



November 1, 2017

URGENT: MEDICAL DEVICE CORRECTION

ATTENTION:

Risk Management/Recall Administration

Our records indicate that you may have received some of the affected products listed below.

Description of the Problem:

Cook Medical is initiating a voluntary market correction for the products and lot numbers listed in Attachment 1. This correction involves applying an additional label that states "Heparin Coated" to the affected products. Cook Medical has identified that the label of these products does not explicitly state that they are heparin coated. The products are labeled with the correct catalog identifier, which includes the suffix "BH" that indicates the product is heparin coated. However, users who are not familiar with the "BH" nomenclature may not be aware that the product contains heparin.

This correction is only related to the label, not the heparin coated products. Only the lot numbers listed are impacted; other lot numbers have been labelled with the heparin coated statement.

To date, no adverse events have been reported due to this issue. Under rare circumstances, these products could unknowingly be used in a patient with a heparin allergy or a patient with a history of Heparin Induced Thrombocytopenia (HIT). Either of these situations could potentially result in serious injury or death.

Details of Affected Devices:

PRODUCT BRAND NAME	CATALOG IDENTIFIER (Prefix/Suffix)	INTENDED USE	LOT NUMBERS
Amplatz Stiff Wire Guide Amplatz Extra Stiff Wire Guide Amplatz Ultra Stiff Wire Guide Coons Interventional Wire Guide Fixed-Core Wire Guide	THSF-/BH	Used to assist in inserting catheters, introducer sheaths, and other medical devices in vascular applications.	Refer to Attachment 1 for lot listing.
Amplatz Extra Stiff Whisker Wire Guide Amplatz Extra Stiff Wire Guide Amplatz Ultra Stiff Wire Guide Fixed-Core Wire Guide Rosen Curved Wire Guide	THSCF-/BH		
Bentson Wire Guide	THSFB-/BH TSFB-/BH		
Bentson Plus Wire Guide	TSFBP-/BH		
Fixed-Core Wire Guide	C-SCF-/BH C-SF-/BH SCF-/BH SF-/BH TSCF-/BH TSCFR-/BH TSF-/BH		



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PRODUCT BRAND NAME	CATALOG IDENTIFIER (Prefix/Suffix)	INTENDED USE	LOT NUMBERS
Double Flexible-Tipped Wire Guide	C-DOC/-BH C-TDOC/-BH TDOC/-BH	Used to assist in inserting catheters, introducer sheaths, and other medical devices in vascular applications.	Refer to Attachment 1 for lot listing.
Movable-Core Wire Guide	TCMTNA/-BH TMTNA/-BH TMT/-BH		
Fixed-Core Bentson	TSCFB/-BH		
Newton Wire Guide	THSFNA/-BH TSCFNA/-BH THSCFNB/-BH TSFNA/-BH TSFNB/-BH		
Newton Wire Guide TFE Coated Curved Newton LLT	TSCFNB/-BH		
Disposable Reuter Tip-Deflecting Wire Guide	DTDW/-BH	Intended for use in curving or deflecting catheter tips for pulmonary angiography, selective angiography, translumbar aortography, bronchography, repositioning of central venous catheter tips, and other vascular and non-vascular applications.	
Reuter Tip-Deflecting Wire Guide	TDW/-BH		
Femoral Artery Pressure Monitoring Set	C-PMS-300- CHILDRENS-A-032988	Used for arterial pressure monitoring and blood sampling.	
Central Venous Catheter Tray	C-PUMY-5014J-35-8.0- BH-OTP	The central venous catheter is designed for treatment of critically ill patients and is suggested for: 1. Continuous or intermittent drug infusions 2. Central venous blood pressure monitoring (CVP) 3. Acute hyperalimentation 4. Blood sampling 5. Delivery of whole blood or blood products 6. Simultaneous, separate infusion of drugs	
Left Atrial Catheter Set	C-ULAP-5.0-60-DTK-BH	Used for postoperative monitoring of left atrial pressure. Pigtail tip configuration helps to maintain proper catheter tip position in left atrium.	



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Action to be Taken:

1. Examine inventory immediately to determine if you have affected product and quarantine affected product(s) for additional labeling. If you no longer have affected product in your inventory, complete the Acknowledgement and Receipt Form and return it via fax (888.912.8457) or email to cookmedical5791@stericycle.com.
2. **If you have affected product in your inventory**, you have two options:
 1. If your facility prefers to add the additional labeling without assistance from a representative, please see the instructions in Attachment 2, use the enclosed labels to complete the correction, and complete the Acknowledgement and Receipt form. To request assistance or additional labels, please contact Stericycle at 855.215.4967.
 2. If you prefer for a representative to support you in applying the labels, please contact Stericycle at 855.215.4967.

Once your affected product has been correctly labeled, please complete the Acknowledgement and Receipt Form within **5 business days** and send it via fax (888.912.8457) or email to cookmedical5791@stericycle.com.

3. For recall related questions, including requests for additional labeling or assistance in labeling, please contact Stericycle at 855.215.4967.
4. Please complete the Acknowledgement and Receipt Form within **5 business days** of receipt of this letter.
5. 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 via CustomerRelationsNA@CookMedical.com.

