Urgent Medical device correction

Regarding

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

7 November 2014

Sender:

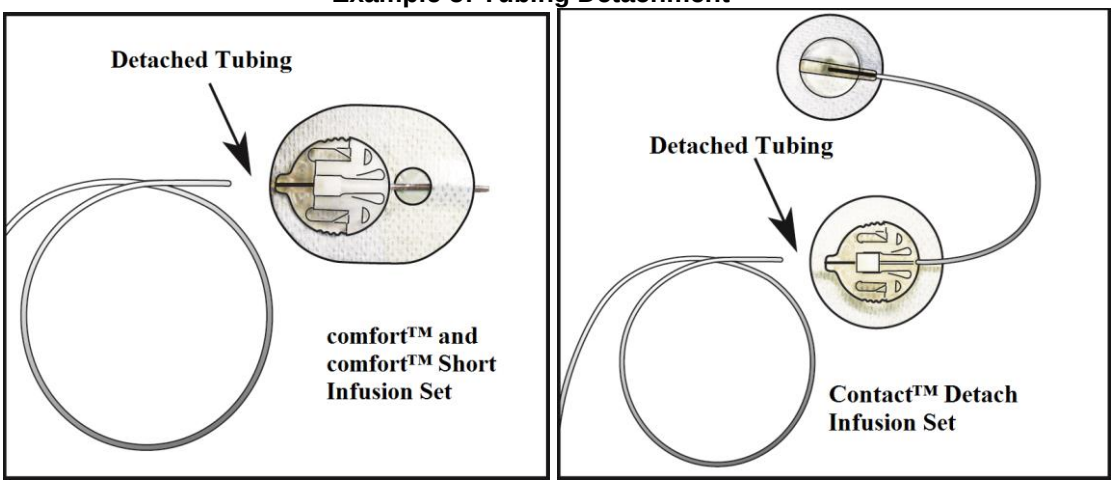
Unomedical a/s
Infusion Devices
Aaholmvej 1-3, Osted
DK - 4320 Lejre
Denmark

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.

Example 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, Osted
DK - 4320 Lejre
Denmark

Roche Diagnostics GmbH
ATT: Torsten Kraft
DCOSI...6164
Sandhofer Straße 116
68305 Mannheim
Germany

Field Safety Notice

Regarding

Unomedical a/s Infusion sets Comfort™, Comfort™ short

7 November 2014

Sender:

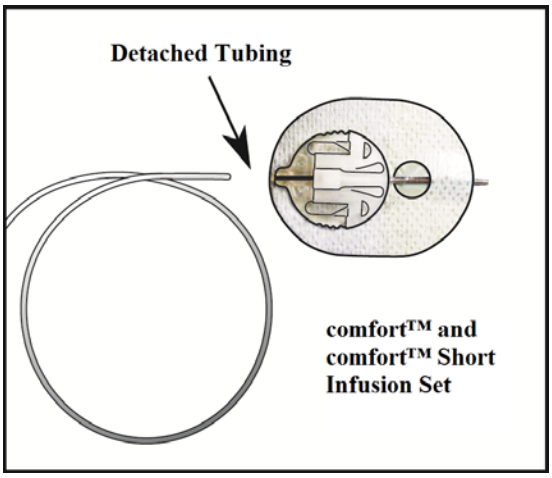
Unomedical a/s
Infusion Devices
Aaholmvej 1-3, Osted
DK - 4320 Lejre
Denmark

Dear Supplier

Today we would like to provide you with some important information regarding the safe use of the following infusion sets: Comfort™, Comfort™ Short.

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.

Example 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. In the list below, you will find information on affected lot numbers already in your possession. We will send you a final notification once we have implemented the improvements. This update will confirm that we no longer ship you devices affected by this Field Safety Notice as well as a list of lot numbers shipped to you between this letter and the final notification.

The following infusion sets are affected by this Field Safety Notice:

Lot	Unomedical Item Number	Product Description	Customer Item Number
5044364	88-060-2552 DIDU	04541464001	AC Tender II 13/60 10+10pcs.
5058502	88-060-2552 DIDU	04541464001	AC Tender II 13/60 10+10pcs.
5044353	88-060-2652 DIDU	04541502001	AC Tender II 17/60 10+10pcs.
5046676	88-060-2652 DIDU	04541502001	AC Tender II 17/60 10+10pcs.
5053301	88-060-2652 DIDU	04541502001	AC Tender II 17/60 10+10pcs.
5061934	88-060-2652 DIDU	04541502001	AC Tender II 17/60 10+10pcs.
5065553	88-060-2652 DIDU	04541502001	AC Tender II 17/60 10+10pcs.
5053291	88-080-2552 DIDU	04541472001	AC Tender II 13/80 10+10pcs.
5078661	88-080-2552 DIDU	04541472001	AC Tender II 13/80 10+10pcs.
5044354	88-080-2652 DIDU	04541529001	AC Tender II 17/80 10+10pcs.
5051306	88-080-2652 DIDU	04541529001	AC Tender II 17/80 10+10pcs.
5058507	88-080-2652 DIDU	04541529001	AC Tender II 17/80 10+10pcs.
5062209	88-080-2652 DIDU	04541529001	AC Tender II 17/80 10+10pcs.
5078668	88-080-2652 DIDU	04541529001	AC Tender II 17/80 10+10pcs.
5052067	88-110-2552 DIDU	04541456001	AC Tender II 13/110 10+10pcs.
5051307	88-110-2652 DIDU	04541499001	AC Tender II 17/110 10+10pcs.
5061935	88-110-2652 DIDU	04541499001	AC Tender II 17/110 10+10pcs.
5078667	88-110-2652 DIDU	04541499001	AC Tender II 17/110 10+10pcs.
5032433	89-030-2522 DISE	04541596001	AC TenderLink I 13/30 10pcs.
5033654	89-030-2522 DISE	04541596001	AC TenderLink I 13/30 10pcs.
5037164	89-030-2522 DISE	04541596001	AC TenderLink I 13/30 10pcs.
5040419	89-030-2522 DISE	04541596001	AC TenderLink I 13/30 10pcs.
5044362	89-030-2522 DISE	04541596001	AC TenderLink I 13/30 10pcs.
5046682	89-030-2522 DISE	04541596001	AC TenderLink I 13/30 10pcs.
5051308	89-030-2522 DISE	04541596001	AC TenderLink I 13/30 10pcs.
5053298	89-030-2522 DISE	04541596001	AC TenderLink I 13/30 10pcs.
5058508	89-030-2522 DISE	04541596001	AC TenderLink I 13/30 10pcs.
5061927	89-030-2522 DISE	04541596001	AC TenderLink I 13/30 10pcs.
5062202	89-030-2522 DISE	04541596001	AC TenderLink I 13/30 10pcs.
5065546	89-030-2522 DISE	04541596001	AC TenderLink I 13/30 10pcs.
5069297	89-030-2522 DISE	04541596001	AC TenderLink I 13/30 10pcs.
5072252	89-030-2522 DISE	04541596001	AC TenderLink I 13/30 10pcs.
5075118	89-030-2522 DISE	04541596001	AC TenderLink I 13/30 10pcs.
5032438	89-030-2622 DISE	04541634001	AC TenderLink I 17/30 10pcs.
5037160	89-030-2622 DISE	04541634001	AC TenderLink I 17/30 10pcs.
5044360	89-030-2622 DISE	04541634001	AC TenderLink I 17/30 10pcs.
5051310	89-030-2622 DISE	04541634001	AC TenderLink I 17/30 10pcs.
5053300	89-030-2622 DISE	04541634001	AC TenderLink I 17/30 10pcs.
5062211	89-030-2622 DISE	04541634001	AC TenderLink I 17/30 10pcs.
5069296	89-030-2622 DISE	04541634001	AC TenderLink I 17/30 10pcs.
5072253	89-030-2622 DISE	04541634001	AC TenderLink I 17/30 10pcs.
5044359	89-060-2522 DIDU	04541405001	AC Tender I 13/60 10pcs.

Lot	Unomedical Item Number	Product Description	Customer Item Number
5053289	89-060-2522 DIDU	04541405001	AC Tender I 13/60 10pcs.
5061929	89-060-2522 DIDU	04541405001	AC Tender I 13/60 10pcs.
5078662	89-060-2522 DIDU	04541405001	AC Tender I 13/60 10pcs.
5032434	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5032435	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5033655	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5033656	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5037165	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5037166	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5040414	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5040415	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5044356	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5044357	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5044358	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5046679	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5046680	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5051301	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5051302	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5053295	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5053296	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5058509	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5058510	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5061937	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5061938	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5062203	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5062204	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5065547	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5065548	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5069293	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5069294	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5072247	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5072248	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5075119	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5075120	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5078678	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5078679	89-060-2522 DISE	04541600001	AC TenderLink I 13/60 10pcs.
5040425	89-060-2622 DIDU	04541430001	AC Tender I 17/60 10pcs.
5044367	89-060-2622 DIDU	04541430001	AC Tender I 17/60 10pcs.
5051305	89-060-2622 DIDU	04541430001	AC Tender I 17/60 10pcs.
5053294	89-060-2622 DIDU	04541430001	AC Tender I 17/60 10pcs.
5061932	89-060-2622 DIDU	04541430001	AC Tender I 17/60 10pcs.
5078663	89-060-2622 DIDU	04541430001	AC Tender I 17/60 10pcs.

Lot	Unomedical Item Number	Product Description	Customer Item Number
5032439	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5032440	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5033659	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5033660	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5037161	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5040422	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5044365	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5046684	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5051303	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5053297	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5058503	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5061939	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5062212	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5065550	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5065551	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5069298	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5072250	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5075121	89-060-2622 DISE	04541642001	AC TenderLink I 17/60 10pcs.
5032437	89-080-2522 DIDU	04541413001	AC Tender I 13/80 10pcs.
5040421	89-080-2522 DIDU	04541413001	AC Tender I 13/80 10pcs.
5053290	89-080-2522 DIDU	04541413001	AC Tender I 13/80 10pcs.
5065549	89-080-2522 DIDU	04541413001	AC Tender I 13/80 10pcs.
5078669	89-080-2522 DIDU	04541413001	AC Tender I 13/80 10pcs.
5032436	89-080-2522 DISE	04541618001	AC TenderLink I 13/80 10pcs.
5033657	89-080-2522 DISE	04541618001	AC TenderLink I 13/80 10pcs.
5037159	89-080-2522 DISE	04541618001	AC TenderLink I 13/80 10pcs.
5040420	89-080-2522 DISE	04541618001	AC TenderLink I 13/80 10pcs.
5044355	89-080-2522 DISE	04541618001	AC TenderLink I 13/80 10pcs.
5046683	89-080-2522 DISE	04541618001	AC TenderLink I 13/80 10pcs.
5051309	89-080-2522 DISE	04541618001	AC TenderLink I 13/80 10pcs.
5053299	89-080-2522 DISE	04541618001	AC TenderLink I 13/80 10pcs.
5058501	89-080-2522 DISE	04541618001	AC TenderLink I 13/80 10pcs.
5061928	89-080-2522 DISE	04541618001	AC TenderLink I 13/80 10pcs.
5062205	89-080-2522 DISE	04541618001	AC TenderLink I 13/80 10pcs.
5065539	89-080-2522 DISE	04541618001	AC TenderLink I 13/80 10pcs.
5069295	89-080-2522 DISE	04541618001	AC TenderLink I 13/80 10pcs.
5072249	89-080-2522 DISE	04541618001	AC TenderLink I 13/80 10pcs.
5075123	89-080-2522 DISE	04541618001	AC TenderLink I 13/80 10pcs.
5078672	89-080-2522 DISE	04541618001	AC TenderLink I 13/80 10pcs.
5040426	89-080-2622 DIDU	04541448001	AC Tender I 17/80 10pcs.
5044368	89-080-2622 DIDU	04541448001	AC Tender I 17/80 10pcs.
5051312	89-080-2622 DIDU	04541448001	AC Tender I 17/80 10pcs.
5058506	89-080-2622 DIDU	04541448001	AC Tender I 17/80 10pcs.

