



Impella® Updates*

NOVEMBER, 2015 Issue 2

RECOMMENDATIONS FOR PROPER REMOVAL OF THE IMPELLA CP® AND IMPELLA® 2.5 HEART PUMPS FROM THE PACKAGING

WHAT'S NEW?

ABIOMED RECOMMENDS THAT THE IMPELLA CP® AND IMPELLA® 2.5 HEART PUMPS BE REMOVED FROM THE PACKAGING BY:

1. SLIDING YOUR FINGERS BETWEEN THE CATHETER AND THE PACKAGING ON EITHER SIDE OF THE PACKAGE PINCH POINTS.
2. REMOVE THE CATHETER BY LIFTING UP ON THE CATHETER BODY (NOT THE PUMP).

FIGURE 1

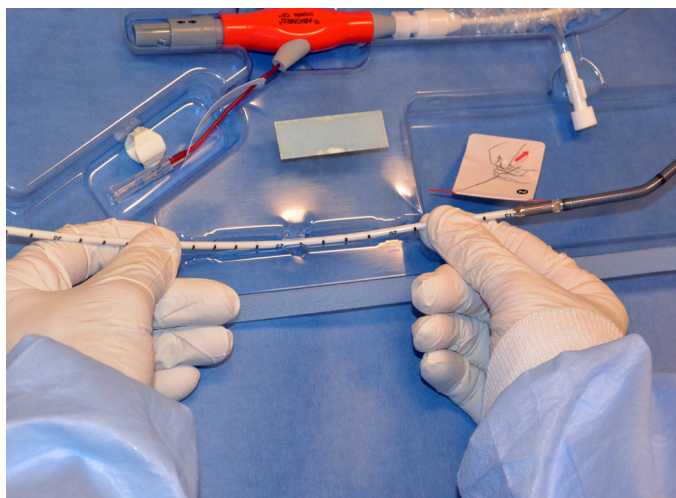


Figure 1: Correct removal

BACKGROUND

Abiomed has observed that hyperextending the joint between the Impella device's motor and the catheter (Figure 2), can result from pulling the catheter back against packaging pinch points. With this inappropriate removal technique it may be possible in certain instances to damage the internal components located where the catheter joins the motor. An undesirable effect of potentially damaging these components is a loss of purge flow to the motor and/or loss of placement signal. In particular if the purge fluid connection is lost this could evolve into an Impella® catheter pump stop over time.

Abiomed recommends the process in Figure 1 be adopted to address this concern.

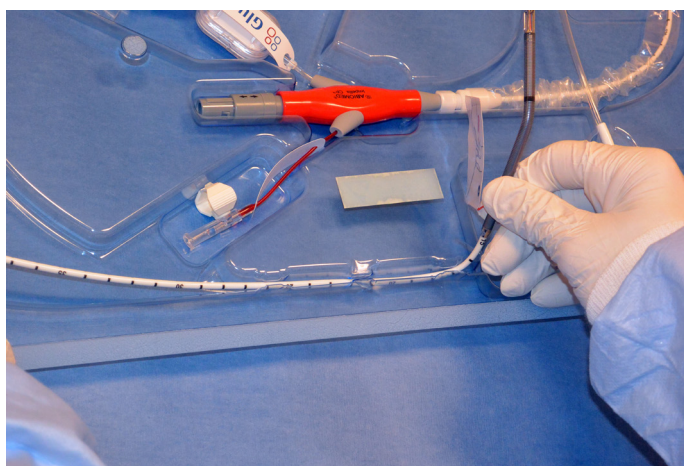


Figure 2: Incorrect removal