

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

25th June 2019

URGENT – FIELD SAFETY NOTICE

Type of Action				ADVISORY NOTICE	
Teleflex Reference				EIF-000362	
Commercial Name				Arterial Catheterization Set	
Product Code	Lot number	Product Code	Lot number	Product Code	Lot number
DE-00820-BAB	71F19B0185	MONZINO-00818	71F19B0193	SAC-00820	71F19B0791
	71F19C1754		71F19C0971		71F19C0256
	71F19C2474	NL-00520-MUMC	71F19B0303		71F19C0257
DE-00820-MKHS	71F19C0729	SAC-00520	71F19A2184		71F19C0463
DE-00820-MSG	71F19C0818		71F19B0021		71F19C0464
DE-00820-OLD	71F19B0184	SAC-00520	71F19C0255		71F19C0466
	71F19C1165		71F19C1529		71F19C1520
	71F19C1782		71F19C2501		71F19C1521
DE-00820-UB	71F19C0809	SAC-00522	71F19C1025		71F19C2023
	71F19C2898		71F19C1687		71F19C2024
DE-00820-VB	71F19C0929	SAC-00524	71F19C1404	SAC-00822	71F19A1924
	71F19C2545	SAC-01218	71F19C0742		71F19C0796
DE-01618-OLD	71F19B0304	SAC-01222	71F19C1651		71F19C1681

Dear Customer,

Arrow International has voluntarily issued a Field Safety Notice for the product codes and lot numbers listed above.

Description of the problem & immediate actions required

Arrow International is voluntarily issuing a Field Safety Notice for these products as they may contain the incorrect IFU, which may lead to a potential delay in procedure.

- Arterial Catheterization Sets, may contain a copy of an IFU for Epidural Catheterization Product. One IFU is packaged in a box containing ten kits. This issue would be readily recognisable by the clinical end user.
- Inspect your stock and should you have the incorrect IFU, you may follow this link to download a copy of the correct IFU <http://teleflex.link/SZ-00520-106A> or alternatively, contact your customer service representative who will issue a copy to you, to replace the incorrect IFU.

No patient injury has been reported pertaining to this issue.

Product code and lot combinations not referenced above are not impacted by this Field Safety Notice.

Product is not being recalled, you may continue to use the products in scope of this advisory notice.

Our records indicate you have received products that are subject to this notification.

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

Device location	Action List Number
Medical facilities	1
Distributors	2

Action list number 1 – Medical facilities

Our records indicate your facility has received product in scope of this Field Safety Notice. Please provide this Field Safety Notice to all those who need to be aware of it within your organisation and should you have stock remaining, review and follow the instructions outlined on page one of this notice. Please consider, clinicians, risk managers, supply chain/distribution centres, etc. in the circulation of this notice.

Action list number 2 – Distributors

If you are a distributor, provide this field safety notice to all your customers who have received product in scope of this Field Action. Should you have stock remaining, review and follow the instructions outlined on page one of this notice. If you have further distributed product outside of your country, please notify Teleflex by return email to the e-Mail address below. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TR area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

Teleflex

Teleflex informs all customers, employees of Teleflex and distributors of this Field Safety Corrective Action.

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice. Maintain awareness of this notice until all required actions have been completed in your organisation.

Contact reference person

Should you require any further information or support concerning this issue, please contact:

Customer Service:

Contact: Nicole Morawiec

Telephone: +41 0 31 818 40 90

FAX: +41 0 31 848 40 93

Email: info.ch@teleflex.com

Please be advised that all Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities to which Teleflex distribute directly will be notified by Teleflex. Teleflex is committed to providing high quality, safe and effective products. We sincerely apologise for any inconvenience this action may cause your operations. If you have any other questions, feel free to contact your local sales representative or Customer Service.

For and on behalf of Arrow International,

Padraig Hegarty

Padraig Hegarty VP, QA (Manufacturing)