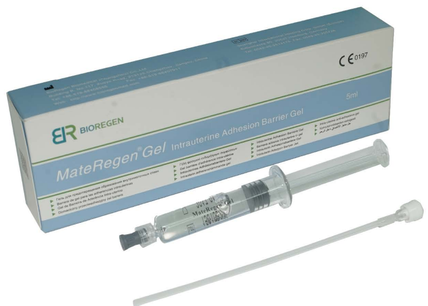
About BIOREGEN

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
40-008-011	MateRegen®	3ml
40-008-005	MateRegen®	5ml

Reference

1. Holmdahl.Lancet 1999;353:1456—7.
2. ASRM: FertilSteril2019;99:15501456,–5.
3. AAGL:Practice guidelines for management of intrauterine synechiae.J Minim Invasive Gynecol 2010;17:1—7.
4. Friedler et al.,Hum Reprod 1993;8:442—4.
5. Kodaman and Arici.Curr Opin Obstet Gyneco 2007;19:207—14.
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7. Thomson et al.,Curr Opin Obstet Gyneco 2009;21:335—41.
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11. Maybin&Critchely,Expert Rev Obstet Gynecol 2009;4:283—298；Gurtner er al.,Nature 2008;435:314—321.
12. Chen&Abatangelo,Functions of hyaluronan in wound repair.Wound Rep Reg 1999;7:79—89.
13.Journal of Minimally Invasive Gynecology, 2017,14 (1):6.
14.Fertility and Sterility® Vol. 107, No. 5, May 2017.

Vision and mission:

Worldwide leader in tissue repair and regeneration

Rejuvenate wound tissue & enjoy beautiful life

MateRegen®

CE 0197

Wound Repair | Adhesion Prevention

Intrauterine Adhesion Barrier Gel

Pure crosslinked Hyaluronan
Facilitating the healing of the endometrium

Changzhou Headquarters
Address：Building B, No. 117, Xueye Road, 213125 Changzhou, Jiangsu, China
Email：info@bioregenmed.com Tel: 0519-88408555 Fax: 0519-88407911

Shanghai Marketing Center
Address: Room 625, Building 2, Germany Center, No. 88, Keyuan Road, Pudong New District, Shanghai; postal code: 200120
Email：info@bioregenmed.com Tel: 021-68911828 Fax: 021-68911828

Germany Office
Email: info@bioregenmed.com Tel: 0049-176-48323307

Beijing/Guangzhou/Chengdu Office
Email: info@bioregenmed.com Tel: 021-68911828

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www.bioregenmed.com
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CFDA Registration number: national device registration permission 20153141542
V1.0 2021.12.15

Background of MateRegen®

Intrauterine adhesion

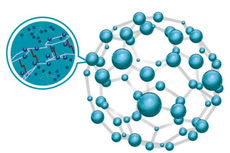
Once intrauterine adhesion forms, it will very likely severely endanger the physical health and fertility function of female, such as infertility and Miscarriage，etc. Nowadays, domestic and overseas gynaecologists are paying more and more attention to intrauterine adhesion, and proposed the concept “Prevention over treatment”, however, traditional packing materials can hardly prevent the occurrence of adhesion.

Product value of MateRegen®

Prefilled in a syinge with flexible delivery cannula Adequate volume (5ml) to the uterine cavity Easy to connect to all hysteroscopes	Preventing IUA after surgeries e.g. abortion and miscarriage Reducing adhesion reformation after adhesiolysis Minimizing the adhesion severity etc.
Approved by CE and CFDA as intrauterine anti-adhesion material	Modulating inflammatory reactions Facilitating the regeneration of the endometrium Improving the endometrium function

About the preparation technique – Self-crosslinking

- Mechanism: it forms stable 3-dimensional network structure by activating internal activity of sodium hyaluronate molecules.
- This novel and unique HA crosslinking technology is protect by dozens of patents



3-dimensional crosslinked network structure

	MateRegen®	Normal sodium hyaluronate (HA)
Efficacy	It is a jelly-like gel, and stably indwells in the uterine cavity	It is fluid like, and flowable
	The time for complete degradation and absorption is 7-14 days.	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
Applicability	It is approved specially used in the surgery for uterine cavity It is able to continuously indwell in and isolate uterine cavity It provides sufficient intervention therapy in the key stage of intimal repair.	No indications of intrauterine surgery; failure of indwelling and effective isolation of uterine cavity; insufficient intervention therapy, and undesirable effect

Reference

The Clinical Guide of Intrauterine Adhesion (jointly released by AAGL and ESGE, 2017) pointed out:

Auto-cross-linked hyaluronic acid gel may be suitable for preventing IUAs because of high sensitivity and prolonged time on an injured surface such as the postoperative endometrium.

