Application Bulletin | Medical

CINCINNATI TEST SYSTEMS
Your Global Leak and Function Test Solution Experts

How to Leak Test Handheld and Robotic Laparoscopy/Endoscopy Instruments

Single-use disposable handheld and robotic laparoscopic/ endoscopic instruments have become mainstream surgical tools for use when performing minimally invasive (aka: keyhole) abdominal surgical procedures. As a result, a wide variety instruments are frequently implemented.

Many of these instruments have complex articulations and may contain within a network of seals designed to prevent loss of insufflated gasses within the patient once they have entered the peritoneal cavity. Such devices are most often tested 100% in production.

Testing of these types of assemblies for leakage ensures correct placement of each seal within the cannula of the instrument during the assembly process and ensures gross leaks will not allow massive gas losses through the device during the procedure.

Common Laparoscopy/ Endoscopy Instruments

- Staplers
- Clip Appliers
- Suturing Devices
- Cutters Shears
- Scissors
- Tissue Dissectors
- Tissue Sealers
- Forceps
- Graspers
- Retractors
- Retrieval Bags
- Catch Bags
- Collection Bags

Leak Testing Method

Testing 100% of parts in production typically requires dry compressed air mass flow methods as their typical allowable leak rates are sufficiently high enough that maintaining the target test pressure throughout the test on some passing parts is difficult and a constant resupply of test air is required for repeatable testing. The single-channel Sentinel Blackbelt or multi-channel Blackbelt Pro mass flow instruments are designed for this purpose.

Most of these assemblies require testing pressures ranging from 10 - 20 mmHg or 0.2 – 0.4 psig as this will approximate typical laparoscopic insufflation pressure.

Sealing the Instrument Cannula for Leak Test

1. The distal/patient end of the instrument's cannula is mated to the test port(s) on either a Sentinel Blackbelt or Sentinel Blackbelt Pro test instrument.
   a. The instrument is most often supplied with an optional CTS CO31 or CO32 (dependent on the instrument diameter) OD Connect controlled by the test instrument.
2. The Start button is pressed by the user and, if equipped, the instrument activates all necessary CTS Connects and/or valves, sealing the cannula to atmosphere.

Pressurization of the Instrument Assembly

3. As the mass flow leak test cycle begins the instrument pressurizes the cannula of the instrument assembly with regulated compressed air for a user-defined Fill time. The pressure is measured by the instrument's pressure transducer and compared to min/max limits, enabling detection of improper pressure supply or massive leaks on the instrument assembly.

Leak Rate Measurement

4. After the Fill timer expires, the source air is routed through the instrument's mass flow transducer where actual flow (leak) through the part to atmosphere is recorded at the end of the user-defined Test time and compared to min/max flow limits to determine whether fine leaks are present, typically in leak rate units of standard cubic centimeters per minute (sccm).

Exhaust

5. After the Test time, source pressure is disconnected from the mass flow measurement circuit and any pressure trapped inside the instrument assembly is vented to atmosphere for a user-defined Exhaust time.

   After Exhaust, the final variable test result data is displayed on the instrument. Highly visible indicators on the display and front panel make it obvious to the operator which assemblies have passed or failed, allowing them to disconnect from the Sentinel instrument and properly move the parts down the production line or into reject containers.

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Solutions for Testing Handheld & Robotic Laparoscopy/Endoscopy Surgical Instruments

Sentinel Blackbelt
Single channel instrument

Sentinel Blackbelt Pro
Multi-channel instrument with features that support 21 CFR Part 11 and EU Annex 11

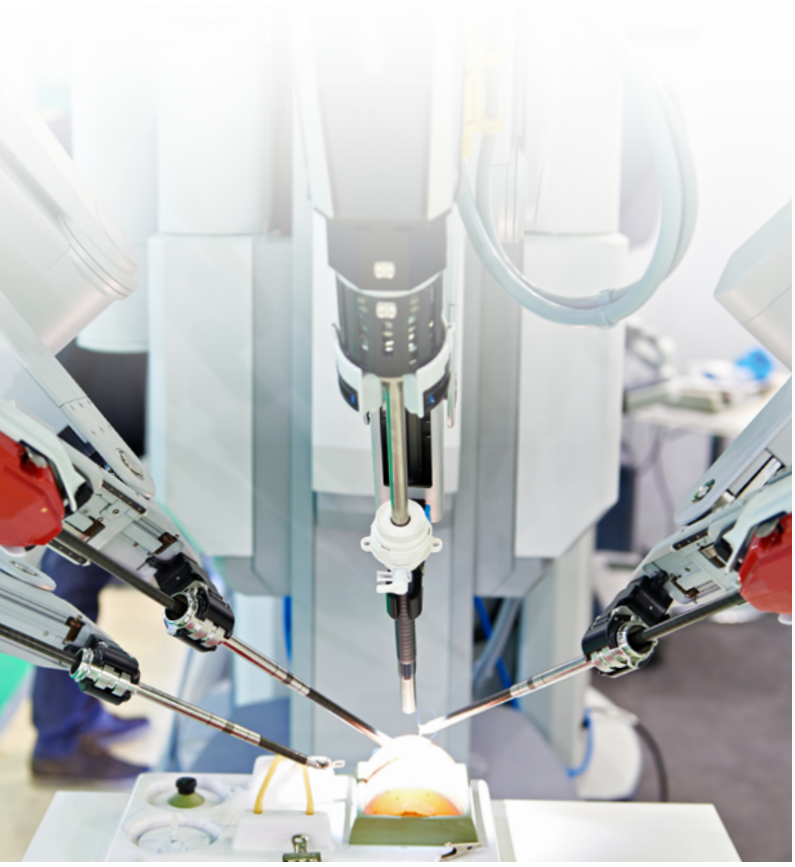
CTS Connects
High quality seals and connectors for medical applications

Total test cycle time is dependent upon different factors, most importantly:

- Reject limit selected
- Volume of the pressurized/evacuated area of the part under test
- Temperature stability of part and testing environment
- Dimensional stability of the part while under test
- Repeatability requirements defined by the user
- Accuracy, precision, and resolution of the instrument executing the test

Ensuring Failed Parts Are Properly Handled

Using CTS Connects driven by the Sentinel Blackbelt or Blackbelt Pro, the test program can be set to leave failed instruments sealed by the Connect, forcing the user to either press a reset button or use a security key or password to release the failed part. This method of forcing the operator to break rhythm limits the risk of rejects being inadvertently placed for downstream operations.



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