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

21st May 2020

URGENT – FIELD SAFETY NOTICE

Type of Action	Advisory
Teleflex Reference	EIF-000400

Model Information	Product Name	Product Code	Serial Numbers
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	AUTOCAT 2	IAP-0400	See Appendix 2
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	AUTOCAT2 SPANISH	IAP-0400E	
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	AUTOCAT2 WAVE	IAP-0500	
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	AUTOCAT2 WAVE SPANISH	IAP-0500E	
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	AUTOCAT2 WAVE ITALIAN	IAP-0500I	
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	AUTOCAT2 WAVE JAPANESE	IAP-0500J	
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	AUTOCAT2 WAVE DUTCH	IAP-0500NL	
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	AEROAUTOCAT 2 WAVE	IAP-0535	
Arrow® AC3 Optimus® Intra-Aortic Balloon Pump	AC3 Optimus IABP NA/EMEA	IAP-0700	
Arrow® AC3 Optimus® Intra-Aortic Balloon Pump	AC3 Optimus IABP NA/AJLA	IAP-0701	

Dear Customer,

Teleflex has initiated a voluntary Field Safety Corrective Action for the above listed product codes and serial numbers of specific models of the Arrow® AutoCAT®2 Intra-Aortic Balloon Pump and the Arrow® AC3 Optimus® Intra-Aortic Balloon Pump (collectively referred to as "IABP"), which are intra-aortic balloon pump systems that provide temporary circulatory support for patients with a variety of acute and sub-acute circulatory conditions.

Description of the problem & immediate actions required

A potential issue with a component ("Component") within the above-referenced IABPs may impact the ability of the devices to operate. A Component within the IABP is susceptible to vibration failure resulting in fretting, charring, and discoloration of motor connector wires, which may result in pump alarms for "System Error 3" and "High Baseline" presented on the screen of the IABP, and potential abrupt cessation of function or inability to start the IABP. The potential for this issue to occur is related to aging of the Component; therefore, IABPs will be addressed by age, and execution will consist of immediate, subsequent, and long-term corrective actions.

To date, there have been no reports of a sudden stoppage without a prior "System Error 3" or "High Baseline" alarm indicative of deterioration of the Component. However, the absence of prior alarms does not ensure that the IABP is not affected by this problem. If a patient requires circulatory support with an IABP and the device does not work, or if therapy abruptly stops during use without a replacement IABP available, device failure may result in immediate and serious health consequences, including death.

Teleflex is issuing this Medical Device Correction to address the potential failure.
Our records indicate that you have received products that are subject to this action.

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

Detection:

"System Error 3" and "High Baseline" alarms, which present on the screen of the device, are indications of imminent failure of the pump. The Component is the motor driver connector, an internal component that is typically white in colour and is only visible during servicing that should be done only by trained company personnel.

Customer Action (Immediate):

Please immediately check your inventory of Arrow® AutoCAT®2 and Arrow® AC3 Optimus® IABPs, whether stored or in use, and determine if you have an IABP with a model number listed above. Please see Appendix 2 for product codes and serial numbers.

If an IABP in the scope of this Medical Device Correction displays a "System Error 3" or "High Baseline" alarm, now or at any point in the future until the Customer Action (Long Term) detailed below occurs, immediately quarantine the device and contact Teleflex at +353014370773 or recalls.intl@teleflex.com to receive support for inspection and servicing of the impacted device.

We recommend against using an IABP for ground or air transport between medical facilities pending implementation of the **Customer Action (Long Term)**. For IABP use during ground or air transport prior to implementation of the **Customer Action (Long Term)**, it is recommended that the risks and benefits of using the IABP be assessed by the medical team treating the patient and that alternative circulatory support devices be considered.

Customer Action (Subsequent):

Teleflex will contact each impacted facility to schedule inspection and servicing of all IABP units that contain this internal component. This inspection and servicing will be performed onsite at facilities, for all IABP units.

Facilities should adhere to the following instructions pending implementation of the Customer Action (Long Term) described later in this letter:

1. **Ensure that a backup IABP is available as instructed within the Operator Manual**. If no such replacement IABP is immediately available, it is recommended that the risks and benefits of using the IABP be assessed by the medical team treating the patient and that alternative circulatory support devices be considered.

2. **IABP units should be closely monitored** during delivery of IABP therapy.

3. As stated in the Arrow® AutoCAT®2 Intra-Aortic Balloon Pump / Arrow® AC3 Optimus® Intra-Aortic Balloon Pump Operator Manuals, if pump shutdown is experienced:

   Pump shutdown requires immediate staff action. Note the time and call knowledgeable maintenance personnel.

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. Consider removing the balloon. Arrow International recommends that you have a back-up IABP system available.

