

Urgent Field Safety Notice

**Covidien Endo GIA™ Auto Suture™ universal articulating loading units
Recall**

August 2020

Medtronic Reference: FA923

Dear Customer / Risk Manager,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific production lots of its
Covidien Endo GIA™ Auto Suture™ universal articulating loading units.
(Item codes 030450, 030451, 030452, 030453, 030454, 030455, 030457, 030458)

Issue Description:

This voluntary recall is being conducted following receipt of one confirmed customer report that the device staples were not properly formed upon application preventing adequate hemostasis. Our investigation identified a potential for a manufacturing assembly error that can contribute to staple malformation. The affected devices were distributed between June 2017 and July 2020. Use of a product with this assembly error may result in incomplete staple formation. In thoracoscopic/laparoscopic cases, this could cause significant hemorrhage including hemothorax and hemoperitoneum potentially requiring an urgent conversion to open surgery. The potential also exists for bleeding, anastomotic leak, pneumothorax or other delayed secondary complications including infection, peritonitis, sepsis and an increased risk of mortality. Manufacturing process improvements have been implemented to remediate this issue.

This voluntary recall affects only the item codes with associated lot numbers listed on Attachment A.

Required Actions:

1. Please immediately quarantine and discontinue use of affected item codes with associated lot numbers listed on Attachment A.
2. Please return affected product as indicated below. All unused products from the affected item codes and associated lot numbers must be returned.
3. If you have distributed the Covidien Endo GIA™ Auto Suture™ universal articulating loading units listed on Attachment A, please promptly forward the information from this letter to those recipients.
4. Complete the Recalled Product Return Form even if you do not have inventory.

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased directly from Medtronic	Please complete the attached Returns Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to the Medtronic contact provided on the verification form.
Purchased from a distributor	Complete all fields on the form and contact your distributor directly to arrange for return of product.	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to your Distributor and to the Medtronic contact provided on the verification form.

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 at <XXXX>.

Sincerely,

Local / BU Manager

Attachment A

Item Code	Description	Lot Number				
030450	Endo GIA™ Auto Suture™ Gray Universal Articulating Loading Unit 30 mm - 2.0 mm	T0A108X	T7H003X	T8D008X	T8K108X	T9G060X
		T0E051X	T7L023X	T8H047X	T8M079X	
		T7G003X	T8D007X	T8K047X	T9F132X	
030451	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 30 mm - 2.5 mm	T0A016X	T8D009X	T8E058X	T8H024X	T9D052X
		T0B130X	T8D010X	T8E069X	T8H025X	T9D149X
		T0D070X	T8D012X	T8H004X	T8H061X	T9E081X
		T7H001X	T8D013X	T8H008X	T8M044X	T9E082X
		T7L024X	T8D041X	T8H009X	T9A032X	T9F133X
		T7L025X	T8D042X	T8H010X	T9A033X	T9G029X
		T8B012X	T8D043X	T8H011X	T9A082X	T9G037X
		T8B013X	T8D044X	T8H012X	T9B039X	T9G085X
		T8C026X	T8D045X	T8H013X	T9B040X	T9G086X
		T8C027X	T8D046X	T8H014X	T9D043X	T9G093X
		T8C045X	T8E049X	T8H022X	T9D050X	T9K069X
		T8C046X	T8E050X	T8H023X	T9D051X	T9M069X
		T8C047X	T8E057X			
030452	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 30 mm - 3.5 mm	T0C085X	T8B048X	T8K049X	T8L087X	T9J072X
		T7H002X	T8B049X	T8K095X	T9G027X	T9J099X
		T7L026X	T8E063X	T8L084X	T9H043X	T9L073X
		T7L027X	T8E064X	T8L085X	T9H115X	T9M016X
		T8B014X	T8E075X	T8L086X	T9H116X	T9M111X
		T8B015X	T8F074X			
030453	Endo GIA™ Auto Suture™ Gray Universal Articulating Loading Unit 45 mm - 2.0 mm	T7F017X	T7J023X	T7L032X	T7L034X	T8L100X
		T7F025X	T7J024X	T7L033X	T7L035X	T9F138X
		T7F026X	T7K020X			
030454	Endo GIA™ Auto Suture Universal Loading Unit 45 mm - 2.5mm	T0A018X	T8B045X	T8E051X	T8L052X	T9E050X
		T0A106X	T8B046X	T8E052X	T8L101X	T9F024X
		T0B131X	T8B047X	T8E065X	T8L131X	T9F037X
		T0D138X	T8C025X	T8E066X	T8L132X	T9F040X
		T0E011X	T8C030X	T8H015X	T8L143X	T9F044X
		T7G001X	T8C031X	T8H016X	T8M080X	T9F045X
		T7H004X	T8C043X	T8H017X	T8M092X	T9F046X
		T7H007X	T8D001X	T8H018X	T8M093X	T9F097X
		T7J025X	T8D002X	T8H049X	T8M094X	T9G031X
		T7K018X	T8D003X	T8J012X	T9A006X	T9G124X
		T7K034X	T8D004X	T8J026X	T9A034X	T9G125X
		T7L022X	T8D005X	T8J039X	T9A035X	T9H041X
		T7L036X	T8D006X	T8J040X	T9A118X	T9H102X
		T7L037X	T8D014X	T8K006X	T9B060X	T9H110X
		T8A058X	T8D015X	T8K008X	T9C023X	T9J071X
		T8A059X	T8D047X	T8L012X	T9C024X	T9J114X
		T8A062X	T8D048X	T8L013X	T9C058X	T9K077X
		T8A063X	T8D049X	T8L014X	T9C059X	T9L021X
		T8A064X	T8D050X	T8L015X	T9D053X	T9L037X
		T8A065X	T8D051X	T8L016X	T9D099X	T9M017X
		T8B001X	T8D052X	T8L049X	T9D124X	T9M018X
		T8B002X	T8D053X	T8L050X	T9D125X	T9C060X
		T8B044X	T8D054X			

