



Rev 1: September 2019

**FSN Ref:** FSN-0492

**FSCA Ref:** BfArM Fall 07882 19/7 TA IQ FWD

**Date:** 24-09-2019

## **Urgent Field Safety Notice** **Device Commercial Name**

For Attention of users of the TA FWD wheelchairs, and the TA Service Dealers

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

<p><b>Australia: Patient Handling. Mail: <a href="mailto:info@patienthandling.com.au">info@patienthandling.com.au</a> - Phone: +61-1300 734 862 Address: 1 Mitchell, St Marrickville, NSW 2204</b></p>
--

<p><b>New Zealand: Morton &amp; Perry. Mail: <a href="mailto:service@mortonperry.co.nz">service@mortonperry.co.nz</a> – Phone: +64-09 441 8495 &amp; +64-0800 238 523 – Address: Unit 4, 39 Porana Road Wairau Valley, North Shore, Auckland</b></p>
--

<p><b>Belgium: Orthobution. Mail: <a href="mailto:info@orthobution.be">info@orthobution.be</a> – Phone: +32-089 3072 39 Address: Henry Fordlaan 43, 3600 Genk</b></p>
---

<p><b>Germany, Holland, Luxemborg, Austria, Switzerland: Reha-Med Hilfsmittel GmbH. Mail: <a href="mailto:kundenservice@rehamedpower.de">kundenservice@rehamedpower.de</a> Phone: +49 231 - 51 91 61 52 Address: Eichwaldstr. 9, 44319 Dortmund</b></p>
---

<p><b>Iceland: Studlaberg. Mail: <a href="mailto:stb@stb.is">stb@stb.is</a> – Phone +354 569-3180 Address: Stórhöfda 25, 110 Reykavík</b></p>
---

<p><b>Cyprus: Able Tools. Mail: <a href="mailto:info@abletools.com.cy">info@abletools.com.cy</a> – Phone +357 22 250 115, Address: Strovolos Avenue 149Ke, Strovolos, Nicosia, 2048, Cyprus</b></p>
---



## **Urgent Field Safety Notice (FSN)**

### **Risk addressed by FSN**

<b>1. Information on Affected Devices*</b>	
1	<b>1. Device Type(s)*</b>
.	TA iQ FWD electric wheelchair
1	<b>2. Commercial name(s)</b>
.	TA iQ FWD (front wheel drive)
1	<b>3. Unique Device Identifier(s) (UDI-DI)</b>
.	Complete when this becomes available.
1	<b>4. Primary clinical purpose of device(s)*</b>
.	TA iQ FWD is a front wheel driven wheel chair, with high manoeuvrability, for use both outdoor and indoor.
1	<b>5. Device Model/Catalogue/part number(s)*</b>
.	Catalog no. 97075
1	<b>6. Software version</b>
.	
1	<b>7. Affected serial or lot number range</b>
.	Where relevant. If not known, use manufacturing/distribution/expiration date as appropriate. Add as Appendix if necessary or provide <a href="#">web-based look-up tool</a> .
1	<b>8. Associated devices</b>
.	TA iQFS (TA iQ Stand-up chair)

<b>2 Reason for Field Safety Corrective Action (FSCA)*</b>	
2	<b>1. Description of the product problem*</b>
.	The FWD electric wheelchair is mounted with a drive unit with a shaft where the wheel is mounted. This shaft may be weakened if it is subjected to greater stresses than described in the user manual, which may include the following, such as a collision, or forcing obstacles higher than 10cm. Whereupon the shaft may subsequently break, as a result of the weakening. The shaft can also be weakened if unauthorized personal did not install the recommended HUB system properly.
2	<b>2. Hazard giving rise to the FSCA*</b>
.	If the shaft breaks while driving, the user may risk injury as the wheelchair stops abruptly, and if the accident occurs on a sloping ground, the wheelchair could risk overturning. The risk of axle breakage is considered minimal, but based on the few known cases, TA Service has decided to offer a upgrade on al previously supplied FWD wheelchairs to the new HUB system. Until this is done, we recommend that caution be exercised when driving with the wheelchair, especially if the user / helper is aware that the wheelchair has been in a collision or has run over larger obstacles than the wheelchair is intended to handle.
2	<b>3. Probability of problem arising</b>
.	Likelihood of a problem occurring is considered to be extremely minimal and it is not believed that further action should be taken than mounting of the new HUB system
2	<b>4. Predicted risk to patient/users</b>
.	It is assessed that there is no predictable risk to the user / helper

