

Ring Protect™ Disposable Wound Protector/Retractor

Instructions for use

Ref. no.: 0221-060070150, 0221-080090150, 0221-120130150, 0221-150160150, 0221-180190250, 0221-180190200, 0221-220230250, 0221-220230200, 0221-270280250, 0221-320330250

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Important:

The instructions provided herein are not intended to serve as a comprehensive manual for surgical techniques related to the use of the Ring Protect™ Disposable Wound Protector/Retractor. Acquiring proficiency in surgical techniques necessitates direct engagement with our company or an authorized distributor to access detailed technical instructions, consult professional medical literature, and complete requisite training under the mentorship of a surgeon skilled in minimally invasive procedures. Prior to utilization of the device, we strongly advise a thorough review of all information contained in this manual. Failure to adhere to these guidelines may result in severe surgical outcomes, including patient injury, contamination, infection, cross-infection, or death.

Product description:

Disposable Wound Protector/Retractor provides 360° of circumferential, atraumatic retraction, maintains moisture at the incision site, reduces superficial surgical site infection following surgeries and prevents transfer of cancer cells into abdominal wall during oncological surgery and tumor removal. The self-retaining design of the Disposable Wound Protector/Retractor allows hands-free access to the operative site, minimizes need for surgical assistance and facilitates specimen removal.

Disposable Wound Protectors/Retractors are sterile, single use, disposable devices and are supplied in a variety of diameters. These products do NOT contain latex or Di-ethyl-hexyl Phthalate (DEHP). Physicians should select the size of device that is appropriate for the specific procedure.

Indications:

Disposable Wound Protectors/Retractors are intended to atraumatically retract surgical wounds and protect their edges from moisture loss, infection and inadvertent contact implantation of tumor cells into the body wall.

Patient target group - adult and young patients, males and females.

Intended users: product is intended to be used exclusively by qualified medical professionals.

Contraindications:

Do not use in the area of local inflammation.

Instructions for use:

1. Prepare the surgical site according to standard procedure.
 2. Open the package using standard aseptic technique and put Wound Protector/Retractor onto the sterile field.
 3. Make an incision that is adequate to accommodate the Wound Protector/Retractor referring to the cutting lengths list provided below.
 4. Insert the colored ring of the Wound Protector/Retractor into the incision.
 5. Grasp the white proximal ring with your hands positioned opposite each other. Pull up on the white proximal ring ensuring that the colored distal ring is fully seated against the peritoneal or pleural layer.
 6. Roll the white proximal ring by curling the top ring edge over until the ring fully inverts. Repeat rolling until the incision is retracted and the Wound Protector/Retractor sleeve is tight against the walls of the incision.
 7. Carefully check that no bowel or tissue is entrapped between the distal ring and the body wall.
- Note: To prevent prolonged ischemia and potential necrosis, any tissue trapped between the retractor and the body wall must be immediately released.**
8. Perform procedure through the fully retracted and protected 360° incision site.
 9. To remove Wound Protector/Retractor insert hand or finger through the opening, grasp colored distal ring and gently pull it out of the incision.

Cutting lengths:

Ref no	Cutting length [cm]		Ref no	Cutting length [cm]
0221-060070150	2 - 5		0221-180190200	9 - 16
0221-080090150	2,5 - 6		0221-220230250	11 - 20
0221-120130150	5 - 10		0221-220230200	11 - 20
0221-150160150	7 - 13		0221-270280250	14 - 25
0221-180190250	9 - 16		0221-320330250	17 - 30



Additional warnings and precautions:

1. Any surgical and minimally invasive procedures should be performed only by persons having adequate training and familiarity with the techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any surgical procedure.
2. Handle sharp instruments or structures (such as staples, gallstones etc.) with care to prevent accidental cutting or puncturing of the Wound Protector/Retractor's sleeve. Accidental damage to the retractor during the procedure may result in fragments of the sleeve being cut off and potentially falling into the body cavity unnoticed.
3. When using instruments connected to diathermy, ensure that the active working element does not remain in contact with the Ring Protect™ Disposable Wound Protector/Retractor material. Activating diathermy in direct contact with the device material may lead to melting, perforation, or damage.
4. Do not extend the body wall incision beyond the recommended limit for the given retractor size. An excessively long incision may cause the colored ring to lose sufficient internal support, leading to potential slippage from the surgical wound and complicating the procedure.
5. Avoid making the incision shorter than the lower limit recommended for the given retractor size. An incision that is too short will cause the retractor sleeve to constrict, reducing the diameter of access to the surgical site and making the procedure more challenging.
6. The colored ring must always be placed inside the body cavity. Reverse placement will prevent the outer ring from rolling up properly and may compromise the correct retraction of the body walls.
7. Insufficient rolling of the proximal ring may cause the wound protector to not retain its proper shape or to fit too loosely on the incision, which may adversely affect the proper wound coverage and stability of the device.
8. Always inspect the site for hemostasis before procedure is finished. Failure to manage bleeding can lead to postoperative bleeding into the body cavity and fever and body integuments hematoma. In extreme cases, reoperation may be necessary.
9. Exercise caution when there is a potential for exposure to blood or bodily fluids. Adhere to hospital protocols regarding the use of protective wear and equipment.
10. Do not use damaged device. Using of damaged Ring Protect™ Disposable Wound Protector/Retractor may result in impaired wound protection, inadequate retraction, loss of sterility leading to increased risk of surgical site infection, tissue trauma, or unintended transfer of tumor cells into the body wall.
11. Dispose of all opened devices, regardless of whether they have been used, to prevent accidental reuse of a potentially contaminated device.
12. Use the device immediately upon opening. Storing the device after the package has been opened may result in contamination, increasing the risk of patient infection. The device's sterility and full functionality can only be ensured if used immediately after opening the packaging.
13. Take care to discard the product and packing after use, as well as unused but opened devices, in accordance with hospital waste disposal practices and local regulations including, without limitation, those pertaining to human health and safety and the environment.
14. This product is intended for single patient and procedure use. Resterilization, reuse, reprocessing, modification may lead to serious consequences with death of patient included.
15. If any serious incident has occurred in relation to the device, it should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
16. Grena does not promote or recommend any specific surgical practices. Surgical technique and types of surgical wounds appropriate for atraumatic retraction with Ring Protect™ Disposable Wound Protector/Retractor are the responsibility of the surgeon.

	Keep dry		Consult electronic instructions for use		Manufacturer		Date of manufacture
	Caution		Do not re-sterilize		Do not use if package is damaged and consult instructions for use		Use-by date
	Authorized Representative in the European Union		Catalogue number		Batch code		Quantity in package
	Sterilized using ethylene oxide		Do not re-use		Medical device		Single sterile barrier system

*The hard copies of instructions for use delivered with Grena products are always in english language.
If you require a hard copy of IFU in other language, you can contact Grena Ltd.
at ifu@grena.co.uk or + 44 115 9704 800.*

*Please scan the below QR code with the appropriate application.
It will connect you with Grena Ltd. website where you can choose eIFU in your preferable language.*

You can enter the website directly by typing in www.grena.co.uk/IFU in your browser.

*Make sure that paper version of IFU in your possession is in the latest revision prior to use of the device.
Always use the IFU in the latest revision.*

