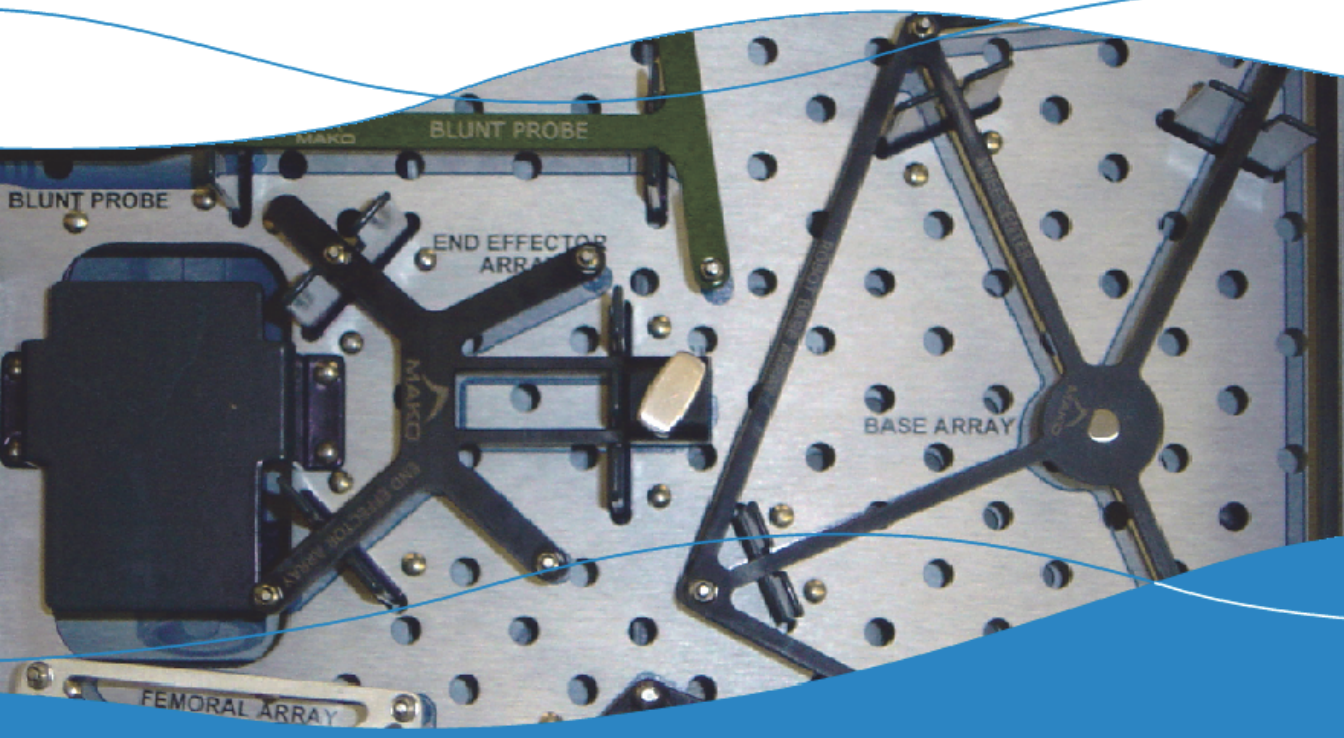
MAKOplasty® Partial Knee Instrument Cleaning and Sterilization Guide

201845 Rev 10



MAKO SURGICAL CORP.®

This page intentionally left blank

Table of Contents

This page intentionally left blank

A. INTRODUCTION

1. About This Manual

This manual describes cleaning and sterilization procedures for MAKO Surgical Corp. instrumentation.

2. Support / Feedback

Corporate Office Phone +1 (954) 927-2044
Corporate Office Fax +1 (954) 927-0446
makosurgical.com

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 Broward County, Florida, and shall be governed by the laws of the State of Florida, without regard to conflicts of laws principles.

5. Manufacturer

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

6. Symbols used in this manual

Useful information or clarification.

