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FIELD SAFETY NOTICE

Issue Date: 23 July 2024

HHE #: HHE-002_SERSQUID_3ML Syringes broken
PURPOSE: Occurrence of crack on SERSQUID_3 syringes – part of SQUID 3ML kit
PRODUCT RANGE: SQUID_3
PRODUCT REF:

Product	UPC Code (=GTIN / UDI-DI)	Product	UPC Code (=GTIN / UDI-DI)
SQUID12_3	03760227470297	EUSQUID12_3	03760227470679
SQUID12LD_3	03760227470334	EUSQUID12LD_3	03760227470686
SQUIDPERI12_3	03760227470327	EUSQUIDPERI12_3	03760227470730
SQUIDPERI12LD_3	03760227470341	EUSQUIDPERI12LD_3	03760227470747
SQUID18_3	03760227470358	EUSQUID18_3	03760227470693
SQUID18LD_3	03760227470372	EUSQUID18LD_3	03760227470709
SQUIDPERI18_3	03760227470365	EUSQUIDPERI18_3	03760227470754
SQUIDPERI18LD_3	03760227470389	EUSQUIDPERI18LD_3	03760227470761
SQUID34_3	03760227470303	EUSQUID34_3	03760227470716
SQUID34LD_3	03760227470402	EUSQUID34LD_3	03760227470723
SQUIDPERI34_3	03760227470396	EUSQUIDPERI34_3	03760227470778
SQUIDPERI34LD_3	03760227470310	EUSQUIDPERI34LD_3	03760227470785

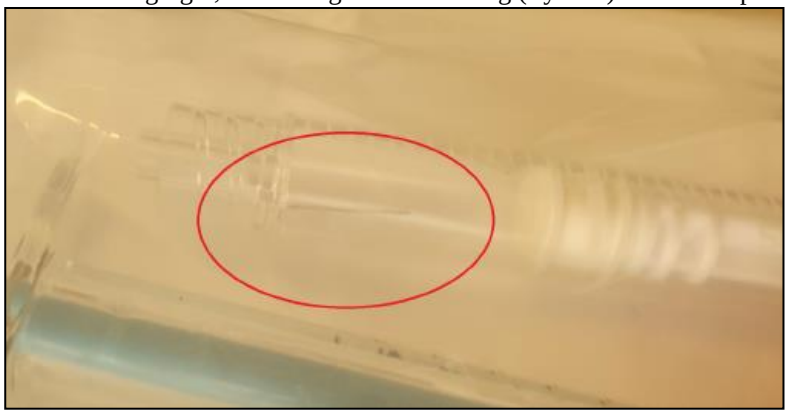
LOTS #: ALL LOT NUMBERS

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

Dear partners,

Since June 2024, we received 2 Complaints for a broken syringe (picture 2) without any patient injury.
During the incoming inspection of SERSQUID_3ML syringes, part of the SQUID 3ML kit, we detected occurrences of crack on the syringe, which can lead to broken syringes. See picture 1 & 2.

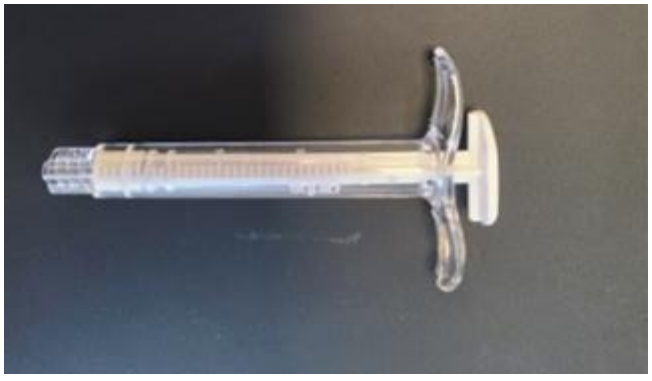
How the issue has been detected:
Our incoming inspection is a visual inspection carried out with the naked eye, on a table, without a specific background, without raking light, and through the sterile bag (Tyveck). No other special conditions are necessary to detect the defect.



