

Erakorraline ohutusteatis

Endo GIA™ kirurgilise klammerdamise ühekordselt kasutatavad laadimisseadmed, Tri-Staple™ 2.0 nutikad täitekomplektid ja kassetid Tagasivõtmine

Mai 2019

Ettevõtte Medtronic viide: FA868

Lugupeetud tervishoiutöötaja

Selle kirja eesmärk on teid teavitada, et Medtronic võtab vabatahtlikult tagasi Endo GIA™ kirurgilise klammerdamise ühekordselt kasutatavate laadimisseadmete ja TriStaple™ 2.0 nutikate täitekomplektide ja kassetide teatud tootepartiid.

Probleemi kirjeldus.

Selle vabatahtliku tagasivõtmise põhjuseks on see, et seadmel võib olla puudu üks kahest tihvti komponendist, mis aitab hoida seadme haarasid joondus. Kahjustatud tooteid levitati ajavahemikul 2014. aasta aprill kuni 2019. aasta aprill. Ilma tihvtita seadme kasutamisel võib tekkida moondunud klamber, mis omakorda võib põhjustada verejooksu, anastomoosi leket, peritoniiti või pneumotooraksit, mis võib kaasa tuua nakkuse ja/või sepsise. See võimalik probleem tuvastati tootmiskohas tootmisaegse kvaliteedikontrolli käigus. Probleemi lahendamiseks on tootmisprotsessi täiustatud. Selle probleemiga seoses pole saadud ühtegi kinnitatud kaebust.

See vabatahtlik tagasivõtmine mõjutab ainult lisas A loetletud kauba koode ja partiisid.

Vajalikud toimingud.

1. Peatage viivitamatult lisas A loetletud tootekoodide ja partiidega mõjutatud toodete kasutamine ning pange need karantiini.
2. Tagastage seotud tooted allkirjeldatud viisil. Kõik mõjutatud tootekoodide ja tootepartiide kasutamata tooted tuleb tagastada.
3. Juhul kui olete andnud lisas A toodud Endo GIA™ kirurgilise klammerdamise ühekordselt kasutatavaid laadimisseadmeid ja Tri-Staple™ 2.0 nutikaid täitekomplekte ja kassette kasutamiseks teistele isikutele, edastage neile kiiresti selles kirjas sisalduv teave.
4. Täitke tagastuse kinnitusvorm ka juhul, kui teil endal puudub kaup.

	Kliendid, kellel on vastav toode inventaris	Kliendid, kellel pole vastavat toodet inventaris	Kuhu saata täidetud vorm?
Toode on ostetud otse ettevõttelt Medtronic	Täitke täielikult lisatud tagastatavate toodete kontrolli vorm. Pärast vormi kättesaamist võtab ettevõtte Medtronic klienditeenindus teiega ühendust, et korraldada toodete tagastamine. Anname teile tagastatud kasutamata seadme(te) eest krediiti.	Täitke vorm ja märkige ruut „Pole inventaris“.	Saatke täidetud vorm meili või faksi teel ettevõtte Medtronic kontaktandmetele, mis on toodud kontrolli vormil.
Ostetud edasimüüjalt	Täitke kõik vormi väljad ja võtke ühendust otse oma edasimüüjaga, et korraldada toote tagastamine.	Täitke vorm ja märgistage ruut „kaup puudub“.	Saatke täidetud vorm meili või faksi teel edasimüüjale ja ettevõtte Medtronic kontaktandmetele, mis on toodud kontrolli vormil.

See teatis tuleb edasi anda kõigile, kes teie organisatsioonis peavad seda infot teadma või mis tahes organisatsioonile, kuhu potentsiaalselt kahjustatud seadmed on edasi antud.

Sellest toimingust on teavitatud ka teie asukohariigi pädevat asutust. Säilitage selle teatise koopia oma dokumentatsioonis.

