



Urgent Medical Device Correction

Contact™ Detach Infusion Sets: Needle May Fracture From the Connect/Disconnect Location

August 10, 2015

Dear Valued Customer:

Unomedical a/s, a ConvaTec Company has initiated an **Urgent Medical Device Correction**. You are receiving this letter because you have received impacted product.

Description of problem:

As part of the Unomedical a/s product quality monitoring process, the company identified a slight increase in reported cases **of the steel needle breaking during use for infusions sets manufactured prior to May 2014**. In a small sub set of these reported cases, this needle breakage has led to hospitalization for the management of glucose levels and/or treatment for removal of the needle.

Needle breakage can result in the interruption of insulin delivery and can cause hyperglycemia, which if left untreated, can result in diabetic ketoacidosis (DKA). DKA is a serious condition that can cause a severe impact to health, including death. Symptoms of DKA may include nausea, vomiting, shortness of breath and excess thirst/urination. Seek medical attention immediately if you are experiencing any of these symptoms. In addition to the interruption of insulin, a needle remaining in the body might, in rare cases, require surgical removal if the needle does not itself migrate to the surface where it can be removed with a pair of tweezers.



Point of needle fracture

An improvement in the manufacturing of the needles was implemented by Unomedical a/s, a ConvaTec Company in May 2014. This improvement has reduced the number of reported needle breakage since implementation. **Please refer to the attached list of lot numbers to determine if you might be in possession of impacted product.**

Actions to be taken:

You can continue to use the affected lots of Contact™ Detach infusion sets, there is no need to return any affected products. **To continue to use the affected Contact Detach infusion sets safely, Unomedical recommends following these actions and those listed in the instructions for use included with the sets.**



Prior to use:

- Carefully remove the needle guard before inserting the infusion set. The needle guard should be removed without the use of any twisting or bending of the needle guard.
- Do not use the infusion set if the needle is bent or has been damaged.
- Do not bend the needle prior to insertion.
- Review site map and consult your healthcare professional for the proper insertion site.

During use:

- As always, it is essential to monitor your blood sugar levels frequently using your blood glucose meter.

After use:

- Carefully remove the infusion set after use to avoid twisting or bending of the needle.
- Please ensure that the needle is present on the used infusion set before discarding it.
- Please contact your health care provider if you suspect that a needle has broken off and remained under the skin.

If you discover the needle has broken:

- Contact your health care provider if you suspect that a needle has broken off and remained under the skin.
- Monitor your blood sugar.

If you experience any issues with your infusion sets, please call Animas Customer Service at 800-205-6642 to report the issue.

We remain committed to providing you with the highest quality products and services, and apologize for any inconvenience this issue may cause. Thank you for your continued support of Animas.

Sincerely,

Animas Customer Service

Enc. Affected Lot Numbers

Contact™ Detach Affected Lot Numbers by Country

Australia							
216296	218110	218111	219075	220163	224283	224284	224285
224286	226940	227063	656782	4263307	4263308	4263329	4263475
4263517	4263529	4263551	4263571	4263665	4263718	4263750	4263778
5000119	5001718	5003702	5006568	5006571	5007991	5009947	5013531
5013532	5015057	5018234	5020466	5020536	5021240	5022268	5025141
5026515	5029022	5029137	5031875	5031883	5031887	5031917	5031922
5031923	5031928	5031929	5031930	5034061	5034231	5034232	5036348
5038182	5038183	5038184	5038187	5038188	5040990	5040992	5045147
5045148	5047241	5047242	5047243	5047245	5054465	5054553	5054554
5057103	5057104	5057105	5058637	5058733	5058734		

Belgium							
210131	227064	229302	4263571	4263719	5008524	5015103	5015177
5041073	5058633	5066512					

