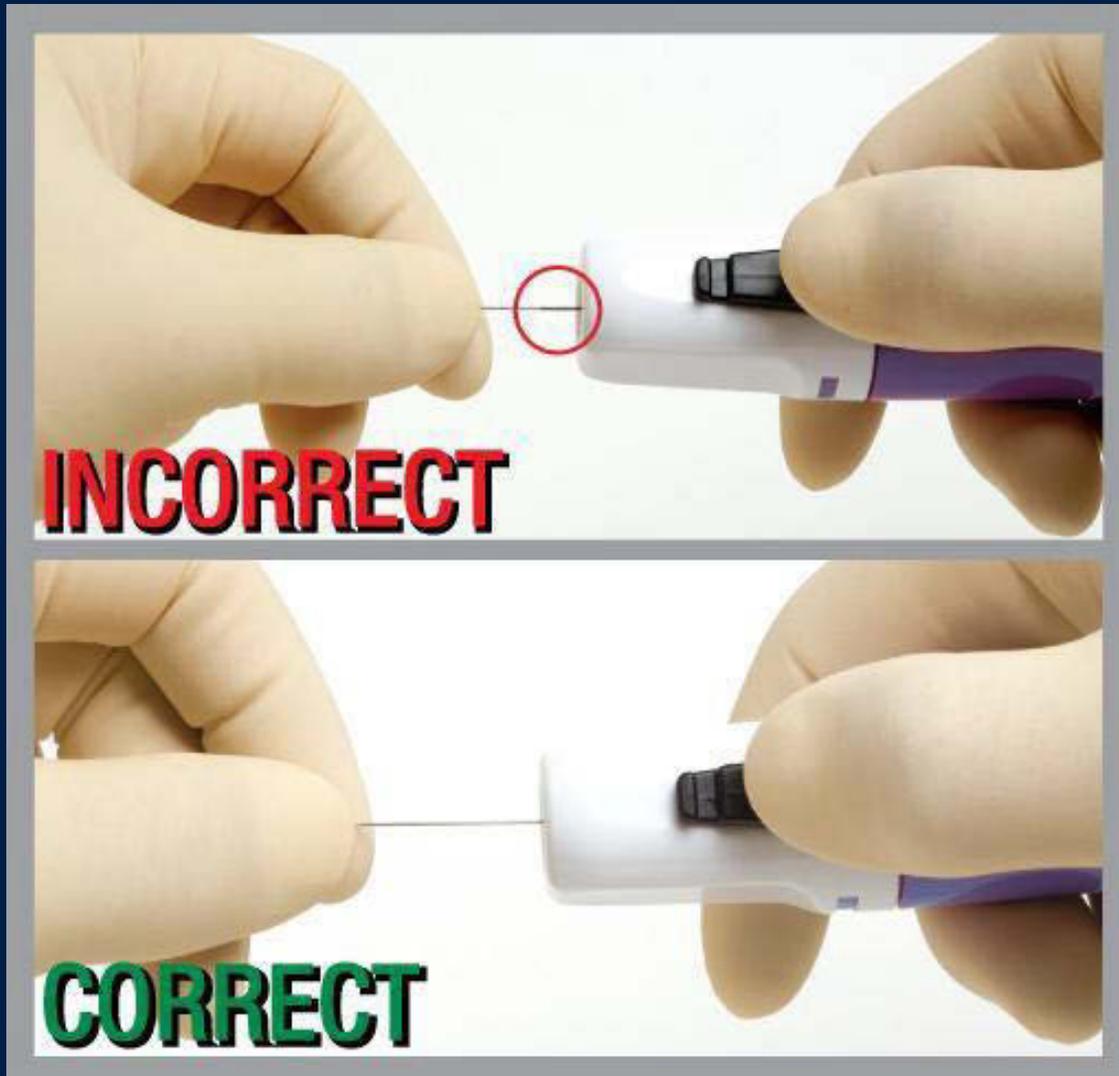
In order to properly remove a kinked pusher, remove the pusher while holding it distal to the kink.

