

## Urgent Field Safety Notice

### Endo GIA™ Surgical Stapling Single Use Loading Units, Tri-Staple™ 2.0 Intelligent Reloads and Cartridges Recall

May 2019

Medtronic reference: FA868

Dear Healthcare Professional,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific production lots of its Endo GIA™ Surgical Stapling Single Use Loading Units, Tri-Staple™ 2.0 Intelligent Reloads and Cartridges.

#### Issue Description:

This voluntary recall is being conducted due to the potential for a device to be missing one of two pin components that maintain alignment of the device jaws. The affected devices were distributed between April 2014 and April 2019. Use of a product without a pin may result in incomplete staple formation, potentially leading to bleeding, anastomotic leak, peritonitis, or pneumothorax which can result in the potential for infection and/or sepsis. This potential issue was identified during in-process quality testing at the manufacturing facility. Manufacturing process improvements have been implemented to address this issue. There have been no confirmed complaints received related to this issue.

This voluntary recall affects only the item codes and lots listed on Attachment A.

#### Required Actions:

1. Please immediately quarantine and discontinue use of affected item codes and lots listed on Attachment A.
2. Please return affected product as indicated below. All unused products from the affected item codes and lots must be returned.
3. If you have distributed the Endo GIA™ Surgical Stapling Single Use Loading Units, Tri-Staple™ 2.0 Intelligent Reloads and Cartridges listed on Attachment A, please promptly forward the information from this letter to those recipients.
4. Complete the Return Verification Form **even if you do not have inventory**.

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased <b>directly</b> from Medtronic	<p>Please complete the attached Returns Verification Form in its entirety.</p> <p>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.</p>	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 <b>distributor</b>	Complete <b>all</b> 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 & to the Medtronic contact provided on the verification form.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

The Competent Authority of your country has been notified of this action. Please maintain a copy of this notice in your records.

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 or concerns, please do not hesitate to contact your Medtronic representative at <XXXXXX>.

Sincerely,

Local / BU Manager

Enclosure: Attachment A: Affected Product List

Attachment A: Affected Product List

Item	Description	Affected Lot					
EGIA30AMT	Endo GIA™ 30 mm Articulating Medium/Thick Reload with Tri-Staple™ Technology	N5A0871KX	N7A0527KX	N7E0441KX	N8J0039KX	N8J0527KX	N8J0820KX
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
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
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
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	N8E0015X	N8K0823KY
		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						

## Attachment A: Affected Product List

Item	Description	Affected Lot Numbers					
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	N8E0378KX
		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
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		N5G0355KX	N6K0824KX	N7F0745KX	N7K0783KX	N8B0905KX	N8H0735KX
		N5G0868KX	N6K0251KX	N7F0224KX	N7K0087KX	N8C0589KX	N8H0759KX
N5G0244KX	N6K0871KX	N7F1052KX	N7K0821KX	N8C0779KX	N8H0683KX		
N5G0339KX	N6K0293KX	N7F1139KX	N7L0057KX	N8C0777KX	N8G0980KX		
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N5K0045KX	N6M0065KX	N7F1019KX	N7L0592KX	N8D0043KX	N8M0168KRY		
N5K0089KX	N6M0134KX	N7F0822KX	N7K1150KX	N8D0142KX	N9A0665KRY		
N5K0115KX	N6L0806KX	N7G0498KX	N7L0361KX	N8D0312KX	N9A0954KRY		
N5J1233KX	N6L0944KX						

