

IV Solutions Update

Frequently Asked Questions

Introduction:

To enhance our reliability and better provide availability of freeflex products in the U.S., Fresenius Kabi is moving the manufacturing of our freeflex IV bags from Europe to two state-of-the-art manufacturing facilities in the U.S. mainland beginning in 2023. To expedite this transition, (13) freeflex products will be taking on new NDCs and product codes. All other freeflex products will retain their current product codes and NDCs.

When/Why:

1. Why is Fresenius Kabi changing select NDCs and product codes?

- Fresenius Kabi is moving the manufacturing of our freeflex IV bags from Europe to the U.S. To expedite this transition, 13 in-demand freeflex products – including Normal Saline, 5% Dextrose, and Lactated Ringer’s solutions – will be taking on new NDCs and product codes. Only 13 product/NDC codes will change. All other products will retain their current product codes and NDCs.

2. Why are you transitioning freeflex product manufacturing to the U.S.?

- Several years ago, Fresenius Kabi recognized the need to invest in American manufacturing to help address the ongoing challenge of extended market shortages. Our onshoring of all freeflex product manufacturing from Europe to the U.S. will help improve our supply chain resilience, increase efficiencies and product supply reliability (particularly during market demand shifts), help address competitive shortages, and bring products closer to our customers and end users.

3. What are the benefits of this change for the customer?

- As part of a broader strategic initiative to meet the needs of the U.S. market, the move of freeflex manufacturing from Europe to the U.S. will:
 - Reduce the length and complexity of our supply chain to shorten lead times.
 - Increase product availability to providers.
 - Bring our supply of freeflex IV bags closer to our end users.
 - Provide additional capacity to flex up the total number of units available to the marketplace.
 - Provide opportunity to further expand our product lines.
 - Enable us to respond faster to competitive shortages and spikes in demand.

4. Where are these products going to be manufactured?

- In Fresenius state-of-the-art manufacturing facilities in Ogden, UT and Wilson, NC.

5. When will this transition take place?

- As you can imagine, this transfer will take time and effort, so it is happening in multiple phases. The phases are:
 - Ogden Phase I: May 1, 2023, the first two products came out of Ogden, UT.
 - Ogden Phase II: Late Summer 2023, another product came out of Ogden, UT.
 - Ogden Phase III: Fall 2023, one more product will come out of Ogden, UT.
 - Wilson Phase I: Early 2024, base solutions products will begin coming out of Wilson, NC.

6. What products transitioned to new NDC and product codes in Ogden Phase I?

- In the first phase, the two products with new codes were:

Product Description	Current EU Product Code	Current EU Product NDC	New USA Product Code	New USA Product NDC	Launch Date
0.9% Sodium Chloride 500 mL FFX Bag	623175	63323-623-75	416620	65219-472-20	May 2023
0.9% Sodium Chloride 1000 mL FFX Bag	623176	63323-623-76	416610	65219-474-10	May 2023

7. What product transitioned to new NDC and product codes in Ogden Phase II?

- In this second transition, the product with new codes was:

Product Description	Current EU Product Code	Current EU Product NDC	New USA Product Code	New USA Product NDC	Launch Date
0.9% Sodium Chloride 250 mL FFX Bag	623174	63323-623-74	416630	65219-470-30	August 2023

8. What product will be transitioning to new NDC and product codes in Ogden Phase III?

- In this third transition, the product with new codes is:

Product Description	Current EU Product Code	Current EU Product NDC	New USA Product Code	New USA Product NDC	Launch Date
Lactated Ringer's Injection, USP 1000 mL FFX Bag	964176	63323-164-76	417710	65219-479-10	November 2023

Ordering/Receiving:

9. How do I order the new products?

- Follow the same process for ordering as you do today – but use the new product code. If you have questions, call Customer Service at 888-386-1300.

10. What happens if I use the old product code on my order?

- If we receive a purchase order with an old NDC/product code that is non-stocked, that line will be rejected from the purchase order. We will ask that a new purchase order be placed for the current product code. For shipping/receiving and billing consistency, it is essential to use the correct NDC/product codes; we cannot substitute (see below).
- If you are ordering on the portal and you use an old code, you will see a message that the old code is “discontinued and is replaced by” the new NDC/product code.
- If you have any questions, call Customer Service at 888-386-1300.

