Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عمان
وزارة الصحة
مركز سلامة الدواء
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 150 **dated** 23/10/2024 **Regarding SFDA Field Safety Notice of POLARX BALLOON CATHETER (Multiple models) from (mfr: Boston Scientific).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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Circular No. 150/ **2024**

19 -04-1446 H
23 -10-2024

Field Safety Notice of POLARX BALLOON CATHETER (Multiple models) from Boston Scientific.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/144
Product	POLARX BALLOON CATHETER (Multiple models).
Manufacturer	Boston Scientific.
Local agent	Global Leading Excellence (GLE).
The affected products	(GTIN Number) (Material Number (UPN)) (Product Description) CRBS POLARX BALLOON CATHETER ST 28MM M004CRBS2000 08714729992561 CRBS POLARX BALLOON CATHETER LT 28MM M004CRBS2100 08714729992660 CRBS POLARX FIT BALLOON CATHETER ST M004CRBS2010 08714729992578 CRBS POLARX FIT BALLOON CATHETER ST M004CRBS2060 08714729992622 CRBS POLARX FIT BALLOON CATHETER LT M004CRBS2110 00191506016456 CRBS POLARX FIT BALLOON CATHETER LT M004CRBS2160 00191506016463
Reason	AE fistula is a known and inherent risk for patients undergoing catheter ablation for atrial fibrillation. Although uncommon, esophageal injury is a potentially life-threatening complication due to proximity of the esophagus to the posterior left atrium.
Action	1. Review the IFU Updates related to AE fistula, as detailed in Appendix 1. 2. Review Table 1 for a summary of cryoablation application parameters from the FROzENAF clinical trial, which demonstrated safety and effectiveness of the POLARx Cryoablation System. 3. To provide awareness of this information, share this communication with clinicians in your hospital that use the Boston Scientific POLARx Cryoablation System, including the POLARx Catheter, the POLARx FIT Catheter and the SMARTFREEZE Console. Also share this communication with any other organization to which these devices may have been transferred. 4. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
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Al-Mowasat Medical
Dr Ahmad Taha
Doctor
Plot 2 Block 3 G 79
31411 Dammam
Saudi Arabia

<Reference: 97251520-FA> 10 October 2024

Urgent Field Safety Notice – Product Advisory
POLARx™ and POLARx™ FIT Cryoablation Catheter Instructions for Use (IFUs) related to the risk of atrio-esophageal (AE) fistula

Dear Dr Ahmad Taha,

This letter provides important information regarding updates to the POLARx™ and POLARx™ FIT Cryoablation Catheter Instructions for Use (IFUs) related to the risk of atrio-esophageal (AE) fistula, as detailed in **Appendix 1**. The POLARx Cryoablation Catheters (applicable device information listed below) are components of the Boston Scientific POLARx Cryoablation System, which is used in conjunction with the SMARTFREEZE™ Console.

POLARx Cryoablation Catheters

Product Description	Material Number (UPN)	GTIN Number
CRBS POLARX BALLOON CATHETER ST 28MM	M004CRBS2000	08714729992561
CRBS POLARX BALLOON CATHETER LT 28MM	M004CRBS2100	08714729992660
CRBS POLARX FIT BALLOON CATHETER ST	M004CRBS2010	08714729992578
CRBS POLARX FIT BALLOON CATHETER ST	M004CRBS2060	08714729992622
CRBS POLARX FIT BALLOON CATHETER LT	M004CRBS2110	00191506016456
CRBS POLARX FIT BALLOON CATHETER LT	M004CRBS2160	00191506016463

Description:
AE fistula is a known and inherent risk for patients undergoing catheter ablation for atrial fibrillation. Although uncommon, esophageal injury is a potentially life-threatening complication due to proximity of the esophagus to the posterior left atrium. Since commercial introduction of the POLARx Cryoablation System in 2020, Boston Scientific has received seven (7) reports (worldwide) of AE fistula occurring following atrial fibrillation ablations; four (4) of these reports were associated with a patient death.

Detailed investigation of the available data associated with these AE fistula events did not identify product performance-related issues with any component of the cryoablation system; however, frequency and intensity of cryoablation applications were observed as possible contributing factors. Therefore, Boston Scientific is updating the POLARx and POLARx FIT cryoablation balloon catheter IFUs to emphasize the risk of AE fistula, as well as practices that may reduce this risk. These IFU updates align with the FROzEN AF clinical trial[1]. Boston Scientific is communicating these IFU updates to all global customers and affected worldwide regulatory authorities to minimize the risk of AE fistula associated with use of the POLARx Cryoablation System. Following applicable regulatory approval, updated IFUs will be packaged and shipped with corresponding POLARx Cryoablation System devices.

Recommendations

1- Review the IFU Updates related to AE fistula, as detailed in **Appendix 1**.

2- Review **Table 1** for a summary of cryoablation application parameters from the FROzEN AF clinical trial, which demonstrated safety and effectiveness of the POLARx Cryoablation System.

