



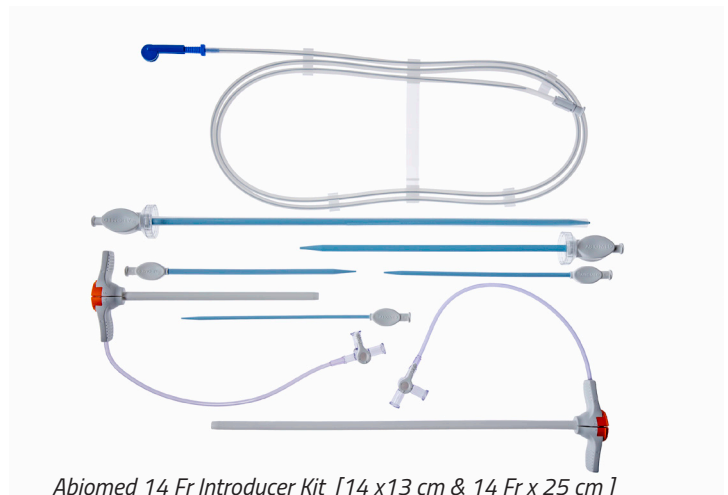
## Best Practices for Impella CP® Use of 14 Fr x 30 cm Cook Introducer Not Recommended

### What's New?

Abiomed no longer recommends the use of the 14 Fr x 30 cm Cook Check-Flo Performer® introducer for use with the Impella CP. This sheath is no longer a qualified alternative sheath for use with the Impella CP and has been removed from the Instructions For Use.

### Overview

There have been increased reports of physicians unable to insert the Impella CP heart pump through the 14 Fr x 30 cm Cook Check-Flo Performer® introducer, resulting in damage to the Impella CP and delayed patient support. Abiomed does not control the size of the Cook introducer and cannot guarantee that it will be compatible with the Impella CP. The provided 14 Fr x 13 and 25 cm introducers in the Impella CP Set-up and Insertion Kit are specifically designed and qualified for use with the Impella CP. In addition, the provided 14 Fr sheaths are peel-away which reduces the risk of leg ischemia for patients that require support outside the catheterization lab.



Abiomed 14 Fr Introducer Kit [14 x13 cm & 14 Fr x 25 cm ]

### Recommendation

All Impella CP Insertion Kits contain a 14 Fr x 13 cm and a 14 Fr x 25 cm peel-away introducer. The Impella CP also comes with the reaccess sheath on the catheter to maintain access after the peel-away is removed. For patients requiring a longer sheath for Impella delivery, use the provided 25 cm sheath. For patients that are transferred to the ICU, peel away the 14 Fr sheath and advance the reaccess sheath. Access to the vessel can be maintained with a 0.035" guidewire through the guidewire access port.

### Summary

Use of the 14 Fr x 30 cm Cook Check-Flo Performer® introducer is not recommended and is not a qualified alternative sheath for the Impella CP.

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

*\*This bulletin is intended for dissemination of technical information only.*