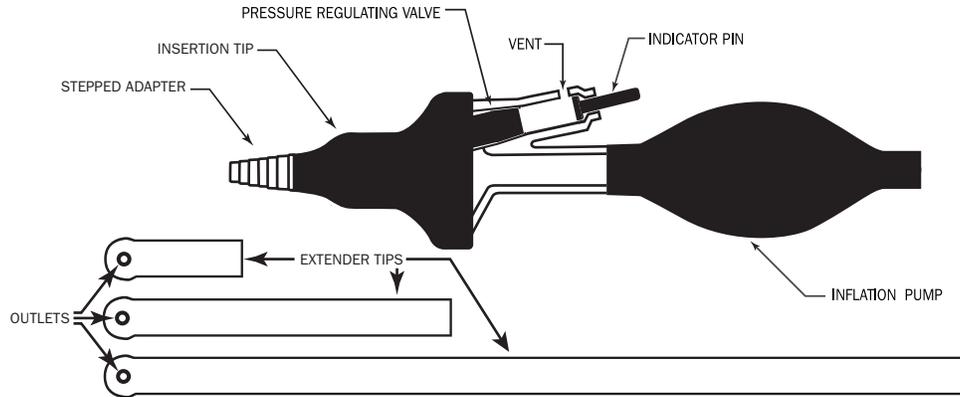


ANASTOMOSIS LEAK TESTER-EX-OP

Catalog No. ALT-EX-30



INDICATIONS:

For intraoperative air leak testing of a colorectal anastomosis in OPEN surgery.

CONTRAINDICATIONS:

The ANASTOMOSIS LEAK TESTER-EX-OP is not intended for use in laparoscopic or robotic surgery.

INSTRUCTIONS FOR USE:

TO TEST AN ANASTOMOSIS:

1. Submerge the anastomosis in saline and completely occlude the bowel above the anastomosis.
2. Choose an EXTENDER TIP, 4 cm, 10 cm or 25 cm, based on the height of the anastomosis, and attach it to the INSERTION TIP via the STEPPED ADAPTER.
3. Push the INDICATOR PIN in, occlude the two EXTENDER TIP OUTLETS with your fingers, and test-fire the device by compressing the INFLATION PUMP until the INDICATOR PIN pops out. **WARNING: Always test-fire the ANASTOMOSIS LEAK TESTER-EX-OP before performing an air leak test in order to ensure proper VALVE and INDICATOR PIN function.**
4. Hold the ANASTOMOSIS LEAK TESTER-EX-OP so that the VENT and INDICATOR PIN are upward, insert the EXTENDER TIP and INSERTION TIP into the anus, and press inward to form a seal at the anal verge.
5. Reset the INDICATOR PIN by pressing it in.
6. Compress the INFLATION PUMP to inflate the bowel. Inflate the bowel with a volume of air according to the surgeon's preference, or to a pressure of 30–40 cmH₂O. Each full compression of the INFLATION PUMP delivers approximately 45 mL of air. Observe and palpate the bowel to monitor the degree of bowel distention. **WARNING: Overdistention of the bowel may injure the anastomosis. Underdistention of the bowel may result in the failure to identify an anastomotic defect or weakness. Ensure that the bowel is completely occluded above the anastomosis in order to prevent distention of proximal bowel.**
7. To inflate to a pressure of 30–40 cmH₂O (22–30 mmHg), compress the INFLATION PUMP slowly and repeatedly. Do not occlude the VENT aperture. Feel for the INDICATOR PIN with your thumb as you pump. The INDICATOR PIN pops out when the intraluminal pressure reaches 30–40 cmH₂O. The PRESSURE REGULATING VALVE and VENT maintain the intraluminal pressure at 30–40 cmH₂O.
8. Observe the pool of saline for bubbles, which indicate an air leak.
9. Repair the anastomosis if necessary, and repeat the air leak test.
10. Deflate the bowel with the 25 cm EXTENDER TIP. If the 25 cm EXTENDER TIP was used for inflation, either separate it from the INSERTION TIP to deflate, or use the 10 cm EXTENDER TIP for deflation.

Rx only

This product contains DEHP

U.S. Patent Nos. 8,216,159 and 10,123,712

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