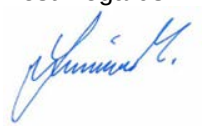
Lot	Unomedical Item Number	Product Description	Customer Item Number
5065552	89-080-2622 DIDU	04541448001	AC Tender I 17/80 10pcs.
5032441	89-080-2622 DISE	04541669001	AC TenderLink I 17/80 10pcs.
5033661	89-080-2622 DISE	04541669001	AC TenderLink I 17/80 10pcs.
5037167	89-080-2622 DISE	04541669001	AC TenderLink I 17/80 10pcs.
5040423	89-080-2622 DISE	04541669001	AC TenderLink I 17/80 10pcs.
5044366	89-080-2622 DISE	04541669001	AC TenderLink I 17/80 10pcs.
5046681	89-080-2622 DISE	04541669001	AC TenderLink I 17/80 10pcs.
5051311	89-080-2622 DISE	04541669001	AC TenderLink I 17/80 10pcs.
5053293	89-080-2622 DISE	04541669001	AC TenderLink I 17/80 10pcs.
5058504	89-080-2622 DISE	04541669001	AC TenderLink I 17/80 10pcs.
5061930	89-080-2622 DISE	04541669001	AC TenderLink I 17/80 10pcs.
5062207	89-080-2622 DISE	04541669001	AC TenderLink I 17/80 10pcs.
5065541	89-080-2622 DISE	04541669001	AC TenderLink I 17/80 10pcs.
5069301	89-080-2622 DISE	04541669001	AC TenderLink I 17/80 10pcs.
5072254	89-080-2622 DISE	04541669001	AC TenderLink I 17/80 10pcs.
5075124	89-080-2622 DISE	04541669001	AC TenderLink I 17/80 10pcs.
5078674	89-080-2622 DISE	04541669001	AC TenderLink I 17/80 10pcs.
5062206	89-110-2522 DIDU	04541391001	AC Tender I 13/110 10pcs.
5033658	89-110-2522 DISE	04541588001	AC TenderLink I 13/110 10pcs.
5044363	89-110-2522 DISE	04541588001	AC TenderLink I 13/110 10pcs.
5065540	89-110-2522 DISE	04541588001	AC TenderLink I 13/110 10pcs.
5078665	89-110-2522 DISE	04541588001	AC TenderLink I 13/110 10pcs.
5040427	89-110-2622 DIDU	04541421001	AC Tender I 17/110 10pcs.
5044352	89-110-2622 DIDU	04541421001	AC Tender I 17/110 10pcs.
5061933	89-110-2622 DIDU	04541421001	AC Tender I 17/110 10pcs.
5075126	89-110-2622 DIDU	04541421001	AC Tender I 17/110 10pcs.
5032442	89-110-2622 DISE	04541626001	AC TenderLink I 17/110 10pcs.
5033662	89-110-2622 DISE	04541626001	AC TenderLink I 17/110 10pcs.
5037162	89-110-2622 DISE	04541626001	AC TenderLink I 17/110 10pcs.
5040424	89-110-2622 DISE	04541626001	AC TenderLink I 17/110 10pcs.
5044361	89-110-2622 DISE	04541626001	AC TenderLink I 17/110 10pcs.
5051304	89-110-2622 DISE	04541626001	AC TenderLink I 17/110 10pcs.
5053292	89-110-2622 DISE	04541626001	AC TenderLink I 17/110 10pcs.
5058505	89-110-2622 DISE	04541626001	AC TenderLink I 17/110 10pcs.
5061931	89-110-2622 DISE	04541626001	AC TenderLink I 17/110 10pcs.
5062208	89-110-2622 DISE	04541626001	AC TenderLink I 17/110 10pcs.
5065542	89-110-2622 DISE	04541626001	AC TenderLink I 17/110 10pcs.
5069302	89-110-2622 DISE	04541626001	AC TenderLink I 17/110 10pcs.
5072251	89-110-2622 DISE	04541626001	AC TenderLink I 17/110 10pcs.
5075125	89-110-2622 DISE	04541626001	AC TenderLink I 17/110 10pcs.

We sincerely apologize for any inconvenience this may have caused. For any questions you may have, please call any of the three contact persons:

Torben Sandgren - VP Global Sales, Marketing and R&D +45 6161 8354, Rabi Gharabli - Director, Diabetes +45 2023 9495, Kim Nielsen - Marketing & Portfolio Manager +45 6155 5175
To report a complaint, please write to BUID.complaints@convatec.com where the complaint will be registered and handled accordingly.

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, Osted
DK - 4320 Lejre
Denmark

Regarding Field Safety Notice for infusion sets

Manufacturer: Unomedical a/s

☐ **I confirm to have read and understood the information in this Field Safety Notice for the above mentioned medical devices and intend to perform the requested actions. Furthermore, as described in the contractual agreement with Unomedical, I will supply the information related to each lot number as requested below on behalf of Roche.**

Company Name:	**Roche**
Company Address:	
Name:	
Signature:	
Date: dd/mm/yyyy	

Please return signed confirmation form and appendix 1 within two weeks from receipt to the following email: buid.complaints@convatec.com

Appendix 1

Lot nr.	Customer Item No	Country code as defined in ISO 3166-1 or full country name	Lot size
5044364	AC Tender II 13/60 10+10pcs.		
5058502	AC Tender II 13/60 10+10pcs.		
5044353	AC Tender II 17/60 10+10pcs.		
5046676	AC Tender II 17/60 10+10pcs.		
5053301	AC Tender II 17/60 10+10pcs.		
5061934	AC Tender II 17/60 10+10pcs.		
5065553	AC Tender II 17/60 10+10pcs.		
5053291	AC Tender II 13/80 10+10pcs.		
5078661	AC Tender II 13/80 10+10pcs.		
5044354	AC Tender II 17/80 10+10pcs.		
5051306	AC Tender II 17/80 10+10pcs.		
5058507	AC Tender II 17/80 10+10pcs.		
5062209	AC Tender II 17/80 10+10pcs.		
5078668	AC Tender II 17/80 10+10pcs.		
5052067	AC Tender II 13/110 10+10pcs.		
5051307	AC Tender II 17/110 10+10pcs.		
5061935	AC Tender II 17/110 10+10pcs.		
5078667	AC Tender II 17/110 10+10pcs.		
5032433	AC TenderLink I 13/30 10pcs.		
5033654	AC TenderLink I 13/30 10pcs.		
5037164	AC TenderLink I 13/30 10pcs.		
5040419	AC TenderLink I 13/30 10pcs.		
5044362	AC TenderLink I 13/30 10pcs.		
5046682	AC TenderLink I 13/30 10pcs.		
5051308	AC TenderLink I 13/30 10pcs.		
5053298	AC TenderLink I 13/30 10pcs.		
5058508	AC TenderLink I 13/30 10pcs.		
5061927	AC TenderLink I 13/30 10pcs.		
5062202	AC TenderLink I 13/30 10pcs.		
5065546	AC TenderLink I 13/30 10pcs.		
5069297	AC TenderLink I 13/30 10pcs.		
5072252	AC TenderLink I 13/30 10pcs.		
5075118	AC TenderLink I 13/30 10pcs.		
5032438	AC TenderLink I 17/30 10pcs.		
5037160	AC TenderLink I 17/30 10pcs.		

Lot nr.	Customer Item No	Country code as defined in ISO 3166-1 or full country name	Lot size
5044360	AC TenderLink I 17/30 10pcs.		
5051310	AC TenderLink I 17/30 10pcs.		
5053300	AC TenderLink I 17/30 10pcs.		
5062211	AC TenderLink I 17/30 10pcs.		
5069296	AC TenderLink I 17/30 10pcs.		
5072253	AC TenderLink I 17/30 10pcs.		
5044359	AC Tender I 13/60 10pcs.		
5053289	AC Tender I 13/60 10pcs.		
5061929	AC Tender I 13/60 10pcs.		
5078662	AC Tender I 13/60 10pcs.		
5032434	AC TenderLink I 13/60 10pcs.		
5032435	AC TenderLink I 13/60 10pcs.		
5033655	AC TenderLink I 13/60 10pcs.		
5033656	AC TenderLink I 13/60 10pcs.		
5037165	AC TenderLink I 13/60 10pcs.		
5037166	AC TenderLink I 13/60 10pcs.		
5040414	AC TenderLink I 13/60 10pcs.		
5040415	AC TenderLink I 13/60 10pcs.		
5044356	AC TenderLink I 13/60 10pcs.		
5044357	AC TenderLink I 13/60 10pcs.		
5044358	AC TenderLink I 13/60 10pcs.		
5046679	AC TenderLink I 13/60 10pcs.		
5046680	AC TenderLink I 13/60 10pcs.		
5051301	AC TenderLink I 13/60 10pcs.		
5051302	AC TenderLink I 13/60 10pcs.		
5053295	AC TenderLink I 13/60 10pcs.		
5053296	AC TenderLink I 13/60 10pcs.		
5058509	AC TenderLink I 13/60 10pcs.		
5058510	AC TenderLink I 13/60 10pcs.		
5061937	AC TenderLink I 13/60 10pcs.		
5061938	AC TenderLink I 13/60 10pcs.		
5062203	AC TenderLink I 13/60 10pcs.		
5062204	AC TenderLink I 13/60 10pcs.		
5065547	AC TenderLink I 13/60 10pcs.		
5065548	AC TenderLink I 13/60 10pcs.		

Lot nr.	Customer Item No	Country code as defined in ISO 3166-1 or full country name	Lot size
5069293	AC TenderLink I 13/60 10pcs.		
5069294	AC TenderLink I 13/60 10pcs.		
5072247	AC TenderLink I 13/60 10pcs.		
5072248	AC TenderLink I 13/60 10pcs.		
5075119	AC TenderLink I 13/60 10pcs.		
5075120	AC TenderLink I 13/60 10pcs.		
5078678	AC TenderLink I 13/60 10pcs.		
5078679	AC TenderLink I 13/60 10pcs.		
5040425	AC Tender I 17/60 10pcs.		
5044367	AC Tender I 17/60 10pcs.		
5051305	AC Tender I 17/60 10pcs.		
5053294	AC Tender I 17/60 10pcs.		
5061932	AC Tender I 17/60 10pcs.		
5078663	AC Tender I 17/60 10pcs.		
5032439	AC TenderLink I 17/60 10pcs.		
5032440	AC TenderLink I 17/60 10pcs.		
5033659	AC TenderLink I 17/60 10pcs.		
5033660	AC TenderLink I 17/60 10pcs.		
5037161	AC TenderLink I 17/60 10pcs.		
5040422	AC TenderLink I 17/60 10pcs.		
5044365	AC TenderLink I 17/60 10pcs.		
5046684	AC TenderLink I 17/60 10pcs.		
5051303	AC TenderLink I 17/60 10pcs.		
5053297	AC TenderLink I 17/60 10pcs.		
5058503	AC TenderLink I 17/60 10pcs.		
5061939	AC TenderLink I 17/60 10pcs.		
5062212	AC TenderLink I 17/60 10pcs.		
5065550	AC TenderLink I 17/60 10pcs.		
5065551	AC TenderLink I 17/60 10pcs.		
5069298	AC TenderLink I 17/60 10pcs.		
5072250	AC TenderLink I 17/60 10pcs.		
5075121	AC TenderLink I 17/60 10pcs.		
5032437	AC Tender I 13/80 10pcs.		
5040421	AC Tender I 13/80 10pcs.		

Lot nr.	Customer Item No	Country code as defined in ISO 3166-1 or full country name	Lot size
5053290	AC Tender I 13/80 10pcs.		
5065549	AC Tender I 13/80 10pcs.		
5078669	AC Tender I 13/80 10pcs.		
5032436	AC TenderLink I 13/80 10pcs.		
5033657	AC TenderLink I 13/80 10pcs.		
5037159	AC TenderLink I 13/80 10pcs.		
5040420	AC TenderLink I 13/80 10pcs.		
5044355	AC TenderLink I 13/80 10pcs.		
5046683	AC TenderLink I 13/80 10pcs.		
5051309	AC TenderLink I 13/80 10pcs.		
5053299	AC TenderLink I 13/80 10pcs.		
5058501	AC TenderLink I 13/80 10pcs.		
5061928	AC TenderLink I 13/80 10pcs.		
5062205	AC TenderLink I 13/80 10pcs.		
5065539	AC TenderLink I 13/80 10pcs.		
5069295	AC TenderLink I 13/80 10pcs.		
5072249	AC TenderLink I 13/80 10pcs.		
5075123	AC TenderLink I 13/80 10pcs.		
5078672	AC TenderLink I 13/80 10pcs.		
5040426	AC Tender I 17/80 10pcs.		
5044368	AC Tender I 17/80 10pcs.		
5051312	AC Tender I 17/80 10pcs.		
5058506	AC Tender I 17/80 10pcs.		
5065552	AC Tender I 17/80 10pcs.		
5032441	AC TenderLink I 17/80 10pcs.		
5033661	AC TenderLink I 17/80 10pcs.		
5037167	AC TenderLink I 17/80 10pcs.		
5040423	AC TenderLink I 17/80 10pcs.		
5044366	AC TenderLink I 17/80 10pcs.		
5046681	AC TenderLink I 17/80 10pcs.		
5051311	AC TenderLink I 17/80 10pcs.		
5053293	AC TenderLink I 17/80 10pcs.		
5058504	AC TenderLink I 17/80 10pcs.		
5061930	AC TenderLink I 17/80 10pcs.		

