Medtronic

MiniMed Silhouette™ and Sure-T™ infusion sets

November 2014

Medtronic reference: FA631

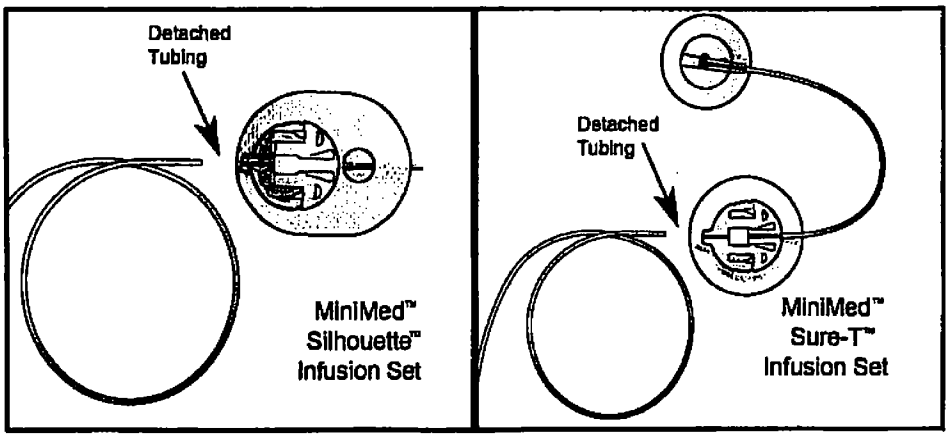
Dear Valued Medtronic Customer,

The purpose of this letter is to inform you of a potential safety issue regarding the **MiniMed Silhouette** and **MiniMed Sure-T** infusion sets*, which our records indicate you have purchased.

As part of our product quality monitoring process, we identified an increase in reports of the tubing becoming detached at the connect/disconnect location on the MiniMed Silhouette and MiniMed Sure-T infusion sets (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 are our top priorities.

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?

By following the advice mentioned below you can continue to use your infusion sets:

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. Do not use the Infusion Set if the package has been opened, damaged, or if you see that the tubing has disconnected from the connect/disconnect point of the infusion set.
3. If the insulin pump dropped check the Infusion Set tubing thoroughly for damages.

*This field notification involves models MMT-862, MMT-862T, MMT-863, MMT-864, MMT-864T, MMT-865, MMT-866, MMT-866T, MMT-873, MMT-874, MMT-874T, MMT-875, MMT-876, MMT-876T, MMT-883, MMT-884, MMT-885, MMT-886, MMT-886T, MMT-368, MMT-371, MMT-373, MMT-377, MMT-371, MMT-373, MMT-377, MMT-378, MMT-381, MMT-382, MMT-383, MMT-384 infusion sets.

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4. If you experience a high blood sugar, check your tubing connections and infusion site closely to ensure your tubing is secure

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.

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 the Medtronic 24-Hour Helpline to report the issue. We will give you instructions on how to return the affected infusion set to us.

We are working in a timely manner to resolve this issue and plan to incorporate improvements into the manufacturing process in the coming months. In the meantime, you will still be able to order these infusion sets.
Other types of infusion sets like MiniMed Quick-Set™ or MiniMed Mio™ infusion sets are not affected by this issue.

Medtronic is committed to keeping you and your healthcare professional informed of issues and solutions concerning our products and services. We have notified your healthcare professional of this issue. If you experience tubing detachment or should you have any questions about this letter, please contact your local Medtronic helpline.

We appreciate your time and attention to this important notification.

Sincerely,

*This field notification involves models MMT-862, MMT-862T, MMT-863, MMT-864, MMT-864T, MMT-865, MMT-866, MMT-866T, MMT-873, MMT-874, MMT-874T, MMT-875, MMT-876, MMT-876T, MMT-883, MMT-884, MMT-885, MMT-886, MMT-886T, MMT-368, MMT-371, MMT-373, MMT-377, MMT-371, MMT-373, MMT-377, MMT-378, MMT-381, MMT-382, MMT-383, MMT-384 infusion sets.

