

URGENT FIELD SAFETY NOTICE
Sterile Blade Single-Use Accessories
Recall

August 2021

Medtronic Reference: FA987

Dear Healthcare Professional,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific lot numbers of sterile blade single-use accessories. Navigation blades are being used to aid in accuracy during the procedure if they wobble that accuracy and precision is diminished. A full list of affected products is included in Appendix A.

The sterile blade is a single-use accessory component of the StraightShot M Series handpieces, which are an integral part of the XPS and IPC Systems.

Issue Description:

As of August 01, 2021, Medtronic has received 120 product complaints related to tip breaks and wobble/vibration in this subset of devices.

No patient impact or injury was reported for any of the 51 Wobble/Vibration complaints. Of the 69 complaints for Break/Tip Break, 2 reported interventional radiology being required to confirm no fragments were left behind, 1 reported a minor delay to the procedure, and interventional radiology, 1 reported an endoscope and forceps were used to remove the fragments, and 1 reported that device fragments remained in the patient. No patient impact was reported for the remaining 64 complaints.

Tip breaks or detachment of fragments may cause harm to the patient, cause lack of oxygenation or foreign body reaction if the fragment were to migrate into the patient's airway or be irretrievable. There is also a chance that the tip may impact critical structures such as nerves and arteries. Blade wobble or vibration may also lead to permanent damage if it causes the blade to impact critical structures.

Actions:

- Identify and quarantine all unused affected Medtronic blades listed in Appendix A. An example of the outer label indicating location of Customer Facing Number (CFN) and Lot Number is provided in Appendix B.
- Return all unused affected devices to Medtronic. Your local Medtronic representative can assist you in the return and replacement of this product as necessary.
- This notice must be communicated to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please maintain a copy of this notice in your records (if appropriate).

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Representative.

Sincerely,

Local / BU Manager

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Table 1: Rotatable Serrated Blades (1882902HRE)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
2.9mm Serrated Blade	00763000036720	1882902HRE	0217969607, 0218283720, 0218283721, 0219215912, 0219435041, 0221527810, 0221969518

Table 2: Rotatable Silver Bullet Blades (1882905HRE)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
2.9mm Silver Bullet Blade	00763000036782	1882905HRE	0217968718, 0217968718, 0217968719, 0218283717, 0218283719, 0218356097, 0218790225, 0219215913, 0220177024, 0220659109, 0220659110, 0220878176, 0221091604, 0221091605, 0221118614, 0221258284, 0221527812, 0221611654

Table 3: Non-Rotatable RAD 60 Curved Blades (1882916)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
RAD 60 SINUS BLADE, 2.9MM 3/BX	20763000041223	1882916	0217968715, 0218283722, 0218283942, 0218356873, 0218356874, 0218356875, 0218623544, 0219369113, 0219501397, 0219700166, 0220118673, 0220659645, 0220784922, 0220826101, 0220826102, 0221020300, 0221118606, 0221118607, 0221118608, 0221198946, 0221198951, 0221198952, 0221430166, 0221489935, 0221611652, 0221791819, 0221791821

Table 4: Rotatable Skimmer Blades (1882924HRE)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
SKIMMER Blade 22CM 2.9MM M4	00763000036744	1882924HRE	0220057236, 0220057237, 0220057238, 0220057239, 0220057241, 0220057242, 0220057243, 0220057244, 0220560777, 0220659671, 0220878169, 0221072336, 0221156836, 0221275006, 0221611653, 0221619324, 0221791822

Table 5: Non-Rotatable Serrated Blades (1882936E)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
ANG TIP SERRATED, 18CMX2.9MM	00763000036799	1882936E	0218377217, 0219660525

Table 6: Non-Rotatable Serrated Blades (1882937E)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
ANG TIP SERRATED, 22CMX2.9MM	00763000036805	1882937E	0218377221, 0219661147, 0221279640

Table 7: Rotatable Skimmer Blades (1882979HRE)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
2.9 mm Skimmer® Angle-Tip Blade	00763000033552	1882979HRE	0217970486, 0217970490, 0218162629, 0218547894

Table 8: Rotatable Trackable Quadcut Blades (1883080EM)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
Trackable Quadcut Blade 3.0mm	00763000034009	1883080EM	0217668426, 0217668430, 0217668431, 0218547904, 0219386765, 0219387546, 0221279639, 0221597049

