Date: October 16, 2024

Canadian Heart Rhythm Society
Ablation Committee

RE: Boston Scientific POLARx™ and POLARx™ FIT Cryoablation Balloon Catheters Instructions for Use Updates Related to Atrio-esophageal Fistula Risk

POLARx Cryoablation Catheters

Product Description	Material Number (UPN)	GTIN Number
CRBS POLARX BALLOON CATHETER ST 28MM OUS	M004CRBS2000	08714729992561
CRBS POLARX BALLOON CATHETER LT 28MM OUS	M004CRBS2100	08714729992561
CRBS POLARX FIT BALLOON CATHETER ST OUS	M004CRBS2010	08714729992578
CRBS POLARX FIT BALLOON CATHETER ST US	M004CRBS2060	00191506016463
CRBS POLARX FIT BALLOON CATHETER LT OUS	M004CRBS2110	08714729992578
CRBS POLARX FIT BALLOON CATHETER LT US	M004CRBS2160	00191506016463

Nature of the Advisory:
Boston Scientific has issued an advisory relating to the occurrence of atrio-esophageal (AE) fistula with the use of the POLARx™ and POLARx™ FIT cryoablation catheters. In post-market surveillance, Boston Scientific has identified a higher-than-expected events of AE fistula. Boston Scientific has not identified any incident of catheter or any equipment malfunction contributing to these cases. However, review of these cases suggested a possible role of the frequency and intensity of cryoablation contributing to adverse outcomes. This has led to updates to the instructions for use, to avoid potential factors that may increase the risk of AE fistula.

Scope of the problem:
In post-market surveillance, there have been seven reports of AE fistula among 69,000 catheters delivered, world-wide. Four of these seven cases have resulted in patient death. Although precise incidence estimates are challenging in this setting, this equates to an approximate risk of

0.010% or 1/10,000 patients. This remains lower than reported rates of AE fistula after radiofrequency ablation (estimated at 0.038% or 3.8/10,000 patients) but higher than the estimated rate with the other cryoablation catheter used for atrial fibrillation ablation (estimated at 0.0015% or 0.15/10,000 patients).

Given the potential association between the intensity of cryo-applications and the occurrence of AE fistula, the manufacturer has recommended to perform esophageal location and temperature monitoring, avoiding direct application of cryoablation over the esophagus, avoiding balloon temperatures of ≤-65 degrees Celsius during ablation, stopping ablation if the esophageal temperature decreases to ≤20 degrees Celsius, and using the minimum amount of cryo-applications to achieve pulmonary vein isolation (avoiding immediate repeat applications).

Response of the CHRS Ablation Committee:
The CHRS Ablation Committee recommends modified use of the POLARx™ and POLARx™ FIT catheters to minimize the occurrence of AE fistula with cryoablation for atrial fibrillation. The manufacturers recommendations are based both on best practice but also reinforce recommendations that mirror the catheter use in the FROzEN AF clinical trial.

The Committee has made the following ***recommendations***, reflecting the contemporary use of the POLARx™ and POLARx™ FIT catheters in Canada:

1. Ablation should be stopped for balloon temperatures ≤-65 degrees Celsius
2. The minimal number of cryo-applications required for pulmonary vein isolation should be used and repeat applications in the same location should be avoided, if possible
3. Esophageal temperature monitoring may be considered, though there is limited evidence supporting the use of routine esophageal monitoring to prevent AE fistulae.
4. If esophageal temperature monitoring is used:
    a. ablation should be stopped if the esophageal temperature is ≤20 degrees Celsius
    b. altered ablation catheter positioning could be considered, if feasible, to limit ablation near the esophagus.
5. Esophageal location tagging, using barium, intra-cardiac echo or other methods may be considered, with altered ablation catheter positioning, if feasible, to limit ablation near the esophagus.

<u>CHRS Ablation Committee</u>
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