

Customer address

4th June 2020

Customer information

Urgent Field Safety Notice

Wrong labelling – wrong package contents

Affected product: JASPIS ST

REF	Description	LOT
NCL00061814	JASPIS ST, Cervical Cage straight 6x18x14mm 0°	820822-AE
NCL08061814	JASPIS ST, Cervical Cage angled 6x18x14mm 8°	820822-AE

Dear Sir or Madam,

As part of SIGNUS 'responsibility for product and patient safety, you are hereby issued with a Notice of Urgent Safety Information that we seek your assistance to implement.

1. Problem description including root cause analysis:

A customer complaint has revealed that the following medical devices were packed with a wrong declared lordosis angle JASPIS ST device.

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Our investigations revealed that a product mix-up occurred. Sterile packaging of the one article was packed in to the outer packaging of the other article.

Only these two articles mentioned and this single batch (LOT) are affected.

Due to the fact that multiple reviews of the product identity by the user are performed prior to use, a low risk to the patient is assumed.

However, there is a potential risk that in a particular case the necessary implant might not be available.

2. Identification of affected medical devices:

The product JASPIS ST and the only affected article number and batch can be clearly identified by the product identification. Figure 1 and 2 show the label of the outer carton:



Figure 1: Label Outer carton 0°



Figure 2 : Label outer carton 8°

3. What action is expected from your side?

The product tracking showed that your facility has received at least one of these devices. Please check immediately if the product is with you.

3.1 You have located the affected product?

Please make sure all products of this reference are blocked for further use immediately.

Please return all affected products to SIGNUS immediately.

Please use the reply form attached on page 4.

In case the products have already been returned to SIGNUS, please **just** send us the completed form on page 4.

You will receive replacements for the products affected immediately.

Contact details – please see chapter 5.

3.2 You have NOT located the affected product:

Please use the **reply form attached** on page 6 for your feedback and send it back by **June 12th 2020**.

4. Disclosure of the information described here:

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

If you have given 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.

The Federal Institute for Drugs and Medical Devices has received a copy of this Urgent Field Safety Notice.

5. Contact:

For product replacement of affected devices please contact directly:

SIGNUS Medizintechnik GmbH
Mrs. Elisa Albert
Industriestr. 2
63755 Alzenau
GERMANY

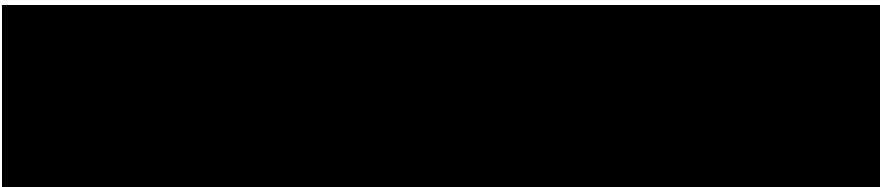
Tel.: 06023 / 9166-145

FAX: 06023 / 9166-161

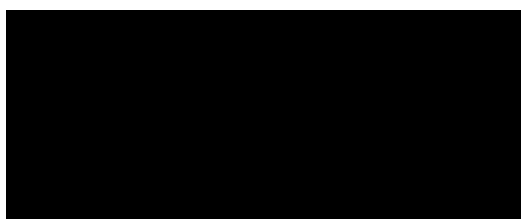
e-mail: kunden@signus.com or e.albert@signus.com

You will receive immediate replacement for the affected devices.

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



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



Fax / e-mail Reply

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

Subject:

Customer information about JASPIS ST, item no.:

NCL00061814, LOT 820822-AE

NCL08061814, LOT 820822-AE

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.

NCL00061814, LOT 820822-AE:

Quantity of pieces handed over to SIGNUS employee on date

or

We return by courier pieces to SIGNUS.

NCL08061814, LOT 820822-AE:

Quantity of pieces handed over to SIGNUS employee on date

or

We return by courier pieces to SIGNUS.

Date / Signature

Name / Position

Please send this Reply form until **June 12th 2020**:

FAX: +49 (0) 6023 – 9166 161

or

e-mail: sicherheitsbeauftragterQM@signus.com

or: QM@signus.com