VITAL HEALTHCARE SDN.BHD.
Add: Lot 3, Jalan Sultan Mohamed 3, Bandar Sultan Sulaiman,
42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia

Field Safety Notice

Immediate actions to mitigate problems encountered in clinical use

FSCA Identifier FSN20180300_

Affected Devices NovaLine® Tubing Sets for Hemodialysis

Product Code	Model	Lot #
		All lots manufactured in year 2017 "2017XXXXXXXX"

Date 27 March 2018

Attention Dialysis Center Nurses, Physician, Nephrologists who may be influenced by the involved devices

Reason Vital Healthcare Sdn. Bhd. has issued a Field Safety Notice based on recent information received from the field

Dear Customers,

Vital Healthcare has identified the possibility of abnormal device behaviors of the NovaLine® Tubing Sets for Hemodialysis listed above.

Under certain rare circumstances, the device may exhibit the following behaviors:
- Configuration / Assembling issues (i.e. disconnected, not proper fitting between components, component missing)
- Functional issues (i.e. air entrance, difficulties to manage pressure monitoring during treatment)
- Clotting issues

Vital Healthcare has taken the customer feedback very seriously and conducted a thorough and detailed investigation to better understand the circumstances of the reported events. Risk analysis executed based on the relevant risk management files has underlined that residual risks are acceptable after taking necessary corrective and preventive actions, minimizing the occurrence of potential risks. Considering that no direct health risk / threat against patients was identified and no serious health threat happened to involved patients, no product recall is needed at present.

The purpose of this Field Safety Notice is to inform you about the:

- Issues and under what conditions they can occur
- Actions that you should take to prevent risks for patients
- Corrective actions from Vital Healthcare to address the issues

The **Annex 1** provides the "Action to be Taken by Customers / Users" on how to identify affected devices and instructions on actions to be taken. To address these actions, Vital Healthcare is providing an

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Instructions for Use (IFU) Addendum in **Annex 2**. This Addendum describes how users can check the suitability of the device for the intended use, providing measures to prevent, or methods to allow the user to correct the abnormal devices.

Vital Healthcare apologizes for any inconvenience this may cause you. If you have questions regarding this notification or need any further information or support, please contact Baxter Quality Department on +33 (0) 1 34 61 54 93.

Please fill out the enclosed Customer Response Form and send it back within 30 days of receipt in **Annex 3**.

Vital Healthcare Sdn. Bhd. confirms that the competent authority has been informed of this Field Safety Notice.

Transmission of this Field Safety Notice:

Please send this notice to all concerned persons of your organization and / or organization where the products were transferred.

Please check the application of this notice to ensure the effectiveness of corrective measures recommended.

Regards,

Vital Healthcare Sdn. Bhd.

***Annex* 1:** *Action to be Taken by Customers / Users*

***Annex* 2:** *Additional Instructions for Use*

***Annex* 3:** *Customer Response Form*

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***Annex* 1** *Action to be Taken by Customers*

Problems 1 Description	One occurrence in which blood pump of the machine didn't automatically stopped when blood reaches the venous extracorporeal blood circuit. Cause: It might be due to that this extrusion tubing is not same transparent as other tubes and the hemodialysis machine cannot identify the presence of blood in this tubing. Potential Risk: Blood loss
Action to be Taken by Customers / Users	Operator must take care about blood pump stopping when the blood reaches the venous drip chamber. If the operator recognizes that is not going to happen once the blood arrive at the right level along the venous line, operator has to stop the blood pump manually and then connect the patient
Actions planned by Vital Healthcare	Considering there is only one incident reported about this problem and the treatment continues without any further problem when the operator manually stopped the pomp. Vital Healthcare will keep monitoring the market feedback. In the meantime, it will keep ensuring the tubing is transparent.

