

AŽURIRANA HITNA SIGURNOSNA OBAVIJEST **Artikulirajuća ponovna punjenja Covidien Endo GIA™.**

01. lipanj 2018.

Oznaka Medtronic: FA816

N/r: Direktor odjela za upravljanje rizikom i voditelji opremanja operacijskih dvorana

Poštovani,

ovim vas dopisom želimo obavijestiti o **ažuriranju** našeg priopćenja od svibnja 2018. u vezi s dobrovoljnim povlačenjem određenih proizvodnih serija artikulirajućih ponovnih punjenja Covidien Endo GIA™ od strane tvrtke Medtronic.

Tom povlačenju dodane su dodatne šifre i serije. Sveobuhvatni popis spornih proizvoda nalazi se u Prilogu A ovog dopisa. Dodatne serije označene su zvjezdicom (*).

Opis problema:

Ovo se dobrovoljno povlačenje provodi zbog mogućeg neispravnog sastavljanja uređaja. Upotreba neispravno sastavljenog uređaja može rezultirati neuspjelim stvaranjem linije spajalica pri čemu se tkivo razdvaja, što može dovesti do krvarenja ili curenja luminalnog sadržaja. Tvrtka Medtronic zaprimila je pet prijava o ozljedama povezanim s tim problemom.

Tvrtka Medtronic zahtijeva da odmah prestanete upotrebljavati sporne proizvode navedene u Prilogu A. Sve nekorištene proizvode s navedenim šiframa i iz navedenih serija stavite u karantenu i vratite. Nekorištene proizvode sa spornim šiframa i iz spornih serija potrebno je vratiti na način opisan u odjeljku Potrebne radnje. Ako ste distribuirali uređaje Endo GIA™ navedene u Prilogu A, što hitnije primateljima prosljedite informacije iz ovog dopisa. Sve nekorištene proizvode sa spornim šiframa i one iz spornih serija potrebno je vratiti.

Potrebne radnje:

1. Odmah prestanite upotrebljavati sporne proizvode sa spornim šiframa i iz spornih serija navedenih u Prilogu A i stavite ih u karantenu.
2. Sporne proizvode vratite na niže navedeni način.
3. Popunite obrazac za potvrdu povrata **čak i ako proizvod nemate na zalihama.**

Stranica 1 od 12

	Korisnik sa zalihama	Korisnik bez zaliha	Kamo poslati popunjeni obrazac
Kupljeno izravno od tvrtke Medtronic	Potpuno popunite priloženi obrazac za potvrdu povrata. Po primitku Vašeg obrasca služba za korisnike tvrtke Medtronic javit će Vam se radi organiziranja vraćanja proizvoda. Za vraćene nekorištene uređaje dobit ćete povrat novca.	Popunite obrazac i potvrdite okvir „bez zaliha”.	Pošaljite popunjeni obrazac e-poštom ili telefaksom kontaktu tvrtke Medtronic navedenom na obrascu za potvrdu.
Kupljeno od distributera	Popunite sva polja u obrascu i izravno se obratite distributeru kako biste dogovorili vraćanje proizvoda.	Popunite obrazac i potvrdite okvir „bez zaliha”.	Pošaljite popunjeni obrazac e-poštom ili telefaksom distributeru i kontaktu tvrtke Medtronic navedenom na obrascu za potvrdu.

Nadležno tijelo u vašoj zemlji (HALMED) obaviješteno je o ovoj radnji. Spremite kopiju ove obavijesti u svoju evidenciju. Obratite se tvrtki Medtronic ako imate poteškoća s kvalitetom ili ako dođe do štetnih događaja.

Ispričavamo se zbog mogućih neugodnosti. Sigurnost bolesnika iznimno nam je važna, stoga cijenimo vašu brzu reakciju u vezi s ovim slučajem. Ako imate kakvih pitanja u vezi s ovim priopćenjem, obratite se lokalnom predstavniku tvrtke Medtronic na g. Alen Galic, email: alen.galic@medtronic.com, ili na Medtronic Adriatic doo, Folnegovičeva 1c, 10000 Zagreb, Hrvatska.

