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## **URGENT NOTICE**

**Medical Device: microcatheter SONIC 1.5F**

**BALT reference: 20170428\_SONIC1.5F**

**Purpose: product recall SONIC 1.5F**

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**Date: 28/04/2017**

**For the attention to:** Distributors, Safety Officers, Vigilance Coordinators and Head of Neuroradiology Department in Healthcare Centers outside the French territory

### **Description:**

In accordance with the decision issued by the French competent authority "ANSM", BALT Extrusion suspends the manufacturing, the marketing, the distribution, the export and the use of microcatheters SONIC 1.5F and implements a recall of the references/lot numbers below mentioned.

Indeed, the notified body has been informed of the modifications of the SONIC 1.5 F, but the device was put on the market before formal approval of these by the notified body.

This recall concerns only the SONIC 1.5F and not the SONIC 1.2F.

### **List of references and lot numbers concerned:**

For each reference, the 1<sup>st</sup> lot number concerned by this recall procedure is mentioned. In other words, all lot numbers superiors to the below mentioned numbers, are concerned by this recall procedure.

<b>Reference</b>	<b>Lot numbers</b>
<b>SONIC1.5F15</b>	<b>00268897 and following</b>
<b>SONIC1.5F15SG</b>	<b>00273800 and following</b>
<b>SONIC1.5F25</b>	<b>00268901 and following</b>
<b>SONIC1.5F25SG</b>	<b>00277109 and following</b>
<b>SONIC1.5F35</b>	<b>00270745 and following</b>
<b>SONIC1.5F35SG</b>	<b>00269607 and following</b>
<b>SONIC1.5F45</b>	<b>00272573 and following</b>

### **Procedure to be followed by distributors:**

- Stop the SONIC 1.5F marketing with no delay;
- Inform your clients about this notice;
- Identify and locate the SONIC1.5F products concerned by this recall procedure;
- Collect and put in quarantine the SONIC 1.5F 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 SONIC 1.5F 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.



**Contact:**

Quality Department

✉ : [recall@balt.fr](mailto:recall@balt.fr)

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

We apologize for any inconvenience that this action may cause, we thank you for your cooperation and will immediately inform you if BALT Extrusion obtains clearance.

**SOPHIE REHAULT**  
Quality and Regulatory Affairs Director  
BALT Extrusion

A handwritten signature in blue ink, appearing to read "S. Reault", is positioned below the printed name and title.