Vabandame võimalike ebamugavuste pärast. Oleme pühendunud patsientide turvalisusele ja oleme tänulikud kiire reageerimise eest. Kui teil on küsimusi või probleeme, võtke ühendust ettevõtte Medtronic kohaliku esindajaga numbril <XXXXXX>.

Lugupidamisega

Kohalik/äriüksuse juht

Kirjaga kaasas olevad dokumendid: Lisa A: mõjutatud toodete nimekiri

Lisa A: mõjutatud toodete nimekiri

Toode	Kirjeldus	Mõjutatud partii					
EGIA30AMT	Endo GIA™ 30 mm Articulating Medium/Thick Reload with Tri-Staple™ Technology	N5A0871KX	N7A0527KX	N7E0441KX	N8J0039KX	N8J0527KX	N8J0820KX
EGIA45AVM	Endo GIA™ 45 mm Extra Thick Black Articulating Reload with Tri-Staple™ Technology	N7K0783KX	N7H0315KX				
EGIA45CTAMT	Endo GIA™ 45 mm Curved Tip Articulating Medium/Thick Reload with Tri-Staple™ Technology	N8L0401KY					
EGIA60AXT	Endo GIA™ 60 mm Extra Thick Black Articulating Reload with Tri-Staple™ Technology	N6B0079KX	N8A0029KX				
EGIA60CTAMT	Endo GIA™ 60 mm Curved Tip Articulating Medium/Thick Reload with Tri-Staple™ Technology	N8L0311KY	N8M0063KY				
SIG30AMT	Tri-Staple™ 2.0 Intelligent Reload for use with Signia™ stapling system 30 mm Medium/Thick	N6E0033UX	N7A0018UX	N7C0238X	N8A0188X	N8E0092X	N8F0819X
		N6H0772UX	N6L0687UX	N7C0470X	N8B0483X	N8E0516X	N8J0440X
		N6H0768UX	N7A0213UX	N7E0496X	N8B0057X	N8E0213X	N8L0589Y
		N6K0522UX	N7A0401UX	N7E1088X	N8B0940X	N8E1178X	N8M0529Y
		N6K0521UX	N6M0399UX	N7F0670X	N8D0649X	N8F0483X	N9A0427Y
		N6K0667UX	N7A0837UX	N7H0962X	N8D0365X	N8F0974X	N9A0050Y
		N6K0668UX	N7B0787UX	N7J0370X			
SIG45AXT	Tri-Staple™ 2.0 Black Intelligent Reload for use with Signia™ stapling system 45 mm Extra Thick	N6E0278UX	N6F0142UX	N6F0340UX	N6G0035UX	N6J0436UX	N6K1110UX
		N6E0176UX	N6F0144UX	N6F0436UX	N6G0036UX	N6K0010UX	N7C0499X
		N6E0584UX	N6F0342UX	N6G0037UX	N6E0587UX	N6K0372UX	N7C0111X
		N6E0589UX	N6F0343UX	N6G0038UX	N6G0125UX	N6K0415UX	N7C0611X
		N6E0590UX	N6F0141UX	N6G0033UX	N6G0744UX	N6K0991UX	N7D0303X
