# GEDSA Unite. Connect. Deliver.

**Unified ENFit Conversion Message** 



Global Enteral Device Supplier Association (614) 800-5458

P.O. Box 250 info@gedsa.org Powell, OH 43065 | www.stayconnected.org

March 14, 2022

To whom it may concern,

On September 14, 2020, the Global Enteral Device Supplier Association (GEDSA) released a revised ENFit® Connector Conversion Schedule for the U.S. and Canada to phase out legacy enteral tubing connectors and switch to ISO 80369-3 compliant ENFit®-only connectors; which improve patient safety by reducing the risks of potentially fatal medical device misconnections and minimize unintentional disconnections, which can lead to the loss of prescribed nutrition.

The schedule stated that on January 1, 2022 "Transition sets and adaptors sold separately from other devices [would] no longer be manufactured," that date has now passed. Many customers are asking suppliers what next steps are in store for this conversion schedule.

GEDSA members who supply the U.S. and Canada have come together to combine their individual ENFit® support and product timelines into a unified message to be shared via GEDSA.

The following pages are the most recent individual company communications that have been dispersed to customers after the release of the REVISED ENFit® Connector Conversion Schedule: U.S. and Canada Legacy Connector Production Phase Out Dates. This document will grow as new statements are released by GEDSA members and supporters of the conversion to ENFit®-only connectors to improve patient safety.

Select supply of stand-alone transition adaptors will be available until no longer warranted. For any questions regarding product availability or transitions to ENFit<sup>®</sup>, please work directly with your supplier. If you cannot get in contact with your supplier and they are a GEDSA member, please contact GEDSA and we will ensure you are connected with a representative. Email <u>info@gedsa.org</u> or visit <u>www.stayconnected.org</u> for more information.

Regards,

Ben Davis

**Executive Director** 

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### **Current GEDSA Members:**

Spectrum Plastics Abbott Enteral Access Medovate Avanos **Technologies** Ucomfor Moog Flat Medical NeoMed Venner Medical Baxter Fresenius Kabi Vesco Medical B Braun Nestle

Boston Scientific GBUK Nipro Corporation Vonco Cardinal Health IMI Nutricia Vygon

Cedic/Entek KB Medical Q Medical Devices Zhejiang Runqiang

Dale Medical Medicina Smiths Medical Medical

Instruments Co.,Ltd

### **GEDSA Supporting Affiliate Manufacturers:**

RxCrush U-Deliver

### **GEDSA Supporting Organizations:**

AAMI BAPEN JASPEN Oley Foundation
AHRMM CHA Joint Commission PENG
ALIVA P. CHESO DATE

OUR DESCRIPTION OF THE PROPERTY OF T

AHVAP CHPSO MNI PINNT
ASHP ECRI Institute MSC Premier
ASHRM Euro Pharmat NHS Vizient
ASPEN FTAF NNNG

AVA HealthTrust NPSF

BRASPEN ISMP nutritionDay U.S.

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January 26, 2022

Dear Valued Customer,

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As you might be aware, the Global Enteral Device Supplier Association (GEDSA) announced in September of 2020 that member manufacturers will phase out legacy enteral feeding products and transition adaptors. This transition will meet ISO standard 80369-3, commonly referred to as ENFit™, which aims to maximize patient safety by reducing the risk of enteral tubing misconnections.

As a founding GEDSA member, Cardinal Health is fully supportive of the transition to ENFit™ products to deliver a safer enteral connection for the patients we serve across the care continuum.

Because we are in the targeted timeline from GEDSA for the U.S. industry to transition to ENFit™, we want to share an update on our transition status. We intended to remove the transition adaptor from our feeding set portfolio this month, but global supply chain challenges have presented risk to the implementation timeline. Therefore, we expect to begin manufacturing feeding sets and gravity sets without a transition adaptor by June 2022.

For non-ENFit<sup>™</sup> products, <u>select categories</u> have planned discontinuation starting in July 2022. Overall, we have shifted manufacturing priority to ENFit<sup>™</sup> and lowered planned production for several Cardinal Health legacy products (non-ENFit<sup>™</sup>). Please review Attachment A below for specific details on each product category.

Please contact your Cardinal Health Sales Representative to develop your ENFit™ conversion plan prior to June 2022.

Patient safety is our focus, and we believe ENFit™ is a safer option for all patients. For additional support and questions regarding your ENFit™ transition, please contact your local Cardinal Health Sales Representative or Cardinal Health Customer Service at (800) 964-5227.

Thank you for your continued support.

Sincerely,

Scott Donnelly Vice President, Product Marketing U.S. Medical Products and Distribution

Cardinal Health





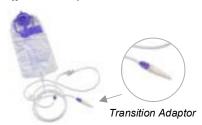
### Attachment A

Transition adaptors will be removed from all Kangaroo™ Enteral Feeding Sets by June 2022.

**Part numbers will not change**; however, additional labeling on the outside case will be added for your awareness. **See Table 1** for a complete list of impacted products.

Several manufacturers plan to sell transition adaptors separately. Industry supply may be limited. We are working toward replenishing and increasing our supply in this part number:

### Kangaroo Pump Set



### Additional Label



| Part Number | Description               | Packaging      |
|-------------|---------------------------|----------------|
| 765000-     | ENFit™ Transition Adaptor | 20 Each / Box, |

Beginning July 2022, all Adult Nasogastric Feeding Tubes, Pediatric Nasogastric Feeding Tubes, Pediatric Extension Sets, and Gastrostomy Feeding Tubes (non-ENFit™) will only be manufactured with the ENFit™ design. **See Table 2** for a complete list of impacted products and their ENFit™ replacement item code.

Please note that we will continue to offer **both** ENFit™ and non-ENFit™ products for the below categories until further notice:

- Cardinal Health Monoject™ Syringes and Kangaroo™ Irrigation Kits
- Salem Sump™ Gastrointestinal Decompression Tubes

| Product Category                          | Non-ENFit™ Discontinuing as of July 2022                          |
|---|---|
| Kangaroo™ Adult Nasogastric Feeding Tubes | <b>✓</b>  |
| Kangaroo™ Pediatric Feeding Tubes         | <b>✓</b>  |
| Kangaroo™ Pediatric Extension Sets        | <b>✓</b>  |
| Kangaroo™ Gastrostomy Feeding Tubes       | <b>✓</b>  |
| Salem Sump™ Gastrointestinal Products     | Will continue to be offered with or without the ENFit™ connection |
| Monoject™ Enteral Feeding Syringes        | Will continue to be offered with or without the ENFit™ connection |
| Kangaroo™ Irrigation Syringes             | Will continue to be offered with or without the ENFit™ connection |
| Kangaroo™ Skin Level Device               | ENFit™ is the only manufactured style since November 2020         |

<sup>\*</sup> Cardinal Health reserves the right to further update the information contained in this communication in its sole discretion.



