COOK MEDICAL
1025 ACUFF ROAD, P.O. BOX 4195
BLOOMINGTON, IN 47402-4195 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

January 04, 2019

URGENT: MEDICAL DEVICE RECALL
PROMPT RESPONSE REQUIRED

ATTENTION:
Risk Management and Recall Administration
Our records indicate that you have received some of the affected products listed below.

Description of the problem

Cook considers the safety and satisfaction of our customers a top priority. We appreciate your time and attention in reading this important notice.

Cook Medical is initiating a voluntary recall of the specific lots listed in Attachment 1. Cook Medical has identified that the affected lots may contain a wire guide that was incorrectly loaded into the wire guide holder. This could lead to the stiff tip of the wire guide being introduced into the patient instead of the flexible tip.

Potential adverse events that may occur if an affected product is used include a delay in procedure or tissue and/or organ injury.

Details about the affected products

Please refer to Attachment 1 for a list of affected products.

Intended use for the affected products

Please refer to Attachment 2 for a list of intended uses for the affected products.

Action to take

1. Examine your inventory immediately to determine if you have affected product(s), and quarantine affected product(s). Immediately cease all distribution and use of these products.
2. Return the affected product(s) to Cook Medical with a copy of the Acknowledgement and Receipt Form to receive a product credit.
   NOTE: Unaffected products that are returned will not be credited.
3. Please complete the Acknowledgement and Receipt Form within 5 business days of receiving this letter. Even if you do not have affected product(s) on hand, you must still complete the Acknowledgement and Receipt Form and return it via fax (812.339.7316) or email (FieldActionsNA@CookMedical.com).
4. Immediately report adverse events to Cook Medical Customer Relations by phone at 800.457.4500 or 812.339.2235, Monday through Friday between 7:30 am and 5:00 pm (Eastern Time) or by email to CustomerRelationsNA@CookMedical.com.

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Adverse events or quality problems experienced with the use of this product may also be reported to the FDA.

- Visit http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm to obtain a form to fax or mail.
- Call the FDA at 800.FDA.1088.

Transmission of this notice

This notice must be shared with appropriate personnel, including down to the user level, within your organization or with any organization where the potentially affected devices have been transferred.

This action is being taken with the knowledge of the Food and Drug Administration.

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 Cook Medical Customer Relations at 800.457.4500 or 812.339.2235. We look forward to your response.

[redacted]

Larry D. Pool
Director, Post Market
Cook Incorporated

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URGENT: PROMPT RESPONSE REQUIRED

Acknowledgement and Receipt Form

You are required to fill out and return this form. Please return it within 5 business days of receipt, even if you do not have any of the affected product(s).

Please complete the following information regarding the recall on the products listed in Attachment 1.

Your customer information

Customer Account Number:	Customer Name:	
Street Address:	City:	
State, Zip Code:	Department:	Phone:
Form Completed By (Printed Name, Signature):		Date:

Actions you have taken

1. I have received the letter titled "URGENT: MEDICAL DEVICE RECALL," and I understand the instructions in the letter. ☐Yes ☐No

Affected product information

Please list the quantity of affected product at your facility to be returned, or write "none" if the affected product is no longer in your inventory or is no longer with your customers.

QUANTITY	PART NUMBER	LOT NUMBER/SERIAL NUMBER

Additional actions for distributors

Share the letter "URGENT: MEDICAL DEVICE RECALL" with appropriate personnel within your organization or with any organization where the potentially affected product(s) have been transferred.
Please confirm the following:

1. I have notified my customers of the recall. ☐Yes ☐No

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Returning this form and affected product(s)

Upon completion of this form, please return it to the Cook Medical Customer Relations department via fax or email. Fax: 812.339.7316 Email: FieldActionsNA@CookMedical.com

For information regarding the recall, medical questions, or to report adverse events, contact Cook Medical Customer Relations at 800.457.4500 or 812.339.2235.

Return affected product(s) and send this form to this address:

Cook Medical
ATTN: Return Good/Recall # FAIP-2018-011
400 Daniels Way
Bloomington, IN 47404

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Attachment 1 – Affected Lot Numbers
Field Action on Reverse Loaded Wire Guides