		N6E0975UX	N6F0143UX	N6G0034UX	N6H0757UX	N6K0990UX	N7C0381X
		N6F0341UX					
SIG45CTAMT	Tri-Staple™ 2.0 Curved Tip Intelligent Reload for use with Signia™ stapling system 45 mm Medium/Thick	N6E0296UX	N6L0721UX	N7F1125X	N7M0203X	N8C0854X	N8E1009X
		N6J1035UX	N7A0414UX	N7A0844UX	N7M0759X	N8D0508X	N8E1028X
		N6J1036UX	N7B0401UX	N7H0540X	N8A0152X	N8D1062X	N8J0178X
		N6J1034UX	N7C0194X	N7H1065X	N8A0977X	N8E0561X	N8M0424Y
		N6L0007UX	N7E0781X	N7K0033X	N8A0404X	N8E0932X	N8M0530Y
		N6L0365UX	N7F0551X	N7K0564X	N8B0943X	N8E0989X	N8M0531Y
		N6M0608UX	N7F1021X	N7L0401X	N8C0165X	N8E1006X	
SIG60AXT	Tri-Staple™ 2.0 Black Intelligent Reload for use with Signia™ stapling system 60 mm Extra Thick	N6C0533UX	N6E0977UX	N6E0976UX	N6G0784UX	N6H0302UX	N6K0970UX
		N6C0582UX	N6F0508UX	N6F0049UX	N6G0785UX	N6H0734UX	N6K1067UX
		N6C0657UX	N6F0509UX	N6F0503UX	N6G0786UX	N6H0693UX	N6L0152UX
		N6C0681UX	N6F0758UX	N6F0504UX	N6H0105UX	N6H0909UX	N6M0328UX
		N6E0115UX	N6F0295UX	N6F0505UX	N6H0106UX	N6H0946UX	N7A0170UX
		N6E0116UX	N6F0748UX	N6E0979UX	N6H0107UX	N6G0068UX	N7C0475X
		N6E0978UX	N6F0759UX	N6F0507UX	N6H0173UX	N6J0092UX	N7C1091X
		N6F0045UX	N6F0760UX	N6F0506UX	N6H0298UX	N6J0040UX	N7C1092X
		N6F0046UX	N6F0786UX	N6G0270UX	N6H0299UX	N6G0486UX	N7D0104X
		N6F0047UX	N6F0787UX	N6G0271UX	N6H0155UX	N6H0174UX	N8A0087X
		N6F0048UX	N6F0788UX	N6G0287UX	N6H0156UX	N6K0302UX	N8D0035X
		N6F0050UX	N6G0288UX	N6G0499UX	N6H0157UX	N6H0522UX	N8D0225X
		SIG60CTAMT	Tri-Staple™ 2.0 Curved Tip Intelligent Reload for use with Signia™ stapling system 60 mm Medium/Thick	N6E0295UX	N7A0415UX	N7H0047X	N8A0655X
N6H0576UX	N7C0112X			N7G0444X	N8B0455X	N8D0907X	N8M0845Y
N6J1092UX	N7D1013X			N7H1067X	N8B0945X	N8G0648X	N8L0166Y
N6K0230UX	N7E1089X			N7J0175X	N8C1213X	N8J0764X	N9A0204Y
N6K0938UX	N7F0275X			N7L0825X	N8C0757X	N8K0840Y	N9B0455Y
N6L0777UX	N7F1126X			N8A0249X	N8D0593X	N8L0436Y	N6L0422URX
N6M0607UX							

