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)







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Vision and mission:

Worldwide leader in tissue repair and regeneration Rejuvenate wound tissue & enjoy beautiful life

MateRegen CE 0197

Self Cross-linked Hyaluronan Gel for Uterine Cavity

(Adhesion Prevention)

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Pure crosslinked Hyaluronan Facilitating the regeneration of the endometrium



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®



efilled in a syinge with flexible delivery cannula Adequate volume(5ml)to the uterine cavity Easy to connect to all hysteroscopes



Approved by CE and CFDA as intrauterine anti-



Preventing IUA after surgeries e.g. abortion

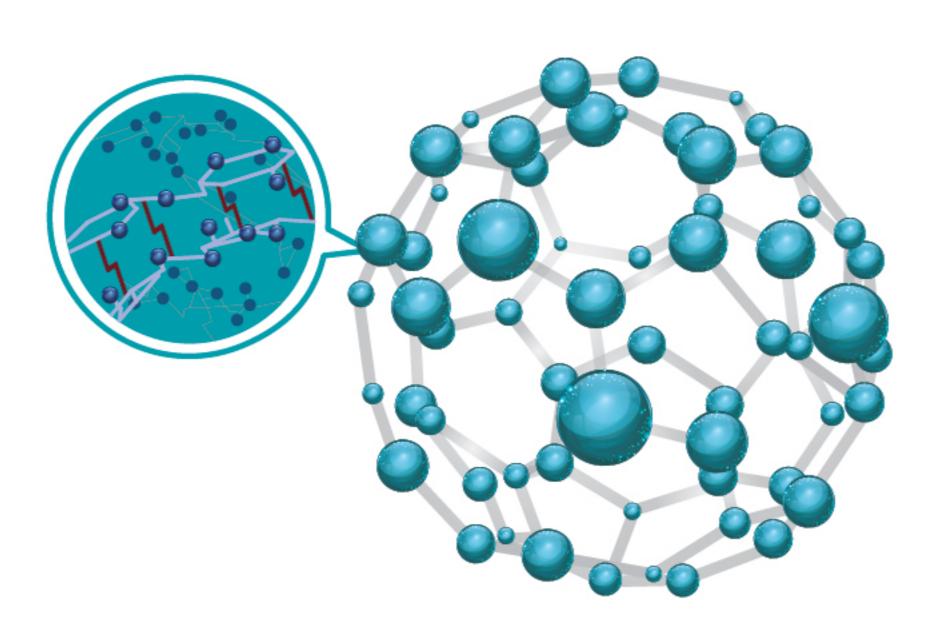
Reducing adhesion reformation after adhesiolysis Minimizing the adhesion severity etc.



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	Endotoxin < 0.15 EU/mL (3% of the national standard)	\sim 5EU/ml (10mg/mL)
	Sterilization assurance level (SAL) < 10 ⁻⁶ (After high-temperature and high-pressure sterilization)	$^{\sim}$ 10 $^{^{-3}}$, high risk of bacterial contamination
Applica bility	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

Uterine cavity

--- vagina

——— MateRegen®

MateRegen® Usage method

Applicable scope

All iatrogenic operations causing endometrium injury or possibly causing intrauterine adhesion (e.g., hysteroscopic surgery, artificial abortion surgery, Dilation and Curettage and intrauterine device extraction, etc.)

