

Scope:

Reprocessing instructions are only to be used for re-usable instruments and accessories.

Reprocessing instructions do not cover the following types of devices or instruments: single use disposable devices, Class II devices, or devices which are not general instruments. Refer to individual IFUs for all other devices.

Sterility	Single use device	Processing required before first use	Processing required after each use
		Yes	No
	No		Yes

Warnings

Do not reprocess single-use instruments

Use only sterilization wraps, pouches, and containers validated according to applicable standards (EN ISO 11607) or approved by the FDA that are suitable for steam sterilization (temperature resistance up to at least 141°C) and contains sufficient steam permeability.

All instruments shall be handled with protective gloves and proper PPE.

Do not place coated (safety, non-conductive, or fully coated) instruments into ultrasonic bath.

Do not use steel or wool brush to manually clean an instrument.

Do not place unlike metals together during cleaning or sterilization

Do not use Cold Sterilizing Methods

Do NOT EXCEED 350°F (177°C) in exposure temperature.

Pre-Treatment/Maintenance after use

1. Completely disassemble instruments if applicable. Remove any debris from the device using a max. 70% isopropyl alcohol wipe, or soft bristle non-metal brush.
2. If instruments that have been in contact or soiled by blood, the instrument shall be fully submerged and soaked after use to prevent soil from drying prior to cleaning. Use an enzymatic cleaner.
3. Thoroughly rinse the device after with plenty of running water for at least 1 minute.

Special Instructions for Pre-Treatment/Maintenance after Use

PTFE Instruments (dilators, cannula tips, cannula acorn, and accessories)	Disassemble after use and run water through the devices.
Reusable electrodes	Char and tissue shall be manually removed from wire filament with a non-abrasive wipe containing max. 70% isopropyl alcohol or wet gauze pad.
Lumen Instruments	Rinse all lumens of instruments a minimum of 5 times with a single-use syringe and DI water or max. 70% isopropyl alcohol.

Cleaning

Manual Cleaning

1. Completely disassemble instruments if applicable.
2. Soak the disassembled instruments in the cleaning solution for at least 20 minutes or according to the cleaning solution manufacturer's recommended soaking time, and make sure that the instruments are sufficiently immersed.
Note: Review special instructions for cleaning solutions to be used.
3. An ultrasonic tank may be used, except as otherwise specified in the "Special Instructions for Cleaning" section. Use the

processing time recommended by the manufacturer of the detergent.

Note: Review special instructions for devices which are not recommended to be placed in ultrasonic tanks.

4. Remove all instruments from the cleaning solution and post rinse them intensively with low contaminated and deionized water.
5. Thoroughly dry the instruments after cleaning.

Automated Cleaning

1. Completely disassemble instruments if applicable.
2. Place the disassembled instruments in a cassette or any other tray system suitable for the instrument and place it in the automated washer disinfectant (no contact between the instruments).
If applicable: Connect the instruments by use of a suitable rinsing adapter to the rinsing port of the automated washer disinfectant.
3. Start the program.
4. Remove the instruments from the automated washer disinfectant after end of the program.
5. Allow post drying step in a clean place.

Special Instructions for Cleaning

Anodized Aluminum Instruments	Use only neutral pH cleaner, do not clean with metal or stainless steel instruments. Do not place in ultrasonic bath. Clean by hand manually or in an automated washer disinfectant. Ensure cleaning agent used is compatible with aluminum.
Hinged instruments	Clean in an open position
Uterine Sounds	Do not place in ultrasonic bath
Non-conductive coated instruments	Do not place in ultrasonic bath, use only neutral pH cleaner
Lateral Retractor	Do not place in ultrasonic bath
Cannulas	Disassemble all components prior to placing in ultrasonic bath

Automated Washer Cycle Parameters

Cycle/ Phase	Time (mm:ss)	Water Temperature	Cleaning Solution
Pre-Rinse	01:00	Cold tap water	N/A
Wash 1	03:00	Hot tap water, 54°C	STERIS® Prolystica® 2X Concentrate Neutral Detergent at 1/8 oz. /gal.
Wash 2	03:00	Hot tap water, 54°C	STERIS® Prolystica® 2X Concentrate Neutral Detergent at 1/8 oz. /gal.
Rinse 1	01:00	Cold tap water	N/A
Rinse 2	01:00	Cold tap water	N/A
Final Rinse	01:00	Hot tap water, 90°C	N/A
Drying	10:00	90°C	N/A

Inspection

1. Inspect all instruments after pre-treatment and cleaning for corrosion, damage, residue or soil. Return the device for re-cleaning if any soil or residue is still visible.
2. Dispose of device where there are signs of corrosion. Decommission and dispose or service and repair any device with damage.

Special Instructions for Inspection

Coated Instruments	Ensure that there are no cracks, chips, or bubbles within coated instruments. If there are any deficiencies within the coating, dispose of the instrument
Hinged instruments	Lubricate using a FDA approved medical device lubricant prior to sterilization

Sterilization

Place cleaned and dried instruments into sterilization pouches, wraps, or suitable sterilization containers validated according to applicable standards (EN ISO 11607) or approved by the FDA.

Do not place dissimilar metals within the same sterilization wrap or pouch.

Do NOT EXCEED 350°F (177°C) in exposure temperature.

Premier recommends the use of Premier's cassettes:

9010901 Accessory Cassette

9010924 Mark IV (12 or 25 instruments) Instrument Cassette

Special instructions for Sterilization

Hinged instruments	Sterilize in open position
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Minimum cycle times for dynamic-air-removal steam sterilization cycles (Pre-Vacuum)

Item	Exposure Temperature	Exposure Time	Drying Times
Wrapped Instruments or Sterile Bags	270°F (132°C)	4 minutes	Minimum 30 minutes

Storage

Please store the instruments after sterilization in a dry and dust-free place in the area indicating the instruments are clean. Sterilization can only be maintained, if the instruments remain packaged or wrapped - impermeable to micro-organisms - following validated standards. The status of the sterilization has to be clearly indicated on the wrapped packages or the containers. For safety reasons, keep sterile and non-sterile instruments strictly apart.

List of Applicable SKUs

SKU	SKU description
1031208	SUCTION TUBE FRAZIER SIZE 8 FR
1031209	SUCTION TUBE FRAZIER SIZE 9 FR
1031210	SUCTION TUBE FRAZIER SIZE 10FR
1031212	SUCTION TUBE FRAZIER SIZE 12FR
1050110	CANNULA, WEBSTER INFUSION - STR
1050112	CANNULA, WEBSTER INFUSION - CVD
1050105	RETRACTOR, SAWYER - SMALL
1050106	RETRACTOR, SAWYER - MEDIUM
1030842	CANNULA KAHN UTERINE TRIGGER
1030840	CANNULA JARCHO SELF-RETAINING

SKU	SKU description
1030582	DILATOR KLEEGMAN NARROW PTFE
1030585	DILATOR - OS (SET OF 3)
1030586	DILATOR - LOCATOR 2.3 cm TIP
1030587	DILATOR - CANAL 4.5cm TIP
1030588	DILATOR - FUNDUS 8.5cm TIP
1032453	ADAPTER NEEDLE 3 IN
1032454	ADAPTER NEEDLE 4 IN
1032455	ADAPTER NEEDLE 5 IN
1032456	ADAPTER NEEDLE 6 IN