Brand Name	Reference Part Number (RPN)	Global Product Number (GPN)	Lot Numbers
Bentson PTFE Wire Guide	635497	G14590	7832513, 7832514, 8062406, 8062407, 8065988, 8065989, 8065992, 8404354, 8404355, 8547811
	638497	G14589	8069648
Fixed Core Straight Safety Wire Guide	638821	G14285	7971639
Heavy Duty PTFE Wire Guide	638453	G14323	7875295
	638854	G14260	8481133, NS8481135
PTFE Wire Guide	635413	G14544	7832498, 7832499, 7832500, 7925385, 7925387, 7930517, 8090868, 8287793, 8287794, 8287799, 8400121, 8548813, 8548815, NS8548814
	638413	G14731	7760235, 7881599, 8062433, 8074027, 8290383, 8290384, 8404559, 8404562
	638813	G15067	7999663, 8077582, 8077583
	635413-10	G34134	8065959
	638413-10	G34133	8073949, 8074014, 8074015
Wire Guide	638123	G14326	7857489
Angled Tip Ureteral Catheter Set	023105	G14598	8023195, 8314384, 8409525, NS8040177
Angled Tip Ureteral Catheter Set With Bentson PTFE Wire Guide	023106	G14587	8018728, 8080823, 8314382, 8409523
	023245	G15302	8023194
Bander Ureteral Diversion Open-End Stent Set	025707-S1	G14822	8011030, 8033568, 8063430, 8063431, 8150491, 8417631, 8417632, 8587162, 8587163, 8590532, 8590533
	025807-S1	G14823	7990830, 8003084, 8033571, 8063428, 8590520, 8590522, 8629475, NS8629473
C-Flex® Double Pigtail Ureteral Stent Set	036510	G14364	NS7953136, NS8169661, NS8180857
	036512	G14365	NS8169662
	036516	G14367	NS8180858, NS8180859, NS8180860
Dretler Ureteroscopy Stent Set	025506-S4	G15735	8023078, 8629460, 8629461
Kwart Retro-Inject™ Ureteral Stent Set	003526	G15016	8011027, 8183322
	003600	G14836	8037660
	003622	G14885	8030233
	003626	G14887	8018054
	AQ-003600	G17151	7994816
Percutaneous Entry Set	080000	G14649	8109245, NS8109246
Percutaneous Malecot Nephrostomy Set	082016	G16714	NS8070854
	082012-ET	G19107	8078209

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Percutaneous Malecot Nephrostomy Set	082014-ET	G19108	8116743
Percutaneous Pigtail Nephrostomy Set	080008	G14094	8112670
	080010	G14095	8113259
	080012	G14899	8113260, 8113261, NS8070847
	080508	G14329	8076035
Sof-Flex® Double Pigtail Ureteral Stent Set	039508	G15076	NS7949093, NS8077953, NS8077954, NS8077955
	039512	G14906	8070691, 8183342, 8183343
	039516	G14840	8070693, 8172134, 8187189, NS8070692
	039610-S2	G17128	7990841
	039612	G14867	7990842
	039616	G14865	8424304
Sof-Flex® Multi-Length Ureteral Stent Set	039500-8-20	G17852	8172131, 8172132, 8193001
	039600	G14773	8011038
	039608	G15000	NS7998389, NS8008388, NS8018651, NS8030247, NS8037667
	039712	G14951	8625597, 8625598, 8599605
Universa® Firm Ureteral Stent and Positioner	UFH-522-T1	G23430	NS7949118
	UFH-624-T1	G23438	NS7990869, NS7990870, NS7990871
Universa® Firm Ureteral Stent Set	UFH-500	G49869	7953153, 8077981
	UFH-522	G49864	8070702
	UFH-524	G49865	NS8176831
	UFH-526	G49866	7999744, 7999746, 8077988, 8077986, 8172070, 8176832, 8176833, 8176834
	UFH-528	G49867	NS7999747
	UFH-530	G49868	NS8180869
	UFH-600	G49877	7990863, 8424316, 8424317, 8424318
	UFH-618	G49870	NS7990867
	UFH-626	G49874	7988039, 7988039X, 7998403, 7998404, 8001365, 8040131, 8193749, 8197930, 8197931, 8412989, 8412990, 8424332
	UFH-628	G49875	8003098, 8506037
	UFH-720	G49879	NS8018667
	UFH-724	G49881	8594594

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Brand Name	Reference Part Number (RPN)	Global Product Number (GPN)	Lot Numbers
Universa® Firm Ureteral Stent Set	UFH-726	G49882	8197932, 8594595
	UFH-820	G49887	NS8197934, NS8417599, NS8417600
	UFH-822	G49888	NS7998407, NS8033592, NS8033593
Universa® Soft Ureteral Stent Set	US-500	G53687	8078013
	US-518	G53145	8172113
	US-526	G53676	8001369, 8183381
	US-528	G53677	NS7994828
	USH-500	G49937	7998415, 8147267, 8187145
	USH-524	G49933	8008415, 8011065, 8078026
	USH-526	G49934	8008416, 8078027, 8078028, 8150465, 8180873
	US-600	G53703	8147249, 8417607, 8600625, NS8417608,
	US-618	G53689	NS7990886
	US-624	G53692	7990888
	US-626	G53693	8594598, 8594599
	US-628	G53694	8056338
	US-700	G53706	8018675
	US-726	G53711	8056337, 8629502
	US-728	G53712	NS8018677
	US-820	G53723	NS8053511
	US-822	G53724	NS8417612
	US-824	G53725	NS8011064
	US-826	G53726	NS8417614, NS8417615
	USH-600	G49945	8008417, 8033600, 8427840, 8427841, 8507952, 8507953, 8507954, 8507955
	USH-622	G49940	7990900, 8003104, NS7990899
	USH-624	G49941	7998422, 7998423, 8047039, 8056331, 8066970, 8066972, 8066973, 8066974, 8147295, 8147296, 8421552, 8427843, 8427847, 8594610
	USH-626	G49942	7994831, 8008426, 8056327, 8066976, 8066977, 8207795
	USH-700	G49953	8629522
	USH-720	G49947	NS8026827, NS8030272, NS8421563
	USH-722	G49948	NS8421564, NS8421566, NS8421567