Item Code	Material/Part Description	Lot Number				
030455	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 45 mm - 3.5 mm	T0A019X	T7K037X	T8H021X	T8L102X	T9E097X
		T0A105X	T7K038X	T8H050X	T8L103X	T9E098X
		T0A117X	T7K039X	T8J044X	T8M010X	T9F025X
		T0A141X	T7K040X	T8J045X	T9A037X	T9F047X
		T0B132X	T7K041X	T8J060X	T9A128X	T9F048X
		T0C045X	T7L040X	T8K044X	T9B002X	T9F098X
		T0C102X	T7L041X	T8K045X	T9B003X	T9H112X
		T0C128X	T8B042X	T8K046X	T9C065X	T9H146X
		T0D057X	T8B043X	T8K052X	T9C066X	T9K003X
		T0D120X	T8C032X	T8K075X	T9C111X	T9L039X
		T7G002X	T8C033X	T8K076X	T9C145X	T9M029X
		T7H005X	T8E059X	T8K092X	T9D140X	T9M049X
		T7H008X	T8E060X	T8L033X	T9E027X	T9M050X
		T7K036X	T8H020X	T8L099X		
030457	Endo GIA™ Auto Suture™ Universal Loading Unit	T0A104X	T7L042X	T8D056X	T8L032X	T9D044X
		T0C041X	T7L043X	T8E053X	T8L051X	T9D047X
		T0C042X	T7L044X	T8E054X	T8L104X	T9D048X
		T7F018X	T7L045X	T8F041X	T8L105X	T9D049X
		T7F023X	T7L046X	T8F042X	T8M045X	T9D055X
		T7F024X	T7L047X	T8F043X	T9A007X	T9E025X
		T7J006X	T8A005X	T8F075X	T9A008X	T9F051X
		T7J011X	T8A006X	T8J011X	T9B041X	T9H144X
		T7J012X	T8A041X	T8K063X	T9B042X	T9J034X
		T7K030X	T8A042X	T8L028X	T9C067X	T9K078X
		T7K031X	T8C039X	T8L029X	T9C068X	T9K079X
		T7K032X	T8C040X	T8L030X	T9C146X	T9L020X
		T7K033X	T8D055X	T8L031X	T9C157X	T9L034X
030458	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 60 mm - 3.5 mm	T0A013X	T7L050X	T8E048X	T8K051X	T9F118X
		T0A051X	T7L051X	T8E055X	T8K093X	T9G028X
		T0A085X	T7L052X	T8E056X	T8L129X	T9G030X
		T0B025X	T7M021X	T8E061X	T8L130X	T9G038X
		T0B032X	T7M022X	T8E062X	T8M009X	T9G088X
		T0B046X	T8A001X	T8E067X	T8M011X	T9G089X
		T0B047X	T8A002X	T8E068X	T8M097X	T9G090X
		T0B056X	T8A003X	T8F001X	T9A009X	T9G094X
		T0B073X	T8A004X	T8F002X	T9A031X	T9G159X
		T0B081X	T8A045X	T8F026X	T9A056X	T9G160X
		T0C043X	T8A046X	T8F045X	T9A099X	T9H042X
		T0C068X	T8A060X	T8F046X	T9B001X	T9H100X
		T0C069X	T8A061X	T8F047X	T9B004X	T9H101X
		T0C070X	T8B003X	T8F077X	T9B005X	T9H113X
		T0C103X	T8B037X	T8H001X	T9B038X	T9H114X
		T0D054X	T8B038X	T8H002X	T9C007X	T9J030X
		T0D059X	T8B039X	T8H003X	T9C008X	T9J035X
		T0D061X	T8B040X	T8H005X	T9C069X	T9J048X
		T0D115X	T8B041X	T8H006X	T9C070X	T9J073X
		T0E050X	T8C012X	T8H019X	T9C071X	T9J096X
		T7F019X	T8C034X	T8H051X	T9C156X	T9J097X
		T7F021X	T8C035X	T8H052X	T9E030X	T9J098X
		T7F022X	T8C041X	T8H072X	T9E069X	T9K002X
		T7J003X	T8C042X	T8J027X	T9E070X	T9K068X
		T7J004X	T8C044X	T8J038X	T9E071X	T9K104X
		T7J005X	T8D011X	T8J041X	T9E072X	T9K105X
		T7J013X	T8D057X	T8J042X	T9E111X	T9L019X
		T7J020X	T8D058X	T8J058X	T9E119X	T9L074X
		T7J032X	T8D059X	T8J067X	T9E120X	T9L075X
		T7L028X	T8D060X	T8K007X	T9F026X	T9L102X
		T7L029X	T8D061X	T8K009X	T9F049X	T9L103X
		T7L030X	T8D062X	T8K043X	T9F050X	T9M109X
		T7L048X	T8E047X	T8K050X	T9F078X	T9M110X
		T7L049X				

