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10th January 2023

URGENT: FIELD SAFETY NOTICE – PI-23-4673

Venovo™ Venous Stent System

REF: See Table 1 **Lot Numbers:** See Table 1

Type of Action: Product Removal

Attention: Clinical & Medical staff, Risk managers, Infection Prevention & Purchasing

This letter contains important information which requires your **immediate** attention.

Dear Customer,

BD is conducting a Field Safety Corrective Action to remove specific lots of **Venovo™ Venous Stent System** and our distribution records indicate your organisation may have received the impacted product. Product was distributed between 2nd December and 19th December 2022.

Product Name	Product Code (REF)	Lot Number	UDI	Expiry Date MM/DD/YYYY	Manufacturer SRN
Venovo 9F 14/120/800mm	VENEM14120	ANFV1885	(01)00801741102264	08/20/2023	DE-MF-000014844
Venovo 9F 14/160/800mm	VENEM14160	ANFW1247	(01)00801741102288	09/10/2023	
Venovo 9F14/140/800mm	VENEM14140	ANFW0738	(01)00801741102271	09/07/2023	
Venovo 9F 14/80/800mm	VENEM14080	ANFW0762	(01)00801741102271	09/07/2023	
Venovo 10F 18/80/800mm	VENEM18080	ANFW0765	(01)00801741102523	09/07/2023	

Table 1: Impacted product

This product removal is limited to the product codes / lot numbers listed in Table 1. No other product codes or lot numbers are affected.

Description of the problem

Based on internal investigation, the lots from Table 1 were errantly distributed and may result in exposure to known issues of potential delayed deployment and silicone embolisation in the event the proximal end of the **Venovo™ Venous Stent System** does not immediately expand upon deployment and remains connected to the stent cushion on the delivery system.

An illustration of the proximal section adhered to the stent cushion may be seen below in Figure 1.

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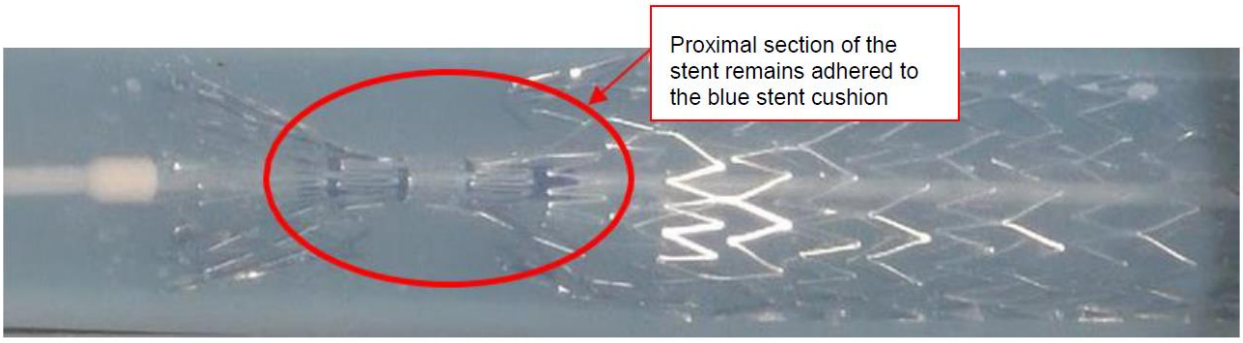

Figure 1: Proximal end of the stent remains connected to the stent cushion material

Clinical risk

In cases where the stent self-expands, there is no incremental risk of harm. Conversely, over-manipulation or forcing the catheter delivery system in attempts to assist the stent's expansion, could potentially have a varying degree of harm associated with it. Potential harm ranges from prolonging the procedure, damaging or deformity of the stent, potential vascular injury and / or hemodynamic disruption affecting the blood flow and / or a thrombotic event.

The hazardous situation is that the stent, in a focal area near its proximal end, doesn't immediately expand at the time of deployment and the physician may not allow enough time for normal expansion, and tries to manipulate the stent or use other intravascular devices or techniques to help expand the stent. This may lead to misplacement or damage to the stent and vascular injury. A transfer of medical grade biocompatible silicone adhered to the inner surface of the stent, if significant in size and detached, could lead to inflammatory responses or blockage/obstruction of the vasculature.

If the product has already been safely used, no patient follow-up activities are required.

There have been no reported complaints to date across the product codes and lot number combinations from Table 1.

Actions taken by BD

The root cause analysis has evaluated the relationship of the stent cushion and its adherence to the stent as a potential contributing factor.

Customer Actions:

- Cease use of any unused affected **Venovo™ Venous Stent System**.
- Identify and quarantine all unused affected **Venovo™ Venous Stent System**.
- Make a note of the lot numbers and a BD representative will contact you on next steps.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 24th January 2023**.
- Circulate this notice to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- If you experience any issues with **Venovo™ Venous Stent System**, please report as a complaint as per your normal process.

Distributor Actions:

- Cease distribution.

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- Identify, quarantine, making a note of the lot numbers of all unused affected **Venovo™ Venous Stent System**. A BD representative will contact you on next steps.
- Identify the facilities where you have distributed affected product and notify them immediately of this notice. Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes by **24th January 2023.**
- Complete and return the Customer Response Form following completion of your reconciliation activities.

	End User with Inventory	**End User with ZERO inventory**	**Where to send completed form**
Purchased **directly** from BD	Complete the form in its entirety Upon receipt, BD will process the response, and you will receive replacements for unused devices	Complete form and check the box indicating "no inventory"	<<insert BD email address>>
Purchased from a **distributor/3rd party**	Complete all fields on the form and contact your distributor to arrange for replacements	Complete form and check the box indicating "no inventory"	Return the form to your distributor

Contact reference person

If you have any questions about this, please contact your local BD representative or the local BD office on <<insert telephone details here>> or e-mail <<insert contact email address here>>.

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,

Lorna Darrock
Associate Director, Post Market Quality
EMEA Quality

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Customer Response Form – PI-23-4673

Venovo™ Venous Stent System

REF: See Table 1 **Lot Numbers:** See Table 1

Return to <*<insert fax/email address here>>* as soon as possible or **no later than the 24th January 2023**

- **I confirm this notice has been read, understood and that all recommended actions have been implemented as required.**

Tick the appropriate box below:

☐ We do not have any of the affected product as listed in Table 1 in our facility or affected product has been used.

All product that is not available for destruction will be considered as dispositioned at your location and therefore physically unavailable unless otherwise specified.

OR

☐ We had the following units of the affected product as listed in Table 1 in our facility and I confirm that the units have been quarantined. (*Please complete the table below to indicate the number of quarantined units and return the form to BD and a BD Representative will contact you. Replacement devices will only be sent on completion and return of this form*).

Product Code (REF)	Lot number	Units Quarantined (insert quantity below)

Account/Organisation Name:	
Department *(if applicable)*:	
Address:	
Postcode:	**City:**
Contact Name:	
Job Title:	
Contact Telephone Number:	**Contact E-mail Address:**
Name of your supplier for this product *(if not direct from BD)*	
Signature:	**Date:**

This form must be returned to BD before this action can be considered closed for your account.

**If you were forwarded this Field Safety Notice via a distributor/3rd party, please return your completed form to that organisation for reconciliation purposes.*