

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

DATE: February 10, 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 voluntary recall of six Disposable Imaging Device Accessories listed below (listing of all impacted lot numbers are indicated on the attached list, pages 3-10).

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 and expiration date for these products are located on the lower right hand corner of the single-use sterilized package. 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 Disposable Imaging Device 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 business response 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 by checking the appropriate box on the business response form. When completed, please email the completed form to [covidien2600@stericycle.com](mailto:covidien2600@stericycle.com) or fax to 888-257-7910. **It is important we receive a response from each customer notified, even if you have no affected product in stock.**

Please use the enclosed pre-paid UPS shipping label to return any recalled product you have in stock. When filling out the packing slip, ensure that your distribution information is completed as this is necessary to assure proper credit is issued. You will receive credit for all returned product from the affected lots.

If this product has been distributed by you to other consignees, we request that you notify these consignees of this recall.



If you have questions about this recall, please call 866-761-9571.

This voluntary recall is being performed by Covidien with the full knowledge of the U.S. Food and Drug Administration.

Please complete the enclosed business notification form by February 24, 2012. It is very important that we receive the information from you so we can expedite the return and credit process. We greatly appreciate your cooperation in this matter.

Regards,

Margaret Besing for  
Dirk Stevens, Ph.D.  
Vice President  
Quality and Regulatory Compliance

**URGENT DEVICE RECALL**

Product Catalog Number	Product Name	Lot number(s)	Expiration date
801104	60 mL Syringe, MR, w/lateral flow needle	9058252	Feb-2012
		9121110	May-2012
		9212120	Aug-2012
		9260020	Sep-2012
		9302042	Oct-2012
		9317041	Nov-2012
		0001110	Jan-2013
		0067041, 0074024	Mar-2013
		0130214	May-2013
		0155164, 0162121	Jun-2013
		0278106	Oct-2013
		0344212, 0351225	Dec-2013
		1021271	Feb-2014
		1210163	Jul-2014
		1336343	Dec-2014

Product Catalog Number	Product Name	Lot number(s)	Expiration date
801103	25 mL Syringe, MR, w/lateral flow needle	0060074	Mar-2013
		0102055	Apr-2013
		0218191	Aug-2013
		1063215	Mar-2014
		9281040	Oct-2012

Product Catalog Number	Product Name	Lot number(s)	Expiration date
801801	60 mL Syringe, MR, w/lateral flow needle	9037138, 9037139, 9044170, 9044184, 9051152, 9051153, 9058256, 9058257	Feb-2012
		9065164, 9065165, 9065448, 9072267, 9079179, 9079180, 9093273, 9093274	Mar-2012
		9100261, 9100262, 9114150, 9114151	Apr-2012
		9128089, 9128090	May-2012
		9156194, 9156195, 9163187, 9163188, 9176144, 9176145	Jun-2012
		9191020, 9191021	Jul-2012
		9219142, 9219143, 9240131, 9240132	Aug-2012
		9247098, 9247099, 9253017, 9253018, 9275101, 9275102	Sep-2012
		9281033, 9281034, 9295029, 9295030	Oct-2012
		9310048, 9310049, 9317055, 9317056, 9331148, 9331149	Nov-2012
		9334065, 9338345, 9351119, 9352231	Dec-2012

Product Catalog Number	Product Name	Lot number(s)	Expiration date
801801	60 mL Syringe, MR, w/lateral flow needle	0008414, 0008415, 0015042, 0015043, 0022236, 0029499, 0029500, 9357639	Jan-2013
		0036252, 0036253, 0060075	Feb-2013
		0064356, 0067043, 0071245, 0074027, 0078240, 0081116, 0085386, 0088170	Mar-2013
		0095186, 0099109, 0102058, 0106079, 0109044, 0113426, 0120272, 0120472	Apr-2013
		0123066, 0134341, 0141207	May-2013
		0155153, 0155154, 0162123	Jun-2013
		0235010, 0235011, 0246196	Aug-2013
		0246197, 0260208, 0260209	Sep-2013
		0300141, 0300142	Oct-2013
		0309197, 0309198, 0316143, 0316144, 0316145, 0323181	Nov-2013
		0337129, 0337130, 1007198, 1007199, 1007200, 1007201, 1021246, 1028228, 1028229, 1028230, 1028231, 1028232	Jan-2014
		1035285, 1035286, 1035287, 1035288, 1042122, 1042123, 1049310, 1049311, 1049312, 1049313, 1056021, 1056022	Feb-2014
		1063219, 1063220, 1070128, 1070129, 1084125, 1084126, 1091216, 1091217	Mar-2014
		1098211, 1098212, 1105219, 1105220, 1119061, 1119062, 1119063, 1119064	Apr-2014
		1147187, 1147188	May-2014
		1154167, 1154168	Jun-2014
		1217151, 1224177, 1231123, 1231124	Aug-2014
		1238134, 1252133, 1252134, 1266175, 1266176, 1273129, 1273130	Sep-2014
		1280130, 1280131, 1287134, 1287135, 1294121, 1294122, 1301132	Oct-2014
		1301131, 1308138, 1315138, 1315139, 1322137	Nov-2014
1336336, 1343177	Dec-2014		

