



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. 2021-3487-A

29 DEC 2021

TO: ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS

SUBJECT: Clarification of FDA Advisory No. 2021-3487 "Voluntary Recall of Rüsç Endotracheal Tube"

The Food and Drug Administration (FDA) clarifies that only the following affected Lots and Batches of Rüsç Endotracheal Tube are being voluntarily recalled by East lane Corporation.:

Product Description	Product Code	Lot Numbers
Slick Set® Cuffed Endotracheal Tube and Stylet Set, oral/nasal	170050	KME20K2551, KME20L1089, KME20L2371, KME21A2064, KME21B2498, KME21C0488
	170055	KME20K0936, KME20K2587, KME20L1469, KME20L2378, KME21A0383, KME21A1901, KME21B2682, KME21C2708
	170060	KME20L1487, KME20L2379, KME20M0494, KME21A0384, KME21A1482, KME21C0293
	170065	KME20K0938, KME20K2623, KME20L0487, KME20L1705, KME20M1578, KME20M1751, KME20M2709, KME21A0385, KME21A1812, KME21B1670, KME21B2499, KME21B2500
	170070	KME20K2544, KME20L0053, KME20L0055, KME20L0942, KME20L2372, KME20M0381, KME20M0665, KME20M1103, KME20M1754, KME20M1755, KME21A0893, KME21A2264, KME21B1074, KME21B1075, KME21C0463, KME21C0464, KME21C1027, KME21C1422, KME21C1592, KME21C2266, KME21C2504, KME21C2706, KME21D1043



	170075	KME20K1352, KME20L1132, KME20M0033, KME20M0382, KME20M1149, KME20M1225, KME20M1227, KME20M1537, KME20M2881, KME20M2882, KME21A0824, KME21A1161, KME21A1813, KME21B0813, KME21C0212, KME21C0213, KME21C1594, KME21C1895, KME21C2855, KME21C3294, KME21C3295
	170080	KME20L0396, KME20L1278, KME20L1279, KME20L2830, KME20M0847, KME21A0386, KME21A2800, KME21A2801, KME21B1245, KME21B1752, KME21B2156, KME21C0465, KME21C0533, KME21C2826
	170085	KME20L0398, KME20L2376, KME20M3247, KME21A1894, KME21C0298, KME21C2385
	170090	KME20L0625
	170095	KME20M0384, KME21B0407
Flexi-Set Cuffed Endotracheal Tube and Style Set, oral/nasal	504550	KME20K0001, KME20K0467, KME20K1581, KME20L0618, KME20L1090, KME20L2027, KME20M0019, KME21A2076, KME21A2787, KME21B1140, KME21C0059, KME21C2363
	504555	KME20K0765, KME20K0766, KME20K0935, KME20K1582, KME20L0619, KME20L1857, KME20L2028, KME20M0020, KME21A1902, KME21A2796, KME21B2681, KME21C2707
	504560	KME20K1550, KME20L0336, KME20L2298, KME20M0021, KME20M0492, KME21A0380, KME21A0817, KME21A1160, KME21A1770, KME21B1137, KME21B1138, KME21B1139, KME21C3255
	504565	KME20K0465, KME20K0939, KME20K1551, KME20K1628, KME20K2246, KME20L0488, KME20L1840, KME20M0022, KME20M0854, KME20M1102, KME20M1579, KME21A0085, KME21A1040, KME21A1292, KME21A2794, KME21B1141, KME21B1669, KME21B2155,

