



24 Nov 2025

Cook Malaysia Field Action Reference Number: RC-25-002-MY

URGENT: MEDICAL DEVICE RECALL

Flexor® Check-Flo® Introducers and Sets Ring Transjugular Intrahepatic Access Sets Rösch-Uchida Transjugular Liver Access Sets

ATTENTION:

Risk Management/Recall Administration

Our records indicate that you have received affected products.

Patient safety and customer satisfaction are Cook Medical's highest priorities. We appreciate your time and attention in reading this important notice.

Purpose of this Letter

The purpose of this letter is to inform you that Cook Medical is voluntarily recalling specific lots of Flexor® Check-Flo® Introducers and Sets, Ring Transjugular Intrahepatic Access Sets, and Rosch-Uchida Transjugular Liver Access Sets.

Reason for Voluntary Recall

Cook Medical identified that products supplied in the affected device lots may have been manufactured out of specification. Impacted products may have been cut to the incorrect length, not correctly trimmed, and not inspected properly.

The issue was identified internally during observation of the manufacturing process, where operators were found deviating from the established procedure. All products manufactured by these operators prior to issue identification are included in scope.

Product Information

Flexor Introducers and Guiding Sheaths are intended to introduce therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature.

Ring Transjugular Intrahepatic Access Sets and Rösch-Uchida Transjugular Liver Access Sets are intended for transjugular liver access in diagnostic and interventional procedures.

See Pages 3 – 10 for a complete list of affected products and lots.

Market Impact

This recall is strictly specific to lots listed in Pages 3 – 10. Unaffected devices will continue to be accessible on the market for purchase based on availability.

Risk to Health

Potential adverse events that may occur if an affected product is used include increased procedural time and vessel injury.



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To date, Cook Medical has not received any customer complaints related to the adverse patient effects listed above for the affected lots.

Actions to be Taken by the Customer

1. Examine inventory immediately to determine if you have affected product(s) and quarantine any affected product that remains unused. Immediately cease all further distribution and use of the affected products.
2. Return the affected product(s) to Cook Medical with a copy of the Acknowledgement and Receipt Form to receive a product credit. Refer to the Acknowledgement and Receipt Form for return instructions.
3. Please complete the Acknowledgement and Receipt Form within **5 business** days of receiving this letter regardless of whether you have affected product(s) on hand. You may return the Form via email (MLY-QA@cookmedical.com).
4. This notice must be shared with appropriate personnel, including down to the user level, within your organization or with any organization where the affected devices have been transferred.
5. Please immediately report adverse events to your local Cook Representative or by email at MLY-QA@cookmedical.com.

Action being Taken by Cook Medical

Cook Medical is removing potentially affected products from the market. Additionally, an investigation has been opened to determine the appropriate actions to prevent reoccurrence of a similar issue.

We recognize that this situation is a potential disruption to your normal operations, and we sincerely apologize. Thank you for your immediate assistance in this matter. If you have any questions or concerns, please contact MLY-QA@cookmedical.com. We look forward to your return of the Acknowledgement and Receipt Form.

