DIRECT FLOW MEDICAL, INC.

Urgent Field Safety Notice

Name of Affected Product: **Direct Flow Medical® Transcatheter Aortic Valve System**
FSCA Identifier: **EU-072016-001**
Type of Action: **Clarification on the pressure limits for the Direct Flow Medical® Transcatheter Aortic Valve System**

Date: 19 July 2016

Attention: Direct Flow Medical Customer

This letter contains important information that requires your immediate attention.

Description of the Problem:	Direct Flow Medical is conducting a Field Safety Corrective Action to re-inforce the original content, and to correct an error, in the Instructions for Use (IFU). 1. Direct Flow Medical has become aware of uses of inflation pressures during positioning greater than indicated in the IFU (16 atm). This Field Safety Corrective Action is intended to remind users to adhere to the pressure limits indicated in the IFU and not exceed 16 atm during the procedure. 2. The IFU allowed for 12-16 atm after the exchange procedure. This Field Safety Corrective Action is intended to inform users that exchange system pressure must be set at 12 atm and no higher prior to position wire disconnect. Failure to adhere to these pressure requirements could result in loss of Bioprosthesis pressure and polymer exposure in the patient. This may result in unstable patient hemodynamics and could require secondary medical intervention(s), up to and including surgical conversion.
Action to be taken by the user:	1. Adhere to the pressure limits in the instructions for use (IFU). Do not exceed 16 atm at any point during the procedure. Per IFU PL 9089 Rev M, Section 10.4, Step 4: "Position the Bioprosthesis, "Inflate the aortic ring to 12 - 16 atm using the inflation device with RES to verify position. Note: The Bioprosthesis pressure should not exceed 16 atm." 2. Reduce the Exchange System pressure to 12 atm, then close the #2 stopcock at the end of the polymer exchange (when the plungers reach the line on the Exchange System). Ensure the pressure is stable at 12 atm before disconnecting the position wires. 3. Complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.
RESOLUTION by Direct Flow Medical:	1. A Direct Flow Medical employee will provide training to emphasize these actions prior to the next clinical use of the product. 2. Direct Flow Medical is in the process of updating the Instructions for Use (IFU).

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This notice needs to be shared with all those who need to be aware within your organization.

The undersign confirms that this notice has been provided to the appropriate Regulatory Agency.

If you have any questions regarding this letter, additional information can be requested by emailing compliance@directflowmedical.com.

We apologize for the inconvenience that this may have caused you.

Sincerely,

[redacted]

Direct Flow Medical, Inc.
451 Aviation Blvd., Suite 107A
Santa Rosa, CA 95403
[redacted]

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Response Form

Name of Affected Product:	**Direct Flow Medical® Transcatheter Aortic Valve System**
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Check the appropriate box below:

☐ I have read the information within the accompanying Direct Flow Medical notification. All relevant personnel in the below mentioned hospital/clinic have been informed of its contents.

Hospital / Clinic: _____

Signed: _____ Date: _____

Name: _____ Title: _____

Telephone: _____ Email: _____

Please return via fax or email:

Direct Flow Medical, Inc.
Attn: Compliance
Email: compliance@directflowmedical.com
Fax: +1 (707) 576-0430

Please include "**EU-072016-001- July 2016**" in the e-mail subject field.