		<p>KME21B2501, KME21B2502, KME21B2855, KME21C0025, KME21C1202, KME21C1331, KME21C1790, KME21C1897, KME21C2188, KME21C2262, KME21C2835</p>
<p>Flexi-Set Cuffed Endotracheal Tube and Style Set, oral/nasal</p>	<p>504570</p>	<p>KME20K0026, KME20K0360, KME20K0361, KME20K0768, KME20K0941, KME20K1148, KME20K1202, KME20K1304, KME20K1552, KME20K1658, KME20K2057, KME20K2187, KME20K3161, KME20K3355, KME20L0057, KME20L0059, KME20L0490, KME20L0623, KME20L0943, KME20L0944, KME20L1091, KME20L1122, KME20L1124, KME20L1475, KME20L1844, KME20L2039, KME20L2258, KME20L2827, KME20M0378, KME20M0379, KME20M0380, KME20M0498, KME20M1105, KME20M1153, KME20M1156, KME21A0228, KME21A0273, KME21A0304, KME21A0305, KME21A1769, KME21A2227, KME21A2228, KME21A2229, KME21A2263, KME21A3119, KME21A3120, KME21A3121, KME21B0261, KME21B0338, KME21B0559, KME21B0750, KME21B1073, KME21B1751, KME21B2107, KME21B2153, KME21B2460, KME21B2719, KME21B2721, KME21C0123, KME21C0376, KME21C0421, KME21C0620, KME21C0634, KME21C1016, KME21C1333, KME21C1416, KME21C1434, KME21C1489, KME21C1593, KME21C1653, KME21C1703, KME21C1786, KME21C1896, KME21C2065, KME21C2146</p>
	<p>504575</p>	<p>KME20K0769, KME20K0770, KME20K1150, KME20K1204, KME20K1665, KME20K2188, KME20K2920, KME20K3016, KME20K3018, KME20K3159, KME20K3575, KME20L1476, KME20L2374, KME20M0383, KME20M1151, KME20M2051,</p>

		<p>KME20M2344, KME20M2376, KME20M2485, KME20M2556, KME21A0084, KME21A0303, KME21A0671, KME21A0672, KME21A0673, KME21A0674, KME21A0812, KME21A1041, KME21A1464, KME21A1605, KME21A2799, KME21A2815, KME21B0753, KME21B0814, KME21B0888, KME21B0889, KME21B0931, KME21B1240, KME21B2461, KME21B2462, KME21B2465, KME21B2716, KME21B2717, KME21C0700, KME21C0972, KME21C1203, KME21C1336, KME21C1435, KME21C1893, KME21C2565, KME21C2610</p>
Flexi-Set Cuffed Endotracheal Tube and Style Set, oral/nasal	504580	<p>KME20K0449, KME20K0450, KME20K1414, KME20K2622, KME20L1277, KME20L1479, KME20L2302, KME20L2828, KME20M1752, KME20M1753, KME21A0381, KME21A0820, KME21A0823, KME21A1291, KME21A1604, KME21B0339, KME21B1241, KME21B1855, KME21B2108, KME21B2154, KME21B2697, KME21C0377, KME21C0623, KME21C2407, KME21C2738, KME21C3448</p>
	504585	<p>KME20K2625, KME20L0624, KME20L1482, KME20L2303, KME20L2832, KME21A0891, KME21A1043, KME21A2802, KME21A2803, KME21B0933, KME21B1250, KME21B1251, KME21B2029, KME21C0506, KME21C2107, KME21C2339, KME21C2341, KME21C2553, KME21D0210</p>
	504590	<p>KME20L0626, KME20M0856, KME20M2091, KME21C0299, KME21C2104, KME21C2105</p>
Endotracheal Tube – with cuff – Murphy – Sterile pack	07802	KME20K1277
	07803	KME20K1379
	07804	KME20K1278
	07805	KME20K1279
	07806	KME20K1280
	07807	KME20K1281

Endotracheal Tube oral/nasal Magill, High Volume, Low Pressure Cuff	112080050	KME20K1512, KME20L1145, KME20M2383, KME21B0357
	112080055	KME20K2579, KME21A2569, KME21C1978
	112080060	KME20M0616, KME20M2112, KME21A2685
	112080065	KME20K2581, KME21C1701
	112080070	KME20K2577, KME20L1985, KME20M1771, KME20M1772, KME20M2856, KME21A2355, KME21B1624, KME21B2490, KME21C1184
	112080075	KME20K0110
	112080080	KME20M0377, KME21B2727, KME21C0500
	112080085	KME20M0909, KME21B0519, KME21C0067
	112080090	KME20K1808, KME20L2352, KME20M2248
	112080095	KME20K2310, KME20L1153
	112080100	KME20K1005, KME20L1144
	Endotracheal Tube oral/nasal Murphy Eye, High Volume, Low Pressure Cuff	112082050
112082055		KME20K0464, KME20K0683, KME20L1703, KME20M0996, KME21A0492, KME21A1433, KME21C0502, KME21C1347, KME21C1496, KME21C2745, KME21D0835
112082060		KME20K0435, KME20K1112, KME20K2168, KME20K3530, KME20L0196, KME20L1143, KME20L1420, KME20L2089, KME20L2783, KME20M0497, KME20M0663, KME20M1064, KME20M1143, KME20M1218, KME21A1521, KME21A1803, KME21A2066, KME21A2344, KME21B0252, KME21B1151, KME21B1592, KME21B2606, KME21B2729, KME21C0483, KME21C1094, KME21C2681, KME21C2996, KME21D0703, KME21D1159, KME21D1326
112082065	KME20K0036, KME20K0259, KME20K0436, KME20K050, KME20K0677, KME20K0881, KME20L1421, KME20L1436, KME20L2349, KME20L2447, KME20L2448, KME20M0710, KME20M0892,	

