

Date: 04-03-2020

Urgent Field Safety Notice
Chest support

For Attention of*: National distributor

Contact details of local representative (name, e-mail, telephone, address etc.)*

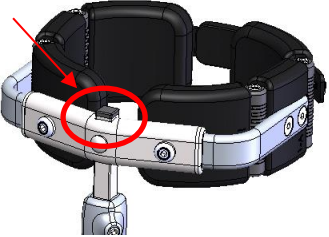
Invaru Limited
Peterburi tee 14A
EE-11411
Tallinn

Email info@invaru.ee
Phone +372 372 6212 582

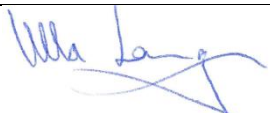
If you have any questions or require further information regarding this important product information, please contact your national distributor

Urgent Field Safety Notice (FSN)
Chest support
Risk addressed by FSN

1. Information on Affected Devices*	
1.	<p>1. Device Type(s)*</p> <p>Chest support for a walking aid for disabled children and adults Chest support for manual standers for disabled children</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div> <p style="display: flex; justify-content: space-around;"> Article no: 861810, 861820, 861830 869810, 869820, 869830 </p>
1.	2. Commercial name(s) Chest support
1.	3. Unique Device Identifier(s) (UDI-DI) N/A
1.	4. Primary clinical purpose of device(s)* The chest support is for support of upper body for persons needing supplementary assistance. The chest support is accessory for R82 medical devices Mustang and Rabbit/Rabbit Up
1.	5. Device Model/Catalogue/part number(s)* Chest support for Rabbit/Rabbit Up (3 sizes): 861810, 861820, 861830, Chest support for Mustang (3 sizes): 869810, 869820, 869830
1.	6. Software version N/A
1.	7. Affected serial or lot number range Manufacturing period: 01-04-2017 to 10-02-2020
1.	8. Associated devices N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	<p>1. Description of the product problem*</p> <p>Chest support has a small plastic plug placed in the centre pole tube.</p>  <p>We have received feedback from market, that plastic plug can come loose without use of a tool.</p>
2.	<p>2. Hazard giving rise to the FSCA*</p> <p>Choking hazard in case of swallowing the loose plastic plug</p>
2.	<p>3. Probability of problem arising</p> <p>The chest support has been manufactured in the period 01-04-2017 to 10-02-2020 without any registered incidents, so probability is low.</p>
2.	<p>4. Predicted risk to patient/users</p> <p>Severity in case of swallowing the loose plastic plug can be high. To date no serious incident involving choking of user have been registered.</p>
2.	<p>5. Further information to help characterise the problem</p> <p>Field Safety Notice (FSN) is to reinforce instructions for use. As small parts may come loose, general information to the user of raised attention on loose small parts possibly causing a choking hazard should be given.</p>
2.	<p>6. Background on Issue</p> <p>Feedback from market.</p>
2.	<p>7. Other information relevant to FSCA</p> <p>Loose plastic plug on the chest support can potentially put the user at risk of choking. The safety of the user is of utmost importance to us and R82 has decided to make an FSN on adding safety information (<i>"This product contains small parts which could present a choking hazard if removed from their intended placing."</i>) regarding small parts to the existing instruction for use.</p>

