



Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: February 11, 2016

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: *Laurie Kidwell*
Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Cook Medical – RECALL [Medical Device]

AFFECTED PRODUCT: Single Lumen Central Venous Catheters and Pressure Monitoring Sets and Trays

SUMMARY: Unclassified Recall; The recall is due to catheter tip fracture and/or separation.

<u>Name of Device</u>	<u>Reference Part Number</u>	<u>Global Product Number</u>	<u>Lot Number</u>
	C-NPMSY-501J-15	G13531	NS6054841, NS6054842, NS6075552, NS6082372, NS6082373
Femoral Artery Pressure Monitoring Catheter Tray	C-PMSY-300-FA	G02962	NS5833887, NS5866959, NS5881272, NS5881334, NS5881335, NS5919925, NS6047449, NS6054847, NS6054848, NS6072526, NS6072555, NS6082379, NS6090277, NS6105921, NS6124989, NS6130501, NS6148639
	C-PMSY-300J-FA	G02795	NS5866961, NS5866962, NS5892115, NS5922709, NS5932844, NS5974256, NS6031988, NS6031990, NS6042578, NS6050052, NS6050053
	C-PMSY-400J-FA	G01925	NS6031992, NS6031993, NS6130504, NS6137424
	C-PMSY-401-FA	G02253	NS6054849
	C-NPMS-501J-15	G13332	6054830, 6054831, 6072436, 6078670, 6081720, 6083977
	C-PMS-300-FA	G02250	NS5833881, NS5881267, NS5881268, NS5892106, NS5892107, NS5892108, NS5914766, NS5922706, NS5928596, NS5932820, NS5932821, NS5967447, NS5967448, NS5967449, NS6014474, NS6014475, NS6014484, NS6014485, NS6042778, NS6042795, NS6042796, NS6050046, NS6063330, NS6063354, NS6075555, NS6100599, NS6100600, NS6108225, NS6124985
Femoral Artery Pressure Monitoring Catheter Set	C-PMS-300J-FA	G04021	NS5888542, NS5928597, NS6028553, NS6042797, NS6090273, NS6090274, NS6100601, NS6130149
	C-PMS-301-FA	G02598	5800570, 5860387, 5891906, 5980254, 6003160, 6062725, 6143835, NS5830771, NS5866956, NS5866957, NS5881269, NS6014460, NS6042798, NS6050047, NS6075534, NS6075556
	C-PMS-301J-FA	G02755	5895598, 6129058, 6148613, NS5932822, NS5932837, NS5994907, NS6130498
	C-PMS-400-FA	G01909	6067782, 6139280, NS6042805, NS6130500
	C-PMS-401-FA	G02058	6049951, 6137353, 6139281
	C-PMS-401J-FA	G02089	6034986, 6049957, 6067784
Radial Artery Pressure	C-PMSY-250-RA	G04528	6124812
	C-PMSY-300-	G01923	5793192, 5824526, 5884647, 5892068, 5942090, 5967410, 6003167, 6059765, 6134128,



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To promote and provide essential public health services.