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

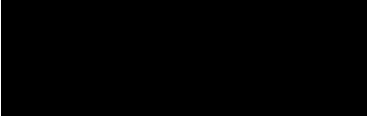
- Online at: <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (form available to fax or mail)
- Call the FDA at: 1.800.FDA.1088

Transmission of this Notice:

This notice must be shared with appropriate personnel, including down to the user level, within your organization or to 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 this situation is a disruption to your normal operations and we sincerely apologize. Thank you again for your immediate assistance in this matter. Should 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.



Larry D. Pool
Director, Post market
Cook Incorporated

Attachments:

- Attachment 1 – Affected lot numbers
- Attachment 2 – Instructions for labeling
- Attachment 3 – Labels



Please reply to this notification within **5 business days** of receipt, even if you do not have any of the affected products.

Date:	Customer Account Number:
Customer Name:	Street Address:
City:	State, Postal Code:
Form Completed By:	Department/Phone Number:

1. I have received the 01Nov2017 Medical Device Correction and understand the instructions provided in the letter.
2. I have examined my inventory and have no affected product.
3. I have examined my inventory and affected product remains in inventory.
 - a. If Yes to Question #3, additional labels have been applied to all remaining inventory. (Note: If you require assistance with labeling activities, please contact Stericycle at 855.215.4967.)
4. I have experienced an adverse event associated with the affected product.
5. If yes, please explain the adverse event below:

☐ Yes ☐ No

1. I have notified my customers of the correction.

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Please list the quantity of affected product at your facility to be relabeled or indicate "NONE" if affected product is no longer in your inventory or with your customers.

[illegible]

- Upon completion, please return this Acknowledgement and Receipt Form to Stericycle Expert Solutions via fax or email.
Fax: 888.912.8457 Email: cookmedical5791@stericycle.com
- For information regarding the correction, contact Stericycle Expert Solutions at 855.215.4967.
- For medical questions or to report adverse events contact Cook Medical Customer Relations at 800.457.4500 or 812.339.2235.

ATTACHMENT 1 HEPARIN COATED WIRE GUIDE FIELD ACTION - AFFECTED LOT NUMBERS

Name of Devices	Catalog Identifier (Prefix/Suffix)	Global Product Number (GPN)		Lot Number Range	
				From	To
Amplatz Extra Stiff Wire Guide Amplatz Stiff Wire Guide Amplatz Ultra Stiff Wire Guide Coons Interventional Wire Guide Fixed-Core Wire Guide	THSF- / -BH	G00422	G03980	3730001	6164916
		G00427	G04048		
		G00788	G04187		
		G00789	G04483		
		G00958	G04970		
		G01202	G06430	F3729969	F4922979
		G02372	G07496		
		G02539	G09955		
		G03042	G09958		
		G03044	G10051		
		G03127	G10052		
		G03219	G10309	NS4928020	NS6203182
		G03264	G10522		
		G03290	G27034		
		G03334	G27036		
		G03373	G27039		
Amplatz Extra Stiff Whisker Wire Guide Amplatz Extra Stiff Wire Guide Amplatz Ultra Stiff Wire Guide Fixed-Core Wire Guide Rosen Curved Wire Guide	THSCF- / -BH	G00964	G03546	3733552	6175191
		G01382	G03547		
		G01428	G03560		
		G02246	G03723		
		G02447	G03884		
		G02541	G03889	F3729974	F4923948
		G02676	G03903		
		G03043	G03973		
		G03053	G04113		
		G03062	G04149		
		G03327	G04167	NS4927345	NS6177894
		G03349	G04422		
		G03372	G04933		
		G03441	G08310		
		G03463	G10523		
Bentson Wire Guide	THSFB- / -BH	G02583		F3813488	F4859795
				NS5327890	NS6060291
	TSFB- / -BH	G00692	G02633	3730884	5984142
		G00793	G03749		
		G00924	G03882	F3746894	F4920488
		G01062	G06805		
		G01369	G12259	NS4937520	NS6252870
		G01431	G28873		
		G01750	G31470		
		G02499			
Bentson Plus Wire Guide	TSFBP- / -BH	G09783		3771080	5942053
		G09784		F4265639	

ATTACHMENT 1

HEPARIN COATED WIRE GUIDE FIELD ACTION - AFFECTED LOT NUMBERS

Name of Devices	Catalog Identifier (Prefix/Suffix)	Global Product Number (GPN)		Lot Number Range			
				From	To		
Fixed-Core Wire Guide	C-SCF- / -BH	G01948 G01967 G03509 G04012	G13438 G29402 G29405	F3753452	F4925547		
				NS5008794	NS6171324		
	C-SF- / -BH	G02291 G02326	F3922830	F4218188			
			NS5470403	NS6020850			
	SCF- / -BH	G00224	F4087814	F4741344			
			NS4929840	NS5104065			
	SF- / -BH	G00289	F4119548	F4920483			
			NS5171771	NS6144080			
	TSCF- / -BH	G00432 G00435 G00437 G00440 G00442 G00448 G00453 G00459 G00465 G00467 G00469 G00472 G00475 G00477 G00489 G00493 G00508 G00510 G00512 G00514 G00518 G00523 G00525 G00528 G00530 G00532 G00540 G00542 G00544 G00547 G00551 G00553 G00846 G00867 G00901 G00907 G00916	G00970 G01052 G01084 G01283 G01337 G01363 G01380 G01419 G01438 G01481 G01527 G01530 G01558 G01567 G01639 G01649 G01878 G01974 G02247 G02482 G02588 G02842 G02848 G03028 G03600 G03671 G03707 G03990 G04735 G06809 G06810 G06830 G06969 G07627 G08949 G11673	3730875	6180567		
				F3730082	F4924418		
				NS4928022	NS6177724		
						NS5185993	

