FIELD SAFETY NOTICE – FRC-015725

Urgent Field Safety Notice

APR-10-2024 | Reference 1004367

10.04.2024

Subject: 1004367- Teleflex Field Action Radialis Needle

Addressee: all users, operators and distributors of Arrow® QuickFlash® Radial Artery Catheterization Kits and Sets.

Products affected:

Our records indicate that PiCCO Radialis Kits have been shipped to you. They are available under Getinge order number 6885059. In addition to Getinge's own products, the kit also contains the Teleflex Radialis needle. Teleflex has issued a voluntary field safety corrective action (FSCA) for the Arrow® QuickFlash® Radial Artery Catheterization Kits and Sets. The affected lots are identified in the attached Teleflex Field Safety Notice.

Product name	REF #	MCC REF #	Serial/Lot numbers affected
PiCCO Radialis Kit	PVPK2014L50-A	6885059	4979823, 4982277, 4858300, 5007220, 5016052, 5019443, 5035508, 5067220, 5048692 Only Radialis Needle is affected with Teleflex REF RA-04220
Radialis Needle Arrow® QuickFlash® Radial Artery Catheterization Kit	RA-04220 (Teleflex REF) DK00148 (Getinge catalogue)	Part of 6885059	Affected Lots are identified by Teleflex see Appendix 2 of FSN EIF-000556

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Serial/Lot numbers affected:

Affected products are identified by the legal manufacturer Teleflex. Appendix 2 of the Field Safety Notice EIF-000556, attached to this Notice, lists all batches of Radialis needels in scope of the Field Safety Notice.

Description of the issue

Teleflex is initiating this voluntary FSCA for the above-mentioned products due to reports received indicating a potentially defective component.

The complaints received relate to resistance of the guidewire handle/chamber during use.

Potential health consequences

The possible immediate health consequences of the component issue are arterial vasospasm and vessel injury arising from multiple arterial punctures with repeated attempts. Any long-range consequences would be contingent on the severity of any immediate consequences. If tested prior to use as directed by the information for use and good clinical practice, the component issue should be discovered.

As of 31-January-2024, a total of 194 complaints reporting resistance of the guidewire handle/chamber during use have been received for the products in scope of this Field Safety Notice. Of these 194 complaints, no complaints reported injury.

Identification of the affected medical devices

Excerpt from Teleflex IFU:The Arrow® Arterial Catheterization Device permits access to the peripheral arterial circulation or to other small vessels

Description	Product name	REF #
Radialis Needle	Arrow® QuickFlash® Radial Artery Catheterization Kits and Sets	RA-04220

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Affected serial/lot numbers

All serial and lot numbers of the listed products in page 1 can be found in Appendix 2 of FSN EIF-000556.

Our records indicate that affected products were delivered to your location. Please verify if you have any of the listed products.

Please refer to the image below, how to locate the batch number on the affected product. Please compare the batch number of your stocked products to the identified batches in Appendix 2.

Which actions are required by the customer?

Getinge has initiated this field action for all affected units. Please

- Verify, if you have any of the products listed on page 1 and Appendix 2.
- Quaranteen products listed on page 1 and Appendix 2, to prohibit any further use.
- Do not use the products listed on page 1 and contact your Getinge local representative to plan the return of the products using the RMA process.
- Complete and return the referenced response forms and maintain awareness of this notice and related actions until the involved products have been removed to ensure effectiveness of the corrective action.

Distribution of the provided Information

This **Field Safety Notice** needs to be distributed to those individuals within your organization who need to be aware of the issue – or to any organization where the potentially affected devices have been transferred.

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Please maintain awareness of this notice and the resulting action until closure of this action.

In the case that you as customer choose not to proceed with completion of the action requirements described above, Getinge cannot accept any responsibility for safety-related issues or legal liabilities caused by the failure to respond to this Field Safety Notice. The local responsible authority has been informed about this communication and issue.

We apologize for any inconvenience this may cause. We will do our outmost to carry through with this action as swiftly as possible.

Should you have questions or require additional information, please feel free to contact us at any time.

Best regards,

Laura Kastenmayer

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Acute Care Therapies, Critical Care

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Referenced documents:

- FSN EIF-000556 Teleflex-Arrow Field safety Notice-EN
- FSN EIF-000556 Teleflex-Arrow Field safety Notice-DE
- Annex I – 1004367 – FRC-015725 Response form end customer (EN)
- Annex II – 1004367 – FRC-015725 Response form distributor (EN)