



October 22, 2019

URGENT: MEDICAL DEVICE RECALL
Torcon NB[®] Advantage Catheter

ATTENTION:

Risk Management/Recall Administration

Our records indicate that you have received affected products.

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

Purpose of this Letter

The purpose of this letter is to advise you that Cook Medical is voluntarily recalling specific lots of the Torcon NB[®] Advantage Catheter. Affected lots are listed in Attachment 1.

The Torcon NB[®] Advantage Catheter is intended for use in angiographic procedures by physicians trained and experienced in angiographic techniques.

Reason for Voluntary Recall

Cook Medical has identified that the pouches for affected lots may be undersealed, potentially compromising the sterility of the product.

Risk to Health

Potential adverse events that may occur if an affected product is used include increased procedural time to obtain a replacement and local or systemic infection.

Product Information

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

Actions to be Taken by the Customer

1. Examine inventory immediately to determine if you have affected product(s), and quarantine affected product(s). Immediately cease all distribution and use of this product.
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 via fax (812.339.7316) or email (FieldActionsNA@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 potentially affected devices have been transferred.
5. Immediately report adverse events to Cook Medical Customer Relations by phone at 800.457.4500 or 812.339.2235, Monday through Friday between 7:30am and 5:00pm (Eastern Time), or by email to: CustomerRelationsNA@CookMedical.com.



COOK MEDICAL
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BLOOMINGTON, IN 47402-4195 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

Additional Action being Taken by Cook Medical

This issue is related to the chevron seal, which is a feature of the pouches supplied to Cook Medical. The supplier has initiated an investigation to determine the appropriate corrective action(s) to prevent reoccurrence of a similar issue.

Other Information

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

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.

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.



Larry D. Pool
Director, Post Market
Cook Incorporated



Attachment 1 - Affected Lot Numbers
Medical Device Recall for Undersealed Pouches on Torcon NB® Advantage Catheters

Reference Part Number (RPN)	Order Number (GPN)	Lot Numbers
HNB6.0-38-100-P-NS-JR4	G04788	9715474
HNB5.0-38-100-P-NS-SIM1	G04922	9700385, 9713001, 9726999
HNB7.0-38-65-P-NS-VERT	G05018	NS9880363, NS9890272, NS9933625
HNB5.0-38-100-P-NS-JR4	G05922	9700390, 9705827, 9709327, 9710351, 9715466, 9715476, 9716493, 9716792, 9719152
HNB5.0-38-100-P-NS-JL4	G05923	9700383, NS9701376
HNB5.0-38-100-P-NS-JL3.5	G05924	9705826, 9707669, 9709326, 9714955, 9716791, 9717961, NS9718543
HNB5.0-38-110-P-6S-PIG	G05925	NS9708132
HNB5.0-38-100-P-NS-JR3.5	G05928	9707478
HNB5.0-38-80-P-NS-C2	G05955	9916981, 9924484, 9924486, 9943478, 9943643, 9943644, 9944133, 9946873, 9946875, 9947569, 9949557, 9949558, 9952694, NS9938577
HNB5.0-38-65-P-NS-SHK1.0	G05975	9900974
HNB5.0-38-100-P-NS-SIM2	G05976	9700386, 9701378, 9707469, 9710399, 9713002
HNB5.0-38-65-P-NS-RIM	G05979	9890936,
HNB5.0-38-100-P-NS-JB1	G05997	9712995, 9726996, NS9700766
HNB5.0-38-100-P-NS-H1	G06005	9698823, 9702704, 9702705, 9702778, 9702809, 9703680, 9707588, 9714540, 9715463, 9716515, 9716516, 9716517, 9719485
HNB5.0-38-100-P-NS-JIM	G06039	NS9715223, NS9718545
HNB5.0-38-100-P-NS-VERT	G06074	9696580, 9707470, 9707471, 9710400, 9710402, 9710403, 9710404, 9710405, 9734099, NS9710401
HNB5.0-38-80-P-NS-MIK	G06108	9903997
HNB5.0-38-100-P-10S-PIG	G06227	9694590, 9700380, 9700381, 9700765, 9703643, 9703644, 9703645, 9703646, 9711281, 9711282
HNB5.0-38-65-P-2S-C2	G06236	9914963
HNB5.0-35-80-P-NS-MPB	G06282	NS9904055, NS9913496, NS9928938, NS9930289, NS9930290, NS9930291
HNB5.0-38-65-P-NS-H1	G06607	NS9904021, NS9913224, NS9945395
HNB5.0-35-80-P-2S-C2	G06622	NS9913495, NS9930288
HNB5.0-38-65-P-2S-C1	G06827	NS9906241
HNB5.0-38-100-P-NS-WNBG	G07099	9716520
HNB5.0-38-100-P-10S-0	G07268	9693491, 9696896, 9700377, 9700378, 9700379, 9710398, 9716496, NS9712994
HNB5.0-38-100-P-NS-HN5	G07300	NS9700775, NS9705496, NS9710350, NS9713694
HNB5.0-38-100-P-NS-HN4	G07940	NS9708134, NS9708135, NS9713695
HNB5.0-38-100-P-NS-MPA	G08153	9696901, 9700384, 9701377, 9708543, 9709229