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

B. DOCUMENT REFERENCES

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

RIO® Technical User Guide - Electrical safety, preventive maintenance, and technical specification information related to the *Robotic Arm Interactive Orthopedic System (RIO®)*.

There are no user serviceable parts in the RIO®, refer to your MAKO authorized personnel for service.

RIO® Knee Application User Guide and *RIO® System User Guide* - Instructions outlining steps to aid in the clinical implementation of a RIO® Knee procedure.

C. INITIAL USE OF INSTRUMENTS

Remove all packaging material from instruments. Open all instrument trays and confirm internal packaging materials are removed.

Probe and Array Preparation.

Remove plastic caps only. DO NOT disassemble probe tip or posts from probes and arrays.

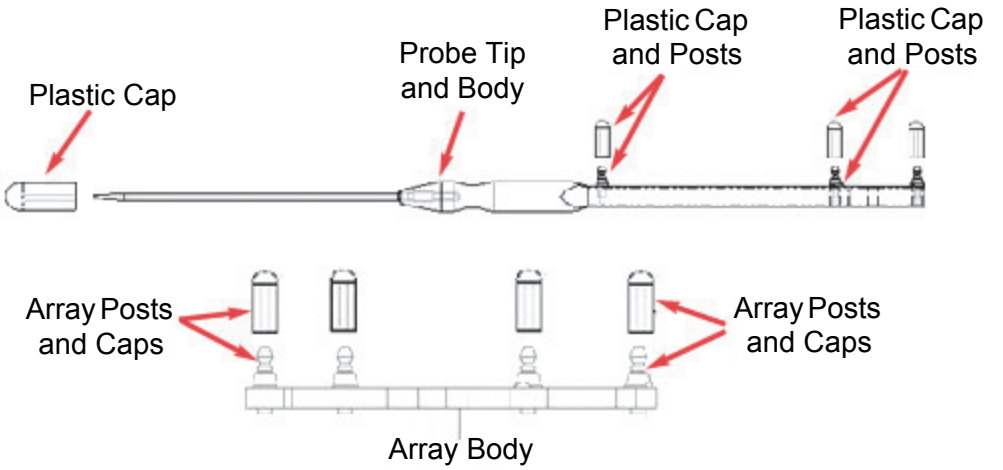


Figure 1. Removal of Packaging Materials

D. INSTRUMENT MATERIALS

Table 1. MAKOplasty® Instrument Tray Material

Tool	Material
Blunt Probe	Al 6061-T6, 17-4 PH Stainless Steel, 303 Stainless Steel
Sharp Probe	Al 6061-T6, 17-4 PH Stainless Steel, Al 6061-T6
Tibial Array	Al 6061 T6, 17-4 PH Stainless Steel
Femoral Array	Al 6061 T6, 17-4 PH Stainless Steel
Base Clamp	316L Stainless Steel, 17-4 PH Stainless Steel, 18-8 Stainless Steel, Nitronic 60 Stainless Steel
Array Clamp	316L Stainless Steel, Nitronic 60 Stainless Steel
Base Array	Al 6061 T6
End Effector	17-4 PH SST, 17-7 PH SST, 305 SST, N3971, Silicone
End Effector Array	Al 6061 T6, 316 Stainless Steel
Drill Guide, Double Barrel	Al 6061 T6, 316L Stainless Steel, 316L Stainless Steel, 316L Stainless Steel
Square Driver	Silicone Stainless Steel 316L
Depth Gauge	304 Stainless Steel
Checkpoint Driver	316L Stainless Steel, Al 6061-T6
Femoral Trial Inserter/ Slaphammer Extractor	316L Stainless Steel or 365C Stainless Steel
Square Drill Adaptor	17-4 PH Stainless Steel
Blunt Introducer	316L Stainless Steel
Cement Removal Tool	17-4 PH Stainless Steel
End Effector Wrench	420 Stainless Steel

