

Bicarby™ Dialysate

K ⁺	3 mEq/l
Na ⁺	140 mEq/l
Ca ²⁺	3 mEq/l
Mg ²⁺	1 mEq/l
Cl ⁻	12 mEq/l
HCO ₃ ⁻	29 mEq/l

Bicarby™ Dialysate
solution for hemodialysis

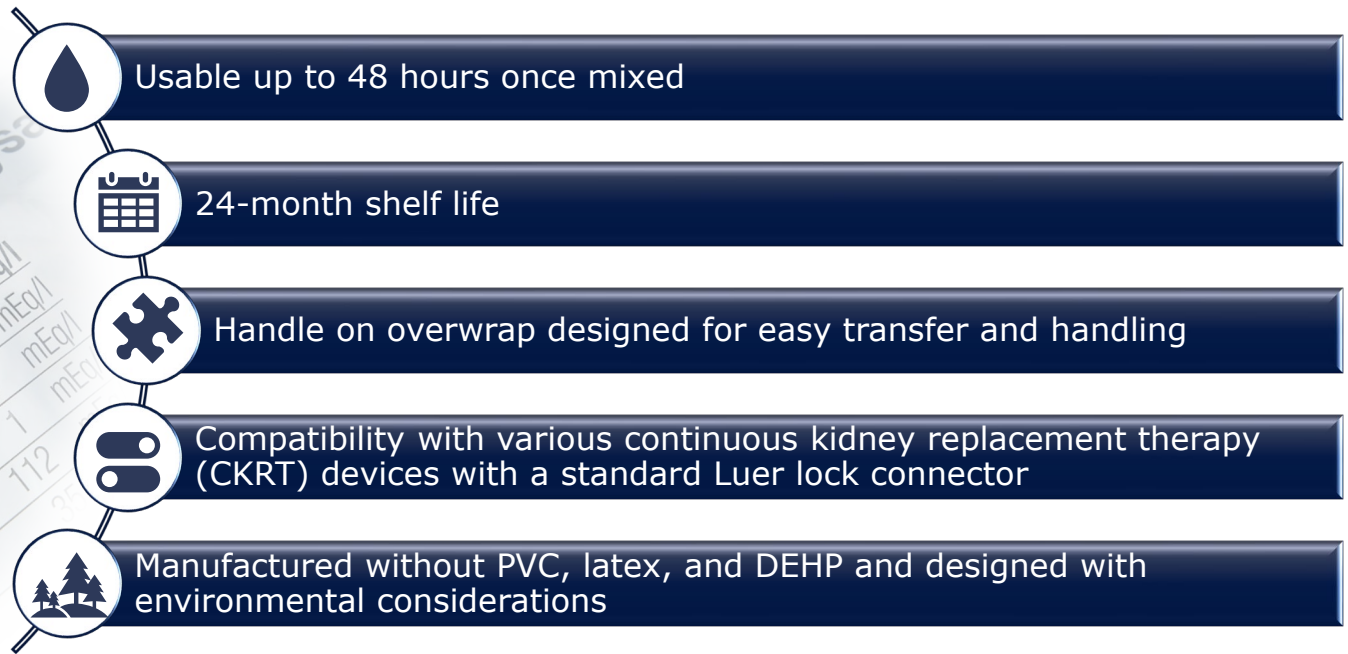
1000 ml of the ready-to-use
Potassium chloride
Sodium chloride
Sodium hydroxide
Calcium chloride
Magnesium chloride

Bicarby™ Dialysate Solution Transition Guide

PureFlow™ RFP-402-W to Bicarby RFP-402-G

Fresenius Medical Care is excited to introduce Bicarby Dialysate Solutions, our new brand of kidney replacement therapy (KRT) fluids brand that will carry forward the legacy and formulations of PureFlow Solutions. Bicarby solutions come from a new production line, expanding manufacturing capabilities across two continents to provide supply chain resiliency.

By maintaining the same features previously introduced with the PureFlow line, the Bicarby product continues to underscore a renewed commitment to quality, ease of use, and enhanced waste management¹:



Over the coming months, we will transition all formulations of PureFlow to Bicarby Dialysate Solutions in phases by SKU. At this time, the transition will include only the PureFlow formulation RFP-402-W. The Bicarby products will keep the same fluid formulations and common identifiers (RFP-402) as the existing PureFlow fluids.

