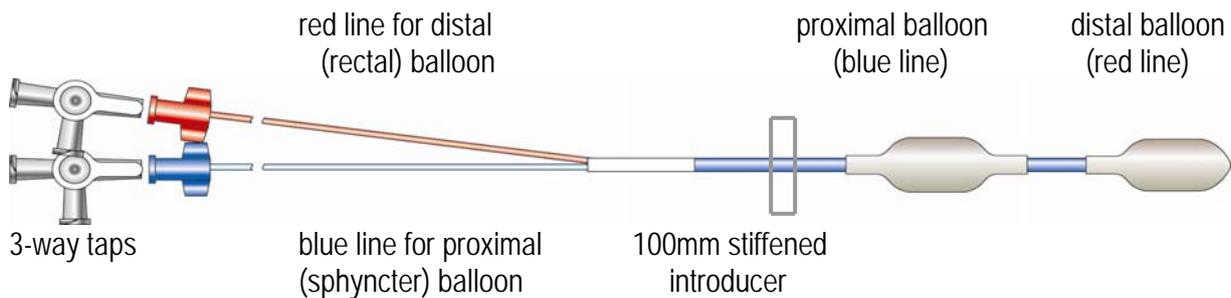


Langley Catheter Protocols

Instructions for use

The 2-balloon Langley catheter has been developed to be multifunctional in the assessment and treatment of male and female bowel dysfunction.

The catheter has two latex balloons fixed in tandem on one 2-channel shaft, each balloon connected to a 1500mm colour coded pressure line. Each line is fitted with a 3-way tap to enable connection to either a manometric measuring device or to a syringe to instil air or water.



The product is CE marked for single patient use. It may be cleaned, stored and re-used by the same patient.

The device may be used for the following applications: -

- Assessment and retraining of rectal sensation/compliance
- Assessment of recto-anal inhibitory reflex (RAIR)
- Assessment of anismus
- Assessment of internal anal sphincter (IAS) resting pressure
- Assessment of external anal sphincter (EAS) squeeze pressure
- Pressure biofeedback training of EAS
- Balloon expulsion and defecation dynamics

Before use of this product in a clinical setting it is recommended that an infection control policy is agreed with the local infection control department, and a signed and dated copy with date for review is kept on file.

Assessment and retraining of rectal sensation/compliance

1. Close the 3-way tap to the distal balloon (red line) and attach a water/air filled syringe (a 50ml syringe is recommended)
2. Cover the catheter with a non lubricated condom
3. Apply lubricating gel to the tip of the condom
4. Insert distal balloon into anal canal and gently push the balloon through the canal until the balloon is positioned in the rectum
5. Open the 3-way tap to the distal balloon (red line)
6. Ask the patient to report:
 - a. Onset of sensation of rectal filling
 - b. Need to defecate – normal call to stool
 - c. Urgency to defecate
7. Slowly instil air or water into the distal balloon (red line), recording the amount of air or water required to elicit: -

	Normal values
• Onset	40 - 50mls
• Need to defecate	80 - 100mls
• Urgency	120 - 150mls

(NB: The balloon may be inflated up to a maximum of 350mls; however in routine clinical practice it is not usually necessary to exceed 200 – 250mls)

To refill syringe use 3-way tap to lock balloon and draw air or water through side of tap

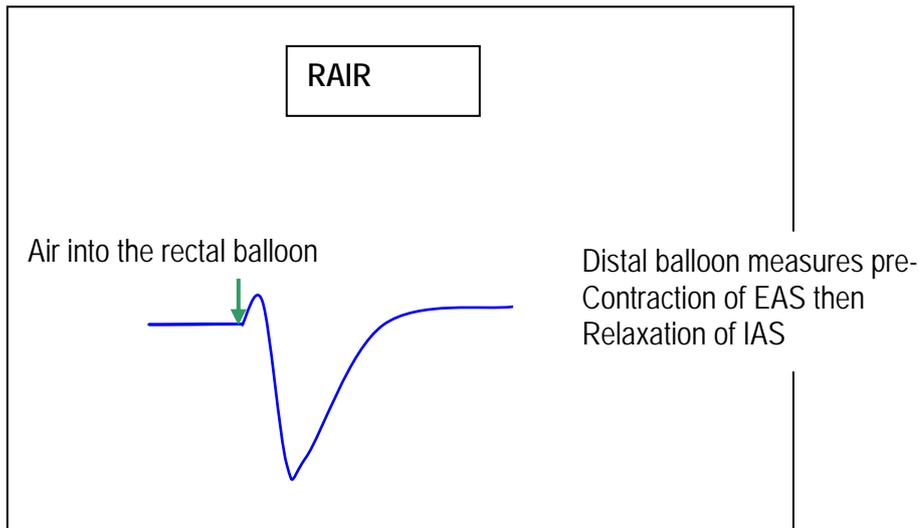
8. At the end of the procedure, warn the patient that the air is to be released. Ensure all air is released from balloon
9. Remove balloon (and condom) from rectum
10. Clean balloon before storing

