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To: Trust and ICB:
- Medical directors
- Clinical directors
- Cardiac services
- Critical care

cc. NHS England regional:
- EPRR leads
- Directors
- Medical directors
- Directors of specialised commissioning
- Medical directors of specialised commissioning

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27 June 2023

Dear colleagues,

Getinge intra-aortic balloon pump (IABP) catheters (FSCA 2249723-05/05/23-008-C)

We are writing to draw your attention to an Urgent Field Safety Notice (FSN) that has been issued by Getinge UK and the MHRA for **Getinge intra-aortic balloon pump (IABP) catheters, as issued on 13th June 2023** (see enclosure 1).

The FSN has been produced following reports of serious incidents occurring during IAB insertion due to the hub of the dilator shearing off within the sheath. This has resulted in Getinge UK withholding shipments of stock whilst the issue was investigated. The FSN provides an update on the issue and notes that a number of events have occurred outside of the UK, which have required vascular surgery intervention, with one of these interventions resulting in a patient death.

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).

Advice for clinicians inserting IAB catheters has been developed in conjunction with the Society for Cardiothoracic Surgery, the British Cardiovascular Intervention Society and the Society of Clinical Perfusion Scientists and is included within enclosure 2. Clinicians

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

Healthcare professionals should report any incidents via the MHRA Yellow Card scheme or via the Yellow Card app and local incident reporting system.

From a supply perspective, the ship hold on Getinge stock has been released and national teams have been working with the Company to ensure that available stock is allocated based on need. While customers with the greatest need should have received some product, others will be allocated stock from a later shipment.

Any Trust that does not receive notification from Getinge that they will be receiving stock from the first allocation and with an urgent need, should contact their Company representative; national teams will continue to work with the Company to ensure fair share allocations based on clinical need until normal stock levels are resumed. NHS service providers that purchase via NHS Supply Chain should check ICN 1943 for updates on stock levels as the products begin to recover and check ICN 2180 for updates of the FSN.

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.

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.

Yours sincerely,

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NHS England

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