Product Catalog Number	Product Name	Lot number(s)	Expiration date
801106	60" Y Tubing, MR, with single check valve	9058264	Feb-2012
		9065162	Mar-2012
		9100338, 9107246, 9107247	Apr-2012
		9121111, 9135200, 9135201, 9149180, 9149181	May-2012
		9163184	Jun-2012
		9191016, 9191017, 9205006, 9205007	Jul-2012
		9240130	Aug-2012
		9247097, 9260010	Sep-2012
		9275099, 9281041, 9295022	Oct-2012
		9317527	Nov-2012
		9338341, 9345195, 9345660	Dec-2012
		0004089, 0022187, 0029497	Jan-2013
		0057616, 0064349, 0067042, 0074025, 0081112	Mar-2013
		0088168, 0095184, 0102056, 0109042, 0120266	Apr-2013
		0127204, 0134340, 0141206	May-2013
		0169314	Jun-2013
		0204181	Jul-2013
		0246195, 0253136, 0267019	Sep-2013
		0288027, 0295179, 0302179	Oct-2013
		0316141, 0323177, 0323178	Nov-2013
		0337126, 0344213, 0344214, 0351233, 0351234	Dec-2013
		1007196, 1007197, 1021229, 1028226	Jan-2014
		1035284, 1049308, 1049309	Feb-2014
		1154164	Jun-2014
1175177	Jul-2014		
1217150, 1224136, 1231122, 1238129, 1238130	Aug-2014		
1266168	Sep-2014		

Product Catalog Number	Product Name	Lot number(s)	Expiration date
801107	90" Y Tubing, MR, with single check valve	0029498, 9022000	Jan-2013
		0032077, 0057617, 0057618	Feb-2013
		0064350, 0081113	Mar-2013
		0095185, 0109043	Apr-2013
		0123064, 0130215, 0148235	May-2013
		0162122, 0169315	Jun-2013
		0197173	Jul-2013
		0225223	Aug-2013
		0253258, 0260252, 0273018, 0273019	Sep-2013
		0278107, 0279093, 0288031, 0288032, 0295180, 0295181	Oct-2013
		0307122, 0307123, 0330175, 0330176, 0330177	Nov-2013
		0337127, 0337128, 0351231, 0351232, 0355139, 0355140	Dec-2013

Product Catalog Number	Product Name	Lot number(s)	Expiration date
801107	90" Y Tubing, MR, with single check valve	1014140, 1014141, 1021230, 1028227	Jan-2014
		1042218, 1042219	Feb-2014
		1056019, 1056020, 1063217, 1063218, 1070126, 1084124	Mar-2014
		1091205, 1098204, 1098205, 1105212, 1105213, 1112018, 1112019, 1119053	Apr-2014
		1126122, 1126123, 1133132, 1133133, 1154165	May-2014
		1154166, 1161159, 1168128, 1175136	Jun-2014
		1182146, 1182147, 1196144, 1196145, 1196146, 1203191, 1203192, 1210164, 1210165	Jul-2014
		1238131	Aug-2014
		1238132, 1252125, 1252126	Sep-2014
		1287132, 1287133	Oct-2014
		1343174, 1343175	Dec-2014
		9037137, 9044169, 9044186, 9058254	Feb-2012
		9058255, 9072268, 9086222	Mar-2012
		9072269, 9100259, 9100260, 9107248, 9107249	Apr-2012
		9114148, 9114149, 9135202, 9135203, 9149184, 9149185	May-2012
		9163185, 9163186, 9170276, 9170277	Jun-2012
		9187008, 9191018, 9191019, 9212121	Jul-2012
		9212122, 9233028, 9233029	Aug-2012
		9260011, 9260012	Sep-2012
		9275100, 9281042, 9295023	Oct-2012
9317046, 9320079, 9327016	Nov-2012		
9334064, 9345196, 9345661	Dec-2012		

Product Catalog Number	Product Name	Lot number(s)	Expiration date
601195	60" Coil Extension Tubing, low pressure	9037131, 9037132, 9037133, 9037134, 9037135, 9037136, 9044165, 9044166, 9044167, 9044168, 9051143, 9051144, 9051145, 9051146, 9058248, 9058249, 9058250, 9058251	Feb-2012
		9065157, 9065158, 9065159, 9065160, 9072261, 9072262, 9072263, 9072264, 9072265, 9072266, 9079181, 9079182, 9079183, 9079184, 9079185, 9079186, 9086216, 9086217, 9086218, 9086219, 9086220, 9086221, 9093277	Mar-2012

