maci autologous cultured chondrocytes on porcine collagen membrane

# MACI Surgical Implantation Kit Instructions for Use (IFU)

### Intended Use & Indications for Use

The MACI Surgical Implantation Kit is intended to assist with MACI® (autologous cultured chondrocytes on porcine collagen membrane) knee surgery.

- Sterilization tray: encloses, organizes, and allows for sterilization of instruments
- Curettes and cutters: instruments used for defect preparation
- Scissors, cutters, cutting block and mallet: instruments used to cut implant
- Adsons: instruments used to transfer the implant

### Limitations of Use

The silicone Cutting Block is single use only, and all other instruments are reusable.

This kit is shipped non-sterile and must be sterilized at the facility prior to surgery. Sterilization of the kit must occur using a legally marketed, validated, FDA-cleared sterilization wrap (not provided with the kit).

### Device Description

The MACI Surgical Implantation Kit contains instruments to assist surgeons with preparing the defect, cutting the implant, and transferring the implant.

### Precautions

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Kit contains sharp instruments.

### Warnings

If cutters or mallet are used in a patient with, or suspected of having Creutzfeldt Jakob Disease (CJD), the devices cannot be reused and must be destroyed due to inability to reprocess or sterilize to eliminate the risk of cross-contamination.[1]

### Contraindications

Use of ring curettes is contraindicated in patients with Creutzfeldt Jakob Disease (CJD), variant Creutzfeldt Jakob Disease (vCJD), Bovine Spongiform Encephalopathy (BSE), and Transmissible Spongiform Encephalopathy (TSE).[2]

### How Supplied

The MACI Surgical Implantation Kit is supplied non-sterile and must be sterilized prior to each use according to the procedures in this document.

### Kit Contents

The MACI Surgical Implantation Kit contains:

1 - Sterilization Tray
1 - Silicone Cutting Block, Single Use Only
1 - Tungsten Carbide Scissors (32-705)[3]
2 - Toothless Adsons (30-1185)[3]
1 - 4.5mm Ring Curette (8435.902)[2]
1 - 6.0mm Ring Curette (8435.903)[2]
1 - Mallet (FL072K)[1]
1 - Cutter Oval 13X20mm (FR730R)[1]
1 - Cutter Oval 15X23mm (FR731R)[1]
1 - Cutter Oval 20X25mm (FR722R)[1]
1 - Cutter Oval 22X32mm (FR723R)[1]
1 - Cutter Round D15mm (FR721R)[1]
1 - Cutter Round D28mm (FR737R)[1]
1 - Cutter Oblong 10X30mm (FR738R)[1]

### Instructions for Use

The MACI Surgical Implantation Kit must be sterilized prior to each use.

### 1. Inspect

Inspect the kit for all instruments listed in the Kit Components section of this document. Check for possible damage or wear to individual instruments. Full details regarding inspection of the individual devices are available at www.MACI.com/surgical-implantation-kit.

### 2. Sterilize

Sterilize kit in conjunction with legally marketed, validated, FDA-cleared sterilization wrap.
Use the following validated autoclave pre-vacuum sterilization cycle parameters:

- Temperature: 270°F (132°C)
- Exposure Time: 4 minutes
- Dry Time: 30 minutes
- Maximum total tray weight (tray, insert, and instruments): 25 lbs.

These sterilization instructions apply to the assembled kit. Individual device instructions regarding sterilization are available at www.MACI.com/surgical-implantation-kit.

### 3. Clean Following Surgery

Ensure kit has been processed at the local site prior to return shipment according to standard post-surgery instrument cleaning processes. Full details regarding cleaning of the individual devices are available at www.MACI.com/surgical-implantation-kit.

### 4. Return Kit

Return kit using provided return mailing label. Refer to Storage and Handling section.

### Storage and Handling

The assembled kit is packaged between two foam caps inside two layers of gusseted poly bag.

The shipping box contains the packaged assembled kit and the Instructions for Use.

Retain shipping box, foam caps, and poly bags for return shipment to reprocessing vendor following surgery. Return mailing label is included in the shipment.

For additional information, including the full Instructions for Use (with reprocessing directions) for the individual devices in this Kit, refer to www.MACI.com/surgical-implantation-kit.

### Symbols Glossary

| | |
|---|---|
| | Manufacturer |
| UDI | Unique Device Identifier |
| | Refer to Instructions for Use |
| NON STERILE | Non-sterile |
| | Caution |
| ℞ ONLY | Rx Only |
| | Single Use Only |

[1] Aesculap, Inc.
[2] Richard Wolf Medical Instruments Corp.
[3] Symmetry Surgical Inc.

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Vericel Corporation
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Cambridge, MA 02139
L65630.2 August 2022

maci
autologous cultured chondrocytes on porcine collagen membrane

# Cutting Block Instructions for Use (IFU)

### Intended Use & Indications for Use

The Cutting Block is intended to provide a sterile cutting surface during surgery. The Cutting Block may be used for cutting the MACI® (autologous cultured chondrocytes on porcine collagen membrane) implant during implantation surgery.

### Limitations of Use

The Cutting Block is single use only.

It is shipped non-sterile and must be sterilized at the facility prior to surgery.

The unwrapped Cutting Block is placed in the designated location within the MACI Surgical Implantation Kit prior to sterilization.

Sterilization must occur using a legally marketed, validated, FDA-cleared sterilization wrap (not provided).

### Device Description

The Cutting Block is a single-use device made of silicone. It provides a sterile surface to cut the MACI implant during surgery.

### Precautions

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

### How Supplied

The Cutting Block is supplied non-sterile and must be sterilized prior to use.

The device may be supplied individually in a sealed pouch, or it may be supplied unwrapped as part of the MACI Surgical Implantation Kit.

### Instructions for Use

The Cutting Block must be sterilized prior to each use.

**1. Inspect**

Inspect the Cutting Block.

**2. Remove from Packaging**

Remove Cutting Block from outer packaging.

**3. Insert into MACI Surgical Implantation Kit**

The Cutting Block should be inserted into the MACI Surgical Implantation Kit prior to sterilization.

**4. Sterilize**

Sterilize inside the MACI Surgical Implantation Kit using a legally marketed, validated, FDA-cleared sterilization wrap.

Use the following validated autoclave pre-vacuum sterilization cycle parameters:

- Temperature: 270°F (132°C)
- Exposure Time: 4 minutes
- Dry Time: 30 minutes
- Maximum total tray weight (tray, insert, and instruments): 25 lbs.

**5. Dispose After Use—Single-Use Only**

Following surgery, dispose of the device according to local site procedures.

### Symbols Glossary

- Manufacturer
- UDI — Unique Device Identifier
- Refer to Instructions for Use
- Non-sterile
- Caution
- Rx ONLY — Rx Only
- Single Use Only

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# SteriZign Instrument Protection Trays

# Instructions for Use

## Indications for use

### Identification

A sterilization wrap (pack, sterilization wrapper, bag, or accessories, is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until it is used.

