18th October 2024

URGENT: FIELD SAFETY NOTICE – PI-24-5089

Venclose™ RF Ablation Catheter

REF: VCOUS6F100, VCOUS6F60 **Lot Numbers:** see Appendix 1

Type of Action: Field Work

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel, Purchasing Managers

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

Dear Customer,

BD is conducting a Field Safety Corrective Action for specific lots of Venclose™ RF Ablation Catheter. According to our distribution records your organisation may have received the impacted product in Appendix 1. Product was distributed between December 2023 and September 2024.

Description of the problem

It has been identified that the Venclose™ RF Ablation Catheters may have been manufactured with internal wiring errors that could cause inaccurate temperature detection. This error in wire configuration would allow inaccurate temperature detection and may result in devices reaching temperatures higher than intended, while the user receives incorrect warnings that the catheter has **not** reached temperature.

Clinical risk

This issue may result in excessive heat that could cause the following issues, potentially requiring additional medical care should they occur: heat-induced injury to nerves, skin burns, difficulty removing the device, damage to treated vessels or adjacent vessels, endothermal heat-induced thrombosis, deep vein thrombosis, pain, skin discoloration, or embolism of device components. Thrombosis and embolism of device components could lead to pulmonary embolism.

To date, there have been four complaints from physicians related to this manufacturing defect and none of the complaints were related to a reportable adverse event. Thus, the observed rate of this issue is approximately 0.002% of products in distribution.

Clinical User Actions

1. Discontinue use of the affected product and quarantine immediately.
2. The affected devices should not be used until the facility's Venclose™ RF Generator, product code VCOUSRFG1 (refer to appendix 2), has had the necessary software upgrade. In all reported cases with these wiring errors, issues achieving the intended

temperature were apparent during the case and no patient harm was reported. Possible adverse events associated with this issue are recognized complications from venous ablation procedures and patients are routinely monitored for these events. Patients who have undergone treatment with a Venclose™ RF Ablation Catheter that experienced difficulties in achieving the desired temperature may require additional follow-up beyond the usual standard of care at the discretion of the treating physician.

3. Once the Venclose™ RF Generator (product code VCOUSRFG1), has received the software upgrade the affected products listed in attachment 1 of this notice can be used.

Note: Venclose™ RF Ablation Catheters that are **not** listed as impacted as per appendix 1, can continue to be used.

BD Actions:

1. BD has investigated the issue and has implemented appropriate measures to prevent recurrence of this product issue.
2. BD has identified that a software upgrade can be made to the Venclose™ RF Generator, subject to validation and regulatory approvals, where applicable, which would allow the Venclose™ RF Generator to identify the wiring errors in the Venclose™ RF Ablation Catheters that are in scope of this notice prior to use.
3. BD will contact your facility in order to arrange the upgrade to your facility's Venclose Generator to revision 3.35. The upgrade, subject to validation and regulatory approvals, will be performed by a BD Representative upon completion of the Customer Response Form.

Customer Actions:

- Cease use of any unused affected Venclose™ RF Ablation Catheter.
- Identify and quarantine all unused affected Venclose™ RF Ablation Catheter.
    - The affected Venclose™ RF Ablation Catheters should not be used until the facility's Venclose™ RF Generator, product code VCOUSRFG1 (refer to appendix 2), has had the necessary software upgrade.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 21st November 2024,** clearly indicating the applicable contact person at your facility to support the software upgrade, when available.
- Circulate this notice to all those who need to be aware within your organization or to any organisation where the potentially affected products have been transferred.
- If you experience any issues, please report as a complaint as per your normal process.

Distributor Actions:

- Cease distribution.
- Identify and quarantine all undistributed affected Venclose™ RF Ablation Catheters.
    - The Venclose™ RF Generator (product code VCOUSRFG1), which is used in conjunction with the Venclose™ RF Catheter, contains software that requires an

upgrade to be performed prior to using the impacted Venclose™ RF Ablation Catheters. Venclose™ RF Ablation Catheters that are not listed as impacted as per appendix 1, can continue to be used by your customers.