Lisa A: mõjutatud toodete nimekiri

Toode	Kirjeldus	Mõjutatud partiiinumbrid					
EGIA45AMT	Endo GIA™ 45 mm Articulating Medium/Thick Reload with Tri-Staple™ Technology	N7L1098KX	N5M0172KX	N6M0095KX	N7G0790KX	N7L0132KX	N8D0483KX
		N7M0592KX	N5M0693KX	N6M0113KX	N7H0012KX	N7L0856KX	N8D0594KX
		N8A0203KX	N5M0662KX	N6M0263KX	N7H0347KX	N7L1004KX	N8D0647KX
		N4D0338KX	N5M0732KX	N7A0293KX	N7G0904KX	N7L0475KX	N8D0311KX
		N4D0328KX	N5M0741KX	N7A0792KX	N7H0174KX	N7K1181KX	N8D0536KX
		N4E0846KX	N6A0913KX	N7B0125KX	N7H0470KX	N7K1183KX	N8D0694KX
		N4E0796KX	N6B0332KX	N7B0154KX	N7H0569KX	N7L0811KX	N8D0482KX
		N4E1018KX	N6C0462KX	N7B0177KX	N7H0520KX	N7M0100KX	N8E0435KX
		N4E1059KX	N6D0388KX	N7B0070KX	N7H0315KX	N7M0132KX	N8E0431KX
		N4E0980KX	N6E0078KX	N7B0946KX	N7H0419KX	N7M0506KX	N8E0498KX
		N4E1654KX	N6E0099KX	N7B0905KX	N7H1017KX	N7M0554KX	N8E0659KX
		N4E1173KX	N6E0129KX	N7B0885KX	N7H1057KX	N7M0778KX	N8E0725KX
		N4E1655KX	N6E0366KX	N7C0387KX	N7H1096KX	N7M0589KX	N8E0567KX
		N4E1269KX	N6E0416KX	N7C0442KX	N7H1141KX	N7M0620KX	N8D1045KX
		N4G0523KX	N6D0506KX	N7C0517KX	N7H1187KX	N7M0918KX	N8E0612KX
		N4H0078KX	N6D0474KX	N7C0405KX	N7J0070KX	N7M0614KX	N8E0700KX
		N4G1541KX	N6F0039KX	N7C0775KX	N7J0099KX	N7M1000KX	N8E0149KX
		N4J0215KX	N6F0088KX	N7C0812KX	N7H0957KX	N7K0904KX	N8E0201KX
		N4J0250KX	N6F0156KX	N7C0899KX	N7J0135KX	N7M0967KX	N8D1067KX
		N4J0271KX	N6F0720KX	N7C0857KX	N7J0174KX	N8A0380KX	N8F0094KX
		N4J1002KX	N6F0780KX	N7C0927KX	N7H0712KX	N8A0381KX	N8F0307KX
		N4J1247KX	N6F0816KX	N7C0977KX	N7H1175KX	N8A0772KX	N8F0183KX
		N4J1217KX	N6G0243KX	N7D0135KX	N7J0483KX	N8A0960KX	N8F0258KX
		N4K1465KX	N6G0280KX	N7D0247KX	N7H0786KX	N8A1028KX	N8F0335KX
		N4M0921KX	N6G0198KX	N7C0485KX	N7J0550KX	N8A1050KX	N8F0347KX
		N5B0340KX	N6G0139KX	N7D0101KX	N7J0508KX	N8A0065KX	N8F0383KX
		N5B0417KX	N6G0191KX	N7C1014KX	N7J0692KX	N8A1119KX	N8F0482KX
		N5B0484KX	N6G0213KX	N7D0182KX	N7J0858KX	N8B0204KX	N8B1048KX
