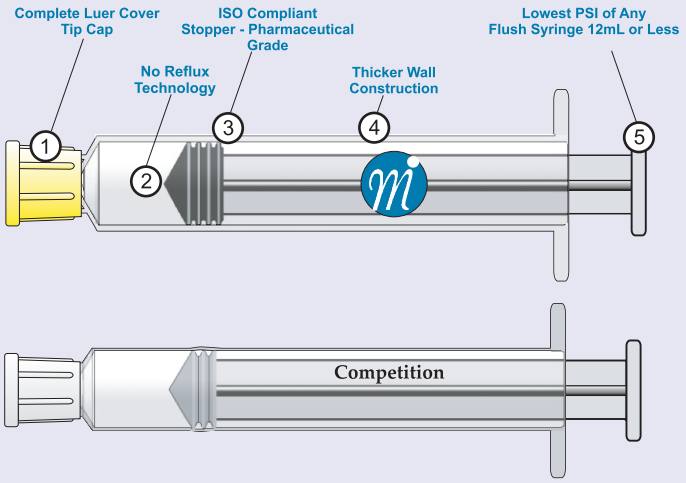
MEDEFIL, INC.

Why Should I Choose **MedeFlush**™?

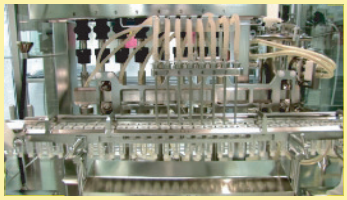
No Reflux Post Flushing = Lower Catheter Occlusion
ISO Compliant Syringe = Helping your Institution Stay Compliant
Pharmaceutical Grade Syringe = Syringe Designed for the Pre-Filled Application
Quality Plastics = No Barrel Distortion = Helps in Maintaining Solution & its Pathway Sterile
Plunger Stopper with Four Rings = ISO Requirements for a Pre-Filled Syringe
Terminally Sterilized Product = Contributes to Patient Safety
Great Pricing

MedeFlush™ Features:

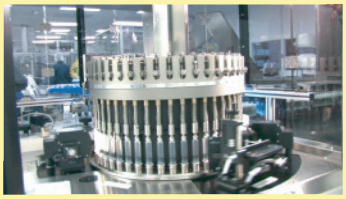
- Contains No Preservatives, Not made with Natural Rubber Latex & DEHP
- Color-Coded Tip Caps and Labels for easier Identification and/or helps Decreased Medication Errors
- Clear Plastic Syringes for Better Visibility of Syringe Contents
- 6mL & 12mL Syringes with Same Large Diameter
- State-of-the-Art Fully Automated Facility
- Minimal Human Interface during Manufacturing Process
- State-of-the-Art Injectables Solution Formulation Plant
- Bar Code, NDC & Catalog Number on Each Syringe
- Two Year Expiry Dating
- Lot Number & Expiration Date on Each Syringe
- Terminally Sterilized with Steam (SAL 10^{-6})
- Compatible with Needleless and I. V. Access Systems



State-of-the-Art Manufacturing

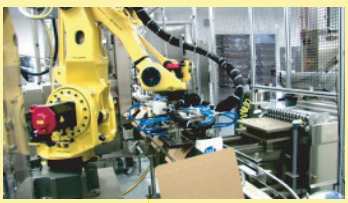

Filling


Terminal Sterilization


Inspection


Labeling


Graduation and Label QC


Packaging

MedeFlush™ larger barrel diameter creates a smooth flow of flush solution with less pressure per square inch. Good for reduced flow catheters. All this with NO REFLUX technology.

MedeFlush™ pre-filled syringes are manufactured in accordance with the applicable provisions of 21 Code of Federal Regulations (CFR) including Current Good Manufacturing Practices (cGMP) and Quality Control Requirements.

