Rev 1: September 2018

FSN Ref: 2102-07-FSN FSCA Ref: 2102-07-FSCA

Date: 06.May.2021

Urgent Field Safety Notice
AUTOSELECTOR

For Attention of*:Swissmedic, Schweizerisches Heilmittelinstitut and Dutch Health and Youth Care Inspectorate (IGJ)

Contact Information
Name: Ace-medical (Manufacturer)
Address: 33, Naeyugil 124beon-gil, Deogyang-gu, Goyang-si, Gyeonggi-do, Republic of Korea
Postcode: 10264
Phone: +82-31-960-9263
E-mail.: dykim@ace-medical.com

ACEMEDICAL

Urgent Field Safety Notice (FSN)
AUTOSELECTOR
Leak in the selector module

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Infusion pump, manually-operated, and sterilized product
1.	2. Commercial name(s)
	AUTOSELECTOR (550mL / B-type)
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	The AutoSelector is intended for continuous and/or intermittent infusion of medication for general infusion use including antibiotic, chemotherapy and pain management therapies.
1.	5. Device Model/Catalogue/part number(s)*
	AFLC-B
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	A200804-PSCFB000CH-1, A200805-PSCFB000CH-1
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Leak in the selector module.
2.	2. Hazard giving rise to the FSCA*
	There was no harm to a patient. However as a result of customer complaint product tests, reported condition was verified. Since we identified the root cause and prevent the same customer complaint, we issue the FSCA.
2.	3. Probability of problem arising
	To prevent the same customer complaint arising, Ace-medical will remove the product LOT number A200804-PSCFB000CH-1 and A200805-PSCFB000CH-1.

2.	4. Predicted risk to patient/users
	If the leaking selector module is attached to the patient, drug can be injected abnormally (At low risk).
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	A number of Autoselectors were returned as customer complaints products. And through the tests of them, Ace-medical found a problem on a material(LOT number A200715) which is used on product LOT number A200804-PSCFB000CH-1 and A200805-PSCFB000CH-1.
2.	7. Other information relevant to FSCA
	N/A

	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 Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	The expected date is mid-May
3.	3. Particular considerations for: MDD Is follow-up of patients or review of patients' previous results recommended? No, as Ace-medical chooses to destroy (remove) the product, we do not need follow-up of patients.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No

3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3	6. By when should the action be completed?	The expected date is mid-May
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*	Update
4.	2. For updated FSN, reference number and date of previous FSN	2102-07-FSN, 28. April. 2021
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	Ace-medical
	b. Address	33, Naeyugil 124beon-gil, Deogyang-gu, Goyang-si, Gyeonggi-do, Republic of Korea
	c. Website address	www.ace-medical.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *No	
4.	9. List of attachments/appendices:	N/A
4.	10. Name/Signature	**Daeyang Kim, Quality Management Manager**  2021. 5. 6

	Transmission of this Field Safety Notice

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