HELIPAC PCD Refill Kit

REF LT 102/134/RF

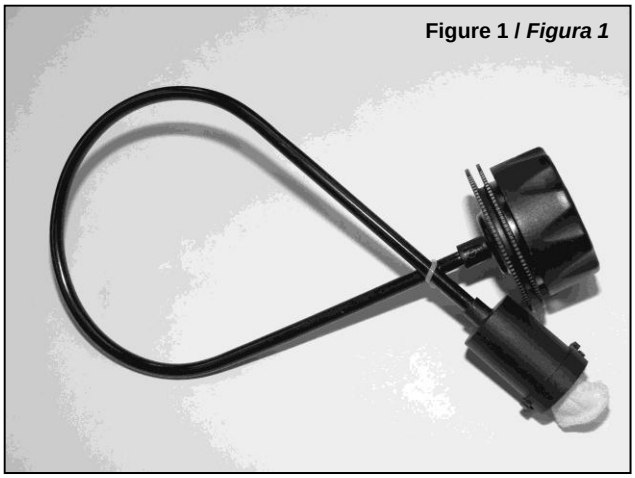
LT 102/121/RF, LT 102/18/RF

Directions for Use

Intended Use

HeliPac PCD (Figure 1) is a Process Challenge Device for pre-vacuum steam sterilization of porous and hollow loads. HeliPac PCD verifies air removal, steam penetration, and exposure levels in lumens and porous items simultaneously. It is a reusable device utilized in each sterilization load as an independent control device for decisions regarding load release.

Figure 1 / *Figura 1*



Packaging

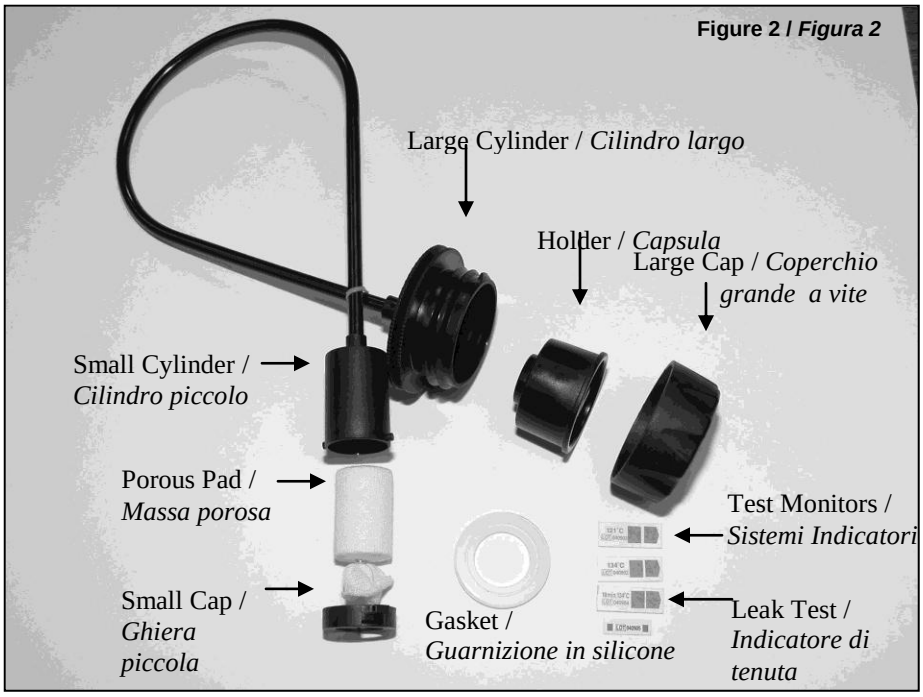
The HeliPac PCD Refill Kit can be reused for 300 cycles and consists of:

- 1 silicone gasket for replacement after approximately 300 cycles.
- 20 porous pad paper stacks, each reusable 15-times.
- 1 resealable foil pouches each containing 300 HeliPac test monitors and 300 Leak Test monitors.

