ensoETM™

For controlling patient temperature and the enteral administration of fluids

Instructions for Use

Caution: Read all instructions prior to use.

- For single use only. Reuse may expose patients to infection risk.
- Provided non-sterile.
- Do not use if packaging is compromised.
- This product does not contain dry natural rubber.

REF ECD03-A

Description

The ensoETM is a non-sterile multi-lumen silicone tube placed in the esophagus for the purpose of cooling or warming a patient while simultaneously allowing gastric decompression, drainage, and the enteral administration of fluids. Modulation and control of the patient's temperature is achieved by connecting the ensoETM to an external heat exchanger. Two lumens connect to the external heat exchanger, while a third central lumen provides stomach access for connection to a fluid collection device with low intermittent suction for gastric decompression or to an enteral administration system for the enteral administration of fluids (Figure 1). The ensoETM is made of standard medical-grade silicone. It is a single-use, disposable, non-implantable device with an intended duration of use of 72 hours or less.

NOTE: This ensoETM (ECD03-A) is designed to be used with the Gaymar Medi-Therm III Conductive Hyper/Hypothermia System (MTA 7900/7912) or Stryker Altrix Model 8001 Precision Temperature Management System with the following operating specifications:

External Heat Exchanger	Dead Head Pressure	Flow	Water Temperature Control Range
Gaymar Medi-Therm III Conductive Hyper/Hypothermia System	Maximum 9 psi (62 kPa)	Minimum 16 gph (60.6 L/h)	4°C - 42°C
Stryker Altrix Precision Temperature Management System	Maximum 7.5 psi (52 kPa)	Minimum 12.7 gph (48 L/h)	4°C - 40°C

Intended Use

The ensoETM is a thermal regulating device, intended to:

- connect to a Gaymar Medi-Therm III Conductive Hyper/Hypothermia System or Stryker Altrix Precision Temperature Management System to control patient temperature,
- allow enteral administration of fluids, and
- provide gastric decompression and suctioning.

Warnings and Precautions

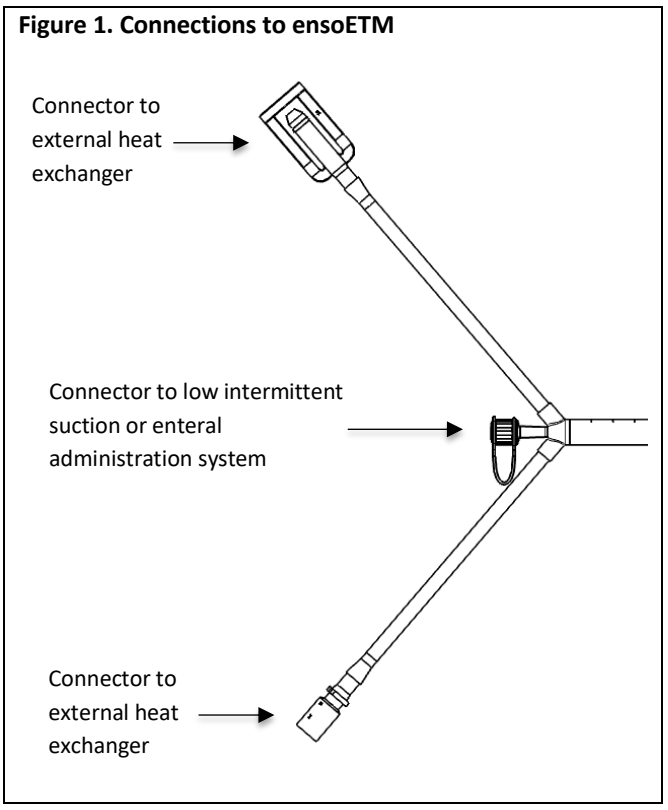
- The ensoETM may cause or exacerbate esophageal tissue damage in patients with known esophageal deformity or evidence of esophageal trauma, or in patients known to have ingested acidic or caustic poisons within the prior 24 hours.
- The safety and effectiveness of the ensoETM have not been evaluated in patients with less than 40 kg of body mass.
- The ensoETM should only be used by healthcare professionals with training in the use of orogastric tubes and the use of the external heat exchanger.
- The ensoETM is intended for esophageal placement. Inserting the ensoETM in the trachea, bronchi or lungs can result in serious patient harm.