SteriZign Precision Technologies' Signatur Device Cassettes and Trays are used to organize, transport, store and protect surgical and other medical devices that are sterilized by a healthcare provider. Signatur Device Cassettes and Trays are intended to allow sterilization of the enclosed medical devices during pre-vacuum steam sterilization cycles. The Signatur Device Cassettes and Trays are not intended to maintain sterility on their own. SteriZign Signatur Device Cassettes and Trays have perforations and are intended to be used in conjunction with legally marketed, validated, FDA-cleared sterilization wrap.

### Validated autoclave pre-vacuum sterilization cycle parameters:

- Temperature: 270°F (132°C)
- Exposure Time: 4 minutes
- Dry Time: 30 minutes
- The total tray weight (tray, insert and instruments): 25 lbs.

### Validated sizes of stainless-steel instrument lumens include:

- 1 each 1mm x 76 mm
- 1 each 1mm x 400 mm
- 1 each 2mm x 400 mm
- 1 each 3mm x 400 mm
- 1 each 5mm x 400 mm

## Device description

SteriZign instrument protection trays (Signatur, Optimyz™ and Kustomyz™ models) are a required containment accessory for complex and delicate surgical instruments and accessories during the sterilization process and subsequent storage and transport. The trays are provided in various sizes of the same basic configuration: a rectangular base with a cover. The trays have perforations designed specifically to allow sterilant penetration. They are constructed with additional silicone brackets in the base and/or cover to provide enhanced organization, stabilization and protection for the instruments and devices within the tray.

## Limitations for use

1) The life of the system is limited only by irreparable physical damage from mishandling. Always inspect the system before each use for wear and damage. Discontinue use if there are visible signs of damage; i.e., flaking, cracking, fading, or sharp edges. Always inspect the system between uses, and repair or replace tray components as necessary. Use only SteriZign original equipment replacement parts. Use of non-SteriZign parts may cause the system to not perform as intended.

2) DO NOT OVERLOAD TRAYS. The total weight of a tray (e.g. tray, insert and instruments) should never exceed 25 lbs.

3) This system must be used in conjunction with a legally marketed, FDA cleared sterilization wrap in order to maintain sterility of the contents. Always follow the wrap manufacturer's instructions when using sterilization wrap. KIMGUARD® ONE STEP® Sterilization Wrap was used during validation of SteriZign sterilization and drying cycle parameters.

4) Instrument lumens validated for sterilization in the Signatur cassettes and trays are limited to:

    - 1 each 1mm x 76 mm
    - 1 each 1mm x 400 mm
    - 1 each 2mm x 400 mm
    - 1 each 3mm x 400 mm
    - 1 each 5mm x 400 mm

5) Complex instruments (e.g. endoscopes and instruments with lumens or channels) should be prepared and sterilized according to the instrument manufacturer's instructions.

## Warnings

SteriZign™ Instrument Protection Tray systems are made with anodized aluminum. A neutral pH (6.0-8.5) detergent that is compatible with anodized aluminum must be used to avoid damaging the finish. A detergent with a highly acidic or highly alkaline pH could permanently damage the finish of the tray and metal components. The use of solvents, abrasive cleaners, wire brushes or scouring pads may also damage the finish.

**IMPORTANT: Clean and visually inspect each tray according to the SteriZign instructions for use, before placing it back into service**. SteriZign trays should be visually clean; if soil is seen, re-clean and re-inspect before placing back into service.

## Point of Use

Always use proper PPE (gloves, face shield, gown, etc., per your facility protocols) while cleaning soiled or contaminated SteriZign trays.

## Cleaning

### Automated washer:

SteriZign Instrument Protection Systems are validated for the automatic wash system cycle in Table 1 below.

Table 1: Instrument and Utensil Cycle

| Phase | | Time | Temperature |
|---|---|---|---|
| Pre-wash | | 2 minutes | Cold tap water (nominal temperature < 21°C or < 70°F) |
| Wash | Stage 1 | 1 minute | 122°F (50°C) |
| | Stage 2 | 2 minutes | 150°F (65.6°C) |
| Rinse | | 15 seconds | Hot tap water (nominal temperature 43 - 66°C or 110-150°F) |
| Thermal Rinse | | 1 minute | 194°F (90°C) |
| Dry | | 5 minutes 30 seconds | N/A |

In addition, the following guidance must be followed:

1) User should follow washer equipment manufacturer's recommended service and maintenance practices.

2) Detergents should be calibrated according to automated washer manufacturer's instructions.

3) Instrument or utensil cycles are acceptable only if the above automated wash cycle parameters are used.

4) Tray hinges should be in the open position when loading into automated washers.

5) Tray lid should be removed and loaded upright to allow for proper drainage.

6) Instrument trays should not be stacked.

7) Inserts should be removed and loaded separately onto washer rack.

8) Trays should be positioned open for proper exposure to washing detergents and rinsing.

9) Tray contents should be loaded and processed according to manufacturers' instructions.

## Disinfection

SteriZign Signatur trays are intended to be terminally sterilized.

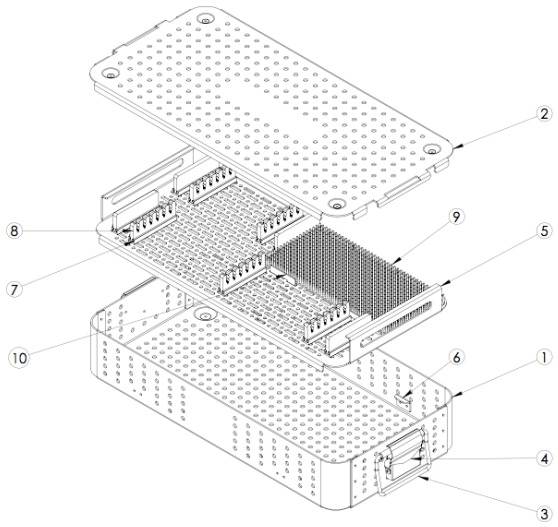
## Maintenance and Inspection

SteriZign Instrument Protection Trays must be inspected after each use for the following signs of mechanical, functional, or surface finish failure:

- Corrosion
- Rust
- Peeling
- Discoloration
- Cracks
- Flaking
- Sharp edges
- Broken or non-working latches
- Missing or torn silicone inserts
- Loose bracket holder

**Parts of the SteriZign Signatur Instrument Protection Tray include:**

1) Base
2) Lid
3) Handles
4) Latches
5) Inserts
6) Insert leveling bracket
7) Aluminum bar holder
8) Silicone bracket
9) Silicone finger mat
10) Mat bracket



## CARE AND HANDLING OF SURGICAL INSTRUMENTS

### PRODUCT DESCRIPTION
Surgical instruments are designed to perform specific functions such as cutting, grasping, clamping, dissecting, probing, retracting, draining, aspirating, suturing, or ligating. Surgical instruments may also be used to facilitate the insertion of surgical implants.

