



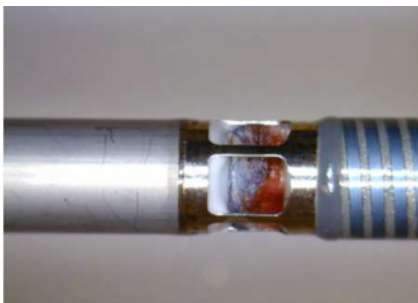
RECOMMENDATION TO AVOID SYNTHETIC OR COTTON FIBER CONTACT WITH IMPELLA® HEART PUMP

WHAT'S NEW?

Do not rinse Impella® Heart Pumps in a water basin or expose the cannula section to any surface or materials where it could inadvertently pick up stray synthetic or cotton fibers. Water basins and sterile towels or drapes may contain fibers that can cause entrainment of the impeller and result in low flow of the Impella® device.

BACKGROUND

Analysis of cases where lower than expected flows were reported has shown clot formation along the internal blood flow path can occur. Examination of the clot composition showed that clots were formed around a matrix comprised of blue or white fibers typically found in sterile towels and drapes.



Clot and fibers lodged in pump

PUTTING THIS INTO PRACTICE

In the event that low flow performance is observed any time after insertion, confirm adequate RV function, volume status, and correct positioning. If RV function, volume status, and incorrect position have been ruled out, pull the Impella® device all the way back into the descending aorta. If a low flow condition persists, remove and replace with a new Impella® device. DO NOT ATTEMPT TO RINSE AND REINSERT THE DEVICE as clots are frequently in locations that cannot be seen or easily rinsed.

To help reduce the possibility of fibers being drawn into the Impella® Heart Pump:

- DO NOT ATTEMPT TO RINSE AND REINSERT THE DEVICE.
- Keep the Impella® Heart Pump in its packaging tray until just before insertion.
- To control blood splatter when inserting the Impella® Heart Pump through the introducer, hold the surgical towel or 4 x 4 gauze pad away from the inflow and outflow windows.

SUMMARY

Abiomed strongly recommends that customers avoid exposing the cannula section of the Impella® Heart Pumps to any surfaces or fluid baths where the device can come into contact with loose or floating fibers.