

PLASMABIOTICS®

IN ASSOCIATION WITH PENTAX MEDICAL

SAS with capital of 48 565 € - N° SIREN 531 066 959 R.C.S. Pontoise
APE CODE 2899B – TVA / VAT : FR42 531 066 959 – EORI : FR53 106 695 900 010

FSN Ref: FSN_en_v02_PlasmaBiotics_RC-PB-23-063_R2311926_Drying_PENTAX_EB11-J10_20230606
ANSM Vigilance N°: R2311926

Date: 2023-06-06

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

À l'attention de* : 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,

A previous Field Safety Notice (FSN v01) informed you of a potential risk of incomplete drying of the PENTAX Medical model EB11-J10 videobronchoscope with the PlasmaTYPHOON product line.

The purpose of this updated Field Safety Notice (FSN v02) is to bring you a validated solution for drying of the PENTAX Medical model **EB11-J10 videobronchoscope** with the **PlasmaTYPHOON** product line.

For further information or assistance please contact your local PENTAX Medical representative.

Contact information for the local representative

PENTAX France
116 Quai de Bezons
95106 Argenteuil Cedex
France
tél : +33 1-3025-7575
email : Clients.fr@pentaxmedical.com

PENTAX Medical EMEA
Julius-Vosseler-Str. 104
22527 Hamburg, Germany
tél: +49 40-56-192-0
email: info.emea@pentaxmedical.com

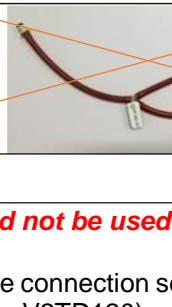
Urgent Field Safety Notice **Connection sets ref. 301027 (model PP EB-J10) & ref. 301027-1** **(model PP EB-J10/A) for PlasmaTYPHOON products**

1. Information on the devices concerned by the FSN

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.

Connection Sets concerned by the Field Safety Notice (FSN v01) are :

- Model PP EB-J10 / Reference N°301027
- Model PP EB-J10/A / Reference N°301027-1

PENTAX Article Code	Photo	PlasmaBiotics Reference
301027		PP EB-J10
301027-1		PP EB-J10/A

These Connection Sets should not be used for drying the EB11-J10 endoscope

The safety notice applies to these connection sets used with PlasmaTYPHOON products (TYPHOON+, Typhoon-V2TD, and Typhoon-V2TD120), in association with PENTAX Medical EB11-J10 videobronchoscopes.

2. Corrective Action Information : solution for EB11-J10 drying

To dry EB11-J10 videobronchoscopes with PlasmaTYPHOON products (TYPHOON+, Typhoon-V2TD, and Typhoon-V2TD120) please use the following connection kit(s) from now on:

- **Model Wol C / Reference N°301029**
- **Model Wol C/A / Reference N°301029-1**

301029		Wol C
301029-1		Wol C/A

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3. Actions to be taken by the users

3.1. First Case

If the connector(s) concerned, reference 301027 and/or 301027-1, is (are) used to dry ONLY the EB11-J10 endoscope, you must return the disinfected connector(s) to your local representative.

Replacement connectors (see section 2 above) will be sent to you to enable you to dry EB11-J10 videobronchoscopes with PlasmaTYPHOON products.

Please refer to the connection card B01-023_3_302_v02 (301029 -- Wol C // 301029-1 - Wol C/A) which will also be sent to you. This connection card shows how to connect the connectors to the endoscope and provides information on compatibility with different endoscope models.

3.2. Second case

If the connector(s) concerned, reference 301027 and/or 301027-1, is (are) used to dry several models of endoscopes, then you should no longer use these connectors to dry the EB11-J10 endoscope, as specified in the previous safety notice (FSN v01).

Other connectors (see section 2 above) will be sent to you in order to dry EB11-J10 videobronchoscopes with PlasmaTYPHOON products.

Please refer to connection cards B01-021_3_302_v02 (301027 -- PP EB-J10 // 301027-1 - PP EB-J10/A) and B01-023_3_302_v02 (301029 -- Wol C // 301029-1 - Wol C/A) which will also be sent to you. These connection cards indicate how to connect the connectors to the endoscope and provide information on compatibility with different models of endoscope.

In both cases, please follow the following instructions for implementing the corrective action within your healthcare facility.