The use of an instrument for tasks other than those for which they are indicated may result in damaged or broken instruments.

Proper cleaning, handling and sterilization and standard routine maintenance (such as sharpening, if applicable) will ensure that the surgical instruments perform as intended and will extend their useful life.

### HOW SUPPLIED
Aesculap's surgical instruments are supplied **non-sterile** and must be cleaned and sterilized prior to each use according to the procedures outlined in this document.

### INSPECTION
Before use, inspect the instruments for possible damage, wear or non-functioning parts. Carefully inspect the critical, inaccessible areas, joints and all movable parts.

Damaged or defective instruments should not be used or processed. Contact your local sales representative or Aesculap, Inc. for repair or replacement.

### PRECAUTIONS
Delicate surgical instruments require special handling to prevent damaging the tips. Use caution during cleaning and sterilization. A non-fibrous sponge should be used to wipe off all blood and debris.

Do not apply excessive stress or strain at joints; misuse will result in misalignment or cracks at the box locks or jaws.

Rongeurs and bone cutting forceps should only be used to cut bone, never wire or pin. Do not twist or apply excessive stress during use.

Wear appropriate protective gloves, eyewear and clothing when handling biologically contaminated instruments.

Instruments manufactured from different metals should be processed separately to avoid electrolytic action between the different metals.

### WARNING
If this device is/was used in a patient with, or suspected of having Creutzfeld Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of crosscontamination.

### CARE AND HANDLING
The procedures outlined below should be followed to ensure safe handling of biologically contaminated surgical instruments. All instruments must be sterilized before use.

#### 1. PRE-CLEANING
Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments.

Remove gross contaminants with a steady stream of lukewarm/cool water (below 110°F/43°C). Rinse each instrument thoroughly. Do not use saline or chlorinated solutions.

Open jaws of hinged instruments for cleaning. Give special attention to joints and serrations. Instruments having more than one part or piece must be disassembled to expose all surfaces to the cleaning process. Retain all parts to facilitate reassembly.

Separate sharps and delicate surgical instruments. Avoid processing instruments of different metallic composition together.

Keep ebonized instruments separate from other stainless steel instruments to avoid scratches to and removal of the ebonized coating.

#### 2. CLEANING
*Cleaning Precautions*

- If appropriate, disassemble surgical instruments prior to cleaning and sterilization.
- Do not soak instruments in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed two hours soaking in any solution.
- Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.
- Microsurgical, plated and delicate instruments should be cleaned chemically or manually and should not be processed in an ultrasonic cleaner. Carefully protect the tips of delicate microsurgical instruments throughout the entire cleaning and sterilization process.
- To preserve the surface coating of ebonized instruments, keep ebonized instruments separate from other instruments and avoid mechanical cleaning and abrasive cleaners as these processes can scratch the surface and remove the surface coating.
- Color anodized aluminum instruments may lose their color through the use of conventional, mechanical treatment processes.

**a. Manual Cleaning**

Hand wash using a low-sudsing protein dissolving detergent. Follow manufacturers' directions regarding concentration, temperature, contact time and reuse.

Totally immerse instruments during cleaning to prevent aerosolization.

Use a large syringe or pulsating water jet to thoroughly flush all channels and lumens with cleaning solution to remove debris.

Use appropriate-sized, soft nylon brushes to clean the instruments and their parts.

**b. Ultrasonic and Mechanical Cleaning**

For ultrasonic cleaning, follow manufacturer's specifications for water level, concentration levels of cleaning agent and temperature.

When using mechanical washer, make sure all instruments stay properly in place and do not touch or overlap each other. Do not allow ebonized instruments to come in contact with each other or other instruments.

Always follow the manufacturer's specifications for automatic washer-sterilizers and use a free-rinsing, low-sudsing detergent with a neutral pH (6.0 - 8.5). Due to variations in water quality, the type of detergent and its concentration may require adjustment for optimal disinfection and cleaning.

**c. Rinsing**

Rinse all instruments thoroughly with tap water, deionized or distilled water to remove all traces of debris and cleansing agents. Make sure all internal lumens and ratchets are thoroughly rinsed.

#### 3. DECONTAMINATION
***Note:*** *The decontamination procedure does not sterilize the instruments. Refer to and process the instruments as outlined in the STERILIZATION section.*

Select a proper product for high-level disinfection such as the glutaraldehyde-family of disinfectant products. Follow the cleaning agent's recommended directions regarding concentration, temperature, contact time and solution re-use.

Do not use high acid (pH 4 or lower) or high alkaline (pH 10 or higher) products for disinfection, such as bleach and bi-chloride of mercury.

Completely immerse instruments in the disinfecting solution, including all lumens and shafts. Force solution into all areas and cavities.

Thoroughly rinse with distilled water to remove all traces of disinfecting solution.

#### 4. DRYING
Instruments must be thoroughly dried and all residual moisture must be removed before they are stored. Use a soft, absorbent towel/cloth to dry external surfaces. Compressed air or a 70% alcohol rinse may be used to aid the drying process.

#### 5. LUBRICATION / ASSEMBLY
Lubrication is essential every time instruments are processed. Special attention should be given to lubrication of joints, boxlocks, and movable parts. Only lubricate dry instruments.

Do not use mineral oil, petroleum, or silicone-based products. To lubricate boxlocks and joints, use a non-silicone, water-soluble lubricant prior to sterilization such as Aesculap Instrument Oil, JG598 or JG600.

Reassemble instruments, as necessary, before assembly into baskets or trays. Inspect instruments for bent tips, pits, cracks, misalignment and corrosion. Remove stained, discolored or damaged instruments. Mechanically test the working parts to verify that each instrument performs correctly.

### STERILIZATION
Surgical instruments should be arranged in an open position or disassembled, where applicable.

Instruments may be packaged in rigid containers, woven or non-woven materials. Packaging should ensure sterility of instruments until opened for use at the sterile field and permit removal of contents without contamination.

Sterilization of instruments may be accomplished by steam or ethylene oxide (EtO) gas.

Surgical instruments may also be placed within an rigid sterilization container (e.g. STERILCONTAINER™) in accordance with the manufacturer instruction for use.

The recommended sterilization parameters are as follows:

| | | MINIMUM EXPOSURE TIME | |
|---|---|---|---|
| **Sterilization Method** | **Temperature** | **Wrapped** | **Rigid Container System** |
| **Pre-Vacuum** | 270°-275°F<br>132°-135°C | 4 minutes | 4 minutes<br>(solid or perforated bottom) |
| **Gravity** | 250°-254°F<br>121°-123°C | 15 - 30 minutes | 40 minutes<br>(perforated bottom only) |
| | 270°-275°F<br>132°-135°C | 10 – 25 minutes | 30 minutes<br>(perforated bottom only) |
| **IUSS***<br>**Pre- Vacuum**<br>*Immediate-use steam sterilization | 270°F/132°C | Refer to manufacturer instruction for use | 3 minutes<br>(non-porous items)<br>4 minutes<br>(non-porous & porous items) |
| **IUSS***<br>**Gravity** | 270°F/132°C | Refer to manufacturer instruction for use | Refer to manufacturer instruction for use |
| **Ethylene Oxide (EtO)** | 131°F/55°C | Concentration: 725mg/L<br>Exposure Time: 60 minutes<br>Humidity: ≥ 50%<br>Aeration: 8 hours (minimum) | |

### MAINTENANCE AND REPAIR
If your Aesculap instruments require repair or maintenance, return the instruments in a sturdy box with adequate foam, bubbles or other packaging material to protect the instruments. Send the packaged instruments to:

Aesculap, Inc.
615 Lambert Pointe Dr.
Hazelwood, MO 63042
***Attn.: Aesculap Technical Services***

Instruments returned to Aesculap for repair must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

Products repaired by Aesculap are guaranteed for 90 days to be free of defects in workmanship and parts when used normally for their intended surgical purpose. Any workmanship or parts proving to be defective will be replaced or repaired, at Aesculap's discretion, at no charge to the customer.

Contact your local Aesculap, Inc. representative if you have any questions.

AESCULAP
Aesculap, Inc.
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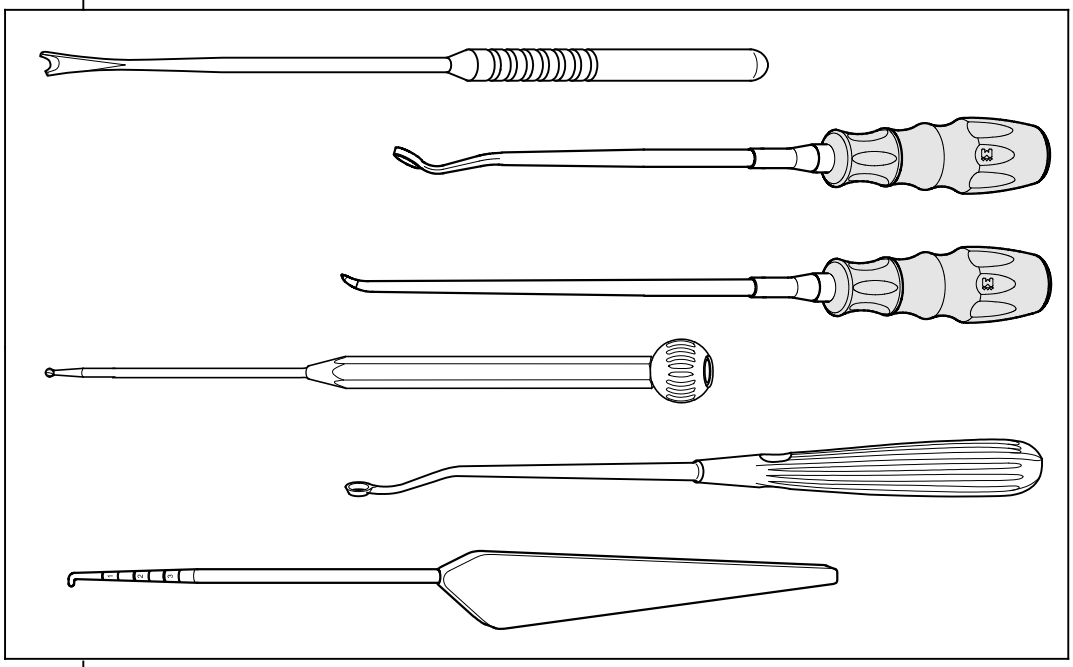
B|BRAUN

SOP-AIC-5000235 Rev. 4 09/15
(IFU-172)

# Instructions



Hand Instruments for Arthroscopy

**GA-B 213** / USA-2.0 / Index: 09-08-3.0 / ÄM: PDI 08-3167

## ⚠ Important general instructions for use ⚠

*Ensure that this product is used only as intended and described in this instruction manual, by adequately trained and qualified personnel, and that maintenance and repair is only carried out by authorized specialized technicians.*

*Use this product only with the combinations and with the accessories and spare parts listed in this instruction manual. Use other combinations, accessories and replacement parts only if they are expressly intended for this use and if the performance and safety requirements are met.*

*Reprocess the products before every application and before returning them for repair as required by the instruction manual in order to protect the patient, user or third parties.*

***Subject to technical changes!***
*Due to continuous development of our products, illustrations and technical data may deviate slightly from the data in this manual.*

*CAUTION :*
*Federal law restricts this device to sale by or on the order of a physician.*

## Safety instructions and levels of danger

| Symbol | Level of danger |
|---|---|
| ⚠ | ***WARNING!***<br>***Failure to observe can result in death or serious injury.*** |
| ⚠ | ***CAUTION!***<br>***Failure to observe can result in slight injury or damage to the product.*** |
| ☞ | ***IMPORTANT!***<br>*Failure to observe can result in damage to the product or surrounding.* |
| ☞ | ***NOTE!***<br>*Tips for optimum use and other useful information.* |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## 1 Technical description

Hand or auxiliary instruments consist of a working element for cutting, ablating, severing or piercing at the distal end and a handle or grip at the proximal end.

These hand instruments are the following:

- ◇ Micro fractors
- ◇ Rasps, files
- ◇ Curettes, spoons
- ◇ Hooks, probes, exploring rods, elevators
- ◇ Scalpels
- ◇ Suture hooks, knot applicators

## 2 Intended use

The instruments listed in the following are used via surgically created passages.

- ◇ **Micro fractors**
  Micro fractors serve to create microfractures in the area of the osteochondral bone to create cell stimulation from the marrow.
- ◇ **Rasps, files**
  Rasps, files etc. are used for freshening ruptured surfaces and in dissecting.
- ◇ **Curettes, spoons**
  Curettes and spoons are used for removing partially severed tissue, tissue stumps, glandular tissue and for dissection.
- ◇ **Hooks, probes, exploring rods, elevators**
  Hooks, probes, exploring rods and elevators are used for blunt preparation, tissue manipulation and elevation as well as for determining the size.
- ◇ **Scalpels**
  Scalpels and scalpel-like instruments are used for the sharp dissection and severing of soft tissue.
- ◇ **Suture hooks, knot applicators**
  Suture hooks and knot applicators are used for manipulating suture material. They facilitate the guiding-out of suture material and serve to push and pull knots tight.

## 3 Indications and field of use

Interventions for diagnosis and treatment in arthroscopy.

For more detailed information on the indications and the field of use of the instruments please refer to the latest catalogue sheets, brochures, or contact Richard Wolf or your representative.