Srdačan pozdrav,

Alen Galić

BU Manager MITG, Adriatic region

Medtronic
Regulatory Affairs

Prilog A
Dodatne serije označene su *

Item Code	Description	Affected Lot Numbers			
EGIA45AMT	Endo GIA™ 45 mm Articulating Medium/Thick Reload with Tri-Staple™ Technology	N7L0521KX*	N7M0047KX*	N7M0592KX*	N7M1001KX*
		N7L0975KX*	N7M0434KX*	N7M0683KX*	N8A0203KX*
		N7L1057KX*	N7M0528KX*	N7M0937KX*	N8A0677KX*
		N7L1098KX*	N7M0529KX*	N7M0949KX*	N8C0144KX*
		N7L1099KX*			
EGIA60AMT	Endo GIA™ 60 mm Articulating Medium/Thick Reload with Tri-Staple™ Technology	N7L0711KX*	N7L1141KX*	N7M0853KX*	N8B0419KX*
		N7L0912KX*	N7M0241KX*	N8A0271KX*	N8C0012KX*
		N7L0973KX*	N7M0353KX*	N8A0684KX*	N8C0143KX*
		N7L1038KX*	N7M0366KX*	N8A0924KX*	N7M0996KX*
		N7L0807KX*	N7M0548KX*	N8A1143KX*	N8A0173KX*
		N7L1050KX*	N7M0617KX*	N8B0161KX*	N8A0488KX*
		N7L1125KX*	N7M0745KX*	N8B0283KX*	N8C0136KX*
EGIA60AXT	Endo GIA™ 60 mm Extra Thick Black Articulating Reload with Tri-Staple™ Technology	N7L0974KX*	N7M0486KX*	N7M0762KX*	N8A0363KX*
EGIA60AVM	Endo GIA™ 60 mm Articulating Vascular/Medium Loading Unit with Tri-Staple™ Technology	N7M0045KX*	N7M0398KX*	N8A0523KX*	N8B0088KX*
		N7M0070KX*	N8A0255KX*	N8B0080KX*	
SIG60AXT	Tri-Staple™ 2.0 Black Intelligent Reload for use with Signia™ stapling system 60 mm Extra Thick	N7L0852X*	N7M0130X*	N8A0145X*	N8A0336X*
		N7L0931X*	N7M0639X*	N8A0796X*	N8B0993X*
SIG30AVM	Tri-Staple™ 2.0 Intelligent Reload for use with Signia™ stapling system 30 mm Vascular/Medium	N7L1019X*	N7M0129X*	N7L0734X*	
EGIA45AV	Endo GIA™ 45mm Gray Articulating Vascular Reload with Tri-Staple™ Technology	N7L0823KX*	N8A0799KX*	N8B1008KX*	
EGIA45AXT	Endo GIA™ 45 mm Extra Thick Black Articulating Reload with Tri-Staple™ Technology	N8A0146KX*	N8A0327KX*	N8A0907KX*	
EGIA45AVM	Endo GIA™ 45 mm Articulating Vascular/Medium Loading Unit with Tri-Staple™ Technology	N7L0551KX*	N7M0877KX*		
EGIA45CTAVM	Endo GIA™ 45mm Curved Tip Articulating Vascular/Medium Reload with Tri-Staple™ Technology	N7L1041KX*	N8A0199KX*		
SIG30AMT	Tri-Staple™ 2.0 Intelligent Reload for use with Signia™ stapling system 30 mm Medium/Thick	N7L0915X*	N7M0468X*		
SIG30CTAVM	Tri-Staple™ 2.0 Curved Tip Intelligent Reload for use with Signia™ stapling system 30 mm Vascular/Medium	N7L1163X*	N7M0156X*		
SIG45CTAVM	Tri-Staple™ 2.0 Curved Tip Intelligent Reload for use with Signia™ stapling system 45 mm Vascular/Medium	N7L1049X*	N7M0723X*		
EGIA30CTAV	Endo GIA™ 30mm Gray Curved Tip Articulating Vascular Reload with Tri-Staple™ Technology	N7G0756KX	N7L0819KX*		
EGIA45CTAV	Endo GIA™ 45mm Gray Curved Tip Articulating Vascular Reload with Tri-Staple™ Technology	N7G0796KX	N7L0818KX*		
SIG30CTAV	Tri-Staple™ 2.0 Curved Tip Gray Intelligent Reload for use with Signia™ stapling system 30 mm Extra Thin/Vascular	N7M0128X*			
SIG45AXT	Tri-Staple™ 2.0 Black Intelligent Reload for use with Signia™ stapling system 45 mm Extra Thick	N7M0669X*			
EGIA30AV	Endo GIA™ 30mm Gray Articulating Vascular Reload with Tri-Staple™ Technology	N7G0757KX			

