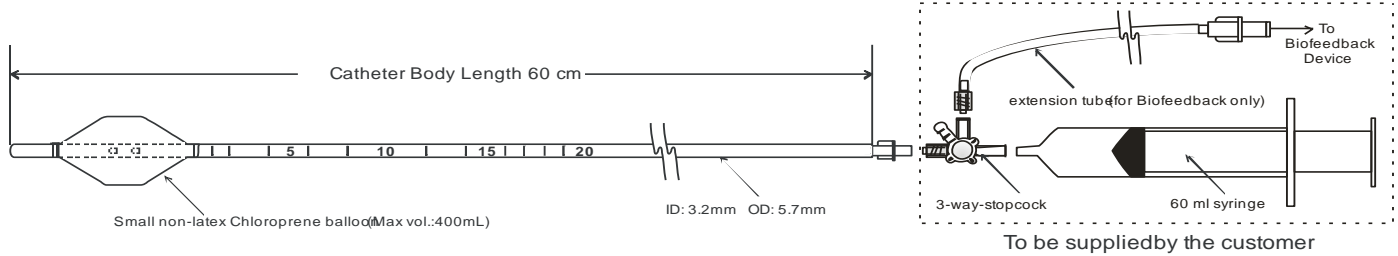




INSTRUCTIONS FOR USE FOR ANORECTAL BALLOON EXPULSION CATHETER



INTENDED USE

The anorectal balloon expulsion catheter is used to evaluate the neuromuscular function of the patient's ability to expel its contents from the rectum.

PRECAUTIONS

- This balloon expulsion catheter is designed for **single-use only**. Attempts to reprocess, re-sterilize, and/or re-use may lead to failure of the device and/or transmission of disease. Immediately dispose of the balloon expulsion catheter after use to avoid re-use.
- Inspect the catheter and packaging for any mechanical damage or imperfections. **Do not use if damaged.**
- **Do not use** silicone-based lubricant with the balloon expulsion catheter.
- Shelf life and lifetime for Anorectal Balloons Expulsion catheter is two years.

BALLOON EXPULSION FUNCTION- INSTRUCTIONS FOR USE

1. Remove the anorectal probe after the HRM study is complete.
2. Insert the balloon expulsion catheter through the anus to a depth of 8-10cm.
3. Attach a 3-way stopcock to the balloon expulsion catheter and fill the balloon with 30-60ml of air or water. Close off the balloon port, and remove syringe.
4. Have the patient go to the toilet / commode and attempt to expel the balloon expulsion catheter.
5. Expulsion of the balloon expulsion catheter within 2-5 minutes indicates normal function.
6. Post-procedure balloon expulsion catheters are contaminated with body fluid. Immediately dispose of the balloon expulsion catheter to avoid re-use.

BIO-FEEDBACK FUNCTION – INSTRUCTIONS FOR USE

For handheld bio-feedback devices:

1. With a 3-way stopcock, attach the balloon expulsion catheter to the male luer end of the stopcock, a syringe to one female luer end and an extension tube (with a male and female luer end) to the other female luer end of the stopcock.
2. Insert the balloon expulsion catheter through the anus to a depth of 8-10cm.
3. Attach the other end of the extension tube to the handheld device and fill the balloon with air accordingly (30-60ml). Close off the syringe port, and remove syringe.
4. Any squeeze pressure by the patient will be displayed on the handheld device.

For use with a water-perfused manometry system:

1. Disconnect the capillary tubing from the bottom of the transducer and allow all the water to drain out of the transducer (for it to be used with air only).
2. Close off the stopcock at the bottom of the transducer (to create a closed system and prevent any water from entering into the transducer).
3. With a 3-way stopcock, attach the balloon expulsion catheter to the male luer end of the stopcock, a syringe to one female luer end and an extension tube (with a male and female luer end) to the other female luer end of the stopcock.
4. Insert the balloon expulsion catheter through the anus to a depth of 8-10cm.
5. Connect the extension tube to the top of the transducer.
6. Inflate the balloon with air accordingly (30-60ml). Close off the syringe port, and remove syringe.
7. Any squeeze pressure by the patient will be displayed on the computer monitor.

STORAGE CONDITIONS:

1. Store in dry and clean location.
2. Temperature: 15°C - 30°C (60.8°F – 80.6°F)
3. Relative humidity: 10% - 75%

Manufacturer's Warranty – 6 months from date of purchase from Mui Scientific for any manufacturer's defects.

User is to contact the manufacturer or competent authority to report serious incidents involving this device.



Authorized Representative in EU: Advena Ltd.
Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013, Malta