



URGENT: Field Safety Notice For Distributor
FCA 19-001-C
Neovasc Reducer™ System
Correction of Expiration Date

DD MMM YYYY

[Distributor Name]
[Distributor Address]
[Distributor Contact Details]

Dear [Distributor Contact Name],

Neovasc has discovered an error in the expiration date of the **Reducer System Lot No. 190131-01**. Since the Reducer Kit expiration date depends on the expiration date of the components, all kits containing the aforementioned Reducer System lot number are also included in this field corrective action.

The **correct expiration date is Jun 2020** but due to a typographical error, the affected products were labelled with an expiration date of Jun 2021.

There is no immediate safety concern for the affected lot as the true expiration date is several months away, however, Neovasc has initiated this Field Corrective Action requiring the following actions be taken immediately to prevent potential use of the products beyond their actual expiration date of Jun 2020.

The Competent Authority of your country has been informed about this communication.

Please complete the following actions and respond to Neovasc with the attached “**Distributor Notification Response**” by [date]:

1. Check your current inventory for the following Reducer Kit lot number/s. The Kit contains Reducer System lot number 190131-01.

Reducer Kit Lot No.
<Refer to GNV-FCP-002 Sec. 3.0 for the Reducer Kit lot number shipped to this distributor>
<Add/delete rows as necessary>

If the lot number is found, separate/quarantine these units for correction. Detailed and site-specific instructions on how to make the correction will be provided after your response is received.



13700 Mayfield Place, Suite 2135
Richmond BC V6V 2E4 Canada
P:604.270.4344 F:604.270.4384
www.neovasc.com

2. Check distribution records for Reducer Kit lot number/s above that were sent to a hospital and could potentially be in inventory at the hospital.

If there is product with this Reducer Kit lot number potentially at a hospital, Neovasc will provide a Customer Letter with further instructions, which includes arrangement to retrieve the units for correction.

3. Complete the “**Distributor Notification Response**” attached to this letter and return to Neovasc before [date].

Please note, there is no safety concern at this time. All product in your inventory currently contains Reducer Systems within their expiration date, however, it is critical for you to respond to this communication in order to prevent potential use of expired product after Jun 2020. Please note, Neovasc has conducted a root cause investigation of this issue and taken the necessary actions to prevent recurrence of this issue.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Thank you for your prompt reaction to this request.

Sincerely,
[Neovasc contact]



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DISTRIBUTOR NOTIFICATION RESPONSE

FSN Date: <DD MMM YYYY>

PRODUCT	PART NO.	LOT NUMBER	FCA NUMBER
Neovasc Reducer™ System	RED-001	190131-01	19-001-C

<input type="checkbox"/>	I confirm the receipt, the reading and understanding of the Field Safety Notice.		
<input type="checkbox"/>	I no longer have any of the Reducer Kits identified in the Field Safety Notice to contain Reducer System Lot No. 190131-01.		
<input type="checkbox"/>	I have some of the Reducer Kits identified in the Field Safety Notice to contain Reducer System Lot No. 190131-01 remaining in inventory.		
	Reducer Kit Lot Number	Quantity Remaining	

<input type="checkbox"/>	I have checked the Distribution Records for the Reducer Kits identified in the Field Safety Notice and determined that they were not distributed to any hospitals.			
<input type="checkbox"/>	I have checked the Distribution Records for the Reducer Kits identified in the Field Safety Notice and determined that they were distributed to the following hospitals. (<i>attach additional page/s if necessary</i>)			
	Hospital Name (include location)	Contact	Quantity Distributed	Quantity Implanted (if known)

Name	
Title	
Organization	
Address	
Telephone Number	
Fax Number	
E-mail	
Signature	
Date Completed	



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It is important that your organization takes the actions detailed in the Field Safety Notice and confirms that you have received the FSN. Your organization's reply is the evidence we need to monitor the progress of the corrective actions. Please return this Response to [Neovasc Contact including email] before [date].

Neovasc Use Only:

Received by (Print name and sign)	
Date received	
Product reconciliation by (Print name, sign and date)	