

**URGENT DEVICE RECALL**  
**Disposable Imaging Device Accessories**  
**Tubing and Syringes**

DATE: February , 2012

RE: Disposable Imaging Device Accessories; Tubing and Syringes (see attached list)

Dear Disposable Imaging Device Customer:

Covidien is sending this communication to provide you with important information regarding our Disposable Imaging Device Accessories; Tubing and Syringes. We have identified sterilized packages of these products that are unsealed. We are, therefore, initiating a recall of six Disposable Imaging Device Accessories listed below (listing of all impacted lot numbers are indicated on the attached list).

Product Catalog Number	Product Description
801104	60 mL Syringe, MR, w/lateral flow needle
801103	25 mL Syringe, MR, w/lateral flow needle
801801	60 mL Syringe, MR, w/lateral flow needle
801106	60" Y Tubing, MR, with single check valve
801107	90" Y Tubing, MR, with single check valve
601195	60" Coiled Extension Tubing, low pressure

The lot number for these products is located on the lower right hand corner of the unit packaging. Additionally, the product label on the shipping case contains the lot number in the upper right hand corner.

According to our records, you have received one or more of the affected Devices Accessories indicated on the attached list. Please check your inventory of these products. If any of the affected products are in your inventory, please discontinue use of the products immediately.

Using the attached verification form, please report the quantity of each lot that is currently in your stock. If you do not have any of these lots in stock, please indicate 0 on the Verification form. When completed, please send the form back to the contact details mentioned on the verification form. **It is important we receive a response from each customer notified, even if you have no affected product in stock.**

You will be contacted by Customer Services to arrange return of your products. You will receive credit for all returned product from the affected lots.

If you or your company has distributed the affected devices accessories to other persons or facilities, please promptly forward the recipients a copy of this letter. Your customers should complete the verification form and return the completed form with affected units directly to you.

If you have questions about this recall, please call [\[enter local contact details\]](#).

This recall is being performed by Covidien with the full knowledge of [\[add local C.A.\]](#)

Please pass the FSN on to all those who need to be aware of it within your organization and please maintain awareness over an appropriate defined period.

It is very important that we receive the information from you as soon as possible so we can expedite the return and credit process.

We greatly appreciate your cooperation in this matter.

Yours sincerely,

	0001101	0225132	1028223	1161157	9044165	9198046
	0001103	0232144	1042117	1161158	9058248	9198047
	0008408	0239176	1042118	1168122	9058249	9198048
	0043274	0239177	1049304	1168123	9065157	9205002
	0057333	0246193	1049305	1168124	9065159	9205003
	0057614	0246194	1056015	1168125	9072262	9212116
	0064341	0253140	1056016	1168127	9072263	9212119
	0071228	0253141	1056018	1175129	9072265	9219138
	0081107	0267014	1070121	1175133	9086217	9219139
	0085369	0267015	1070122	1175134	9086218	9219141
	0085372	0267016	1070123	1182174	9086219	9226085
	0092279	0277048	1077273	1182175	9086220	9226086
	0099103	0288071	1077274	1182176	9086221	9226088
	0099104	0288072	1077275	1196143	9093277	9226089
	0099105	0295173	1077276	1203142	9093278	9233009
	0113415	029174	1084122	1203146	9093279	9233010
	0113418	0299094	1091208	1210158	9093280	9233011
	0120204	0299095	1098206	1217147	9093281	9233012
	0120205	0299096	1098207	1217148	9093282	9233013
<b>601195</b>	0127199	0306046	1098208	1217149	9100253	9240125
	0141203	0316133	1098209	1224131	9100255	9240126
	0141204	0316134	1105214	1224132	9107243	9240127
	0141205	0316135	1105215	1231119	9121107	9240128
	0148232	0316136	1105216	1231121	9121108	9240129
	0148234	0323172	1105217	1238124	9135198	9246055
	0182133	0330166	1112023	1238125	9135199	9246057
	0182134	0337120	1119040	1238126	9142035	9246058
	0190243	0337121	1119041	1238127	9142037	9253013
	0197169	0337122	1140140	1238128	9149178	9331142
	0197170	0337123	1140141	1245114	9156192	9331143
	0197172	1007191	1140167	1259109	9163179	9351087
	0204150	1007192	1147133	1266162	9163180	9352192
	0204151	1007193	1147134	1266164	9163181	9352193
	0204152	1007194	1147135	1280125	9163182	9352194
	0204153	1007195	1147136	1280127	9163183	9352195
	0211153	1014119	1147137	1287128	9170272	9352196
	0211154	1014120	1154162	1287129	9170273	9357632
	0218189	1021228	1154163	1287130	9170274	9357634
	0218190	1028221	1161155	1322131	9176139	
	0225130	1028222	1161156	9037133	9191015	
<b>801103</b>	0102055	9281040				
<b>801104</b>	0001110	0130214	0278106	9058252	9212120	9302042
	0067041	0155164	0344212	9121110	9260020	9317041
	0074024	0162121	1210163			