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Urgent Field Safety Notice

MiniMed Silhouette™ and Sure-T™ infusion sets

Recommendations regarding potential tubing detachment issue

November 2014

Medtronic reference: FA631

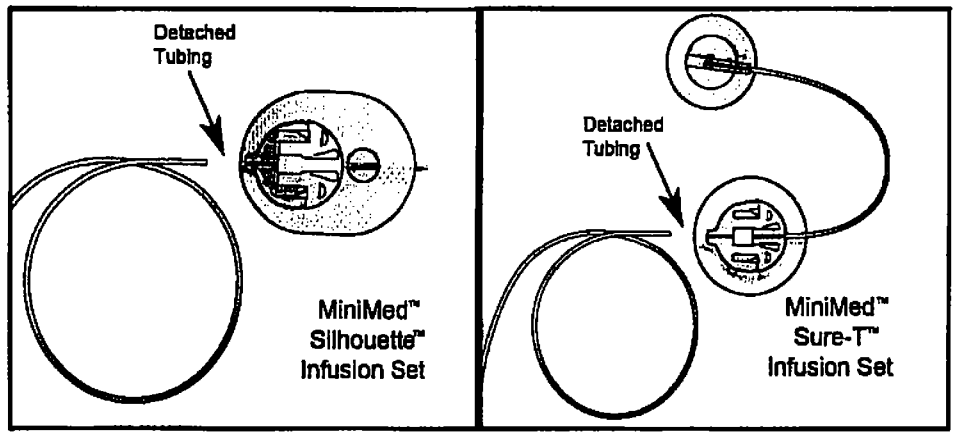
Dear Healthcare professional,

The purpose of this letter is to inform you of a potential safety issue regarding the **MiniMed Silhouette** and **MiniMed Sure-T** infusion sets*. Medtronic is informing directly your patients, no action is required from your side.

As part of our product quality monitoring process, we identified an increase in reports of the tubing becoming detached at the connect/disconnect location on the MiniMed Silhouette and MiniMed Sure-T infusion sets (please see images below). While the number of these reports remains low, we are notifying you of this potential issue because your patient's safety and experience with our products are our top priorities.

If tubing detachment occurs, insulin delivery is interrupted and the pump will not alarm to notify your patient. 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. Patients should seek medical attention immediately if they experience any of these symptoms.

Example of Tubing Detachment



Your patients can continue to use these infusion sets by following the advice below:

*This field notification involves models MMT-862, MMT-862T, MMT-863, MMT-864, MMT-864T, MMT-865, MMT-866, MMT-866T, MMT-873, MMT-874, MMT-874T, MMT-875, MMT-876, MMT-876T, MMT-883, MMT-884, MMT-885, MMT-886, MMT-886T, MMT-368, MMT-371, MMT-373, MMT-377, MMT-371, MMT-373, MMT-377, MMT-378, MMT-381, MMT-382, MMT-383, MMT-384 infusion sets.

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1. When changing the infusion set, your patients should follow the instructions for use included in the product box. Your patients should check the tubing at the connect/disconnect location identified in the drawings above to make sure it is not loose.
2. Patients should not use the Infusion Set if the package has been opened, damaged, or if the tubing has disconnected from the connect/disconnect point of the infusion set.
3. If the insulin pump dropped patients should check the Infusion Set tubing thoroughly for damages.
4. If your patients experience a high blood sugar, they should check the tubing connections and infusion site closely to ensure tubing is secure.

As always, it is essential your patients monitor blood sugar levels frequently using a blood glucose meter. They should proactively check the tubing connections occasionally throughout the day to ensure tubing is secure. It is especially important your patients check blood sugar and tubing connections at bedtime to confirm insulin delivery is occurring.

If your patient discovers the tubing is detached, we have advised to take following action:

1. Your patient should not attempt to reattach the tubing. They should replace the infusion set immediately.
2. Your patient should treat any high blood sugar based on the guidelines you provided.
3. Call the Medtronic 24-Hour Helpline to report the issue. We will give your patient instructions on how to return the affected infusion set to us.

We are working in a timely manner to resolve this issue and plan to incorporate improvements into the manufacturing process in the coming months. In the meantime, your patient will still be able to order these infusion sets.
Other types of infusion sets like MiniMed Quick-Set™ or MiniMed Mio™ infusion sets are not affected by this issue.

The Competent Authority of your country has been notified of this issue.

Medtronic is committed to keeping you and your patients informed of issues and solutions concerning our products and services. If you have any questions about this letter, please contact Medtronic.

We appreciate your time and attention to this important notification.

Sincerely,

*This field notification involves models MMT-862, MMT-862T, MMT-863, MMT-864, MMT-864T, MMT-865, MMT-866, MMT-866T, MMT-873, MMT-874, MMT-874T, MMT-875, MMT-876, MMT-876T, MMT-883, MMT-884, MMT-885, MMT-886, MMT-886T, MMT-368, MMT-371, MMT-373, MMT-377, MMT-371, MMT-373, MMT-377, MMT-378, MMT-381, MMT-382, MMT-383, MMT-384 infusion sets.