<u>Name of Device</u>	<u>Reference Part Number</u>	<u>Global Product Number</u>	<u>Lot Number</u>
Monitoring RA Catheter Tray	C-PMSY-301-RA	G02052	6153124, 6168137, 6254068
	C-PMS-250-RA	G02926	5793193, 5866995, 5892069, 5942092, 6003168, 6025099, 6067664, 6168138
	C-PMS-251-RA	G02930	6049998, 6160195, 6160212, NS5898558, NS6063328, NS6178204, NS6178206
			5895605, 6191185
			5793196, 5800313, 5800443, 5800569, 5806981, 5810905, 5810917, 5824484, 5824546, 5824547, 5824548, 5866984, 5866985, 5866986, 5870319, 5881447, 5881519, 5889496, 5891905, 5911486, 5922847, 5922848, 5925742, 5928632, 5939446, 5939447, 5939448, 5976502, 6025016, 6025094, 6033768, 6034981, 6034983, 6050000, 6062738, 6062742, 6067675, 6067676, 6075206, 6075207, 6083936, 6083954, 6083985, 6083986, 6129056, 6148790, 6160236, 6165591, 6174974, 6175289, 6191362, 6269150, NS6063331, NS6108226, NS6170739, NS6170767
Radial Artery Pressure Monitoring Set	C-PMS-300-RA-CHOP	G50148	5905252, 6003109
			5793197, 5800571, 5800572, 5824485, 5824551, 5845063, 5864072, 5866988, 5873125, 5881151, 5881152, 5884641, 5884642, 5889464, 5892063, 5892064, 5922850, 5939431, 5942091, 5951549, 5953768, 5954322, 5967404, 5974281, 5994817, 5996926, 6003161, 6003162, 6017048, 6025095, 6025145, 6034984, 6042699, 6050002, 6075210, 6075211, 6075212, 6081723, 6083988, 6100756, 6124809, 6125111, 6148791, 6153122, 6160239, 6160240, 6168131, 6171368, 6187477, 6250532
	C-PMS-301-RA	G02054	6059759, NS6047396, NS6047397, NS6047398, NS6047399, NS6047440, NS6047442
	C-PMS-301J-RA	G02133	NS6072553
	C-PMS-250-PED	G04889	NS6168054, NS6178118
	C-PMS-251J-PED	G05345	NS6063352
	C-PMS-300-CHILDRENS-032285	G02805	NS5855441
Single Lumen Central Venous Catheter Set	C-PMS-301J-PED	G03117	5824486, 5898058, 5967405, 6079119, NS5932737, NS6028554, NS6042799
	C-PMS-301J-PED-BH	G06993	NS5922707, NS5932811
	C-PMS-301-PED	G02990	NS6145002
	C-PUM-300J	G02140	NS5970942
	C-PUM-301	G02225	NS5954223
	C-PUM-301J	G02128	5945120, NS5954224
	C-PMSY-250	G02854	5987014
	C-PMSY-251	G03241	NS6178099
	C-PMSY-251J	G05434	NS6028540
	C-PMSY-300	G01926	NS5830758, NS5866960, NS5918174, NS5974263, NS6042577, NS6047450, NS6090278, NS6105922, NS6124990
	C-PMSY-300J	G01927	NS5881337, NS5892116, NS6031991
	C-PMSY-300J-UT-A	G06141	5782006, 5855241
Single Lumen Central Venous Catheter Tray	C-PMSY-300-PED	G12497	NS5881336, NS5892113, NS5945282
	C-PMSY-301J	G02244	6062729
	C-PMSY-301J-BH	G02570	NS5970950, NS6108255, NS6153173
	C-PMSY-301J-PED	G03433	5793198, 5925744, 6010406, 6148800
	C-PMSY-301J-PED-OTP	G10375	NS5796483, NS5928602
	C-PMSY-400-HURLEY-022388	G04755	NS6047451
	C-PUMY-301J	G02157	5973354
Single	C-PMS-250	G02838	6028502, 6034979, 6083984, 6194848, NS6014456, NS6014457

<u>Name of Device</u>	<u>Reference Part Number</u>	<u>Global Product Number</u>	<u>Lot Number</u>
Lumen Pressure Monitoring Set	C-PMS-2502-15-3.5	G07943	6148788, 6254047
	C-PMS-2502-15-5.0	G03425	5906417, 6160213
	C-PMS-250-MONTES-A-092084	G03079	NS6064797
	C-PMS-251	G02833	NS6014483, NS6175149, NS6184593, NS6187516
	C-PMS-251J	G02925	NS6014458
	C-PMS-300	G01911	5889463, 5898283, 5922849, 5941909, 5964565, 5976506, 6021072, 6028497, 6143834, 6160238
	C-PMS-300-CHILDRENS-A-032988	G04448	NS5933957
	C-PMS-300J	G01912	5828147, 5941919
	C-PMS-301	G01961	NS5932835, NS5932836, NS6050233, NS6072523, NS6108227, NS6130497
	C-PMS-301J	G02061	5803601, 6034985, 6075213
	C-PMS-301J-PKG	G06296	NS5833882, NS5892109, NS5892110, NS5919920, NS6021136, NS6054843, NS6072524, NS6075557, NS6082375, NS6108228, NS6148658
	C-PMS-400J	G01914	6067668

The recalled products were distributed nationwide.

