



Edwards

PLEASE ADVISE ALL STAFF USING SWAN-GANZ MODELS POST THIS NOTICE AS A REMINDER

There have been a growing number of complaints of leaks/breakage involving failures of the (blue) proximal injectate lumen hub on Swan-Ganz catheters. The issue is linked to manufacturing process and material changes and is associated with situations where the (blue) proximal injectate hub and lumen experience frequent manipulation or flexing. Most complaints are associated with performance of bolus thermodilution cardiac output procedures.

Advice for users and instructions to mitigate hub breakage issues:



When using Swan-Ganz catheters consider the following instructions to reduce the potential for hub breakage issues:



- Minimize manipulation of the Swan-Ganz (blue) proximal injectate hub and lumen
- Pay frequent attention to the (blue) proximal injectate lumen for leakage or breakage, and exchange with another catheter if the issue is encountered.
- Modify existing clinical workflows to minimize flexing and stress of (blue) proximal injectate lumen. For example:
 - Securing the catheter lumens to an IV arm board to mitigate bending/flexing of the lumen(s)
 - Consider using the stopcock on white hub to allow for intermittent transducer pressure tubing changes without twisting white hub on Swan-Ganz (blue) proximal injectate lumen.
 - Prevent CO-Set syringe and (blue) proximal injectate lumen from dangling/hanging without support of the CO-Set and (blue) proximal injectate lumen from the IV pole or OR/ICU bed.
 - Change to automated cardiac output models to mitigate stress placed on (blue) proximal injectate lumen during Intermittent Cardiac Output (iCO) with CO-Set.
- Providers and institutions with appropriate capabilities may choose to utilize transthoracic or transesophageal echocardiography in combination with techniques to monitor central venous pressure via a central venous catheter in patients in need of right ventricle monitoring and management.

Technical Assistance

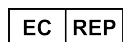
For technical assistance or device exchange, please contact your local Customer Service.

Symbol Legend

English	
	Conformité Européenne (CE Mark) of TÜV SÜD Product Service GmbH (notified body)
	Authorized representative in the European Community/European Union

English	
	Manufacturer
	Importer

Note: Not all symbols may be included in the labeling of this product.




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03/26
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