

# TECHNICAL BULLETIN

## Helipac

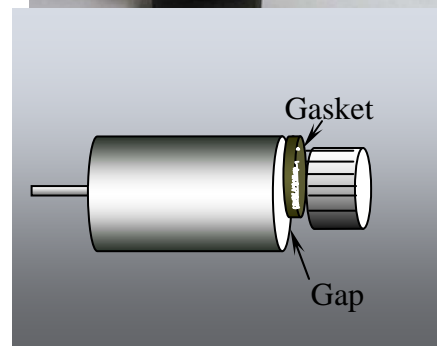
### Introduction

The new Helipac process challenge device (PCD) is the next generation of PCD now available to the conscientious healthcare professional. Its new design takes advantage of cutting edge technology to provide an easy-to-use and inexpensive aid to decisions regarding quality of a sterilization cycle. For example, it's volume, not length that counts. Scientific studies have shown that the overall volume of air inside a lumen device is the critical variable for air removal challenge. This means shorter length lumens can provide as great a challenge to air removal as longer lumens with narrower diameter. The following additional features are the basis of this new step forward in cycle monitoring technology.



### Seal failure – the Achilles heel of helix devices on the market today

Seal failure and its resulting leak can occur at any time. It can be a result of a cracked O-ring gasket or just a poorly executed tightening of the end cap. In order for any helix device to work properly, all steam access to the indicator chamber must be via the hollow tubing only. Any leakage of steam into the indicator chamber via a cracked gasket or poorly tightened end cap invalidates the test.



The real danger in this failure mode comes from the fact that a steam leak looks like a PASS result.

Steam leaking from the poor seal can cause the internal indicator to change completely to a PASS appearance. Healthcare personnel do not look for reasons to doubt the PASS result and therefore do not verify that this result is correct. Verification of adequate seal strength and absence of steam leaks has not been possible until now.

### Helipac Leak Test

The capability for verifying the absence of a steam leak in a helix device is a break-through, only available to the healthcare community through the use of Helipac. Helipac has a unique design that allows the testing for steam leaks with each and every use. Under its broad silicone gasket, Helipac has a test chamber where a Leak Test Indicator Strip is



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placed. This Leak Test Indicator Strip changes color if steam leaks into the sealing area. If this indicator remains unchanged, the user knows the system was sealed properly and did not leak. This ability to verify proper sealing is the major feature that sets Helipac apart from its competitors.

## Sterilant Specific Integrator

The steam integrator used to verify steam penetration all the way to the terminal end of the Helipac changes color from purple to green when all three parameters for steam sterilization are correct. These parameters are time, temperature and presence of saturated steam. In addition, the chemistry used in this integrator is STERILANT SPECIFIC. This means that high energy H<sub>2</sub>O is actually part of the chromophore (color generating molecule). It will no longer be possible to change the indicator used in a hollow load test using heat energy alone. This indicator requires the presence of saturated steam. It meets ISO 11140-1 class 5 requirements.



The indicator timing has been adjusted to provide the maximum possible safety margin in the sterilization cycle. Sub-optimal cycles with insufficient energy, steam quality and exposure time will not be able to turn the indicator to its correct green color.



The indicator strip has two inks, one in the middle box and one for the pointed box on the end. The pointed box indicator has the special ink timing that provides the greatest safety margin. The center box gives a preliminary reading to show if steam was present but perhaps with insufficient strength or exposure time to provide good sterilization conditions. The combination of results from the leak test and from the sterilant specific integrator provide the all-encompassing verification that process challenge devices (PCDs) have been unable to provide in the past.

## The Porous Mass

In addition to the high quality indicator strips verifying conditions inside the Helipac device, the open end of the device contains a further innovation that sets itself apart from the competition. The open end of Helipac contains a removable porous mass component that is re-usable 15 times. The air removal



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and steam penetration challenge provided by this porous mass component were not previously available in competitive hollow load challenge devices. Now, a dual challenge for hollow load and porous load environments is available in one all-encompassing device.

