



HyaRegen[®] CE 0123

Self cross-linked hyaluronan gel

(Wound Repair)

(Adhesion Prevention)

Unique Cross-linked Hyaluronic Acid Gel for Prevention of Adhesion

- 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.







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

Ideal Material



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 Optimised viscosity and absorption time Excellent biocompatibility



Proven efficacy and safe from randomised clinical trials

Regulate inflammatory reaction, prevent adhesion and protect organs



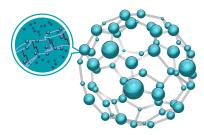
Approved by CE certification as absorbable adhesion barrier gel for adhesion prevention



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

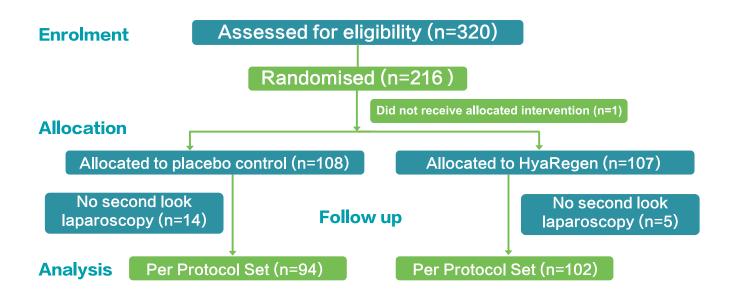


3-dimensional crosslinked network structure

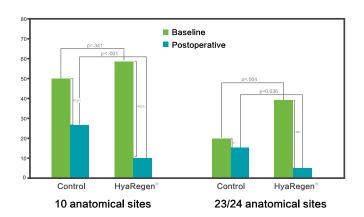
HyaRegen® evidence-based medicine verification

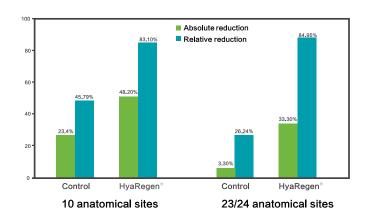
Clinical trial

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



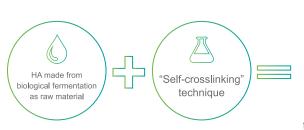
- ☆Randomised, controlled, multiple center clinical study (Level I).
- ☆ Laparoscopic gynecological surgery; 2nd look laparoscopy at 9 PO weeks.
- ☆Modified American Fertility Society (mAFS) adhesion scores quantified blindly
- ☆ Adhesions observed in 10 anatomic sites (ovaries and tubes) and 23/24 sites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





⁸Liu C. et al. A randomised 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.

Unique Features of HyaRegen® Gel



Increased dynamic viscosity & broader coverage



Creation of moist environment facilitating scar free tissue regeneration Prolonged absorption time & comprehensive protection



Controlled degradation profile: physical barrier during the critical period of tissue healing Further improved product safety & efficacy



No secondary damage to the regenerated tissue and no potential reactions to xenogeneic proteins

	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 high-temperature and high-pressure sterilization)	\sim 10 $^{-3}$, high risk of bacterial contamination

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

Tissue repair Gel volume

HyaRegen® Gel degrades for up to 14 days

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

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.