		N5B0285KX	N6G0099KX	N7D0226KX	N7J0636KX	N8A1099KX	N8F0428KX
		N5B0680KX	N6H0168KX	N7D0264KX	N7J0897KX	N8B0114KX	N8D0394KX
		N5D0467KX	N6H0291KX	N7D0495KX	N7J1014KX	N8B0137KX	N8E0233KX
		N5D0497KX	N6H0327KX	N7D0416KX	N7K0270KX	N8B0571KX	N8E0266KX
		N5D0550KX	N6H0370KX	N7D0538KX	N7K0307KX	N8B0666KX	N8F0691KX
		N5D0609KX	N6H0433KX	N7D0591KX	N7J1155KX	N8B0805KX	N8F0773KX
		N5D0660KX	N6H0466KX	N7D0918KX	N7K0225KX	N8B0885KX	N8F0378KX
		N5D0736KX	N6E0117KX	N7D0473KX	N7K0500KX	N8B0641KX	N8F0658KX
		N5D0765KX	N6H0247KX	N7D0945KX	N7K0008KX	N8B0709KX	N8F0858KX
		N5D1008KX	N6H0456KX	N7E0372KX	N7K0085KX	N8C0159KX	N8F0879KX
		N5E0068KX	N6H0827KX	N7E0518KX	N7K0154KX	N8B0849KX	N8F1015KX
		N5E0143KX	N6H0792KX	N7E0565KX	N7K0272KX	N8B1009KX	N8F0976KX
		N5E0297KX	N6J0152KX	N7E0610KX	N7K0303KX	N8B1034KX	N8E0321KX
		N5E0727KX	N6J0185KX	N7E0920KX	N7K0400KX	N8B0769KX	N8E0699KX
		N5E0756KX	N6J0243KX	N7E0962KX	N7K0443KX	N8B0958KX	N8F1046KX
		N5F0096KX	N6J0476KX	N7F0093KX	N7K0544KX	N8C0324KX	N8E0081KX
		N5F1223KX	N6K0209KX	N7F0186KX	N7K0956KX	N8C0340KX	N8G0871KX
		N5F1382KX	N6K0676KX	N7F0094KX	N7K0562KX	N8C0470KX	N8G0942KX
		N5G0414KX	N6K0739KX	N7F0663KX	N7K0711KX	N8C0546KX	N8F0921KX
		N5G0329KX	N6K0774KX	N7F0696KX	N7K0742KX	N8C0718KX	N8G0911KX
		N5G0355KX	N6K0824KX	N7F0745KX	N7K0783KX	N8B0905KX	N8H0735KX
		N5G0868KX	N6K0251KX	N7F0224KX	N7K0087KX	N8C0589KX	N8H0759KX
		N5G0244KX	N6K0871KX	N7F1052KX	N7K0821KX	N8C0779KX	N8H0683KX
N5G0339KX	N6K0293KX	N7F1139KX	N7L0057KX	N8C0777KX	N8G0980KX		
N5G0405KX	N6K1137KX	N7G0016KX	N7L0091KX	N8C0816KX	N8J0819KX		
N5G0809KX	N6K0160KX	N7F0662KX	N7L0403KX	N8C1338KX	N8L0895KY		
N5J1153KX	N6L0909KX	N7G0241KX	N7K1052KX	N8D0083KX	N9B0348KY		
N5J1201KX	N6L0942KX	N7G0279KX	N7L0431KX	N8C1339KX	N6L0814KRX		
N5K0045KX	N6M0065KX	N7F1019KX	N7L0592KX	N8D0043KX	N8M0168KRY		
N5K0089KX	N6M0134KX	N7F0822KX	N7K1150KX	N8D0142KX	N9A0665KRY		
N5K0115KX	N6L0806KX	N7G0498KX	N7L0361KX	N8D0312KX	N9A0954KRY		
N5J1233KX	N6L0944KX						