Learn more about Medefil's **MedeFlush™** Products
Please call (630) 682-4600 or via e-mail at: info@medefilinc.com
Visit the company's website at www.medefilinc.com

Products and Packaging

Normal Saline I. V. Flush Syringes [0.9% Sodium Chloride Injection] 510(k) K091583

Catalog #	NDC Number	Description	Box / Case Quantity
MIS-1123	64253-0111-23	3mL fill in 6mL Syringe	60/Box, 960/case
MIS-1125	64253-0111-25	5mL fill in 6mL Syringe	60/Box, 960/case
MIS-1133	64253-0111-33	3mL fill in 12mL Syringe	60/Box, 960/case
MIS-1135	64253-0111-35	5mL fill in 12mL Syringe	60/Box, 960/case
MIS-1130	64253-0111-30	10mL fill in 12mL Syringe	60/Box, 960/case

1 USP Unit/mL Heparin I. V. Flush Syringes 510(k) K092491

Catalog #	NDC Number	Description	Box / Case Quantity
MIH-4422	64253-0444-22	2mL fill in 6mL Syringe	60/Box, 960/case
MIH-4425	64253-0444-25	5mL fill in 6mL Syringe	60/Box, 960/case

Heparin I.V. Flush Syringes in 0.9% Sodium Chloride

10 USP Units/mL Heparin I. V. Flush Syringes 510(k) K092491

Catalog #	NDC Number	Description	Box / Case Quantity
MIH-2221	64253-0222-21	1mL fill in 6mL Syringe	60/Box, 960/case
MIH-2223	64253-0222-23	3mL fill in 6mL Syringe	60/Box, 960/case
MIH-2233	64253-0222-33	3mL fill in 12mL Syringe	60/Box, 960/case
MIH-2235	64253-0222-35	5mL fill in 12mL Syringe	60/Box, 960/case

Heparin I.V. Flush Syringes in 0.9% Sodium Chloride

100 USP Units/mL Heparin I. V. Flush Syringes 510(k) K092491

Catalog #	NDC Number	Description	Box / Case Quantity
MIH-3321	64253-0333-21	1mL fill in 6mL Syringe	60/Box, 960/case
MIH-3323	64253-0333-23	3mL fill in 6mL Syringe	60/Box, 960/case
MIH-3333	64253-0333-33	3mL fill in 12mL Syringe	60/Box, 960/case
MIH-3335	64253-0333-35	5mL fill in 12mL Syringe	60/Box, 960/case

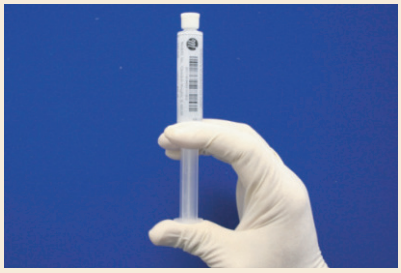
Heparin I.V. Flush Syringes in 0.9% Sodium Chloride

MEDEFIL, INC.
250 Windy Point Drive
Glendale Heights Illinois 60139
Phone (630) 682-4600
Fax (630) 681-9100
www.medefilinc.com

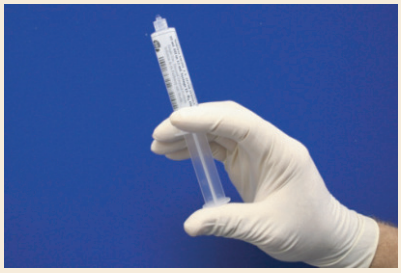
MED-12-001, Rev. 001, 07/2016

Instructions for Use

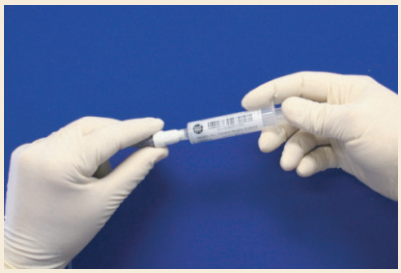
Open using the perforation on the package.



With the tip cap of the syringe on, press the syringe forward to activate syringe.