EMEA Kit Descriptions	Affected Lots				
BOX 01KBAR006116V PROC BYPASS 01KBAR0061	0219677912	0218347808	0217944342	0216551116	0216332308
	0219217644	0218328164			
BOX AIWABYPASS GASTRIC BYPASS AIWA CLINI	0218273965	0216418075	0216318316	0216318314	0216277519
	0218133841	0216418074	0216318315	0216318313	0216277518
	0218132278				
BOX AIWABYPASSV2 BOX BYPASS AIWA CLINIC	0219648778	0219316351	0218927176	0218485692	0218485691
	0219636951	0219211072	0218927175		
BOX AIWABYPASSV3 BYPASS AIWA CLINIC V3	0220345676				
BOX BARLIND4NOB ZESTAW BARIATRYCZNY	0219340691				
BOX BARLIND6N ZESTAW BARIATRYCZNY 6N	0219318156				
BOX BOX00053V1 ALTERNATIV KIT APPENDIX	0219972863	0219972862	0219972861	0219972860	
BOX BOX00151V2 TORSBY LGBP	0219719139	0219465076	0219028636		
BOX BOX00172V1 GASTRECTOMIA TUBULAR	0219648779				
BOX BOX00179V1 BYPASS GASTRICO	0219578602				
BOX BOX00210V1 KIT P VORWALDGASTBYPASS	0219628302	0219579680	0219066784		
BOX BOX00483V1 APPENDIX BRUEWER	0220292908	0219940462	0219921686	0219844458	0219726156
	0220116393	0219932161			
BOX BOX00512V1 BYPASSKIT LEGACY	0220216256	0220109712	0219627898	0219627897	0219524461
	0220216255	0220109711			
BOX BOX00555V1 ZESTAW NR 1 MIS V2	0219860000	0219859999	0219859998	0219859997	0219859996
BOX BOX00619V1 GPB BOX MET SONI 39CM	0220313301	0220313300	0220312394	0220312393	
BOX BOX00764V1 LAP COLON LINKS	0220344381	0220234792	0220076974	0220073503	0220073502
	0220313079	0220179783			
BOX BOX00771V1 LAP APPENDIX	0220234791	0220234790	0220077668	0220077667	
BOX BOX00772V1 LAP COL RECHTS OHNE TRO	0220179782	0220073491	0220073490	0220066914	0220066913
BOX BOX00773V1 LAP SIGMA OHNE TROKARE	0220109692	0220109691	0220064625	0220053125	
BOX BOX00794V1 LAP APP KIT	0220353249	0220285408	0220173903	0219970697	0219802821
	0220353248	0220248724	0220135522	0219927122	
BOX BOX1073076GASB1 BBR GASTRIC BYPASS S	0220223665	0217344693	0217162855	0216269069	0215973118
	0220223664	0217207694	0216410105		
BOX BOX1073180APPE1 APPENDIX KIT ZAMS	0218317931	0218195537	0217486472	0217427394	0217427393
	0218228400	0217977370	0217443309		
BOX ENDOSTAPLERY MIS	0220107873	0220107872			
BOX GASTRICOTWLINS GASTRIC BYPASS	0219315063				
BOX HEMICX1 ZESTAW DO HEMICOLECTOMII	0220119082	0219675114	0218238044	0217530983	0217303656
	0219844459	0218361878	0217960205		
BOX KIT00713 KIT BY PASS	0219280062	0218151676	0217336904	0216644672	0216301450
	0218782053	0217834004			

