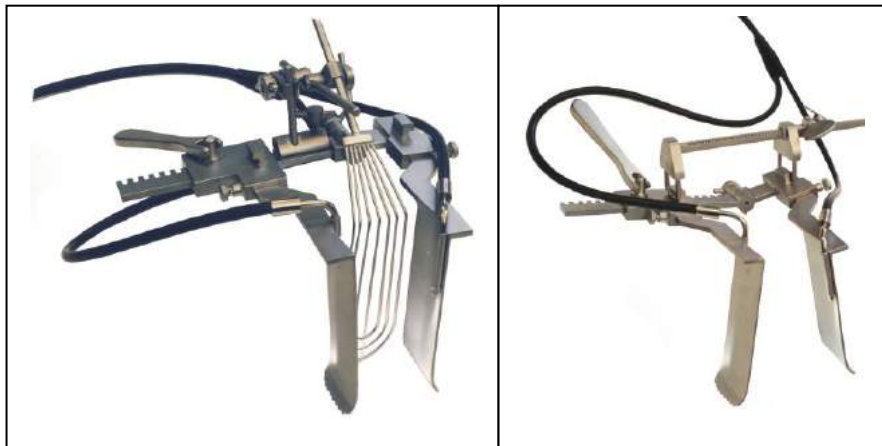


INSTRUCTIONS FOR USE
The Hardy Spinal Retractor



Manufactured by:

Kapp Surgical Instrument, Inc.

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Rx only



Consistent and excellent exposure of the spinal column is fundamental to spinal surgery procedures. By using the Kapp Hardy Spinal Retractor, the surgeon can gain the optimum exposure necessary for a successful surgical outcome.

DESCRIPTION / INTENDED USE

This retractor is intended for trans-thoracic disc excisions through limited exposure. It also can be used for lumbar laminectomies and can be adapted for trans-abdominal exposures to support cage insertion or other applications. Recommendations for cleaning and sterilization are included in this manual.

The device is supplied non-sterile and must be cleaned and sterilized before use.

PRE-SURGICAL ASSEMBLY

Figure #1 Assemble Left rack to right end block, tighten hinge locking nut. Slide left end block and handle onto rack. Use handle to adjust block.

Figure #2 Select and insert blades into the end blocks, pull out (spring loaded) lock pin to insert selected retractor blades. Then assemble the “U” shaped locking clamp with screw over the hinge locking mechanism on main rack. This will keep retractor in a straight plane.

Optional **Figure #2B** Insertion of Fiber optic cables

KAPP-HARDY SPINAL RETRACTOR Surgical procedure to access surgical site:

Figure #3 Close retractor blades after soft tissue surgery is completed. (Fig 2). Place lifting tower (Fig 3) on the right and left end block, securing the tower base onto the main body anchor blocks. Remove the “U” shape locking clamp and screw. Note: this will allow the main retractor rack to lift proximal for removal of the disc or repair of the vertebral body.

Figure #4 Turn close the thumb screw on lifting tower and adjust the angle for maximum surgical exposure. When finished release the lifting tower lever to allow the blades to return the main rack to its natural straight position. Insert “U” shaped locking clamp with screw to assure a ridged straight retracting procedure.

Figure #5 As an option mount the rigid stabilizer to utilize the lung retractor option.

NOTE: All screws on the Kapp Hardy Spinal Retractor are non-removable.

CLEANING

Immediately after surgery, rinse the instruments under warm, not hot, water to remove all blood, body fluids and tissue. If delays prevent immediate rinsing, soak the instrument in a solution of water and neutral (pH 7) detergent prior to cleaning.

ULTRASONIC CLEANING

Separate the components and place them into the ultrasonic cleaner. Clean per instrument protocol. Rinse the instruments with water immediately after ultrasonic cleaning.

AUTOMATIC WASHER STERILIZERS

Follow manufacturer's recommendations ensuring instruments are lubricated after last rinse cycle and before sterilization cycle.

