Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Westmeath, Ireland

April-2023

URGENT – FIELD SAFETY NOTICE

Type of Action	Advisory Notice	
Teleflex Reference	EIF-000522-01	
Model Information	Product Name	Product Code
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	AutoCAT 2 Spanish	IAP-0400E
	AutoCAT 2 French	IAP-0400F
	AutoCAT 2	IAP-0400
	AutoCAT 2 Japanese	IAP-0400J
	AutoCAT 2 Refurbished	IAP-0400X
	AEROAUTOCAT2	IAP-0435
	AutoCAT 2 WAVE	IAP-0500
	AutoCAT 2 WAVE German	IAP-0500D
	AutoCAT 2 WAVE Spanish	IAP-0500E
	AutoCAT 2 WAVE Refurbished Spanish	IAP-0500EX
	AutoCAT 2 WAVE French	IAP-0500F
	AutoCAT 2 WAVE Italian	IAP-0500I
	AutoCAT 2 WAVE Japanese	IAP-0500J
	AutoCAT 2 WAVE Dutch	IAP-0500NL
	AutoCAT 2 WAVE Swedish	IAP-0500SV
	AutoCAT 2 WAVE Refurbished	IAP-0500X
	AEROAUTOCAT 2 WAVE	IAP-0535
	AEROAUTOCAT 2 WAVE Spanish	IAP-0535E
	AEROAUTOCAT 2 WAVE Italian	IAP-0535I
	AEROAUTOCAT 2 WAVE Japanese	IAP-0535J
	AEROAUTOCAT 2 WAVE Refurbished	IAP-0535X
Arrow® AC3 Optimus® Intra-Aortic Balloon Pump	AC3 IABP NA/EMEA	IAP-0600
	AC3 IABP NA/AJLA	IAP-0601
	AC3 Optimus IABP NA/EMEA	IAP-0700
	AC3 Optimus IABP NA/EMEA Refurbished	IAP-0700X
	AC3 Optimus IABP NA/EMEA	IAP-0701

Dear Customer,

Details of impacted devices

Arrow International LLC, a subsidiary of Teleflex Incorporated, has initiated a voluntary Field Safety Corrective Action (FSCA) for the product codes referenced above due to a potential issue with short battery run-times on the affected intra-aortic balloon pump (IABP) devices. These IABP devices can be powered either by connecting to an AC power source or with battery power for mobile use.

This voluntary field correction is an expansion to a recent Teleflex voluntary field correction (Teleflex reference EIF-000522), based on the outcome of further investigation, with additional customers having been identified.

If you did not receive a copy of the Field Safety Notice for EIF-000522 but are receiving a copy of this Field Safety Notice, Teleflex has identified that you only received product in scope of the expanded voluntary field correction, EIF-000522-01. Regardless, if you previously responded to the initial notification (EIF-000522), or are just receiving notification for the first time, Teleflex requests that you review this notice and complete the applicable actions identified herein.

Description of the issue & immediate actions required

Teleflex is initiating this voluntary FSCA for the above-mentioned products due to reports of a potential issue with short battery run-times on the affected intra-aortic balloon pump (IABP) devices. These IABP devices can be powered either by connecting to an AC power source or with battery power for mobile use.

When operating the IABP device using battery power, the expected duration of pumping, after a full charge, is 90 minutes. However, Teleflex has received complaints reporting that some users of the affected IABP devices have experienced short battery run-times, including loss of power during use.

The IABP is designed with alarms to indicate that there are 20, 10, and 5 minutes of battery life remaining. In the past two years, Teleflex has received one complaint reporting that the unit shut off without the time remaining alarms and thirteen complaints reporting missing alarms, where the time remaining was reported to be inaccurate based on how quickly the battery was depleting.

The immediate health consequences of battery failure are the cessation of intra-aortic balloon counter-pulsation with a potentially life-threatening reduction in cardiac output, which if left untreated, could result in death.

As of March 21, 2023, no patient injuries or deaths have been reported.

Actions to take to reduce the risk of short battery run time:

- Ensure the IABP is plugged into an AC outlet whenever possible during patient use to prevent the battery from depleting.
- Ensure the IABP is plugged into an AC outlet when the system is not in use as the batteries should be kept at a full charge even when not being used on a patient.
- Prior to transporting patients, ensure the battery is fully charged.
- Ensure a backup IABP device is fully charged and readily available.
- As described in the Arrow® AutoCAT®2 Intra-Aortic Balloon Pump / Arrow® AC3 Optimus® Intra-Aortic Balloon Pump Operator Manuals, it is recommended to replace the batteries when:
    - Battery run time is less than 90 minutes
    - There is visual damage to the battery
    - There has been 3 years of service with the battery
- As described in the Operator Manuals, Teleflex recommends that a battery load test is performed at least every 12 months by qualified service personnel. If an issue with the battery load is identified, immediately quarantine the device and contact Teleflex Customer Service using the contact details provided below to report the issue and receive support for servicing the affected IABP device.
  Note: If a battery load test has not been performed in the past 12 months, Teleflex advises against transporting patients with affected IABP devices until the battery load test is performed.

