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 174 **dated** 23/12/2024 **Regarding Field Safety Corrective Action of ACURATE neo2TM and ACURATE PrimeTM Aortic Valve Systems (Transcatheter Aortic Valve Implantation (TAVI)) 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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Ministry of Health
Drug Safety Center
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سلطنة عمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 174 / 2024

22-06-1446 H
23-12-2024

FSCA of ACURATE neo2TM and ACURATE PrimeTM Aortic Valve Systems (Transcatheter Aortic Valve Implantation (TAVI)) from Boston Scientific.

Source	Boston Scientific through their local distributor Global Leading Excellence (GLE).
Product	ACURATE neo2TM and ACURATE PrimeTM Aortic Valve Systems (Transcatheter Aortic Valve Implantation (TAVI)).
Manufacturer	Boston Scientific.
Local agent	Global Leading Excellence (GLE).
The affected products	Multiple Models & Codes. Please refer to attachment.
Reason	New information related to valve under expansion, that emerged from review of the 1-year clinical trial data from the ACURATE IDE. Detailed investigation of the 1-year data identified valve under expansion as a potential leading contributing factor of the missed primary endpoint. ACURATE neo2 valve under expansion was associated with an increased rate of primary endpoint events compared to cases where the ACURATE neo2 valve was expanded. However, valve under expansion was not previously identified through clinical experiences with the ACURATE neo2 valve nor through ACURATE neo2 post market surveillance.
Action	1. For ACURATE neo2, review IFU updates related to valve under expansion, as detailed in the attachment. 2. For ACURATE neo2, complete training on the importance of valve expansion which will be provided by Boston Scientific. 3. For ACURATE Prime, follow existing IFUs and training provided by Boston Scientific. 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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Healthcare Professionals
Cardio

<Reference: 97307925-FA> 7 November 2024

Urgent Field Safety Notice – Product Advisory
ACURATE neo2™ and ACURATE Prime™ Aortic Valve Systems
(Transcatheter Aortic Valve Implantation (TAVI))

Subject: ACURATE *neo2*™ Aortic Valve System (TAVI) Instructions for Use and Physician Training Updates, and recommendations for ACURATE Prime™, related to Valve Under Expansion Risk.

Dear Healthcare Professionals,

This letter provides important information regarding updates to the ACURATE *neo2*™ Aortic Valve System Instructions for Use (IFUs) and Physician Training related to the risk of valve under expansion, as detailed in **Appendix 1**.

The updates related to the risk of valve under expansion are already included in the ACURATE Prime™ Instructions for Use (IFUs) and Physician Training. Due to its recent launch (October 2024), ACURATE Prime may not yet be available in all regions.

Key Points:

- Physicians who use ACURATE *neo2* should follow the recommendations laid out in this letter.
- Physicians who use ACURATE Prime should continue to follow the current IFU and training already provided.
- Patients who have been treated with an ACURATE *neo2* or an ACURATE Prime valve do not require additional patient management and should continue to follow standard patient care at the discretion of their physician.

Boston Scientific is not asking for the return of any product. The ACURATE *neo2* and ACURATE Prime products continue to meet required specifications and remain available for use.

Device Description:
ACURATE *neo2*™ Aortic Valve System consists of the ACURATE *neo2*™ Valve, which is used in conjunction with the ACURATE *neo2*™ Transfemoral Delivery System and the ACURATE *neo2*™ Loading Kit.

ACURATE Prime™ Aortic Valve System consists of the ACURATE Prime ™ Valve, which is used in conjunction with the ACURATE Prime ™ Delivery System and the ACURATE Prime™ Loading Kit.

Our records indicate that your facility received some of the concerned product. Th**e table below provides a complete list of all affected products**, including Product Description, Material Number (UPN), GTIN, and Lot/Batch numbers. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice**.

