



Recommended Care, Cleaning & Sterilization Instructions for Reusable Instruments.

These instructions pertain to Class I Surgical Instruments.




CARDIC INSTRUMENTS

P.O. Box 147, Nishat Park,
Opposite Sialkot Chamber of
Commerce & Industry,
Sialkot – Pakistan
TEL: +92 524 267708
EMAIL: info@cardic.com.pk
www.cardic.com.pk



CMC MEDICAL DEVICES & DRUGS, S.L

C/ Horacio Lengo n18
C.P 29006
Málaga-Spain
Phone+34 951 214 054
Email: info@cmcmedicaldevices.com

	INSTRUCTIONS FOR USE – REUSABLE INSTRUMENTS		IFU-01
OPERATING MANUAL	REVISION # 2	DATE: 06.01.2019	APPROVED BY:
THIS POLICY WILL BE REVIEWED ON : MARCH, 2021		LAST REVIEW: 23.09.2019	QA MANAGER

Reusable surgical instruments and accessories supplied by Cardiac Instruments and intended for reprocessing in a health care facility setting. All instruments and accessories may be safely and effectively reprocessed using the manual or combination manual/automated cleaning instructions and sterilization parameters provided in this document.

In countries where reprocessing requirements are more stringent than those provided in this document it is the responsibility of the user/processor to comply with those prevailing laws and ordinances

Any deviation by the user/hospital/health care provider from these instructions should be evaluated for effectiveness to avoid potential adverse consequences.

DESCRIPTION & INSTRUCTIONS

WARNINGS



- Cardiac’s reusable instruments are provided **NON-STERILE** and must be cleaned and sterilized according to these instructions prior to use.
- If present, safety caps and other protective packaging material must be removed from the instruments prior to the first cleaning and sterilization.
- Ethylene oxide (EO), gas plasma and dry heat sterilization methods are **not recommended** for sterilization.
- Caution should be exercised while handling, cleaning, or wiping instruments with sharp cutting edges, tips, and teeth.
- Saline and cleaning/disinfection agents containing aldehyde, chloride, active chlorine, bromine, bromide, iodine or iodide are corrosive and **should not** be used.
- **Do not allow biologic soil to dry on contaminated devices.** All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids and tissue debris to dry on used instruments.
- Metal brushes and scouring pads must not be used during manual cleaning. Use only soft bristle nylon brushes with different shapes, lengths and sizes to aid with manual cleaning.
- When processing instruments do not place heavy devices on top of delicate instruments.
- **Use of hard water should be avoided.** Softened tap water may be used for most rinsing however purified water should be used for final rinsing to prevent mineral deposits.

	<ul style="list-style-type: none"> • Oils or silicone lubricants should not be used on surgical instruments.
LIMITATIONS ON REPROCESSING	<ul style="list-style-type: none"> • Repeated processing according to these instructions has minimal effect upon metal. End of life for stainless steel instruments is generally determined by wear and damage incurred during the intended surgical use. • Non-foaming, neutral pH enzymatic and cleaning agents are recommended for processing reusable instruments and accessories.
REPROCESSING INSTRUCTIONS	
POINT OF USE	<ul style="list-style-type: none"> • Remove excess biologic soil from the instruments with a disposable wipe. Place Devices in a container of distilled water or cover with damp towels. • If instruments cannot be soaked or maintained damp then they should be cleaned as soon as possible (within 60 minutes is recommended) after use to minimize the potential for drying prior to cleaning. • Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.
TRANSPORTATION	<ul style="list-style-type: none"> • Used instruments must be transported to the decontamination area for reprocessing in closed or covered containers to prevent unnecessary contamination risk.
PRE-CLEANING	<ul style="list-style-type: none"> • All devices should be cleaned in the open position to allow solution to contact all surfaces. • Contaminated instruments should be cleaned as soon as possible. • Rinse off device to remove any excess gross soil. • Submerge instruments in an enzymatic/ neutral pH detergent bath and allow soaking between 5 and 10 minutes. • Use a soft bristled brush and gently remove any visible soil still remaining on the device. Be sure to clean hinges, crevices and other difficult to reach areas. Lumens should be cleaned with a soft bristled pipe cleaner of corresponding width and length to ensure the entire lumen has been scrubbed. • Rinse instruments in purified water for a minimum of 2 minutes. Flush lumens, hinges, crevices and other difficult to reach areas until the water exiting the device is clear of soil and detergent. If soil still remains, repeat the steps above.
MANUAL CLEANING	<ul style="list-style-type: none"> • Rinse under cool running tap water to remove gross soil. • Bathe in enzymatic detergent per manufacturer's recommendation using lukewarm tap water for 1 minute. • Scrub thoroughly with a soft bristled brush to remove soil. Pass a stylet through lumens a minimum of 3 times and, using a syringe, aggressively flush lumens with

