

Urgent Field Safety Corrective Action Notice

Date: 13th October 2023

Field Safety Notice Number: RFA-2

Dear Customer,

Our records indicate that we have supplied your company with **The Insides Driver**, including a specific manufacturing batch of units that **could present a risk to users**. The Insides Driver is a component of The Insides System and The Insides Patient Education Model.

The Insides Company received notice on 12th October 2023 from a customer that a single unit of The Insides Driver overheated, caught fire, and exploded while being recharged from a low battery state.

Our initial evaluation of worst-case scenarios has concluded that there could be a risk of injury to users of a specific manufacturing batch of The Insides Driver during the recharging operation. Our evaluation suggests these devices do not pose a risk if not in use and not being recharged. Please remember that The Insides Driver is labelled for single patient use only.



This letter is official notice that The Insides Company is requesting action from you to prevent a possible hazard to persons and equipment.

Our requested actions for the affected units of The Insides Driver listed on Page 3 are:

1. Please communicate this Field Safety Corrective Action Notice to all relevant staff and users.
2. Please do not distribute or recharge affected units that are in your possession.
3. Where applicable, please communicate this Field Safety Corrective Action Notice to third parties you have supplied affected units to.
4. Please return all affected units to the return address specified on the Customer Response Form.
5. Please complete the **Customer Response Form**, on Page 4, and email it to tina.mason@theinsides.co
6. Upon receipt of the completed Customer Response Form, **The Insides Company will arrange replacements for the affected devices.**

We sincerely regret any inconvenience that this Urgent Field Safety Corrective Action Notice may cause, however, we greatly appreciate your understanding as we take actions to ensure patient safety and continued customer satisfaction.

The undersigned confirms that the Urgent Field Safety Corrective Action Notice will be notified to the appropriate Regulatory Agency. Should you have questions or need additional information, please contact The Insides Company.

Kindest Regards






Tina Mason
Quality, Regulatory & Sustainability Manager
The Insides Company
tina.mason@theinsides.co

Urgent Field Safety Corrective Action Notice

Date: 13th October 2023

Field Safety Notice Number: RFA-2

Date:	13 October 2023
Manufacturer Single Registration Number (SRN)	NZ-MF-000011306
Product Affected	<p>The Insides Driver Part Number: PS001</p>  <p>The Insides Driver is a component of:</p> <p>The Insides System Part Numbers: PS005 = UK/EU and PS006 = NZ/AU/ZA)</p>  <p>The Insides System Patient Education Model (PEM) Part Number: MK-1R001</p> 
Product Issue:	<p>The Insides Driver overheated while being recharged. This resulted in the device exploding, scattering parts to a 1 meter radius, with some parts on fire. Fumes were also emitted.</p>
Resolution:	<p>While the investigation into the root cause of this issue is being conducted, we request that you discontinue use of all affected units, listed below, with immediate effect.</p>

Urgent Field Safety Corrective Action Notice

Date: 13th October 2023

Field Safety Notice Number: RFA-2

Affected LOTs / Serial Numbers:	PS005 The Insides System			
	The Insides System UDI	The Insides System Serial Number	The Insides Driver UDI	The Insides Driver Serial Number
	01094219054470341725021010000022121050000F8	050000F8	0109421905447010172502101000002122101000257	01000257
	01094219054470341725021010000022121050000F9	050000F9	0109421905447010172502101000002122101000253	01000253
	01094219054470341725021010000022121050000FA	050000FA	010942190544701017250210100000212210100024B	0100024B

Customer Response Form

Reference: Field Safety Corrective Action Notice: RFA-2

Our records indicate that the The Insides Driver (included in PS005/PS006 The Insides System and Patient Education Model) shown below was provided to you. Please verify that you have the listed device and complete the information below.