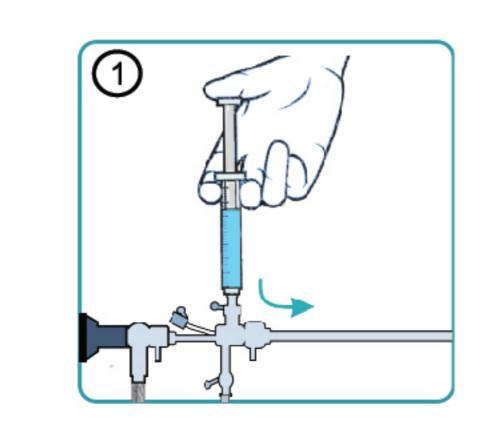


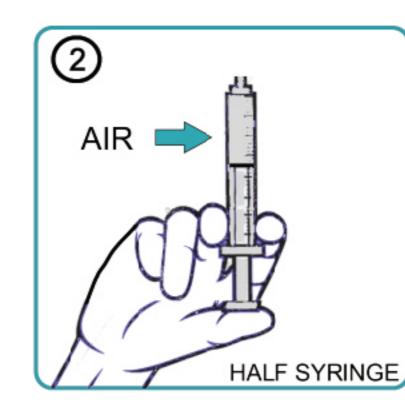
Introduction for use

- 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 connect the syringe Luer-lock to the delivery cannula that is provided in the same package.
- 3. After hysteroscopy or other intrauterine procedures, insert the delivery cannula to the bottom of uerine cavity and then slowly
- instill enough MateRegen® Gel to fill the whole uterine cavity by pushing the
- 4. To avoid washing out the gel product, do not irrigate the uterine cavity after gel application unless under the discretion of the physiscians.

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.

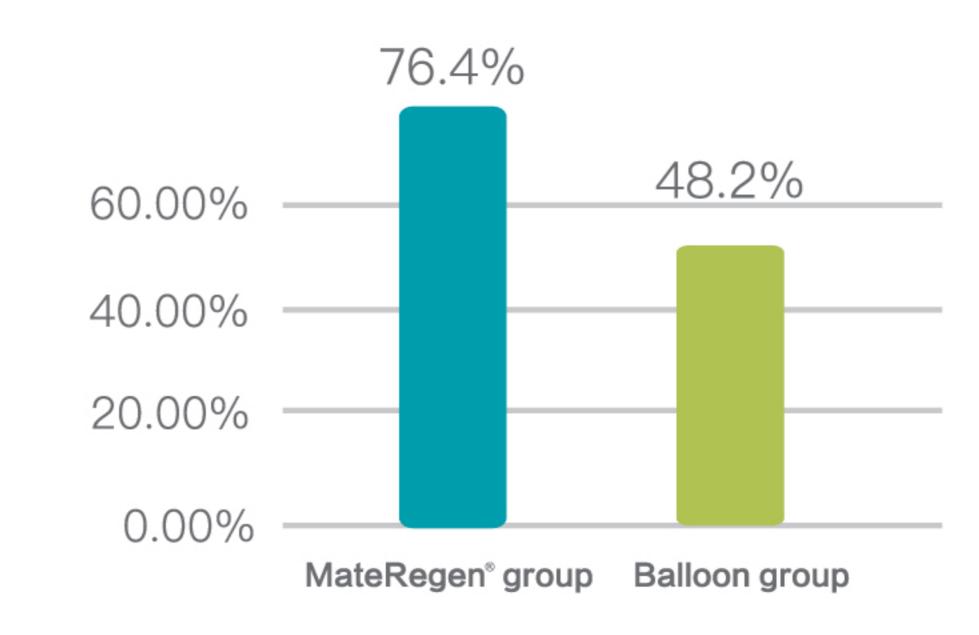
3-Connect again the syringe and drive out the remaining gel in the hysteroscope, withdrawing it very slightly.

