Inari Medical, Inc. - Field Safety Notice (Product Removal)

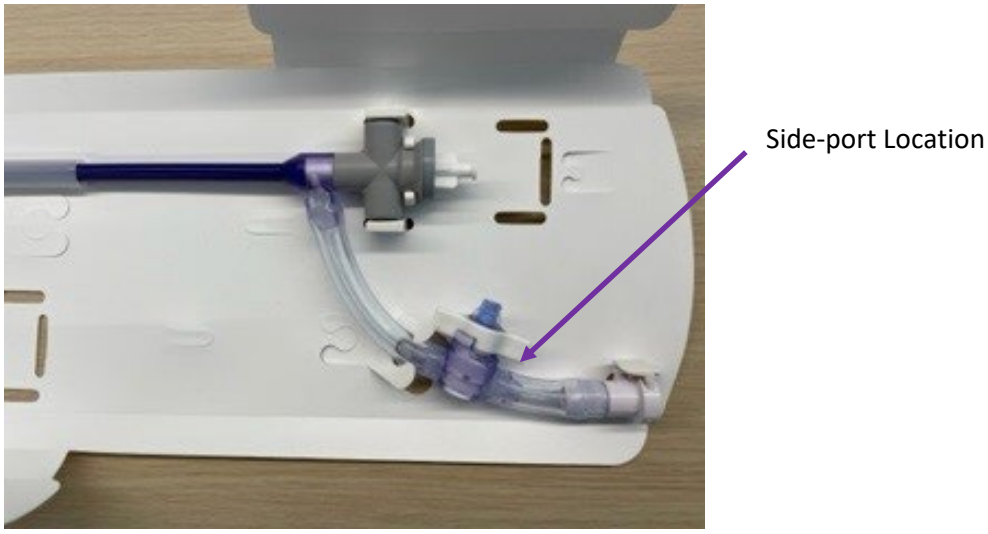
Date:	December 27, 2022
Device Name:	Triever24
Model #:	22-101
Lot #:	22100019, 22100020, 22100024, 22100025, 22100026
Attention:	Facility Interventional Radiologist

Dear Customer,

As part of our product surveillance program, we identified a potential product issue that could impact the performance of the Triever24 Catheter which is indicated for the non-surgical removal of emboli and thrombi from blood vessels, and injection, infusion and/or aspiration of contrast media and other fluids into or from a blood vessel. The device is provided in sterile condition.

Issue identified and potential risks

There is a potential malfunction with the side-port of the Triever 24 Catheter. The side-port may potentially leak or dislodge during device preparation or during actual use. The side-port of the Triever24 Catheter is used in combination with a 60cc large bore syringe to facilitate aspiration of thrombotic material.



There are risks associated with the use of the device based on our hazard analysis.

- Blood Loss

    - If the side-port is dislodged during use, blood leak/loss could occur requiring intervention by the user
    - A new Triever24 should be used
- Air Embolization (theoretical risk)
    - If the side-port is dislodged during use, air may be introduced through the side-port
    - A new Triever24 should be used
    - Note that comprehensive flow model testing was not able to replicate this risk of air introduction during reasonable simulated use cases. However, such risk cannot be excluded.

There are no known patient harms reported by users to date as a result of using the defective device, however in an abundance of caution, it is important that these devices are **not** used to maintain patient safety.

Actions to be taken

If you have any of the above referenced product lot numbers at your facility, we request that:

1. you immediately stop selling the device (for importers/distributors)/discontinue their use by placing the product in a quarantine location (end users);
2. destroy the products; and
3. complete the reply form attached to this notice (importers/distributors and end users). Your reply form should be sent to qa@inarimedical.com by 13 January 2023.

We are working to resolve issue with the side-port and will provide replacement products beginning on 27th December 2022. Please note that the Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organizations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

If you need any further information or support concerning this, please reach out to our company representative:

Kit Cariquitan
Person Responsible for Regulatory Compliance
Vice President, Regulatory Affairs & Quality Assurance
Office: 877-923-4747
FAX: 949-570-0263
Email: Kit.cariquitan@inarimedical.com

Best regards,

Digitally signed by Kit Cariquitan
Date: 2022.12.27 13:53:35 -10'00'

Kit Cariquitan
Vice President, Regulatory Affairs & Quality Assurance

Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2022-T24_22-101
FSN Date	23 December 2022
Product/ Device name	Triever24
Product Code(s)	22-101
Lot Number (s)	22100019 22100020 22100024 22100025 22100026

2. Customer Details	
Account Number	
Healthcare Organization Name*	
Organization Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organization			
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A	
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A	
☐	I have destroyed affected devices – enter number	Qty:	Lot/Serial Number:
		Qty	Lot/Serial Number:

3. Customer action undertaken on behalf of Healthcare Organization			
	destroyed and date complete.	N/A	Comments:
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
☐	Other Action (Define):		
☐	I do not have any affected devices.	Customer to complete or enter N/A	
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query	
Print Name*		Customer print name here	
Signature*		Customer sign here	
Date*			

4. Return acknowledgement to sender	
Email	qa@inarimedical.com
Customer Helpline	877-923-4747
Postal Address	6001 Oak Canyon, Suite 100 Irvine, CA 92618 USA
Fax	949-570-0263
Deadline for returning the customer reply form*	31 January 2023

*Mandatory fields

Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2022-T24_22-101
FSN Date	23 December 2022
Product/ Device name	Triever24
Product Code(s)	22-101
Batch/Serial Number (s)	22100019 22100020 22100024 22100025 22100026

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:

3. Distributors/Importers (Tick all that apply)		
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	Neither I nor any of my customers has any affected devices in inventory	
	Print Name*	Distributor/Importer print name here
	Signature*	Distributor/Importer sign Here
	Date *	

Mandatory fields are marked with *