Sincerely,

 24 Nov 2025

Chloe Seet
QA Specialist
Cook South East Asia Pte Ltd



Table 1 – Product Information

PRODUCT LABEL NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	LOT NUMBER	UNIQUE DEVICE IDENTIFIER (UDI)
Flexor® Check-Flo® Introducer	KCFW-9.0-18/38- 45-RB-ANL0-HC	G49101	16683401	(01)00827002491014(17)280708(10)16683401
			16724211	(01)00827002491014(17)280804(10)16724211
			16709814	(01)00827002491014(17)280724(10)16709814
			16742116	(01)00827002491014(17)280814(10)16742116
Flexor® Check-Flo® Introducer	KCFW-10.0-35-45- RB-HFANL0-HC	G56278	16652188	(01)00827002562783(17)280619(10)16652188
			16653824	(01)00827002562783(17)280620(10)16653824
			16662713	(01)00827002562783(17)280626(10)16662713
			16662715	(01)00827002562783(17)280626(10)16662715
			16675034	(01)00827002562783(17)280701(10)16675034
			16696277	(01)00827002562783(17)280716(10)16696277
			16703198	(01)00827002562783(17)280721(10)16703198
			16704975	(01)00827002562783(17)280722(10)16704975
			16709796	(01)00827002562783(17)280724(10)16709796
			16720389	(01)00827002562783(17)280731(10)16720389
			16647121	(01)00827002562783(17)280617(10)16647121
			16727475	(01)00827002562783(17)280806(10)16727475
			16657923	(01)00827002562783(17)280624(10)16657923
			16699001	(01)00827002562783(17)280717(10)16699001
16742100	(01)00827002562783(17)280814(10)16742100			
16742118	(01)00827002562783(17)280814(10)16742118			
Flexor® Check-Flo® Introducer	KCFW-12.0-35-45- RB-HFANL0-HC	G56279	NS16692276	(01)00827002562790(17)280714(10)NS16692276
			16637317	(01)00827002562790(17)280610(10)16637317
			16649121	(01)00827002562790(17)280618(10)16649121
			16716240	(01)00827002562790(17)280729(10)16716240
			16614648	(01)00827002562790(17)280523(10)16614648
			16638978	(01)00827002562790(17)280611(10)16638978
			16734533	(01)00827002562790(17)280811(10)16734533
			16675041	(01)00827002562790(17)280701(10)16675041
			16699011	(01)00827002562790(17)280717(10)16699011
			16721854	(01)00827002562790(17)280801(10)16721854
16705000	(01)00827002562790(17)280722(10)16705000			



PRODUCT LABEL NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	LOT NUMBER	UNIQUE DEVICE IDENTIFIER (UDI)
Flexor® Check-Flo® Introducer	KCFW-9.0-18/38-45-RB-ANL1-HC	G49102	16685978	(01)00827002491021(17)280709(10)16685978
			NS16724225	(01)00827002491021(17)280804(10)NS16724225
			NS16733075	(01)00827002491021(17)280808(10)NS16733075
			16709794	(01)00827002491021(17)280724(10)16709794
			NS16716258	(01)00827002491021(17)280729(10)NS16716258
			NS16737154	(01)00827002491021(17)280812(10)NS16737154
Flexor® Check-Flo® Introducer	KCFW-10.0-35-45-RB-HFANL1-HC	G47700	16707723	(01)00827002477001(17)280723(10)16707723
			16727474	(01)00827002477001(17)280806(10)16727474
			16629368	(01)00827002477001(17)280604(10)16629368
			16664784	(01)00827002477001(17)280627(10)16664784
			16700816	(01)00827002477001(17)280718(10)16700816
			16635805	(01)00827002477001(17)280609(10)16635805
Flexor® Check-Flo® Introducer	KCFW-12.0-35-45-RB-HFANL1-HC	G47701	16699013	(01)00827002477018(17)280717(10)16699013
			16616270	(01)00827002477018(17)280527(10)16616270
			16635801	(01)00827002477018(17)280609(10)16635801
			16653825	(01)00827002477018(17)280620(10)16653825
			16664786	(01)00827002477018(17)280627(10)16664786
			16677072	(01)00827002477018(17)280702(10)16677072
			16712983	(01)00827002477018(17)280728(10)16712983
			16712985	(01)00827002477018(17)280728(10)16712985
			16720393	(01)00827002477018(17)280731(10)16720393
			16739603	(01)00827002477018(17)280813(10)16739603
			16607958	(01)00827002477018(17)280520(10)16607958
			16632678	(01)00827002477018(17)280605(10)16632678
			16677073	(01)00827002477018(17)280702(10)16677073
			16690408	(01)00827002477018(17)280711(10)16690408
			16742097	(01)00827002477018(17)280814(10)16742097
			16742088	(01)00827002477018(17)280814(10)16742088
			16699003	(01)00827002477018(17)280717(10)16699003
			16716238	(01)00827002477018(17)280729(10)16716238
16718221	(01)00827002477018(17)280730(10)16718221			
16720394	(01)00827002477018(17)280731(10)16720394			



