



**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Stradis Healthcare Unable to Confirm that Women’s Health Devices were Produced According to Design and Manufacture Standards**

Recall Date	Product Description	Recalling Firm	Recall Reason
10/27/2021	<p><b>Medtronic sterile single-use blades that are components of the StraightShot M Series Handpiece and Fusion ENT Navigation Software, and the Midas Rex Microsaw and Triton System</b></p> <p>(1) REF 1882916, RAD 60 Sinus Blade, 11 cm x 2.9 mm; (2) REF 1883514, RAD 12 Curved Sinus Blade, 11 cm x 3.5 mm; (3) REF 1884013, Powered Tonsillectomy Blade, 11 cm x 4 mm; (4) REF 1884020, Tricut Laryngeal Blade, 22.5 cm x 4 mm; (5) REF 1884032, Tracheal Blade, 37 cm x 4 mm; (6) REF 1884033, Tracheal Blade, Angle Tip; (7) REF 1882902HRE, Serrated Blade, 11 cm X 2.9 mm, Rotatable; (8) REF 1882905HRE, Silver Bullet Blade, 11 cm x 2.9 mm, Rotatable; (9) REF 1882924HRE, Skimmer Blade, 27 cm x 2.9 mm, Rotatable; (10) REF 1882936E, Angle-Tip Serrated Blade, 18 cm x 2.9 mm; (11) REF 1882937E, Angle-Tip Serrated Blade, 22 cm x 2.9 mm; (12) REF 1882979HRE, Skimmer Blade, 13 cm x 2.9 mm, Rotatable; (13) REF 1883080HRE, Quadcut Blade, 3.0 mm, Rotatable; (14) REF 1883480HRE, Quadcut Blade, 3.4 mm, Rotatable; (15) REF 1883502HRE, Serrated Blade, 11 cm x 3.5 mm, Rotatable; (16) REF 1883506HRE, RAD 40 Blades, 11 cm x 3.5 mm, Rotatable; (17) REF 1883512HRE, RAD 12 Blade, 11 cm x 3.5 mm, Rotatable; (18) REF 1883516HRE, RAD 60 Blade, 11 cm x 3.5 mm, Rotatable; (19) REF 1884005HRE, Silver Bullet Blade, 11 cm x 4 mm, Rotatable; (20) REF 1884030HRE, Tricut Airway Blade, Angled Tip, 22 cm x 4 mm, Rotatable; (21) REF 1884031HRE, Tricut Airway Blade, Angled Tip, 27 cm x 4 mm, Rotatable; (22) REF 1884033HRE, Tricut Airway Blade, Angled Tip, 37 cm x 4 mm, Rotatable; (23) REF 1884380HR,</p>	<p><b>Medtronic Xomed Inc,</b>            Jacksonville, Florida</p>	<p>There was an increase in complaints related to tip breaks and wobble/vibration.</p>

