Rigicon®

Innovative Urological Solutions

Instructions for Use

Reusable HL Dilator

℞ ONLY

SYMBOLS

R_X Only	Caution: Federal Law (U.S.) restricts this device to sale by or on the order of a physician
	Manufacturer Information
	Date of Manufacture
	Lot Number
	Consult Instructions for Use
	Caution
	Temperature limit
	Keep dry
	Keep away from sunlight
CE	CE Marking of Conformity

SUMMARY

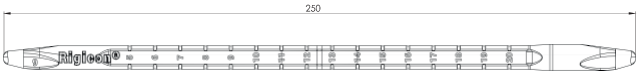
DEVICE DESCRIPTION

Rigicon Reusable HL Dilator is non-sterile and reusable surgical instrument.

Rigicon Reusable HL Dilator is made of a smooth, solid, biocompatible stainless steel, providing high rigidity and strength.

The total length of each dilator is 25 cm, and there are four different diameters available for the product.

Four dilators provide various dilation dimensions: 9/10, 10/12, 11/12, and 13/14 mm sizes.



Rigicon Reusable HL Dilator

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INDICATIONS FOR USE

Rigicon Reusable HL Dilator is intended for dilating the corpora cavernosa of the penis prior to the insertion of a penile prosthesis. The device is also used for measuring each corpus proximally and distally .

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

WARNINGS AND PRECAUTIONS

- The surgical instrument shall be operated by physicians such as urologists or plastic surgeons.
- The surgical instrument shall only be reprocessed and resterilized by trained and experienced professionals.
- Tissue damage may occur in case of excessive force applied to the device.
- The device is not implantable.
- Pre- and post-sterilization conditions should be carefully inspected.
- Any contact between the surgical instrument and any electro medical device or electro surgical appliance should be avoided.
- The surgical instrument is supplied non-sterile and must be cleaned and sterilized before use, in compliance with hospital protocol and Rigicon Reusable Surgical Instruments Reprocessing Instructions.
- When the surgical instrument 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.

WARNINGS AND PRECAUTIONS

- Repeated processing and resterilization have minimal effect on the surgical 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.
- Improper usage of the surgical tool may cause erosion in case of a prosthesis implantation. If erosion occurs and has not been evaluated or treated in a timely manner, it can result in a substantially worsening case and can lead to infection and loss of tissue.

POTENTIAL RISKS OR ADVERSE EVENTS

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

Advisory Note: For more further information about potential risks or adverse events, refer to the Instructions for Use of the selected penile prothesis.

USE OF INSERTION TOOL

1. Introduce the distal end of the Dilator by applying gentle pressure into the distal portion of the corpora after incising the tunica albuginea. Keep the Dilator laterally and observe the tip while it advances against the lateral wall of the tunica albuginea.

2. Perform palpation to the glans to detect when the Dilator reaches the end of the distal portion of the corpora.

3. Remove the Dilator and insert the distal end proximally dilating the tissue to the point of corporal insertion at the ischial tuberosity.

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 product 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 REUSABLE HL DILATOR AND COMPONENTS (THE "PRODUCT") HAVE BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, RIGICON, INC. AND ITS AFFILIATES (HEREINAFTER "RIGICON") HAS 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 SUCHDAMAGES 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.

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RECOMMENDED CARE, CLEANING AND STERILIZATION INSTRUCTIONS

DESCRIPTION

These instructions provide information on the use, care, cleaning, maintenance, and sterilization of reusable surgical instruments supplied by Rigicon intended for reprocessing in a health care facility.

Rigicon reusable surgical instruments may be safely and effectively reprocessed using the manual cleaning instructions and sterilization parameters provided.

Equipment, operators, cleaning agents and procedures all contribute to the efficacy of the processing. The healthcare facility should ensure that the selected reprocessing steps are safe and effective. Alternative methods of reprocessing outside the scope of these instructions may be suitable for reprocessing; however, those must be validated by the end user.

In states or 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 apply to:

- Reusable Non-Sterile surgical instruments supplied by Rigicon
- Instruments intended for reprocessing in a health care facility setting
- and do not apply to single-use devices.

WARNINGS

- Rigicon reusable surgical instruments are provided NON-STERILE and must be cleaned and sterilized according to these instructions prior to use.
- Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated instruments.
- Caution should be exercised while handling, cleaning, or wiping instruments with sharp cutting edges, tips, and teeth.
- 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.
- 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.
- 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.
- Do not use saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine, or iodide. These are corrosive and should not be used.
- Do not place or soak instruments in Ringers Solution.

- Do not use oil-lubricants. Because these may:
  - coat microorganisms,
  - prevent direct contact of the surface with steam
  - and are difficult to remove.
- When processing instruments do not place heavy devices on top of delicate instruments.
- Steam (moist heat) is the recommended method.
- Do not use the product if the package has been previously opened or if there is visual damage to the package or product.
- Devices that fail functional checks, have identification markings that are not legible, and/or have visible wear, rust, or pitting should be safely disposed of in accordance with standard biohazard practices. Devices that have visible soil after repeated cleaning should be disposed of in accordance with standard biohazard practices.
- Articulating devices such as the Furlow Inserter Tool) should be disassembled when being cleaned. Failure to disassemble devices could result in the retention of tissues or fluids that will prevent the device from being used as intended.
- Any physician using the surgical instruments should be thoroughly familiar with and trained in the surgical procedure being performed prior to using these tools.

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. Careful inspection 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 medical devices in closed boxes to avoid drying of soil.
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.

	• 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

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.

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