Prilog A
Dodatne serije označene su s *

Item Code	Description	Affected Lot Numbers		
030450	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 30mm- 2.0mm	N7L0306KX	N8B0724KX	N8C1303KRX
		N7M0221KX	N8C0958KX	
030451	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 30mm - 2.5mm	N7L0071KX	N7M0464KX	N8A1014KX
		N7L0527KX	N7M0786KX	N8B0304KX
		N7L0792KX	N8A0154KX	N8C0830KX
		N7L0914KX	N8A0553KX	N8C0847KRX
		N7L1014KX	N8A0850KX	N8C0848KRX
		N7L1159KX		
030452	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 30mm - 3.5mm	N7L0191KX	N8B0234KX	N8C0147KX
		N7M0944KX		
030454	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 45mm - 2.5mm	N7K1146KX	N7M0509KX	N8A0434KX
		N7L0355KX	N7M0520KX	N8A0435KX
		N7L1119KX	N7M0521KX	N8B0487KX
		N7M0088KX	N8A0312KRX	N8C0026KX
		N7M0343KX	N8A0360KX	N8C0119KX
		N7M0477KRX	N8A0433KX	N8C0630KX
030455	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 45mm- 3.5mm	N7F0576KX	N7M0383KX	N8A0324KX
		N7L0032KX	N7M0584KX	N8A0477KRX
		N7L0239KX	N7M0696KX	N8A0551KX
		N7L0519KX	N8A0036KX	N8C0357KX
		N7M0104KX		
030457	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 60mm -2.5mm	N7D0492KRX	N7L0699KX	N8A0213KX
		N7F0518KX	N7L0732KX	N8B0002KX
		N7F0651KX	N7L1043KX	N8C0429KX
		N7L0270KX		
030458	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 60mm - 3.5mm	N7F0631KX	N7M0646KX	N8B0099KX
		N7L0117KX	N7M0740KX	N8C0008KX
		N7L0397KX	N7M0972KX	N8C0205KX
		N7L0465KX	N8A0172KX	N8C0532KX
		N7L0768KX	N8A0539KX	N8C0571KX
		N7L0911KX	N8A0679KX	N8C0758KX
		N7L1075KX	N8A0910KX	N8C0795KX
		N7M0067KX	N8A0961KX	N8C1284KRX
		N7M0314KX	N8B0054KX	

Prilog A
Dodatne serije označene su s *

Item Code	Item Description	Affected Lots			
00KGS003-115	00KGS003-115 KIT ULTRASHORT 60 AMT X1	0214958901*	0214966911*	0215071041*	0215077621*
		0215077622*	0215104936*	0215104937*	0215108745*
00KBAR004-114	00KBAR004-114 KIT BARIATRIQUE	214985527*	0215334151*		
00KBAR019116	BOX 00KBAR019116 BAR 00KBAR019116	0214909769*	0214950780*		
00KGS014115	BOX 00KGS014115 ULTRA XL 60 AXT	0215176646*	0215326555*	0215326556*	0215326557*
		0215325397*			
00KTHO019116	00KTHO019116 KIT THORACIQUE	0214985108*	0214985112*	0214985114*	0215115642*
		0214985111*	0214985113*		
00KVES003-114	00KVES003-114 BOX CHOLE COLON GAUCHEX1	0214956051*			
00KVES019116	00KVES019116 BOX BAR X1	0214909864*	0214925915*	0214951146*	0215029926*
017621	017621 ROTICULATING STAPLING LAR KITX1	0215289614*			
01KBAR006116V	BOX 01KBAR006116V PROC BYPASS 01KBAR0061	0214710711*			
04KVES002115V	04KVES002115V BOX VES002 BYPASS	0215350790*			
BARLINDP	BOX BARLINDP ZESTAW BARIATRYCZNY	0214762745*			
BOX1073076GASB0	BOX BOX1073076GASB0 BBR STEVIT GASTRIC B	0214043771*	0214375093*	0215132607*	215227169
		0214232317*	0215113531*		
BOX1073180APPE1	BOX BOX1073180 APPE1 APPENDIX KIT ZAMS	0214050554*	0214991119*	0215130754*	0215158268*
		0214907029*			
BOX1073180GBYP0	BOX BOX1073180GBYP0 ZAMS GASTRIC BYPASS	0214907030*			
BOX1073445OMEG0	BOX BOX1073445OMEG0 PK JOSEFSTADT OMEGAL	0214785797*			
BOX1113629GBP1	BOX BOX1113629GBP1 GMUNDEN OMEGA LOOP	0214923520*	0215085374*		
BYPASSW2	BYPASSW2 BARIATRIC KIT X1	0214905888*	0214905890*		
		0214905889*			
HEMIGX1	BOX HEMIGX1 ZESTAW DO HEMICOLECTOMII	0214909888*	0214916144*		
K-BE-BAR201-202	K-BE-BAR201-202 KIT BARIATRIC 201-202 X1	0214941743*	0215100567*	0215317546*	
K-BE-BAR239-239	K-BE-BAR239-239 BAR GENERAL 239 X1	0214784975*	0214976184*		
K-BE-LGBP10-100	K-BE-LGBP10-100 LAP GASTRIC BYPASS 10	0215340547*			
K-BE-THO109-109	K-BE-THO109-109 THORAX GENERAL 109 X1	0215009257*			
K-BE-VATS101-10	K-BE-VATS101-10 THORACIC VATS 101 X1	0214915751*			
K-BE-VATS60-601	K-BE-VATS60-601 THORACIC VATS 600 X1	0214795607*	0215051986*		
KIT001006GBP3	KIT001006GBP3 001006 BHS GASTRIC BP	0214881740*			
KIT002019OMEGAV	KIT002019OMEGAV 002019 BARIATRIC OMEGA	0214789304*	0215075886*		
KIT00486R	KIT00486R OBESIDAD D. WORWORLD 2 X1	0213984473*	0213596057*	0213589227*	
		0213583578*	0214068986*	0215350726*	
KIT00542V1	BOX KIT00542V1 KIT GASTRECTOMIA TUBULAR	0214966840*	0215092198*		
KIT00547V	KIT00547V BY PASS TROCAR OPTICO X1	0214785279*	0215059829*		