Lot nr.	Customer Item No	Country code as defined in ISO 3166-1 or full country name	Lot size
5062207	AC TenderLink I 17/80 10pcs.		
5065541	AC TenderLink I 17/80 10pcs.		
5069301	AC TenderLink I 17/80 10pcs.		
5072254	AC TenderLink I 17/80 10pcs.		
5075124	AC TenderLink I 17/80 10pcs.		
5078674	AC TenderLink I 17/80 10pcs.		
5062206	AC Tender I 13/110 10pcs.		
5033658	AC TenderLink I 13/110 10pcs.		
5044363	AC TenderLink I 13/110 10pcs.		
5065540	AC TenderLink I 13/110 10pcs.		
5078665	AC TenderLink I 13/110 10pcs.		
5040427	AC Tender I 17/110 10pcs.		
5044352	AC Tender I 17/110 10pcs.		
5061933	AC Tender I 17/110 10pcs.		
5075126	AC Tender I 17/110 10pcs.		
5032442	AC TenderLink I 17/110 10pcs.		
5033662	AC TenderLink I 17/110 10pcs.		
5037162	AC TenderLink I 17/110 10pcs.		
5040424	AC TenderLink I 17/110 10pcs.		
5044361	AC TenderLink I 17/110 10pcs.		
5051304	AC TenderLink I 17/110 10pcs.		
5053292	AC TenderLink I 17/110 10pcs.		
5058505	AC TenderLink I 17/110 10pcs.		
5061931	AC TenderLink I 17/110 10pcs.		
5062208	AC TenderLink I 17/110 10pcs.		
5065542	AC TenderLink I 17/110 10pcs.		
5069302	AC TenderLink I 17/110 10pcs.		
5072251	AC TenderLink I 17/110 10pcs.		
5075125	AC TenderLink I 17/110 10pcs.		

Chris Tupper:
Medtronic, Inc. | Diabetes
18000 Devonshire St
Northridge, CA 91325 USA

Urgent Medical device correction

Regarding

Unomedical a/s Infusion sets **MiniMed® Silhouette®** and **MiniMed® Sure-T®** infusion sets*.

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7 November 2014

Sender:

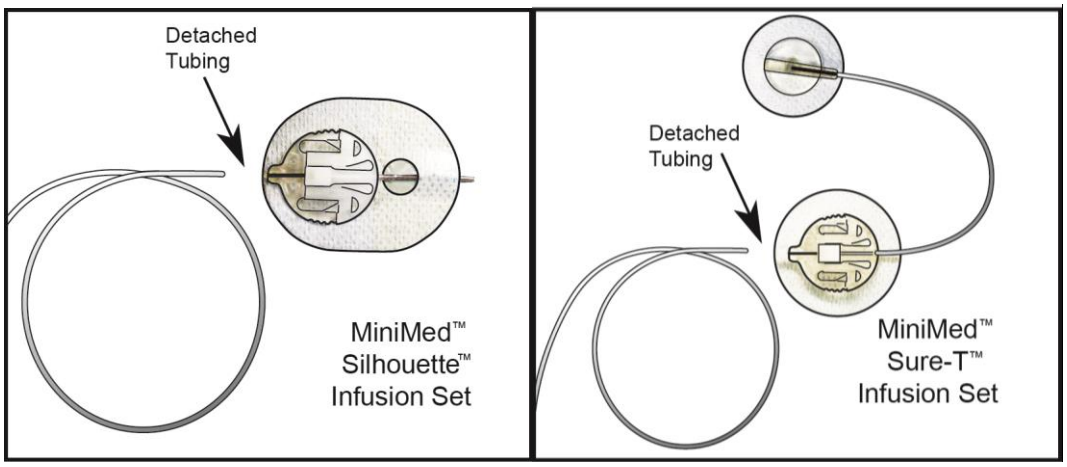
Unomedical a/s
Infusion Devices
Aaholmvej 1-3, Osted
DK - 4320 Lejre
Denmark

Dear Supplier

Today we would like to provide you with some important information regarding the safe use of the following infusion sets: Silhouette® and Sure-T®

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 Silhouette® and Sure-T® (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.

Example 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. In the list below, you will find information on affected lot numbers already in your possession. We will send you a final notification once we have implemented the improvements. This update will confirm that we no longer ship you devices affected by this Field Safety Notice as well as a list of lot numbers shipped to you between this letter and the final notification.

Unomedical a/s
A ConvaTec Company
Aaholmvej 1-3, Osted
4320 Lejre, Denmark

Tel +45 4816 7000
Fax +45 4642 7865
www.convatec.com
www.infusion-set.com

CVR No. 6415 3315

The following infusion sets are affected by this Field Safety Notice:

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5038024	89-046-2543 MCNI	MMT-368600	Silhouette Paradigm 13mm, 18"
5046572	89-046-2543 MCNI	MMT-368600	Silhouette Paradigm 13mm, 18"
5065533	89-046-2543 MCNI	MMT-368600	Silhouette Paradigm 13mm, 18"
5068324	89-046-2543 MCNI	MMT-368600	Silhouette Paradigm 13mm, 18"
5052493	89-046-2543 MCNI	MMT-368600	Silhouette Paradigm 13mm, 18"
5031734	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5034234	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5034311	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5035640	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5036333	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5037019	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5037922	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5037923	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5039570	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5040033	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5040162	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5040476	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5041194	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5043391	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5043392	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5046554	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5047941	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5048106	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5049985	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5051351	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5054982	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5056181	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5056651	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5057784	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5058432	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5059299	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5059931	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5064182	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5064183	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5064848	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5064849	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5066434	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5066634	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5067602	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5067603	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5078887	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5052913	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5053724	89-046-2543 MINI	MMT-368	Silhouette Paradigm 13mm, 18"
5021341	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5032634	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5032755	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5032756	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5032757	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5034243	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5035648	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5037023	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5042475	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5042719	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5042720	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5046575	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5047125	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5047940	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5048112	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5049135	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5051478	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5052497	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5052920	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5053757	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5057968	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5057970	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5059946	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5060849	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5060850	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5060851	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5061648	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5061649	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5068332	89-060-2543 MCNI	MMT-381600	Silhouette Paradigm 13mm, 23"
5031739	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5031740	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5031741	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5031742	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5032656	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5032657	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5032761	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5032762	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5033425	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5033426	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5034237	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5034317	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5034318	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5034319	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5034320	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5034321	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5035645	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5035708	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5035709	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5035710	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5036335	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5036336	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5037022	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5037924	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5037925	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5037926	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5037927	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5038849	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5038850	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5040036	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5040037	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5040038	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5040166	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5040167	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5040168	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5041849	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5041850	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5041851	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5041852	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5041853	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5041854	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5042472	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5042473	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5042555	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5042562	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5043401	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5043402	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5043403	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5043404	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5043405	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5043406	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5043407	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5043408	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5044098	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5044099	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5044100	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5044101	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5044102	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5046403	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5046404	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5046405	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5046564	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5046565	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5046566	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5046567	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5047503	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5047504	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5047505	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5047506	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5048109	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5048411	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5048412	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5048413	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5049550	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5049552	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5049553	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5049554	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5049555	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5049562	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5049838	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5049839	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5051359	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5051360	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5051361	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5051362	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5051363	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5051364	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5055338	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5055339	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5055892	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5055893	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5055894	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5055899	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5055900	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5055906	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5055907	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5055908	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5056652	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5056653	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5056654	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5056655	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5057109	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5057110	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5057787	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5057788	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5058437	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5058438	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5059303	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5059304	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5059938	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5059939	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5059940	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5059941	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5060842	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5060843	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5060844	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5061642	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5061643	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5061644	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5061645	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5064186	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5064187	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5064188	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5064189	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5064190	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5064856	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5064857	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5065536	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5065537	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5065538	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5066396	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5066397	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5066398	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5066433	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5066501	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5066552	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5066645	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5066646	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5066647	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5067488	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5067489	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5067491	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5067492	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5067498	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5067499	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5067500	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5067594	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5067595	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5067596	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5067597	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5067598	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5067599	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5067600	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5070169	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5049561	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5052915	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5052916	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5053727	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5053728	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5053729	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5053730	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5055336	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5055337	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5055392	89-060-2543 MINI	MMT-381	Silhouette Paradigm 13mm, 23"
5032623	89-060-2623 MINI	MMT-373	Silhouette 23"
5038026	89-060-2623 MINI	MMT-373	Silhouette 23"
5038063	89-060-2623 MINI	MMT-373	Silhouette 23"
5038064	89-060-2623 MINI	MMT-373	Silhouette 23"
5038065	89-060-2623 MINI	MMT-373	Silhouette 23"
5040032	89-060-2623 MINI	MMT-373	Silhouette 23"
5040475	89-060-2623 MINI	MMT-373	Silhouette 23"
5042573	89-060-2623 MINI	MMT-373	Silhouette 23"
5044092	89-060-2623 MINI	MMT-373	Silhouette 23"
5048408	89-060-2623 MINI	MMT-373	Silhouette 23"
5052912	89-060-2623 MINI	MMT-373	Silhouette 23"
5053723	89-060-2623 MINI	MMT-373	Silhouette 23"
5055807	89-060-2623 MINI	MMT-373	Silhouette 23"
5057783	89-060-2623 MINI	MMT-373	Silhouette 23"
5058431	89-060-2623 MINI	MMT-373	Silhouette 23"
5059298	89-060-2623 MINI	MMT-373	Silhouette 23"
5061640	89-060-2623 MINI	MMT-373	Silhouette 23"
5051350	89-060-2623 MINI	MMT-373	Silhouette 23"
5021333	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5032633	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5032766	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5042477	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5043412	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5043413	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5046574	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5047124	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5047939	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5049577	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5049837	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5051367	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5052496	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5052919	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5053732	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5057966	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5059945	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5060847	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5060848	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5068328	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5068331	89-060-2643 MCNI	MMT-378600	Silhouette Paradigm 23"
5030865	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5031737	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5031738	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5032665	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5032670	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5032671	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5032759	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5032760	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5033423	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5033424	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5034312	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5034313	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5034314	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5034315	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5034316	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5036334	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5038842	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5038843	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5039574	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5039988	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5039989	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5039990	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5039991	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5039992	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5039993	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5040164	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5040165	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5041846	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5041847	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5041848	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5041855	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5041856	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5042469	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5042470	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5042471	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5042548	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5042549	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5042550	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5042592	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5042593	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5043394	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5043395	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5043396	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5043397	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5043398	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5043399	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5043400	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5046464	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5046465	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5046560	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5046561	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5046562	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5046563	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5047497	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5048108	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5048409	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5048410	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5049133	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5049134	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5049570	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5050058	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5052914	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5055346	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5055347	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5055390	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5055391	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5056165	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5056167	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5056174	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5057107	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5057108	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5057785	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5057786	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5058434	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5058435	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5058436	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5059300	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5059301	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5059302	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5059934	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5059935	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5059936	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5059937	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5060839	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5060840	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5060841	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5061641	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5063529	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5063530	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5063531	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5063532	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5064184	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5064185	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5064852	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5064853	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5064854	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5064855	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5065534	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5065535	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5066616	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5066630	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5066631	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5066632	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5066633	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5067481	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5067606	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5067607	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5070167	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5070168	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5070835	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5070836	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5072352	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5075677	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5047498	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5049568	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5049569	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5051355	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5051356	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5051357	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5051358	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5053725	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5053726	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5054287	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5054288	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5055389	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5049834	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5049835	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5049836	89-060-2643 MINI	MMT-378	Silhouette Paradigm 23"
5051477	89-080-2543 MCNI	MMT-383600	Silhouette Paradigm 13mm, 32"
5056184	89-080-2543 MCNI	MMT-383600	Silhouette Paradigm 13mm, 32"
5028970	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5030872	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5033532	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5034324	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5037928	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5037929	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5042480	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5042718	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5046570	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5047123	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5048111	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5049988	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5055809	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5055988	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5056656	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5057790	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5058440	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5059306	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5059943	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5064858	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5066432	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5066652	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5067385	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5070838	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5073131	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5076282	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5050061	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5052918	89-080-2543 MINI	MMT-383	Silhouette Paradigm 13mm, 32"
5058711	89-080-2643 MCNI	MMT-384600	Silhouette Paradigm 32"
5032630	89-080-2643 MINI	MMT-384	Silhouette Paradigm 32"
5038025	89-080-2643 MINI	MMT-384	Silhouette Paradigm 32"
5038072	89-080-2643 MINI	MMT-384	Silhouette Paradigm 32"
5038073	89-080-2643 MINI	MMT-384	Silhouette Paradigm 32"
5042577	89-080-2643 MINI	MMT-384	Silhouette Paradigm 32"
5043411	89-080-2643 MINI	MMT-384	Silhouette Paradigm 32"
5046406	89-080-2643 MINI	MMT-384	Silhouette Paradigm 32"
5049989	89-080-2643 MINI	MMT-384	Silhouette Paradigm 32"
5057112	89-080-2643 MINI	MMT-384	Silhouette Paradigm 32"

