

How to Leak Test Laparoscopy/Endoscopy Access Ports & Trocars



Single-use disposable laparoscopic/endoscopic access ports and trocars are often used during minimally invasive (aka: keyhole) abdominal surgery to permit access of various vision and surgical instruments – such as grippers, cutters, electro-surgical tissue sealers, dissection bags, etc. – as well as gas into the abdomen via compliant slitted aperture seals.

These devices, especially the aperture seal, cannot leak excessively or else the peritoneal cavity would not be adequately insufflated, preventing completion of the surgical procedure in a minimal timeframe. As many of these devices incorporate the insufflation pathway, testing for potential blockages is also often done.

Testing of these types of assemblies often requires a multi-step process to detect both leaks and potential blockages. These issues may be caused during the assembly process where various engineered slitted aperture seals exist, and could be damaged or mispositioned or malformed during assembly.

Common Trocars

- Bladed Trocar
- Bladeless Trocar
- Blunt-Tipped Trocar
- Dilating Trocar
- Cutting Trocar
- Optical Trocar
- Hasson Trocar
- Pediatric Trocar
- Disposable Trocar
- Universal Cannula
- Universal Sleeve
- Disposable Cannula
- Optical Access Port
- Working Access Port
- Camera Access Port
- Disposable Access Port

Test Methods

Testing 100% of parts in production typically requires dry compressed air mass flow methods. 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 Cannula or Sleeve for Test

1. The stopcock valve on the insufflation port is closed and the distal/patient end of the cannula or sleeve 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 trocar 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 Trocar Assembly

3. As the mass flow leak test cycle begins the instrument pressurizes the cannula or sleeve of the trocar assembly – also filling the insufflation line from the cannula tip all the way back to the closed stopcock – 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 gross leaks on the trocar 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).

Test methods continued on next page...

The With and Without Probe Test

Some users opt to challenge the engineered slitted seal which allows passage into and out of the abdominal cavity by various optical and/or surgical tools both with and without a mock pin or tool penetrating through the seal.

In these cases, they utilize a custom machined probe as a simulator. The leak test test (steps 1-5) is performed twice, once with the probe inserted through the seal and then again after the probe has been removed to ensure that the seal is able to return to its original state following probe exit.

Solutions for Testing Trocar Assemblies and Access Ports



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

Test Methods Continued

Exhaust

5. After the Test time, source pressure is disconnected from the mass flow measurement circuit and any pressure trapped inside the trocar assembly is vented to atmosphere for a user-defined Exhaust time.
After the Exhaust time, the final variable test result data is displayed on the instrument. If a Reject, the test is halted and operator receives the reject indication both on the display and front panel as well as an audible alarm if desired. If Accept, the instrument halts awaiting the operators next initiation of the start button.

Inspecting for Partial Blockages of Insufflation Circuit using Mass Flow

6. The operator opens the insufflation port stopcock on the proximal/clinician end of the trocar assembly to allow the insufflation line to be vented to ATM. Typically, the OD Connect of the cannula remains actuated/sealed to ATM.
7. The Start button is pressed by the user and, if equipped, the instrument starts the mass flow blockage test. Air is intended to flow from the OD Connect through the insufflation line and out to ATM via the operator-opened stopcock.

Pressurization of the Insufflation Line

8. As the mass flow blockage test cycle begins the instrument pressurizes the cannula or sleeve of the trocar 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 on the insufflation line.

Flow Rate Measurement

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

Exhaust

10. After the Test time, source pressure is disconnected from the mass flow measurement circuit and any pressure trapped inside the trocar 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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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 trocars 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 failed parts being inadvertently placed for downstream operations.