DELIVERY AND DEPLOYMENT:



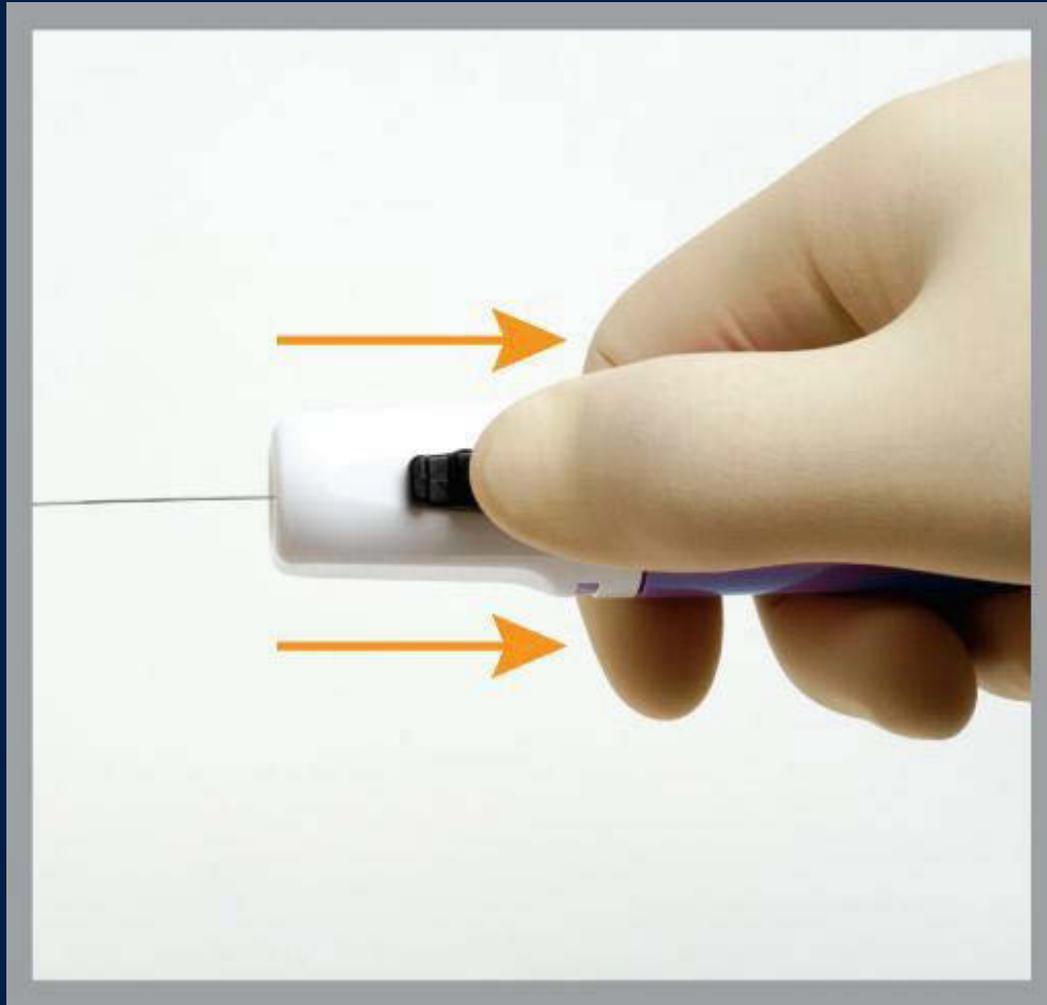
Advance the implant until the coil alignment marker is just distal to the proximal catheter marker band, then retract the pusher until the "T" is formed with the catheter marker band and coil alignment marker.

