Rigicon®

Innovative Urological Solutions

Rigicon

HL Dilator

Instructions for Use

℞ ONLY

CAUTION: Federal law restricts this device to sale by or on the order of a physician

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Symbols on Label

	Manufacturer Information
	Date of Manufacture
	Use by YYYY-MM-DD
	LOT Number
	Sterilized Using Ethylene Oxide
	Consult Instructions for Use
	Prescription
	Caution
	Do not use if package is damaged
	Temperature limit
	Keep dry
	Keep away from sunlight
CE 2764	CE Mark - CE2764 – Notice Notified Body

EC-REP Information:

Saturnusstraat 46-62, 2132 HB Hoofddorp, Netherlands

1. GENERAL INFORMATION ABOUT THE DEVICE

1.1. INTENDED USE

Rigicon 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.

1.2. DEVICE DESCRIPTION AND CHARACTERISTICS

Rigicon HL Dilator is a surgical instrument, and it is designed as a rod-like surgical instrument, it is available in a set of graduated sizes that are applied in succession during a penile implant procedure.
Rigicon HL Dilator is made of resin rod. The duration of contact of the instrument with the tissue is less than 30 minutes during the operation.

Figure 1. Rigicon HL Dilator

LIMITATIONS ON REPOROCESSING

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 surgical instrument. Evidence of damage and wear on a device may include but is not limited to corrosion (i.e., 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, andpackaged.

The Rigicon HL Dilator is a reusable surgical instrument. This surgical instrument is marketed sterile, and when it is re-used the applied

sterilization method must be EtO sterilization method, and the number of recommended reuses for this surgical instrument is onlyone. Before reuse, surgical instrument must be sterilized with EtO sterilization method. The surgical instrument is non-pyrogenic. The color of the prosthesis is white.

Please see the diagram above.

Rigicon HL Dilator

Product Catalogue Code	*Product Code*	Product diameters	Product Lengths
RSUD-0910	RSUD-0910	09-10 mm	25 cm
RSUD-1112	RSUD-1112	11-12 mm	25 cm
RSUD-1314	RSUD-1314	13-14 mm	25 cm
RSUD-1012	RSUD-1012	10-12 mm	25 cm
RSUD-1516	RSUD-1*516*	15-16 mm	25 cm

1.3 PROCEDURE

Rigicon HL Dilator is used 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.
It is designed as a rod-like surgical instrument, it is available in a set of graduated sizes that are applied in succession during a penile implant procedure.

2. INDICATIONS FOR USE

Rigicon 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.

3. CONTRAINDICATIONS

The device is contraindicated in patients:

- With urogenital infections and skin infections,
- Whose total corporal length is less than the instrument size,
- With Sensitivity to resin materials,
- Who are physically or mentally not suitable candidates, determined by the physician,
- Who often need endoscopic procedure,
- Who have active urogenital infections or active skin infections in the region of surgery,

- ❖ Whom the physician determines to be poor candidates due to risks associated with opensurgical procedures and /or the patient's medical history (physical and mentalconditions).

4. WARNINGS

Known and potential complications include, but are not limited to:

4.1. OPERATIONAL TECHNIQUE

- ❖ Direct contact of surgical instruments to the prosthesis may result in damage, rendering it unsuitable for implantation.
- ❖ Careful intraoperative sizing is required to ensure proper instrument operation.

4.2. INFECTION

Usage of the surgical tool during the implantation of prosthesis may result in infection. As with each surgical prosthesis, patients with diabetes, skin infection in the surgical area, open sores or urinary tract infections can have an increased risk of prosthetic associated infections. The use of sterile techniques and appropriate antibiotic prophylaxis will reduce the risk of infection. The patient should be monitored for any infection risk and cured accordingly.

4.3. EROSION

Erosion is the breakdown/disruption of the tissues around the prosthesis and may occur after placement. Erosion can be caused by tissue injury, inappropriate sizing, inappropriate positioning, improper usage of the surgical tool, infection, or pressure. The most common areas experiencing erosion are the glans, urethra, and skin. 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.

4.4. SENSITIVITY TO RESIN MATERIAL

Resin is used in the manufacturing process of the surgical tools. For many years, resin material has been commonly used as a biocompatible material in a variety of biomedical sectors. Scientific literature indicates there can be adverse events and other complications for patients with contacting surgical instruments. According to

these reports, the adverse events/complications specify allergic symptoms related to immunological disorders and have no relevance between the events and the resin material.

Comprehensive tests including cytotoxicity, implantation, sensitization, irritation, subchronic toxicity, acute systemic toxicity and genotoxicity were performed on resil material which is used for manufacturing of the surgical instruments.

4.5. LIFE EXPECTANCY OF THE PRODUCT / MECHANICAL FAILURES

The surgical instrument is not a lifetime device. It will experience fatigue over time. As with other surgical instrument, product wear and mechanical problems can occur after a period of usage. The surgical instrument may break as a result of excessive bending and pressure during the operation.

5. PRECAUTIONS

5.1. SURGERY RELATED

- Direct contact of surgical instruments to the prosthesis may result in damage, rendering it unsuitable for implantation.
- Careful intraoperative sizing is required to ensure proper instrument operation.

5.2. DEVICE RELATED

- Usage of a surgical dilator that has been previously in contact with or contaminated by body tissue or fluid, regardless of intervening, cleaning, or sterilization of the dilator, is prohibited.
- The surgical dilator is presented in double pouch package and inside a protective box. The package should be checked in terms of damage, tearing and puncture. Do not use the damaged, torn, and punctured packages.
- Before unpacking, the expiration date of the product should be checked. Do not use the products past their expiration date. Sterilization of the products with passed expiration dates cannot be guaranteed.

5.3. PATIENT RELATED

- A thorough preoperative consultation should include a discussion between patient and physician of all available treatment options and their risks and benefits.
- Uncircumcised patients may have an increased risk of postoperative complications with the sub-coronal approach. Surgeons may wish to discuss performing a circumcision to reduce the risks of post-operative complications associated with this approach.

6. PRE-OPERATIVE CONSIDERATIONS

CAUTION: Rigicon HL Dilator have to be used only by physicians who are knowledgeable in the use of penile prostheses implantation (e.g. urologists). This document is not intended to be a complete reference.

Proper patient selection is important before the usage of the surgical instrument during the implantation of the prosthesis.

Prior to the operation:

- The urine of the patient should be sterile.
- An antimicrobial shower should be given the night before the operation.
- An antibacterial prophylaxis should be given to the patient.
- The surgeon should scrub their hands for 10 minutes.

In the operating room:

- Parenteral antibiotics can be used on the patient according to the surgeon's discretion.
- The patient's genital area should be shaved.
- The skin should be prepared with a 10-minute scrub of providone-iodine soap.

7. WARNINGS OF THE USAGE

- Use of excessive force may cause tissue damage or create other hazards.
- Applying unbalanced forces to the Rigicon HL Dilator may cause the tool to fail

and cause impairment to surgery or other hazards.

- Use caution when palpating tissue or using surgical implants while using this product.
- Improper use may cause rod to suddenly break under tension and may lead to patient or operator injury.

8. SUPPLY AND STORAGE

WARNING: Contents are supplied STERILE. Do not use if sterile barrier is damaged. If damage is found, please call your Rigicon representative.

The Rigicon HL Dilator is supplied sterile. Store the device in a clean, dry, dark area at room temperature.

DISCLAIMER:

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

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EC REP

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Customers outside the United States and Canada should contact their local Rigicon Representatives.

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