



# Symmetry Sharp Kerrison® Information Packet

# Symmetry Sharp Kerrison®

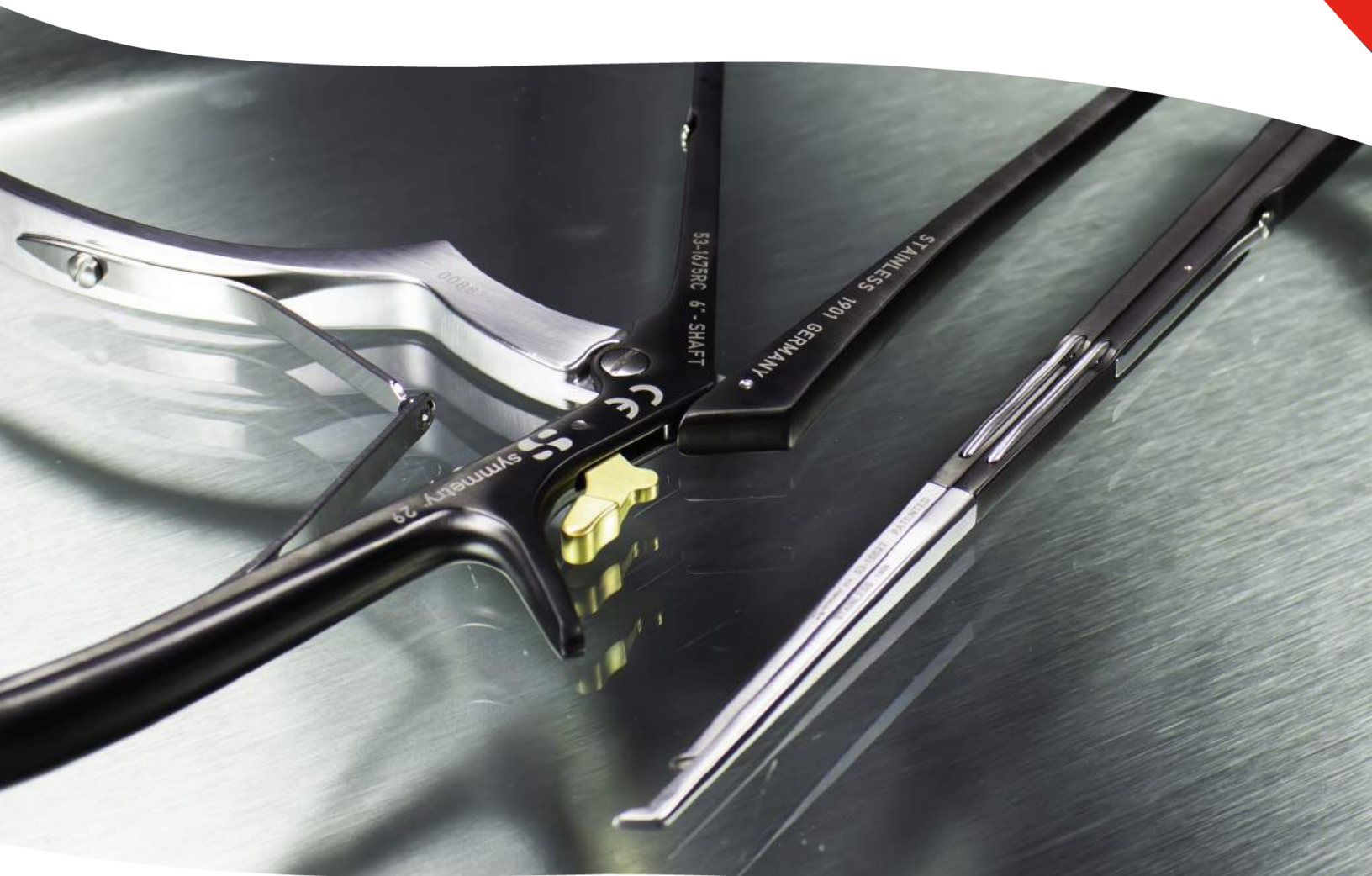
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This product information packet is designed to provide you with clinical and product information on the patented Symmetry Sharp Kerrison®. Please contact your sales representative if you have additional questions about the product.

- Symmetry Sharp Kerrison® Brochure
- Ordering Information
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- Symmetry Sharp Kerrison® White Paper
- 510k Clearance Summary Information



**WHAT IF YOUR BIGGEST  
CHALLENGES WITH KERRISONS  
COULD BE SOLVED WITH ONE PRODUCT?**



**INTRODUCING  
THE RAPIDCLEAN® SYMMETRY SHARP KERRISON®**

# WHAT IF...

**YOU COULD  
HAVE A  
PRODUCTIVE  
BITE EVERY  
TIME?**

**YOU NEVER  
HAD TO USE A  
DULL KERRISON  
AGAIN?**

**YOU COULD  
MINIMIZE THE  
RISK OF DURAL  
TEARS?**

**ALL OF THIS WAS  
POSSIBLE WITH  
ONE PRODUCT?**

**YOU COULD  
REDUCE HAND  
AND ARM  
FATIGUE?**

**YOU COULD  
EASILY OPEN THE  
KERRISON FOR  
CLEANING?**

**YOU NO LONGER  
HAD TO OPEN  
MULTIPLE TRAYS?**

# SHARP TIP EVERY TIME

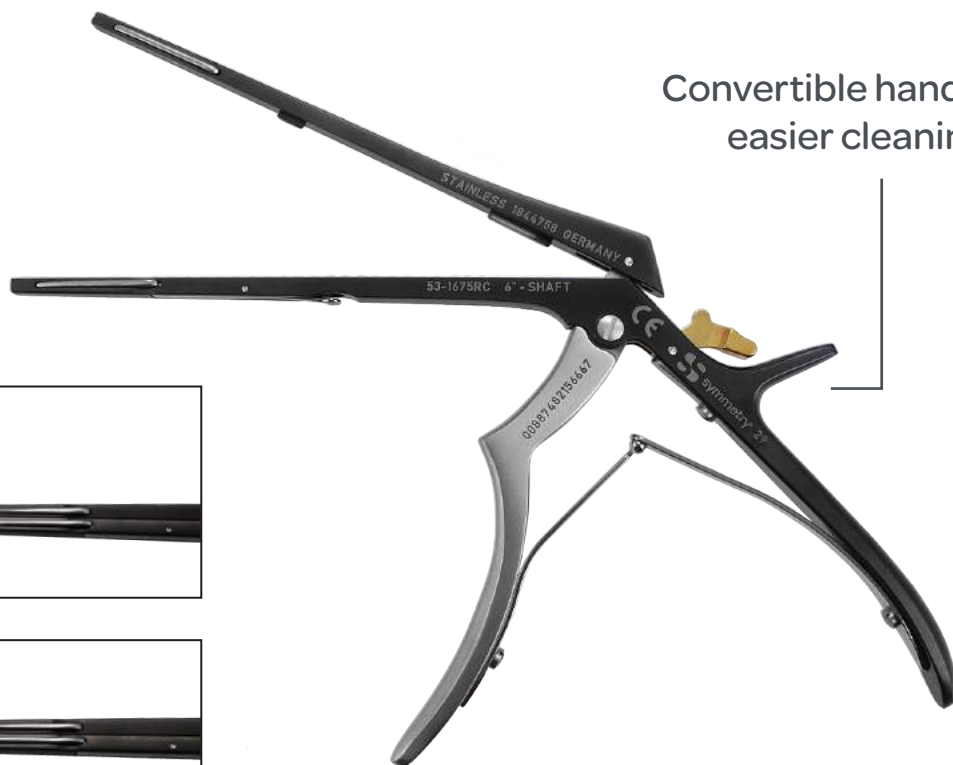
*“I choose to use the Symmetry Sharp Kerrisons for my ACD cases because they reduce the decompression time and improve the efficiency of the procedure.”*

Neurosurgeon, Louisiana

*“If one has to tug and twist the Kerrison the risk of a dural tear is much higher.”*

Neurosurgeon, Virginia

Convertible handle for easier cleaning



Single-Use Tip

The single-use tips ensure a sharp tip every time, reducing the number of passes required and limiting surgeon hand fatigue.

Convenient hinge design opens easily for cleaning, inspection and lubrication while eliminating the risk of misplacing pieces during processing.

# Symmetry Sharp Kerrison®

## Ordering Information

Visit [symmetrysurgical.com](http://symmetrysurgical.com) or contact your local Sales Representative to order or learn more about the innovative Symmetry Sharp Kerrison®.

### Reusable Handles

Ceramic Coated



DESCRIPTION	RAPIDCLEAN®	ONE-PIECE
5" (125 mm) Handle for 7" (178 mm) Kerrison	53-1674RC	53-1674
6" (152 mm) Handle for 8" (203 mm) Kerrison	53-1675RC	53-1675
7" (178 mm) Handle for 9" (229 mm) Kerrison	53-1676RC	53-1676

### Single-Use Tips

40° Up, 9 mm Opening, 2" (50 mm) Tip Length  
Packaged sterile, 3 per box



DESCRIPTION	THIN FOOTPLATE	STANDARD FOOTPLATE
1 mm Tip	53-1661T	53-1661
2 mm Tip	53-1662T	53-1662
3 mm Tip	53-1663T	53-1663
4 mm Tip	53-1664T	53-1664

### Ordering Information

Symmetry Surgical is proud to provide quality products, combined with exceptional customer service, for the complete product line. Our customer service team is available 8:30 AM to 6:30 PM (EST), Monday through Friday, excluding holidays.

# Symmetry Sharp Kerrison®

## Ordering Information

### GLOBAL HEALTHCARE EXCHANGE (GHX)

Symmetry Surgical offers secure online ordering through the Global Healthcare Exchange. GHX provides a connection point for healthcare buyer organizations to electronically trade with their vendors through the GHX exchange. Existing GHX Connect Plus Customers can set up ordering from Symmetry Surgical by completing a supplier on-boarding form through GHX.

### ORDER ONLINE AT SYMMETRYSURGICAL.COM

Our website, [symmetrysurgical.com](http://symmetrysurgical.com), enables licensed medical facilities to easily and quickly order products via a secure Internet connection. To sign up for online ordering, please visit [symmetrysurgical.com](http://symmetrysurgical.com) and click on the Login link in the top menu bar. Follow the instructions and our team will have your account created and ready for ordering quickly.

### ORDER BY PHONE

Our Customer Service representatives are available by phone Monday through Friday between the hours of 8:30 AM and 6:30 PM (EST) at 1.800.251.3000.

### ORDER BY FAX

You may fax your order 24 hours a day via our toll free fax number 1.800.342.3272 (US). A full confirmation of your order, including reference number and pricing information, will be faxed to you within 24 hours Monday through Friday.

### ORDER BY EMAIL

You may email your order 24 hours a day to [orders@symmetrysurgical.com](mailto:orders@symmetrysurgical.com). A full confirmation of your order, including reference number and pricing information, will be emailed back to you within 24 hours, Monday through Friday.



# Symmetry Sharp Kerrison®

## Instructions For Use

The English version of the Symmetry Sharp Kerrison® IFU is below for your convenience.

A printable version of this IFU can be found our on Website at [symmetrysurgical.com](http://symmetrysurgical.com).

Our IFUs online supersede the following information, which is provided for your convenience.

### ENGLISH

## SYMMETRY SHARP KERRISON® RONGEUR

### 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 either:
  - 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 or Symmetry Sharp Kerrison® RapidClean® Handle. Use **only** the Symmetry Sharp Kerrison® Tips or the Reusable Tips with the Symmetry Sharp Kerrison® Handle. Please consult your Symmetry Surgical® Sales Representative for ordering information.






# Symmetry Sharp Kerrison®

## Instructions For Use

How Supplied		
Symmetry Sharp Kerrison® Tips (sterile, single-use)	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 resterilized, nor accept for credit or exchange any Symmetry Sharp Kerrison® Tip that has been opened and not used.</p> <p>As long as the inner pouch is not opened or damaged, the product is sterile through the expiration date.</p>	<p>The Symmetry Sharp Kerrison® Handle and Symmetry Sharp Kerrison® RapidClean® 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>	<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 their initial use. Failure to follow these procedures will invalidate the instrument's warranty and can cause the instrument to fail.</p>

# Symmetry Sharp Kerrison®

## Instructions For Use

Precautions		
Symmetry Sharp Kerrison® Tips (sterile, single-use)	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"> <li>the package or seal appears to be breached or damaged,</li> <li>contents appear to be damaged, or</li> <li>the expiry date has passed.</li> </ul> <p>The tips are for <b>single-use only</b>. <b>Do not reuse.</b></p> <p>Reuse can also compromise device performance. 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 or the screws on the handle.</p> <p>When using the Sharp Kerrison® RapidClean® handle, do not attempt to completely separate top sliding piece from the handle. The top is meant to pivot.</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> <div style="text-align: center;"> <p>Lot Number      Mating Number</p> <p>↓                      ↓</p>  <p><b>Top tip component size marking:</b></p>  <p><b>Bottom tip component size marking:</b></p>  </div> <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. <b>DO NOT sharpen tips.</b></p>

### Warnings

Incorrect handling can cause damage to or destruction of the rongeur tips and handles.

- Use the rongeur tips and handles only for their intended use.
- Avoid overstraining the rongeur tips and handles by twisting or levering them 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.

# Symmetry Sharp Kerrison®

## Instructions For Use

### INSTRUCTIONS FOR USE

#### Product Assembly:

After reprocessing, assembly is required for the Symmetry Sharp Kerrison® RapidClean® Rongeur Handle to secure the shafts prior to inserting tips.

1. Align top and bottom of shaft parts into one another with the lever in the down position.



2. Squeeze the handle together with the lever remaining in the down position.



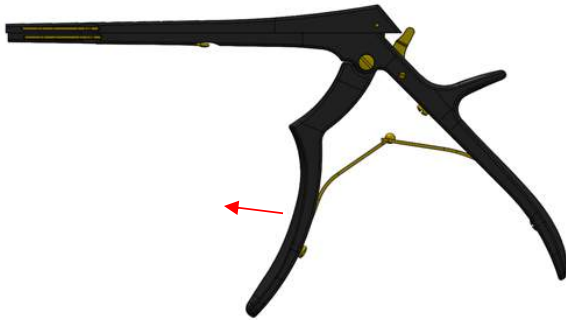
3. With the handle closed, push the lever upwards



# Symmetry Sharp Kerrison®

## Instructions For Use

4. Open the handle to lock the lever in place with the lever remaining in the up position.



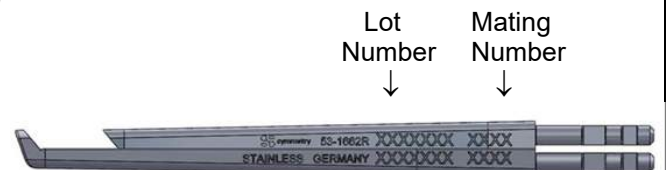
**WARNING:** Handle the working end of the tips with care; the jaws (cups) are sharp and can cause injury.

### Symmetry Sharp Kerrison® Tips (sterile, single-use) and the Symmetry Sharp Kerrison® Handle

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.

### Reusable Tips for the Symmetry Sharp Kerrison® Handle and the Symmetry Sharp Kerrison® Handle

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 hands and gloves.



**Top tip component size marking:**



**Bottom tip component size marking:**



2. Depress the safety-locking lever on the underside of the Symmetry Sharp Kerrison® Handle (See Figure 2).

2. Depress the safety-locking lever on the underside of the Symmetry Sharp Kerrison® Handle (See Figure 2).

# Symmetry Sharp Kerrison®

## Instructions For Use

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).	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).
4. Release the safety-locking lever.	4. Release the safety-locking lever.
5. Ensure that the shaft keys of both upper and lower jaws of the tip are completely inserted into the receptacles. 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.	5. Ensure that the shaft keys of both upper and lower jaws of the tip are completely inserted into the receptacles. 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.
6. If the tips are not fully seated in the handle, repeat steps 2 through 4.	6. If the tips are not fully seated in the handle, repeat steps 2 through 4.
7. Remove the protective tube from the tips if it is still in place.	7. Carefully actuate the handle to verify smooth movement and function of the tips after their insertion. <b>CAUTION: Do not close the rongeur tips while they are empty. Metal-on-metal contact will dull the jaws of the tips prematurely.</b>
8. Carefully actuate the handle to verify smooth movement and function of the tips after their insertion. <b>CAUTION: Do not close the rongeur tips while they are empty. Metal-on-metal contact will dull the jaws of the tips prematurely.</b>	

# Symmetry Sharp Kerrison®

## Instructions For Use

<b>Disassembly and Disposal:</b> 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:	
<b>Symmetry Sharp Kerrison® Tips (sterile, single-use) and the Symmetry Sharp Kerrison® Handle</b>	<b>Reusable Tips for the Symmetry Sharp Kerrison® Handle and the Symmetry Sharp Kerrison® Handle</b>
1. Using the right hand, depress the safety-locking lever on the underside of the Kerrison handle (See Figure 5).	1. Using the right hand, depress the safety-locking lever on the underside of the Kerrison handle (See Figure 5).
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. <b>DO NOT RELEASE THE TIP RELEASE LEVERS.</b> (See Figure 6)	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. <b>DO NOT RELEASE THE TIP RELEASE LEVERS.</b> (See Figure 6)
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)	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)
4. If tips are not releasing from the handle receptacles, repeat steps 1 through 3.	4. If tips are not releasing from the handle receptacles, repeat steps 1 through 3.
5. Dispose of the tips in accordance with your facility's guidelines for biohazardous sharps.	5. If the reusable tips have become dull, dispose of the tips in accordance with your facility's guidelines for biohazardous sharps.
	6. If the reusable tips are not dull, disassemble the top and bottom tip components for cleaning and sterilization.

# Symmetry Sharp Kerrison®

## Instructions For Use

After the tips are removed from the handle, when using the Symmetry Sharp Kerrison® RapidClean® Rongeur Handle, it should be in the open position for cleaning.

### Disassembly

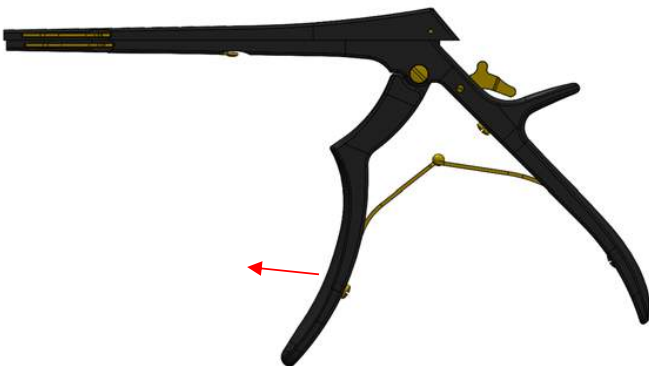
1. Squeeze the handle together with the lever in the up position.



2. With the handle closed, push the lever downwards



3. Release handle to opened position with the lever remaining down.

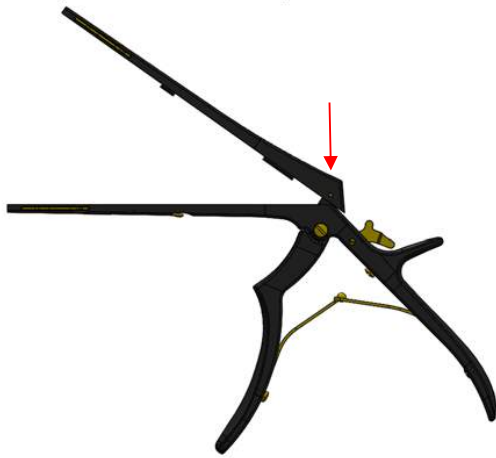




# Symmetry Sharp Kerrison®

## Instructions For Use

4. Push downwards on top shaft to allow top shaft to swing open (Note: top shaft is designed to pivot and not separate from handle)



**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 disassembled 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 be reprocessed and sterilized separately once they have been disassembled.**

### **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 handle in a basin of distilled water or in a tray covered with damp towels.

# Symmetry Sharp Kerrison®

## Instructions For Use

### Cleaning

- Symmetry Surgical® recommends that the reusable tips and handle be cleaned as soon as possible after each surgical procedure in order to limit the drying time provided for residue biologic soil left on the instruments.
- Water quality used for diluting cleaning agents and for rinsing the reusable tips and handle 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 their manufacturer's recommendations. 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. Keep Sharp Kerrison® RapidClean® Handle in open position. 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 nylon 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 handle, 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. Clean Sharp Kerrison® RapidClean® Handle while in the open position.  
**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 on 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 Symmetry Sharp Kerrison® 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.

# Symmetry Sharp Kerrison®

## Instructions For Use

### 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 nylon bristle brush, sponge, or cloth to remove all traces of blood and debris. When cleaning the Symmetry Sharp Kerrison® Handle, clean exposed surfaces thoroughly while squeezing the handle to retract the crossbar. When cleaning the Symmetry Sharp Kerrison® RapidClean® Handle, clean exposed surfaces while rongeur is in open position. 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 handle 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, manually lubricate moving parts with a water-soluble lubricant (such as PRESERVE®) in accordance with the manufacturer's instructions.

# Symmetry Sharp Kerrison®

## Instructions For Use

### 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 (see figure 1) 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 handle by squeezing the handle. If the crossbar or handle 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.
- The Symmetry Sharp Kerrison® RapidClean® Handle can be sterilized in the closed/assembled position.
- 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, wrap, or sterilization containers. 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:

# Symmetry Sharp Kerrison®

## Instructions For Use

Product Code	Description	Mass (oz)
53-1661R	1 mm Reusable Tip for the Symmetry Sharp Kerrison® Handle	0.2 ± 0.1
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	Symmetry Sharp Kerrison® Rongeur Handle, for 7 inch Kerrison	6.5 ± 0.2
53-1675	Symmetry Sharp Kerrison® Rongeur Handle, for 8 inch Kerrison	7.0 ± 0.2
53-1676	Symmetry Sharp Kerrison® Rongeur Handle, for 9 inch Kerrison	7.4 ± 0.2
53-1674RC	Symmetry Sharp Kerrison® RapidClean® Handle, for 7 inch Kerrison	6.5 ± 0.2
53-1675RC	Symmetry Sharp Kerrison® RapidClean® Handle, for 8 inch Kerrison	7.1 ± 0.2
53-1676RC	Symmetry Sharp Kerrison® RapidClean® Handle, for 9 inch Kerrison	7.6 ± 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