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5058710	89-080-2643 MINI	MMT-384	Silhouette Paradigm 32"
5067386	89-080-2643 MINI	MMT-384	Silhouette Paradigm 32"
5073132	89-080-2643 MINI	MMT-384	Silhouette Paradigm 32"
5051366	89-080-2643 MINI	MMT-384	Silhouette Paradigm 32"
5034242	89-110-2543 MCNI	MMT-382600	Silhouette Paradigm 13mm, 43"
5049578	89-110-2543 MCNI	MMT-382600	Silhouette Paradigm 13mm, 43"
5052499	89-110-2543 MCNI	MMT-382600	Silhouette Paradigm 13mm, 43"
5057972	89-110-2543 MCNI	MMT-382600	Silhouette Paradigm 13mm, 43"
5059947	89-110-2543 MCNI	MMT-382600	Silhouette Paradigm 13mm, 43"
5032628	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5032763	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5034322	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5034323	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5038030	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5038069	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5038070	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5038071	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5040039	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5040169	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5042569	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5042571	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5042572	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5042716	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5042717	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5043409	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5043410	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5048110	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5051365	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5052917	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5053731	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5054289	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5055811	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5055813	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5055989	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5057111	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5058439	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5059305	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5059942	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5060845	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5060846	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5063533	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5063534	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5063535	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5063536	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5063629	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5067610	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5046568	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5057789	89-110-2543 MINI	MMT-382	Silhouette Paradigm 13mm, 43"
5032622	89-110-2623 MINI	MMT-371	Silhouette 43"
5032758	89-110-2623 MINI	MMT-371	Silhouette 43"
5034233	89-110-2623 MINI	MMT-371	Silhouette 43"
5034310	89-110-2623 MINI	MMT-371	Silhouette 43"
5035639	89-110-2623 MINI	MMT-371	Silhouette 43"
5037920	89-110-2623 MINI	MMT-371	Silhouette 43"
5037921	89-110-2623 MINI	MMT-371	Silhouette 43"
5037930	89-110-2623 MINI	MMT-371	Silhouette 43"
5039572	89-110-2623 MINI	MMT-371	Silhouette 43"
5040161	89-110-2623 MINI	MMT-371	Silhouette 43"
5043390	89-110-2623 MINI	MMT-371	Silhouette 43"
5046552	89-110-2623 MINI	MMT-371	Silhouette 43"
5048407	89-110-2623 MINI	MMT-371	Silhouette 43"
5049831	89-110-2623 MINI	MMT-371	Silhouette 43"
5050059	89-110-2623 MINI	MMT-371	Silhouette 43"
5051349	89-110-2623 MINI	MMT-371	Silhouette 43"
5066394	89-110-2623 MINI	MMT-371	Silhouette 43"
5067601	89-110-2623 MINI	MMT-371	Silhouette 43"
5075676	89-110-2623 MINI	MMT-371	Silhouette 43"
5078884	89-110-2623 MINI	MMT-371	Silhouette 43"
5032632	89-110-2643 MCNI	MMT-377600	Silhouette Paradigm 43"
5032765	89-110-2643 MCNI	MMT-377600	Silhouette Paradigm 43"
5052495	89-110-2643 MCNI	MMT-377600	Silhouette Paradigm 43"
5057965	89-110-2643 MCNI	MMT-377600	Silhouette Paradigm 43"
5058441	89-110-2643 MCNI	MMT-377600	Silhouette Paradigm 43"
5031735	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5031736	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5032662	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5032663	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5034236	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5035643	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5035644	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5037021	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5038839	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5039986	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5039987	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5040035	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5040163	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5042478	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5042575	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5042576	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5042714	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5042715	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5043393	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5046462	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5046463	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5047107	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5047491	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5047943	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5050057	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5051352	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5051353	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5051354	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5058433	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5059933	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5061646	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5061670	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5061967	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5063527	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5063528	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5063628	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5066395	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5067505	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5067604	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5067605	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5070166	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5070833	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5072351	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5075366	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5077550	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5046558	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5047942	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5050056	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5057791	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5025162	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5025163	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5025164	89-110-2643 MINI	MMT-377	Silhouette Paradigm 43"
5040464	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5038783	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5043414	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5043415	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5042582	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5046638	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5046639	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5042584	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5049122	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5052904	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5052903	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5057953	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5060205	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5061496	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5063694	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5064402	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5057219	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5068555	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5071403	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5047168	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5056680	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5057241	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5068516	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5073682	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5075554	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5076349	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5072333	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5079260	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5079682	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5077119	81-046-2946 MIMX	MMT-862	SureT G29 6mm, 18", Paradigm
5043121	81-060-2926 MIMX	MMT-863	SureT G29 6mm, 23"
5044843	81-060-2926 MIMX	MMT-863	SureT G29 6mm, 23"
5057215	81-060-2926 MIMX	MMT-863	SureT G29 6mm, 23"
5064141	81-060-2926 MIMX	MMT-863	SureT G29 6mm, 23"
5068515	81-060-2926 MIMX	MMT-863	SureT G29 6mm, 23"
5072635	81-060-2926 MIMX	MMT-863	SureT G29 6mm, 23"
5035649	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5040158	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5040159	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5040465	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5040467	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5040466	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5040468	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5039578	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5035690	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5039579	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5039581	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5039580	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5042578	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5042581	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5042580	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5043387	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5043418	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5043419	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5043094	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5046395	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5046396	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5043095	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5043417	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5046641	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5047582	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5046640	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5047580	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5047581	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5049123	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5050036	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5050034	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5050035	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5046393	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5043100	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5051560	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5051562	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5043106	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5051561	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5047170	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5052905	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5053786	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5053787	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5047171	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5052906	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5053788	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5057242	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5057251	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5057243	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5057955	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5057954	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5057047	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5060206	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5060208	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5060207	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5057221	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5060946	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5060947	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5060948	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5060949	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5057226	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5060989	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm

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CVR No. 6415 3315

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5063695	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5063696	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5057232	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5057231	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5065089	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5064143	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5065090	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5065106	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5064144	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5066513	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5064142	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5066445	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5066514	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5067182	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5064145	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5067587	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5067183	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5067589	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5067590	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5066524	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5070664	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5047510	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5054558	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5047511	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5054559	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5055496	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5055497	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5056681	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5056682	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5060988	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5068520	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5068518	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5072716	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5072717	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5068522	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5075402	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5075403	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5075555	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5075556	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5071380	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5075557	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5077462	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5076350	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5078949	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5077461	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5079262	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5079261	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5079683	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5072335	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5079688	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5079685	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5079684	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5082372	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5082374	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5082373	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5079686	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5079687	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5072341	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5083297	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5083299	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5084121	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5083298	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5084120	81-060-2946 MIMX	MMT-864	SureT G29 6mm, 23", Paradigm
5053658	81-080-2926 MIMX	MMT-865	SureT G29 6mm, 32"
5064299	81-080-2926 MIMX	MMT-865	SureT G29 6mm, 32"
5080458	81-080-2926 MIMX	MMT-865	SureT G29 6mm, 32"
5040469	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5032640	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5041195	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5039582	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5043420	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5043421	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5046397	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5039589	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5047583	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5049124	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5050037	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5051563	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5043329	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5047172	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5052907	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5053661	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5059551	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5059552	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5060209	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5058702	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5060950	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5061497	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5058704	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5063697	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5064403	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5066515	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5067592	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5059523	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5071405	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5072718	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5047175	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5056683	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5057244	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5067184	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5068528	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5075404	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5075558	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5076351	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5077463	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5072347	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5079263	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5079689	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5079690	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5079691	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5082342	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5081996	81-080-1946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5081997	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5077131	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5082443	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5083300	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5079900	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5084122	81-080-2946 MIMX	MMT-866	SureT G29 6mm, 32", Paradigm
5038779	81-060-2928 MIMX	MMT-873	SureT G29 8mm, 23"
5040470	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5040471	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5041196	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5032646	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5043422	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5043423	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5043112	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5047584	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5050038	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5043114	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5051564	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5044841	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5052908	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5060951	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5060210	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5060952	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5060990	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5055463	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5055465	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5070666	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5067593	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5047177	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5056684	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5057245	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5067185	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5071406	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5072719	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5068526	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5075405	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5076352	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5077464	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5078950	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5072627	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5079692	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5079693	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5082444	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5082343	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5072629	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5084123	81-060-2948 MIMX	MMT-874	SureT G29 8mm, 23", Paradigm
5057216	81-080-2928 MIMX	MMT-875	SureT G29 8mm, 32"
5032652	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5040472	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5040473	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5043425	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5043427	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5043426	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5046644	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5046645	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5049125	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5043117	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5053789	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5047179	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5059553	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5058706	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5060953	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5060991	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5066516	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5058708	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5070667	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5055498	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5071407	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5068531	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5076348	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5076353	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5072631	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5077465	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm

Lot No.	Unomedical Model No.	Customer Model No	Product Description
5079264	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5078951	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5079694	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5079695	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5077117	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5082445	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5083301	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5084124	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5084823	81-080-2948 MIMX	MMT-876	SureT G29 8mm, 32", Paradigm
5040474	81-060-2941 MIMX	MMT-884	SureT G29 10mm, 23", Paradigm
5039586	81-060-2941 MIMX	MMT-884	SureT G29 10mm, 23", Paradigm
5072633	81-060-2941 MIMX	MMT-884	SureT G29 10mm, 23", Paradigm
5079671	81-060-2941 MIMX	MMT-884	SureT G29 10mm, 23", Paradigm
5072636	81-080-2921 MIMX	MMT-885	SureT G29 10mm, 32"
5043428	81-080-2941 MIMX	MMT-886	SureT G29 10mm, 32", Paradigm
5043429	81-080-2941 MIMX	MMT-886	SureT G29 10mm, 32", Paradigm
5038787	81-080-2941 MIMX	MMT-886	SureT G29 10mm, 32", Paradigm
5053790	81-080-2941 MIMX	MMT-886	SureT G29 10mm, 32", Paradigm
5043124	81-080-2941 MIMX	MMT-886	SureT G29 10mm, 32", Paradigm
5064404	81-080-2941 MIMX	MMT-886	SureT G29 10mm, 32", Paradigm
5064146	81-080-2941 MIMX	MMT-886	SureT G29 10mm, 32", Paradigm
5068557	81-080-2941 MIMX	MMT-886	SureT G29 10mm, 32", Paradigm
5068530	81-080-2941 MIMX	MMT-886	SureT G29 10mm, 32", Paradigm
5072634	81-080-2941 MIMX	MMT-886	SureT G29 10mm, 32", Paradigm
5079696	81-080-2941 MIMX	MMT-886	SureT G29 10mm, 32", Paradigm
5083604	81-080-2941 MIMX	MMT-886	SureT G29 10mm, 32", Paradigm

We sincerely apologize for any inconvenience this may have caused. For any questions you may have, please call any of the three contact persons:

Torben Sandgren - VP Global Sales, Marketing and R&D +45 6161 8354, Rabi Gharabli - Associate Director, Diabetes +45 2023 9495, Kim Nielsen - Marketing & Portfolio Manager +45 6155 5175
To report a complaint, please write to BUID.complaints@convatec.com where the complaint will be registered and handled accordingly.

