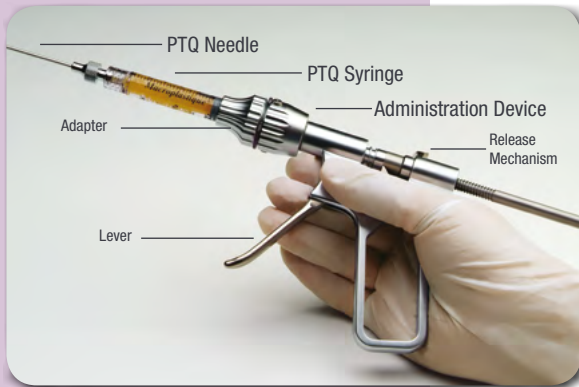




Bulking Procedure for Faecal Incontinence



Materials for Procedure

3 - 4 PTQ Implants, 2.5 ml units (PTQ-2.5)

1 PTQ Needle

1 Uroplasty Administration Device with Adapter
Broad-spectrum antibiotics (e.g., gentamicin and metronidazole)

Iodine solution (e.g., povidone-iodine)

Local anesthetic with epinephrine

Prepare the PTQ System



Slide adapter over syringe. Lock adapter on the Administration Device.



Remove plastic tip from syringe and attach needle.



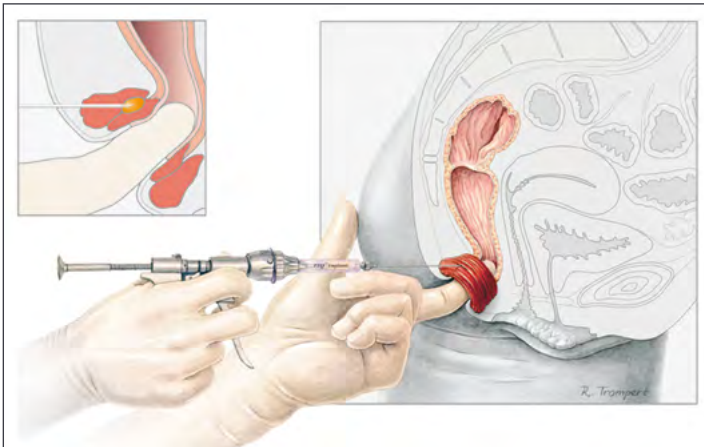
Prime the needle by pulling and releasing the Administration Device lever several times until PTQ is visible at the tip. To stop flow, depress the release mechanism.

Pre-Operative Care

1. Complete anorectal physiological testing and endoanal ultrasound.
2. Prescribe laxatives (e.g., oral lactulose, 15 ml) for 2 days prior to procedure for patients incontinent to solid stool.
3. Administer prophylactic broad-spectrum antibiotics immediately prior to injection (e.g., intravenous injection of 160 mg gentamicin and 500 mg metronidazole, or oral).
4. Administer an enema before procedure to prevent stooling.
5. Place the patient in either the lithotomy or modified jackknife position. Clean the area with an appropriate surgical skin preparation. Irrigate the anal canal with a suitable antimicrobial agent (e.g., povidone-iodine).
6. Use a local anaesthetic with epinephrine to infiltrate the skin 25 mm from the anal margin. Continue infiltrating the subcutaneous tissues and in a track leading up to the internal sphincter in the area of the anal cushions. The epinephrine in the anaesthetic maximizes vascular constriction and minimizes the risk of hematoma. Use the minimum volume of local anaesthetic that achieves optimal anaesthesia to avoid tissue distortion.
7. Prepare the PTQ system (see sidebar).

Procedure

1. PTQ should be injected circumferentially around the internal anal sphincter in 3-4 positions that correspond with the anal cushions in the mid and upper anal canal. Use ≤ 2.5 ml in each injection site. The number and location of injections should be adjusted according to sphincter disruption and patient anatomy.
2. Insert the prepared needle into the skin, 25 mm from the anal margin.
3. At the level of, or slightly above, the dentate line, direct the needle medially and upwards, trans-sphincterically across the external sphincter and longitudinal muscle towards the internal anal sphincter.



4. Place a finger in the anal canal to ensure correct needle placement for PTQ injection. Avoid penetration of the anal mucosa.
5. Slowly inject ≤ 2.5 ml of PTQ in each position. After each injection, wait approximately 30 seconds before withdrawing the needle from the tissue. To change syringe, press the release mechanism at the top of the Administration Device, retract the dosage rod and remove the syringe and needle. Reload the system.

6. Do not insert instrumentation, such as a proctoscope or ultrasound device, into the anal canal following the procedure as bolus disruption and/or loss of tissue bulking may occur.

Post-Operative Care

1. Observe patient for 4 hours prior to discharge to ensure no early complications.
2. Prescribe the following medications for 7 days:
 - Oral antibiotics (e.g., oral cephalexin, 500 mg q.i.d. and metronidazole, 400 mg t.d.s.)
 - Laxatives (e.g., oral lactulose 15 ml)
 - Oral analgesia
3. Patients should avoid all forms of sexual intercourse, rigorous exercise and heavy lifting for 1 month following surgery.

Additional Treatment

If further treatment is required, wait 12 weeks to allow the host tissue to fully mature. It is essential to repeat the pre-operative evaluation, including complete anorectal physiological testing and endoanal ultrasound prior to determining the parameters for retreatment.

For complete instructions for use, storage, warnings, indications, contraindications, precautions, adverse reactions and disclaimer of warranties, please refer to the insert accompanying each PTQ product or online at www.cogentixmedical.com. PTQ is manufactured by Uroplasty, LLC. PTQ is a registered trademark. © 2015 Cogentix Medical. All rights reserved. 65004B 06/15

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