

Field Safety Notice

Supplement and more precise information for product data sheets/advice for users for MELAdes 800 and MELAdes 801

Sender:

MELAG Medizintechnik GmbH & Co. KG
Geneststraße 6-10
10829 Berlin
Germany

Addressee:

To all distributors

Identification of the medical devices concerned:

Product designation	Product number
MELAdes 800 Instrument disinfection 2x5L	11803
MELAdes 800 Dosing bottle 1L	11804
MELAdes 801 Drill disinfection 2x5L	11811

Description of the problem including the determined cause:

The instructions of use for the MELAdes 800 and MELAdes 801 products do not fully comply with the German KRINKO-BfArM recommendation regarding the treatment and preparation of reusable medical devices.

The KRINKO-BfArM recommendation clearly describes in two separate work steps "disinfecting cleaning" and subsequent "disinfection". The intention here is to reduce potential transfer of contaminations into the disinfection phase.

The unmistakable clear reference to these two separate work steps is not included in the product data sheets of MELAdes 800 and MELAdes 801 products.

The current data sheet of the MELAdes 800 also contains the statement "Its excellent cleaning power enables disinfection and cleaning in a single work step". The MELAdes 800 and MELAdes 801 products can basically clean and disinfect at the same time according valid certificates. This property is also used purposefully in the "disinfecting cleaning" for the protection of the user. This note naturally does not exclude carrying out the second preparation/treatment step of "disinfection" separately according to the KRINKO-BfArM recommendation, but could be misinterpreted by qualified personnel with poor professional knowledge.

Risk consideration: According to the underlying test and certificates, the effectiveness of MELAdes 800 and MELAdes 801 has been demonstrated with "high organic exposure (dirty conditions)", according to the VAH Directives. If users follow the specification in the product data sheet regarding the immediate changing of the working solution at least daily or in case of visible dirt, the risk of insufficient disinfection effectiveness is unlikely for the subsequent further preparation/treatment of the medical devices. Rather, proper cleaning is decisive for these further treatment/preparation steps.

It has been decided to supplement and more precisely describe the usage of the MELAdes 800 and MELAdes 801 products according to the KRINKO-BfArM recommendation.

The technical product data sheets of the instrument disinfectant MELAdes 800 and MELAdes 801 have been thoroughly revised. In particular, clear separation of the cleaning and disinfection in two separate work steps in compliance with the KRINKO-BfArM recommendation has been incorporated as follows:

“Disinfecting cleaning” in the immersion bath method: Place the instruments, after any preliminary cleaning that may be necessary, into the working solution and clean mechanically where required. All surfaces and cavities must be wetted completely by the working solution. After the exposure time has elapsed, rinse the instruments thoroughly with water and continue processing. Change working solution if there is any visible contamination but at least once every working day.

“Disinfection” in immersion bath method: Place the instruments, after any preliminary cleaning, into the working solution. All surfaces and cavities must be wetted completely by the working solution. After the exposure time has elapsed, rinse the instruments thoroughly with suitable water, dry and, where necessary, continue processing. Change working solution if there is any visible contamination but at least once every working day.

Actions to be carried out by the distributors

Please ensure, through your organisation, that all users of the above-named products and other persons to be informed receive knowledge of this Field Safety Notice. If you have handed over the products to third parties, please forward a copy of this information to them.

Please keep this information, at least until the action has been completed.

Please send us verifying documentation that all users have received knowledge of this corrective action.

The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte) has received a copy of this “Field Safety Notice”.

Contact:

Guido Schröter
Safety Officer for Medical Devices
Phone: +49 30 757911-1092
Fax: +49 30 7579977- 99
Email: schroeter@melag.de

With best wishes,

MELAG Medizintechnik GmbH & Co. KG