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Product Code Cross Walk

- The table below shows interchangeable PureFlow and Bicarby fluid formulations with the common identifier “RFP-402.”
- 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 RFP-402-W contains the same fluid formulation as Bicarby RFP-402-G

Common Identifier	Current PureFlow SKU	New Bicarby SKU
RFP-402	RFP-402-W	RFP-402-G

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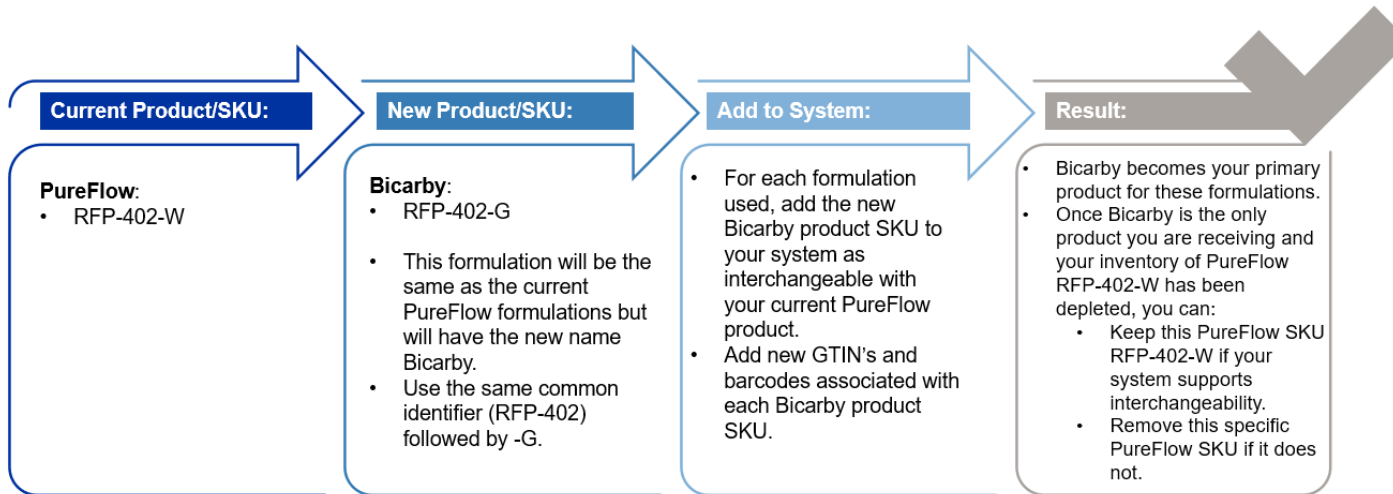
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Transition Overview: Product Code RFP-402

- 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-402-G product to be added to your system as interchangeable with the current PureFlow RFP-402-W product.
- Existing PureFlow product code RFP-402-W (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.
 - At that time, if your system allows for maintaining two interchangeable codes, we recommend retaining the PureFlow RFP-402-W code as a backup supply option, if needed.



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Details of Each Fluid Code (by Common Identifier)

Current PureFlow Product			New Bicarby Product			
Common Identifier	Name	Product Code	Name	Product Code	GTIN	Barcode (bag)
RFP-402	PureFlow	RFP-402-W	➔ Bicarby	RFP-402-G	GTIN Bag: 00840861102822 GTIN Case: 10840861102829	

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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 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 RFP-402-G product is 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 SKU's (RFP-402-W).
- 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 SKUs for these formulations (along with associated GTINs, barcodes, etc.), should remain active in your system until you have fully transitioned all product to Bicarby SKUs.
 - At that time, if your system allows for maintaining two interchangeable codes, we recommend retaining the PureFlow RFP-402-W code as a backup supply option, if needed.

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Procurement/Ordering of RFP-402-G

- a) 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-402).
 - We will convert your orders automatically.
- b) 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-402).
- c) If you prefer not to give a blanket approval, please order the specific Bicarby SKU: RFP-402-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 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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Product Implementation Instructions, cont.

Bicarby Case Product Labels

Bicarby RFP-402-G case labels are identical in appearance, contents, and color coding as each of their PureFlow formulation equivalents you currently use, with the only difference being the name Bicarby.

