

Grifols' Coagulation Products

Packaged with Mix2Vial® 15 Micron Filter Transfer Set†

Customized plastic, needle-free transfer device for use with Sterile Water for Injection vials



DemoPack shown on back page

†Mix2Vial® is a registered trademark of Medimop Medical Projects, Ltd., a subsidiary of West Pharmaceutical Services, Inc.

GRIFOLS

Mix2Vial® - 15 Micron Filter Transfer Set

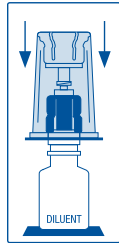
Instructions for Use

1



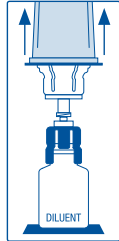
- Place the DILUENT vial and the PRODUCT vial on a flat even surface, such as a counter or table
- Remove the flip off caps from the DILUENT and PRODUCT vials
- Gently swab the exposed stopper surfaces with alcohol
- Open Mix2Vial package by peeling away the lid
- Leave Mix2Vial in the clear outer packaging

2



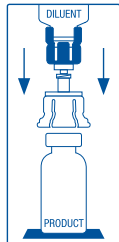
- Place DILUENT upright on a flat even surface, hold vial tight, and pick up Mix2Vial in its outer packaging
- Holding DILUENT securely, push **blue** end of Mix2Vial vertically down through DILUENT stopper

3



- While holding onto DILUENT, remove outer packaging from Mix2Vial, ensuring it remains attached to DILUENT

4

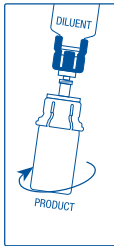


- Place PRODUCT vial upright on a flat even surface, invert with Mix2Vial attached
- While holding PRODUCT vial securely on a flat even surface, push **clear** end of Mix2Vial **vertically down** through PRODUCT stopper
- DILUENT will automatically transfer into PRODUCT vial
- NOTE: If Mix2Vial is connected at an angle, vacuum may be released from PRODUCT vial and DILUENT will not transfer

Mix2Vial® - 15 Micron Filter Transfer Set

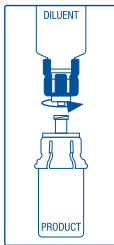
Instructions for Use

5



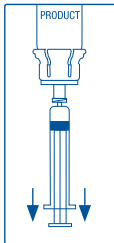
- Gently swirl PRODUCT to ensure it is fully dissolved
- Reconstitution requires less than 5 minutes
- Do not shake the vial

6



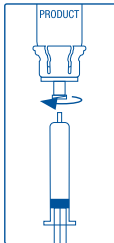
- Disconnect DILUENT vial by twisting off, counterclockwise
- After separating, discard DILUENT with **blue** end of Mix2Vial

7



- Draw air into an empty, sterile syringe
- Keeping PRODUCT upright with **clear** end of Mix2Vial attached, screw disposable syringe onto the **white** luer lock by pressing and twisting clockwise
- Inject air into PRODUCT
- While keeping syringe plunger depressed, invert system upside down and draw reconstituted PRODUCT into syringe (see number 7)

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- When reconstituted PRODUCT has been transferred, firmly hold barrel of syringe and **clear** vial adapter and unscrew syringe from Mix2Vial by twisting off, counterclockwise
- Hold syringe upright and push plunger until no air is left
- Attach syringe to venipuncture set and follow normal safety practices to administer the drug

DemoPacks are available for instructional purposes so that patients, parents and nurses can become familiar with this easy to use transfer set.



Contents include: Empty product vial, Diluent (Sterile Water for Injection USP 5 mL) and Mix2Vial® 15 micron filter transfer set.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Grifols Inc.

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