	Quadcut Blade, 4.3 mm, Rotatable; (24) REF 1884380HRE, Quadcut Blade, 4.3 mm, Rotatable.		
10/27/2021	<p><b>Medtronic sterile single-use blades that are components of the StraightShot M Series Handpiece and Fusion ENT Navigation Software, and the Midas Rex Microsaw and Triton System</b></p> <p>(1) REF 1883080EM, Rotatable Fusion Blade, Quadcut 3.0 mm x 13 cm; (2) REF 1883480EM, Rotatable Fusion Blade, Quadcut, 3.4 mm x 13 cm; (3) REF 1884006EM, Rotatable Fusion Blade, RAD 40; (4) REF 1884012EM, Rotatable Fusion Blade, RAD 12; (5) REF 1884080EM, Rotatable Fusion Blade, Tricut, 13 cm; (6) REF 1884380EM, Rotatable Fusion Blade, Quadcut, 4.3 mm x 13 cm.</p>	<p><b>Medtronic Xomed Inc,</b> Jacksonville, Florida</p>	There was an increase in complaints related to tip breaks and wobble/vibration..
10/27/2021	<p><b>Medtronic sterile single-use blades that are components of the StraightShot M Series Handpiece and Fusion ENT Navigation Software, and the Midas Rex Microsaw and Triton System</b></p> <p>(1) REF 40A2500, Nucleus Removal Angled Blade, 25 cm x 4.0 mm; (2) REF 40R2000, Nucleus Removal Set, 20 cm x 4.0 mm; (3) REF 40R2500, Nucleus Removal Set, 25 cm x 4.0 mm; (4) REF 40S2000, Nucleus Removal Straight Blade, 20 cm x 4.0 mm; (5) REF 40S2500, Nucleus Removal Straight Blade, 25 cm x 4.0 mm; (6) REF 45A2000, Nucleus Removal Angled Blade, 20 cm x 4.5 mm; (7) REF 45A2500, Nucleus Removal Angled Blade, 25 cm x 4.5 mm; (8) REF 45R2000, Nucleus Removal Set, 20 cm x 4.5 mm; (9) REF 45R2500, Nucleus Removal Set, 25 cm x 4.5 mm; (10) REF 45S2000, Nucleus Removal Straight Blade, 20 cm x 4.5 mm; (11) REF 45S2500, Nucleus Removal Straight Blade, 25 cm x 4.5 mm.</p>	<p><b>Medtronic Xomed Inc,</b> Jacksonville, Florida</p>	There was an increase in complaints related to tip breaks and wobble/vibration.

Recall Class	Product Identification	Distribution	Affected Dates
Voluntary	<p><b>Medtronic sterile single-use blades</b> (1) REF 1882916, GTIN/UPN 20763000041223 - Lot/serial numbers 0217968715, 0218283722, 0218283942, 0218356873, 0218356874,</p>	274,991 units Nationwide	August 2021 and prior

0218356875, 0218623544, 0219369113,  
0219501397, 0219700166, 0220118673,  
0220659645, 0220784922, 0220826101,  
0220826102, 0221020300, 0221118606,  
0221118607, 0221118608, 0221198946,  
0221198951, 0221198952, 0221430166,  
0221489935, 0221611652, 0221791819,  
0221791821; (2) REF 1883514, GTIN/UPN  
20763000040967 - Lot/serial numbers  
0218283532, 0218791333, 0219215919; (3) REF  
1884013, GTIN/UPN 20763000041230 -  
Lot/serial numbers 0217969616, 0217969617,  
0218283944, 0218572177, 0219010745,  
0219110914, 0221170726, 0221603993,  
0221783424, 0221791809; (4) REF 1884020,  
GTIN/UPN 20763000040301 - Lot/serial numbers  
0219501396, 0220648062, 0220649166,  
0220892207, 0221156835, 0221271500; (5) REF  
1884032, GTIN/UPN 00763000036140 -  
Lot/serial numbers 0220057395, 0220057397;  
(6) REF 1884033, GTIN/UPN 00763000036447 -  
Lot/serial numbers 0220057389, 0220057390,  
0220057392; (7) REF 1882902HRE, GTIN/UPN  
00763000036720 - Lot/serial numbers  
0217969607, 0218283720, 0218283721,  
0219215912, 0219435041, 0221527810,  
0221969518; (8) REF 1882905HRE, GTIN/UPN  
00763000036782 - Lot/serial numbers  
0217968718, 0217968719, 0218283717,  
0218283719, 0218356097, 0218790225,  
0219215913, 0220177024, 0220659109,  
0220659110, 0220878176, 0221091604,  
0221091605, 0221118614, 0221258284,  
0221527812, 0221611654; (9) REF  
1882924HRE, GTIN/UPN 00763000036744 -  
Lot/serial numbers 0220057236, 0220057237,  
0220057238, 0220057239, 0220057241,  
0220057242, 0220057243, 0220057244,  
0220560777, 0220659671, 0220878169,  
0221072336, 0221156836, 0221275006,  
0221611653, 0221619324, 0221791822; (10)  
REF 1882936E, GTIN/UPN 00763000036799 -  
Lot/serial numbers 0218377217, 0219660525;  
(11) REF 1882937E, GTIN/UPN  
00763000036805 - Lot/serial numbers  
0218377221, 0219661147, 0221279640; (12)  
REF 1882979HRE, GTIN/UPN 00763000033552  
- Lot/serial numbers 0217970486, 0217970490,  
0218162629, 0218547894; (13) REF  
1883080HRE, GTIN/UPN 00763000033989 -  
Lot/serial numbers 0217261083, 0217261084,  
0217261085, 0218354891, 0218421177,  
0218790160, 0219036457; (14) REF  
1883480HRE, GTIN/UPN 00763000033996 -  
Lot/serial numbers 0217261083, 0217261084,  
0217261085, 0218354891, 0218421177,  
0218790160, 0219036457; (15) REF  
1883502HRE, GTIN/UPN 00763000036713 -  
Lot/serial numbers 0217666178, 0217666179,  
0218356088, 0218356089, 0218790221,  
0219215911, 0219435040, 0220929595,  
0221072335, 0221110715, 0221110717,  
0221118531, 0221182357, 0221468015; (16)  
REF 1883506HRE, GTIN/UPN 00763000037376  
- Lot/serial numbers 0217666180, 0217666181,

