



INSTRUCTION FOR USE FOR THE RAPID BAROSTAT BAG CATHETER

INTENDED USE

This catheter is designed specifically to be used with the Rapid Barostat Bag Pump to measure rectal capacity as well as rectal volume at points of sensation, urge, and discomfort, to determine hypersensitivity, hyposensitivity, or normal rectal sensations. These determinations aid in the diagnosis of anorectal disorders, such as fecal incontinence and constipation.

WARNING

- This catheter is designed for **Single-Use Only**. Any attempts to reprocess, sterilize, and/or reuse may lead to failure of the device and/or transmission of disease.
- Use of this catheter is restricted to a trained healthcare professional.
- Do not use catheter past expiry date (2 years from manufacture date).
- Digital rectal examination should be performed prior to inserting the catheter into the patient.
- Do not use the device on patients with pre-existing rectal pain or bleeding (at the discretion of the physician).
- **DO NOT USE IF DAMAGED.**

INSTRUCTION FOR USE

1. Ensure the Rapid Barostat Bag (RBB) pump has been turned ON, and the patient's information has been entered.
2. Have the patient assume the left lateral decubitus position.
3. Attach the luer end of the RBB catheter to the luer at the top left hand side of the RBB pump.
4. Press the "Empty" button on the touch screen to remove any existing air from the RBB catheter.
5. Lubricate the RBB catheter and insert into the patients rectum until the 5 cm marking is at the anus. Tape down the catheter to the buttocks.
6. When the patient has become acclimated, press the "Start" button to commence the "Capacity Measurement" study.
7. Follow the RBB pump prompts to commence the "Sensation Measurement" study.
8. Follow the RBB pump prompts to "Repeat" or "End" the study.
9. Upon completion of study, immediately dispose of catheter to prevent re-use and cross contamination.

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

MUI SCIENTIFIC IS NOT LIABLE FOR ANY DAMAGE TO THE CATHETER, OR HARM TO PATIENTS OR PERSONNEL, CAUSED BY IMPROPER USE.