Rev. 1: June 2025

FSN Ref : PM6/SS14/FSN FSCA Ref : PM6/SS14/FSCA

Date: 26/06/2025

# Urgent field safety notice
# Easymoov6 Enteral feeding pump

For the attention of*: biomedical manager, quality manager

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

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# Urgent Field Safety Notice (FSN)
# Easymoov6 Enteral feeding pump
# Risk addressed by FSN

| | |
|---|---|
| | 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 |

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| 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 |

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| 2 | **Reason for safety corrective action in the field (FSCA)* (in English)** |
| 2 | 1. Product problem description |
| | Medwin was informed of an incident in a healthcare facility. The user failed to place the silicone tubing around the rotor, resulting in a significant overflow. |
| 2 | 2. Risks behind the FSCA |
| | Risk of overflow and free flow |
| 2 | 3. Probability of a problem occurring |

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| | This is the second report of this problem, it can also arise from incomplete user training. |
| 2 | 4. Foreseeable risk for patients/users |
| | Overfeeding, Digestive disorders |
| 2 | 5. Additional information to help characterize the problem |
| | N/A |
| 2 | 6. Context of the question |
| 2. | 7. Other FSCA information |
| | N/A |

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| **3.** | **3. Type of action to mitigate risk*.** | |
| **3.** | **1. Measures to be taken by the user***<br>☐ Identify device ☐ Quarantine device ☐ Return device ☐ Destroy device<br>☐ Modify/inspect device on site<br>☐ Follow recommendations for patient management<br>☐ Take note of modification/strengthening of instructions for use (IFU)<br>☑ Other ☐ None<br><br>It is advisable to remind users, especially lay users, of the correct way to install the tubing on the enteral nutrition pump.<br>A reminder of the rules and instructions for use is presented in the appendix.<br>Also, for information, a new cover with an added security has been designed and is now available.<br>Medwin France proposes the following options to replace the cover:<br>• The user decides to make the change by himself, in that case, Medwin France will provide a notice and appropriate tools to make the change easily,<br>• The user decides that the change will be made by Medwin France services : the user will have to send the pumps to Medwin France facility. The pump's cover will be changed and returned to the user. | |
| 3. | 2. When must the action be completed? | As soon as possible |
| 3. | 3. Special considerations for : N/A.<br>Is patient follow-up or review of previous patient results recommended? N/A. | |
| 3. | 4. Does the customer have to reply? *<br>(If yes, form attached specifying deadline for return) | Yes |
| 3. | **5. Measures taken by the manufacturer**<br>☐ Withdrawal of product ☐ Modification/inspection of device on site<br>☐ Software update ☐ Modification of IFU or labeling<br>☑ Other ☐ None<br>Proposition to replace the covers by using one of the two options listed above. | |
| 3 | 6. When must the action be completed? | As soon as possible |
| 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 appendixes | |

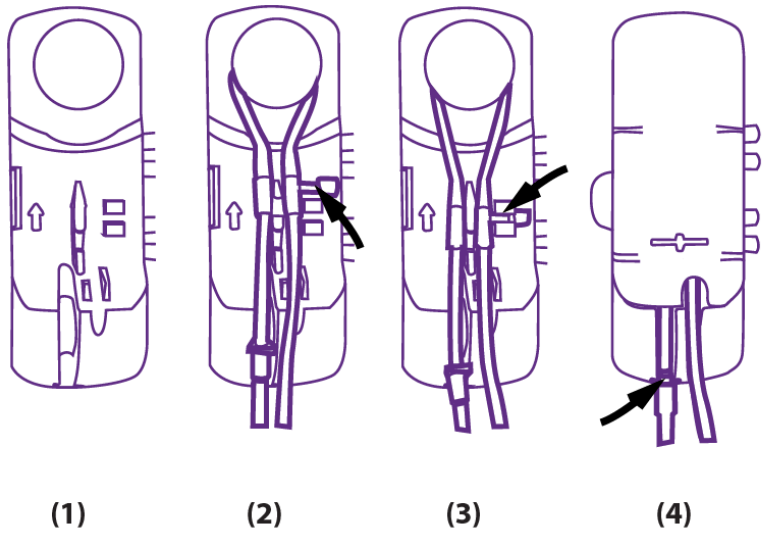
| 4. General information | | |
|---|---|---|
| 4. | 1. FSN Type* | Initial |
| 4. | 2. For the updated FSN, the reference number and date of the previous FSN. | N/A |
| 4. | 3. For the updated FSN, enter the new information as follows: | |
| | Remind of the instructions to set up the enteral feeding set on the rotor. And information about the new cover with an added security. | |
| 4. | 4. Other advice or information already expected as part of the FSN follow-up? * | N/A |
| 4 | 5. If a follow-up FSN is planned, what should the additional advice cover? | |
| | N/A | |
| 4 | 6. Timeframe for FSN follow-up | N/A |
| 4. | 7. Manufacturer information (for contact details of local representative, see page 1 of this memo) | |
| | a. Company name | MEDWIN France |
| | b. Address | 9, allée de la Vigne Grande<br>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 : Instructions for use (set-up of the enteral feeding set)<br>Appendix 2 : Cover change<br>Acknowledgement of receipt |
| 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)<br>Please forward this notice to other organizations on which this action has an impact. (if applicable)<br>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.<br>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 FSNs. Other fields are optional.

**Apendix 1 : Reminder on tubing installation on Eaymoov6 enteral feeding pumps**

To install the tubing, follow the steps below:

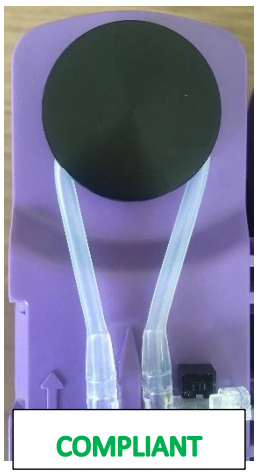
- Connecting the tubing to the nutrient bag :
- After checking the integrity of the packaging, remove the tubing from the bag.
- Connect the tubing to the nutrient bag and suspend the bag.
- Install the tubing on the pump and bleed it in accordance with the table below taken from the operating instructions:

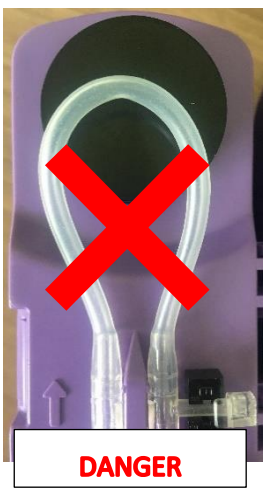
| | |
|---|---|
| **(1)** Open Easymoov6 pump cover. |  |
| **(2)** Place the silicone loop around the rotor and make sure the cassette is in the right direction. | |
| **(3)** Push the cassette in the middle of the pins with your thumb and make sure the cassette is well postioned between the two black pins. Guide both tubes down, in line with their respective slots. | |
| **(4)** Close the pump cover, then place the adapter into the designated slot. | |
| Remove the protective cap from the tubing. | |
| Launch automatic priming (see section 3.5). | |
| Connect the tubing to the patient enteral feeding tube and program the pump. | |



**Please note** :

- **not to connect the tubing to the probe** before priming,
- **to check the correct position of the silicone tube** around the rotor:



**Apendix 2 : Security added to the cover**

| Cover without the security | Cover with the security |
|---|---|
|  |  |