Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
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 105 **dated** 24/5/23 **Regarding NCMDR Field Safety Notice of Impella 5.5 with SmartAssist heart pump from (mfr: ABIOMED Inc).**

Copy to:

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

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

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

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Circular No. 105 / 2023

04 -11-1444 H

24 -05-2023

Field Safety Notice of Impella 5.5 with SmartAssist heart pump from ABIOMED Inc.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19516
Product	Impella 5.5 with SmartAssist heart pump.
Description	Intracardiac pump for supporting the left ventricle.
Manufacturer	ABIOMED Inc.
The affected products	Refer to "Attachment 1" in the attached FSN.
Reason	Purge fluid leaks from the purge sidearm.
Action	1. Remind all users at your site to the correct purge solution according to the approved Instructions for Use: 5% glucose in water (5%-20% acceptable) with 25 or 50 IU heparin /ml. 2. Abiomed offers to exchange Impella 5.5 with SmartAssist pumps listed in the attached FSN. 3. 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: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

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Danvers, MA 01923 USA
Phone: 978-646-1400
Fax: 978-777-8411
www.abiomed.com

FSN Ref: P2023-0185-FSN

FSCA Ref: P2023-0185-FSCA

Date: 2023-04-17

Field Safety Notice
Impella 5.5 with SmartAssist heart pump

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Karsten Wallbrück / Max Eisen
kwallbrueck@abiomed.com – phone +49 151 544 55 114
meisen@abiomed.com – phone +49 151 544 55 226
Abiomed Europe GmbH, Neuenhofer Weg 3, D-52074 Aachen

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FSCA Ref: P2023-0185-FSCA

Field Safety Notice (FSN)
Impella 5.5 with SmartAssist heart pump
Risk of purge leak

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The Impella 5.5® with SmartAssist® heart pump is a temporary left ventricular support pump that delivers up to 5.5 liters of blood per minute from the left ventricle into the aorta to support a patient's hemodynamic system. Abiomed is issuing a medical device recall of a subset of Impella 5.5 with SmartAssist Sets only. Our records show that your facility received one or more units of the devices subject to this recall.
1.	2. Commercial name(s)*
	Impella 5.5 with SmartAssist
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	The Impella 5.5 with SmartAssist heart pump is an intracardiac pump for supporting the left ventricle. It is intended for clinical use in cardiology and in cardiac surgery for up to 30 days for the following indications, as well as others:
	• The Impella 5.5 with SmartAssist is a cardiovascular support system for patients with reduced left ventricular function, e.g., post cardiotomy, low output syndrome, cardiogenic shock after acute myocardial infarction. • The Impella 5.5 with SmartAssist may also be used as a cardiovascular support system during coronary bypass surgery on the beating heart, particularly in patients with limited preoperative ejection fraction with a high risk of postoperative low output syndrome.
1.	5. Device Model/Catalogue/part number(s)*
	0550-0007; distributed as pump set with model number 0550-0002
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	A hospital specific list of affected products is provided in the attachment
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Specific Impella 5.5® with SmartAssist® Sets are being recalled as result of Abiomed receiving complaints of purge fluid leaks from the purge sidearm related to the Impella 5.5 with SmartAssist pump. Investigations conducted at the time these complaints were received showed that the root causes for the increases in purge sidearm leak complaints were related to (i) damage to the purge sidearm (identified in 2019), and (ii) interaction of