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Name of Devices	Catalog Identifier (Prefix/Suffix)	Global Product Number (GPN)		Lot Number Range	
				From	To
Fixed-Core Wire Guide	TSF- / -BH	G00584	G00656	3730101	6181269
		G00586	G00662		
		G00588	G00665		
		G00591	G00671		
		G00597	G00675		
		G00599	G00681	F3734860	F4923958
		G00601	G00808		
		G00603	G01190		
		G00606	G01288		
		G00610	G01316		
		G00612	G01331	NS4927349	NS6203187
		G00618	G01710		
		G00621	G07017		
		G00625	G07183		
		G00632	G07966		
G00639	G08466				
G00644	G09484				
G00651					
Double Flexible-Tipped Wire Guide	C-DOC- / -BH	G03256	F3749839	F4849938	
			NS5085893	NS5827127	
	C-TDOC- / -BH	G29434	F4628078	F4856722	
			TDOC- / -BH	G00361 G00363 G01365 G03745	3763189
	F3739663	F4916737			
	NS4980257	NS6098990			
	Movable-Core Wire Guide	TCMTNA- / -BH	G01716 G01717 G01720 G01765 G03137	3774481	6145673
F3876320				F4894841	
NS4963396				NS5144675	
TMTNA- / -BH		G06850	F4608907		
TMT- / -BH		G01663	3758468	6167814	
Fixed-Core Bentson	TSCFB- / -BH	G00865 G01863 G02650 G03865	G03918 G04011 G28843 G28844	F3734676	F4911986
				NS4938980	NS6144078
Newton Wire Guide	THSFNA- / -BH	G10524 G10525		3733537	5803299
				F3762971	F4692445
				NS5043714	NS5900771
	TSCFNA- / -BH	G00558 G00560 G00562 G00563 G00566 G00568	G00570 G01556 G02266 G02856 G03191	3766161	5925080
				F3753484	F4887253
				NS4938982	NS5932560
				THSCFNB- / -BH	G11843
	NS6024246				

ATTACHMENT 1 HEPARIN COATED WIRE GUIDE FIELD ACTION - AFFECTED LOT NUMBERS

Name of Devices	Catalog Identifier (Prefix/Suffix)	Global Product Number (GPN)	Lot Number Range	
			From	To
Newton Wire Guide	TSFNA- / -BH	G00702 G00703 G00706 G00709	3741877	5929842
			F3749985	F4903656
			NS4928037	NS5963186
	TSFNB- / -BH	G00716 G00717 G00720	3744567	6253002
			F3763300	F4900931
			NS4928039	NS59824
Newton Wire Guide TFE Coated Curved Newton LLT	TSCFNB- / -BH	G00573 G00575 G00577 G00579 G00581	G00904 G01271	3741882
			G01281	6142463
			G02845	F3884311
			G05624	F4903643
Disposable Reuter Tip-Deflecting Wire Guide	DTDW- / -BH	G07672 G07751 G08159	NS5044201	NS5963180
			3730008	6164931
			F4374635	F4791430
Reuter Tip-Deflecting Wire Guide	TDW- / -BH	G07351 G28702	NS5034700	NS5562947
			F4423853	F4898351
			NS5072022	NS6166764

ATTACHMENT 1 HEPARIN COATED CATHETER SETS FIELD ACTION - AFFECTED LOT NUMBERS

Name of Devices	Catalog Identifier	Global Product Number (GPN)	Lot Numbers
Femoral Artery Pressure Monitoring Set	C-PMS-300-CHILDRENS-A-032988	G04448	All lots
Central Venous Catheter Tray	C-PUMY-5014J-35-8.0-BH-OTP	G10560	All lots
Left Atrial Catheter Set	C-ULAP-5.0-60-DTK-BH	G07498	All lots



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ATTACHMENT 2 – INSTRUCTIONS FOR LABELING

Step 1

- Determine if your product is included in the affected lot ranges by comparing your lot number to the listing provided.
- If your product **is not** affected, complete the Acknowledgement and Receipt Form.
- If your product **is** affected, proceed to Step 2.



Step 2

- Remove a “Heparin Coated” label from the label sheet provided and apply to the top right corner of your affected unit.
 - If you need additional labels, please contact Stericycle at 855.215.4967.

If you would like assistance, representatives are available to support you. To request assistance, please contact Stericycle at 855.215.4967





Heparin Coated



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