Bicarby Product Code and Box Label

Bicarby™ Dialysate RFP-402

Solution for hemodialysis

1,000 mL of the ready-to-use solution contains:

Calcium chloride	0.130 mmol/L
Sodium bicarbonate	2.500 mmol/L
Calcium chloride dihydrate	0.200 mmol/L
Magnesium chloride hexahydrate	0.500 mmol/L
Glucose	1.000 g/L
Chloride	1.000 g/L

Water for injection, hydrochloric acid 25%, sodium bicarbonate and sodium chloride dihydrate dihydrate

K⁺ 0 mEq/L

5000 mL x 2

Bicarby™ Dialysate RFP-402 potassium-free  **RFP-402-G**

Bicarby™ Dialysate RFP-402

5000 mL x 2

 **RFP-402-G**

Bicarby™ Dialysate RFP-402

Ca	0 mmol/L	0 mEq/L
Na	140 mmol/L	610 mEq/L
Ca ²⁺	1.5 mmol/L	3 mEq/L
Mg ²⁺	0.5 mmol/L	1 mEq/L
Cl ⁻	109 mmol/L	109 mEq/L
NaCl	20 mmol/L	20 mEq/L
Glucose	1 g/L	g/L
pH	7.4	
Total osmolality	290 mOsm/L	

5000 mL x 2

 **RFP-402-G**

FRESENIUS MEDICAL CARE

Manufactured by:
Fresenius Medical Care of Mexico
C.P. 45010, Zapopan, Jalisco, Mexico

Manufactured for:
Fresenius Medical Care LLC
Waltham, MA 02451
1-800-329-5188

RFP-402-G

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Pallets and Packaging

	PureFlow RFP-402-W	Bicarby RFP-402-G
UOM: Purchased	Case	Case
UOM: Qty of eaches	Two 5L/bags	Two 5L/bags
UOM: Case Qty	52 (13 layers)	60 (12 layers)
Pallet Weight (lbs)	1,320	1,540
Pallet Length (in)	47.3	48.0
Pallet Width (in)	31.5	40.0
Pallet Height (in)	63	60.5
Case Weight (lbs)	24.6	24.7
Case Length (in)	23.2	23.5
Case Width (in)	15.4	15.0
Case Height (in)	4.4	4.6
Bag Weight (lbs)	11.5	11.5
Bag Length (in)	23.2	23.2
Bag Width (in)	16.3	16.3
Bag Height (in)	2.9	2.9

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Example Product Images

PureFlow RFP-4XX-W



Bicarby RFP-4XX-G



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

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Frequently Asked Questions (FAQs)

Q: Why are you making a product change?

A: Fresenius Medical Care is committed to maintaining the same trusted products and features that healthcare providers rely on. The Bicarby Dialysate Solutions will retain the same formulations and common identifiers as the previous PureFlow product equivalents to help maintain consistency.

These Bicarby products leverage a Fresenius Medical Care-owned manufacturing facility that is geographically closer to our customers, enhancing efficiency and strengthening our supply chain. Additionally, we are maintaining the option to use the additional manufacturing facility, further supporting supply chain resiliency and management of potential disruptions in the event it is needed.

These updates reflect our dedication to providing reliable, high-quality products while optimizing production and delivery processes to better meet the 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 products. Please see [Pallet and Packaging](#) for details.

Q: Is the transition from PureFlow RFP-402-W to Bicarby RFP-402-G mandatory?

A: Yes, the transition is mandatory as Fresenius Medical Care will produce Bicarby for the U.S. market at a geographically closer manufacturing site, while maintaining PureFlow as a backup to help provide supply chain reliability.

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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Customer Service Information

If you have any questions regarding the above instructions or have questions not addressed in the document, please contact your Area Sales Manager, Therapy Specialist, Clinical Consultant, or Sales Director. If you need assistance in reaching them, please contact us at 1-866-NXSTAGE (697-8243) or via email at acuteorders@freseniusmedicalcare.com.

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Product Code Cross Walk

- The table below shows interchangeable PureFlow and Bicarby fluid formulations with the common identifier “RFP-402.”
- 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 RFP-402-W contains the same fluid formulation as Bicarby RFP-402-G

Common Identifier	Current PureFlow SKU	New Bicarby SKU
RFP-402	RFP-402-W	RFP-402-G

Formulations

The formulations listed below are the same for all Bicarby SKU's 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 HCO3-	Glucose (mg/dL)	Osmolarity (mOsm/L)
RFP-402	0	3	1	140	109	35	100	292

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Opening and Mixing:

Both the opening of the overwrap and the activation of the peel seam on Bicarbys bags are the same as current PureFlow RFP-402-W. Guidance on these processes can be found here:

- [Opening and Mixing](#)

Scanning Bags:

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



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

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Luer Connection:

PureFlow RFP-402-W fluid bags, as well as their Bicarby equivalents, are designed with a single Luer connector for dialysate tubing. This connector is identified by the beige-capped port located in the middle of the bag. See the image below highlighting this port:

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



Option 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:

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Please note that Bicarby retains the same trusted formulation and stability as the current PureFlow RFP-402-W products. Once removed from the overwrap and activated, Bicarby remains stable for 48 hours. We recommend reviewing and updating any relevant policies and practices within your facility, as needed, to ensure alignment with this information.