Table 1: Kangaroo™ Enteral Feeding Sets Impacted by the Transition Adaptor Removal

| Product Category                         | Part Number | Product Description  | ENFit™<br>Compatible |
|--|-------------|--|----------------------|
|  | 772055      | Kangaroo ePump™ 500 mL Pump Set                            | <b>~</b>             |
|  | 773656      | Kangaroo ePump™ 1000 mL Pump Set                           | <b>~</b>             |
|  | 674668      | Kangaroo ePump™ 500 mL Feed Set with 500 mL Flush<br>Bag   | <b>✓</b>             |
|  | 773662      | Kangaroo ePump™ 1000 mL Feed Set with 1000 mL<br>Flush Bag | <b>✓</b>             |
|  | 716154      | Kangaroo ePump™ Sterile 100 mL Burette Set                 | <b>~</b>             |
|  | 775659      | Kangaroo ePump™ ENPlus Spike Set                           | <b>~</b>             |
|  | 775100      | Kangaroo ePump™ ENPlus Spike with 1000 mL Flush Bag        | <b>~</b>             |
|  | 776150      | Kangaroo ePump™ 100 mL Burette Recertification Set         |                      |
|  | 762055      | Kangaroo Joey™ 500 mL Pump Set                             | <b>~</b>             |
|  | 763656      | Kangaroo Joey™ 1000 mL Pump Set                            | <b>~</b>             |
| Kangaroo™ Enteral<br>and Gravity Feeding | 763662      | Kangaroo Joey™ 1000 mL Pump Set with Flush Bag             | <b>~</b>             |
| Sets                                     | 765100      | Kangaroo Joey™ Safety Screw Spike with 1000 mL Flush Bag   | <b>✓</b>             |
|  | 765559      | Kangaroo Joey™ ENPlus Spike Set                            | <b>✓</b>             |
|  | 77000FD     | Kangaroo Connect™ ENPlus Spike Set                         | <b>✓</b>             |
|  | 77100FD     | Kangaroo Connect™ 1000 mL Bag Set                          | <b>✓</b>             |
|  | 77500FD     | Kangaroo Connect™ 1000 mL Bag Set                          | <b>✓</b>             |
|  | 1KCP        | Kangaroo Connect™ ENPlus Spike ENtelliSet                  | <b>✓</b>             |
|  | 1000KCP     | Kangaroo Connect™ ENtelliset 1000 mL                       | <b>~</b>             |
|  | 500KCP      | Kangaroo Connect™ ENtelliset 500 mL                        | <b>✓</b>             |
|  | 702505      | 1000 mL Large Bore Gravity Set                             | <b>~</b>             |
|  | 8884702500  | 1000 mL Gravity Bag  | <b>✓</b>             |

<sup>\*</sup> Cardinal Health reserves the right to further update the information contained in this communication in its sole discretion.

**Table 2: Non-ENFit™ Product Discontinuation** 

| Product Family                            | Discontinuation<br>Date | Non-ENFit™<br>Code for<br>Discontinuation | ENFit™ Code  | Description  |
|---|-------------------------|---|--|--|
|   |                         | 8884715122                                | 8884715122E  | Gastrostomy Feeding Tube with Y-Port 12FR ENFit    |
| Kangaroo™<br>Gastrostomy<br>Feeding Tubes | luly 4, 2022            | 8884715148                                | 8884715148E  | Gastrostomy Feeding Tube with Y-Port<br>14FR ENFit |
|   | 8884720163              | 8884720163E                               | Gastrostomy Feeding Tube with Y-Port<br>16FR ENFit |  |
|   |                         | 8884720189                                | 8884720189E  | Gastrostomy Feeding Tube with Y-Port<br>18FR ENFit |





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| I                           |              | l          |             |  |
|-----------------------------|--------------|------------|-------------|--|
|                             |              | 8884720205 | 8884720205E | Gastrostomy Feeding Tube with Y-Port 20FR ENFit                      |
|                             |              | 8884720221 | 8884720221E | Gastrostomy Feeding Tube with Y-Port 22FR ENFit                      |
|                             |              | 8884720247 | 8884720247E | Gastrostomy Feeding Tube with Y-Port<br>24FR ENFit                   |
|                             |              | 8884720265 | 8884720265E | Gastrostomy Feeding Tube with Y-Port<br>26FR ENFit                   |
|                             |              | 8884720285 | 8884720285E | Gastrostomy Feeding Tube with Y-Port<br>28FR ENFit                   |
|                             |              | 8884751622 | 8884751622E | 16 Fr Y-port/P.E.G. Adapter  |
|                             |              | 8884752042 | 8884752042E | 20 Fr Y-port/P.E.G. Adapter  |
|                             |              | 8884720817 | 8884720817E | Entriflex Feeding Tube without Stylet<br>ENFit, 8FR x 36in, 3g       |
|                             |              | 8884720825 | 8884720825E | Entriflex Feeding Tube with Stylet, 8FR x 36in, 3g                   |
|                             |              | 8884720841 | 8884720841E | Entriflex Feeding Tube without Stylet, 8FR x 43in, 3g                |
|                             |              | 8884720855 | 8884720855E | Entriflex Feeding Tube with Stylet ENFit,<br>8FR x 55in, 3g          |
|                             |              | 8884720858 | 8884720858E | Entriflex Feeding Tube with Stylet, 8FR x 43in, 3g                   |
|                             |              | 8884721055 | 8884721055E | Entriflex Feeding Tube with Stylet, 10FR x 55in, 5g                  |
|                             |              | 8884721088 | 8884721088E | Entriflex Feeding Tube with Stylet, 10FR x 43in, 5g                  |
|                             |              | 8884721096 | 8884721096E | Entriflex Feeding Tube without Stylet,<br>10FR x 43in, 5g            |
| Kangaroo™                   | Kangaroo™    | 8884721211 | 8884721211E | Entriflex Feeding Tube without Stylet,<br>12FR x 36in,5g             |
| Adult<br>Nasogastric        | July 1, 2022 | 8884721237 | 8884721237E | Entriflex Feeding Tube without Stylet 12FR x 43in, 5g                |
| Feeding Tubes               |              | 8884721252 | 8884721252E | Entriflex Feeding Tube with Stylet, 12FR x 43in, 5g                  |
|                             |              | 8884721255 | 8884721255E | Entriflex Feeding Tube with Stylet, 12 FR X 55in, 5g                 |
|                             |              | 8884710826 | 8884710826E | Dobbhoff™ Feeding Tube with Stylet, 8FR x 55in, 7g                   |
|                             |              | 8884710842 | 8884710842E | Dobbhoff <sup>™</sup> Feeding Tube without Stylet,<br>8FR x 43in, 7g |
|                             |              | 8884710859 | 8884710859E | Dobbhoff™ Feeding Tube with Stylet, 8FR x 43in, 7g                   |
|                             |              | 8884710867 | 8884710867E | Dobbhoff™ Feeding Tube with Stylet, 8FR x 43in, 5g                   |
|                             |              | 8884711006 | 8884711006E | Dobbhoff™ Feeding Tube with Stylet,<br>10FR x 43in, 7g               |
|                             |              | 8884711246 | 8884711246E | Dobbhoff™ Feeding Tube without Stylet,<br>12FR x 43in, 7g            |
|                             |              | 8884711253 | 8884711253E | Dobbhoff™ Feeding Tube with Stylet,<br>12FR x 43in, 7g               |
|                             |              | 35ES       | 35ENS       | 35 in Pediatric Extension Set  |
|                             |              | 60ES       | 60ENS       | 60 in Pediatric Extension Set  |
| Kangaroo™                   |              | 35EY       | 35ENY       | 35 in Bifurcated (y-port) Pediatric<br>Extension Set                 |
| Pediatric<br>Feeding System | July 1, 2022 | 60EY       | 60ENY       | 60" Bifurcated (y-port) Pediatric Extension<br>Set                   |
| and Accessories             |              | N/A        | 4VENS       | Kangaroo™ Vented Gravity Set   |
|                             |              | N/A        | 60VENS      | Kangaroo™ 60 in Vented Gravity<br>Extension Set                      |
|                             |              | N/A        | 60VENY      | Kangaroo™ 60 in Vented Bifurcated<br>Gravity Extension               |
|                             | •            |            |             |  |



