

# Hyalobarrier<sup>®</sup>

GEL | GEL ENDO

## THE NATURAL CHOICE IN ADHESION PREVENTION



## WHY USE HYALOBARRIER GEL?

- ✓ 100% natural product consisting of pure hyaluronic acid auto-crosslinked. <sup>(1-12)</sup>
- ✓ The gel, which is a natural product produced by biofermentation (no animal origin, from natural hyaluronan); bioabsorbable and inherent in the body, creates a mechanical barrier between organs after surgery at the site where there is a risk of adhesions. <sup>(1-12)</sup>
- ✓ Highly viscous, sticks firmly to the application site, thus fulfilling the essential function of these devices - to stay where it is needed. <sup>(1-12)</sup>
- ✓ Hyalobarrier remains in the area of application for 7 days, protecting the organism during the 3-5 days of adhesion risk and completely degrades within 30 days (bioabsorbable). <sup>(1-12)</sup>
- ✓ Significant reduction of post-surgical adhesions. <sup>(14)</sup>
- ✓ Significant reduction of post-surgical intrauterine adhesions. <sup>(15,16)</sup>
- ✓ Significant increase in the pregnancy rate. <sup>(18)</sup>
- ✓ Effectiveness in laparotomy, laparoscopy and hysteroscopy. <sup>(13-23)</sup>
- ✓ Completely safe - tested in over 500,000 patients since year 2000 with no adverse effects being reported.





### Characteristics

Hyalobarrier<sup>®</sup> is a bioabsorbable, transparent and highly viscous gel, composed of 100% pure hyaluronic acid auto-crosslinked without the introduction of any foreign substances.

Thanks to its viscosity, Hyalobarrier<sup>®</sup> adheres perfectly 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.

### Indications

Hyalobarrier<sup>®</sup> is indicated to prevent or reduce the post-surgical adhesion.

### Instructions for use

1. Take the product out of refrigeration and let it warm at room temperature. Open the pouch and introduce the syringe into the operating field, adopting the normal aseptic techniques used in the surgical theatre.
2. Remove the protective cap on the tip of the syringe and connect the enclosed cannula to the luer-lock end of the syringe. The cannula for Hyalobarrier<sup>®</sup> gel endo has been designed to be utilized with a 0.5 cm diameter trocar.
3. Apply the gel inside the wound site by pushing the plunger.
4. 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.
5. Do not irrigate the surgical field after application of the product.

### Contraindications

Known hypersensitivity to the product, like other implant materials, the device must not be used in patients with active infection or contamination of the surgical site.

### Storage

Keep refrigerated (2-8°C).

Do not freeze.

### Shelf life

Three years.

### Preclinical publications

1. Mensitieri M et al., Viscoelastic properties modulation of a novel autocrosslinked hyaluronic acid polymer. J MaterSci MaterMed 1996;7, 695-698
2. De Iaco PA et al., A novel hyaluronan-based gel in laparoscopic adhesion prevention: preclinical evaluation in an animal model. Fert Ster 1998 Feb; 69[2]:318-23
3. Koçak I et al., Reduction of adhesion formation with cross-linked hyaluronic acid after peritoneal surgery in rats. Fertility and Sterility 1999 Nov; vol.72.N°5
4. Belluco C et al., Prevention of postsurgical adhesion with an autocrosslinked hyaluronan derivative gel. J Surg Res 2001 Oct; 100[2]:217-21
5. De Iaco PA et al., Efficacy of hyaluronan derivative gel in postsurgical adhesion prevention in the presence of inadequate hemostasis. Surgery 2001 Jul; 130[1]:60-4
6. Pucciarelli S et al., Effect of antiadhesive agent on peritoneal carcinomatosis in an experimental model. Br J Surg 2003 Jan; 90[1]:66-71
7. Renier D et al., Pharmacokinetic behaviour of ACP gel, an autocrosslinked hyaluronan derivative, after intraperitoneal administration. Bio materials 2005 Sep; 26(26):5368-74
8. Wallwiener M. et al, Innovative barriers for peritoneal adhesion prevention: liquid or solid? A rat uterine horn model. Fertil Steril Vol. 86, Suppl 3, October 2006 (1266 - 1276).
9. Shamiyeh A. et al.: Effect of Hyaluron Derivate Gel in Prevention of Postsurgical Peritoneal Adhesions - An Experimental Study in Pigs. Hepato-Gastroenterology 54 (2007), 1121-1124.
10. Binda MM, Molinas CR, Bastidas A et al. Efficacy of barriers and hypoxia-inducible factor inhibitors to prevent CO2 pneumoperitoneum enhanced adhesions in a laparoscopic mouse model. J Min Inv Gynecol 2007; 14:591-599.
11. Blinda MM and Koninckx PR. Prevention of adhesion formation in a laparoscopic mouse model should combine local treatment with peritoneal cavity conditioning. Hum Reprod. 2009 Jun; 24(6):1473-9. Epub 2009 Mar 3.
12. Binda MM and Koninckx PR. Hyperoxia and prevention of adhesion formation: a laparoscopic mouse for open surgery. BJOG. 2010 Feb; 117(3):331-9. Epub 2009 Oct

### Warnings and precautions

Even if the efficacy of the product is not compromised in the presence of difficult haemostasis, the use of Hyalobarrier<sup>®</sup> on patients affected by alterations of blood coagulation, severe allergies or previous recognized anaphylaxis episodes is at total discretion of the surgeon.

