

FIELD SAFETY NOTICE

Medical Device: microcatheter SONIC
BALT reference: 20170530_SONIC
Purpose: Safety Information for SONIC Use

Date: 30/05/2017

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

Description:

BALT Extrusion recently received complaints related to ruptures or inflations of microcatheters SONIC during the injections of contrast liquid or embolie agents.

The SONIC devices are designed in order to be thin and very flexible which allows them to reach very distal locations. Special attention shall be given during the injections in order to avoid any overpressure complications.

Please ensure and follow the instructions below to prevent any incidents:

- **Do not exceed the maximum pressure indicated on the label (7 bars/100psi);**
- **Flush the microcatheter before use;**
- **Verify that the microcatheter lumen is not occluded before any injection by gently pushing the syringe plunger at the beginning of the injection;**
- **Immediately stop the injection if the liquid is not visualized exiting the tip;**
- **At the slightest resistance, immediately stop the injection and pull out the microcatheter;**
- **Prevent any solidification of the embolie agents inside the microcatheter by respecting the instructions of the concerned manufacturers.**

Contact:

Quality Department

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

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BALT Extrusion