

Customer Address

Customer ID: 2021-03-21

Customer information

**Urgent Field Safety Notice
regarding a possible incorrect product sterilization**

Affected products:

REF	Description	LOT
SM-SF0927	Cement delivery cannula Ø1,8mm, length 273mm	19123119
SM-BAN1115D	Bone access needle 11G / length 15cm	2003722

Dear Sir or Madam,

With regards to the responsibility of SIGNUS for product and patient safety, we hereby notify you about an urgent Field Safety Notice of our Supplier **BIOPSYBELL SRL**, for the implementation of which we kindly ask for your assistance.

1. Problem description

Our Supplier **BIOPSYBELL SRL** has been informed by one of its sterilization service suppliers of a potential risk of incorrect sterilization of product batches sterilized by this supplier.

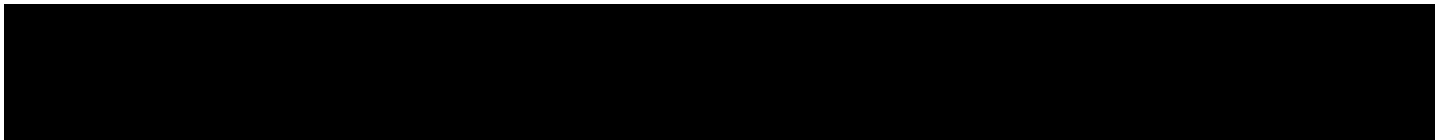
The affected medical devices distributed by SIGNUS are the following:

REF	Description	LOT	Quantity
SM-SF0927	Cement delivery cannula Ø1,8mm, length 273mm	19123119	
SM-BAN1115D	Bone access needle 11G / length 15cm	2003722	

For more details please refer to the enclosed **URGENT SAFETY NOTICE – FSN01-2021** of the manufacturer **BIOPSYBELL SRL**.

2. What action is expected from your side?

Please read the enclosed Urgent Safety Notice carefully and follow the instructions of the manufacturer **BIOPSYBELL SRL**.



2.1 You have located the affected product:

In coordination with the manufacturer BIOPSYBELL please return the affected devices to SIGNUS.

Please complete the SIGNUS contact form (page 4) and send it to **SIGNUS**, your supplier of the product concerned.

Only in this way **SIGNUS** can identify and replace possibly deficient products still on the market.

SIGNUS will provide replacements for returned products immediately.

SIGNUS contact details – please see chapter 4.

2.2 You have NOT located the affected product:

Please use the attached SIGNUS contact form (page 4) for your feedback and send it to **SIGNUS** by April 30th 2021.

3. Disclosure of the information described here:

Please make sure within your organization that all users of the affected product and other persons to be informed receive this Urgent Field Safety Notice.

If you have provided the products to third parties, please forward a copy of this information or inform the contact person listed below.

Please retain this information until the action at your facility has been completed.

4. Contact:

For product replacement of affected devices please contact:

SIGNUS Medizintechnik GmbH
attn. Renate Kasper
Industriestr. 2
63755 Alzenau
Deutschland

Tel.: 06023 / 9166-148

FAX: 06023 / 9166-161

e-mail: r.kasper@signus.com

For more information about this Urgent Field Safety Notice please contact:

Mr. Frank Oczkowski – Quality management officer

Tel.: 06023 / 9166-216

FAX: 06023 / 9166-161

e-mail: qm@signus.com or f.oczkowski@signus.com

If you have any questions about the product, our sales representatives or your SIGNUS customer service team is always at your disposal.

Frank Oczkowski
Quality management

Attachement:

Biopsybell: URGENT SAFETY NOTICE – FSN01-2021

Fax / e-mail Reply

To: SIGNUS Medizintechnik GmbH, Industriestr. 2, 63755 Alzenau, GERMANY

Subject: BIOPSYBELL FSN

Customer: _____

Contact: _____

Address: _____

Post code: _____

Please confirm receipt of customer information to meet regulatory requirements with this response:

I have received this Urgent Field Safety Notice.

SM-SF0927, LOT 19123119

Quantity on stock:

Quantity of pieces we return to SIGNUS.

SM-BAN1115D, LOT 2003722:

Quantity on stock:

Quantity of pieces we return to SIGNUS.

Date / Signature

Name / Position

Please send this Reply form until **April 30th 2021**:

FAX: +49 (0) 6023 – 9166 161

or

e-mail: sicherheitsbeauftragterQM@signus.com

or: QM@signus.com or kunden@signus.com