EMEA Kit Descriptions	Affected Lots				
BOX KIT00714 KIT SLEEVE	0219280063	0218535274	0217305933	0216431840	0216301451
	0218719777	0218477757			
BOX KIT1095V KIT OBESITAS	0218366492	0217286987	0217286986		
BOX KIT1171C KIT LAP CYSTECTOMY	0217148829	0217148828	0217081133	0217081132	
BOX KITBAR021A BARIATRIC KIT PRIVATE	0220031307	0219601679			
BOX KITDE0083V2 APPENDEDEKTOMIE KIT NAUE	0220243033	0220205405	0219167820	0219163616	0219075322
	0220205667	0219330570	0219163618	0219076266	
	0220205666	0219179366	0219163617	0219075323	
BOX KITDE0108 BYPASS KIT LUEBECK	0217776125	0217776124	0216671997	0216671996	0216418500
BOX KITDE0108V2 BYPASS KIT	0220055683	0220055684	0218763419		
BOX KITDE0143 BYPASS BOX	0218646589	0218337737	0218042780	0217268505	0216744649
	0218621324				
BOX KITDE0154 BYPASS KH NORTHWEST	0215973342	0215973341			
BOX KITDE0183 APPENDIX LIPPE DETMOLD	0220370129	0220052460	0218377333	0218063041	0217314206
	0220370128	0220052459	0218377332	0218006871	0217314105
	0220312108	0219977233	0218282731	0217745961	0217295181
	0220173900	0219977232	0218282730	0217745960	0217295180
	0220162081	0218419492	0218282729	0217569287	0217198506
	0220086339	0218419491	0218177058	0217569286	0217105047
	0220086338	0218419490	0218143122	0217477017	
BOX KITDE0223 APPENDIX KIT NEUSS	0217384761	0217384760	0217019027	0217019026	0216930627
BOX KITDE0230 LAP BYPASS ELISABETH HALLE	0218679471	0218212081			
BOX KITDE0245 APPENDIX KIT NEUSS	0220285162	0219765390	0219128697	0218407261	0217710289
	0220285161	0219765389	0219066632	0218407260	0217710288
	0220285160	0219765388	0218782193	0218149992	0217710287
	0220285159	0219765387	0218782192	0218013478	0217307333
	0219940842	0219467438	0218782191	0218013477	0217275242
	0219940841	0219467437	0218782190	0218013476	0217150227
	0219940840	0219467436	0218407263	0218013475	0217150226
	0219940839	0219467435	0218407262	0217710290	0217149045
BOX LAPGAR6 ZESTAW GASTRIC BYPASS	0219127984				
BOX LAPIMBGP1 ZESTAW DO MGBP	0218494795	0217814637	0217387125	0217083837	0216978527
	0217903640	0217566139	0217252940	0217016256	0216433821
	0217876074	0217471685	0217252939	0217016255	0216369155
	0217821863	0217471684	0217196286		
BOX LAPISG1 ZESTAW DO SG	0218494797	0218346493	0217876076	0217834054	0216228738
	0218494796	0217914224	0217876075	0216228739	0216067127
	0218435610				
BOX LAPISGW ZESTAW DO SG	0216410953	0216313521	0216241849		
BOX LAPIZD5 ZESTAW DO RESEKCJI MANKIETOW	0218444164	0218444163			
BOX LAPPH ZASTAW DO PRAWEJ HEMIKOLEKTOMI	0219759944	0219759942	0219759941	0219759940	0216455137
	0219759943				
BOX LAPSLEEVEWSZ SLEEVE BOX	0218395652	0217094691			

