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: INNOVAHealth AG Address: De Castella-Platz 4, 3280 Greng, Switzerland Telephone: +41 (0)71 952 27 00 E-mail: office@innovahealth.ch Web: http://www.innovahealth.ch

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Field Safety Notice (FSN)
MANI TROCAR KIT
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.

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.

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. 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 To reconsider the package design to make blister tray move hardly inside Tyvek package.		
3.	5. By when should the action be completed?	as soon as reasonably possible	
3.	6. Is the FSN required to be communicated to the patient /lay user?	No	

4. General Information*		
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	3. 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.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. List of attachments/appendices:	Appendix 1
4.	6. Name/Signature	Hideo Matsumoto

	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.

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Product Name	Manufacturing Date	Model / Catalogue Number	Lot Number
MANI TROCAR KIT	2021/03/02	MTK25S	V210003300
MANI TROCAR KIT	2021/03/02	MTK23S	V210006300
MANI TROCAR KIT	2021/03/02	MTK23S	V210006200
MANI TROCAR KIT	2021/03/16	MTK23S	V210006500
MANI TROCAR KIT	2021/03/16	MTK23S	V210006600
MANI TROCAR KIT	2021/03/31	MTK23S	V210007300
MANI TROCAR KIT	2021/04/12	MTK23S	V210009500
MANI TROCAR KIT	2021/04/12	MTK25S	V210007400
MANI TROCAR KIT	2021/04/28	MTK25S	V210009900
MANI TROCAR KIT	2021/04/28	MTK23S	V210009700
MANI TROCAR KIT	2021/05/14	MTK23S	V210006900
MANI TROCAR KIT	2021/05/14	MTK25S	V210006701
MANI TROCAR KIT	2021/05/14	MTK23S	V210011400
MANI TROCAR KIT	2021/05/27	MTK25S	V210006700
MANI TROCAR KIT	2021/05/27	MTK23S	V210007100
MANI TROCAR KIT	2021/06/10	MTK23S	V210009401
MANI TROCAR KIT	2021/07/08	MTK25S	V210006801
MANI TROCAR KIT	2021/08/05	MTK23S	V210011802
MANI TROCAR KIT	2021/08/26	MTK25S	V210019400
MANI TROCAR KIT	2021/09/09	MTK25S	V210020000
MANI TROCAR KIT	2021/12/10	MTK25S	V210006800
MANI TROCAR KIT	2021/12/23	MTK25S	V210009101
MANI TROCAR KIT	2022/01/07	MTK23S	V210011804
MANI TROCAR KIT	2022/01/13	MTK23S	V210011800
MANI TROCAR KIT	2022/02/08	MTK23S	V210015701
MANI TROCAR KIT	2022/02/22	MTK23S	V210015702
MANI TROCAR KIT	2022/02/22	MTK25S	V210009103
MANI TROCAR KIT	2022/03/24	MTK23S	V210015700
MANI TROCAR KIT	2022/04/27	MTK23S	V210028903
MANI TROCAR KIT	2022/05/13	MTK25S	V220000703
MANI TROCAR KIT	2022/05/26	MTK27S	V220017100
MANI TROCAR KIT	2022/05/26	MTK23S	V210032901
MANI TROCAR KIT	2022/06/24	MTK23S	V210032900
MANI TROCAR KIT	2022/06/24	MTK25S	V220005903
MANI TROCAR KIT	2022/06/24	MTK27S	V220021100
MANI TROCAR KIT	2022/08/05	MTK23S	V220001601

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Product Name	Manufacturing Date	Model / Catalogue Number	Lot Number
MANI TROCAR KIT	2022/08/05	MTK23S	V220001602
MANI TROCAR KIT	2022/08/05	MTK25S	V220009304
MANI TROCAR KIT	2022/08/05	MTK25S	V220009305
MANI TROCAR KIT	2022/08/29	MTK25S	V220009306
MANI TROCAR KIT	2022/09/09	MTK23S	V220001600
MANI TROCAR KIT	2022/09/09	MTK23S	V220004701
MANI TROCAR KIT	2022/10/13	MTK23S	V220004702
MANI TROCAR KIT	2022/10/28	MTK27S	V220032400
MANI TROCAR KIT	2022/10/28	MTK25S	V220013400
MANI TROCAR KIT	2022/12/23	MTK23S	V210027300