de Gebrauchsanweisung
en User's Manual
fr Mode d'emploi
it Istruzioni per l'uso
es Instrucciones de empleo
pt Manual de operação
ru Руководство по применению

MEDIZINTECHNIK seit 1890
KaWe

Scheidenspekula

User's Manual
Vaginal specula

Dear buyer! Thank you for choosing a KaWe product. Our products are known for high quality and durability. This KaWe device complies with the provisions of Regulation EU 2017/745 (European Regulation on Medical Devices), whereby it is classified as a medical product of class 1.

Please, read this user's manual attentively and carefully and pay attention to the maintenance recommendations prior to use.

Application: Only qualified medical professionals can use the vaginal specula.

Intended use: A medical device for gynecological examination of the vagina and cervix.

Group of patients with indications for use: Girls/women from adolescence.

Improper use of the device/contraindications for use: Any other use of use outside the above intended use shall be considered improper. The manufacturer is not responsible for the damage caused as a result of such use; the responsibility for the risks in this case rests solely with the user. Inflammation of the labia or the vulvar vestibule can lead to mechanical damage when a speculum is inserted.

Warnings and safety instructions:

- Special attention is required when cleaning reusable tools. Do not exceed 134°C.
- Before the first sterilization, possible leftover oil or grease should be removed by cleaning the specula.

- If the speculum is inserted too quickly/ abruptly into the vagina, local pressure or, in rare cases, short-term pain may occur. The same applies to the wrong choice of the speculum size.
- KaWe specula are made of chromium-nickel steel and can cause an allergic reaction in people with a strong allergy to nickel.
- When sterilizing several devices in autoclave, do not exceed the maximum load indicated by the sterilizer manufacturer.

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Additional information: The device will serve for years with proper handling and storage.

Secondary treatment limitations: Secondary treatment has a minor effect on these devices. The service life of the product is usually defined based on the degree of wear and use-related damage. Prompt secondary processing of the tool is recommended after its application.

Instructions:

Storage: Avoid humidity and do not transport together with wet items. Exclude exposure to direct sunlight when storing and transporting. Store sterilized specula in a dry place, protected from dust and contamination.

Preparation for cleaning: Clean and disinfect immediately after use. The machine method should be generally used (washing device for tools). Prepare the cleaning and disinfection as described below. You can use any suitable cleaning/disinfecting agents listed for this purpose by the German Society for Hygiene and Microbiology (DGHM).

Manual cleaning: According to the recommendations of the Robert Koch Institute (RKI), the mechanical processing method is preferred. Manual cleaning is not recommended.

Automatic cleaning: Equipment:
310 CM (Maquet), cleaning agent (neodisher®FA forte 0,4%/neodisher®Z 0.2%)
G7828 (Miele) cleaning agent (Mucapur®XL 0.4 %/Mucapur®Z 0.15 %) WD 390 (Belimed), cleaning agent (Mucapur®AF 0.5 %/Mucapur®Z 0.1 %)

1. Thoroughly wash the tools under running water before treatment to avoid the remnants of cleaning/disinfecting agents entering the machine. **2.** Place the tools in a special container. **3.** Place the tool container in the cleaning and disinfection equipment so that the water jets directly fall on the tool. **4.** Follow the instructions for the cleaning agent dosage. **5.** Start the Vario TD program followed by thermal disinfection. Thermal disinfection is provided in accordance with the established value of A0 (the disinfection time, in seconds, at a certain temperature) and in accordance with national regulations (EN ISO 15883). **6.** When the program is completed, remove the tolls from the device for cleaning and disinfection and dry them (the Robert Koch Institute (RKI) recommends to dry with compressed air). Special attention should be paid to the places of the tool container that are difficult to reach during drying. **7.** Visual check for integrity and cleanliness with the help of a suitable magnification object (based on experience, an 8-fold magnification is sufficient for visual inspection). If there are traces of dirt on the tools after mechanical processing, repeat cleaning and disinfection until they are completely cleaned. **8.** Attention! If the instruments are only mechanical cleaned (without demonstrable disinfection), a final thermal disinfection in a steam sterilizer in suitable racks or trays is required.

Disinfection: The efficiency of the used cleaning and disinfection method must be recognized (for example, it should be listed as disinfectants and methods tested and recognized by the Robert Koch Institute/ German Society of Hygiene and Microbiology) and validated: for example, with the help of Helipur. The concentrations and exposure time are given by the manufacturer.

Sterilization: The specula can be successfully sterilized with the following parameters: Fractional pre-vacuum (three times), sterilization temperature: min. 132 °C, max. 137 °C, exposure time: at least 3 min. (full cycle), drying time: 10 min.

Recognized preparation method: The efficiency of this method was confirmed with a Maquet GM 310 disinfectant using neodisher®FA forte as a cleaning agent in combination with neodisher®Z 0.2 % as a neutralizing agent from Chemische Fabrik Dr. Weigert, Hamburg.

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Maintenance: Remove or replace the damaged parts. Surgical lubricant can be applied to moving parts, such as hinges.

Control and functional check: Check the ease of movement of moving parts, for example, installation screws. All tools: Visually check for damages and wear.

Package: Separate/Non-sterile: A standard plastic bag can be used. The bag must be of sufficient size for the item so that the clasp is not under tension. Sterile: The sterile packaging must comply with the DIN EN 868/ISO 11607 standard and be suitable for steam sterilization.

Environment conditions:

Temperature

Operation: Room temperature

Transportation and storage: from -20 °C to +65 °C

Relative humidity

30% to 75%

Disposal: After processing, the product is subject to separate collection of scrap metal in accordance with local regulations.

General accessories: To find out more about the products, visit our homepage: **www.kawemed.com**

Manufacturer: **KaWe**

Manufacturer's contact details: Dealer's address or phone number: +49-7141-68188-0.

Basic UDI-DI: 4030155KaWe1104Z6

Legend:

	Attention		CE conformity mark
	Manufacturer & date of manufacture		Article number
	Lot code		Medical device
	Please follow the User's Manual		UDI Data Carrier

Warranty: The warranty for the device totals two years from the date of purchase with proper handling and following the operation manual. If you have any additional questions or need repair, please, contact your dealer.

Information for users and patients:
All serious incidents involving this device must be immediately reported to the manufacturer and the competent authorities of the respective Member State in which the user and/or patient is located.

MEDIZINTECHNIK seit 1890

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