

November 2, 2022

URGENT: MEDICAL DEVICE FIELD SAFETY NOTICE

CooperSurgical NEO-fit™ Neonatal Endotracheal Tube Grip

Part Number: 42-2540

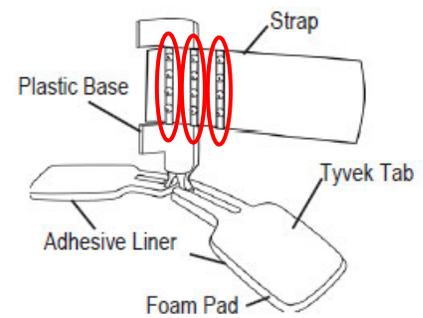
Dear Valued CooperSurgical Customer or Distributor,

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 4).

***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**.

Sincerely,


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 November 2, 2022. Yes No

NEO-fit™ Neonatal Endotracheal Tube Grip Devices (part number: 42-2540, affected lots listed on page 4)

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 November 2, 2022. Yes No

NEO-fit™ Neonatal Endotracheal Tube Grip Product (part number: 42-2540, affected lots listed on page 4)

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 | |