Remove tip cap and prime the syringe luer.



Per Institution protocol, attach flush syringe to access device and flush.

Dispose of used syringe in an appropriate container.

MEDEFIL, INC.

Peach Color Coded Tip Caps & Labels

Medefil, Inc. Sodium Chloride Injection, USP, 0.9%

Medefil, Inc. is the first manufacturer in the U.S. of Sodium Chloride Injection, USP, 0.9% in a Pre-filled syringe for human use [New Drug Application (NDA) 202832]. Medefil is manufacturer of pre-filled syringes since 2000 and is committed to provide the highest quality of products.

Indication of Use of Medefil's Sodium Chloride Injection, USP, 0.9% Syringe:

- For diluting or dissolving the drugs for intravenous, intramuscular or subcutaneous injection.

Medefil, Inc. Sodium Chloride Injection, USP, 0.9% Characteristics are:


Robotic Loading System

- ✔ Sterile
- ✔ Nonpyrogenic
- ✔ An isotonic solution
- ✔ Formulated with Sodium Chloride, USP in Water for Injection, USP
- ✔ Terminally sterilized using steam
- ✔ Contains no preservatives
- ✔ Contains no components made of natural rubber latex
- ✔ Label and tip cap color coded
- ✔ Single use syringe
- ✔ Convenient to use

Medefil Uses an Automated, State-of-the-Art Manufacturing Process:

Medefil's manufacturing process adheres to the parental drug manufacturing industry quality standards for product safety and efficacy. Our automated vision inspection system diligently inspects for particulate matter ensuring that we produce Quality Products.

Learn More about Medefil's Sodium Chloride Injection, USP, 0.9%:
Please call (630) 682-4600 or via e-mail at: info@medefilinc.com
Visit the company's website at www.medefilinc.com

MEDEFIL, INC.

Products & Packaging:

Sodium Chloride Injection, USP, 0.9% Syringe

Medefil Catalog #	NDC Number	Description	Box/Case Quantity
MSD-0230	64253-0202-30	10mL Fill in 12mL Syringe	60/Box, 960/Case

Important Safety Information:

WARNINGS AND PRECAUTIONS

General - When used to dilute drug products, consult the drug product manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving drugs to be injected including the route and rate of injection. Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration. Do not use Sodium Chloride Injection, USP, 0.9% if the solution is discolored, cloudy, hazy, or contains a precipitate, or if the syringe is damaged.

For Single Use Only - Re-use of single-use product creates a potential risk to the user. Contamination of product and/or limited functionality of the device may lead to injury, illness or death. Discard any unused portion.

ADVERSE REACTIONS - Adverse reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include, but are not limited to, air embolization, febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and if possible, retrieve and save the remainder of unused vehicle for examination if deemed necessary.

DRUG INTERACTIONS - Some drugs or injections may be incompatible when combined with 0.9% sodium chloride. Before Sodium Chloride Injection, USP, 0.9% is used as a vehicle for the administration of a drug, the drug product manufacturer's instructions or other specic references should be checked for any possible incompatibility with sodium chloride. Consult with a pharmacist, if unsure of compatibility.

For complete prescribing information, refer to the package insert.

MEDEFIL, INC.
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MED-12-002, Rev. 002. 07/2016

Learn More about Medefil's Sodium Chloride Injection, USP, 0.9%:
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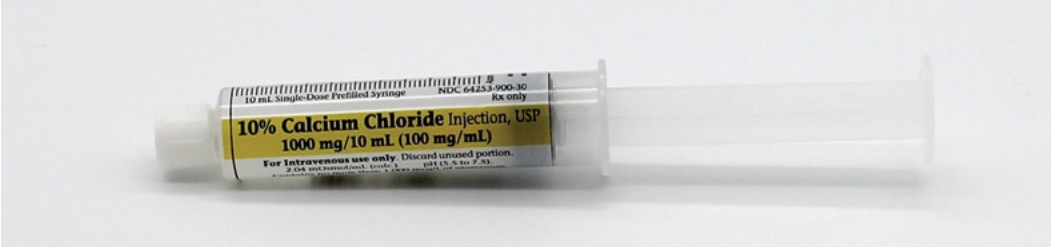
Visit the company's website at www.medefilinc.com