- ◇ **Micro fractors**
  Micro fractures are typically used in the case of cartilage lesions (bone marrow stimulation).
- ◇ **Curettes, spoons, rasps, files and scalpels**
  - In arthroscopy:
    e.g. notchplasty, cruciate ligament stump resection, cartilage lesion, torn meniscus, Bankart operations.
  - Hyperhidrosis:
    e.g. removal of axillary sweat glants.
- ◇ **Hooks, probes, exploring rods, elevators**
  e.g. for diagnosis to establish findings, tension test, function test.
- ◇ **Suture hooks, knot applicators**
  e.g. in case of ruptures of the rotator cuffs and luxation of the shoulder joint.

## 4 Contraindications

**CJD** – **C**reutzfeldt **J**akob Disease or
**vCJD** – **V**ariant Creutzfeldt **J**akob Disease
**BSE** – **B**ovine **s**pongiform **E**ncephalopathy; so-called mad cow disease (e.g. Creutzfeldt Jakob Disease)
**TSE** – **T**ransmissible **s**pongiform **e**ncephalopathy

On the basis of the patient's general condition the doctor in charge must decide whether the planned use is possible or not.
Comply with the laws and regulations valid in your country.
For further notes and instructions please refer to the latest medical literature.
Contraindications directly related to the product are currently unknown.

## 5 Combinations

The hand instruments are combined with the instruments used in arthroscopy.
The instruments should be selected on the basis of the indication and as required by the surgeon.

⚠ ***CAUTION!***
***Do not combine products incorrectly!***
***The patient, user or others may be injured and the product may become damaged.***
***Combine products only if their indications and relevant technical data (working length, diameter, etc.) are the same.***
***Follow the instruction manuals of the products used in combination with this product.***

## 6 Legend and identification

| Symbol | Designation |
|---|---|
| **REF** | Order number |
| LOT | Lot designation |
| **SN** | Serial number |
| CE | Identification in conformity with medical devices directive 93/42/EEC only valid if the product and/or packaging is marked with this symbol. Products of category IIa and above, as well as sterile products or products with measuring function of category I, are additionally marked with the code no. of the notified body (0124). |

# 7 Use

⚠ ***CAUTION!***
***The products have only limited strength!***
***Excessive force will cause damage, impair the function and therefore endager the patient.***
***Immediately before and after each use, check the products for damage, loose parts and completeness.***
***Make sure that no missing parts remain in the patient.***
***Do not use the products if they are damaged or incomplete or have loose parts.***

## 7.1 Preparation

◇ Run through the checks: see section 8

## 7.2 Additional notes and instructions for use

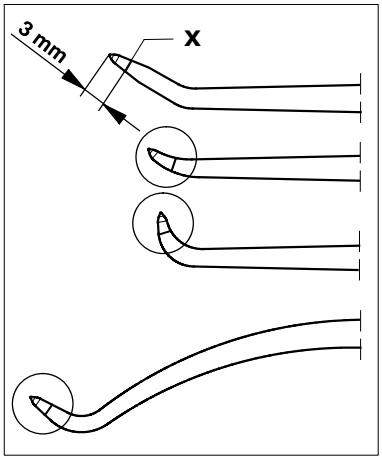
### 7.2.1 Use of curettes for removing loose parts of cartilage

◇ Use a curette for sharp dissection of the undermined cartilage edges up to the solid cartilage.
◇ Place the curettes against the tissue area to be treated.
◗ The edge of the cartilage must be at a right angle to the bone.
◗ Clean the cartilage surfaces from loose fibrous cartilage residues.
◗ Mind the interface to the subchondral bone.

### 7.2.2 Use of micro fractors

◇ Trepanation of the bone surface at distances of approx. 3 mm. Depending on the bone hardness tapping with the hand or a slight blow with the hammer is sufficient.

◗ Select the depth of the impression in such a way that fat droplets emerge. (**BMS**= **B**one **m**arrow **s**timulation)
◗ The conical shape of the micro fractor causes fine bone fissures around each perforation point.




**Micro fractors with distally graduated ring**

◇ The penetration depth up to the graduated ring (x) represents a depth of 3 mm.

## 8 Checks

⚠ ***CAUTION!***
***Be careful if products are damaged or incomplete!***
***Injuries of the patient, user or others are possible.***
***Run through the checks before and after each use.***
***Do not use the products if they are damaged, incomplete or have loose parts.***
***Return damaged products together with any loose parts for repair.***
***Do not attempt to do any repairs yourself.***

### 8.1 Visual check

◇ Check the instruments, in particular their distal area, and the accessories for:
- ◗ damage
- ◗ sharp edges not suitable for the application
- ◗ loose or missing parts
- ◗ rough surfaces.

◇ Any lettering, labeling or identification necessary for the safe intended use must be legible.
- ◗ Missing or illegible lettering, labeling or identifications which can cause wrong handling and reprocessing must be reinstated.

### 8.2 Function check

**Cutting instruments**

◇ Check the necessary sharpness of the instruments.

**Instruments guided in a sleeve**

◇ Check the instruments for easy insertion in the instrument sleeve.
- ◗ Do not use bent instruments.

**Instruments with a rotary ball on the handle**

◇ Check the ball for easy rotation on the handle.

# 9 Reprocessing and maintenance

⚠ ***WARNING!***
***Creutzfeldt Jakob Disease!***
***If the patient is suspected of having the Creutzfeldt Jakob Disease (CJD) or a variant of the Creutzfeldt Jakob Disease (vCJD) or the latter have been diagnosed, adequate measures must be taken to prevent possible transmission to other patients, users and thrid parties.***
***For this purpose apply the country-specific reprocessing guidelines and regulations.***

☞ ***IMPORTANT!***
*Further notes and instructions on reprocessing are described in manual GA-J020* ***"Reprocessing of RICHARD WOLF Heat-Stable Instruments",*** *and these must be followed.*

## 9.1 Manual reprocessing

◇ Wet preparation at the point of use
◇ Manual cleaning with approved enzymatic cleaner.

## 9.2 Machine reprocessing

◇ Dry preparation at the point of use
◇ Machine cleaning with approved enzymatic cleaner.

## 9.3 Checks

◇ Carry out a visual check: see section 8.1

## 9.4 Sterilization

### 9.4.1 Steam sterilization

◇ Steam sterilization at 132° C (270° F) using a Pre-Vac cycle at an exposure time of 4 minutes with a 20 minute dry time.

### 9.4.2 Gas sterilization

◇ Gas sterilization using ethylene oxide (EtO).

### 9.4.3 STERRAD® sterilization

The label claims for Systems (100S or 50) have been expanded to include:
Medical devices with only a single stainless steel lumen in the configurations of:
- An inside diameter of 1 mm (0.04") or larger and a length of 125 mm (5") or shorter.
- An inside diameter of 2 mm (0.08") or larger and a length of 250 mm (10") or shorter
- An inside diameter of 3 mm (0.12") or larger and a length of 400 mm (16") or shorter.
- Titanium is a compatible material.