## Summary Results of Evaluation of Integrator Performance in the Helipac PCD

### 1. 134°C pre-vacuum cycles (subatmospheric)

Sterilization time	No Failure Cycle	Reduced Air Removal Level I <sup>1</sup>	Reduced Air Removal Level II <sup>2</sup>	Induced Air Leak <sup>3</sup>
3 minutes <sup>4</sup>	Fail	Fail	Fail	Fail
5 minutes <sup>4</sup>	Pass	Fail (borderline)	Fail	Fail (borderline)

### 2. 121°C pre-vacuum cycles (subatmospheric)

Sterilization time	No Failure Cycle	Reduced Air Removal Level I <sup>1</sup>	Reduced Air Removal Level II <sup>2</sup>	Induced Air Leak <sup>3</sup>
10 minutes	Fail	Fail	Fail	not tested
15 minutes	Fail (borderline)	Fail	Fail	not tested
18 minutes	Pass	Fail (borderline)	Fail	not tested

### 3. 18 minutes at 134°C pre-vacuum cycles (subatmospheric)

Sterilization time	No Failure Cycle	Reduced Air Removal Level I <sup>1</sup>	Reduced Air Removal Level II <sup>2</sup>	Induced Air Leak <sup>3</sup>
15 minutes <sup>5</sup>	Fail	Fail	Fail	not tested
18 minutes <sup>5</sup>	Pass	Fail	Fail	not tested

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- Notes :
- Pass = complete color change from purple to green
  - Fail = incomplete color change from purple to green with clearly visible purple parts
  - Fail (borderline) = detectable minor purple spots, reading requires bright light conditions
    - Air removal adjusted to reflect a small fault (reflects EN 867-4 minimum failure for BD testing)
  - 1) Air removal adjusted to reflect a significant fault
  - 2) Induced air leak level as used to reflect EN 867-4 minimum failure for BD testing
  - 3) Regular 134°C Helipac Integrator
  - 4) 18min, 134°C Helipac Integrator

## Summary Results of Evaluation of LEAK TEST Performance in the Helipac PCD

### 1. 134°C pre-vacuum cycles (subatmospheric)

Sterilization cycle + process failure	No LEAK	Minor Leakage I	Minor Leakage II	No Seal
5 min, no failure	Pass	Fail	Fail	Fail
5 min, air removal level I <sup>1</sup>	Pass	Fail	Fail	Fail
5 min, air removal level II <sup>2</sup>	Pass	Fail*	Fail	Fail
5 min, induced air leak <sup>3</sup>	Pass	Fail	Fail*	Fail

### 2. 121°C pre-vacuum cycles (subatmospheric)

Sterilization cycle + process failure	No LEAK	Minor Leakage I	Minor Leakage II	No Seal
10 min, no failure	Pass	Fail	Fail	Fail
15 min, no failure	Pass	Fail	Fail	Fail
15 min, air removal level I <sup>1</sup>	Pass	Fail	Fail	Fail

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## 3. 18 minute 134°C pre-vacuum cycles (subatmospheric)

Sterilization cycle + process failure	No LEAK	Minor Leakage I	Minor Leakage II	No Seal
18 min, no failure	Pass	Fail	Fail	Fail
18 min, air removal level I <sup>1</sup>	Pass	Fail	Fail	Fail
18 min, air removal level II <sup>2</sup>	Pass	Fail*	Fail	Fail

Notes : Pass = no color change from blue to black

Fail = complete or partial color change from blue to black

Fail\* = simultaneous process and leak failure detected in the main chamber with the Helipac Integrator

- 1) Air removal adjusted to reflect a small fault (reflects EN 867-4 minimum failure for BD testing)
- 2) Air removal adjusted to reflect a significant fault
- 3) Induced air leak level as used to reflect EN 867-4 minimum failure for BD testing

# **SteriTec**

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