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	sodium hydrogen carbonate with the luer locking mechanism on the purge sidearm that connects to the purge cassette (identified in 2021). The integrity of the purge sidearm is critical to the delivery of the purge fluid that prevents blood ingress in the pump motor. After introducing accessories and communications relaying best practices to mitigate these issues, the complaint rate for purge leak due to sidearm damage has decreased but continues to be higher than devices with the preinstalled retainer and new yellow luer. Currently, product in the field includes units with and without the preinstalled retainer and with or without the new yellow luer components.
2.	2. Hazard giving rise to the FSCA*
	The function of the purge fluid is to prevent blood ingress to the motor, which is responsible for the main pumping function of the Impella pump. If a purge leak occurs, initially the system will experience low purge pressures, prompting alarms and requiring evaluation of the system. If a temporary solution to the leak is available and the pump continues to work during the time support is needed, there is no harm to the patient. In the event that the issue is not resolved, it may lead to persistent low purge pressure and purge flow and **will eventually lead to pump stop and loss of therapy**. In critical patients with need for full support, failure of support can lead to further deterioration and worsening of their critical situation.
2.	3. Probability of problem arising
	Purge leak may occur in up to 2.7% of cases using the older pump type without pre-installed retainer and new yellow luer.
2.	4. Predicted risk to patient/users
	Pump stops may occur in up to 0.3% of cases using the older pump type without pre-installed retainer and new yellow luer
2.	5. Further information to help characterise the problem
	Use of sodium hydrogen carbonate as purge fluid additive increases the likelihood of luer failure. Mechanical stress to the purge sidearm and use of alcohol-based cleaning fluids on the purge sidearm increases the likelihood of damages to the purge system. The Impella 5.5 with SmartAssist Sets with the preinstalled Sidearm Retainer and the new yellow luer are not part of this recall.
2.	6. Background on Issue
	Overall, there were 179 separate complaints received for the impacted products worldwide, thereof 165 in the USA, 12 in Germany and 2 in Switzerland. Eleven (11) complaints in the US were associated with product malfunction or serious injury considered reportable. None of the complaints in Europe was assessed a reportable incident.
2.	7. Other information relevant to FSCA
	All users are reminded to the correct purge solution according to the approved Instructions for Use: 5% glucose in water (5%-20% acceptable) with 25 or 50 IU heparin /ml;In the event that a patient is intolerant to heparin, due to heparin-induced thrombocytopenia (HIT) or bleeding, physicians should use their clinical judgment to assess the risks versus benefits of operating the Impella System without heparin. Initial testing has been performed with sodium hydrogen carbonate 8.4% 25 mEq in 1L Glucose 5% in water as an alternative purge solution in order to preserve pump purge performance for patients who cannot tolerate heparin in the purge. However, sodium hydrogen carbonate additive is not approved outside of the US; Impella 5.5 pumps with serial numbers listed in the attachment do not include the latest design updates to minimize the risk of failure of the

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	yellow luer on the purge line. Avoid using sodium hydrogen carbonate additive to the purge solution for patients supported by any of these pumps. Abiomed does not endorse or recommend the use of Impella devices in any manner other than as described in the instructions for use manual. Our provision of this information in no way constitutes a recommendation for patients suffering from HIT. Physicians should use their clinical judgment to assess the risk versus benefits of operating the Impella system without heparin in the purge.
	Please also follow these recommendations to further minimize the risk of purge leak and pump stop: • Prior to implant, ensure the Impella Sidearm Retainer is in place. • As per the Instructions for Use (IFU), sterilization solutions which contain isopropyl alcohol (IPA) should never be applied to the Impella sidearm and purge filter. • Purge cassette changes can be performed less frequently (purge cassettes have been tested with sodium hydrogen carbonate for 5 days).

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification / inspection ☒ Follow patient management recommendations ☐ Take note of amendment / reinforcement of Instructions For Use (IFU) ☒ Other ☐ None Remind all users at your site to the correct purge solution according to the approved Instructions for Use: 5% glucose in water (5%-20% acceptable) with 25 or 50 IU heparin /ml.	
3.	2. By when should the action be completed?	Remind users of the IFU indicated purge solution as soon as possible. Check your site's inventory of Impella 5.5 with SmartAssist Pumps to identify pumps listed in the attached serial number listing and return the attached response form to the above listed local contact as soon as possible.
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. Provide further details of patient-level follow-up if required or a justification why none is required.	

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3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer*** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Abiomed offers to exchange Impella 5.5 with SmartAssist pumps listed in the attachment. Please note that the Impella 5.5 with SmartAssist Sets with the preinstalled Sidearm Retainer and the new yellow luer are not part of this recall (removal).	
3.	6. By when should the action be completed?	Abiomed will contact you as soon as replacement devices become available. The exchange will likely be executed between June 02 and July 28.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

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FSN Ref: **P2023-0185-FSN** FSCA Ref: **P2023-0185-FSCA**

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant.
4.	3. For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc.	
4.	6. Anticipated timescale for follow-up FSN	
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Serial number listing
4.	10. Name/Signature	Shashi Thoutam - Sr. Manager, Global Quality Systems

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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	Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

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Field Safety Notice (FSN)
Impella 5.5 with SmartAssist heart pump
Risk of purge leak
Business Reply Form

Response is required

Recall Coordinator
<Customer Address>

By Signing this form, I am confirming that I have read and understand the recall (removal) instructions provided in this letter dated *<date>*