cervix —

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

30.00% ———

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

MateRegen® group Balloon group

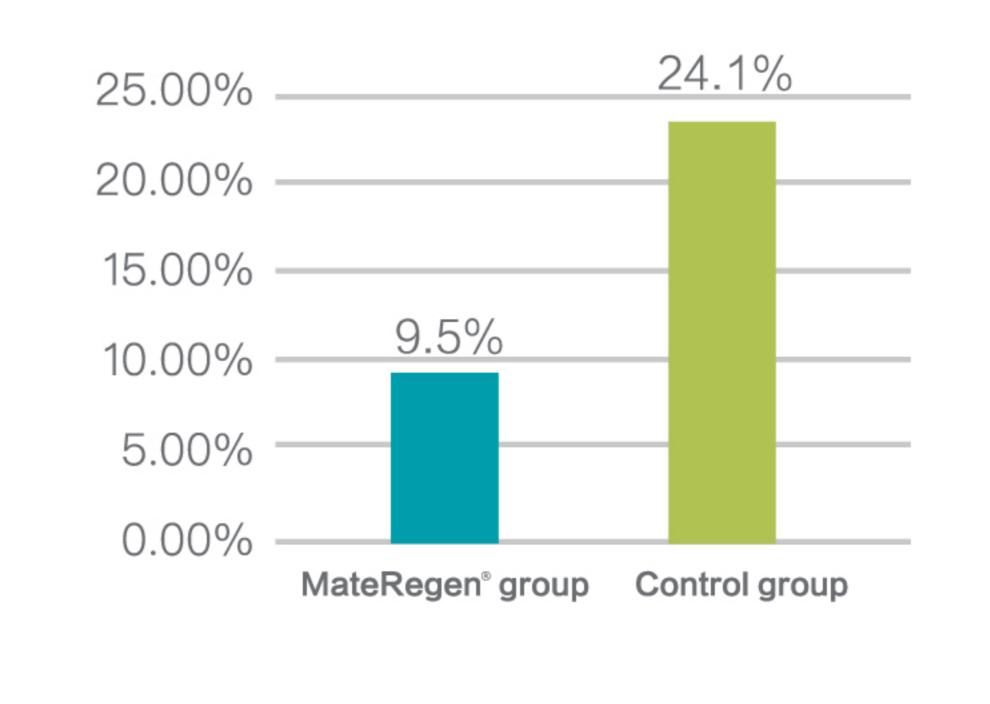
- Used the multi-centered, randomized, parallel and controlled design protocol
- Enrolled 120 patients with moderate and severe intrauterine adhesion after the surgery
- Study group: MateRegen® + Balloon control group: Balloon
- Received the second hysteroscopy in 3 months after the surgery
- The intrauterine 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



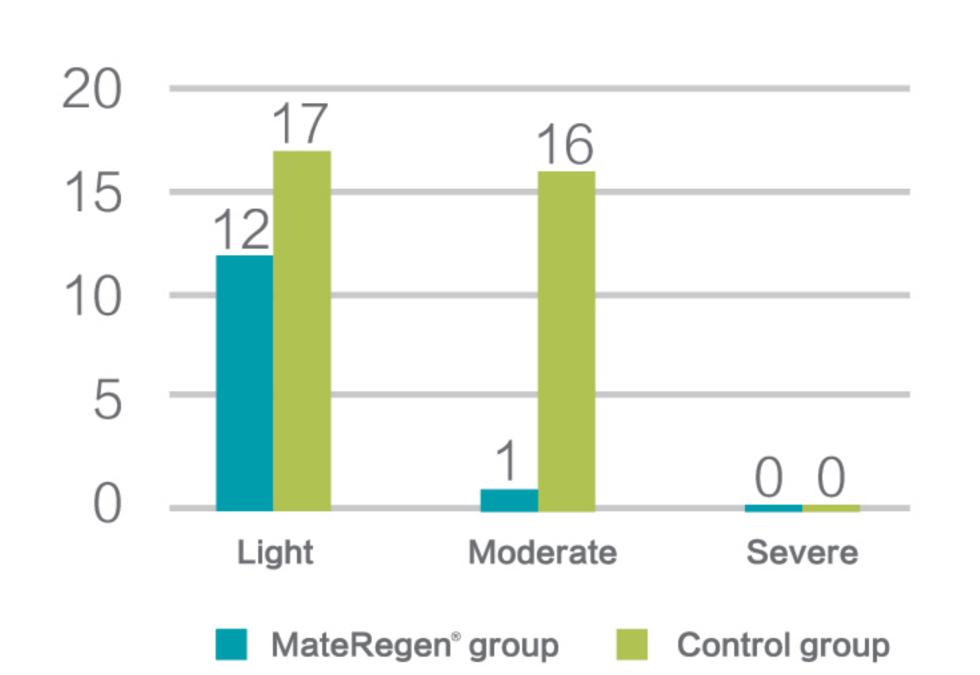
The adhesion incidence of the MateRegen® group was 60.6% lower than that of the control group

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

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

Related papers will be soon published on Journal of Minimally Invasive Gynecology (JMIG)