

Manufacturer name:	Smith Medical																					
About the Recall:	This notice has been issued because Smiths Medical has identified a timeframe where there is uncertainty in the seal integrity of the packaging. The potential risk of uncertainty in the seal integrity of sterile packaging is that a product labeled as sterile, may not be sterile, which could potentially lead to infection.																					
Products(s) numbers/models that are affected:	<table border="1" data-bbox="394 814 1503 984"> <thead> <tr> <th data-bbox="394 814 513 869">MMS #</th> <th data-bbox="513 814 716 869">MFG Catalog #</th> <th data-bbox="716 814 1109 869">Description</th> <th colspan="3" data-bbox="1109 814 1503 869">Affected Lot(s)</th> </tr> </thead> <tbody> <tr> <td data-bbox="394 869 513 984" rowspan="4">566849</td> <td data-bbox="513 869 716 984" rowspan="4">100/582/000</td> <td data-bbox="716 869 1109 984" rowspan="4">EXCHANGER, THERMOVENT HEAT/MOISTURE (20/CS)</td> <td data-bbox="1109 869 1227 896">4088216</td> <td data-bbox="1227 869 1346 896">4109285</td> <td data-bbox="1346 869 1503 896">4119729</td> </tr> <tr> <td data-bbox="1109 896 1227 924">4135055</td> <td data-bbox="1227 896 1346 924">4135057</td> <td data-bbox="1346 896 1503 924">4135061</td> </tr> <tr> <td data-bbox="1109 924 1227 951">4088217</td> <td data-bbox="1227 924 1346 951">4109287</td> <td data-bbox="1346 924 1503 951">4131584</td> </tr> <tr> <td data-bbox="1109 951 1227 978">4135056</td> <td data-bbox="1227 951 1346 978">4135059</td> <td data-bbox="1346 951 1503 978">4135063</td> </tr> </tbody> </table>	MMS #	MFG Catalog #	Description	Affected Lot(s)			566849	100/582/000	EXCHANGER, THERMOVENT HEAT/MOISTURE (20/CS)	4088216	4109285	4119729	4135055	4135057	4135061	4088217	4109287	4131584	4135056	4135059	4135063
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URL Link(s) to Manufacturer Notice/Web Site:	For further information regarding the recall, you may contact Smiths Medical directly by calling customer service at 1 (800) 258-5361 or email at customerservice@icumed.com .																					
Actions to be taken by customer/Patient:	Patients should check their supplies to ensure that they do not have any affected products. Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed above. If you have no product matching the affected item(s) and lot number(s), no further action is needed.																					