Field Safety Notice

URGENT PRODUCT SAFETY INFORMATION

Type of action: Recall

Commercial name of the affected product: BIP O-Twist Marker SRX

Date: 2022-01-31

BIP-Reference: CN-104

Sender:

BIP Biomed. Instrumente & Produkte GmbH, Am Brand 1, 82299 Türkenfeld, Germany

Recipient:

To all customers (distributors and end users) of the affected medical devices

Dear valued customer,
In course of continuous development of our products and their production processes, we have identified a potential problem with one of our products BIP O-Twist Marker SRX during sterile packaging testing and therefore request your urgent attention.
BIP O-Twist Marker SRX is a sterile, single-use product used for percutaneous marking of lesions in breast tissue and is intended for use in combination with BARD Enspire EnCor® Biopsy System 7G / 10G.

We kindly ask you to carefully review the following safety instructions and to assist us in complying with and performing the measures described.

Details on affected devices:

Only the following medical devices are affected:
(hereinafter also referred to as "product" or "OTM-SRX")

REF/Cat No.	Tradname	LOT-Numbers
OTM3.0SRX	**BIP O-Twist Marker SRX**	**0919,** **0220, 0920, 1220** **0121, 0221, 0321, 0421, 0721, 0821**

The corresponding LOT number can be found on the respective product packaging (see Fig.1)

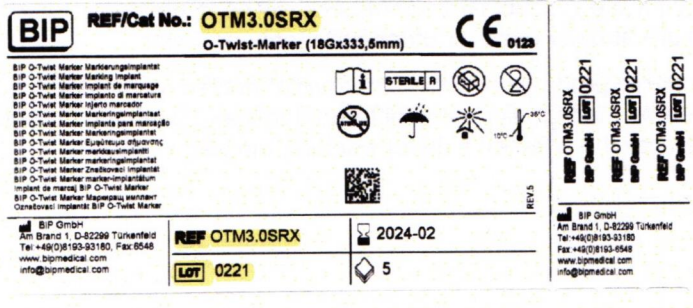

Fig.1: Example label

Description of the problem including root cause:

In the course of performing dye penetration tests in accordance with ASTM F1929-15 on currently used sterile peel pouches of the concerned products, it was found that in isolated cases penetration of the used test liquid can occur at a specific point of the sealing seam (see Fig. 3).
This could have the consequence that the integrity of the sterile barrier is no longer given and the sterility of the products cannot be guaranteed beyond the shelf life of 3 years as indicated on the packaging.

The affected sealing seam is located on the side for opening the sterile pouch, on the side with the guide sleeve (see Fig.2, red marking)

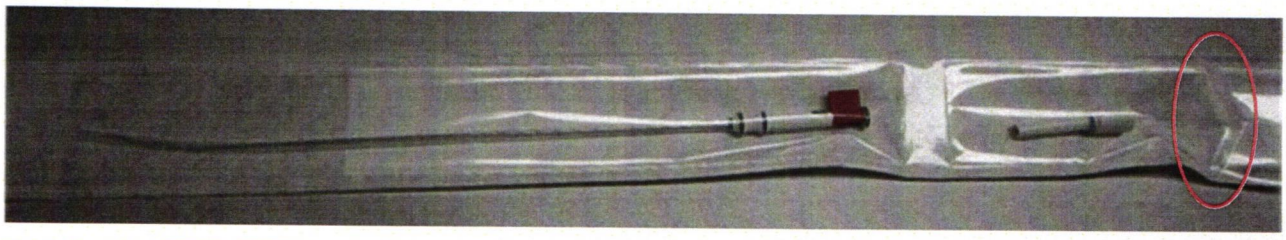

Fig.2: Product OTM3.0SRX, application cannula with implantable marking ring (left) and guide sleeve (right), separated by an intermediate sealing seam. Red marking = affected sealing seam.

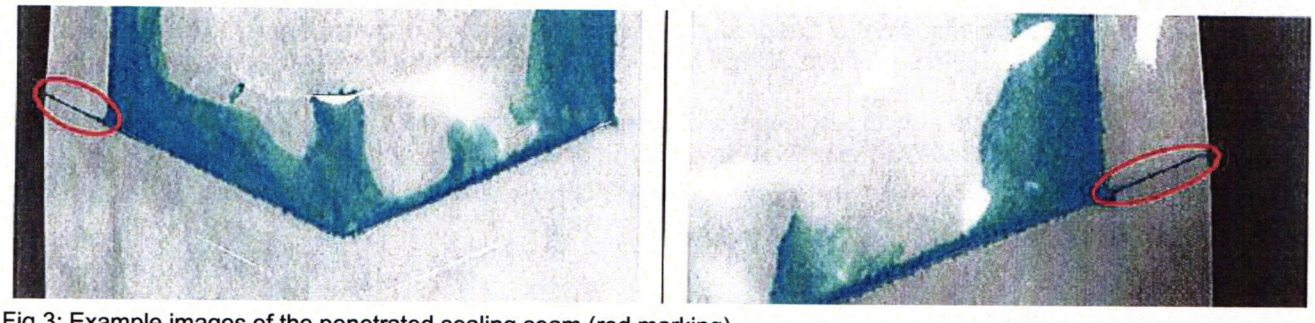

Fig.3: Example images of the penetrated sealing seam (red marking)

The used sterile peel pouches are purchased as prefabricated components from a supplier in Germany and are used at BIP GmbH exclusively for the product REF OTM3.0SRX.

