



## URGENT MEDICAL DEVICE RECALL

September 1, 2020

Dear Customer:

This is to inform you of a product recall involving:

### **30-0171 NAR RESPONDER 4" FLAT EMERGENCY TRAUMA DRESSING LOT TSD3819 AND LOT TSD0320**

### **30-0171 IS A COMPONENT OF THE FIRST AID KITS IDENTIFIED IN ENCLOSURE 2**

See enclosed 1 product label for ease in identifying the product at user level.

North American Rescue (NAR) is voluntarily recalling product 30-0171 Lot TSD3819 and Lot TSD0320. We are recalling these products due to a manufacturing deviation which resulted in a lack of the assurance in the sterility of the 30-0171.

Affected product was shipped between December 23, 2019 and August 3, 2020. This product was shipped individually and in kits (affected kit product codes are listed below). Included is a list of affected product and kit lot numbers, listed by product code (see Enclosure 2).

Product Code	Item Description	Product Code	Item Description
80-0890	M-FAK Mini First Aid Kit, Basic – RED	85-1942	Survival IFAK Kit
80-0891	M-FAK Mini First Aid Kit, with Bleeding Control Dressing – RED	85-1953	First Aid Pelican Kit
80-0892	M-FAK Mini First Aid Kit, Advanced – RED	85-1970	Crisis Kit – BLK
80-0913	M-FAK Mini First Aid Kit, Basic – RTC	85-2150	IFAK Kit
80-0914	M-FAK Mini First Aid Kit, with Bleeding Control Dressing – RTC	85-2176	PABC Kit
80-0947	Trauma and First Aid Kit – Class A, with Compressed Gauze	85-2327	SRAK Kit
80-0948	Trauma and First Aid Kit – Class B, with Compressed Gauze	85-2425	EMT Kit
80-0951	Public Access Bleeding Control Twin Pack, Basic	85-2426	Medical AEMT Kit



<b>Product Code</b>	<b>Item Description</b>
80-0952	Public Access Bleeding Control Twin Pack, Intermediate
80-0953	Public Access Bleeding Control Twin Pack, Advanced BCD
80-1033	Trauma and First Aid Kit Hard Case – Class A, with Compressed Gauze
80-1034	Trauma and First Aid Kit Hard Case – Class B, with Compressed Gauze
80-1045	Trauma and First Aid Kit – Class A, with Bleeding Control Dressing
80-1046	Trauma and First Aid Kit Hard Case – Class A, with Bleeding Control Dressing
80-1047	Trauma and First Aid Kit – Class B, with Bleeding Control Dressing
80-1048	Trauma and First Aid Kit Hard Case – Class B, with Bleeding Control Dressing
82-0002	Micro IFAK
85-0404	Individual Aid Kit
85-0757	Kit
85-0834	Combat Officer Response Emergency (CORE) Kit
85-1128	Reaction Kit with S-Rolled Gauze
85-1502	M-FAK Kit with S-Rolled Gauze – BLK
85-1574	Bleeding Control Kit – STB
85-1583	Trauma Emergency Bleed Kit – RED
85-1759	Bleeding Control Kit
85-1907	TORK Kit – BLK

<b>Product Code</b>	<b>Item Description</b>
85-2430	Bleeding Control Kit, Basic (Nylon)
85-2432	Individual Bleeding Control Kit, with Bleeding Control Dressing (Nylon)
85-2539	Individual Bleeding Control Kit
85-2833	EDC/Compact Carry Kit
85-2886	Resupply Kit (Zip Bag)
85-2920	M-FAK Kit – BLK
85-3022	Individual First Aid Kit, Expanded #2
85-3046	Kit
85-3050	Company IFAK Kit
85-3052	PAK Kit
85-3067	First Aid Kit, with CAT and Bleeding Control Dressing – COY
85-3068	Enhanced First Aid Kit, with CAT and Bleeding Control Dressing – ODG
85-3069	Enhanced First Aid Kit, with CAT and Bleeding Control Dressing – RED
85-3078	Resupply Kit
85-3082	PABC Kit
85-3084	MCC IFAK Small Supply Kit
85-3085	MCC IFAK Large Supply Kit



**This recall is only for 30-0171 NAR Responder 4" Flat Emergency Trauma Dressing. All other components packaged in the first aid kit are not affected by this recall.**

