# ALLWIN STYLETS & SOFT OBTURATOR

**Description:**

| CODE | Description |
|---|---|
| STY18 | Stylet for Embryo Trans / Echo Trans Embryo Transfer Catheter (18 cm) |
| STY23 | Stylet for Embryo Trans / Echo Trans Embryo Transfer Catheter (23 cm) |
| STY-BU | Stylet For Bulb Trans Ultra / Bulb Trans Star / Bulb Trans Ultra Plus / Bulb Trans Star Plus Embryo Transfer Catheter-Bulb Tip |
| STY-PE | Stylet for Pro Embryo Trans / Pro Echo Trans / Embryo Transfer Catheter |
| STY18-OS | Stylet with outer sheath for Embryo Trans / Echo Trans Catheter (18cm) |
| STY23-OS | Stylet with outer sheath for Embryo Trans / Echo Trans Catheter (23cm) |

| | |
|---|---|
| SB-PE | Soft Obturator for Pro Embryo Trans Pro Echo Trans Catheter |

**Indication for use:**
Allwin Stylets and Soft Obturators are intended to assist uterine access of a cleared, dimensionally compatible embryo transfer device for placement of in vitro fertilized (IVF) embryos into the uterine cavity.

**Contraindications:**
This catheter should not be used on a patient with an active vaginal or intrauterine infection, a sexually transmitted disease, uterine perforation, a recent pelvic inflammatory disease, chronic cervical infection, a recent pelvic inflammatory disease, a recent pregnancy (or is currently pregnant), confirmed or suspected intrauterine device.

**Complications:**
- Urinary tract Infection
- Pelvic inflammatory disease
- Uterine infection
- Bleeding
- Endometrial / Endocervical damage
- Endometrial lesions

**Caution:**
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- The patients should be with a full bladder for performing transabdominal Ultrasound

**Warning / Precaution:**
- Do not use if package is opened or damaged.
- Do not force the Stylet against resistance while inserting into the uterine cavity, as forcing the catheter may result in damage to the endometrial tissue and bleeding
- This device is supplied sterile and intended for single use only.
- Do not re-sterilize.
- Only experienced practitioner should use this device.
- Inner and outer hub must be locked together, removing the stylet from the outer sheath before placement, may result in bleeding
- Gently uncouple and remove the inner stylet leaving the outer sheath in place
- Infection may occur due to bacterial contamination of the device during vaginal manipulation, and result in urinary tract infection (UTI), pelvic inflammatory disease (PID), or uterine infection.
- Recommendations to minimize infection include the use of only embryo compatible materials, flushing the catheter (an any other accessories used) with sterile, compatible culture media, and closely adhering to sterile techniques.
- Bleeding may occur as a result of the trauma due to insertion of the catheter through the cervix and has been reported to be associated with a lower pregnancy rate. A simple and atraumatic transfer method has been noted to offer the best condition for success
- Dispose in accordance with recognized medical practice and under observance of applicable law and regulation.
- Storage temperature between 5ºC to 30ºC.

**Instruction for Use:**
1. Place Patient in a lithotomy.
2. Insert vaginal speculum to expose the cervix. And clean with a cotton swab moistened with normal saline or medium.
3. With the hubs locked in position, advance the stylet along with the catheter through the cervical os into canal.

**Do not reuse, reprocess & resterilize:**
Reuse, Reprocessing & resterilization may compromise the structural integrity, can also create risk of contamination & may not give desired result or create complications, infections which may result in injury, illness or death.

**Limited Express Warranty:**
The limited express warranty as set forth herein is exclusive and in lieu of all warranties of merchantability and fitness for use, remedies, obligations and liabilities for consequential damages. The products are being sold only for the purpose described herein and such limited express warranty runs only to the original user. In no event shall ALLWIN be liable for any breach of warranty in any amount exceeding the purchase price of the product. ALLWIN reserves the right to make design changes to products without liability to incorporate said changes in ALLWIN products previously designed or sold.

REF Catalogue Number | LOT Batch Code | Date of Manufacture | Use By | Do not re-use | Do not Re-Sterilize | Rx only Caution: Federal Law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.

Consult Instruction for use | Do not use if Packing is damaged | Caution | Keep out of sunlight | Keep Dry | MD Medical Device | STERILE EO Sterilized using ethylene oxide | Not made with natural rubber latex | Temperature Limit

EU REP
CMC Medical Devices & Drugs S. L.
C/Horacio Lengo N' 18, CP 29006, Malaga, Spain
Tel.: +34 951 214 054
E-mail : info@cmcmedicaldevices.com

CE 0123

Allwin Medical Devices, Inc.
3305 E. Miraloma Ave., Suite 176 Anaheim, CA 92806 (USA)
Tel. : +1 714-572-1709
Email : info@allwinmedical.com | www.allwinmedical.com