

Date 20. February 2024

Safety notice | Urgent notification: Risk of infection. Non-sterile products from Andratec have been stolen

To whom it may concern,

Andratec GmbH hereby issues a safety notice regarding stolen medical devices. These products were stolen on their way to Andratec between 31. January 2024 and 07. February 2024.

Required actions

- Check your stocks for affected products
- Discard such products
- Check all incoming shipments for affected products

If there is suspicion or certainty that the non-sterile products listed below have been used, it is recommended that healthcare professionals monitor and treat patients for adverse events such as post-operative infections.

If any of the medical devices listed below are already in your current stock or if such product batches will be delivered in the future, please do not use these products and contact Andratec at +49(0) 261 100 49 653.

The table below contains a complete list of all affected products, including product description, product code and lot number. Please note that only the material listed in the table below is affected. No other Andratec products are affected by this safety notice.

Product name	Product description	Product code	Lot number
AltoSa-XL-Gemini Balloon Catheter	Balloon catheter for the dilation of stenoses in vessels. For the insertion, dilatation and post-dilatation of balloon-expandable stents/stent grafts.	GM-16-40	385661
AltoSa-XL-Gemini Balloon Catheter		GM-16-30	385645
AltoSa-XL-Gemini Balloon Catheter		GM-16-30	385646
AltoSa-XL-Gemini Balloon Catheter		GM-18-30	385663
AltoSa-XL-Gemini Balloon Catheter		GM-16-40	385661

We are very grateful for your increased vigilance with regard to suspicious transactions in connection with the above-mentioned medical products. For example, unusually low price offers could indicate that the products have been stolen.

Anyone with information about this incident or who has received unsolicited offers for the above medical devices after the date of the theft is urged to contact AndraTec on +49(0) 261 100 49 653.

Please forward this message to all medical personnel in your organization who need to be informed of these procedures and to any organizations to which potentially affected products may be forwarded.

The authorities responsible for you have been informed of this safety notice.

We regret any inconvenience and thank you for your understanding that we are taking this action to ensure patient safety and customer satisfaction

If you have any further questions or require support regarding this safety notice for practical use, please contact AndraTec on +49(0) 261 100 49 653.

With kind regards,



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