

<b>Manufacturer name:</b>	Ambu Inc																																																																			
<b>About the Recall:</b>	Ambu received 5 complaints concerning Ambu SPUR II deviating from the design with the manometer port being blocked rendering the manometer non-functional. As a result, users are unable to use the attached manometer to monitor the patient’s airway pressure.																																																																			
<b>Products(s) numbers/models that are affected:</b>	<table><tr><th>MMS #</th><th>MFG Catalog #</th><th>Description</th><th colspan="2">Affected Lot(s)</th></tr><tr><td>770644</td><td>523211000</td><td>RESUSITATOR, SPUR II BG RSVR ADLT (12/CS)</td><td>1001113554</td><td>1001118764</td></tr><tr><td>557737</td><td>530212000</td><td>SPUR II, MEDI PORT TOD MASK PEDI BAG (12/CS)</td><td>1001113557</td><td></td></tr><tr><td rowspan="2">533885</td><td rowspan="2">530213000</td><td rowspan="2">RESUSCITATOR, SPUR II PED TOD MASK (12/CS)</td><td>1001110299</td><td>1001118767</td></tr><tr><td>1001113558</td><td>1001106634</td></tr><tr><td>1067666</td><td>530213030</td><td>SPUR II CHILD RESC W/MANOMETER(12/CS)</td><td>2000016409</td><td></td></tr><tr><td>821459</td><td>530213031</td><td>RESUSCITATOR, SPUR II BG RESVRPED (12/CS)</td><td>1001113560</td><td>1001118769</td></tr><tr><td>555742</td><td>530214000</td><td>RESUSCITATOR, SPUR PED BG MEDIPRT /INF/TODD (12 AMBU)</td><td>1001106636</td><td>1001113561</td></tr><tr><td rowspan="2">544776</td><td rowspan="2">530613000</td><td rowspan="2">RESUSCITATOR, SPUR W/MASK PED</td><td>1001110301</td><td>1001106637</td></tr><tr><td>1001121455</td><td>1001118771</td></tr><tr><td rowspan="2">545840</td><td rowspan="2">531613000</td><td rowspan="2">RESUSCITATOR, SPUR II W/CORR TU PED MASK (6/CS)</td><td>1001118773</td><td>1001106640</td></tr><tr><td>1001121460</td><td></td></tr><tr><td rowspan="2">1205547</td><td rowspan="2">523611051E</td><td rowspan="2">RESUSCITATOR, MANUAL SPUR II ADLT MED MASK (6/CS)</td><td>2000015292</td><td>2000016401</td></tr><tr><td>2000015559</td><td></td></tr><tr><td>876838</td><td>530213000B</td><td>BAG, RESUSCITATION PED W/MASK (12/CS)</td><td>1001113559</td><td></td></tr></table>					MMS #	MFG Catalog #	Description	Affected Lot(s)		770644	523211000	RESUSITATOR, SPUR II BG RSVR ADLT (12/CS)	1001113554	1001118764	557737	530212000	SPUR II, MEDI PORT TOD MASK PEDI BAG (12/CS)	1001113557		533885	530213000	RESUSCITATOR, SPUR II PED TOD MASK (12/CS)	1001110299	1001118767	1001113558	1001106634	1067666	530213030	SPUR II CHILD RESC W/MANOMETER(12/CS)	2000016409		821459	530213031	RESUSCITATOR, SPUR II BG RESVRPED (12/CS)	1001113560	1001118769	555742	530214000	RESUSCITATOR, SPUR PED BG MEDIPRT /INF/TODD (12 AMBU)	1001106636	1001113561	544776	530613000	RESUSCITATOR, SPUR W/MASK PED	1001110301	1001106637	1001121455	1001118771	545840	531613000	RESUSCITATOR, SPUR II W/CORR TU PED MASK (6/CS)	1001118773	1001106640	1001121460		1205547	523611051E	RESUSCITATOR, MANUAL SPUR II ADLT MED MASK (6/CS)	2000015292	2000016401	2000015559		876838	530213000B	BAG, RESUSCITATION PED W/MASK (12/CS)	1001113559	
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<b>URL Link(s) to Manufacturer Notice/Web Site:</b>	Ambu.com
<b>Actions to be taken by customer/Patient:</b>	Check your supply against the product list above, should you have any affected product evaluate the product for any possible defect and contact Ambu Inc. for product replacement. If you have any questions regarding this Urgent Medical Device Recall notice, please contact Ambu Inc. (800) 262-8462 for further information.