

Medical Safety Information

Pharmaceuticals and Medical Devices Agency

pmda No. 22 February, 2011

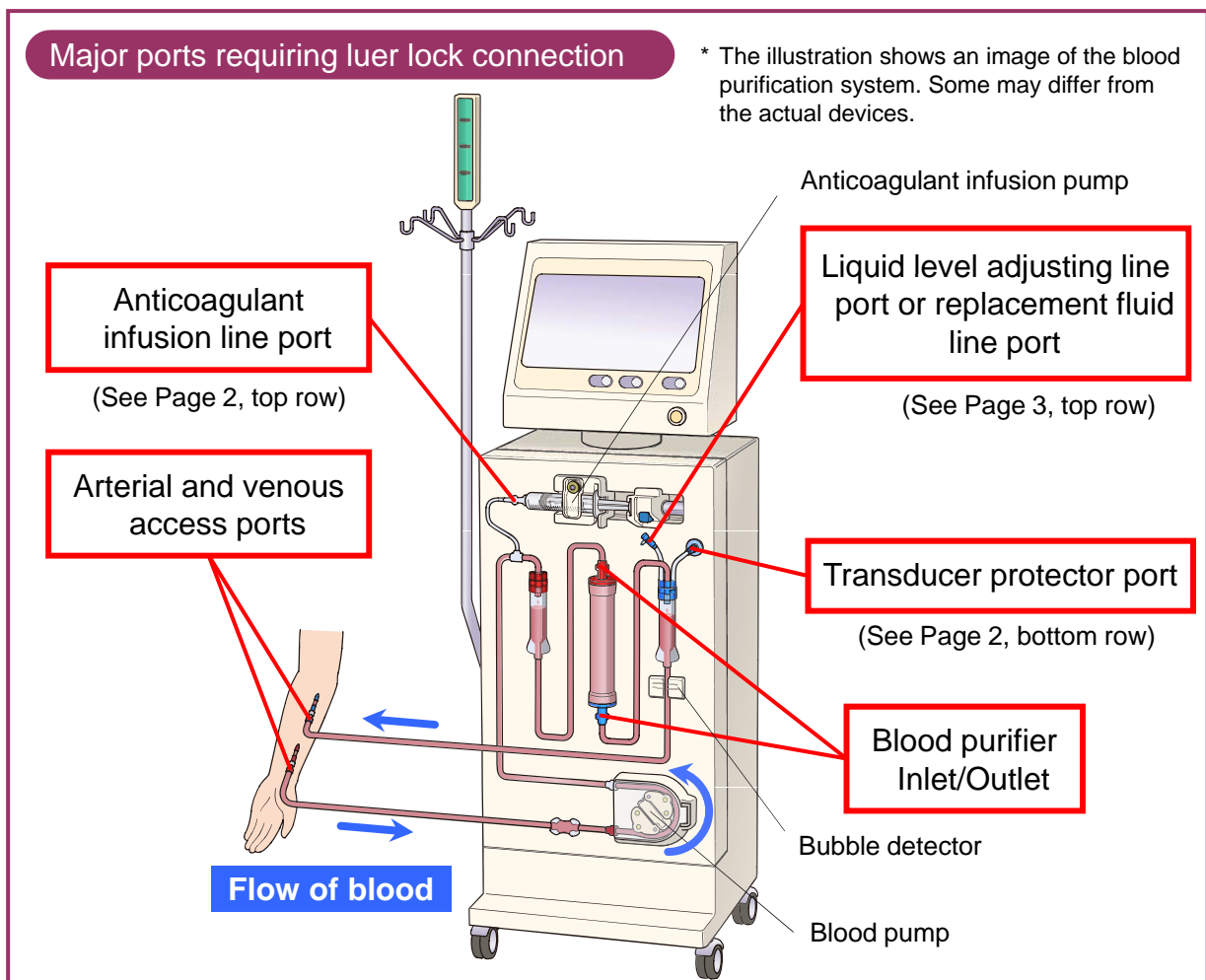
Precautions in Handling Blood Tubing Sets used for Blood Purification

