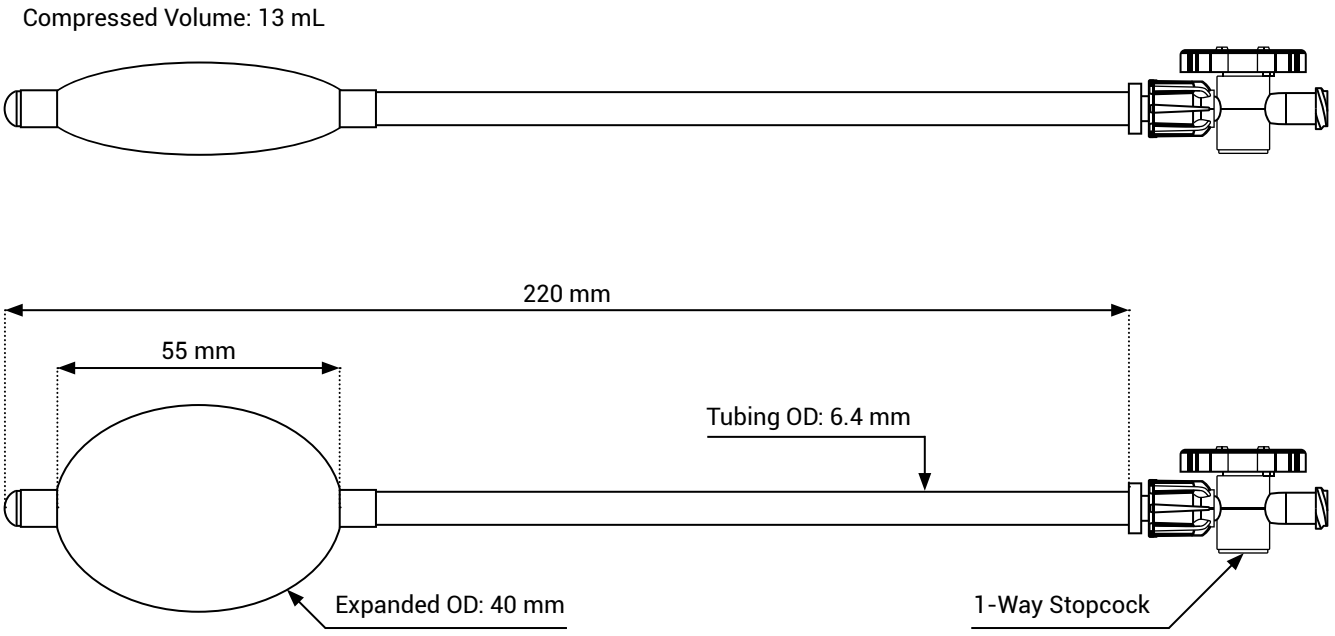

Indications for Use

RED is used to evaluate the neuromuscular function of the patient's ability to expel its contents from the rectum and as a qualitative test for rectal hypersensitivity. RED helps identify patients with rectal hypersensitivity who experience desire or urge-to-defecate at lower volumes of distension. RED is intended to be used in a clinical setting by trained health care providers in adult populations.

Precautions

- Device 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 Device after use to avoid re-use.
- Device is NOT intended to be used with any other bio-feedback or manometry equipment.
- Inspect Device for any evidence of mechanical damage or imperfections before usage. **Do not use Device if any damage is noted.**
- **Do not use** silicone-based lubricant with the Device.
- **Device must be open to ambient for removal.** Do not attempt to insert or remove the device in the expanded (inflated) state with the stopcock closed.
- Do not use beyond expiration date.
- If you cannot perform a rectal exam, the patient refuses a rectal exam, there is a mass, stricture or stenosis, or if there is pain during the digital rectal exam **do not insert the device.**
- Because there are ranges of rectal pressures from 60ml up to as high as 108ml through which hypersensitivity can be identified according to the London Classification tables for Desire to Defecate and this device only tests a volume of 60ml, there is a risk for false negative such that this device may not diagnose some patients who do have rectal hypersensitivity. Please consider additional testing for patients in whom there is a high suspicion for rectal hypersensitivity.

Procedure

If performing both Sensation Test and Balloon Expulsion Test, start with the Baseline Sensation Test first.