4. **A copy of this notice should be kept with each IABP at all times until complete implementation of the below Customer Action (Long Term).**

5. If "System Error 3" and "High Baseline" alarms are experienced at a later time, quarantine the device for inspection taking into consideration the use of available alternative therapies, and adhering to the instructions under the above heading "ACTIONS TO BE TAKEN BY FACILITIES"

Customer Action (Long Term):

Teleflex has initiated a new design of the motor connector Component that will be released this year. Teleflex will replace the existing Component with the new design in all IABPs at all facilities. At the time the proposed modification is ready for implementation, a subsequent notification will be sent to all impacted customers to schedule and commence replacement of the Component. Any facilities which have a previously serviced IABP under the scope of this Medical Device Correction will be revisited to install the new design of the motor connector Component in a subsequent visit from Teleflex personnel.

Action list number 2 – Distributors

1. Read the Customer Action list number 1 above to ensure you understand the customer requirements.
2. Provide this field safety notice to all customers who have received product in scope of this FSCA. Your customer is then required to complete the acknowledgement form and return to you.
3. We request that you check your inventory for product within the scope of this FSCA.
4. Affix a copy of this notice to each individual unit prior to onward distribution.
5. Liaise with Teleflex per the contact details below to ensure each of your customers is being supported initially with the immediate action required, the subsequent actions and the longer-term action.
6. As a distributor, you are then required to confirm to Teleflex that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.
7. Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Teleflex distribute directly will be notified by Teleflex.
8. If you have further distributed product outside of your country, please notify Teleflex by return email to the e-Mail address below.
9. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TR region, 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: Shane Kenny
Telephone: +353 0 90 64608769
FAX: +353 0 14370773
Email: recalls.intl@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 Teleflex,

Padraig Hegarty

Vice President, Global Quality Assurance (Manufacturing)

Teleflex MEDICAL

Appendix 1

Customer No _____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000400

Arrow® AutoCAT®2 Series Intra-Aortic Balloon Pump and
Arrow® AC3 Optimus® Intra-Aortic Balloon Pump

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +353 0 14370773 **Email: recalls.intl@teleflex.com**

☐ We confirm receipt of this FSN and have completed the required actions contained therein. We confirm that our inventory does **NOT** include products affected by this Field Action.	☐ We confirm receipt of this FSN and confirm our inventory **DOES** include products affected by this Field Action. We have quarantined any IABP units displaying "System Error 3" or "High Baseline" alarms. We understand Teleflex will contact our facility to schedule onsite inspection and servicing of all IABP units.

Location	Quantity of IABP at Facility

PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY

Serial Number	Has IABP displayed "System Error 3" or "High Baseline" alarm?	Has IABP been removed from service?
	☐ Yes ☐ No	☐ Yes ☐ No
	☐ Yes ☐ No	☐ Yes ☐ No
	☐ Yes ☐ No	☐ Yes ☐ No
	☐ Yes ☐ No	☐ Yes ☐ No
	☐ Yes ☐ No	☐ Yes ☐ No
	☐ Yes ☐ No	☐ Yes ☐ No

Complete this Acknowledgement form and return immediately by using fax number or e-Mail address above.

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSITIUTION ADDRESS	**Phone/FAX**
FORM COMPLETED BY:	**Stamp**
PRINT NAME: _____ **SIGNATURE:** _____	
DATE	

Appendix *2*

MODEL INFORMATION	PRODUCT NAME	PRODUCT CODE	SERIAL NUMBER RANGE
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	**AUTOCAT 2**	IAP-0400	140868V
			140901V through 140909V
			140914V through 140920V
			150102V
			150106V through 150107V
			150110V through 150113V
			150115V through 150116V
			150220V
			150401V
			150407V
			150409V
			150507V through 150513V
			150601V through 150605V
			150608V through 150611V
			150625V
			150702V through 150705V
			150707V
			150720V
			150801V through 150802V
			150821V
			150824V
			150827V through 150830V
			150901V through 150906V
			150908V through 150912V
			150919V through 150923V
			150925V through 150939V
			151009V through 151013V
			151015V through 151016V
			151019V
			151021V through 151027V
			151029V
			151102V through 151103V
			151105V
			151108V
			151111V
			151113V
			151201V through 151208V
			151210V through 151212V
			151214V through 151218V

MODEL INFORMATION	PRODUCT NAME	PRODUCT CODE	SERIAL NUMBER RANGE
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	**AUTOCAT 2**	IAP-0400	151220V
			160101V through 160103V
			160105V through 160109V
			160112V through 160118V
			160120V
			160122V
			160126V
			160201V through 160209V
			160211V
			160213V through 160214V
			160216V through 160217V
			160219V
			160312V through 160314V
			160316V through 160323V
			160325V through 160327V
			160331V
			160401V through 160410V
			160412V
			160418V through 160422V
			160519V
			160525V
			160529V through 160530V
			160605V
			160614V
			160618V
			160630V
			160638V through 160639V
			160645V
			160703V
			160718V
			160720V
			160726V
			160728V through 160730V
			170101V through 170110V
			170401V through 170410V
			170501V through 170520V
			170601V through 170625V
			170811V through 170830V
			171021V through 171030V
			171037V through 171046V
			171106V through 171115V
			180131V through 180150V