11. Why can't the system auto-substitute the new product code for the old one?

- We cannot auto-substitute new codes for old codes because then the purchase order wouldn't match the delivered product. The delivery might be rejected when being received by the customer. Returned products cannot be restocked and must be destroyed.
- That's why it's so important that products be ordered by their new and correct codes once the switch over to the new codes takes place. If you have any questions, call Customer Service at 888-386-1300.

12. If I have problems ordering, what should I do?

- If you have any questions, call Customer Service at 888-386-1300 or speak to your IV Therapy Sales Representative.

13. As we transition from one code to another on these 13 products, what is your plan for working with customers to help avoid disruption?

- We don't anticipate major disruptions. We will go above and beyond to manage the inventory we have and build up inventory from Europe to anticipate demand during the transition. And once that inventory is depleted, we will switch over to a large inventory of U.S. products that will be ready in the warehouse to send out to customers.

14. Will there be any disruption for me in receiving the products I am currently ordering?

- When we switch over to the 13 new codes manufactured in the U.S., we all will need to transition from the old codes to the new codes. We will communicate regularly on both the timing of the switch-over dates and the new codes that you will need to use when ordering moving forward.

15. Will the new product codes be shipped from the same locations that I am currently receiving from?

- Over the past several years, we have created three state-of-the-art distribution centers in Pleasant Prairie, WI; Duncan, SC; and Las Vegas, NV. You should already be receiving products from one or more of these conveniently located distribution centers.

16. Will the pallet configurations be changing?

- Yes, most of the pallet configurations will be changing per the table below:

Format	Units per Case/Carton		Units per Pallet	
	Current	New	Current	New
50 mL	60	60	3,000	3,840
100 mL	50	50	2,500	3,200
250 mL	30	30	1,500	1,920
500 mL	20	20	1,000	1,200
1000 mL	10	10	640	640

17. When I order the product in the future, do I need to change the quantities I am ordering?

- No, since orders are placed by the carton – and the number of units you will receive in each case or carton will not change. For example, if you order five cases of product, the quantity you receive will be the same as now.

Product Focus:

18. Are the formulations or contents of the product changing?

- No.

19. Will the shelf life/expiry dates be the same as my current product?

- The shelf life/expiry dates of these products will be the same as you are currently buying – even though it’s important to note that several of our products already have extended dating (36 months), with more products in the future transitioning to this extended dating.

20. Will the product look any different from the current product?

- No. The only change will be some enhancements we’ve made to the label (see below).

21. Does anything change on the label?

- Two things will change:
 - There will be a different manufacturing location in the bottom left corner.
 - There will be a 2-D data matrix bar code on the label of products made in the U.S.

Deployment:

22. Will I receive notice of upcoming changes before the current product is out of stock?

- We will give you as much notice as possible before current products run out and we switch over to new product codes. Speak to your IV Therapy Sales Representative for the latest information or call Customer Service at 888-386-1300.

23. Will you take back my current inventory of product prior to the changes?

- We will only take back eligible returns according to our current returned goods policy. If you have any questions, call Customer Service at 888-386-1300.

24. How will Fresenius Kabi avoid supply interruption during the transition?

- Given the recent history of recurring, extended shortages in the IV solutions market, Fresenius Kabi made the strategic decision years ago to onshore our IV bag manufacturing – which in turn will translate into added manufacturing capacity for the U.S. and shorter lead times for product supply. As with any change of this magnitude, it is a major undertaking and will require a concerted effort. We will do our best to coordinate with every customer to ensure the smoothest transition possible. It is essential that you contact your Fresenius Kabi IV Therapy Sales Representative to confirm your annual requirements and contract status, or call Customer Service at 888-386-1300.

25. How will Fresenius Kabi work with and communicate to distributors to assure a smooth transition to the new codes?

- Fresenius Kabi has already shared the NDC codes with wholesalers and distributors, and new individual wholesaler product codes have already been assigned. Please contact your Fresenius Kabi IV Therapy Sales Representative for the wholesaler/distributor updated product code list, or call Customer Service at 888-386-1300.

26. How will Fresenius Kabi work with and communicate to end customers to assure a smooth transition to the new codes?

- Your Fresenius Kabi IV Therapy Sales Representative will be reaching out to you, if they have not already done so, to keep you informed of these changes and ensure a smooth transition to the new codes. If you have questions, please call Customer Service at 888-386-1300.