Table 9: Rotatable Quadcut Blades (1883080HRE)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
3.0mm Quadcut Blade	00763000033989	1883080HRE	0217261083, 0217261084, 0217261085, 0218354891, 0218421177, 0218790160, 0219036457

Table 10: Rotatable Trackable Quadcut Blades (1883480EM)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
Trackable Quadcut Blade 3.4mm	00763000034016	1883480EM	0218355352, 0218355353, 0218355354, 0218548106, 0218975242, 0218975243, 0219488206, 0219810719, 0221111103, 0221275012, 0221367934, 0221597050, 0221791924

Table 11: Rotatable Quadcut Blades (1883480HRE)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
3.4mm Quadcut Blade	00763000033996	1883480HRE	0218354892, 0218547901, 0218790209, 0219434900, 0219501394, 0219859948, 0220070443, 0220073722, 0220118769, 0220659679, 0220929475, 0220929476, 0220929477, 0221115259, 0221170624, 0221275017, 0221359897, 0221477053, 0221599106, 0221603991, 0221792015, 0222007858

Table 12: Rotatable Serrated Blades (1883502HRE)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
3.5mm Serrated Blade	00763000036713	1883502HRE	0217666178, 0217666179, 0218356088, 0218356089, 0218790221, 0219215911, 0219435040, 0220929595, 0221072335, 0221110715, 0221110717, 0221118531, 0221182357, 0221468015

Table 13: Rotatable RAD 40 Blades (1883506HRE)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
Rad 3.5mm 40 deg blade	00763000037376	1883506HRE	0217666180, 0217666181, 0217667208, 0218356103, 0218790743, 0219728474, 0220070439, 0220118669, 0220158600, 0220484568, 0221119048, 0221258278, 0221468019, 0221611257, 0221611258

Table 14: Rotatable RAD 12 Blades (1883512HRE)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
Rad 3.5mm 12 deg blade	00763000037369	1883512HRE	0218356098, 0218356099, 0218356100

Table 15: Non-Rotatable RAD 12 Blades (1883514)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
RAD 12 BLADE, 3.5MM 5/BX	20763000040967	1883514	0218283532, 0218791333, 0219215919

Table 16: Rotatable RAD 60 Blades (1883516HRE)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
Rad 3.5mm 60 deg blade	00763000037383	1883516HRE	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

Table 17: Rotatable Silver Bullet Blades (1884005HRE)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
4.0mm Silver Bullet Blade	00763000036737	1884005HRE	0217968722, 0218161789, 0218161790, 0218356090, 0218790222

Table 18: Rotatable RAD 40 Tracking Blades (1884006EM)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
Trackable Rad 4.0mm 40 deg blade	00763000043254	1884006EM	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

Table 19: Rotatable RAD 12 Tracking Blade (1884012EM)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
Trackable Rad 4.0mm 12 deg blade	00763000043247	1884012EM	0217667211, 0217667212, 0217667213, 0217667214, 0217667215, 0217667216, 0218159075, 0218159076, 0218159077, 0218159452, 0218159453, 0218159455, 0218159456, 0218159457, 0218159458, 0218423331, 0218975832, 0219036454, 0219036455, 0219122536, 0219122537, 0221791915

Table 20: Non-Rotatable Tonsillectomy Blades (1884013)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
TONSILLECTOMY Blade 4MM	20763000041230	1884013	0217969616, 0217969617, 0218283944, 0218572177, 0219010745, 0219110914, 0221170726, 0221603993, 0221783424, 0221791809

Table 21: Non-Rotatable RAD Airway Laryngeal Blades (1884020)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
RAD AIRWAY LARYNGEAL BLADE	20763000040301	1884020	0219501396, 0220648062, 0220649166, 0220892207, 0221156835, 0221271500

Table 22: Rotatable Tricut Blades (1884030HRE)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
Tricut Blade 22CM X 4MM,M4	00763000036751	1884030HRE	0219968104, 0220031839, 0220031841, 0220031842, 0220031843, 0220484572, 0220560783, 0221118618, 0221258283, 0221468017, 0221698794, 0222008093

Table 23: Rotatable Tricut Blades (1884031HRE)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
Tricut Blade 27CM X 4MM,M4	00763000036768	1884031HRE	0219968105, 0220032167, 0220032168, 0220032169, 0220468850, 0220583927, 0220934514, 0221072334, 0221279641, 0221792010, 0222008095

