

Site Seal is a closure device, designed to simulate external compression, but removes the associated variables. Site Seal's advantages are:

Not limited by sheath size, including EVAR, TEVAR, TAVAR

No patient limitation: size, anti-coagulation, calcification, etc.

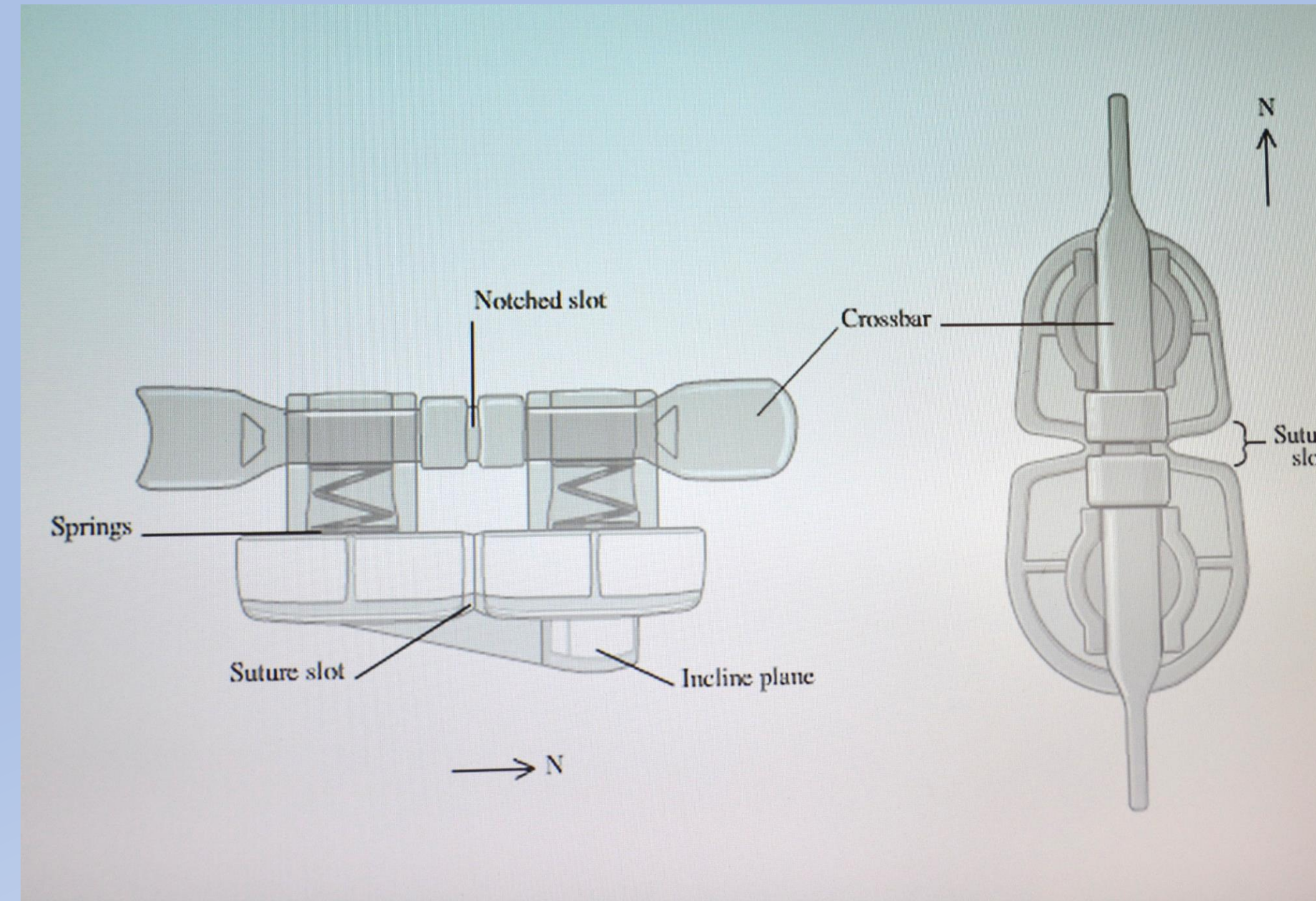
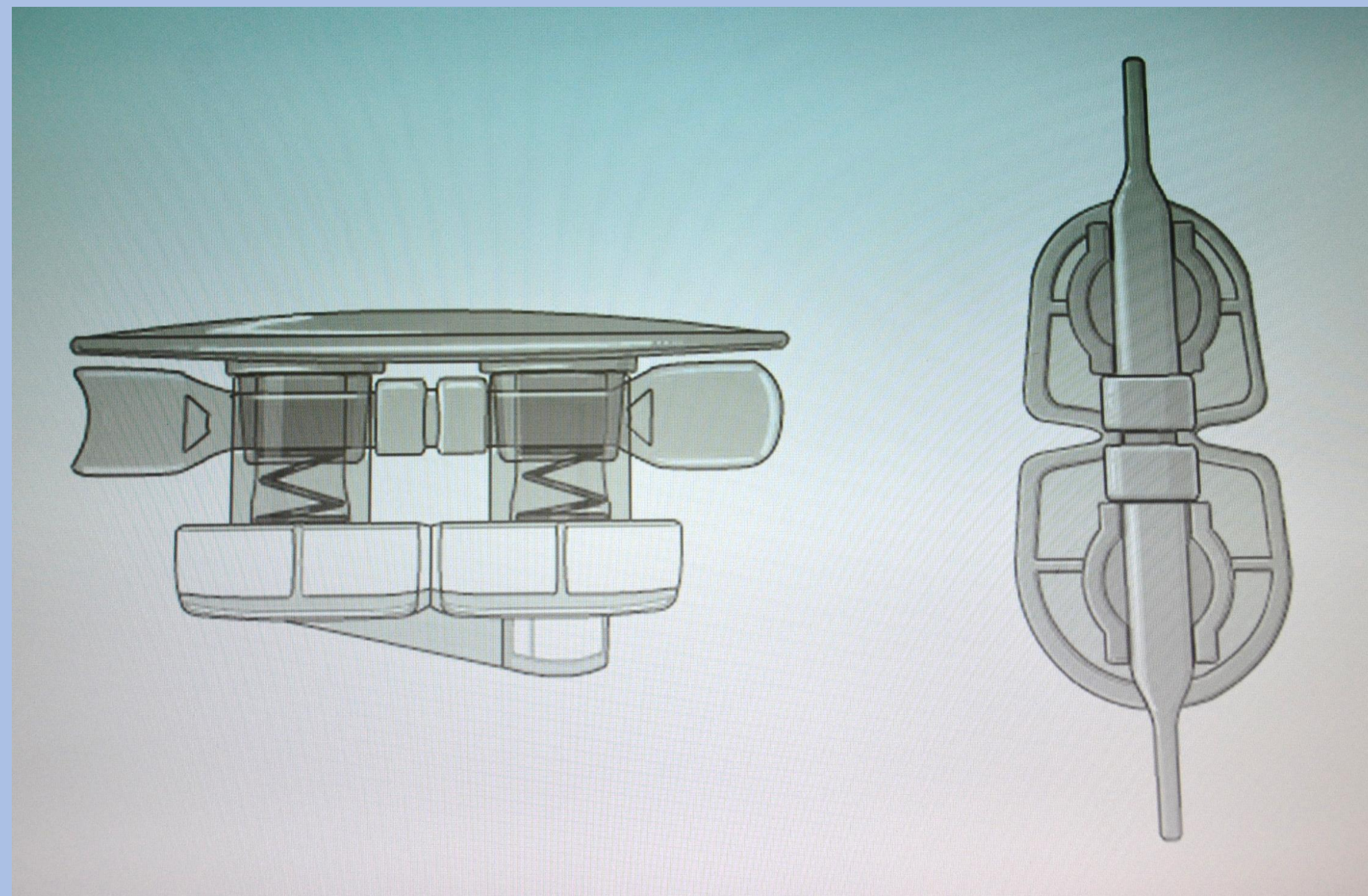
Simple and rapid deployment