EMEA Kit Descriptions		Affected Lots			
BOX LAPSLEVEWSZ LAPSLEVEWSZ	0219465082				
BOX LAPZD5 ZESTAW DO RESEKCJI MANKIETOWE	0216399447				
BOX LAPZD7 ZESTAW MANKIETOWE JZOLADKA	0220210650	0220210649	0219511923		
BOX LARCX1 ZESTAW DO NISKIEJ RESEKCJI	0219675115				
BOX LGBPTOR1 LAP GASTRIC BY PASS	0219498527	0219369948	0219369947	0219369946	
BOX LGSLAP ZESTAW DO LAP GASTRIC SLEEVE	0220271073	0219658791	0217321047		
BOX LSGTOR1 LAP SLEEVE GASTRECTOMY	0220249367	0219690522	0219280121	0218486015	0218355434
	0220249366	0219510824	0218918778	0218486014	0218355433
	0220249365	0219280122			
BOX LSGTORI ZESTAW LAP SLEEVE GASTRECTOMY	0220199954	0220199953			
BOX MEDIBAR BARIATRYCZNY SLEEVE	0219294917	0218870835	0218407254	0217827490	
BOX MGBCLOCX1 ZESTAW MINIGASTRIC BYPASS	0220353364	0220353363	0220292458		
BOX MGBGLOCX1 ZESTAW MINIGASTRIC BYPASS	0220119083	0218836471	0218444457	0217775563	0217522273
	0219675116	0218602096	0218354906	0217652915	0217355769
	0218836472				
BOX MGBGLOGX1 ZESTAW MINI GASTRIC BYPASS	0217109707	0216935772			
BOX MGBXL GASTRIC BY PASS LINIOWY	0219759939	0218752584	0218752581	0218463106	0217924905
BOX MGBXL GASTRIC BY PASS LINIOWY	0219759938	0218752583	0218463108	0217929966	0217123006
BOX MGBXL GASTRIC BY PASS LINIOWY	0219759937	0218752582			
BOX MSZSG ZESTAW DO SG	0218223366	0218203480	0217876069	0217840146	0217318029
	0218222985	0217920387	0217855970	0217832725	0217305940
	0218222984	0217884235	0217855969	0217762873	0217305939
	0218203481	0217876070	0217842332	0217762872	
BOX MSZVATSS ZESTAW DO VATS	0219945933	0219049060	0218629101	0218222607	0216672011
	0219743225	0218862247	0218589650	0217788811	0216439913
	0219526386				
BOX NEFLIND ZESTAW NEFREKTOMIA BIALY	0219351252	0218078029	0217974953		
BOX PSK139 ZEST DO MANK RESEKCJI ZOLA	0220179780	0219715133	0219619444	0219346259	0218884676
BOX PSK139 ZEST DO MANK RESEKCJI ZOLA	0220110194				
BOX PSK144 ZEST DO MANKIET RESEK ZOLADKA	0220141676	0219458641			
BOX PSK4VATS1 ZESTAW NR 1 MIS	0219760132	0219154201			
BOX PST01199 BARIATRIC TRISTAPLE	0219621625	0219162035	0218328165	0217216666	0216124930
	0219354432	0218577127	0218023009	0216665650	

