

GranuFlo® Acid Concentrate

GranuFlo Acid Mixing Procedure Card

This card is intended to be a supplement to the Fresenius Renal Technologies Dry Acid Dissolution Unit Operator's Manual and the GranuFlo Operator's Manual and product labels. Refer to the Fresenius Renal Technologies Dry Acid Dissolution Unit Operator's Manual and the GranuFlo acid concentrate product labels for a complete description of mixing instructions, hazards, contraindications and precautions.

Preparation for Dissolution Cycle

- i** Note: GranuFlo Concentrate Dissolution Units are designed for use with GranuFlo acid product only.
Dry Acid Dissolution Units are designed for use with Citrasate® Dry acid or GranuFlo acid products only.
Note: Do not use GranuFlo acid concentrate cases if package is opened or damaged.

- 1 Determine how much product is required for mixing (See Table I below).**

Dry Acid Dissolution Unit	No. of Cases Needed
99 gallon mixer	6
132 gallon mixer	8

Table I: GranuFlo Acid Concentrate Case Requirements

- 2 Check case labels to ensure all cases are of the same catalog number.**
- 3 Complete the Dry Acid Batch Production Record form.**
- 4 Use water that meets or exceeds ANSI/AAMI RD62 or ISO 13959 hemodialysis water quality standards. Water temperature should be 20°C-30°C (68°F-86°F) for proper dissolution.**

Instructions for Dissolution

- i** Note: The contents in the GranuFlo acid cases may clump or harden. This does not affect the chemical composition of the product. While the images below depict the GranuFlo Dissolution Unit, the following instructions are for GranuFlo Concentrate Dissolution Units and Dry Acid Dissolution Units.

Rinse cycle must be completed prior to initiating the batch of concentrate.

- 1 Ensure access port lid is in place, main transfer ball valve is closed and Input Water Source is On.**
- 2 Press the RINSE START button.**



- 3 Begin the Fill Cycle on the Dry Acid Dissolution Unit by pressing the DISSOLUTION START button.**
- 4 Wait for the ADD GRANULES light prior to adding dry acid product.**
- 5 Using eye protection and gloves is recommended. If contact with eyes occurs, flush immediately for 15 minutes. If contact with skin occurs, rinse with plenty of soap and water.**



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Instructions for Dissolution (Continued)

6 Remove small access lid on GranuFlo Dissolution Unit or Dry Acid (Dissolution Unit).



7 Open a case of GranuFlo concentrate and cut off the tops of all bags just below the bag seal, leaving as much extra bag length as possible.

8 Gather extra bag material at the top with your thumb facing down. This will allow the proper hand position when the bag is inverted.



9 Grab the flap on the bottom of the bag and invert the bag. Insert the gathered end into the small opening in Dissolution Unit.



10 Release the gathered end of the bag and allow the contents to empty into the tank. Once all of the powder has transferred to the dissolution unit remove and discard the empty bag.



11 Repeat steps 7-10 until the correct number of bags have been emptied into the Dissolution Unit.



Note: Each case contains three bags. The contents of the bags in each case are different. All bags must be used.

12 Dry off the Final Fill Sensors.

Label the Dissolution Unit with contents and dates prepared.



13 Replace the small access lid and press the **DISSOLUTION START** button. The Dissolution Unit will proceed to the Mix Operation. Follow the instructions to complete the mixing process as directed by the Operator's Manual for your specific Dissolution Unit.



14 Once the Transfer Indicator Light flashes, the concentrate can be tested for the specific gravity.



15 After the specific gravity value is within recommended limits, follow the instructions in your operators manual to transfer the solution to appropriate storage containers.



Note: Reconstituted acid concentrate should not be stored in the Dissolution Unit tank for longer than two weeks from the date of dissolution.

Indications for Use: GranuFlo Dry Acid Concentrate is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure. GranuFlo Dry Acid Concentrate is intended to be used as one component in the preparation of dialysate in a three-stream proportioning hemodialysis machine according to a physician's prescription.

The Fresenius Medical Care Dry Acid Dissolution Unit mixes Fresenius Medical Care distributed dry acid concentrate products with hemodialysis quality water. The resulting liquid acid concentrates are intended for use in three-stream hemodialysis machines calibrated for acid and bicarbonate concentrates.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

Note: Read the Instructions for Use for safe and proper use of this device. For a complete description of hazards, contraindications, side effects and precautions, see full package labeling at www.fmcna.com.

Customer Service: 800-323-5188 • Technical Support: 800-227-2572



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