



Technical Data Sheet

Product specification

1. Product Name	USP Normal Saline														
2. Description	Sodium Chloride Irrigation USP (100 mL, 250 mL, 500 mL, 1000 mL bottle)														
3. Characteristics	Sterile normal saline for wound cleansing, wound dressing and device irrigation.														
4. Intended use	This device is intended for moistening absorbent wound dressings and for moistening, debriding and cleaning acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts abrasions and minor skin irritations and for device irrigation.														
5. Instructions for use	See Directions for Use on label.														
6. Sizes and REF numbers	<table border="1"> <thead> <tr> <th>Part Number</th><th>Size/Volume</th></tr> </thead> <tbody> <tr> <td>6240</td><td>100 mL, bottle</td></tr> <tr> <td>6270</td><td>250 mL, bottle</td></tr> <tr> <td>6280</td><td>500 mL, bottle</td></tr> <tr> <td>6281</td><td>1000 mL, bottle</td></tr> <tr> <td>6380</td><td>500 mL, bottle</td></tr> <tr> <td>6381</td><td>1000 mL, bottle</td></tr> </tbody> </table>	Part Number	Size/Volume	6240	100 mL, bottle	6270	250 mL, bottle	6280	500 mL, bottle	6281	1000 mL, bottle	6380	500 mL, bottle	6381	1000 mL, bottle
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Technical information

	Component name	Material
1. List of materials	Bottle	HDPE
	0.9% Normal Saline Solution	Sodium Chloride Irrigation USP
2. Latex free	Not made with natural latex rubber	
3. PHT / DEHP / BPA free	Yes	
4. Shelf life	2 years	

5. Sterilization method		Gamma irradiation	
6. Packaging specification	Sales Unit	Part Number	Units per Case
		6240	48
		6270	24
		6280	18
		6281	6
		6380	18
		6381	6

Quality and Regulatory Information

1. Quality certificate	COA	
2. Product classification	FDA: Unclassified; Health Canada: Class 2	
3. List of standards	The product is compliant with the following standards and regulations:	
	Document reference	Title
	USP <85>	Bacterial Endotoxins Test
	USP Monograph	Sodium Chloride Irrigation USP
	ANSI/AAMI/ISO 11737-2	Sterilization of Medical Devices-Microbiological Methods-Part 2: Tests of Sterility Performed in the Definition, Validation and Maintenance of a Sterilization Process
	ANSI/AAMI/ISO 11737-1	Sterilization of Health care products-Microbiological methods-Part 1: Determination of a Population of Microorganisms on Products
	ANSI/AAMI/ISO 11137-2	Sterilization of Health care products-Radiation-Part 2: Establishing the Sterilization Dose
	ANSI/AAMI/ISO 11137-1	Sterilization of Health care products-Radiation-Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices