




SYMMETRY SHARP KERRISON® RONGEUR



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CE
0086

These instructions pertain to both
Class I (CE) and Class IIa (CE0086) devices.

LCN 206835-001 Rev H
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Revised 11/16



ENGLISH

IMPORTANT INFORMATION

Please Read Before Use

Indications

The Symmetry Sharp Kerrison® Rongeur is indicated for cutting bony tissue of the spine. The Symmetry Sharp Kerrison® Rongeur is a manually operated instrument that consists of a handle and tips (Symmetry Sharp Kerrison® Tips (single use) or Reusable Tips for the Symmetry Sharp Kerrison® Handle).




Product Description

The Symmetry Sharp Kerrison® Rongeur (Figure 1) is a manually operated instrument that consists of:

- A reusable Symmetry Sharp Kerrison® Handle
- A pair of mated tips
 - Sold as single-use, sterile Symmetry Sharp Kerrison® Tips or
 - Non-Sterile Reusable Tips for the Symmetry Sharp Kerrison® Handle.

The handles are available in various working lengths. The tips are available in a variety of footplate sizes. Any pair of mated tips can be used with any size Symmetry Sharp Kerrison® Handle. Use **only** the Symmetry Sharp Kerrison® Tips or the Reusable Tips for the Symmetry Sharp Kerrison® Handle. Please consult your Symmetry Surgical® Sales Representative for ordering information.

How Supplied		
Symmetry Sharp Kerrison® Tips:	Symmetry Sharp Kerrison® Handle	Reusable Tips for the Symmetry Sharp Kerrison® Handle
<p>Symmetry Sharp Kerrison® Single Use devices are supplied sterile and have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use.</p> <p>Symmetry Surgical® will not be responsible for single use devices that are re-sterilized, nor accept for credit or exchange any Sharp Kerrison® Rongeur that has been opened and not used.</p> <p>As long as the inner pouch is not opened or damaged, the product is sterile.</p>	<p>The Symmetry Sharp Kerrison® Handle is provided non-sterile and must be cleaned, lubricated and sterilized before use, including prior to its initial use. Failure to follow these procedures will invalidate the instrument's warranty and can cause the instrument to fail.</p>	<p>The Reusable Tips for the Symmetry Sharp Kerrison® Handle are provided non-sterile and must be cleaned, lubricated and sterilized before use, including prior to its initial use. Failure to follow these procedures will invalidate the instrument's warranty and can cause the instrument to fail.</p>

Precautions		
Symmetry Sharp Kerrison® Tips	Symmetry Sharp Kerrison® Handle	Reusable tips for the Sharp Kerrison® Handle
<p>Inspect the sterile package carefully. Do not use if:</p> <ul style="list-style-type: none"> the package or seal appears to be breached or damaged, contents appear to be damaged, or the expiry date has passed. <p>The tips are for single use only. Do not reuse.</p> <p>Reuse can also compromise device performance and any usage beyond the design intent of this single-use device can result in unpredictable use hazards or loss of functionality.</p> <p>Sterilization of the tips by any method could cause a malfunction, resulting in patient injury. Do not use the tips if they have been resterilized by any means.</p> <p>Use sterile technique in all phases of handling this product.</p>	<p>Do not attempt to adjust or disengage the spring on the handle.</p>	<p>The reusable tips are mated parts. The tip components must be mated to ensure product performance. The product is mated properly by ensuring the lot number, mating number, and product size marked on the top and bottom components match. If the product is not mated correctly, the tips will not function as expected.</p> <p style="text-align: center;"> Lot Mating Number Number ↓ ↓ </p>  <p style="text-align: center;">Top tip component size marking:</p>  <p style="text-align: center;">Bottom tip component size marking:</p>  <p>The reusable tips are to be used until they become dull. Note that the Reusable Tips for the Symmetry Sharp Kerrison® Handle are not covered under warranty for dulling after use. The tips should be disposed of in accordance with your facility's guidelines for biohazard sharps materials and replaced with another pair of reusable tips.</p> <p>DO NOT sharpen tips.</p>




Warnings

Incorrect handling can cause damage to or destruction of the product.

- Use product for its intended use.
- Avoid overstraining the product by twisting or levering the product during the procedure.

Discard all product components after suspected Creutzfeldt-Jakob disease (CJD) exposure; the rongeur tips and handles have not been validated to withstand the chemical and thermal exposures recommended to eradicate prions.

INSTRUCTIONS FOR USE

<p>Product Assembly: WARNING: Handle the working end of the tips with care; the jaws (cups) are sharp and can cause injury.</p>	
<p>Symmetry Sharp Kerrison® Tips (sterile, single-use) and the Symmetry Sharp Kerrison® Handle</p>	<p>Reusable Tips for the Symmetry Sharp Kerrison® Handle and the Symmetry Sharp Kerrison® Handle</p>
<p>1. Remove the tips from the sterile package. Leave the protective tube in place on the jaws of the tips to protect hands and gloves. The shaft keys will be protruding from the tube. If insertion without the protective tube is necessary, use sterile gauze around the jaws of the tips to protect hands and gloves.</p>	<p>1. Prepare tips for insertion into the handle. If the tip components are not already mated, mate the top and bottom tip components properly by ensuring the lot number, mating number, and product size marked on the top and bottom components match. Use sterile gauze around the jaws of the tips to protect handle and gloves.</p> <div style="text-align: center;"> <p>Lot Number Mating Number</p> <p>↓ ↓</p>  <p>Top tip component size marking:</p>  <p>Bottom tip component size marking:</p>  </div>
<p>2. Depress the safety-locking lever on the underside of the Symmetry Sharp Kerrison® Handle (See Figure 2).</p>	<p>2. Depress the safety-locking lever on the underside of the Symmetry Sharp Kerrison® Handle (See Figure 2).</p>
<p>3. While continuing to depress the safety-locking lever, with the jaws of the tips correctly oriented, insert the tip shaft keys into the receptacles in the handle (See Figure 3). Push the tips in until a double clicking sound is heard and they are firmly attached to the handle. The tip shafts can be inserted either together or singly until they are fully seated (See Figure 4).</p>	<p>3. While continuing to depress the safety-locking lever, with the jaws of the tips correctly oriented, insert the tip shaft keys into the receptacles in the handle (See Figure 3). Push the tips in until a double clicking sound is heard and they are firmly attached to the handle. The tip shafts can be inserted either together or singly until they are fully seated (See Figure 4).</p>
<p>4. Release the safety-locking lever.</p>	<p>4. Release the safety-locking lever.</p>
<p>5. Ensure that the shaft keys of both upper and lower jaws of the tip are completely inserted into the receptacle. Use sterile gauze around the jaws of the tips to protect hands and gloves if the protective tube is no longer in place. Check the security of the tips by attempting to pull them out of the handle without depressing the tip release levers of the handle or the safety-locking lever.</p>	<p>5. Ensure that the shaft keys of both upper and lower jaws of the tip are completely inserted into the receptacle. Use sterile gauze around the jaws of the tips to protect hands and gloves. Check the security of the tips by attempting to pull them out of the handle without depressing the tip release levers of the handle or the safety-locking lever.</p>

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<p>6. If the tips are not fully seated in the handle, repeat steps 2 through 4.</p>	<p>6. If the tips are not fully seated in the handle, repeat steps 2 through 4.</p>
<p>7. Remove the protective tube from the tips if it is still in place.</p>	<p>7. Carefully actuate the handle to verify smooth movement and function of the tips after their insertion. CAUTION: Do not close the rongeur tips while they are empty. Metal-on-metal contact will dull the jaws of the tips prematurely.</p>
<p>8. Carefully actuate the handle to verify smooth movement and function of the tips after their insertion. CAUTION: Do not close the rongeur tips while they are empty. Metal-on-metal contact will dull the jaws of the tips prematurely.</p>	

<p>Disassembly and Disposal: Use sterile gauze around the jaws of the tips to protect hands and gloves. Disassemble the tips from the handle by executing the following steps:</p>	
<p>Symmetry Sharp Kerrison® Tips (sterile, single-use) and the Sharp Kerrison® Handle</p>	<p>Reusable Tips for the Symmetry Sharp Kerrison® Handle and the Symmetry Sharp Kerrison® Handle</p>
<p>1. Using the right hand, depress the safety-locking lever on the underside of the Kerrison handle (See Figure 5).</p>	<p>1. Using the right hand, depress the safety-locking lever on the underside of the Kerrison handle (See Figure 5).</p>
<p>2. While keeping the safety-locking lever depressed, use the left thumb to depress with force the proximal end of both tip release levers at the same time. Both tips should slightly eject from the handle receptacles. DO NOT RELEASE THE TIP RELEASE LEVERS. (See Figure 6)</p>	<p>2. While keeping the safety-locking lever depressed, use the left thumb to depress with force the proximal end of both tip release levers at the same time. Both tips should slightly eject from the handle receptacles. DO NOT RELEASE THE TIP RELEASE LEVERS. (See Figure 6)</p>
<p>3. While keeping the tip release levers depressed with the left hand, release the safety-locking lever and using the right hand, remove the tips. (See Figure 7)</p>	<p>3. While keeping the tip release levers depressed with the left hand, release the safety-locking lever and using the right hand, remove the tips. (See Figure 7)</p>
<p>4. If tips are not releasing from the handle receptacles, repeat steps 1 through 3.</p>	<p>4. If tips are not releasing from the handle receptacles, repeat steps 1 through 3.</p>
<p>5. Dispose of the tips in accordance with your facility's guidelines for biohazardous sharps materials.</p>	<p>5. If the reusable tips have become dull, dispose of the tips in accordance with your facility's guidelines for biohazardous sharps materials.</p>
	<p>6. If the reusable tips are not dull, disassemble the top and bottom tip components for cleaning and sterilization.</p>

REPROCESSING INSTRUCTIONS – Reusable Tips for the Symmetry Sharp Kerrison® Handle (also known as reusable tips) and Symmetry Sharp Kerrison® Handle (also known as handle) Only.

WARNINGS:

- **Do not allow the reusable tips or handle to soak in a saline bath as this may promote premature corrosion.**

The reusable tips must be disassembled from the handle prior to reprocessing and sterilization. The handle and tips must remain disassembled for reprocessing and sterilization.

Limitations of Reprocessing

End of life for stainless steel or other metal surgical instruments is normally determined by wear and damage due to the intended use or misuse, and not reprocessing.

Point of Use Pre-cleaning

Remove excess biologic soil and tissue from the handle and reusable tips using disposable wipes.

As soon as possible after use, set reusable tips and handles in a basin of distilled water or in a tray covered with damp towels.

Cleaning

- Symmetry Surgical® recommends that the reusable tips and handles be cleaned as soon as possible after each surgical procedure in order to limit the drying time of residue biologic soil left on the instruments.
- Water quality used for diluting cleaning agents and for rinsing the reusable tips and handles should be carefully considered. Use of distilled water for cleaning and distilled or sterile water for rinsing is recommended. Avoid using hot water as this will coagulate and harden protein based soil.
- Cleaning agents and disinfectants must be prepared according to the recommendations of their manufacturer. Only use cleaning agents and disinfectants that have a nearly neutral pH and are approved for use on surgical instruments.

A. Manual Cleaning

1. Prepare an enzymatic (protease-based) cleaning solution in accordance with the manufacturer's instructions.
2. After the reusable tips have been disassembled from the handle, separate the reusable tip components from each other and soak both the reusable tips and the handle for a minimum of 10 minutes. Brush all surfaces as described below.
3. While cleaning, fully immerse the reusable tip components and handle in the cleaning solution to avoid aerosol generation. Brush the reusable tips and handle with a soft non-metallic bristle brush, sponge, or cloth to remove all traces of blood and debris, paying particular attention to challenging features and hard to reach areas. When cleaning the handles clean the exposed surfaces thoroughly while squeezing the handle to retract the crossbar. Use a snug fitting pipe cleaner or channel cleaning brush (5mm recommended) to access blind holes or lumens.
WARNING: Use care when cleaning the handle to eliminate the potential for scratching the titanium nitrate coating. DO NOT USE A WIRE BRISTLE BRUSH TO CLEAN. Use a nylon bristle brush, sponge, or cloth to clean.
4. Thoroughly flush the channels of the reusable tips, the dead-end lumens at the tip of the handle, and all other hard to reach features of the device with a syringe (10ml – 30ml recommended).
5. Rinse the reusable tips and handle thoroughly with warm purified water. Actuate the handle while rinsing.
6. Ultrasonically clean the reusable tips and handle for 10 minutes in a neutral pH detergent, prepared in accordance with the manufacturer's instructions.
7. Rinse the reusable tips and handle with warm purified water for a minimum of one minute or until all visual evidence of debris, soil, and cleaning solution are gone.
8. Dry the reusable tips and handle with a clean, absorbent non-shedding wipe. Clean, filtered compressed air may be used to remove moisture from any channels, lumens, and difficult to reach areas.
9. After cleaning, thoroughly inspect the reusable tips and handle for residue, biologic soil, or detergent. If contamination is still present, repeat the cleaning process.

