Rev 1: September 2018

FSN Ref: FSN-2021-01 FSCA Ref: FSCA-2021-01

Date: 02.04.2021

Urgent Field Safety Notice
Sterilized Drape for PDE

For Attention of*:User

Contact details of local representative (name, e-mail, telephone, address etc.)*
Hamamatsu Photonics Deutschland GmbH Arzbergerstrasse 10 D-82211 Herrsching Germany Tel:+49-8152-375-203 Fax: +49-8152-375-222

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Urgent Field Safety Notice (FSN)
Sterilized Drape for PDE
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	This product is a sterilized, disposable **cover** made exclusively for the "Infrared Observation Camera System (Product Name: Photodynamic Eye PDE and pde-neoII) " manufactured by Hamamatsu Photonics.  
1.	2. Commercial name(s)
	Sterile Drape for PDE
1.	3. Unique Device Identifier(s) (UDI-DI)
	4544050088459
1.	4. Primary clinical purpose of device(s)*
	This product is used to prevent contamination of the human body or camera.
1.	5. Device Model/Catalogue/part number(s)*
	0823802
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	ALL LOT numbers
1.	8. Associated devices
	N/A

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	**1. Description of the product problem***
	"STERILE" is included in the CE product label, but the notified body pointed out that it does not meet the "STERILE" label requirement (SAL ≤10^{-6}) of EN 556-1: 2001.
2.	**2. Hazard giving rise to the FSCA***
	There have been no reports of sterilization defects or infectious diseases caused by the product in Europe and Japan. Sterility assurance level of drape SAL = 10^{-3} is even in compliance with US national standard ANSI / AAMI ST67: 2019. Based on these facts, this product will continue to undergo gamma ray sterilization at the sterility assurance level SAL = 10^{-3} with no effect on the safety of this product. For the products which will be shipped in the future, the word "STERILE" will be removed from the label and IFU. Although "STERILE" will be removed from the labelling, this drape can continue to be used clinically as a sterilized disposable.
2.	**3. Probability of problem arising**
	Not applicable
2.	**4. Predicted risk to patient/users**
	There is no new risk to patient and users.
2.	**5. Further information to help characterise the problem**
	Sterility assurance level of drape SAL = 10^{-3} even complies with the US national standard ANSI / AAMI ST67: 2019. The product will therefore continue to be sterilized with gamma-rays at the sterility assurance level SAL = 10^{-3}.
2.	**6. Background on Issue**
	This product is a sterilized, disposable cover made exclusively for the "Infrared Observation Camera System (Product Name: Photodynamic Eye PDE and pde-neoII) " manufactured by Hamamatsu Photonics. Gamma ray sterilization (SAL = 10^{-3}) has been performed in the manufacturing process since it first went on sale. According to ISO11137-1: 2006, the international standard for radiation sterilization validation, sterility assurance level SAL = 10^{-3} is recognized for sterilization of medical devices. Sterility assurance level SAL = 10^{-3} is even in compliance with US national standard ANSI / AAMI ST67: 2019 for drapes that do not come into contact with the living body. We therefore determined that sterility assurance level SAL = 10^{-3} is adequate for the latest equipment. European sterilization labelling standard EN556-1: 2001 however requires sterility assurance level SAL = 10^{-6} when "STERILE" is displayed on the labelling of CE products and the notified body pointed out that this product did not meet the requirements at the latest audit.
2.	**7. Other information relevant to FSCA**
	As a corrective action, we will remove "STERILE" on the product label and IFU and change the label to indicate that gamma ray irradiation is performed at the sterility assurance level (SAL = 10^{-3}). In addition, we will cancel the CE certificate specializing in sterilization and re-submit as a normal class I. We will stop shipping to Europe until the label and IFU are revised. For already distributed products on the EU market, we distribute this FSN and notification letter that explains the background and our corrective action to users.

	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?	End of May,2021
3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? No	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None	
3	6. By when should the action be completed?	End of May, 2021
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? No	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
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:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Fuji Systems Corporation, Shirakawa Plant
	b. Address	200-2 Aza-Ohira, Odakura, Nishigo, Nishi Shirakawa Gun, Fukushima 961-8061 JAPAN
	c. Website address	http://www.fujisys.co.jp/en/index.html
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * No	
4.	9. List of attachments/appendices:	**Notification Letter attached**
4.	10. Name/Signature	…….

	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.