Rev. 1: March 2024

FSN Ref: PM6/SS13/FSN FSCA: PM6/SS13/FSCA

Date: 08/03/2024

Urgent field safety notice
Easymoov6 enteral feeding pump
Safety information

For the attention of*: Person responsible for medical device safety/vigilance, biomedical manager, quality manager - To be forwarded to all user departments and all users.

Contact details of local representative (name, e-mail, telephone, address, etc.) *.
This may be a distributor or a local branch of the manufacturer. To be added at the appropriate stage in the various local languages.

	1. **Information on the devices concerned*.**
1	1. Type(s) of device(s)*
	Enteral feeding pump
1	2. Trade name(s)
	Easymoov6
1	3. Unique device identifier(s) (UDI-DI)

Reference	*UDI-ID*
0VEPM6	03660812096560
0VEPM6A06	03660812096669
0VEPM6C02	03660812096577
0VEPM6C06	03660812096614
0VEPM6C10	03660812099028
0VEPM6C11	03660812144360
0VEPM6D02	03660812106160
0VEPM6G02	03660812096553

1	4. Primary clinical purpose of the device(s)*.
	Enteral feeding
1	5. Device model/catalog/parts number(s)*.
	See reference 1.3
1	6. Software version
	All software versions
1	7. Range of serial or batch numbers concerned
	All serial numbers
1	8. Associated devices
	N/A

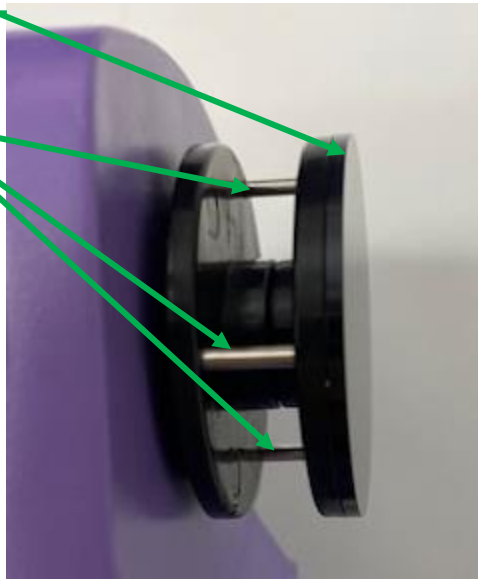
2 **Reason for safety corrective action in the field (FSCA)* (in French)**	
2	1. Product problem description
	Medwin has been informed of an incident involving an Easymoov6 enteral nutrition pump. The pump's rotor no longer had the rollers required for rotary peristalsis, which can lead to significant overflow.
2 .	2. Risks behind the CASF
	Risk of serious digestive problems caused by a too fast feeding.
2	3. Probability of a problem occurring
.	The problem may arise if the following steps occur chronologically: 1. The screw holding the two rotor flanges is unscrewed by a third party. 2. Both flanges are stressed and come loose, 3. The rollers are released from their housing and fall
2	4. Foreseeable risk for patients/users
	Overeating and severe digestive disorders, including vomiting.
2	5. Additional information to help characterize the problem
	N/A
2	6. Context of the question
	Medwin has been informed of 2 incidents caused by the fault described in 2.1. Only the Easymoov6 pump is affected by the problem
2.	7. Other FSCA information
	N/A

3.	**3. Type of action to mitigate risk*.**	
3.	**1. Measures to be taken by the user*** ☒ Identify the device ☐ Quarantine the device ☐ Return device ☐ Destroy device ☒ Modify/inspect device on site ☐ Follow recommendations for patient management ☐ Take note of modification/strengthening of instructions for use (IFU) ☐ Other ☐ None • Identify pumps whose rotor does not have the 3 rollers required for correct pump operation. (See pictures in annex) • Immediately repair the pump. Contact your local Vygon representative to arrange rotor replacement if necessary. • Make nursing staff aware of the problem, so that they check the rotor before feeding. • Remind staff that : - Any dismantling of the rotor, for cleaning purposes for example, must be carried out by a competent and trained member of the plant, - The use of the automatic purge function at each tubing change also reveals any occlusion defects in the rotor.	
3.	2. When must the action be completed?	As soon as possible
3.	3. Special considerations for : N/A. Is patient follow-up or review of previous patient results recommended? N/A.	
3.	4. Does the customer have to reply? * (If yes, form attached specifying deadline for return)	Yes
3.	5. Measures taken by the manufacturer ☐ Product withdrawal ☐ Modification/inspection of device on site ☐ Software update ☐ Modification of IFU or labeling ☒ Other ☐ None The rotor assembly method used in production has been modified to avoid separating the flanges and freeing the rollers.	
3.	7. Should the FSN be communicated to the patient/end user?	Yes
3	8. If yes, has the manufacturer provided additional information tailored to the patient/user in a letter/information sheet for the patient/bed user or lay user?	
.	See Appendix 1	

4. General information		
4.	1. FSN Type*	New
4.	2. For the updated DSF, the reference number and date of the previous DSF.	N/A
4.	3. For the updated DSF, enter the new information as follows:	
	N/A	
4.	4. Other advice or information already expected as part of the DSF follow-up? *	Not yet planned
4	5. If a follow-up NSF is planned, what should the additional advice cover?	
	N/A	
4	6. Timeframe for FSN follow-up	N/A
4.	7. Manufacturer information	
	a. Company name	MEDWIN France
	b. Address	9, allée de la Vigne Grande 34600 Les Aires
	c. Website address	www.vygon.com
4.	8. The competent (regulatory) authority in your country has been informed of this communication to customers. *	
4.	9. List of attachments/appendices :	Appendix 1: Differences between an operational rotor and a faulty rotor
4.	10. Name/Signature	Jérémy Imbert, Quality Manager
	Transmission of this safety notice to the field	
	This notice must be sent to all persons who need to be informed within your organization or to any organization to which the potentially affected devices have been transferred. (if applicable) Please forward this notice to other organizations on which this action has an impact. (if applicable) We ask you to remain attentive to this notice and the resulting action for an appropriate period of time to ensure the effectiveness of the corrective action. Please report all incidents relating to the device to the manufacturer, distributor or local representative, as well as to the relevant national authority where applicable, as this provides important feedback.*.	

Note: Fields marked with an asterisk (*) are considered necessary for all DSFs. Other fields are optional.

APPENDIX 1

Operating rotor	
• Retaining screw tightened • 3 rollers	

Faulty rotor	
• Loose retaining screw • No rollers