

Medical Safety Information

Pharmaceuticals and Medical Devices Agency

pmda No. 24 June 2011

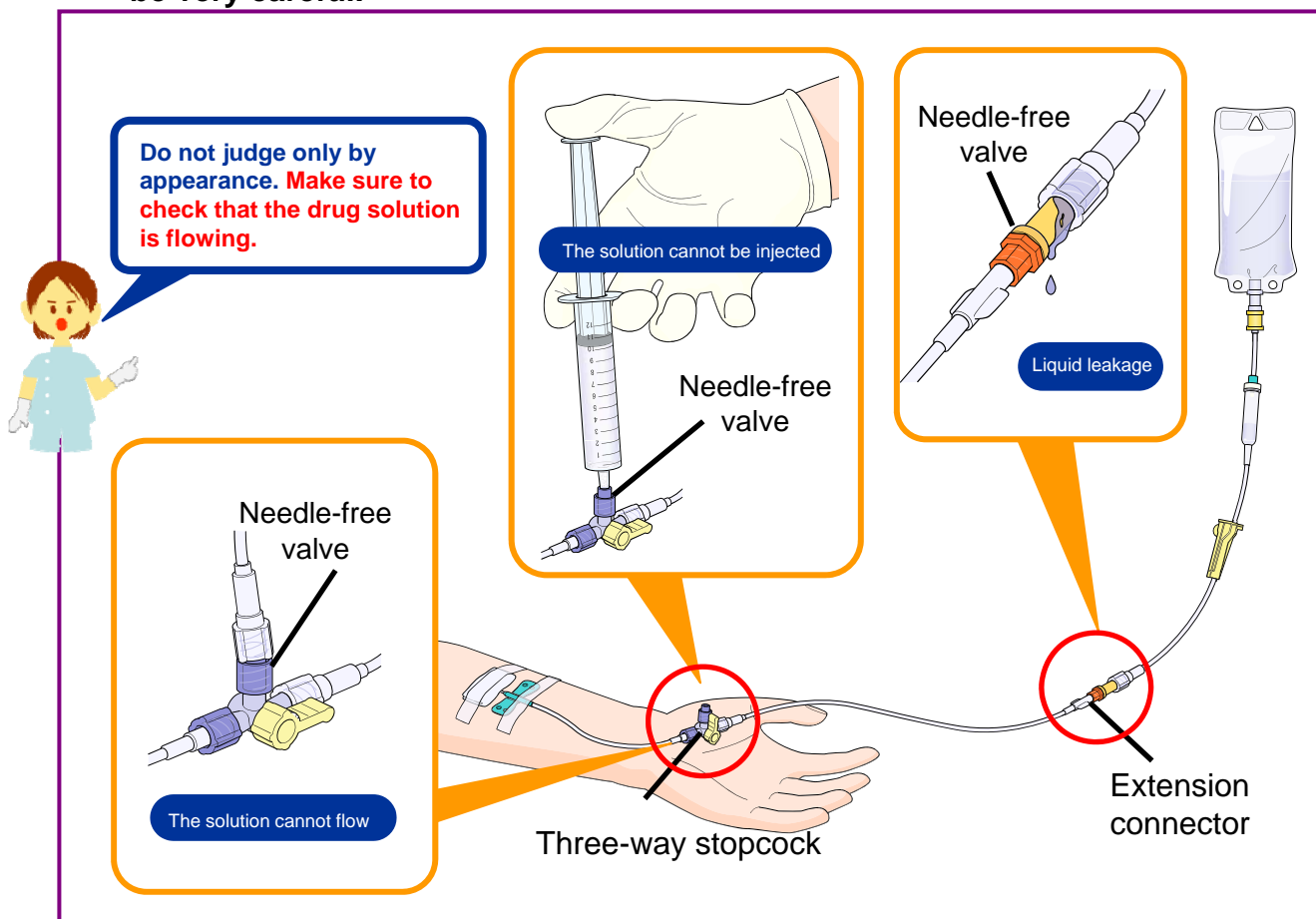
Precautions in Using Needle-free Valves