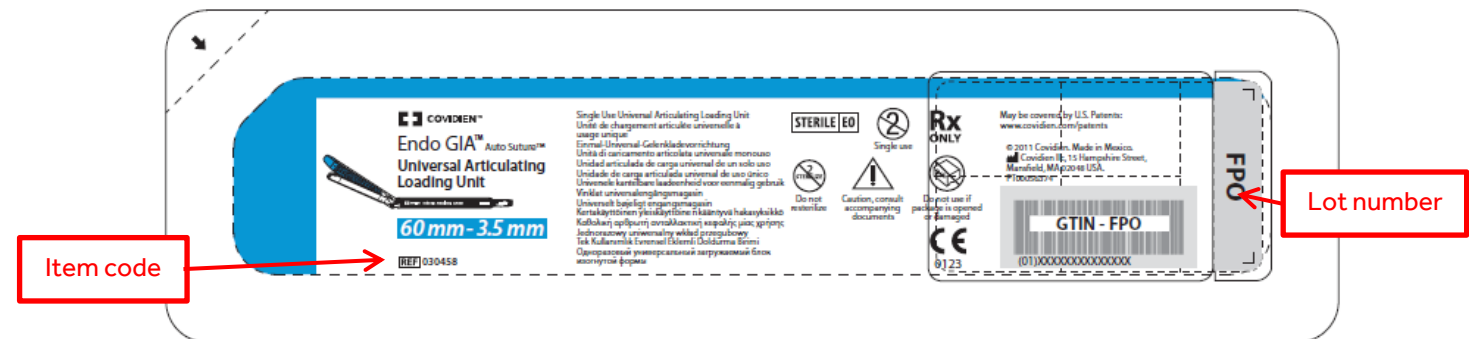
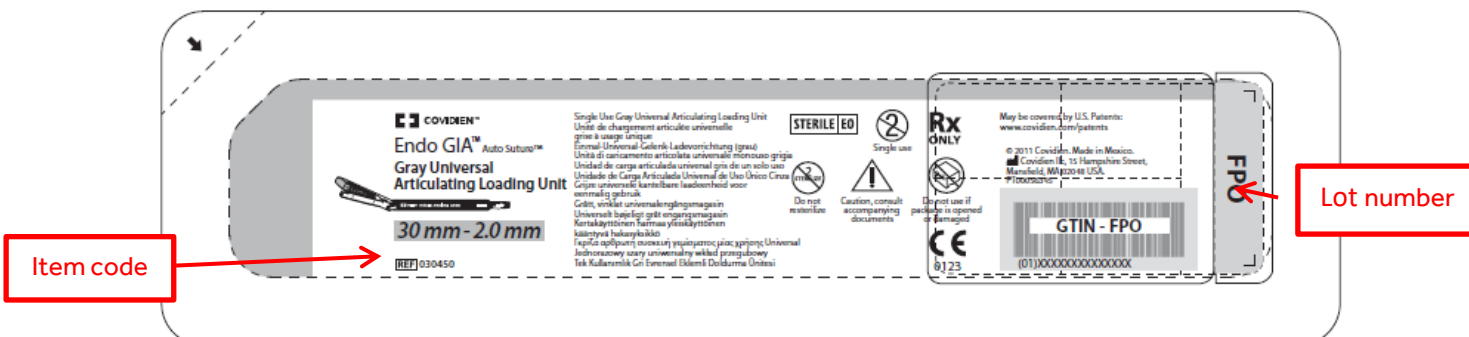
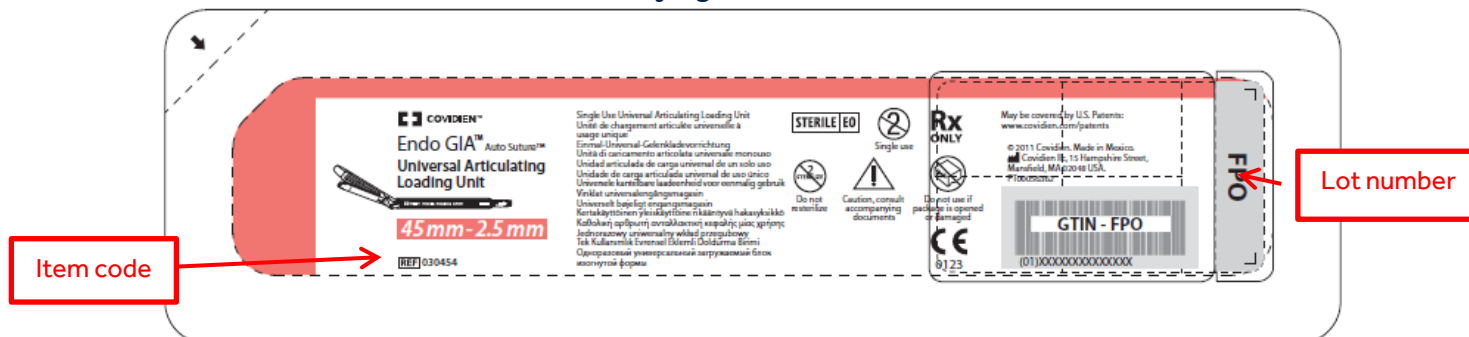
EMEA Kit Descriptions	Affected Lots				
BOX PST03533 KIT APP STAPLER	0219719145	0218782105	0217717074	0217599368	0217119263
	0219719144	0218782104	0217717073	0217599367	0217103557
	0219707335	0218782103	0217710025	0217599366	0217103556
	0219706602	0218782102	0217710024	0217582687	0217092211
	0219696655	0218782101	0217710023	0217574770	0217090294
	0219578595	0218421589	0217710022	0217517087	0217082855
	0219578594	0218421588	0217702265	0217517086	0217082854
	0219214886	0218395577	0217702264	0217516085	0217082853
	0219211505	0218391303	0217692356	0217493818	0217082852
	0219211504	0218281702	0217680681	0217493817	0217024019
	0219137870	0218281701	0217680680	0217493816	0217024018
	0219126838	0218264323	0217680679	0217489566	0217019846
	0219066458	0218264322	0217680669	0217477867	0216964763
	0219066457	0218264321	0217664138	0217195730	0216952845
	0219066456	0217937327	0217664137	0217188006	0216952844
	0219066455	0217788825	0217664136	0217179325	0216657313
	0219066454	0217762725	0217664135	0217155516	0216657312
	0219066453	0217762528	0217664134	0217155515	0216592977
	0218782112	0217762527	0217627876	0217155514	0216592976
	0218782107	0217762526	0217625323	0217155513	0216592975
	0218782106	0217761565	0217599369		
BOX PST03534 KIT LAP APPENDECTOMY	0217672408	0216935374	0216935371	0216737788	0216730664
	0217672407	0216935373	0216935370	0216737787	0216730663
	0217672406	0216935372	0216737789	0216730665	0216730662
	0216935375				
BOX PST03535 KIT APP	0219983401	0219927762	0219810528	0217775561	0217495778
	0219983400	0219927761	0219725304	0217763626	0217495777
	0219983399	0219876380	0219725303	0217702946	0217495776
	0219980357	0219874181	0219636374	0217698505	0217495775
	0219951496	0219817164	0217797192	0217598453	0217495774
	0219951495	0219817163	0217797191	0217598452	0217448753
	0219951342	0219817162	0217797190	0217496908	0217092210
	0219951341	0219817161	0217783456	0217496907	0216928292
BOX PST03699 KIT APP MED ALTERNATIV STAP	0218435293	0217198489	0217033299	0217033296	0217033293
	0218435292	0217178825	0217033298	0217033295	0217033292
	0218435291	0217178824	0217033297	0217033294	0216769316
	0218435290				
BOX PST04089 SLEEVE AIWA CLINIC	0217834093	0216423580	0216423579		
BOX PST04089V2 BOX SLEEVE AIWA CLINIC V2	0219648777	0219636950	0219299299	0219299298	
BOX PST04089V3 SLEEVE AIWA CLINIC V3	0220345675				
BOX PST04090 BYPASS AIWA CLINIC	0215944150				
BOX PST05329 SLEEVE KIT PROF DIETRICH	0220106359	0220106360	0219659807		
BOX PST05912 LAP GBP KIT WO HERNIA AND A	0219763111	0219687499			
BOX PST06244V2 APPENDIX KIT 2020 BRAUNSC	0219672763	0219672762			
BOX PST644348644 KORTE KIT	0216362057				
BOX RAD01 DO RADYKALIZACJI	0219448032	0218337684			
BOX SESLEEVEAX SESLEEVEAX	0219621624	0219396705	0217295083		

