**1. Product Name**

Silicone Rubber Uterine Drug-Eluting Stent System

**2. Product Description**

The silicone rubber uterine drug-eluting stent system mainly consists of a silicone rubber uterine drug stent and a delivery system. The silicone rubber contains estradiol medication and the silicone stent is implanted in the uterus with the aid of a delivery system. The silicone rubber physically blocks the anterior and posterior walls of the uterus to prevent re-adhesion of the uterine cavity after surgery, while a low dose of estradiol is continuously released in the silicone rubber to promote endometrial repair, and is removed 2 months after implantation.

The silicone rubber uterine drug-eluting stent system is a single use sterile medical device.

**3. Product Models**

| Product Model | Top base (mm) | Height (mm) | Lower base (mm) | Thickness (mm) |
|---|---|---|---|---|
| S01 | 22 | 30 | 8 | 0.7 |
| S02 | 20 | 30 | 8 | 0.7 |
| S03 | 16 | 28 | 8 | 0.7 |
| S04 | 14 | 28 | 8 | 0.7 |

**4. Indication**

The Silicone Rubber Uterine Drug-Eluting Stent System is intended for intrauterine placement following endometrial surgery for the prevention of post-operative uterine adhesions and promote endometrium repair.

**5. Contraindication**

The use of this product is strictly prohibited for the following types of patients:

- Patients with allergy to estradiol and its metabolites;
- Patients with allergy to silicone rubber-based products;
- Patients with known or suspected breast cancer;
- Patients with known or suspected estrogen-dependent tumors;
- Patients with acute thrombophlebitis or thromboembolism;
- Patients with history of thrombophlebitis or thromboembolism with past use of estradiol.
- Patients with history of cholestatic jaundice;
- Patients with irregular vaginal bleeding without definitive diagnosis;
- Nursing mothers;
- Pregnant females;
- Patients with hepatic and renal insufficiency;
- Patients with uterine cancer;
- Patients with breast cancer;
- Patients with phlebitis;
- Patients with gallbladder disease;
- Patients with diabetes;
- Uterine fibroids.

This product contains estradiol and shall be used with caution by individuals with the following conditions if the benefits of use outweigh its potential harms:

- Asthma;
- Cardiac insufficiency;
- Epilepsy;
- Depression;
- Migraines;
- Benign breast disease;
- Cerebrovascular disorders;
- Coronary artery disorders;
- Endometriosis;
- Excessive blood calcium with tumours or metabolic bone disorders;
- Hypertension;
- Jaundice or history of jaundice during pregnancy and estradiol increases the risk of recurrence of liver injury;
- Acute, intermittent or complicated hepatic porphyria;
- Thyroid disorders.

**6. Warnings**

- The Silicone Rubber Uterine Drug-Eluting Stent System is a single-use product and shall not be sterilized for reuse.
- Before use, please check the package carefully; do not use the product when the package is open or damaged.
- Please check the expiry date of the product carefully before use and do not use expired products.
- Surgical operations shall be performed by a qualified doctor who has been trained in the implantation of this product.
- Please read the instructions before using the product. Please take note of all the notices and precautions, or else it will lead to accidents.
- Target patient: Age:adult, Weight: N/A, Gender: Female.

**7. Precautions**

• Only qualified physicians trained in the implantation of uterine stents may perform the implantation procedure;

• The stent must be removed two months after its implantation by a medical specialist at the hospital.

**8. Side Effects**

1.Potential risks induced by stent implantation

• Unexpected stent displacement

• Stent falling out of the uterus

2.Potential drug-induced risks

Unusual or rare but noteworthy adverse reactions:

• Irregular vaginal bleeding, spotting, breakthrough bleeding, prolonged bleeding or amenorrhea;

• Drowsiness;

• Frequent or painful urination;

• Severe or sudden headaches;

• Sudden loss of coordination and involuntary sharp movements (chorea);

• Pain in the chest, upper abdomen (stomach), groin or legs, especially gastrocnemius pain and weakness or numbness in the arms or legs;

• Sudden shortness of breath of unknown cause;

• Sudden slurred speech or pronunciation;

• Sudden changes in vision (bleeding or blood clots in the fundus of the eye);

• Rise in blood pressure;

• Small lumps in the breast;

• Depression; yellow staining of conjunctiva or skin, suggestive of hepatitis or biliary obstruction.

• Skin rashes;

• Thick and white curd-like vaginal discharge (Candidiasis);

Relatively common but often decreases with continued administration:

• Abdominal cramping or flatulence

• Poor appetite

• Nauseating

• Ankle and foot edema

• Breast distention or (and) swelling

• Weight gain or loss.

**9. Sterilization**

The silicone rubber uterine drug-eluting stent system is sterilized with ethylene oxide, pyrogen-free, and for single use only.

**10. Shelf Life and Storage Conditions**

The shelf life of devices is 2 years. Store at between max. 27 °C and min. 10 °C until expire date within the original package. Keep away from moisture, keep away from sunlight and heat.

**11. Use of Device**

- **Open the package of the sterile stent delivery system in sterile state.**

Check carefully before opening the package to see if the product has exceeded its expiration date and if the product's packaging has been damaged. Please do not use if product's packaging has been damaged. Open the inner package, remove the products out and put it in the sterile area with sterile utensils.

- **Pre-use inspection**

Carefully remove the delivery system from the box and inspect the system for bends, twists or other damages, and for cracks at each interface. Do not use if any of the above damages are observed.

