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April 27, 2011

Dear Customer:

InHealth Technologies, a division of Helix Medical LLC., is conducting a voluntary recall on select lots of Smith & Nephew products in the United States and other countries. This recall is being initiated at the direction of the manufacturer, Smith & Nephew. Smith & Nephew has advised us to notify our customers to **discontinue use of specific lots** of these products. We are taking this voluntary action because you may have purchased one or more of these Smith & Nephew products which are distributed through our company.

This recall affects the REMOVE® Universal Adhesive Remover Wipes, (distributed by InHealth Technologies under catalog number 4031-00), and SKIN-PREP® Protective Wipes, (distributed by InHealth Technologies under catalog number 4204-00). Please see the attached matrix for lot numbers affected.

Smith & Nephew has notified their distributors that they have decided to voluntarily recall these products, due to conditions at the factory of one of their contract manufacturers. **Smith & Nephew has performed testing on lots already distributed and test results received to date show no contamination.** However, Smith & Nephew states that "out of an abundance of caution", they have decided to recall these products. Please see the attached excerpt from the Smith & Nephew Device Recall letter.

As the Smith & Nephew letter requests, our company as distributor, has been asked to direct our customers to discard or return the REMOVE and SKIN-PREP products with the Smith & Nephew lot numbers listed above.

In addition, you may have purchased our Blom-Singer® ATSV II Kit, BE 8024H, see lot numbers in the attached matrix.

InHealth Technologies, a division of Helix Medical, LLC, is the manufacturer of the ATSV II device and provides a kit which, for customer convenience, contains 5 packets each of REMOVE® and SKIN-PREP®.

Please discard or return the packets of REMOVE and SKIN-PREP included for convenience within this kit. This voluntary recall by Smith & Nephew does not affect the Blom-Singer® ATSV II Kit.

No other InHealth product is affected by this recall action. This voluntary action is being conducted in the United States with the knowledge of the U.S. Food and Drug Administration.

Smith & Nephew's return policy requires that we direct our customers to return the unused product to our facility. We are only able to provide product replacement to you as a result of product return.

If you have product to return, please contact our Customer Service Center at (800) 477- 5969.

Smith & Nephew has communicated to us that they are already shipping replacement product to their distributors, so we will be able to continue to distribute these to our customers as soon as product is received.

Although our company is not the manufacturer of these Smith & Nephew products, InHealth regrets that you, our valued customer, may have been affected by this action. Please don't hesitate to contact us if we can assist you in any way.

Sincerely,

InHealth Technologies

**HELIX MEDICAL LOT NUMBER MATRIX  
SMITH & NEPHEW VOLUNTARY RECALL**

Product	InHealth Catalog Number	Supplier Lot#
Remove	4031-00	OJ233
		OG116
		OF242
Skin-Prep	4204-00	OJ147
		OG117
		OG225

Product	InHealth Catalog Number	InHealth Lot#	Supplier Lot#
ATSV II Starter Kit	BE8024H	955895	OF242
		958035	OG117
		960000	OG116
		960796	OJ233
		964214	
		964802	
		965053	
		965958	
		967741	
		970204	
		970951	
		971679	
		972535	
		975155	
		978481	
		979331	
		980028	
980918			
981833			
982496			

**URGENT: DEVICE RECALL****EXCERPT FROM SMITH & NEPHEW VOLUNTARY RECALL NOTIFICATION  
TO HELIX MEDICAL**

**RE: Product Names: REMOVE<sup>®</sup> Universal Adhesive Remover Wipes, UNI-SOLVE<sup>®</sup> Adhesive Remover Wipes, SKIN-PREP<sup>®</sup> Protective Wipes, PERI-PREP Protective Wipes, and NO-STING SKIN-PREP<sup>®</sup> Protective Wipes  
Product Code Numbers: 420400, 420471, 59420425, 403100, 402300, 59403125, 59420600  
Lot Numbers: -See Attached Form**

Dear Customer:

Smith & Nephew, Inc., Advanced Wound Management Division is voluntarily recalling multiple lot numbers of the following products: REMOVE<sup>®</sup> Universal Adhesive Remover Wipes, UNI-SOLVE<sup>®</sup> Adhesive Remover Wipes, SKIN-PREP<sup>®</sup> Protective Wipes, PERI-PREP Protective Wipes, and NO-STING SKIN-PREP<sup>®</sup> Protective Wipes. Our shipping records indicate that you received one or more of the affected lots of these wipes as indicated on the attached inventory Form.

The decision was made to recall these affected lots after a thorough review of available information regarding conditions at the manufacturing site of the contract manufacturer, H&P Industries dba The Triad Group. It has been determined that the recalled lots were made in the same facility as other wipe products, including wipes, swabs and swab sticks, that are the subject of other voluntary recalls due to a potential bacterial contamination issue of these products.

Testing has been performed on some Smith & Nephew products lots already distributed and/or under quarantine and test results received to date show no contamination.

Out of an abundance of caution, however, Smith & Nephew has decided to voluntarily recall the affected wipe products identified in this notice. Smith & Nephew is committed to providing our customers with high quality, reliable products. We are taking this action to remove the product lots identified in this notice from the market as a prudent, cautious and conservative measure to assure patient safety and product performance.