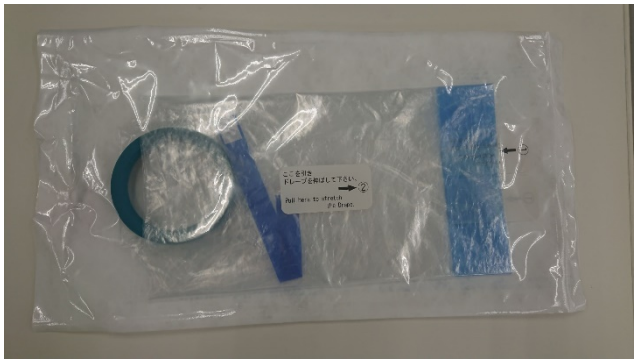
Fuji Systems

27. Apr. 2021

Notification Letter

Dear sir or madam,

Product Name : Drape for PDE
Manufacturer Device Model/Catalogue/part number(s): 0823802
Distributor Device Model/Catalogue/part number(s): A9951-01



This product is a single-use disposable cover made exclusively for the "Infrared Observation Camera System (Product Name: Photodynamic Eye PDE and pde-neoII)" manufactured by Hamamatsu Photonics. After manufacturing the device is irradiated with Gamma rays in order to achieve a 99,9% freedom from bacterial contamination. It is not a sterile product according to European sterilization standards, which require a freedom from contamination of 99,9999%. Nevertheless, due to the Gamma irradiation it can safely be used in the operating room, provided that the following precautions are observed:

- Do not touch the sterile zone (skin, wound, sterile covers) with the drape, keep at a distance of 5 cm to 30cm from such surfaces.
- The operator handling the infrared camera should also be dressed in sterile clothing (sterile gloves, gown), but shall also not touch the sterile zone, even after handling of the drape-covered camera, as the persons gloves will not meet the sterility requirements of the sterile zone after handling the camera.

While the product was labelled as “sterile” product in the past, this product will no longer be labelled as “sterile”. The reason for this change is as follows:
We applied for CE mark certification in 2008. The submission document relating to gamma ray irradiation indicated a 99,9% freedom from bacterial contamination. The respective documents were reviewed by the notified body who concluded it was adequate. As a result, the device was certified by the notified body on May 22nd, 2008 (Certificate number

CE77715), since then the product was CE marked as a sterile product with the number of the Notified Body. Although the document related to the Gamma irradiation has been reviewed by notified body periodically, nothing of significance was subsequently pointed out. It was therefore determined that the labeling was adequate.

European sterilization labelling standard EN556-1:2001 however requires a freedom from bacterial contamination of 99,9999%, when "STERILE" is displayed on the labelling of CE marked products. Only recently during the latest audit the notified body pointed out that this product did not meet the requirements.

As a corrective action for this labeling non-conformity, the "STERILE" symbol and wording will be removed from the product labeling. Also, we have voluntarily revoked the CE certification as a sterile product and will in the future label the product as a normal class I device. Notified body number will also be removed from the labeling.

There have been no reports of infectious diseases caused by the product in Europe and Japan.

Although the word and symbol as a sterile product will be removed for the products which will be shipped in the future, the device assures a certain freedom from bacterial contamination and thus this drape can continue to be used clinically as a safe disposable even in a sterile surrounding.

Distributer:
Diagnostic Green GmbH
HAMAMATSU PHOTONICS FRANCE S.A.R.L.

Manufacturer:
Fuji Systems Corporation

Sign:_____
Shingo Ueki
Director, Plant Manager

Rev 1: September 2018
FSN Ref: FSN-2021-01-CH

Fuji Systems

FSCA Ref: FSCA-2021-01

Date: 27.04.2021

Urgent Field Safety Notice
Drape for PhotoDynamicEye

For Attention of*:User / Operator

Contact details of local representative (name, e-mail, telephone, address etc.)*
Diagnostic Green GmbH Otto-Hahn-Straße 20 85609 Aschheim-Dornac, Germany Tel : +49 89 1241477-20
HAMAMATSU PHOTONICS FRANCE S.A.R.L. Swiss Office Dornacherplatz 7, 4500 Solothurn, Switzerland Tel:+ (41)32-625-60-60 Fax: +(41)32-625-60-61

Contact details of Importer (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

