

Medical Safety Information

Pharmaceuticals and Medical Devices Agency

Pmda No. 17, May 2010

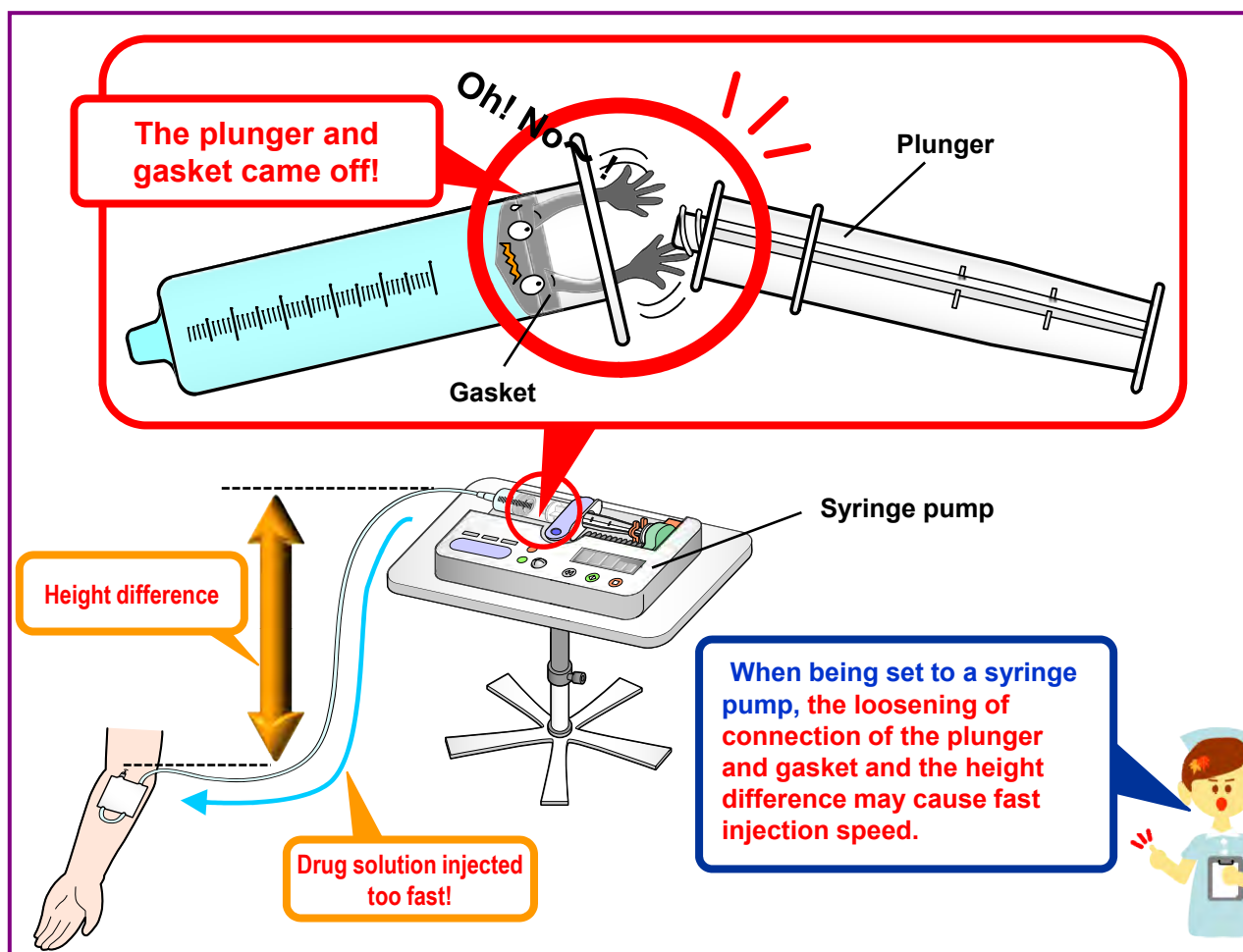
Precautions in Handling of Prefilled Syringes

POINT Key points for safe use

(Case 1) During administration of dopamine via a syringe pump, a pre-filled syringe's plunger came off from the gasket, and the drug solution ended up being injected too fast to a patient.