Problems 2 Description	An exceptionally rare event of kinking of the blood pump segment Cause: This might be caused by the worker's improper tubing placing and the inspector fails to pick it out during 100% final product inspection and sampling inspection. Potential Risk: Hemolysis
Action to be Taken by Customers / Users	Operator must check the presence of kinking all along the bloodline before use. In case the operator recognizes the presence of kinking, the tubings must be scrapped.

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Actions Planned by Vital Healthcare	Re-train the workers on tubing rolling process as well as workers on 100% final inspection of finished products

Problems 3 Description	Some events of loose component inside primary packaging such as detached drainage bag and detached Transducer Protector (TP) Cause: Improper operation of the worker. Components may not be tightly screwed during production and become loose after long time transportation. Potential Risk: Contamination / Infection / Clotting
Action to be Taken by Customers / Users	Operator must check the presence of detached components before open the primary packaging and take care during packaging opening that no loose components fall on contaminated surfaces (i.e floor).

- If loose components fall onto the floor they must be scrapped and a entire new bloodline must be used.
- If detached bags or TP are found inside primary packaging it could be easily reconnected.

Actions Planned by Vital Healthcare	Retrain the workers. Increase the sampling amount for inspection.

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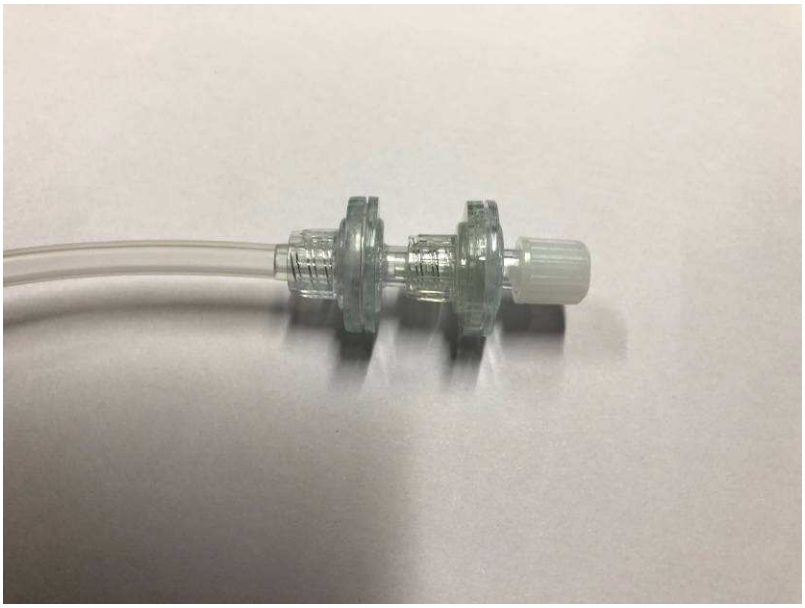
Problems 4 Description	Rare events of air entrance in the extracorporeal blood circuit. Majority parts of the events involve the transducer protector. The first TP was glued to the tubing and the second TP was screwed to the first TP manually. The second TP might not be firmly connected. Cause: Improper operation of the worker. Components may not be tightly screwed during production and become loose after transportation. If the connection is not tightened by operator according to section 5.4 of the manual, air entrance may occur. Potential Risk: Clotting
Action to be Taken by Customers / Users	Operator must check the tightening of all the bloodlines connection before use according to section 5.4 of relevant product *Instructions for Use*. The critical connection to check is illustrated below:



Actions Planned by Vital Healthcare	The double TP should be glued to ensure they're leak-proof and reduce the risk

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Problems 5 Description	Rare events of not proper fitting between arterial chamber and machine holders. Cause: There are different machine holder types for arterial chamber. One machine holder has several holes/places for fitting different chamber types. The arterial chamber may be placed at wrong hole/place of the machine holder and is not properly fitted in. Potential Risk: The falling-down of the chamber from the machine holder. The air at the top of the chamber may come into the bloodline circuit.
Action to be Taken by Customers / Users	Operator must check that the arterial chamber is placed at the right hole of the holder suiting its size and is properly fitted in.
Actions Planned by Vital Healthcare	Develop an arterial chamber with same size as the ones that the users used previously.

