

January 11, 2023

URGENT: MEDICAL DEVICE FIELD SAFETY NOTICE

CooperSurgical NEO-fit™ Neonatal Endotracheal Tube Grip

Part Number: 42-2540

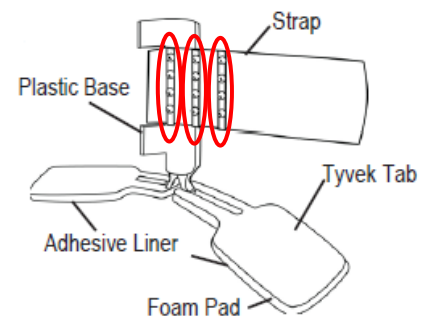
Dear Valued CooperSurgical Customer or Distributor,

CooperSurgical is hereby issuing a Medical Device Field Safety Notice (FSN) for all **NEO-fit™ Neonatal Endotracheal Tube Grip** devices. All devices that are still in distribution, up to 220,500 unexpired individual devices*, are potentially susceptible to this issue. A list of lot numbers of potentially affected devices is included in the appendix of this packet (page 5).

***Note:** Each sales unit of this product contains twenty (20) individual devices having the same lot number.

Reason for Voluntary Field Safety Corrective Action (FSCA):

CooperSurgical has become aware of a **potential health risk in which metal clips (encircled in red in the image to the right) used to grip the endotracheal tube may fracture and detach from the strap and then be ingested by the patient.**

**Risk to Health:**

If detached metal clips are ingested, there is a potential for laceration to the gastrointestinal tract as the clip passes through the patient's body.

Actions to be Taken:

Our records indicate that you may have purchased the affected product from CooperSurgical. Please take the following steps to ensure the safe return of the affected products:

- 1) Inspect your inventory and quarantine any affected product.
- 2) Complete the appropriate version of the attached form (**Customer Acknowledgement Form** or **Distributor Acknowledgement Form**). Once completed, return the form to CooperSurgical as indicated at the top of the form. Note: Even if you do not have any affected product in your inventory (or have not distributed any affected product to customers), please complete and return the enclosed form so that we may document receipt of this FSN.

When the completed form is received by CooperSurgical, arrangements will be made for the return of any affected product at no additional cost to you. Credit will be applied to your account for product returned under this action.

CooperSurgical is committed to high-quality, safe, and effective products. This corrective action has been initiated to ensure this failure mode does not reoccur and future potential patient harms can be avoided.

We sincerely apologize for the inconvenience caused by this notice. If you have any questions, please feel free to reach us at **203-601-5200** ext. **3300** or recall@coopersurgical.com, or our Local Representative for Ireland.

Caroline Holvey, Regional Business Manager • Sales, caroline.holvey@coopersurgical.com

Sincerely,



CooperSurgical®

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Trumbull, CT 06611
T: 203 601 5200
www.coopersurgical.com

Daniel Heuer
Manager of Risk Management

Customer Acknowledgement Form

IMMEDIATE RESPONSE REQUIRED – TIME-SENSITIVE ACTION NEEDED

Please complete this form and return it via email to recall@coopersurgical.com or via fax to **203.601.9870**, ATTN: **Product Surveillance**.

Customer Account #:		Account Name:	
Street Address:		Town, State, & Zip Code:	
Contact Name:	Phone Number:	Email address:	

I have read and understand the notice instructions provided in the letter dated January 11, 2023. Yes No

NEO-fit™ Neonatal Endotracheal Tube Grip Devices (part number: 42-2540, affected lots listed on page 5)

Please check the appropriate box below and complete the table if applicable.

- We have no inventory within the scope of this action.
- We have the following affected product at our facility and will discontinue use and quarantine the affected product for return to CooperSurgical:

Part Number	Lot Numbers	Quantity of Devices to be Returned (20 devices per sales unit)
42-2540		

Have any adverse events been associated with affected product(s)? Yes No

If yes, please explain: _____

If you have additional questions, please contact a CooperSurgical Product Surveillance representative at **203.601.5200 Ext. 3300** or email us at recall@coopersurgical.com.



Distributor Acknowledgement Form

IMMEDIATE RESPONSE REQUIRED – TIME-SENSITIVE ACTION NEEDED

Please complete this form and return it via email to **recall@coopersurgical.com** or via fax to **203.601.9870, ATTN: Product Surveillance.**

FOR DISTRIBUTORS ONLY:

Customer Account #:		Account Name:	
Street Address:		Town, State, & Zip Code:	
Contact Name:	Phone Number:	Email address:	

I have read and understand the notice instructions provided in the letter dated January 11, 2023. Yes No

NEO-fit™ Neonatal Endotracheal Tube Grip Product (part number: 42-2540, affected lots listed on page 5)

Please check the appropriate box below and complete the table if applicable.

- We have no inventory within the scope of this action.
- We have the following affected product at our facility and will discontinue use and quarantine the affected product for return to CooperSurgical:

Part Number	Lot Numbers	Quantity of Devices to be Returned (20 devices per sales unit)
42-2540		

Quantity of devices shipped to customers: _____ (20 devices per sales unit)

If affected product has been distributed to customers, please select one of the following options:

<input type="checkbox"/> I have identified and notified all customers to whom the affected product may have been distributed.	Date and Method of Notification:
<input type="checkbox"/> I am providing a list of all customers to whom affected product may have been distributed along with their contact information.	

Signature

Printed Name



Appendix – Lot Numbers of Potentially Affected Devices (Part Number: 42-2540)

Lot Number	Lot Number	Lot Number	Lot Number
247020	292892	298064	307729
269476	292893	298065	307730
269477	292894	301600	308590
269478	292895	301601	308591
269479	292896	301602	309456
269480	292897	301603	309544
269481	292898	301604	309910
269482	292899	301605	309912
269483	292900	301606	309913
272992	292901	301607	309914
274957	292902	302944	311350
274958	292903	303769	311465
274959	292904	303771	311533
274960	296234	303772	311690
274961	296235	303949	312729
274962	296236	303950	312730
274963	296237	304053	312731
286859	296238	304363	313142
286861	296239	304364	313273
286862	296240	305016	313274
286863	296241	305017	314493
291949	296890	305018	314675
291950	296891	305019	314676
291951	296892	305020	314969
291952	296893	305021	315504
291953	297033	306282	315505
292878	297034	306339	315626
292879	297035	306340	315810
292880	297036	306341	316162
292881	297037	306342	316866
292882	298047	306343	316976
292883	298048	307080	317032
292884	298049	307081	318970
292885	298051	307616	319205
292886	298053	307723	319298
292887	298054	307724	320400
292888	298055	307725	321242
292889	298056	307726	
292890	298062	307727	
292891	298063	307728	