Product Catalog Number	Product Name	Lot number(s)	Expiration date
601195	60" Coil Extension Tubing, low pressure	9093278, 9093279, 9093280, 9093281, 9093282, 9100253, 9100254, 9100255, 9100256, 9100257, 9100258, 9107242, 9107243, 9107244, 9107245, 9114144, 9114145	Apr-2012
		9121106, 9121107, 9121108, 9121109, 9135196, 9135197, 9135198, 9135199, 9142035, 9142036, 9142037, 9142038, 9149173, 9149177, 9149178, 9149179	May-2012
		9156189, 9156190, 9156191, 9156192, 9156193, 9163179, 9163180, 9163181, 9163182, 9163183, 9170272, 9170273, 9170274, 9170275, 9176139, 9176140, 9176141, 9176142	Jun-2012
		9188000, 9191012, 9191013, 9191014, 9191015, 9198046, 9198047, 9198048, 9205002, 9205003, 9205004, 9205005, 9212116, 9212117, 9212118, 9212119	Jul-2012
		9219138, 9219139, 9219140, 9219141, 9226084, 9226085, 9226086, 9226087, 9226088, 9226089, 9233009, 9233010, 9233011, 9233012, 9233013, 9240125, 9240126, 9240127, 9240128, 9240129	Aug-2012
		9246055, 9246056, 9246057, 9246058, 9253013, 9253014, 9253015, 9253016, 9260005, 9260006, 9260007, 9260008, 9260009, 9267039, 9267040, 9267041, 9267042, 9275094, 9275095, 9275096	Sep-2012
		9275097, 9275098, 9281035, 9281036, 9281037, 9281038, 9288015, 9288016, 9288017, 9288018, 9288019, 9288020, 9295024, 9295025, 9295026, 9295027, 9295028, 9302037, 9302038, 9302039, 9302040, 9302041	Oct-2012
		9310043, 9310044, 9310045, 9310046, 9310047, 9313024, 9317023, 9317024, 9317025, 9317026, 9320072, 9324163, 9324164, 9324165, 9324166, 9331139, 9331140, 9331141, 9331142, 9331143, 9338332, 9338333, 9338334	Nov-2012

Product Catalog Number	Product Name	Lot number(s)	Expiration date
601195	60" Coil Extension Tubing, low pressure	9338335, 9338336, 9345150, 9345151, 9345152, 9345153, 9345154, 9351087, 9352192, 9352193, 9352194, 9352195, 9352196, 9357266, 9357267, 9357632, 9357634, 0001101, 0001102, 0001103	Dec-2012
		0004086, 0008405, 0008406, 0008407, 0008408, 0015031, 0015032, 0015033, 0015034, 0015035, 0022157, 0022158, 0022159, 0022160, 0022161, 0029487, 0029488, 0029489, 0029490, 0029491	Jan-2013
		0036242, 0036243, 0036244, 0036245, 0036246, 0039037, 0043271, 0043272, 0043273, 0043274, 0043275, 0053046, 0057333, 0057334, 0057335, 0057336, 0057613, 0057614	Feb-2013
		0064338, 0064339, 0064340, 0064341, 0064342, 0071225, 0071226, 0071227, 0071228, 0071229, 0078225, 0078226, 0078227, 0078228, 0078229, 0081107, 0085369, 0085370, 0085371, 0085372, 0088166, 0092279, 0092280	Mar-2013
		0095183, 0099103, 0099104, 0099105, 0106068, 0106069, 0106070, 0106071, 0113415, 0113416, 0113417, 0113418, 0120203, 0120204, 0120205	Apr-2013
		0127197, 0127198, 0127199, 0134337, 0134338, 0134339, 0141203, 0141204, 0141205, 0148232, 0148233, 0148234	May-2013
		0169313, 0176210, 0176211, 0182133	Jun-2013
		0182134, 0190241, 0190242, 0190243, 0197169, 0197170, 0197171, 0197172, 0204150, 0204151, 0204152, 0204153, 0211150, 0211151, 0211152, 0211153, 0211154	Jul-2013
		0218187, 0218188, 0218189, 0218190, 0225129, 0225130, 0225131, 0225132, 0232144, 0232145, 0239174, 0239175, 0239176, 0239177	Aug-2013



