

Instructions for sterilisation

Components: Vagiwell® Dilators

Vagiwell® Dilators (vaginal dilators sizes 1 – 5 and special size no. 6)

1. Dilators for practicing (“dilating”) by the user and to “keep it open after surgery”
2. *Packaging:* The dilators will not arrive in a sterile packaging. The dilators must be cleaned and sterilized individually or as a set prior to every **clinical** use
3. *Cleaning and disinfection:* Avoid body fluids from drying onto the dilators by cleaning them as quickly as possible after use.
 - 3.1. *Preparations:* Automatic cleaning may not be effective. A thorough, manual cleaning process is recommended
 - 3.2. *Cleaning and disinfection:*
 - 3.2.1. Cleaning agents: Cleaning agents containing aldehydes may not be used.
Recommended preparations: Helix Ultra by BBRAUN or Ultradesmit AF by esteer Pharma
 - 3.2.2. Initial manual cleaning: If the dilators exhibit severe soiling, initial cleaning is suggested. Use soft brushes (no metal bristles) for removing residues completely.
 - 3.2.2.1. Wipe off the dilators using a soft, lint-free disposable cloth.
 - 3.2.2.2. Soak in a solution for 20 minutes.
 - 3.2.2.3. The general precautions for handling contaminated and biohazardous materials should be adhered to.
 - 3.3. *Routine cleaning:*
 - 3.3.1. Clean the dilators with a broad-spectre cleaning solution. Rinse with water and dry thoroughly.
4. *Packing for sterilization:* Put the product to be sterilized into a standard polyethylene / Tyvek-sterilization bag (or similar bag). For the purpose of sterilization, dilators can be loaded onto special instrument tablets used for this purpose or onto general tablets.
5. *Sterilization:* Steam sterilization with a gravitation cycle for 15 minutes at a minimum temperature of 132°C. To avoid deforming, the surgical tablet may not touch the walls of the steam sterilizer. When sterilizing several dilators in one steam sterilization cycle, ensure that the maximum load requirements of the manufacturer of the sterilizer are adhered to. The drying times vary depending on the size of the load.

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