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, Osted
DK - 4320 Lejre
Denmark

Regarding Field Safety Notice for infusion sets

Manufacturer: Unomedical a/s

☐ **I confirm to have read and understood the information in this Field Safety Notice for the above mentioned medical devices and intend to perform the requested actions. Furthermore, as described in the contractual agreement with Unomedical, I will supply the information related to each lot number as requested below on behalf of Medtronic MiniMed**

Company Name:	
Company Address:	
Name:	
Signature:	
Date: dd/mm/yyyy	

Please return signed confirmation form and appendix 1 within two weeks from receipt to the following email: buid.complaints@convatec.com

Unomedical a/s
A ConvaTec Company
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4320 Lejre, Denmark

Tel +45 4816 7000
Fax +45 4642 7865
www.convatec.com
www.infusion-set.com

CVR No. 6415 3315

Appendix 1

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5038024	MMT-368600		
5046572	MMT-368600		
5065533	MMT-368600		
5068324	MMT-368600		
5052493	MMT-368600		
5031734	MMT-368		
5034234	MMT-368		
5034311	MMT-368		
5035640	MMT-368		
5036333	MMT-368		
5037019	MMT-368		
5037922	MMT-368		
5037923	MMT-368		
5039570	MMT-368		
5040033	MMT-368		
5040162	MMT-368		
5040476	MMT-368		
5041194	MMT-368		
5043391	MMT-368		
5043392	MMT-368		
5046554	MMT-368		
5047941	MMT-368		
5048106	MMT-368		
5049985	MMT-368		
5051351	MMT-368		
5054982	MMT-368		
5056181	MMT-368		
5056651	MMT-368		
5057784	MMT-368		
5058432	MMT-368		
5059299	MMT-368		
5059931	MMT-368		
5064182	MMT-368		
5064183	MMT-368		
5064848	MMT-368		

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5064849	MMT-368		
5066434	MMT-368		
5066634	MMT-368		
5067602	MMT-368		
5067603	MMT-368		
5078887	MMT-368		
5052913	MMT-368		
5053724	MMT-368		
5021341	MMT-381600		
5032634	MMT-381600		
5032755	MMT-381600		
5032756	MMT-381600		
5032757	MMT-381600		
5034243	MMT-381600		
5035648	MMT-381600		
5037023	MMT-381600		
5042475	MMT-381600		
5042719	MMT-381600		
5042720	MMT-381600		
5046575	MMT-381600		
5047125	MMT-381600		
5047940	MMT-381600		
5048112	MMT-381600		
5049135	MMT-381600		
5051478	MMT-381600		
5052497	MMT-381600		
5052920	MMT-381600		
5053757	MMT-381600		
5057968	MMT-381600		
5057970	MMT-381600		
5059946	MMT-381600		
5060849	MMT-381600		
5060850	MMT-381600		
5060851	MMT-381600		
5061648	MMT-381600		
5061649	MMT-381600		

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5068332	MMT-381600		
5031739	MMT-381		
5031740	MMT-381		
5031741	MMT-381		
5031742	MMT-381		
5032656	MMT-381		
5032657	MMT-381		
5032761	MMT-381		
5032762	MMT-381		
5033425	MMT-381		
5033426	MMT-381		
5034237	MMT-381		
5034317	MMT-381		
5034318	MMT-381		
5034319	MMT-381		
5034320	MMT-381		
5034321	MMT-381		
5035645	MMT-381		
5035708	MMT-381		
5035709	MMT-381		
5035710	MMT-381		
5036335	MMT-381		
5036336	MMT-381		
5037022	MMT-381		
5037924	MMT-381		
5037925	MMT-381		
5037926	MMT-381		
5037927	MMT-381		
5038849	MMT-381		
5038850	MMT-381		
5040036	MMT-381		
5040037	MMT-381		
5040038	MMT-381		
5040166	MMT-381		
5040167	MMT-381		
5040168	MMT-381		

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CVR No. 6415 3315

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5041849	MMT-381		
5041850	MMT-381		
5041851	MMT-381		
5041852	MMT-381		
5041853	MMT-381		
5041854	MMT-381		
5042472	MMT-381		
5042473	MMT-381		
5042555	MMT-381		
5042562	MMT-381		
5043401	MMT-381		
5043402	MMT-381		
5043403	MMT-381		
5043404	MMT-381		
5043405	MMT-381		
5043406	MMT-381		
5043407	MMT-381		
5043408	MMT-381		
5044098	MMT-381		
5044099	MMT-381		
5044100	MMT-381		
5044101	MMT-381		
5044102	MMT-381		
5046403	MMT-381		
5046404	MMT-381		
5046405	MMT-381		
5046564	MMT-381		
5046565	MMT-381		
5046566	MMT-381		
5046567	MMT-381		
5047503	MMT-381		
5047504	MMT-381		
5047505	MMT-381		
5047506	MMT-381		
5048109	MMT-381		
5048411	MMT-381		

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5048412	MMT-381		
5048413	MMT-381		
5049550	MMT-381		
5049552	MMT-381		
5049553	MMT-381		
5049554	MMT-381		
5049555	MMT-381		
5049562	MMT-381		
5049838	MMT-381		
5049839	MMT-381		
5051359	MMT-381		
5051360	MMT-381		
5051361	MMT-381		
5051362	MMT-381		
5051363	MMT-381		
5051364	MMT-381		
5055338	MMT-381		
5055339	MMT-381		
5055892	MMT-381		
5055893	MMT-381		
5055894	MMT-381		
5055899	MMT-381		
5055900	MMT-381		
5055906	MMT-381		
5055907	MMT-381		
5055908	MMT-381		
5056652	MMT-381		
5056653	MMT-381		
5056654	MMT-381		
5056655	MMT-381		
5057109	MMT-381		
5057110	MMT-381		
5057787	MMT-381		
5057788	MMT-381		
5058437	MMT-381		
5058438	MMT-381		

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5059303	MMT-381		
5059304	MMT-381		
5059938	MMT-381		
5059939	MMT-381		
5059940	MMT-381		
5059941	MMT-381		
5060842	MMT-381		
5060843	MMT-381		
5060844	MMT-381		
5061642	MMT-381		
5061643	MMT-381		
5061644	MMT-381		
5061645	MMT-381		
5064186	MMT-381		
5064187	MMT-381		
5064188	MMT-381		
5064189	MMT-381		
5064190	MMT-381		
5064856	MMT-381		
5064857	MMT-381		
5065536	MMT-381		
5065537	MMT-381		
5065538	MMT-381		
5066396	MMT-381		
5066397	MMT-381		
5066398	MMT-381		
5066433	MMT-381		
5066501	MMT-381		
5066552	MMT-381		
5066645	MMT-381		
5066646	MMT-381		
5066647	MMT-381		
5067488	MMT-381		
5067489	MMT-381		
5067491	MMT-381		
5067492	MMT-381		

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Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5067498	MMT-381		
5067499	MMT-381		
5067500	MMT-381		
5067594	MMT-381		
5067595	MMT-381		
5067596	MMT-381		
5067597	MMT-381		
5067598	MMT-381		
5067599	MMT-381		
5067600	MMT-381		
5070169	MMT-381		
5049561	MMT-381		
5052915	MMT-381		
5052916	MMT-381		
5053727	MMT-381		
5053728	MMT-381		
5053729	MMT-381		
5053730	MMT-381		
5055336	MMT-381		
5055337	MMT-381		
5055392	MMT-381		
5032623	MMT-373		
5038026	MMT-373		
5038063	MMT-373		
5038064	MMT-373		
5038065	MMT-373		
5040032	MMT-373		
5040475	MMT-373		
5042573	MMT-373		
5044092	MMT-373		
5048408	MMT-373		
5052912	MMT-373		
5053723	MMT-373		
5055807	MMT-373		
5057783	MMT-373		
5058431	MMT-373		

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5059298	MMT-373		
5061640	MMT-373		
5051350	MMT-373		
5021333	MMT-378600		
5032633	MMT-378600		
5032766	MMT-378600		
5042477	MMT-378600		
5043412	MMT-378600		
5043413	MMT-378600		
5046574	MMT-378600		
5047124	MMT-378600		
5047939	MMT-378600		
5049577	MMT-378600		
5049837	MMT-378600		
5051367	MMT-378600		
5052496	MMT-378600		
5052919	MMT-378600		
5053732	MMT-378600		
5057966	MMT-378600		
5059945	MMT-378600		
5060847	MMT-378600		
5060848	MMT-378600		
5068328	MMT-378600		
5068331	MMT-378600		
5030865	MMT-378		
5031737	MMT-378		
5031738	MMT-378		
5032665	MMT-378		
5032670	MMT-378		
5032671	MMT-378		
5032759	MMT-378		
5032760	MMT-378		
5033423	MMT-378		
5033424	MMT-378		
5034312	MMT-378		
5034313	MMT-378		

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Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5034314	MMT-378		
5034315	MMT-378		
5034316	MMT-378		
5036334	MMT-378		
5038842	MMT-378		
5038843	MMT-378		
5039574	MMT-378		
5039988	MMT-378		
5039989	MMT-378		
5039990	MMT-378		
5039991	MMT-378		
5039992	MMT-378		
5039993	MMT-378		
5040164	MMT-378		
5040165	MMT-378		
5041846	MMT-378		
5041847	MMT-378		
5041848	MMT-378		
5041855	MMT-378		
5041856	MMT-378		
5042469	MMT-378		
5042470	MMT-378		
5042471	MMT-378		
5042548	MMT-378		
5042549	MMT-378		
5042550	MMT-378		
5042592	MMT-378		
5042593	MMT-378		
5043394	MMT-378		
5043395	MMT-378		
5043396	MMT-378		
5043397	MMT-378		
5043398	MMT-378		
5043399	MMT-378		
5043400	MMT-378		
5046464	MMT-378		

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Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5046465	MMT-378		
5046560	MMT-378		
5046561	MMT-378		
5046562	MMT-378		
5046563	MMT-378		
5047497	MMT-378		
5048108	MMT-378		
5048409	MMT-378		
5048410	MMT-378		
5049133	MMT-378		
5049134	MMT-378		
5049570	MMT-378		
5050058	MMT-378		
5052914	MMT-378		
5055346	MMT-378		
5055347	MMT-378		
5055390	MMT-378		
5055391	MMT-378		
5056165	MMT-378		
5056167	MMT-378		
5056174	MMT-378		
5057107	MMT-378		
5057108	MMT-378		
5057785	MMT-378		
5057786	MMT-378		
5058434	MMT-378		
5058435	MMT-378		
5058436	MMT-378		
5059300	MMT-378		
5059301	MMT-378		
5059302	MMT-378		
5059934	MMT-378		
5059935	MMT-378		
5059936	MMT-378		
5059937	MMT-378		
5060839	MMT-378		

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5060840	MMT-378		
5060841	MMT-378		
5061641	MMT-378		
5063529	MMT-378		
5063530	MMT-378		
5063531	MMT-378		
5063532	MMT-378		
5064184	MMT-378		
5064185	MMT-378		
5064852	MMT-378		
5064853	MMT-378		
5064854	MMT-378		
5064855	MMT-378		
5065534	MMT-378		
5065535	MMT-378		
5066616	MMT-378		
5066630	MMT-378		
5066631	MMT-378		
5066632	MMT-378		
5066633	MMT-378		
5067481	MMT-378		
5067606	MMT-378		
5067607	MMT-378		
5070167	MMT-378		
5070168	MMT-378		
5070835	MMT-378		
5070836	MMT-378		
5072352	MMT-378		
5075677	MMT-378		
5047498	MMT-378		
5049568	MMT-378		
5049569	MMT-378		
5051355	MMT-378		
5051356	MMT-378		
5051357	MMT-378		
5051358	MMT-378		

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5053725	MMT-378		
5053726	MMT-378		
5054287	MMT-378		
5054288	MMT-378		
5055389	MMT-378		
5049834	MMT-378		
5049835	MMT-378		
5049836	MMT-378		
5051477	MMT-383600		
5056184	MMT-383600		
5028970	MMT-383		
5030872	MMT-383		
5033532	MMT-383		
5034324	MMT-383		
5037928	MMT-383		
5037929	MMT-383		
5042480	MMT-383		
5042718	MMT-383		
5046570	MMT-383		
5047123	MMT-383		
5048111	MMT-383		
5049988	MMT-383		
5055809	MMT-383		
5055988	MMT-383		
5056656	MMT-383		
5057790	MMT-383		
5058440	MMT-383		
5059306	MMT-383		
5059943	MMT-383		
5064858	MMT-383		
5066432	MMT-383		
5066652	MMT-383		
5067385	MMT-383		
5070838	MMT-383		
5073131	MMT-383		
5076282	MMT-383		

