



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

 Grena Ltd , 1000 Great West Road, Brentford, Middlesex TW8 9HH, United Kingdom	Contact information: Phone/ Fax: + 44 115 9704 800	<div style="border: 1px solid black; padding: 2px; display: inline-block;">EC REP</div> MDML INTL LTD. 10 McCurtain Hill Clonakilty, Co. Cork, P85 K230, Republic of Ireland	 0197	ENG IFU-DRA-ENG-06
--	--	---	--	------------------------------

Attention:

These Instructions For Use cannot be used as a surgical manual describing the use of Disposable Wound Protectors / Retractors. As needed, please contact our company or your authorized distributor. You should acquaint yourself with appropriate technical instructions, review the professional medical literature, and obtain formal graduate training under the supervision of a surgeon experienced in surgical techniques. We recommend thoroughly reviewing all information in this IFU; inattention to the instructions provided below may have serious clinical consequences such as patient injury, contamination, 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.

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 by using standard aseptic technique and put Wound Protector / Retractor on the sterile field.
3. Make an incision adequate to accommodate the Wound Protector / Retractor (refer to cutting lengths list below).
4. Insert the coloured ring of the Wound Protector / Retractor into the incision.
5. Grasp the white proximal ring in a manner that your hands are opposite to each other. Pull up on the white proximal ring ensuring that the coloured 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 to ensure that no bowel or tissue entrapment between the distal ring and the body wall has occurred.
8. Perform procedure through 360° retracted and protected incision site.
9. To remove Wound Protector / Retractor unroll the white proximal ring, insert hand or finger through the opening, grasp coloured distal ring and pull it out of the incision.

Cutting lengths:

Ref no	Cutting lenght [cm]	Ref no	Cutting lenght [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. Do not use after expiry date.
2. Use immediately after opening.
3. Sharp instruments should be handled with care to avoid accidental cutting or puncturing of the Wound Protector / Retractor's sleeve.
4. Check haemostasis of the wound edges after Wound Protector / Retractor is removed.
5. Caution should be used when the possibility for exposure to blood or body fluids exists. Follow hospital policy regarding the use of protective wear.
6. This product is intended for single patient and procedure use. Resterilization, reuse, modification may lead to serious consequences with death of patient included.
7. To be used by qualified physician only
8. 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.
9. 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.



Keep dry



Consult instructions for use



Manufacturer



Date of manufacture



Caution, consult accompanying documents



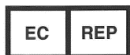
Do not resterilize



Do not use if package is damaged



Expiry date



Authorized representative in UE



Catalogue number



Batch code



Quantity in package



Sterilized using ethylene oxide



Do not re-use