☞ ***IMPORTANT!***
*Compatibility issues exist for instruments with black chrome plating. The black pigmentation lifts and rubs off. At this time, we do not recommend reprocessing the following instruments with STERRAD®(100S or 50):*
- *Grasping Forceps and Scissors with black metal handles.*
- *Resectoscope working elements.*

*For instruments with long lumens, insure the sterilization medium reaches all surfaces that require sterilization. Follow the sterilizer manufacturer's instruction.*

☞ ***NOTE!***
*Some materials, such as a black anodized aluminum or plastic can become severely discolored. Discoloration will not impair the instruments function.*

## 10 Technical data and order data

For additional information on the reprocessing, see Manual GA-J 020 **“Reprocessing of RICHARD WOLF Heat Stable Instruments”.**

The products can be combined as required provided the relevant technical data and intended uses are observed. For a complete overview please refer to the latest catalogue sheets and brochures or contact Richard Wolf or your representative.

## 11 Operating, storage, transport and shipping conditions

| | |
|---|---|
| Operating conditions | +10°C to +40°C, 30% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa |
| Storage, transport and shipping conditions | -20°C to +60°C, 10% to 90% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa |

☞ ***NOTE!***
*To prevent damage during transport or shipment of the products we recommend using the original packaging material.*

### 11.1 Disposal of product, packaging material and accessories

For the disposal follow the regulations and laws valid in your country.

➧ For further information please contact the manufacturer.

## 12 Warranty and Customer Service

Richard Wolf guarantees our instruments to be free from any defects in materials and workmanship under normal use and service for one year. Richard Wolf general terms and conditions may be found on the back of our invoice.

Parts delivered separately by Richard Wolf are subject to all of the same general terms and conditions for our products, including the limitations of warranty and liability.

All products should be returned to Richard Wolf for any necessary or desired repair or part replacement. No product repair or part replacement should be done other than by Richard Wolf unless the care and instruction manual or other written information indicates that repair or part replacement is authorized. If authorized, parts must be replaced only by parts supplied or specified by Richard Wolf, and product repair and part replacement must be done in strict conformance with Richard Wolf specifications and instructions for repair and part replacement, including post replacement testing and recalibration. Failure to follow this requirement in any way can be dangerous to you, your personnel and your patients and voids the warranty for the product repaired or the product in which the part was replaced and if the part was supplied by Richard Wolf, for that part.

Delivery by Richard Wolf of technical documents such as circuit or other design diagrams does not constitute authorization for product repair or part replacement. Richard Wolf instruments and other products should never be modified or altered under any circumstances.

Contact Richard Wolf if you have any question (1) whether replacement of a part or a repair is authorized by Richard Wolf, or (2) whether you have complete instructions and specifications for part replacement or repair.

These instructions do not attempt to cover all details or variations in equipment, nor to provide for every possible contingency to be met in connection with installation, operation, or maintenance. Should further information be required or should problems arise which are not covered sufficiently for the purchaser's purpose, the matter should be referred to Richard Wolf Medical Instruments Corporation.

Our national sales and service offices, as well as our manufacturing facility, are located in Illinois. Trained manufacturer's representatives are located throughout the U.S. to serve you. For any questions regarding these instruments, or to place an order, contact Richard Wolf customer service department at 847-913-1113 or 800-323-WOLF (9653).

**INSTRUMENT ORDERING POLICY**
Richard Wolf reserves the right to make substitutions, if necessary, without prior notice.

**REPAIR POLICY**
Defective merchandise will be repaired or replaced at no charge to the customer, provided the customer delivers such defective merchandise prepaid. Any repairs, maintenance or servicing of Richard Wolf merchandise by anyone other than a factory authorized representative will render our warranty null and void.

**REPAIR SHIPMENTS**
When returning your instrument for repair, we suggest that you prevent shipping damage to the instrument by reusing the box that it was originally shipped in. Richard Wolf also recommends that the instrument be insured for an amount to cover the cost of replacement.

**IMPORTANT**
For general safety and health reasons, Richard Wolf requires that you clean and sterilize all instruments before returning them for repair. If instruments are received in an unsanitary condition, Richard Wolf will clean and sterilize each instrument and add a $ 100.00 cleaning charge for each instrument requiring cleaning.

# Recommended Care, Cleaning and Sterilization Instructions for Reusable Instruments & Accessories

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Antioch, TN 37013 USA
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CE
0086

**(These instructions pertain to both Class I and Class II devices)**

**LCN 204233-0EN/F**
**Symmetry Surgical Inc. ®**
**Revised 10/15**

# Recommended Care, Cleaning and Sterilization Instructions for Reusable Instruments & Accessories

These instructions are in accordance with ISO 17664 and AAMI ST81. They apply to:

- Reusable surgical instruments and accessories supplied by Symmetry and intended for reprocessing in a health care facility setting. All Symmetry 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 **UNLESS otherwise noted in instructions accompanying a specific instrument.**

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.

These reprocessing instructions have been validated as being capable of preparing reusable Symmetry instruments and accessories for surgical use. It is the responsibility of the user/hospital/health care provider to ensure that reprocessing is performed using the appropriate equipment, materials and that personnel have been adequately trained in order to achieve the desired result; this normally requires that equipment and processes are validated and routinely monitored. Any deviation by the user/hospital/health care provider from these instructions should be evaluated for effectiveness to avoid potential adverse consequences.

| **WARNINGS** ⚠ | |
|---|---|
| | • Symmetry reusable instruments are provided NON-STERILE (NON STERILE) and must be cleaned and sterilized according to these instructions prior to use.<br>• If present, safety caps and other protective packaging material must be removed from the instruments prior to the first cleaning and sterilization.<br>• Ethylene oxide (EO), gas plasma and dry heat sterilization methods are **not recommended** for sterilization of Symmetry reusable instruments. Steam (moist heat) is the recommended method.<br>• Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated instruments.<br>• Caution should be exercised while handling, cleaning, or wiping instruments with sharp cutting edges, tips, and teeth.<br>• Saline and cleaning/disinfection agents containing aldehyde, chloride, active chlorine, bromine, bromide, iodine or iodide are corrosive and **should not** be used.<br>• **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.<br>• Automated cleaning using a washer/disinfector alone **may not** be effective for instruments with lumens, blind holes, cannulas, mated surfaces and other complex features. A thorough manual cleaning of such device features is recommended |