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5050061	MMT-383		
5052918	MMT-383		
5058711	MMT-384600		
5032630	MMT-384		
5038025	MMT-384		
5038072	MMT-384		
5038073	MMT-384		
5042577	MMT-384		
5043411	MMT-384		
5046406	MMT-384		
5049989	MMT-384		
5057112	MMT-384		
5058710	MMT-384		
5067386	MMT-384		
5073132	MMT-384		
5051366	MMT-384		
5034242	MMT-382600		
5049578	MMT-382600		
5052499	MMT-382600		
5057972	MMT-382600		
5059947	MMT-382600		
5032628	MMT-382		
5032763	MMT-382		
5034322	MMT-382		
5034323	MMT-382		
5038030	MMT-382		
5038069	MMT-382		
5038070	MMT-382		
5038071	MMT-382		
5040039	MMT-382		
5040169	MMT-382		
5042569	MMT-382		
5042571	MMT-382		
5042572	MMT-382		
5042716	MMT-382		
5042717	MMT-382		

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Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5043409	MMT-382		
5043410	MMT-382		
5048110	MMT-382		
5051365	MMT-382		
5052917	MMT-382		
5053731	MMT-382		
5054289	MMT-382		
5055811	MMT-382		
5055813	MMT-382		
5055989	MMT-382		
5057111	MMT-382		
5058439	MMT-382		
5059305	MMT-382		
5059942	MMT-382		
5060845	MMT-382		
5060846	MMT-382		
5063533	MMT-382		
5063534	MMT-382		
5063535	MMT-382		
5063536	MMT-382		
5063629	MMT-382		
5067610	MMT-382		
5046568	MMT-382		
5057789	MMT-382		
5032622	MMT-371		
5032758	MMT-371		
5034233	MMT-371		
5034310	MMT-371		
5035639	MMT-371		
5037920	MMT-371		
5037921	MMT-371		
5037930	MMT-371		
5039572	MMT-371		
5040161	MMT-371		
5043390	MMT-371		
5046552	MMT-371		

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5048407	MMT-371		
5049831	MMT-371		
5050059	MMT-371		
5051349	MMT-371		
5066394	MMT-371		
5067601	MMT-371		
5075676	MMT-371		
5078884	MMT-371		
5032632	MMT-377600		
5032765	MMT-377600		
5052495	MMT-377600		
5057965	MMT-377600		
5058441	MMT-377600		
5031735	MMT-377		
5031736	MMT-377		
5032662	MMT-377		
5032663	MMT-377		
5034236	MMT-377		
5035643	MMT-377		
5035644	MMT-377		
5037021	MMT-377		
5038839	MMT-377		
5039986	MMT-377		
5039987	MMT-377		
5040035	MMT-377		
5040163	MMT-377		
5042478	MMT-377		
5042575	MMT-377		
5042576	MMT-377		
5042714	MMT-377		
5042715	MMT-377		
5043393	MMT-377		
5046462	MMT-377		
5046463	MMT-377		
5047107	MMT-377		
5047491	MMT-377		

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5047943	MMT-377		
5050057	MMT-377		
5051352	MMT-377		
5051353	MMT-377		
5051354	MMT-377		
5058433	MMT-377		
5059933	MMT-377		
5061646	MMT-377		
5061670	MMT-377		
5061967	MMT-377		
5063527	MMT-377		
5063528	MMT-377		
5063628	MMT-377		
5066395	MMT-377		
5067505	MMT-377		
5067604	MMT-377		
5067605	MMT-377		
5070166	MMT-377		
5070833	MMT-377		
5072351	MMT-377		
5075366	MMT-377		
5077550	MMT-377		
5046558	MMT-377		
5047942	MMT-377		
5050056	MMT-377		
5057791	MMT-377		
5025162	MMT-377		
5025163	MMT-377		
5025164	MMT-377		
5040464	MMT-862		
5038783	MMT-862		
5043414	MMT-862		
5043415	MMT-862		
5042582	MMT-862		
5046638	MMT-862		
5046639	MMT-862		

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Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5042584	MMT-862		
5049122	MMT-862		
5052904	MMT-862		
5052903	MMT-862		
5057953	MMT-862		
5060205	MMT-862		
5061496	MMT-862		
5063694	MMT-862		
5064402	MMT-862		
5057219	MMT-862		
5068555	MMT-862		
5071403	MMT-862		
5047168	MMT-862		
5056680	MMT-862		
5057241	MMT-862		
5068516	MMT-862		
5073682	MMT-862		
5075554	MMT-862		
5076349	MMT-862		
5072333	MMT-862		
5079260	MMT-862		
5079682	MMT-862		
5077119	MMT-862		
5043121	MMT-863		
5044843	MMT-863		
5057215	MMT-863		
5064141	MMT-863		
5068515	MMT-863		
5072635	MMT-863		
5035649	MMT-864		
5040158	MMT-864		
5040159	MMT-864		
5040465	MMT-864		
5040467	MMT-864		
5040466	MMT-864		
5040468	MMT-864		

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5039578	MMT-864		
5035690	MMT-864		
5039579	MMT-864		
5039581	MMT-864		
5039580	MMT-864		
5042578	MMT-864		
5042581	MMT-864		
5042580	MMT-864		
5043387	MMT-864		
5043418	MMT-864		
5043419	MMT-864		
5043094	MMT-864		
5046395	MMT-864		
5046396	MMT-864		
5043095	MMT-864		
5043417	MMT-864		
5046641	MMT-864		
5047582	MMT-864		
5046640	MMT-864		
5047580	MMT-864		
5047581	MMT-864		
5049123	MMT-864		
5050036	MMT-864		
5050034	MMT-864		
5050035	MMT-864		
5046393	MMT-864		
5043100	MMT-864		
5051560	MMT-864		
5051562	MMT-864		
5043106	MMT-864		
5051561	MMT-864		
5047170	MMT-864		
5052905	MMT-864		
5053786	MMT-864		
5053787	MMT-864		
5047171	MMT-864		

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Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5052906	MMT-864		
5053788	MMT-864		
5057242	MMT-864		
5057251	MMT-864		
5057243	MMT-864		
5057955	MMT-864		
5057954	MMT-864		
5057047	MMT-864		
5060206	MMT-864		
5060208	MMT-864		
5060207	MMT-864		
5057221	MMT-864		
5060946	MMT-864		
5060947	MMT-864		
5060948	MMT-864		
5060949	MMT-864		
5057226	MMT-864		
5060989	MMT-864		
5063695	MMT-864		
5063696	MMT-864		
5057232	MMT-864		
5057231	MMT-864		
5065089	MMT-864		
5064143	MMT-864		
5065090	MMT-864		
5065106	MMT-864		
5064144	MMT-864		
5066513	MMT-864		
5064142	MMT-864		
5066445	MMT-864		
5066514	MMT-864		
5067182	MMT-864		
5064145	MMT-864		
5067587	MMT-864		
5067183	MMT-864		
5067589	MMT-864		

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5067590	MMT-864		
5066524	MMT-864		
5070664	MMT-864		
5047510	MMT-864		
5054558	MMT-864		
5047511	MMT-864		
5054559	MMT-864		
5055496	MMT-864		
5055497	MMT-864		
5056681	MMT-864		
5056682	MMT-864		
5060988	MMT-864		
5068520	MMT-864		
5068518	MMT-864		
5072716	MMT-864		
5072717	MMT-864		
5068522	MMT-864		
5075402	MMT-864		
5075403	MMT-864		
5075555	MMT-864		
5075556	MMT-864		
5071380	MMT-864		
5075557	MMT-864		
5077462	MMT-864		
5076350	MMT-864		
5078949	MMT-864		
5077461	MMT-864		
5079262	MMT-864		
5079261	MMT-864		
5079683	MMT-864		
5072335	MMT-864		
5079688	MMT-864		
5079685	MMT-864		
5079684	MMT-864		
5082372	MMT-864		
5082374	MMT-864		

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Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5082373	MMT-864		
5079686	MMT-864		
5079687	MMT-864		
5072341	MMT-864		
5083297	MMT-864		
5083299	MMT-864		
5084121	MMT-864		
5083298	MMT-864		
5084120	MMT-864		
5053658	MMT-865		
5064299	MMT-865		
5080458	MMT-865		
5040469	MMT-866		
5032640	MMT-866		
5041195	MMT-866		
5039582	MMT-866		
5043420	MMT-866		
5043421	MMT-866		
5046397	MMT-866		
5039589	MMT-866		
5047583	MMT-866		
5049124	MMT-866		
5050037	MMT-866		
5051563	MMT-866		
5043329	MMT-866		
5047172	MMT-866		
5052907	MMT-866		
5053661	MMT-866		
5059551	MMT-866		
5059552	MMT-866		
5060209	MMT-866		
5058702	MMT-866		
5060950	MMT-866		
5061497	MMT-866		
5058704	MMT-866		
5063697	MMT-866		

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Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5064403	MMT-866		
5066515	MMT-866		
5067592	MMT-866		
5059523	MMT-866		
5071405	MMT-866		
5072718	MMT-866		
5047175	MMT-866		
5056683	MMT-866		
5057244	MMT-866		
5067184	MMT-866		
5068528	MMT-866		
5075404	MMT-866		
5075558	MMT-866		
5076351	MMT-866		
5077463	MMT-866		
5072347	MMT-866		
5079263	MMT-866		
5079689	MMT-866		
5079690	MMT-866		
5079691	MMT-866		
5082342	MMT-866		
5081996	MMT-866		
5081997	MMT-866		
5077131	MMT-866		
5082443	MMT-866		
5083300	MMT-866		
5079900	MMT-866		
5084122	MMT-866		
5038779	MMT-873		
5040470	MMT-874		
5040471	MMT-874		
5041196	MMT-874		
5032646	MMT-874		
5043422	MMT-874		
5043423	MMT-874		
5043112	MMT-874		

Unomedical a/s
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4320 Lejre, Denmark

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Fax +45 4642 7865
www.convatec.com
www.infusion-set.com

CVR No. 6415 3315

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5047584	MMT-874		
5050038	MMT-874		
5043114	MMT-874		
5051564	MMT-874		
5044841	MMT-874		
5052908	MMT-874		
5060951	MMT-874		
5060210	MMT-874		
5060952	MMT-874		
5060990	MMT-874		
5055463	MMT-874		
5055465	MMT-874		
5070666	MMT-874		
5067593	MMT-874		
5047177	MMT-874		
5056684	MMT-874		
5057245	MMT-874		
5067185	MMT-874		
5071406	MMT-874		
5072719	MMT-874		
5068526	MMT-874		
5075405	MMT-874		
5076352	MMT-874		
5077464	MMT-874		
5078950	MMT-874		
5072627	MMT-874		
5079692	MMT-874		
5079693	MMT-874		
5082444	MMT-874		
5082343	MMT-874		
5072629	MMT-874		
5084123	MMT-874		
5057216	MMT-875		
5032652	MMT-876		
5040472	MMT-876		
5040473	MMT-876		

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CVR No. 6415 3315

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5043425	MMT-876		
5043427	MMT-876		
5043426	MMT-876		
5046644	MMT-876		
5046645	MMT-876		
5049125	MMT-876		
5043117	MMT-876		
5053789	MMT-876		
5047179	MMT-876		
5059553	MMT-876		
5058706	MMT-876		
5060953	MMT-876		
5060991	MMT-876		
5066516	MMT-876		
5058708	MMT-876		
5070667	MMT-876		
5055498	MMT-876		
5071407	MMT-876		
5068531	MMT-876		
5076348	MMT-876		
5076353	MMT-876		
5072631	MMT-876		
5077465	MMT-876		
5079264	MMT-876		
5078951	MMT-876		
5079694	MMT-876		
5079695	MMT-876		
5077117	MMT-876		
5082445	MMT-876		
5083301	MMT-876		
5084124	MMT-876		
5084823	MMT-876		
5040474	MMT-884		
5039586	MMT-884		
5072633	MMT-884		
5079671	MMT-884		

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CVR No. 6415 3315

Lot No.	Customer Model No	Country code as defined in ISO 3166-1 or full country name	Lot Size
5072636	MMT-885		
5043428	MMT-886		
5043429	MMT-886		
5038787	MMT-886		
5053790	MMT-886		
5043124	MMT-886		
5064404	MMT-886		
5064146	MMT-886		
5068557	MMT-886		
5068530	MMT-886		
5072634	MMT-886		
5079696	MMT-886		
5083604	MMT-886		

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CVR No. 6415 3315

Harada Corporation
Attn.: Yukiko Minari
2-10-14, Minami-Semba
Chuo-ku
542-0081 Osaka
Japan

Field Safety Notice

Regarding

Unomedical a/s Infusion sets Comfort™, Comfort™ Short

7 November 2014

Sender:

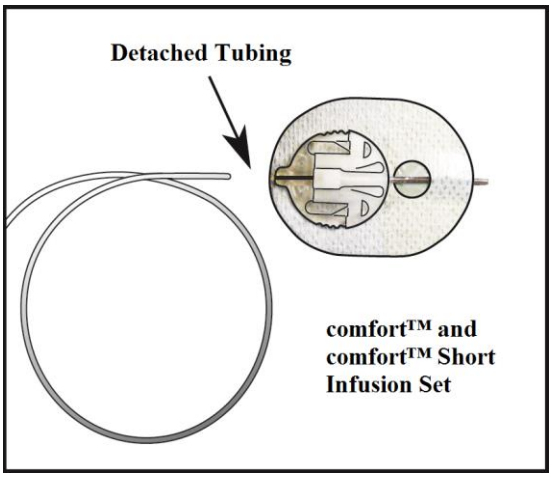
Unomedical a/s
Infusion Devices
Aaholmvej 1-3, Osted
DK - 4320 Lejre
Denmark

Dear Supplier

Today we would like to provide you with some important information regarding the safe use of the following infusion sets: Comfort™, Comfort™ Short.

