stryker

LEG POSITIONER

Cleaning and Sterilization Guide

Leg Positioner

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Table of Contents

Caution

The Stryker Leg Positioner has been designed, verified, and validated for use with Stryker components referenced in this user manual and contained in the optional self-retraction kit. Other Stryker components or components from different manufacturers should not be used with the self-retraction option.

Introduction

1. About This Manual

This manual describes cleaning and sterilization procedures for the Stryker Leg Positioner instrumentation used during manual or robotic-assisted knee procedures.

2. Support / Feedback

Customer Service Phone (855) 303-6256

3. Copyrights and Trademarks

4. Governing Law

Any legal action or proceeding related to this manual or the information contained in it shall be brought exclusively in a court in Bergen County, New Jersey, and shall be governed by the laws of the State of New Jersey, without regard to conflicts of laws principles.

5. Manufacturer

MAKO Surgical Corp. 2555 Davie Rd. Ft. Lauderdale, FL 33317

6. Symbols used in this manual

Note — Useful information or clarification.

Caution — Indicates situations or actions which could cause damage to equipment and/or result in user/patient injury.

Document References

The following reference manuals are available with information pertaining to Stryker products:

Stryker Leg Positioner User Guide (PN 210470) describes how to use the Stryker Leg Positioner to aid the surgeon in holding and positioning the patient's leg at different internal/external rotation angles and at different flexion/extension angles as needed during manual or robotic-assisted knee procedures.

INSTRUMENT MATERIALS

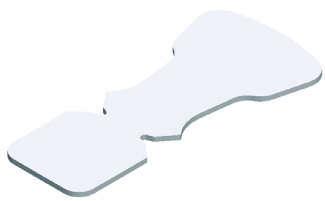
Table 1. Stryker Leg Positioner Instrument Kit

Tool	Material
Rail Clamp	Aluminum, Stainless Steel, Bronze
Base Bar	Carbon Fiber, Aluminum, Stainless Steel
Sled	Aluminum, Stainless Steel, Bronze
Boot	Carbon Fiber, Aluminum, Stainless Steel, Bronze, Ceramic, PEEK
Extension Bar	Carbon Fiber, Aluminum, Stainless Steel, Bronze
Short Antler	Aluminum
Long Antler	Aluminum
Bent Hohmann Retractor	Stainless Steel
Rake Retractor	Stainless Steel
Smiley Retractor	Stainless Steel
PCL Retractor	Stainless Steel
Patella Retractor	Stainless Steel
Patella Protector	Stainless Steel

DISPOSABLES

Table 2 lists items that are designated as disposable and should be used as single use only during patient surgery. These items should NOT be cleaned or sterilized.

Table 2. Disposable Instruments

Tool	Image	Material
Silicone Retractor Cord		Platinum Silicone 6.35mm Dia x 610mm Long
Foam Pad		9.5mm Thick Gray Polyurethane Open Cell Memory Foam
Coban Wrap		Black Coban Adhesive Tape

PRE-CLEANING CONSIDERATIONS

Any medical equipment that has patient contact in a surgical procedure requires cleaning and sterilization.

Before cleaning, some instruments may need to be disassembled.

- Remove and discard all disposables from instruments prior to cleaning.
- Disassemble instruments with multiple components before cleaning. Refer to the Stryker Leg Positioner User Guide (PN 210470) for disassembly instructions.
- Before starting the cleaning and sterilization process, visually inspect all instruments for damage. Remove any damaged parts from use and have them returned to MAKO Surgical Corp. after cleaning and sterilizing.

INSTRUMENT CLEANING GUIDELINES

To properly clean, disinfect and sterilize the Leg Positioner instrument tray, a cleaning procedure must be completed prior to autoclave sterilization. Use the following general guidelines:

- Wear eye protection and gloves when cleaning or handling contaminated instruments
- Do not immerse electronic equipment or cables in water or other liquids
- Unless specified otherwise, do not disassemble instruments during cleaning or sterilization
- Use only the indicated solvents on equipment.

Caution

All health care workers should become familiar with the necessary Universal Precautions of preventing injuries caused by sharp instruments when handling these devices during, after surgical procedures and during reprocessing.

Caution

Protect and handle delicate instruments so as to avoid damage during the cleaning process.

Caution

Cleaning, disinfecting, and sterilization should be performed by trained personnel only.

Caution

Do not allow blood and/or bodily fluids to dry on the instruments. The decontamination process should begin immediately after completion of the surgical procedure.

Note

Pay particular attention to crevices, serrations, grooves, cannulas, screw holes, screw threads, and other difficult to clean areas until all soil has been removed. Any instruments with moving components should be set in motion during cleaning to ensure all surfaces are cleaned.

Note

If damage is detected on any instrument, please contact MAKO Surgical Corp.'s parent company (Stryker Corporation).

Note

Complete removal of soil from crevices depends on instrument construction, exposure time, pressure of delivered solution, and pH of the detergent solution, and thus may require prior brushing.

INSTRUMENT CLEANING GUIDELINES (CONTINUED)

AUTOMATED CLEANING

1. **Disconnect** the tools and accessories and disassemble instruments with multiple attachments/ components. (Refer to the Stryker Leg Positioner User Guide, PN 210470 for disassembly instructions).
2. **Pre-soak** the instruments in Prolystica Enzymatic for five (5) minutes. Prepare the Prolystica Enzymatic bath according to manufacturer's recommended dilution levels. Fully immerse the instruments and tray separately in the bath during the pre-soak. Clean all hard to reach areas, crevices, and cracks using a soft brush. Prepare the sled for cleaning as shown in the steps on the right.
3. **Rinse** instruments and trays; brush all internal and external surfaces of instruments using soft brushes. Actuate all moving parts while brushing to remove any visible soil.
4. **Arrange the instruments in the trays** as indicated in the tray laminate provided. All tray lids should be removed.