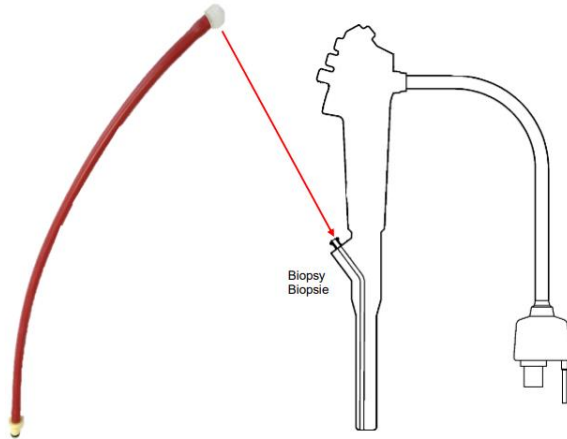
FSN Ref: FSN_en_v02_PlasmaBiotics_RC-PB-23-063_R2311926_Drying_PENTAX_EB11-J10_20230606
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4. Corrective Action Implementation Instructions

4.1. Connection set use

The EB11-J10 videobronchoscope must be dried with PlasmaTYPHOON products using the connectors listed in section 2 of this safety data sheet (connector references 301029 and 301029-1).

Connection to the endoscope is via a connection at the biopsy channel:

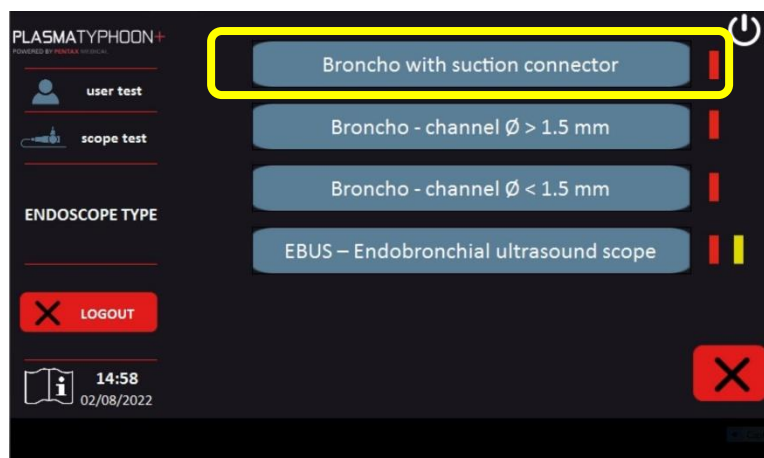
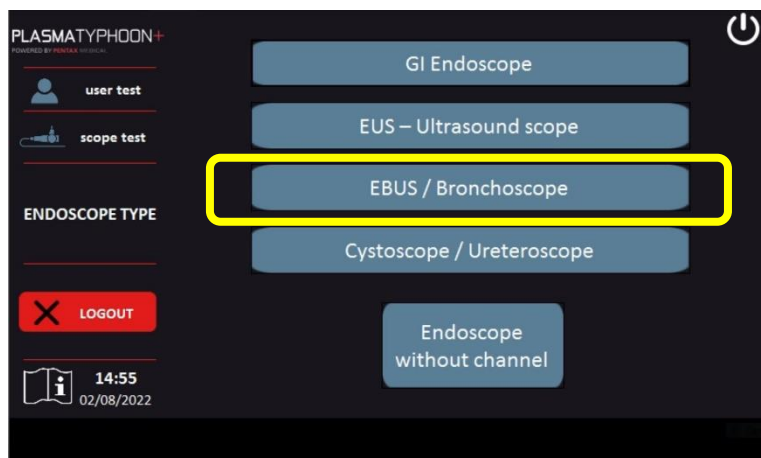


This information is found in connection card B01-023_3_302_v02 (301029 -- Wol C // 301029-1 – Wol C/A) attached with the connection set.

4.2. Drying EB11-J10 vidéobronchoscopes with PlasmaTYPHOON+

4.2.1. Manual click drying

If drying is carried out by manual selection of the cycle, please select the cycle **"EBUS/Bronchoscope"** then **"Broncho with suction connector"**:



4.2.2. Automatic drying via the ENDO base

If drying is carried out by automatic cycle selection via the ENDO database, please update the ENDO database* by replacing the current type with **BR-SC** :



N°	Type	Brand	Model	Serial N°	Inventory N°
001	GI-WJ	PENTAX	EC38-I10L	A289536	
002	GI-NWJ	PENTAX	ED-3490TK	B785648	
003	GI-DOCWJ	PENTAX	EG-3890TK	C898756	
004	EUS-EC	PENTAX	EG-3870UTK	A958435	
005	EUS-NEC	PENTAX	EG-3670URK	A958652	
006	BR-EBUS	PENTAX	EB-1970UK	B853984	
007	BR-SC	PENTAX	EB11-J10	XXXXXX	

