Instruction for Use
External Temperature Sensor

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Before using the ProSense system with its accessories you must read and fully understand the ProSense system User Manual. While this document is designed to provide instructions in the use of the **external temperature sensor** with the ProSense ® cryoablation system, it is not intended to take the place of the User Manual and of the user training course which must be completed before using the system.

Intended use / Indications for Use

The temperature sensor is a single use accessory that provides real time temperature measurements when inserted in tissue during cryoablation procedures.

Clinical decisions

The practitioner is solely responsible for all clinical use of the ProSense® cryoablation system and for any result obtained with the device and its accessories.
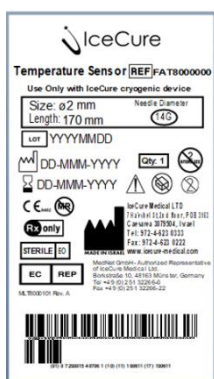
A number of internationally recognized symbols relating to safety requirements and standards are found on the temperature sensor label. These symbols are listed in the ProSense® cryoablation system user manual.

Figure 1: Single use temperature sensor

Use of Temperature Sensor

The temperature sensor is a single use accessory that provides real time temperature measurements when inserted in tissue.

⚠ **The temperature sensor doesn't replace the need for an appropriate imaging system like Ultrasound or CT. It provides pin point measurement of the temperature. Temperature sensor insertion and navigation within tissue must be done under guidance of an appropriate imaging device.**

Prior to starting a procedure, the temperature sensor is connected to the system and then inserted into the desired location within the tissue before or during the procedure.
Insert the sensor at location that gives useful information about the progress of the freezing procedure. For example, the temperature sensor can be placed near the boundary of a tumor to ensure that the entire tumor has been frozen.

Alternatively, the temperature sensor may be placed near an organ that should not be frozen during the procedure to ensure that the ice front has not advanced to this location.

The temperature sensor is not indicated for measuring the body temperature, but only for getting temperature indication around cryoablated areas.

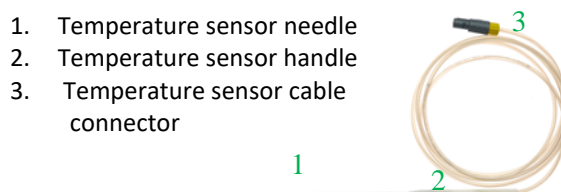The temperature sensor and its components are depicted in the following figure.

1. Temperature sensor needle
2. Temperature sensor handle
3. Temperature sensor cable connector

Figure 2: The temperature sensor and its components

⚠ **Temperature Sensors are not compatible with magnetic resonance imaging**

If you decide to use a temperature sensor, connect it per the following instructions while maintaining sterility:

1. Remove the temperature sensor from the sterile package.
2. Connect the cable connector to the panel connector and ensure the temperature sensor is securely connected.
3. The measured temperature from the sensor tip will appear on the right lower corner of the screen.
4. **Under imaging guidance,** insert the tip of the temperature sensor into the tissue you aim to measure the temperature.
5. At the end of the procedure, gently remove the temperature sensor from the tissue and discard it.

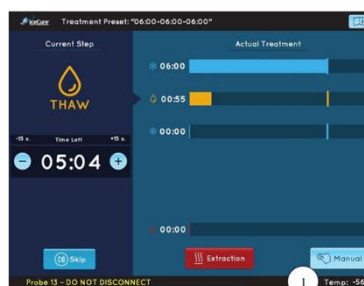Figure 3: Temperature display of sensor in the procedure screen (see No   1)

At the end of the cryoablation procedure the temperature sensor should be removed from the tissue

by carefully pulling it. The extraction should be done only after a passive thaw of a few minutes since the temperature sensor can be surrounded by ice. Removing it too quickly before thawing can damage the target tissue.

⚠ **Before removing the temperature sensor from the tissue, make sure the freeze effect has been deactivated and the sensor can be easily withdrawn. Never use excessive force to extract the temperature sensor.**

Figure 4: ProSense® cryoablation system

Potential Adverse Events and Contraindications

As the usage of the temperature sensor is associated to the cryoablation procedure, the potential Adverse events and contraindications are similar and thus, specified in the user manual of IceCure's cryoablation system and the cryoprobe IFU.

Disassembling the temperature sensor

After using a temperature sensor, pull the gray part of the cable connector backwards to release it, and then pull the cable connector away from the front panel. Following each cryosurgical procedure, discard the single use devices (single-use cryoprobe, single-use temperature sensor, cryohandle cover, and sleeves for the flexible hose and touch screen).
All single use devices are considered to be medical waste and must be disposed of in accordance with medical waste laws and hospital standards. Sharp objects such as the temperature sensor must be disposed of in an adapted container.

⚠ **Temperature sensors are single use and are supplied in a single use packaging. Never reuse a single-use temperature sensor. For each patient, ensure that the previously used single-use temperature sensor have been removed and discarded. Any used temperature sensor should be related as used sharp biohazard waste. Reprocessing a single use device could affect the mechanical or performance or microbiological properties of the product.**

Temperature Sensor technical specifications

Ref number: FAT 8000000
Max temperature: 260 ºC
Needle length: 170 ± 1 mm
Needle diameter: 2 ± 0.02 mm
Wire length: 200 ± 1 cm
Thermocouple wire type K

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