Insertion procedure for performing all tests

1. Prior to beginning the evaluations confirm the device can be inserted by performing a digital rectal exam.
2. Place the patient in the left, lateral decubitus position.
3. With stopcock open, compress the balloon with your hand, and at the same time, use other the other hand to close the stopcock on the Device to maintain a compressed state for insertion.
4. Lubricate device according to clinic protocol.
5. Insert Device through the anus to a depth of 8 – 10 cm.

Baseline Sensation (self-inflating) Test – Instructions for use

1. Open the stopcock to allow the balloon to self-inflate in the patient's rectum.
2. Once inflated, rotate the device to ensure that the inflated rectal portion rests freely in the rectum.
3. Ask the patient the following questions:

   Does the balloon give you the feeling that you have to defecate?

   - If the patient answered NO, then the baseline rectal sensation testing is completed. Continue to the Expulsion Test.
   - If patient answered YES, then also ask the following questions:

     Imagine that you are watching your favorite TV show and it is the series finale. The show just started and is an hour long.

     - *With the balloon inserted, do you feel like you have to defecate **right now** and miss part of the show?* **Yes/No**
     - *With the balloon inserted, do you feel like you have to defecate **at the next commercial break** and possibly miss part of the show?* **Yes/No**
4. If performing an Expulsion Test, then continue to Expulsion Test section.
5. If no further testing is indicated, then ask the patient to relax and gently pull on the device to remove with the stopcock opened.
6. Immediately dispose of the Device per local healthcare policy and procedures to avoid re-use.

Expulsion Test – Instructions for Use

1. To complete this test the device should be located in the patient's rectum, stopcock open to ambient, and the device able to rotate freely.
2. While in the left lateral position, have the patient push to defecate the device as if having a bowel movement. Expulsion of Device within 5 to 120 seconds indicates normal function.
3. If the patient cannot expel the device after 120 seconds, with the stopcock opened, ask the patient to relax and gently pull on the device to remove. The balloon will deflate as it is removed.
4. Post procedure devices are contaminated with body fluid. Immediately dispose of the Device per local healthcare policy and procedures to avoid re-use.

Returned Devices

Returned devices must be cleaned and then returned in the original packaging. If the original packaging is no longer available the device must be suitably packaged for the method of shipping chosen.

Manufacturer Liability

The manufacturer and supplier of the device will not accept any liability in the following cases: If the device is not used in accordance with the instructions for use. If the operator is inadequately qualified or is not sufficiently informed about the functioning of the device on the basis of the instructions for use and the safety instructions. If any defects are discovered when the contents of the packages are examined, the complete unit including all components must be returned as described in section “Returned Devices” to the manufacturer's local representatives.

Warranty Conditions

The manufacturer guarantees the product for the period up to the use by date printed on the label located on front of device package. This guarantee applies to flaws of material and workmanship. Claims are only accepted under the following terms: The manufacturer and/or supplier is informed immediately of the fault for which the warranty claim is being made. The instructions of the manufacturer and/or supplier on storage or return of the device are within compliance. Presentation of a legible copy of the invoice for that particular device, showing the date of purchase. An exact description by the customer of the defect or fault identified.

IMPORTANT

The manufacturer's warranty will be void if it is found that the device was damaged by force, operator error, or that it was used in any way contrary to the instructions for use and the safety instructions. If the manufacturer is required to meet a warranty claim in accordance with these terms, the customer shall bear the cost and risk of transporting the device to and from the place of use. The manufacturer and/or supplier under no circumstances assumes liability for ordinary negligence. Claims for compensation for loss of earnings and profits will likewise not be accepted.

Operation / Transport / Storage

Recommend no prolonged storage / exposure outside the recommended ranges for operation, transport, and storage:

- Temperature: -20°C to 50°C
- Relative Humidity: 25% to 90%

The product has a limited shelf life. Details are printed on the label located on front of device package. Values higher or lower than the ranges specified above will shorten the useful life of the device or may cause certain components to be damaged.

Symbol	Meaning
	Do Not Reuse
	Non-Sterile
	Consult Instructions for Use
	Manufacturer
	Not made with DEHP
Rx ONLY	Prescription use only
	Lot Number
	Use By
QTY	Quantity
	Catalog Number
	Not made with natural rubber latex

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