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

Circular No. 8 **/ 2022**

21 -06-1443 H

24 -01-1443

Recall of Percutaneous Thrombolytic Device from Arrow International Inc.

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15999
Product	Arrow-Trerotola Over-The-Wire PTD Kit Percutaneous Thrombolytic Device, Arrow-Trerotola PTD Set Percutaneous Thrombolytic Device, Arrow-Trerotola Kit Percutaneous Thrombolytic Device.
Description	Percutaneous Thrombolytic Device.
Manufacturer	Arrow International Inc.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Please refer to "Product Code and Lot Number" in the attached recall.
Reason	PTD tip separation during use.
Action	1. Users should cease use and distribution of impacted product and quarantine immediately. 2. 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

NHR ✓

Dr. Mohammed Hamdan Al Rubaie

Director General

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

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.8/2022**. dated** 24/1/2022 **Regarding NCMDR Recall of Percutaneous Thrombolytic Device from (mfr: Arrow International 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
ISO 9001:2015 CERTIFIED

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**

Teleflex

ARROW INTERNATIONAL

Arrow International LLC
c/o Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Westmeath, Ireland

January 2022

URGENT – FIELD SAFETY NOTICE

Type of Action	Recall					
Teleflex Reference	EIF-000499					
Commercial Name	Arrow-Trerotola™ Over-The-Wire PTD Kit® Percutaneous Thrombolytic Device Arrow-Trerotola™ PTD Set® Percutaneous Thrombolytic Device Arrow-Trerotola™ Kit® Percutaneous Thrombolytic Device					
Product Code	**Lot Number**					
PT-12709-WC	13F20C0094	13F20G0284	13F20L0282	13F21A0497	13F21A0718	13X21E0008
	13F21F1187					
PT-65709-HFWC	13F20A0323	13F20B0139	13F20C0594	13F20F0083	13F20F0230	13F20F0577
	13F20H0756	13F20K0849	13F20L0283	13F20M0182	13F21A0498	13F21B0158
	13F21C0747	13F21E0555				
PT-65709-W	13F19M0129	13F20B0053	13F20C0595	13F20F0231	13F20G0361	13F20K0632
	13F21A0353	13F21C0748	13F21D0721	13F21E0823	13F21F1189	
PT-65709-WC	13F20C0596	13F20F0081	13F20F0229	13F20F0509	13F20F0578	13F20G0177
	13F20G0566	13F20H0531	13F20J0379	13F20L0514	13F21A0354	13F21C0081
	13F21C0749	13F21D0870	13F21E0415	13F21F1188		
PT-45509	13F20A0209	13F20B0054	13F20B0527	13F20C0427	13F20D0127	13F20D0402
	13F20F0390	13F20G0285	13F20J0545	13F20J0933	13F20K0851	13F20M0174
	13F21A0662	13F21C0079	13F21C0751	13X21D0027	13F21F0399	13F21G0226
	13F21G1343	13F21H0639	13F21H1272	13F21L0900		
PT-65509-HFC	13F20A0359	13F20A0519	13F20B0140	13F20B0423	13F20C0223	13F20C0593
	13F20D0128	13F20D0386	13F20F0576	13F20G0176	13F20J0139	13F20J0547
	13F20K0212	13F20L0160	13F20M0183	13F21B0224	13F21C0080	13F21C0366
	13F21D0106	13X21D0026	13F21E0078	13F21E0557	13F21G1344	13F21H0213
	13F21H0659	13F21J0455	13F21K0897	13F21L0901		
PT-65509	13F20A0286	13F20A0426	13F20A0640	13F20B0141	13F20B0276	13F20B0353
	13F20B0424	13F20C0352	13F20C0425	13F20C0426	13F20D0122	13F20D0123
	13F20D0124	13F20D0403	13F20E0204	13F20F0232	13F20F0389	13F20G0353
	13F20H0729	13F20J0378	13F20J0546	13F20J0771	13F20K0503	13F20K0504
	13F20K0630	13F20K0631	13F20M0175	13F20M0176	13F20M0177	13F20M0178
	13F20M0181	13F21A0352	13F21B0159	13F21B0222	13F21B0519	13F21C0364
	13F21C0365	13F21D0462	13F21E0079	13F21E0259	13F21E0260	13F21E0556
	13F21F0641	13F21G0227	13F21G0401	13F21G0772	13F21H0447	13F21K0827
	13F21K0898	13F21L0227	13F21L0507	13F21L0898		
Note: Refer to Appendix 3 for Unique Device Identifier (UDI) Information						

Teleflex

ARROW INTERNATIONAL

Dear Customer,

Details of affected devices

Arrow International LLC, a subsidiary of Teleflex Incorporated, has initiated a voluntary Field Safety Corrective Action (FSCA) for 5FR and 7FR Percutaneous Thrombolytic Device (PTD®) Sets and Kits; refer to appendix 2 for a list of product codes and lots impacted.

IMPORTANT NOTE REGARDING SCOPE – The scope of this action includes all 5FR and 7FR devices within shelf life. 7FR devices are also in scope of a previous Field Safety Corrective Action. For safety reasons, Teleflex is including all information in this new action.

Description of the problem & immediate actions required

Teleflex is initiating a voluntary Field Safety Corrective Action due to reports received indicating PTD® tip separation during use. If the tip separates during use, clinicians may exercise their medical judgment to either retrieve endovascularly with a snare device or with a minor surgical procedure or elect not to retrieve the tip given the recognition that embolism of a small and inert tip may be less likely to be harmful than extraordinary attempts to retrieve said tip. Partial or full embolization of foreign material into the arterial or venous circulation is possible, potentially leading to vascular complications, including but not limited to mechanical obstruction of an artery or vein, arterial or venous thrombosis, ischemia, or infarction in the territory subtended by an obstructed or thrombosed artery (including pulmonary embolism and infarction), and remotely, endovascular infection. The consequences of embolizing foreign material into the peripheral or pulmonary circulation or components thereof are substantially determined by the size of the embolus. Clinicians may also elect to exclude the embolus from the circulation by trapping the embolus outside a newly deployed stent.

As of December 2021, a total of 35 complaints reporting tip separation have been received for 5FR and 7FR products in scope combined. Of these 35 complaints (30 for 5FR; 4 for 7FR; 1 for unknown), 9 complaints (9 for 5FR) involved use of a stent to manage the embolism. No deaths or long-term patient injuries have been reported at this time.

Our records indicate you have received products that are in scope of this Field Safety Notification.

Depending on your device location please adhere to the following Action list:

Device location	Action List Number
Medical facilities (hospitals, medical staff, etc.)	1
Distributors	2

Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Medical Devices Sector
قطاع الأجهزة الطبية

NCMDR
National Center for Medical Devices Reporting
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 017 01 22 000 Back
Date submitted: 1/16/2022

Manufacturer:	Arrow International Inc.
Device Type:	Arrow-Trerotola Over-The-Wire PTD Kit Percutaneous Thrombolytic Device, Arrow-Trerotola PTD Set Percutaneous Thrombolytic Device, Arrow-Trerotola Kit Percutaneous Thrombolytic Device
Description:	Percutaneous Thrombolytic Device
Medical Device Identifier:	Please refer to "Product Code and Lot Number" in the attached FSN.
Reason of Field Safety Corrective Action:	PTD tip separation during use.
Remedy Action:	1- Users should cease use and distribution of impacted product and quarantine immediately. 2- Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.
Athorized Representative/Importer/Distributor:	Gulf Medical Co.
Report Source:	NCMDR
Source Ref. Number:	9130CD148B22D
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	Arrow International Inc..pdf

View History