1 Precautions when using prefilled syringes (Part 1)

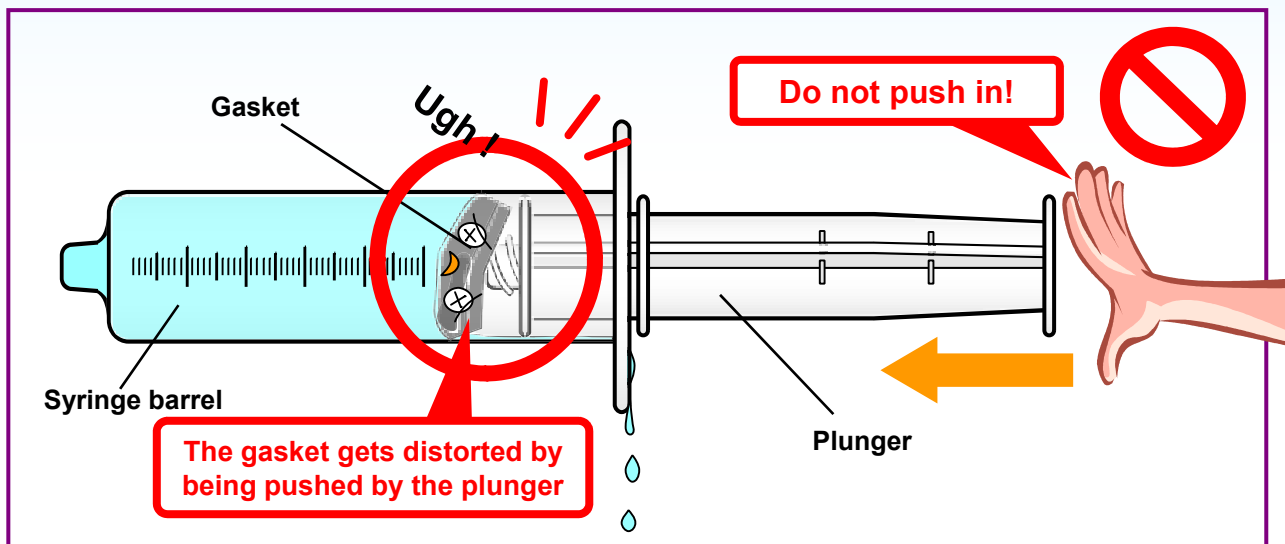
- A prefilled syringe's plunger is screwed into the gasket and connected together. The connection may become loose during use, so be very careful.



(Case 2) The prefilled syringe's gasket was distorted, so the drug solution leaked out from the opening between the syringe barrel and the gasket.

2 Precautions when using prefilled syringes (Part 2)

- When assembling a prefilled syringe, make sure to screw in the plunger by rotating it.



Distortion of gasket may cause drug solution leakage and air bubble entry. When assembling a prefilled syringe, do it correctly following the instructions on the Package Insert, etc.



Prefilled syringes that are assembled for use.

Kyowa Hakko Kirin Co., Ltd.



INOVAN Injection 0.1% syringe



INOVAN Injection 0.3% syringe



INOVAN Injection 0.6% syringe

Terumo Corporation



DOBUPUM Injection 0.1% syringe



DOBUPUM Injection 0.3% syringe



DOBUPUM Injection 0.6% syringe

AstraZeneca K.K.



1% Diprivan Injection-kit
(200mg 20mL cylinder)