Assessment of recto-anal inhibitory reflex

1. Close the 3- way taps to both the proximal (blue line) and distal (red line) balloons
2. Attach a water/air filled syringe to the distal (red line) balloon
3. Attach a manometric measuring device to the proximal (blue line) Balloon
4. Cover the catheter with a non lubricated condom
5. Apply lubricating gel to the tip of the condom

6. Insert the distal (red line) balloon through the anal canal in the rectum and position the proximal (blue line) balloon in the mid-anal canal
7. Open both 3-way taps
8. Instil 50ml of air/water into the distal (red line) balloon
9. Observe IAS resting pressure on manometric device
10. Observe pre-contraction of EAS in response to rectal distension, then relaxation of IAS with gradual return to normal resting

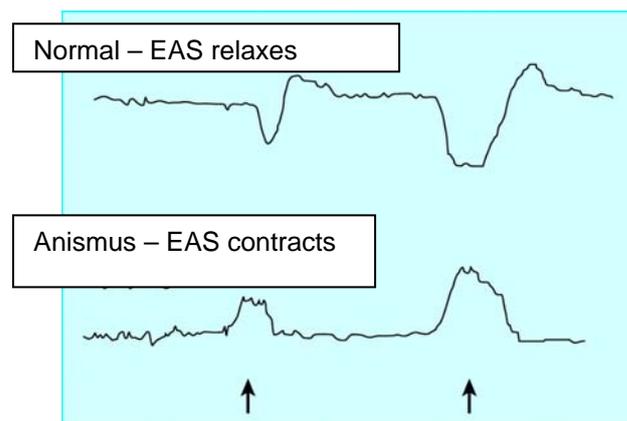
Pressure of IAS



Assessment of Anismus

Follow steps 1 – 7 of RAIR assessment:

8. Instil sufficient air into the distal (red line) balloon to produce the sensation of the need to defecate
9. Observe EAS resting pressure on manometric device
10. Ask the patient to strain as if trying to expel the balloon
11. An excessive increase in the pressure tracing of EAS demonstrates an abnormal contraction of the EAS during straining – anismus



Assessment of internal anal sphincter resting pressure

1. Close the 3-way tap to the distal balloon (red line)
2. Connect 3-way tap to manometric measuring device
3. Cover the catheter with a non lubricated condom
4. Apply lubricating gel to the tip of the condom
5. Insert distal balloon into mid anal canal
6. Open the 3-way tap
7. Move distal balloon along the length of the anal canal to record maximal resting pressure of IAS

Assessment of external anal sphincter resting pressure

1. Close the 3-way tap to the distal balloon (red line)
2. Connect 3-way tap to manometric measuring device
3. Cover the catheter with a non lubricated condom
4. Apply lubricating gel to the tip of the condom
5. Insert distal balloon into mid anal canal
6. Open the 3-way tap
7. Move distal balloon along the length of the anal canal to record maximal resting pressure
8. Ask the patient to perform a voluntary contraction of the EAS with the balloon positioned at the point of maximum resting pressure
9. Record maximum voluntary squeeze pressure of EAS

Pressure biofeedback training of EAS

Follow steps 1 – 9 for assessment of EAS resting pressure

- Use the manometric device to display voluntary effort and train to increase endurance (length) of contraction, coordination of contraction and release of contraction
- Training of EAS may also be coordinated with RAIR. When the patient observes the IAS pressure dropping during the RAIR, a learned sustained submaximal contraction of the EAS will inhibit defecation and provoke a reverse peristalsis of rectal contents away from the ano-rectal junction.

Balloon expulsion and defecation dynamics

1. Close the 3-way tap to the distal balloon (red line) and attach a water/air filled syringe (A 50ml syringe is recommended)
2. Cover the catheter with a non lubricated condom
3. Apply lubricating gel to the tip of the condom
4. Insert distal balloon into anal canal and gently push the balloon through the canal until the balloon is positioned in the rectum
5. Open the 3-way tap to the distal balloon (red line)
6. Instil sufficient air/water to produce a sensation of the need to defecate
7. Instruct the patient to try to push the balloon out
8. This may be carried out on a commode chair which will allow the patient to adopt the correct defecation position
9. This procedure may also be enhanced by positioning the proximal balloon in the mid anal canal and connecting the 3-way tap to a manometric device. Instruct the patient to attempt to push the balloon out whilst relaxing the EAS

END