HNB5.0-35-100-P-10S-PIG	G08201	9700004, 9703928, NS9703929
HNB7.0-38-100-P-NS-MPA	G08591	9713048, 9718539, NS9718416
HNB5.0-38-100-P-NS-MPB	G08878	NS9713000
HNB5.0-38-100-P-NS-DAV	G08895	9693495, 9701375, 9703638, 9703647, 9703648, 9708138, 9708139, 9708140, 9708542, 9709228, 9709932, 9712996, 9715458, 9715462, 9715468, 9715469, 9716505, 9733722, 9734096
HNB5.0-38-80-P-NS-JR2.5	G08985	NS9906245
HNB5.0-38-80-P-NS-C3	G09521	9926069, NS9926068
HNB5.0-38-80-P-NS-MPB	G09631	9936120
HNB5.0-38-100-P-NS-JL2	G09757	9716495
HNB5.0-35-80-P-2S-C1	G09875	NS9939340
HNB5.0-38-100-P-NS-C2	G10262	9729997
HNB5.0-NT-80-P-NS-MPA	G10354	9930261
HNB5.0-38-80-P-NS-HS2	G10598	NS9904742, NS9906243, NS9906244, NS9914968, NS9914970, NS9928941, NS9943480, NS9943481
HNB5.0-38-80-P-NS-HS1	G10599	NS9903072, NS9904741, NS9914967, NS9928940, NS9933626, NS9942737
HNB5.0-38-100-P-NS-JL5	G10661	9700389
HNB5.0-38-100-P-NS-JR5	G10727	9718544
HNB5.0-38-80-P-NS-JR2	G10733	NS9906320, NS9906321
HNB5.0-38-110-P-12S-PIG	G10741	9706696, 9707671, 9709328, 9711384, 9718538
HNB5.0-38-80-P-NS-JL2.5	G10742	NS9933622
HNB5.0-38-100-P-NS-AR2	G10748	9714133
HNB5.0-38-100-P-NS-AL2	G10750	9710345
HNB5.0-38-100-P-NS-AR1	G10751	9707476
HNB5.0-38-100-P-NS-VTK	G10756	9712522
HNB5.0-38-80-P-NS-EKISAI-111984	G10796	NS9904740
HNB5.0-38-80-P-NS-RIM	G10885	NS9939355
HNB5.0-38-100-P-NS-JR2	G10924	NS9712997, NS9712998
HNB5.0-38-100-P-NS-JR3	G10930	9714956, 9719147
HNB5.0-38-100-P-NS-JL3	G10998	9712521, 9732872, NS9717350
HNB5.0-35-100-P-8S-NEFF	G11026	NS9720276
HNB5.0-38-80-P-NS-RC1	G11543	9906464
HNB5.0-38-100-P-4S-NIH	G11749	9700773, 9705822
HNB4.1-35-80-P-NS-NTR	G12517	NS9930287
HNB5.0-38-65-P-1S-VA-070793	G12783	NS9933578
HNB5.0-38-110-P-12S-PED	G13077	9700036, 9707670
HNB5.0-35-65-P-NS-TIPS	G19706	9890919
HNB5.0-35-100-P-NS-JR2	G27617	NS9705494
HNB5.0-35-75-P-NS-CHG-B	G27640	NS9913494
HNB5.0-38-70-P-NS-SHK1.0	G27689	NS9904739
HNB5.0-38-75-P-NS-C1	G27702	NS9928939
HNB5.0-38-80-P-NS-JR1.5	G30163	NS9933623
HNB6.0-38-65-P-NS-BMC	G32465	9908469, 9911359, 9936124

HNB5.0-38-100-P-NS-SHET-TY-050181-01	G47168	NS9717356
HNB5.0-38-65-P-NS-KMP-01	G47185	9908502
HNB5.0-38-65-P-NS-TC-01	G47192	9903996