

Important Safety Information – Safety Notice

Company sending the information: Toruńskie Zakłady Materiałów Opatrunkowych SA
87-100 Toruń, ul. Żółkiewskiego 20/26, Poland

Trade name of the product which the notice relates to:
MATOSET sterile sets (with components made of gauze with X-ray detectable thread)

List of product codes in **Appendix**.

FSCA identifier (Field Safety Corrective Action): RI/17.01.2020.

Corrective actions: product recall

Date: **20/01/2020**

For information to: Customers who have received the products listed in **Appendix** to this notice.

Problem description:

As a result of internal control and basing on the information obtained from the dressing gauze supplier, we would like to inform you that the aforementioned gauze products can potentially contain crumbling X-ray detectable thread.

So far, we have not received any complaints or reports about adverse events from the market.

Potential hazards: This problem may result in leaving a fragment of the device in the patient's body, and as a result may cause additional complications, granulomas formation, severe patient pain, and the possibility of reoperation.

Recommended actions that the user should take:

For safety reasons, we have decided to stop the production and withdraw the products containing the defective X-ray thread.

We kindly ask you to complete the attached form (**Appendix**) and send it to the address provided.

We apologise for the inconvenience caused by shortages in product deliveries and thank you for your understanding! We want to ensure you that patient safety is most important to our company.

Forwarding the safety notice:

This notice should be forwarded to all persons who should be informed about this event within your organisation and to all other organisations where the listed products have been transferred. Please take the appropriate actions.

Please keep knowledge of this notice for an appropriate period of time and any actions initiated as a result of this to ensure that corrective actions are effective.

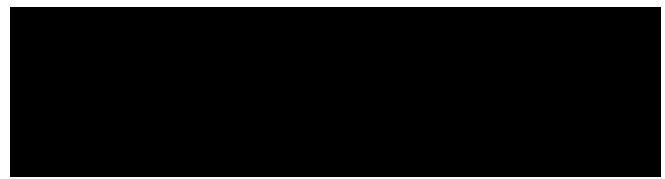
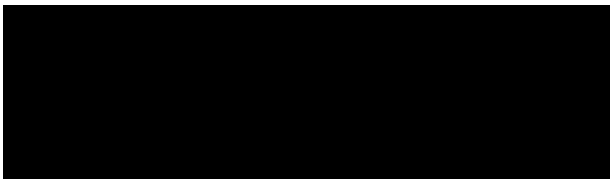
Contact person:

Name and Surname: Joanna Muzioł

E-mail address: : joanna.muziol@tzmo.de

Phone number: +49333745132976

The undersigned confirms that this notice has been forwarded to the appropriate authority competent for the countries where the product is sold.



Appendix:

Name and address of the customer:

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Please send back via e-mail:

joanna.muziol@tzmo.de

Toruńskie Zakłady Materiałów Opatrunkowych SA
87-100 Toruń, Poland
ul. Żółkiewskiego 20/26

till the day: 10.02.2020

Withdrawal from trading of MATOSET sterile sets (with components made of gauze with X-ray detectable thread) in accordance with the detailed list of products:

Product code	Product name	LOT NR
MA-991-ZESA-661	EX DE MEDIKA ZESTAW ZABIEGOWY: KINDER-SET X-RAY TPF J D	190511P
		191115P
		190715P
		191121P

We confirm the receipt of the information sent by **Toruńskie Zakłady Materiałów Opatrunkowych SA** with the date of 20.01.2020 and forwarding it to all persons who should receive this information in our organisation or to all other organisations where the products listed in above have been provided.

The result of our inventory evaluation is as follows:

Please tick as appropriate:

After careful examination, no inventories affected by the potential 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