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Urgent Field Safety Notice

BioPath™ 035 Paclitaxel releasing over the wire (OTW*) PTA balloon catheter
FSCA/2015/0001
Advice given by the manufacturer regarding the use of the device

February 19th, 2015

Attention: Interventional Radiology, Interventional Cardiology and Endovascular Surgery

Affected Devices

- BioPath™ 035 – **Model BPTH-35-60100L** (Balloon diameter 6.0 x 100mm length – catheter length 135cm)
- **All lot numbers for this model manufactured prior to November 2014 are affected by this FSCA**

Problem Description

Biosensors has received a report regarding a compatibility issue with the recommended sheath introducer size. The product is currently labeled for a 5F sheath introducer compatibility when the product specification is indicating a 6F recommendation. As a result Biosensors is initiating this advisory safety notice for the affected device.

This mislabeling has no impact on the patient safety however it may lead to prolonged procedure. All of the affected devices have been identified by product part number. This issue is related exclusively to the one model of BioPath™ 035 (BPTH-35-60100L). Patients who have already been successfully treated with an affected device are not impacted by this action.

Required Actions by Users

- Please identify and quarantine any devices with product part number **BPTH-35-60100L** in your inventory.
- For any affected devices in your possession, please complete the enclosed Field Safety/Corrective Action (FSCA) response form **immediately** and return it by fax to: **+41 21 804 8001** or by email to **fieldsafetynotice@biosensors.com** or **to your distributor contact**
- Upon receipt of the completed FSCA response form, a Biosensors representative will contact you to arrange the corrective action.
- If you have any questions or concerns, please contact your Biosensors representative, or contact our customer service team by email at: **fieldsafetynotice@biosensors.com**

Required Actions for Distributors

- For the inventory of the product part number **BPTH-35-60100L** still at your facilities, please identify and quarantine them.
- Please complete the enclosed Field Safety/Corrective Action (FSCA) response form **immediately** and return it by fax to: **+41 21 804 8001** or by email to **fieldsafetynotice@biosensors.com**
- Provide a copy of this FSN and the FSCA response form to all customers who may have received affected devices (product part number **BPTH-35-60100L**).

Biosensors Europe SA
Rue de Lausanne 29
CH – 1110 MORGES
SWITZERLAND
Tel: +41 (0) 21 804 80 00 Fax: +41 (0) 21 804 80 02
www.biosensors.com

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- Ask these customers to perform the "**Required Action by Users**" as mentioned in the respective above section and return immediately the FSCA response form completed and any unused affected devices to you.
- Confirm to Biosensors that you have completed the required activity for all of your impacted customers.
- Forward all completed FSCA response forms received from customers to Biosensors at the addresses listed above.

Transmission of this Field Safety Notice

Please provide a copy of this notice to all individuals within your organization, as well as to any third parties with whom you interact, who may have access to or knowledge of affected devices. Please maintain awareness of this Field Safety Notice as appropriate to ensure its effectiveness.

Contact Reference Person

Debashis Dutta, Vice President Quality Assurance, **fieldsafetynotice@biosensors.com**, Biosensors Europe SA - Switzerland

The undersigned confirm that Biosensors has provided a copy of this FSN to its notified body and to the relevant competent authorities as required by law.

We regret any inconvenience that this action may have caused for you or your staff. Biosensors places patient safety first and we appreciate your understanding as we work together with you to address this issue.

[redacted]

Debashis Dutta [redacted]
Vice President, Quality Assurance
Biosensors Europe SA

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Field Safety Corrective Action (FSCA) Response Form

Ref. No.: **FSCA/2015/0001**
Date: **19 February 2015**

Affected Devices

- BioPath™ 035 – **Model BPTH-35-60100L** (Balloon diameter 6.0 x 100mm length – catheter length 135cm)
- **All lot numbers for this model manufactured prior to November 2014 are affected by this FSCA**

Please complete this form even if you do not have any remaining affected product in your inventory and return by fax to: **+41 21 804 80 01** or by email to: **fieldsafetynotice@biosensors.com**

I/We acknowledge receipt of the FSCA referenced above and that the information therein has been shared with all recipients/users of the affected devices within our organization, as well as with any third parties to whom we may have transferred any affected devices.

First Name		**Last Name**	
Title/Designation		**Department**	
Organization/ Company		**Email**	
Street Address			
Postal Code		**City**	
Country		**Contact Telephone**	
Signature		**Date**	

☐ We do not have any of the affected devices mentioned in this Field Safety Notice

☐ We have the following affected devices:

Product Part Number	Lot No.	Quantity	Stock Location
BPTH-35-60100L			
BPTH-35-60100L			
BPTH-35-60100L			

Note: Please use separate sheets, if necessary

Upon receipt of this completed form, a Biosensors representative will contact you to arrange the corrective action.

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