biocon Medizintechnik GmbH | Triebweg 1-3| 63933 Mönchberg | Germany

biocon Medizintechnik GmbH
· OP-Sets
· Medizinische Schlauchsysteme
· Kundenindividuelle Lösungen

Urgent Field Safety Notice

Recall

concerning certain article numbers and batches of procedure packs

biocon reference number: **FID 193 O**

5th January 2022

For the attention of: Sales customers, clinical staff, risk managers and PRRC

Dear valued customer,

With this letter we would like to inform you that biocon Medizintechnik has issued a safety notice concerning the following products:

Identification of the affected products

Article number	Lot number
91373054	11040/A
91483001	11040/A
91483027	11040/A
92203668	11040/A
92603350	11040/A
92603918	11040/A
92603975	10939/A
92604089/2	10939/A
92604177	11040/A
92604255	11040/A
93153009	10939/A
93153010	10728/A
93153015	10939/B
93153016	11040/A
93452445	11040/A
95103089	10939/B
95103175	11040/A
95103197	10417/B
95103197	10624/B

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info@biocon-online.de
www.biocon-online.de

HypoVereinsbank Aschaffenburg
BIC (SWIFT): HYVEDEMM407
IBAN: DE85 7952 0070 0366 8300 06

Postbank Nürnberg:
BIC (SWIFT): PBNKDEFF
IBAN: DE89 7601 0085 0000 5418 52

Sitz der Gesellschaft:
Mönchberg

Ust.-ID-Nr.:
DE 132076541

Geschäftsführer:
Gerhard Pfetzing
Jutta Pfetzing

Amtsgericht:
Aschaffenburg HRB 2636

In this context, we ask for your assistance!

With this **urgent field safety notice** we inform you about:

- What exactly the problem is.
- What measures must be taken by the customer/user to avoid endangering patients.

The **urgent field safety notice** contains information on the identification of the affected items as well as instructions on the required measures. Please follow the information in this document in the section **" What measures are to be taken by you?"**

Problem description:
Routine testing of the surgical gowns contained in the affected biocon surgical sets revealed an unusually high microbiological load prior to sterilization. Therefore, biocon had the sterility of the surgical gowns contained in selected sterilized surgical sets tested in accordance with ISO 11737. These conducted tests have shown that the sterility of the products cannot be guaranteed.

Potential risk:
The surgical gowns do not have direct patient contact when used as intended. However, contamination of the surgical staff in the sterile field may occur due to possible contamination of the products during handling.
To date, we are not aware of any incidents resulting from the use of these products. However, patients may suffer from inflammations caused by possible contamination of the products.

What measures are to be taken by you?
Please return all affected procedure packs available at your company to biocon Medizintechnik.
Please confirm the quantity of returned procedure packs in the customer feedback form in the attachment.
Please also inform us about the quantity of the already used procedure packs in the customer feedback form in the attachment.
Please also forward this urgent field safety notice including the customer feedback form to your customers / the users, if applicable.
Please forward all customer feedback, including feedback from your customers, to biocon Medizintechnik immediately.

Forwarding of the information described here
Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this **urgent field safety notice**.

Please confirm receipt of this letter and the implementation of the measures within 5 working days using the attached customer feedback form.

If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.
Please keep this information at least until the measure has been completed.
The German Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this urgent field safety notice.

Contact person:
For questions regarding this urgent field safety notice, please contact

Biocon Medizintechnik GmbH
Abteilung Qualitätsmanagement
Triebweg 1-3
D-63933 Mönchberg

Dr. Monika Knuth

Tel. +49 9374 9730 34
Fax +49 9374 7311
complaints@biocon-online.de

For questions regarding existing orders, please contact OP-Sets@biocon-online.de

This corrective action has already been reported to the relevant authorities.

We thank you for your support and cooperation and apologize for any inconvenience caused.

Sincerely yours,

Biocon Medizintechnik GmbH

[redacted]

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Customer Feedback Form

1. Field Safety Notice (FSN) Information

FSN reference number:
FSN Date: 5th Januar 2022
Internal reference number: FID 193 O

2. Actions carried out at the customer:

☐	I hereby confirm that I have read and understood the attached safety information.	Please mark with a cross or cancel with N/A
☐	This safety information has been forwarded to the relevant people within the organization.	Please mark with a cross or cancel with N/A
☐	This safety information has been forwarded to relevant customers / users.	Please mark with a cross or cancel with N/A
☐	I confirm that I have implemented the measures to be taken accordingly and have returned the following items to biocon.	Comments:

	Article number	Lot number	Total amount	Amount returned	Quantity already used

3. Customer data:

Name of Organization	
Name of signer	
Date, Signature	

4. Reconfirmation to the sender

E-mail	complaints@biocon-online.de
Fax	+49 9374 7311
Return deadline	15th January 2022