Table 2. RESTORIS® Tibial Onlay Instrument Set Materials

Tool	Material
Onlay Tibial Stylus	316 Stainless Steel, Nitronic 60 Stainless Steel, 17-4 PH Stainless Steel
Onlay Baseplate Templates	17-4 PH Stainless Steel
Onlay Trial Baseplates	17-4 PH Stainless Steel
Onlay Trial Inserts	Acetyl Copolymer
Baseplate Keel Cutter	17-4 PH Stainless Steel
Anterior Cut Reference Guide	17-4 PH Stainless Steel
Quick Release Bone Pin	17-4 PH Stainless Steel
Quick Release Fitting	17-4 PH Stainless Steel
Onlay Gap Gauge 9 mm, 10 mm, 11 mm	Acetyl Copolymer
.125" Drill	17-4 PH Stainless Steel
Cement Removal Tool	17-4 PH Stainless Steel
Angled Insert Impactor	17-4 PH Stainless Steel, Acetyl Copolymer
Baseplate Impactor	17-4 PH Stainless Steel, Acetyl Copolymer
Onlay Handle	17-4 PH Stainless Steel
Baseplate Post Drill Guide	17-4 PH Stainless Steel
Extension EM Guide	Nitronic 60 Stainless Steel, 17-4 PH Stainless Steel
Saw Block RM/LL, LM/RL Assembly	Nitronic 60 Stainless Steel, 17-4 PH Stainless Steel
EM Varus/Valgus Ankle Guide	Nitronic 60 Stainless Steel, 17-4 PH Stainless Steel
Insert Impactor	17-4 PH Stainless Steel, Acetyl Copolymer
Post Drill	17-4 PH Stainless Steel

Table 3. RESTORIS® Femoral Instrument Set Materials

Tool	Material
.125 Inch Drill Bit	17-4 PH Stainless Steel
Head and Headless Pin Puller	17-4 PH Stainless Steel
Headed Pins	17-4 PH Stainless Steel
Femoral Templates	17-4 PH Stainless Steel
Peg Drill	17-4 PH Stainless Steel
Femoral Template Handle	17-4 PH Stainless Steel
Uni knee Sizers	17-4 PH Stainless Steel
Femoral Trials (All sizes)	CoCr
Femoral Impactor	17-4 PH Stainless Steel, Acetyl Copolymer or PPSU (Radel R5500)
Headed Pin Pusher	17-4 PH Stainless Steel

Table 4. RESTORIS® Tibial Onlay Instrument Set Materials

Tool	Material
Alignment Rod	17-4 PH Stainless Steel
Tibial Leveling Guide (All sizes)	17-4 PH Stainless Steel
Tibial Implant Gage	17-4 PH Stainless Steel
Tibial Inlay Implant Trials (All sizes)	Acetyl Copolymer
Tibia Inserter	17-4 PH Stainless Steel
Distractor Assembly	416 Stainless Steel 17-4 PH Stainless Steel, Nitronic 60 Stainless Steel
Distractor Pin	17-4 PH Stainless Steel
4.5 mm Straight Shaft Drill	17-4 PH Stainless Steel

Table 5. RESTORIS® MCK Uni-Instrument Set Materials

Tool	Material
Femoral Trial (All Sizes)	CoCr
Inlay Trials (All Sizes)	PPSU (Radel R5500)
Baseplate Trials (All Sizes)	17-4 PH Stainless Steel
Onlay Insert Trials (All Sizes)	PPSU (Radel R5500)
Impactor Handles	17-4 PH Stainless Steel
Impactor Heads	PPSU (Radel R5500)
One Piece Impactors	PPSU (Radel R5500)
Onlay Insert Extractor	316, 420, 17-4 or 18-8 PH Stainless Steel