SUGGESTED

ACTION: For consumer inquiry only. Consumers with questions may contact Cook Medical Customer Relations at 1-800-457-4500 or 1-812339-2235, Monday through Friday, between 7:30 a.m. and 5:00 p.m. Eastern time or via email at FieldActionsNA@cookmedical.com.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Cook Medical Issues Global Recall of Select Lots of Central Venous Catheters and Pressure Monitoring Sets and Trays

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

For Immediate Release

February 10, 2016

Contact

Consumers

Cook Medical Customer Relations
FieldActionsNA@cookmedical.com
1-800-457-4500

Media

Moriah Sowders
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812-339-2235, ext. 4357

Firm Press Release
[View Product Photos](#)

On January 6, 2016, Cook Medical initiated a voluntary recall of 360 specific lots of Single Lumen Central Venous Catheters and Pressure Monitoring Sets and Trays due to catheter tip fracture and/or separation. Globally, 17,827 devices are subject to this recall. The recalled products are specific versions and lot numbers of the Single Lumen Central Venous Catheter Sets and Trays, Single Lumen Pressure Monitoring Sets, Femoral Artery Pressure Monitoring Catheter Sets and Trays, and Radial Artery Pressure Monitoring Catheter Sets and Trays. These products are intended for use in venous or arterial pressure monitoring, blood sampling, and administration of drugs and fluids.

During an internal inspection, a catheter exhibited the potential for catheter tip fracture and/or separation. Further investigation revealed that the technique used by the product assembler while tipping the catheter likely contributed to this nonconformance. No reports of illness or injury have been associated with this issue to date. Potential adverse events that may occur as a result of catheter tip fracture and/or separation include loss of device function, the need for medical intervention to retrieve a separated segment, and complications resulting from a separated tip occluding blood flow to end organs. Examples of such complications include stroke, kidney injury, or damage to the intestines or limbs.

The Single Lumen Central Venous Catheters and Pressure Monitoring Sets and Trays in this recall were distributed globally between April 24, 2015, and October 23, 2015. Product can be identified by the part number and lot number that are provided on the outer package product label. The lot numbers for products that are subject to this recall can be found below:

Name of Device	Reference Part Number	Global Product Number	Lot Number
	C-NPMSY-501J-15	G13531	NS6054841, NS6054842, NS6075552, NS6082372, NS6082373
Femoral Artery Pressure Monitoring Catheter Tray	C-PMSY-300-FA	G02962	NS5833887, NS5866959, NS5881272, NS5881334, NS5881335, NS5919925, NS6047449, NS6054847, NS6054848, NS6072526, NS6072555, NS6082379, NS6090277, NS6105921, NS6124989, NS6130501, NS6148639
	C-PMSY-300J-FA	G02795	NS5866961, NS5866962, NS5892115, NS5922709, NS5932844, NS5974256, NS6031988, NS6031990, NS6042578, NS6050052, NS6050053
	C-PMSY-400J-FA	G01925	NS6031992, NS6031993, NS6130504, NS6137424
	C-PMSY-401-FA	G02253	NS6054849
	C-NPMS-501J-15	G13332	6054830, 6054831, 6072436, 6078670, 6081720, 6083977
	C-PMS-300-FA	G02250	NS5833881, NS5881267, NS5881268, NS5892106, NS5892107, NS5892108, NS5914766, NS5922706, NS5928596, NS5932820, NS5932821, NS5967447, NS5967448, NS5967449, NS6014474, NS6014475, NS6014484, NS6014485, NS6042778, NS6042795, NS6042796, NS6050046, NS6063330, NS6063354, NS6075555, NS6100599, NS6100600, NS6108225, NS6124985
Femoral Artery Pressure Monitoring Catheter Set	C-PMS-300J-FA	G04021	NS5888542, NS5928597, NS6028553, NS6042797, NS6090273, NS6090274, NS6100601, NS6130149
	C-PMS-301-FA	G02598	5800570, 5860387, 5891906, 5980254, 6003160, 6062725, 6143835, NS5830771, NS5866956, NS5866957, NS5881269, NS6014460, NS6042798, NS6050047, NS6075534, NS6075556
	C-PMS-301J-FA	G02755	5895598, 6129058, 6148613, NS5932822, NS5932837, NS5994907, NS6130498
	C-PMS-400-FA	G01909	6067782, 6139280, NS6042805, NS6130500
	C-PMS-401-FA	G02058	6049951, 6137353, 6139281
	C-PMS-401J-FA	G02089	6034986, 6049957, 6067784

