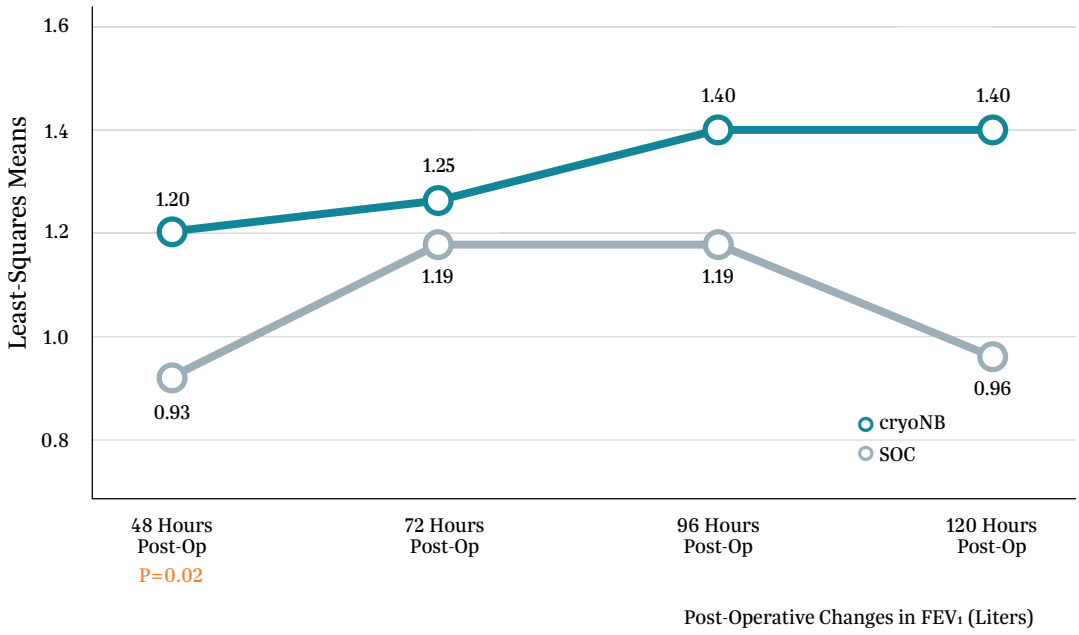
Cryo Nerve Block (FROST Study)

Randomized Clinical Trial

The cryoICE® Cryo Nerve Block (cryoNB) Study for Pain Management in Post Thoracic Procedures via Intercostal Cryoanalgesia (FROST Study)

- **Patients undergoing unilateral thoracotomy cardiac procedures**
- **Co-primary end points at 48 hours**
  - **FEV1** (Forced Expiratory Volume)
  - **VAS** (Visual Analogue Scale)

Respiratory function (FEV_1) through 120 hours post procedure



Results

- FEV1 significantly improved at 48-hours in the treatment arm (p=0.02) and the trend was maintained through 120-hours post procedure
- FEV1 was analyzed using mixed model repeated measures with baseline FEV1 as a covariate

AtriCure

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Objective

ClinicalTrials.gov identifier: NCT02922153

Demonstrate that intraoperative intercostal cryoanalgesia in conjunction with standard of care provides improved analgesic efficacy in patients undergoing unilateral thoracotomy cardiac procedures as compared to current standard of care.

Elucidate complementary strategies for enhanced postoperative pain management of patients at risk for postoperative pulmonary complications from unilateral thoracotomy cardiac procedures.

Device

cryoICE cryoablation system includes:

- cryoICE cryoablation probe, CRYO2* with Cryo1 probe form tool
- AtriCure Cryo Module
- AtriCure Cryo1 Accessory Kit

**The CRYO2 probe is also intended for use in blocking pain by temporarily ablating peripheral nerves.*

Number of Subjects and Sites

Subjects: 83
Patients in cryoNB control arm: 64
Patients in Standard of Care (SOC) arm: 19
Sites: 4 total in the United States

- Beaumont Health System, Royal Oaks, MI
- University of Michigan Hospital, Ann Arbor, MI
- Allina Health United Hospital, St. Paul, MN
- Keck Medicine of USC, Los Angeles, CA

Study Design

Prospective, multi-center, randomized (3:1), blinded study

Patient Population

Patients age 18-85 years, undergoing unilateral thoracotomy cardiac procedures

Study Duration

Approximately 180 days post index procedure

FROST Study Results

Primary Endpoint VAS Pain Scores

Mean VAS pain scores at surgical site at 48 hours post procedure (co-primary endpoint) and through 120 hours were similar between the two study arms. The difference was non-significant.

Secondary Endpoint Long-Term Allodynia

All patients in the cryoNB control treatment arm underwent allodynia screening at 3 and 6 month visit post procedure. One incidence of allodynia (1.6%, 1/64), as confirmed by cotton swab test at 6 months was reported. No further intervention was needed to address allodynia at 10 month visit post procedure.

For more information on the FROST clinical trial visit: https://clinicaltrials.gov/ct2/show/NCT02922153.

For more information on the FROST clinical trial publication visit: https://link.springer.com/article/10.1007/s40122-021-00318-0.

Note: *This AtriCure communication is intended to provide objective information about the use of AtriCure's Technology, including where and how the device can be used within the continuum of care. The results of this study have not been evaluated by FDA for new indications or intended uses.*

Indications for Use: ***For Adult Patients*** *AtriCure's Cryo2 cryoICE cryoablation probes are sterile, single use devices intended for use in the cryosurgical treatment of cardiac arrhythmias by freezing target tissues, creating an inflammatory response (cryonecrosis) that blocks the electrical conduction pathway. The Cryo2 cryoICE cryo-ablation probes are also intended for use to temporarily block pain by ablating peripheral nerves.* ***For Adolescent Patients*** *The Cryo2 cryoICE cryo-ablation probes are intended for use to temporarily block pain by ablating intercostal nerves under direct visualization[1] in adolescent patients of at least 12 years of age. [1]Direct 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.* ***Rx Only.***

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