

Urgent Field Safety Notice

Beware of the battery securing parts of the Diabecare DANA-i insulin pump

Devices: Diabecare DANA-i Insulin pump (Manufactured before October 2022)

JULY 2023

To Users of Diabecare DANA-i insulin pump,

Since the release of "Diabecare DANA-i" (Hereinafter referred to as "DANA-i") insulin pump, SOOIL has continuously been monitoring its safe use. Recently, we have observed an increasing number of fractures in the battery securing parts of this model, and therefore, we are issuing a safety notice to all users.

Description of the product problem:

During the insulin pump use, if the device is dropped or excessive force is applied, some of the device's battery securing parts may break.



<Battery securing parts of DANA-i insulin pump>

If the battery securing parts is broken, the insulin pump will no longer function, rendering it unusable. In such a situation, if the user has no alternative way to deliver insulin, there is a risk of hyperglycemia and diabetic ketoacidosis (DKA).

Action To Be Taken by the User:

The following are recommended for the user to ensure the user's safety.

- When replacing the battery, avoid applying excessive force to the battery securing parts.
- Before use, carefully inspect and observe the battery securing parts for any signs of damage.
- Users of insulin pumps should have alternative methods of insulin delivery prepared in case the insulin pumps become inoperable. Situations such as power failures can render the pump unusable.
- If the battery securing parts are broken, immediately stop using the insulin pump and seek assistance from the distributor or a healthcare professional.
- It is strictly prohibited to attempt any repairs or use arbitrary methods, such as taping, to secure the battery.

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We have already received reports of incidents where users attempted to tape the battery securing parts after it was broken, resulting in DKA. Any arbitrary actions taken with the insulin pump can be extremely dangerous. Never attempt to repair the insulin pump by yourself.

Seek guidance and advice from a healthcare professional on managing elevated glucose levels and ketones, as well as alternative methods of administering insulin if necessary.

Further information to help characterize the problem:

An improved version of the battery securing parts has been implemented since October 2022. The improved battery securing parts is designed to be much stronger than the previous version.

You can confirm your DANA-i insulin pump's manufacturing date through the device's marking. The date of manufacture is indicated by the year and month after the date of manufacture symbol (⏏).



(e.g., The date of manufacture of the insulin pump in the photo is June-2022.)

If the user of DANA-i wants to apply for the improved product, please contact the distributor below.

Note: The following cases are devices with improvements already applied. Please verify this with the distributor in advance.

- Some devices manufactured in September 2022 and Devices repaired after October 2022 have already had improvements applied.

The contact person in your country is:

Once we receive your application for replacement, we will proceed with the insulin pump replacement sequentially as soon as possible. The Competent Authority in your country has been informed of this action. SOOIL is committed to providing a safer insulin pump.

We appreciate your time and attention to review our safety notice.

Sincerely,

██████████
██████████

SOOIL Development Co., Ltd

THE URGENT FIELD SAFETY NOTICE

User Acknowledgement Form

Please, return this acknowledgement form to the distributor;

Contact reference person:

By post to:

Please check the following options.

- I confirm receipt of the Field Safety Notice and that I read and understood its content. And I do not hope to replace the insulin pump.

- I confirm receipt of the Field Safety Notice and that I read and understood its content. And I hope to replace it with a new insulin pump.

Please fill in your information:

Name	
Serial Number of Diabecare DANA-i	
Email	
Postal Address	
Phone	
Signature	