INSTRUCTIONS FOR USE FOR
ANORECTAL BALLOON EXPULSION / BIO-FEEDBACK 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 expansion 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 expansion catheter after use to avoid re-use.
- Inspect the catheter for any evidence of mechanical damage or imperfections before usage.
- **Do not use** silicone-based lubricant with the balloon expansion catheter.
- **Do not use balloon expansion catheter if any damage is noted.**

BALLOON EXPULSION CATHETER - INSTRUCTIONS FOR USE
1. Remove the anorectal probe after the HRM study is complete.
2. Insert the balloon expansion catheter through the anus to a depth of 8-10cm.
3. Attach a 3-way stopcock to the balloon expansion 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 expansion catheter.
5. Expulsion of the balloon expansion catheter within 2-5 minutes indicates normal function.
6. Post-procedure balloon expansion catheters are contaminated with body fluid. Immediately dispose of the balloon expansion 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 expansion 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 expansion 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 expansion 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 expansion catheter through the anus to a depth of 8-10cm.
5. Connect the stopcock 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.

Manufacturer’s Warranty – 6 months from Manufactured Date for any manufacturer’s defects (I.e. defects in materials and/or workmanship).