Lisa A: mõjutatud toodete nimekiri

Toode	Kirjeldus	Mõjutatud partiiinumbrid					
EGIA60AMT	Endo GIA™ 60 mm Articulating Medium/Thick Reload with Tri-Staple™ Technology	N4C1545KX	N5J0532KX	N6D0903KX	N7F0868KX	N8G0752KX	N8L0327KY
		N4D0042KX	N5J0658KX	N6D0924KX	N7F0923KX	N8G0839KX	N8L0440KY
		N4C1718KX	N5J0816KX	N6E0002KX	N7F0589KX	N8G0879KX	N8L0163KY
		N4D0366KX	N5H0100KX	N6E0244KX	N7F0903KX	N8G0880KX	N8L0204KY
		N4D0453KX	N5H0481KX	N6E0287KX	N7F0964KX	N8G1025KX	N8L0351KY
		N4D0589KX	N5J0418KX	N6E0335KX	N7G0062KX	N8H0016KX	N8K1023KY
		N4D0605KX	N5J0572KX	N6D0607KX	N7G0209KX	N8H0089KX	N8L0099KY
		N4D0688KX	N5J0694KX	N6D0285KX	N7F0961KX	N8H0135KX	N8L0368KY
		N4D0814KX	N5J0966KX	N6D0536KX	N7G0246KX	N8G0217KX	N8L0471KY
		N4D0897KX	N5J0775KX	N6D0580KX	N7G0287KX	N8H0372KX	N8L0594KY
		N4D1145KX	N5J1099KX	N6D0160KX	N7G0689KX	N8G0936KX	N8L0534KY
		N4E1383KX	N5J1130KX	N6D0180KX	N7G0723KX	N8H0159KX	N8L0765KY
		N4E1505KX	N5H0970KX	N6D0230KX	N7G0775KX	N8F1045KX	N8L0527KY
		N4F0006KX	N5K0139KX	N6D0283KX	N7G0661KX	N8G0983KX	N8L0570KY
		N4F0076KX	N5K0208KX	N6D0334KX	N7H0396KX	N8H0175KX	N8L0733KY
		N4F0114KX	N5K0308KX	N6D0376KX	N7H0493KX	N8H0220KX	N8L0633KY
		N4F0516KX	N5K0374KX	N6D0672KX	N7H0102KX	N8H0298KX	N8M0004KY
		N4F0853KX	N5K0412KX	N6E0068KX	N7H0762KX	N8H0332KX	N8L0715KY
		N4F0719KX	N5K0429KX	N6E0573KX	N7H0827KX	N8H0406KX	N8L0772KY
		N4F0929KX	N5K0564KX	N6E0600KX	N7H0422KX	N8H0506KX	N8L0822KY
		N4F0695KX	N5K0629KX	N6E0691KX	N7H0464KX	N8H0600KX	N8M0026KY
		N4F0981KX	N5K0665KX	N6E0652KX	N7H0716KX	N8H0613KX	N8M0035KY
		N4F1092KX	N5K0700KX	N6F0165KX	N7H0867KX	N8H0868KX	N8L0073KY
		N4F1331KX	N5K0732KX	N6F0232KX	N7J0254KX	N8H0434KX	N8M0064KY
		N4F1450KX	N5K0848KX	N6F0279KX	N7J0371KX	N8H0474KX	N8M0100KY
		N4F1163KX	N5K0895KX	N6B0081KX	N7J0420KX	N8H0776KX	N8M0178KY
		N4F1542KX	N5K0941KX	N6E0462KX	N7J0454KX	N8H0574KX	N8M0140KY
		N4F1159KX	N5K0775KX	N6F0307KX	N7J0214KX	N8H0606KX	N8M0243KY
		N4F1383KX	N5K0992KX	N6F0385KX	N7J0286KX	N8H0652KX	N8L0673KY
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		N4M1062KX	N5M0827KX	N6F0659KX	N7L0894KX	N8J0443KX	N8M0621KY
		N4M0982KX	N5M0459KX	N6F0705KX	N7M0322KX	N8J0301KX	N8M0394KY
		N5A0364KX	N5M0632KX	N6F0935KX	N7L0957KX	N8J0414KX	N8M0588KY
		N5A0345KX	N6A0004KX	N6J0202KX	N7M0323KX	N8J0564KX	N8M0713KY
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		N5B0700KX	N6A0124KX	N6K0742KX	N8A0098KX	N8J0762KX	N8M0763KY
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Lisa A: mõjutatud toodete nimekiri

