About BIOREGEN

Established in 2008, BioRegen Biomedical (Changzhou) Co., LTD., with its original proprietary self-crosslinking technology prepared sodium hyaluronate gel, which has been protected by 44 international patents, has been widely used in gynecology, otolaryngology, ophthalmology, medical beauty and other fields in China and abroad.

Order Information

REF CODE#	Product	Volume
40-012-010	HyaRegen® Gel (Pack)	10ml

Reference

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.
8. Liu C et al.: JMIG 2015; 22:853.

BIOREGEN

Vision and mission:

Worldwide leader in tissue repair and regeneration

Rejuvenate wound tissue & enjoy beautiful life

HyaRegen®

CE 0123

Wound Repair | Adhesion Prevention

Absorbable Adhesion Barrier Gel

New Crosslinked Hyaluronic Acid Gel
Functional healing material and adhesion barrier for OB/GYN surgeries

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FOLLOW US:

CFDA Registration number: national device registration permission 20223140092
Version: V2.4 Date: 2023.08.21

Background of HyaRegen®

Post-surgery adhesion

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]

Patient benefits

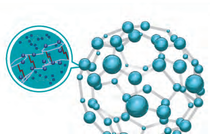
- ★ Reduced adhesions
- ★ Enhanced pregnancy rate
- ★ Limited bowel obstruction
- ★ Improved quality of life
- ★ Prevented re-admission

Product value of HyaRegen®

Effective and safe with 2nd look laparoscopic clinical evidence	Technology with 44 international patents Modified molecular structure and stability Improved material performance
CFDA approved and CE marked Launched in 40+ countries	Use-friendly and no refrigeration required Flexible to be used in endoscopic and open surgeries with broad coverage

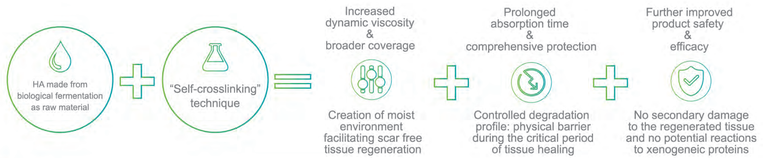
Proprietary technique: Self-crosslinking

◆Mechanism: it forms stable 3D network structure by activating internal activity of hyaluronic acid molecules
◆No additive, no crosslink agent residue, gentle material modification chemistry: preserved the biological function of natural hyaluronic acid



3-dimensional crosslinked network structure

Unique Features of HyaRegen® Gel



	HyaRegen®	Normal sodium hyaluronate (HA)
Efficacy	Jelly-like gel with high dynamic viscosity and mouldability	It is fluid like, and flowable
	The time for complete degradation and absorption is 7-14 days, it can provide complete coverage during the critical period of tissue repair	1-2 days (Too fast, unmatched to the key stage of intima repair)
Safety	Sterilization assurance level (SAL) < 10^{-6} (After steam sterilization)	~10^{-3}, high risk of bacterial contamination

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

HyaRegen® Gel degrades in abdominopelvic cavity for up to 14 days

- ●Covers traumatized organ surfaces during the critical period of tissue repair processes
- ●Provides effective barrier to separate the organs

HyaRegen® Usage method

Applicable scope

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

Usage Steps

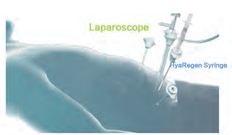
1. Open the protective package (Tyvek pouch or blister tray) and introduce the syringe to the operating field, adopting the normal aseptic techniques used in the surgical theatre.

2. Remove the protective cap on the tip of the syringe, and 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).

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

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

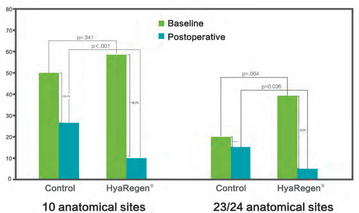
5. Do not irrigate the surgical field after application of the product.

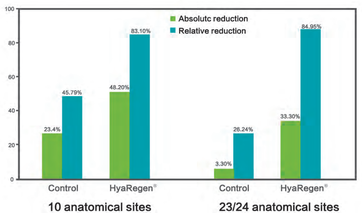


HyaRegen® evidence

Clinical Trial Example 1

- A prospective, multicenter, randomized, negative controlled trial
- Study group: HyaRegen; Control group: Saline Solution
- Patients: 216 women scheduled for gynecologic laparoscopic surgery for primary removal of adhesions, myomas, ovarian cysts, or endometriotic cysts.
- Evaluation:
  2LL (2nd look laparoscopy) at the 9 week follow up visit;
  A modified American Fertility Society (mAFS) scoring system was used for the incidence, extent, and severity of pre-existing and postoperative adhesions at the 10 anatomic sites of ovaries/tubes and at the expanded 23 or 24 anatomic sites throughout the abdominopelvic cavity by laparoscopy.



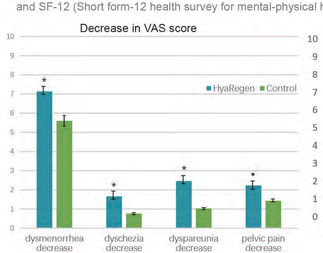


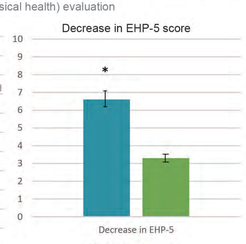
- **Conclusion:** HyaRegen Gel proved to be safe and significantly reduced the severity of adhesion and its incidence in the entire abdominopelvic cavity.

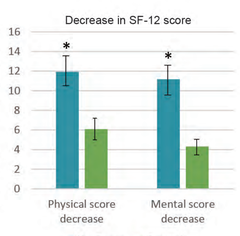
Liu et. Al, J Minim Invasive Gynecol. 2015 Jul-Aug;22(5):853-63.

Clinical Trial Example 2

- a randomized controlled pilot study
- Study group: HyaRegen; Control group: Saline Solution
- Patients: 60 patients for deep infiltrating endometriosis surgery
- 3 and 6 months after surgery conduct the VAS (visual analogue scale), EHP-5 (Endometriosis health profile-5) and SF-12 (Short form-12 health survey for mental-physical health) evaluation







- **Conclusion:** Using NHC gel in addition to standard surgical procedure improves postoperative VAS scores, and provides better quality of life scores.

Murat Ekin et. al., Journal of Obstetrics and Gynaecology 2020, 41:2, 263-268