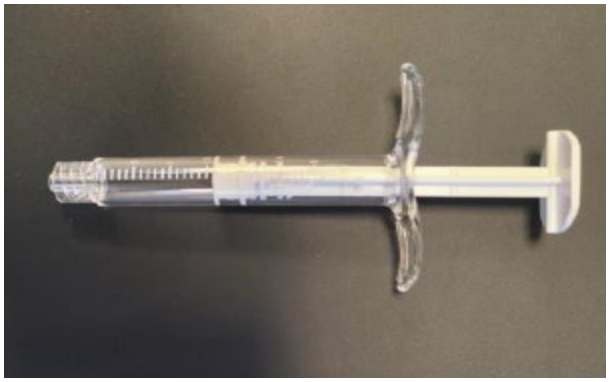
Picture 1: crack on syringe body

Picture 2: Broken syringe

Detail of our investigations:
We defined corrective actions linked to this process to avoid this defect. The pushed position of the piston (Picture 3) which favors cracking or breakage of the syringe is systematically avoided. The only position which avoid this failure is the "middle of the syringe" position (Picture 4).



Picture 3: plunger pushed



Picture 4: Plunger in middle position

Risk for patient :
The only risk associated to this failure is the **extension of procedure for the patient.**
The fissure/crack of syringes causing leakage of the liquid embolic. A full broken syringe does not allow to perform the operation. It is easily detected by the user, so it is improbable that syringe failure will cause patient injury as the leakage will be observed during use.

Mitigation of the risk :
Following the results of our investigations, corrective actions are in place to ensure the sending of the next syringes to the market without any risk of default.

Residual risk after mitigation:
After investigation, it appears that SQUID kits including syringes with plunger pushed does not present any risk for the patient. For this reason, we recommend continuing to use the SQUID. I case of any occurrence of defect, follow the basic complaint process.

Procedure to be applied by distributors:
- Inform your customers and your local competent authority about this notice (outside EEA, UK, Switzerland, and Turkey).
- Complete and return the "Notice Receipt form" below (Appendix section) as soon as possible to the e-mail address: QA@baltgroup.com
- Contact EMBOFLU for any additional information.

Procedure to be applied by the hospital staff:
- Communicate this information to staff within the hospital that may use SQUID 3ML references and lots or any other person if deemed necessary.
- Complete and return the "Notice Receipt form" below (Annex section) as soon as possible to the e-mail address: QA@baltgroup.com
  By returning the completed Notice Receipt form by e-mail or mail, you acknowledge that you have read and understood this Field Safety Notice.
- Contact your local distributor for any additional information.
- In case of any defect occurrence, follow the basic complaint process (productcomplaint.usa@baltgroup.com).

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

Contact:
Quality Department
✉ For FSCA, recall, or FSN : QA@baltgroup.com
✉ For complaint / claim : productcomplaint.usa@baltgroup.com
Embo-Flüssigkeiten A .G.
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Quality	Regulatory
Name: Thomas COLSON Title: VP Global Quality Assurance Date / Signature: 22 August , 2024	Name: Claus Freyinger Title: VP Global Regulatory and Clinical Affairs Date / Signature: 22.08.2024

[redacted]

Appendix: Notice Receipt ref. # HHE-002_SERSQUID_3ML Syringes broken

RETURN THE FULFFILED RECEIPT BY: MAIL: Embo-Flüssigkeiten A .G. Route de Avouillons 30 | CH-1196 GLAND | Switzerland (Quality Department) / **E-MAIL:** QA@baltgroup.com

Please check the two boxes below:

☐ ***We confirm that I have received and read this Field Safety Notice and acknowledge informations related to the SQUID 3ML kits.***
☐ ***We hereby acknowledge that all required personnel or customers have been notified of this Field Safety Notice,***

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

For BALT Extrusion SAS data consolidation purposes, please provide the number of units initially delivered:

Product reference	QTY Initially Delivered + Lot Number	QTY Used/Discarded + Lot Number

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