

05th June 2019

URGENT – FIELD SAFETY NOTICE

Type of Action	Advisory Notice
Teleflex Reference	EIF-000347 _ EIF-000348
Commercial Name	Pleur-Evac
Product Code	Lot/Batch
S-1100-08LF S-1200-08LF	Refer to Appendix 1 for list of lots impacted

Dear Customer,

Teleflex Medical has voluntarily issued an advisory notice for the product codes and lot numbers listed above.

Description of the problem & immediate actions required

Teleflex is voluntarily issuing an advisory notice for these products because the IFU contains two errors.

- The IFU in the shipping container identifies the increment measurements on the collection chamber of the device incorrectly. The increments printed on the device are correct and the set-up instructions packaged within each device are accurate.
- The French translation of the IFU incorrectly lists the component “Needleless Injection Site” under part D instead of the correct component “High Negativity Relief Valve”.

No patient injury has been reported. Product code and lot combinations not referenced in Appendix 1 are not impacted by this notification. Our records indicate you have received products that are subject to this notification.

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

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 advisory notice. Please provide this Advisory Notice to all those who need to be aware of it within your organisation and place a copy with affected product. Please consider, clinicians, risk managers, supply chain/distribution centres, etc. in the circulation of this notice. There is no further action required.

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. There is no further action required.



If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TK area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Arrow International.

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

FAX: +41 0 31 848 40 93

Telephone: +41 0 31 818 40 90

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 Teleflex,

Padraig Hegarty

Padraig Hegarty VP, QA (Manufacturing)

Appendix 1 - Product codes and Lots in Scope

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
S-1100-08LF	74A1700365	S-1100-08LF (Cont.)	74B1701886	S-1100-08LF (Cont.)	74C1801760
	74A1701042		74B1701887		74C1802184
	74A1701615		74B1702685		74C1802185
	74A1701616		74B1800749		74C1802186
	74A1702021		74B1800750		74C1802322
	74A1702022		74B1800763		74C1802840
	74A1702023		74B1800764		74D1700239
	74A1703010		74B1800765		74D1700240
	74A1703063		74B1801535		74D1700241
	74A1800680		74B1801538		74D1700936
	74A1800681		74B1801540		74D1701155
	74A1800682		74B1802286		74D1701156
	74A1800683		74B1802287		74D1701660
	74A1801158		74B1802288		74D1702354
	74A1801160		74B1900211		74D1702355
	74A1801161		74B1900322		74D1800538
	74A1801820		74B1900323		74D1800539
	74A1801861		74B1900324		74D1800577
	74A1801863		74B1900873		74D1801083
	74A1801864		74B1901036		74D1801236
	74A1802399		74B1901328		74D1801237
	74A1802400		74B1901329		74D1801763
	74A1802401		74B1901998		74D1801764
	74A1802402		74B1901999		74D1801765
	74A1802912		74B1902000		74D1802410
	74A1802914		74C1700397		74D1802411
	74A1900260		74C1700398		74E1601754
	74A1900371		74C1700399		74E1602420
	74A1900736		74C1701417		74E1602628
	74A1900737		74C1701418		74E1602629
	74A1900738		74C1701419		74E1602892
	74A1901787		74C1701909		74E1700404
	74A1901788		74C1702769		74E1700405
	74A1901789		74C1703153		74E1700406
	74A1902116		74C1703154		74E1700407
	74A1902117		74C1800446		74E1701191
	74A1902742		74C1800447		74E1701192
	74A1903160		74C1800448		74E1701193
	74B1700274		74C1800923		74E1701194
	74B1700275		74C1800924		74E1701803
	74B1700902		74C1800925		74E1701804
	74B1700903		74C1801550		74E1701805
	74B1700904		74C1801551		74E1701806
74B1701885	74C1801552	74E1702502			