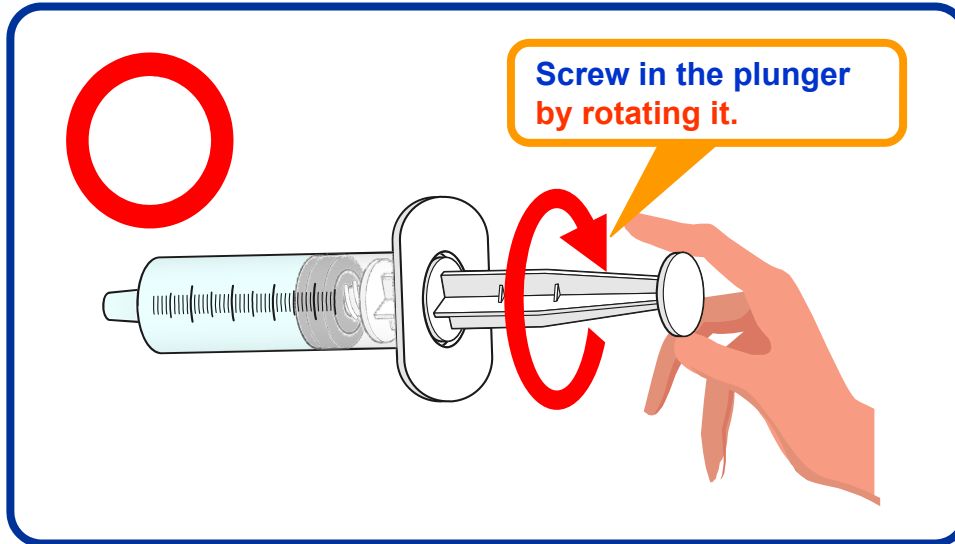


1% Diprivan Injection-kit
(500mg 50mL cylinder)

Eisai Co., Ltd.



Nitrolor Injection for Continuous
 Infusion 25mg Syringe

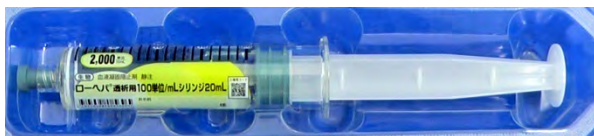


Prefilled syringes that have already been assembled

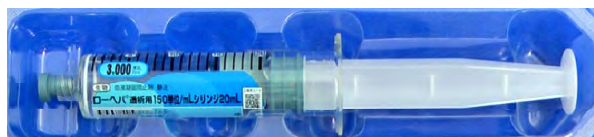


Even a prefilled syringe that has already been assembled
 may become loose during handling, so be very careful.

Ajinomoto Pharmaceuticals Co., Ltd.



LOWHEPA 100 U/mL SYRINGE 20mL

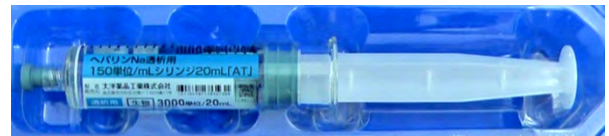


LOWHEPA 150 U/mL SYRINGE 20mL



LOWHEPA 200 U/mL SYRINGE 20mL

Taiyo Yakuin Co., Ltd.



Heparin Sodium 150 Units/mL "AT" 20 mL for Dialysis



Heparin Sodium 200 Units/mL "AT" 20 mL for Dialysis

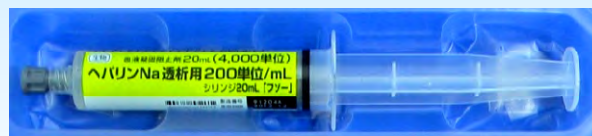


Heparin Sodium 250 Units/mL "AT" 20 mL for Dialysis

Fuso Pharmaceutical Industries, Ltd.



Heparin Sodium 150 Units/mL Syringe 20mL "Fuso" for Dialysis



Heparin Sodium 200 Units/mL Syringe 20mL "Fuso" for Dialysis

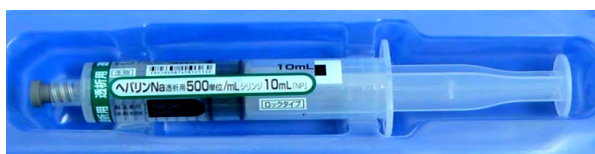


Heparin Sodium 250 Units/mL Syringe 20mL "Fuso" for Dialysis



Heparin Sodium 350 Units/mL Syringe 20mL "Fuso" for Dialysis

Nipro Pharma Corporation



HEPARIN SODIUM 500 units/mL for dialysis use



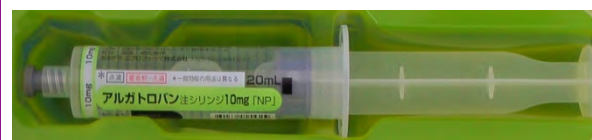
HEPARIN SODIUM 500 units/mL for dialysis use

Otsuka Pharmaceutical Factory, Inc.



HEPAFILLED for Dialysis 250 Units/mL SYRINGE 20mL

Nipro Pharma Corporation



ARGATROBAN INJECTION SYRINGE

When setting these heparin syringes to dialysis devices as well as syringe pumps, be careful that the plungers do not become disconnected from the gasket.



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.