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Frequently Asked Questions (FAQs)

Q: Why are you making a product change?

A: Fresenius Medical Care is committed to maintaining the same trusted products and features that healthcare providers rely on. The Bicarby Dialysate Solutions will retain the same formulations and common identifiers as the previous PureFlow product equivalents to help maintain consistency.

These Bicarby products leverage a Fresenius Medical Care-owned manufacturing facility that is geographically closer to our customers, enhancing efficiency and strengthening our supply chain. Additionally, we are maintaining the option to use the additional manufacturing facility, further supporting supply chain resiliency and management of potential disruptions in the event it is needed.

These updates reflect our dedication to providing reliable, high-quality products while optimizing production and delivery processes to better meet the 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: The products are identical in formulation and design, with no changes to the trusted features or functionality. The only difference is the manufacturing facility, which provides a more geographically efficient supply chain while maintaining product quality and reliability.

Both RFP-4XX-G and RFP-4XX-W feature a single Luer lock connection, identified by the beige cap, which is used to connect the dialysate tubing. For further details on how to use the Luer connection, please see the provided instructions [here](#). If additional support is needed while transitioning healthcare providers to using the Luer connector, please reach out to our clinical team for assistance.

Q: We still have PureFlow 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 and Bicarby fluid formulations with the common identifier “RFP-402.”
- 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 RFP-402-W contains the same fluid formulation as Bicarby RFP-402-G

Common Identifier	Current PureFlow SKU	New Bicarby SKU
RFP-402	RFP-402-W	RFP-402-G

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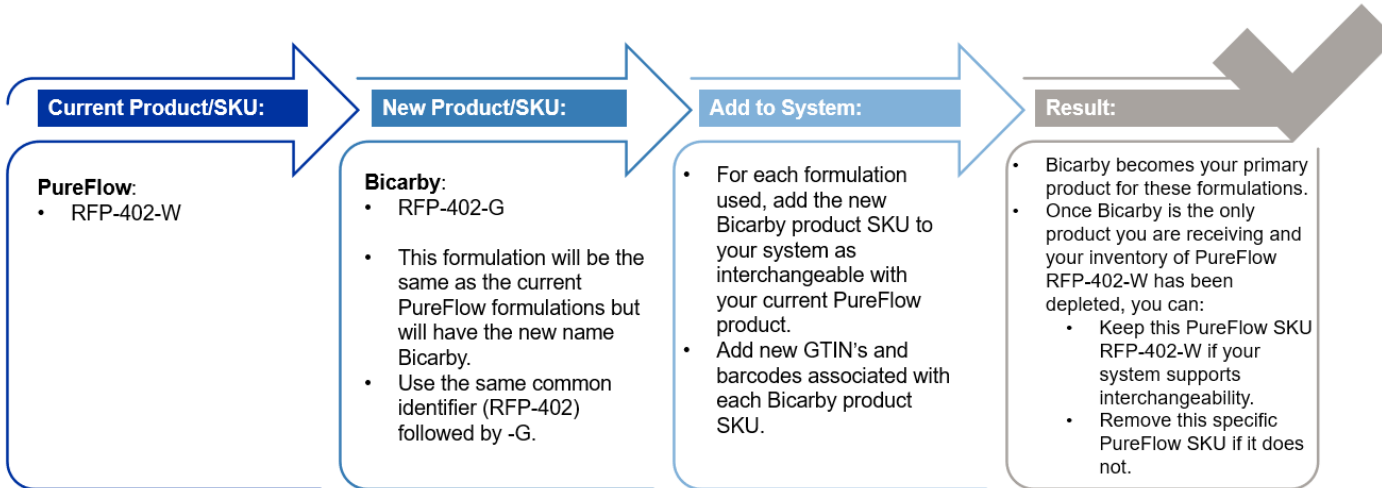
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Transition Overview: Product Code RFP-402

- 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-402-G product to be added to your system as interchangeable with the current PureFlow RFP-402-W product.
- Existing PureFlow product code RFP-402-W (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.
 - At that time, if your system allows for maintaining two interchangeable codes, we recommend retaining the PureFlow RFP-402-W code as a backup supply option, if needed.