Product Description	Material Number (UPN)	GTIN Number	Lot Number
ACURATE *neo2*™ Valve	SYM-SV23-004	07640168110130	ALL
	SYM-SV25-004	07640168110147	
	SYM-SV27-004	07640168110154	
	SYM-SV23-005	00191506022228	
	SYM-SV25-005	00191506022235	
	SYM-SV27-005	00191506022242	
ACURATE *neo2*™ Transfemoral Delivery System	SYM-DS-005	07640168110123	ALL
	SYM-DS-010	00191506019402	
ACURATE *neo2*™ Loading Kit	SYM-AC-010	00191506019419	ALL
ACURATE Prime™ Valve	H74939690230	00191506030858	ALL
	H74939690250	00191506030865	
	H74939690270	00191506030872	
	H74939690290	00191506030889	
ACURATE Prime™ Delivery System	H749396822325	00191506030933	ALL
	H749396822729	00191506030940	
ACURATE Prime™ Loading Kit	H749396942325	00191506030971	ALL
	H749396942729	00191506030988	

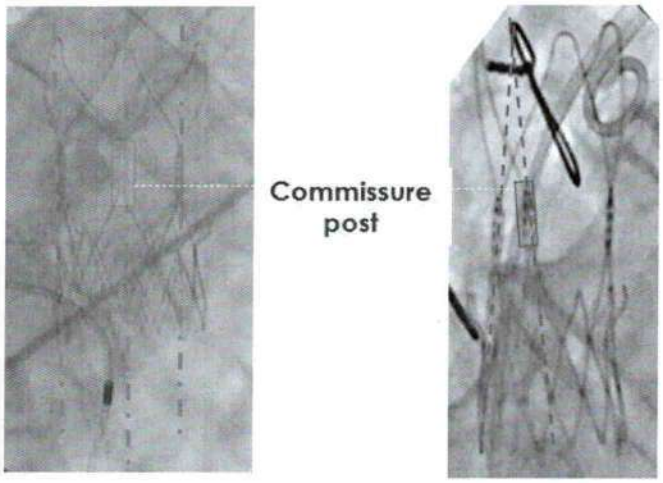
Description
Boston Scientific has become aware of new information related to valve under expansion, that emerged from review of the 1-year clinical trial data from the ACURATE IDE.

The ACURATE IDE clinical study is a prospective, multi-centre study of US and Canada sites only. It is designed to evaluate the safety and effectiveness of the ACURATE *neo2* Aortic Valve System for TAVI in subjects with severe native aortic stenosis who are indicated for TAVI.

The Main Randomized Cohort represents 1:1 randomization of ACURATE neo2 as the test article versus the Control which is the commercially available SAPIEN 3 (Edwards) or Evolut (Medtronic). At 1-year, the ACURATE IDE missed its primary endpoint (ACURATE *neo2* non-inferiority to the Control group for the composite of death, stroke and rehospitalization).

Detailed investigation of the 1-year data identified valve under expansion as a potential leading contributing factor of the missed primary endpoint. ACURATE *neo2* valve under expansion was associated with an increased rate of primary endpoint events compared to cases where the ACURATE *neo2* valve was expanded. However, valve under expansion was not previously identified through clinical experiences with the ACURATE *neo2* valve nor through ACURATE *neo2* post market surveillance.

Figure 1: ACURATE valve under fluoroscopy - valve under expansion is recognized as a non-parallel Commissure Post



Parallel Commissure Post
Valve is Expanded

Non-Parallel Commissure Post
Valve is Under Expanded

Valve under expansion can be seen under fluoroscopy (as shown in **Figure 1**) during the index procedure and mitigated with appropriate pre-dilation and post-dilation practices. Therefore, Boston Scientific has updated the ACURATE *neo2* IFUs for the risk of valve under expansion and the practices that may reduce this risk, as follows:

- Increased emphasis on pre-dilation with an appropriately sized valvuloplasty balloon.
- Use of a second fluoroscopy view during the procedure to recognize non-parallel commissure posts and under expansion.
- Post-dilation, in accordance with IFU, to improve valve under expansion.

As ACURATE *neo2* is a product with mandatory physician training, Boston Scientific is also updating the ACURATE *neo2* global physician training program for the risk of valve under expansion and the practices that may reduce this risk. This is consistent with ACURATE PRIME training already available and deployed to new ACURATE Prime users.

Recommendations

1- For ACURATE *neo2,* review IFU updates related to valve under expansion, as detailed in **Appendix 1**.

2- For ACURATE *neo2, c*omplete training on the importance of valve expansion which will be provided by Boston Scientific.

3- For ACURATE Prime, follow existing IFUs and training provided by Boston Scientific.

4- To provide awareness of this information, share this notice with any other clinicians in your hospital who use the Boston Scientific ACURATE *neo2* or ACURATE Prime Aortic Valve Systems. Also share this communication with any other organization to which these devices may have been transferred. Please maintain awareness of this notice for an appropriate period to ensure its effectiveness.