0217667208, 0218356103, 0218790743,  
0219728474, 0220070439, 0220118669,  
0220158600, 0220484568, 0221119048,  
0221258278, 0221468019, 0221611257,  
0221611258; (17) REF 1883512HRE, GTIN/UPN  
00763000037369 - Lot/serial numbers  
0218356098, 0218356099, 0218356100; (18)  
REF 1883516HRE, GTIN/UPN 00763000037383  
- Lot/serial numbers 0217665427, 0217665428,  
0217665429, 0217666173, 0217666174,  
0217666175, 0217666176, 0217666177,  
0218572169, 0219699597, 0219728468,  
0219728469, 0219848777, 0219848778,  
0219848779, 0219859949, 0220124591,  
0220124592, 0220124593, 0220266094,  
0220313525, 0220313606, 0220313607,  
0220313608, 0220313609, 0220313610,  
0220313611, 0220313612, 0220484569,  
0220484570, 0220891745, 0220892206,  
0221111087, 0221111089, 0221111092,  
0221111093, 0221118545, 0221261887,  
0221271501, 0221279626, 0221279627,  
0221477061, 0221477062, 0221477063,  
0221477064, 0221611647, 0221611648,  
0221611649, 0221791908, 0221791910,  
0221791911; (19) REF 1884005HRE, GTIN/UPN  
00763000036737 - Lot/serial numbers  
0217968722, 0218161789, 0218161790,  
0218356090, 0218790222; (20) REF  
1884030HRE, GTIN/UPN 00763000036751 -  
Lot/serial numbers 0219968104, 0220031839,  
0220031841, 0220031842, 0220031843,  
0220484572, 0220560783, 0221118618,  
0221258283, 0221468017, 0221698794,  
0222008093; (21) REF 1884031HRE, GTIN/UPN  
00763000036768 - Lot/serial numbers  
0219968105, 0220032167, 0220032168,  
0220032169, 0220468850, 0220583927,  
0220934514, 0221072334, 0221279641,  
0221792010, 0222008095; (22) REF  
1884033HRE, GTIN/UPN 00763000036775 -  
Lot/serial numbers 0220057245, 0220057386,  
0220057387; (23) REF 1884380HR, GTIN/UPN  
20763000038162 - Lot/serial numbers  
0217261579, 0217261580, 0217261581,  
0217261582, 0217911696, 0217911698,  
0217968713, 0218283533, 0218356295,  
0218356302, 0218356303, 0218356304,  
0218356305, 0218356866, 0218356867,  
0218356870, 0218356871, 0218356872,  
0218404708, 0218404710, 0218572170,  
0218572171, 0218572172, 0218572173,  
0218572174, 0218572175, 0218653925,  
0218655886, 0218655887, 0218655888,  
0218790744, 0218790745, 0218791326,  
0218791327, 0218791328, 0218791329,  
0218791330, 0218791331, 0218791332,  
0219215917, 0219423535, 0219488214,  
0219488215, 0219488216, 0219488217,  
0219488218, 0219501398, 0219501399,  
0219501400, 0219501401, 0219550301,  
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0219569001, 0219594771, 0219594772,  
0219594773, 0219619651, 0219632566,  
0219632567, 0219679070, 0219679071,

