SIGNUS Medizintechnik GmbH, Industriestr. 2, 63755 Alzenau

Diemme srl C/O la Società S.G.M.
Via R. Luxemburg, 27/29
20085 Locate Triulzi (MI)
ITALY

8th Aug. 2019

Customer Information

Urgent Field Safety Notice

Labelling Error – Wrong Contents in Package
Affected Product: RABEA

REF	Description	LOT
WK061214	RABEA PEEK Cervical cage angled 6x12x14mm 5°	815993-KU

Dear Sir or Madam,

As part of SIGNUS' responsibility for product and patient safety, you hereby receive a notification about an Urgent Safety Information for the implementation of which we seek your assistance.

1. Problem Description Including Root Cause Analysis:

A customer complaint has revealed that a product in sterile packaging

REF	Description	LOT
WK061214	RABEA PEEK Cervical cage angled 6x12x14mm 5°	815993-KU

was found in the outer packaging of the following product:

REF	Description	LOT
B070928	MOBIS PEEK Lumbar cage straight 7x9x28mm 0°	815993-CC

Our investigations revealed that a product mix-up occured. At present we are assuming that the mix-up happened during the packaging process.
Consequently, it is possible that in an outer packaging of RABEA, REF WK0612114, LOT 815993-KU, there could in fact be a MOBIS cage, REF B070928, instead of the RABEA cage.
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 Medical Devices Affected:

The product RABEA and the only article code and lot number affected can be clearly identified by the product identification labels. Figure 1 shows the label on the outer packaging (folding box):

Label on Outer Packaging
Figure 1

Figures 2 and 3 show the correct content of the folding box:

Product RABEA

Label on inner sterile packaging

Figure 2

Label Sheet

Implant Identity Card

Figure 3

3. What Action is to be Taken from your Side?

The product tracking showed that your facility received the product RABEA, REF WK061214, LOT 815993-KU.
Please check if the product is with you.

3.1 You Have Located the Product Affected?

You may have all devices RABEA, REF WK061214, LOT 815993-KU, in your stock replaced by our customer service (contact see chapter 5).

Alternatively, you can carry out the following control steps yourself:

- Remove the protective film from the outer packaging without damaging the label
- Open the package at the bottom and compare the label on the folding box with the label on the sterile packaging as shown in fig. 2 and 3.
-

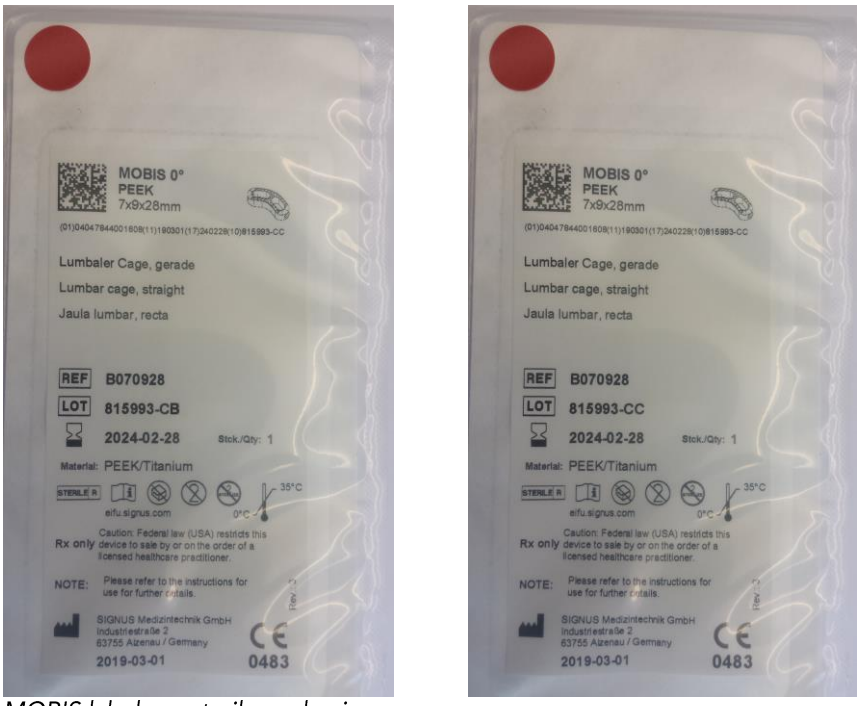
If the content matches the sample photos shown in figures 2 and 3, you can safely use the medical device.

If the content does NOT match the sample photos shown in figures 2 and 3, please return the product to us.

Figure 4 shows the possible **wrong content**:
This would be MOBIS, REF B070928, LOT: 815993-CB or LOT 815993-CC.

Please use the **reply form attached** on page 6 for your feedback and return it by August 20th 2019. Thank you.

wrong product MOBIS



MOBIS labels on sterile packaging

Figure 4

3.2 You Have NOT Located the Product Affected:

Please use the **reply form attached** on page 6 for your feedback and return it by August 20th 2019. Thank you.

4. Disclosure of the Information Described Herein:

Please make sure that all users of the product affected and other persons to be informed receive this Urgent Field Safety Notice by your organization.
If you have already handed over the products to third parties, please forward a copy of this information or inform the contact person listed below.

Please keep this Customer 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 Person:

For a product replacement or for the return of the products identified by you as FALSE please contact:

SIGNUS Medizintechnik GmbH
Mrs. Renate Kasper
Industriestr. 2
63755 Alzenau
GERMANY

Tel.: 06023 / 9166-148
FAX: 06023 / 9166-161
e-mail: r.kasper@signus.com

You will receive a replacement for the product returned immediately.

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

Mr. Frank Oczkowski – Quality Management Representative
Tel.: 06023 / 9166-216
FAX: 06023 / 9166-161
e-mail: f.oczkowski@signus.com

Should you have any questions on the product, our sales representatives or our SIGNUS customer service team will be happy to assist you.

Frank Oczkowski
Quality Management

Fax / E-mail Reply

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

Subject:
Customer Information on RABEA, REF WK061214, LOT 815993-KU

Customer: Diemme srl C/O la Società S.G.M.

Contact person: _____

Address: _____

Post code: _____

Please confirm the receipt of our customer information with this reply form in order to meet regulatory requirements:

I have received the Urgent Field Safety Notice.

We would like to have the products affected exchanged: YES / NO

In case of „YES": Quantity: ……

In case of „NO":

The examination of the products being in our stock has revealed the following:

Stock acc. to SIGNUS Files (Quantity)	REF	LOT	Quantity of Articles Implanted	Quantity with Correct Content on Stock	Quantity with Wrong Content on Stock
2	WK061214	815993-KU			

Date / Signature Name / Position

Please return this Reply form until August 20th 2019 to:

FAX: +49 6023 – 9166 161

e-mail: sicherheitsbeauftragterQM@signus.com
or: QM@signus.com