Table 24: Non-Rotatable Tracheal Blades (1884032)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
TRACHEAL BLADE,4MM,37CM LENGTH	00763000036140	1884032	0220057395, 0220057397

Table 25: Non-Rotatable Tracheal Blades (1884033)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
TRACHEAL BLADE,CVD TIP,37CM	00763000036447	1884033	0220057389, 0220057390, 0220057392

Table 26: Rotatable Tricut Blades (1884033HRE)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
Tricut Blade,37CM X 4MM,M4	00763000036775	1884033HRE	0220057245, 0220057386, 0220057387

Table 27: Rotatable Trackable Tricut Blades (1884080EM)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
Trackable 4.0mm Tricut Blade	00763000033842	1884080EM	0217258058, 0217258057, 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, 0222196973

Table 28: Rotatable Trackable Quadcut Blades (1884380EM)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
Trackable Quadcut Blade 4.3mm	00763000034023	1884380EM	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

Table 29: Rotatable Quadcut Blade (1884380HR)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
4.3mm Quadcut Blade	20763000038162	1884380HR	0217261579, 0217261580, 0217261581, 0217261582, 0217911696, 0217911698, 0217968713, 0218283533, 0218356295, 0218356302, 0218356303, 0218356304, 0218356305, 0218356866, 0218356867, 0218356870, 0218356871, 0218356872, 0218404708, 0218404710, 0218572170, 0218572171, 0218572172, 0218572173,

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
			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, 0219556484, 0219568999, 0219569000, 0219569001, 0219594771, 0219594772, 0219594773, 0219619651, 0219632566, 0219632567, 0219679070, 0219679071, 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

Table 30: Rotatable Quadcut Blade (1884380HRE)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
4.3mm Quadcut Blade	00763000033910	1884380HRE	0217663791, 0217663792, 0217663793, 0217663794, 0217663795, 0217663796, 0218179447, 0218283718, 0218319250, 0218322548, 0219214785, 0219728473, 0220118670, 0220118671, 0221275019, 0221429981, 0221429982, 0221619338, 0221791811, 0221791812

Table 31: Spine Blades (40A2500)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
ANGLED Blade 4.0MM NUCLEOTOMY	00763000033835	40A2500	0220002825

Table 32: Spine Blades (40R2000)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
NUCLEUS REMOVAL SET 4.0MM	00763000033866	40R2000	0218179458

Table 33: Spine Blades (40R2500)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
NUCLEUS REM SET 4.0MM ML	00763000033798	40R2500	0218299192

Table 34: Spine Blades (40S2000)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
NUCLEUS REMOVAL Blade 4.0MM	00763000033873	40S2000	0218179459

Table 35: Spine Blades (40S2500)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
BLADE STRAIGHT 4.0MM NUCLEOTOMY	00763000043193	40S2500	0220226674

Table 36: Spine Blades (45A2000)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
NUCLEUS REMOVAL ANG 4.5MM	00763000033880	45A2000	0220443669

Table 37: Spine Blades (45A2500)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
BLADE ANGLED 4.5MM NUCLEOTOMY	00763000043223	45A2500	0218323602

Table 38: Spine Blades (45R2000)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
NUCLEUS REMOVAL SET 4.5MM	00763000033897	45R2000	0218284087, 0218292178, 0218973633

Table 39: Spine Blades (45R2500)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
NUCLEUS REM SET 4.5MM ML	00763000033811	45R2500	0218297618

Table 40: Spine Blades (45S2000)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
BLADE NUCLEUS REMOVAL 4.5MM	00763000033903	45S2000	0218299193


Table 41: Spine Blades (45S2500)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
BLADE 4.5MM NUCLEOTOMY	00763000043216	45S2500	0218297619

Appendix B: Examples of Labeling

CFN → REF 1884380EM x1

Rotatable Fusion® Blade, Quadcut®, 4.3 mm x 13 cm



Buchoiz Freehand®
Made in Dominican Republic

Medtronic
Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, CO 80027 USA

Distributed by:
Medtronic Xomed, Inc.
6743 Southpoint Drive North
Jacksonville, FL 32216 USA

STERILE EO ROTATABLE R Only

9999-09-09

LOT 0999999999

M980867A001 A 0001

REF 1884380EM x1

Rotatable Fusion® Blade, Quadcut®, 4.3 mm x 13 cm

CFN → REF 1884380EM x1

Rotatable Fusion® Blade, Quadcut®, 4.3 mm x 13 cm



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REF 1884380EM
LOT 0999999999
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