Instruction leaflet for Risk Class I medical devices made by the company Kögel:

CE

Applies to: Kögel medical devices, MEDSolutions V211, article no. 22.216.*****; 28.216.*****;
product name: Wistainer, small-parts trays, instrument trays, endoscopy baskets, sterile goods baskets and components.

Manufacturer: Kögel GmbH, D-75038 Oberderdingen, Germany

Contact:

Kögel GmbH	T.: +49 (0) 7045 982-0
MED Solutions	F: +49 (0) 7045 982-22
Hagenfeldstr.4	e-mail: med@mk-koegel.de
D-75038 Oberderdingen, Germany	Web: www.mk-koegel.de

Symbols used:

See instruction leaflet

Attention

CE certification marking

Manufacturer article number

Store in a dry place

Protect against sunlight

Not sterile!

Important general safety information:

By purchasing one of the above devices, you have acquired a high-grade Kögel medical device, Risk Class I according to Regulation (EU) 2017/745. The devices are reusable. They are made entirely from stainless steel and are used for organising, storing, transporting and subsequent reprocessing of medical instruments. The intended areas of application are medical care, diagnostics and treatment. The components of Kögel devices must be selected in accordance with their intended use and may have to be ordered individually. Our Sales team will be happy to assist you with all their dedication and expertise. Please also see our reprocessing instructions.

Please read the entire instruction leaflet and reprocessing instructions carefully prior to using the device for the first time. Always act as instructed in these leaflets. Keep the instructions in a safe place.
The above devices may only ever be used and reprocessed by suitably qualified personnel.

If these devices are used for patients with Creutzfeldt-Jakob disease (CJD) of even if CJD is only suspected, the device must not be used again and has to be destroyed instead. Please follow the guidelines published by the Robert Koch Institute (RKI).
When reprocessing the devices (cleaning, disinfection, drying and sterilisation), temperatures may rise to up to 134 °C. This means that improper handling may cause injuries. Wear protective gloves when handling the devices.
Once reprocessing is complete, the devices must be checked for damage and correct functioning. Damaged devices must be replaced immediately (risk of infection as a result of injury to the skin).
Only the manufacturer may make repairs. Only dispose of devices once decontamination is verified. Components containing plastic parts are not suitable for plasma reprocessing. Components containing plastic parts are not suitable for hot-air reprocessing. This may cause permanent damage or destroy the components.

Do not stack more than three organised devices on top of each other!
Do not stack more than five open, unorganised devices on top of each other!

The packaging of our devices must be disposed of in line with environmental protection guidelines after receipt. Please check your local regulations.
The maximum loading weight of a device with the base dimensions 1 STE must not exceed 10 kg! Mechanical overloading of devices may cause destruction when in use, resulting in injuries.
When transporting the devices, please comply with our reprocessing instructions, instructions for storage and transport, and the instructions of the Instrument Reprocessing Working Group (Arbeitskreis Instrumentenaufbereitung, AKI).
Devices may only be moved and transported by trained professionals.
When using a laser workstation, you must comply with the pertinent legal regulations (avoiding uncontrolled reflection).

Our devices are supplied in non-sterile form. Prior to first use, they must complete a certified machine reprocessing cycle. Please also comply with any internal hygiene regulations of your facility as well as national and regional hygiene regulations for medical practices, reprocessing centres and/or hospitals!

1. **Operating life:**
   The operating life of the devices is not limited. In compliance with standards DIN 58952-2, DIN 58952-3, they can be used for at least 500 utilisation cycles. The minimum operating life of all elastomers is 350 utilisation cycles. Irrespective of the above minimum utilisation cycles, you are responsible for checking the devices for further suitability for use after each use!

2. **Functional check:**
   You can find information on the functional check in our reprocessing instructions.
   Functional checks must always be performed by trained and qualified professionals! The selection of methods and processes is your responsibility. Guidelines are provided in the requirements published by the Deutsche Gesellschaft für Sterilgutversorgung (DGSV) and the Instrument Reprocessing Working Group (AKI).
   The reprocessing entity is responsible for ensuring that reprocessing with the selected equipment, materials and personnel yields the desired results. The success of reprocessing is the sole responsibility of the operator.
   To check the functioning of the Kögel medical devices after reprocessing and prior to new instrument organisation, all components of the product in question should be at least inspected visually. Each frame and wire mesh (corpus) and all components must be checked for damage.
   Visual check of the silicone instrument holders for surface damage. Damaged parts must be replaced immediately! Risk of injury/infection!
   Furthermore, a batch check should be performed using at least three identical devices.
   Please return any defective device you find fully reprocessed and clearly labelled using the return form to Kögel GmbH for technical inspection. Label the packaged device!

3. **Tray organisation / equipping:**
   The devices may only even be equipped and organised under specialist medical supervision!

4. **Storage and transport:**

    The aforementioned devices may only be stored and transported in clean, dry, well-ventilated rooms and using transport equipment that is easy to clean and disinfect. Transport must comply with the specifications set out in DIN 58983-8 for transporting sterile goods.

5. **Return form:**
   Any issues with the device, including its accessories, must be reported using the attached return form!
   Please report serious incidents connected to the devices to the manufacturer and the competent authorities.

6. **Limitation of liability:**
   Kögel GmbH, Oberderdingen, Germany does not accept any liability for any application, reprocessing or use of the products, including their components, that is not in line with this instruction leaflet. This leaflet assumes use as intended as well as professional operation and reprocessing.

7. **Warranty:**
   The warranty period is outlined in the general terms and conditions of Kögel GmbH and starts on the day of delivery/commissioning by Kögel or a specialist company authorised and named by Kögel. Any violation invalidates the warranty. If you have any questions regarding the service, compatible components or warranty, please contact Kögel GmbH by e-mail to the following address: med@mk-koegel.de.

Oberderdingen, on 19 July 2021