Name of Device	Reference Part Number	Global Product Number	Lot Number	
Pressure Monitoring Catheter Tray	C-PMSY-250-RA	G04528	6124812	
	C-PMSY-300-RA	G01923	5793192, 5824526, 5884647, 5892068, 5942090, 5967410, 6003167, 6059765, 6134128, 6153124, 6168137, 6254068	
	C-PMSY-301-RA	G02052	5793193, 5866995, 5892069, 5942092, 6003168, 6025099, 6067664, 6168138	
	C-PMS-250-RA	G02926	6049998, 6160195, 6160212, NS5898558, NS6063328, NS6178204, NS6178206	
	C-PMS-251-RA	G02930	5895605, 6191185	
Radial Artery Pressure Monitoring Catheter Set	C-PMS-300-RA	G01908	5793196, 5800313, 5800443, 5800569, 5806981, 5810905, 5810917, 5824484, 5824546, 5824547, 5824548, 5866984, 5866985, 5866986, 5870319, 5881447, 5881519, 5889496, 5891905, 5911486, 5922847, 5922848, 5925742, 5928632, 5939446, 5939447, 5939448, 5976502, 6025016, 6025094, 6033768, 6034981, 6034983, 6050000, 6062738, 6062742, 6067675, 6067676, 6075206, 6075207, 6083936, 6083954, 6083985, 6083986, 6129056, 6148790, 6160236, 6165591, 6174974, 6175289, 6191362, 6269150, NS6063331, NS6108226, NS6170739, NS6170767	
	C-PMS-300-RA-CHOP	G50148	5905252, 6003109	
	C-PMS-301-RA	G02054	5793197, 5800571, 5800572, 5824485, 5824551, 5845063, 5864072, 5866988, 5873125, 5881151, 5881152, 5884641, 5884642, 5889464, 5892063, 5892064, 5922850, 5939431, 5942091, 5951549, 5953768, 5954322, 5967404, 5974281, 5994817, 5996926, 6003161, 6003162, 6017048, 6025095, 6025145, 6034984, 6042699, 6050002, 6075210, 6075211, 6075212, 6081723, 6083988, 6100756, 6124809, 6125111, 6148791, 6153122, 6160239, 6160240, 6168131, 6171368, 6187477, 6250532	
	C-PMS-400-RA	G02092	6059759, NS6047396, NS6047397, NS6047398, NS6047399, NS6047440, NS6047442	
	C-PMS-301J-RA	G02133	NS6072553	
	C-PMS-250-PED	G04889	NS6168054, NS6178118	
	C-PMS-251J-PED	G05345	NS6063352	
	C-PMS-300-CHILDRENS-032285	G02805	NS5855441	
	Single Lumen Central Venous Catheter Set	C-PMS-301J-PED	G03117	5824486, 5898058, 5967405, 6079119, NS5932737, NS6028554, NS6042799
		C-PMS-301J-PED-BH	G06993	NS5922707, NS5932811
C-PMS-301-PED		G02990	NS6145002	
C-PUM-300J		G02140	NS5970942	
C-PUM-301		G02225	NS5954223	
C-PUM-301J		G02128	5945120, NS5954224	
C-PMSY-250		G02854	5987014	
C-PMSY-251		G03241	NS6178099	
C-PMSY-251J		G05434	NS6028540	
C-PMSY-300		G01926	NS5830758, NS5866960, NS5918174, NS5974263, NS6042577, NS6047450, NS6090278, NS6105922, NS6124990	
C-PMSY-300J		G01927	NS5881337, NS5892116, NS6031991	
C-PMSY-300J-UT-A		G06141	5782006, 5855241	
C-PMSY-300-PED		G12497	NS5881336, NS5892113, NS5945282	
C-PMSY-301J		G02244	6062729	
C-PMSY-301J-BH		G02570	NS5970950, NS6108255, NS6153173	
Single Lumen Central Venous Catheter Tray	C-PMSY-301J-PED	G03433	5793198, 5925744, 6010406, 6148800	
	C-PMSY-301J-PED-OTP	G10375	NS5796483, NS5928602	

