

MIRROR™

Partial Knee System: Instrument Care and Cleaning

GENERAL CARE OF REUSABLE SURGICAL INSTRUMENTS

INSTRUMENT LONGEVITY THROUGH PROPER CARE

By following these guidelines our customers can ensure many years of productive and satisfactory performance. When handling the instruments, be very careful not to damage their fine tips and mechanisms.

DISCLAIMER

- 1) Instrument cases are intended to protect instruments and facilitate the sterilization process by allowing steam penetration and drying, but DO NOT provide a sterile barrier.
- 2) Specific sterilization methods and cycles have been validated by Cayenne Medical, Inc.; however, health care personnel bear the ultimate responsibility for processes ensuring sterilization.

RESPONSIBILITIES OF THE USER

- 1) Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material is suitable for use in sterilization processing and sterility maintenance.
- 2) The health care facility is responsible to ensure that conditions essential to safe handling, decontamination, sterilization and storage of sterile instruments are maintained.
- 3) The health care facility is responsible for determining an appropriate shelf life for wrapped instrument sets based on recommendations from the sterile wrap manufacturer.

NEW OR REUSED INSTRUMENTS

Prior to use, new or maintained instruments (supplied non-sterile) must be cleaned, lubricated and autoclaved.

WARNINGS AND PRECAUTIONS

- 1) If instruments are grossly damaged, or demonstrate difficult assembly or function, contact your distributor. Use of damaged or poorly assembled instruments poses risk of ineffectiveness.
- 2) Use of damaged or poorly assembled instruments can lead to spontaneous disassembly during surgery.
- 3) Use of instruments for purposes other than their intended use is not indicated. The user is responsible for any damage arising from misuse or handling of the instruments.
- 4) Inspect instruments regularly during, between and after use to prevent improper function in subsequent procedures.
- 5) Always sterilize, store and transport the instruments in their proper position in the instrument case. Sterilization and storage outside of the supports in the case can lead to instrument damage.
- 6) **DO NOT** submerge electronic devices, including the Cutter Drive, during cleaning; permanent damage may occur as a result of submersion. **DO NOT** use ultrasonic cleaners or automated washers to clean electronic equipment.
- 7) Unless otherwise indicated, instrument sets are NOT sterile and must be thoroughly cleaned and sterilized prior to use.
- 8) Instruments may become contaminated with body fluids containing hepatitis virus, HIV or other pathogens. Health care workers should be familiar with Universal Precautions for preventing injuries caused by sharps when handling instruments. It is recommended that proper personal protective equipment is worn while handling contaminated instruments; such as gown, mask, goggles or face shield, gloves and shoe covers.

QUICK INSTRUMENT CARE CHECKLIST

- 1) Rinse and soak soiled instruments immediately after use and thoroughly clean them before autoclaving. DO NOT submerge Cutter Drive.
- 2) Clean, autoclave and sterilize instruments in an open position.
- 3) Do not stack or entangle instruments.
- 4) Follow the manufacturer's recommendations when using equipment, cleaning solutions and lubricants.
- 5) Keep instruments properly lubricated.
- 6) Inspect instruments regularly.

MAINTAINING REUSABLE INSTRUMENTS

Water and Stainless Steel: Ordinary tap water contains minerals that can cause discoloration and staining. Therefore, it is recommended that de-ionized (DI) water be used for cleaning, disinfecting, sterilizing and rinsing instruments. To avoid staining, use a cleaning solution with a pH near neutral (7). Instruments should be placed in DI water immediately after use. They should never be placed in saline solution, as it may cause corrosion and eventually irreversible pitting. Many compounds, including certain cleaners, are highly corrosive to stainless steel. If instruments have been exposed to any potentially harmful substances, rinse and dry them immediately. If instruments appeared to be damaged notify customer service at the number listed below.



Customer Service:
1(480) 502-3661
1(888) 229-3661
www.CayenneMedical.com

MANUFACTURED BY:
Cayenne Medical, Inc.
16597 North 92nd St., Suite 101,
Scottsdale, Arizona 85260

CLEANING AND DECONTAMINATION

Instruments that have been exposed to blood, tissue, saline or other foreign material must be cleaned before these substances are allowed to dry. Failure to do so may result in corrosion.

