

Savary-Gilliard® Dilators and Wire Guides FAQs

What material are Savary-Gilliard Dilators made from?

Savary-Gilliard Dilators are made from polyvinylchloride (PVC).

How should the dilators be cleaned?

Savary-Gilliard Dilators should be cleaned following the cleaning instructions as detailed in the device's Instructions for Use (IFU).

CLEANING INSTRUCTIONS

Caution: Savary-Gilliard Dilators cannot be autoclaved, EO sterilized, dry heat sterilized, or gamma irradiated.

Note: Betadine and acetone are not recommended for use for cleaning or disinfection of Savary-Gilliard Dilators.

Note: The following cleaning instructions have been validated using the Steris Prolystica® Enzymatic Cleaner.

1. Immediately after use, soak dilator in a solution of warm tap water and enzymatic cleaning solution.

Note: Refer to enzymatic cleaning solution instructions for recommended duration of cleaning, temperature, and concentration of cleaning solution.

2. Scrub external surfaces of dilator with warm water and enzymatic solution. Using a Savary Cleaning Brush (sold separately), brush wire guide lumen of dilator.
3. Rinse dilator thoroughly with clean, running water. Attach suction to tapered end of dilator or utilize Savary-Gilliard Dilator Washer flushing adapter (sold separately) to suction water through wire guide lumen.
4. Wipe external portions of dilator dry with a lint-free cloth. Use medical-grade (oil-free) forced air to dry wire guide lumen of dilator.
5. Proceed with high-level disinfection of dilator.

HIGH-LEVEL DISINFECTION

Note: A list of disinfectant solutions validated for use with this device is as follows:

- MetriCide® 28 (glutaraldehyde-based solution)
- Cidex® OPA (ortho-phthalaldehyde-based solution)
- Revital-Ox® RESERT® (hydrogen peroxide-based solution)

1. Completely immerse dilator in a disinfectant.

Note: Refer to disinfectant solution instructions for recommended duration of immersion, temperature, and concentration required for high-level disinfection.

If difficulty is encountered with solution penetrating lumen, we recommend attaching suction to tapered end of dilator or utilize a Savary-Gilliard Dilator Washer flushing adapter (sold separately).

Note: Discoloration of dilator may occur following use of these solutions. This is not harmful to device.

2. Rinse dilator thoroughly with clean, running water, utilizing above method for thoroughly rinsing lumen. Attach suction to tapered end of dilator or utilize Savary-Gilliard Dilator Washer flushing adapter (sold separately) to suction water through wire guide lumen.

Note: Proper rinsing with clean water and drying of dilator are necessary following use of these solutions.

3. Dry external portions of dilator completely with a lint-free cloth. Use medical-grade (oil-free) forced air to dry wire guide lumen. Ensure that both the external and internal surfaces of the dilator are dry prior to packaging and/or storing the device.
4. Upon cleaning, inspect integrity and function of device. If kinks, bends, or breaks exist, do not use.

What other cleaning accessories does Cook offer?

The Savary Cleaning Brush is supplied non-sterile and is single-use only. The Savary-Gilliard Dilator Washer is also supplied non-sterile and is reusable, as long as the device's integrity remains intact. The cleaning brush and dilator washer can be used to clean and disinfect the dilators and are discussed in the IFU.

Can other cleaners or disinfectants not discussed in the IFU be used to reprocess the dilators?

The disinfectant solutions listed in the IFU have been validated for use with the Savary-Gilliard Dilators, and Cook has data on file to support their compatibility. However, many facilities use existing hydrogen peroxide-based cleaning solutions to disinfect their dilators, and it is up to the discretion of each facility's reprocessing team to establish cleaning and disinfecting protocols.

Some recent Joint Commissions surveys have indicated that the Savary-Gilliard Dilators need to be reprocessed at a similar interval to reprocessing scopes (i.e., if a scope is reprocessed every seven days, then the Savary-Gilliard Dilators need to be reprocessed every seven days as well). Where does Cook stand on this?

After use, the Savary-Gilliard Dilators should be cleaned and prepared for future use. Many of our customers choose to sterilize their dilators every seven days as a standard process. However, any additional protocols, such as the implementation of a cleaning interval, is at the discretion of the facility.

What are the storage recommendations for the dilators?

The storage recommendations are listed in the IFU.

PACKAGING/STORAGE AFTER INITIAL USE

1. Following cleaning and disinfection, package the dilator per institutional guidelines and best practices.
2. Store the dilator in a dry environment away from temperature extremes, referring to institutional guidelines and best practices.

Why aren't there markings on the Savary-Gilliard Dilators?

The IFU discusses using a Savary-Gilliard Wire Guide (sold separately) that has distal markings every 20 cm (from 40 to 140 cm). Continuous fluoroscopic monitoring of the wire guide is essential to ensure proper placement and position of the wire guide. The markings on the distal portion of the wire guide may also be used to determine wire guide position.

What is the code printed on Savary-Gilliard Dilators?

(See image below.) The code printed on the proximal end of a dilator is the device's unique device identification (UDI) code. It is also on the product label. The UDI code is a regulatory requirement to ensure that a user can adequately identify a

device. All production identifiers that appear on the device label are required to be part of the UDI. This includes the production lot number and expiration date, for example.

The device expiration date is set at three years from the date of manufacture. The expiration date (YYMMDD format) appears between the second and third sets of parentheses (as highlighted in the red box below). In this example, the device's expiration date is February 13, 2027.

In the case of reusable devices, such as our Savary-Gilliard Dilators, the expiration date is used as a production identifier and is not indicative of the useful life of the device. As a reusable device, a Savary-Gilliard Dilator may be used as long as the device is intact and functional.

What are the inner lumen dimensions of the dilators?

The inner lumen diameters for the dilators range from 0.059 to 0.079 inch.

What are the dimensions of the Savary-Gilliard Wire Guide?

The wire guide has a diameter of 0.032 inch, with a 0.071 inch diameter tip, and it can be placed through a scope with a 2.8 mm working channel.



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CustomerSupport@CookMedical.com

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