POINT Key points for safe use

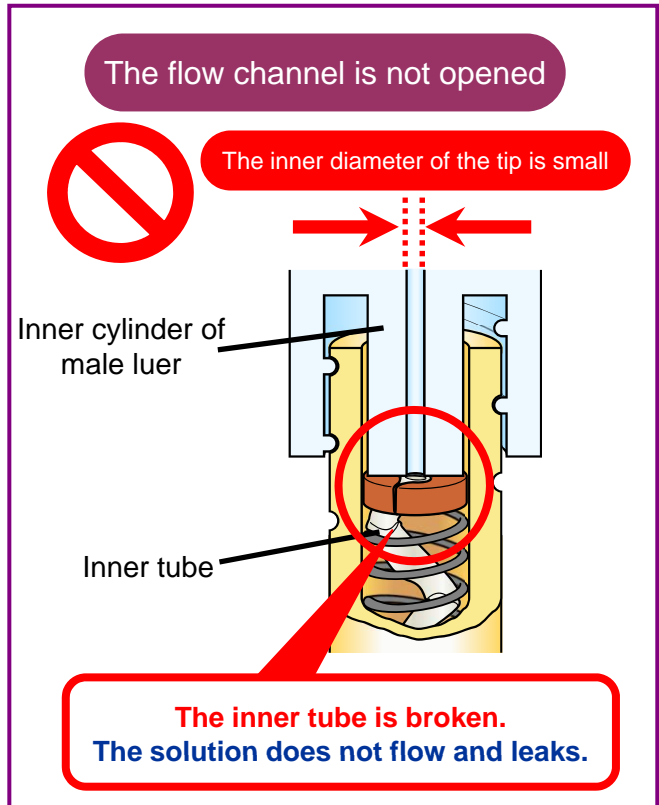
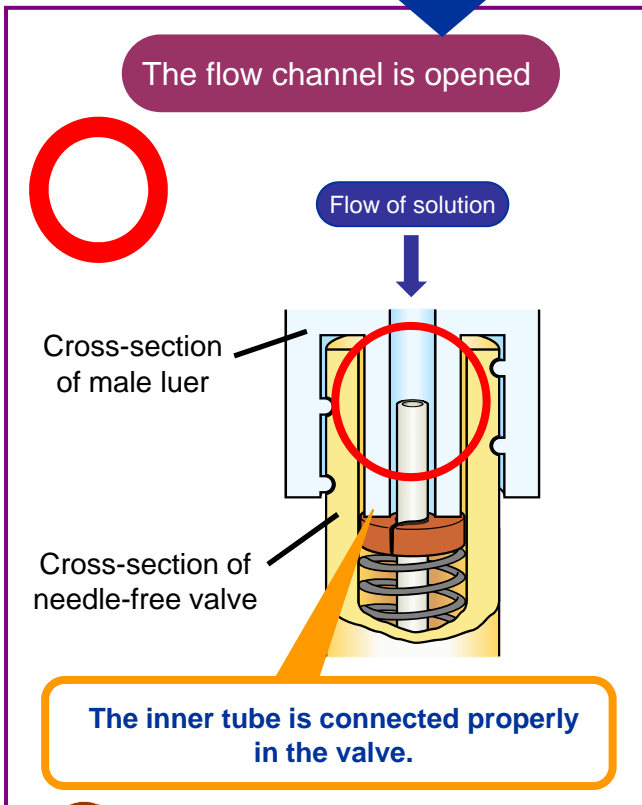
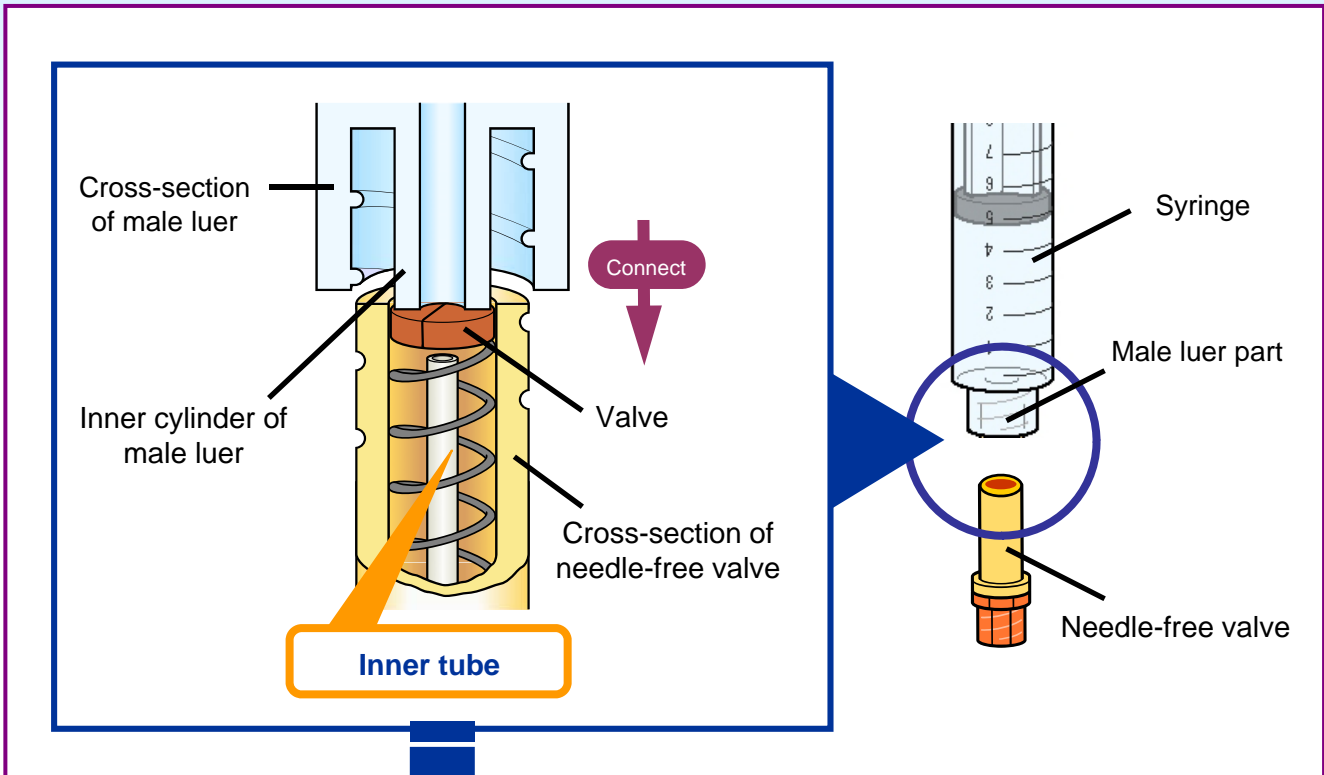
(Case) When injecting a drug solution through a needle-free valve, the flow channel failed to open, so the solution could not flow. Medical staff checked the device and found that the needle-free valve was broken.