The root cause was clearly identified as a defect at the supplier's sealing tool, which is used for this transverse sealing seam. So far, only one series batch has been produced with the defective tool and it could be proven on the basis of the performed tests that the defect only appeared in a few sterile pouches.

The defect can be clearly narrowed down to the affected products and corresponding batch numbers produced and packed with these pouches.

As a corrective action, a change in sterile packaging for the product REF OTM-SRX will be implemented and alternative sterile pouch types shall be used, which are already used for other BIP sterile products.

An identical error can be excluded for all other BIP sterile products and the other prefabricated sterile pouch types, as these sterile pouch types are manufactured by the supplier using different tools and have a different continuous circumferential shape of the sealing seam on the affected side for opening the sterile pouch.

Assessment of possible risks:

In case of using a non-sterile product, postoperative infections or inflammatory reactions of the patient may occur.

The risk of such a complication resulting from an affected product, as well as an associated long-term risk for patients implanted with a marker ring using the affected products, is considered unlikely for the following reasons:

- BIP GmbH has not yet received any complaints or other information regarding the product REF OTM3.0SRX which refer to a faulty or defective product. Consequently, no post-operative infections of patients have been reported in connection with the product, which would indicate the application of a non-sterile product.
- The possibly defective sealing seam is located on the side of the guide sleeve and is separated from the application cannula by another intermediate sealing seam. The application cannula is protected by an additional protective sleeve and the implantable marking ring is located inside the application cannula. A possible carry-over of germs via the identified weak point of the sealing seam to the implantable marking ring is therefore considered unlikely.
- Current investigations have shown that only a few products or sterile pouches have a weak point in the affected sealing seam / sterile barrier.

Nevertheless, as an extended precautionary measure, BIP GmbH is performing a recall of all unused products of the affected lots whose shelf life of 3 years has not yet expired.

Advise on action to be taken by the user:

According to our records or those of our distributors, your facility has purchased the affected products. Therefore, we would like to request you to perform the following actions:

- Check your inventory of affected products REF OTM3.0SRX (see page 1 for LOT numbers).
- Immediately discontinue further use of all affected products, remove them from your inventory and put them into quarantine until they are returned to BIP GmbH.
- Complete enclosed response and return to the contact information provided.
- Return all affected products REF OTM3.0SRX (see page 1 for LOT numbers) that have not yet been in use and whose expiration date has not yet lapsed to the following address **by February 28, 2022**:

  BIP Biomed. Instrumente & Produkte GmbH
  Am Brand 1,
  82299 Türkenfeld,
  Germany
- You will receive a credit note for the returned products.
- If you have resold the affected products, please immediately locate the customers concerned and forward this safety information to them. In this case, please document your communication with the customers and inform us accordingly.

Field Safety Notice

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

BIP Biomed. Instrumente & Produkte GmbH

Department QM/RA: Roland Renner (QMB, PRRC) / Christian Lechner (PRRC)

Am Brand 1,

82299 Türkenfeld,

Germany

Tel.: +49 - (0)8193 – 9318-0

Fax: +49 (0)8193 6548

Email: qm@bipmedical.com

We deeply regret for the inconvenience and thank you very much for your support!

[redacted]

Field Safety Notice

Receipt of Field Safety Notice regarding BIP O-Twist Marker SRX dated 2022-01-31

Please fully complete this receipt and mark with a tick the appropriate boxes.

Please also inform us in that case if you have no pieces of the listed medical devices on stock.

Medizinprodukt:	**BIP O-Twist Marker SRX**
Artikelnummer:	**OTM-3.0SRX**
LOT-Nummern:	**0919,**
	0220, 0920, 1220
	0121, 0221, 0321, 0421, 0721, 0821

☐ We acknowledge receipt of this Field Safety Notice and return _____ pieces of the affected products to you for credit.

☐ We acknowledge receipt of this Field Safety Notice and have no pieces of affected products in stock.

Name of organization / customer: _____

Name of contact reference person: _____

Address: _____

Telephone / E-mail: _____/_____

Please return this receipt to the following address:

BIP Biomed. Instrumente & Produkte GmbH
Am Brand 1,
82299 Türkenfeld, Germany
Tel.: +49 - (0)8193 - 9318-0
via E-mail to info@bipmedical.com
or via FAX to +49 (0)8193 6548

If you have any questions regarding the handling of returns, please contact our internal sales department via this contact address.