| | |
|---|---|
| | before any automated cleaning process.<br>• Metal brushes and scouring pads must not be used during manual cleaning. These materials will damage the surface and finish of the instruments. Use only soft bristle nylon brushes with different shapes, lengths and sizes to aid with manual cleaning.<br>• When processing instruments do not place heavy devices on top of delicate instruments.<br>• **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.<br>• Do not process instruments with polymer components at temperatures equal to or greater than 140°C/285°F because severe surface damage to the polymer will occur.<br>• Oils or silicone lubricants **should not** be used on surgical instruments. |
| **Limitations on Reprocessing** | • Repeated processing according to these instructions has minimal effect upon metal Symmetry reusable instruments and accessories unless otherwise noted. End of life for stainless steel or other metal surgical instruments is generally determined by wear and damage incurred during the intended surgical use.<br>• Symmetry instruments comprised of polymers or incorporating polymer components can be sterilized using steam however they are not as durable as their metal counterparts. If polymer surfaces show signs of excessive surface damage (e.g. crazing, cracks or delamination), distortion or are visibly warped they should be replaced. Contact you Symmetry representative for your replacement needs.<br>• Non-foaming, neutral pH enzymatic and cleaning agents are recommended for processing Symmetry reusable instruments and accessories.<br>• Alkaline agents with a pH of 12 or less may be used to clean stainless steel and polymer instruments in countries where required by law or local ordinance; or where prion diseases such as Transmissible Spongiform Encephalopathy (TSE) and Creutzfeld-Jakob Disease (CJD) are a concern. **It is critical that alkaline cleaning agents are completely and thoroughly neutralized and rinsed from the devices or degradation may occur that limits the device life.** |

| **REPROCESSING INSTRUCTIONS** | |
|---|---|
| **Point of Use** | • Remove excess biologic soil from the instruments with a disposable wipe. Place devices in a container of distilled water or cover with damp towels.<br><br>**Note: Soaking in an enzymatic solution prepared according to the manufacturer will facilitate cleaning especially in instruments with complex features such as lumens, mating surfaces, blind holes and cannulas.**<br><br>• 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. |
| **Containment and Transportation** | • Used instruments must be transported to the decontamination area for reprocessing in closed or covered containers to prevent unnecessary contamination risk. |

| | |
|---|---|
| **Preparation for Cleaning** | • Instruments designed to come apart must be disassembled prior to cleaning. Disassembly, where necessary, is generally self-evident however for more complicated instruments instructions are provided and should be followed.<br><br>**Note: All recommended disassembly will be possible by hand. Never use tools to disassemble instruments beyond what is recommended.**<br><br>• All cleaning solutions should be prepared at the dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning solutions.<br><br>**Note: Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (turbid).** |
| **Manual Cleaning Steps** | • **Step 1**: Prepare a proteolytic enzyme solution according to the manufacturer's instructions.<br>• **Step 2**: Completely submerge instruments in the enzyme solution and gently shake them to remove trapped bubbles. Actuate instruments with hinges or moving parts to ensure contact of the solution with all surfaces. Lumens, blind holes and cannulas should be flushed with a syringe to remove bubbles and ensure contact of the solution with all instrument surfaces.<br>• **Step 3**: Soak instruments for a minimum of 10 minutes. While soaking scrub surfaces using a soft nylon-bristled brush until all visible soil has been removed. Actuate moveable mechanisms. Particular attention should be given to crevices, hinged joints, box locks, instrument teeth, rough surfaces and areas with moving components or springs.<br>Lumens, blind holes and cannulas should be cleaned using a snug fitting round nylon bristle brush. Insert the snug fitting round brush into the lumen, blind hole or cannula with a twisting motion while pushing in and out multiple times.<br><br>**Note: All scrubbing should be performed below the surface of the enzyme solution to minimize the potential of aerosolizing contaminated solution.**<br><br>• **Step 4**: Remove the instruments from the enzyme solution and rinse in tap water for a minimum of one (1) minute. Actuate all moveable and hinged parts while rinsing. Thoroughly and aggressively flush lumens, holes, cannulas and other difficult to access areas.<br>• **Step 5**: Prepare an ultrasonic cleaning bath with detergent according to the manufacturer's recommendations. Completely submerge instruments in the cleaning solution and gently shake them to remove any trapped bubbles. Lumens, blind holes and cannulations should be flushed with a syringe to remove bubbles and ensure contact of the solution with all instrument surfaces. Sonically clean the instruments at the time, temperature and frequency recommended by the equipment manufacturer and optimal for the detergent used. A minimum of ten (10) minutes is recommended. |

| | |
|---|---|
| | **Notes:**<br>**- Separate stainless steel instruments from other metal instruments during ultrasonic cleaning to avoid electrolysis.**<br>**- Fully open hinged instruments and use wire mesh baskets or trays designed for ultrasonic cleaners.**<br>**- Regular monitoring of sonic cleaning performance by means of an ultrasonic activity detector, aluminum foil test, TOSI™ or SonoCheck™ is recommended.**<br><br>• **Step 6**: Remove the instruments from the ultrasonic bath and rinse in purified water for a minimum of one (1) minute or until there is no sign of residue detergent or biologic soil. Actuate all moveable and hinged parts while rinsing. Thoroughly and aggressively flush lumens, holes, cannulas and other difficult to access areas.<br>• **Step 7**: 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. |
| | |
| **Combination Manual/Automated Cleaning Steps** | • **Step 1**: Prepare a proteolytic enzyme solution according to the manufacturer's instructions.<br>• **Step 2**: Completely submerge instruments in the enzyme solution and gently shake them to remove trapped bubbles. Actuate instruments with hinges or moving parts to ensure contact of the solution with all surfaces. Lumens, blind holes and cannulas should be flushed with a syringe to remove bubbles and ensure contact of the solution with all instrument surfaces.<br>• **Step 3**: Soak instruments for a minimum of 10 minutes. While soaking scrub surfaces using a soft nylon-bristled brush until all visible soil has been removed. Actuate moveable mechanisms. Particular attention should be given to crevices, hinged joints, box locks, instrument teeth, rough surfaces and areas with moving components or springs.<br>Lumens, blind holes and cannulas should be cleaned using a snug fitting round nylon bristle brush. Insert the snug fitting round brush into the lumen, blind hole or cannula with a twisting motion while pushing in and out multiple times.<br><br>**Note: All scrubbing should be performed below the surface of the enzyme solution to minimize the potential of aerosolizing contaminated solution.**<br><br>• **Step 4**: Remove the instruments from the enzyme solution and rinse in tap water for a minimum of one (1) minute. Actuate all moveable and hinged parts while rinsing. Thoroughly and aggressively flush lumens, holes, cannulas and other difficult to access areas.<br>• **Step 5**: Place instruments in a suitable validated washer/disinfector. Follow the washer/disinfector manufacturer's instructions for loading the instruments for maximum cleaning exposure; e.g. open all instruments, place concave instruments on their side or upside down, use baskets and trays designed for washers, place heavier instruments on the bottom of trays and baskets. If the washer/disinfector is equipped with special racks (e.g. for cannulated instruments) use them according to the manufacturer's instructions.<br>• **Step 6**: Process instruments using a standard washer/disinfector instrument cycle |

