

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:

MATOSSET, Sets with cardboard dishes. List of product codes in **Appendix 2**.

FSCA identifier (Field Safety Corrective Action): RI/22.08.2019.

Corrective actions: product recall

Date: **23/08/2019**

For information to: Customers who have received the products listed in **Appendix 2** to this notice.

Problem description:

We would like to kindly inform you about a possible problem with the sterility of the cardboard container that can be used as a carrier tray for sterile medical instruments/devices.

The component is included in the specified MATOSSET sets listed in **Appendix 2**.

The cardboard containers are intended for the reception of waste and/or as a collection container for smaller waste in the medical field for short-term use.

One of our suppliers of the cardboard containers has found cases of non sterile containers in sterilised sets which could have infected instruments and products.

Potential hazards: This problem may result in the use of a non sterile surgical set **in** the surgical area and the contamination of surgical equipment, potentially infecting patients.

Recommended actions that the user should take:

For safety reasons, we have decided to stop the production and withdraw the sets containing cardboard containers.

As of August 6, 2019, sets with cardboard containers are not manufactured and implemented on the market.

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: TZMO Benelux, Martin Bulthuis

E-mail address: m.bulthuis@tzmo.nl

Phone number: 06-31647085

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

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