

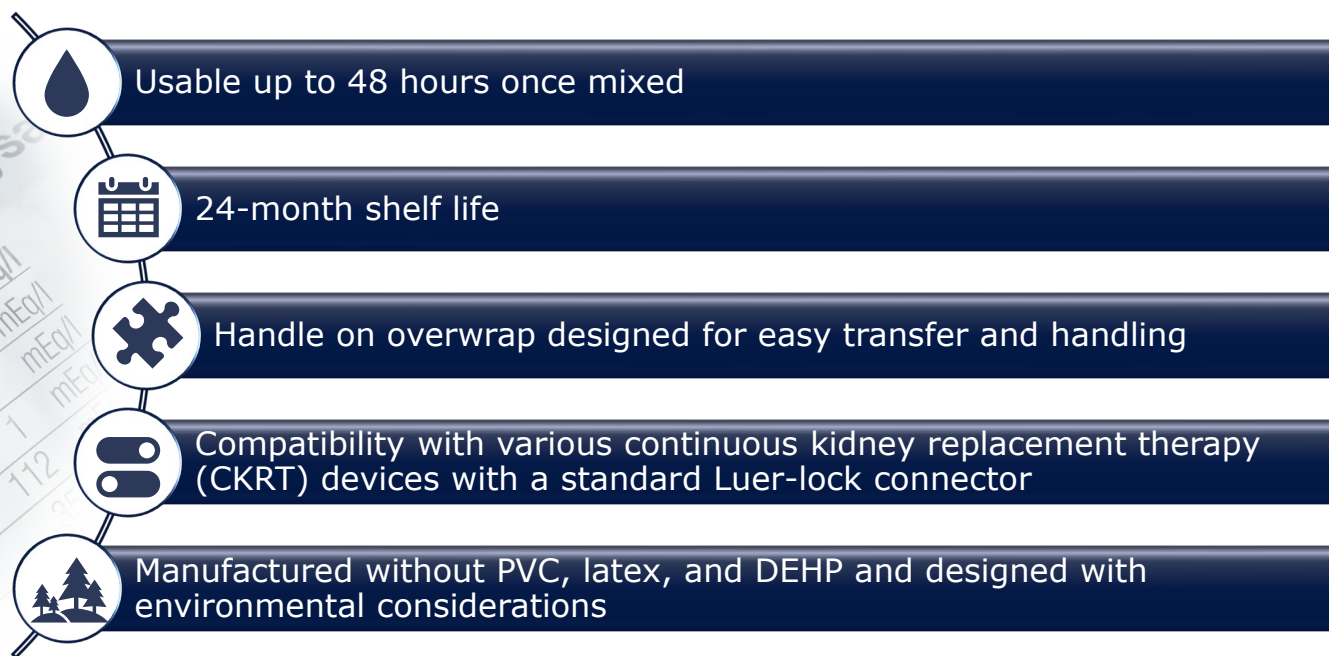
Bicarby™ Dialysate

Bicarby™ Dialysate
solution for hemodialysis
1000 ml of the ready-to-use
Potassium chloride
Sodium chloride
Sodium hydroxide
Calcium chloride
Magnesium chloride

Bicarby™ Dialysate Solution Transition Guide

PureFlow™ B (RFP-404) to Bicarby (RFP-404-G)

Fresenius Medical Care is excited to introduce Bicarby Dialysate Solutions, our new kidney replacement therapy (KRT) fluids brand that will carry forward the legacy and formulations of PureFlow B Solutions. Bicarby Dialysate Solutions come from a new production line in Guadalajara, Mexico, expanding manufacturing capabilities across two continents to improve supply chain resiliency. The Bicarby product underscores a renewed commitment to quality, ease of use, and enhanced waste management reflected in the following features¹:



The Guadalajara facility will eventually manufacture all KRT fluid products for the U.S. market. Over the next 12 months, we will transition all PureFlow B formulations to Bicarby Dialysate Solutions in phases by SKU.

