Absorbable Adhesion Barrier Gel (HyaRegen® Gel)

INSTRUCTION FOR USE

Product Description

Abdomino-pelvic surgical procedures are a frequent cause of adhesion formation, which may induce pelvic pain and/or infertility. These post-surgical adhesions are due to the formation of areas of contact, made of fibrous tissue, between adjacent internal organs. In order to prevent the formation of post-surgical adhesions it is recommended to use a product able to form a barrier against the contact between adjacent tissues, and to remain on the site of application for a period of time sufficient to avoid the formation of adhesions.

HyaRegen® Gel is a sterile, transparent and highly viscous gel. The active component is cross-linked molecules of hyaluronan (HA) from non-animal source. HA is one of the main components of human connective tissue and of epithelial and mesothelial tissues. The cross-linking process makes HA more viscous and persisting longer in vivo. Therefore, HyaRegen® Gel has increased viscosity and extended residence time, and could also keep the same tolerability and biocompatibility with the original polymer.

HyaRegen® Gel is intended to be absorbed for not more than 30 days. One - two weeks after the application, the HyaRegen® Gel is almost completely reabsorbed, no matter what tissue or area was applied. Thanks to its viscosity, HyaRegen® Gel adheres to the tissue surface and creates an anti-adhesion barrier which keeps the adjacent tissues separated during the repair phase subsequent to a surgical procedure.

Intended Use

HyaRegen® Gel is indicated for the prevention or reduction post-surgical adhesion formation in the abdomino-pelvic area after laparoscopic/hysteroscopic and open surgical procedures.

Instructions for Use

---Open the protective packaging (Tyvek pouch or blister tray) and introduce the syringe into the operating field, adopting the normal aseptic techniques used in the surgical theatre.

---Remove the protective cap on the tip of the syringe, and when appropriate connect the luer-lock end of the syringe to a large-pore cannula (for example an I.V catheter, 14 gauge or larger)

--- Apply the gel inside the abdomino-pelvic cavity or uterine cavity by pushing the plunger.

---Cover all areas to be treated with enough gel.

---Do not irrigate the surgical field after application of the product.

Contraindications

Known hypersensitivity to hyaluronan or its derivatives.

The device must not be used in patients with infection or contamination of the surgical site.

Warnings and Precautions

---Confirm that the surgical site is free of excessive bleeding. Excessive bleeding should be controlled prior to HyaRegen® Gel instillation.

---HyaRegen® Gel does not have intrinsic bacteriostatic or bactericidal activity. It is not bacteriostatic toward pre-existing infections, nor does it prevent the occurrence of new infections. In the case of pre-existing infections, appropriate treatment should be instituted.

---The concomitant use of HyaRegen® Gel with other anti-adhesion device has not been evaluated.

---HyaRegen® Gel has not been evaluated with a dose of over 2 ml/kg of body weight. It is not recommended to use HyaRegen® Gel over a dose of 2 ml/kg of body weight unless at the discretion of the physician.

---HyaRegen® Gel has not been evaluated in patients affected by malignant tumors. Preclinical evidence has shown that the products have no influence on neoplastic diffusion.

---Data on the use of HyaRegen® Gel on pregnant women are not available. The use of the products is not recommended in this condition. It is also recommended to avoid pregnancy during the first complete menstrual cycle subsequent to the treatment.

---Do not inject intravascularly.

---HyaRegen® Gel is provided in single-use, pre-filled syringes. The syringe content only is provided sterile. The external surface of the syringe has a very low controlled bioburden. The syringe is packaged into a protective blister tray or Tyvek pouch to prevent the contamination of its outer surface and to allow the use of the devices in the surgical theatre. Do not resterilize the syringe content.

---It is recommended to use the product immediately after opening the pouch.

---All the assembling operations of the device must be performed in the surgical theatre.

---The syringe is single-use; any non-used product must be discarded accordingly. The reuse of the product may cause serious infection.

---The empty containers have to be discarded accordingly.

---Keep out of reach of children.

---If the syringe and /or protective pouch or the blister is damaged, do not use the product and contact local distributor.

---Do not use the product after the expiration date.

---HyaRegen® Gel must be used according to the instruction for use. Read instructions prior to use.

Adverse Events

The type and frequency of adverse events reported are consistent with events typically seen following surgery. No device-related adverse effects were reported in the two completed clinical studies. However, as with any surgically implanted biomaterials there might be the potential for adverse reactions, such as infection, foreign body reaction, and allergic reaction etc. in rare circumstances.

Storage

HyaRegen® Gel should be stored at 2°-30℃ and protection from sunlight. **DO NOT FREEZE**.

Shelf-life

24 months from date of manufacture.

How Supplied

HyaRegen® Gel is supplied in a 2.25ml glass syringe containing 2ml HyaRegen® Gel, in a 5ml glass syringe containing 3 or 5ml HyaRegen® Gel, in a 10 ml glass syringe containing 6, 8 or 10ml HyaRegen® Gel, or in a 20ml glass syringe containing 15 or 20ml HyaRegen® Gel.

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CE Marking

CE 0123