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.

Example of Tubing Detachment



<u>What action do I need to take if I experience detached tubing?</u>
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. In the list below, you will find information on affected lot numbers already in your possession. We will send you a final notification once we have implemented the improvements. This update will confirm that we no longer ship you devices affected by this Field Safety Notice as well as a list of lot numbers shipped to you between this letter and the final notification.

The following infusion sets are affected by this Field Safety Notice:

Lot	Unomedical lot No.	Customer Item No.	Product Description
5037135	89-060-2622	38006-002	COMFORT 60CM
5070653	89-060-2622	38006-002	COMFORT 60CM

We sincerely apologize for any inconvenience this may have caused. For any questions you may have, please call any of the two contact persons:

Torben Sandgren - VP Global Sales, Marketing and R&D +45 6161 8354, Pia Damgaard - Sales Support Manager +45 2910 9980.
To report a complaint, please write to BUID.complaints@convatec.com where the complaint will be registered and handled accordingly.

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, Osted
DK - 4320 Lejre
Denmark

Regarding Field Safety Notice for infusion sets

Manufacturer: Unomedical a/s

☐ **I confirm to have read and understood the information in this Field Safety Notice for the above mentioned medical devices and intend to perform the requested actions. Furthermore, as described in the contractual agreement with Unomedical, I will supply the information related to each lot number as requested below on behalf of Harada**

Company Name:	**Harada**
Company Address:	
Name:	
Signature:	
Date: dd/mm/yyyy	

Lot number	Customer Item Number	Country code as defined in ISO 3166-1 or full country name	Lot size
5037135	38006-002		
5070653	38006-002		

Please return signed confirmation form within two weeks from receipt to the following email:
buid.complaints@convatec.com

James Elliott and Eric Thoms:
Animas Corporation
200 Lawrence Drive
West Chester, PA 19380, USA

Field Safety Notice

Regarding

Unomedical a/s Infusion sets Comfort™, Comfort™ Short and Contact™ Detach

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7 November 2014

Sender:

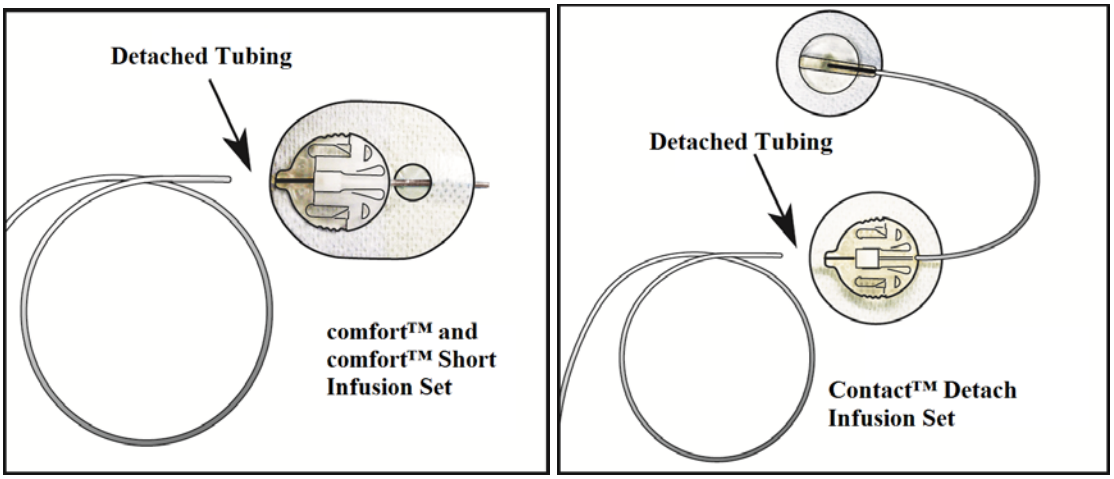
Unomedical a/s
Infusion Devices
Aaholmvej 1-3, Osted
DK - 4320 Lejre
Denmark

Dear Supplier

Today we would like to provide you with some important information regarding the safe use of the following infusion sets: Comfort™, Comfort™ Short and Contact™ Detach.

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.

Example of Tubing Detachment



<u>What action do I need to take if I experience a detached tubing?</u>
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We are working to resolve this issue and plan to incorporate improvements into the manufacturing process in the coming months. In the list below, you will find information on affected lot numbers already in your possession. We will send you a final notification once we have implemented the improvements. This update will confirm that we no longer ship you devices affected by this Field Safety Notice as well as a list of lot numbers shipped to you between this letter and the final notification.

Unomedical a/s
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www.convatec.com
www.infusion-set.com

CVR No. 6415 3315

The following infusion sets are affected by this Field Safety Notice:

Lot nr.	Unomedical Items No	Customer Item No	Product Description
5035097	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5034232	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5038182	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5038184	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5038183	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5038185	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5038186	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5041073	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5040990	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5041074	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5040991	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5045147	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5045148	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5047241	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5047242	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5047243	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5047245	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5048097	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5054550	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5053689	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5057103	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5057104	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5058731	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5058732	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5058633	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5058733	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5062811	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5062812	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5062813	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5062769	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5066512	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5066999	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5067219	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5068464	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5067220	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5067222	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29

Lot nr.	Unomedical Items No	Customer Item No	Product Description
5067223	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5067574	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5068465	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5071889	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5067221	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5073670	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5067224	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5067225	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5075532	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5076079	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5076080	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5077534	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5077532	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5077533	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5080736	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5080734	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5081993	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5082761	81-060-2926 ANIM	100-905-00	Contact Detach 6mm, 23", G29
5038187	81-060-2928 ANIM	100-905-01	Contact Detach 8mm, 23", G29
5031810	81-060-2928 ANIM	100-905-01	Contact Detach 8mm, 23", G29
5043079	81-060-2928 ANIM	100-905-01	Contact Detach 8mm, 23", G29
5040992	81-060-2928 ANIM	100-905-01	Contact Detach 8mm, 23", G29
5057106	81-060-2928 ANIM	100-905-01	Contact Detach 8mm, 23", G29
5057105	81-060-2928 ANIM	100-905-01	Contact Detach 8mm, 23", G29
5058637	81-060-2928 ANIM	100-905-01	Contact Detach 8mm, 23", G29
5058734	81-060-2928 ANIM	100-905-01	Contact Detach 8mm, 23", G29
5062770	81-060-2928 ANIM	100-905-01	Contact Detach 8mm, 23", G29
5067226	81-060-2928 ANIM	100-905-01	Contact Detach 8mm, 23", G29
5073671	81-060-2928 ANIM	100-905-01	Contact Detach 8mm, 23", G29
5075509	81-060-2928 ANIM	100-905-01	Contact Detach 8mm, 23", G29
5076081	81-060-2928 ANIM	100-905-01	Contact Detach 8mm, 23", G29
5077502	81-060-2928 ANIM	100-905-01	Contact Detach 8mm, 23", G29
5036348	81-110-2926 ANIM	100-905-02	Contact Detach 6mm, 43", G29
5054465	81-110-2926 ANIM	100-905-02	Contact Detach 6mm, 43", G29
5054553	81-110-2926 ANIM	100-905-02	Contact Detach 6mm, 43", G29
5062780	81-110-2926 ANIM	100-905-02	Contact Detach 6mm, 43", G29

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www.infusion-set.com

CVR No. 6415 3315

Lot nr.	Unomedical Items No	Customer Item No	Product Description
5067227	81-110-2926 ANIM	100-905-02	Contact Detach 6mm, 43", G29
5080702	81-110-2926 ANIM	100-905-02	Contact Detach 6mm, 43", G29
5034061	81-110-2928 ANIM	100-905-03	Contact Detach 8mm, 43", G29
5054466	81-110-2928 ANIM	100-905-03	Contact Detach 8mm, 43", G29
5054554	81-110-2928 ANIM	100-905-03	Contact Detach 8mm, 43", G29
5067228	81-110-2928 ANIM	100-905-03	Contact Detach 8mm, 43", G29
5021251	87-060-2552 ANIM	100-240-04	Comfort 13mm, 23", STD 5/5
5021253	87-060-2552 ANIM	100-240-04	Comfort 13mm, 23", STD 5/5
5034064	87-060-2552 ANIM	100-240-04	Comfort 13mm, 23", STD 5/5
5041057	87-060-2552 ANIM	100-240-04	Comfort 13mm, 23", STD 5/5
5044882	87-060-2552 ANIM	100-240-04	Comfort 13mm, 23", STD 5/5
5053669	87-060-2552 ANIM	100-240-04	Comfort 13mm, 23", STD 5/5
5054460	87-060-2552 ANIM	100-240-04	Comfort 13mm, 23", STD 5/5
5056817	87-060-2552 ANIM	100-240-04	Comfort 13mm, 23", STD 5/5
5065701	87-060-2552 ANIM	100-240-04	Comfort 13mm, 23", STD 5/5
5066984	87-060-2552 ANIM	100-240-04	Comfort 13mm, 23", STD 5/5
5067134	87-060-2552 ANIM	100-240-04	Comfort 13mm, 23", STD 5/5
5071891	87-060-2552 ANIM	100-240-04	Comfort 13mm, 23", STD 5/5
5071892	87-060-2552 ANIM	100-240-04	Comfort 13mm, 23", STD 5/5
5076082	87-060-2552 ANIM	100-240-04	Comfort 13mm, 23", STD 5/5
5033753	87-060-2652 ANIM	100-006-03	Infusion set, Comfort,23",STD5/5
5034062	87-060-2652 ANIM	100-006-03	Infusion set, Comfort,23",STD5/5
5040943	87-060-2652 ANIM	100-006-03	Infusion set, Comfort,23",STD5/5
5041053	87-060-2652 ANIM	100-006-03	Infusion set, Comfort,23",STD5/5
5041054	87-060-2652 ANIM	100-006-03	Infusion set, Comfort,23",STD5/5
5047115	87-060-2652 ANIM	100-006-03	Infusion set, Comfort,23",STD5/5
5054456	87-060-2652 ANIM	100-006-03	Infusion set, Comfort,23",STD5/5
5058640	87-060-2652 ANIM	100-006-03	Infusion set, Comfort,23",STD5/5
5067126	87-060-2652 ANIM	100-006-03	Infusion set, Comfort,23",STD5/5
5079193	87-060-2652 ANIM	100-006-03	Infusion set, Comfort,23",STD5/5
5067135	87-110-2552 ANIM	100-240-05	Infusion set, Comfort,43",STD5/5
5043820	87-110-2652 ANIM	100-006-02	Infusion set, Comfort,43",STD5/5
5062782	87-110-2652 ANIM	100-006-02	Infusion set, Comfort,43",STD5/5
5067127	87-110-2652 ANIM	100-006-02	Infusion set, Comfort,43",STD5/5
5029813	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5031822	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10

