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URGENT: MEDICAL DEVICE CORRECTION (NOTIFICATION)

SUBJECT DEVICES:
This information concerns all lots for the following Impella heart pumps:

Impella® RP Flex with SmartAssist

Dear Valued Customer,

This letter is to notify you about important information that Abiomed, Inc. ("Abiomed") is providing for the continued safe use of Impella® RP Flex with SmartAssist heart pumps in patients undergoing hemodialysis with sub-therapeutic anticoagulation.

REASON FOR NOTIFICATION:

In the early clinical experience of the Impella® RP Flex with SmartAssist, a higher than expected rate of thrombus deposition within the pump inlet has been observed. Thrombus formation or deposition presents a risk to the operation of the Impella® RP Flex with SmartAssist.

It has been observed that cases which do not meet the IFU recommended levels of anticoagulation (ACT of 160 to 180 seconds), and are also undergoing hemodialysis through central venous catheters, present a risk to the operation of the Impella® RP Flex. In these situations, the risk is for thrombus formation or that thrombus deposits on indwelling central venous lines or cannulas may break free and enter into the Impella RP Flex, resulting in reduced flow, loss of support, or hemolysis.

To date, thrombus deposition events have been confirmed in 22 RP Flex usages. 16 of these events occurred with indwelling central venous lines (i.e., hemodialysis catheters, PA catheters) and systemic anticoagulation below IFU recommendation of 160-180s. The information provided in this safety notification and within the IFU is intended to make users aware of the potential risks outlined above.

This information is relevant to maintain the benefit /risk profile for use of the device in patients with acute right heart failure.

IFU UPDATE:

Abiomed has revised the Impella® RP Flex with SmartAssist IFU to include the following statements regarding use of the RP Flex with SmartAssist with patients undergoing hemodialysis with sub-therapeutic anticoagulation:

> "Anti-coagulate patients as needed to maintain recommended ACT (160-180s), in particular when indwelling central venous lines or cannulas (i.e. hemodialysis, PA catheters, ECMO) are present. ACT below this level may increase the risk of thrombus formation or deposition. If either internal thrombus forms within or external thrombus deposits in the Impella RP Flex with SmartAssist, this may result in reduced flow, loss of support, or hemolysis.
>
> Thrombus formation or deposits on indwelling central venous lines or cannulas (i.e. hemodialysis catheters, PA catheters, ECMO) may break free and enter into the Impella RP Flex with SmartAssist inlet, resulting in reduced flow, loss of support, or hemolysis. Assess the risk for extraluminal thrombus on indwelling lines placed prior to initiation of support."

For complete updated IFU, please see HeartRecovery.com and/or ACE.

RISK FACTORS:

It has been observed that the highest risk of thrombus formation or deposition is in the setting of:

- Systemic anticoagulation below IFU guidance of ACT of 160 to 180 seconds, in particular when indwelling central venous lines (i.e., hemodialysis catheters, PA catheters) are present during the operation of the Impella® RP Flex with SmartAssist
- Chronic indwelling lines prior to initiation of support (i.e., hemodialysis catheters, PA catheters)

Several other factors may increase the risk of thrombus formation or deposition are noted in "best practices pathway" on Figure 5.2 of IFU:

- Active infection (two of the following three: White Blood Cell (WBC) count >12,500, positive blood culture or fever)
- Patients on right-sided support or Extracorporeal Membrane Oxygenation (ECMO)
- Documented Deep Vein Thrombosis (DVT)
- Mural thrombus of the right atrium or vena cava

RECOMMENDATIONS:

To minimize risk of thrombus formation or deposition, the following is recommended:

- Maintenance of systemic anticoagulation (ACTs of 160-180 seconds) in particular when indwelling central venous lines (i.e., hemodialysis, PA catheters) are present, for the duration of Impella® RP Flex with SmartAssist support as clinically feasible.
- Assess the risk for extraluminal thrombus on indwelling lines (i.e., hemodialysis catheters, PA catheters) placed prior to initiation of support.
- Users are reminded of the recommendations included in the "best practices pathway" on Figure 5.2 of IFU for optimal patient selection. In particular, elements that relate to the risk factors identified above:
    - Evidence of end-organ failure (bilirubin >5 or creatinine >4 within 24 hrs of implant)
    - Active infection (two of the following three: White Blood Cell (WBC) count >12,500, positive blood culture or fever)
    - Documented Deep Vein Thrombosis (DVT)
    - Patients on right-sided support or Extracorporeal Membrane Oxygenation (ECMO)

INTENDED USE:

The Impella® RP Flex with SmartAssist is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥1.5 m^2 who develop acute right heart failure or decompensation for less than 48 hours following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery, without the presence of profound shock, end organ failure, or acute neurologic injury.

The intent of the therapy with the Impella RP Flex with SmartAssist is to provide a percutaneous circulatory support system to restore normal right heart hemodynamics, reduce right ventricular work, and allow the right heart time to potentially recover adequate contractile function or to be bridged to the next therapy.

ACTIONS TO BE TAKEN BY CUSTOMER/USER

- Product is NOT being removed from the field and does not need to be returned.
- Review, complete all fields, sign, and return the attached business response form (BRF) provided to impacted customers and send it to recallcoordinators@abiomed.com. Forward this notice to anyone in your facility that needs to be informed (i.e., those who manage, transport, store, stock, or use the subject products).
- If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice.
- Post a copy of this notice in a visible area for awareness of this field safety notice.
- Follow the recommendations outlined above to assist in minimizing the risk of thrombus formation or deposition.
- As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting Program using the link below: https://www.fda.gov/safety/medwatch-fda-safety- information-and-adverse-event-reporting-program/reporting-serious-problems-fda

If you have questions or concerns regarding this notice, please contact Shashi Thoutam directly at +1 (734) 262-6255 and/or your local clinical field staff. Thank you for your cooperation.

Respectfully,

Shashi Thoutam
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