



Instructions for use

1. Open the protection box and pull the product out.
2. Follow the indication, peel-open the blister tray, remove the HyaRegen® Gel syringes and place on sterile field.
3. Remove the tip cap from the syringe; attach a large-bore sterile delivery cannula with a standard luer lock.
4. Upon completion of the procedures in the abdominal or the pelvic cavity, simply instill the HyaRegen® Gel into the cavity via the delivery cannula to completely cover the surface of the organs.
5. In order to achieve the best adhesion prevention results, the gel should not only applied to the organs that are operated on but organs away from the surgical area should be also covered as much as possible.
6. The maximum volume of HyaRegen® gel used for one patient is upto 2.0ml* per kg of bodyweight.
7. Upon completion of the gel application, withdraw the catheter. Do Not lavish the cavity.

*According to the results of a safety study in animal, this max. volume is still 10 times lower than the highest safety margin.

Order information

Item #	Description	Quantity
40-012-001	HyaRegen® Gel	1 syringe/box (10cc)
40-012-120	HyaRegen® Gel	1 syringe/box (20cc)



References

1. De Wilde RL et al.: Arch Gynecol Obstet. 2014; 290:581
2. Lower AM et al.: BJOG. 2000; 107:855
3. Ellis H: Ann Chir Gynaecol. 1998; 87:9
4. Ellis H et al.: Lancet. 1999; 353:1476
5. Lower AM et al.: Hum Reprod. 2004; 19:1877
6. Salamonsen LA: Reproduction 2003, 125:301
7. Brown CB et al.: Fertil Steril. 2007; 88:1413

HyaRegen® Gel

Unique Crosslinked Hyaluronic Acid Gel for
Prevention of Adhesion in Abdominopelvic Cavity

- ★ Complete Coverage
- ★ Comprehensive Protection
- ★ Proven Efficacious and Safe

BioRegen Biomedical CO., Ltd.
A Sino-USA Company

Post-surgery adhesions

Significant challenge to physicians Facts^{1,2}

- ◆ 93%: after abdominal / pelvic surgery
- ◆ 85%: after adhesiolysis
- ◆ 30%: re-intervention in 10 years

Impacts to patient Related consequences^{3,4,5}

- ◆ Small bowel obstruction > 74%
- ◆ Chronic pelvic pain > 40%
- ◆ Secondary infertility in women > 40%
- ◆ Re-operative complications > 56%

Prevention of Adhesion

- ◆ Meticulous and careful surgical technique
- ◆ Prophylactic application of adhesion barrier

ESGE Consensus guideline: Using adhesion reduction agents as important part of adhesion reduction strategy; achieving full prevention de novo and reformed adhesions.¹

Ideal Material



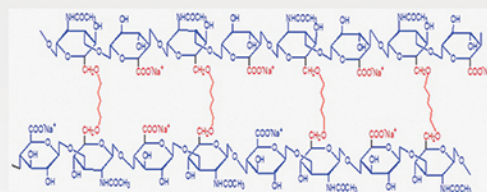
Patient benefits

- ★ Reduced adhesions
- ★ Enhanced pregnancy rate
- ★ Limited bowel obstruction
- ★ Improved quality of life
- ★ Prevented re-admission

HyaRegen® Gel



Novel and unique crosslinking technology



Unique features and functions

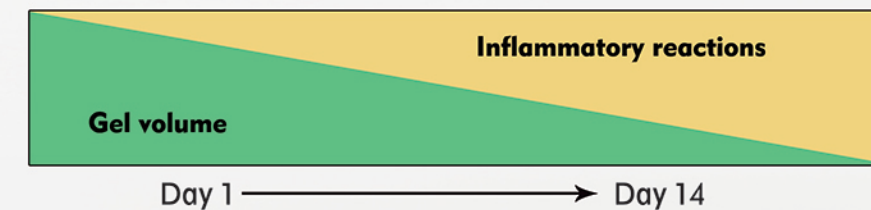
- ★ Easy to use via endoscopy or open surgery
- ★ Absorbable upto 14 days to provide complete coverage during the critical period of inflammatory reactions
- ★ Preventing adhesion in surgical intervention area and remote locations in entire abdominopelvic cavity
- ★ Proven efficacious and safety from randomized clinical trial

HyaRegen® Gel: unique material features

- ★ Proprietary crosslinking technique: no toxic residual and xenogeneic proteins, excellent biocompatibility, reduced inflammatory reaction
- ★ Gentle material modification method: Preserved the nature features of hyaluronic acid
- ★ Adequate viscosity and hydrophilic property: creation of moist environment facilitating re-mucosalization, moderate expansion upon implantation could stop minor bleeding and effective barring
- ★ Controlled degradation profile: physical barrier during the tissue healing critical period to prevent adhesion and scar formation
- ★ Terminal sterilization: maximized safety after application
- ★ Dissolvable: avoid secondary damage to the regenerated tissue
- ★ Easy to use: no mixing required, flexible delivery cannula to facilitate application and to reach the desired location

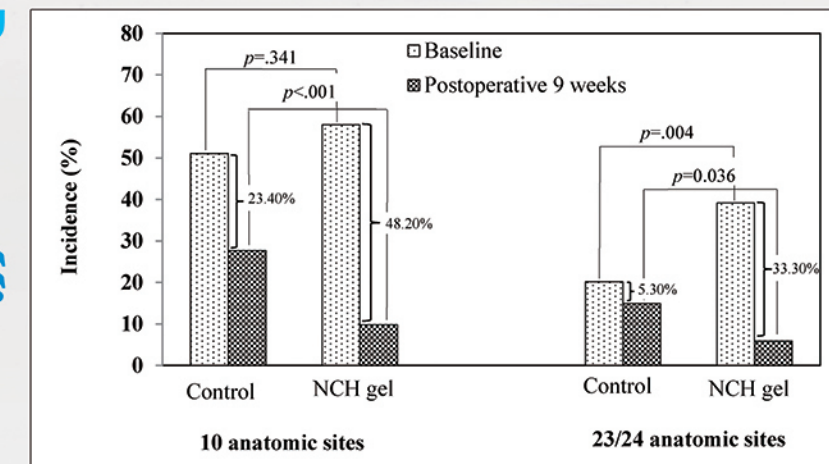


Optimized and controlled degradation of the Gel ensure complete coverage and protection to the organs



- HyaRegen® Gel degrades in abdominopelvic cavity for upto 14 days
- ★ Covers traumatized organ surfaces during the critical period of inflammatory reaction and healing processes⁷
- ★ Provides effective barrier to separate the organs

Proven efficacy
of HyaRegen® Gel*



- ★ Randomized, controlled, multiple center clinical study (Level I)
- ★ Laparoscopic gynecological surgery; 2nd look laparoscopy at 9 PO weeks
- ★ American Fertility Society (AFS) adhesion scores quantified blindly
- ★ Adhesions observed in 10 anatomic sites (ovaries and tubes) and 23/24 sites (covering entire abdominopelvic cavity)⁷
- ★ Conclusions: Application of HyaRegen® Gel (NCH) significantly reduced the severity of adhesion and its incidence in the entire abdominopelvic cavity.

*Liu C. et al. A randomized controlled trial on the efficacy and safety of a new crosslinked hyaluronan gel in reducing adhesions after gynecological laparoscopic surgeries. JMIG 2015; 22:853-863.

HYAREGGEN® GEL