PRODUCT	SN/LOT	CURRENT LOCATION
PS005	050000F8	
PS005	050000F9	
PS005	050000FA	
TOTAL AFFECTED PRODUCT 3		

Please check the appropriate boxes below:

- I acknowledge receipt of the Field Safety Corrective Action Notice dated 13 October 2023 related to the above product. We have read and we understand the communication and the required actions.
If checked : please provide information below.

Field Safety Notice Receipt and Customer Response Form Completion

Organisation	SANYKO D.O.O		
Contact Name / Title			
Address (no PO boxes, please)			
City, State, Zip			
Phone Number		Fax:	
E-Mail Address:			
Signature		Date	

- We have supplied potentially affected product to another organisation.
If checked : please provide new organisation information below.

<u>New</u> Organisation Name			
Contact Name / Title			
Address*			
City, State, Zip			
Phone Number		Fax:	
E-Mail Address:			

PLEASE RETURN YOUR COMPLETED FORM BY EMAIL TO: tina.mason@theinsides.co

Customer Response Form

Address to Return Product To:

JAN KREDIET VENLO
Jacob Roggeveenweg 8-10
5928 LS Venlo
Netherlands

PLEASE RETURN YOUR COMPLETED FORM BY EMAIL TO: tina.mason@theinsides.co

Obavijest o hitnoj sigurnosnoj korektivnoj radnji

Datum: 13. listopada 2023

Broj obavijesti o sigurnosti na terenu: RFA-2

Dragi kupče,

Naši zapisi pokazuju da smo vašoj tvrtki isporučili **The Insides Driver**, uključujući određenu proizvodnu seriju jedinica koje **bi mogle predstavljati rizik za korisnike**. Insides Driver komponenta je The Insides System i The Insides Patient Education Model.

The Insides Company primila je obavijest 12. listopada 2023. od kupca da se jedna jedinica The Insides Drivera pregrijala, zapalila i eksplodirala dok se punila iz stanja niske baterije.

Naša početna procjena najgoreg mogućeg scenarija zaključila je da bi moglo postojati rizik od ozljeda za korisnike određene proizvodne serije The Insides Driver tijekom postupka ponovnog punjenja. Naša procjena sugerira da ti uređaji ne predstavljaju rizik ako se ne koriste i ne pune. Upamtite da je The Insides Driver označen samo za upotrebu od jednog pacijenta.



Ovo pismo je službena obavijest da The Insides Company od vas zahtijeva da poduzmete radnje kako biste spriječili moguću opasnost za osobe i opremu.

Radnje koje zahtijevamo za pogođene jedinice The Insides Driver navedene na stranici 3 su:

1. Prenesite ovu obavijest o sigurnosnim korektivnim radnjama svom relevantnom osoblju i korisnicima.
2. Molimo nemojte distribuirati niti puniti pogođene jedinice koje su u vašem posjedu.
3. Gdje je primjenjivo, ovu obavijest o sigurnosnim korektivnim radnjama na terenu prosljedite trećim stranama kojima ste isporučili zahvaćene jedinice.
4. Molimo vratite sve zahvaćene jedinice na povratnu adresu navedenu u obrascu za odgovor korisnika.
5. Ispunite **obrazac za odgovor kupca** na stranici 4 i pošaljite ga e-poštom na tina.mason@theinsides.co
6. Po primitku ispunjenog obrasca za odgovor korisnika, **The Insides Company će organizirati zamjene za pogođene uređaje.**

Iskreno žalimo zbog neugodnosti koje ova Obavijest o hitnoj sigurnosnoj korektivnoj radnji može prouzročiti, međutim, jako cijenimo vaše razumijevanje dok poduzimamo radnje kako bismo osigurali sigurnost pacijenata i kontinuirano zadovoljstvo korisnika.

Dolje potpisani potvrđuje da će Obavijest o hitnoj sigurnosnoj korektivnoj radnji biti dostavljena odgovarajućoj regulatornoj agenciji. Ako imate pitanja ili trebate dodatne informacije, obratite se tvrtki The Insides Company.

