



March 01, 2024

URGENT: MEDICAL DEVICE RECALL
Select Needles, Peel-Away[®] Introducers, Entuit[™]
Secure Adjustable Gastrointestinal Suture Anchor Sets,
and Select Dilators

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 various products that share the same packaging material.

Reason for Voluntary Recall

Cook Medical identified that packaging for the affected device lots may have low seal strength and do not meet peel strength specifications. Samples from this packaging material failed visual peel and seal strength testing. Subsequently, Cook Medical contacted the supplier, who confirmed a manufacturing issue had occurred during production of the impacted packaging material. This creates a potential of a sterile barrier failure that could result in compromised device sterility.

Product Information

Select lots of Chiba Biopsy Needles, Trocar Needles, Yueh Centesis Disposable Catheter Needles, Peel-Away[®] Introducers, Entuit[™] Secure Adjustable Gastrointestinal Suture Anchor Sets, Dilators, Dilators With AQ[®] Hydrophilic Coating, and Dilators - Coons Taper are implicated in this recall.

Chiba Biopsy Needles are intended for use for aspiration biopsy. Trocar Needles are intended for use for introduction in nonvascular access procedures. Yueh Centesis Disposable Catheter Needles are intended for use for percutaneous fluid aspiration.

The Peel-Away[®] Introducer is intended for the percutaneous introduction of balloon, electrode and closed or non-tapered end catheters into central and peripheral vasculature, and for nonvascular use.

The Entuit[™] Secure Adjustable Gastrointestinal Suture Anchor Set is intended for anchoring the anterior wall of the stomach to the abdominal wall prior to introduction of interventional catheters.

Dilators, Dilators With AQ[®] Hydrophilic Coating, and Dilators - Coons Taper are intended to be used for dilating puncture sites or catheter tracts for percutaneous placement of devices for vascular and non-vascular applications such as in the venous, arterial, biliary and renal systems.

See Pages 4 – 6 for a complete list of affected products and lots.



Market Impact

This recall is strictly specific to lots listed in Pages 4 – 6. Unaffected devices will continue to be accessible on the market for purchase based on availability.

Risk to Health

The affected devices may be non-sterile or contaminated with microorganisms. Potential adverse events that may occur if an affected product is used include increased procedural time and infection, potentially being life-threatening and/or requiring medical/surgical intervention.

To date, Cook Medical has not received any customer complaints related to the adverse patient effects listed above for the affected lots. However, please be advised that compromised device sterility may go undetected by the user.

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 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. Please 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.

Action being Taken by Cook Medical

Cook Medical is removing potentially affected products from the market. Additionally, a supplier investigation has been opened 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.



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

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 return of the Acknowledgement and Receipt Form.

A handwritten signature in black ink that reads "Larry D. Pool".

Larry D. Pool
Director, Post Market
Cook Incorporated



PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	DEVICE IDENTIFIER (DI)	LOT NUMBERS
Chiba Biopsy Needle	DCHN-18-10.0	G01559	(01)00827002015593(17)	15787141 15787142 15787693 15794668 15794669 15794728 15797998
	DCHN-18-10.0-U	G05040	(01)00827002050402(17)	NS15781793 NS15781794 NS15783895 NS15783896 NS15783899 NS15783900 NS15784336 NS15808535 NS15808536 NS15808537
	DCHN-18-15.0	G00850	(01)00827002008502(17)	15595244
	DCHN-22-10.0	G00852	(01)00827002008526(17)	15628472
	DCHN-22-10.0-U	G03978	(01)00827002039780(17)	15614507
	DCHN-22-15.0	G00012	(01)00827002000124(17)	15628470 15785990 15791249 15794719
	DCHN-22-15.0-U	G03314	(01)00827002033146(17)	15784638 15784722 15784724 15795935 15797991 15797992
	DCHN-22-20.0	G00013	(01)00827002000131(17)	15629865
	DCHN-22-20.0-U	G04338	(01)00827002043381(17)	NS15808547
	Trocar Needle	DTN-18-20.0	G01377	(01)00827002013773(17)
Yueh Centesis Disposable Catheter Needle	DTVN-5.0-19-10.0-YUEH	G09490	(01)00827002094901(17)	15787864 15804398
Peel-Away® Introducer	PLVW-7.0-35	G00925	(01)00827002009257(17)	15777767
	PLVW-8.0-35	G01844	(01)00827002018440(17)	NS15787532



PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	DEVICE IDENTIFIER (DI)	LOT NUMBERS
Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set	GIAS-SRM-ADJ-2	G35562	(01)00827002355620(17)	15791906
Dilator	JCD10.0-38-20	G00993	(01)00827002009936(17)	15794371 15794373 15794374 15806068 15816198 15816199 15816200
	JCD20.0-38-20	G01471	(01)00827002014718(17)	15784153 15784159 15784160 15794192 15794199 15794202 15804028
	JCD22.0-38-20	G01472	(01)00827002014725(17)	15794207 15806062
	JCD6.0-38-15	G00944	(01)00827002009448(17)	15814407
	JCD8.0-38-15	G00999	(01)00827002009998(17)	15797971 15797979
	JCD8.0-38-20	G00980	(01)00827002009806(17)	15791073
	Dilator With AQ® Hydrophilic Coating	JCD10.0-38-20-HC	G10207	(01)00827002102071(17)
JCD14.0-38-20-HC		G10293	(01)00827002102934(17)	15778297 15787264
JCD16.0-38-20-HC		G10206	(01)00827002102064(17)	15794375
JCD6.0-38-20-HC		G10285	(01)00827002102859(17)	NS15808469
JCD8.0-38-20-HC		G10289	(01)00827002102897(17)	15761259
Dilator - Coons Taper	JCD10.0-38-20-COONS	G03928	(01)00827002039285(17)	15787236
	JCD12.0-38-20-COONS	G03929	(01)00827002039292(17)	15774752 15774753
	JCD14.0-38-20-COONS	G03932	(01)00827002039322(17)	15797981 15784149 15797975 15797976 15797982



PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	DEVICE IDENTIFIER (DI)	LOT NUMBERS
Dilator - Coons Taper	JCD16.0-38-20-COONS	G03947	(01)00827002039476(17)	15794190 15794191 15808405
	JCD18.0-38-20-COONS	G04051	(01)00827002040519(17)	15794189 15797973
	JCD20.0-38-20-COONS	G04264	(01)00827002042643(17)	15784152 15784156 15784158 15784164 15794195 15804033
	JCD22.0-38-20-COONS	G04443	(01)00827002044432(17)	15767086 15784163 15794203 15806060
	JCD6.0-38-20-COONS	G04221	(01)00827002042216(17)	15787237 15787244
	JCD8.0-38-20-COONS	G03927	(01)00827002039278(17)	15797985 15797999 15798003