Product Catalog Number	Product Name	Lot number(s)	Expiration date
601195	60" Coil Extension Tubing, low pressure	0246191, 0246192, 0246193, 0246194, 0253138, 0253139, 0253140, 0253141, 0260206, 0260207, 0260334, 0267014, 0267015, 0267016, 0267017	Sep-2013
		0277047, 0277048, 0277049, 0277050, 0288071, 0288072, 0288073, 0288074, 0288278, 0295169, 0295170, 0295171, 0295172, 0295173, 0295174, 0299094, 0299095, 0299096, 0299097, 0299098	Oct-2013
		0305209, 0305210, 0306045, 0306046, 0307121, 0316132, 0316133, 0316134, 0316135, 0316136, 0323168, 0323169, 0323170, 0323171, 0323172, 0330166	Nov-2013
		0337120, 0337121, 0337122, 0337123, 0337124, 0337125, 0344201, 0344202, 0344203, 0344204, 0344205, 0344206, 0351215, 0351216, 0351217, 0351218, 0351219, 0351220, 0356030, 0356031, 0356032, 0356033, 0363161, 0363162, 0363163	Dec-2013
		1007191, 1007192, 1007193, 1007194, 1007195, 1014119, 1014120, 1014121, 1014122, 1014123, 1014124, 1021223, 1021224, 1021225, 1021226, 1021227, 1021228, 1028221, 1028222, 1028223, 1028224, 1028225	Jan-2014
		1035289, 1035290, 1035291, 1035293, 1042117, 1042118, 1042119, 1042120, 1042121, 1049303, 1049304, 1049305, 1049306, 1049307, 1056013, 1056014, 1056015, 1056016, 1056017, 1056018, 1056341	Feb-2014
		1063209, 1063210, 1063211, 1063212, 1063213, 1063214, 1070120, 1070121, 1070122, 1070123, 1077273, 1077274, 1077275, 1077276, 1077277, 1084119, 1084120, 1084121, 1084122, 1084123, 1084306, 1084307, 1084308, 1091208, 1091209, 1091210, 1091211, 1091212	Mar-2014
		1098206, 1098207, 1098208, 1098209, 1098210, 1105214, 1105215, 1105216, 1105217, 1105218, 1112020, 1112021, 1112022, 1112023, 1119040, 1119041	Apr-2014

Product Catalog Number	Product Name	Lot number(s)	Expiration date
601195	60" Coil Extension Tubing, low pressure	1119042, 1119043, 1126118, 1126119, 1126120, 1126121, 1133128, 1133129, 1140139, 1140140, 1140141, 1140167, 1147133, 1147134, 1147135, 1147136, 1147137	May-2014
		1154159, 1154160, 1154161, 1154162, 1154163, 1154216, 1161154, 1161155, 1161156, 1161157, 1161158, 1168122, 1168123, 1168124, 1168125, 1168126, 1168127, 1175129, 1175130, 1175131, 1175132, 1175133, 1175134, 1175135	Jun-2014
		1182173, 1182174, 1182175, 1182176, 1182177, 1182178, 1189146, 1189147, 1189148, 1189149, 1196138, 1196139, 1196140, 1196141, 1196142, 1196143, 1203142, 1203143, 1203144, 1203145, 1203146, 1203147, 1210157, 1210158, 1210159	Jul-2014
		1210160, 1210161, 1217144, 1217145, 1217146, 1217147, 1217148, 1217149, 1224130, 1224131, 1224132, 1224133, 1231117, 1231118, 1231119, 1231120, 1231121, 1238124, 1238125, 1238126, 1238127, 1238128	Aug-2014
		1245114, 1245115, 1245116, 1245117, 1245118, 1252120, 1252121, 1252122, 1252123, 1252124, 1259109, 1259110, 1259111, 1266162, 1266163, 1266164, 1266165, 1266166	Sep-2014
		1280125, 1280127, 1280128, 1280129, 1287127, 1287128, 1287129, 1287130, 1294099, 1294100, 1294101, 1294102, 1301123, 1301124, 1301125, 1301126, 1301127, 1301128	Oct-2014
		1308133, 1315133, 1315135, 1315137, 1322131, 1322244, 1336330	Nov-2014
		1336331, 1336332, 1336333, 1336334, 1343168, 1343169, 1343170, 1343171, 1343172, 1350136, 1350137, 1350138, 1350139	Dec-2014

**BUSINESS RESPONSE FORM / PACKING SLIP**

**Please make a copy of this form to include with your product return shipment.**



February 10, 2012

*Please complete the business response form by February 24, 2012. It is very important that we receive the information from you so we can expedite the return and credit process. Please check your status below:*

Check here if you do not have any affected product on hand.

We are returning # \_\_\_\_\_ syringes and/or # \_\_\_\_\_ tubing.

Distributor Name \_\_\_\_\_

Distributor City \_\_\_\_\_ Distributor State \_\_\_\_\_

Please complete and fax or email to: Fax – 1-888-257-7910 Email - [covidien2600@stericycle.com](mailto:covidien2600@stericycle.com)

Product Catalog Number	Lot Number(s)	Quantity in Stock	Lot Number(s)	Quantity in Stock	Lot Number(s)	Quantity in Stock
801104						
801103						
801801						
801106						
801107						
601195						