Rigicon®

Innovative Urological Solutions

Instructions for Use

HL-LEVINE Combo Prosthesis Tool

℞ ONLY

SYMBOLS

	Manufacturer Information
	Date of Manufacture
EC REP	The authorized representative in the European Community
LOT	Lot Number
	Consult Instructions for Use
R_X Only	Presciption
	Caution
	Keep dry
	Keep away from sunlight
CE	CE Mark

SUMMARY

Rigicon®
Innovative Urological Solutions

SYMBOLS ON LABEL

Rigicon HL - LEVINE Combo Prosthesis Tool is a non-sterile, reusable surgical instrument made of smooth, solid, biocompatible stainless steel, providing high rigidity and strength. The HL - LEVINE Combo Prosthesis Tool combines the properties of the Furlow Insertion Tool and the HL Dilator. [See product-specific IFUs for more information.]

The total length of the HL - LEVINE Combo Prosthesis Tool is 25 cm, and the product is available in two models.

The two models provide different dilation dimensions: 10/12 mm and 10/14 mm.

Product Name	Product Code	Product Diameters	Product Lenghts
Rigicon HL - LEVINE Combo Prosthesis Tool	RSSL-1012	10-12 mm	25 cm
Rigicon HL - LEVINE Combo Prosthesis Tool	RSSL-1014	10-14 mm	25 cm

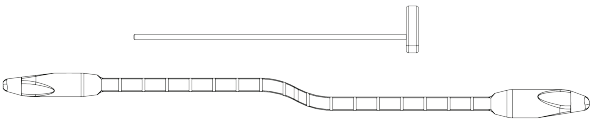

Figure: Rigicon HL - LEVINE Combo Prosthesis Tool

INDICATIONS FOR USE

The HL – LEVINE Combo Prosthesis Tool is intended for dilating the corpora cavernosa and passing the traction sutures through the glans to help with the distal placement of the inflatable penile prosthesis cylinders. The device can also be utilized for measuring the corpus cavernosum proximally and distally to help the implanting surgeon decide on the diameter and length of the prosthesis.

Different usage areas in specific procedures may occur considering the individual technique and patient anatomy.

WARNINGS AND PRECAUTIONS

- The HL – LEVINE Combo Prosthesis Tool should only be used by physicians who have been trained in dilator & insertion tool use and application.
- The device must be cleaned and sterilized before use, in compliance with hospital protocol and Rigicon Reusable Surgical Instruments Reprocessing Instructions.
- This device should only be reprocessed and restrelizied by trained and experienced professionals.
- Repeated processing and resterilization are expected to have minimal effects on the instrument. End of life is normally determined by wear or damage due to use.
- When multiple instruments are sterilized in one autoclave cycle, ensure that the maximum load of the sterilizer is not exceeded.

WARNINGS AND PRECAUTIONS

- When the device is used in patients known to be infected with Non-Conventional Transmissible Agents (N.C.T.A.s or prions), it is no longer reusable and shall be disposed of.
- Tissue damage may occur if excessive force is applied to the device.
- If tunical trauma and perforations are not assessed and treated promptly, the situation may significantly deteriorate and potentially result in infection and/or tissue loss.
- Pre-existing penile or corporal scarring may make surgical use of the device more complicated or impractical.
- Contact with any electro-medical device or electro-surgical appliance should be avoided.
- The device is not implantable.

POTENTIAL RISKS OR ADVERSE EVENTS

Possible risks or adverse events include:

- Allergic Reactions
- Altered Therapeutic Response
- Tunical Trauma/Perforation
- Infection
- Chronic Pain
- Prolonged Procedure
- Tissue Damage
- Urethral trauma/perforation
- Sensory loss

USE OF HL - LEVINE COMBO PROSTHESIS TOOL

- Introduce the distal end of the HL – LEVINE Combo Prosthesis Tool by applying gentle pressure into the distal portion of the corpora after incising the tunica albuginea. Keep the HL - LEVINE Combo Prosthesis Tool laterally and observe the tip while it advances against the lateral wall of the tunica albuginea.

- Palpate the glans to detect when the HL - LEVINE Combo Prosthesis Tool reaches the end of the distal portion of the corpora.

- Remove the HL - LEVINE Combo Prosthesis Tool and insert the distal end proximally dilating the tissue to the point of corporal insertion at the ischial tuberosity.