Allows immediate re-access

Minimizes patient discomfort...allowing immediate head elevation to 30° with no restriction to leg movement

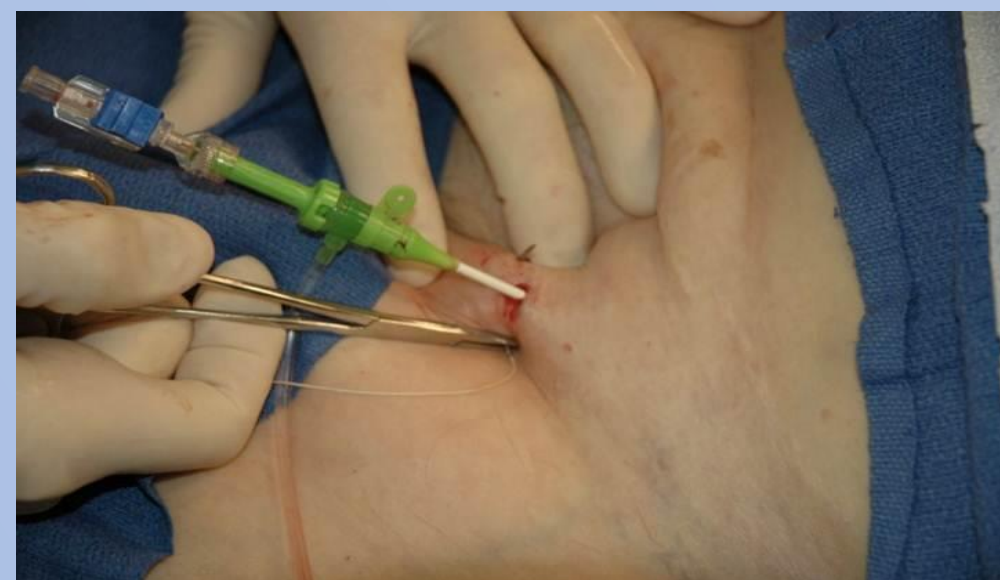
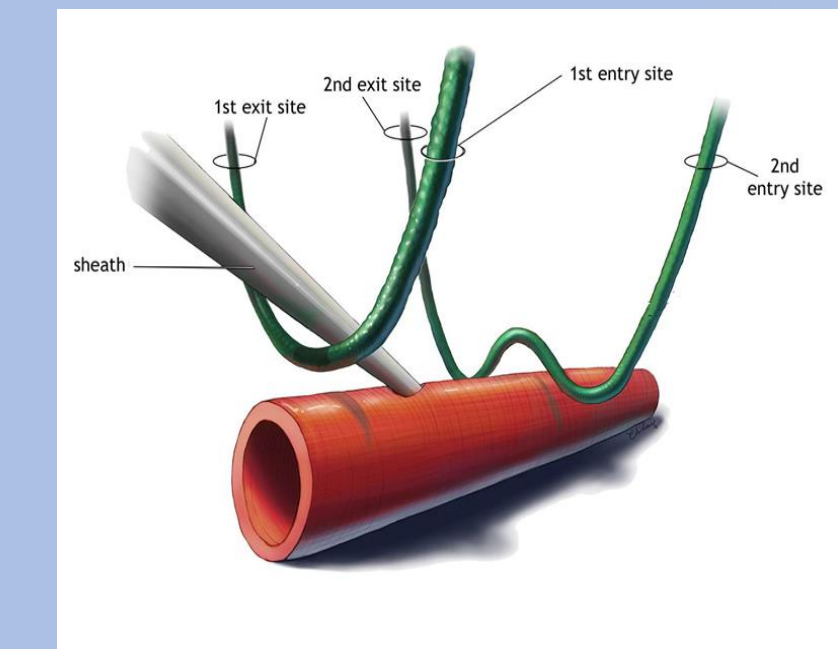
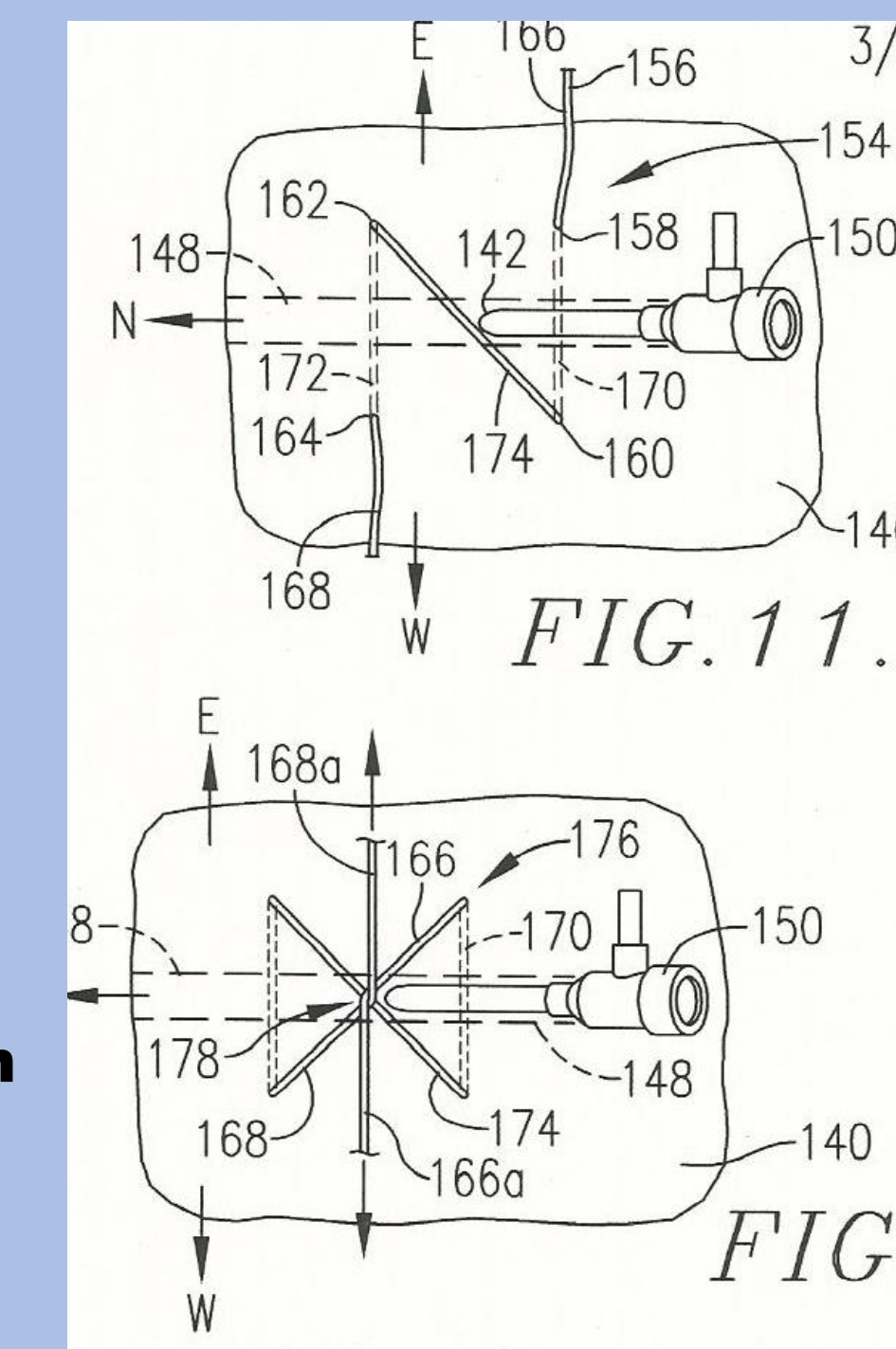
Early ambulation