	<p>0219679075, 0219679076, 0219707520, 0219745043, 0219745044, 0219745286, 0219810724, 0219810725, 0219811246, 0219884815, 0219890990, 0220659889, 0220772116, 0220827732, 0220827733, 0220880530, 0220907638, 0220907639, 0220907640, 0220907641, 0220907642, 0220907643, 0220907644, 0221072339, 0221111098, 0221111099, 0221118616, 0221118617, 0221242884, 0221242885, 0221252436, 0221252970, 0221275018, 0221281290, 0221349775, 0221477148, 0221489408, 0221489409, 0221603994, 0221611646, 0221618122, 0221618123, 0221618124, 0221618125, 0221619306, 0221619307, 0221619308, 0221735536, 0221735537, 0221791815, 0221793344, 0221805399, 0221805400, 0221805401, 0221824456, 0221824458, 0222006442, 0222007433, 0222007434, 0222007435, 0222007436; (24) REF 1884380HRE, GTIN/UPN 00763000033910 - Lot/serial numbers 0217663791 0217663792, 0217663793, 0217663794, 0217663795, 0217663796, 0218179447, 0218283718, 0218319250, 0218322548, 0219214785, 0219728473, 0220118670, 0220118671, 0221275019, 0221429981, 0221429982, 0221619338, 0221791811, 0221791812.</p>		
Voluntary	<p><b>Medtronic sterile single-use blades</b>  (1) REF 1883080EM, GTIN/UPN 00763000034009, Lot/serial numbers: 0217668426, 0217668430, 0217668431, 0218547904, 0219386765, 0219387546, 0221279639, 0221597049; (2) REF 1883480EM, GTIN/UPN 00763000034016, Lot/serial numbers: 0218355352, 0218355353, 0218355354, 0218548106, 0218975242, 0218975243, 0219488206, 0219810719, 0221111103, 0221275012, 0221367934, 0221597050, 0221791924; (3) REF 1884006EM, GTIN/UPN 00763000043254, Lot/serial numbers: 0217260953, 0217260954, 0217260955, 0217260956, 0217260957, 0217260958, 0217260959, 0217969622, 0217969623, 0217969624, 0217969625, 0217970026, 0217970027, 0218162408, 0218162409, 0218282135, 0218282136, 0218282139, 0218311142, 0218311143, 0218311144, 0218311145, 0218356286, 0218356287, 0218356288, 0218356289, 0218356290, 0218356291, 0218356292, 0218975837, 0219215914, 0219215915, 0219215916, 0219715476, 0219715477, 0219811260, 0220659888, 0220804521, 0220826103, 0220878167, 0220878168, 0220929588, 0220996074, 0221199850, 0221367938, 0221477065, 0221477146, 0221586895, 0221618118, 0221791912, 0222046728, 0222046729; (4) REF 1884012EM,</p>	274,991 units Nationwide	August 2021 and prior