At this time, the transition will include only the PureFlow B formulation RFP-404. The Bicarby products will keep the same fluid formulations and common identifiers (RFP-404) as the existing PureFlow B fluids.

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Product Code Cross Walk

- The table below shows interchangeable PureFlow B and Bicarby fluid formulations with the common identifier "RFP-404".
- Bicarby product's common identifiers will be followed by a "-G" to indicate the new production line location.
- When the common identifier "RFP-4XX" remains the same, that indicates the fluid formulation is identical.
 - Example: PureFlow B RFP-404 contains the same fluid formulation as Bicarby RFP-404-G

Common Identifier	Current PureFlow B SKU	New Bicarby SKU
RFP-404	RFP-404	RFP-404-G

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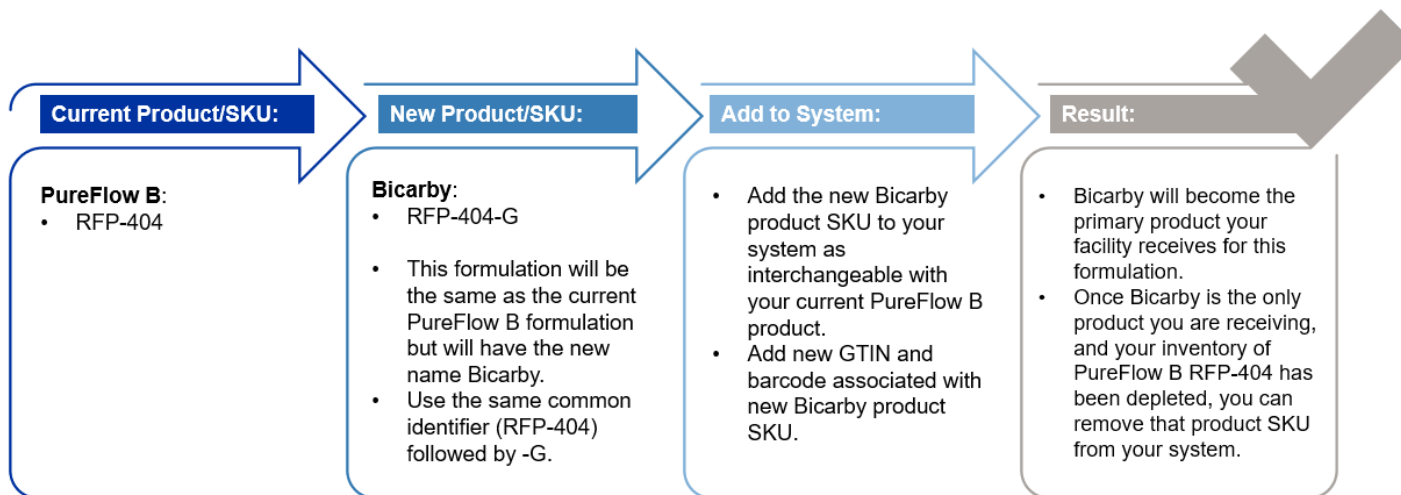
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Transition Overview: Product Codes RFP-404

- Bicarby products are intended to be the primary source of KRT fluid solutions in the US going forward.
- The intent during the transition period is for the Bicarby RFP-404-G product to be added to your system as interchangeable with the current PureFlow B RFP-404 product.
- Existing PureFlow B product code RFP-404 (along with associated GTINs, barcodes, etc.), should remain active in your system until the transition is complete and only Bicarby product is available for ordering and in your warehouse.



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Details of Fluid Code (by Common Identifier)

Current PureFlow B Product			New Bicarby Product			
Common Identifier	Name	Product Code	Name	Product Code	GTIN	Barcode (bag)
RFP-404	PureFlow B	RFP-404	➔ Bicarby	RFP-404-G	GTIN Bag: 00840861102914 GTIN Case: 10840861102911	

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Product Implementation Instructions

The information below outlines our recommendation for the management of our product line in your Enterprise Resource Planning (ERP) systems. We recognize that these instructions may not be applicable for every ERP system but believe that this information will provide your organization's supply chain team with better visibility to how we intend to support the transition of our product offerings. If there are any questions regarding these instructions or their application, please see the [transition overview](#) included with these instructions or you can reach out to us using the contact details provided in the [Customer Service](#) section of this document.

