TROKAMED GmbH · Kleine Breite 17 · 78187 Geisingen

22.07.2026

Field Safety Notice (FSN)

Update to the Instructions for Use (IFU) Regarding the Contraindication for CIDEX® OPA Disinfectant

Applicable to

IFUs listed in Appendix

Issuer:	TROKAMED GmbH Kleine Breite 17 78187 Geisingen Germany
Adressee:	Users, Operators and Distributors of the Product
Identification of the affected Medical Devices:	Instructions for Use (IFUs) – Recommended Disinfectant (see Appendix)
Description of the Problem, Including the Identified Cause	Description of the Issue As part of our ongoing post-market surveillance activities, we identified that the Instructions for Use (IFUs) for our products do not include an important safety warning regarding the reprocessing disinfectant. The manufacturer of the disinfectant CIDEX® OPA specifies the following contraindication: *"CIDEX OPA should not be utilized to process any urological instrumentation used to treat patients with a history of bladder cancer."* As our products may be reprocessed using this disinfectant, this contraindication is relevant to the reprocessing of our products. Corrective Action / We have promptly revised the Instructions for Use (IFUs) for the affected products by adding the above contraindication to the section containing validation information for reprocessing. Root Cause: Compliance with the existing requirement to include relevant cleaning and reprocessing validation studies in the Master Validation Plan was not adequately monitored and verified.

	At this time, we are not aware of any incidents or adverse health effects affecting patients or users related to this issue. This action is being taken as a precautionary measure to complete the safety and reprocessing information in accordance with the manufacturer's instructions for CIDEX® OPA. Potential Health Risks The active ingredient in CIDEX® OPA (ortho-phthalaldehyde, OPA) may increase the risk of severe allergic reactions in patients with a history of bladder cancer. In addition, anaphylactic reactions may occur if instruments reprocessed with OPA retain residual disinfectant that comes into contact with the mucous membranes of the urinary tract.
Actions to be taken by the Adressee	• Inform all medical personnel using the affected products of this Field Safety Notice. • Ensure that all users and reprocessing personnel are specifically informed of the updated contraindication regarding the disinfectant CIDEX® OPA. • Replace the current Instructions for Use (IFUs) with the enclosed updated versions (see Appendix). This action does not constitute a product recall or reportable incident. The affected products may continue to be used, provided that this Field Safety Notice and the updated Instructions for Use are followed. • If you are uncertain whether the disinfectant used is appropriate for your patient population, temporarily discontinue its use for reprocessing these instruments and contact the disinfectant manufacturer for further guidance.

Dissemination of This Field Safety Notice
Please ensure that all users of the above-mentioned products and all other relevant personnel within your organization are made aware of this **Field Safety Notice**. If you have supplied the affected products to third parties, please forward a copy of this notice to them or inform the contact person listed below.

A copy of this Field Safety Notice has been submitted to the German Federal Institute for Drugs and Medical Devices (BfArM).

If you have any questions or concerns regarding this notice, please contact your local distributor.

[redacted]

Field Safety Notice Reference Number: 2026-01