PRODUCT LABEL NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	LOT NUMBER	UNIQUE DEVICE IDENTIFIER (UDI)
			16704974	(01)00827002477018(17)280722(10)16704974
			16711473	(01)00827002477018(17)280725(10)16711473
			16683413	(01)00827002477018(17)280708(10)16683413
Flexor® Check-Flo® II Introducer Set	KCFW-9.0-35-38.5-RB-RTPS-100	G13160	NS16703184	(01)00827002131606(17)280721(10)NS16703184
			16707656	(01)00827002131606(17)280723(10)16707656
			16635746	(01)00827002131606(17)280609(10)16635746
			16721867	(01)00827002131606(17)280801(10)16721867
			16653802	(01)00827002131606(17)280620(10)16653802
Flexor® Check-Flo® II Introducer Set	KCFW-10.0-35-RB-RTPS-100	G13081	16641423	(01)00827002130814(17)280612(10)16641423
			16649110	(01)00827002130814(17)280618(10)16649110
Flexor® Check-Flo® Introducer	KCFW-9.0-38-55-RB-RAABE	G36393	16607912	(01)00827002363939(17)280520(10)16607912
			16707643	(01)00827002363939(17)280723(10)16707643
			16614609	(01)00827002363939(17)280523(10)16614609
Flexor® Check-Flo® Introducer	KCFW-9.0-38-70-RB-RAABE	G12606	16690398	(01)00827002126060(17)280711(10)16690398
			16703171	(01)00827002126060(17)280721(10)16703171
			16621284	(01)00827002126060(17)280529(10)16621284
			16653803	(01)00827002126060(17)280620(10)16653803
			16614610	(01)00827002126060(17)280523(10)16614610
			16690399	(01)00827002126060(17)280711(10)16690399
			16718180	(01)00827002126060(17)280730(10)16718180
			16712975	(01)00827002126060(17)280728(10)16712975
			NS16625115	(01)00827002126060(17)280602(10)NS16625115
Flexor® Check-Flo® Introducer Set	KCFW-9.0-38-80-RB	G09442	NS16707657	(01)00827002094420(17)280723(10)NS16707657
			NS16602824	(01)00827002094420(17)280515(10)NS16602824
			NS16635753	(01)00827002094420(17)280609(10)NS16635753
			NS16638955	(01)00827002094420(17)280611(10)NS16638955
			16685924	(01)00827002094420(17)280709(10)16685924
			16690400	(01)00827002094420(17)280711(10)16690400



PRODUCT LABEL NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	LOT NUMBER	UNIQUE DEVICE IDENTIFIER (UDI)
Flexor® Check-Flo® Introducer Set	KCFW-10.0- 38-RB	G13031	16643081	(01)00827002130319(17)280613(10)16643081
			16693981	(01)00827002130319(17)280715(10)16693981
			16614624	(01)00827002130319(17)280523(10)16614624
			16638970	(01)00827002130319(17)280611(10)16638970
			16716197	(01)00827002130319(17)280729(10)16716197
			16724162	(01)00827002130319(17)280804(10)16724162
Flexor® Check-Flo® Introducer Set	KCFW-10.0- 38-30-RB	G13032	16716200	(01)00827002130326(17)280729(10)16716200
			16680569	(01)00827002130326(17)280707(10)16680569
Flexor® Check-Flo® Introducer Set	KCFW-10.0- 38-40-RB	G32233	16607936	(01)00827002322332(17)280520(10)16607936
			16638956	(01)00827002322332(17)280611(10)16638956
			16637278	(01)00827002322332(17)280610(10)16637278
			16637282	(01)00827002322332(17)280610(10)16637282
			16644768	(01)00827002322332(17)280616(10)16644768
			16647072	(01)00827002322332(17)280617(10)16647072
			16647073	(01)00827002322332(17)280617(10)16647073
			16657904	(01)00827002322332(17)280624(10)16657904
			16657905	(01)00827002322332(17)280624(10)16657905
			16673098	(01)00827002322332(17)280630(10)16673098
			16673112	(01)00827002322332(17)280630(10)16673112
			16673113	(01)00827002322332(17)280630(10)16673113
			16688777	(01)00827002322332(17)280710(10)16688777
			16688778	(01)00827002322332(17)280710(10)16688778
			16690378	(01)00827002322332(17)280711(10)16690378
			16693991	(01)00827002322332(17)280715(10)16693991
			16704894	(01)00827002322332(17)280722(10)16704894
			16704906	(01)00827002322332(17)280722(10)16704906
			16709786	(01)00827002322332(17)280724(10)16709786
			16709787	(01)00827002322332(17)280724(10)16709787
16716212	(01)00827002322332(17)280729(10)16716212			
16704892	(01)00827002322332(17)280722(10)16704892			
16724177	(01)00827002322332(17)280804(10)16724177			
16739591	(01)00827002322332(17)280813(10)16739591			