POINT Key points for safe use

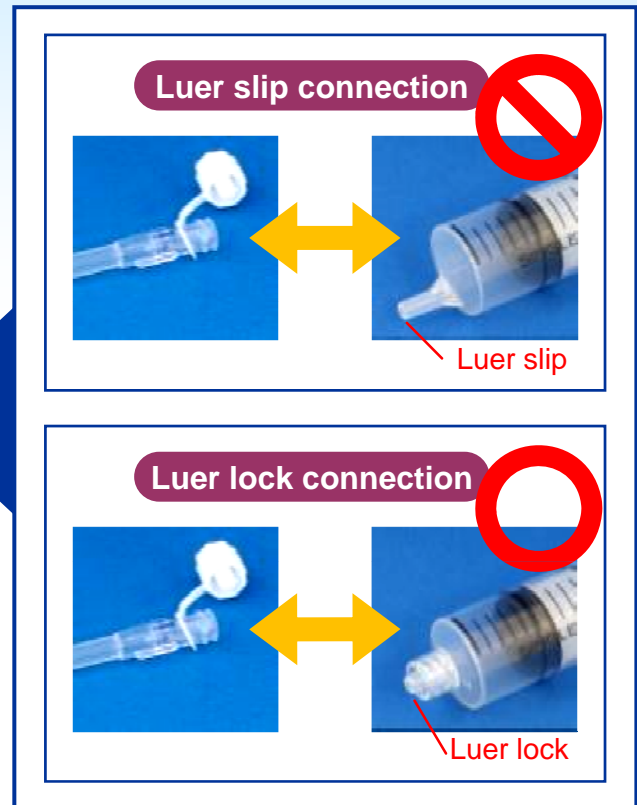
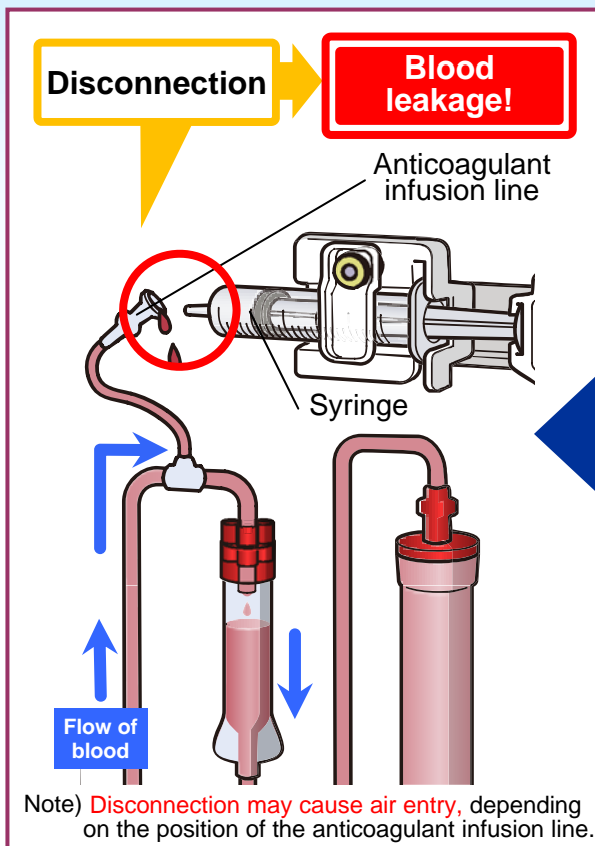
(Case) An alarm went off while conducting hemodialysis. Medical staff checked the devices and found that the luer slip connection between the transducer protector and the venous pressure monitoring line had disconnected causing blood leakage.