Table 6. RESTORIS® MCK Patellofemoral Instrument Set Materials

Tool	Material
PF Trials	CoCr
Patella Dome Trials	PPSU (Radel R5500)
Patella Sizing Guides and Handle	17-4 PH Stainless Steel 316L Stainless Steel
Patellar/Tibial Drill	17-4 PH Stainless Steel
Goelet Retractor	300 Series Stainless Steel
Patella Protector	300 Series Stainless Steel
Townley Caliper	300 and 400 Series Stainless Steel
Impactor Handles	17-4 PH Stainless Steel
Impactor Heads	PPSU (Radel R5500)
Patella Clamp	17-4 PH Stainless Steel and 316L Stainless Steel
Patella Saw Guides	17-4 PH Stainless Steel
Patella Cement Jaw	PPSU (Radel R5500)
Anterior Cut Reference Guide	304, 316, 410 or 17-4 PH Stainless Steel
One Piece Impactors	PPSU (Radel R5500)

Table 7. RESTORIS® MCK Manual Instrument Set Materials

Tool	Material
Femoral Templates	17-4 PH Stainless Steel
PF Templates	17-4 PH Stainless Steel
Baseplate Templates	17-4 PH Stainless Steel
Drills	17-4 PH Stainless Steel
Pin Pusher	17-4 PH Stainless Steel
Pin Puller	17-4 PH Stainless Steel
Pins	17-4 PH Stainless Steel
Onlay Handle	17-4 PH Stainless Steel

E. DISPOSABLES

Table 8 lists items that are designated as disposable and should be used for a single MAKOplasty® surgery. These items should NOT be cleaned or sterilized.

Table 8. Disposable Instruments

Tool	Image	Material
RIO® Drape Kit	N/A	LDPE, HDPE, Tyvek, PE film, EMA
2 mm Fluted Ball Burr		M2 Tool Steel
6 mm Fluted Ball Burr		M2 Tool Steel
2 mm Fluted Router		M2 Tool Steel
1.4 mm Fluted Router		M2 Tool Steel
Irrigation Tube	N/A	Tygon (Latex Free)
Irrigation Clip HD	N/A	304 Stainlees Steel / PEEK
VISADISC		Polycarbonate Resin, 3M 3150A reflective material
Femoral Checkpoint		316L Stainless Steel
Tibial Checkpoint		316L Stainless Steel

Table 8. Disposable Instruments

Tool	Image	Material
Bone Pins		316L Stainless Steel

F. 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 (VIZADISC®, bone pins, etc.) from instruments prior to cleaning. When removing VIZADISC®, gently twist the VIZADISC® clockwise and pull.
- Disassemble instruments with multiple components before cleaning. Some instruments are not intended to be disassembled. Refer to Table 9.
- 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.

Table 9. Instrument Disassembly

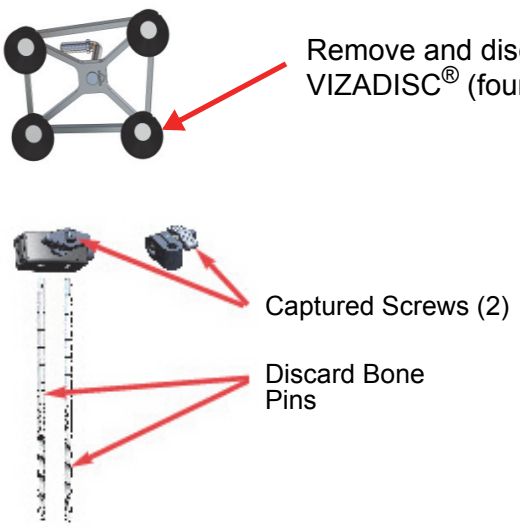
Part Name	Image
Femoral and Tibial Array Assembly	

Table 9. Instrument Disassembly (continued)