Prilog A (nastavak)
Dodatne serije označene su s *

Item Code	Item Description	Affected Lots			
KIT00570R1	BOX KIT00570R1 KIT RECTO LAP	0214925462*			
KIT00604B	KIT00604B OBESIDAD SLEEVE -B X1	0214907027*			
KIT00633R	BOX KIT00633R KIT COLON HPE	0214977049*	0214977050*		
KIT1095V	BOX KIT1095V KIT OBESITAS	0214062622			
KIT00713	BOX KIT00713 KIT BY PASS	0214364763	0214456590	0214435328	0214983139
		0215234651	0215288296	0215042012	
KIT00675V	BOX KIT00675V KIT SEGMENTECTOMIA ENDOSCO	0214954169*			
KIT00677	BOX KIT00677 KIT COLON DERECHO	0214954171*	0215117455*		
KIT00678	BOX KIT00678 KIT COLON IZQUIERDO Y RECTO	0214954172*	0215117456*		
KIT00679V	BOX KIT00679V KIT BY PASS GASTRICO	0214954173*	0215117457*		
KIT00714	BOX KIT00714 KIT SLEEVE	0214915642	0214983138	0215159225	0215234652
KIT00725R3	BOX KIT00725R3 KIT COLON DERECHO	0214899872*			
KIT00784	BOX KIT00784 KIT BARIATRICA	0214901583*	0215237561*		
KIT00788	BOX KIT00788 KIT LOBECTOMIA	0214745979*	0214746085*	0214954170*	
KIT00806	BOX KIT00806 KIT BARIATRIC OBESITY	0215083348*			
KIT00879	BOX KIT00879 KIT COLON	0214999114*			
KIT00896	BOX KIT00896 KIT COLON DERECHO	0215035027*			
KIT00897	BOX KIT00897 KIT COLON IZQUIERDO	0215035028*			
KIT1073433OMEGO	BOX KIT1073433OMEGO KIT AKH WIEN OMEGA L	0214793815*	0215066773*		
KIT1082E	KIT1082E GAVLE LG8P X1	0215049715*			
KIT1103V	BOX KIT1103V KIT GASTRIC BYPASS	0214809603*			
KIT1136X	BOX KIT1136X KIT GASTRIC BYPASS	0214789183*			
KIT1146	KIT1146 LAP SLEEVE GASTRECT TRISTAPLEX1	0214763983*	0214916257*	0215350756*	
KIT1152V	BOX KIT1152V KIT LAP GASTRIC BYPASS	0214784971*	0214787298*	0215341606*	
KIT1157A	KIT1157A KAROLINSKA UNIVERS HUDDINGEX1	0214567098*	0214833542*	0214917886*	
KIT1171C	BOX KIT1171C KIT LAP CYSTECTOMY	0214090852	0215153445	0215350563*	0215153445
		0214522213	0215009132		
KIT2948V	BOX KIT2948V KIT GASTRIC BYPASS	0214900223*	0215007432*	0215236666*	0215350551*
KIT2958	KIT2958 LAP. GAST SLEEVE ESBJERG	0214900224*			
KIT4184	KIT4184 APEN LOBECTOMY KIT X1	0214962218			
KIT4226B	KIT4226B LAP GASTRIC BYPASS KIT X1	0214915696*			
KIT4239	KIT4239 LAP SLEEVE GASTRECTOMY KIT X1	0214798691*	0214905637*	0215041899*	
KIT4252	KIT4252 LAP SLEEVE GASTRECTOMY KIT X1	0214781296*	0214876747*		

Prilog A (nastavak)
Dodatne serije označene su s *

Item Code	Item Description	Affected Lots			
KITBAR021	KITBAR021- BARIATRIC KIT X1	0215065486			
KITBAR028	BOX KITBAR028 BARIATRIC KIT 28	0214893704*			
KITBAR030	BOX KITBAR030 BARIATRIC KIT 30	0214918122*			
KITD002	KITD002 DERBY GBP KIT X1	0214994363*			
KIT-DE-0059	KIT-DE-0059 SLEEVE KIT LOHNE X1	0214935169*			
KITDE0066	BOX KITDE0066 LAP BYPASS KIT VAREL	0214763196*	0214917970*	0215124515*	
KIT-DE-0080	KIT-DE-0080 BYPASS KIT LOHNE X1	0214049646	0214370002	0214470664	0214773050*
		0215208426			
KIT-DE-0083	KIT-DE-0083 APPENECTOMIE KIT NAUJENX1	0214618312	0215010930	0215132611	0215264173
		0214795633	0215010931	0215132612	0214798114
		0215002022	0215010932	0215132613	
KIT-DE-0105	KIT-DE-0105 VATS KIT BOGENHAUSEN X1	0214882756*			
KITDE0108	BOX KITDE0108 BYPASS KIT LUEBECK	0214894171			
KITDE0110	KITDE0110 BYPASS KIT WISMAR	0214806940*			
KITDE0119	KITDE0119 OESOPHAGUS KIT OFFENBACH	0214951153*			
KITDE0183	BOX KITDE0183 APPENDIX LIPPE DETMOLD	0214014173	0214573291	0214621781	0214909631
		0215068744	0215068743	0215108744	0215108743
		0215276369			
KITDE0194	BOX KITDE0194 SLEEVE FRANZISKUS KOELN	0214962211*			
KIT-LA0546A	KIT-LA0546A KIT TRISTAPLE COLORETTALE X1	0214901592*			
KITLA0655	KITLA0655 X1	0214985118*			
KITLA0728	BOX KITLA0728 KIT BARIATRICA OLMI 2017	0214745107*	0214924024*		
KITLA0728	BOX KITLA0728 KIT BARIATRICA OLMI 2017	0214924024*	0214745107*		
KITSLEEVEPB	BOX KITSLEEVEPB KIT SLEEVE	0214860889*	0214957130*	0215294319*	
KITSPIREMANNUR	BOX KITSPIREMANNUR MR MANNUR SPIRE KIT	0215200315*	0215201775*	0215217361*	0215236661*
KITW030	KITW030 BP030 X1	0215026388*			
KLGBP110	KLGBP110 LAP GASTRIC BYPASS KIT 110	0214835662*	0215357259*	0215357260*	0215357281*
KLGBP212	KLGBP212 LAP GASTRIC BYPASS 212	0214899358*			
KLGBP224	KLGBP224 LAP GASTRIC BY PASS KIT 224	0215144161*	0215200748*		
LAPBARLECZNA	LAPBARLECZNA ZESTAW BARIATRYCZNY LECZNA.	0214762759*	0214946636*	0215274505	
LAPGAR	BOX LAPGAR ZESTAW DO GB35	0214049704	0214529057		
		0215176564			
LAPIMBGP1	BOX LAPIMBGP1 ZESTAW DO MGBP	0214930629	0215068848	0215124285	0215243237
		0214993038	0215124286	0215130759	0214793818
	BOX LAPISG1 ZESTAW DO SG	0214793817	0215068849	0215124284	0215243236
LAPISG1		0214930628	0214930630	0214993037	
LAPISGW	BOX LAPISGW ZESTAW DO SG	0215120700			

