Scope:

Reprocessing instructions are only to be used for re-useable 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 FDA approved sterilization wraps, pouches, and containers 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 an 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 within 2 hours after use. 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)	Dis-assemble after use and run water through the devices.
Reuseable electrodes	Char and tissue shall be manually removed from wire filament with non-abrasive alcohol wipe 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 isopropyl alcohol.

Cleaning

Manual Cleaning

1. Completely disassemble instruments if applicable
2. Soak the disassembled instruments for the recommended soaking time in the cleaning solution and make sure that the instruments are sufficiently immersed Note: review special instructions for cleaning solutions to be used.
3. An Ultrasonic Tank can be used. 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 disinfector (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 disinfector.
3. Start the program.
4. Remove the instruments from the automated washer disinfector 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 disinfector. 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

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 FDA approved sterilization pouches, wraps, or suitable sterilization containers. 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
9010904 Mark I (4 or 8 instruments) Instrument Cassette
9010908 Mark VI (8 or 16 Instruments) Instrument Cassettes
9010924 Mark IV (12 or 25 instruments) Instrument Cassette

Special instructions for Sterilization

Hinged instruments	sterilize in open position

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.

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