Nothing left behind...the potential of minimal risk of vessel wall injury, infection, or embolization



Z stitch in place

Z stitch closed to create an X which will invert the skin



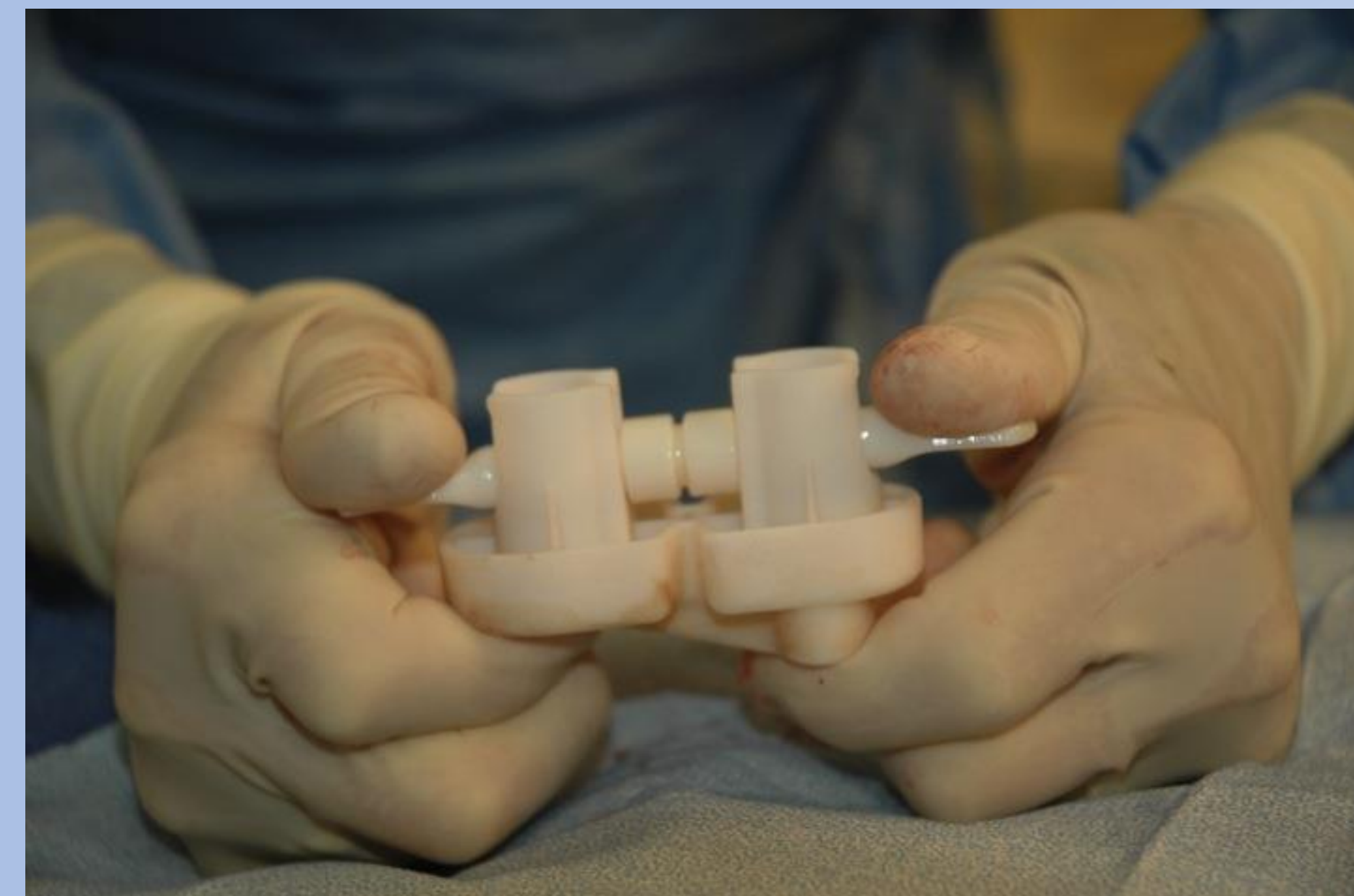
The suture exits up from the second hole of the Z stitch.



The needle comes up over the sheath out of hole #4.



The suture is pulled tight, closing the X, inverting the skin and pulling powder into tract.



The device is cocked.



The sheath is removed. Pressure is held by upward force of the first double half knot and downward pressure on the device.