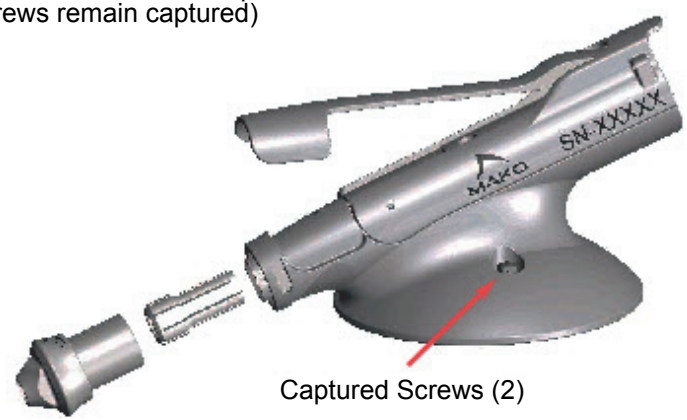
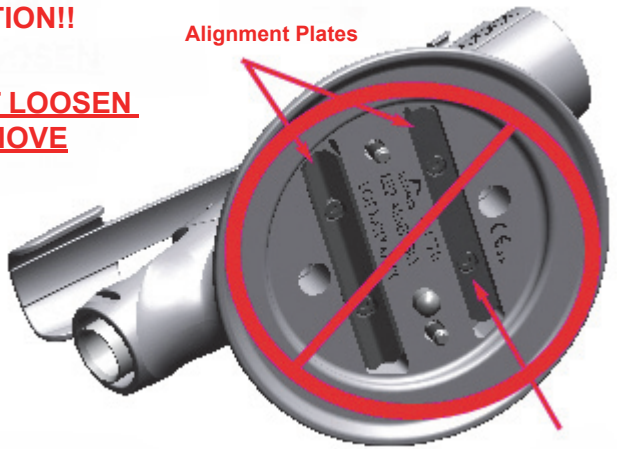
Part Name	Image
End Effector Assembly	Disassemble into 3 components (screws remain captured)  Captured Screws (2)
	ATTENTION!! **DO NOT LOOSEN OR REMOVE**  Loosening or removing the alignment plate screws will damage the End Effector

Table 9. Instrument Disassembly (continued)

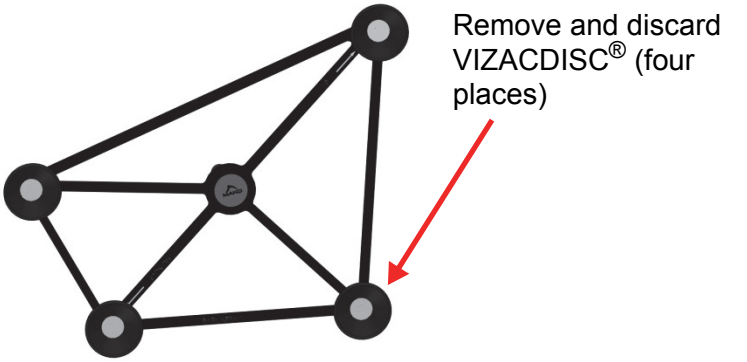
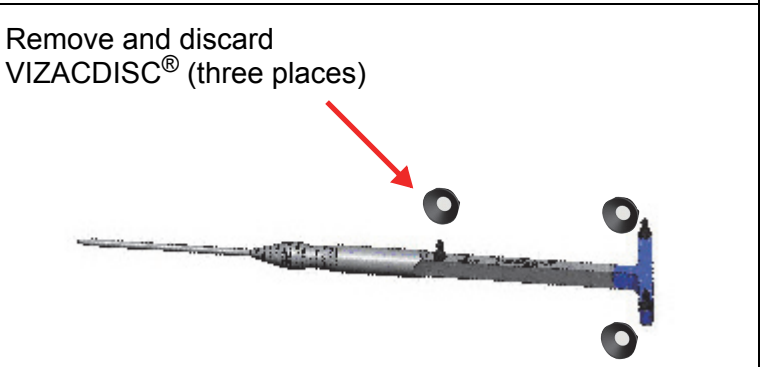
Part Name	Image
Base Array Assembly	

Table 9. Instrument Disassembly (continued)

Part Name	Image
End Effector Array Assembly	
Sharp and Blunt Probes	
Motor and Attachment	

G. INSTRUMENT CLEANING GUIDELINES

To properly clean, disinfect and sterilize MAKO instruments, a cleaning procedure must be completed prior to autoclave sterilization. Manual cleaning methods are to be followed if an ultrasonic cleaner is available. Follow the Automated Cleaning Procedures when using an automated washer system.

