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Advice for UK clinicians for intra-aortic balloon pump (IABP) catheters

Developed in conjunction with the Society for Cardiothoracic Surgery, The British Cardiovascular Intervention Society and the Society of Clinical Perfusion Scientists

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1. Introduction

1.1 This document has been created in response to the global safety issue with Getinge intra-aortic balloon pump (IABP) catheters. Reports have been raised of serious incidents occurring during IAB insertion due to the hub of the dilator shearing off within the sheath. This resulted in the company withholding shipments of stock whilst the issue was investigated.

1.2 This document signposts best practice guidance and practical advice for use of the IABP catheters as directed by the field safety notice (FSN), in different scenarios, and on the conservation of existing stock.

1.3 An FSN from Getinge is available to view and provides an update on the issue with the catheters. The FSN notes that a number of events have occurred, requiring vascular surgery intervention, with one of these interventions resulting in a patient death.

1.4 In terms of liability and use of the IABP catheters, advice as per the Getinge supplied FSN reiterates that liability will be with the manufacturer so long as clinicians administer and use IABP catheter as per FSN advice. Deviations from the FSN may result in the clinician taking on liability should any complications occur. With any guidance, the advice per the FSN should be considered and adapted as appropriate to the specific situation and the specific needs of the patient (taking into account any particular preferences, needs or characteristics they may have or any risks that may apply).

1.5 Clinicians using the IAB catheter in line with the FSN will, as per normal practice, be covered by NHS indemnity.

1.6 In the context of an acute shortage of Getinge IABP catheter products, this document can continue to support local efforts to safely manage a shortage of particular products.

2. Best practice guidance on appropriate use of IAB catheters

2.1 Reduced use of prophylactic or temporising IABPs and earlier definitive revascularisation strategies in ACS patients, where possible.

2.2 Careful pre-operative planning, case selection and use of dual-consultant operating / surgical council MDT discussion for high-risk patients undergoing cardiac surgical intervention.

2.3 Development of local and regional collaborative networks and MDT infrastructure to provide guidance regarding the use of Impella and ECMO for post-cardiotomy support where available.

3. Risk stratification

3.1 The FSN lists options in order of risk mitigation, including returning the catheter and insertion kit to the manufacturer.

3.2 Sheathless insertion may be performed by an appropriately trained and experienced operator using the vessel dilator supplied in the kit for sheathless insertion (this is different from the sheath dilator).

3.3 Sheathed insertion may be performed with an alternate dilator/sheath assembly. The FSN details the requirements for a wire-reinforced sheath, which should be larger than the supplied Datascope/Getinge sheath. Also note that alternate sheaths will use different sized guide wires than the IAB catheter can accommodate and will need to be exchanged.

3.4 Sheathed insertion can be performed with the supplied Datascope/Getinge dilator and sheath noting that if the dilator fractures during insertion, remove the dilator, sheath and wire together.

We will continue to communicate with you as more information becomes available but as you will appreciate, the situation is fluid and we are working to find a resolution as quickly as possible.

Please contact your respective professional society if you have any clinical questions.

There are specific reporting arrangements for healthcare professionals to follow in each of the devolved administrations. Healthcare professionals should report any incidents as follows:

- In England and Wales to the MHRA Yellow Card scheme or via the Yellow Card app and local incident reporting system
- In Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system;
- In Northern Ireland to the Northern Ireland Adverse Incident Centre and their local incident recording system.

Where an urgent supply need cannot be met by the company or through mutual aid, please contact the National Supply Disruption Response (NSDR) Centre via the: 0800 915 9964 (Freephone number in the UK), and a Direct Line from overseas: 0044 (0) 207 972 1071. The line is open Monday to Friday 9am-6pm except public holidays.