

Optimal Device Performance Guidance

Impella RP Flex™ with SmartAssist® Best Practices – Anticoagulation, Line Management & Patient Selection

Maintenance of systemic anticoagulation for the duration of Impella™ RP Flex with SmartAssist® support, in particular when indwelling lines are present:



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.

IFU 10003286 Section 2.1 Warnings

Assess the risk for extraluminal thrombus on indwelling lines prior to initiation of support:



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.

IFU 10003286 Section 2.1 Warnings

Use the “Best Practices Pathway” for patient selection:

Elements that also relate to the risk factors for thrombus formation or deposition are:

- 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)

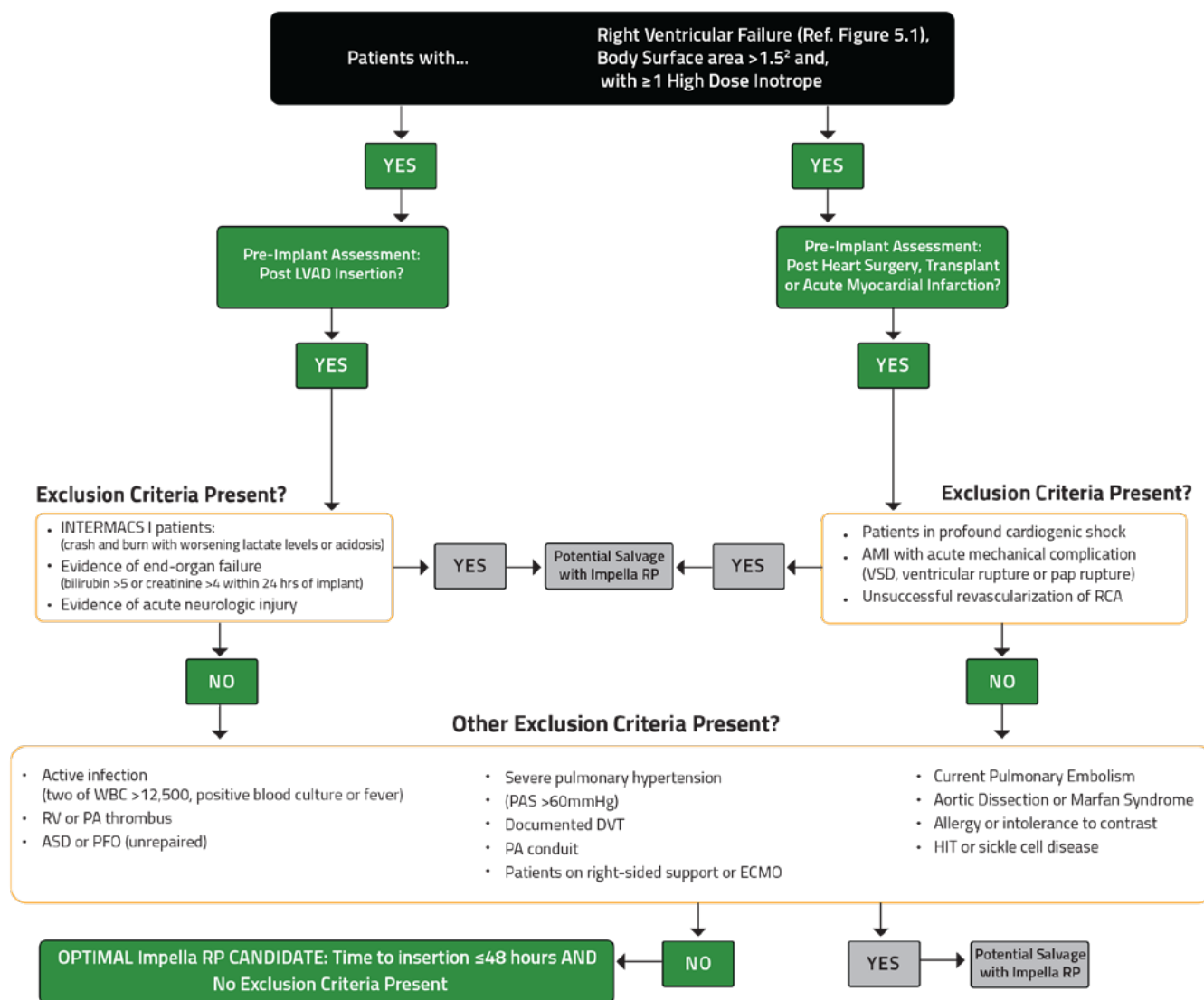
Figure 5.2 Impella RP Flex™ with SmartAssist® Best Practice Section Algorithm

IFU 10003286 Section 5.1 Impella RP Flex™ with SmartAssist® Patient Selection

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert and/or Impella RP Flex™ with SmartAssist® IFU 10003286. November 2024

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Anderson MB, et al. J Heart Lung Transplant. 2015; 34(12):1549-1560

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