- Use the HL - LEVINE Combo Prosthesis Tool and the Keith Needle (included in the Inflatable Penile Prosthesis Accessory Kit) to help introduce cylinders into the corpora cavernosa.

- Check the function of the HL - LEVINE Combo Prosthesis Tool by withdrawing the obturator to the locking groove, for the "retracted" position and then fully inserting the obturator until its tip appears at the end.

- Withdraw the obturator to a "retracted" or "locked" position. Pass both ends of the traction suture through the eye of the Keith Needle.

Note: Infla10® Inflatable Penile Prosthesis is supplied with a traction suture placed in the distal tip of each cylinder.

- Load the blunt end of the Keith needle into the HL - LEVINE Combo Prosthesis Tool

- Completely retract the suture into the slot and fully draw the needle into the barrel of the tool.
- Hold the four strands of the suture against the tool and introduce the tool into the distal portion of the corporal body until the front tip is beneath the glans. The HL - LEVINE Combo Prosthesis Tool should be in the ipsilateral corpora at the distal tip.
- Place the penis on a mild stretch; push the needle through the glans by fully inserting the obturator into the barrel.
- Grasp the needle with a needle holder or mosquito hemostat and pull it completely through the glans.
- Detach the needle from the suture.
- Attach a rubber-shod hemostat to the traction sutures to prevent inadvertent retraction through the glans.
- Remove the HL - LEVINE Combo Prosthesis Tool from the corporal body and continue to follow the "Operating Room Protocol" instructions for further cylinder placement.

HOW SUPPLIED AND STORAGE

WARNING: Contents are supplied NON-STERILE.

Insufficient sterilization/resterilization may cause contamination of the device and/or cause patient infection or cross-infection including the transmission of infectious disease(s) from one patient to another. When the end of life is reached, dispose the product in accordance with hospital, administrative and/or local government policy.

Store the device in a clean, dry, dark area at room temperature.

PACKAGING

The HL - LEVINE Combo Prosthesis Tool is supplied to the market inside a protective carton box.

DISCLAIMER:

The manufacturer Rigicon, Inc. reserves the right to make technical or design changes as part of the device's continual improvement process.

ALTHOUGH THE HL - LEVINE COMBO PROSTHESIS TOOL AND COMPONENTS (THE "PRODUCT") HAVE BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, RIGICON, INC. AND ITS AFFILIATES (HEREINAFTER "RIGICON") HAVE NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. RIGICON THEREFORE DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. RIGICON SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL. DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE, OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT, OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND RIGICON TO ANY REPRESENTATION OR WARRANTY WITH REGARD TO THE PRODUCT.

RECOMMENDED CARE, CLEANING AND STERILIZATION INSTRUCTIONS

LIMITATIONS ON REPROCESSING

The useful life of the surgical instruments depends on many factors including the method and duration of each use, and the handling between uses. Carefulinspection and functional test of the device before use is the best method of determining the end of serviceable life for the medical device. Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear, and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices should not be used. If surgical instruments are to be returned to Rigicon, they must be clean, packaged, and sterilized.

CLEANING, INSPECTION, PACKAGING STEPS

STEP -1- Pre-treatment at the point-of-use	As soon as after use, remove excessive soiling with a disposable wipe, rinse, and flush the device with sterile or deionized water to prevent the drying of soil and/or debris to the inside.
STEP -2- Containment and transportation	• Process instruments as soon as is reasonably possible after use. It is recommended not to delay cleaning for more than 2 hours. • If transfer to the reprocessing area likely to be delayed, consider covering the medical devices with a damp cloth or store the device in a clean, dry, dark area at room temperature.
STEP -3- Disassembly	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. Note: All recommended disassembly will be possible by hand. Never use tools to disassemble instruments beyond what is recommended.

STEP -4- Preparation for Cleaning	• 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. Note: Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (turbid). • Soft-bristled brushes, lint-free cloths, syringes, pipettes in various sizes and/or water jet, ultrasonic cleaner, cleaning bath or vessel large enough to allow complete immersion of the instruments.
STEP -5- Manual cleaning	• Soak soiled instruments and prevent air bubbles to ensure that all surfaces have contact in an enzyme solution for a minimum recommended time specified by the enzymatic cleaning solution manufacturer or 20 minutes, whichever is longer. • Brush the instruments with cleaned soft-bristled, nylon brush to clean to remove all traces of blood and debris. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipecleaner brush). For flexible shafts and springs, flex and relax the instrument under the cleaning solution while brushing.