Hyalobarrier<sup>®</sup> does not have intrinsic bacteriostatic or bactericidal activity.

The concomitant use of the product together with other anti-adhesion devices or with solutions instilled intraperitoneally, has not been evaluated.

The safety of Hyalobarrier<sup>®</sup> has not been evaluated in patients affected by malignant tumours.

The syringes are single-use. Non-utilized portions of the product must be discarded.

The cannula is single-use.

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.

### Presentations

#### Hyalobarrier<sup>®</sup> gel

Indicated for use in open surgery procedures.

The package includes:

- three individually-packaged, single-use, sterile syringes, each containing 10ml of gel
- three individually-packaged, sterile, 5 cm-cannulae.

#### Hyalobarrier<sup>®</sup> gel endo

Indicated for use in laparoscopic and hysteroscopic surgical procedures.

The package includes:

- three individually-packaged, single-use, sterile syringes, each containing 10ml of gel
- three individually-packaged, sterile, 30cm-cannulae. These cannulae have been designed to be utilized with a 0.5cm diameter trocar.

### Clinical publications

13. De Iaco PA et al., Hyaluronan derivative gel (HYALOBARRIER<sup>®</sup> gel) in intrauterine adhesion (IUA) prevention after operative hysteroscopy. Ellipse 2003; 19(1):15-18
14. Pellicano M et al., Effectiveness of autocrosslinked hyaluronic acid gel after laparoscopic myomectomy in infertile patients: a prospective, randomized, controlled study. Fertil Steril 2003 Aug; 80[2]:441-4
15. Acunzo G et al., Effectiveness of auto-cross-linked hyaluronic acid gel in the prevention of intrauterine adhesions after hysteroscopic adhesiolysis: a prospective, randomized, controlled study. Hum Reprod 2003 Sep; 18[9]:1918-21
16. Guida M. et al., Effectiveness of auto-crosslinked hyaluronic acid gel in the prevention of intrauterine adhesions after hysteroscopic surgery: a prospective, randomized, controlled study. Hum Reprod 2004 Jun; 19[6]:146-4
17. Carta G et al., Postoperative adhesion prevention in gynecologic surgery with hyaluronic acid. Clin Exp Obstet Gynecol. 2004; 31[1]:39-41
18. Pellicano M et al., Reproductive outcome after autocrosslinked hyaluronic acid gel application in infertile patients who underwent laparoscopic myomectomy. Fertil Steril 2005 Feb; 83[2]:498-500
19. Mais V. et al, Reduction of postoperative adhesions with an auto-crosslinked hyaluronan gel in gynaecological laparoscopic surgery: a blinded, controlled, randomized, multicentre study. Hum Reprod. 2006 May; 21(5):1248-54. Epub 2006 Jan 26.
20. Metwally M. et al, Hyaluronic acid fluid agents for the prevention of adhesions after fertility-preserving gynecological surgery: a meta-analysis of randomized controlled trials. Fertil Steril. 2007 May; 87(5):1139-46.
21. Salman MC, Beksac S, Dogan NU Use of hyaluronic acid for vaginal stenosis in a woman with a history of imperforate hymen and transverse vaginal septum: a case report. Source J Reprod Med. 2009 Jun; 54(6):397-400.
22. Beksac MS, Salman MC, Dogan NU A new technique for surgical treatment of vaginal agenesis using combined abdominal-perineal approach. Case Report Med. 2001; 2011:120175. Epub 2011 Apr 26.
23. Mais V, Cirronis MG, Peiretti M, Ferrucci G, Cossu E, Melis GB Efficacy of auto-crosslinked hyaluronan gel for adhesion prevention in laparoscopy and hysteroscopy: a systematic review and meta-analysis of randomized controlled trials. Eur J Obstet Gynecol Reprod Biol. 2012 Jan; 60(1):1-5. Epub 2011 Sep 25. Review

### Manufacturer:



**ANIKA THERAPEUTICS S.R.L.**  
Corso Stati Uniti 4/U - 35127 Padova, Italy  
Tel. 0039 049-295-8311  
www.anikatherapeutics.com

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### Marketed by (Sabah):



**Dr. Device & Lab**  
D.D.L. Medical Supplies

**D.D.L. Medical Supplies** (121957)  
Ground Floor, Lot 348, Lorong 7A, Jalan Ang Cheng Ho,  
93100 Kuching, Sarawak, Malaysia.  
Email: drdevicemed@gmail.com  
Website: www.drdevicelab.com