Table 1: Cryoablation Parameters from the FROzEN AF Clinical Trial

Parameters	Left Inferior (LIPV	Left Superior (LSPV)	Right Inferior (RIPV)	Right Superior (RSPV)
# of cryo applications	1.67 ± 1.18	1.77 ± 1.23	1.8 ± 1.42	1.86 ± 1.24
# of cryo applications >60s	1.54 ± 0.97	1.61 ± 0.96	1.63 ± 1.12	1.63 ± 0.95
Lowest Measured Balloon Temperature (°C)	−53.95 ± 7.45	−58.29 ± 5.96	−55.63 ± 6.43	−58.36 ± 6.33
Total Duration (min)	4.34 ± 2.36	4.41 ± 2.35	4.49 ± 2.82	4.3 ± 2.22

3- To provide awareness of this information, share this communication with clinicians in your hospital that use the Boston Scientific POLARx Cryoablation System, including the POLARx Catheter, the POLARx FIT Catheter and the SMARTFREEZE Console. Also share this communication with any other organization to which these devices may have been transferred.

4- Maintain a copy of this notice in your facility's records.

Instructions:

- **Immediately post this information on or near the product to ensure this information is easily accessible to all users of the device.**
- Please **complete the enclosed Acknowledgment Form** and **send it to Boston Scientific at Najwa Alkenani - najwa.alkenani@bsci.com by 30 October 2024.**
- Any adverse events or quality concerns associated with use of this product should be reported to Boston Scientific.

[1] Ellenbogen LA, Mittal S, Varma N, et al. One-year outcomes of pulmonary vein isolation with a novel cryoballoon: primary results of the FROZEN AF trial. *J Cardiovasc Electrophysiol*. 2024;35:832-842. doi:10.1111/jce.16220

Although Boston Scientific is not physically recalling any product, your Competent Authority is being notified of this Field Safety Notice.

Patient safety remains Boston Scientific's highest priority. We are committed to ensuring you have timely, relevant information for managing your patients and optimizing safe and effective product use. If you have additional questions regarding this communication, please contact your local Boston Scientific sales representative.

Sincerely,

Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Attachments: - APPENDIX 1 – IFU Updates
- Acknowledgment Form

APPENDIX 1 – Updates to POLARx™ and POLARx™ FIT Instructions for Use (IFU)

NOTE: Table 2 provides additional warnings and procedural instruction updates to various sections of the IFU for the POLARx and POLARx FIT Catheters; the updated wording is provided in red text.

Table 2: Updates to POLARx and POLARx FIT IFU

Section	Labeling Updates
Warnings	• Cryoablations may cause collateral thermal injury to the esophagus and in rare instances atrio-esophageal (AE) fistulas. ~~Temperature monitoring with a probe placed within the esophagus may mitigate this risk.~~ To minimize potential esophageal injury, the following is recommended: - Monitor the location of the cryoballoon relative to the esophagus prior to delivering cryotherapy. - Avoid performing cryoablation directly over the esophagus. - DO NOT perform cryoablation directly on the posterior wall of the left atrium, as this may place the cryoballoon over the esophagus and increase the risk of freezing injury to the esophagus. - Avoid catheter manipulation that may deform the cryoballoon or displace the atrium towards the esophagus. - Ablate cautiously if the balloon is within close proximity to the esophagus. Stop the ablation if the balloon temperature decreases to -65 °C and avoid repeating ablations immediately in the same location to minimize potential for thermal accumulation. - Utilize temperature monitoring with a probe placed in the esophagus. Stop the ablation if the esophagus probe measurement decreases to 20 °C and allow the esophagus probe temperature to return to baseline levels before initiating another cryoablation application.
Procedure	16. Perform the cryoablation. (Refer to the SMARTFREEZE Console User's Manual for setup, setting and use). To minimize the potential for unintended thermal injury, the following is recommended: • Utilize standard-of-care practices for verifying balloon position, esophageal monitoring, and phrenic nerve monitoring. • Ensure the balloon is appropriately positioned prior to starting cryoablation. • Utilize the minimum number of cryoablation applications necessary to achieve PV isolation and avoid immediately repeating ablations in the same location. Note the POLARx FIT cryoablation catheter demonstrated effectiveness in the FROzEN AF clinical trial without use of additional applications following PV isolation. • Stop the ablation if the balloon temperature decreases to -65 °C.

Boston Scientific

Please complete the form & Send it to:
Najwa Alkenani - najwa.alkenani@bsci.com

744072 - Al-Mowasat Medical - Dammam - Saudi Arabia

Acknowledgement Form – Urgent Field Safety Notice

POLARx™ and POLARx™ FIT Cryoablation Catheter Instructions for Use (IFUs) related to the risk of atrio-esophageal (AE) fistula

97251520-FA

By signing this form, I confirm that

I have read and understood
the Boston Scientific Field Safety Notice

dated 10 October 2024 for

POLARx™ and POLARx™ FIT Cryoablation Catheter Instructions for Use (IFUs) related to the risk of atrio-esophageal (AE) fistula

NAME* _____ Title _____

Telephone _____ Email _____

SIGNATURE* _____ **DATE*** _____
* Required field dd/mm/yyyy