Cardinal Health Medical Segment 7200 Cardinal Place Dublin, OH 43017

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|  | 460208  | 460208E | Purple Pediatric PVC Feeding Tube 10FR x 107cm              |
|--|---------|---------|---|
|  | 460406- | 460406E | Purple Pediatric PVC Feeding Tube, 8FR x 107cm              |
|  | 460604  | 460604E | Purple Pediatric PVC Feeding Tube, 8FR x 41cm               |
|  | 460711  | 460711E | Purple Pediatric PVC Feeding Tube,<br>6.5FR x 41cm          |
|  | 460802  | 460802E | Purple Pediatric PVC Feeding Tube, 5FR x 41cm               |
|  | 461008  | 461008E | Purple Pediatric PVC Feeding Tube, 5FR x 91cm               |
|  | 461206  | 461206E | Purple Pediatric PVC Feeding Tube, 3.5Fr x 31cm             |
|  | 461042  | 461042E | Purple Pediatric Polyurethane Feeding Tube, 10Fr x 107cm    |
|  | 461355  | 461355E | Purple Pediatric Polyurethane Feeding<br>Tube, 3.5Fr x 31cm |
|  | 461412  | 461412E | Purple Pediatric Polyurethane Feeding<br>Tube, 5 FR X 20in  |
|  | 461420  | 461420E | Purple Pediatric Polyurethane Feeding Tube, 6.5Fr x 51cm    |
|  | 461438  | 461438E | Purple Pediatric Polyurethane Feeding<br>Tube, 6.5Fr x 91cm |
|  | 461503  | 461503E | Purple Pediatric Polyurethane Feeding<br>Tube, 5Fr x 91cm   |
|  | 461701  | 461701E | Purple Pediatric Polyurethane Feeding<br>Tube, 8Fr x 51cm   |
|  | 461800  | 461800E | Purple Pediatric Polyurethane Feeding Tube, 8Fr x 107cm     |
|  | 461000  | 461000E | Kangaroo™ Milk Straw - 5in (12.7 cm)                        |

<sup>\*</sup> Cardinal Health reserves the right to further update the information contained in this communication in its sole discretion.



Cardinal Health Medical Segment 7200 Cardinal Place Dublin, OH 43017

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May 26, 2022

Dear Valued Customer,

As you might be aware, the Global Enteral Device Supplier Association (GEDSA) announced in September of 2020 that member manufacturers will phase out legacy enteral feeding products and transition adaptors. This transition will meet ISO standard 80369-3, commonly referred to as ENFit™, which aims to maximize patient safety by reducing the risk of enteral tubing misconnections.

As a founding GEDSA member, Cardinal Health is fully supportive of the transition to ENFit™ products to deliver a safer enteral connection for the patients we serve across the care continuum.

Because of our commitment to the U.S. industry to transition to ENFit™, we want to share a reminder on our transition status. As previously communicated in January 2022, Cardinal Health will begin manufacturing feeding sets and gravity sets without a transition adaptor **by June 2022**. Customers can expect to see feeding sets without the transition adapter integrated into their shipments throughout the summer. Timing for initial shipments will vary by item code and will be dependent on current inventory levels for that item. Please review Attachment A below for specific details on Kangaroo™ Enteral Feeding Sets Impacted by the Transition Adaptor Removal.

For non-ENFit<sup>™</sup> products, <u>select categories</u> will cease manufacturing beginning in July 2022. Overall, we have shifted manufacturing priority to ENFit<sup>™</sup> and lowered planned production for several Cardinal Health legacy products (non-ENFit<sup>™</sup>). Please review Attachment A below for specific details on each product category.

Please contact your Cardinal Health Sales Representative to develop your ENFit™ conversion plan within the next 30 days.

Patient safety is our focus, and we believe ENFit™ is a safer option for all patients. For additional support and questions regarding your ENFit™ transition, please contact your local Cardinal Health Sales Representative or Cardinal Health Customer Service at (800) 964-5227.

Thank you for your continued support.

Sincerely,

Candace Underhill

Vice President, Product Marketing U.S. Medical Products and Distribution

Cardinal Health



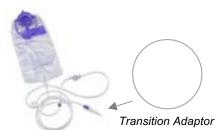


### Attachment A

Transition adaptors will be removed from all Kangaroo™ Enteral Feeding Sets by June 2022.

**Part numbers will not change**; however, additional labeling on the outside case will be added for your awareness. **See Table 1** for a complete list of impacted products.

Kangaroo Pump Set



Additional Label



Several manufacturers plan to sell transition adaptors separately. Overall, industry supply may be limited. We have added an additional transition adaptor code to help support increased demand for this item. The new code, **F00071ED**, will be available in limited quantities beginning in late **June 2022** with increasing availability over the course of the next several months. For pricing and contract information, please contact your Cardinal Health Sales Representative.

| Part Number | Description                     | Packaging     |
|-------------|---------------------------------|---------------|
| F00071ED    | New - ENFit™ Transition Adaptor | 30 Each / Box |
| 765000-     | ENFit™ Transition Adaptor       | 20 Each / Box |

Beginning July 2022, all Adult Nasogastric Feeding Tubes, Pediatric Nasogastric Feeding Tubes, Pediatric Extension Sets, and Gastrostomy Feeding Tubes (non-ENFit™) will only be manufactured with the ENFit™ design. **See Table 2** for a complete list of impacted products and their ENFit™ replacement item code.