		<p>KME20M0928, KME20M1806, KME20M1923, KME20M2249, KME20M2450, KME20M2708, KME21A0338, KME21A0404, KME21A0695, KME21A1588, KME21A1779, KME21A2102, KME21A2230, KME21A2572, KME21B1352, KME21B2607, KME21B2789, KME21B2856, KME21C0504, KME21C0981, KME21C0983, KME21C1035, KME21C1036, KME21C1097, KME21C1925, KME21C2997, KME21C3166, KME21C3456</p>
<p>Endotracheal Tube oral/nasal Murphy Eye, High Volume, Low Pressure Cuff</p>	<p>112082070</p>	<p>KME20J2802, KME20K0061, KME20K0437, KME20K0462, KME20K0585, KME20K1007, KME20K3013, KME20K3014, KME20K3145, KME20K3365, KME20K3448, KME20K3518, KME20K3560, KME20L0276, KME20L0371, KME20L0785, KME20L0928, KME20L1691, KME20L1752, KME20L1858, KME20L1874, KME20L1923, KME20L2111, KME20L2210, KME20L2273, KME20L2350, KME20L2373, KME20L2463, KME20L2478, KME20L2499, KME20L2699, KME20L2826, KME20M0490, KME20M0664, KME20M0712, KME20M0762, KME20M0774, KME20M0839, KME21A1121, KME21A1215, KME21A1328, KME21A2220, KME21A2345, KME21A2574, KME21A2984, KME21A3038, KME21B0136, KME21B0711, KME21B2898, KME21C0505, KME21C0567, KME21C0701, KME21C0737, KME21C0822, KME21C0854, KME21C0971, KME21C0973, KME21C1279, KME21C1328,</p>

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<p>Endotracheal Tube oral/nasal Murphy Eye, High Volume, Low Pressure Cuff</p>	<p>112082075</p>	<p>KME20J3284, KME20K0052, KME20K0181, KME20K1113, KME20K3044, KME20K3577, KME20L0484, KME20L0755, KME20L1092, KME20L1156, KME20L1298, KME20L1299, KME20L1704, KME20L1924, KME20L1983, KME20L2605, KME20L2798, KME20M0034, KME20M0321, KME20M1067, KME20M1507, KME20M1890, KME20M2212, KME21A3004, KME21A3259, KME21B0179, KME21B0823, KME21B2480, KME21B2482, KME21C0239, KME21C0264, KME21C0614, KME21C0615, KME21C0661, KME21C0702, KME21C0730, KME21C0826, KME21C0855, KME21C1093, KME21C1223, KME21C1323, KME21C1399, KME21C1601, KME21C1704, KME21C1746, KME21C1944, KME21C2008, KME21C2026, KME21C2051, KME21C2066, KME21C2195, KME21C2499, KME21C2615, KME21C2680, KME21C2766, KME21C2908, KME21C2964, KME21C3394, KME21D0029, KME21D0058, KME21D0186, KME21D0586, KME21D0648, KME21D0775, KME21D1103, KME21D1400, KME21D1423</p>
	<p>112082080</p>	<p>KME20J2998, KME20J3341, KME20K3520, KME20L0194, KME20L1157, KME20L1237, KME20L1706, KME20L2207, KME20L2333, KME20L2375, KME20L2607, KME20L2696, KME20M0577, KME20M1043, KME20M1069, KME20M1260, KME20M1342, KME20M1780, KME20M2363, KME21A0082,</p>