Canada							
212482	213576	214511	218685	219030	220161	220163	223775
224283	224286	226939	226940	227062	227064	227065	229302
657341	657966	669845	4262780	4262792	4263099	4263100	4263112
4263131	4263132	4263171	4263172	4263240	4263307	4263308	4263328
4263329	4263372	4263393	4263400	4263421	4263458	4263475	4263476
4263517	4263529	4263551	4263571	4263580	4263631	4263694	4263695
4263718	4263738	4263750	4263778	5000120	5001718	5003921	5006040
5006571	5007991	5008526	5012473	5015057	5015176	5018233	5018234
5020466	5021244	5022266	5022268	5025141	5026515	5029023	5029137
5031874	5031883	5031887	5031900	5031921	5031922	5031923	5031924
5031928	5031929	5031930	5034059	5034061	5036348	5038182	5038187
5038188	5040991	5040992	5045147	5047241	5047242	5047245	5048097
5054465	5054466	5054553	5054554	5057103	5057105	5057106	5058637
5058733	5058734	5062813					

Czech Republic							
216296	224286	226940	669845	4263094	4263131	4263240	4263421
4263529	4263694	5006040	5006571	5007991	5015103	5026515	5029147
5031900	5031931	5038187	5054554	5062770			

Contact™ Detach Affected Lot Numbers by Country

Finland							
212482	213575	214509	218685	220160	220161	224284	224286
227062	227064	232701	656782	657836	4263094	4263098	4263130
4263131	4263171	4263240	4263241	4263372	4263393	4263552	4263571
4263580	4263624	4263665	4263678	4263719	5006567	5006571	5008524
5015102	5015103	5015177	5018162	5020390	5031807	5031810	5031927
5034325	5041073	5053689	5054550	5058633	5062770		

France							
5018234	5026432	5026515	5029147	5031807	5031810	5031887	5031900
5031927	5031931	5034061	5034325	5041073	5041074	5053689	5054465
5054466	5054550	5058633	5062769	5066512			

Germany							
210131	212482	213575	216296	218685	220160	220161	223771
224286	226939	226940	227064	227894	229302	231124	232701
233875	656782	669845	4263171	4263240	4263307	4263308	4263329
4263529	4263551	4263718	5000119	5000120	5006040	5006567	5006571
5007991	5008524	5015102	5015103	5015177	5018162	5018234	5020390
5021570	5026432	5026515	5029147	5031807	5031810	5031887	5031900
5031926	5031927	5031931	5034061	5034325	5035097	5038187	5041073
5041074	5053689	5054465	5054466	5054550	5054554	5057106	5058633
5062769	5062770	5066512					

Hungary							
212482	216296	224286	227064	5006567	5015103	5020390	5029147
5031810	5031931	5038187	5041073	5053689	5054550	5057106	

Ireland							
218685	5000120	5006567	5008524	5015102	5034325	5041073	5053689
5062769							

Italy							
212482	213575	214509	216296	218685	224286	232701	657836
4263094	4263130	4263372	4263458	4263552	4263624	5000120	5015102
5015103	5020390	5029147	5031807	5031887	5035097	5041073	5041074
5053689	5054550	5058633	5062769				

Contact™ Detach Affected Lot Numbers by Country

Martinique	
5031931	

Netherlands							
210131	216296	220160	226940	227064	229302	233875	669845
4263308	4263529	4263551	5000120	5006040	5006567	5006571	5007991
5015103	5015177	5020390	5026515	5029147	5031807	5031810	5031927
5031931	5034061	5034325	5038187	5041073	5041074	5053689	5054466
5054550	5054554	5057106	5058633	5062770	5066512		

New Zealand							
213575	216295	216296	218111	219030	223771	223775	224282
224286	226935	226940	227063	656785	657836	4262780	4262781
4262831	4263094	4263099	4263113	4263171	4263307	4263329	4263393
4263420	4263475	4263571	4263572	4263609	4263631	4263678	4263694
4263696	4263718	4263750	4263778	5000119	5001718	5006568	5006571
5008526	5009948	5013531	5013532	5015054	5015057	5015177	5018233
5020466	5020536	5021244	5021312	5025138	5025139	5026515	5029136
5029137	5031883	5031900	5031918	5031925	5031929	5031930	5034061
5034232	5038186	5038187	5038188	5040990	5045147	5047241	5047242
5054466	5054554	5057103	5057105	5058637	5058731	5058734	5062811

