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. 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 a wall suction adapter that can be requested when ordering the device. 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

Contact Channel Medsystems (+1-510-338-9301 or support@cerene.com) for any incident. In the EU, any serious incident that has occurred in relation to the device should be reported to 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 FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. In the UK, report to the Yellow Card scheme in England and Wales, to the Northern Ireland Adverse Incident Centre in Northern Ireland, and to Health Facilities Scotland online incident reporting system in Scotland.

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: The Exhaust Collection Bag can be emptied via wall suction using an adapter that can be requested when ordering the device. Attach the barbed end of the adapter to wall suction. Then, connect the adapter to the mating fitting at the bottom of the bag.

PACKAGING AND STORAGE

The *Exhaust Collection Bag* is provided non-sterile and individually packaged.
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	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
℞Only	21 CFR 801.109	Prescription only	Requires a prescription in the United States.

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