Hyalobarrier GEL Hyalobarrier GEL ENDO

STERILE H_2O_2	Sterilized using vaporized hydrogen peroxide
STERILE	Sterilized using steam
STERILE EO	Sterilized using ethylene oxide

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Product information

Abdomino-pelvic surgical procedures are a frequent cause of adhesion formation, which may induce pelvic pain and/or infertility (1). 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 at the site of application for a period of time sufficient to avoid the formation of adhesions (2).

The medical devices HYALOBARRIER® GEL and HYALOBARRIER® GEL ENDO are sterile, transparent and highly viscous gels, based on ACP® (auto-crosslinked polysaccharide), which is obtained through crosslinking by condensation of hyaluronic acid, one of the main components of human connective tissue and of epithelial and mesothelial tissues. Thanks to their viscosity, HYALOBARRIER® GEL and HYALOBARRIER® GEL ENDO perfectly adhere to the tissue surface and to the abdominal wall, creating an anti-adhesion barrier which keeps the adjacent tissues separated during the repair phase subsequent to a surgical procedure. Seven days after application, the gel is completely reabsorbed (3). The efficacy of the products has been demonstrated through clinical studies (4-13) performed in abdomino-pelvic surgeries. HYALOBARRIER® GEL and HYALOBARRIER® GEL ENDO are designed to satisfy the needs of the different techniques used in abdomino-pelvic surgery.

Indications

HYALOBARRIER® GEL and HYALOBARRIER® GEL ENDO are indicated for the prevention or reduction of post-surgical adhesion formation in the abdomino-pelvic area.

HYALOBARRIER® GEL is indicated for use in open surgery procedures.

HYALOBARRIER® GEL ENDO is indicated for use in laparoscopic and hysteroscopic surgical procedures.

Contraindications

Known hypersensitivity to the product.

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

Storage

- Keep refrigerated (2-8°C). The product may be stored at room temperature only for a limited time (no longer than 7 days), after which it should be refrigerated again.
- Do not freeze.

Instructions for use

HYALOBARRIER® GEL and HYALOBARRIER® GEL ENDO are provided in sterile single-use, pre-filled syringes. The syringe content is sterilized using steam. The pouch with syringe is sterilized using vaporized hydrogen peroxide to assure sterility of the whole pouch content, including outer syringe surfaces. Cannulas are sterilized by ethylene oxide.

1. Take the product out of refrigeration and let it warm to room temperature (minimum 30-40 minutes in ambient room temperature). Open the pouch and introduce the syringe into the sterile operating field, adopting the normal aseptic techniques used in the surgical theatre.
2. Open the cannula's blister and transfer the cannula into the sterile field, adopting the normal aseptic techniques used in the surgical theatre.
3. Remove the syringe protective cap on the tip of the syringe. With a twisting motion connect the cannula to the luer-lock end of the syringe. Gently tug on the cannula. If the cannula is properly fitted on the syringe, it should not pull off. The cannula for HYALOBARRIER® GEL ENDO has been designed to be utilized with a 0.5 cm diameter trocar.
4. Apply the gel inside the abdomino-pelvic cavity by pushing the plunger.
5. Cover the areas to be treated with the gel. It is recommended to apply a 1-2 mm thick layer of gel. The thickness of the gel layer does not influence the efficacy of the product.
6. In case of pack with 2 syringes and 1 cannula, if a second syringe of gel is required, twist the syringe off of the cannula in use and follow step 3 above to attach the second syringe to the cannula.
7. Do not irrigate the surgical field after application of the product.

Warnings and precautions

- HYALOBARRIER® GEL and HYALOBARRIER® GEL ENDO are intended for surgical use by specialized surgeons only.
- HYALOBARRIER® GEL and HYALOBARRIER® GEL ENDO must not be injected intravenously.
- On the basis of preclinical evidence, the efficacy of HYALOBARRIER® GEL and HYALOBARRIER® GEL ENDO is not compromised in the presence of difficult haemostasis (14). The use of the products in patients affected by alterations of blood coagulation, severe allergies or known former cases of anaphylaxis is at discretion of the surgeon.
- HYALOBARRIER® GEL and HYALOBARRIER® GEL ENDO do not have intrinsic bacteriostatic or bactericidal activity.
- The concomitant use of HYALOBARRIER® GEL and HYALOBARRIER® GEL ENDO with other anti-adhesion devices or with intraperitoneally instilled solutions has not been evaluated.
- HYALOBARRIER® GEL and HYALOBARRIER® GEL ENDO have not been evaluated in patients affected by malignant tumours. Preclinical evidence has shown that the products have no influence on neoplastic diffusion (15).
- Data on the use of HYALOBARRIER® GEL and HYALOBARRIER® GEL ENDO 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.
- The use of HYALOBARRIER® GEL and HYALOBARRIER® GEL ENDO has not been evaluated in children or in nursing mothers.
- It is recommended to use the syringe and cannula immediately after opening the pouch.
- All the assembling operations of the device must be performed in the surgical theatre.
- To avoid damage to the luer-lock connection, it is recommended not to use the cannula-syringe system as a manipulating laparoscopic instrument, e.g., for displacing tissues and organs.
- The syringe is single-use; any non used product must be discarded.
- The cannula is single-use; do not sterilize again.
- There is a risk of non sterile product and patient infection, in case any unused gel and/or the cannula were to be re-used after application.
- The empty containers have to be discarded according to national regulations.
- If the 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.

How supplied

- In each pack, HYALOBARRIER® GEL is available in individually packaged syringes each containing 10 ml of 40 mg ACP®/ml sterile gel. Individually packaged 5-cm long cannulas are enclosed for application.
- In each pack, HYALOBARRIER® GEL ENDO is available in individually packaged syringes each containing 10 ml of 30 mg ACP®/ml sterile gel. Individually packaged 30-cm long cannulas are enclosed for application.

References

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