FIELD SAFETY NOTICE

Medical Device: double lumen catheters ECLIPSE2L and COPERNIC2L
BALT reference: 20171003_EC2L-COP2L
Purpose: Safety Information on the use of double lumen catheters ECLIPSE2L and COPERNIC2L

Date: 03/10/2017

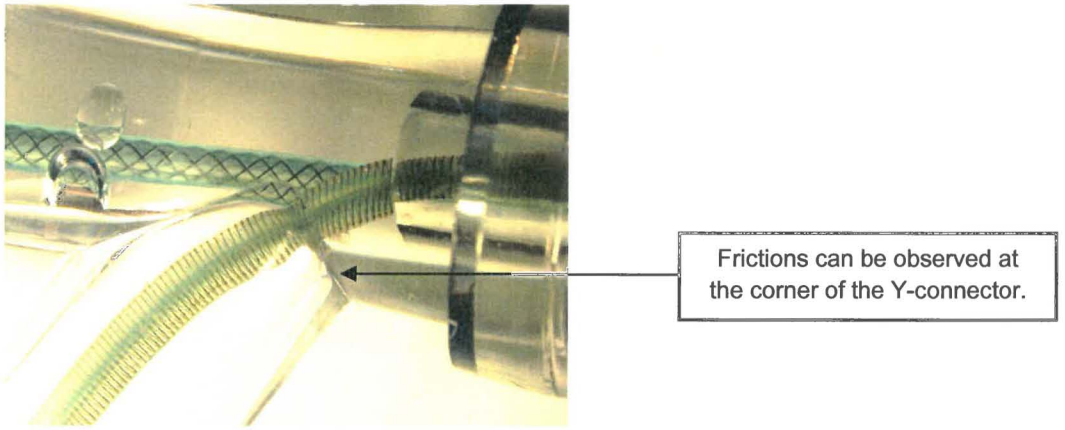
Who may be affected: Distributors, Safety Officers, Vigilance Coordinators and Head of Neuroradiology Department in Healthcare Centers outside the French territory

Description:
Damages on the catheters' tubes have been observed during post-marketing surveillance program. This may lead to the following unusual balloon's behavior during the contrast liquid injection through the guiding catheter:

- Unexpected inflation;
- Difficult deflation.

For the 3 cases reported to BALT Extrusion, there have been of no reports of patient injury due to these types of failures on the devices. However, these kinds of product issues may lead to patient injury with vascular trauma if the devices are not used in accordance with our recommendations.

Root cause and corrective action:
The root cause analysis has determined that the tubes can be damaged if the catheter is inserted through the perfusion-arm of the Y-connector.



Please, follow the instruction below to prevent any balloon's issue during the procedure:

- **Do not insert the double lumen catheters ECLIPSE2L and COPERNIC2L through the Y-connector's side-arm; they shall be inserted through the axial-arm to prevent any deterioration of the tube.**

The instructions for use will be updated accordingly.

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We confirm that the French competent authority "ANSM" has been beforehand informed about this notice. We thank you for your cooperation.

SOPHIE REHAULT
Quality and Regulatory Affairs Director
BALT Extrusion

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