		KME21A1435, KME21A1522, KME21A1524, KME21A2014, KME21A2058, KME21A2576, KME21B0049, KME21B0137, KME21B0248, KME21B0428, KME21B0616, KME21B0709, KME21B0863, KME21B1214, KME21B1284, KME21B2488, KME21B2489, KME21C0705, KME21C0706, KME21C1063, KME21C1325, KME21C1441, KME21C1745, KME21C1785, KME21C2068, KME21C3283, KME21C3320
Endotracheal Tube oral/nasal Murphy Eye, High Volume, Low Pressure Cuff	112082085	KME20J2999, KME20K0923, KME20K1114, KME20K1273, KME20K1513, KME20K3020, KME20K3034, KME20K3146, KME20L0670, KME20L0756, KME20L0757, KME20L1437, KME20L1549, KME20L1678, KME20L1707, KME20L1867, KME20L2274, KME20L2831, KME20M1511, KME20M1548, KME20M1849, KME20M3122, KME20M3248, KME21A0697, KME21A1093, KME21A2265, KME21A2577, KME21B0932, KME21B0958, KME21B1215, KME21C3024, KME21C3324, KME21D0061
	112082090	KME20K0180, KME20K0212, KME20K0600, KME20K0978, KME20K1434, KME20K3021, KME20K3525, KME20L0805, KME20L1142, KME21A2016, KME21A2676, KME21A3263, KME21B0632, KME21B1283
	112082095	KME20K1583, KME20K1831, KME20K2166, KME20K2574, KME20L1041, KME20L1592, KME20L2462, KME20L2557, KME20M2115, KME20M2198, KME21A2346, KME21A3264, KME21B1895, KME21C3326
	112082100	KME20K0977, KME20K1809, KME20K2553, KME20L0335, KME20M1341, KME20M2113, KME21A2342, KME21A2668, KME21C0017, KME21C0068, KME21D0827, KME21D1219

Ruschelit® Safety Clear Plus
Tracheal Tube, oral/nasal,
cuffed

112080-000055	KME21C1977
112080-000060	KME20M0614, KME21A2570
112080-000065	KME20M0233
112080-000070	KME20K2219, KME20L1984, KME20M2855, KME21D0826
112080-000075	KME20K3531, KME20M0511, KME20M2857
112080-000080	KME20L0174, KME20M0376, KME20M2197, KME20M2865, KME21A2808, KME21B1150, KME21B2728, KME21C0501, KME21C1185, KME21C3319
112080-000090	KME20K3532, KME20K3670, KME20L2623, KME20M0777
112080-000095	KME20L1152
112082-000050	KME20K2560, KME20L0855
112082-000055	KME20K0434, KME20K0598, KME20K1036, KME20L1986, KME20M0997, KME21A0757, KME21A1434, KME21C2746
112082-000060	KME20K0206, KME20K0746, KME20K1008, KME20K1182, KME20K1412, KME20K1733, KME20K3529, KME20M1257, KME21A2055, KME21B2605, KME21D1158
112082-000065	KME20J3330, KME20K0207, KME20K0957, KME20K1023, KME20K1153, KME20K1212, KME20K1413, KME20K1558, KME20K2352, KME20K3556, KME20L1238, KME20M0711, KME20M1924, KME20M2114, KME21A0921, KME21A2571, KME21A3003, KME21B2551, KME21B2788, KME21C0070, KME21C0503, KME21C0984, KME21C1098, KME21C1230, KME21C3455
112082-000070	KME20K0198, KME20K0199, KME20K0260, KME20K0732, KME20K0747, KME20K0800, KME20K0871, KME20K0958, KME20K0976, KME20K1101, KME20K1274, KME20K1480, KME20K1559, KME20K1660, KME20K2179, KME20K2226, KME20K2306, KME20K2327, KME20K2351, KME20K2490, KME20L1151, KME20L2074, KME20L2198, KME20L2700, KME20M0489, KME20M0840, KME20M1018,