<b>801106</b>	0004089	0127204	0323177	1035284	9107247	9240130
	0022187	0134340	0323178	1049308	9121111	9247097
	0029497	0141206	0337126	1049309	9135200	9260010
	0064349	0169314	0344213	1154164	9135201	9275099
	0074025	0204181	0344214	1175177	9149180	9281041
	0081112	0246195	0351233	1217150	9149181	9317527
	0088168	0253136	0351234	1224136	9163184	9338341
	0095184	0267019	1007196	9058264	9191016	9345195
	0102056	0288027	1007197	9065162	9205006	
	0109042	0295179	1021229	9100338	9191017	
0120266	0316141	1028226	9107246	9205007		
<b>801107</b>	0029498	0225223	0355139	1126122	9107248	9260011
	0032077	0253258	0355140	1126123	9107249	9275100
	0057617	0273018	1014141	1133132	9114148	9281042
	0057618	0279093	1021230	1133133	9135202	9295023
	0064350	0288031	1056019	1154165	9135203	9317046
	0095185	0295180	1063217	1154166	9149184	9320079
	0109043	0307123	1063218	1168128	9149185	9327016
	0123064	0330175	1091205	1175136	9163186	9334064
	0130215	0330177	1098204	1182146	9170276	9345661
	0148235	0337127	1098205	9022000	9170277	
	0162122	0337128	1105213	9058255	9212121	
	0169315	0351231	1112019	9100259	9233028	
0197173	0351232	1119053	9100260	9233029		
<b>801801</b>	0015042	0162123	1035288	1154167	9065165	9240131
	0015043	0235010	1042122	1217151	9065448	9240132
	0022236	0235011	1049310	1224177	9072267	9247098
	0029499	0246196	1049311	1231123	9079179	9247099
	0029500	0246197	1049312	1231124	9079180	9253017
	0036252	0260208	1056022	1266176	9093274	9253018
	0036253	0300141	1063219	1273129	9100262	9275101
	0071245	0309197	1070128	1273130	9114150	9281033
	0074027	0309198	1070129	1280130	9128089	9281034
	0088170	0316143	1084125	1280131	9128090	9295029
	0095186	0323181	1084126	1287134	9156194	9317056
	0099109	1007200	1091216	1287135	9156195	9331148
	0102058	1007201	1098211	1294121	9163187	9331149
	0106079	1021246	1105220	1301131	9163188	9334065
	0109044	1028228	1119061	9037138	9176144	9338345
	0120472	1028230	1119062	9044170	9176145	9357639
	0123066	1028231	1119064	9051152	9191020	
0141207	1028232	1147187	9051153	9219142		
0155153	1035285	1147188	9065164	9219143		

**URGENT MEDICAL DEVICE FSCA**  
**PRODUCT RECALL**  
**Disposable Imaging Device Accessories**  
**Tubing and Syringes**  
**VERIFICATION FORM**

Customer Contact Details	Covidien Contact Details
<b>Hospital Name:</b>	<b>To:</b> <i>[please insert name Covidien commercial office]</i>
<b>Address:</b>	<b>Address:</b> <i>[please insert Covidien address]</i>
<b>Telephone n°:</b>	<b>Telephone n°:</b> <i>[please insert Covidien telephone number]</i>
<b>Fax n°:</b>	<b>Fax n°:</b> <i>[please insert Covidien fax number]</i>
<b>E-mail:</b>	<b>E-mail:</b> <i>[please insert contact e-mail address]</i>

Please list the quantity of affected product at your facility, if you have no stock, please indicate '0'.

Code	Lot number	Quantity

Please fax this form to the fax number referenced at the top of this form.

Customer Service will contact you directly to issue credit and to organise return of affected products.

Name:  
(please print)

Signature:

Date: