

Urgent Medical Device Notification

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

August 10, 2015

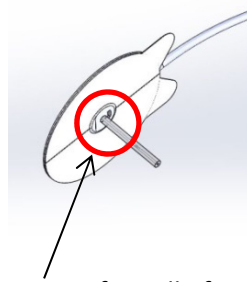
Dear Valued Customer:

Unomedical a/s, a ConvaTec Company has initiated an **Urgent Medical Device Notification**. 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 infusion 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 incidents 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 a/s 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 healthcare provider if you suspect that a needle has broken off and remained under the skin.

If you discover the needle has broken:

- Contact your healthcare 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 1-800-205-6642 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 Infusion Set Affected Lot Number List (Canada)

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	231130	227894	232701	226935	