Attachment A: Affected Product List

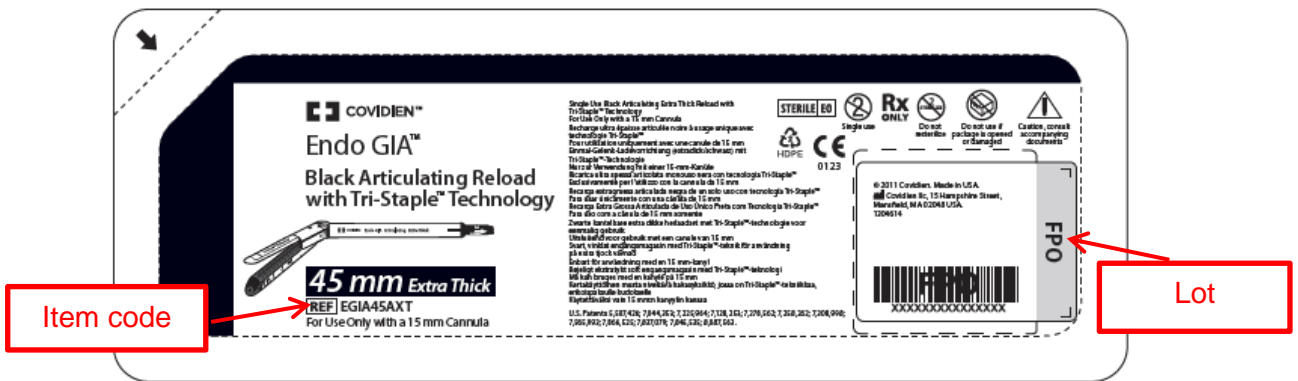
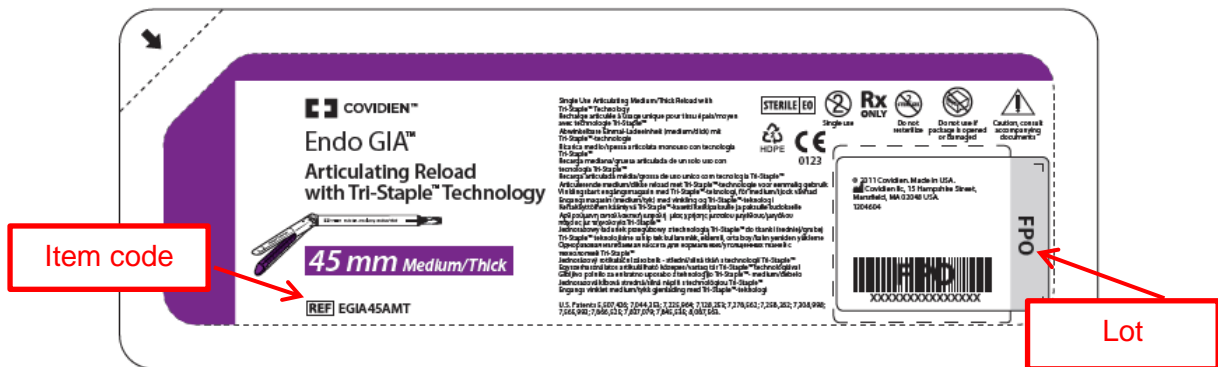
Item	Description	Affected Lot Numbers					
EGIA60AMT	Endo GIA™ 60 mm Articulating Medium/Thick Reload with Tri-Staple™ Technology	N4C1545KX	N5J0532KX	N6D0903KX	N7F0868KX	N8G0752KX	N8L0327KY
		N4D0042KX	N5J0658KX	N6D0924KX	N7F0923KX	N8G0839KX	N8L0440KY
		N4C1718KX	N5J0816KX	N6E0002KX	N7F0589KX	N8G0879KX	N8L0163KY
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		N4F1542KX	N5K0941KX	N6E0462KX	N7J0454KX	N8H0574KX	N8M0140KY
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		N4M0982KX	N5M0459KX	N6F0705KX	N7M0322KX	N8J0301KX	N8M0394KY
		N5A0364KX	N5M0632KX	N6F0935KX	N7L0957KX	N8J0414KX	N8M0588KY
		N5A0345KX	N6A0004KX	N6J0202KX	N7M0323KX	N8J0564KX	N8M0713KY
		N5A0286KX	N6A0034KX	N6J0314KX	N7M0864KX	N8J0617KX	N8M0793KY
N5A1461KX	N6A0086KX	N6J0364KX	N7M0785KX	N8J0686KX	N8M0796KY		
N5B0700KX	N6A0124KX	N6K0742KX	N8A0098KX	N8J0762KX	N8M0763KY		
N5B0757KX	N6A0520KX	N6L0523KX	N8A0744KX	N8H0894KX	N9A0013KY		
N5B0031KX	N6A0527KX	N6L0634KX	N8A0882KX	N8J0060KX	N9A0092KY		
N5B0794KX	N6A0428KX	N6L0946KX	N8A0818KX	N8J0313KX	N9A0171KY		
N5B0856KX	N6B0052KX	N6L0527KX	N8A0911KX	N8J0523KX	N8M0849KY		