		<p>KME20M1019, KME20M1044, KME20M1700, KME20M3246, KME21A0080, KME21A0339, KME21A0495, KME21A0732, KME21A0733, KME21A0863, KME21A1329, KME21A1802, KME21A2573, KME21A2780, KME21B0514, KME21B0792, KME21B1282, KME21B1593, KME21B2095, KME21B2608, KME21B2850, KME21B2851, KME21C1096, KME21C1191, KME21C1914, KME21C2067, KME21C2519, KME21C2520, KME21C2747, KME21C2953</p>
<p>Ruschelit® Safety Clear Plus Tracheal Tube, oral/nasal, cuffed</p>	<p>112082-000075</p>	<p>KME20J3329, KME20K0182, KME20K0208, KME20K0599, KME20K0705, KME20K0734, KME20K1122, KME20K1183, KME20K1222, KME20K1236, KME20K1349, KME20K1410, KME20K1529, KME20K1555, KME20K1763, KME20K1858, KME20K2103, KME20K2319, KME20L1155, KME20L1692, KME20L1753, KME20L2740, KME20M0180, KME20M0448, KME20M0496, KME20M0612, KME20M1152, KME20M2213, KME20M2606, KME20M2774, KME20M2993, KME20M3120, KME20M3121, KME20M3245, KME20M3317, KME21A0583, KME21A2077, KME21A2575, KME21A2678, KME21A2795, KME21A2983, KME21A3122, KME21A3123, KME21B2092, KME21B2093, KME21B2604, KME21B2651, KME21B2786, KME21C0066, KME21C0236, KME21C0825, KME21C1225, KME21C1379, KME21C2613, KME21C2845, KME21C3302, KME21D0323, KME21D0436, KME21D0504, KME21D0773</p>
	<p>112082-000080</p>	<p>KME20J2949, KME20K0711, KME20K0748, KME20K1037, KME20K1123, KME20K1137,</p>

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Ruschelit® Safety Clear Plus Tracheal Tube, oral/nasal, cuffed	112082-000085	KME20K0168, KME20K0261, KME20K0749, KME20K1044, KME20K1213, KME20K1215, KME20K1276, KME20K1417, KME20K1530, KME20K1661, KME20K1702, KME20L2351, KME20M1510, KME21D0060
	112082-000090	KME21A2015, KME21A3262
	112082-000100	KME20M1340
Ruschelit® Super Safety Clear Tracheal Tube, oral/nasal, cuffed	112480-000050	KME20M3309, KME21A2073, KME21A2995, KME21A2996, KME21B1192, KME21C3174, KME21D0829
	112480-000055	KME21A2563, KME21A2605, KME21B0980, KME21C0291, KME21D1120, KME21D1121
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	<p>112480-000080</p>	<p>KME21A1455, KME21A1528, KME21A2035, KME21A2061,</p>

Ruschelit® Super Safety Clear Tracheal Tube, oral/nasal, cuffed		KME21A2141, KME21A2473, KME21A2474, KME21A2664, KME21A2724, KME21A3242, KME21B0163, KME21B0192, KME21B0239, KME21B0345, KME21B0791, KME21B0809, KME21B0960, KME21B1116, KME21B1153, KME21B1687, KME21B1965, KME21B2168, KME21B2324, KME21B2547, KME21B2724, KME21C1395, KME21C1629, KME21C2070, KME21C2436, KME21C2569, KME21C2763, KME21C2846, KME21C2874, KME21C3025, KME21C3175, KME21C3206, KME21D0067, KME21D0561, KME21D0717, KME21D0845, KME21D1116
	112480-000085	KME21A1805, KME21A2340, KME21A2472, KME21A2526, KME21B0982, KME21B1035, KME21B1279, KME21B1650, KME21B2857, KME21B2896, KME21B2929, KME21C1901, KME21D1252, KME21D1401, KME21D1484
	112480-000090	KME21A1275, KME21A1806, KME21A2062, KME21A3072, KME21C0265, KME21C0556, KME21C0868, KME21C1808, KME21C1900, KME21C2664, KME21D1538
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	112480-000100	KME21A2687, KME21B0979, KME21B1212, KME21B1277, KME21C1207, KME21D0590, KME21D0925
Ruschelit® Super Safety Clear Tracheal Tube, oral/nasal, cuffed	112482-000050	KME21A0753, KME21A1152, KME21A1280, KME21A2564, KME21A3116, KME21B0550, KME21B1155, KME21B1255, KME21B1818, KME21B1901, KME21B2169, KME21B2546, KME21B2858, KME21C0065, KME21C0181, KME21C0183, KME21C0185, KME21C2824, KME21D0137, KME21D0185, KME21D0322, KME21D0644, KME21D0712
	112482-000055	KME21A0395, KME21A0638, KME21A1153, KME21A1879, KME21A2143, KME21A2565, KME21A3000, KME21B0422, KME21B0710, KME21B1590, KME21B1819, KME21B1902,