1 Precautions when using needle-free valves

- A proper connection may not be achieved, depending on the inner structure of needle-free valve and the inner diameter at the tip of prefilled syringe, so be very careful.



Inner structure of the needle-free valve and cross-section of the luer connection



Some prefilled syringes have a small inner diameter at the tip which may break the inner tube of the needle-free valve.

Examples of needle-free valves that have inner tubes inside

Appearance	Marketing Authorization Holder (MAH)	Brand Name
	Sumic International Inc.	BIONECTOR 2
	Forte Grow Medical Co., Ltd.	Disposable Infusion Set
	Palmedical, Inc.	CLAVE Connector
	Forte Grow Medical Co., Ltd.	Disposable Infusion Set Zeon TPN Lines A
	NIPRO Corporation	Nipro Sterile Disposable Infusion Filter Set Nipro Disposable Infusion Set, etc.

Note: Some products shown in the above may be incorporated as part of the transfusion line, etc.



Liquid leakage and clogging have occurred at the site of the connection with a prefilled glass syringe shown below.

Examples of prefilled syringes

<p>Kyowa Hakko Kirin Co., Ltd.</p>  <p>ESPO INJECTION 3000 SYRINGE, etc.</p>  <p>GRAN SYRINGE 75, etc.</p>	<p>Mitsubishi Tanabe Pharma Corporation</p>  <p>PROSCOPE 300 Syringe 100 mL, etc.</p>  <p>Liple Kit INJECTION 10 µg</p>	<p>Taiyo Pharmaceutical Industry Co., Ltd.</p>  <p>FUROSEMIDE Injection 20 mg Syringe "Taiyo"</p>
<p>Bayer Yakuin, Ltd.</p>  <p>Magnevist iv inj. Syringe</p>  <p>EOB Primovist Inj. Syringe</p>	<p>Sawai Pharmaceutical Co., Ltd.</p>  <p>Granisetron Intravenous Injection 1 mg Syringe "NK", etc.</p>	<p>Chugai Pharmaceutical Co., Ltd.</p>  <p>EPOGIN Injection Syringe 3000, etc.</p>
		<p>Taisho Pharmaceutical Co., Ltd.</p>  <p>Palux inj. Dispo 10 µg</p>

When using these prefilled syringes, you can prevent connection-related defects and failures by using needle-free valves that have no inner tubes or by using injection adapters ^{Note)}.



Note) Information on injection adapters is available at the PMDA Information website (Japanese only).
<http://www.info.pmda.go.jp/downfiles/md/whatsnew/companylist/companyframe.html>

2 Package insert of needle-free valve that has an inner tube inside

The package insert of a needle-free valve with an inner tube contains precautions for use such as information about the inner diameter at the tip of male luers that can be connected.

This product should not be connected to a prefilled syringe whose inner diameter at the tip is 1.4 mm or smaller, or an extension tube whose inner diameter at the tip is 3.4 mm or larger. [If the product is connected to a prefilled syringe whose inner diameter at the tip is 1.4 mm or smaller, there is a risk that the tip of the product or the prefilled syringe may be broken, causing leakage of drug solution or infections. If the product is connected to an extension tube whose inner diameter at the tip is 3.4 mm or larger, the flow channel may not be opened. These numerical values are based on our company data.]

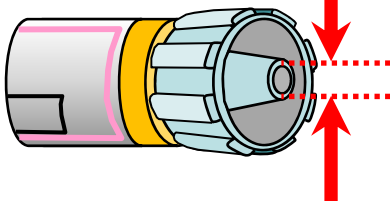
**This part is indicated in Japanese.*

Precautions, such as those shown on the left, are described in the package insert of a needle-free valve.

[Excerpts from the package insert of BIONECTOR 2 (Sumic International Inc.)]



Prefilled syringe



An inner diameter at the tip of XX mm or smaller should not be used.
etc.

* Confirm with the MAH of needle-free valves if you are unsure whether the connections can be made or not.

The Ministry of Health, Labour and Welfare (MHLW) has issued notifications that are related to the issues in this PMDA Medical Safety Information No. 24.

- "Revision of Precautions Section in the Package Insert of Needle-free devices" (PFSB/SD Notification No. 0803001 dated on August 3, 2007)

Information on this notification is available at the Pharmaceuticals and Medical Devices Information website (in Japanese). <http://www.info.pmda.go.jp/mdevices/md2007-0803001.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.