Semi-solid barriers such as auto-cross-linked hyaluronic acid gel reduce adhesion reformation. Level A.

The Clinical Guide for Intrauterine Adhesion (released by AAGL, 2010 version) pointed out:

Auto-cross-linked hyaluronic acid gel may also be suitable for preventing IUAs because of high sensitivity and prolonged residency time on an injured surface.

The incidence of intrauterine adhesion following the injection of auto-cross-linked sodium hyaluronate after the surgery for the female with at least one uterine apoxesis: short-term results of a multi-centered, prospective, randomized and controlled trial pointed out that:

Prevention of IUAs is essential and application of ACP gel may be considered to reduce the incidence and severity of IUAs.

Extracted from Fertility and Sterility Vol. 107, No. 5, May 2017

MateRegen® Usage method

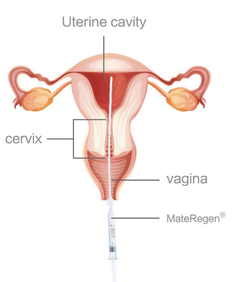
Applicable scope

MateRegen® Gel is indicated for use in patients after hysteroscopic surgeries as barrier to prevent or reduce post-operative intrauterine adhesions. MateRegen® Gel functions to fill intrauterine cavities following surgery, keep the traumatic surfaces separated during the healing process and act as an adjunct to facilitate the natural healing process.

Introduction for use

1. Open the protective packaging and introduce the syringe into the operating field, following normal aseptic techniques used in the surgical theatre.
2. Remove the protective cap on the tip of the syringe and connect the syringe to a compatible cannula, for example an 18 gauge or larger I.V catheter. For type II product of MateRegen® Gel, an Injection Cannula is provided in the same box.
3. After hysteroscopic surgery or other intrauterine procedures, insert the delivery cannula to the bottom of uterine cavity and then slowly instill enough MateRegen® Gel to fill the whole intrauterine cavity by pushing the plunger.
4. To avoid washing out the gel, do not irrigate the uterine cavity after gel application unless under the discretion of the physicians.

Note: Before using this product, try to evacuate the fluid in the uterine cavity



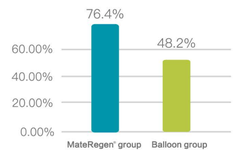
Connect to Hysteroscope

1-Connect the syringe to the flushing channel and press the plunger all the way down.
2-After removing the syringe, refil it halfway with only air.
3-Connect again the syringe and drive out the remaining gel in the hysteroscope, withdrawing it very slightly.

MateRegen® evidence-based medicine verification

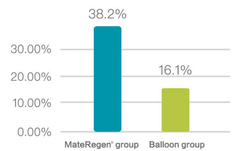
Clinical trial I

Prevention efficacy rate p = 0.0009



The effective rate for the prevention of MateRegen® group was 58.5% higher than that of balloon group

Complete cure rate p = 0.0006



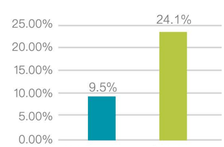
The complete curate rate of the MateRegen® group was 137.3% higher than that of balloon group

- Used the multi-centered, randomized, parallel and controlled design protocol
- Enrolled 120 patients with moderate and severe intrauterine adhesion after the surgery
- Study group: MateRegen® + Balloon control group: Balloon
- Received the second hysteroscopy in 3 months after the surgery
- The intrauterine adhesion scoring system of the American Filtration and Separations Society (AFS) is used as the evaluation standard

China J Obstet Gynecol, January 2015, Vol.50，No.1

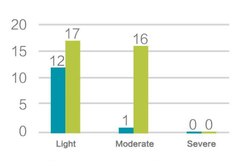
Clinical trial II

Adhesion incidence p = 0.0012



The adhesion incidence of the MateRegen® group was 60.6% lower than that of the control group

Cases of adhesion p = 0.0087



The incidence of mild and moderate adhesion of the MateRegen® group was obviously lower than that of the control group

- Used multi-centered, randomized, parallel and negative control
- Enrolled 300 patients with missed abortion
- Study group: MateRegen® control group: conventional surgical treatment
- Received hysteroscopy in 3 months after the surgery
- The intrauterine adhesion scoring system of the American Filtration and Separations Society (AFS) is used as the evaluation standard

A, Xueying Li , et al. Journal of Minimally Invasive Gynecology 26. 1(2019):94-99