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Problems 6 Description	Rare events of not proper fitting between venous chamber and machine holders. Cause: The involved materials are harder than the lines which they used previously. Potential Risk: Difficulty to close the machine holder, malfunction on the air bubble detection.
Action to be Taken by Customers / Users	Operator must check that the venous chamber is clamped/ fastened surely
Actions Planned by Vital Healthcare	Reduce the material rigidness.

Problems 7 Description	Some events of clotting occurred. Causes: a) The double transducer protector is loosely screwed, causing air entrance in the tubing and clotting. b) If the blood volume level inside the arterial chamber and venous chamber is too high, the blood on top may get stagnant, which leads to clotting. c) The clamp does not clamp tight, causing blood level inside the chamber to increase and the blood at surface may become stagnant, which may cause clotting. d) NovaLine tubing's venous chamber filter is short filter, which may not allow too much blood pass through the filter at same time. When the blood volume is big at the venous chamber, the blood surface in the venous chamber may become clotted. e) The drip chamber does not attach to the machine clamp well, causing the air alarm and clotting after pump stops. Potential Risk: Blood Loss
Action to be Taken by Customers / Users	Adjust the anti-coagulation prescription if necessary. Monitor the blood volume inside the chamber, it is recommended the blood volume inside arterial chamber should be no more than 2/3 of the chamber volume and the blood volume/surface inside the venous chamber should be at same level as the dropper end. Once when coagulation is observed (by visual check or by an increasing venous pressure detected by monitor), stop the treatment, rinse back blood to patient in a safe manner and change the circuit according to indications provided by relevant *Instructions for Use*.

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Actions Planned by Vital Healthcare

1. Change the double TP to be glued together to reduce air entrance risk.
2. Change the clamp to clamp of another type with better closure.
3. Change the short filter of the venous chamber to long filter.
4. Decrease the rigidity of the venous chamber so that it can be better attached to the machine holder.

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***Annex* 2** *Additional Instructions for Use*

Keep this Addendum with your NovaLine® Instructions for Use.

1) Be careful during primary package opening that don't let the detached component (i.e. drainage bag) fall onto the floor. If happened, scrap the product and replace with a new product. If there are detached component and it doesn't touch the floor, reconnect the component.

2) Tighten every connection before use.

3) Check the presence of kinking before use. In case of kinking finding, scrap the product and replace with a new product.

4) Operator must check that the chamber is clamped/ fastened surely.

5) In case of presence of air / bubbles which can be removed by standard procedures, tighten the connection and repeat the degassing / air removal procedures

6) Take care about machine blood pump stopping when the blood reaches the venous drip chamber, if not happened, stop the blood pump manually and then connect the patient.

7) In case of:

   a) The clamp on the line on top of the arterial chamber is not closive, which may lead to undesired level increasing

   b) fixed arterial or TMP pressure monitored by the machine

   c) presence of air / bubbles which can not be removed after applying section 5 instruction above.

   stop the treatment rinse back blood to patient in a safe manner and change the circuit according to indications provided by relevant *Instructions for Use*.

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***Annex* 3** *Customer Response Form*

Please complete and return this form by FAX to the number below: +33 (0) 1 34 61 55 25 or by Email: mv_france@baxter.com

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Subject: NovaLine® Tubing Sets for Hemodialysis – Instructions for handling problems encountered in clinical use

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Facility Name: _____

Establishment Address: _____

City / Country: _____

Name of the Representative of the Establishment: _____

Please write legibly

Signature: _____

Title: _____ **Date:** ___ / ___ / ___

Telephone: _____ **Fax:** _____

Check the Action Taken:

☐ **We acknowledge receipt of this notice which has been forwarded to all concerned persons of our organization and / or organization where the relevant products have been transferred.**

☐ **Our products are not concerned.**