Immediate actions to take should an IABP battery fail:

- If the IABP device battery fails while in use, immediately connect to an AC power source to continue therapy
- If a source of AC power is not readily available, transfer the patient to an alternative IABP. Teleflex recommends that you have a back-up IABP device fully charged and readily available.
- If pumping cannot be restored within 15 – 30 minutes, manually inflate and deflate the IAB several times per hour to reduce the risk of thrombus formation and consider removing the balloon. Refer to the IAB user manual for additional instructions, cautions and warnings for proper battery operation and maintenance.

Our records indicate you have received products that are in scope of this corrective notice.

Product is not being removed; you may continue to use the products in scope of this advisory notice in accordance with the mitigation actions listed above.

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

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

Action list number 1 – Medical facilities

1. Please send a copy of this notification to all relevant personnel in your organisation, including, at a minimum, personnel in the following departments: Coronary Care Unit, Interventional Cardiology Department, Cardiac Catheter Lab, Anesthesiology Department, Intensive Care Departments (Adult, Paediatric, Neonatal), Critical Care Department, Emergency Department, Vascular Access Service, Operating Room/Service, Surgical Department, Resident Training Department, and Biomedical Engineering Department.
2. Immediately check your inventory of Arrow® AutoCAT®2 and Arrow® AC3 Optimus® IABPs, whether stored or in use.
3. If you do not have affected product, mark the applicable checkbox on the Acknowledgement Form (Appendix 1) and return the form to Teleflex Customer Service at the contact details provided below.
4. If you have affected product, mark the applicable checkbox on the Acknowledgement Form (Appendix 1), return the form to Teleflex Customer Service at the contact details provided below, and place a copy of this corrective notice with all affected products.

Action list number 2 – Distributors

1. Provide this field safety notice to all customers who have received impacted product. Each of your customers is then required to complete the Acknowledgement Form and return it to you. **– If your customers who previously received impacted product subject to EIF-000522 have not yet responded, distributors are required to notify their customers of this FSCA (EIF-000522-01).**
2. We request that you **immediately** check your inventory for impacted product. Should you have impacted product in inventory contact Teleflex customer service using the contact details outlined below.

3. As a distributor, you are then required to confirm to Teleflex that you have completed the field activity outlined in actions 1 and 2 of this Action List Number 2. Upon completion of your actions, please forward the completed Acknowledgement Form (Appendix 1) to Teleflex Customer Service.
4. Affix a copy of this notice to each individual unit prior to onward distribution.
5. Please be aware that all European Economic Area/Switzerland, United Kingdom (EEA/CH/UK) and Turkey (TR) Competent Authorities in which **Teleflex distribute directly** will be notified by Teleflex.
6. If you have further distributed product outside of your country, please notify Teleflex Customer Service by return email to the email address below.
7. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/UK/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.

Adverse events or quality problems experienced with the use of this product should be reported to Teleflex Customer Service using the contact details provided below.

Transmission of this Corrective Notice

This corrective notice should be given 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, service departments, etc., in the circulation of this notice.

Contact reference person

Should you require any further information or support concerning this issue, please contact Teleflex Customer Service via email, phone, or fax.

Customer Service:
Contact: Customer Service **Telephone:** 0711 / 20 90 80 00
Email: recalls.de@teleflex.com

Teleflex and its subsidiary Arrow International LLC are committed to providing high quality, safe and effective products. We regret any inconvenience this action may cause your operations. If you have any other questions, please contact your local Teleflex sales representative or Teleflex Customer Service.

The undersign confirms this notice has been notified to the appropriate Regulatory Authorities.

For and on behalf of Teleflex and Arrow International LLC,

[redacted]

Appendix 1

Customer No

_____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY ARROW INTERNATIONAL LLC – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000522-01

RETURN COMPLETED FORM IMMEDIATELY TO:

Email: recalls.de@teleflex.com

☐ We confirm receipt of this corrective notice and completion of the required actions contained therein. We further confirm that our inventory does **NOT** include products affected by this corrective notice.	☐ We confirm receipt of this corrective notice and completion of the required actions contained therein. We further confirm our inventory **DOES** include products affected by this corrective notice.

Complete this Acknowledgement Form and return the completed form immediately using the contact information above.

INSTITUTION NAME (E.G., NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSTITUTION ADDRESS	**PHONE/FAX**
FORM COMPLETED BY	**STAMP**
PRINT NAME: _____ **SIGNATURE:** _____	
DATE:	