GTIN/UPN 00763000043247, Lot/serial numbers: 0217667211, 0217667212, 0217667213, 0217667214, 0217667215, 0217667216, 0218159075, 0218159076, 0218159077, 0218159452, 0218159453, 0218159455, 0218159456, 0218159457, 0218159458, 0218423331, 0218975832, 0219036454, 0219036455, 0219122536, 0219122537, 0221791915; (5) REF 1884080EM, GTIN/UPN 00763000033842, Lot/serial numbers: 0217258057, 0217258058, 0217258059, 0217258060, 0217258061, 0217258062, 0217258063, 0217922715, 0217922716, 0217968723, 0217968724, 0217968725, 0217969086, 0217969087, 0217969088, 0217969089, 0217969090, 0217969091, 0217969092, 0217969093, 0217969094, 0217969095, 0217969096, 0217969098, 0217969099, 0217969100, 0218351460, 0218351462, 0218351463, 0218351464, 0218351465, 0218354786, 0218354787, 0218354788, 0218354789, 0218496725, 0218569925, 0218572166, 0218572167, 0218577805, 0218578866, 0218578867, 0218578868, 0218761931, 0218761932, 0218761933, 0218761934, 0218761935, 0218761936, 0218772873, 0218795848, 0218795849, 0218795850, 0218795851, 0218962903, 0218972892, 0218972893, 0218972894, 0218972895, 0218972896, 0219090839, 0219180699, 0219214780, 0219214781, 0219214782, 0219214783, 0219214784, 0219434676, 0219488207, 0219745076, 0220804698, 0220929480, 0220929481, 0220929482, 0220929483, 0221091281, 0221111100, 0221279635, 0221430167, 0221476225, 0221477046, 0221477047, 0221477048, 0221477049, 0221477051, 0221619326, 0221619330, 0221619331, 0221619332, 0221619333, 0221619334, 0221784366, 0221786297, 0221791918, 0221805157, 0221805158, 0221824122, 0221824123; (6) REF 1884380EM, GTIN/UPN 00763000034023, Lot/serial numbers: 0217258064, 0217258065, 0217260946, 0217260947, 0217260948, 0217260949, 0217260950, 0217260951, 0217260952, 0217262726, 0218179453, 0218348413, 0218355677, 0218355678, 0218355679, 0218355680, 0218355681, 0218355682, 0218355683, 0218355684, 0218355685, 0218422557, 0218422558, 0218496125, 0218497688, 0218497689, 0218497690, 0218572168, 0218683395, 0218683396, 0218683397, 0218683398, 0218795858, 0218795859, 0218795860, 0218975828, 0218975829, 0218975830, 0219215906, 0219215907, 0219215908, 0219215910, 0219653288, 0219653289, 0219802564, 0219834731, 0219848776, 0219854757, 0219890572, 0219890573, 0220484577, 0220484578, 0220659891, 0220659896, 0220703724, 0220703986, 0220703987, 0220703988, 0220703989,

	0220878170, 0220878171, 0220878172, 0220878173, 0221072337, 0221110719, 0221110720, 0221118536, 0221118537, 0221118538, 0221118539, 0221181704, 0221182518, 0221271504, 0221278671, 0221279628, 0221279629, 0221305678, 0221319087, 0221468021, 0221477059, 0221477060, 0221489745, 0221489926, 0221611261, 0221616348, 0221619315, 0221619316, 0221619317, 0221619318, 0221792011, 0221805165, 0221805386, 0221805388, 0221824447, 0221824448, 0221824449;		
Voluntary	<p><b>Medtronic sterile single-use blades</b></p> <p>(1) REF 40A2500, GTIN/UPN 00763000033835, Lot/serial number 0220002825; (2) REF 40R2000, GTIN/UPN 00763000033866, Lot/serial number 0218179458; (3) REF 40R2500, GTIN/UPN 00763000033798, Lot/serial number 0218299192; (4) REF 40S2000, GTIN/UPN 00763000033873, Lot/serial number 0218179459; (5) REF 40S2500, GTIN/UPN 00763000043193, Lot/serial number 0220226674; (6) REF 45A2000, GTIN/UPN 00763000033880, Lot/serial number 0220443669; (7) REF 45A2500, GTIN/UPN 00763000043223, Lot/serial number 0218323602; (8) REF 45R2000, GTIN/UPN 00763000033897, Lot/serial numbers 0218284087, 0218292178, 0218973633; (9) REF 45R2500, GTIN/UPN 00763000033811, Lot/serial number 0218297618; (10) REF 45S2000, GTIN/UPN 00763000033903, Lot/serial number 0218299193; (11) REF 45S2500, GTIN/UPN 00763000043216, Lot/serial number 0218297619.</p>	274,991 units Nationwide	August 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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