Instructions for Use General Purpose (Esophageal/Rectal) Temperature Probe

Thermistor: YSI 400 Series Equivalent

REF 4009-ER, 40012-ER

	Read Instructions for use
	Single patient use
	Do not use if package is damaged
	Product does not contain natural rubber latex
STERILE EO	Sterilized with Ethylene Oxide
Rx only	Federal (U.S.A.) Law restricts this device to be sold by or on the order of a physician.

DESCRIPTION:

The Starboard Medical General Purpose (Esophageal/Rectal) temperature probe is used for routine monitoring of body temperature. The probe is designed to be inserted into the esophagus, nasopharynx, or rectum. The temperature monitoring sensor is located inside the probe at the proximal end. The accuracy of the sensor is: ±0.1˚C at 37˚C and ±0.2˚C at 5˚C and 45˚C. The Starboard Medical General Purpose temperature probe is designed for use with patient temperature monitoring equipment compatible with YSI 400 Series or equivalent thermistors. The general purpose probe interfaces with Starboard Medical cables (C400MP-M, C400P-M, and C400MR) for connection to the temperature monitoring equipment. The probes are disposable and available in size 9 and 12 French.

INDICATIONS:

The Starboard Medical General Purpose (Esophageal/Rectal) temperature probe is indicated for continuous patient temperature monitoring when these placement sites are clinically recommended. The probe is designed for insertion into the esophagus, nasopharynx, or rectum.

CONTRAINDICATIONS:

The General Purpose (Esophageal/Rectal) temperature probe may be contraindicated in neonates or small infants. Esophageal placement is contraindicated in patients with esophageal diverticulum or stenosis and/or in patients undergoing laser surgery, internal jugular artery catheterization, or tracheotomy procedures.

ADVERSE REACTIONS:

The following adverse reactions have been reported during clinical application of the general purpose (esophageal/rectal) temperature probe:

- Accidental tracheal or bronchial placement accompanied with an airway obstruction.
- Esophageal abrasion and/or perforation, nasal pharyngeal abrasion and/or bleeding, rectal abrasion, perforation and/or bleeding.
- Tissue burns due to aberrant electro-cautery radiofrequency current pathways

WARNINGS:

If the esophageal/rectal temperature probe is utilized during surgical procedures using electrocautery, the following may occur:

- Artificial fluctuations in temperature readings.
- Localized tissue burns due to the thermistor and lead wire acting as an alternate path for the radiofrequency current to return to ground.

Note: This product has been tested for biocompatibility-Category B Prolonged Mucosal Tissue Contact (24h-30d), per ISO 10933.

The risk of localized tissue burns can be minimized by having the active and ground probes of the electro-cautery system in a close proximity to each other. All parts of the esophageal/rectal temperature probe and cable shall be away from the electro-cautery probes and connecting cables and, therefore, outside of the radio-frequency current field.

- The Starboard Medical General Purpose temperature probe has not been evaluated for safety and compatibility in the MR environment.

DIRECTIONS FOR USE:

1. Verify the compatibility of the temperature probe, connecting cable, and temperature monitoring equipment.
2. Remove the probe from its sterile package.
3. Lubricate probe with suitable water-soluble lubricant prior to insertion and place the probe in situ in accordance with currently accepted clinical practices.
   a. In patients requiring intubation, intubate the patient first and then insert the probe into the esophagus.
4. Verify its location in accordance with currently accepted clinical practices.
5. Connect the probe to the appropriate reusable temperature cable. Align the connectors and push firmly together. Misalignments and forced connections may cause probe failure.
6. Connect the cable to the temperature cable receptacle on the temperature monitoring equipment. Secure the cable to avoid pulling the temperature probe.
7. Follow clinical best practices to reduce the risk of device related pressure injury. Do not place the probe or cable directly under the patient.
8. Check location of device regularly.
9. Upon completion of temperature monitoring, carefully remove the probe from the insertion location according to currently accepted clinical practice.
   a. If placed in the esophagus, remove the probe prior to endotracheal tube removal.
10. Disconnect the probe from the cable by grasping both the cable connector and probe connector firmly and pulling apart.
11. Dispose of the probe according to facility protocol.

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