Rev 1: September 2018
FSN Ref: PH_CCR_300422 FSCA Ref: PH_CCR_300422

Date: 17. AUG. 2021

Urgent Field Safety Notice
Transition Coupling

For Attention of*: Customers in Holland, Norway, Sweden, Switzerland, UK.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Etac AS, Moss, Norway – mail: hilde.gravnaas@etac.com ; Etac Holland: Ferre Leujes: fele@r82.com ; Etac Sweden: Christian Söderberg, Christian.soderberg@etac.com, Switzerland: Philippe Richter : phrichter@sodimed.ch ; UK: Andrew King, aki@r82.com

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Urgent Field Safety Notice (FSN)
Transition Coupling
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Transitions couplings supplied in Patient Lifting System – mounted in ceiling
1.	2. Commercial name(s)
	Molift
1.	3. Unique Device Identifier(s) (UDI-DI)
	5707995013217
1.	4. Primary clinical purpose of device(s)*
	Patient Lifting System intended for sitting and horizontal transfer as well as standing and gait training situations
1.	5. Device Model/Catalogue/part number(s)*
	Article number: 1109650
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
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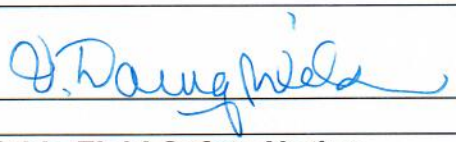
1.	8. Associated devices
	N/A

2	**Reason for Field Safety Corrective Action (FSCA)***

2.	1. Description of the product problem*
	It comes clear that when installing the patient lifting system the transition coupling may not lock as intended.
2.	2. Hazard giving rise to the FSCA*
	If the patient lifting system is used and the transitions coupling is not locked as intended, there is a potential risk that the hoist system can be detached from the rails and the motor can fall down.
2.	3. Probability of problem arising
	It may happen in limited cases.
2.	4. Predicted risk to patient/users
	If the detachment happen when lifting a patient, the patient might get injury due to the fall.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Root cause is due to manufacturing site that by assembly has added too much loctite material.
2.	7. Other information relevant to FSCA
	Rework instruction for installers has been developed and are forwarded to relevant customers.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device	
	☒ On-site device modification/inspection	
	☐ Follow patient management recommendations	
	☐ Take note of amendment/reinforcement of Instructions For Use (IFU)	
	☐ Other ☐ None	
	Re-Work Instruction has been developed and the steps should be followed in order to eliminate the risk.	
3.	2. By when should the action be completed?	Before putting the system into service
3.	3. Particular considerations for: Is follow-up of patients or review of patients' previous results recommended? The system is normally checked at installation, where the issue will arise.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Corrective Action has been forwarded to relevant customers	
3	6. By when should the action be completed?	Before putting the system into service
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	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?	

	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:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	
	b. Address	
	c. Website address	
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**Potential affected serial numbers, countries of customers and delivered amount**
4.	10. Name/Signature	**Vibeke Damgaard Nielsen** 

	Transmission of this Field Safety Notice
	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) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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..*

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