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Urgent Field Safety Notice

Comfort™, Comfort™ Short, and Contact™ Detach Infusion Sets - Tubing May Detach From the Connect/Disconnect Location

January 5, 2015

Dear Valued Customer:

At Animas, we hold our products to the highest standards of quality and are committed to communicating with you when we learn of a product that does not fully meet our customers' expectations.

Unomedical a/s, a ConvaTec Company that manufactures the Comfort™, Comfort™ Short, and Contact™ Detach Infusion Sets distributed by Animas has initiated an **Urgent Field Safety Notice** for these products.

Please refer to the enclosed Unomedical a/s Urgent Medical Device Correction and list of Impacted Product Lot Numbers to learn more about this issue and what you should do.

If you experience any issues with your infusion sets, please call **Animas Customer Service at 0800 055 6606** 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. Unomedical Urgent Medical Device Correction
Comfort & Comfort Short Lot Numbers
Contact Detach Lot Numbers

Urgent Medical device correction

Regarding

Unomedical a/s infusion sets comfort™, comfort™ short and contact™ detach

7 November 2014

Sender:

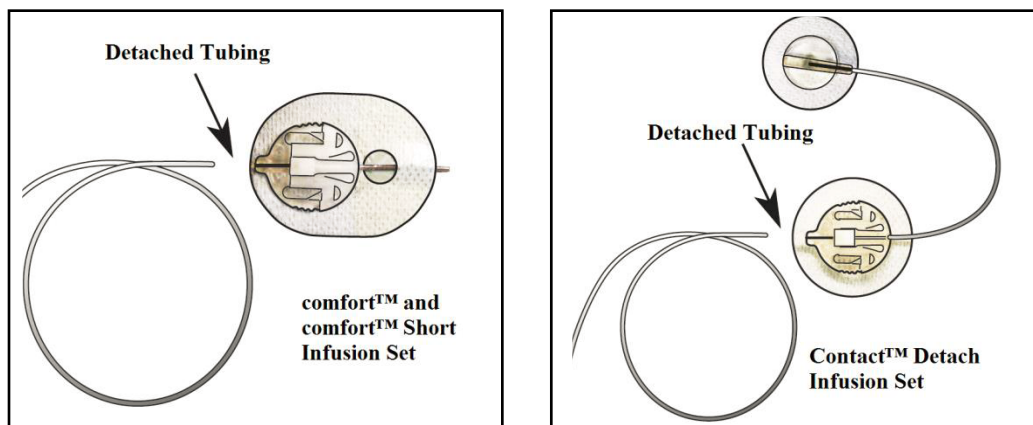
Unomedical a/s
Infusion Devices
Aaholmvej 1-3, Osted
DK - 4320 Lejre
Denmark

Dear Valued Unomedical Customer

Unomedical is committed to keeping you and your healthcare professional informed of issues and solutions concerning our infusion sets. Today we would like to provide you with some important information regarding the safe use of the comfort™, comfort™ short and contact™ detach which you may have purchased from your distributor.

As part of Unomedical a/s product quality monitoring process, we identified an increase in reports of the tubing becoming detached at the connect/disconnect location on the infusion sets comfort™, comfort™ short and contact™ detach (please see images below). While the number of these reports remains low, we are notifying you of this potential issue because your safety and experience with our products is our top priority. If tubing detachment occurs, insulin delivery is interrupted and the pump will not alarm to notify you. The interruption of insulin delivery 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.

Examples of Tubing Detachment



What action do I need to take if I experience a detached tubing?

You can continue to use your infusion sets by following the advice below.

1. When changing your infusion set, closely follow the instructions for use included in the product box. Check the tubing at the connect/disconnect location identified in the drawings above to make sure it is not loose.
2. As always, it is essential to monitor your blood sugar levels frequently using your blood glucose meter. Proactively check your tubing connections occasionally throughout the day to ensure tubing is secure. It is especially important to check your blood sugar and tubing connections at bedtime to confirm insulin delivery is occurring.
3. If you experience a high blood sugar, check your tubing connections and infusion site closely to ensure your tubing is secure.

If you discover the tubing is detached:

1. Do not attempt to reattach the tubing. Replace the infusion set immediately.
2. Treat any high blood sugar based on guidelines provided by your healthcare professional.
3. Call your distributor's Helpline to report the issue. They will give you instructions on how to return the affected infusion set.

We are working to resolve this issue and plan to incorporate improvements into the manufacturing process in the coming months.