Attachment A: Affected Product List

Item	Description	Affected Lot Numbers					
EGIA60AMT	Endo GIA™ 60 mm Articulating Medium/Thick Reload with Tri-Staple™ Technology	N5C0465KX	N6B0028KX	N6L0556KX	N8A1044KX	N8J0534KX	N9A0139KY
		N5C0639KX	N6B0135KX	N6M0737KX	N8B0372KX	N8J0810KX	N9A0329KY
		N5C0725KX	N6B0105KX	N6M0329KX	N8B0411KX	N8J0102KX	N9A0151KY
		N5C0986KX	N6B0177KX	N6M0556KX	N8B0458KX	N8J0882KX	N8M0711KY
		N5C0668KX	N6B0270KX	N6M0698KX	N8B0311KX	N8J0952KX	N9A0358KY
		N5C0914KX	N6B0219KX	N7A0131KX	N8A0819KX	N8J0787KX	N9A0460KY
		N5E0348KX	N6B0323KX	N7A0167KX	N8B0497KX	N8J1064KX	N9A0497KY
		N5D0862KX	N6B0386KX	N7A0208KX	N8C0112KX	N8J1019KX	N9A0423KY
		N5F0181KX	N6B0477KX	N6M0729KX	N8B0553KX	N8J0723KX	N8M0820KY
		N5F0330KX	N6B0405KX	N7A0227KX	N8C0638KX	N8J0852KX	N9A0366KY
		N5E1158KX	N6B0504KX	N7A0086KX	N8D0183KX	N8H0940KX	N9A0400KY
		N5E1245KX	N6B0541KX	N7A0941KX	N8D0226KX	N8J0005KX	N9A0186KY
		N5F0260KX	N6B0624KX	N7B0024KX	N8D0242KX	N8J0990KX	N9A0267KY
		N5F0348KX	N6B0722KX	N7B0123KX	N8D0314KX	N8J1070KX	N9A0544KY
		N5C0758KRX	N6B0746KX	N7B0345KX	N8E1013KX	N8K0016KX	N9A0636KY
		N5E1213KX	N6B0788KX	N7B0591KX	N8E1175KX	N8K0081KX	N9A0652KY
		N5G0114KX	N6B0852KX	N7B0739KX	N8E1177KX	N8K0110KX	N9A0765KY
		N5G0154KX	N6B0923KX	N7C0332KX	N8E0676KX	N8K0180KX	N9A0725KY
		N5G0186KX	N6A0253KX	N7C0275KX	N8E0687KX	N8K0212KX	N9A0787KY
		N5G0877KX	N6A0255KX	N7C0371KX	N8E1135KX	N8K0231KX	N8L0853KY
		N5G0983KX	N6C0398KX	N7C0833KX	N8F0098KX	N8K0319KX	N9A0618KY
		N5G1011KX	N6C0355KX	N7C0959KX	N8E0814KX	N8K0136KX	N9A0812KY
		N5G1122KX	N6C0369KX	N7C0756KX	N8F0581KX	N8K0361KX	N9A0827KY
		N5G0660KX	N6C0370KX	N7C0799KX	N8F0523KX	N8K0452KX	N9A0880KY
		N5G1147KX	N6C0524KX	N7D0453KX	N8G0035KX	N8K0393KX	N9A0937KY
		N5G1248KX	N6C0589KX	N7E0043KX	N8G0067KX	N8K0492KX	N9A0521KY
		N5H0250KX	N6C0562KX	N7E0148KX	N8E1060KX	N8K0254KX	N9A0696KY
		N5H0623KX	N6C0509KX	N7D0592KX	N8G0179KX	N8K0584KX	N9B0020KY
		N5H0676KX	N6C0598KX	N7D0632KX	N8F1111KX	N8K0762KY	N9B0049KY
		N5H0226KX	N6C0678KX	N7D0690KX	N8G0244KX	N8K0632KX	N9B0220KY
		N5H0730KX	N6C0701KX	N7E0223KX	N8G0122KX	N8K0421KX	N9B0122KY
		N5H0838KX	N6C0737KX	N7D0908KX	N8G0284KX	N8K0697KY	N9B0084KY
		N5H0949KX	N6C0800KX	N7E0304KX	N8F0619KX	N8K0709KY	N9B0299KY
		N5H1013KX	N6C0841KX	N7D0744KX	N8G0566KX	N8K0898KY	N9B0522KY
		N5H1082KX	N6C0889KX	N7D0949KX	N8G0624KX	N8K0939KY	N9B0066KY
		N5H1111KX	N6C0913KX	N7E0109KX	N8E0633KX	N8K0842KY	N9B0298KY
		N5H1158KX	N6C0938KX	N7E0188KX	N8G0202KX	N8K0437KX	N9B0201KY
		N5H1186KX	N6C0972KX	N7E0726KX	N8G0388KX	N8K0800KY	N9B0389KY
		N5H0993KX	N6D0009KX	N7E0806KX	N8G0440KX	N8K0971KY	N9B0570KY
		N5J0220KX	N6D0051KX	N7E0605KX	N8G0351KX	N8K0996KY	N9B0490KY
		N5J0266KX	N6D0070KX	N7F0157KX	N8G0468KX	N8K1063KY	N9B0540KY
		N5J0295KX	N6D0091KX	N7F0307KX	N8G0489KX	N8L0016KY	N9B0722KY
		N5J0321KX	N6D0715KX	N7F0173KX	N8G0513KX	N8L0072KY	N9B0403KY
		N5H0762KX	N6D0735KX	N7E0990KX	N8G0688KX	N8K0531KX	N9C0450KY
		N5J0492KX	N6D0757KX	N7F0370KX	N8G0780KX	N8K0983KY	N5L0673KRX
		N5H1216KX	N6D0796KX	N7F0500KX	N8G0550KX	N8L0234KY	N9A0773KRY
		N5J0512KX	N6D0830KX	N7F0061KX	N8G0697KX	N8L0283KY	



Identifying Affected Product



Parent Code

ORDER NO:	19936878	67090146	KIT PARENT:	0022199	
NAME:	MARY HITCHCOCK MEMORIAL HOSP				
Qty	Code	Description	Qty	Code	Description
1	EG1AR40MT	EGIA RADIAL MED THK RELOAD			
1	EG1AUSTND	EGIA 4 HANDLE STANDARD			