Please note that we will continue to offer **both** ENFit™ and non-ENFit™ products for the below categories until further notice:

- o Cardinal Health Monoject™ Syringes and Kangaroo™ Irrigation Kits
- Salem Sump™ Gastrointestinal Decompression Tubes



| Product Category                          | Non-ENFit™ will cease manufacturing as of July 2022               |
|---|---|
| Kangaroo™ Adult Nasogastric Feeding Tubes | <b>✓</b>  |
| Kangaroo™ Pediatric Feeding Tubes         | <b>✓</b>  |
| Kangaroo™ Pediatric Extension Sets        | <b>✓</b>  |
| Kangaroo™ Gastrostomy Feeding Tubes       | <b>✓</b>  |
| Salem Sump™ Gastrointestinal Products     | Will continue to be offered with or without the ENFit™ connection |
| Monoject™ Enteral Feeding Syringes        | Will continue to be offered with or without the ENFit™ connection |
| Kangaroo™ Irrigation Syringes             | Will continue to be offered with or without the ENFit™ connection |
| Kangaroo™ Skin Level Device               | ENFit™ is the only manufactured style since<br>November 2020      |

 $<sup>\</sup>star$  Cardinal Health reserves the right to further update the information contained in this communication in its sole discretion.

Table 1: Kangaroo<sup>™</sup> Enteral Feeding Sets Impacted by the Transition Adaptor Removal

| Product Category                         | Part Number | Product Description   | ENFit™<br>Compatible |
|--|-------------|---|----------------------|
|  | 772055      | Kangaroo ePump™ 500 mL Pump Set                             | <b>✓</b>             |
|  | 773656      | Kangaroo ePump™ 1000 mL Pump Set                            | <b>✓</b>             |
|  | 674668      | Kangaroo ePump™ 500 mL Feed Set with 500 mL Flush<br>Bag    | <b>~</b>             |
|  | 773662      | Kangaroo ePump™ 1000 mL Feed Set with 1000 mL<br>Flush Bag  | <b>✓</b>             |
|  | 716154      | Kangaroo ePump™ Sterile 100 mL Burette Set                  | <b>✓</b>             |
|  | 775659      | Kangaroo ePump™ ENPlus Spike Set                            | <b>✓</b>             |
|  | 775100      | Kangaroo ePump™ ENPlus Spike with 1000 mL Flush Bag         | <b>~</b>             |
| Manager TM Fortage I                     | 776150      | Kangaroo ePump™ 100 mL Burette Recertification Set          |                      |
| Kangaroo™ Enteral<br>and Gravity Feeding | 762055      | Kangaroo Joey™ 500 mL Pump Set                              | <b>~</b>             |
| Sets                                     | 763656      | Kangaroo Joey™ 1000 mL Pump Set                             | <b>~</b>             |
|  | 763662      | Kangaroo Joey™ 1000 mL Pump Set with Flush Bag              | <b>✓</b>             |
|  | 765100      | Kangaroo Joey™ Safety Screw Spike with 1000 mL Flush<br>Bag | <b>✓</b>             |
|  | 765559      | Kangaroo Joey™ ENPlus Spike Set                             | <b>✓</b>             |
|  | 77000FD     | Kangaroo Connect™ ENPlus Spike Set                          | <b>✓</b>             |
|  | 77100FD     | Kangaroo Connect™ 1000 mL Bag Set                           | <b>✓</b>             |
|  | 77500FD     | Kangaroo Connect™ 1000 mL Bag Set                           | <b>✓</b>             |
|  | 1KCP        | Kangaroo Connect™ ENPlus Spike ENtelliSet                   | <b>✓</b>             |



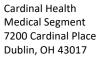
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| 1000KCP    | Kangaroo Connect™ ENtelliset 1000 mL | <b>✓</b> |
|------------|--------------------------------------|----------|
| 500KCP     | Kangaroo Connect™ ENtelliset 500 mL  | <b>✓</b> |
| 702505     | 1000 mL Large Bore Gravity Set       | <b>✓</b> |
| 8884702500 | 1000 mL Gravity Bag                  | <b>✓</b> |

<sup>\*</sup> Cardinal Health reserves the right to further update the information contained in this communication in its sole discretion.

**Table 2: Non-ENFit™ Product Discontinuation** 

| Product Family               | Discontinuation<br>Date | Non-ENFit™<br>Code for<br>Discontinuation | ENFit™ Code | Description  |
|------------------------------|-------------------------|---|-------------|--|
|                              |                         | 8884715122                                | 8884715122E | Gastrostomy Feeding Tube with Y-Port 12FR ENFit                |
|                              |                         | 8884715148                                | 8884715148E | Gastrostomy Feeding Tube with Y-Port<br>14FR ENFit             |
|                              |                         | 8884720163                                | 8884720163E | Gastrostomy Feeding Tube with Y-Port<br>16FR ENFit             |
|                              |                         | 8884720189                                | 8884720189E | Gastrostomy Feeding Tube with Y-Port<br>18FR ENFit             |
| Kangaroo™                    |                         | 8884720205                                | 8884720205E | Gastrostomy Feeding Tube with Y-Port 20FR ENFit                |
| Gastrostomy<br>Feeding Tubes | July 1, 2022            | 8884720221                                | 8884720221E | Gastrostomy Feeding Tube with Y-Port 22FR ENFit                |
|                              |                         | 8884720247                                | 8884720247E | Gastrostomy Feeding Tube with Y-Port 24FR ENFit                |
|                              |                         | 8884720265                                | 8884720265E | Gastrostomy Feeding Tube with Y-Port 26FR ENFit                |
|                              |                         | 8884720285                                | 8884720285E | Gastrostomy Feeding Tube with Y-Port 28FR ENFit                |
|                              |                         | 8884751622                                | 8884751622E | 16 Fr Y-port/P.E.G. Adapter                                    |
|                              |                         | 8884752042                                | 8884752042E | 20 Fr Y-port/P.E.G. Adapter                                    |
|                              |                         | 8884720817                                | 8884720817E | Entriflex Feeding Tube without Stylet<br>ENFit, 8FR x 36in, 3g |
|                              |                         | 8884720825                                | 8884720825E | D825E Entriflex Feeding Tube with Stylet, 8FR 36in, 3g         |
|                              |                         | 8884720841                                | 8884720841E | Entriflex Feeding Tube without Stylet, 8FR x 43in, 3g          |
|                              |                         | 8884720855                                | 8884720855E | Entriflex Feeding Tube with Stylet ENFit,<br>8FR x 55in, 3g    |
|                              |                         | 8884720858                                | 8884720858E | Entriflex Feeding Tube with Stylet, 8FR x 43in, 3g             |
| Kangaroo™<br>Adult           | July 1, 2022            | 8884721055                                | 8884721055E | Entriflex Feeding Tube with Stylet, 10FR x 55in, 5g            |
| Nasogastric<br>Feeding Tubes | July 1, 2022            | 8884721088                                | 8884721088E | Entriflex Feeding Tube with Stylet, 10FR x 43in, 5g            |
|                              |                         | 8884721096                                | 8884721096E | Entriflex Feeding Tube without Stylet,<br>10FR x 43in, 5g      |
|                              |                         | 8884721211                                | 8884721211E | Entriflex Feeding Tube without Stylet,<br>12FR x 36in,5g       |
|                              |                         | 8884721237                                | 8884721237E | Entriflex Feeding Tube without Stylet 12FR x 43in, 5g          |
|                              |                         | 8884721252                                | 8884721252E | Entriflex Feeding Tube with Stylet, 12FR x 43in, 5g            |
|                              |                         | 8884721255                                | 8884721255E | Entriflex Feeding Tube with Stylet, 12 FR X 55in, 5g           |