EMEA Kit Descriptions	Affected Lots				
BOX SGGLOCX1 ZESTAW DO BARIATRII	0219627135	0219448200	0219431651	0218498741	0217840150
	0219627134	0219433553	0218836474	0218434860	0217303657
	0219511086	0219433552	0218836473	0218354907	
BOX SGNSOLXZ ZESTAW BARIATRYCZNY	0220369261	0220175230	0220175229	0220141443	0219519953
	0220360694				
BOX SLC1 ZESTAW DO BARIATRII	0217863911				
BOX SLC2 ZESTAW DO BARIATRII	0219697900	0219656405	0219374718	0218496669	0218405894
	0219697899				
BOX SLEEVEGK3	0216284902				
BOX SLEEVEGKAXT SLEEVE GASTRECTOMY AXT	0220351759	0220211926	0219355183	0218751566	0218452691
	0220289501	0220180210	0219330671	0218475902	0218451930
	0220211933	0220127716	0218916118	0218461839	0217871335
	0220211932	0219778132	0218916117	0218452692	0217871334
BOX SLEEVEJAW3III SLEEVE GASTRECTOMY KIT	0220186264	0219650226	0219549718	0219340511	0218534121
BOX SLEEVEJAWI SLEEVE GASTRECTOMY BOX	0216109782				
BOX SLEEVEOPLF SLEEVEGASTRECT	0220232707	0219626632	0219487952	0219331062	
BOX SLEEVEOPZ ZESTAW BARIATRYCZNY	0217823836				
BOX SLEEVEOTW BARIATRYCZNY ZESTAW LAP	0219448473	0219356516			
BOX SLH2 ZESTAW DO BARIATRII 2	0218435620	0218435619	0217267518	0216377852	
BOX SLH6 ZESTAW DO BARIATRII 6	0219369960				
BOX SPSK4VATS2 ZESTAW NR 2 MIS	0219884086	0219850877	0219850876	0219850875	0219850874
	0219850879				
BOX TGGLOCX1 DO TOTALNEJ RESEKCJI ZOLADK	0218361879				
BOX TORKIT TORAKOCHIRURGIA ZESTAW	0219426513				
BOX UCKMGBP01 DO MINI GASTRIC BYPASS	0220353358	0220107883	0219510873	0219411143	0218346126
	0220107884				
BOX UCKSG DO SLEEVE GASTECTOMY	0220250209	0220243031	0220107882	0219706579	0219411141
	0220250208	0220180312	0220107881	0219667612	0219318225
	0220243032	0220180311	0219706580	0219411142	
BOX USK001 ZESTAW DO SG	0218421961	0218421960	0218421959		
BOX VATS1LF19X VATS LOBECTOMY	0219932155	0219496016	0219067833	0218550410	0218246920
	0220118269	0219288903	0218671646	0218523305	0216873448
	0219762202				
BOX VATS1SCDX DO ZABIEGOW VATS	0219488478	0216820585	0216565039		
BOX VATSLOB11 ZESTAW DO VATS LOBECTOMII	0220007939	0219720657	0219042929	0218395679	0217824048
	0220007938	0219717783	0219034706	0218395678	0217250401
	0220122865	0219706570	0218874358	0218367322	0217250400
	0220122864	0219414606	0218725641	0218175985	0216716545
	0219760138	0219412965	0218636756	0218175984	0216716544
	0219721175	0219042930	0218636755	0217888966	0216511363
	0219721174				

EMEA Kits Containing Affected Lots (Page 6 of 6)

