FSN Ref: FSN_en_v01_PlasmaBiotics_RC-PB-23-063_R2311926-R2311964_Drying_PENTAX_EB11-J10_20230516
ANSM Vigilance N°: R2311926 / R2311964

Date:2023 05 16

Urgent Field Safety Notice
Connection sets ref. 301027 (model PP EB-J10) & ref. 301027-1 (model PP EB-J10/A) for PlasmaTYPHOON products

Attention*: **All healthcare facilities/services/professionals using connection set reference 301027 (model PP EB-J10) and/or connection set reference 301027-1 (model PP EB-J10/A) to dry PENTAX Medical model EB11-J10 videobronchoscopes with the PlasmaTYPHOON product line.**

Dear users,

The purpose of this letter is to inform you that Plasmabiotics is issuing a Field Safety Notice (FSN) to inform you of a potential risk of incomplete drying of the PENTAX Medical model **EB11-J10** videobronchoscope with the **PlasmaTYPHOON** product line.

We apologize for any inconvenience resulting from this issue.

For further information, assistance or reporting of any adverse health consequences related to the issue described in this Field Safety Notice (FSN), please contact your local PENTAX Medical representative.

Contact information for the local representative
PENTAX France **116 Quai de Bezons** **95106 Argenteuil Cedex** **France** **Phone: +33 1-3025-7575** **Email: Clients.fr@pentaxmedical.com**
PENTAX Medical EMEA **Julius-Vosseler-Str. 104** **22527 Hamburg, Germany** **Phone: +49 40-56-192-0** **Email: info.emea@pentaxmedical.com**

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Urgent Field Safety Notice
Connection sets ref. 301027 (model PP EB-J10) & ref. 301027-1 (model PP EB-J10/A) for PlasmaTYPHOON products

1. Device information*

1. Device Type(s)*

PENTAX Article Code	Photo	PlasmaBiotics Reference	Designation
301027		PP EB-J10	Standard connection set for video- bronchoscopes PENTAX MedicalJ10 series
301027-1		PP EB-J10/A	Autoclavable version of PP EB-J10

Connection sets 301027 and 301027-1 used in combination with the PENTAX Medical EB11-J10 videobronchoscope.

2. Commercial name(s)*

PP EB-J10 & PP EB-J10/A

3. Unique Device Identifier(s) (UDI-DI)

-

4. Primary intended clinical use of device(s)*

The device has no clinical purpose. The connection sets are used to connect the endoscope (i.e. the endoscope channels) to the PlasmaTYPHOON to perform the drying cycle with medical air.

5. Device Model/Catalogue/part number(s)*

- Model PP EB-J10 / Part Number 301027
- Model PP EB-J10/A / Part Number N°301027-1

6. Software Version

-

7. Affected serial or lol numbers range

All

8. Associated devices

PlasmaTYPHOON Products (TYPHOON+, Typhoon-V2TD, and Typhoon-V2TD120), Video- bronchoscopes PENTAX Medical EB11J10

2. Reason for Field Safety Corrective Action (FSCA)*

1. Description of the product problem*

This notice is intended for all users of the PlasmaTYPHOON products to dry **the PENTAX Medical videobronchoscope model EB11-J10.** It has recently come to our attention that the EB11-J10 videobronchoscope may not be effectively dried with the 301027 and 301027-1 connection sets.

2. Hazard giving rise to the FSCA*

There is a risk that the endoscope will not correctly dried. Water residual may subsist in the endoscope channels thus a risk of contamination during storage of the endoscope.

3. Probability of problem arising

The probability of occurrence is medium.

4. Predicted risk to patients/users

	Indirect risk to the patient: The EB11-J10 endoscope may be stored with residual water after PlasmaTYPHOON drying. This may lead to a potential increase in contamination of the endoscope during storage.
2.	5. Additional information to help characterize the problem
	-
2.	6. Background to the issue
	No history of drying problems with this endoscope: first problem identified with the drying of the PENTAX Medical endoscope model EB11-J10.
2.	5. Other information relevant to the FSCA
	-

3. Type of risk mitigation 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

Do not dry the EB11-J10 videobronchoscope with Typhoon Plasma family products (TYPHOON+, Typhoon-V2TD, and Typhoon-V2TD120).

Note:
EB11-J10 videobronchoscopes channels can be dried manually using medicinal air.
Ensure that the endoscope channels are completely dry before storage and follow the manufacturer's recommendations. The air gun supplied with the PlasmaTYPHOON can be used for this purpose.
Following the drying step, the endoscopes can be stored as usual using our PlasmaBAG device in combination with the PlasmaTYPHOON (use of the storage cycle, without prior drying cycle).
Ensure compliance with internal health facility requirements and procedures.

3.	2. By when should the action be completed?	Action to be taken upon receipt of this notice.
3.	3. Particular considerations: - Is follow-up of patients or review of patients' previous results recommended? : -	
3.	4. Is the customer's response required? * (Form attached specifying the deadline for return)	Yes

3. 5. Action to be taken by the manufacturer*

☐ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☒ Other ☐ None

PlasmaBiotics is investigating to find a corrective action (validate another connection kit for drying the EB11-J10 endoscope model).
The solution will be provided to users as soon as possible.

3.	6. By when should the action be completed	As soon as 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? : -	

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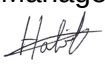
4. General Information *		
4.	1. FSN Type *	New.
4.	2. For updated FSN, reference number and date of previous FSN	-
4.	3. For Updated FSN, key new information as follows:	
	-	
4.	4. Further advice or information already expected in follow-up FSN? *	A notification will be made at a later date.
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	-	
4.	6. Anticipated timescale for follow-up FSN	-
4.	7. Manufacturer Information (For the contact details of the local representative, see page 1 of this FSN)	
	a. Company Name	PLASMABIOTICS
	b. Address	116 quai de Bezons, 95106 Argenteuil Cedex, FRANCE
	c. Website address	-
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of annexes	Annex: **Customer Response Form for a Field Safety Notice** ***To be returned completed and signed.***
4.	10. Name/Signature	Habib Halouani QARA Manager 

	Transmission of this safety advisory
	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.

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Customer Response Form for Field Safety Notice

1. Security Advisory Information (NSF)	
FSN Reference Number*	FSN_en_v01_PlasmaBiotics_RC-PB-23-063_Drying_PENTAX_EB11-J10_20230516
FSN Date*	16/05/2023
Product/Device Name*	Connection kits ref. 301027 (model PP EB-J10) and ref. 301027-1 (model PP EB-J10/A) for the PlasmaTYPHOON product line.
Product code(s)	301027 301027-1
Batch/serial number	All

2. Customer Details	
Customer account number	
Healthcare Organization Name**	
Organization Address*	
Department/Unit	
Shipping address if different to above	
Contact person Name*	
Title or function	
Phone Number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organization	
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.
☐	The information and required actions have been brought to the attention of all relevant users and executed.
☐	I am not using the affected devices / I do not have any affected devices.
☐	I have a query please contact me. *Customer to enter contact details if different from above and brief description of query*

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Print Name*	*Customer print name here*
Signature*	*Customer sign here*
Date*	

4. Return acknowledgement to sender	
Email	service-plasmabiotics@pentaxmedical.com
Customer Helpline	+33 1 30 25 96 76
Postal Address	PlasmaBiotics 116 Quai de Bezons 95106 Argenteuil Cedex FRANCE
Web Portal	-
Fax	-
Deadline for returning the customer reply form*	30/06/2023

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.