

FIELD SAFETY NOTICE (FSN)

Issue Date: 14 MAR 2019

FSN #: 20190227_SILK VISTA BABY_FISH-MOUTH

PURPOSE: Fish-mouth effect on stent flow-diverter SILK Vista Baby

PRODUCT RANGE: SILK VISTA BABY (stent flow-diverter for interventional neuradiology)

PRODUCT REF: ALL

LOTS #: ALL

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

Dear Customers,

During the post-marketing surveillance program, Balt Extrusion received two complaints related to the use of the flow-diverter SILK Vista Baby where the device edge tended to assume a cone-shaped morphology (or “fish-mouth” effect).

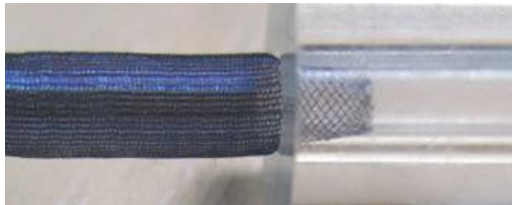


Figure 1: simulation of fish-mouth effect with Silk Vista Baby during bench-testing.

This kind of issue can lead to vessels occlusion and so, represents a risk of serious injury for patients.

The investigations revealed that the most probable causes of the issues experienced were a slight oversizing of the stent compared to arteries diameters, a forward load that led to stents compacting during deployment and short “landing zones” on aneurysm neck extremities.

As a result, the following directions should be applied to prevent the “fish-mouth” effect occurrence:

- **Select an appropriately sized SILK Vista Baby such that its fully expanded diameter is:**
 - the closest one to the target vessels and;
 - superior to the target vessels.
- **Ensure at least a “landing-zone” of 4mm on each aneurysm neckside;**
- **Avoid any excessive application of forward tension onto the freely open portion of the stent.**

Failure to comply with the above-mentioned directions could represent a postoperative risk with the stent deformation despite a satisfying positioning during the implantation and could imply, if deemed necessary by the physician, a patient specific follow-up, especially for procedures dated before the communication of this field safety notice.

The labels and the instructions for use will be updated accordingly.

Procedure to be applied by distributors:

- Inform your clients and your local competent authority about this notice;
- Contact BALT Extrusion for any additional information.

Procedure to be applied by the hospital staff:

- Inform, within your hospital, the safety officers, the vigilance coordinators and the neuroradiology department staff, as well as any other person if deemed necessary;
- Contact your local distributor for any additional information.



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

Contact:

Quality Department

✉ : claim@balt.fr

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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.

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Page 2 sur