1 Precautions when connecting blood tubing sets used for blood purification

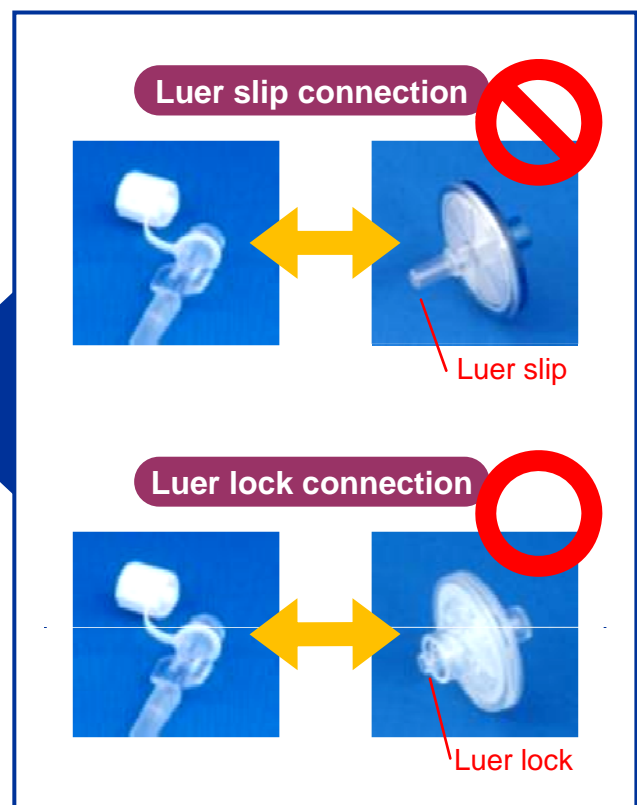
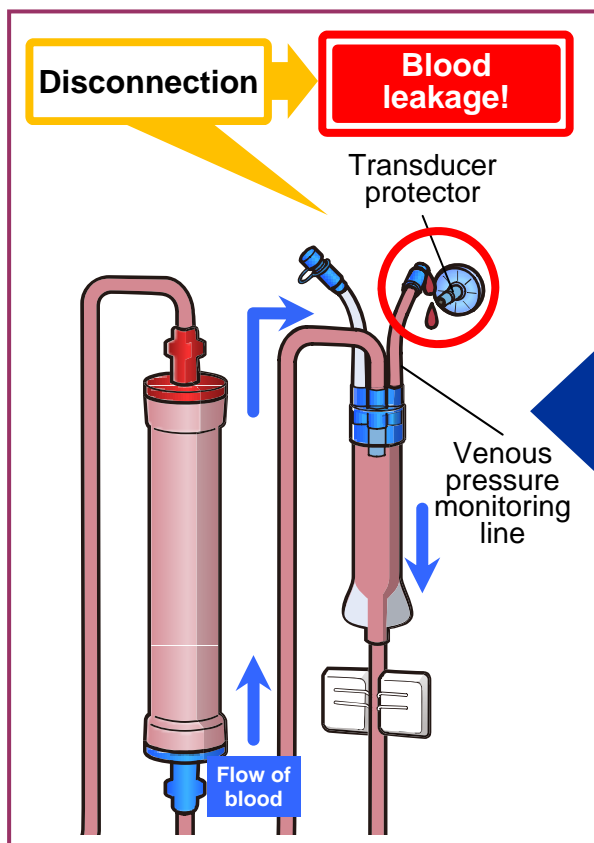
- All connections of blood tubing sets used for blood purification should consist of luer lock connectors.



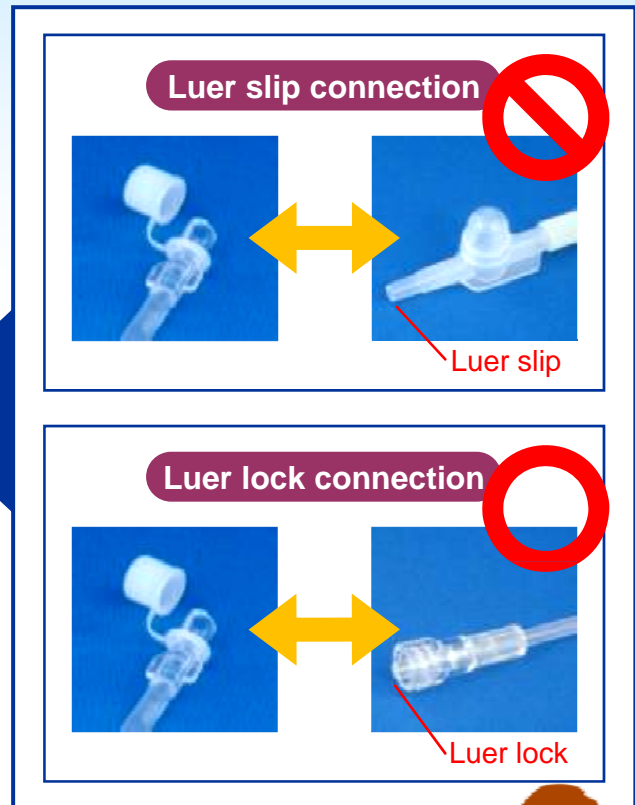
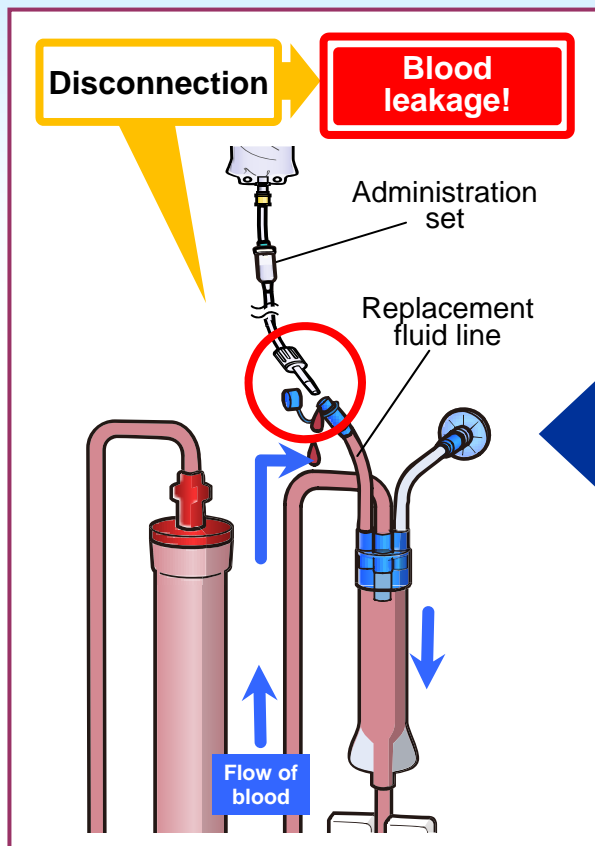
Example of connection (1) : Anticoagulant infusion line and syringes



