Field Safety Notice

Date: 30 November 2023 **Field Safety Notice Number: RFA-2A**

Dear Customer,

Our records indicate that we have supplied your organisation with **The Insides Driver (Driver)**. The Driver is a component of The Insides System and The Insides Patient Education Model.

The Insides Driver

As you may be aware, on the 12th of October a Driver overheated at a hospital in Europe. We traced it back to a small number of units that contained a faulty internal battery from a 3rd party supplier. We then voluntarily and urgently recalled all of these affected units from the field, while continuing with a full investigation.

We have now concluded this investigation. This has identified opportunities to add additional safety mechanisms to the Driver, and these additions are currently being implemented in a new version of the device.

As a result of this investigation and with an abundance of caution, we have decided to voluntarily recall all remaining Drivers, and replace them with a new version of the Driver that contains the additional safety mechanisms.

We do not perceive there to be any risk in patients continuing to perform chyme reinfusion with their existing Drivers (with the exception of the initial urgently recalled devices). Please note that the immediate cessation of patient use of the device without replacement could put patients at risk of dehydration, hospitalisation, and invasive procedures (eg: central line placement).

The Insides Company will supply **Driver Replacement Kits** to make this replacement as easy as possible. Each kit contains a new Driver, an updated IFU, and replacement instructions.

The Company is doing this to ensure all patients, healthcare professionals, and our distribution partners have access to this new version of the Driver with the additional safety mechanisms. We expect the Driver Replacement Kits will be available and ready to ship in December.

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Our Requested Actions for all Units of The Insides Driver listed on Page 6 are

1. Please communicate this Field Safety Notice to all relevant staff and users.
2. Where applicable, please communicate this Field Safety Notice to third parties you have supplied Drivers to.
3. Please complete the **Customer Response Form**, provided as an editable attachment, and email it to:

   Tina Mason: tina.mason@theinsides.co
   Garth Sutherland garth.sutherland@theinsides.co
4. Upon receipt of the completed Customer Response Form, The Insides Company will arrange Driver Replacement Kits.
5. Once you receive the Driver Replacement Kits, please replace the following Drivers:
   a. Unused Drivers contained in The Insides System, and
   b. Drivers that are in use with a first patient (as Drivers are Single Patient Use Only).
6. At this time please also collect all used Drivers and Patient Education Models (PEMs).
7. Return all used Drivers, Drivers that have been replaced and Patient Education Models (PEMs) to the return address specified on the Customer Response Form.

We are seeking assistance from our Distribution partners and direct customers to replace all Drivers at their premises, and at their hospitals.

Patients using their Drivers at home can have them replaced by hospital staff when the patient returns to hospital for their monthly tube change.

Drivers that have been used to complete treatment on a single patient will not be replaced, as all Drivers are Single Patient Use only, and must not be used on more than one patient.

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Given that the Driver is designated for single patient use, it's probable that the majority of devices have been made inactive and discarded following the completion of chyme reinfusion therapy by the patients.

Patient Education Models (PEMs) also contain Drivers. These will also need to be returned to have their Drivers replaced.

The Insides Company has temporarily paused supplying any new consignments of The Insides System, until the new Drivers are available. As soon as the new Driver is available all outstanding orders will be fulfilled with priority.

We sincerely regret the inconvenience that this Field Safety Notice will cause. We greatly appreciate your understanding as we take actions to prioritise, and healthcare professional safety.

The undersigned confirms that the Field Safety Notice has been notified to the appropriate Regulatory Agency. Should you have questions or need additional information, please contact The Insides Company.

Kindest Regards

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Existing Driver and Replacement Driver (v4)

Existing Drivers
have a
WHITE Label

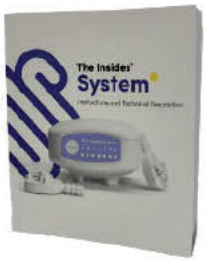
New (Replacement) Drivers
have a
PURPLE Label

Driver Replacement Kits and Contents

The Insides Driver v4

RETURNED
DRIVER
SN:_____

Returned Device Sticker



The Insides System IFU v 25.0

Replacement
Work
Instruction

Replacement Instructions

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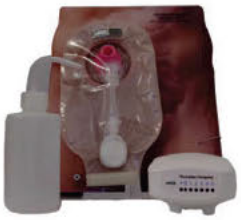
Manufacturer Single Registration Number (SRN)	NZ-MF-000011306
Product Affected	**The Insides Driver** Part Number: PS001(Rest of World) & PS009 (US)  The Insides Driver is a component of: **The Insides System** Part Numbers: PS004 = US; PS005 = UK/EU and PS006 = NZ/AU/ZA)  **The Insides System Patient Education Model (PEM)** Part Number: MK-1R001 
Product Issue	As you may be aware, on the 12th of October a Driver overheated at a hospital in Europe. We traced it back to a small number of units that contained a faulty internal battery from a 3rd party supplier. We then voluntarily and urgently recalled all of these affected units from the field, while continuing with a full investigation. We have now concluded this investigation. This has identified opportunities to add additional safety mechanisms to the Driver, and these additions are currently being implemented in a new version of the device.
Resolution	As a result of this investigation and with an abundance of caution, we have decided to voluntarily recall all remaining Drivers, and replace them with a new version of the Driver that contains the additional safety mechanisms. The Company is doing this to ensure all patients, healthcare professionals, and our distribution partners have access to this new version of the Driver with the additional safety mechanisms.

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Affected Units • **Product Code & Description** • **LOT Range** • **Serial Number Range** • **UDIs**	**The Insides System**	**The Insides Driver***
	PS004 The Insides System US LOT Range: LOT0000150 - LOT0000277 SN Range: 04000001 - 0400002D UDI: 09421905447065 **PS005 The Insides System (UK/EU)** LOT Range: LOT0000038 - LOT0000274 SN Range: 05000001 - 0500016D UDI: 09421905447034 **PS006 The Insides System (NZ/AU/ZA)** LOT Range: LOT0000039 -LOT0000275 SN Range: 06000001 - 060000AB UDI: 09421905447058	**PS001 The Insides Driver (ROW)** LOT Range: LOT0000036 - LOT0000281 SN Range: 01000001 - 0100032C UDI: 09421905447010 **PS009 The Insides Driver US** LOT Range: LOT0000134-LOT0000276 SN Range: 09000001 - 09000023 UDI: 09421905447089

* Individual Driver LOT & SN details are provided in addition to the System details as if these are in use in the field, access to the corresponding System LOT & Serial numbers may no longer be available in the event the System packaging was disposed of.

Drivers that are part of a Patient Education Model (PEM) will not have a System associated with them.