

**CARDIOVASCULAR PROCEDURE KIT -
Centurion Medical Products**

Cardiovascular Procedure Kit

DESCRIPTION

This preparation is designed solely for parenteral use only after addition of drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection. 0.9% Sodium Chloride Injection, USP is a sterile, non-pyrogenic isotonic solution of sodium chloride and water for injection. It contains no bacteriostat, antimicrobial agent or added buffer and is supplied only in single-dose containers to dilute or dissolve drugs for injection. The solution may contain hydrochloric acid and/or sodium hydroxide for pH adjustment. pH 5.0 (4.5 to 7.0). Sodium Chloride, USP is chemically designated NaCl, a white crystalline compound freely soluble in water.

Sodium Chloride Label

	<p>10 mL <small>Single-dose</small> 25 Units/NDC 0409-4888-10 0.9% Sodium Chloride Injection, USP Rx only</p> <p>FOR USE AS A STERILE DILUENT </p>  <p>(01) 2 030409 488810 5</p>	
<p>Use Ampicillin Technique Remove cover from Ripstop vial and cleanse stopper with antiseptic.</p> <p>With Sterile Syringe and Needle:</p> <ol style="list-style-type: none"> 1. Aspirate desired portion of vial contents and add to suitable container. 2. Discard any remaining fluid in Ripstop vial. <p>With DNTD (Double Needle Transfer Device), Lot No. 497:</p> <ol style="list-style-type: none"> 1. Prepare IV solution container. 2. Remove one sheath from DNTD and insert needle through rubber diaphragm of Ripstop vial. 3. Remove sheath from DNTD, invert Ripstop vial, and insert through rubber stopper of IV solution container. (Fluid in Ripstop vial will be drawn into IV solution container by vacuum.) 4. After additive is delivered, remove DNTD and Ripstop vial simultaneously. 		<p>Printed in USA Hospira, Inc., Lake Forest, IL 60045 USA</p> <p>Each mL contains sodium chloride, 9 mg. May contain HCl and/or NaOH for pH adjustment. Sterile, nonpyrogenic. 0.308 mEq/mL (calcl.)</p> <p>Mix thoroughly after dilution. Use only if clear and seal is intact and undamaged. Preservative-free. Use promptly. Discard unused portion. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]</p> <p>IM-11924</p>
	<p>FOR USE AS A STERILE DILUENT </p> <p>0.9% Sodium Chloride Injection, USP Rx only 25 Units/NDC 0409-4888-10</p>  <p>109</p>	

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CENTURION®

032312G

Example

Product

Example Cardiovascular Kit

Reorder

XXXXXXXXXX

CONTENTS:

1 STERILE EXAMPLE CARDIOVASCULAR KIT

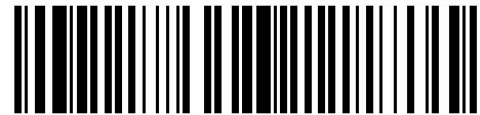
1 STERILE SODIUM CHLORIDE SOLUTION

Example Only - Components & Title May Vary

LOT 0000000000



N/A



(01) 1 0653160 00000 6

NOTES:

Store between 20-25°C (68-77°F).



Do not reuse.
Single use only.

LATEX FREE



Consult
instructions
for use.

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

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CARDIOVASCULAR PROCEDURE KIT

cardiovascular procedure kit kit

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:24840-1133
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:24840-1133-2	10 in 1 CASE		
1	NHRIC:24840-1133-1	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL, SINGLE-DOSE	10 mL

Part 1 of 1**SODIUM CHLORIDE**

sodium chloride injection, solution

Product Information

Item Code (Source)	NDC:0409-4888
Route of Administration	INTRAVENOUS, INTRAMUSCULAR

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-4888-10	10 mL in 1 VIAL, SINGLE-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018803	09/08/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
exempt device	OEZ	01/01/2012	

Labeler - Centurion Medical Products (017246562)

Establishment

Name	Address	ID/FEI	Business Operations
Centurion Medical Products		017246562	manufacture, repack

Establishment

Name	Address	ID/FEI	Business Operations
Centurion Medical Products		148522279	manufacture, repack

Establishment

Name	Address	ID/FEI	Business Operations
Centurion Medical Products		626660810	manufacture, repack

Establishment

Name	Address	ID/FEI	Business Operations
Hospira Inc		093132819	manufacture

Revised: 9/2012

Centurion Medical Products