

FIELD SAFETY NOTICE (FSN) / PRODUCTS RECALL

Issue Date: 21 DEC 2018

FSN #: 20181219_ECL2L6X20

PURPOSE: Balloon Deflation Issue

PRODUCT RANGE: ECLIPSE2L (temporary occlusion catheter for interventional neuradiology)

PRODUCT REF: ECL2L 6X20

LOTS #: 00321583 and 00332661

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

Dear Partners,

During Balt Extrusion's post-marketing surveillance program, Balt Extrusion received a total of 2 complaints, implying 3 units, related to **balloon deflation**. The **ECL2L 6x20** are the only model that has been affected. This issue is isolated to lot numbers # **00321583** and # **00332661**.

It was observed "slow-flow" strokes for one of the two complaints. The 2nd complaint did not lead to any patient injury. Generally, the balloon deflation issues may imply risks of neurological sequelae related to a too long vascular occlusion and/or to vessel damages during the withdrawal of the balloon catheter partially inflated. However, no similar complaint has been notified to BALT Extrusion on these 2 lots nor on any other lot.

We have not been able to reproduce, using representative and repeatable test methods, the failure mode in our laboratory and no evidenced root cause has been identified to date. The review of the lot history records did not highlight any anomaly that could potentially explain the issue experienced by the users.

However, it has been decided, by precautionary measure, to recall from the market the units of these 2 lots.

Procedure to be applied by distributors:

- Inform your clients and your local competent authority about this notice;
- Identify and locate the ECL2L 6x20 products concerned by this recall procedure;
- Collect and put in quarantine the ECL2L 6x20 products concerned by this recall procedure and then return them to BALT Extrusion through the usual "RMA" (Return Material Authorization) procedure by contacting our sales administration department;
- Keep informed BALT Extrusion about the status of every unit of ECL2L 6x20 products concerned by this recall procedure;
- Fulfill the receipt (cf. annex) then return it to BALT Extrusion via the indicated contact;
- Contact BALT Extrusion for any additional information.

Should you require any additional information about this field safety notice, do not hesitate to contact our Quality Department.

Contact:

Quality Department

✉ : claim@balt.fr

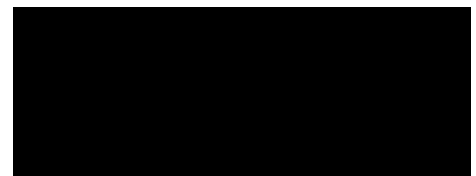
BALT EXTRUSION

10 RUE DE LA CROIX VIGNERON 95160 MONTMORENCY - France

☎ : +33.1.39.89.46.41 / Fax: +33.1.34.17.03.46

We confirm that the French competent authority "ANSM" has been beforehand informed about this field safety notice.

We apologize for any inconvenience that this action may cause and we thank you for your cooperation.



Annex: Notice Receipt ref. # 20181219_ECL2L6X20

RETURN THE FULFILED RECEIPT BY: FAX: +33.1.34.17.03.46 / MAIL: BALT EXTRUSION 10 RUE DE LA CROIX VIGNERON 95160 MONTMORENCY (Quality Department) / E-MAIL: claim@balt.fr

We hereby acknowledge the receipt of the notice reference "20181219_ECL2L6X20" and we undertake to implement the actions therein mentioned.

NAME:	
TITLE:	
COMPANY:	
LOCATION:	
CONTACT (E-MAIL AND/OR PHONE):	
DATE:	
SIGNATURE:	

We confirm that, after verification of our stock and the stocks of our users, we declare having no product concerned by this recall procedure.

If not, please, indicate the volume of ECL2L 6x20 product(s) concerned by this recall procedure:

Product reference	Lot number	Quantity to return (distributor and hospitals)
ECL2L 6x20	00321583	
ECL2L 6x20	00332661	

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