PCD Description

The disassembled HeliPac PCD device consists of the following parts (Figure 2). A central lumen simulator connected at both ends to cylinders. The large cylinder is for use with the HeliPac test monitor and Leak Test monitors. The small cylinder at the opposite end is for use with the porous pads. Porous pads can be re-used 15-times and represent a standardized porous load. The porous pad cylinder locks the porous pad safely into the device. The large cylinder holds the HeliPac test monitor and the Leak Test monitor to verify the absence of leaks of the PCD. It includes a silicone gasket and screw cap for easy and positive connection to the hollow load device.

Figure 2 / *Figura 2*



Instructions for Use

1. Open the large cylinder, by unscrewing the large outer cap. Remove the monitor holder from the cylinder, by holding onto the rectangular protrusion and pulling out. (Figure 3)
2. Remove a HeliPac test monitor (purple ink) from the protective pouch and insert it into the center cavity of the monitor holder with the indicator ink end inserted first to assure that the indicator ink is as close the dead end of the cavity as possible. (Figure 4)
3. Insert a Leak Test monitor (blue ink) into the smaller cavity located at the outer ring of the indicator chamber. (Figure 5)
4. Place the silicone gasket inside the large cylinder. (Figure 6)
   NOTE: The hole in the seal allows steam to access the Leak Test chamber via the groove in the indicator chamber. If a leak is present anywhere in the HeliPac device steam will migrate to the Leak Test chamber. The location of the hole on the seal is not important, it will always line-up with the groove.

Figure 3 / *Figura 3*

5. Replace the monitor holder in the large cylinder. Lock it in place by adding the screw cap and twisting manually until snug. *NOTE: It is not necessary to over tighten the cap using tools.*
6. On the opposite end of the device, twist the small cylinder cap open and insert one porous pad with the loose clipped end hanging out. Replace the cap and twist to lock closed. The device comes with one porous pad already in place. (Figure 7)
7. Place the assembled HeliPac device in a fully loaded sterilizer, in a horizontal position near the coolest location in the sterilizer (usually near the drain next to the door). *NOTE: The HeliPac device should not be hung in the chamber nor be placed in an upright position to prevent condensate accumulation in the indicator chamber.*
8. Conduct the intended sterilization cycle.
9. At the end of the sterilization cycle, remove the HeliPac PCD from the chamber, and WAIT ONE MINUTE TO ALLOW THE DEVICE TO COOL BEFORE OPENING. ***CAUTION: The HeliPac PCD device may still be hot. Hand protection is recommended when removing the device from the sterilizer.***
10. Open the indicator chamber and remove the HeliPac test monitor and the Leak Test monitor and read the results.
11. Document the results as required by hospital procedures. Disassemble the device and place a mark on the porous pad with a waterproof pen to show it has been used for a sterilizer cycle. Allow the device to cool and dry for at least 30 minutes prior to next use. *NOTE: It is recommended to allow the porous pad to dry for two hours prior to next use.*
12. When 15 marks are present on the porous pad, discard and replace with a fresh Porous Pad.

Interpretation of Results

1. **HeliPac Test Monitor:** Color change from purple to green indicates satisfactory air removal and steam penetration within the load. An incomplete color change indicates insufficient sterilization conditions and re-sterilization is recommended. Follow hospital procedures for re-sterilization of the load.
2. **LEAK TEST Monitor:** Proper sealing of the PCD is demonstrated if steam DOES NOT penetrate to the Leak Test monitor. In the unlikely event of gasket failure or inadequate tightening, the LEAK TEST monitor will change color from blue to a dark grey or black. If this happens, the device should be checked for tightness. If it is found to be tight, then the gasket should be replaced and the sterilization cycle should be repeated to verify sterilization. *NOTE: Leakage can be caused by the development of condensation in the Leak Test cavity and may result in a wet Leak Test monitor. A slight color change of the Leak Test monitor to a darker blue may be observed from time to time. This slight darkening is not an indication of leakage.*

Storage

- Store at room temperature 50° - 100° F(10°-38°C).
- Do not remove HeliPac test monitors from protective pouch until ready for processing. Protect all components from moisture and excess humidity by resealing the foil bags after each use.
- The expiry date is printed on the product packaging.
- Once processed the monitors are stable and require no special storage conditions.

