

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:
MATOCOMP gauze swabs non sterile 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 (**Appendix**).

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 1**) 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.

Our Representative as well as the Customer Service Department provide help and advice:


Contact person:


Name and Surname: Liga Goldberga

E-mail address: liga@tzmo.lv

Phone number: +371 67382585

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

Signature  *Agnieszka Górna*
Member of the Management Board
Member of the Board TZMO SA

.....  *Jolanta Kruszyńska*
Pełnomocnik Prezesa Zarządu ds. zarządzania jakością
Management representative for QM, TZMO SA