3. Type of Action to mitigate the risk*							
3.	<p>1. Action To Be Taken by the User*</p> <p> <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>This field safety notice is for informational purposes only. It is not necessary to return devices or loose plastic plugs, if any. In case of question the user can contact the national distributor If a loose plug is found replacement plug (2504000) can be requested at national distributor</p>						
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 35%;">2. By when should the action be completed?</td> <td style="width: 15%; text-align: center;">N/A</td> <td style="width: 50%;">Specify where critical to patient/end user safety</td> </tr> </table>	2. By when should the action be completed?	N/A	Specify where critical to patient/end user safety			
2. By when should the action be completed?	N/A	Specify where critical to patient/end user safety					
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 65%;">3. Particular considerations for:</td> <td style="width: 35%;">Choose an item.</td> </tr> <tr> <td colspan="2">Is follow-up of patients or review of patients' previous results recommended?</td> </tr> <tr> <td colspan="2" style="text-align: center;">No</td> </tr> </table>	3. Particular considerations for:	Choose an item.	Is follow-up of patients or review of patients' previous results recommended?		No	
3. Particular considerations for:	Choose an item.						
Is follow-up of patients or review of patients' previous results recommended?							
No							
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)</td> <td style="width: 30%; text-align: center;">No</td> </tr> </table>	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No				
4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No						
3.	<p>5. Action Being Taken by the Manufacturer</p> <p> <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input checked="" type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Update of IFU regarding increased awareness of loose small parts. Updated IFU will be available on www.r82.org</p>						
3	<table border="1" style="width: 100%;"> <tr> <td style="width: 35%;">6. By when should the action be completed?</td> <td style="width: 15%; text-align: center;">N/A</td> <td style="width: 50%;">Specify where critical to patient/end user safety</td> </tr> </table>	6. By when should the action be completed?	N/A	Specify where critical to patient/end user safety			
6. By when should the action be completed?	N/A	Specify where critical to patient/end user safety					
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">7. Is the FSN required to be communicated to the patient /lay user?</td> <td style="width: 30%; text-align: center;">Yes</td> </tr> </table>	7. Is the FSN required to be communicated to the patient /lay user?	Yes				
7. Is the FSN required to be communicated to the patient /lay user?	Yes						
3	<table border="1" style="width: 100%;"> <tr> <td colspan="2">8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?</td> </tr> <tr> <td style="width: 15%; text-align: center;">Yes</td> <td>Appended to this FSN</td> </tr> </table>	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?		Yes	Appended to this FSN		
8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?							
Yes	Appended to this FSN						

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows: N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to: Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	R82
	b. Address	Parallelvej 3, 8751 Gedved
	c. Website address	www.R82.org
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	N/A
4.	10. Name/Signature	Ulla Lange Director QA and Regulatory Affairs
		

Transmission of this Field Safety Notice	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*</p>

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Safety information page to include in User Guide

User Guide M1250 Mustang
User Guide M1130 Rabbit (discontinued 31-01-2019)
User Guide M1062 Rabbit Up

Please include this page to Safety section.

EN: This product contains small parts which could present a choking hazard if removed from their intended placing

DE: Dieses Produkt enthält kleine Teile, die bei Verschlucken eine Erstickungsgefahr darstellen können, wenn sie von ihrer vorgesehenen Platzierung entfernt werden.

NL: Dit product bevat kleine onderdelen die ingeslikt kunnen worden. Verstikkingsgevaar als ze worden verwijderd van hun oorspronkelijke plaats

DK: Dette produkt indeholder små dele som kan udgøre kvælningfare hvis de fjernes fra deres tiltænkte placering

NO: Dette produktet inneholder små deler som kan utgjøre kvelningsfare hvis de fjernes fra sin tiltenkte plassering

SV: Den här produkten innehåller små delar som kan utgöra en kvävningrisk om de tas bort från deras avsedda plats

FIN: Tämä tuote sisältää pieniä osia, jotka voivat aiheuttaa tukehtumisvaaran, jos ne irrotetaan paikoiltaan

ES: Este producto contiene piezas pequeñas que podrían presentar riesgo de asfixia si se retiran del lugar donde están instaladas

FR: Ce produit contient des petites pièces qui, si elles sont détachées de leur emplacement, peuvent constituer un risque de suffocation.

IT: Questo prodotto contiene componenti di piccole dimensioni che potrebbero costituire un pericolo di soffocamento se rimossi dalla posizione prevista

PT: Este produto contém pequenas peças que podem apresentar risco de asfixia se forem retiradas do seu respetivo local

BR: Este produto contém peças pequenas, que podem apresentar risco de asfixia se forem removidas de seu local original

RU: Это изделие содержит мелкие детали, которые представляют опасность удушья, если не закреплены на месте.

PL: Ten produkt zawiera małe części, które mogą stanowić zagrożenie udławieniem, jeśli zostaną usunięte z miejsca, w którym zostały umieszczone

CZ: Tento produkt obsahuje malé části, které by mohly představovat riziko udušení, pokud by se dostaly z určeného místa

GR: Το προϊόν αυτό περιέχει μικρά μέρη που θα μπορούσαν να προκαλέσουν κίνδυνο πνιγμού, εάν αφαιρεθούν από την προοριζόμενη θέση τους