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EN11 0BZ, England****Telephone No. +44 (0)3452 414818****E-Mail: instrumentinfo@steris.com****Web: www.steris-ims-instruments.com****STERIS Ireland Limited.****IDA Business and Technology Park,****Tullamore, County Offaly,****R35 X865, Ireland****Vaginal Dilator - Washing, Decontamination & Sterilising instructions – INS008 issue 004****Intended Use**

Used to mechanically enlarge the vagina during examination, or medical treatment.

Contraindications

Any use of the Vaginal Dilator that is not corresponding with the intended use.

Product characteristics

Vaginal Dilators are supplied in non-sterile conditions, multiple patient multiple use instrument.



The decontamination and sterility of any instrument prior to use is the responsibility of the Customer.



Instruments to be used by licensed medical professionals trained in their use, or by patients instructed under the guidance of a medical professional, including appropriate selection of instrument size for the application.



Instrument proper functionality, including verification of decontamination or sterilisation, shall be verified prior to each use. Instrument lifetime is determined by instrument proper functionality and careful care during use. End of lifetime is determined by wear and damage caused by use. Damaged or worn Vaginal Dilators should be removed from service and not used. Instruments can be damaged due to inappropriate selection for use, cleaning, decontamination and/or sterilization.



Physical removal of gross debris and bioburden, through soaking and wiping of Vaginal Dilators with water should be initiated immediately after the procedure, at the point of use. Where practical, keep instruments moist prior to processing. Do not use metal or wire brushes, abrasive detergents or isopropyl alcohol on instruments.

Washing, Decontamination & Sterilizing instructions

Use only those cleaning agents that have been tested according to national public health regulations and local medical practice.

The Decontamination Process is dependent on effective cleaning and washing of instruments by staff appropriately trained to your local procedures for the process. Severe soiling should be removed by submerging the instruments in the detergent solution and, using brushes and rigid nylon bristles to brush the items clean while holding them below the surface until no soil can be detected visually. Attention should be paid to any areas where debris may enter. Staff carrying out decontamination and washing process should operate according to local policy and procedures.

Following pre-cleaning, the instrument should be washed in a washer-disinfector meeting the requirements of the ISO 15883 series, using a neutral, neutral enzymatic or alkaline detergent (pH 7-10), and incorporating a thermal disinfection cycle (minimum 90°C for 1 minute) using high purity RO water for the rinse. If an appropriate machine is not available, a manual process can also be used. However, the low effectiveness and reproducibility shall be considered. Furthermore, the manual cleaning and disinfection process must be assured under the responsibility of the user (additional product and process-specific standardization).

Effective cleaning and disinfection are prerequisites for effective sterilization. Sterilisation of the Vaginal Dilators must be conducted using validated equipment meeting the requirements of the ISO 17665 series and processed in accordance with national standards and guidelines. The standard parameters of 134-137°C for 3 – 3 ½ minutes are appropriate. A vacuum assisted air removal phase prior to steam admission for sterilisation is recommended.

Packaging materials used should conform to EN ISO 11607 or the relevant parts of EN 868-7.

For further information, related to the use of these instruments, please contact your STERIS Instrument Management Services Limited representative.

Home Cleaning, Care and Storage Instructions

The Vaginal Dilators must only be used under the guidance of a medical professional. Your medical professional will have given you specific training and guidance as to the use, cleaning and storage of your dilator. This specific training and guidance should always be followed. The following recommendation is for informational purposes only and is not intended to replace professional medical advice:

You should clean your Vaginal Dilator after each use. Wash your Vaginal Dilator in warm, soapy water, using an antibacterial liquid soap, rinse thoroughly and ensure dry before storing in an airtight container.

Return of instruments

Before returning any instrument to STERIS Instrument Management Services Limited, please ensure that washing and sterilizing has been carried out in accordance with national standards and guidelines. All used and returned instruments must reference washing and sterilization cycles onto the decontamination certificate.

Damaged Instruments

If any instruments have been damaged or are found to be below your standard of expectation, please supply details so that we may investigate and rectify and situation.

Serious Incidents

Serious incidents that have occurred in relation to this medical instrument should be reported to STERIS Instrument Management Services Limited representative and competent authority in the country where the incident occurred.

Disposal after use














The instrument itself does not require special disposal instructions. The instrument should be cleaned and disinfected to remove any possibility of infection. When disposing of or recycling an instrument, and its packaging, please follow all national regulations and standards.

Repair Service

For any repair service inquiries, please contact your STERIS Instrument Management Services representative.

Glossary

Please refer to the table below for definitions of the symbols used within the labelling.

Symbol	Meaning
	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the date when the medical device was manufactured.
	Indicates the medical device manufacturer.
	Indicates the authorized representative in the European Community.
	Indicates the medical device CE marking.
	Indicates a medical device that has not been subjected to a sterilization process.
	Indicates a medical device that needs protection from light sources.
	Indicates a medical device that needs to be protected from moisture.
	Indicates the need for the user to consult the instructions for use.
	Indicates the need for the user to consult the instructions for use for important cautionary information.
	Indicates a Medical Device.
	Indicates Unique Device Identifier.