



Urgent Field Safety Notice

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

August 24, 2015

Dear Valued Customer:

Unomedical a/s, a ConvaTec Company has initiated an **Urgent Field Safety Notice**. 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 the **Animas Customer Service Team at 0800 055 6606 (UK) or 1800 812 715 (Ireland)** to report the issue.

The Competent Authority in your country has been informed of this 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



ContactTM Detach Affected Lot Numbers in UK and Ireland

United Kingdom and Ireland							
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		