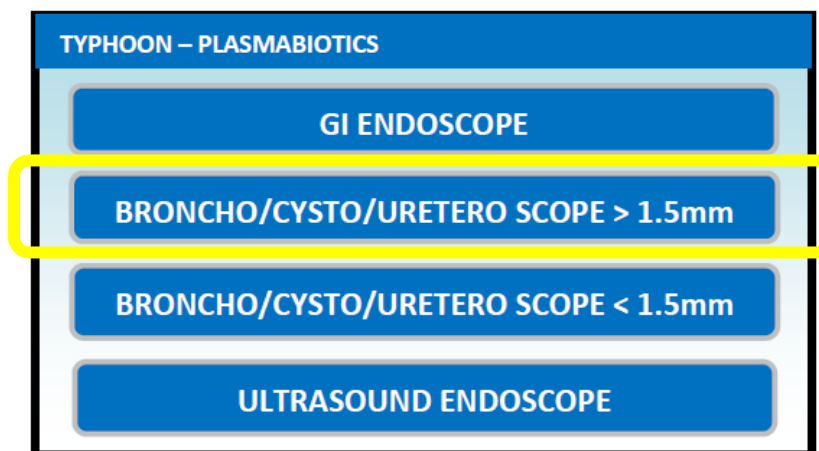
*To update the ENDO database, please refer to the PlasmaTYPHOON+ Technical User Manual (PB-TMU_A02-001 PlasmaTYPHOON+ Technical Manual User)

The ENDO database must be updated by the biomedical engineer or a local representative technician.

4.3. Drying EB11-J10 vidéobronchoscopes with PlasmaTYPHOON V2TD and PlasmaTyphoon V2TD120

4.3.1. Manual click drying

If drying is carried out by manual selection of the cycle, please select the cycle « **BRONCHO/CYSTO/URETERO SCOPE > 1,5mm** » :



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4.3.2. Automatic drying via the ENDO base

If drying is carried out by automatic cycle selection via the ENDO database, please update the ENDO database* by replacing the current type with **BRO** :

	A	B	C	D	E	F
1	ID Num	Type	Brand	Model	Serial Num	Inventory Num
2	0118	DIG	PENTAX	ED-34-i10T	ABCDEF	
3	0119	DIG	PENTAX	EC-3890FI	ABCDEF	
4	0120	ECH	PENTAX	EG-3870UTK	ABCDEF	
5	0121	BRO	PENTAX	EB-1570K	ABCDEF	
6	0122	DIG	PENTAX	EG-2990i	ABCDEF	
7	xxx	BRO	PENTAX	EB11-J10	xxx	
8						

*To update the ENDO database, please refer to the PlasmaTYPHOON+ Technical User Manual (PB-TMU_A02-001 PlasmaTYPHOON+ Technical Manual User)

The ENDO database must be updated by the biomedical engineer or a local representative technician.

1. Manufacturer Information

(For the contact details of the local representative, see page 1 of this FSN)

Nom : PLASMABIOTICS

Adresse : 116 quai de Bezons, 95106 Argenteuil Cedex, France

Nom/Signature	Habib Halouani QARA Manager 
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This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organizations 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. Field Safety Notice Information	
FSN Reference Number*	FSN_en_v02_PlasmaBiotics_RC-PB-23-063_R2311926_Drying_PENTAX_EB11-J10_20230606
FSN Date*	06/06/2023
Product/Device Name*	Connection sets 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	
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.
<input type="checkbox"/>	My health care facility is in the first case where the connector(s) reference 301027 and/or 301027-1 are used for drying ONLY the endoscope model EB11-J10 : <ul style="list-style-type: none">- I undertake to return the disinfected connector(s) to the local representative.- I certify that the replacement connectors (listed in section 2 of this FSN v02) have been received with the connection card B01-023_3_302_v02 (301029 -- Wol C // 301029-1 - Wol C/A).- Please let us know how many 301027 and/or 301027-1 connectors have been returned: :

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<input type="checkbox"/>	My health care facility is in the second case where the connector(s) concerned, references 301027 and/or 301027-1, are used for drying several models of endoscope. - I undertake to stop using these connectors for drying the EB11-J10 endoscope as specified in the previous safety notice (FSN v01). - I certify that I have received the connectors (listed in section 2 of this FSN v02) and the connection cards B01-021_3_302_v02 (301027 -- PP EB-J10 // 301027-1 - PP EB-J10/A) and B01-023_3_302_v02 (301029 -- Wol C // 301029-1 - Wol C/A).
<input type="checkbox"/>	I have a query please contact me. <i>Customer to enter contact details if different from above and brief description of query</i>
Print Name*	<i>Customer print name here</i>
Signature*	<i>Customer sign here</i>
Date*	

4. Return acknowledgement to sender	
Email	vigilance.emea@pentaxmedical.com
Customer Helpline	+49 40-56-192-0
Postal Address	PENTAX Medical EMEA Julius-Vosseler-Str. 104 22527 Hamburg, Germany
Deadline for returning the customer reply form*	15/07/2023

Mandatory fields are marked with *

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

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