cardinalhealth.com

|                             |              | 8884710826 | 8884710826E | Dobbhoff™ Feeding Tube with Stylet, 8FR x 55in, 7g             |  |
|-----------------------------|--------------|------------|-------------|--|--|
|                             |              | 8884710842 | 8884710842E | Dobbhoff™ Feeding Tube without Stylet,<br>8FR x 43in, 7g       |  |
|                             |              | 8884710859 | 8884710859E | Dobbhoff™ Feeding Tube with Stylet, 8FR                        |  |
|                             |              | 8884710867 | 8884710867E | x 43in, 7g  Dobbhoff™ Feeding Tube with Stylet, 8FR x 43in, 5g |  |
|                             |              | 8884711006 | 8884711006E | Dobbhoff™ Feeding Tube with Stylet,<br>10FR x 43in, 7g         |  |
|                             |              | 8884711246 | 8884711246E | Dobbhoff™ Feeding Tube without Stylet,<br>12FR x 43in, 7g      |  |
|                             |              | 8884711253 | 8884711253E | Dobbhoff™ Feeding Tube with Stylet,<br>12FR x 43in, 7g         |  |
|                             |              | 35ES       | 35ENS       | 35 in Pediatric Extension Set                                  |  |
|                             | July 1, 2022 | 60ES       | 60ENS       | 60 in Pediatric Extension Set                                  |  |
|                             |              | 35EY       | 35ENY       | 35 in Bifurcated (y-port) Pediatric Extension Set              |  |
|                             |              | 60EY       | 60ENY       | 60" Bifurcated (y-port) Pediatric Extension Set                |  |
|                             |              | N/A        | 4VENS       | Kangaroo™ Vented Gravity Set                                   |  |
|                             |              | N/A        | 60VENS      | Kangaroo™ 60 in Vented Gravity<br>Extension Set                |  |
|                             |              | N/A        | 60VENY      | Kangaroo™ 60 in Vented Bifurcated<br>Gravity Extension         |  |
|                             |              | 460208     | 460208E     | Purple Pediatric PVC Feeding Tube 10FR x 107cm                 |  |
|                             |              | 460406-    | 460406E     | Purple Pediatric PVC Feeding Tube, 8FR x 107cm                 |  |
|                             |              | 460604     | 460604E     | Purple Pediatric PVC Feeding Tube, 8FR x 41cm                  |  |
| Kangaroo™                   |              | 460711     | 460711E     | Purple Pediatric PVC Feeding Tube,<br>6.5FR x 41cm             |  |
| Pediatric<br>Feeding System |              | 460802     | 460802E     | Purple Pediatric PVC Feeding Tube, 5FR x 41cm                  |  |
| and Accessories             |              | 461008     | 461008E     | Purple Pediatric PVC Feeding Tube, 5FR x 91cm                  |  |
|                             |              | 461206     | 461206E     | Purple Pediatric PVC Feeding Tube, 3.5Fr x 31cm                |  |
|                             |              | 461042     | 461042E     | Purple Pediatric Polyurethane Feeding<br>Tube, 10Fr x 107cm    |  |
|                             |              | 461355     | 461355E     | Purple Pediatric Polyurethane Feeding Tube, 3.5Fr x 31cm       |  |
|                             |              | 461412     | 461412E     | Purple Pediatric Polyurethane Feeding<br>Tube, 5 FR X 20in     |  |
|                             |              | 461420     | 461420E     | Purple Pediatric Polyurethane Feeding<br>Tube, 6.5Fr x 51cm    |  |
|                             |              | 461438     | 461438E     | Purple Pediatric Polyurethane Feeding Tube, 6.5Fr x 91cm       |  |
|                             |              | 461503     | 461503E     | Purple Pediatric Polyurethane Feeding<br>Tube, 5Fr x 91cm      |  |
|                             |              | 461701     | 461701E     | Purple Pediatric Polyurethane Feeding<br>Tube, 8Fr x 51cm      |  |
|                             |              | 461800     | 461800E     | Purple Pediatric Polyurethane Feeding<br>Tube, 8Fr x 107cm     |  |
|                             |              | 461000     | 461000E     | Kangaroo™ Milk Straw - 5in (12.7 cm)                           |  |

<sup>\*</sup> Cardinal Health reserves the right to further update the information contained in this communication in its sole discretion.



Dale<sup>®</sup> Medical Products fully supports the ISO 80369-3 ENFit<sup>®</sup> Global Safety Initiative. Our sales teams have been tasked with focusing on converting current existing Dale Legacy products to the equivalent Dale ISO 80369-3 ENFit style, and ENFit products specifically, on all new enteral applications, in the most timely manner possible.

Dale Medical is fully committed to ISO 80369-3 ENFit conversions, but we are mindful that each customer's individual timelines and budgets to convert may vary, and Dale Medical will be respectful of this. At this time, Dale Medical plans to maintain Legacy product availability to support all of our customers not yet ready to convert.

Dale Medical will also provide its customers with appropriate technical recommendations to those clinicians/facilities that have experienced technical roadblocks with large bore Salem Sump Tubes and Suction Hoses with respect to ENFit compatible connections.

It is Dale's expectation on all enteral products, that the ENFit ISO 80369-3 Standard will soon become the only connection standard for enteral going forward, both domestic and globally. Dale Medical will provide whatever support is necessary to accomplish this end goal.

Respectfully,

**Dale Medical Products, Inc.** 

Franklin, MA

Dale® is a registered trademark of Dale Medical Products, in the USA ENFIT® is a registered trademark of GEDSA used with their permission

Dale Medical Products Inc.



GBUK Enteral Ltd. Woodland House Blackwood Half Business Park North Duffield, Selby North Yorkshine YOB SDD T +44 (0) 1757 282 945 W www.gbukenteral.com E Info@gbukenteral.com ■ ■GBUK Group ■ (+GBUKEnteral GBUK Group GBUK Group

February 1, 2022

Dear Valued Customer.

As you may be aware, the Global Enteral Device Supplier Association (GEDSA) announced in September of 2020 that member manufacturers will phase out legacy enteral feeding products and transitional adaptors. This transition will meet ISO Standard 80369-3, commonly referred to as ENFit™, which aims to maximize patient safety by reducing the risk of enteral tubing misconnections.

As an original member of GEDSA, and a worldwide leading provider of ENFit™ products, GBUK Enteral is committed to this important patient safety initiative and the conversion timeframe. GBUK Enteral offers ENFit® products exclusively and is ready to support your enteral supply needs and assist in your conversion plans.