Item Master (ERP)

We recommend you treat each of the new Bicarby SKUs (see [Product Cross Walk](#)) as individual item numbers within your ERP system, built with the same unit of measure (UOM), manufacturer information, and item description as your current PureFlow B products based on the shared common identifier.

- a) The SKUs in the column marked "New Bicarby SKU" are the same fluid formulations (functional equivalents) and should be considered interchangeable product codes with any that share the same common identifiers.
- b) Since the new Bicarby SKUs are sourced from the Guadalajara manufacturing location, they will have different packaging and barcodes but contain the same product formulation.
- c) The UOM and pricing for Bicarby SKU will be the same as your current equivalent PureFlow B SKU RFP-404.
- d) We recommend that the barcodes supporting each Bicarby SKU be built within your ERP system to aid in inventory management (see [Transition Details](#))
- e) Existing PureFlow B SKUs (along with associated GTINs, barcodes, etc.), should remain active in your system until you have fully transitioned all products to Bicarby SKUs.

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Product Implementation Instructions, cont.

Procurement/Ordering of RFP-404-G

If you have previously given us blanket approval to substitute your orders with “like” product, you may continue to order based off the common identifier RFP-404

- We will convert your orders automatically.
- a) If no blanket approval has been given, you can do so by sending an email to acuteorders@freseniusmedicalcare.com stating "We authorize Fresenius Medical Care/NxStage to automatically substitute RFP-4XX with the same formulations with a suffix of -BB / -W / -G interchangeably." Then, you may continue to order based on the common identifier RFP-404.
- b) If you prefer not to give a blanket approval, please order the specific Bicarby SKU RFP-404-G.

Inventory Management

- a) Depending on your ERP system's capability you may wish to set up the new Bicarby SKU items as replacement items within your system ([Product Cross Walk](#)). While this is not necessary, it may make the inventory replenishment process smoother.
- b) Regardless of ERP set up, we recommend stocking the items with the common identifier in your normal pick pathing location. We also recommend your inventory locations have a designated shelf location for both the PureFlow B and Bicarby products as necessary.
- c) Long term we will be moving to a complete Bicarby dialysate product line; therefore, separate inventory locations will not be necessary except in the event of substitutions.

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Bicarby Case Product Labels

Current PureFlow B Product Code and Box Label



RFP-404-G

New Bicarby Product Code and Box Label



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Product Implementation Instructions, cont.

Pallets and Packaging

	PureFlow B RFP-404	Bicarby RFP-404-G
UOM: Purchased	Case	Case
UOM: Qty of eaches	Two 5L/bags	Two 5L/bags
UOM: Case Qty	60 (6 layers)	60 (12 layers)
Pallet Weight (lbs)	1,453	1,540
Pallet Length (in)	48.0	48.0
Pallet Width (in)	40.0	40.0
Pallet Height (in)	46.3	60.5
Case Weight (lbs)	23.3	24.7
Case Length (in)	18.0	23.5
Case Width (in)	9.5	15.0
Case Height (in)	7.0	4.6
Bag Weight (lbs)	11.5	11.5
Bag Length (in)	18.0	23.2
Bag Width (in)	8.5	16.3
Bag Height (in)	3.5	2.9

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Example of Fluid Product Pictures

PureFlow B RFP-4XX



Bicarby RFP-4XX-G



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Frequently Asked Questions (FAQs)

Q: Why are you making a product change?

A: Fresenius Medical Care is embracing resilience for growth and improvement. We've expanded our manufacturing with two additional Fresenius Medical Care-owned production lines, intended to strengthen our supply chain and minimize disruptions.