Prilog A (nastavak)
Dodatne serije označene su s *

Item Code	Item Description	Affected Lots			
LAPPH	BOX LAPPH ZASTAW DO PRAWEJ HEMIKOLEKTOMI	0215015272	0215298205		
LAP2D	BOX LAP2D ZESTAW DO SG	0215082707	0215176563		
LSBDG5	BOX LSBDG5 ZESTAW LAP SG	0214761358*			
MBYPASSLHY	BOX MBYPASSLHY MINI BYPASS WITH BLADED T	0214905792*	0214905793*		
MEDIBAR	BOX MEDIBAR BARIATRYCZNY SLEEVE	0214762385*			
MGBGLOGX1	BOX MGBGLOGX1 ZESTAW MINI GASTRIC BYPASS	0215124172	0215253056		
MGBX	MGBX ZESTAW GBLS X1	0215017845	0215002541	0215104507	
PST00532	BOX PST00532 KIT BY PASS TIVOLI	0214824309*	0214966837*	0215025798*	0215086707*
		0214878481*			
PST00740V2	BOX PST00740V2 BOX LGBP KIT CURV	0214806957*	0215051785*	0215062647*	0215263937*
		0214882752*			
PST00826A	BOX PST00826A SLEEVE KIT	0215217362*	0215350554*	0215350555*	
PST00904	BOX PST00904 NCFK GASTRIC SLEEVE	0214768633*			
PST00948	BOX PST00948 SPIRE MURRAYFIELD GASTRIC S	0214902176*	0214966839*	0215350547*	
PST01199	BOX PST01199 BARIATRIC TRISTAPLE	0214109631	0214909770		
PST01299	BOX PST01299 LSC BYPASS KIT	0215020579*			
PST01591	BOX PST01591 SLEEVEKIT SODERTALJE	0214901910*			
PST01594	BOX PST01594 SLEEVEKIT M VERRES	0214893690*	0215036236*	0215274346*	
PST01664	BOX PST01664 KIT GBP REDO DR DONIGA	0214695001*			
PST01672	BOX PST01672 AME NAEF BYPASS KIT	0215019607*			
PST01684	BOX PST01684 VATS	0214762196*			
PST01691A	BOX PST01691A LAP GASTRIC SLEEVE POWER K	0214785795*	0215214418*	0215217841*	
PST01769	BOX PST01769 KIT SLEEVE DRTACCHINO NO CL	0214780416*			
PST01770	BOX PST01770 KIT MINI BYPASS DRTACCHINO	0214780417*	0214922337*		
PST01774	BOX PST01774 KIT SLEEVE DOTT ZANONI	0214780418*			
PST01796	BOX PST01796 KIT BYPASS DR TERRY N	0215318215*			
PST01798	BOX PST01798 KIT GASTRIC SLEEVE	0214772129*			
PST02330	BOX PST02330 LARKITBT4	0215015271*			
PST02403	BOX PST02403 GHP SLEEVE KIT W SIGNIA	0214985087*	0215018852*		
PST02609	BOX PST02609 PHOENIX SLEEVE	0214977044*			
PST02610	BOX PST02610 PHOENIX MINIGBP	0214902178*	0214977046*		
PST02742	BOX PST02742 KIT MINI BYPASS DOTT SCIRET	0214744602*			
PST02775	BOX PST02775 SLEEVE BOX	0214745108*	0214909335*		