☐ Yes

Indicate disposition of product subject to this recall (removal) by marking the appropriate check box, filling out the Subject Product Information Table, and signing the acknowledgement signature section:

☐ Subject Unit(s) Have already been returned (Specify date(s) for appropriate serial number(s) in table below)

AND/OR

☐ Subject Unit(s) have been held for return (Indicate which serial number(s) below)

AND/OR

☐ Subject Unit(s) Have Been Used (Specify date(s) for appropriate serial number(s) in table below)

Subject Product Information Table

Impella 5.5 with Smart Assist Model Number:

Serial Number(s)	Disposition *(as indicated above)*	Date of Return/Use *(if applicable)*
<SN listing>		

Acknowledgement Signature		**Date**	
Print Name		**Telephone**	
Email			
Comment			

Please scan and email completed response to
sthoutam@abiomed.com
kwallbrueck@abiomed.com
meisen@abiomed.com.

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Attachment 1 to FSCA report P2023-0185

#	Serial Number	Expiration Date	Country
1	370130	31.01.2024	SA
2	370129	31.01.2024	SA
3	375223	29.02.2024	NO
4	375221	29.02.2024	NO
5	375671	29.02.2024	KW
6	381808	31.03.2024	DE
7	381809	31.03.2024	KW
8	403886	31.08.2024	HR
9	405433	30.11.2024	DE
10	384612	30.04.2024	DE
11	405714	30.11.2024	DE
12	405715	30.11.2024	DE
13	406330	30.11.2024	DE
14	405435	30.11.2024	DE
15	384834	30.04.2024	DE
16	397290	30.06.2024	DE
17	395381	30.06.2024	DE
18	394926	30.06.2024	DE
19	398208	31.07.2024	DE
20	398567	31.07.2024	DE
21	397295	30.06.2024	RS
22	397309	30.06.2024	SA
23	397284	30.06.2024	KW
24	403884	31.08.2024	DE
25	397198	30.06.2024	DE
26	397281	30.06.2024	KW
27	397499	30.06.2024	SA
28	397294	30.06.2024	RS
29	403771	31.08.2024	DE
30	397307	30.06.2024	SA
31	397200	30.06.2024	KW
32	397496	30.06.2024	SA
33	397310	30.06.2024	SA
34	404028	31.08.2024	HR
35	403114	31.08.2024	DE
36	397500	30.06.2024	SA
37	397291	30.06.2024	SA
38	397498	30.06.2024	SA
39	397306	30.06.2024	SA
40	408363	30.09.2024	CH
41	408365	30.09.2024	IT
42	407868	30.09.2024	DE
43	407873	30.09.2024	GB
44	411385	30.09.2024	DE

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#	Serial Number	Expiration Date	Country
45	407872	30.09.2024	GB
46	411444	30.09.2024	DE
47	408572	30.09.2024	DE
48	407234	30.09.2024	DE
49	407858	30.09.2024	DE
50	412360	30.09.2024	AT
51	416785	30.11.2024	DE
52	413930	31.10.2024	FR
53	413931	31.10.2024	DE
54	413643	31.10.2024	DE
55	412012	30.09.2024	DE
56	412359	30.09.2024	ES
57	413091	30.09.2024	DE
58	413092	30.09.2024	DE
59	360280	30.11.2023	HR
60	360511	30.11.2023	HR
61	367019	31.12.2023	HR
62	367021	31.12.2023	RS
63	365273	31.12.2023	HR
64	365274	31.12.2023	HR
65	334696	31.07.2023	HR
66	333043	31.07.2023	SI
67	345239	31.08.2023	DE
68	333035	31.07.2023	DE
69	321271	30.04.2023	DE
70	404938	30.11.2024	DE
71	405946	30.11.2024	CH
72	405434	30.11.2024	DE
73	406378	30.11.2024	CH
74	406381	30.11.2024	DE
75	405607	30.11.2024	DE
76	405710	30.11.2024	DE
77	406329	30.11.2024	DE
78	406331	30.11.2024	AT
79	404452	30.11.2024	AT
80	405469	30.11.2024	CH
81	404940	30.11.2024	DE
82	405709	30.11.2024	DE
83	405947	30.11.2024	CH
84	404808	31.12.2024	ES
85	405147	31.12.2024	DE
86	404964	31.12.2024	IT
87	404915	31.12.2024	DE
88	404916	31.12.2024	DE