

Manufacturer name:	Coloplast												
About the Recall:	<p>AdaptHealth has been made aware of a voluntary medical device recall from Advanced Medical Solutions regarding the following products; Silvercel Hydro Alginate, Silvercel Non-Adherent, Tegaderm Alginate, ActivHeal Alginate, ActivHeal Aquafibre, ActivHeal Non-Adhesive Foam, ActivHeal Non Adhesive Tracheostomy, ActivHeal PHMB Foam Non-Adhesive, ActivHeal Raponice Ultra, Biatain Alginate, Hyalo 4 High Gelling Fire, Caldicare Reinforced Aquafibre, Nurocel Extra, Maxorb Extra.</p> <p>Advanced Medical Solutions has become aware of a defect in primary packaging pouches and has determined this could compromise sterility and impact patient safety. The AMS FSN states that a device with compromised sterility carries a worst-case potential harm to cause a major infection to the patient. AMS has determined that any potentially affected Product in the market presents a low probability of risk to a patient's health. AMS recommends that where Product has already been used with patients, those patients should be monitored for symptoms during routine clinical follow up.</p>												
Products(s) numbers/models that are affected:	<table border="1"> <thead> <tr> <th data-bbox="459 1352 578 1409">MMS #</th> <th data-bbox="578 1352 781 1409">MFG Catalog #</th> <th data-bbox="781 1352 1349 1409">Description</th> <th data-bbox="1349 1352 1560 1409">Affected Lot(s)</th> </tr> </thead> <tbody> <tr> <td data-bbox="459 1409 578 1451">313944</td> <td data-bbox="578 1409 781 1451">3710</td> <td data-bbox="781 1409 1349 1451">DRESSING, SEASORB ALGINATE 4X4(10/BX)</td> <td data-bbox="1349 1409 1560 1451">W00069434</td> </tr> <tr> <td data-bbox="459 1451 578 1493">480057</td> <td data-bbox="578 1451 781 1493">3715</td> <td data-bbox="781 1451 1349 1493">DRESSING, SEASORB ALGINATE 6"X6" (10/BX)</td> <td data-bbox="1349 1451 1560 1493">W00068269</td> </tr> </tbody> </table>	MMS #	MFG Catalog #	Description	Affected Lot(s)	313944	3710	DRESSING, SEASORB ALGINATE 4X4(10/BX)	W00069434	480057	3715	DRESSING, SEASORB ALGINATE 6"X6" (10/BX)	W00068269
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URL Link(s) to Manufacturer Notice/Web Site:	<p>Coloplast.com</p> <p>For questions regarding this notification, please contact Coloplast at (800) 533-0464.</p>												
Actions to be taken by customer/Patient:	<p>Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed above. If you have no product</p>												

	matching the affected item(s) and lot number(s), no further action is needed.
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