MIVI FAI 21-002

Date: August 4, 2021

Urgent Field Safety Notice (FSN) - Recall
MIVI Super 90 Guide Catheter

For Attention of: Distributors and Users of MIVI Super 90 Guide Catheter

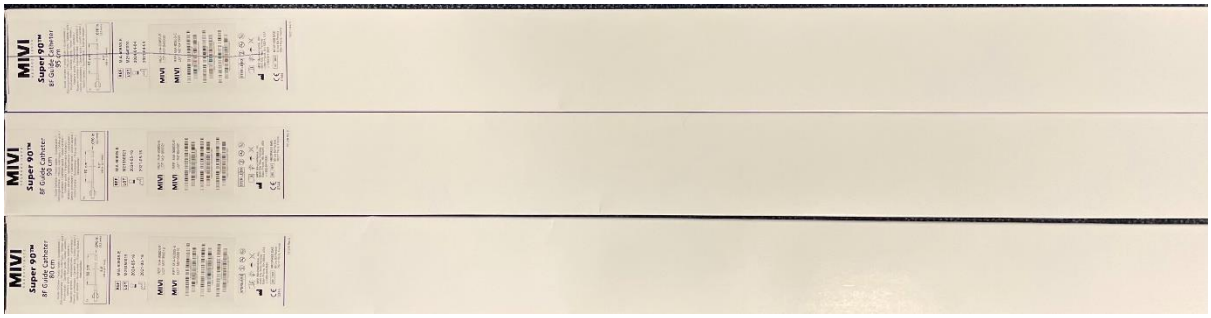
Contact details of local representative (name, e-mail, telephone, address etc.)
MIVI Neuroscience, Inc.; customerservice@mivineuro.com; +01-952-944-3834; 6545 City West Parkway, Eden Prairie, MN 55344, USA

Urgent Field Safety Notice (FSN)
MIVI Super 90 Guide Catheter
Risk addressed by FSN

1. Information on Affected Devices	
1.	1. Device Type(s)
	MIVI Super 90 Guide Catheter
1.	2. Commercial name(s)
	MIVI Super 90 Guide Catheter
1.	3. Unique Device Identifier(s) (UDI-DI)
1.	4. Primary clinical purpose of device(s)
	Indicated for use in facilitating the insertion and guidance of catheters into a selected blood vessel in the peripheral and neuro vascular system. It may also be used as a diagnostic angiographic catheter.
1.	5. Device Model/Catalogue/part number(s)
	MIA-9080S-E; MIA-9090S-E; MIA-9095S-E
1.	6. Software version
	Not applicable
1.	7. Affected serial or lot number range

M Lot	Model	Exp Date
M20080005	MIA-9090S-E	8/6/2021
M20090011	MIA-9090S-E	9/10/2021
M20090012	MIA-9095S-E	9/10/2021
M20110005	MIA-9090S-E	10/27/2021
M20110007	MIA-9095S-E	10/26/2021
M21010008	MIA-9090S-E	12/10/2021
M21010011	MIA-9080S-E	12/10/2021
M21030005	MIA-9080S-E	10/27/2023
M21030013	MIA-9080S-E	4/30/2023
M21030014	MIA-9090S-E	12/10/2023
M21030015	MIA-9090S-E	12/10/2023
M21030017	MIA-9095S-E	10/26/2023
M21030018	MIA-9095S-E	9/10/2023
M21050013	MIA-9090S-E	12/10/2023
M21030015	MIA-9090S-E	12/10/2023
M21040003	MIA-9095S-E	4/24/2024
M21050014	MIA-9095S-E	1/27/2023
M21050015	MIA-9095S-E	1/27/2023
M21060002	MIA-9095S-E	2/7/2023
M21060003	MIA-9095S-E	3/12/2023
M21060007	MIA-9090S-E	10/30/2022
M21060008	MIA-9090S-E	10/30/2022
M21060009	MIA-9090S-E	1/27/2023
M21060010	MIA-9090S-E	1/27/2023
M21060011	MIA-9090S-E	3/12/2023
M21060012	MIA-9090S-E	12/10/2023
M21060014	MIA-9080S-E	10/10/2022
M21060015	MIA-9080S-E	10/22/2022
M21060016	MIA-9080S-E	4/3/2023
M21060017	MIA-9080S-E	12/10/2023

	A representative photo of the MIVI Super 90 Guide Catheter is shown below. These products should be checked for the lot number and expiration dates referenced above.
1.	8. Associated devices
	Not applicable



	2 Reason for Field Safety Corrective Action (FSCA)
2.	1. Description of the product problem
	MIVI was issued an advisory notice by the pouch vendor of a possible sterility breach of the pouch used on the Super 90 Guide Catheter.
2.	2. Hazard giving rise to the FSCA
	This issue may affect the ability to maintain final product sterility for the MIVI Super 90 Guide Catheters
2.	3. Probability of problem arising
	There is insufficient information to allow an estimate of probability of non-sterility. No complaints associated with the sterile barrier have been received.
2.	4. Predicted risk to patient/users
	The probability of occurrence cannot be determined, but the consequence would be clinical use of a non-sterile product, which could lead to infection.
2.	5. Further information to help characterise the problem
	No further relevant information is available
2.	6. Background on Issue
	MIVI was issued an advisory notice by the pouch vendor of a possible sterility breach of the pouch used on the Super 90 Guide Catheter.
2.	7. Other information relevant to FSCA
	No further relevant information is available

	3. Type of Action to mitigate the risk
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None

3.	2. By when should the action be completed?	August 28, 2021
3.	Is follow-up of patients or review of patients' previous results recommended? No	
3.	3. Is customer reply required? (If yes, form attached specifying deadline for return)	Yes
3.	**4. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3	5. By when should the action be completed?	August 28, 2021
3.	6. Is the FSN required to be communicated to the patient /lay user?	No
3	7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	

	4. General Information	
4.	1. FSN Type	New
4.	2. For updated FSN, reference number and date of previous FSN	Not applicable
4.	**3.** For Updated FSN, key new information as follows:	
	Not applicable	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Not applicable.	
4	6. Anticipated timescale for follow-up FSN	Not applicable
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	MIVI Neuroscience
	b. Address	6545 City West Parkway, Eden Prairie, MN 55344
	c. Website address	www.mivineuro.com
4.	8. The Competent (Regulatory) Authority of your country will be informed about this communication to customers. YES	
4.	9. List of attachments/appendices:	Not applicable
4.	10. Name/Signature	Randy LaBounty, VP Quality, Clinical and Regulatory Affairs 

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations 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.