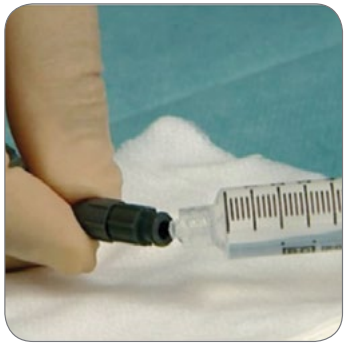
PURPOSEFULLY DESIGNED

BoNee®

Bladder Injection Needle

BoNee® Procedural Technique

These instructions are for general use of this device in the treatment of female stress urinary incontinence and should not replace the instructions for use (IFU). Variations in use may occur due to individual technique and patient anatomy.

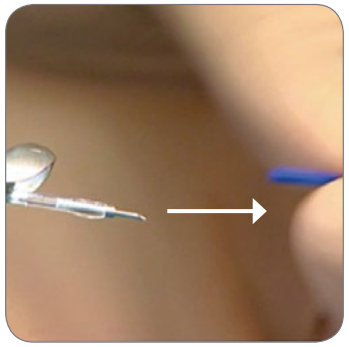


STEPS 1-3

1. Prepare the injectable solution, strictly referring to the instructions for use of the injectable solution.
2. Connect the syringe used for the injections of the solution to the Luer connector at the proximal end of the device.
3. Flush the tubing and the BoNee needle.

STEP 4

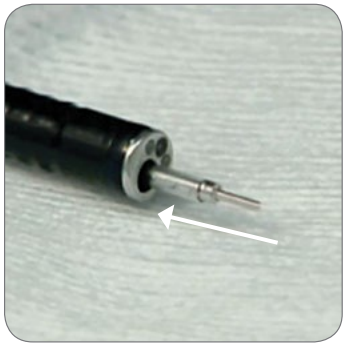
4. Insert the capped BoNee needle into the working channel of the cystoscope.



STEP 5

5. Advance the needle beyond the cystoscope, remove the cap.

Additional steps on back side



STEPS 6 & 7

6. Withdraw the BoNee needle inside the cystoscope until its tip is just inside the scope exit.

Caution: Ensure that BoNee needle is passed through the cystoscope with the cap fitted to prevent damage to the working channel and needle bevel. Remember to remove cap before the cystoscope-needle is introduced into the patient. If the needle cap is lost it may give rise to infection or stone formation.

7. Introduce the scope into the patient's bladder in the usual way.

STEP 8

8. Continue using whichever of the two techniques described below is appropriate:

a. **BoNee needle may be manipulated directly:** Advance the BoNee needle to make the injection into the bladder wall, strictly referring to the instructions for use of the injected solution and the clinical injection protocol. Withdraw the needle in between injections.

b. **Tuohy Borst adapter may be used for the BoNee needle to the cystoscope, after setting of the intended needle protrusion length:** The resultant cystoscope needle unit can then be advanced for injections and withdrawn in between injections. Make injections into the bladder wall, strictly referring to the instructions for use of the injected substance and the clinical injection protocol.

STEP 9

9. When all injections have been made, remove the BoNee needle from cystoscope and inspect for integrity of the needle.

BONEE® - NEEDLE FOR BLADDER INJECTIONS

Indication:
The Bonee needle is used to deliver injectable materials into the urinary bladder wall during the transurethral endoscopic procedure.

Contraindications:
The Bonee needle is contraindicated for use in patients with the following conditions:
- Coagulation disorders
- Any know allergies to the medical device materials
- Any contraindication related to cystoscopy

Warnings:
Ensure that Bonee needle is passed through the cystoscope with the cap fitted, to prevent damage to the working channel and the needle bevel.
Remember to remove the cap before the cystoscope-needle unit is introduced into the patient. If the needle cap is lost in the bladder, it may give rise to infection or stone formation.
Ensure that the working channel of the cystoscope will be compatible with the dimensions of the device (for details, see device label).
Strictly refer to the instructions for use of the injected substance and the clinical injection protocol.
While moving the Bonee needle back and forth, take care to avoid snagging of the needle on the edge of the working channel.
After withdrawal of the device, check for integrity of the needle.

Precautions:
The choice of the size of the needle is the responsibility of the physician.
Any use other than stated indications is the responsibility of the physician.
This type of needle must only be used by trained and experienced professionals.
The Bonee needle is provided sterile (ethylene oxide sterilization) and is for single-use only.

Potential Complications:
Potential complications related to injection into the bladder wall include: bleeding, bladder wall perforation. Potential complications related to the passage of the cystoscope-needle unit into the bladder include: tears or perforation of the meatus and/or the urethra if the device is advanced with the needle protruding, pain, urinary tract infection.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.us.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Ostomy Care / Continence Care / Wound & Skin Care / Urology Care

Coloplast Corp. Minneapolis, MN 55411 / Urology Care Surgical Support 1-800-258-3476
www.coloplast.us

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