

## Intended Use

The ElbowLOC® Arm Positioning System is an arm positioning device that is used as an accessory to general arm surgery.

Instrument utilization is determined by the user's experience and training in surgical procedures. Do not use this instrument for any purpose outside the intended use of the device, as it may seriously affect the safety and function of the product.

## Recommendations for Care, Cleaning and Sterilization of Hunter Medical Surgical Instruments

Thorough cleaning and rinsing are vital to reprocessing reusable medical devices. Effective cleaning must be carried out to achieve appropriate decontamination. All cleaning should be performed in a manner designed to minimize exposure to blood borne pathogens. Reusable medical devices should be kept moist immediately after use until cleaning. Devices capable of disassembly must be disassembled prior to cleaning. Thorough cleaning and rinsing should be carried out as soon as possible. Manual cleaning should be done while the instrument is immersed. The purpose of cleaning and rinsing is to remove all adherent visible soil and to reduce the number of particulates, microorganisms and pyrogens. Furthermore, thorough rinsing is necessary to remove any residual cleaning agents from the medical devices which could reduce the effectiveness of the sterilization process and protect microorganisms from destruction. Medical devices that will be stored between cleaning and decontamination should be dried with a low tinting, non-abrasive soft cloth to prevent microbial contamination that could result from wet instruments.

### Cleaning Agents and Equipment

**Detergents:** Mild enzymatic detergent with a low pH should be used.

**Water:** The quality of water should be considered when preparing enzymatic detergents for rinsing and cleaning. Water hardness is a concern because deposits left on medical devices may result in ineffective cleaning and decontamination. Deionized water can help prevent discoloration and staining associated with mineral residues found in tap water.

**Ultrasonic Cleaner:** Ultrasonic cleaners are designed for fine cleaning of medical devices, *not for disinfection or sterilization*. They are used to remove soil from joints, crevices, cannulations, and other difficult to access locations.

**Cleaning Instruments:** Use general purpose cleaning brushes, pipe cleaners, nonabrasive low tinting cloths, and/or ultrasonic cleaner.

**NOTE:** Brushes and pipe cleaners should have light fit but be able to move back and forth in the area being cleaned.

### Cleaning categories and Instructions

Cleaning procedures are dependent on component features. Therefore, the following cleaning instructions are based on component features which present challenges to the cleaning process and not on specific products. Complex components usually contain component features falling into more than one of the categories listed below. For each component, a combination of cleaning procedures for the appropriate categories must be utilized.

**NOTE:** Manual cleaning is **NOT** a disinfection process.

### Hinged Components

#### Cleaning procedure:

1. Soak devices for a minimum of 3 minutes in mild enzymatic detergent in fully open position.
2. Use a cleaning brush/ pipe cleaner to remove additional soil from between the hinged areas.
3. Process devices for a minimum of 5 minutes in an ultrasonic cleaner containing warm enzymatic detergent.
4. Rinse thoroughly with warm water making sure to flush the hinged areas.
5. Inspect the devices for visible soil.
6. Repeat if soil is visible.

### Special Instructions

Even with proper handling, correct care and maintenance, reusable instruments should not be expected to last indefinitely. This is also true for some of the ElbowLOC® components. Parts with hinges, locking bolts or clamping features will wear over time.

Before each use carefully inspect each component for signs of excessive wear or reduced functionality. Before cleaning, the ElbowLOC® should be completely disassembled to its component parts.

Place all ElbowLOC® components in their respective support position in the carrier case before sterilization.

### Specifications

Materials used in Hunter Medical's instruments have been used in nearly all modern sterilization methods with excellent results. For typical steam autoclave cycles, the following are recommended times and temperatures developed from outside testing using AAMI established guidelines:

#### 1. Gravity Displacement Sterilizer

Wrapped cases and instruments should be exposed to a minimum of 132 degrees C (270 degrees F) for 15 minutes. The drying time is to be a minimum of 40 minutes.

#### 2. Prevacuum Autoclave Cycle

Prevacuum (dynamic-air-removal method) of 132 degrees C (170 degrees F) for 4 minutes, which requires local validation and routine monitoring of the process. The drying time is to be a minimum of 30 minutes.

### Automated Washer-Disinfectors:

Use only validated washer-disinfector machines with low-foaming, non-ionizing cleaning agents and detergents, following the manufacturers' instructions for use warnings, concentrations and recommended cycles.

Load instruments carefully, with any joints in the open position.

Place heavy instruments in the bottom of containers, taking care not to overload.

Place instruments with concave surfaces facing down to prevent pooling of water.

The parameters for the pre-programmed cycle:

TREATMENT	TIME (MM:SS)	TEMPERATURE	CLEANING SOLUTION
Enzymatic Wash	04:00	60 degrees C	Steris® Klenzyme® (1/4 fl. oz. per gallon)
Wash	02:00	Warm Tap Water	Steris® Criti-Klenz® (1/4 fl. oz. per gallon)
Rinse	02:00	70 degrees C	N/A
Dry	15:00	80 degrees C	N/A

### Limitations on Reprocessing:

Repeated processing has minimal effect on stainless steel surgical instruments. End of life is normally determined by wear and damage in use. Any specific limitations on the number of reprocessing cycles shall be made available with the instrument.

It is the responsibility of the healthcare facility to ensure that reprocessing is performed using equipment that is validated and the personnel performing the associated reprocessing activities are properly trained and competent. To achieve this it is recommended that local validation and routine monitoring of the reprocessing activities be implemented.

### Single Use Components

-Disposable Support Pads  Catalog 22187-1600 

-All components labeled **Single Use** are intended to be used one time and then discarded.

-Risks of reusing single use devices include but are not limited to infection to the patient, or reduced reliability of function.

### Reusable Components

The ElbowLOC® Arm Positioner complete set is packaged 



www.huntermed.net

IFU 22187-3001 Rev. C 0920



Symbol for "Manufacturer"



Symbol for "do not reuse",  
"single use", or "use only once"

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