Exhaust Collection Bag
Accessory to Cerene Cryotherapy Device
Instructions for Use (IFU)

CAUTION: UNITED STATES FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN TRAINED IN THE USE OF THE CERENE CRYOTHERAPY DEVICE

INDICATIONS FOR USE

The *Cerene Exhaust Collection Bag* (*Exhaust Collection Bag*) is indicated for use with the *Cerene Cryotherapy Device*. The *Exhaust Collection Bag* collects the nitrous oxide (N_2O) gas exhausted from the *Cerene Cryotherapy Device* during the endometrial cryoablation procedure and facilitates disposal of the gas when the procedure is completed.

DEVICE DESCRIPTION

The *Exhaust Collection Bag* is made of a polyurethane blend and is provided non-sterile and individually labeled in boxes of ten. The *Exhaust Collection Bag* has a port that should be connected with the *Exhaust Hose* of the *Cerene Cryotherapy Device* (*Cerene Device*) prior to the procedure. The *Exhaust Collection Bag* can be emptied via wall suction once the procedure is complete by using the wall suction adapter provided in the box of ten *Exhaust Collection Bags*. The Exhaust Collection Bag can also be emptied outdoors by opening the plug at the bottom of the bag and rolling the bag down to release the exhaust gas.

WARNINGS

- The *Exhaust Hose* must not be occluded during treatment. *Exhaust Hose* occlusion will cause the *Cerene Device* to shut down to avoid excessive uterine pressures and may result in early termination of the procedure.
- Always connect the *Exhaust Hose* to the *Exhaust Collection Bag* prior to turning on the *Cerene Device*. Connecting the *Exhaust Hose* to the *Exhaust Collection Bag* during the procedure could result in a temporary occlusion, could cause the *Cerene Device* to shut down to avoid excessive uterine pressures, and may result in early termination of the procedure.
- Modification of the *Exhaust Collection Bag* may result in serious patient injury.

PRECAUTIONS

- Inhalation of nitrous oxide gas (exhaust gas) can cause short-term effects such as breathing difficulty, drowsiness, headache, and asphyxia. Use of the *Exhaust Collection Bag* accessory is required.
- Chronic exposure to nitrous oxide gas (exhaust gas) can lead to adverse reproductive, neurological, and hematological effects. Use of the *Exhaust Collection Bag* accessory is required.

PERFORMANCE CHARACTERISTICS

The *Exhaust Collection Bag* provides a means of containing and safely disposing of the nitrous oxide gas from a Cerene procedure in order to minimize the occupational risks associated with long-term, nitrous oxide exposure.

SERIOUS INCIDENT REPORTING

In the European Union, any serious incident that has occurred in relation to the device should be reported to Channel Medsystems (+1-510-338-9301 or support@cerene.com) and the competent authority of the Member State in which the user is established. To report a product complaint or adverse event in the United States, please contact Channel Medsystems (+1-510-338-9301 or support@cerene.com) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Figure 1. *Exhaust Collection Bag (an accessory to the Cerene Cryotherapy Device), shown here hanging from an IV pole*

GENERAL INSTRUCTIONS

- Hang the *Exhaust Collection Bag* on an IV pole.
- Before the *Cerene Device* is turned on, connect the end of the *Exhaust Hose* to the *Exhaust Collection Bag* until you hear an audible click.

NOTE: Ensure that the *Exhaust Hose* is not kinked or obstructed at any time.

NOTE: Do not connect the *Exhaust Hose* to a scavenging system or to wall suction directly.

DISPOSAL

- Once the *LCD Screen* indicates the *Cerene Device* is safe for disposal, disconnect the *Exhaust Collection Bag* from the *Cerene Device*, and dispose of the *Cerene Device* per local procedure.
- Empty the *Exhaust Collection Bag* and dispose per custom and practice.
  - Outdoors: Open the plug, hold the bag below waist level, and roll the bag from the top down.
  - Via wall suction: Attach the wall suction adapter found in the box of *Exhaust Collection Bags* to the mating fitting at the bottom of the bag. Attach the adapter to wall suction.

PACKAGING AND STORAGE

The *Exhaust Collection Bag* is provided non-sterile and individually packaged, or individually packaged in boxes of ten.
Do not use the *Exhaust Collection Bag* if the package appears damaged in any way.
Do not reuse the *Exhaust Collection Bag*. Re-use of the *Exhaust Collection Bag* could promote cross-contamination.
Store the *Exhaust Collection Bag* at -18°C – 55°C.

SYMBOL DEFINITIONS

Symbol	Standard/Symbol Reference Number	Title of Symbol	Definition
REF	ISO 15223-1, Clause 5.1.6	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	ISO 15223-1, Clause 5.1.1	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1, Clause 5.4.3	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1, Clause 5.4.2	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
-18°C 55°C	ISO 15223-1, Clause 5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
LOT	ISO 15223-1, Clause 5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1, Clause 5.1.4	Use by date	Indicates the date after which the medical device is not to be used.
NON STERILE	ISO 15223-1, Clause 5.2.7	Not sterile	Indicates a medical device that has not been subjected to a sterilization process
MD	ISO 15223-1, Clause 5.7.7	Medical device	Indicates the item is a medical device
	ISO 15223-1, Clause 5.1.8	Importer	Indicates the entity importing the medical device into the locale
EC REP	ISO 15223-1, Clause 5.1.2	Authorized representative in the European Community	Indicates the authorized representative in the European Community.
CE	Medical Device Regulation 2017/745	CE marking	'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with MDR 2017/745 and other applicable Union harmonisation legislation
UK CA	UK MDR 2002	UK Conformity Assessed Marking	Indicates that a device is in conformity with UK MDR 2002
Rx Only	21 CFR 801.109	Prescription only	Requires a prescription in the United States.

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