		KME21B2257, KME21B2820, KME21B2927, KME21C0499, KME21C0631, KME21C1326, KME21C2825, KME21C3168, KME21C3207, KME21C3325, KME21D0138, KME21D0212, KME21D0503, KME21D1476
	112482-000060	KME21A1021, KME21A1022, KME21A1276, KME21A2013, KME21A2730, KME21A3254, KME21B0060, KME21B1271, KME21B1626, KME21B1744, KME21B1944, KME21B2166, KME21C0071, KME21C0364, KME21C0484, KME21C1329, KME21C1443, KME21C2189, KME21C2397, KME21C2437, KME21C3169, KME21D0410, KME21D0990, KME21D1036, KME21D1152, KME21D1251, KME21D1464, KME21D1465
	112482-000065	KME20M2668, KME21A0919, KME21A1023, KME21A1107, KME21A1277, KME21A1814, KME21A1916, KME21A1938, KME21A2169, KME21A2470, KME21A2663, KME21A3078, KME21A3255, KME21B1185, KME21B1256, KME21B1273, KME21B1718, KME21B1741, KME21B1814, KME21B2002, KME21B2096, KME21B2167, KME21B2260, KME21B2545, KME21B2725, KME21C0009, KME21C0363, KME21C1227, KME21C1388, KME21C1479, KME21C1600, KME21C1747, KME21C1748, KME21C1899, KME21C2139, KME21C2286, KME21C2398, KME21C2492, KME21C2909, KME21C3027, KME21C3054, KME21C3145, KME21C3170, KME21C3430, KME21C3454, KME21C3517, KME21D0057, KME21D0345, KME21D0489, KME21D0633, KME21D0713, KME21D1118, KME21D1250
Ruschelit® Super Safety Clear Tracheal Tube, oral/nasal, cuffed	112482-000070	KME21A0600, KME21A0860, KME21A0861, KME21A0918, KME21A0982, KME21A1105, KME21A1278, KME21A1290, KME21A1412, KME21A1425, KME21A1490, KME21A1501, KME21A1584, KME21A1696, KME21A1860, KME21A1861,

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<p>Ruschelit® Super Safety Clear Tracheal Tube, oral/nasal, cuffed</p>	<p>112482-000075</p>	<p>KME21A0267, KME21A0694, KME21A0731, KME21A0924, KME21A0926, KME21A0984, KME21A1106, KME21A1154, KME21A1251, KME21A1330,</p>

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KME21A1915, KME21A1939,
KME21A1942, KME21A2034,
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KME21A2456, KME21A2608,
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KME21C2024, KME21C2153,
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Ruschelit® Super Safety Clear Tracheal Tube, oral/nasal, cuffed	112482-000080	KME21A0394, KME21A0635, KME21A0737, KME21A0985, KME21A1018, KME21A1091, KME21A1098, KME21A1157, KME21A1394, KME21A1427, KME21A1428, KME21A1479, KME21A1581, KME21A1760, KME21A1801, KME21A1877, KME21A1943, KME21A2011, KME21A2057, KME21A2174, KME21A2175, KME21A2466, KME21A2529, KME21A2611, KME21A2731, KME21A2843, KME21A2892, KME21A3071, KME21A3114, KME21A3115, KME21A3193, KME21A3257, KME21B0156, KME21B0292, KME21B0501, KME21B0511, KME21B0629, KME21B0756, KME21B0764, KME21B1036, KME21B1275, KME21B1528, KME21B1564, KME21B1632, KME21B1743, KME21B1817, KME21B1943, KME21B2050, KME21B2088, KME21B2094, KME21B2694, KME21B2718, KME21B2785, KME21C0005, KME21C0087, KME21C0308, KME21C0407, KME21C0444, KME21C0568, KME21C0632, KME21C0666, KME21C0911, KME21C0966, KME21C1039, KME21C1182, KME21C1205, KME21C1226, KME21C1394, KME21C1455, KME21C1476, KME21C1635, KME21C1706, KME21C1782, KME21C1846, KME21C1902, KME21C2193, KME21C2440, KME21C2493, KME21C2571, KME21C2616, KME21C2638, KME21C2678, KME21C2768, KME21C2769, KME21C3051, KME21C3111, KME21C3301, KME21C3318, KME21C3393, KME21D0019, KME21D0165, KME21D0229, KME21D0305, KME21D0341, KME21D0760, KME21D0928, KME21D0968, KME21D0989, KME21D1410, KME21D1534
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Ruschelit® Super Safety
Clear Tracheal Tube,
oral/nasal, cuffed