5- Maintain a copy of this notice in your facili²ty's records.

6- Continue to report all device-related incidents or quality concerns experienced with the use of these devices to Boston Scientific, distributor or local representative and the national Competent Authority if appropriate (in accordance with all applicable local regulations).

Instructions:

1- **Please complete the attached Acknowledgement Form** even if you do not have any affected product.

2- **When completed, please return the Acknowledgement Form to your Boston Scientific office** for the attention of **Najwa Alkenani - najwa.alkenani@bsci.com** on or before **27 November 2024**.

Your national Competent Authority has been informed of this Field Safety Notice.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.
If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

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

Attachments: - APPENDIX 1 – IFU Updates
- Acknowledgment Form

APPENDIX 1 – Updates to ACURATE *neo2*™ Aortic Valve System Instructions for Use (IFU)

NOTE: Table below provides ACURATE neo2™ Aortic Valve System IFU updates; the updated wording is provided in blue text.

Delivery System and Loading Kit IFU(s)	
Changing From	Changing To
Precautions During Use: The implant procedure should be conducted under fluoroscopic guidance.	***Precautions During Use:*** The implant procedure should be conducted under fluoroscopic guidance. The correct fluoroscopy projection for implantation of the Valve is when all three (3) native aortic valve cusps are in the same plane. After final deployment of the Valve, the use of more than one fluoroscopic projection supports assessment and evaluation of Valve position and expansion.
Pre-dilation of Native Valve: Prepare the appropriate Balloon Valvuloplasty Catheter (BVC) according to its Instructions For Use	***Pre-dilation of Native Valve:*** Prepare the appropriate Balloon Valvuloplasty Catheter (BVC) according to manufacturer's Instructions For Use. NOTE: It is important to correctly size the BVC for effective pre-dilation. Effective pre-dilation can help reduce the need for post-dilation.
Verification of Valve Position and Post-Implant Monitoring: Leaving the guidewire in position across the Valve, measure both invasive and non-invasive hemodynamic parameters to check positioning and function of the Valve. Perform an angiogram to evaluate device performance and coronary patency after Valve deployment. The use of echocardiographic imaging supports the assessment of the position of the Valve and an evaluation of the para-valvular and intravalvular leakage. Post-dilation of ACURATE neo2 Aortic Valve is recommended in the presence of significant paravalvular leak.	***Verification of Valve Position and Post-Implant Monitoring:*** With pigtail catheter in position across the Valve, measure both invasive and non-invasive hemodynamic parameters to check positioning and function of the Valve. Perform an angiogram to evaluate Valve performance, position, expansion and coronary patency after Valve deployment. The use of echocardiographic imaging supports assessment and evaluation of Valve function, including paravalvular and intravalvular leakage. The use of a second fluoroscopy projection supports assessment and evaluation of Valve expansion. Post-dilation of ACURATE neo2 Aortic Valve is recommended in the presence of valve under-expansion and significant valve dysfunction (paravalvular leak, elevated gradient).
Valve IFU(s)	
Changing From	Changing To
WARNINGS: Post-dilation of the Valve could damage the device integrity or cause migration of the Valve. Proceed with caution if it is necessary to post-dilate the Valve. Ensure post-dilation balloon shape, dimensions and tolerances are suitable for the Valve.	***WARNINGS:*** If performing post-dilation of the Valve, please refer to the Instructions for Use of the ACURATE neo2 Delivery System/Loading Kit for Operational Instructions. Post-dilation of the Valve could cause device complications (damaged integrity, migration of the Valve) and patient complications (rupture). Proceed with caution if it is necessary to post-dilate the Valve. Ensure post-dilation balloon shape, dimensions and tolerances are suitable for the Valve and patient anatomy.
Precautions During Use: Implantation of the Valve shall be preceded by dilation of the stenotic native aortic valve by means of balloon aortic valvuloplasty.	***Precautions During Use:*** Pre-dilation of the stenotic native aortic valve by means of balloon aortic valvuloplasty is required prior to implantation of the prosthesis. Ensure pre-dilation is effective by selecting the appropriate size Balloon Valvuloplasty Catheter (BVC) in accordance with manufacturer's Instructions For Use. Effective pre-dilation can help reduce the need for post-dilation.