To ensure that you and your institution are prepared for the transition to ENFit™ please contact myself, your local GBUK Enteral distributor, or our Customer Service Department at (866)528-9422. To view all GBUK products, please visit our website; https://www.gbukgroup.com/brands/gbuk-enteral/

GBUK stands committed to patient safety and we believe the transition to ENFit™ is the best option for your enteral products and we stand ready to assist in your transition.

Sincerely,

Kevin Maki Head of North American Sales **GBUK Group Ltd** Kevin.Maki@gbukgroup.com Cell:608-347-3476



2981 Gateway Dr. Pompano Beach, FL 3069 954-917-9570

**IMIWEB.COM** 

February 21, 2022

Dear Valued Customer,

On September 14th, 2020 the Global Enteral Device Supplier Association (GEDSA) announced that member manufacturers will phase our legacy enteral feeding products and transition adapters. This transition aims to maximize patient safety by reducing the risk of enteral tubing misconnections and will meet ISO standard 80369-3, commonly referred to as ENFit®.

### **IMI'S POSITION**

- As a longstanding member of GEDSA, IMI fully supports the transition to ENFit products as a method to provide safer enteral delivery of nutritional and drug products to patients.
- Ensuring the safe delivery of mediations has always been a central mission for IMI. The GEDSA initiative to reduce the occurrence of misconnections perfectly aligns with that mission.
- IMI supports the ENFit transition by manufacturing Prep-Lock™ Tamper Evident Caps, the only tamper-evident cap for Enteral syringes available.

IMI will continue to support the needs of our hospital pharmacy and outsource compounding operations with high-quality, American-made products that enhance drug security. Through our alliance with GEDSA and member organizations, IMI is ready to support the ENFit transition with helpful tools and educational resources. As always, IMI will continue to deliver world-class customer support. For all inquiries, please contact IMI customer service as (800) 344-2554.

Thank you for your continued support of IMI,

Sincerely,

Bryan McGurn

Senior Vice President Sales & Marketing

IMI 18



Date: 3/14/2022

## KB Medical Group Actively Participating in ENFit® Transition

As stated earlier by the Global Enteral Device Supplier Association (GEDSA) and its supporting organizations, "GEDSA members are committed to providing a continued supply of the enteral products that are currently being utilized in healthcare systems worldwide. GEDSA remains committed to ENFit, supports its use and acknowledges that it is the [standardized] ISO [80369-3] compliant option used globally in these times where the potential for a misconnection is exceptionally high."

KB Medical Group Inc. as a GEDSA member and one of the earliest manufacturers in the world to provide ENFit products to the medical device market, we are fully supportive of the transition to ENFit products. Because we are in the targeted timeline from GEDSA for the U.S. industry to transition to ENFit, KB intends to phase out our production for Legacy feeding bag from our products portfolio by the end of 2022 and dedicated to the safer ISO 80369-3 compliant ENFit products.

Healthcare systems are seeing increased demand for services and critical supplies, constant strain on front-line caregivers, and surging patient needs across the country. KB Medical Group will continue to work with GEDSA, professional societies and institutions, customers, and partners to reduce the chance of medical device misconnections, ensure patient safety, and facilitate the availability of products that work for the multitude of patient populations, uses, and care environments.

For additional support and questions regarding your ENFit transition, please contact your local KB Medical Group Representative or Customer Service 949-333-3785, info@kbmed.com.

Thank you for your continued support,

KB Medical Group Inc.

9650 Research Dr.,

Irvine, CA 92618

Add.: 9650 Research Dr, Irvine CA 92618 USA
Web: www.kbmed.com www.kbmednutrition.com

Email: Info@kbmed.com, Phone: +1 (949) 333-3785, Fax: +1 (262) 263-2383



Dear Valued Customer,

As you may be aware, on September 14<sup>th</sup>, 2020, the Global Enteral Device Supplier Association (GEDSA) released a revised conversion schedule indicating that member manufacturers will phase out legacy enteral feeding products and transition adapters. This transition will meet ISO standard 80369-3, commonly referred to as ENFit®.

As a member of GEDSA, Moog fully supports this essential safety initiative, and we are committed to removing the transitional connector from our products so that they are ENFit-only compatible. In an effort to better align with the transition schedules of other manufacturers in the enteral industry, beginning early in the second quarter of 2022 Moog will discontinue the manufacture of our feeding sets with transition connectors and will move forward with ENFit-only connectors on our Infinity® and Infinity® Orange® enteral feeding pump sets and gravity sets.

Because some inventory with transitional connectors is already in the field, you may not begin receiving the ENFit-only sets until the latter part of the second quarter of 2022 or shortly thereafter. In the interim, we strongly encourage you to prepare yourselves for this transition so that you will be able to meet the ENFit needs of your patients.

For a short period after Moog introduces the ENFit-only feeding sets, we will sell separately packaged transitional connectors to accommodate patients with non-ENFit feeding tubes as they are transitioned to ENFit feeding tubes. This offering of transitional connectors will be available for a limited time only. Other suppliers may also offer transition connectors for purchase. Check with your distribution channels regarding transition connector availability.

With the transition to ENFit-only enteral feeding sets, Moog will be changing current product code part numbers. Attachment A below includes a crosswalk of current ENFit product codes with transitional connectors to ENFit-only codes without transitional connectors. You will note that the only change to the product codes is the change from a "-A" (*Adapter*) suffix to a "-E" (*ENFit only*) suffix. As "-A" product inventories are depleted, we will fulfill orders with the new "-E" codes.

Moog is committed to the safety of our customers and patients. We believe the use of ENFit products will contribute to improved patient safety. If you have any questions regarding the ENFit initiative or how you can prepare for these changes, please contact your local Moog sales representative, customer service at (800) 970-2337, or email us at clinicalsupport@moog.com.

Sincerely,

John Bacon

Sr. Product Manager

John Ban

Moog Medical

Moog Medical 4314 Zevex Park Lane Salt Lake City, UT 84123 USA www.moogmedical.com

> tel 801.264.1001 toll free 800.970.2337 fax 801.264.1051



Dear Valued Customer,

As you may be aware, in September 2020, the Global Enteral Device Supplier Association (GEDSA) released a revised conversion schedule indicating that member manufacturers will phase out legacy enteral feeding products and transition adapters. This transition will meet ISO standard 80369-3, commonly referred to as ENFit®.

As a member of GEDSA, Moog fully supports this essential safety initiative, and we are committed to removing the transitional connector from our products so that they are ENFit-only compatible. Moog communicated in February 2022 its plans to discontinue the manufacture of its enteral feeding sets with transition connectors and to solely manufacture enteral sets with ENFit-only connectors on the Infinity® Orange® enteral feeding pump sets and gravity sets.

That transition is in process and Moog is currently only manufacturing ENFit-only compatible enteral feeding sets. With this transition, Moog is changing its enteral set product code part numbers. Attachment A below includes a crosswalk of current ENFit product codes with transitional connectors to the new ENFit-only codes without transitional connectors. You will note that the only difference in the product codes is the change from a "-A" (Adapter) suffix to a "-E" (ENFit only) suffix. As "-A" product inventories are depleted, we will fulfill orders with the new "-E" codes.