B. Automated Cleaning:

WARNING: When using a washer/disinfector to clean the handle and reusable tips always follow the equipment manufacturer's instructions. After the tips have been disassembled from the handle, manually clean the handle and the reusable tips prior to automated cleaning:

1. Prepare an enzymatic (protease-based) presoak and cleaner in accordance with the manufacturer's instructions.
2. After the tips have been disassembled from the handle, separate the reusable tip components from each other, and soak both the reusable tips and handle for 10 minutes in the presoak/cleaner. Brush all surfaces.
3. While cleaning, fully immerse the reusable tip components and the handle in the cleaning solution to avoid aerosol generation. Brush the reusable tips and handle with a soft non-metallic bristle brush, sponge, or cloth to remove all traces of blood and debris. When cleaning the handles, clean exposed surfaces thoroughly

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while squeezing the handle to retract the crossbar. Use a snug fitting pipe cleaner or channel cleaning brush (5mm recommended) to access blind holes and lumens.

CAUTION: Use care when cleaning the handle to eliminate the potential for scratching the titanium nitrate coating. DO NOT USE A WIRE BRISTLE BRUSH TO CLEAN. Use a nylon bristle brush, sponge, or cloth to clean.

4. Rinse the reusable tips and handle thoroughly with warm purified water; actuate the handle while rinsing.
5. Place reusable tip components and handle in a suitable validated washer/disinfector. Follow the washer/disinfector manufacturer's instructions for loading the instruments for maximum cleaning exposure. Use baskets and trays designed for washers, place heavier instruments on the bottom of trays and baskets.
6. Process the reusable tip components and handles using a standard washer/disinfector instrument cycle according to the manufacturer's instructions. The following minimum wash cycle parameters are recommended:

Cycle	Description
1	Pre-wash • Cold Softened Tap Water • 2 minutes
2	Enzyme Spray & Soak • Hot Softened Tap Water • 1 minute
3	Rinse • Cold Softened Tap Water
4	Detergent Wash • Hot (64-66°C/146-150°F) Tap Water • 2 minutes
5	Rinse • Hot (64-66°C/146-150°F) Purified Water • 1 minute
6	Hot Air Dry (116°C/240°F) • 7 – 30 minutes

7. After cleaning, thoroughly inspect the reusable tips and handle for residue biologic soil or detergent. If contamination is still present, repeat the cleaning process.

C. Lubrication

After cleaning and prior to sterilization, lubricate moving parts with a water-soluble lubricant (such as PRESERVE®) in accordance with the manufacturer's instructions.

D. Inspection

Inspect the reusable tips.

1. Check for damage to the mating features or the cutting surfaces. If damaged, the reusable tips should not be used again.
2. Check for corrosion or rust. Do not use the reusable tips again if corrosion or rust is present.
3. If the tips are damaged and cannot be used, dispose of the tips in accordance with your facility's guidelines for biohazard sharps materials.

Inspect the handle.

1. Check the spring for damage. If damaged, return the handle for service.
2. Check the tip release levers and the safety-locking lever for function by depressing and releasing them. If any of the levers fail to depress (Note: the bottom tip release lever will only depress if the safety-locking lever is depressed) or do not spring back after release, return the handle for service.
3. Check the function of the crossbar and handles by squeezing the handles. If the crossbar or handles do not move freely, return the handle for service.
4. Check for corrosion or rust. Do not use the handle again if corrosion or rust is present.

Note: End of life for stainless steel or other metal surgical instruments is normally determined by wear and damage due to the intended use or misuse, and not reprocessing.