Use the following general guidelines for all instruments:

- 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

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

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

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.

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.

If damage is detected on any instrument, please contact MAKO Surgical Corp.

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.

Manual Cleaning

1. **Disconnect** the tools and accessories and disassemble instruments with multiple attachments/components. (e.g., clamp assemblies).
2. **Pre-rinse** to remove all blood, tissue, and visible soil.
3. **Soak** tools in a disinfecting solution for a minimum of five (5) minutes (use manufacturer's recommended dilution rate.)
4. **Thoroughly clean** each part with a soft bristled brush, pipe cleaner, or syringe while soaking. Actuate handles, hinges, and retractable features. Pay particular attention to crevices, cannulas, threads, and other hard to clean areas.
5. **Rinse** parts in water for five (5) minutes while continuing to clean with a syringe or pipe cleaner.
6. **Ultrasonically clean** all parts in disinfecting solution for twenty (20) minutes.
7. **Rinse** parts in water for five (5) minutes while continuing to clean with a syringe or pipe cleaner.
8. **Dry** parts using a clean soft cloth.

Cleaning instructions for Cutting Tool Attachment

Wear eye protection. DO NOT IMMERSE except as specified below. Do not use ultrasonic equipment or corrosive or harsh chemical soaps. Do not rinse attachment with saline solution.

1. Remove attachment and cutting tool from motor handpiece.
2. Fully immerse attachment in an enzymatic cleaner (Alkaline, non-chlorinated detergent (i.e., Steris Liqui-Jet2™)), prepared as described on product label, at room temperature, in a suitable container and agitate for 15 seconds.
3. Gently insert and remove Anspach Attachment Cleaning Brush (ACB) wetted with enzymatic cleaner through distal (tip) opening of attachment as many times as necessary to remove any foreign debris. DO NOT FORCE brush into or through attachment.
4. Remove brush (ACB).
5. Rinse attachment in a suitable container filled with water and agitate for 15 seconds.
6. Repeat steps 1 and 2 if there is evidence of soils or residuals on attachment surface.
7. After cleaning and rinsing, fully immerse attachment in instrument milk (non-silicone based medical lubricant (i.e., Steris Hinge Free Medical Instrument Lubricant)) prepared as described on product label, at room temperature, in a suitable container and agitate for 15 seconds.

8. Remove attachment and allow it to drain.
   a. DO NOT rinse out instrument milk (lubricant).
   b. DO NOT apply mineral oil or other lubricants, which may cause attachment to overheat.

Pre-Sterilization

Wear eye protection. DO NOT IMMERSE! Do not insert brush into motor housing. Do not use saline solution for cleaning. Do not use cleaners containing chlorinated phenois of any concentration. Using cleaners/disinfecting agents containing chlorinated phenois will result in premature hose failure.

Prior to sterilization, wipe with a clean, water-dampened cloth and mild detergent. Silicon Spray or Instrument Milk may be added to lubricate motor/handpiece knurled knob. Silicon spray may be used on hose to prolong its flexibility and to facilitate foreign particle removal.

The motor/handpiece should be tested by running it with an attachment and cutting burr at least every three months for one minute to determine the temperature. If distal tip and main body of motor/handpiece are uncomfortably hot to the touch return instrument to Anspach for servicing.

If occlusion of the motor/handpiece outer hose was suspected or if the pressure relief valve was actuated return instrument to Anspach for servicing.

Motor/Handpiece must not be exposed to ingress of water or to severe physical trauma; degradation of unit function and/or performance may occur.

Instrument Lubrication

For the Onlay Insert Extractor, spray all joints and moving points with Barrier Milk Lubricant (or equivalent) prior to sterilization.

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

Automated Cleaning

Initial Cleaning

1. **Disconnect** the tools and accessories and disassemble instruments with multiple attachments/components. (e.g., clamp assemblies).

