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## URGENT FIELD SAFETY NOTICE

**Commercial name:** BALTACCI Infusion Catheters **all references and all lot numbers**

**FSCA-identifier:** R2011-199

**Type of action:** IFU modification

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February 2<sup>nd</sup>, 2012

Attention: **BALTACCI users**

This FSN is issued based on an incident which has been reported in Czech Republic. This incident mentions the rupture of a BALTACCI 1,5F catheter during ONYX ® injection with a 1 cc syringe **despite it was stated in all the versions of the IFU that the injection should not be done with a syringe smaller than 2.5cc.**

There were no clinical consequences for the patient.

Although the material of the micro catheter BALTACCI is compatible to DMSO, the tubes are not braided and hence the catheter pressure resistance is limited.

The liquid embolic devices, containing DMSO, are provided with 1 cc. syringes which can lead to high pressure during injection which could induce catheter rupture.

To avoid any confusion, we have deleted the mention "DMSO compatible" in the Instruction for Use and replaced it by :

**CAUTION:** the BALTACCI catheters are not compatible with embolization agents containing DMSO

**PRECAUTIONS:** never use the BALTACCI catheters with embolization agents containing DMSO

The actual version 7 of the IFU, inserted in the boxes in November 2011 contains this information.

Transmission of this Field Safety Notice:

**addresses of the users**

Please forward this document to any person concerned in your organization.

Please maintain the awareness on this notice and store it till you are sure that all BALTACCI catheters you have in stock, are packed with the new IFU version 7.

**Please send back as soon as possible the attached form "acknowledgment receipt".**

Contact reference person:

**Mr. Eric LARGEN**

Phone : +33 (0)1.39.34.61.84

Fax : +33 (0)1.34.17.03.46

Email : [quality.manager@balt.fr](mailto:quality.manager@balt.fr)

**BALT Extrusion**

10, rue de la Croix Vigneron

95160 MONTMORENCY

FRANCE

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

Signature



Eric LARGEN, Quality & Regulatory Affairs Manager



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### FSN ACKNOWLEDGMENT RECEIPT

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February 2<sup>nd</sup>, 2012

I hereby certify that I have read the attached Field Safety Notice related to the above mentioned FSCA.

The new IFU version 7 must be added to all the devices with a lot n° before 00204879. Therefore, the distributors must check their stock. In case they have such devices, we will send them the new IFU, in order they can add it to the concerned devices in replacement of the previous IFU version 6.

BALTACCI catheters in stock:      yes ☐      no ☐

If yes, please indicate :

Reference	Lot number	Quantity

**Date:**

**Name:**

**Address**

**Signature:**

**stamp of the company**

This document should be returned by email to the contact reference person:

**Mr. Eric LARGEN**

Phone : +33 (0)1.39.34.61.84

Fax : +33 (0)1.34.17.03.46

Email : [quality.manager@balt.fr](mailto:quality.manager@balt.fr)

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