Attachment A also provides an update to our anticipated availability for each product code. You will note that two products are now fully converted to ENFit-only connections and that all but one of the remaining products will be available in early July. Because some inventory with the current transitional connectors is already in distributor distribution centers, you may not begin receiving the ENFit-only sets until the mid to latter part of the third quarter of 2022. In the interim, we strongly encourage you to prepare yourselves for this transition so that you will be able to meet the ENFit needs of your patients.

For a short period after Moog introduces the ENFit-only feeding sets, we will sell separately packaged transitional connectors to accommodate patients with non-ENFit feeding tubes as they are transitioned to ENFit feeding tubes. This offering of transitional connectors will be available for a limited time only. Other suppliers may also offer transition connectors for purchase. Check with your distribution channels regarding transition connector availability. The Moog transitional connector ordering information is listed in Attachment B below.

Moog is committed to the safety of our customers and patients. We believe the use of ENFit products will contribute to improved patient safety. If you have any questions regarding the ENFit initiative or how you can prepare for these changes, please contact your local Moog sales representative, customer service at (800) 970-2337, or email us at clinicalsupport@moog.com.

Sincerely,

John Bacon

Sr. Product Manager

Moog Medical

Moog Medical 4314 Zevex Park Lane Selt Lake City, UT 84123 USA www.moogneedical.com

> tel 801.264.1001 toll free 800.970.2337 fax 801.264.1051

Infinity® and Infinity Orange® are trademarks of Zevex, Inc. ENFit® is a trademark of GEDSA



### **Attachment A**

| Current ENFit Administration Transitional Connector  |                 | Future ENFit-Only Administration Sets without Transitional Connectors             |                 |                           |
|--|-----------------|---|-----------------|---------------------------|
| Product Description  | Product<br>Code | Product Description   | Product<br>Code | Anticipated availability* |
| Infinity® Safety Screw Enteral<br>Pump Delivery Set with ENFit®<br>Connector System and<br>Transitional Stepped Connector      | INF0020-A       | Infinity® Safety Screw<br>Enteral Pump Delivery Set<br>with ENFit® Connector      | INF0020-E       | Available<br>Now          |
| Infinity® 500ml Enteral Pump Delivery Set with ENFit® Connector System and Transitional Stepped Connector                      | INF0500-A       | Infinity® 500 mL Enteral<br>Pump Delivery Set with<br>ENFit® Connector            | INF0500-E       | Available<br>Now          |
| Infinity® 1200ml Enteral Pump<br>Delivery Set with ENFit®<br>Connector System and<br>Transitional Stepped Connector            | INF1200-A       | Infinity® 1200 mL Enteral<br>Pump Delivery Set with<br>ENFit® Connector           | INF1200-E       | Early July                |
| Infinity® Orange® Screw Cap<br>Enteral Pump Delivery Set with<br>ENFit® Connector System and<br>Transitional Stepped Connector | INFOCAP-A       | Infinity® Orange® Screw<br>Cap Enteral Pump Delivery<br>Set with ENFit® Connector | INFOCAP-E       | Early July                |
| Infinity Orange 100mL Enteral<br>Pump Delivery Set with ENFit®<br>Connector System and<br>Transitional Stepped Connector       | INF0100-A       | Infinity Orange 100mL<br>Enteral Pump Delivery Set<br>with ENFit® Connector       | INF0100-E       | Early July                |
| 1200ml Gravity Feeding Delivery Set with ENFit® Connector System and Transitional Stepped Connector                            | GR1200-A        | 1200mL Gravity Feeding<br>Delivery Set with ENFit®<br>Connector                   | GR1200-E        | August                    |

<sup>\*</sup>Note: anticipated availability is from Moog distribution centers. If sets are ordered through distributors, availability will vary based upon distributor inventories of current non-ENFit only products.

### **Attachment B**

| ENFit® Transitional Connector Ordering Information |   |  |  |  |
|--|---|--|--|--|
| Product Description                                | Enteral Distal End ENFit® Transition Connector with cap                                     |  |  |  |
| Product Code                                       | F00071  |  |  |  |
| Packaging  | Individual blister pack with transition connector, protective cover, and directions for use |  |  |  |
| Quantity per case                                  | 30 eaches (available only in cases)   |  |  |  |





Dear Valued Business Partner,

On September 14th, 2020, the Global Enteral Device Supplier Association (GEDSA) released a <u>REVISED ENFit® Connector Conversion Schedule</u> to phase out legacy Enteral Feeding Products and Transition Adaptors, where member manufacturers will discontinue legacy enteral feeding devices and transition adaptors as late as July 1<sup>st</sup>, 2021. This transition meets ISO80369-3, commonly known as ENFit®.

Ucomfor is in full supportive of this announcement to maximize patient safety by minimizing the enteral device misconnection risk.

Meanwhile, as a Contract Manufacturer of PVC and PVC free Enteral Feeding Devices, Ucomfor has been keeping the manufacturing capability and capacity to respond to the request from global customers for both FNfit® and legacy connectors.

For all other enquiries, please call Ucomfor Customer Service at +86-521-58665665 or visit www.ucomfor.com.

Thanks to all customers for your continuous support and business!

ancisti 02.16, 2022

Sincerely,

Managing Director

Ucomfor Scientific Co., Ltd.



February 1, 2022

Dear Vesco Medical Customers & Colleagues,

In 2020, The Global Enteral Device Supplier Association (GEDSA) released an ENFit Connector Conversion Schedule in which members agreed to no longer manufacture legacy enteral feeding devices and transition connectors. Due to the persistence of the pandemic and related global supply chain challenges, implementation timelines for most manufacturers have been delayed. However, our resolve to maximize patient safety by reducing the risk of enteral tubing misconnections remains. Now is the time to transition to safer ISO 80369-3 standard ENFit connectors once and for all.

To support a cohesive and safe transition, Vesco will continue to offer products with ENFit Transition Connectors (TCs) to our committed customers for a period of time after the last anticipated manufactured date while supplies last. See adjacent table with crosswalk of existing items with TCs and the corresponding item numbers without TCs. Separate items numbers should improve tracking inventory levels and ordering with or without TCs. Individually packaged Sterile, Clean Non-Sterile and bulk, non-sterile **ENFit syringes without TCs are readily available today**. The following outlines our projected availability and the month we anticipate running out of product with TCs in pack:

| Product Line                                  | Last Manufactured Date |
|---|------------------------|
| Gravity Sets with Transition Connectors       | July, 2022             |
| ENFit Syringes with Transition Connectors     | July, 2022             |
| ENFit Transition Connectors (sold separately) | September, 2022        |

At Vesco we are **All ENFit All the Time!** We remain fully committed to supporting the industry-wide transition. We carry a full range of ENFit products to support your evolving enteral device needs. Patient safety is of the utmost importance. Our team of ENFit experts are prepared to help solve any transition challenges or questions. For assistance, please reach out to us at (855) 239-0131 or <a href="info@vescomedical.com">info@vescomedical.com</a>.