Norway							
5031807	5031927	5031931	5034325	5035097	5038187	5041073	5041074
5062770							

Spain							
210131	216296	669845	4263240	4263308	4263393	4263458	4263572
4263580	4263665	4263678	5031810	5041074			

Contact™ Detach Affected Lot Numbers by Country

Sweden							
210131	212482	213575	214509	216175	216295	218111	219030
220160	220161	220163	223771	224284	224285	227062	227064
227892	227894	231124	232701	233875	656782	656785	657341
657836	669845	4263094	4263098	4263099	4263112	4263130	4263131
4263170	4263171	4263172	4263240	4263241	4263372	4263391	4263393
4263400	4263421	4263458	4263476	4263552	4263571	4263572	4263580
4263609	4263624	4263678	4263694	4263695	4263696	4263718	4263738
4263778	5006040	5006567	5008524	5015102	5015103	5015177	5018162
5020390	5021570	5029146	5029147	5031807	5031810	5031926	5031927
5031931	5034325	5035097	5036348	5041073	5041074	5047243	5053689
5054550	5057106	5058633	5062769	5062770	5066512		

Switzerland				
220161	224286	4263171	4263307	

United Kingdom							
210131	212482	213575	214509	216175	216296	218111	218685
220160	220161	220161	223771	224284	224286	226939	226940
227062	227064	227892	227894	229302	231124	232701	233875
656782	657836	669845	4263094	4263098	4263130	4263131	4263170
4263171	4263178	4263240	4263241	4263307	4263308	4263329	4263372
4263393	4263421	4263458	4263476	4263529	4263551	4263552	4263571
4263572	4263580	4263624	4263665	4263678	4263694	4263718	4263719
5000120	5006040	5006567	5006571	5007991	5008524	5015102	5015103
5015177	5018162	5018234	5020390	5021570	5026432	5026515	5029147
5031807	5031810	5031887	5031926	5031927	5031931	5034061	5034325
5035097	5038187	5041073	5041074	5053689	5054465	5054466	5054550
5054554	5057106	5058633	5062769	5062770	5066512		

Contact™ Detach Affected Lot Numbers by Country

United States							
210131	212482	213575	213576	214509	214511	216175	216295
216296	218110	218111	218685	219030	219075	220160	220163
223771	223775	224282	224283	224284	224285	224286	226935
226939	226940	227062	227063	227064	227065	227892	229302
656782	656785	657341	657836	657966	667536	669845	4262779
4262780	4262781	4262790	4262792	4262831	4262832	4262873	4262892
4262911	4263093	4263094	4263095	4263098	4263099	4263100	4263112
4263113	4263130	4263131	4263132	4263170	4263171	4263172	4263178
4263240	4263307	4263308	4263328	4263329	4263372	4263391	4263393
4263394	4263400	4263420	4263421	4263458	4263474	4263475	4263476
4263486	4263517	4263529	4263551	4263552	4263571	4263572	4263580
4263609	4263624	4263631	4263665	4263677	4263678	4263694	4263695
4263696	4263716	4263718	4263719	4263738	4263750	4263778	5000119
5000120	5001718	5003702	5003920	5003921	5006040	5006041	5006567
5006568	5006571	5007991	5008524	5008525	5008526	5009947	5009948
5012473	5013531	5013532	5015053	5015054	5015057	5015176	5015177
5018162	5018230	5018233	5018234	5020462	5020466	5020536	5021240
5021244	5021308	5021312	5022266	5022267	5022268	5025138	5025139
5025140	5025141	5026432	5026515	5029022	5029023	5029136	5029137
5031874	5031875	5031883	5031887	5031900	5031917	5031918	5031919
5031920	5031921	5031922	5031923	5031924	5031925	5031928	5031929
5031930	5031932	5034059	5034061	5034231	5034232	5036348	5038182
5038183	5038184	5038185	5038186	5038187	5038188	5040990	5040991
5040992	5045147	5045148	5047241	5047242	5047243	5047245	5048097
5054465	5054466	5054553	5054554	5057103	5057104	5057105	5057106
5058637	5058731	5058732	5058733	5058734	5062811	5062812	5062813