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Brand Name	Reference Part Number (RPN)	Global Product Number (GPN)	Lot Numbers
Universa® Soft Ureteral Stent Set	USH-724	G49949	8599661
	USH-726	G49950	8421568
	USH-728	G49951	NS8599665
	USH-800	G49961	NS8060481
	USH-820	G49955	NS8033606
	USH-822	G49956	NS8629506, NS8629507
	USH-824	G49957	NS8008428, NS8421571, NS8421572, NS8599666, NS8599667
	USH-826	G49958	NS8147321, NS8421573
	USH-828	G49959	NS8008429
Urethral Dilation Balloon Catheter with Open Tip	UDBS-070029-OW	G17844	8494465, 8513227, 8537103, 8537104, 8552050, 8552051, 8567256, 8576963, 8632766, 8639366, 8659206, 8683459, 8754089, NS8513228
Urethral Dilator Set	073701	G14185	8401849, 8404945, 8404946, 8404946X, 8417702
Roadrunner® Hydrophilic PC Wire Guide	RFSPC-035145-0-I-AQ	G18629	7853231, 7853232, 7853233, 7853239, 7853240, 7853241, 7853242, 7853243, 7853245, 7853247, 7901140, 7901141, 7982113, 7982118, 7982133, 8050291, 8241613, 8241616, 8252179, 8252181, 8252186, 8258553, 8283322, 8407934, 8460985, 8474895, 8474898, 8474905, 8474906, 8474908, 8474909, 8474910
	RFSPC-038145-0-I-AQ	G17866	7936207

Attachment 2 – Intended Use
Field Action on Reverse Loaded Wire Guides

Brand Name	Intended Use
Bentson PTFE Wire Guide	Used primarily in urology to establish a tract and assist in the placement of a surgical device. These are not intended for PTCA use.
Fixed Core Straight Safety Wire Guide	
Heavy Duty PTFE Wire Guide	
PTFE Wire Guide	
Wire Guide	
Angled Tip Ureteral Catheter Set	Used for directing a flexible tipped wire guide in the ureter.
Angled Tip Ureteral Catheter Set With Bentson PTFE Wire Guide	
Bander Ureteral Diversion Open-End Stent Set	Used for intraoperative placement to stent the ureter during ureteroileal conduit construction and continent urinary diversions.
C-Flex® Double Pigtail Ureteral Stent Set	Used for temporary internal drainage from the ureteropelvic junction to the bladder.
Dretler Ureteroscopy Stent Set	Used for post-ureteroscopy stenting of the ureter.
Kwart Retro-Inject™ Ureteral Stent Set	Used for retrograde injection during E.S.W.L. and leaving an indwelling ureteral stent post-E.S.W.L.
Percutaneous Entry Set	Used to establish a percutaneous tract into the renal pelvis for catheter placement or stone manipulation.
Percutaneous Malecot Nephrostomy Set	Used for percutaneous placement of a Malecot catheter in the renal pelvis.
Percutaneous Pigtail Nephrostomy Set	Used for percutaneous placement of a pigtail catheter in the renal pelvis for nephrostomy drainage.
Sof-Flex® Double Pigtail Ureteral Stent Set	Used for temporary internal drainage from the ureteropelvic junction to the bladder.
Sof-Flex® Multi-Length Ureteral Stent Set	
Universa® Firm Ureteral Stent and Positioner	
Universa® Firm Ureteral Stent Set	
Universa® Soft Ureteral Stent Set	
Urethral Dilation Balloon Catheter with Open Tip	Used to dilate the male or female urethra to treat stricture disease.
Urethral Dilator Set	Used for urethral dilation.
Roadrunner® Hydrophilic PC Wire Guide	Used to gain ureteral access, to establish a tract, and to assist in the placement, replacement, and exchange of medical devices during urological and gynecologic procedures