Instructions for Use
Tympanic Temperature Sensor

Thermistor: YSI 400 Series Equivalent

REF 400-TY, 400-TYP

	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 Tympanic temperature sensor is intended for use in routine continuous monitoring of the tympanic temperature as an indicator of core body temperature when this type of measurement is clinically indicated. The tympanic temperature sensor is designed for atraumatic placement within the ear canal in proximity of the tympanic membrane. The tympanic temperature sensor is placed at the end of the PVC tubing with the sensor's tip outside of the tubing. A small compressible foam on the sensor tip guards against traumatic effects on the tympanic membrane. A large compressible foam distal to the tip secures the sensor in place and prevents the communication of air between the ear canal and the outside. 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 Tympanic temperature sensors are designed for use with patient temperature monitoring equipment compatible with YSI 400 Series or equivalent thermistors. The tympanic sensors interface with Starboard Medical cables (C400MP-M, C400P-M, and C400MR) for connection to the temperature monitoring equipment. The tympanic temperature sensors are disposable, single patient use only. The sensors are available in pediatric and adult sizes.

INDICATIONS:

The Starboard Medical Tympanic temperature sensor is indicated for continuous monitoring of patient temperature when the ear canal placement site is clinically recommended. The probe is designed for insertion into the ear canal in the proximity of the tympanic membrane.

CONTRAINDICATIONS:

Use of the tympanic temperature sensor is contraindicated in neonates and patients having ear pathology, such as: infections, tumors, perforated ear drums, and polyps. It is contraindicated in neonates and in patients whose ear is too small or with anatomical shape and size not suitable for insertion of the temperature probe.

ADVERSE REACTIONS:

Reported adverse reactions associated with the usage of tympanic sensors are ear-ache, otitis externa, decreased hearing, bleeding from tympanic membrane or ear canal, and perforation of the tympanic membrane.

WARNINGS:

During insertion, if resistance is felt, stop, and pull the sensor back slightly. Following in situ sensor placement, no extra pressure by any external means should be applied to the sensor. Extra pressure may traumatize the tympanic membrane. In neonates and pediatric patients because of short ear canal, extra care should be applied while using this approach to monitor temperature. If the tympanic temperature sensor is utilized during surgical procedures using electro-cautery, 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 radio-frequency current to return to ground.

The risk of localized tissue burns can be minimized by having the active and ground probes of the electro-cautery system in proximity to each other. All parts of the tympanic temperature sensor and cable shall be away from the electrocautery probes and connecting cables and, therefore, outside of the radiofrequency current field.

- The Starboard Medical Tympanic temperature sensor has not been evaluated for safety and compatibility in the MR environment.

DIRECTIONS FOR USE:

1. Verify the compatibility of the temperature sensor, connecting cable, and temperature monitoring equipment.
2. Remove the tympanic sensor from its sterile package.
3. Prior to insertion, verify that the ear canal designated for insertion of the sensor does not have any pathology or obstruction.
4. Insert the sensor following clinically accepted practices:
   a. Squeeze and roll both small and large foam cylinders between your fingers.
   b. Pull the pinna (upper portion of the earlobe) in a superior and posterior direction.
   c. Verify that both foams are in a squeezed position, if they are not, repeat step (a).
   d. Hold the tube portion of the sensor and insert it inside the ear with a gentle twisting motion. Do not over insert sensor. If resistance is felt, stop, and slightly withdraw the sensor.
   e. In awake patients who experience discomfort, the sensor should be withdrawn until the discomfort disappears.
   f. Tape the lead wire to the patient's head to secure sensor in situ. Caution should be used not to apply additional pressure on the sensor by touching or by moving the patient's head over the sensor or by any other means.
   g. Align the temperature sensor's connector with the instrument's cable connector and push firmly to ensure proper contact.
   h. Allow several minutes of equilibration prior to the start of monitoring.
   i. When monitoring is completed, remove the sensor as follows: disconnect the sensor from the instrument cable, hold the tube portion and carefully remove the sensor from the ear canal, remove the tape. Perform otoscopic examination.
5. To reduce the risk of pressure injury, do not place sensor cable connection directly under a patient.
6. Check the area of placement of the device regularly.
7. When monitoring is completed, remove the sensor as follows: disconnect the sensor connector from the instrument cable, hold the tube portion and carefully remove the sensor from the ear canal, remove the tape. Perform otoscopic examination.
8. Disconnect the sensor from the cable by grasping both the cable connector and sensor connector firmly and pulling apart.
9. Dispose of the sensor according to facility protocol.

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