Caution

Components must be placed in trays as pictured in applicable tray laminates to achieve proper sterilization.

Sled Cleaning Prep Step 1

Start with the ball lock lever in the fully open position by turning the ball lock lever counter clockwise in the direction of the green arrow until you hit a physical stop.

Sled Cleaning Prep Step 2

Hold the sled upside down and look for the release lever. Push release lever towards the stop post (in the direction of the green arrow). This will release the hard stop and allow additional rotation of the ball lock lever.

Sled Cleaning Prep Step 3

While holding the release lever, turn the ball lock lever counter clockwise to release the tension on the ball. The ball should now freely rotate.

INSTRUMENT CLEANING GUIDELINES (CONTINUED)

WASHER CYCLE

5. **Pre-wash** with cold water for two (2) minutes.
6. **Enzyme Wash** with hot water, using a disinfecting (enzymatic) solution, for a minimum of five (5) minutes (use manufacturer's recommended dilution rate).
7. **Wash** with Prolystica or similar detergent for ten (10) minutes at set point temperature of 66°C / 150°F.
8. **Rinse** with heated water for five (5) minutes at approximately 80°C / 176°F.
9. **Final Rinse** with heated water for ten (10) minutes at approximately 80°C / 176°F.

DRYING

10. **Remove** the tray from the washer.
11. **Dry** the tray and its contents using a clean soft cloth or by using pressurized air, not exceeding forty (40) psi.
12. **Visually** examine all instruments for any noticeable soil. Repeat the cleaning process, if necessary.

Table 3. Automated Cleaning Parameters

Phase	Recirculation Time (Minutes)	Temperature	Solution
Pre-wash	02:00	Cold tap water	N/A
Enzymatic Wash	05:00	Hot tap water	Prolystica 2x Concentrate Enzymatic (1/8 oz per gallon)
Wash 1	10:00	66°C / 150°F	Prolystica 2x Concentrate Enzymatic (1/8 oz per gallon)
Rinse 1	05:00	80°C / 176°F	N/A
Rinse 2	10:00	80°C / 176°F	N/A
Drying	07:00	115.5°C / 239.9°F	N/A

INSTRUMENT LUBRICATION

Spray all joints and moving parts with Barrier Milk Lubricant (or equivalent) prior to sterilization.

Caution

Failure to lubricate instruments with Barrier Milk Lubricant (or equivalent) may reduce instrument life and reduce mechanical function.

STERILIZATION GUIDELINES

Caution

The presence of blood, tissue, soil, or soap residue may prevent the tool(s) from being properly sterilized. Remove all debris and residue prior to sterilization. Failure to comply may prevent the tool(s) from being properly sterilized.

Sterilization trays do not by themselves provide a sterile barrier and must be used in conjunction with sterilization wrap to maintain sterility.

Sterilization trays can be cleaned with water and a mild detergent.

Cleaned instruments should be assembled into the appropriate instrument tray.

Note

Ensure all instruments are removed from shipping packaging materials and thoroughly cleaned prior to sterilization.

The set parameters indicated were validated with only one instrument set in the sterilizer. It is the responsibility of the healthcare facility to qualify their sterilizer's maximum load capacity and determine what effect the loading pattern of the sterilizer has on the sterilization of devices.

Note

The healthcare facility is ultimately responsible for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance. Testing must be conducted in the healthcare facility to validate that conditions essential to sterilization can be achieved.

Note

Refer to the appropriate steam sterilizer instructions for use for complete information on the operation and use of these types of sterilizers.

Caution

Do not sterilize the rubber protection caps, packaging materials, package insert, and labels. Prior to sterilization, remove the rubber protection caps from the instruments. Discard rubber protection caps and packaging material.

STERILIZATION GUIDELINES (CONTINUED)

Table 4 describes the sterilization process in terms of temperature required, cycle time and dry time for all instruments and trays.

Table 4. Sterilization Techniques

Method	Cycle	Temperature	Exposure Time (in minutes)	Drying Time (in minutes)
Moist Heat Sterilization according to ANSI/AAMI ST79	Pre-Vacuum (Pre-Vac)	132°C (270°F)	4 (minimum)	30 (minimum, in chamber)

REUSABILITY

Surgical instruments and trays are susceptible to damage from prolonged use, misuse or inappropriate handling. Care must be taken to avoid compromising their performance. To minimize damage:

- Inspect trays and instruments for damage when received and after each use
- Improperly cleaned instruments should be re-cleaned, and those that need repair returned for servicing.

CONDITIONS FOR STORAGE

STORAGE AND SHELF LIFE

Caution

Instruments and accessories should be stored in a dry, clutter-free area and positioned so that trays are protected from being bumped or damaged.

Instrument trays that have been wrapped and sterilized should be stored in a manner to avoid extremes in temperature and moisture. Care must be taken in handling wrapped trays to prevent damage to the sterile wrap. It is the responsibility of the healthcare facility to establish a shelf life for wrapped instrument trays, based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer.

Note

Shelf life and handling may affect sterility over time.

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A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. The products depicted are CE marked according to the Medical Device Directive 93/42/EEC. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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