MY01

FSN Ref: FSN-2021-001
FSCA Ref: FSCA-2021-001

Date: 25-Jun-2021

FIELD SAFETY NOTICE
MY01 Continuous Compartmental Pressure Monitor

Dear Customer,

This is to inform you of a voluntary product removal involving the **MY01 Continuous Compartmental Pressure Monitor®** (Image 1)

Commercial Name: MY01 Continuous Compartmental Pressure Monitor

Catalogue Number: MY01-0001

UDI: 07540162030017

Intended Use: The MY01 Continuous compartmental Pressure Monitor is intended for real-time and continuous measurement of compartmental pressures. The measured compartmental pressures can be used as an aid in the diagnosis of compartment syndrome. The trend arrows displayed are meant for qualitative purposes only and are not intended to have any clinical significance. The MY01 Mobile Application is an optional application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device. The data is for informational purposes only and is not intended to be used for diagnosis of any nature or active patient monitoring.

Image 1: *MY01 Continuous Compartmental Pressure Monitor*

Description of the issue:

For the affected product Lots listed in Appendix 1, MY01 Inc. has identified that there is a potentially nonconforming version of the needle used in the introducer of the device. The affected Lots were manufactured using needles with a needle trocar geometry which is out of specification and may require a slightly higher push force from the user to penetrate the patient skin.

Potential Patient risk:

The predicted risks to the patient are:

- Most probable situation: Minor delay in diagnosis in the event where it would take the user more effort/ time in introducing the device. The diagnosis is always given by the health care professional and never by the device.
- Highest severity situation: patients may need professional medical intervention to retrieve a separated segment or treat localized infection at insertion site.

Action to be taken by the User:

1) **Identify the affected devices.**
2) **Return affected devices before 07-Jul-2021.**
3) **Other:**
   Please complete the enclosed Reply Form. Where product is indicated as being returned, our Client Success department will contact you to organize the return and issue you with the relevant Returns Authorization number. Please include contact details on the Reply Form.

   The affected devices are to be returned to the following address:

   MY01 Inc.
   Attention: Regulatory Affairs & Quality Management
   400 Boul de Maisonneuve Ouest,
   Suite 700
   Montreal, Quebec,
   Canada
   H3A 1L4

Dr. Ed Harvey
Chief Medical Officer

Charles Allan
Chief Executive Officer

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-2021-001
FSN Date*	25-Jun-2021
Product/ Device name*	MY01 Continuous Compartmental Pressure Monitor
Product Code(s)	MY01-0001
Batch/Serial Number (s)	Refer to Appendix 1

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
○	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
○	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
○	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
○	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		N/A	Comments:	

○	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		Qty	Lot/Serial Number:
		N/A	Comments:
○	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
○	Other Action (Define):		
○	I do not have any affected devices.	Customer to complete or enter N/A	
○	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query	
Print Name*		Customer print name here:	
Signature*		Customer sign here:	
Date*			

4. Return acknowledgement to sender	
Email	help@my01.io
Customer Helpline	+1(855)-292-6901
Postal Address	MY01 Inc. Attention: Regulatory Affairs & Quality Management 400 Boul de Maisonneuve Ouest, Suite 700 Montreal, Quebec, Canada H3A 1L4
Web Portal	N/A
Fax	N/A
Deadline for returning the customer reply form*	07-Jul-2021

Mandatory fields are marked with *

Appendix 1: Affected Lots

Reference Number	Product name	Lots
MY01-0001	MY01 Continuous Compartmental Pressure Monitor	9448532
		9448838
		9448979
		9449237