Medtronic

Urgent Field Safety Notice
MiniMed Silhouette™ and Sure-T™ infusion sets

Recommendations regarding potential tubing detachment issue

November 2014

Medtronic reference: FA631

Dear Healthcare professional,

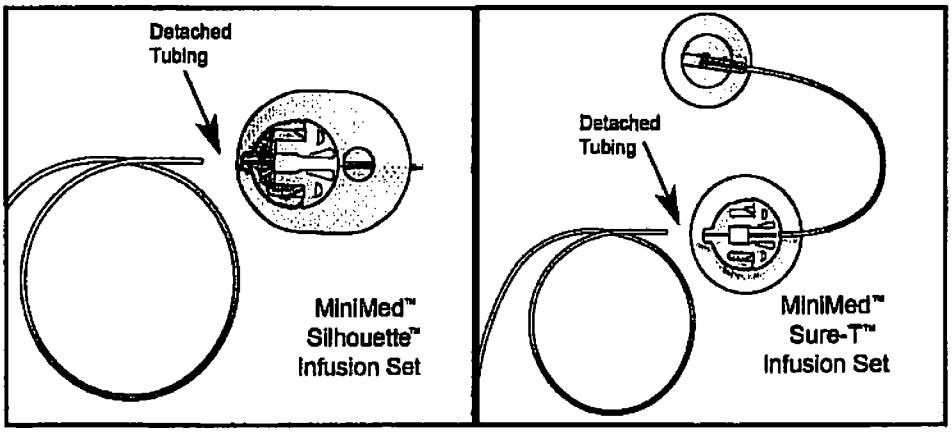
The purpose of this letter is to inform you of a potential safety issue regarding the **MiniMed Silhouette** and **MiniMed Sure-T** infusion sets*.

Because Medtronic does not have your patients' records on file, we kindly ask you to inform patients who use MiniMed Silhouette, MiniMed Sure-T or MiniMed Duo infusion sets using the enclosed letter.

As part of our product quality monitoring process, we identified an increase in reports of the tubing becoming detached at the connect/disconnect location on the MiniMed Silhouette and MiniMed Sure-T infusion sets (please see images below). While the number of these reports remains low, we are notifying you of this potential issue because your patient's safety and experience with our products are our top priorities.

If tubing detachment occurs, insulin delivery is interrupted and the pump will not alarm to notify your patient. 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. Patients should seek medical attention immediately if they experience any of these symptoms.

Example of Tubing Detachment



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Your patients can continue to use these infusion sets by following the advice below:

1. When changing the infusion set, your patients should follow the instructions for use included in the product box. Your patients should check the tubing at the connect/disconnect location identified in the drawings above to make sure it is not loose.
2. Patients should not use the Infusion Set if the package has been opened, damaged, or if the tubing has disconnected from the connect/disconnect point of the infusion set.
3. If the insulin pump dropped patients should check the infusion Set tubing thoroughly for damages.
4. If your patients experience a high blood sugar, they should check the tubing connections and infusion site closely to ensure tubing is secure.

As always, it is essential your patients monitor blood sugar levels frequently using a blood glucose meter. They should proactively check the tubing connections occasionally throughout the day to ensure tubing is secure. It is especially important your patients check blood sugar and tubing connections at bedtime to confirm insulin delivery is occurring.

If your patient discovers the tubing is detached, we have advised to take following action:

1. Your patient should not attempt to reattach the tubing. They should replace the infusion set immediately.
2. Your patient should treat any high blood sugar based on the guidelines you provided.
3. Call the Medtronic 24-Hour Helpline to report the issue. We will give your patient instructions on how to return the affected infusion set to us.

We are working in a timely manner to resolve this issue and plan to incorporate improvements into the manufacturing process in the coming months. In the meantime, your patient will still be able to order these infusion sets.
Other types of infusion sets like MiniMed Quick-Set™ or MiniMed Mio™ infusion sets are not affected by this issue.

The Competent Authority of your country has been notified of this issue.

Medtronic is committed to keeping you and your patients informed of issues and solutions concerning our products and services. If you have any questions about this letter, please contact Medtronic.

We appreciate your time and attention to this important notification.

Sincerely,

*This field notification involves models MMT-862, MMT-862T, MMT-863, MMT-864, MMT-864T, MMT-865, MMT-866, MMT-866T, MMT-873, MMT-874, MMT-874T, MMT-875, MMT-876, MMT-876T, MMT-883, MMT-884, MMT-885, MMT-886, MMT-886T, MMT-368, MMT-371, MMT-373, MMT-377, MMT-371, MMT-373, MMT-377, MMT-378, MMT-381, MMT-382, MMT-383, MMT-384 infusion sets.

