MANI, INC.

Rev 2: February 2020

FSN Ref: MD2023-073FN FSCA Ref: MD2023-073F

Date: 2023-03-06

Field Safety Notice
MANI TROCAR KIT

For Attention of*:Importers, Distributors and Medical institutions in affected countries

Contact details of local representative (name, e-mail, telephone, address etc.)*
Name: iRIS EYE GmbH Address: Lise-Meitner-Strasse 21, D-52511 Geilenkirchen, Germany Telephone: +49 (0) 2451 - 90 70 97 0 E-mail: info@iriseye.de Web: www.iriseye.de

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Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	MANI Trocar Kit consists of (1) Trocar S and (2) Infusion Cannula. and is supplied sterile. (1) Trocar S It is composed of a blade for the prepared hole and valved cannula, which structure is to place cannula at the same time as incision is made onto the ocular globe with the blade for the prepared hole. (2) Infusion Cannula S It is a tube intended for use in injecting perfusate or aspirating out intraocular materials.
1.	2. Commercial name(s)*
	MANI TROCAR KIT
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	This product is a cylindrical instrument with a tube intended for use in injecting perfusate or aspirating out intraocular materials during ophthalmic surgery. This product is designed to be single use.
1.	5. Device Model/Catalogue/part number(s)*
	Please refer to the Appendix 1.
1.	6. Software version
	Only where relevant.
1.	7. Affected serial or lot number range
	Please refer to the Appendix 1.
1.	8. Associated devices
	Within context of the FSCA eg for IVD reagents and platforms.

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	MANI TROCAR KIT with damaged sterile package was found at a facility of our customer. Our investigation revealed that there is a possibility of same defect may happen to same type of sterile packages.
2.	2. Hazard giving rise to the FSCA*
	If a device with damaged sterile package were used for a treatment, sterility is compromised which may cause deterioration in state of health of a patient such as infection.
2.	3. Probability of problem arising
	The film part of unit package (sterile package) might be damaged due to anticipated vibration and drop impact. The outer package (containing three packs) itself is more likely to be damaged from vibration or drop impact than against the carton.
2.	4. Predicted risk to patient/users
	For the anticipated hazard itself, we have evaluated that the severity of the anticipated hazard could be critical, although the frequency of occurrence is considered to be slight. If an infection occurs, diagnosis and treatment for the symptom will be necessary.

	However, we have determined that the damaged sterile packages are unlikely used on patients, since the defect can be confirmed visually when opening the packages, and that appropriate medical treatment will not result in serious health hazard.
2.	5. Further information to help characterise the problem
	We have not received any health hazard resulting from this matter.
2.	6. Background on Issue
	A defect that the sterile package had a hole was reported to MANI, INC. by a medical institution. No holes in the packaging materials were found in the same product delivered to the institution, however, damages that appeared to be caused by contact with product tray was observed in several packages. – Reason for identifying the affected lot number: the affected lot numbers within the shelf life of this product, which is defined as two years were identified.
2.	7. Other information relevant to FSCA
	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

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 Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Promptly
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. Provide further details of patient-level follow-up if required or a justification why none is required.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer***	
	☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None	

	To reconsider the package design to make blister tray move hardly inside Tyvek package.	
3.	6. By when should the action be completed?	as soon as reasonably possible
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant.
4.	3. For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc.	
4.	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	MANI, INC.
	b. Address	8-3 Kiyohara Industrial Park, Utsunomiya, Tochigi, 321-3231, Japan
	c. Website address	https://www.mani.co.jp/en/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Appendix 1
4.	10. Name/Signature	[redacted]

	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.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.