

The Curette Dilator is a manual surgical instrument used during neurosurgical procedures to cut, hold, or manipulate tissue (i.e. to scrape and remove soft and osseous tissue).

The Curette Dilator is classified on the Spaulding Scale as a “critical” device. The device is supplied non-sterile and must be cleaned and sterilized in accordance with these instructions prior to use.

Any packaging material and tip protectors included in the original shipment should be disposed of prior to usage or sterilization. A sterilization tray is provided with the Curette Dilator. Refer to included instructions for use before handling the sterilization tray.



### Warnings

1. Automated cleaning may not be effective. A thorough, manual cleaning process is required.
2. Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Enzymatic and cleaning agents with neutral pH are recommended.

### Reprocessing Limitations

Repeated processing, according to the instructions below, has minimal effect on reusable manual instruments. End of life is normally determined by wear and damage due to use. Use/service life is restricted by mishandling or inadequate protection. We cannot make any statement about how long the device will last; however, the Curette Dilator is designed to be robust when the procedures described herein are followed. Visually verify cutting edges of the curette are intact prior to use. Any un-useable devices should be properly disposed of per standard hospital procedures.

### Containment/ Transportation

1. Universal precautions for handling contaminated/biohazardous materials should be observed.
2. Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.

**A. Decontamination and Sterilization Procedure**

**Preparation:** As with any decontamination procedure, wear protective attire including heavy duty rubber gloves, plastic apron, eye protection, and mask.

**Pre-Cleaning:** Keep instrument free of gross soil during the procedure. Wipe off debris as necessary using sponges and sterile water. The Curette Dilator does not require disassembly. Do not allow blood and debris to dry on the device. Clean instrument as quickly as possible after the procedure in order to prevent blood and debris from drying on the instrument.

**B. Manual Decontamination**

Rinse the device under running cold tap water for a minimum of 1 minute until all visible soil is removed. (Use of hot water will denature the proteins in blood, making their removal much more difficult.) Follow applicable standards regarding water quality.

**Enzymatic Soak:** Presoak in neutral pH enzyme detergent for a minimum of 2 minutes or per enzyme detergent manufacturer's instructions using lukewarm tap water. Follow manufacturer's instructions regarding ratio of detergent to water.

**Manual Cleaning:** A nonabrasive, low-foaming, free-rinsing cleaning agent is recommended. Follow manufacturer's instructions for using cleaning agent.

Submerge instrument under water and use soft bristled brush to vigorously scrub all surfaces assuring all hard-to-reach areas are accessed. A syringe and pipe cleaner may be used if applicable. Make sure instrument and brush remain submerged during cleaning to prevent splashing. Do not leave instruments in cleaning or disinfecting solutions for extended lengths of time (overnight). If at anytime during the cleaning the detergent becomes grossly contaminated, prepare a fresh batch using the manufacturer's recommendations.

Rinse thoroughly with lukewarm tap water for a minimum of 1 minute, making sure all cleaning agent is removed. Use a syringe to assist in the rinsing.

**Ultrasonic Cleaning:** Perform ultrasonic cleaning per manufacturer's instructions. After ultrasonic cleaning, rinse with lukewarm running tap water for a minimum of 1 minute. Use a syringe to assist in rinsing.

**Drying:** Dry the device using a clean lint-free cloth. Pressurized air can be used to dry the device if applicable.

**Inspect:** Visually inspect that all blood and debris has been removed and that no visible damage is present on the device.

**C. Automated Decontamination**

These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.

**D. Terminal Sterilization**

The Curette Dilator devices are provided non-sterile and must be steam sterilized prior to use. Verify devices have been properly cleaned or devices may be inadequately sterilized. Place curettes into the brackets of the provided tray or an appropriate tray used for similar surgical instruments. Secure the lid. Wrap in standard medical grade steam sterilization wrap following the AAMI double wrap method. (ANSI/AAMI ST46-1993).

The Curette Dilator devices have been validated to the the following sterilization parameters using the tray provided with them:

Sterilizer	Minimum Exposure Temperature	Minimum Exposure Time	Minimum Drying Time
Pre-Vacuum (wrapped)	132°C	4 min	30 min

If not using the included sterilization tray, the Curette Dilator devices must be sterilized in accordance with standard hospital sanitization and sterilization procedures for similar surgical instruments, but must not be less than the parameters above.

When sterilizing multiple instruments in one steam sterilization cycle, ensure that the sterilizer manufacturer’s maximum load is not exceeded. Drying times will vary according to load size and should be increased for larger loads.

Visually inspect the device prior to use to ensure cleanliness and integrity of parts. Do not use if device is damaged following sterilization.

**E. Storage**

Store the device in a clean and dry environment until ready to use.








**G. Additional Information:**

Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.

Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.

*The CDC document, **Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008** may be consulted for guidance on general cleaning and sterilization of reusable surgical instruments such as that provided. Follow applicable standards and guidelines required by the institution for cleaning and resterilization of reusable surgical devices.*

**Symbols:**

Symbol	Description
	Manufacturer
	Lot Number
	Model Number
	Use by YYYY-MM-DD
	Do Not Use if Package is Open or Damaged
	Consult Instructions for Use
	Contents
<b>Rx only</b>	Caution – Federal (USA) law restricts this device to sale by or on the order of a physician.

Manufactured in the USA by:



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