E. Sterilization

- Moist heat/steam sterilization is the recommended method for the Symmetry Sharp Kerrison® Handle and the Reusable Tips for the Symmetry Sharp Kerrison® Handle.
- Always consult and follow the sterilizer manufacturer’s instructions for equipment operation. Sterilizing equipment should have demonstrated efficacy (e.g. FDA approval, process validation, maintenance records).
- Individual devices may be packaged in a 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 AAMI double wrap or equivalent method. The wrap should be cleared for use in the 132°C, 4 minutes pre-vacuum steam sterilization cycle.
- Follow the load configurations specified by the sterilization container and sterilizer manufacturers. The handle and reusable tips may be sterilized with a combined load of up to 17 lbs. The mass of the tips and handle are:

Product Code	Description	Mass (oz)
53-1662R	2 mm Reusable Tip for the Symmetry Sharp Kerrison® Handle	0.4 ± 0.1
53-1663R	3 mm Reusable Tip for the Symmetry Sharp Kerrison® Handle	0.4 ± 0.1
53-1664R	4 mm Reusable Tip for the Symmetry Sharp Kerrison® Handle	0.5 ± 0.1
53-1674	5 inch Symmetry Sharp Kerrison® Handle	6.5 ± 0.2
53-1675	6 inch Symmetry Sharp Kerrison® Handle	7.0 ± 0.2
53-1676	7 inch Symmetry Sharp Kerrison® Handle	7.4 ± 0.2

- Effective steam sterilization can be achieved using the following parameters.

Sterilization Parameters			
Cycle Type	Minimum Temperature	Minimum Exposure Time	Drying Time
Pre-vacuum	132°C/270°F	4 minutes	30 minutes
Pre-vacuum	134°C/273°F*	3 minutes	30 minutes

**These sterilization parameters are for outside the US only and should not be used within the United States. These parameters are not validated for use with FDA-cleared sterilizers.*

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F. Inspection after Sterilization

Inspect the tips. Confirm the top and bottom tip components are properly mated. The product is mated properly by ensuring the lot number, mating number, and product size marked on the top and bottom components match. If product is not mated correctly, tips will not function as expected.

Lot
Number Mating
Number

↓ ↓



Top tip component size:



Bottom tip component size:



Service

For service outside the United States, contact your local authorized Symmetry Surgical® representative. Inside the United States, send all instruments for service to:

Symmetry Surgical, Inc,
3034 Owen Drive
Antioch, TN 37013 USA

Always include the purchase order number and a written description of the problem with your returned instrument.

Callouts:

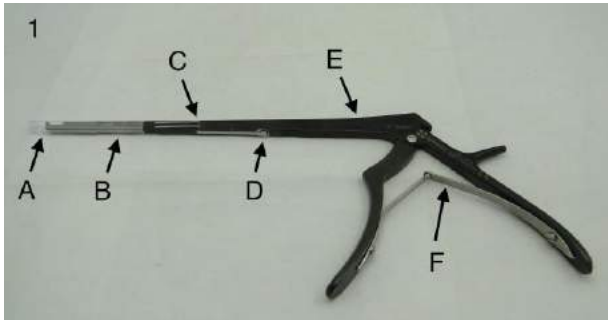


Figure 1

- A. Protective Tube (single use tips only)
- B. Tips
- C. Tip Release Levers
- D. Safety-Locking Lever
- E. Sharp Kerrison Handle
- F. Spring



