Rigicon®

Innovative Urological Solutions

Instructions for Use

Rigicon Surgical Retractor

℞ 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

Rigicon®
Innovative Urological Solutions

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

DEVICE DESCRIPTION

Rigicon Surgical Retractor is sterile, single-use, and disposable surgical instrument.

Rigicon Surgical Retractor is made of a smooth, solid, biocompatible thermoplastic material, providing high rigidity and strength.

There are four different retractor frames available as: Snowman, Eight Shaped, Semilunar, and Quadratic Retractor Frame.

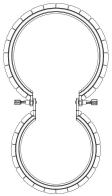

Figure 1: Rigicon Eight Shaped Retractor Frame

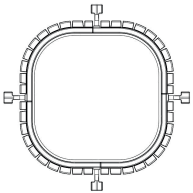

Figure 2: Rigicon Quadratic Retractor Frame

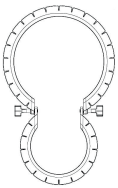

Figure 3: Rigicon Snowman Retractor Frame

Figure 4: Rigicon Semilunar Retractor Frame

INDICATIONS FOR USE

Rigicon Surgical Retractor is intended to be used to separate/draw aside the margins of an incision to allow access to tissues/organs during open surgery. The device belongs to the surgical instrument category.

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 Surgical Retractor 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 the user. Reprocessing, washing, disinfection and/or sterilization of Rigicon Surgical Retractor 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 prothesis 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 further information about potential risks or adverse events, refer to the Instructions for Use of the selected penile prothesis.

USE OF SURGICAL RETRACTOR:

1. Place retractor over surgery site. Connect elastic stays by using hooks to secure to tissue and elastic to retractor. Move around in opposing quadrants with equal tension to hold Surgical Retractor in place.

2. As dissection progresses, advance the hooks into deeper tissue.

3. Maintain constant, opposing tension of elastic stays to hold retractor in place for duration required.

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 result 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 of the product and package in accordance with the 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 SURGICAL RETRACTOR 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.

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

Rev 00 - 12.01.2021

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