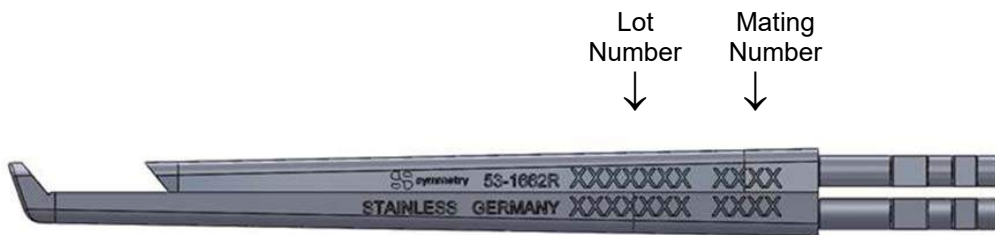
*\*These sterilization parameters are for outside the US only and should not be used within the United States. These parameters are not validated for use with FDA-cleared sterilizers.*

# Symmetry Sharp Kerrison®

## Instructions For Use

### F. Inspection after Sterilization

Inspect the handle as recommended in Section D above. Single-use Tips do not require additional inspection as they are not meant to be resterilized. Inspect the Reusable 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.



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:

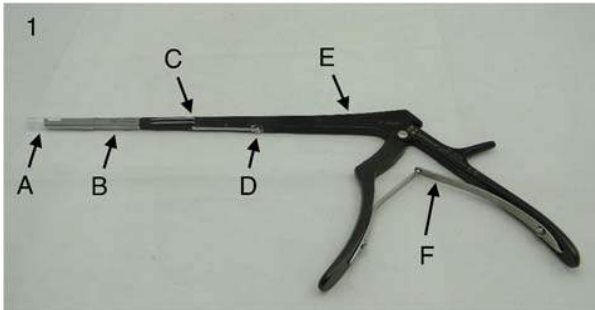
Symmetry Surgical Inc.  
3034 Owen Drive  
Antioch, TN 37013 USA