According to the Robert Koch Recommendations from September 2012, mechanical cleaning and disinfection should be conducted at temperatures in excess of 93° C.

AUTOCLAVE STERILIZATION

Prior to autoclave sterilization, lubricate all instrument parts which have metal-to-metal contact using surgical lubricants such as instrument milk. Do not use industrial lubricants. Instruments must be unlocked before cleaning to prevent any cracks that may occur from heat expansion during the autoclave cycle. Do not overload the autoclave chamber. The manufacturer's recommended sterilization protocol is:

Sterilizer Type:	Pre-vacuum
Preconditioning Pulses:	3
Minimum Temperature:	132° C
Full Cycle Time:	4 minutes
Minimum Dry Time:	30 minutes
Article Configuration:	Wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600-510(K) K082554) using sequential envelope folding techniques.

The following cycle should be used when there is an immediate need for the device and there are no other alternatives:

Sterilizer Type:	Pre-vacuum
Preconditioning Pulses:	3
Minimum Temperature:	132° C
Full Cycle Time:	3 minutes (IUSS)
Minimum Dry Time:	0 Minutes
Article Configuration:	Wrapped in two layers of 1-ply polypropylene Wrap (Kimguard KC600-510(K) K082554) using sequential envelope folding techniques.

Kapp Surgical Instrument, Inc. confirms that the processing recommendations related to machine cleaning and sterilization by Robert Koch Recommendations from September 2012 may be used. Specifically, Kapp Surgical Instrument, Inc. confirms that sterilization times and temperatures may be extended to 5 minutes and 134° C.

MAINTENANCE REQUIREMENTS

All Kapp Hardy Spinal Retractors and attachments should be serviced at least annually. Your retractor should be refurbished by the original manufacturer and original patent holder, Kapp Surgical Instrument, Inc. There is no limit to the number of reuses of this device as long as it is appropriately maintained and serviced by Kapp Surgical Instrument, Inc.

NOTE: All screws on the Kapp Hardy Spinal Retractor are non-removable. These screws are peened over to prevent the screws from falling into the surgical field.

DO NOT SEND THIS INSTRUMENT OUT TO BE SERVICED TO YOUR LOCAL SURGICAL INSTRUMENT REPAIR COMPANY. PLEASE SEND ALL REPAIRS AND REFURBISHING BACK TO THE ORIGINAL MANUFACTURER:



Kapp Surgical Instrument, Inc.

4919 Warrensville Center Rd.

Cleveland, Ohio 44128, USA

1-800-282-5277 or 216-587-4400

INSTRUMENT COMPONENTS

The Kapp Hardy Spinal Retractor is made from instrument-grade quality stainless steel. **NOTE:** This product is normally intended to be used for less than 60 minutes.

WARRANTY

Kapp Surgical instruments are guaranteed to be free from defects in workmanship and material. Any instrument that proves defective in workmanship or material will either be repaired or replaced at our discretion, without charge.

Kapp Surgical Instrument, Inc. warrants the guarantee of this instrument for the life of this product under the normal surgical use for which it was intended.

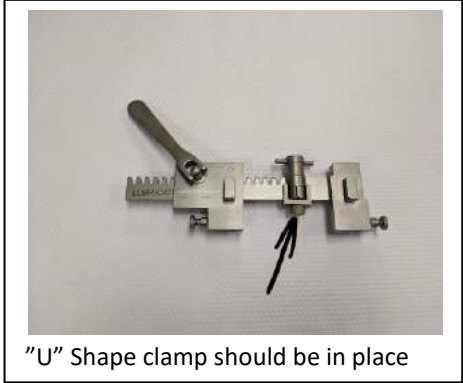
Kapp Surgical Instrument, Inc. quality management system is **EN ISO 13485: 2016 Certified.**

Illustrations:

Figure #1



Figure #1B



"U" Shape clamp should be in place

Figure #2



Figure #2B



Figure #3



Remove "U" shape locking clip

Figure #4



Thumb screw on lifting tower

Figure #5



Figure #6

