



## RECOMMENDATION TO REMOVE THE PEEL-AWAY SHEATH POST-PROCEDURE

### RECOMMENDATION

**ABIOMED recommends removing the peel-away sheath and inserting the repositioning sheath into the artery post-procedure when longer duration support is required.**

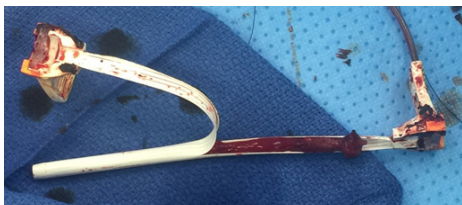
**ABIOMED DOES NOT recommend the following:**

- Inserting the repositioning sheath into the introducer
- Securing the peel-away sheath with sutures instead of removing the sheath

### BACKGROUND

During instances when longer duration of support is required, ABIOMED has observed physicians leaving the peel-away sheath in place, instead of removing it post-procedure and inserting the repositioning sheath. The peel-away sheath is intended solely for procedural support and leaving the sheath in for longer duration of support has the following risks:

- Clot formation in the sheath.
- Blood leaking at the valve.
- Cracking of the introducer resulting in bleeding and/or damage to the arteriotomy.
- Leaving the peel-away sheath in the femoral artery post procedure could result in arterial injury or thrombosis with the potential for limb loss.



Clot Formation in Peel-Away Sheath

These risks are further increased when the repositioning sheath is inserted into the peel-away sheath and both are left in place post-procedure when a longer duration of support is required.

### PUTTING IT INTO PRACTICE

In the event that a patient needs Impella heart pump support post-procedure, the following steps are strongly recommended:

1. Remove the peel-away sheath.
2. Insert the repositioning sheath into the artery.
3. Attach the sterile sleeve.
4. Remove catheter slack.
5. Tighten tuohy at both ends of the sleeve.

**DO NOT PEEL THE SHEATH AWAY WHILE STILL IN THE VESSEL.**

### SUMMARY

The risks of bleeding, clot formation, and cracking increase if the repositioning sheath is inserted into the peel-away sheath for longer duration of support. ABIOMED strongly recommends that customers remove the peel-away sheath and insert the repositioning sheath into the artery to avoid these additional risks.

If you have any questions or would like to discuss this recommendation further, please contact the ABIOMED training team.

To learn more about the Impella platform of heart pumps, including important risk and safety information associated with the use of the devices, please visit: [www.protectedpci.com/hcp/information/isi](http://www.protectedpci.com/hcp/information/isi) and [www.cardiogenicshock.com/information/isi](http://www.cardiogenicshock.com/information/isi)