Figure 2

- A. Safety-Locking Lever

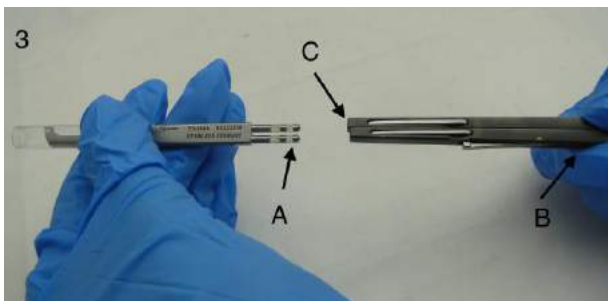


Figure 3

- A. Tip Shaft Keys
- B. Safety-Locking Lever
- C. Handle Receptacles

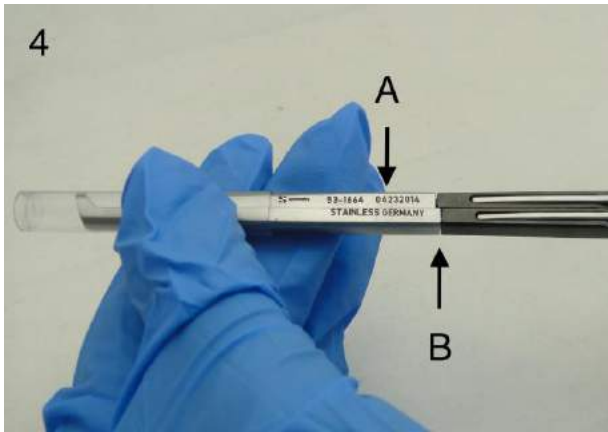


Figure 4

- A. Tips
- B. Tips Seated in Handle Receptacles

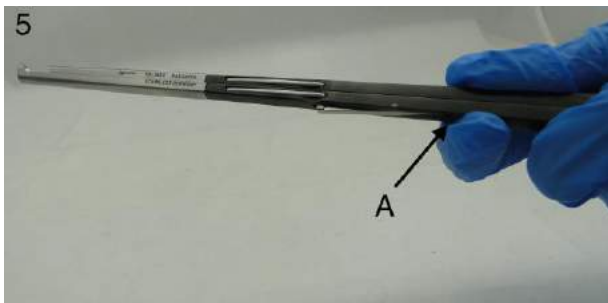


Figure 5

- A. Depressing Safety-Locking Lever

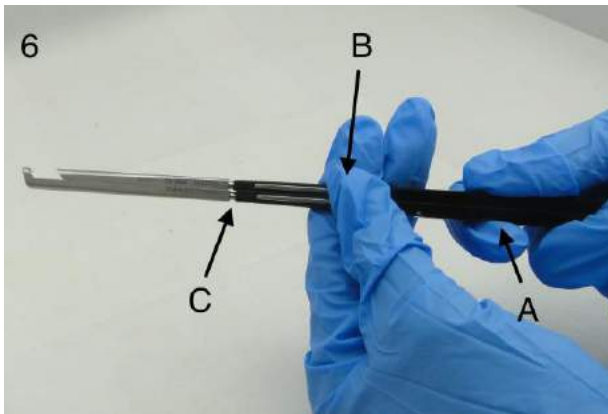


Figure 6

- A. Depressing Safety-Locking Lever
- B. Depressing Proximal End of Tip Release Levers
- C. Tip Shaft Keys Slightly Ejecting from Handle Receptacles

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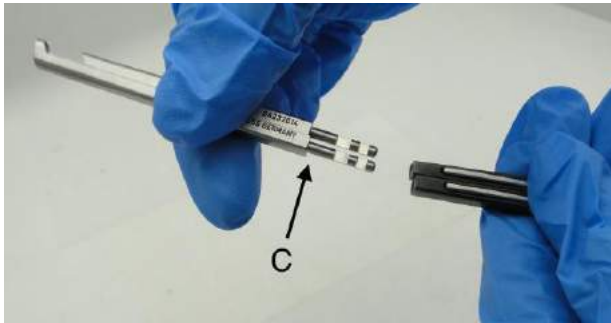
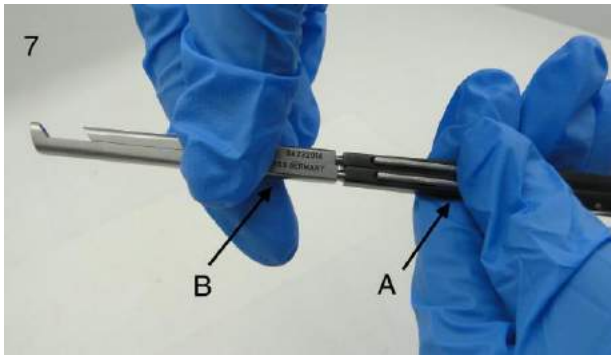


Figure 7

A. Depressing the Tip Release Levers

B. Removing the tips

C. Removal of tips

Warranty

Symmetry Surgical® warrants that this medical device is free from defects in both materials and workmanship. **Any other expressed or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer's instructions for use. There are no warranties that extend beyond the description on the face hereof.**

PRESERVE® is a registered trademark of Symmetry Surgical®.

U.S. Patent No. 8,657,823

Symbols:



Authorized European Representative



Do not resterilize



Do not use if package is damaged



Prescription device only (USA)



Manufacturer



Made in



Quantity

Manufacturer Address:



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