PRODUCT LABEL NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	LOT NUMBER	UNIQUE DEVICE IDENTIFIER (UDI)
			16742003	(01)00827002322332(17)280814(10)16742003
			16721877	(01)00827002322332(17)280801(10)16721877
			16673087	(01)00827002322332(17)280630(10)16673087
			16721878	(01)00827002322332(17)280801(10)16721878
Flexor® Check-Flo® Introducer Set	KCFW-10.0- 38-40-RB (continued)	G32233	16716213	(01)00827002322332(17)280729(10)16716213
			16721859	(01)00827002322332(17)280801(10)16721859
			16721860	(01)00827002322332(17)280801(10)16721860
			16721868	(01)00827002322332(17)280801(10)16721868
			16721875	(01)00827002322332(17)280801(10)16721875
			16721876	(01)00827002322332(17)280801(10)16721876
			16602829	(01)00827002322332(17)280515(10)16602829
			16607937	(01)00827002322332(17)280520(10)16607937
			16614632	(01)00827002322332(17)280523(10)16614632
			16623383	(01)00827002322332(17)280530(10)16623383
			16632466	(01)00827002322332(17)280605(10)16632466
			16637284	(01)00827002322332(17)280610(10)16637284
			16638969	(01)00827002322332(17)280611(10)16638969
			16673114	(01)00827002322332(17)280630(10)16673114
16643080	(01)00827002322332(17)280613(10)16643080			
Flexor® Check-Flo® Introducer Set	KCFW-10.0- 38-80-RB	G13033	16621305	(01)00827002130333(17)280529(10)16621305
			16614616	(01)00827002130333(17)280523(10)16614616
			NS16637285	(01)00827002130333(17)280610(10)NS16637285
			NS16647074	(01)00827002130333(17)280617(10)NS16647074
			NS16716215	(01)00827002130333(17)280729(10)NS16716215
			16716214	(01)00827002130333(17)280729(10)16716214
			16673115	(01)00827002130333(17)280630(10)16673115
			NS16718189	(01)00827002130333(17)280730(10)NS16718189
Flexor® Check-Flo® Introducer Set	KCFW-12.0- 38-40-RB	G32373	16632469	(01)00827002323735(17)280605(10)16632469
			16683354	(01)00827002323735(17)280708(10)16683354
			16652152	(01)00827002323735(17)280619(10)16652152
			16703175	(01)00827002323735(17)280721(10)16703175
			NS16724169	(01)00827002323735(17)280804(10)NS16724169



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PRODUCT LABEL NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	LOT NUMBER	UNIQUE DEVICE IDENTIFIER (UDI)
Flexor® Check-Flo® Introducer Set	KCFW-12.0- 38-80-RB	G49487	16727445	(01)00827002494879(17)280806(10)16727445
			16621277	(01)00827002494879(17)280529(10)16621277
			16627324	(01)00827002494879(17)280603(10)16627324
			16621278	(01)00827002494879(17)280529(10)16621278
			16720362	(01)00827002494879(17)280731(10)16720362
			16613273	(01)00827002494879(17)280522(10)16613273
			16614607	(01)00827002494879(17)280523(10)16614607
			16618070	(01)00827002494879(17)280528(10)16618070
			16725621	(01)00827002494879(17)280805(10)16725621
			16720364	(01)00827002494879(17)280731(10)16720364
			16725622	(01)00827002494879(17)280805(10)16725622
Ring Transjugular Intrahepatic Access Set	RTPS-100	G06541	16705779	(01)00827002065413(17)280722(10)16705779
			NS16712524	(01)00827002065413(17)280725(10)NS16712524
Ring Transjugular Intrahepatic Access Set	RTPS-100-10.0	G29769	16659044	(01)00827002297692(17)280624(10)16659044
			16676115	(01)00827002297692(17)280701(10)16676115
			16708987	(01)00827002297692(17)280723(10)16708987
			16719365	(01)00827002297692(17)280730(10)16719365