Name of Device	Reference Part Number	Global Product Number	Lot Number
Single Lumen Pressure Monitoring Set	C-PMSY-400-HURLEY-022388	G04755	NS6047451
	C-PUMY-301J	G02157	5973354
	C-PMS-250	G02838	6028502, 6034979, 6083984, 6194848, NS6014456, NS6014457
	C-PMS-2502-15-3.5	G07943	6148788, 6254047
	C-PMS-2502-15-5.0	G03425	5906417, 6160213
	C-PMS-250-MONTES-A-092084	G03079	NS6064797
	C-PMS-251	G02833	NS6014483, NS6175149, NS6184593, NS6187516
	C-PMS-251J	G02925	NS6014458
	C-PMS-300	G01911	5889463, 5898283, 5922849, 5941909, 5964565, 5976506, 6021072, 6028497, 6143834, 6160238
	C-PMS-300-CHILDRENS-A-032988	G04448	NS5933957
	C-PMS-300J	G01912	5828147, 5941919
	C-PMS-301	G01961	NS5932835, NS5932836, NS6050233, NS6072523, NS6108227, NS6130497
	C-PMS-301J	G02061	5803601, 6034985, 6075213
	C-PMS-301J-PKG	G06296	NS5833882, NS5892109, NS5892110, NS5919920, NS6021136, NS6054843, NS6072524, NS6075557, NS6082375, NS6108228, NS6148658
	C-PMS-400J	G01914	6067668

Shipments were made globally to the following regions: Australia, Belgium, Brazil, Canada, Chile, Denmark, Dominican Republic, Finland, France, Germany, India, Israel, Italy, Jordan, Kuwait, Netherland, New Zealand, Panama, Puerto Rico, Spain, Switzerland, United Arab Emirates, United Kingdom, and United States of America.

Cook Medical notified its customers and distributors by recall notification letters in January. All customers and distributors should quarantine and discontinue use of all affected units and return the affected product to the company as soon as possible for credit.

Cook Medical notified the FDA and other global regulatory agencies of this action.

Consumers with questions may contact Cook Medical Customer Relations at 1-800-457-4500 or 1-812339-2235, Monday through Friday, between 7:30 a.m. and 5:00 p.m. Eastern time or via email at FieldActionsNA@cookmedical.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, via regular mail or via fax. Complete and submit the report online at www.fda.gov/medwatch/report.htm or via regular mail or fax. Download the form at www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, and then complete and return to the address on the preaddressed form, or submit via fax to 1-800FDA-0178.

Adverse events may also be reported to Cook Medical Customer Relations at 1-800-457-4500 or 1812-339-2235, Monday through Friday, between 7:30 a.m. and 5:00 p.m. Eastern time or via email at CustomerRelationsNA