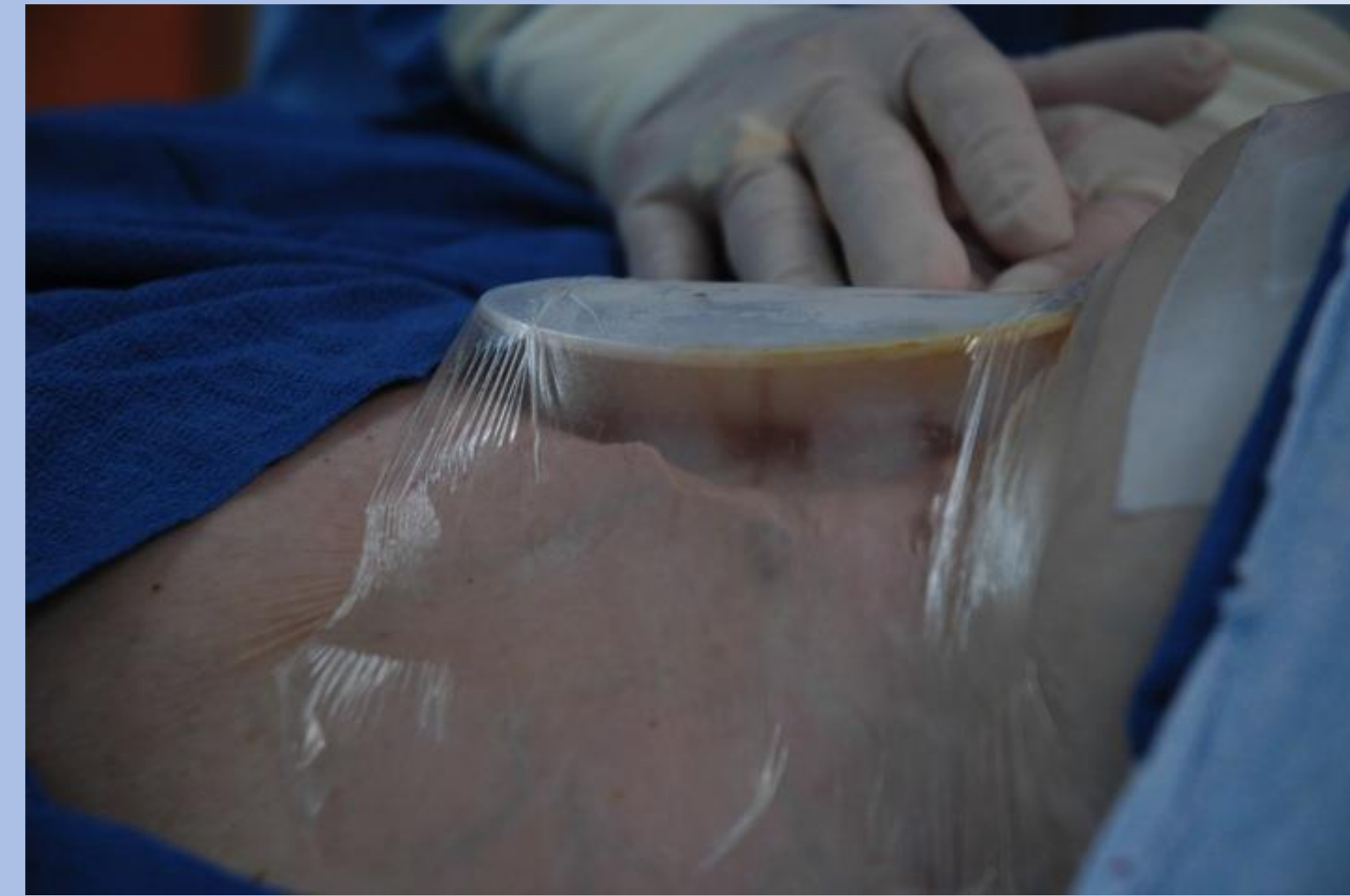
The device is pushed into the skin (see the indentation) and a securing knot is placed.