With this expansion, we're also introducing Bicarby, which offers the same trusted formulations but with significant improvements, including a 2-year shelf life and extended stability, up to 48 hours¹, after opening and mixing, compared to previous PureFlow B products².

These changes enhance our manufacturing resilience and reinforce our commitment to delivering reliable, high-quality products that meet the evolving needs of healthcare providers and patients.

Q: Will there be any pallet size, packaging, or distribution concerns Bicarby products?

A: Bicarby will have different packaging and pallet dimensions compared to PureFlow B products. Please see [Pallet and Packaging](#) for details.

Q: Is the transition from PureFlow B RFP-404 to Bicarby RFP-404-G mandatory?

A: The PureFlow B product version of these formulations will be discontinued, providing the same formulations provided under the Bicarby product line.

Q: We still have PureFlow B and/or PureFlow –W product in other formulations, is that an issue?

A: No, this is not an issue. The transition to Bicarby is phased by formulation over time. You will eventually see all Bicarby products, but in the meantime, you can continue using the PureFlow products as usual.

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Product Code Cross Walk

- The table below shows interchangeable PureFlow B and Bicarby fluid formulations with the common identifier "RFP-404".
- Bicarby product's common identifiers will be followed by a "-G" to indicate the new production line location.
- When the common identifier "RFP-4XX" remains the same, that indicates the fluid formulation is identical.
 - Example: PureFlow B RFP-404 contains the same fluid formulation as Bicarby RFP-404-G

Common Identifier	Current PureFlow B SKU	New Bicarby SKU
RFP-404	RFP-404	RFP-404-G

Formulations

The formulation listed below is the same for the Bicarby SKU with the same common identifier.

----- All Measurements Below Listed in mEq/L -----

Common Identifier	Potassium K+	Calcium Ca+	Magnesium Mg+	Sodium Na+	Chloride Cl-	Bicarbonate HCO ₃ ⁻	Glucose (mg/dL)	Osmolarity (mOsm/L)
RFP-404	4	2.5	1.5	140	113	35	100	300

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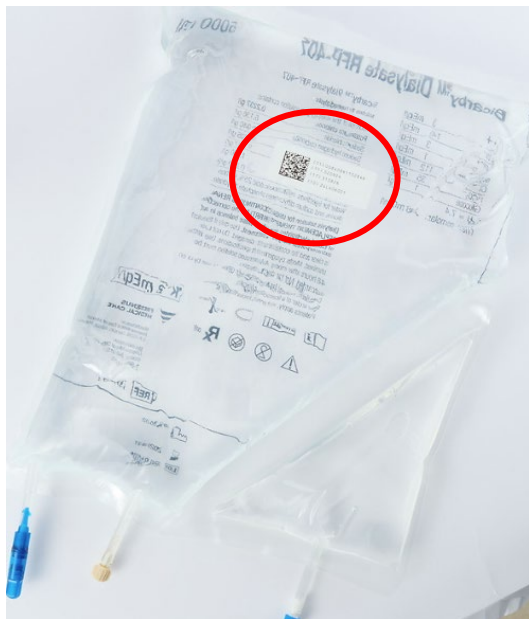
Opening and Mixing:

Both the opening of the overwrap and the activation of the peel seam on Bicarbly bags are slightly different compared to PureFlow B. When the product is ready to be used, guidance on opening the overwrap and the peel seam between the two compartments can be found here:

- [Opening and Mixing](#)

Scanning Bags:

If your facility scans the Bicarbly product as part of the patient's EMR, please find the barcode on the back of the bag (see image below):



*Product images are for illustrative purposes only and may not reflect the exact SKU.

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Luer Connection:

Current PureFlow B fluid bags have one Luer connector and one spike connector for the dialysate lines. Bicarby bags have one Luer connector, identified by the beige-capped port in the middle of the bag. See the images below of the connector ports for comparison.

PureFlow B
(ex: RFP-4XX)



Options for Connection:

One spike port and one Luer lock port.
Only Luer port contains a frangible (cone) housed inside.