Lot nr.	Unomedical Items No	Customer Item No	Product Description
5032578	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5033754	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5034063	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5035086	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5035100	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5037025	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5038110	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5040382	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5040944	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5040945	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5040946	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5041055	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5041056	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5044879	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5044880	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5044881	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5047117	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5047118	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5047119	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5053668	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5053670	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5054457	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5054458	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5054467	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5056856	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5056857	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5058632	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5058641	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5058642	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5062768	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5062815	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5066992	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5067128	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5067129	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5067130	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5067131	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10

Lot nr.	Unomedical Items No	Customer Item No	Product Description
5067132	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5075507	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5075510	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5076039	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5077504	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5077505	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5079194	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5080706	89-060-2522 ANIM	100-240-01	Comfort 13mm, 23", hosp 10
5021247	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5031820	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5032577	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5033752	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5034200	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5035085	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5035085	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5035099	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5037024	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5038106	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5038107	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5038108	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5038109	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5040940	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5040941	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5040942	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5044875	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5044876	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5044877	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5044878	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5047112	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5047113	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5053663	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5053664	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5053665	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5053666	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5053667	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5054453	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10

Lot nr.	Unomedical Item No	Customer Item No	Product description
5054455	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5058622	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5058636	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5058638	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5058735	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5060034	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5060036	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5060037	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5060038	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5060042	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5062779	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5062814	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5067121	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5067122	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5067123	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5075508	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5075533	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5077501	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5077535	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5080701	89-060-2622 ANIM	100-006-01	Infusion set, Comfort,23",Hosp10
5031823	89-080-2522 ANIM	100-240-02	Comfort 13mm, 31", hosp 10
5047121	89-080-2522 ANIM	100-240-02	Comfort 13mm, 31", hosp 10
5067137	89-080-2522 ANIM	100-240-02	Comfort 13mm, 31", hosp 10
5031821	89-080-2622 ANIM	100-006-11	Infusion set, Comfort,31",Hosp10
5047116	89-080-2622 ANIM	100-006-11	Infusion set, Comfort,31",Hosp10
5062796	89-080-2622 ANIM	100-006-11	Infusion set, Comfort,31",Hosp10
5077508	89-080-2622 ANIM	100-006-11	Infusion set, Comfort,31",Hosp10
5033755	89-110-2522 ANIM	100-240-03	Comfort 13mm, 43", hosp 10
5034199	89-110-2522 ANIM	100-240-03	Comfort 13mm, 43", hosp 10
5051915	89-110-2522 ANIM	100-240-03	Comfort 13mm, 43", hosp 10
5054459	89-110-2522 ANIM	100-240-03	Comfort 13mm, 43", hosp 10
5062783	89-110-2522 ANIM	100-240-03	Comfort 13mm, 43", hosp 10
5066981	89-110-2522 ANIM	100-240-03	Comfort 13mm, 43", hosp 10
5067133	89-110-2522 ANIM	100-240-03	Comfort 13mm, 43", hosp 10
5031819	89-110-2622 ANIM	100-006-00	Infusion set, Comfort,43",Hosp10
5035098	89-110-2622 ANIM	100-006-00	Infusion set, Comfort,43",Hosp10

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Lot nr.	Unomedical Item No	Customer Item No	Product description
5040939	89-110-2622 ANIM	100-006-00	Infusion set, Comfort,43",Hosp10
5044874	89-110-2622 ANIM	100-006-00	Infusion set, Comfort,43",Hosp10
5047110	89-110-2622 ANIM	100-006-00	Infusion set, Comfort,43",Hosp10
5047111	89-110-2622 ANIM	100-006-00	Infusion set, Comfort,43",Hosp10
5056855	89-110-2622 ANIM	100-006-00	Infusion set, Comfort,43",Hosp10
5058639	89-110-2622 ANIM	100-006-00	Infusion set, Comfort,43",Hosp10
5062781	89-110-2622 ANIM	100-006-00	Infusion set, Comfort,43",Hosp10
5066393	89-110-2622 ANIM	100-006-00	Infusion set, Comfort,43",Hosp10
5067124	89-110-2622 ANIM	100-006-00	Infusion set, Comfort,43",Hosp10
5067125	89-110-2622 ANIM	100-006-00	Infusion set, Comfort,43",Hosp10
5070832	89-110-2622 ANIM	100-006-00	Infusion set, Comfort,43",Hosp10
5077503	89-110-2622 ANIM	100-006-00	Infusion set, Comfort,43",Hosp10

We sincerely apologize for any inconvenience this may have caused. For any questions you may have, please call any of the three contact persons:

Torben Sandgren - VP Global Sales, Marketing and R&D +45 6161 8354, Rabi Gharabli - Director, Diabetes +45 2023 9495, Kim Nielsen - Marketing & Portfolio Manager +45 6155 5175
To report a complaint, please write to BUID.complaints@convatec.com where the complaint will be registered and handled accordingly.

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, Osted
DK - 4320 Lejre
Denmark

Regarding Field Safety Notice for infusion sets

Manufacturer: Unomedical a/s

☐ **I confirm to have read and understood the information in this Field Safety Notice for the above mentioned medical devices and intend to perform the requested actions. Furthermore, as described in the contractual agreement with Unomedical, I will supply the information related to each lot number as requested below on behalf of Animas.**

Company Name:	**Animas**
Company Address:	
Name:	
Signature:	
Date: dd/mm/yyyy	

Please return signed confirmation form and appendix 1 within two weeks from receipt to the following email: buid.complaints@convatec.com

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Appendix 1

Lot number	Customer Item Number	Country code as defined in ISO 3166-1 or full country name	Lot size
5035097	100-905-00		
5034232	100-905-00		
5038182	100-905-00		
5038184	100-905-00		
5038183	100-905-00		
5038185	100-905-00		
5038186	100-905-00		
5041073	100-905-00		
5040990	100-905-00		
5041074	100-905-00		
5040991	100-905-00		
5045147	100-905-00		
5045148	100-905-00		
5047241	100-905-00		
5047242	100-905-00		
5047243	100-905-00		
5047245	100-905-00		
5048097	100-905-00		
5054550	100-905-00		
5053689	100-905-00		
5057103	100-905-00		
5057104	100-905-00		
5058731	100-905-00		
5058732	100-905-00		
5058633	100-905-00		
5058733	100-905-00		
5062811	100-905-00		
5062812	100-905-00		
5062813	100-905-00		
5062769	100-905-00		
5066512	100-905-00		
5066999	100-905-00		
5067219	100-905-00		
5068464	100-905-00		

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Lot number	Customer Item Number	Country code as defined in ISO 3166-1 or full country name	Lot size
5067220	100-905-00		
5067222	100-905-00		
5067223	100-905-00		
5067574	100-905-00		
5068465	100-905-00		
5071889	100-905-00		
5067221	100-905-00		
5073670	100-905-00		
5067224	100-905-00		
5067225	100-905-00		
5075532	100-905-00		
5076079	100-905-00		
5076080	100-905-00		
5077534	100-905-00		
5077532	100-905-00		
5077533	100-905-00		
5080736	100-905-00		
5080734	100-905-00		
5081993	100-905-00		
5082761	100-905-00		
5038187	100-905-01		
5031810	100-905-01		
5043079	100-905-01		
5040992	100-905-01		
5057106	100-905-01		
5057105	100-905-01		
5058637	100-905-01		
5058734	100-905-01		
5062770	100-905-01		
5067226	100-905-01		
5073671	100-905-01		
5075509	100-905-01		
5076081	100-905-01		
5077502	100-905-01		

Lot number	Customer Item Number	Country code as defined in ISO 3166-1 or full country name	Lot size
5036348	100-905-02		
5054465	100-905-02		
5054553	100-905-02		
5062780	100-905-02		
5067227	100-905-02		
5080702	100-905-02		
5034061	100-905-03		
5054466	100-905-03		
5054554	100-905-03		
5067228	100-905-03		
5021251	100-240-04		
5021253	100-240-04		
5034064	100-240-04		
5041057	100-240-04		
5044882	100-240-04		
5053669	100-240-04		
5054460	100-240-04		
5056817	100-240-04		
5065701	100-240-04		
5066984	100-240-04		
5067134	100-240-04		
5071891	100-240-04		
5071892	100-240-04		
5076082	100-240-04		
5033753	100-006-03		
5034062	100-006-03		
5040943	100-006-03		
5041053	100-006-03		
5041054	100-006-03		
5047115	100-006-03		
5054456	100-006-03		
5058640	100-006-03		
5067126	100-006-03		
5079193	100-006-03		
5067135	100-240-05		

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Lot number	Customer Item Number	Country code as defined in ISO 3166-1 or full country name	Lot size
5043820	100-006-02		
5062782	100-006-02		
5067127	100-006-02		
5029813	100-240-01		
5031822	100-240-01		
5032578	100-240-01		
5033754	100-240-01		
5034063	100-240-01		
5035086	100-240-01		
5035100	100-240-01		
5037025	100-240-01		
5038110	100-240-01		
5040382	100-240-01		
5040944	100-240-01		
5040945	100-240-01		
5040946	100-240-01		
5041055	100-240-01		
5041056	100-240-01		
5044879	100-240-01		
5044880	100-240-01		
5044881	100-240-01		
5047117	100-240-01		
5047118	100-240-01		
5047119	100-240-01		
5053668	100-240-01		
5053670	100-240-01		
5054457	100-240-01		
5054458	100-240-01		
5054467	100-240-01		
5056856	100-240-01		
5056857	100-240-01		
5058632	100-240-01		
5058641	100-240-01		
5058642	100-240-01		
5062768	100-240-01		

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Lot number	Customer Item Number	Country code as defined in ISO 3166-1 or full country name	Lot Size
5062815	100-240-01		
5066992	100-240-01		
5067128	100-240-01		
5067129	100-240-01		
5067130	100-240-01		
5067131	100-240-01		
5067132	100-240-01		
5075507	100-240-01		
5075510	100-240-01		
5076039	100-240-01		
5077504	100-240-01		
5077505	100-240-01		
5079194	100-240-01		
5080706	100-240-01		
5021247	100-006-01		
5031820	100-006-01		
5032577	100-006-01		
5033752	100-006-01		
5034200	100-006-01		
5035085	100-006-01		
5035085	100-006-01		
5035099	100-006-01		
5037024	100-006-01		
5038106	100-006-01		
5038107	100-006-01		
5038108	100-006-01		
5038109	100-006-01		
5040940	100-006-01		
5040941	100-006-01		
5040942	100-006-01		
5044875	100-006-01		
5044876	100-006-01		
5044877	100-006-01		
5044878	100-006-01		
5047112	100-006-01		

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Lot number	Customer Item Number	Country code as defined in ISO 3166-1 or full country name	Lot size
5047113	100-006-01		
5053663	100-006-01		
5053664	100-006-01		
5053665	100-006-01		
5053666	100-006-01		
5053667	100-006-01		
5054453	100-006-01		
5054455	100-006-01		
5058622	100-006-01		
5058636	100-006-01		
5058638	100-006-01		
5058735	100-006-01		
5060034	100-006-01		
5060036	100-006-01		
5060037	100-006-01		
5060038	100-006-01		
5060042	100-006-01		
5062779	100-006-01		
5062814	100-006-01		
5067121	100-006-01		
5067122	100-006-01		
5067123	100-006-01		
5075508	100-006-01		
5075533	100-006-01		
5077501	100-006-01		
5077535	100-006-01		
5080701	100-006-01		
5031823	100-240-02		
5047121	100-240-02		
5067137	100-240-02		
5031821	100-006-11		
5047116	100-006-11		
5062796	100-006-11		
5077508	100-006-11		
5033755	100-240-03		

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Lot number	Customer Item Number	Country code as defined in ISO 3166-1 or full country name	Lot size
5034199	100-240-03		
5051915	100-240-03		
5054459	100-240-03		
5062783	100-240-03		
5066981	100-240-03		
5067133	100-240-03		
5031819	100-006-00		
5035098	100-006-00		
5040939	100-006-00		
5044874	100-006-00		
5047110	100-006-00		
5047111	100-006-00		
5056855	100-006-00		
5058639	100-006-00		
5062781	100-006-00		
5066393	100-006-00		
5067124	100-006-00		
5067125	100-006-00		
5070832	100-006-00		
5077503	100-006-00		

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