Rigicon®

Innovative Urological Solutions

Instructions for Use

Single Use HL Dilator

℞ ONLY

SYMBOLS

℞ ONLY	Caution: Federal law (US.) restricts this device to sale by or on the order of a physician
	Manufacturer Information
	Date of Manufacture
	Use by YYYY-MM-DD
	LOT Number
	Sterilized Using Ethylene Oxide
	Consult Instructions for Use
	Do not use if package is damaged
	Storage Temperature Limits
	Keep dry
	Keep away from sunlight
	Do Not Reuse
	Do Not Resterilize
	Caution

SUMMARY

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⚠ **WARNING:** Do not use if package is opened or damaged

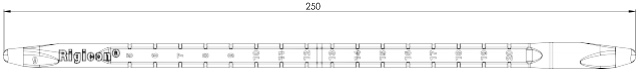
DEVICE DESCRIPTION

Rigicon Single Use HL Dilator is sterile, single-use, and disposable surgical instrument.

Rigicon Single Use HL Dilator is made of a smooth, solid, biocompatible thermoplastic material, providing high rigidity and strength.

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

Five dilators provide various dilation dimensions: 9/10, 11/12, 13/14, 15/16, and 10/12 mm sizes.



Rigicon Single Use HL Dilator

INDICATIONS FOR USE

Rigicon Single Use HL Dilator is intended for dilating the corpora cavernosa of thepenis 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.
- Tissue damage may occur in case of excessive force applied to the device.
- The device is not implantable.
- Before unpacking, the expiration date of the product should be checked. Do not use the products with passed expiration date. Sterilization of the products with passed expiration dates cannot be guaranteed.
- Rigicon Single Use HL Dilator is presented in a double pouched package, in a protective carton box. The package should be checked for damage, tearing, and puncture. Do not use the damaged, torn, and punctured packages.
- The reuse of this single use device may create potential harm to theuser. Reprocessing, washing, disinfection and/or sterilization of Rigicon Single Use HL Dilator may compromise product characteristics and cause additional risks of physical harm and/or infection.
- 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 prosthesis.

USE OF DILATOR:

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 STERILE. Do not use if the sterile barrier is damaged. If damage is found, please contact Rigicon, Inc.

For single use only. Do not reuse, reprocess, or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure may resulting in patient injury, illness, or death. Reuse, reprocessing or resterilization may also 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. After use, dispose the product and package 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 in a sealed, double pouch and 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 SINGLE USE 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 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.

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