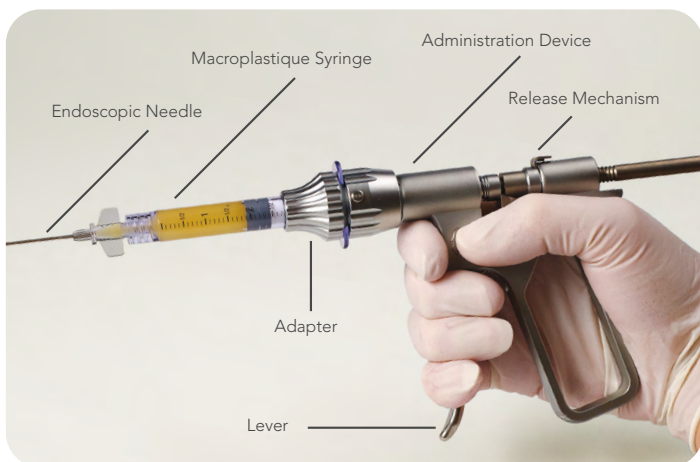


PREPARATION AND USE OF THE MACROPLASTIQUE® SYSTEM



Innovation for Health



THE MACROPLASTIQUE SYSTEM

MATERIALS FOR PROCEDURE

- 2 Macroplastique 2.5 ml units (MPQ-2.5)
 - 1 Laborie Medical Endoscopic Needle
 - 1 Control Flow Administration Device with Adapter
 - 1 Cystoscope
 - 1 Intermittent catheter 8 – 12 Fr.
- Local anesthetic - i.e., 2% lidocaine, injectable
Sterile water/sterile saline

PREPARE ADMINISTRATION DEVICE IN ADVANCE (SEE IFU FOR MORE DETAILS)

- ▶ Thoroughly clean and dry the Administration Device, then disinfect or sterilize using one of the following methods:
 - High level disinfection (manual) with 2% HLD solution (e.g., alkaline glutaraldehyde) or low-level thermal disinfection (automated)
 - Steam sterilization
 - Gravity (unwrapped): ≥ 3.5 min at $\geq 132^{\circ}$ C (270° F)
 - Gravity (wrapped/unwrapped): ≥ 20 min at $\geq 121^{\circ}$ C (250° F)
 - Pre-vacuum (wrapped/unwrapped): ≥ 3 min at $\geq 132^{\circ}$ C (270° F)

PREPARE MACROPLASTIQUE SYSTEM



Slide adapter over syringe



Lock adapter on the administration device

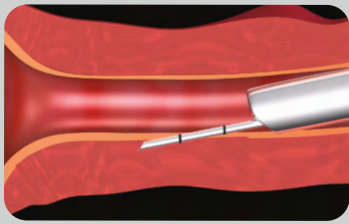


Remove plastic tip from syringe and firmly tighten needle to syringe

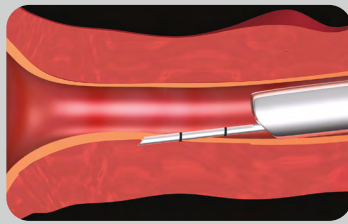
ADDITIONAL RESOURCES



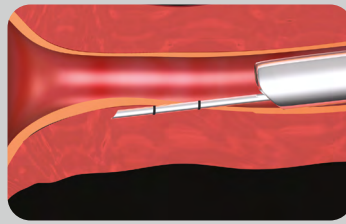
TECHNIQUE



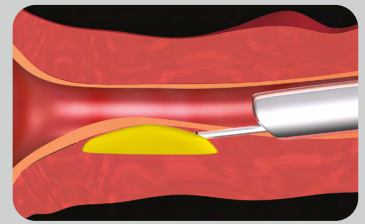
Tilt scope to a 30–45° angle. Orient needle with bevel toward urethral lumen. Advance needle into tissue to the first mark ~ 0.5 cm deep.



Reduce scope angle to 0°.



To create a tissue tunnel, advance the needle to the second mark ~ 1 cm deep.



Implant a small amount of Macroplastique to confirm appropriate needle placement. If tissue bulking appears in the urethral mucosa, continue to inject Macroplastique per recommended volume.

PRE-IMPLANTATION

1. Administer broad-spectrum antibiotics. Administer local anesthetic into the urethra.
2. Prime the needle by squeezing the lever of the Administration Device. When the product begins to extrude from the needle tip, depress the release mechanism to stop flow.
3. Fill the bladder to approximately 50% capacity with sterile water or sterile saline.

MACROPLASTIQUE IMPLANTATION PROCEDURE

1. Insert the cystoscope into the bladder. Retract the scope to visualize bladder neck and locate a mid-urethral position.
2. Advance the needle through the working channel of the scope to visualize the needle tip. Insert needle into the urethral wall, taking care to ensure that the needle bevel is facing the center of the urethral lumen. If available, use the vertical marking at the tip of the needle to orient the bevel.
3. Using tissue tunneling technique, inject the recommended volume of Macroplastique in each location (see sidebar), starting with the 6 o'clock position.

- Implant product slowly; wait several seconds between pulls of the Administration Device lever. If injection becomes progressively more difficult, increase the time between pulls of the lever to equilibrate pressure in the syringe.
 - Wait approximately 30 seconds before withdrawing the needle from the tissue to limit product extravasation.
 - Use caution and avoid passing the cystoscope over the implantation site as this could potentially disrupt product placement.
4. Retract scope and change syringes. Repeat steps 1–3 of the implantation procedure, injecting the recommended volume in the 10 o'clock and 2 o'clock positions.



POST-IMPLANTATION

- ▶ Confirm satisfactory voiding before the patient leaves the clinic. If necessary, use a small intermittent catheter (8–12 Fr.) to drain the bladder.
- ▶ It is recommended that a broad-spectrum antibiotic be prescribed. Any possible post treatment discomfort can usually be managed with oral analgesics.

Macroplastique is indicated for transurethral injection in the treatment of adult women diagnosed with SUI primarily due to ISD. Contraindications: Not to be used in patients with acute urogenital tract inflammation/infection or fragile urethral mucosal lining. Warnings: Do not use in patients with obstructive conditions until such conditions have been corrected. Overcorrection may lead to urinary obstruction. Adverse events associated with Macroplastique are typically non-serious and transient. Potential genitourinary adverse effects that may occur include: post-operative catheterization, UTI, urinary retention, dysuria, hematuria, pain at implantation site, frequency, urgency. Other post-treatment complications associated with the implant, and the patient's general tolerance to any injected material, may occur, such as erosion, implant exposure and potential stone formation on the surface of the implant material (if exposed). Caution: Federal law (USA) restricts this device to sale by or on the order of a physician trained in diagnostic and therapeutic cystoscopy. For complete instructions for use, storage, warnings, indications, contraindications, precautions, adverse reactions, and disclaimer of warranties, please refer to the insert accompanying each Macroplastique product. Macroplastique is a registered trademark. Macroplastique is manufactured by Uroplasty LLC. Models are for illustrative purpose only. ©2021 LABORIE. All rights reserved.

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