	<p>enzymatic detergent to remove soil.</p> <ul style="list-style-type: none"> • Rinse under cool running tap water and aggressively flush lumens with a syringe to remove detergent residuals. • Bathe in a neutral detergent per manufacturer’s recommendation using warm tap water for 3 minutes. • Scrub thoroughly with a soft bristled brush to remove soil. Pass a stylet through lumens a minimum of 3 times and, using a syringe, aggressively flush lumens with neutral detergent to remove soil. • Rinse under running reverse osmosis/deionized (RO/DI) water to remove detergent residuals. • Sonicate in enzymatic detergent per manufacturer’s recommendation for 10 minutes. • Rinse under running RO/DI water and aggressively flush lumens with a syringe. • Dry with a disposable, lint free cloth. • Visually inspect for cleanliness. Repeat cleaning process, as necessary, until visually clean.
<p>ULTRASONIC CLEANING</p>	<ul style="list-style-type: none"> • Follow Pre-Cleaning steps outlined above. • Submerge instruments fully opened in Ultrasonic Washer with cold distilled water and the minimum effective concentration of enzymatic cleaner per manufacturer’s recommendation. • Ultrasonically clean instruments at 45kHz for 10 minutes. • Rinse under cool running RO/DI water for 2 minutes and aggressively flush lumens with a syringe until water exiting instrument is clear of detergent. • Dry with a disposable, lint free cloth. • Visually inspect for cleanliness. Repeat cleaning process, as necessary, until visually clean.
<p>AUTOMATED CLEANING</p>	<ul style="list-style-type: none"> • Follow Pre-Cleaning steps outlined above. • Load instruments into automatic washer per manufacturer’s recommended orientation. • Wash instruments per Mechanical Washer Parameters in Table 1.

Phase	Time	Description	Detergent
Pre-Wash 1	2 min	Pre wash with cold tap water	None
Enzyme Wash	1 min	Enzyme spray and soak with hot tap water	Enzymatic Detergent
Cold Tap Water Rinse	15 sec	Cold tap water rinse (2x)	None
Wash 1	2 min	Detergent wash with hot tap water	Neutral pH Cleaner
Rinse 1 Hot Tap Water	15 sec	Hot tap water rinse	None
Pure Rinse	10 sec	Hot purified water	None
Drying	7 min	Hot air dry	None

DISINFECTION	<ul style="list-style-type: none"> The chemical disinfection follows the manual cleaning. A detergent, suitable for surgical instruments made of stainless steel must be used. 												
DRYING	<ul style="list-style-type: none"> Dry instruments with a clean, absorbent non-shedding lint free cloth. Clean, filtered compressed air may be used to remove moisture from lumens, holes, cannulas and difficult to access areas. 												
INSPECTION & TESTING	<ul style="list-style-type: none"> Visual inspection for cleanliness, assembling and functional testing according to instructions of use. If necessary, perform reprocessing process again until the instruments are visibly clean. Lubrication of the device after each reprocessing process is very important. 												
PACKAGING	<ul style="list-style-type: none"> Appropriate packaging for sterilization according ISO 11607 and EN 868 Any divergences from the recommended packaging must be validated. 												
STERILIZATION	<p>Only use the following methods to sterilize Cardic's Instruments.</p> <ul style="list-style-type: none"> Fractional vacuum method/pre-vacuum method or gravitational method Steam sterilizer according to DIN EN 13060 or DIN EN285 Validated according to DIN EN ISO/ANSI AAMI ISO 17665 Use the following cycle for steam sterilization <table border="1"> <thead> <tr> <th>Cycle Type</th> <th>Minimum Sterilization Exposure Time (minutes)</th> <th>Minimum Sterilization Exposure Temperature</th> <th>Minimum Dry Time (minutes)</th> </tr> </thead> <tbody> <tr> <td>Gravity</td> <td>10</td> <td>135°C (275°F)</td> <td>20-30</td> </tr> <tr> <td>Pre-vacuum</td> <td>4</td> <td>132°C (270°F)</td> <td>20-30</td> </tr> </tbody> </table>	Cycle Type	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Minimum Dry Time (minutes)	Gravity	10	135°C (275°F)	20-30	Pre-vacuum	4	132°C (270°F)	20-30
Cycle Type	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Minimum Dry Time (minutes)										
Gravity	10	135°C (275°F)	20-30										
Pre-vacuum	4	132°C (270°F)	20-30										

	<p><u>CAUTIONS:</u></p> <ul style="list-style-type: none"> • Ensure that the sterilizer manufacturer’s maximum load is not exceeded. • Make sure autoclave chambers are cleaned regularly and as recommended by the manufacturer.
STORAGE	<ul style="list-style-type: none"> • All Sterile packaged instruments should be stored in an area that is well ventilated and provides protection against dust, moisture, insects and humidity extremes. • The maximum temperature of the storage facility must be 45°C. • Direct sunlight must be avoided as well.
DISPOSAL	<ul style="list-style-type: none"> • Surgical instruments have to be disposed of professionally.