Srdačan pozdrav






Tina Mason
Voditelj za kvalitetu, regulativu i održivost
The Insides Company
tina.mason@theinsides.co

Obavijest o hitnoj sigurnosnoj korektivnoj radnji

Datum: 13. listopada 2023

Broj obavijesti o sigurnosti na terenu: RFA-2

Datum:	13. listopada 2023
Jedinstveni registracijski broj proizvođača (SRN)	NZ-MF-000011306
Zahvaćen proizvod	<p>The Insides Driver Broj dijela: PS001</p>  <p>The Insides Driver je komponenta:</p> <p>The Insides System Brojevi dijelova: PS005 = UK/EU i PS006 = NZ/AU/ZA)</p>  <p>The Insides System Patient Education Model (PEM) Broj dijela: MK-1R001</p> 
Problem s proizvodom:	The Insides Driver se pregrijavao tijekom punjenja. To je dovelo do eksplozije uređaja, raspršivanja dijelova u radijusu od 1 metra, a neki dijelovi u plamenu. Ispuštale su se i pare.
rezolucija:	Dok se provodi istraga temeljnog uzroka ovog problema, tražimo da prekinete korištenje svih pogodnih jedinica, navedenih u nastavku, s trenutačnim učinkom.

Obavijest o hitnoj sigurnosnoj korektivnoj radnji

Datum: 13. listopada 2023

Broj obavijesti o sigurnosti na terenu: RFA-2

Zahvaćeni LOT-
ovi/serijski brojevi:

PS005 The Insides System

The Insides System UDI	Serijski broj The Insides System	The Insides Driver UDI	Serijski broj The Insides Driver
01094219054470341725021010000022121050000F8	050000F8	0109421905447010172502101000002122101000257	01000257
01094219054470341725021010000022121050000F9	050000F9	0109421905447010172502101000002122101000253	01000253
01094219054470341725021010000022121050000FA	050000FA	010942190544701017250210100000212210100024B	0100024B

Obrazac za odgovor korisnika

Referenca: Obavijest o sigurnosnim korektivnim radnjama: RFA-2

Naši zapisi pokazuju da vam je dostavljen The Insides Driver (uključen u PS005/PS006 The Insides System and Patient Education Model) prikazan u nastavku. Provjerite imate li navedeni uređaj i ispunite podatke u nastavku.

PROIZVOD	SN/LOT	TRENTNA LOKACIJA
PS005	050000F8	
PS005	050000F9	
PS005	050000FA	
UKUPNO POGODENI PROIZVOD 3		

Označite odgovarajuće okvire u nastavku:

- Potvrđujem primitak Obavijesti o sigurnosnim korektivnim radnjama na terenu od 13. listopada 2023. u vezi s gore navedenim proizvodom. Pročitali smo i razumijemo komunikaciju i potrebne radnje.
Ako je označeno: navedite podatke u nastavku.

Field Safety Notice Receipt and Customer Response Form Completion

Organizacija	SANYKO D. OO		
Ime/titula kontakta			
Adresa (bez poštanskih pretinaca, molim)			
Grad, država, poštanski broj			
Broj telefona		Faks	
Email adresa:			
Potpis		Datum	

- Isporučili smo potencijalno pogođeni proizvod drugoj organizaciji .
Ako je označeno: unesite nove informacije o organizaciji u nastavku.

Novi naziv organizacije			
Ime/titula kontakta			
Adresa*			
Grad, država, poštanski broj			
Broj telefona		Faks	
Email adresa:			

MOLIMO VRATITE SVOJ POPUNJENI FORMULAR E-POŠTOM NA: ina.mason@theinsides.co

Obrazac za odgovor korisnika

Adresa za povrat proizvoda:

JAN KREDIET VENLO
Jakova Roggeveenweg 8-10
5928 LS Venlo
Nizozemska