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.
6. Yu D et.,Fertil Steril 2008;89:759—79.
7. Thomson et al.,Curr Opin Obstet Gyneco 2009;21:335—41.
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9. Taskin O,et al.；J Am Assoc Gynecol Laparosc 2000;7:351—4.
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11. Maybin＆Critchely,Expert Rev Obstet Gynecol 2009;4:283—298；Gurtner er al.,Nature 2008;435:314—321.
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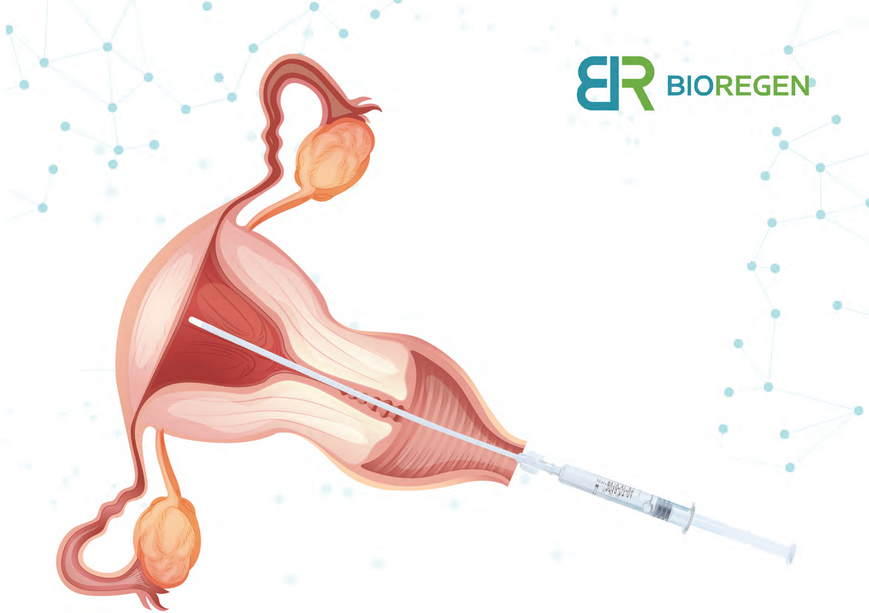

BIOREGEN

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

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BIOREGEN

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FOLLOW US:

CFDA Registration number: national device registration permission 20153141542
Version: V2.4. Date: 2023.08.21

Background of MateRegen®

Intrauterine adhesion

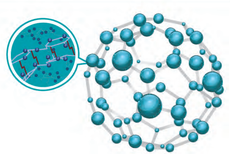
Once intrauterine adhesion forms, it will very likely severely endanger the physical health and fertility function of female, such as infertility and miscarriage, etc. Nowadays, gynaecologists are paying more and more attention to intrauterine adhesion, and proposed the concept "Prevention over treatment",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

Product value of MateRegen®

Effective and safe with clinical evidence Prevent IUA, improve endometrial quality and increase pregnancy rate	Technology with 44 international patents Modified molecular structure and stability Improved material performance
CFDA approved and CE marked Launched in 40+ countries	Adequate volume (5ml) for uterine cavity Use-friendly and no refrigeration required

About the preparation technique – Self-crosslinking

- Mechanism: it forms stable 3-dimensional network structure by activating internal activity of sodium hyaluronate molecules.



3-dimensional crosslinked network structure

Non-animal sourced HA + Self-crosslinking Technology = Optimized viscosity + Prolonged degradation time + Improved safety and efficacy

	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 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 stages of intimal repair.	No indications of intrauterine surgery; failure of indwelling and effective isolation of uterine cavity; insufficient intervention therapy, and undesirable effect

MateRegen® Usage method

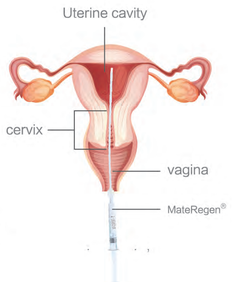
Applicable scope

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

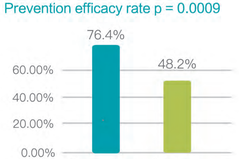
1-Connect the syringe to the flushing channel and press the plunger all the way down.
2-After removing the syringe, refil it halfway with only air.
3-Connect again the syringe and drive out the remaining gel in the hysteroscope, withdrawing it very slightly.

MateRegen® evidence

Clinical Trial Example 1

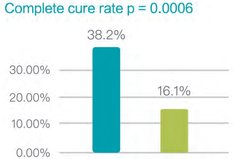
- Multi-center RCT study
- 120 adhesiolysis cases enrolled
- Study group: MateRegen + Balloon; Control group: Balloon
- 2nd look hysteroscopy after 3 months, evaluation with AFS score system

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



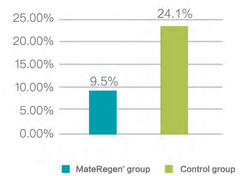
The complete curate rate of the MateRegen® group was 137.3% higher than that of balloon group

Xiao et. al. Giorn. It. Ost. Gin. 2015; 27(4): 216-219

Clinical Trial Example 2

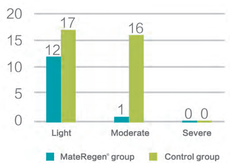
- Multi-center RCT study
- 300 delayed miscarriage cases enrolled
- Study group: D&C + MateRegen; Control group: D&C
- 2nd look hysteroscopy after 3 months, evaluation with AFS score system

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

Li et al. J Minim Invasive Gynecol. 2019 Jan;26(1):94-99

Clinical Trial Example 3

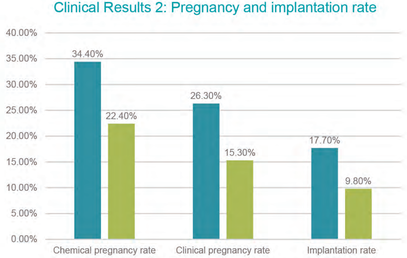
- RCT study
- 306 IVF cases enrolled
- Study group: MateRegen; Control group: Standard hysteroscopy
- Evaluation: clinical pregnancy rate, implantation rate, endometrial thickness on the day of embryo transfer

Clinical Results 1: Endometrial thickness

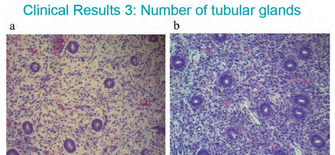
	MateRegen	Control group	P value
Endometrial thickness before operation (mm)	6.35 ± 0.92	6.28 ± 0.69	0.243
Endometrial thickness on the day of embryo transfer (mm)	7.97 ± 1.37	7.50 ± 0.60	< 0.001
Average change in endometrial thickness(%)	+ 27.5%	+ 20.7%	0.048

- The endometrial thickness on the day of embryo transfer was significantly higher in MateRegen group (P < 0.001).
- Both the chemical and clinical pregnancy rate, and the implantation rate were higher in MateRegen group (P < 0.05).

Clinical Results 2: Pregnancy and implantation rate



Clinical Results 3: Number of tubular glands



beore MateRegen 15.1 ± 13.2 after MateRegen 28.8 ± 30.4

- From the histological assessment of the paired endometrial tissues biopsy, there was increased endometrial quality with doubled tubular glands in MateRegen group.
- **Conclusion:** the application of MateRegen gel in patients with moderate to severe IUA during hysteroscopy can improve the quality of endometrium and uterine receptivity and consequently enhance the clinical pregnancy rate after IVF/ICSI and FET.

Mao et. al. Archives of Gynecology and Obstetrics 2019 Jan;26(1):94-99