<table>
<tr><td></td><td>according to the manufacturer's instructions. The following minimum wash cycle parameters are recommended:<br><br>
<table>
<tr><th>Cycle</th><th>Description</th></tr>
<tr><td>1</td><td>Pre-wash --▪-- Cold Softened Tap Water --▪-- 2 minutes</td></tr>
<tr><td>2</td><td>Enzyme Spray & Soak --▪-- Hot Softened Tap Water --▪-- 1 minute</td></tr>
<tr><td>3</td><td>Rinse --▪-- Cold Softened Tap Water</td></tr>
<tr><td>4</td><td>Detergent Wash --▪-- Hot Tap Water (64-66°C/146-150°F) --▪-- 2 min.</td></tr>
<tr><td>5</td><td>Rinse --▪-- Hot Purified Water (64-66°C/146-150°F) --▪-- 1 minute</td></tr>
<tr><td>6</td><td>Hot Air Dry (116°C/240°F) --▪-- 7 to 30 minutes</td></tr>
</table>
<br>Notes:<br>
- The washer/disinfector manufacturer's instructions should be followed.<br>
- A washer/disinfector with demonstrated efficacy (e.g. FDA approval, validated to ISO 15883) should be used.<br>
- Dry time is shown as a range because it is dependent upon the load size placed into the washer/disinfector.<br>
- Many manufacturers pre-program their washer/disinfectors with standard cycles and they may include a thermal low-level disinfection cycle after the detergent wash. The thermal disinfection cycle should be performed to achieve a minimum value $A_0$ = 600 (e.g. 90°C/194°F for 1 minute according to ISO 15883-1) and is compatible with Symmetry instruments.<br>
- If a lubrication cycle is available that applies a water-soluble lubricant such as Preserve®, Instrument Milk or equivalent it is acceptable to use on Symmetry Instruments unless otherwise indicated.</td></tr>
<tr><td>Disinfection</td><td>• Symmetry Surgical instruments must be terminally sterilized prior to use. See sterilization instructions below.<br>• Low level disinfection may be used as part of a washer/disinfector cycle but the devices must also be sterilized before use.</td></tr>
<tr><td>Drying</td><td>• 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.</td></tr>
<tr><td>Inspection & Testing</td><td>• After cleaning, all devices should be thoroughly inspected for residue biologic soil or detergent. If contamination is still present repeat the cleaning process.<br>• Visually inspect each device for completeness, damage and excessive wear. If damage or wear is observed that might compromise the function of the device, do not process them further and contact your Symmetry representative for a replacement.<br>• When inspecting devices look for the following:<br>o Cutting edges should be free of nicks and have a continuous edge.<br>o Jaws and teeth should align properly.<br>o Movable parts should operate smoothly throughout the intended range of motion.<br>o Locking mechanisms should fasten securely and close easily.<br>o Long thin instruments should be free of bending or distortion.</td></tr>
</table>

| | |
|---|---|
| | ○ Where instruments form part of a larger assembly, check that all components are available and assemble readily. |
| **Maintenance and Lubrication** | • After cleaning and before sterilization, instruments with moving parts (e.g. hinges, box-locks, sliding or rotating parts) should be lubricated with a water-soluble lubricant such as Preserve®, Instrument Milk or equivalent material intended for medical device application. Always follow the lubricant manufacturer's instructions for dilution, shelf life and application method. |
| **Packaging for Sterilization** | • Single devices may be packaged in an approved (e.g. FDA cleared or ISO 11607 compliant) medical grade sterilization pouch or wrap. Care should be used when packaging so that the pouch or wrap is not torn. Devices should be wrapped using the double wrap or equivalent method (ref: AAMI ST79, AORN Guidelines).<br>• Reusable wraps are not recommended.<br>• Instruments may be packaged in an approved (e.g. FDA cleared or ISO 11607 compliant) general-use perforated tray or case along with other devices under the following conditions:<br>○ Arrange all devices to allow access of steam to all surfaces. Open hinged devices and ensure devices are disassembled if it is recommended.<br>○ The case or tray must be wrapped in an approved (e.g. FDA cleared or ISO 11607 compliant) medical grade sterilization wrap by following the double wrap method or equivalent (ref: AAMI ST79, AORN Guidelines).<br>○ Follow the case/tray manufacturer's recommendations for loading and weight. Total weight of a wrapped case or tray should not exceed 11.4kg/25lbs.<br>• Instruments may be packaged in an approved (e.g. FDA cleared or ISO 11607 compliant) rigid container systems (i.e. those with filters or valves) along with other devices under the following conditions:<br>○ The container manufacturer's recommendations should be followed regarding preparation, maintenance and use of the container.<br>○ Arrange all devices to allow access of steam to all surfaces. Open hinged devices and ensure devices are disassembled if it is recommended.<br>○ Follow the container manufacturer's recommendations for loading and weight. Total weight of a filled container system should not exceed 11.4kg/25lbs. |
| **Sterilization** | • Moist heat/steam sterilization is the recommended method for Symmetry instruments.<br>• Use of an approved chemical integrator (class 5) or chemical emulator (class 6) within each sterilization load is recommended.<br>• Always consult and follow the sterilizer manufacturer instructions for load configuration and equipment operation. Sterilizing equipment should have demonstrated efficacy (e.g. FDA clearance, EN 13060 or EN 285 compliance). Additionally the manufacturer's recommendations for installation, validation, and maintenance should be followed.<br>• Validated exposure times and temperatures to achieve a $10^{-6}$ sterility assurance |

level (SAL) are listed in the following table.

| Cycle Type | Minimum Temperature | Minimum Exposure Time |
|---|---|---|
| **United States Recommended Parameters** | | |
| Pre-vacuum / Vacuum Pulse | 132°C/270°F | 4 minutes |
| **Cycle Type** | **Minimum Temperature** | **Minimum Exposure Time** |
| **European Recommended Parameters** | | |
| Pre-vacuum / Vacuum Pulse | 134°C/273°F | 3 minutes |

**Drying & Cooling**

- The recommended drying time for single wrapped instruments is 20 minutes unless otherwise noted in device specific instructions.
- Drying times for instruments processed in containers and wrapped trays can vary depending upon the type of packaging, type of instruments, type of sterilizer and total load. A minimum dry time of 30 minutes is recommended but to avoid wet packs, extended dry times greater than 30 minutes may be needed for larger loads under certain conditions or if otherwise recommended in accompanying documentation. For large loads verification of dry times by the health care provider is recommended.

- A 30 minute minimum cooling time is recommended after drying but longer times may be necessary because of load configuration, ambient temperature and humidity, device design and packaging used.

**Note: Disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is a concern about TSE/CJD contamination are: 134°C/273°F for 18 minutes. Symmetry medical devices are compatible with these parameters.**

**Storage**

- Sterile packaged instruments should be stored is a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin and temperature/humidity extremes.

**Note: Inspect every package before use to ensure that the sterile barrier (e.g. wrap, pouch or filter) is not torn, perforated, shows signs of moisture or appears to be tampered with. If any of those conditions are present then the contents are considered non-sterile and should be re-processed through cleaning, packaging and sterilization.**

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