We sincerely apologize for any inconvenience this may have caused. For any questions you may have, please contact your distributor.

We appreciate your time and attention to this important notification.

Best Regards



Mr. Søren Melsted
Vice President QA/RA Infusion Devices & Industrial Sales

Unomedical a/s
Aaholmvej 1-3, Østved
DK - 4320 Lejre
Denmark

Safety Notice: Impacted Lot numbers of Comfort™ & Comfort™ Short Infusion Sets

Lot No	Part No	Product Description	Lot No	Part No	Product Description
5021251, 5021253, 5034064, 5041057, 5044882, 5053669, 5054460, 5056817, 5065701, 5066984, 5067134, 5071891, 5071892, 5076082	100-240-04	Comfort 13mm, 23", STD 5/5	5021247, 5031820, 5032577, 5033752, 5034200, 5035085, 5035099, 5037024, 5038106, 5038107, 5038108, 5038109, 5040940, 5040941, 5040942, 5044875, 5044876, 5044877, 5044878, 5047112, 5047113, 5053663, 5053664, 5053665, 5053666, 5053667, 5054453, 5054455, 5058622, 5058636, 5058638, 5058735, 5060034, 5060036, 5060037, 5060038, 5060042, 5062779, 5062814, 5067121, 5067122, 5067123, 5075508, 5075533, 5077501, 5077535, 5080701,	100-006-01	Infusion set, Comfort, 23" Hosp10
5067135	100-240-05	Infusion set, Comfort, 43", STD5/5	5031823, 5047121, 5067137	100-240-02	Comfort 13mm, 31", hosp 10
5033753, 5034062, 5040943, 5041053, 5041054, 5047115, 5054456, 5058640, 5067126, 5079193	100-006-03	Infusion set, Comfort, 23", STD5/5	5031821, 5047116, 5062796, 5077508	100-006-11	Infusion set, Comfort, 31", Hosp10
5043820, 5062782, 5067127	100-006-02	Infusion set, Comfort, 43", STD5/5	5033755, 5034199, 5051915, 5054459, 5062783, 5066981, 5067133	100-240-03	Comfort 13mm, 43", hosp 10
5029813, 5031822, 5032578, 5033754, 5034063, 5035086, 5035100, 5037025, 5038110, 5040382, 5040944, 5040945, 5040946, 5041055, 5041056, 5044879, 5044880, 5044881, 5047117, 5047118, 5047119, 5053668, 5053670, 5054457, 5054458, 5054467, 5056856, 5056857, 5058632, 5058641, 5058642, 5062768, 5062815, 5066992, 5067128, 5067129, 5067130, 5067131, 5067132, 5075507, 5075510, 5076039, 5077504, 5077505, 5079194, 5080706	100-240-01	Comfort 13mm, 23", hosp 10	5031819, 5035098, 5040939, 5044874, 5047110, 5047111, 5056855, 5058639, 5062781, 5066393, 5067124, 5067125, 5070832, 5077503	100-006-00	Infusion set, Comfort, 43", Hosp10

Safety Notice: Impacted Lot numbers of Contact™ Detach Infusion Sets

Lot No	Part No	Product Description	Lot No	Part No	Product Description
5034232, 5038182, 5038184, 5038183, 5038185, 5038186, 5040990, 5040991, 5045147, 5045148, 5047241, 5047242, 5047243, 5047245, 5048097, 5057103, 5057104, 5058731, 5058732, 5058733, 5062811, 5062812, 5062813, 5067220, 5067222, 5067223, 5067574, 5067221, 5067224, 5067225, 5075532, 5076079, 5076080, 5077534, 5077532, 5077533, 5080736, 5080734, 5082761, 5035097, 5041073, 5041074, 5054550, 5053689, 5058633, 5062769, 5066512, 5066999, 5068464, 5068465, 5071889, 5073670, 5081993, 5067219	100-905-00	Contact Detach 6mm, 23", G29	5038187, 5043079, 5040992, 5057106, 5057105, 5058637, 5058734, 5067226, 5075509, 5076081, 5077502, 5031810, 5062770, 5073671, 5036348, 5054465, 5054553, 5062780, 5080702, 5067227, 5034061, 5054466, 5054554, 5067228	100-905-01, 100-905-02, 100-905-03	Contact Detach 8mm, 23", G29 Contact Detach 6mm, 43", G29 Contact Detach 8mm, 43", G29