All caddies must be removed from instrument tray and prepared as an instrument/ tray.

2. **Pre-soak** the instruments in Enzol for five (5) minutes. Prepare the Enzol bath according to manufacturer's recommendations using lukewarm water. Fully immerse the instruments in the bath during the pre-soak.

All instruments and caddies must be soaked in Enzol separately, then placed within the caddy.

3. **Rinse tray and caddy** in lukewarm water after presoak.
4. **Arrange the instruments in the trays** as indicated in the tray laminates provided. The top level of each tray should be placed in the washer separately. All tray lids should be removed. All caddies should be placed in water separately with the caddy lid in the open position.

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

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 Renu-Klenz® or similar detergent for fifteen (15) minutes at set point Temperature of 60 °C / 140 °F.
8. **Final Rinse** with heated water for five (5) minutes at approximately 43 °C / 109 °F.

Drying

9. **Remove** the tray from the washer.
10. **Dry** the tray and its contents using a clean soft cloth or by using pressurized air, not exceeding forty (40) psi. Place caddies back into the tray position as indicated on the tray laminate.

H. STERILIZATION TRAYS

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.

I. STERILIZATION GUIDELINES

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

Place attached protective cap over electical connector on Anspach electrical Motor/ Handpiece prior to sterilization.

Validation of Process and Responsibility

The following is a list of MAKO Surgical Corp instrument trays which may be sterilized using the sterilization parameters described in this manual.

1. MAKOplasty® Instrument Tray
2. Motor Instrument Tray
3. RESTORIS® MCK Implant System
   a. Uni Instrument Set
   b. Patellofemoral Instrument Set
   c. Manual Instrument Set
4. RESTORIS® Uni Knee System.
   a. Onlay Instrument Set
   b. Inlay Instrument Set
   c. Femoral Manual Instrument Set
   d. Tibial Onlay Manual Instrument Set
   e. Tibial Inlay Manual Instrument Set

MAKO Surgical Corp instruments not included in an instrument tray

Instruments should be cleaned and sterilized separately. Standard cleaning and sterilization parameters described in this manual should be followed.

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

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.

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

Table 10 describes the sterilization process in terms of temperature required, cycle time and dry time for all instruments and trays. 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.

Table 10. Standard Sterilization Techniques

Method	Pre-conditioning Pulses	Minimum Temp	Cycle Time (min.)	Double Wrapped Minimum Drying Time (min)
Gravity Steam Sterilization	N/A	270° to 275 °F (132° to 135 °C)	10	30
Pre-vacuum Steam Sterilization	3	270° to 275 °F (132° to 135 °C)	4	30
Flash Parameters for Pre-vacuum Steam Sterilization	3	270° to 275 °F (132° to 135 °C)	4	N/A

**Flash sterilization can be used for rapid sterilization just prior to use when no dry time is required; flash sterilization is not applicable for the Motor Instrument Tray.*

***If the Onlay Insert Extractor is present, the Double Wrapped Minimum Drying Time (min) must be extended to 45 minutes.*

**** Increase Steam sterilization method to 15 minute cycle time for the Motor Instrument Tray.*

J. 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

K. CONDITIONS FOR STORAGE

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

Storage and Shelf Life

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.

Shelf life and handling may affect sterility over time.

This page intentionally left blank

MAKO Surgical corp. is dedicated to advancing orthopedics through the discovery and development of quality innovative robotic and implantable surgical solutions that consistently, reproducibly, and precisely restore patient quality of life.

All claims of product performance and indications for use contained within this document relate only to data submitted to and reviewed by regulatory authorities in those jurisdictions in which clearance(s) and/or approval(s) have been obtained, including the United States. No product performance claims or indications for use are made for jurisdictions in which such clearance(s) and/or approval(s) have not been obtained.

MAKO SURGICAL CORP.®

MAKOplasty® Partial and Total Knee I MAKOplasty® Total Hip I RESTORIS® Implants
2555 Davie Road I Fort Lauderdale, FL 33317 I 866.647.6256 I makosurgical.com