MODEL INFORMATION	PRODUCT NAME	PRODUCT CODE	SERIAL NUMBER RANGE
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	**AUTOCAT 2**	IAP-0400	180211V through 180230V
			180411V through 180420V
			180441V through 180450V
			180521V through 180530V
			180621V through 180630V
			180711V through 180720V
			180741V through 180750V
			180811V through 180820V
			181011V through 181040V
			181111V through 181130V
			190121V through 190130V
			190141V through 190150V
			190211V through 190220V
			190411V through 190420V
			190431V through 190440V
			190531V through 190540V
			190701V through 190712V
			190737V through 190748V
			190813V through 190824V
			190837V through 190848V
			190913V through 190924V
			190937V through 190948V
			191001V through 191012V
			191025V through 191036V
			191101V through 191112V
			191137V through 191148V
			200113V through 200136V
			200314V through 200324V
	AUTOCAT2 SPANISH	IAP-0400E	150301V
			160119V
			160429V through 160430V
			160634V
			160643V
	AUTOCAT2 WAVE	IAP-0500	140861W through 140865W
			140910W through 140913W
			150101W
			150103W through 150105W
			150108W through 150109W
			150114W
			150119W
			150202W through 150219W
			150303W

MODEL INFORMATION	PRODUCT NAME	PRODUCT CODE	SERIAL NUMBER RANGE
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	**AUTOCAT2 WAVE**	IAP-0500	150306W
			150310W
			150404W through 150406W
			150410W
			150501W through 150506W
			150515W
			150606W through 150607W
			150612W through 150622W
			150701W
			150706W
			150708W through 150712W
			150717W through 150719W
			150803W through 150820W
			150822W through 150823W
			150825W
			150913W through 150918W
			150924W
			150940W
			151001W through 151008W
			151017W through 151018W
			151020W
			151028W
			151109W
			151112W
			151115W through 151120W
			160104W
			160110W through 160111W
			160121W
			160123W through 160125W
			160127W through 160130W
			160210W
			160212W
			160215W
			160218W
			160220W
			160301W through 160304W
			160307W through 160311W
			160315W
			160324W
			160328W through 160330W
			160332W through 160340W
			160411W

MODEL INFORMATION	PRODUCT NAME	PRODUCT CODE	SERIAL NUMBER RANGE
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	**AUTOCAT2 WAVE**	IAP-0500	160413W through 160417W
			160423W through 160424W
			160428W
			160501W through 160502W
			160504W through 160507W
			160520W through 160524W
			160526W through 160528W
			160601W through 160604W
			160606W through 160613W
			160615W through 160617W
			160620W through 160629W
			160632W through 160633W
			160701W through 160702W
			160704W
			160706W through 160713W
			160716W through 160717W
			160719W
			160721W through 160725W
			160727W
			160734W through 160742W
			160744W through 160745W
			160801W through 160803W
			160805W through 160823W
			160825W through 160827W
			160829W through 160830W
			160901W through 160917W
			160920W through 160945W
			170201W through 170203W
			170207W through 170208W
			170211W through 170220W
			170222W through 170230W
			170301W
			170303W through 170307W
			170309W through 170327W
			170329W through 170330W
			170606W through 170610W
			170921W through 170927W
			170929W through 170930W
			170941W through 170950W
			171101W through 171104W
			171118W
			171202W through 171205W

MODEL INFORMATION	PRODUCT NAME	PRODUCT CODE	SERIAL NUMBER RANGE
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	**AUTOCAT2 WAVE**	IAP-0500	180111W through 180119W
			180302W through 180308W
			180310W
			180331W through 180332W
			180334W through 180340W
			180501W through 180510W
			180531W through 180540W
			180611W through 180620W
			180721W through 180730W
			180751W through 180760W
			180831W through 180839W
			180932W through 180938W
			180940W through 180941W
			181051W through 181053W
			181055W
			190111W through 190118W
			190222W
			190227W through 190228W
			190230W
			190321W through 190330W
			190511W
			190513W
			190515W through 190518W
			190520W through 190530W
			190621W through 190630W
			190634W through 190640W
			190849W through 190860W
			191043W through 191046W
			191048W
			200213W through 200236W
	AUTOCAT2 WAVE SPANISH	IAP-0500E	150302W
			150304W
			150402W through 150403W
			150408W
			150514W
			150826W
			151014W
			151107W
			151110W
			160425W through 160427W
			160508W through 160510W
			160518W

