

*cryo***SPHERE**[®]
PROCEDURAL GUIDE



**The Coolest Innovation
in Pain Management.**

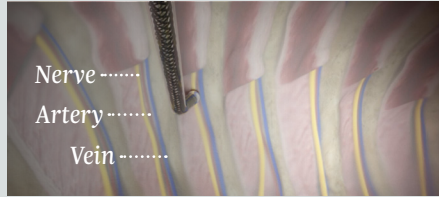
AtriCure

Cryo Nerve Block (cryoNB) Procedure

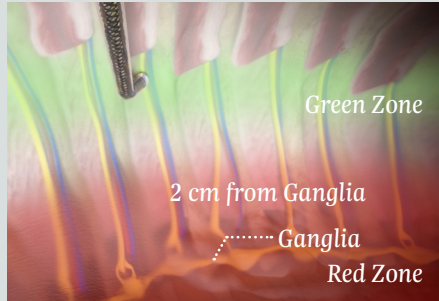
1 / BEND PROBE to ensure optimal placement on the intercostal nerve.



2 / LOCATE THE NERVE in the incisional intercostal space and place the probe on top of it. The ball tip of the probe should be in or walked slightly off the intercostal groove. Maintain gentle probe pressure on tissue throughout cryoablation. Do not move the probe during cryoablation.



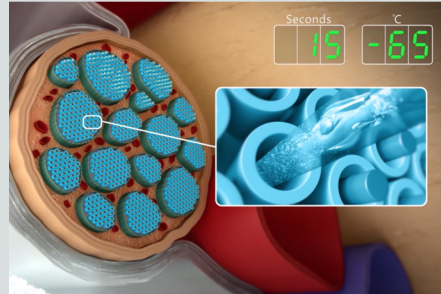
3 / ABLATE at the margin of the membranous section of the intercostal muscle (Green Zone). Maintain a distance of at least 2 cm from the ganglia or 4 cm from the base of the spine to avoid the Red Zone.



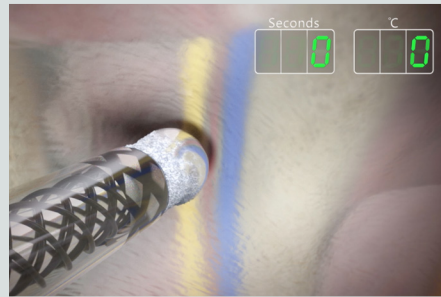
- Cryoablation time should be performed for 120 seconds. The cryoSPHERE probe is designed to operate within the -50 to -70°C range, which should be verified during ablation.
- Five total ablations are recommended: two intercostal spaces above the incision, two below, and one at the level of the incision itself. Cryoablation above the 3rd intercostal space is not recommended due to proximity of the sympathetic trunk. Cryoablation below the 9th intercostal space may cause temporary abdominal muscle bulging. Avoid cryoablation of disturbed incision tissues.



- The therapeutic effect of cryoNB will be a function of location of the nerve ablation and not the length of actual nerve ablated. Degeneration of the nerve occurs from the cryoablation site to the end organ (towards the sternum).

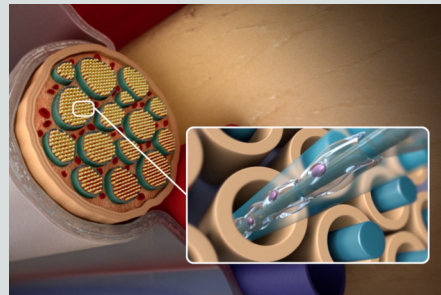


- 4 / As an ablation cycle ends, the probe's **ACTIVE DEFROST** feature allows it to warm to ambient temperature. The probe should be movable without resistance once the frost disappears.



- 5 / **POST-OPERATIVELY, REGENERATION OF THE AXONS** occurs from the cryoablation site to the end organ (towards the sternum).

- Axons within the intercostal nerve that send pain signals are destroyed distal to the cryoablation site. The tubule structures (epineurium, perineurium and endoneurium) of the nerve remain intact allowing the axons to regenerate and nerve function to resume over the course of roughly 1-3 months.



References Available at AtriCure.

U.S. Indications: **For Adult Patients** AtriCure's cryoICE® cryoSPHERE® cryoablation probes are sterile, single use devices intended for use performed by freezing target tissues, creating an inflammatory response (cryonecrosis) for blocking pain by temporarily ablating peripheral nerves. **For Adolescent Patients** The cryoICE cryoSPHERE cryoablation probes are intended for use to temporarily block pain by ablating intercostal nerves under direct visualization¹ in adolescent patients of at least 12 years of age.

¹Direct visualization, in this context, requires that the surgeon is able to see the targeted tissue for cryoablation directly or with assistance from a camera, endoscope or other similar optical technology.

Please review the Instructions for Use for a complete listing of contraindications, warnings, precautions and potential adverse events prior to using these devices.

Rx Only.

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