	Note: All scrubbing should be performed below the surface of the enzyme solution to minimize the potential of aerosolizing contaminated solution. • Flush each difficult brush area thoroughly and aggressively in cold tap water for a minimum of 30 seconds. Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces. Repeat Step 2 and 3 until no visual soil has been removed. • Rinse the instruments in cold top water for a minimum of 3 minutes. • Dry the instruments after final rinse with a clean towel or compressed air until visibly dry.
STEP -6- Inspection and Functional Check	• After cleaning, all devices should be thoroughly inspected for residue biologic soil or detergent. If contamination is still present repeat the cleaning process. • 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 Rigicon representative for a replacement.

	• When inspecting devices look for the following: - Cutting edges should be free of nicks and have a continuous edge. - Jaws and teeth should align properly. - Movable parts should operate smoothly throughout the intended range of motion. - Locking mechanisms should fasten securely and close easily. - Long thin instruments should be free of bending or distortion
STEP -7- 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). To double pouch: a) Place the tool in a smaller pouch and seal the pouch. b) Place the smaller sealed pouch in a larger pouch and seal it. • Reusable wraps are not recommended.

STEAM STERILIZATION

Use of ANSI/AAMI ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care is recommended. A verified, properly maintained, and calibrated steam sterilizer is recommended. The process parameters of sterilization should be followed explicitly. It is the responsibility of the medical facility to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained.
Load trays per the sterilization equipment manufacturer's instructions.

In the United States

Sterilization Method	Exposure Temperature	Minimum Exposure Time	Minimum Drying Times
Pre-vacuum	270°F (132°C)	4 minutes	20 minutes

Outside the United States

Sterilization Method	Exposure Temperature	Minimum Exposure Time	Minimum Drying Times
Pre-vacuum	134°C	3 minutes	30 minutes

STORAGE CONDITIONS

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.

REPROCESSING INSTRUCTIONS AUTOMATED CLEANING WASHER

AUTOMATED CLEANING WASHER/DISINFECTOR INSTRUCTIONS

WARNING:

Failure to properly clean could lead to inadequate sterilization. The cleaning procedure outlined in these instructions must be performed as stated prior to steam sterilization.

CAUTION:

- Chemical disinfection programs should not be used due to the potential for chemical residues to remain on the tools. These residues could interfere with sterilization efficacy.
- Follow the washer/disinfector manufacturer's instructions for use.
- Use a washer/disinfector with demonstrated efficacy.
- Increase the dry time as the load size increases. Follow the washer/disinfector manufacturer's instructions.
- Low-level disinfection must be used as part of a washer/disinfector cycle, but the devices must also be sterilized before use.
- Use critical water for the final rinse.

1. If not already disassembled, disassemble the Furlow Insertion Tool, HL Dilators and/or HL LEVINE Combo Penile Prosthesis Tool, if used.
2. Place tools in a washer/disinfector basket. Observe the manufacturer's loading requirements. Follow the cycle parameters given in Table 1.
3. Avoid contact between devices as movement during washing could cause damage and washing action could be obstructed.

The following minimum wash cycle parameters are recommended:

Table 1 Minimum Automated Washer/ Disinfector Cycle for Surgical Tools

STEPS	DESCRIPTION
STEP 1	4 minutes; 50-55° C enzymatic wash
STEP 2	2 minutes; 50-55° C wash
STEP 3	2 minutes; 50-55° C final rinse
STEP 4	10 minutes; 70° C Thermal disinfection
STEP 5	15 minutes 80° C air dry

4. Upon completion, unload the washer/disinfector.
5. Visually inspect the tools with sufficient magnification and light to verify that all soil and detergent residue has been removed. If it has not, repeat the cleaning process.
6. If needed, dry tools with an absorbent, low-lint cloth, or clean, filtered compressed air.

Rigicon®
Innovative Urological Solutions

Rigicon, Inc.
2805 Veterans Memorial Hwy STE 5
Ronkonkoma, NY 11779
United States of America
operations@rigicon.com
Phone: +1 (888) 202-9790

Issue Date: 20.08.2020; Rev.01; Rev. Date: 14.02.2024

Rigicon, Inc.
2805 Veterans Memorial Hwy STE 5
Ronkonkoma, NY 11779 United States of America
operations@rigicon.com Phone: +1 (888) 202-9790
www.rigicon.com