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

# Symmetry Sharp Kerrison®

## Instructions For Use

### Callouts:



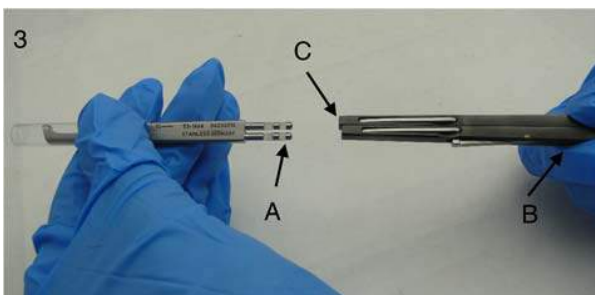
**Figure 1**

- 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



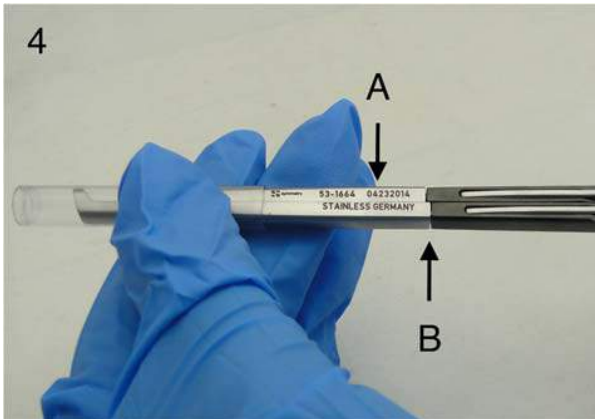
**Figure 3**

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



# Symmetry Sharp Kerrison<sup>®</sup>

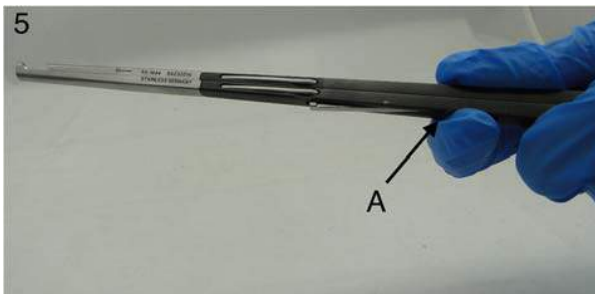
## Instructions For Use



**Figure 4**

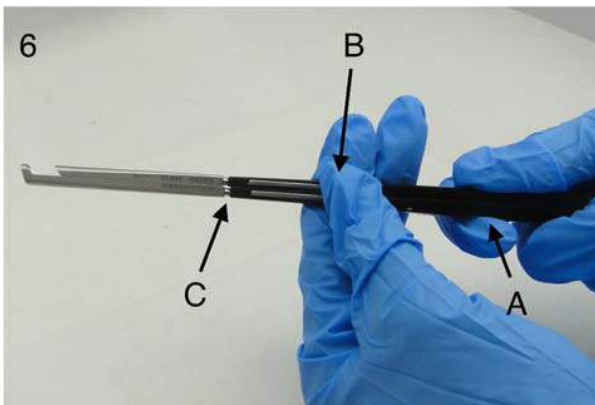
**A.** Tips

**B.** Tips Seated in Handle Receptacles



**Figure 5**

**A.** Depressing Safety-Locking Lever



**Figure 6**

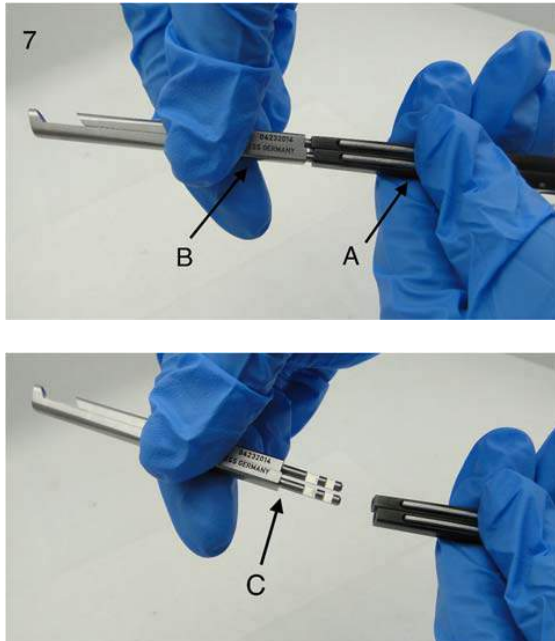
**A.** Depressing Safety-Locking Lever

**B.** Depressing Proximal End of Tip Release Levers

**C.** Tip Shaft Keys Slightly Eject from Handle Receptacles

# Symmetry Sharp Kerrison®

## Instructions For Use



**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.**

### **CAUTION**

USA federal law restricts the use of this device to sale by, or on the order of a physician.

PRESERVE® is a registered trademark of Symmetry Surgical®.













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

# Symmetry Sharp Kerrison®











## Instructions For Use

### Symbols:

#### Sterile device symbols


	Made in
	Quantity
	Manufacturer
	Authorized European Representative
	Manufacture Date
	Use by
	Sterilized using radiation
	Do not reuse
	Do not resterilize
	Consult Instructions For Use
	US Federal law restricts this device to sale by or on the order of a physician
	Conformance to 93/42/EEC

#### Non-Sterile device symbols


	Made in
	Quantity
	Manufacturer
	Authorized European Representative
	Manufacture Date
	Non-Sterile
	Do not use if package is damaged
	Caution: Consult Instructions For Use
	US Federal law restricts this device to sale by or on the order of a physician
	Conformance to 93/42/EEC

### Manufacturer Address:



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# How a neurosurgeon eliminated dull, inefficient Kerrisons with a novel device that produces a sharp productive bite throughout the procedure

## Introduction

The challenges of performing precise and complex procedures with dull Kerrisons are well known among neurosurgeons and orthopedic spine surgeons worldwide. This case study evaluated a new device that utilizes a novel approach to provide sharp, productive bites throughout the entire procedure, allowing the surgeon to complete the procedure safely, accurately, and efficiently.

## Current Kerrison Challenges

Kerrisons are widely used in neurosurgery and orthopedic spine surgery including Discectomy, Cervical and Lumbar Laminectomy, and Fusion procedures. The most common surgeries are Anterior Cervical Discectomy and Fusion with Instrumentation and Lumbar Laminectomy with or without Discectomy and Fusion.