Example of connection (2) : Venous pressure monitoring line and transducer protector



Example of connection (3) : Replacement fluid line and administration sets



Connection between the blood tubing set and syringe, administration set, etc. **should consist of luer lock connectors.** Luer-slip connectors are liable to disconnect, which makes luer-slip connectors dangerous.

Example of appropriate connections



Warnings such as shown on the right are described in package inserts of blood tubing sets used for hemodialysis and apheresis and so on.

*This part is indicated in Japanese.

[WARNING]

- When diluted or dissolved anticoagulants such as heparin sodium are continuously administered, a luer lock syringe or infusion line should be used to connect with the blood line. [Inadvertent disconnection of a syringe etc. may cause blood leakage or air entry.]
- When drug etc. is continuously administered on the arterial or venous line, a luer lock administration set etc. should be used for connection unless using an access port that prevents blood leakage etc. in cases of disconnection. [Inadvertent disconnection of administration sets etc. may cause blood leakage or air entry.]

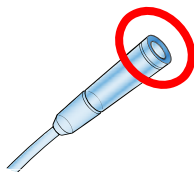
2 Switching to luer lock type blood tubing sets

Since September 2009, manufacturers of blood tubing sets has begun **switching all the connectors of blood tubing sets to luer lock type**.

Please **switch to luer lock type products immediately** if your facility is using luer slip type.



Luer slip connector



Switching
under way

Luer lock connector



* Information regarding switching to luer lock type products and contact list of various companies are available at the Japan Medical Devices Manufacturers Association website (in Japanese)
<http://www.jmed.jp/jp/ikiko/safety-use/100401.php>



Along with the switching of blood tubing sets to luer lock types, also make sure to **switch syringes and administration sets etc., which are connected to the blood tubing sets, to luer lock types**.

The Ministry of Health, Labour and Welfare (MHLW) has issued notifications that are related to the issues in this PMDA Medical Safety Information No. 22.

- "Adoption of a Luer Lock Connector for Blood Circuits in Hemodiafiltration Therapy (Provision of information to users)" (Joint Notification of HPB/GAD No. 0924-1 and PFSB/SD No. 0924-1 dated on September 24, 2009)

Information on this notification is available at the Pharmaceuticals and Medical Devices Information website (in Japanese) <http://www.info.pmda.go.jp/iryujiko/file/20090924.pdf>

Notices from organizations and groups that are related to this medical safety information are available at the website below

(in Japanese) http://www.info.pmda.go.jp/anzen_gyoukai/anzen_info.html

About this information

- * PMDA Medical Safety Information is issued by the Pharmaceuticals and Medical Devices Agency for the purpose of providing healthcare providers with clearer information from the perspective of promoting the safe use of pharmaceuticals and medical devices. The information presented here has been compiled, with the assistance of expert advice, from cases collected as Medical Accident Information Reports by the Japan Council for Quality Health Care, and collected as Adverse Drug Reaction and Malfunction Reports in accordance with the Pharmaceutical Affairs Law.
- * We have tried to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy in the future.
- * This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided as a support to promote the safe use of pharmaceuticals and medical devices by healthcare professionals.