- 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 **21st November 2024**.
- Complete and return the Customer Response Form following completion of your reconciliation activities.
- If you experience any issues, please report as a complaint as per your normal process.

	End User with Inventory	**End User with ZERO inventory**	**Where to send completed form**
Purchased, received **directly** from BD	Complete the form in its entirety and ensure that all recommended actions have been implemented as required	Complete form and check the box indicating "no inventory". Retain a copy of this notification for your records	BDFieldActions@bd.com
Purchased, received from a **distributor/3rd party**	Complete the form in its entirety and ensure that all recommended actions have been implemented as required	Complete form and check the box indicating "no inventory". Retain a copy of this notification for your records	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,

Kinga Stolinska
Director, Post Market Quality
EMEA Quality

Customer Response Form - PI-24-5089

Venclose™ RF Ablation Catheter

REF: VCOUS6F100, VCOUS6F60 **Lot Numbers:** see Appendix 1

Return to BDFieldActions@bd.com as soon as possible or **no later than the 21st November 2024.**

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

Please check (✓) the following options:

Option 1: We **do not** have any of the affected product as listed in **Appendix 1** in our facility. Affected product has been used. *(Your Venclose™ RF Generator will therefore not require the software upgrade, as described in this notice).*
All product that is not available for quarantine will be considered as dispositioned at your location and therefore physically unavailable unless otherwise specified. ☐

Option 2: We have the following units of the affected product as listed in **Appendix 1** in our possession and I confirm that the units have been **quarantined** *(Please complete the table below with the lot number and the number of units quarantined).* ☐

REF:	Lot Number(s):	Units Quarantined (insert quantity below)

For Option 2: *Please provide a contact name of a representative from your organisation who will be the point of contact to support the Venclose™ RF Generator software upgrade:*

Contact Name	Job Title	Telephone	Email

For Option 2: We **do not** have a Venclose™ RF Generator ☐

Account/Organisation Name:	
Department *(if applicable)*:	
Address:	
Postcode:	**City:**
Contact Name:	**Job Title:**
Contact Telephone Number:	**Contact E-mail Address:**
Signature:	**Date:**

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

Appendix 1 - Product Code and Lot numbers

This notice is limited to the product codes and lot numbers listed in Appendix 1. No other product codes are affected.

Manufacturer's SRN: US-MF-000001372

Product Name	Product Code (REF)	Lot Number	UDI-DI	Expiration Date
Venclose™ RF Ablation Catheter	VCOUS6F100	73310842	(01)00858254006244(17)251005(10)73310842	5 October 2025
		73319925	(01)00858254006244(17)251009(10)73319925	9 October 2025
		73388088	(01)00858254006244(17)251023(10)73388088	23 October 2025
		73623196	(01)00858254006244(17)251109(10)73623196	9 November 2025
		73923359	(01)00858254006244(17)251112(10)73923359	12 November 2025
		73954408	(01)00858254006244(17)251114(10)73954408	14 November 2025
		73987507	(01)00858254006244(17)251116(10)73987507	16 November 2025
		74020834	(01)00858254006244(17)251214(10)74020834	14 December 2025
		73319926	(01)00858254006244(17)251214(10)73319926	14 December 2025
		74507761	(01)00858254006244(17)260107(10)74507761	7 January 2026
		76413837	(01)00858254006244(17)260404(10) 76413837	4 April 2026
	VCOUS6F60	73319896	(01)00858254006251(17)251020(10)73319896	20 October 2025
		73573950	(01)00858254006251(17)251107(10)73573950	7 November 2025
		73890876	(01)00858254006251(17)251119(10)73890876	19 November 2025
		74507759	(01)00858254006251(17)260208(10)74507759	8 February 2026

Appendix 2 – Venclose™ RF Generator Product Image

Venclose™ RF Generator, product code VCOUSRFG1 previously VC-RFG-1

Venclose™ RF Ablation Catheter