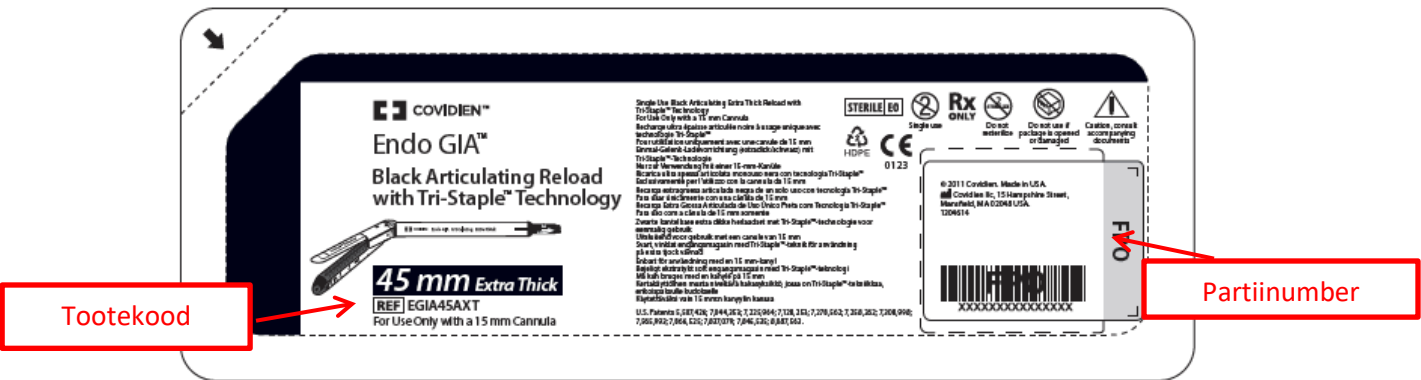
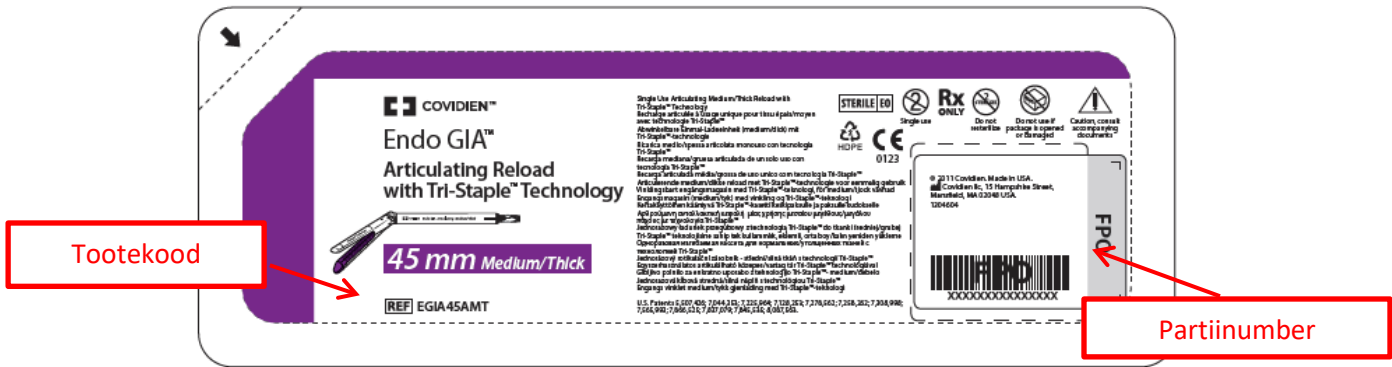
Toode	Kirjeldus	Mõjutatud partiiinumbrid					
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		N5C0914KX	N6B0219KX	N7A0131KX	N8A0819KX	N8J0787KX	N9A0460KY
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		N5H1186KX	N6C0972KX	N7E0726KX	N8G0388KX	N8K0800KY	N9B0389KY
		N5H0993KX	N6D0009KX	N7E0806KX	N8G0440KX	N8K0971KY	N9B0570KY
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Lisa A: mõjutatud toodete nimekiri

For use in EU countries where Kits were distributed

Item / KIT	Description	Affected Lot

Mõjutatud toote tuvastamine



Emakood

ORDER NO: 19936878 67090146 KIT PARENT: 0022199

NAME: MARY HITCHCOCK MEMORIAL HOSP

Qty	Code	Description	Qty	Code	Description
1	EGIA4AMT	EGIA RADIAL MED THK RELOAD			
1	EGIA45MTD	EGIA 4 HANDLE STANDARD			