Bicarby Product
(ex: RFP-4XX-G)



Options for Connection:

One Luer lock port.
The Luer port contains a frangible (cone) housed inside.

Please note: it is imperative to completely open the frangible in the Luer connector port for adequate dialysate flow. When connecting the Bicarby bag to the dialysate line of your cartridge and breaking the frangible, instructions can be found here:

- [Luer Connection Instructions](#)

*Product images are for illustrative purposes only and may not reflect the exact SKU.

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Please note that Bicarby is stable for 48 hours once removed from the overwrap and immediately activated¹. This represents an increase from the 24-hour stability of the previous PureFlow B product². Update any policies and practices within your facility to reflect this change, as appropriate.

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Frequently Asked Questions (FAQs)

Q: Why are you making a product change?

A: Fresenius Medical Care is embracing resilience for growth and improvement. We've expanded our manufacturing with two additional Fresenius Medical Care-owned production lines, intended to strengthen our supply chain and minimize disruptions.

With this expansion, we're also introducing Bicarby, which offers the same trusted formulations but with significant improvements, including a 2-year shelf life and extended stability, up to 48 hours¹, after opening and mixing, compared to previous PureFlow B products².

These changes enhance our manufacturing resilience and reinforce our commitment to delivering reliable, high-quality products that meet the evolving needs of healthcare providers and patients.

Q: What is the difference between the products? Are there any formulation differences we need to be aware of?

A: RFP-4XX includes the option of one spike and one Luer lock to make connections (either one can be used). RFP-4XX-G has one Luer lock connection, identified by the beige cap. The Luer connection will be used to connect the dialysate. Please see details on using the [Luer Connection Here](#), or for additional support transitioning healthcare providers to using the Luer lock connector, please reach out to our clinical team for support as needed.

The formulations are the same for all Bicarby replacements with the same common identifier, please see [Formulations](#) for more details.

Q: We still have PureFlow B and/or PureFlow –W product in other formulations, is that an issue?

A: No, this is not an issue. The transition to Bicarby is phased by formulation over time. You will eventually see all Bicarby products, but in the meantime, you can continue using the PureFlow products as usual.

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Product Code Cross Walk

- The table below shows interchangeable PureFlow B and Bicarby fluid formulations with the common identifier “RFP-404”.
- Bicarby product's common identifiers will be followed by a "-G" to indicate the new production line location.
- When the common identifier “RFP-4XX” remains the same, that indicates the fluid formulation is identical.
 - Example: PureFlow B RFP-404 contains the same fluid formulation as Bicarby RFP-404-G

Common Identifier	Current PureFlow B SKU	New Bicarby SKU
RFP-404	RFP-404	RFP-404-G

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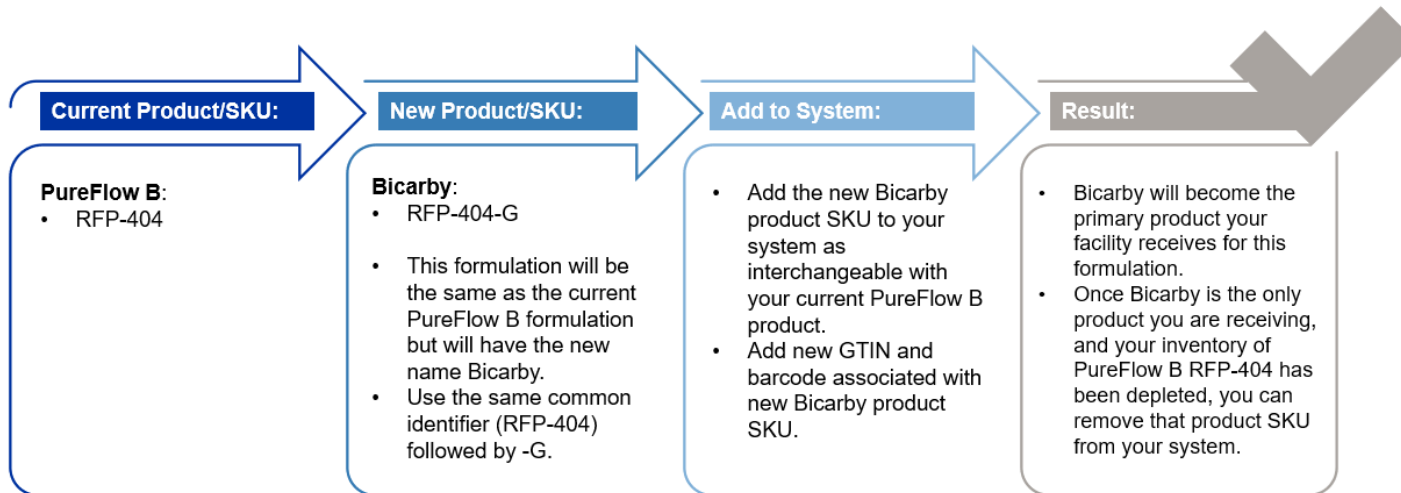
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Transition Overview: Product Code RFP-404