Prilog A (nastavak)
Dodatne serije označene su s *

Item Code	Item Description	Affected Lots			
PST02814	BOX PST02814 KIT SLEEVE PELGRIMS	0214946971*			
PST02871	BOX PST02871 BARIATRIE BOX	0214838765*	0215045762*		
PST02995	BOX PST02995 GASTRIC BYPASS BOX	0214895366*	0214982070*	0214982071*	
PST03007	BOX PST03007 LGBP NO TROCARS	0214962212*			
PST03116	BOX PST03116 STG GBP SIGNIA M 5 MAG	0214907372*			
PST03373	BOX PST03373 BAR OLMI SIGNIA 1 VASC	0215115628*	0215217372*		
PST03377	BOX PST03377 SAMARITERHEMMET LAP GBP KIT	0215027677*	0215027678*		
PST03403	BOX PST03403 ALTERNATIVE APPENDIX KIT	0214975597			
PST03427	BOX PST03427 BO KIT GBP SODERTALJE	0215041896*			
PST03435	BOX PST03435 MR GIBSON SLEEVE GASTRECTOM	0214977043*			
PST03441	BOX PST03441 GBP	0214902262*			
PST03464	BOX PST03464 BO GBP KIT ALERIS	0214877236*			
PST03465	BOX PST03465 BO SLEEVE KIT ALERIS	0214877235*			
PST03533	BOX PST03533 KIT APP STAPLER	0215036240	0215068747	0215068746	0215125964
		0215036239	0215068748	0215117409	0215275313
		0215036238	0215050427	0215117411	0215275315
		0215018854	0215102246	0215117410	0215275314
		0215018855	0215050429	0215125963	0215282505
		0215102248	0215050428	0215125962	0215282506
		0215102247	0214860061		
PST03558	BOX PST03558 GBP KIT	0215217373*			
PST03594	BOX PST03594 GASTRIC SLEEVE HH	0214951127*			
PST03699	BOX PST03699 KIT APP MED ALTERNATIV STAP	0215050309	0215050308	0215050313	0215108008
		0215108007	0215050311	0215037144	
		0215050310	0215050312	0215037143	
PST03627	BOX PST03627 BYPASS AIWA CLINIC	0214701832	0214999435		
PST03644	BOX PST03644 SKOVDE LAP SLEEVE KIT	0215037145*			
PST03695	BOX PST03695 MR AHMED SLEEVE	0214904595*			
PST03814	BOX PST03814 RSA SLEEVE KIT	0214956050*			
PST03818	BOX PST03818 MR AHMED BYPASS SIGNIA KIT	0215341609*			
PST03824	BOX PST03824 LAPKOLON LEFT	0214764343*			
PST03978	BOX PST03978 GASTRIC BYPASS LHOOK	0215201095*	0215272696*	0215272698*	0215272699*
		0215272695*	0215272697*		

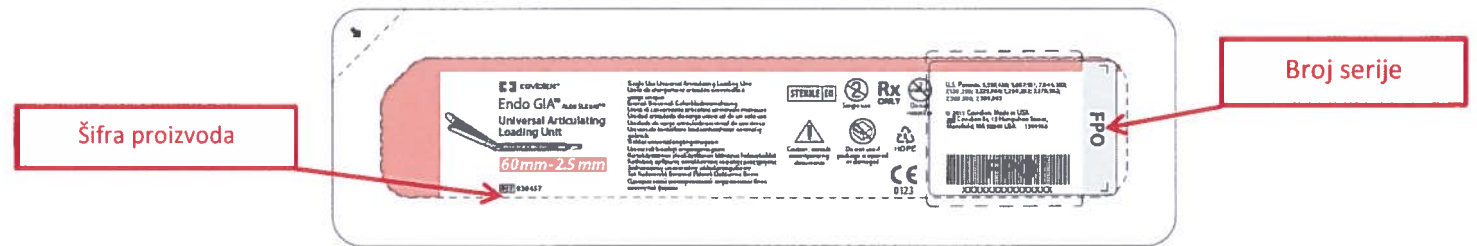
Prilog A (nastavak)
Dodatne serije označene su s *