2	<b>5. Further information to help characterise the problem</b>
.	Based on the 2 known cases where a shaft is broken and where the user in one case previously had an event that could lead to a weakening of the drive shaft, when the wheelchair was overturned and that this could have weakened the shaft. The risk of shaft breakage is considered extremely minimal.
2	<b>6. Background on Issue</b>
.	The cause of shaft breakage is due to a sudden load on the shaft, which may have been due to collision with the obstacle, or the forcing of objects larger than 10cm. The manufacturer of the drives has examined one shaft and seen pictures of the fracture on the other, and from that they have not been able to see that the fracture is due to mold defects in the shafts.
2	<b>7. Other information relevant to FSCA</b>
.	TA service has implanted the HUB system as standard on all wheelchairs, this was done from end Juli 2018, and the reason for this change was only done to help by changing the wheel, but it also had the advantage that the HUB reinforced the shaft. TA Service will offer a change to this HUB system to all to all FWD wheelchairs delivered before the end of July 2018. This will start as soon as delivery of the extra HUB will take place in end of 2019

<b>3. Type of Action to mitigate the risk*</b>			
<b>3.</b>	<b>1. Action To Be Taken by the User*</b>  <input checked="" type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device  <input checked="" type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> Follow patient management recommendations  <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)  <input type="checkbox"/> Other <input checked="" type="checkbox"/> None  Provide further details of the action(s) identified.		
<b>3.</b>	<table border="1" style="width: 100%;"> <tr> <td style="width: 30%; vertical-align: top;">2. By when should the action be completed?</td> <td style="vertical-align: top;">           Specify where critical to patient/end user safety            The replacement will take place in cooperation with the dealers in the respective countries and will be able to begin as soon as TA Service receives HUBs for this change, and it should be finished start 2020.         </td> </tr> </table>	2. By when should the action be completed?	Specify where critical to patient/end user safety The replacement will take place in cooperation with the dealers in the respective countries and will be able to begin as soon as TA Service receives HUBs for this change, and it should be finished start 2020.
2. By when should the action be completed?	Specify where critical to patient/end user safety The replacement will take place in cooperation with the dealers in the respective countries and will be able to begin as soon as TA Service receives HUBs for this change, and it should be finished start 2020.		
<b>3.</b>	3. Particular considerations for: IVD  Is follow-up of patients or review of patients' previous results recommended? No  Follow-up on this case is only done if the user / helper does not respond to the call for replacement of the drives		
<b>3.</b>	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%; vertical-align: top;"> <b>4. Is customer Reply Required? *</b>  <b>(If yes, form attached specifying deadline for return)</b> </td> <td style="vertical-align: top; text-align: center;">Yes</td> </tr> </table>	<b>4. Is customer Reply Required? *</b> <b>(If yes, form attached specifying deadline for return)</b>	Yes
<b>4. Is customer Reply Required? *</b> <b>(If yes, form attached specifying deadline for return)</b>	Yes		

3.	<b>5. Action Being Taken by the Manufacturer</b>	
	<div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Product Removal  <input type="checkbox"/> Software upgrade  <input checked="" type="checkbox"/> Other </div> <div> <input type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> IFU or labelling change  <input type="checkbox"/> None </div> </div> <p>The installation of the HUB system on TA iQ FWD will be done in collaboration with the dealers in the respective countries, and the user / helper will then receive a call to change the drive either in the dealer's workshop, or at a collection site set up for the purpose, by an installer. This is decided on the basis of the individual cases in consultation between the dealer and the user / helper</p>	
3	6. By when should the action be completed?	7. Replacements are expected to be completed by the start of 2020
3.	8. Is the FSN required to be communicated to the patient /lay user?	Yes
3	9. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No      Appended to this FSN	

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	
4.	3. For Updated FSN, key new information as follows:	
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	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * No	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	Insert Name and Title here and signature below

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.