- Bicarby products are intended to be the primary source of KRT fluid solutions in the US going forward.
- The intent during the transition period is for the Bicarby RFP-404-G product to be added to your system as interchangeable with the current PureFlow B RFP-404 product.
- Existing PureFlow B product code RFP-404 (along with associated GTINs, barcodes, etc.), should remain active in your system until the transition is complete and only Bicarby products are available for ordering and in your warehouse



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Transition Details

Details of Fluid Code (by Common Identifier)

Current PureFlow B Product			New Bicarby Product			
Common Identifier	Name	Product Code	Name	Product Code	GTIN	Barcode (bag)
RFP-404	PureFlow B	RFP-404	➔ Bicarby	RFP-404-G	GTIN Bag: 00840861102914 GTIN Case: 10840861102911	

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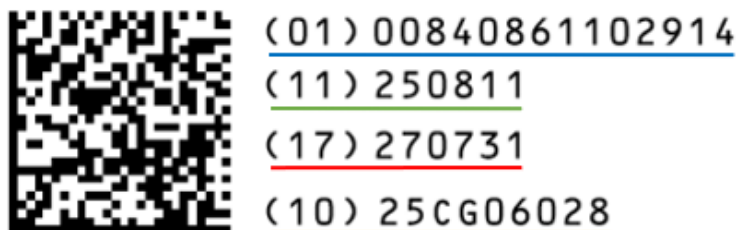
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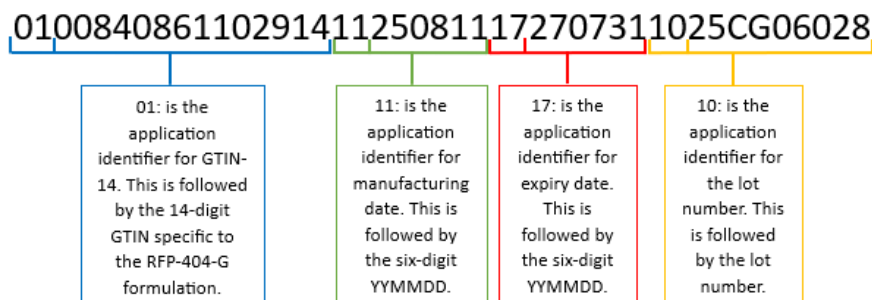
Barcode Product Identification Information

The current PureFlow B product's DI (GTIN) Issuing Agency is HIBCC; Bicarby product's DI (GTIN) Issuing Agency is GS1. Configuration changes may need to be made in your system to accommodate this.

