Reprocessing instructions/disinfection of Class I products from Dr. Arabin GmbH & Co KG Perfektan Active® by Dr. Schumacher

(e.g. fitting sets for urogynaecological pessaries/vaginal dilators)

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The reprocessing of semi-critical medical devices is a key aspect of hygiene in accordance with the recommendations of the Commission for Hospital Hygiene and Infection Prevention and the Federal Institute for Medicines and Medical Devices. As a rule, semi-critical medical devices **do not necessarily** need to be **sterilized** after reprocessing, given that they are stored aseptically following disinfection and come into contact only with mucous membranes.
Our fitting sets and vaginal dilators, classified as MDR Class I, fall under the category of Class A semi-critical devices. The reprocessing for the disinfection of Class I (MDR) urogynaecological pessaries **in an immersion bath** is based on an evaluation by the manufacturer of the disinfectant PEFEKTAN ACTIVE® and therefore applies only to this specific disinfectant produced by Schumacher (see: www.dr-arabin.de/Quality/Reprosessing / www.schumacher-online.com).

Standards

EN ISO 17664 for manufacturers' information on medical devices
ISO 15883 for cleaning and disinfection
EN 14885 for the efficacy of chemical disinfectants

Warnings for Perfektan Avtive® 	None of the Class I devices should remain in the body for more than 60 minutes or subjected to forceful manipulation. Store Perfektan Active® away from direct contact with reactive substances such as gas, ozone or mineral oil, or radioactive radiation. It may intensify a fire and cause eye damage on direct contact. For safety precautions, see the Perfektan Active® operating instructions. (www.dr-arabin.de/Quality/Reprocessing)
Restrictions on reprocessing	Use only the disinfectant approved for the reprocessing of medical devices. Follow the manufacturer's instructions. Based on current knowledge, the shelf life of the pessary is limited by the material's ability to retain its mechanical properties over time due to wear and tear and sterilisation cycles (inert material). No product changes have been observed as a result of reprocessing or disinfection. Wear and tear cannot be ruled out over time with frequent use; the products must not be used if damaged.
Initial fitting at the point of use	Once fitting has been completed and the device has been removed from a patient, all parts must be cleaned. This can be done under running water (of at least drinking water quality) and, if necessary, using damp gauze or a soft brush. If necessary, use a cleaning agent suitable for the reprocessing of medical devices.
Preparation for cleaning	The surface of the pessaries should be visibly clean.

Manual cleaning and disinfection	Place the pessaries in the disinfectant solution (immersion bath); if necessary, use instrument forceps to submerge them deeply so that the surface is fully wetted inside and out. The following times have been validated to ensure effectiveness: 60 minutes in a 1% solution 15 minutes in a 2% solution. Staff should wear protective gloves tested in accordance with DIN EB 420 or 374 during cleaning and disinfection.
Final rinsing and drying	Once the exposure time has elapsed, the pessaries are removed and inspected whilst wearing new protective clothing and clean protective gloves, taking care to avoid contamination. Any rinsing must be carried out using water of at least drinking water quality, free from pathogenic microorganisms and, ideally, fully desalinated.
Machine cleaning and disinfection	Disinfection in the washer-disinfector is also possible in principle. In this case, other disinfectants must be used in accordance with EN ISO 15883-1 and -2 (cleaning and disinfection equipment), the items to be processed in the washer-disinfector must be placed in sieve trays, and the equipment manufacturer's instructions for use must be followed.
Storage	According to the guidelines of the RKI, semi-critical medical devices should, following disinfection, be stored unpackaged, dry and protected from dust and contamination (e.g. in closed cupboards, drawers or tins) in a hygienic manner in a designated, easily accessible area with restricted access, which offers protection from dust, insects, vermin and extreme temperatures (not < 1 /> 50 degrees C) and humidity.
Additional information	The instructions are recommended by the manufacturer of both the disinfectant and the medical device as SUITABLE for preparing a medical device for reuse. It is the responsibility of the healthcare facility to ensure that the reprocessing carried out by trained staff using the appropriate materials achieves the desired result. This requires validation and routine monitoring of the process. Similarly, any deviation from the reprocess or the recommendations should be assessed for efficacy and potential adverse consequences. Users should draw up a cleaning protocol for the reusable custom-made pessaries used at their sites in accordance with the recommendations and, where necessary, validate it to account for local variables.
Contact the manufacturer	See above

As the manufacturer, we confirm the reprocessing procedures described above for our semi-critical Class A products (customisation sets, vaginal dilators, Class I according to the MDR).

Witten/Berlin, 15 July 2026 Signature: 

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