Kerrisons are designed to cut bone, ligament and cartilage in a controlled and exacting manner. After using the Kerrison to take an accurate bite of the intended tissue, the surgeon will then remove the Kerrison and tissue, exiting along the same straight path utilized to initiate the bite. Dr. James Wolter who works at the Kansas City Medical Center states, *"Dull instruments are the bane of surgery. The inability to progress with efficiency in an operation greatly frustrates surgeons. The temptation to deviate from acceptable technique with suboptimally sharp or dull instruments can result in twisting or tearing tissue rather than performing a true cut."*

This deviation from optimal technique can have untoward consequences such as an unintended durotomy or CSF leak. Other more serious complications include neurovascular damage. In a recent poll of neurosurgeons surveyed at the American Association of Neurological Surgeons Annual Scientific Meeting (AANS), 95% of respondents reported that dull Kerrisons increased the risk of dural tears.

Surgeons may start a procedure with sharp instruments that seem to become dull after multiple bites in a case. Most surgeons have the unfortunate experience of halting the surgery while the OR scrub nurse searches for freshly sharpened instruments. Dr. Wolter added, *"There is no guarantee that the instrument in the peel pack is going to be sharp or last any longer than the one that was used at the beginning of the case."*

## Assessment of Current State

Facilities utilize several solutions to ensure a supply of sharp Kerrisons, including preventative maintenance programs that entail sharpness testing and routine sharpening. According to sterilization expert David Narance, RN, BSN, CRCST, *"Being proactive is critical. You want to catch a problem in the department (SPD), where it can be addressed properly, as opposed to having the surgeon discover it during the procedure."*

An effective preventative maintenance program must involve frequently sending Kerrisons out for sharpening and repair. However, this process can only be an effective solution when the facility maintains a sufficient number of Kerrisons to rotate through procedures and out for sharpening. Maintaining such an extensive inventory represents a substantial financial and tracking challenge.

## An Innovative Solution

Advancements in surgical instruments have led to the development of a reusable Kerrison handle with a detachable, disposable tip. With this innovative solution, surgeons can simply replace a Kerrison tip whenever needed, enabling them to perform procedures with confidence knowing that they can rely on a sharp tip every time. This innovation virtually eliminates Kerrison-related issues such as ineffective bites, insufficient surgical progress, increased number of bites, increased risk for dural tears, poor surgical technique, surgical delays and increased length of surgery time. In the words of Dr. Wolter, *"The use of disposable tips has greatly improved efficiency in the operating room. The handles are standardized, and the scrub nurse can replace the tips in a matter of seconds allowing the case to proceed without delays thereby eliminating physician fatigue and frustration. Although there are no studies directly examining better patient outcomes, I am certain that the disposable sharp tips lead to better patient outcomes."*

### Neurosurgeon survey results of Kerrison performance conducted at American Association of Neurological Surgeons Annual Scientific Meeting (AANS):

95%

Dull Kerrisons increase the risk of dural tears

100%

Dull Kerrisons increase procedure length

100%

A Kerrison with a sharp tip provides a more productive bite

## Clinical Advantages

Surgeons are achieving optimal results with the clinical advantages afforded by Kerrisons that have sharp tips every time. Three of the most compelling clinical advantages are the following:

1. **Progress occurs with every bite**
2. **Proper technique for the intended surgery is possible**
3. **Greater clinical decompression efficiency is created**

## Summary

Traditional Kerrisons perform well until the tip becomes dull, at which point clinical issues arise that increase the risk to the patient and may lead to suboptimal surgical outcomes. Rather than cycle a large inventory of Kerrisons through procedures and sharpening, utilizing the Symmetry Sharp Kerrison® eliminates the risks presented by a dull Kerrison and avoids the need to carry a large inventory of Kerrisons. Using a detachable, disposable sharp tip Kerrison allows the surgeon to get the job done safely and correctly, leading to optimal patient outcomes, decreased OR time and less risk to the patient.

*Dr. James A Wolter has disclosed that he has no financial interest or agreements with Symmetry Surgical® or any other medical company. Although Dr. Wolter is employed by the Kansas City VA, the VA does not endorse any products.*

### References Available Upon Request.

1 Williamson, Julie "Proactive preventive maintenance can curb costly device repairs," <https://cdn.hpnonline.com/inside/2012-04/1204-CS-Maintenance.html>," Accessed May 29, 2019.

2 Kerrison Survey, American Association of Neurological Surgeons, San Diego, CA 17 April 2019.



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**For more information, contact your sales representative  
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[symmetrysurgical.com](https://www.symmetrysurgical.com)

# Symmetry Sharp Kerrison®

## 510(k) Information

The Symmetry Sharp Kerrison® is 510(k) cleared.

**As a medical manufacturer, we cannot distribute our 510(k) for promotional purposes, however it is public information and accessible at the instructions below.**

To view a summary of this device's 510(k) clearance:

- Visit the FDA website
  - o Direct link: [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm)
- Search for 510(k) Number **K130541**.