Bain Medical Equipment (Guangzhou) Co., Ltd
Add: 10.Juncheng Rood, Eastern Section, Guangzhou Economic & Technological Development District, Guangzhou, China 510760

Field Safety Notice

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

No.: FSN202203001

Type of Action: Notification to clients in France

Date: 8 March 2022

EU importer info: NIKKISO Europe GmbH

Attention: NIKKISO Europe GmbH

Compatible Dialysis Machine: DBB-EXA

Product in cope:

Models	Lot Numbers		
BAIN-BL-075E	2101100393	2101100432	2101100364
	2101100456	2101010969	2101100143
	2101100005	2101100088	
BAIN-BL-076E	2101010965	2101011046	2101011012
	2101011080	2101100075	2101100076
	2101100087	2101100150	

This Field Safety Notice intends to provide advices on clinical use.

Description of the Problems:

Recently we received feedbacks about micro-bubbles and clotting of above tubing sets products, the potential risk of which may be interruption of treatment or difficulty in restitution of blood.

Advise on action to be taken by the user

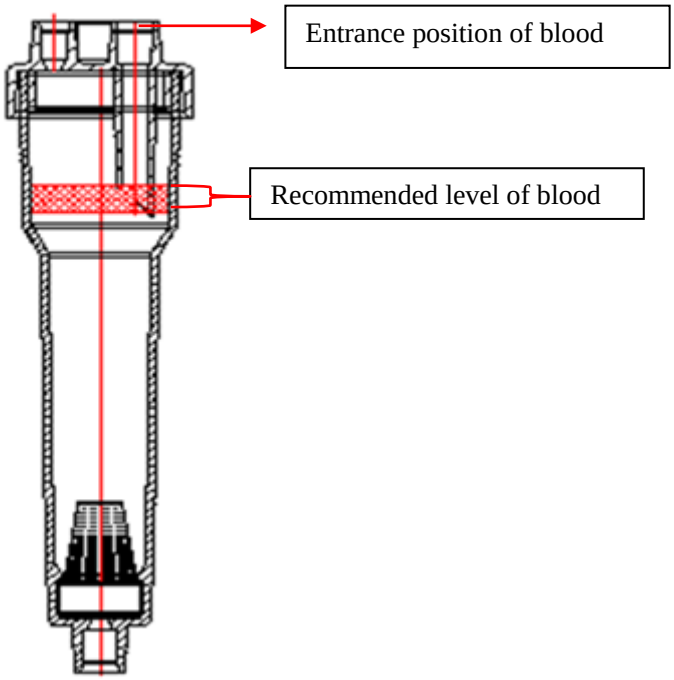
When using the tubing sets, please refer to Instruction for use for the DORA Tubing Sets for Hemodialysis and the instruction for use of the dialysis device on which you use the DORA tubing sets.

1. When using the tubing sets, please refer to Instruction for use for following instructions, in order to ensure the tightness of connection:
Article 4. Recommended usage method of Instruction for use
Item 4）Recheck all the connectors, make sure all of the connectors are tight.
Article *6. Precautions in use*
Item 5）This product is intended to be used with A.V. Fistula needle, dialysis catheter, dialyzer and dialysis machine. Make sure the product is compatible with the devices which are equipped with standard luer lock. The safety of the connection to dialyzers should be guaranteed. Do not use this product if the dialyzer connectors of this product cannot fit for the dialyzer. Make sure that all of connectors are tight to prevent blood leakage or any air entry, otherwise readjustment should be performed. In case no improvement is made, replace with another new one. The product should be properly installed to the dialysis machine to prevent kinking during treatment.

2. Increase priming volume and priming time. It is recommended to implement a priming volume of 2800ml or more, and priming time of 14 minutes or more.

3. Adjust the anti-coagulation prescription if necessary.

4. Adjust the blood level in venous blood chamber as following diagram.



Please fill out the enclosed Customer Response Form / Receipt and send it back within* 10 *days of receipt.

Transmission of this Field Safety Notice

1. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them
2. If you are a dealer, wholesaler, or distributor/reseller that distributed any affected product to other facilities, please notify your customers of this Device Correction in accordance with your customary procedures

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Contact:

If you have any questions about this information, please contact

the manufacturer, Bain Medical, Email: zoe@baingz.com

or the importer, Nikkiso Europe, Email: regulatory@nikkiso-europe.eu

Regards,
Bain Medical Equipment(Guangzhou)Co., Ltd

Annex*: *Customer Response Form

Bain Medical Equipment (Guangzhou) Co., Ltd
Add: 10.Juncheng Rood, Eastern Section, Guangzhou Economic &
Technological Development District, Guangzhou, China 510760

Annex: Customer Response Form

Please complete and return this form by Email: zoe@baingz.com

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

Facility Name: _____

Establishment Address: _____

City / Country: _____

Name of the Representative of the Establishment: _____

Please write legibly

Signature: _____

Title: _____ **Date:** ____ / ____ / ____

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.**