**INDICATION FOR USE**

The cryoICE cryoFORM cryoablation probe, CRYOF™ (also referred to as PROBE) was designed for treatment of cardiac arrhythmias by freezing target tissues, creating an inflammatory response (cryonecrosis) that blocks the electrical conduction pathway.

**DESCRIPTION**

The PROBE is a sterile, single-use cryosurgical instrument designed to achieve controlled temperatures ranging from -50°C to -70°C. It is compatible with the ACM. The PROBE is for single patient use only. Sterility is guaranteed unless the package is opened prior to shipping. If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment. Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number should be followed.

**CAUTION**

- The PROBE is supplied as a sterile instrument and is for single patient use only. Sterility is guaranteed unless the package is opened prior to shipping. If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment. Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number should be followed.

**RECYCLING**

- This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

**IMPORTANT!**

- AtriCure, Inc., prior to shipping. If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment. Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number should be followed.

**NOTE:**

- Do not remove or install PROBE from console unless the ACM is in the Stand-By Mode (ACM V6) and fully vented (ACM V5).

**IMPORTANT:**

- Do not use the PROBE if damaged in any way.
- To avoid damage to the device, do not drop or toss the PROBE. If the PROBE is dropped, do not use. Replace with a new PROBE.
- Do not reprocess or reuse the PROBE. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.

**SYSTEM PERFORMANCE**

- The cryoICE cryoablation system can be sensitive to electrostatic discharge (ESD) and RF emissions, which may temporarily reduce system performance.

**WARNING**

- The PROBE contains pressurized gas during operation. Discontinue use immediately if a breach in the PROBE is suspected, as this may result in release of pressurized gas and injury to the patient or the user.

**CAUTION**

- Do not restrict, kink, clamp, or otherwise damage PROBE malleable tip, rigid shaft, or tubing.
- Ensure there is no undesired tissue contact with the malleable tip or rigid shaft.
- Take care not to restrict, kink, clamp, or otherwise damage PROBE malleable tip during bending.
- Do not use excessive force when using the PROBE in order to avoid tissue damage.
- Do not use the PROBE to freeze tissue inside the beating heart. Use of the PROBE to freeze tissue inside the beating heart may result in patient injury.
- The PROBE is only compatible with the ACM. Use of the PROBE with another manufacturer’s system may damage the device and/or system performance.
- Do not use the PROBE if damage is visible. A new PROBE should be ordered.
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