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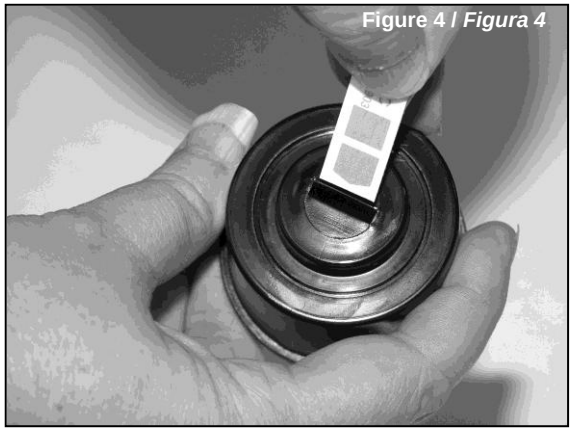
Figure 4 / *Figura 4*

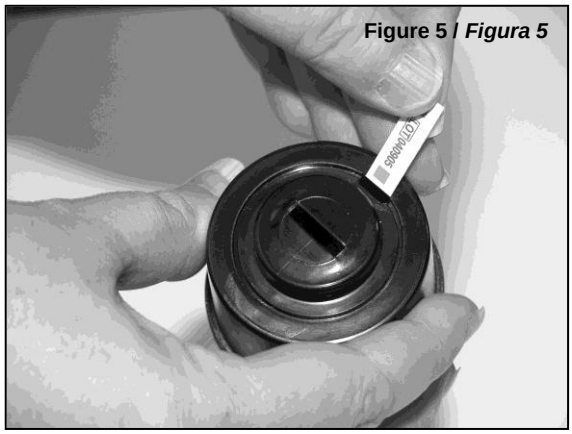
Figure 5 / *Figura 5*

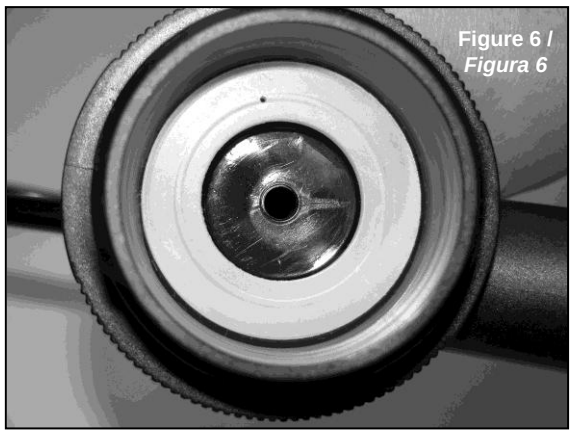
Figure 6 / *Figura 6*

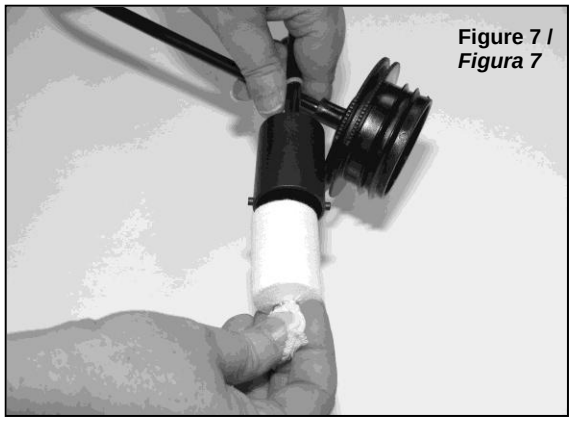
Figure 7 / *Figura 7*