- If a suction collection system for the gastric tube is connected to the ensoETM, it should be monitored throughout treatment of the patient. If the accumulation of liquid is greater than expected, treatment should be stopped and the ensoETM should be removed and examined for the presence of leaks.
- Always follow the Instructions for Use for the external heat exchanger, and monitor it for alerts. If a low water alert or an occlusion alert occurs and the cause of this decreased amount of water or obstruction of water flow is not found, treatment should be stopped and the ensoETM should be removed and examined for failure.
- The coolant (water) ports on the ensoETM (Figure 1) are intended to connect only to the external heat exchanger. The central lumen is intended to connect to a suction canister with low intermittent suction or an enteral administration system (Figure 1). The ensoETM has the potential to misconnect with connectors of other healthcare applications. Attachment of the ensoETM to unapproved or unintended connections can result in serious patient harm.
- The presence of the ensoETM may interfere with other devices in the esophagus or mouth. Dual placement of other devices in the esophagus with the ensoETM is an unintended use and may result in patient harm. Do not use an esophageal temperature probe, oral thermometer, esophageal Doppler stethoscope, or enteral feeding tube with the ensoETM in place.
- In patients with intact dentition, a bite block may be required to prevent damage to the ensoETM.
- Periodically reposition the ensoETM in accordance with hospital protocol. Prolonged excessive pressure may cause dermal injury, tissue ischemia, or necrosis.
- Large patients with a body mass greater than 120 kg may exhibit slower responses to intended temperature changes. Small patients with a body mass less than 60 kg may exhibit faster cooling than anticipated, and may exhibit slower rewarming than anticipated. Environmental conditions, such as the temperature of the room, may also affect patient temperature. Removing or adding blankets or sheets may be necessary if the desired cooling or warming rate is not being achieved.
- Avoid pinching or kinking the ensoETM during placement or use, because this may cause the flow of coolant to become occluded.

Placement of the ensoETM

1. The external heat exchanger must be in proper operating condition and must have received all the required maintenance. Failure to ensure that the heat exchanger is in proper condition may result in suboptimal performance. Ensure that no contaminants are present in the heat exchanger water.
2. Measure the patient for ensoETM placement carefully before use. Insertion of an excessive length of the ensoETM into the stomach may lead to coiling, kinking, knotting, or breakage of the ensoETM. To measure the patient for ensoETM placement, extend the ensoETM from the patient's lips to the earlobe and then from the earlobe to the tip of the xiphoid process (xiphisternum). Mark the location on the ensoETM.
3. Follow the Instructions for Use for the external heat exchanger for all device operations, including connections to electric wall power, patient probes, and tube set connections. Connect the ensoETM (Figure 1) to the external heat exchanger in place of a blanket or pad, using a Gaymar DBK9 or DBK35CE connector hose for the Gaymar Medi-Therm III Conductive Hyper/Hypothermia System (MTA 7900/7912) or a Stryker Model 8001-064-035 Insulated Clik-Tite Hose for the Stryker Altrix Model 8001 Precision Temperature Management System with the connectors as shown in Figure 1. Turn on the external heat exchanger.

Figure 1. Connections to ensoETM



4. Ensure that the patient has two (2) temperature probes with separate monitors in use (for example, a Foley catheter temperature probe and a rectal temperature probe). One of the temperature probes must be connected to the external heat exchanger, as directed in the external heat exchanger's Instructions for Use. Ensure that both temperature monitors are functioning correctly and that the temperature probes are not damaged, expired, or compromised in any other way.