Removal of Gross Contamination

Grossly soiled instruments should be decontaminated by rinsing thoroughly with room temperature DI water and all visible debris removed with a soft bristle, non-metallic brush. Care should be taken to avoid splashing and generating of aerosols. Remove Shims, Pins and Alignment Guides; disassemble Cutters/Planers™, from Cutter Drive and Cutting Guides prior to cleaning. Cutters/Planers™, Guides, Balancer™ (Distraction Platform) and Cutter Drive are not designed for further disassembly. DO NOT attempt to disassemble these components. Do not immerse Cutter Drive. Immerse and soak the instruments in a vessel containing a solution of ENZOL® Enzymatic Detergent (concentration of 15 ml per 1L of DI water) for a minimum of 10 minutes. After soak, manually clean with a soft bristle, non metallic brush and enzymatic detergent solution. Rinse with DI water.

Ultrasonic Cleaning

Place instruments into an ultrasonic cleaning tank containing a solution of ENZOL® Enzymatic Detergent (concentration of 15 ml per 1L of DI water) and sonicate for a minimum of 10 minutes. In addition, the following are recommended:

- Do not mix dissimilar metals while ultrasonic cleaning.
- Clean instruments in the open, unlocked or disassembled state for optimal cleaning.
- Avoid piling instruments on top of each other when loading.
- Remove and rinse off instruments immediately after the cycle is finished.
- DO NOT ultrasonic clean electronic components including Cutter Drive.

Upon completion of ultrasonic cycle, immediately remove the instruments and rinse with DI water. Allow instruments to dry thoroughly.

INSTRUMENT CHECKUP

The best times to review the condition of instruments are after they have been cleaned and lubricated and have cooled off. Carefully inspect surfaces for any sign of staining, cracking or other irregularities. Check all instruments with cutting edges to ensure that the edges are sharp and are not worn or dull. Common sources of staining are:

- Inadequate cleaning.
- Mixing dissimilar metals.
- Impurities in the water.
- Unsuitable or improper preparation and usage of cleaning and disinfecting or maintenance agents.
- Noncompliance with operating procedures of cleaning and sterilizing equipment.

Use of cleaning methods other than those described is the responsibility of the user. Alternative methods must be qualified by established processes.

LUBRICATION

All instruments with moving parts must be properly cleaned and lubricated before autoclaving; apply lubricant to moving parts, such as sliding surfaces, hinges, gears and bearings; actuate mechanisms through their range of motion following lubrication. Use surgical lubricants compatible with sterilization process. DO NOT use lubricants containing silicone or mineral oil. Always sterilize instruments in the open, unlocked or disassembled position.

STERILIZATION

The validated microbicidal processes for surgical instruments is STEAM and FLASH STERILIZATION. Validated parameters for the cycles available for use in health care facilities are as follows:

Gravity Displacement Steam Sterilization (Full Cycle)

Wrapped items:

Purge:	1 minute
Temperature:	250°F to 255°F (121°C to 124°C)
Exposure time:	30 minutes

Gravity Displacement Flash Sterilization (point-of-use)

Unwrapped items:

Purge:	1 minute
Temperature:	275°F to 280°F (135°C to 138°C)
Exposure time:	3 minutes

Pre-vacuum Steam Sterilization (Hi-Vac)

Wrapped items:

Purge:	1 minute
Vacuum Pulses:	4
Temperature:	270°F to 275°F (132°C to 135°C)
Exposure time:	5 minutes

Pre-vacuum Flash Sterilization (point-of-use)

Unwrapped items:

Purge:	1 minute
Temperature:	275°F to 280°F (135°C to 138°C)
Exposure time:	3 minutes

Use of sterilization cycle parameters or methods other than those validated by the manufacturer is the responsibility of the practitioner and institution. Alternative parameters must be qualified by established processes.

STORAGE

Once thoroughly dry, store wrapped instrument sets in a clean, dry environment in the instrument case. Never put them in areas where chemicals may emit corrosive vapors or where temperature and moisture variations could cause condensation on the instruments. Use care when handling wrapped instrument sets to prevent damage to the sterile barrier.

It is the responsibility of the user to qualify any deviations from the recommended method of care and cleaning.