MODEL INFORMATION	PRODUCT NAME	PRODUCT CODE	SERIAL NUMBER RANGE
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	**AUTOCAT2 WAVE SPANISH**	IAP-0500E	160631W
			160637W
			160642W
			160644W
			160705W
			160919W
			170204W through 170206W
			170221W
			170308W
			170328W
			170928W
			171116W
			180333W
			180840W
			180939W
			181054W
			181056W through 181060W
			190229W
			190512W
			190514W
			190519W
			190631W through 190633W
	AUTOCAT2 WAVE ITALIAN	IAP-0500I	160516W
			160619W
			160804W
			160828W
			170209W through 170210W
			170302W
			180309W
	AUTOCAT2 WAVE JAPANESE	IAP-0500J	140866W through 140867W
			150117W through 150118W
			150120W
			150201W
			150305W
			150307W through 150309W
			150623W through 150624W
			150713W through 150716W
			151114W
			151209W
			151213W
			151219W
			160503W

MODEL INFORMATION	PRODUCT NAME	PRODUCT CODE	SERIAL NUMBER RANGE
Arrow® AutoCAT®2 Intra-Aortic Balloon Pump	**AUTOCAT2 WAVE JAPANESE**	IAP-0500J	160511W through 160515W
			160517W
			160635W through 160636W
			160640W through 160641W
			160731W through 160733W
			171105W
			171117W
			171119W through 171120W
			171201W
			180120W
			180301W
	AUTOCAT2 WAVE DUTCH	IAP-0500NL	160714W through 160715W
			160918W
	AEROAUTOCAT 2 WAVE	IAP-0535	150907W
			151030W
			151101W
			151104W
			151106W
			160305W through 160306W
			160743W
			160824W
			190119W through 190120W
			190221W
			190223W through 190226W
			191047W
Arrow® AC3 Optimus® Intra-Aortic Balloon Pump	**AC3 Optimus IABP NA/EMEA**	IAP-0700	150312F through 150313F
			150315F
			150318F
			150321F
			150324F through 150326F
			161101F through 161110F
			161112F through 161120F
			161201F through 161210F
			170101F through 170120F
			170701F through 170710F
			170801F through 170810F
			170901F through 170920F
			170931F through 170940F
			171002F through 171010F
			171031F through 171036F
			171126F through 171130F
			180101F through 180105F

MODEL INFORMATION	PRODUCT NAME	PRODUCT CODE	SERIAL NUMBER RANGE
Arrow® AC3 Optimus® Intra-Aortic Balloon Pump	**AC3 Optimus IABP NA/EMEA**	IAP-0700	180121F through 180125F
			180201F through 180210F
			180311F through 180330F
			180401F through 180410F
			180421F through 180425F
			180431F through 180440F
			180511F through 180520F
			180601F through 180605F
			180701F through 180710F
			180801F through 180810F
			180821F through 180825F
			180922F through 180931F
			181041F through 181050F
			181101F through 181110F
			181201F through 181210F
			190101F through 190110F
			190131F through 190135F
			190201F through 190210F
			190231F through 190250F
			190301F through 190303F
			190305F through 190320F
			190331F through 190335F
			190401F through 190410F
			190421F through 190430F
			190441F through 190450F
			190501F through 190510F
			190541F through 190550F
			190601F through 190620F
			190641F through 190645F
			190713F through 190730F
			190801F through 190812F
			190826F through 190834F
			190901F through 190912F
			190925F through 190930F
			191013F through 191018F
			191037F through 191042F
			191049F through 191054F
			191113F through 191136F
			191201F through 191212F
			200101F through 200106F
			200137F through 200148F
			200201F through 200212F

MODEL INFORMATION	PRODUCT NAME	PRODUCT CODE	SERIAL NUMBER RANGE
Arrow® AC3 Optimus® Intra-Aortic Balloon Pump	**AC3 Optimus IABP NA/EMEA**	IAP-0700	200301F through 200306F
			200325F through 200326F
			200328F through 200339F
			200341F through 200348F
	AC3 Optimus IABP NA/AJLA	IAP-0701	170831F through 170840F
			171011F through 171020F
			171121F through 171125F
			180106F through 180110F
			180126F through 180130F
			180426F through 180430F
			180606F through 180610F
			180731F through 180740F
			180826F through 180830F
			180901F through 180910F
			180912F through 180921F
			181001F through 181010F
			190136F through 190140F
			190336F through 190340F
			190646F through 190650F
			190731F through 190736F
			190931F through 190936F
			191019F through 191024F
			191055F through 191060F
			200107F through 200112F
			200308F through 200311F