	KME21B0425, KME21B0516, KME21B0836, KME21B0883, KME21B1019, KME21B1258, KME21B1344, KME21B1634, KME21B2097, KME21B2476, KME21B2652, KME21C1206, KME21C1700, KME21C2267, KME21C2338, KME21C2356, KME21C2402, KME21C2498, KME21C2521, KME21C2618, KME21C2829, KME21C2873, KME21D0411, KME21D0718, KME21D0847, KME21D0992, KME21D1154
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112482-000100	KME21A2729, KME21A3243, KME21B0967, KME21B1254, KME21B2326, KME21D0587, KME21D0969, KME21D1133, KME21D1223, KME21D1224
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112482055LA	KME21C0591, KME21D1270
112482060LA	KME21C1442, KME21C2959
112482065LA	KME20M1333, KME21C3026
112482070LA	KME21B1898, KME21B1959, KME21B1998, KME21B2048, KME21C2847, KME21C3052, KME21C3110
112482075LA	KME20M0908, KME21B2049, KME21B2576, KME21C2828, KME21C2995, KME21C3018, KME21C3071, KME21C3107, KME21C3269
112482080LA	KME20M0891, KME21B2472, KME21B2648, KME21C2721, KME21C2787, KME21C2910, KME21C2988, KME21C3028
112482085LA	KME21B1900, KME21B2475, KME21C2958, KME21D0183, KME21D0306, KME21D0758, KME21D0922, KME21D1039
112482090LA	KME21D0182, KME21D0878, KME21D0987
112482095LA	KME21C0867

Super Safety Clear Flexiset
Tracheal tube, oral/nasal,
with cuff and insertion aid

112481-000050	20DT14, 20DT29, 20DT37, 20ET08, 20FT10, 20FT18, 20GT25, KME20H0523, KME20H1286, KME20H1940, KME20H3040, KME20J2865, KME20J3125, KME20K3588, KME20M0842, KME21A2789, KME21A2790, KME21C0016, KME21C1975, KME21C1976, KME21D0625, KME21D1080
112481-000055	20DT37, 20FT39, 20GT06, KME20H2241, KME20H2784, KME20H3041, KME20K0161, KME20K0162, KME20K0760, KME20L1489, KME20M0790, KME20M3271, KME21A2792, KME21C1183, KME21C1195, KME21C2740
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112481-000070	20DT22, 20ET08, 20ET37, 20ET49, 20FT18, 20FT39, 20FT44, 20FT61, 20FT65, 20GG41, 20GG45, 20GT06, 20GT14, 20GT25, 20GT31, KME20G0054, KME20H0252, KME20H0384, KME20H0778, KME20H1938, KME20H1939, KME20H2154, KME20H3042, KME20H3043, KME20J1577, KME20J1689, KME20J2867,

