About BIOREGEN

BIOREGEN is a high-tech Sino-US joint venture founded by world-renowned scientists in 2008. Specialized in novel therapeutic biomaterials and regenerative medicine, BIOREGEN is committed to develop solutions for unmet needs in clinical both in China and abroad. With the unique and proprietary technology, advanced biomaterial products developed by the company have been successfully launched in the market of Euro-American countries, such as US, UK, France and Germany, and widely recognized and applied by the medical experts.

The company has been invested with over RMB 160 million by renowned venture capitals, such as Cenova Ventures (a fund from the High-Tech Department of National Development and Reform Commission), Fidelity Growth Partners Asia and Fidelity bioscience of US etc. (Note: Fidelity is one of the largest assets management companies of America)

Order Information

REF CODE#	Product	Volume
40-012-010	HyaRegen® Gel (Pack)	10ml
40-012-020	HyaRegen® Gel (Pack)	20ml

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.

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BIOREGEN
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BIOREGEN

Vision and mission:

Worldwide leader in tissue repair and regeneration

Rejuvenate wound tissue & enjoy beautiful life

HyaRegen®

CE 0123

Self corss-linked hyaluronan gel for abdominopelvic cavity

Wound Repair | Adhesion Prevention

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

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

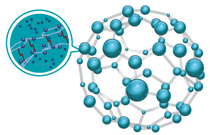
- ★ Reduced adhesions
- ★ Enhanced pregnancy rate
- ★ Limited bowel obstruction
- ★ Improved quality of life
- ★ Prevented re-admission

Product value of HyaRegen®

Novel and unique crosslinking technology Optimized viscosity and absorption time Excellent biocompatibility	Proven efficacy and safe from randomized clinical trials Regulate inflammatory reaction, prevent adhesion and protect organs
Approved by CE certification as absorbable adhesion barrier gel for adhesion prevention in abdomino-pelvic area	Easy to use via endoscopy or open surgery Economical and practical for clinical usage Easy to store and transport

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	Endotoxin < 0.15 EU/mL (3% of the national standard)	~5EU/ml (10mg/mL)
	Sterilization assurance level (SAL) < 10^{-6} (After high-temperature and high-pressure 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 processes7
- ●Provides effective barrier to separate the organs

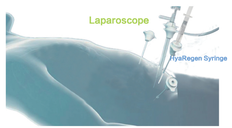
HyaRegen® Usage method

Applicable scope

HyaRegen® Gel could be used in the abdomino-pelvic area after laparoscopic/hysteroscopic and open surgical procedures e.g. ovary surgery, fallopian surgery, myomectomy, surgery for endometriosis, adhesiolysis etc.

Usage Steps

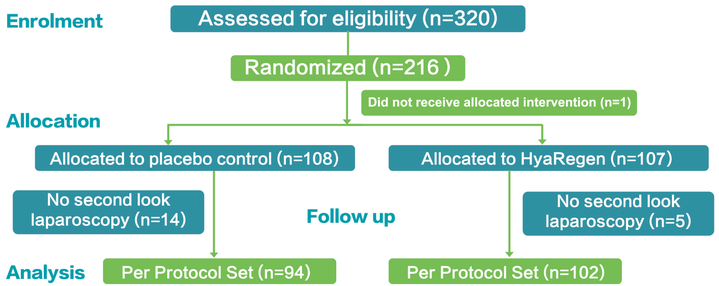
1.Open the protection box and pull the product out.
2.Follow the indication, peel-open the blister tray, remove the HyaRegen® Gel syringe and place on sterile field.
3.Remove the tip cap from the syringe; attach the sterile delivery cannula with a standard luer lock.
4.Upon completion of the procedures 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 up to 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.



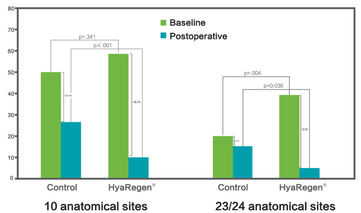
HyaRegen® evidence-based medicine verification

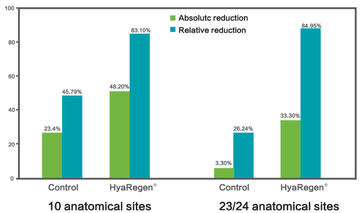
Clinical trial

A randomized Controlled Trial on the Efficacy and Safety of a New Crosslinked Hyaluronan Gel in Reducing Adhesion after Gynecologic Laparoscopic Surgeries.[8]



- ☆Randomized, controlled, multiple center clinical study (Level I).
- ☆Laparoscopic gynecological surgery; 2nd look laparoscopy at 9 PO weeks.
- ☆Modified American Fertility Society (mAFS) 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 significantly reduced the severity of adhesion





[8]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.