

ESSITY/BSN-Letterhead

BSN ADDRESS

NAME OF RESPONSIBLE (The responsible for the recall in this country)

DATE

Customer's address

**Urgent Field Safety Notice**

***Recall***  
***concerning***

**CUTISOFT PACK *Catheter Change Set***

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***Concering all users of Cutisoft Pack Catheter Change Set***

***Identification of Affected Devices:***

<i>Cutisoft Pack Catheter Change Set</i>
REF: 71116-01
LOT-Code(s): all LOT numbers

***Description of the problem:***

We would like to inform you about a possible problem with the sterility of the cardboard container that can be used as a carrier for the components in the kit and which is included in the above mentioned *Cutisoft Pack Catheter Change Set*.

We were informed by our supplier that they have found cases of non-sterile containers in sterilized sets.

Potential Hazard: This problem may result in the use of a non-sterile procedure set in a sterile working environment and the contamination of sterile equipment which increases the risk of infection.

***What measures should be taken from you?***

Please check your stock of *Cutisoft Pack Catheter Change Set*

and send back all goods of the above listed order number (REF) 71116-01 of any lot code (LOT) you hold on stock.

To simplify processing for you, please find attached a fax response form and prepared labels for the return.

Please indicate on the fax response form:

- \_ the number of goods to be taken back,
- \_ the date of when we may collect the goods, and
- \_ the place where we can pick up the items.

Please also use the fax form to inform us in case you have already used up all the products from the above-mentioned lots in full.

After having received your fax response we will arrange for collection of the affected goods by **NAME OF COURIER TO BE FILLED IN**.

We apologize for any inconvenience that might be associated with this recall.

Please be assured that the quality of our products and their reliability in daily use are our highest priority.

***Disclosure of the information described here***

Please ensure that all users and individuals to be informed in your organization receive informational aware of this Urgent Field Safety Notice.

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

Please keep this information at least as long, until the recall action has been completed.

The German competent authority - Bundesinstitut für Arzneimittel und Medizinprodukte - has been provided with a copy of this Urgent Field Safety Notice.

***Contact Person***

Our colleague, **NAME; PHONE NUMBER TO BE FILLED IN** is at your disposal for any questions.

Yours sincerely,

Essity/BSN medical GmbH

Attachment: Fax response form

Appendix 1:

Name and address of the customer:

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**Please send back via e-mail to the given address:**

[anna.wroblewska@tzmo-global.com](mailto:anna.wroblewska@tzmo-global.com)

**till the day: 31.08.2019**

**Toruńskie Zakłady Materiałów Opatrunkowych SA**

**87-100 Toruń, Poland**

**ul. Żółkiewskiego 20/26**

**Withdrawal from trading of sterile MATOSET sets in accordance with Appendix 2 containing the detailed list of products.**

We confirm the receipt of the information sent by **Toruńskie Zakłady Materiałów Opatrunkowych SA** with the date of 23.08.2019 and forwarding it to all persons who should receive this information in our organisation or to all other organisations where the products listed in Appendix 2 have been provided.

The result of our inventory evaluation is as follows:

Please tick as appropriate:

After careful examination, no inventories affected by the defect were found

Existing stock:

Invoice no. / material release receipt	Product code	Product name	Batch number	Quantities returned

We confirm that all these products have been blocked and will be:

Please tick as appropriate:

returned to TZMO SA

destroyed on the spot and confirmation sent to TZMO SA

Date: \_\_\_\_\_

Stamp and Signature

## Appendix 2

List of withdrawn sterile MATOSET sets:

Product code	Product name
<b>MA-991-ZEST-013</b>	<b>EX DK ZESTAW DO ZMIANY OPATRUNKU J TPF</b>