PRODUCT LABEL NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	LOT NUMBER	UNIQUE DEVICE IDENTIFIER (UDI)
Rosch-Uchida Transjugular Liver Access Set	RUPS-100	G06929	16659065	(01)00827002069299(17)280624(10)16659065
			16646117	(01)00827002069299(17)280616(10)16646117
			16651355	(01)00827002069299(17)280618(10)16651355
			16651356	(01)00827002069299(17)280618(10)16651356
			16651357	(01)00827002069299(17)280618(10)16651357
			16651358	(01)00827002069299(17)280618(10)16651358
			16652795	(01)00827002069299(17)280619(10)16652795
			16662118	(01)00827002069299(17)280625(10)16662118
			16662121	(01)00827002069299(17)280625(10)16662121
			16659066	(01)00827002069299(17)280624(10)16659066
			16679321	(01)00827002069299(17)280703(10)16679321
			16681725	(01)00827002069299(17)280707(10)16681725
			16681726	(01)00827002069299(17)280707(10)16681726
			16705820	(01)00827002069299(17)280722(10)16705820
			16723846	(01)00827002069299(17)280804(10)16723846
			16673663	(01)00827002069299(17)280630(10)16673663
			16674074	(01)00827002069299(17)280630(10)16674074
			16712525	(01)00827002069299(17)280725(10)16712525
			16723841	(01)00827002069299(17)280804(10)16723841
			16723843	(01)00827002069299(17)280804(10)16723843
			16723847	(01)00827002069299(17)280804(10)16723847
			16689869	(01)00827002069299(17)280710(10)16689869
			16689875	(01)00827002069299(17)280710(10)16689875
			16689876	(01)00827002069299(17)280710(10)16689876
			16693105	(01)00827002069299(17)280714(10)16693105
			16695311	(01)00827002069299(17)280715(10)16695311
			16705811	(01)00827002069299(17)280722(10)16705811
			16708988	(01)00827002069299(17)280723(10)16708988
16712517	(01)00827002069299(17)280725(10)16712517			
16723839	(01)00827002069299(17)280804(10)16723839			
16723842	(01)00827002069299(17)280804(10)16723842			
16723844	(01)00827002069299(17)280804(10)16723844			



PRODUCT LABEL NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	LOT NUMBER	UNIQUE DEVICE IDENTIFIER (UDI)
			16738879	(01)00827002069299(17)280812(10)16738879
			16646119	(01)00827002069299(17)280616(10)16646119
			16638465	(01)00827002069299(17)280610(10)16638465
			16646109	(01)00827002069299(17)280616(10)16646109
			16646120	(01)00827002069299(17)280616(10)16646120
			16646121	(01)00827002069299(17)280616(10)16646121
			16664979	(01)00827002069299(17)280627(10)16664979
			16673659	(01)00827002069299(17)280630(10)16673659
			16673661	(01)00827002069299(17)280630(10)16673661
			16673662	(01)00827002069299(17)280630(10)16673662
			16673665	(01)00827002069299(17)280630(10)16673665
			16673666	(01)00827002069299(17)280630(10)16673666
			16674075	(01)00827002069299(17)280630(10)16674075
			16681728	(01)00827002069299(17)280707(10)16681728
			16689877	(01)00827002069299(17)280710(10)16689877
			16705812	(01)00827002069299(17)280722(10)16705812
			16708989	(01)00827002069299(17)280723(10)16708989
			16708990	(01)00827002069299(17)280723(10)16708990
			16712518	(01)00827002069299(17)280725(10)16712518
			16712527	(01)00827002069299(17)280725(10)16712527
			16712528	(01)00827002069299(17)280725(10)16712528
			16723848	(01)00827002069299(17)280804(10)16723848
			16723881	(01)00827002069299(17)280804(10)16723881
			16678439	(01)00827002069299(17)280702(10)16678439
			16714326	(01)00827002069299(17)280728(10)16714326

Note: Above is the complete global list of affected lots identified by product owner. If you have any questions or concerns on the affected product list, please contact MLY-QA@cookmedical.com.