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<p>Super Safety Clear Flexiset Tracheal tube, oral/nasal, with cuff and insertion aid</p>	<p>112481-000075</p>	<p>20DT09, 20DT22, 20DT29, 20ET08, 20ET37, 20ET49, 20FT18, 20FT23, 20FT44, 20FT54, 20FT61, 20FT65, 20GT06, 20GT14, 20GT25, 20GT38, KME20G0055, KME20G0188, KME20H2248, KME20J1581, KME20J1583, KME20J1933, KME20J2423, KME20J2424, KME20J2425, KME20J2980, KME20J3132, KME20J3133, KME20J3135, KME20K0023, KME20K0120, KME20K0150, KME20K1757, KME20K2463, KME20K2876, KME20K3002, KME20K3003, KME20L0180, KME20L0622, KME20L1871, KME20L2218, KME20L2300, KME20L2301, KME20M0800, KME20M1107, KME20M1251, KME20M2582, KME21A0226, KME21A2338, KME21A2840, KME21A3118, KME21B1249, KME21B1872, KME21B2028, KME21B2859, KME21C0452, KME21C1197, KME21C2151, KME21C2544, KME21C3359, KME21C3390, KME21D0699</p>
	<p>112481-000080</p>	<p>20DT14, 20DT22, 20ET04, 20ET08, 20ET21, 20ET28, 20ET37, 20ET39, 20ET49, 20FT10, 20FT39, 20FT44, 20FT61, 20GT06, 20GT14,</p>

		<p>20GT25, 20GT31, 20GT49, KME20G0243, KME20G0244, KME20G0245, KME20G0382, KME20G0392, KME20G0394, KME20G0396, KME20G0397, KME20H0380, KME20H0381, KME20H0387, KME20H0524, KME20H0525, KME20H0526, KME20H0527, KME20H0528, KME20H0529, KME20H0530, KME20H0779, KME20H1542, KME20H1543, KME20H1652, KME20H1792, KME20H1936, KME20H1937, KME20H2249, KME20H2250, KME20J0158, KME20J1697, KME20J1698, KME20J2181, KME20J2183, KME20J2403, KME20J2870, KME20K0024, KME20K0025, KME20K0362, KME20K1758, KME20K2251, KME20K2252, KME20K2364, KME20K3005, KME20K3354, KME20K3567, KME20L0181, KME20L2219, KME20L2257, KME21A1293, KME21A1323, KME21A1325, KME21A2144, KME21A2145, KME21A2510, KME21A2842, KME21A3112, KME21B0395, KME21B1899, KME21B1938, KME21B2279, KME21B2355, KME21C0750, KME21C1169, KME21C1170, KME21C2034, KME21C2071</p>
<p>Super Safety Clear Flexiset Tracheal tube, oral/nasal, with cuff and insertion aid</p>	<p>112481-000085</p>	<p>20DT14, 20DT29, 20ET08, 20ET37, 20FT10, 20FT44, 20FT54, 20FT65, 20GT25, 20GT38, KME20H1103, KME20J1578, KME20J1579, KME20J2255, KME20J2256, KME20K2189, KME20K2368, KME20K2505, KME20K2921, KME20K3107, KME20K3150, KME20K3568, KME20L1474, KME20L2031, KME20L2729, KME20M2370, KME20M2484, KME20M3251, KME20M3252, KME21A0187, KME21A2357, KME21B0340, KME21B1252, KME21B2030, KME21C1595, KME21C1597</p>
	<p>112481-000090</p>	<p>KME21A0753, KME21A1152, KME21A1280, KME21A2564, KME21A3116, KME21B0550, KME21B1155, KME21B1255,</p>

		KME21B1818, KME21B1901, KME21B2169, KME21B2546, KME21B2858, KME21C0065, KME21C0181, KME21C0183, KME21C0185, KME21C2824, KME21D0137, KME21D0185, KME21D0322, KME21D0644, KME21D0712
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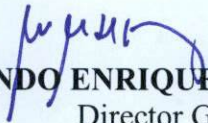
In light of the foregoing, all concerned healthcare professionals, establishments, and the general public are warned to discontinue further use, sale, and distribution of the said affected lots/batch of Rüsç Endotracheal Tube.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that product is not sold or made available in the market or areas of jurisdiction.

Any suspected adverse reaction experienced from the use of the medical device but not limited to the lots/batches stated above should be reported immediately to FDA.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at cdrhr@fda.gov.ph, or call (02) 8857-1900 loc. 8301.

Dissemination of this advisory to all concerned is hereby requested.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN 20211021135043