EMEA Kit Descriptions	Affected Lots				
BOX VATSLOBII ZESTAW DO VATS LOBECTOMII	0219387322	0219386429			
BOX VMIN ZESTAW DO VATS PODSTAWOWY	0219297069	0216222095	0216222094	0216094371	
BOX VMIN2 ZESTAW DO VATS PODSTAWOWY	0216730183	0216339446			
BOX VMIN3 ZESTAW DO VATS PODSTAWOWY	0218544949	0218544948	0218148622	0218148621	
BOX VMINN ZESTAW DO VATS PODSTAWOWY	0219874655	0219768468	0219768029		
BOX VWR ZESTAW DO VATS KLIN	0219612410	0219612408	0218444464	0217775383	0216321530
	0219612409	0218444465	0218113025	0216321531	
BOX WEJGB1 DO MGBP	0219619441	0219404186			
BOX WEJSG1 DO SG	0220292853	0219619442	0218710943	0218364409	0217874161
	0220234793	0219564021			
BOX ZGVATSKLIN1 ZESTAWVATSRESEKCJIKLINOW	0218132184				
KIT00486R OBESIDAD D. WORWARLD 2 X1	0217269675	0216339448			
KIT4184 APEN LOBECTOMY KIT X1	0217959213	0217874162	0217252968		
KITBAR021- BARIATRIC KIT X1	0219671433	0218686808	0217309606		
KIT-DE-0080 BYPASS KIT LOHNE X1	0219650231	0219404193	0217156177	0216776355	0216226592
KIT-DE-0083 APPENEKTOMIE KIT NAUENX1	0219155154	0218281514	0218037139	0217415847	0217132689
	0219155153	0218037234	0217824055	0217227954	0217227952
	0219155152	0218037233	0217761681	0217227953	0216907424
	0218782176	0218037232			
LAPBARLEczNA ZESTAW BARIATRYCZNY LECZNA.	0220334630	0220225684	0218782325	0218364414	0216431540
	0220334629	0219369977	0218364415	0217274718	0216431539
	0220330046	0219369976			
MGBX ZESTAW GB LS X1	0218346506	0217260338	0216003037	0215951407	0215951406
	0217260339	0216003038			
SEGB1A SEGB1A X1	0216214573				
SLEEVEGK1 ZESTAW DO ZABIEGOW SLEEVE X1	0219656402	0219280269			
SSLEEVE ZEST DO SLEEVE GASTREKTOMIIX1	0219759949	0219759946	0218752578	0218346505	0217260336
	0219759948	0219759945	0218752577	0217823594	0216455151
	0219759947	0218752579	0218451939	0217260337	

Identifying Affected Product



Medtronic

Best Practices™
Procedure Kit

Kit Components:

Qty	CFN#	Description
3	030454	030454 ENDO GIA R/OR 45 2.5MM
1	030457	030457 ENDO GIA R/OR 60 2.5MM
1	176674PF	176674PF VISIPOINT PLUS 5-12 W
1	EGIAUXL	EGIAUXL ENDOGIA ULTRA UNIV XL
1	EEAXL2535	EEAXL2535 EEA XL 25MM-3.5
3	EGIA45AMT	EGIA45AMT EGIA 45 ARTIC MED
3	EGIA60AMT	EGIA60AMT EGIA 60 ARTIC MED
1	NONB12STF	NONB12STF NO BLADE 12 STD FIX

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Covidien Inc, 15 Hampshire Street, Mansfield, MA 02048 USA.
Covidien Ireland Limited, IDA Business & Technology Park, Tullamore, Ireland.
www.medtronic.com PT00091508 Page: 1 of 1

Kit Parent Code (REF 00Z2117, LOT 0010241323, 2022-10-31)

RETURN VERIFICATION FORM

FA923: Covidien Endo GIA™ Auto Suture™ universal articulating loading units

Please complete this form and return it to Medtronic even if you do not have affected inventory

[Please insert date the form was sent]

Customer Contact Details	Medtronic Contact Details
Hospital Name:	To: [please insert name]
Covidien/Medtronic Account Number:	
Account Address: Street: Postal Code: City: Department: Contact Person at Point of Collection: Opening Hours: Name of person completing this form:	Address: [please insert Medtronic address]
Telephone:	Telephone: [please insert Medtronic telephone number]
Fax:	Fax: [please insert Medtronic fax number]
E-mail:	E-mail: [please insert contact e-mail address]

Please list the quantity of affected product at your facility, if you have **no** inventory, please tick the box below.

No Inventory (Please tick): ☐

Item Code	Invoice or Despatch Note (if available)	Lot number	Quantity (Eaches or Cases) Please specify

Information for the courier:

Number of parcels to collect: _____

Number of these parcels that weigh more than 45 KG: _____

By signing this form, I confirm that I have read and understand the Urgent Field Safety Notice from Medtronic regarding the Covidien Endo GIA™ Auto Suture™ universal articulating loading units dated August 2020.

I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of the Covidien Endo GIA™ Auto Suture™ universal articulating loading units noted in this letter.

Name: (print)

Signature:

Date:

- Please fax or email this form back to Medtronic within 10 days using the contact details referenced at the top of this form.
- Customer Service will contact you directly to organise return of affected products and credit will be given for returned products.
- Please don't send the goods back before having received the return documentation.