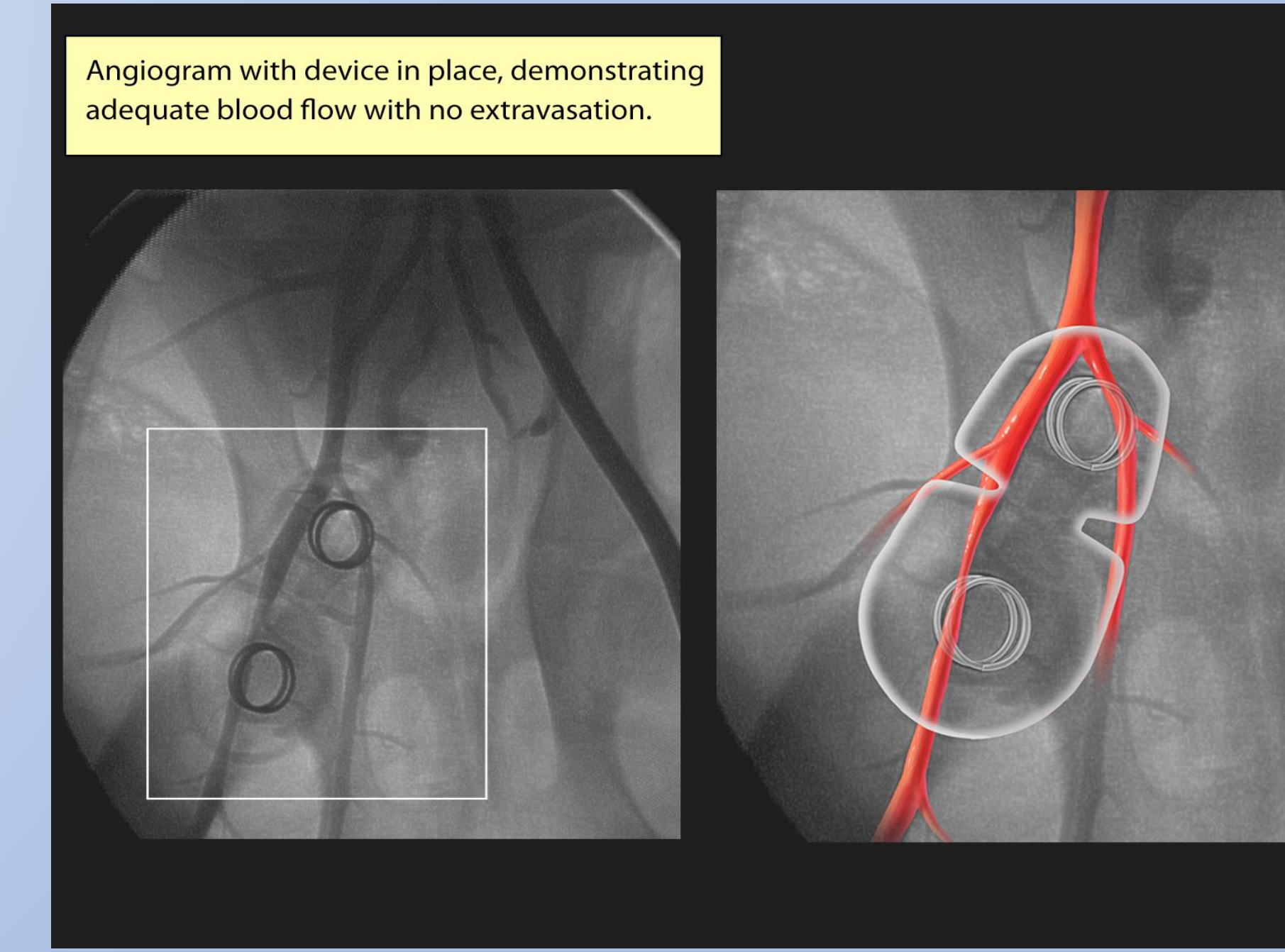
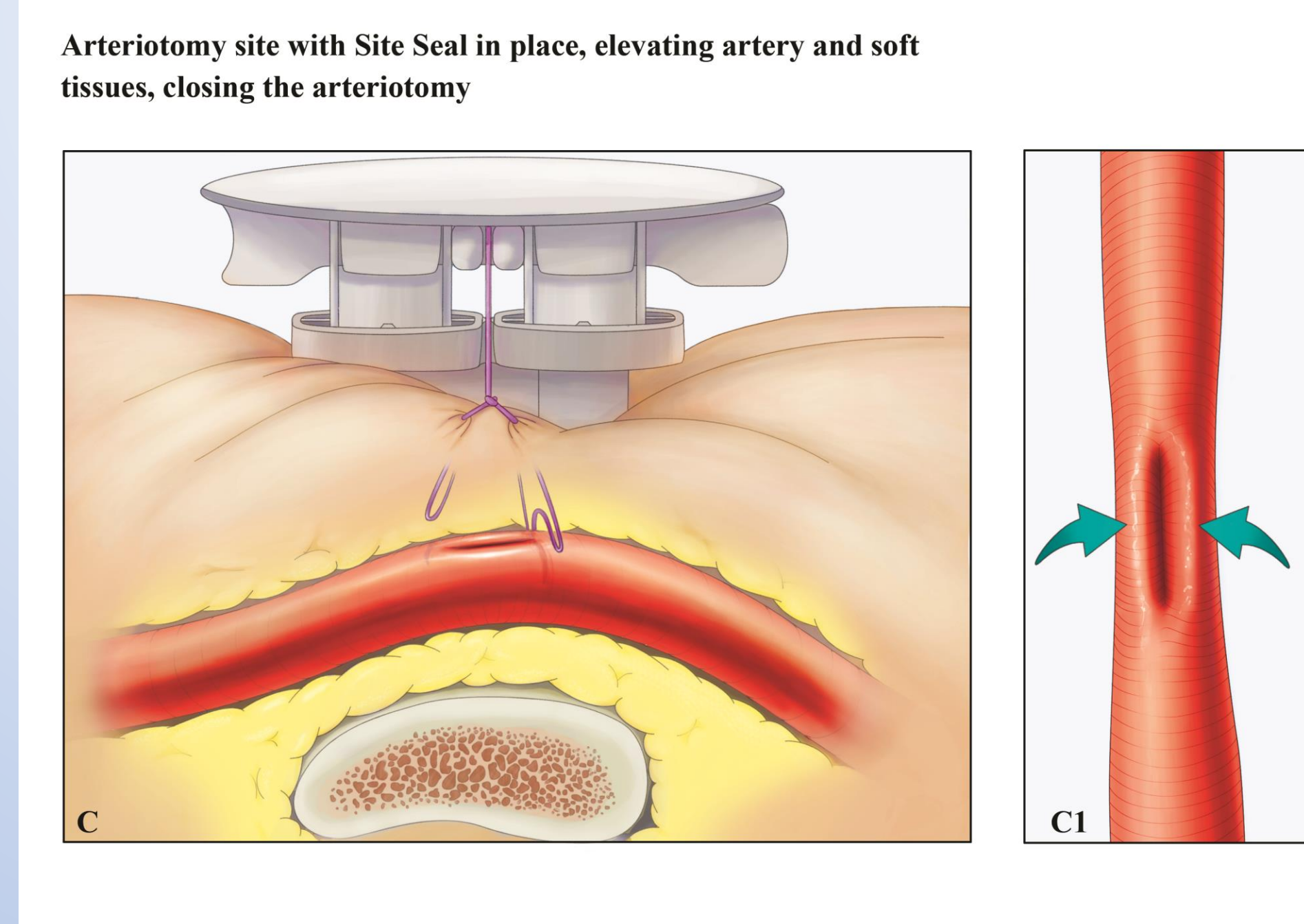
Springs are released, causing the suture to be pulled upward, closing the arteriotomy site and applying downward pressure.



The roof is placed over the device.



Lateral view of device in place. No bleeding or hematoma.



AAA Repair



24 hour post ambulation after Site Seal removal from AAA repair



Impella removal



24 hour post ambulation after Site Seal removal from Impella

As of this date, 45 EVAR and 23 Impella procedures have been performed using Site Seal without any hematoma formation at discharge, 24 hours, 7 day and 30 day follow up.