Item Code	Item Description	Affected Lots			
PST03984	BOX PST03984 SLEEVE KIT	0215341610*			
PST03991	BOX PST03991 SLEEVE KIT	0214907129*			
PST03996	BOX PST03996 NEWLGBP KIT	0215028742*			
PST04044	BOX PST04044 LAP SLEEVE	0214977220*	0214993281*	0214993282*	
PST04045	BOX PST04045 GASTRIC BYPASS	0215237037*	0215237038*	0215237039*	
PST04089	BOX PST04089 SLEEVE AIWA CLINIC	0215237526	0214991350	0215157998	0215157997
		0214991351			
PST04090	BOX PST04090 BYPASS AIWA CLINIC	0215237527	0214991349	0214991348	0214991347
		0215282382			
PST04118	BOX PST04118 MR AHMED SLEEVE KIT	0215227407*	0215247191*	0215247192*	
PST04344	BOX PST04344 LAP SLEEVE GASTRECTOMY	0215291959*			
SGGLOGX1	BOX SGGLOGX1 ZESTAW DO BARIATRII	0214958855*	215017846	0215191012	
SGSWP1	BOX SGSWP1 ZESTAW DO RESEKCIJ REKAWOWEJ	0215218687			
SLEEVEGK1	SLEEVEGK1 ZESTAW DO ZABIEGOW SLEEVEK1	0215244887			
SLEEVEGK3	BOX SLEEVEGK3	0215050387	0215193250		
SLEEVEGK4	BOX SLEEVEGK4 SLEEVE GASTRECTOMY	0214933111			
SSLEEVE	SSLEEVE ZEST DO SLEEVE GASTREKTOMIIX1	0214985253	0215104506	0215298203	
TGGLOGOWX1	BOX TGGLOGOWX1 DO TOTAL GASTRECTOMIII	0214726876			
UCKVATS	BOX UCKVATS ZESTAW DO VATS	0215042113*			
VATS1SCDX	BOX VATS1SCDX DO ZABIEGOW VATS	0214874566	0215001737	0215151361	
VATSLOB11	BOX VATSLOB11 ZESTAW DO VATS LOBECTOMII	214993030	0214866335	0215178525	
VATSMAX1	BOX VATSMAX1 VATS LOBECTOMY KIT	0214785516*	0214893802*	0214956049*	0215068842*
VATSMED1	BOX VATSMED1 VATS LOBECTOMY NIMI KIT	0214833522*			
VMIN	BOX VMIN ZESTAW DO VATS PODSTAWOWY	0215122341	0215226207		
VWR	BOX VWR ZESTAW DO VATS KLIN	0215122344			
KITDE0143	BOX KITDE0143 BYPASS BOX	0214463634	0215280952		
KITDE0154	BOX KITDE0154 BYPASS KH NORTHWEST	0214013887	0214144177	0214260194	0214470767
		0214620382	0214744957	0214956044	0215079103
		0215151206			
SLEEVEJAWI	BOX SLEEVEJAWI SLEEVE GASTRECTOMY BOX	0214030210	0215041719	0215161529	0215272924
00KGS007-115	00KGS007-115 KIT ULTRA STD 60 AMT X1	0214958902	0214958903	0214982072	0214962213
		0214977053	0215299592		

Prilog A (nastavak)
Dodatne serije označene su s *

Item Code	Item Description	Affected Lots			
00KGS008-115	00KGS008-115 KIT ULTRA STD 60 AVM X1	0215228326			
00KGS012-115	00KGS012-115 KIT ULTRA XL 60 AMT X1	0214909779	0214909778	0214904600	0214909777
		0214909861	0214909862	0214909780	0214930402
		0214935167	0214935168	0214938611	0214938612
		0214941733	0214941734	0214962214	0215297695
		0215299496	0215299661		
00KGS013-115	00KGS013-115 KIT ULTRA XL 60 AVM X1	0215350746			
KITDE0140	BOX KITDE0140 VATS KIT	0214755094			
KITDE0141	BOX KITDE0141 VATS KIT	0214710698	0214722466	0214752167	
KITDE0182	BOX KITDE0182 SLEEVE LEVERKUSEN 2017	0214916240			
KITPOWER051	BOX KITPOWER051 KIT BYPASS POWER	0214794532	0215052360	0215066746	0214951122
PST02792	BOX PST02792 KIT SLEEVE BERTOLANISCIRETT	0214780415	0214780414		
SLEEVEKITX	SLEEVEKITX SLEEVE GASTRECTOMY X1	0214946638			

Prilog B



Medtronic

KUNDENSPEZIFISCHE BEHANDLUNGSEINHEIT

REF KITDE0154

Name des Kits

Anzahl	REF	Bezeichnung(s)
1	EQ1AUG7MD	EQ1AUG7MD ENDOGIA ULTRA UNIV ISTD STAPLER
2	Q35458	Q35458 ENDO GIA LHM PLOT AS 3 S DL13
2	Q35458	Q35458 ENDO GIA LHM PLOT AS 3 S DL13
1	U30436	U30436 ENDO GIA LHM PLOT AS 3 S DL13
2	Q36457	Q36457 ENDO GIA PLOT RD 3 S DL13

BOX KITDE0154 BYPASS KH NORDWEST

CE

CE Mark	Manufacturer
CE0123	Covidien Bt
CE0123	Covidien Bt
CE0123	Covidien Bt
CE0123	Covidien Bt
CE0123	Covidien Bt

2018-05-02
YYYY MM DD

2020-05-02
YYYY MM DD

LOT 0114470787

PIN No. KITDE0154

FW NUMBER: M966602A-007 (Rev. A)
German - large
FILE NAME: M966602A007A.PDF

UNIVERSAL LABELSET COVIDIEN CPK M964599A001 Rev.01

COVIDIEN AG, Victor von Brunssstrasse 19, 8212 Neuhausen am Rheinfall, Switzerland

SH-ELF BOX LABEL