For SKU Bicarby RFP-404-G the sample 2-D barcode provided has the following information associated with it:



When scanned the following will appear with four sections, each representing a different application identifier for the formulation (RFP-404-G):



- 01: GTIN-14: will remain the same for all subsequent RFP-404-G formulation products
- 11: Manufacturing date: will change in subsequent RFP-404-G and should be reflected as such when building the product into your system
- 17: Expiry date: will change in subsequent RFP-404-G and should be reflected as such when building the product into your system
- 10: Lot Number: will change in subsequent RFP-404-G and should be reflected as such when building the product into your system

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Assuming your EMR system is not interfaced with your ERP systems item master, we recommend you treat each of the new Bicarby SKUs (see [Product Cross Walk](#)) as individual item numbers within your EMR system, built with the same UOM, manufacturer information, and item description as your current PureFlow B products based on the shared common identifier.

- a) The SKUs in the column marked “New Bicarby SKU” are the same fluid formulations (functional equivalents) and should be considered interchangeable product codes with any that share the same common identifiers.
- b) We strongly encourage that the barcodes supporting each Bicarby product are built to ensure seamless clinical documentation (see [Transition Details for barcodes](#)).
- c) Current PureFlow B SKUs (along with associated GTINs, barcodes, etc.), should remain active in your system until the transition is complete.

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EMR Details, cont.

We recommend you contact your Medical Executive Committee and inform them that the product numbers referenced and shown below are being updated, and as such, need approval to update the EMR standing order to reflect the new product numbers.

- a) Once you have approval from your Medical Executive Committee, you will need to instruct your EMR Developers to update the EMR standing order.
- b) To reduce the frequency of change we recommend using the wording “Fresenius Medical Care/NxStage RFP-4XX(+/- G) 5000mL...”
 - a. Please note this is an example of interchangeable fluid codes, which share the common identifier “RFP-404” followed by -G at the end. For these interchangeable codes, it is crucial to configure your order sets and EMR system to recognize any product codes with common identifiers representing the same formulation.

Order Set Build	Product Details
RFP-404 (+/- G)	Contains: K+ 4 mEq/L, Ca+ 2.5 mEq/L, Na+ 140 mEq/L, Mg+ 1.5 mEq/L, HCO3- 35 mEq/L, Cl- 113 mEq/L, Glucose 1 g/L, Osmolarity 300 mOsmol/L

- b. Building your EMR system to recognize both formulations associated common identifier “RFP-404” will allow interchangeable product to be acknowledged. Your order sets should ideally identify both barcodes that share the common identifier.

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Example Product Pictures

PureFlow B RFP-4XX



Bicarby RFP-4XX-G



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Frequently Asked Questions (FAQs)

Q: Why are you making a product change?

A: Fresenius Medical Care is embracing resilience for growth and improvement. We've expanded our manufacturing with two additional Fresenius Medical Care-owned production lines, intended to strengthen our supply chain and minimize disruptions.

With this expansion, we're also introducing Bicarby, which offers the same trusted formulations but with significant improvements, including a 2-year shelf life and extended stability, up to 48 hours¹, after opening and mixing, compared to previous PureFlow B products².

These changes enhance our manufacturing resilience and reinforce our commitment to delivering reliable, high-quality products that meet the evolving needs of healthcare providers and patients.

Q: Are there differences in the barcodes of PureFlow B and Bicarby products?

A: Yes, PureFlow B's barcode issuing agency is HIBCC, and Bicarby's is GS1. See [the Barcode Product Information](#) for more details on Bicarby barcodes.

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EMR/IT

INDICATIONS FOR USE

NxStage PureFlow B Solution

NxStage PureFlow B Solution is indicated for use with renal replacement therapy systems that utilize sterile premixed dialysate during hemodialysis.

Bicarby Dialysate RFP-404

Bicarby Dialysate solutions are indicated for use as a dialysis fluid for adult patients in acute care settings, requiring Kidney Replacement Therapy.

1. Bicarby Dialysate RFP-404 IFU, E1443/01 01/25
2. Data on file, 2023

CAUTION: Federal law restricts this device to sale by or on the order of a physician.
Frequency, duration, and parameters of treatment are to be determined by the prescribing physician.

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