- **Stent implantation procedures**

**Operating steps:**

The operator shall wear sterile gloves before directly contacting the stent.

1.Remove the drug stent and delivery system and straighten the black tail strings and blue pull strings.

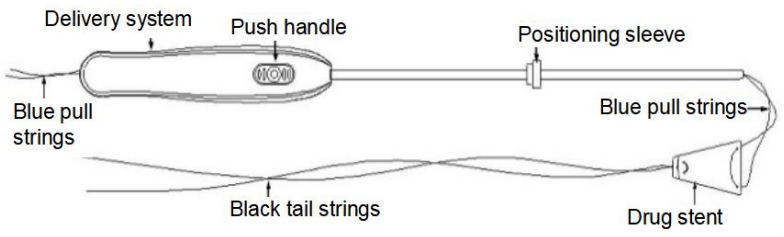



**Figure 1**

2.Hold the delivery system firmly, press down on the handle, and slowly pull the proximal blue strings to tighten the distal blue pull strings and stent until the stent is shaped as shown in Figure 2 below. Release the handle. If the shape of the stent after retraction is the same as shown in Figure 3, manually adjust the shape of the stent to that shown in Figure 2.

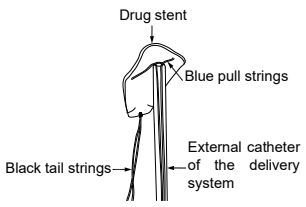



**Figure 2**

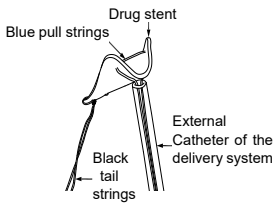



**Figure 3**

3.Press down on the handle and continue to pull the blue strings until the stent is fully retracted as shown in Figure 4. Release the handle and pull the blue strings tightly and snap them into the goove at the end of the delivery system as shown in Figure 4:

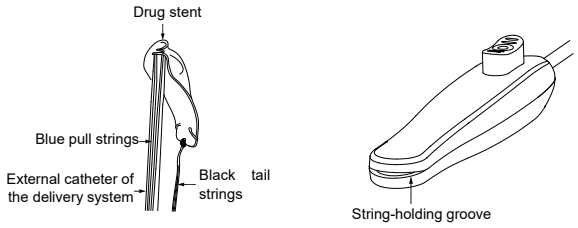
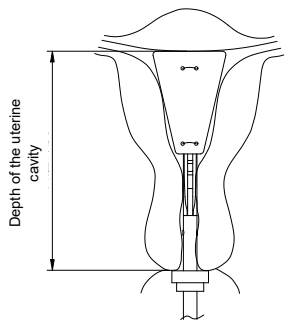


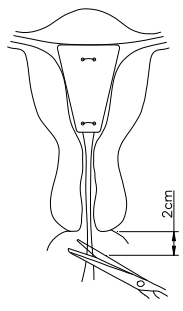

**Figure 4**

4.Adjust the position of the positioning sleeve according to the depth of the uterine cavity. Hold the delivery system steadily, and slowly deliver the distal end of the product into the uterus until the positioning sleeve touches the cervix.




5.Once in position, keep the delivery system in place and press down on the handle. Slowly pull the blue strings until they are fully pulled out.

6.Release the handle, disengage the delivery system from the product, and withdraw the delivery system slowly. Cut the black tail strings at 2 cm from the cervix to complete the insertion.




- **Stent removal procedures**

Two months after stent implantation, the stent is directly pulled out of the uterus by a physician by holding the lower end of the tail strings with clamping forceps.

**12. Disposal Method**

For single use only, remove the residual gel from application area. If the content is not used completely, the container and unused gel must be discarded.

**13. After-sales Service**

Yipurun (Shanghai) Biotechnology Co., Ltd. guarantees that the products manufactured by the company will be free from material or manufacturing defects at the time of receipt by the customer, and any remaining questions regarding the products shall be directed to the company.

**14. Disclaimer**

Yipurun (Shanghai) Biotechnology Co., Ltd. specifies that the silicone rubber uterine drug-eluting stent system manufactured by our company is for single use and shall not be reused. Yipurun (Shanghai) Biotechnology Co., Ltd. will not be responsible for any product damage or surgical failure caused by improper selection of product specifications, incorrect operation or any other man-made accidents. Yipurun (Shanghai) Biotechnology Co., Ltd. does not recommend, indicate, or imply in any way the reusability of the system, and is not responsible for accidents or product damage caused by reuse.

**15. Information about Manufacturer**

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**16. Symbol List**

| | | | |
|---|---|---|---|
| UDI | Unique Device Identifier | REF | Catalog / Model Number |
| MD | Medical Device | LOT | Batch Code/Lot Number |
| | Information of Manufacturer | | Consult Instructions for Use |
| | Date of Manufacture | | Caution |
| | Do Not Reuse | | Use-By Expiration Date |
| STERILE EO | Sterilized by ethylene oxide | | Do Not Use If Package Is Damaged |
| | Keep Dry | SN | Serial Number |
| 10°C 27°C | Lower and Upper Limit of Temperature | 2 STERILIZE | Do not re sterilize |
| | Protect from Heat and Radio-Active Sources | 70 % 20 | Humidity Limitation |
| | Single sterile barrier system | EC REP | Information of ec-rep |
| | Contains a medicinal substance | / | / |