

INSTRUCTIONS FOR USE

MateRegen® Gel IU

ABSORBABLE INTRAUTERINE ADHESION BARRIER

Caution: Do not use if blister tray or Tyvek Pouch is opened or damaged.

PRODUCT DESCRIPTION

MateRegen® Gel IU is a sterile, non-pyrogenic, transparent, viscoelastic, bioresorbable gel composed of cross-linked molecules of hyaluronan from non-animal sources. This gel is prefilled in glass syringes with elastomeric cap, elastomeric plunger stopper and plastic plunger rod, and do not contain any medicinal, human or animal components. MateRegen® Gel IU is used as a bioresorbable adhesion barrier to prevent or reduce post-surgical adhesion formation in the intrauterine cavity.

INDICATIONS FOR USE

MateRegen® Gel IU is indicated for use in patients undergoing hysteroscopic surgeries or other intrauterine procedures as absorbable barrier to prevent or reduce post-surgical intrauterine adhesions. MateRegen® Gel IU functions to fill intrauterine cavity following surgery, keep the trauma surfaces separated during the healing process, and act as an adjunct to aid in the natural healing process.

CONTRAINDICATIONS

Known hypersensitivity to hyaluronan or its derivatives.

The device should not be used in patients with infection or contamination of the surgical site.

INSTRUCTIONS FOR USE

1. Open the protective package and introduce the syringe and the plunger to the sterile operating field, following the standard sterile approaches used in the surgical theatre.
2. Remove the protective cap on the tip of the syringe and connect the luer-lock end of the syringe to a delivery cannula with a standard luer-lock (supplied in a separate package).
3. After hysteroscopic surgery or other intrauterine surgery, insert the delivery cannula into the bottom of uterine cavity. Stop inserting delivery cannula when feel resistance. Slowly instill MateRegen® Gel IU into the uterine cavity. When small quantity (about 1-2ml) of gel is left in the syringe, withdraw delivery cannula to the inner opening of cervical canal and gradually inject the gel into cervical canal.
4. To avoid washing out of product, do not irrigate the surgical field after application unless under the discretion of the physician.

WARNINGS AND PRECAUTIONS

1. Confirm that the surgical site is free of active bleedings. Any visible active bleedings should be controlled prior to installing MateRegen® Gel IU.
2. MateRegen® Gel IU exhibits no antimicrobial properties. It is not bacteriostatic toward pre-existing infections, nor does it prevent the occurrence of new infections. In the case of pre-existing infections, appropriate treatment should be provided.

3. The concomitant use of MateRegen® Gel IU with other non-standard anti-adhesion devices has not been evaluated.
4. MateRegen® Gel IU has not been evaluated in patients affected by malignant tumors.
5. It is recommended to avoid pregnancy during the first complete menstrual cycle subsequent to the treatment with the product.
6. MateRegen® Gel IU is provided in single-use, pre-filled syringes. The syringe filled with gel is sterilized by autoclave, and then aseptically packaged into a protective sterile blister tray or Tyvek pouch. Do not re-sterilize!
7. The use of the product must be performed in the surgical theatre.
8. It is recommended to use the product immediately after opening the protective package.
9. The syringe is single-use, any non-used product and empty container must be discarded accordingly.
10. Do not inject intravascularly.
11. Do not use the product after the expiration date.
12. If the protective packaging is damaged, do not use the product and contact local distributor.
13. MateRegen® Gel IU shall be used following Instructions for Use (IFU). Read IFU prior to use.

STORAGE

MateRegen® Gel IU should be stored at 2°- 30°C (36° - 86°F) and protected from sunlight.

DO NOT FREEZE.

SHELF-LIFE

Twenty four (24) months from date of manufacture.

HOW SUPPLIED

MateRegen® Gel IU is supplied in a glass syringe containing 5ml gel. Package of 1 syringe (5ml) or 2 syringe (10ml) are available.



167-5 East East Road, Changzhou, China 213025

BioRegen Biomedical (Changzhou) Co., Ltd.

Tel : (+86) 519-88408555 Fax: (+86) 519-88407911

E-mail: info@bioregenmed.com







Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg, Germany

Tel : 0049-40-2513175 Fax: 0049-40-255726

CE 0197

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	Single use only		Handle with care		Caution		Keep dry

	Temperature limitation		Don't use if pack damaged or open		Consult IFU		Keep away from sunlight
---	------------------------	---	-----------------------------------	---	-------------	---	-------------------------