

Silicone Sling Instructions for use

Ref. No.: 0218-01151040B, 0218-01241240B, 0218-01241275B, 0218-01501540B, 0218-01151040R, 0218-01241240R, 0218-01241275R, 0218-01501540R,
0218-01151040Y, 0218-01241240Y, 0218-01241275Y, 0218-01501540Y, 0218-01151040W, 0218-01241240W, 0218-01241275W, 0218-01501540W

 <p>GRENA[®] Think Medical Grena (Qingdao) Medical Devices Ltd., No 318 Huanghe West Road, Huangdao District, Qingdao City, Shandong Province, 266555, China</p>	<p>Contact information: Phone: +86 0532-86769190 Fax: +86 0532-86767322</p>	<table border="1" style="margin: auto;"> <tr> <td style="padding: 2px 5px;">EC</td> <td style="padding: 2px 5px;">REP</td> </tr> </table> <p>MDML INTL Limited, 10 McCurtain Hill Clonakilty, Co. Cork Republic of Ireland</p>	EC	REP	
EC	REP				

Important:

This instruction cannot be used as a manual for surgical techniques used during the work with silicone sling. To learn adequate knowledge about surgical technique it is necessary to contact our company or authorized distributor and to acquaint with appropriate technical instructions, professional medical literature and graduate proper training under supervision of surgeon experienced in surgical techniques. Before use we recommend reading precisely all information included in this manual. Not being obedient to this information may lead to serious surgical consequences such as patient injury, infection, cross-infection tissue necrosis or death.

Indications:

Silicone sling is a disposable device used to retract vessels, nerves, ureters and other tissues from operating site during surgical procedures. It can be also used for temporary vessel closure during surgery.

Description:

Slings are made of medical grade silicone and are visible in X-ray. Four sizes are available: Ø1,5 x 1,0 mm x 40 cm, Ø2,4 x 1,2 mm x 40 cm, Ø2,4 x 1,2 mm x 75 cm, Ø5,0 x 1,5 mm x 40 cm to facilitate use on tissue structures of different diameters. Each size can be supplied in 4 colors: blue, red, yellow and white for easy and fast identification of the tissue. Oval cross-section and optimal level of extensibility protects tissue structures from trauma.

Contraindications:

1. Use on any tissues which strangulation can result in severe consequences like, for example ischemia, is relative contraindication.
2. Use on any tissues which can be easily destroyed by excessive force or which can, if too much force applied, destroy surrounding tissues is relative contraindication.

Instructions for use:

1. Chose colors and sizes expected to be used during surgery. It is recommended to use following colors for the tissue types as a standard: blue for veins, red for arteries, yellow for ureters and white for nerves.
2. Open the package using aseptic technique and put slings on a sterile field.
3. Grasp one end of each Silicone Sling with atraumatic forceps.
4. Pass forceps tip with a sling under the tissue structure to be retracted as far as sling end will be clearly visible on the other side of the tissue structure.
5. Open the forceps and grasp the sling's end from the other side of the tissue structure and pull it up until parts of the sling on both sides of the tissue will have the same length.
6. Grasp both ends of sling together with the forceps. Use forceps as a holder to retract tissue if necessary. In case sling encompasses vessel pulling it affects blood flow to the extend depending on the force used.
7. To remove sling open the forceps and close it on one end of the sling. Then pull it until whole sling will slide out.
8. Leave the sling on sterile instrument tray together with the forceps closed on its end not to let it get accidentally into the operating site.

Additional warnings and precautions:

1. Care should be taken to avoid contact of the sling with sharp instruments and cutting devices.
2. Excessive forces should be avoided during retraction as they could cause tissue trauma. Surgeon is responsible to apply retraction force within tissue tolerance without causing any damage to the retracted and surrounding tissues.
3. Retraction of the vessel can close its lumen. Never keep vessel lumen closed for a period which could cause dangerous organ ischemia. This is responsibility of a surgeon to properly estimate accepted ischemia time in case of use on a given vessel.
4. During the whole surgical procedure never leave the sling without atraumatic forceps closed on it not to abandon it in the surgical site.
5. Always count slings used in the procedure at the beginning and at the end of surgery and ensure both results are the same. In case any slings were added during operation they should be also taken into count.
6. Length of slings is optimal and they should be never shortened during surgery to avoid cut-off ends to fall into and to be left in the operating site.
7. Dispose all opened products whether used or unused.
8. Use immediately after opening.
9. Product requires appropriate disposal after use in accordance with all applicable local regulations including, without limitation, those pertaining to human health and safety and the environment.
10. This product is intended for single patient and procedure use. Resterilization, reuse, modification may lead to serious consequences with death of patient included.
11. Product is intended to be used exclusively by qualified medical staff.