Thank you for your attention to this important matter.

Kind Regards,

Tom Hancock

President & Founder, Vesco Medical

### **Vesco Medical**

<sup>&</sup>lt;sup>1</sup> To read GEDSA's full communication and/or learn more about the industry's recommendations to support a smooth ENFit transition, please visit <a href="www.stayconnected.org">www.stayconnected.org</a> or contact <a href="mailto:info@gedsa.org">info@gedsa.org</a>.



March 16, 2022

Dear Valued Customer,

As you may be aware, as of September 14, 2020, the Global Enteral Device Supplier Association (GEDSA) released that manufacturer members will begin phasing out legacy enteral feeding products and transitional adapters. The transition will meet ISO standard 80369-3, commonly referred to as ENFit™. The goal is to maximize patient safety by minimizing the risk of enteral tubing misconnections.

As a member of GEDSA, Vonco understands the importance of the transition to these patients in order provide safe and efficient delivery of enteral nutrition. With this initiative and conversion schedule in mind, Vonco recently patented the EnteraLoc™ Flow device and was granted 510(k) clearance by the U.S. Food and Drug Administration (FDA). This groundbreaking enteral device sets the bar for future direct connect to ENFit™ delivery of nutrition − blended and non-blended.

Vonco intends to provide continued support to GEDSA and their conversion to ENFit™ delivery of nutrition. We believe that these enteral products will provide patients with better nutrition, less waste, more mobility, and better safety. We want to ensure that you and your institution are prepared and understand the changes taking place during this transition. If you have any questions regarding the ENFit™ initiative or the EnteraLoc™ Flow device itself, please contact us at (800) 323-9077.

Sincerely,

Brittany Pullen
Marketing and Communications Manager
Vonco Products, LLC
brittany@vonco.com

Vonco Products, LLC 25



5405 Windward Parkway Alpharetta, GA 30004

T 1-844-428-2667 www.avanos.com

March 22<sup>nd</sup>, 2022

Dear Valued Customer.

On September 14<sup>th</sup>, 2020, the Global Enteral Device Supplier Association (GEDSA) announced that member manufacturers will phase out legacy enteral feeding products and transition adapters to meet ISO standard 80369-3, commonly referred to as ENFit®.

Additionally, on January 26<sup>th</sup>, 2022, Cardinal Health announced their intention to remove the transition adapter from their feeding set portfolio by June 2022. <u>NOTE</u>: Transition adapters will continue to be available in the marketplace but will need to be purchased separately once this change takes place.

### **AVANOS' POSITION:**

- Avanos remains supportive of GEDSA's mission to maximize patient safety by reducing the risk of enteral tubing misconnections.
- We recognize that the choice to convert to ENFit® is clinical in nature and understand there are many factors that play a role in making this decision.

### **AVANOS' COMMITMENT:**

- We will respond to market demand for ENFit® devices and will adjust production accordingly.
  - We will continue to manufacture both ENFit & non-ENFit products. As the conversion rate increases, we will reassess market needs and phase-out timing of non-ENFit devices.
  - At this time, we believe that 45-50% of the North American market has converted to ENFit®.
- To ensure conversion timing is impacted as little as possible, Avanos is working closely with supply chain partners to mitigate raw material shortages and transportation challenges driven by the global COVID-19 pandemic.

### **IMPORTANT NOTES & NEXT STEPS:**

- Avanos is committed to supporting your ENFit® transition with proven conversion processes, tools & educational resources.
- To ensure a smooth transition, please discuss your ENFit® conversion timeline with your Avanos sales representative at least 120 days prior to your go-live date.
- For personalized support, please contact your Avanos Digestive Health or NeoMed sales representative.

For all other inquiries, please call Avanos Customer Service at 1-844-4AVANOS (1-844-428-2667).

Sincerely,

James Zacha

Associate Marketing Director, Digestive Health

Jane Jula

Avanos | NeoMed 26

<sup>\*</sup>Registered Trademark or Trademark of Avanos Medical, Inc., or its affiliates. © 2022 AVNS. All rights reserved. COPY-05883



# Resolve Designs



Feb 18, 2022

Re: GEDSA Position Statement

Dear Valued Customer:

Resolve Designs is the maker of the RxCrush branded Pill Crushing System. We offer pill crushers, pouches, syringes and adapters to easily and quickly crush pills for injection into enteral feeding tubes and systems. Our aim from the beginning was to incorporate the ENFit™ ISO 80369-3 standard into our products to improve patient safety and to support the GEDSA initiative to transition to the ENFit standard. However, we have also offered adapters to help customers transition to ENFit.

Given the GEDSA established timeline of phasing out legacy enteral feeding products as of September 2020, Resolve Designs is planning to phase out transition adapters in conjunction with other manufacturers. The availability of the following products will be affected throughout 2022:

- EL02 Female Locking ENFit to Female Luer Lock Adapter
- EL06 Female Locking ENFit to Female Luer Lock Adapter
- ET01 Male ENFit Tree Style Transition Connector

Patient safety is our focus, and we believe ENFit is a safer option for all patients. For additional support and questions regarding your ENFit transition, please contact your RxCrush Sales Representative at 877.343.2783. Thank you for your continued support.

Sincerely,

Aaron Collett

Managing Director

Resolve Designs LLC dba Rx Crush

lou Alexo

RxCrush.com



Feb 17, 2022

To The pFed System Community of Users.

From the introduction of the bFed® System in 2018 U Deliver Medical has been committed to "Tupe Feeding Made Easy" and removing all barriers to tube fed patients at home which prevent them from receiving the nutrition heeded to maintain health.

Inat commitment includes ensuring safe delivery of nutrition. All b5od System delivery sets. Bot nk\* Large Cap, Botink Small Cap and now Bolink D Cap - utilize the ENFit\* connector system and are compliant with ISO 80369-03. The ENFit connector reduces the risk of dangerous tubing misconnections as well as lowering the chance that delivery systems will bisconnect during feeding, preventing the complete delivery of the nutrition patients need to maintain their health. Our connectors on the container side are also compliant with ISO 18250-03 which supports attachment to nutrition products only.

As part of U Deliver Medical or other organizations, the U Deliver Team has been involved in the ENFIL project (or over 10 years. We see no reason why all tube fed patients and their caregivers should not experience the benefits of the ENFIL connector system, it is time to complete the conversion of all enteral feeding tubes, sets and syringes to the ENFIL System. We welcome and support the efforts of GEDSA and its members to make this happen in 2022.

Sincerely

Brian Johnson

President and Co-Founder

U Deliver Medical, LLC

Fred Reuning

Vice President and Co-Founder

U Deliver Medical, LLC

**UDeliver Medical** 

# **More Statements Forthcoming**

Submit to info@gedsa.org