

**GENERAL INFORMATION AND CONTACT**

SpiraLith®Ca is a medical grade carbon dioxide absorbent indicated for use in human and veterinary anesthesia for absorption / neutralization of endogenously produced CO<sub>2</sub>. Manufactured in the USA to Quality System ISO9001: 2015.

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**PRODUCT CODES**

**RX-0719A:** Reusable housing for use with GE Aespire, Aisys, Avance, and ADU anesthesia machines

**RX-2616C:** Disposable canister for use with GE Aestiva, GE Excel, GE Modulus, Mindray, Penlon, Siemens, and Spacelabs anesthesia machines.

**RX-2719C:** Disposable cartridges for RX-0719A reusable housing for GE Aespire, Aisys, Avance, and ADU anesthesia machines

**RX-2903C:** Disposable canister for use with Draeger Apollo, Cicero, Fabius, Julian, Zeus, Pallas, and Primus anesthesia machines.

**RX-3719C:** Disposable canister for use with GE Aespire, Aisys, Avance, and ADU anesthesia machines.

**RX-3903C:** Disposable canister for use with Draeger Perseus anesthesia machines and side-mounted Apollo and Fabius machines

**Note:** Other than that of the applicable regulatory body, approval and use of these products DOES NOT REQUIRE APPROVAL OF A THIRD-PARTY OR MANUFACTURER OF THE ANESTHESIA MACHINE they are to be used upon. Any inference by GE or Draeger Medical that their device warranties are in any way affected by the use of these products is rejected on the grounds it breaches EU and UCC competition law, specifically regarding abuse of a dominant market position through anti-competitive behavior.

**SYMBOLS**

Symbol	Description	Symbol	Description
	Consult Instructions for Use		Keep Dry
	Irritant		Storage Temperature Range
	Use by / Expiration Date		Keep out of Sunlight
	Fragile / Handle with Care		Manufacturer
	Corrosive		Serial Number
	Unique Device Identifier		Catalogue or Model Number

**PREPARATION**

- Inspect packaging prior to use. Damaged or missing packaging materials may indicate product damage or CO<sub>2</sub> exposure and product should not be used.
- Remove from packaging.
- For product code RX-2719C remove cartridge from clear tube (\*\*DO NOT\*\* remove the label or plastic wrap).
- Conduct visual examination of cartridge or cannister for cracks, dents, blocked channels, etc. Prefilled cannisters with cracks should not be used and disposed of immediately. Cannisters or cartridges with blocked channels may reduce product performance. Blocked channels in the vicinity of the color indicator windows may slow or prevent color indicator change.

## INSTALLATION

- Push the button to open the Draeger Clic® adaptor or GE EZchange cassette.
- Slide the SpiraLith®Ca canister into the Draeger Clic® adaptor or GE EZchange cassette.
- For products with color indicator windows ensure they are positioned so they are visible to the anesthesia provider.
- Ensure cannisters are fully seated.
- To close, push backwards on the cannister until it audibly clicks into place.
- To ensure proper installation, as well as detect potential leaks, perform necessary equipment pre-use checks in accordance with the machine manufacture instructions.
- For Prepack installation (RX-2616C) remove from packaging by removing the foil seal and plastic retainer lid, but DO NOT remove cartridge shrink wrap. When placing the cartridge into the absorber canister, ensure no foreign materials are present as this may cause gas to bypass the cartridge seal
- For cartridge installation (RX-2719C) you will first need to open the reusable housing (Rx-0719A), place the Lid/Lock Ring Assembly upside down on a solid surface, place the cartridge into the Lid/Lock Ring assembly, and align the cartridge so that the "FLOW ARROW" is pointing to one of the slots in the lid (Figure 1, below). Next, ensure the cartridge is seated properly in the lid, place the housing over the cartridge so the Handle and Flow Arrow are aligned (Figure 2), carefully align the 4 tabs in the housing with the slots in the lid (Figure 3), press down on the housing until it is fully seated in the lock ring/lid assembly and turn the locking ring to the locked position (Figure 4). You will feel/hear a "click" when cap is in the proper locked position (Figure 5).

## COLOR INDICATOR WINDOWS

SpiraLith®Ca CO<sub>2</sub> absorbents contain a new, easy to interpret color indicator system. The indicator bars will start to turn violet as the absorbent becomes exhausted. Depending on conditions, the last bar may not change before exhaustion. Color change is useful in estimating the remaining absorbent life, but does not replace monitoring of FiCO<sub>2</sub>. The absorbent should be replaced when FiCO<sub>2</sub> exceeds your hospital's limit (i.e. 0.5% volume or 4mm Hg). Color indicator windows are sensitive to UV light and may be ineffective if subjected to prolonged UV exposure.

## HANDLING, STORAGE AND DISPOSAL

- Avoid contact with eyes, skin and clothing.
- Wear gloves when handling cartridges.
- Avoid exposure to direct sunlight.
- Store in an environment that minimizes exposure to UV or artificial light.
- Store in ambient humidity above 15°C / 59°F.
- Dispose of in accordance with the hospital's waste management protocol for non-contaminated clinical waste<sup>1</sup>.
- It should be noted traces of volatile anesthetic may be present within exhausted cannisters and, therefore, they should not be incinerated, as combustion is possible.

## CLEANING REUSABLE HOUSING (RX-0719A)

- Cleaning the Housing: 1. Open canister and rinse the canister and the lid thoroughly inside and out with fresh running water. 2. Immerse the canister and lid in a sink with water and cleaning agent for at least 3 minutes. The water temperature should be about 40°C / 104°F. 3. Rinse the canister and lid thoroughly with fresh running water. 4. Air or wipe dry prior to installing new cartridge.
- \*\*DO NOT use cleaning agents containing butoxyethanol or other alcohols. These solvents are known to cause stress cracking in polycarbonate materials.
- \*\*DO NOT attempt to autoclave or otherwise sterilize housing.



Figure 1

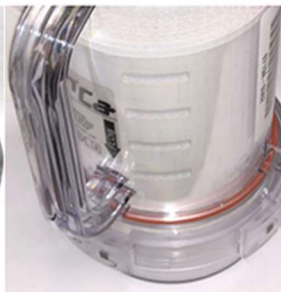


Figure 2

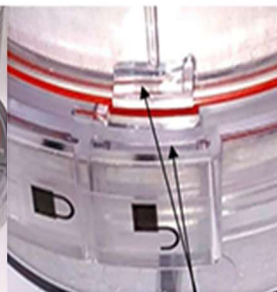


Figure 3



Figure 4

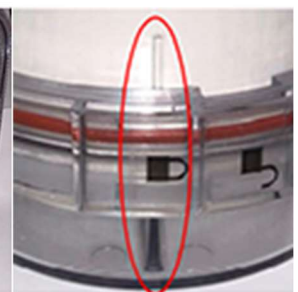


Figure 5