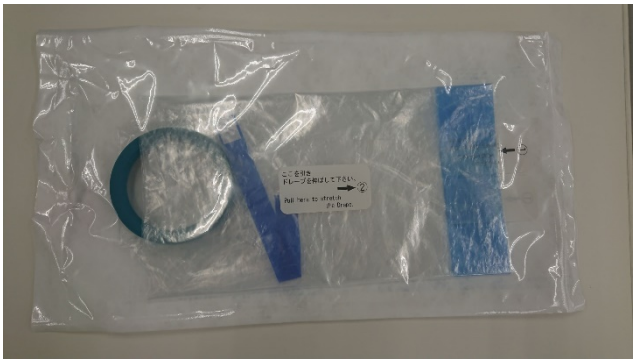
Contact details of EU REP (name, e-mail, telephone, address etc.)*
MedDevConsult GmbH Address: Airport Center (Building C) Flughafenstrasse 52a 22335 Hamburg Germany Tel: +49 40 53299-461 Fax: +49 40 53299-100

Rev 1: September 2018
FSN Ref: FSN-2021-01-CH

Fuji Systems

FSCA Ref: FSCA-2021-01

Urgent Field Safety Notice (FSN)
Drape for PhotoDynamicEye

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	This product is a single use, 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)
	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)*
	Manufacturer Device Model/Catalogue/part number(s): 0823802 Distributor Device Model/Catalogue/part number(s): A9951-01
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	ALL LOT numbers
1.	8. Associated devices
	Photodynamic Eye PDE and pde-neoII

	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 (freedom from bacterial contamination of 99,9999%) of EN 556-1: 2001. However, the product is irradiated by Gamma rays in order to achieve a 99,9% freedom from bacterial contamination.
2.	2. Hazard giving rise to the FSCA*
	There have been no reports of infectious diseases caused by the product in Europe and Japan. Although the word and symbol as a sterile product will be removed for the products which will be shipped in the future, the device assures a 99,9% freedom from bacterial contamination and thus this drape can continue to be used clinically as a safe disposable even in a sterile surrounding.
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
	European sterilization labelling standard EN556-1:2001 however requires a freedom from bacterial contamination of 99,9999%, when "STERILE" is displayed on the labelling of CE marked products. Only recently during the latest audit the notified body pointed out that this product did not meet the requirements.
2.	6. Background on Issue
	This product is a single-use disposable cover made exclusively for the "Infrared Observation Camera System (Product Name: Photodynamic Eye PDE and pde-neoII)" manufactured by Hamamatsu Photonics. After manufacturing the device is irradiated with Gamma rays in order to achieve a 99,9% freedom from bacterial contamination. It is not a sterile product according to European sterilization standards, which require a freedom from contamination of 99,9999%. Nevertheless, due to the Gamma irradiation it can safely be used in the operating room, provided that the following precautions are observed: - Do not touch the sterile zone (skin, wound, sterile covers) with the drape, keep at a distance of 5 cm to 30cm from such surfaces. - The operator handling the infrared camera should also be dressed in sterile clothing (sterile gloves, gown), but shall also not touch the sterile zone, even after handling of the drape-covered camera, as the persons gloves will not meet the sterility requirements of the sterile zone after handling the camera. While the product was labelled as “sterile” product in the past, this product will no longer be labelled as “sterile”. The reason for this change is as follows: We applied for CE mark certification in 2008. The submission document relating to gamma ray irradiation indicated a 99,9% freedom from bacterial contamination. The respective documents were reviewed by the notified body who concluded it was adequate. As a result, the device was certified by the notified body on May 22nd, 2008 (Certificate number CE77715), since then the product was CE marked as a sterile product with the number of the Notified Body. Although the document related to the Gamma irradiation has been reviewed by notified body periodically, nothing of significance was subsequently pointed out. It was therefore determined that the labelling was adequate.

2.	7. Other information relevant to FSCA
	As a corrective action for this labelling non-conformity, we will remove the "STERILE" symbol and wording on the product label and IFU. In addition, we have voluntarily revoked the CE certification as a sterile product and will in the future label the product as a normal class I device. We will stop shipping devices 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?	14 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, Reply 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		
3	6. By when should the action be completed?	14 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. * Yes	
4.	9. List of attachments/appendices:	**Notification Letter attached**
4.	10. Name/Signature	Shingo Ueki

	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.