**Immediately:**

1. **Examine** your inventory and quarantine all product and kits identified in this recall notification, refer to enclosure 2.
2. **Discontinue** all distribution or use of the recalled products identified in this recall notification.
3. **Identify** the 30-0171, with the aid of enclosure 1, and verify the recalled lot TSD3819 or TSD0320.
4. **Remove** the recalled lot TSD3819 or TSD0320 from the kit and quarantine.
5. **Contact** NAR Customer Service toll free at 1-888-689-6277 to receive a replacement and arrange for the return of the recalled lots. (Please have your customer order number available to reference.)

This recall should be carried out to the user level. Your assistance is appreciated and necessary to prevent patient harm. If you have further distributed this product, please:

1. Identify your customers and immediately notify them of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

Please complete and return the response form, in enclosure 3, as soon as possible. If you have any questions, call William Slevin at (864) 675-9800.

This recall is being made with the knowledge of the Food and Drug Administration.

Once again, we regret this situation and desire to make sure that a replacement is available to you without cost and with minimum inconvenience. North American Rescue remains committed to provide only the highest quality products and services for you, our valued customer.

William Slevin  
Director, QA/RA

Enclosures (3)



**NORTH AMERICAN RESCUE®**

ENCLOSURE 1





## ENCLOSURE 2

NAR Product Numbers and Lot Numbers Subject to Recall	
Product Code	Lot Number
30-0171	TSD3819
30-0171	TSD0320

NAR First Aid Kit Numbers and Lot Numbers Subject to Recall			
Kit Product Code	Kit Lot Number	Kit Part Number	Kit Lot Number
80-0890	80-0890032420	80-1047	80-1047031720
80-0891	80-0891032520	80-1047	80-1047032120
80-0891	80-0891032620	80-1047	80-1047032420
80-0891	80-0891032720	80-1047	80-1047040720
80-0891	80-0891040620	80-1047	80-1047060420
80-0891	80-0891042020	80-1047	80-1047072220
80-0891	80-0891050420	80-1047	80-1047072920
80-0891	80-0891050620	80-1048	80-1048032720
80-0891	80-0891051120	80-1048	80-1048052020
80-0891	80-0891051920	80-1048	80-1048073020
80-0891	80-0891052120	82-0002	82-0002031620
80-0891	80-0891052220	82-0002	82-0002031820
80-0891	80-0891072920	82-0002	82-0002032020
80-0892	80-0892042720	82-0002	82-0002033020
80-0892	80-0892052020	82-0002	82-0002040720
80-0913	80-0913031320	82-0002	82-0002042320
80-0913	80-0913032020	82-0002	82-0002042720
80-0913	80-0913032420	82-0002	82-0002042820
80-0913	80-0913032620	82-0002	82-0002051320
80-0913	80-0913042120	82-0002	82-0002072420
80-0913	80-0913042820	82-0002	82-0002072820
80-0913	80-0913050620	85-0404	85-0404032320
80-0913	80-0913051120	85-0404	85-0404032520
80-0913	80-0913072920	85-0404	85-0404050720
80-0914	80-0914041520	85-0404	85-0404050820
80-0914	80-0914072920	85-0404	85-0404051120
80-0947	80-0947031720	85-0404	85-0404051220
80-0947	80-0947032420	85-0404	85-0404052220