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
	74E1702503		74F1801986		74H1601760
	74E1800309		74F1801987		74H1602622
	74E1800310		74F1801988		74H1602623
	74E1800311		74F1802511		74H1602624
	74E1801287		74F1802512		74H1700786
	74E1801288		74G1600572		74H1700787
	74E1801289		74G1600589		74H1700788
	74E1801902		74G1600590		74H1700946
	74E1801903		74G1600591		74H1701207
	74E1801904		74G1601534		74H1701208
	74E1802468		74G1601543		74H1701209
	74E1802469		74G1601544		74H1701687
	74E1802470		74G1601820		74H1701688
	74F1600341		74G1601821		74H1701689
	74F1600349		74G1601822		74H1702493
	74F1600468		74G1700107		74H1703210
	74F1600469		74G1700108		74H1800532
	74F1600470		74G1700136		74H1800533
	74F1600471		74G1700137		74H1800534
	74F1602374		74G1700138		74H1801035
S-1100-08LF	74F1602375	S-1100-08LF	74G1700139	S-1100-08LF	74H1801036
(Cont.)	74F1602376	(Cont.)	74G1701259	(Cont.)	74H1801037
	74F1603156		74G1701260		74H1801656
	74F1603157		74G1701261		74H1801657
	74F1700245		74G1701825		74H1801658
	74F1700246		74G1701826		74H1802126
	74F1700247		74G1701827		74H1802127
	74F1700249		74G1701828		74H1802128
	74F1700641		74G1800481		74H1802710
	74F1700642		74G1800482		74H1802711
	74F1702078		74G1800483		74H1802712
	74F1702079		74G1801222		74J1600202
	74F1702080		74G1801223		74J1600203
	74F1702492		74G1801224		74J1600204
	74F1702493		74G1801553		74J1600610
	74F1702494		74G1801554		74J1600611
	74F1702994		74G1801555		74J1600974
	74F1800453		74G1802383		74J1601645
	74F1800454		74G1802385		74J1601646
	74F1800455		74H1600745		74J1601647
	74F1800696		74H1600746		74J1602157
	74F1800697		74H1600747		74J1602158
	74F1801033		74H1601154		74J1602159
	74F1801358		74H1601155		74J1602955
	74F1801359		74H1601156		74J1602956
	74F1801360		74H1601759		74J1700279

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
	74J1700280		74K1702701		74L1801123
	74J1700550		74K1702702		74L1801492
	74J1700551		74K1800211		74L1801596
	74J1700552		74K1800547		74L1801597
	74J1701471		74K1800548		74L1801598
	74J1701472		74K1800550		74L1801599
	74J1701473		74K1801260		74L1801987
	74J1702265		74K1801278		74L1801988
	74J1702266		74K1801279		74L1801989
	74J1702267		74K1801280		74M1600327
	74J1703040		74K1801913		74M1600561
	74J1800697		74K1801914		74M1600562
	74J1800745		74K1801915		74M1601351
	74J1800746		74K1802519		74M1601503
	74J1800946		74K1802520		74M1601935
	74J1800947		74K1803031		74M1602262
	74J1800948		74L1600165		74M1602383
	74J1800949		74L1600166		74M1700250
	74J1800950		74L1600167		74M1700251
	74J1800951		74L1601368		74M1700751
S-1100-08LF	74J1802103	S-1100-08LF	74L1601369	S-1100-08LF	74M1700752
(Cont.)	74J1802229	(Cont.)	74L1601876	(Cont.)	74M1700753
	74J1802727		74L1602152		74M1700754
	74K1600251		74L1602198		74M1701489
	74K1600252		74L1602513		74M1701490
	74K1600253		74L1602514		74M1701491
	74K1601372		74L1700456		74M1701492
	74K1601373		74L1700457		74M1701811
	74K1601374		74L1700458		74M1701812
	74K1601636		74L1700820		74M1702041
	74K1601784		74L1700821		74M1702042
	74K1601785		74L1700822		74M1702748
	74K1602263		74L1700823		74M1800699
	74K1602479		74L1701455		74M1800700
	74K1602480		74L1701456		74M1800705
	74K1700349		74L1701457		74M1800706
	74K1700350		74L1701458		74M1800707
	74K1700701		74L1702017		74M1800727
	74K1700702		74L1702018		74M1800728
	74K1701309		74L1702019		74M1800729
	74K1701310		74L1702020		74M1800734
	74K1701311		74L1702647		74M1800735
	74K1702049		74L1800467		74M1800736
	74K1702050		74L1800962		74M1801634
	74K1702051		74L1800963		74M1801635
	74K1702700		74L1800964		74M1801648

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
S-1200-08LF (Cont.)	74A1900902				
	74B1700279				
	74C1802844				
	74E1700410				
	74G1701829				
	74H1601159				
	74J1601649				
	74J1800955				
	74K1601385				
	74K1801901				
	74K1801902				
	74L1701469				
	74M1701495				