
















Instructions for Use

Rigicon Retractor

R ONLY

SYMBOLS

	Caution: Federal law (US.) restricts this device to sale by or on the order of a physician
	Manufacturer Information
	The authorized representative in the European Community
	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
	CE Mark

EC-REP Information: Rigicon B.V.:
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Netherlands

SUMMARY

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WARNING: Do not use if package is opened or damaged

STORAGE CONDITIONS

Store device at room temperature.

STERILE

The Rigicon Retractor is supplied as sterile.

LIMITATIONS ON REPROCESSING

The Rigicon Retractor is a reusable surgical instrument. This surgical instrument is marketed as sterile, and when it is re-used the applied sterilization method has to be EtO sterilization method and it is recommended only one more reuse of this surgical instrument with an EtO sterilization method. The surgical instrument is non-pyrogenic.

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, and packaged.

INTENDED USE

The Rigicon 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.

CONTRAINDICATIONS

The device is contraindicated for patients with sensitivity to resin

PRODUCT DESCRIPTION

The Rigicon Retractor is a surgical instrument and is designed to be used as an independent device (i.e., not a mounting ring, or table-fixed assembly) having two frames with distal hooked blades and a self-retaining mechanism to maintain the frames in an open position for retraction. The Rigicon Retractor is made of a resin material.

DIRECTIONS FOR USE

- 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 Retractor in place.
- As dissection progresses, advance the hooks into deeper tissue.
- Maintain constant, opposing tension of elastic stays to hold retractor in place for duration required.

WARNINGS AND PRECAUTIONS

- Read all instructions prior to use
- Do not use if the patient has a known allergy to resin
- Use of excessive force may cause tissue damage or create other hazards.
- Applying unbalanced forces to the retractor may cause impairment to surgery or other hazards.
- Use caution when palpating tissue or using surgical implants while using this product.
- Improper use may cause retractor to suddenly break under tension and may lead to patient or operator injury.
- Care must be taken to avoid mishandling components. Use caution when handling components to avoid inadvertent punctures. When surgical instruments and accessories from different manufacturers are employed together, ascertain their compatibility prior to the procedure.
- Contents are supplied STERILE. Do not use if sterile barrier is damaged.
- Store device at room temperature. Avoid exposure to prolonged elevated temperatures.
- Dispose of device in accordance with accepted medical practice and applicable local and federal laws and regulations.

RETRACTOR MODELS

Product Code	Product Name
RSMRF-1000	Rigicon Snowman Retractor Frame
RESRF-1000	Rigicon Eight Shaped Retractor Frame
RSLRF-1000	Rigicon Semilunar Retractor Frame
RQRRF-1000	Rigicon Quadratic Retractor Frame
RSHSF-4008	Rigicon Sharp Hook Single Finger 4 mm 8 pieces/pack
RSHSF-4004	Rigicon Sharp Hook Single Finger 4 mm 4 pieces/pack
RSHSF-4050	Rigicon Sharp Hook Single Finger 4 mm 50 pieces/pack
RSHSF-5004	Rigicon Sharp Hook Single Finger 5 mm 4 pieces/pack
RSHSF-5008	Rigicon Sharp Hook Single Finger 5 mm 8 pieces/pack
RSHSF-5050	Rigicon Sharp Hook Single Finger 5 mm 50 pieces/pack
RSHSF-8004	Rigicon Sharp Hook Single Finger 8 mm 4 pieces/pack
RSHSF-8008	Rigicon Sharp Hook Single Finger 8 mm 8 pieces/pack
RSHSF-8050	Rigicon Sharp Hook Single Finger 8 mm 50 pieces/pack
RFHDF-1404	Rigicon Fork Hook Dual Finger 14 mm 4 pieces/pack
RFHDF-1604	Rigicon Fork Hook Dual Finger 16 mm 4 pieces/pack
RFHDF-1804	Rigicon Fork Hook Dual Finger 18 mm 4 pieces/pack
RFHDF-2004	Rigicon Fork Hook Dual Finger 20 mm 4 pieces/pack
RBHSF-1204	Rigicon Blunt Hook Single Finger 12 mm 4 pieces/pack
RBHSF-1208	Rigicon Blunt Hook Single Finger 12 mm 8 pieces/pack
RBHSF-1250	Rigicon Blunt Hook Single Finger 12 mm 50 pieces/pack
RBHDF-1204	Rigicon Blunt Hook Dual Finger 12 mm 4 pieces/pack
RBHDF-1208	Rigicon Blunt Hook Dual Finger 12 mm 8 pieces/pack
RBHDF-1250	Rigicon Blunt Hook Dual Finger 12 mm 50 pieces/pack
RRFS-1000	Rigicon Retractor Fixation Support
RD-1000	Rigicon Deaver
RTP-1000	Rigicon Tissue Protector
RCH-1000	Rigicon Catheter Holder
RUGRK-1000	Rigicon Urogynecology Retractor Kit
RCRRK-1000	Rigicon Colorectal Retractor Kit
RSRK-1000	Rigicon Surgical Retractor Kit

RETRACTORS SHAPES

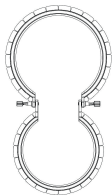


Figure 1: Rigicon Eight Shaped Retractor Frame

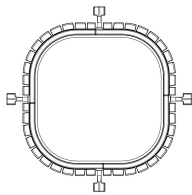


Figure 2: Rigicon Quadratic Retractor Frame

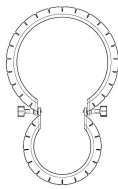


Figure 3: Rigicon Snowman Retractor Frame

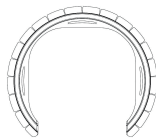


Figure 4: Rigicon Semilunar Retractor Frame

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 RIGICON RETRACTORS 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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