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Details of Each Fluid Code (by Common Identifier)

Current PureFlow Product			New Bicarby Product			
Common Identifier	Name	Product Code	Name	Product Code	GTIN	Barcode (bag)
RFP-402	PureFlow	RFP-402-W	➔ Bicarby	RFP-402-G	GTIN Bag: 00840861102822 GTIN Case: 10840861102829	

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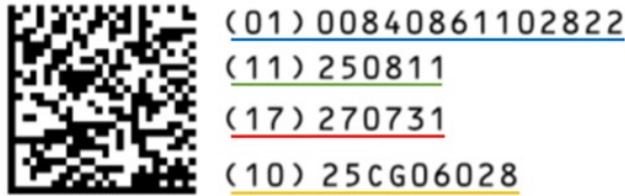
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Barcode Product Identification Information

Both the PureFlow and Bicarby product's DI (GTIN) Issuing Agency is GS1. Bicarby SKU RFP-402-G will feature distinct GTINs associated with their barcodes, different from the PureFlow version for each formulation.

For the Bicarby RFP-402-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-402-G):

010084086110282211250811172707311025CG06028

01: is the application identifier for GTIN-14. This is followed by the 14-digit GTIN specific to the RFP-402-G formulation.

11: is the application identifier for manufacturing date. This is followed by the six-digit YYMMDD.

17: is the application identifier for expiry date. This is followed by the six-digit YYMMDD.

10: is the application identifier for the lot number. This is followed by the lot number.

- 01: GTIN-14: will remain the same for all subsequent RFP-402-G formulation products
- 11: Manufacturing date: will change in subsequent RFP-402-G and should be reflected as such when building the product into your system
- 17: Expiry date: will change in subsequent RFP-402-G and should be reflected as such when building the product into your system
- 10: Lot Number: will change in subsequent RFP-402-G and should be reflected as such when building the product into your system

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EMR Details

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 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 provide seamless clinical documentation (see [Transition Details for barcodes](#)).
- c) Current PureFlow SKUs (along with associated GTINs, barcodes, etc.), should remain active in your system until the transition is complete.
 - At that time, if your system allows for maintaining two interchangeable codes, we recommend retaining the PureFlow RFP-402-W codes as a backup supply option, if needed.

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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-402” 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-402 (+/- G or W)	Contains: K+ 0 mEq/L, Ca+ 3 mEq/L, Na+ 140 mEq/L, Mg+ 1 mEq/L, HCO3- 35 mEq/L, Cl- 109 mEq/L, Glucose 1 g/L, Osmolarity 292 mOsmol/L

- b. Building your EMR system to recognize both products associated with the common identifier “RFP-402” will allow an interchangeable product to be acknowledged. Your order sets should ideally identify both barcodes that share the common identifier.

[Product Code Cross Walk](#)

[Transition Overview](#)

[Transition Details](#)

[Barcode Product Identification Information](#)

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Supply Chain

Clinical

EMR/IT

Example Product Images

PureFlow RFP-4XX-W



Bicarby RFP-4XX-G



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

Supply Chain

Clinical

EMR/IT

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Frequently Asked Questions (FAQs)

Q: Why are you making a product change?

A: Fresenius Medical Care is committed to maintaining the same trusted products and features that healthcare providers rely on. The Bicarby Dialysate Solutions will retain the same formulations and common identifiers as the previous PureFlow product equivalents to help maintain consistency.

These Bicarby products leverage a Fresenius Medical Care-owned manufacturing facility that is geographically closer to our customers, enhancing efficiency and strengthening our supply chain. Additionally, we are maintaining the option to use the additional manufacturing facility, further supporting supply chain resiliency and management of potential disruptions in the event it is needed.

These updates reflect our dedication to providing reliable, high-quality products while optimizing production and delivery processes to better meet the needs of healthcare providers and patients.

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

A: Bicarby SKUs RFP-402-G will feature distinct GTINs associated with their barcodes, different from the PureFlow version of the formulation. See [the Barcode Product Information](#) for more details on Bicarby barcodes.

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Customer Service Information

If you have any questions regarding the above instructions or have questions not addressed in the document, please contact your Area Sales Manager, Therapy Specialist, Clinical Consultant, or Sales Director. If you need assistance in reaching them, please contact us at 1-866-NXSTAGE (697-8243) or via email at acuteorders@freseniusmedicalcare.com.

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INDICATIONS FOR USE

PureFlow

PureFlow solutions are indicated for use as a dialysate in Continuous Renal Replacement Therapy.

Bicarby Dialysate

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

1. Bicarby RFP-402 IFU, E1406/02 01/25

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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D/N US-Bicarby-000020 Rev. A 08/2025