DETACHMENT:



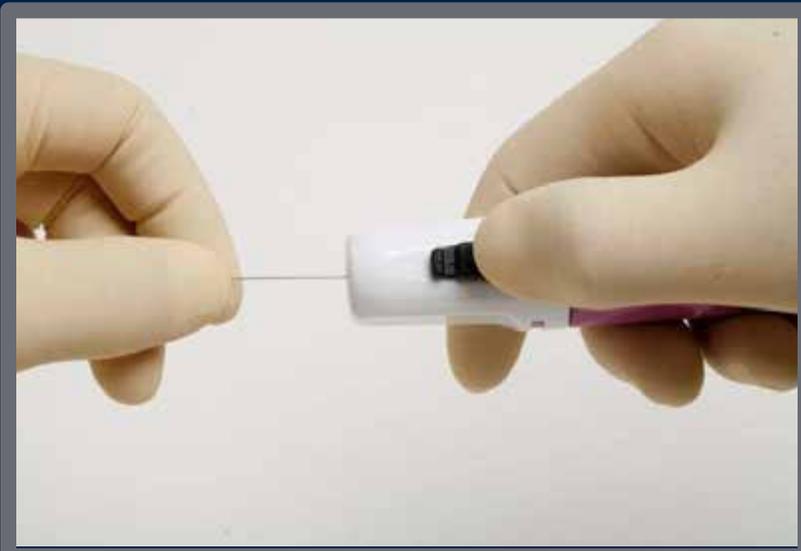
Advance the Axium™ Instant Detacher over the pusher until the pusher is fully seated (i.e. the black positive load indicator is fully inserted in the Axium™ Instant Detacher funnel).

DETACHMENT:



To detach the implant, retract the thumb slide back until it stops and clicks.

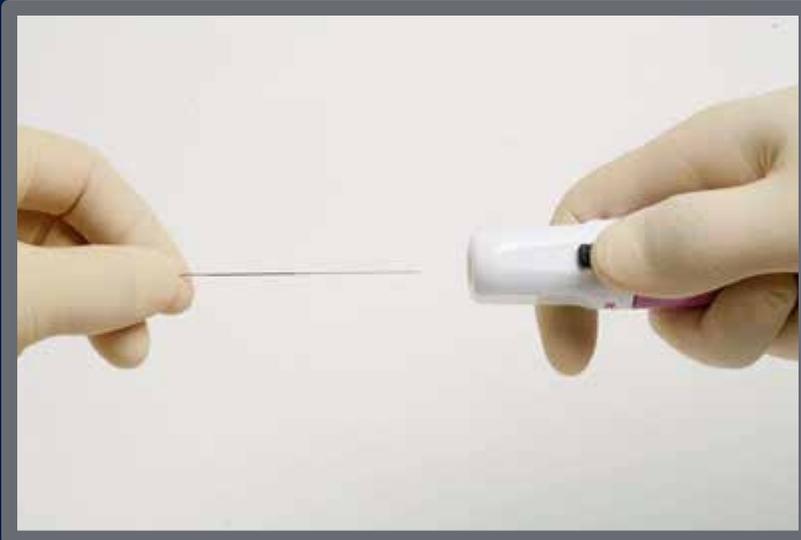
DETACHMENT:



Remove the pusher from the Axium™ Instant Detacher :

Pusher Removal Option 1:

Slowly allow the thumb slide to return to its original position. Then remove the pusher.



Pusher Removal Option 2:

Retain the thumb slide in the retracted position. Remove the pusher.

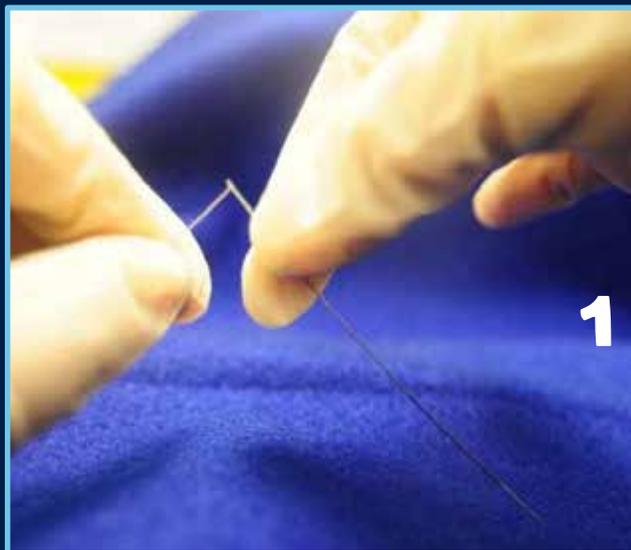
DETACHMENT CONFIRMATION AND RETRIEVAL OF PUSHER:

1. Verify successful coil detachment under fluoroscopic monitoring to ensure that the coil has detached.
2. To do this, slowly pull back the implant pusher under fluoroscopy to make sure that the coil does not move.
3. Remove the pusher from the micro catheter.

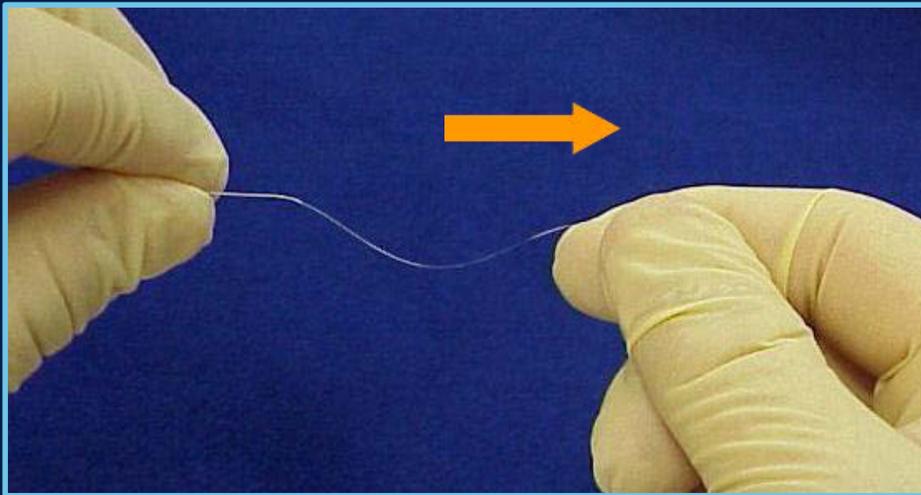
DETACHMENT—BACKUP METHOD:

In the rare event that the coil does not detach and cannot be removed from the implant delivery pusher, use the following steps for detachment.

1. Grip the hypotube approximately 5cm distal of the positive load indicator at the hypotube break indicator (HBI) and bend the implant delivery pusher just distal to the HBI 180 degrees. (Figure 1)
2. Next straighten the pusher back, continue bending and straightening until the pusher tubing opens exposing the release element. (Figure 2)



DETACHMENT CONFIRMATION AND PUSHER RETRIEVAL— BACKUP METHOD:



3. Gently separate the proximal and distal ends of the open pusher. Then, under fluoroscopy, pull the proximal portion of the implant delivery pusher approximately 2-3 cm to confirm implant detachment per IFU (Steps 17.1 -17.3).
4. Slowly pull back the implant pusher under fluoroscopy to make sure that the coil does not move.
5. Remove the pusher from the micro catheter

DETACHMENT:

WARNING

In Case of:

- False Positive (attempted detachment failed)
 - Remove coil from treatment area and micro catheter and replace with a new Axium™ detachable coil (extra soft)

- False Negative (coil becomes prematurely detached)
 - Remove implant pusher and:
 - Advance next coil to push remaining tail of prematurely detached coil into treatment area
 - or
 - Remove prematurely detached coil with the appropriate retrieval device

Indication: Axium™ and Axium™ Prime detachable coils are intended for the endovascular embolization of intracranial aneurysms. Axium™ and Axium™ Prime detachable coils are also intended for the embolization of other neuro vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.

Axium™ and Axium™ Prime procedural steps taken from IFU. For complete instructions for use please see IFU. All images are the property of Medtronic.

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