**NAR First Aid Kit Numbers and Lot Numbers Subject to Recall**

80-0947	80-0947032720	85-0404	85-0404052620
80-0947	80-0947033120	85-0404	85-0404052720
80-0947	80-0947040220	85-0404	85-0404072320
80-0947	80-0947040620	85-0757	85-0757050420
80-0947	80-0947041720	85-0757	85-0757050520
80-0947	80-0947042320	85-0834	85-0834051120
80-0947	80-0947052820	85-0834	85-0834051220
80-0947	80-0947072720	85-0834	85-0834051420
80-0948	80-0948031620	85-0834	85-0834051520
80-0948	80-0948032020	85-0834	85-0834051820
80-0948	80-0948032420	85-0834	85-0834051920
80-0948	80-0948032620	85-0834	85-0834052120
80-0948	80-0948033020	85-0834	85-0834052620
80-0948	80-0948033120	85-1128	85-1128031820
80-0948	80-0948040720	85-1128	85-1128031920
80-0948	80-0948041720	85-1502	85-1502040620
80-0948	80-0948042320	85-1574	85-1574031320
80-0948	80-0948072320	85-1574	85-1574031620
80-0951	80-0951031820	85-1574	85-1574032520
80-0951	80-0951032320	85-1574	85-1574032620
80-0951	80-0951032420	85-1574	85-1574050520
80-0951	80-0951032620	85-1574	85-1574050620
80-0951	80-0951042020	85-1574	85-1574050720
80-0951	80-0951042220	85-1574	85-1574050820
80-0951	80-0951042820	85-1574	85-1574051220
80-0951	80-0951042920	85-1583	85-1583040320
80-0951	80-0951050420	85-1583	85-1583042420
80-0951	80-0951051120	85-1759	85-1759031320
80-0951	80-0951051520	85-1907	85-1907033020
80-0951	80-0951052020	85-1907	85-1907033120
80-0952	80-0952040220	85-1942	85-1942032020
80-0952	80-0952042020	85-1942	85-1942040820
80-0952	80-0952042920	85-1942	85-1942042120
80-0952	80-0952051820	85-1942	85-1942052020
80-0952	80-0952052220	85-1953	85-1953043020



**NAR First Aid Kit Numbers and Lot Numbers Subject to Recall**

80-0953	80-0953050420	85-1970	85-1970040220
80-0953	80-0953051220	85-2150	85-2150032620
80-0953	80-0953051820	85-2176	85-2176031620
80-0953	80-0953072220	85-2327	85-2327040720
80-1033	80-1033032320	85-2425	85-2425072920
80-1033	80-1033032420	85-2426	85-2426072920
80-1033	80-1033040220	85-2430	85-2430031820
80-1033	80-1033040320	85-2432	85-2432042920
80-1033	80-1033051820	85-2539	85-2539042920
80-1033	80-1033052020	85-2539	85-2539051220
80-1033	80-1033052120	85-2539	85-2539052820
80-1034	80-1034031320	85-2539	85-2539072320
80-1034	80-1034031720	85-2833	85-2833043020
80-1034	80-1034031920	85-2886	85-2886032420
80-1034	80-1034040720	85-2920	85-2920032420
80-1034	80-1034042120	85-2920	85-2920040120
80-1034	80-1034042220	85-3022	85-3022031820
80-1034	80-1034052020	85-3046	85-3046051320
80-1034	80-1034052120	85-3050	85-3050040220
80-1034	80-1034072820	85-3052	85-3052042120
80-1045	80-1045031820	85-3052	85-3052051820
80-1045	80-1045032620	85-3067	85-3067042820
80-1045	80-1045033120	85-3068	85-3068042920
80-1045	80-1045052620	85-3069	85-3069042920
80-1045	80-1045072720	85-3078	85-3078050620
80-1046	80-1046032420	85-3082	85-3082050620
80-1046	80-1046042320	85-3084	85-3084052020
80-1046	80-1046042720	85-3085	85-3085052020



## ENCLOSURE 3

## Recall Return Response Form

**30-0171 NAR RESPONDER 4" FLAT EMERGENCY TRAUMA DRESSING, LOT TSD3819 & TSD0320**

Please fill out and fax/email this form within 10 business days, even if you do not have the recalled product.

**Please check ALL appropriate boxes.**

- ☐ I have read and understand the recall instruction provided in the September 1, 2020 letter.
- ☐ I have inspected our inventory and have no product related to this recall.
- ☐ I have inspected our inventory and have the following product related to this recall:

Product Code	Lot Number	Quantity

Any adverse events associated with recalled product? ☐ Yes ☐ No

If yes, please explain: \_\_\_\_\_

- ☐ I have identified and notified my customer(s) that were shipped or may have been shipped this product by (**specify date and method of notification**).

Form completed by:

Name:	Firm name:
Title:	Address:
Tel.:	City/State:

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Please fax completed response form to (864) 675-9880 or email to [wslevin@narescue.com](mailto:wslevin@narescue.com)**

**Or mail to:**

ATTN: William Slevin  
North American Rescue  
35 Tedwall Ct, Greer, SC 29650