LAUNCHING

10% Calcium Chloride Injection, USP



Benefits and Features

- Drug shortage product*
- Ready-to-administer prefilled syringe
- Labeled over-pouch packaging takes less space in crash carts/ADMs
- No preservatives
- Not made with natural rubber latex, DEHP, or PVC
- AP rated
- Bar coded

NDC	Description	Strength	Fill Volume	Concentration	Unit of Sale	Bar Coded
64253-0900-36	Syringe	1000 mg/ 10 mL	10 mL	100 mg/mL	60	✓

Wholesaler Item Number

AmerisourceBergen	Cardinal Health	Morris & Dickson	McKesson MedSurg
10229819	5566435	781773	1158369

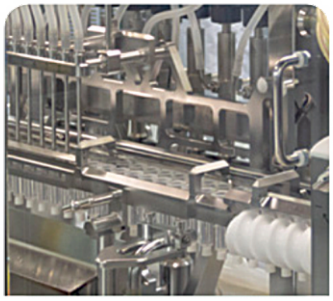
To learn more about Medefil's 10% Calcium Chloride Injection USP please visit our website at www.medefilinc.com, call (630) 682-4600, or via email at: info@medefilinc.com

*On FDA and ASHP drug shortage list

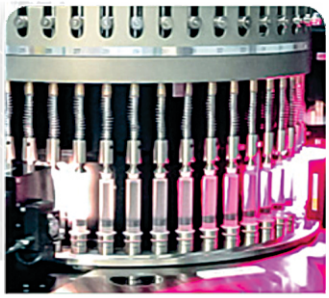
About Medefil

Medefil is growing as a fully integrated specialty pharmaceutical company. At Medefil our goal is to develop and manufacture injectable products where quality and supply reliability are crucial, and safety and ease-of use are of utmost importance. Medefil has state-of-the-art scientific research infrastructure and high quality manufacturing capabilities leading to effective execution on development and product supply.

State of the Art Manufacturing



Filling



Inspection

Labeling

Packaging

Important Safety Information

Warnings:

10% Calcium chloride Injection, USP is irritating to veins and **must not be injected into tissues,** since severe necrosis and sloughing may occur. Great care should be taken to avoid extravasation or accidental injection into perivascular tissues.

Warning: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissues loading may occur at even Lower rates of administration.

Precautions:
Do not administer solution is clear and seal is intact. Discard unused portion.

Because of its additive effect, calcium should be administered very cautiously to a patient who is digitalized or who is taking effective doses of digitalis or digitalis-like preparations.

Injection should be made slowly through a small needle into a large vein to minimize venous irritation and avoid undesirable reactions.

It is particularly important to prevent a high concentration of calcium from reaching the heart because of the danger of cardiac syncope.

For Single Use Only:
Reuse of single-use products contains a potential risk to the user. Contamination of the product and/or limited functionality of the device may lead to injury, illness or death. Discard unused portion.

Adverse Reactions:
Rapid injection may cause the patient to complain of tingling sensations, a calcium taste, a sense of oppression or “heat wave”.

Injections of calcium chloride are accompanied by peripheral vasodilatation as well as a local “burning” sensation and there may be a moderate fall in blood pressure.

Should perivascular infiltration occur, I.V. administration at that site should be discontinued at once. Local infiltration of the affected area with 1% procaine hydrochloride, to which hyaluronidase may be added, will often reduce venospasm and dilute the calcium remaining in the tissues locally. Local application of heat may also be helpful.

To report SUSPECTED ADVERSE RECATIONS, contact Medefil, Inc. at 1-630-682-4600 or www.medefilinc.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For complete prescribing information, refer to the package insert.