Medtronic

Urgent Field Safety Notice
MiniMed Silhouette™ and Sure-T™ infusion sets

Recommendations regarding potential tubing detachment issue

November 2014

Medtronic reference: FA631

Dear Distributor/Provider Partner,

The purpose of this letter is to inform you of a potential safety issue regarding the **MiniMed Silhouette** and **MiniMed Sure-T** infusion sets*, which our records indicate you have purchased.

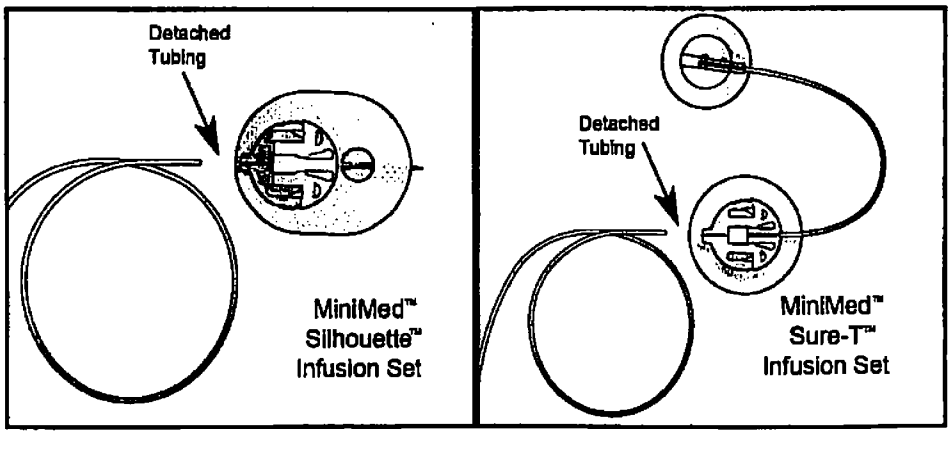
ACTION:

1) Please take the time to review the safety information in this letter.
2) Please compile your own customer mailing list i.e. Healthcare Professionals (HCP) and Patients who are impacted (see affected Infusion Set models below)
3) Please use the attached letters to notify starting **5 November 2014**

As part of our product quality monitoring process, we identified an increase in reports of the tubing becoming detached at the connect/disconnect location on the MiniMed Silhouette and MiniMed Sure-T infusion sets (please see images below). While the number of these reports remains low, we are notifying you of this potential issue because patients' safety and experience with our products are our top priorities.

If tubing detachment occurs, insulin delivery is interrupted and the pump will not alarm to notify the patient. The interruption of insulin delivery can cause hyperglycaemia, 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. We are advising patients to seek medical attention immediately if they are experiencing any of these symptoms.

Example of Tubing Detachment



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Medtronic

Patients can continue to use these infusion sets by following the advice below:

1. When changing the infusion set, patients should follow the instructions for use included in the product box. Patients should check the tubing at the connect/disconnect location identified in the drawings above to make sure it is not loose.
2. Patients should not use the infusion Set if the package has been opened, damaged, or if the tubing has disconnected from the connect/disconnect point of the infusion set.
3. If the insulin pump dropped patients should check the infusion Set tubing thoroughly for damages.
4. If patients experience high blood sugar, they should check the tubing connections and infusion site closely to ensure tubing is secure.

As always, it is essential patients monitor blood sugar levels frequently using a blood glucose meter. They should proactively check the tubing connections occasionally throughout the day to ensure tubing is secure. It is especially important patients check blood sugar and tubing connections at bedtime to confirm insulin delivery is occurring.

If patient discovers the tubing is detached, we advise the patient to take following action:

1. Patient should not attempt to reattach the tubing. They should replace the infusion set immediately.
2. Patient should treat any high blood sugar based on the guidelines you provided.
3. Call the Medtronic 24-Hour Helpline to report the issue. We will give the patient instructions on how to return the affected infusion set to us.

We are working in a timely manner to resolve this issue and plan to incorporate improvements into the manufacturing process in the coming months. In the meantime, you will still be able to order these infusion sets.
Other types of infusion sets like MiniMed Quick-Set™ or MiniMed Mio™ infusion sets are not affected by this issue.

The Competent Authority of your country has been notified of this issue.

Medtronic is committed to keeping you, patients and Healthcare Professionals informed of issues and solutions concerning our products and services. If you have any questions about this letter, please contact Medtronic.

We appreciate your time and attention to this important notification.

Sincerely,

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