5. If present, release the Tube Set Pinch clamps and select AUTO or MANUAL control mode to start the flow of water in the ensoETM. If using auto control mode, set the control option and target patient temperature on the external heat exchanger. Ensure that water is flowing through the ensoETM, and that no leaks are present. Failure to initiate water flow prior to insertion may hinder placement of the ensoETM.
6. Lubricate the ensoETM generously with water soluble lubricant prior to insertion. Do NOT use petroleum-based products, because these may be harmful to the respiratory tract.
7. Insert the ensoETM using gentle pressure posteriorly and downwards through the mouth, past the oropharynx and into the esophagus. Gently assist the passage of the ensoETM with light pressure until the required length of tube has been inserted.
8. Do not use force during insertion of the ensoETM, because this may cause bleeding and/or damage to the oropharynx or other structures. If resistance is encountered during insertion of the ensoETM, immediately stop the procedure.
9. Confirm placement of the ensoETM by the following:
    a. injecting 5 to 20 mL of air (with a 50 or 60 mL syringe) through the central lumen while auscultating over the stomach for a “swoosh” or a “burp” indicating gastric placement,
    b. aspirating gastric contents with a syringe (using a 50 or 60 mL syringe) through the central lumen, and
    c. confirming the location and placement of the ensoETM with an x-ray.
10. Secure the ensoETM with a securement device or tape in accordance with hospital protocol. Do not secure the ensoETM to the endotracheal tube because it may displace the endotracheal tube. Ensure the ensoETM and tube set connections are not in contact with the patient’s skin. Direct contact between the ensoETM and exposed skin may cause shivering.
11. For stomach decompression, connect the central lumen of the ensoETM (Figure 1) to low-intermittent suction using standard suction tubing (not supplied) and adaptor (not supplied). Always use the lowest suction setting that will effectively decompress the stomach.
12. For enteral administration of fluids, connect the central lumen of the ensoETM (Figure 1) to an enteral administration system with an ISO 80369-3 compliant female connector (not supplied). Flush the tube with 15 to 30 mL of water before and after the enteral administration of fluids. Flush the tube with 15 to 30 mL of water every 4 to 6 hours during continuous enteral administration of fluids. If using an electrically operated enteral administration system, it must (a) be rated at least type BF for patient contact, (b) meet the applicable requirements of IEC 60601-1, and (c) have a maximum pressure of not more than 20 psi.
13. If the central lumen of the ensoETM becomes blocked or clogged, standard approaches for clearing blocked gastric tubes are recommended. For example, disconnect the ensoETM from wall suction or the enteral administration system and use a saline flush. If the standard approaches are unsuccessful, it may be necessary to remove and then replace the ensoETM.
14. Monitor patient temperature using both monitors during use. Ensure that the temperature monitors are reporting temperatures that are in agreement; if the discrepancy between the two monitors is greater than 0.5°C, discontinue treatment and investigate the cause of the discrepancy. Replace the temperature probes or secondary monitor if necessary. Ensure both temperature probes remain in place without accidental dislodgement during the entire course of patient treatment. Monitor circulating coolant temperature and ensure that it does not fall below 4°C or exceed 42°C.

Note: After this product has been used it may be a potential biohazard. Handle and dispose of the device in a biohazard waste container in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

Note: Report any serious incident that has occurred in relation to this device to Attune Medical and the applicable regulatory authority for the location in which the user and/or patient is established.

Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician.

U.S. Patents # 8,231,664, # 8,444,684, # 8,523,929 and # 9,326,890. International Patent # EP2401023B1. European Registered Community Design (No. 002243055-0001). Additional U.S. and International patents pending.

An electronic version of this instructions for use is available at: www.attune-medical.com/ifu/ecd03-a.

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Symbol Glossary

Symbol	Symbol Title	Explanatory Text	Symbol Reference Number	Standard Title and Designation Number
	Manufacturer	Indicates the medical device manufacturer.	5.1.1	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Use-by date	Indicates the date after which the medical device is not to be used.	5.1.4	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	5.4.3	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Do not reuse	Indicates a medical device that is intended for one single use only.	5.4.2	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	5.2.8	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	5.2.7	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Not made with natural rubber latex	Indicates that natural rubber latex was not used in the construction within the medical device or the packaging of a medical device.	5.4.5 & Annex B.2 Negation Symbol	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Medical device	Indicates the item is a medical device.	5.7.7	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Prescription only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.	N/A	21 CFR 801.109, Labeling-Prescription Devices 21 CFR 801.15(c)(1)(i)F, Labeling- Medical devices; prominence of required label statements; use of symbols in labeling