

Medical Safety Information

Pharmaceuticals and Medical Devices Agency



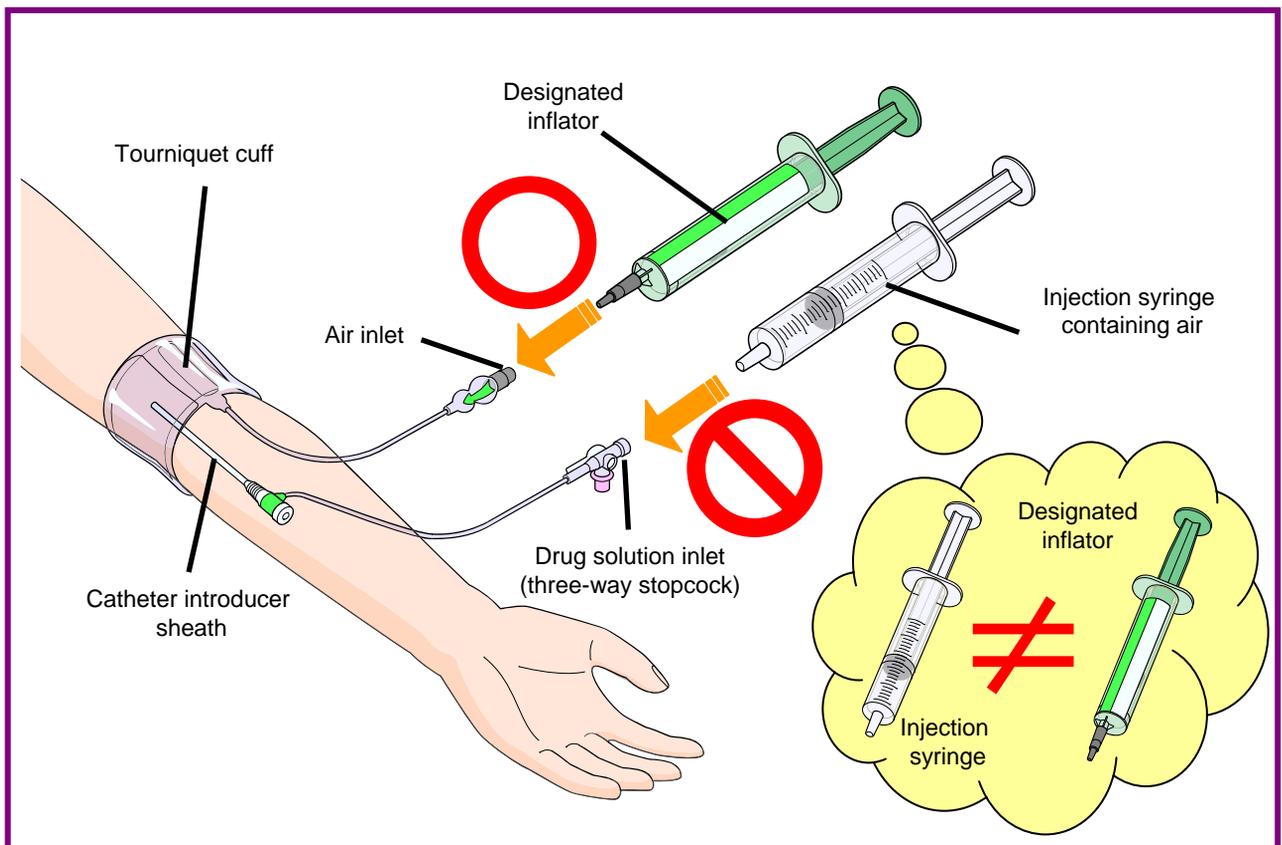
No. 12 September, 2009

Misconnection of tourniquet cuff

POINT Key points for safe use

(Case 1) Instead of connecting the designated inflator to the air inlet to apply compression, an injection syringe containing air was used. It was erroneously connected to the three-way stopcock of the catheter introducer sheath for injection of drug solution, and air was pumped into the blood vessel.

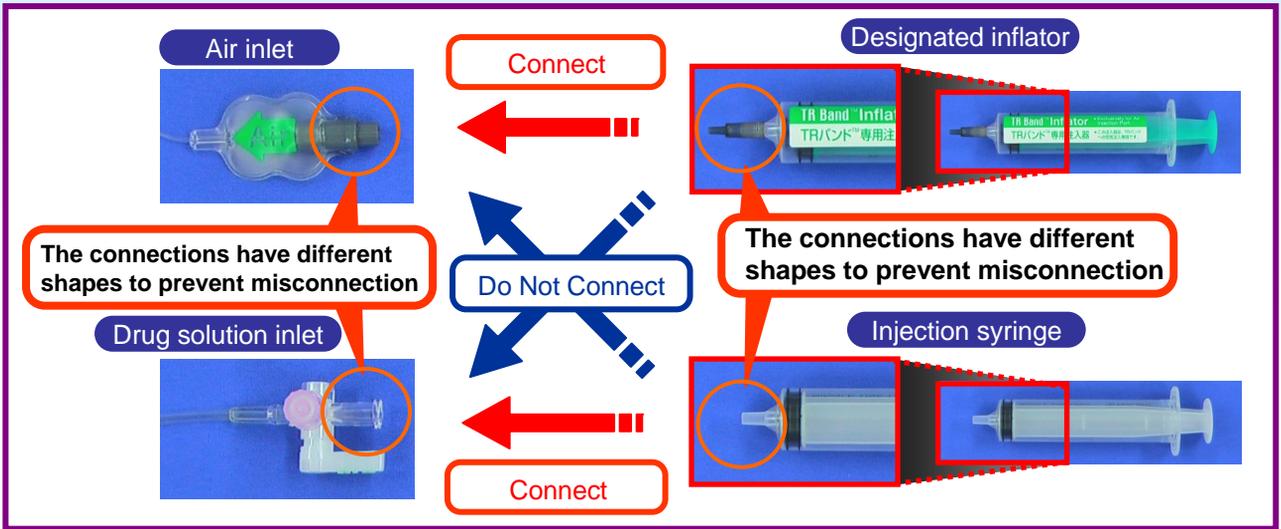
1 Precaution when using a tourniquet cuff -1



Use only the Designated Inflator that comes with the product when using a tourniquet cuff!
Never employ a general-use injection syringe!

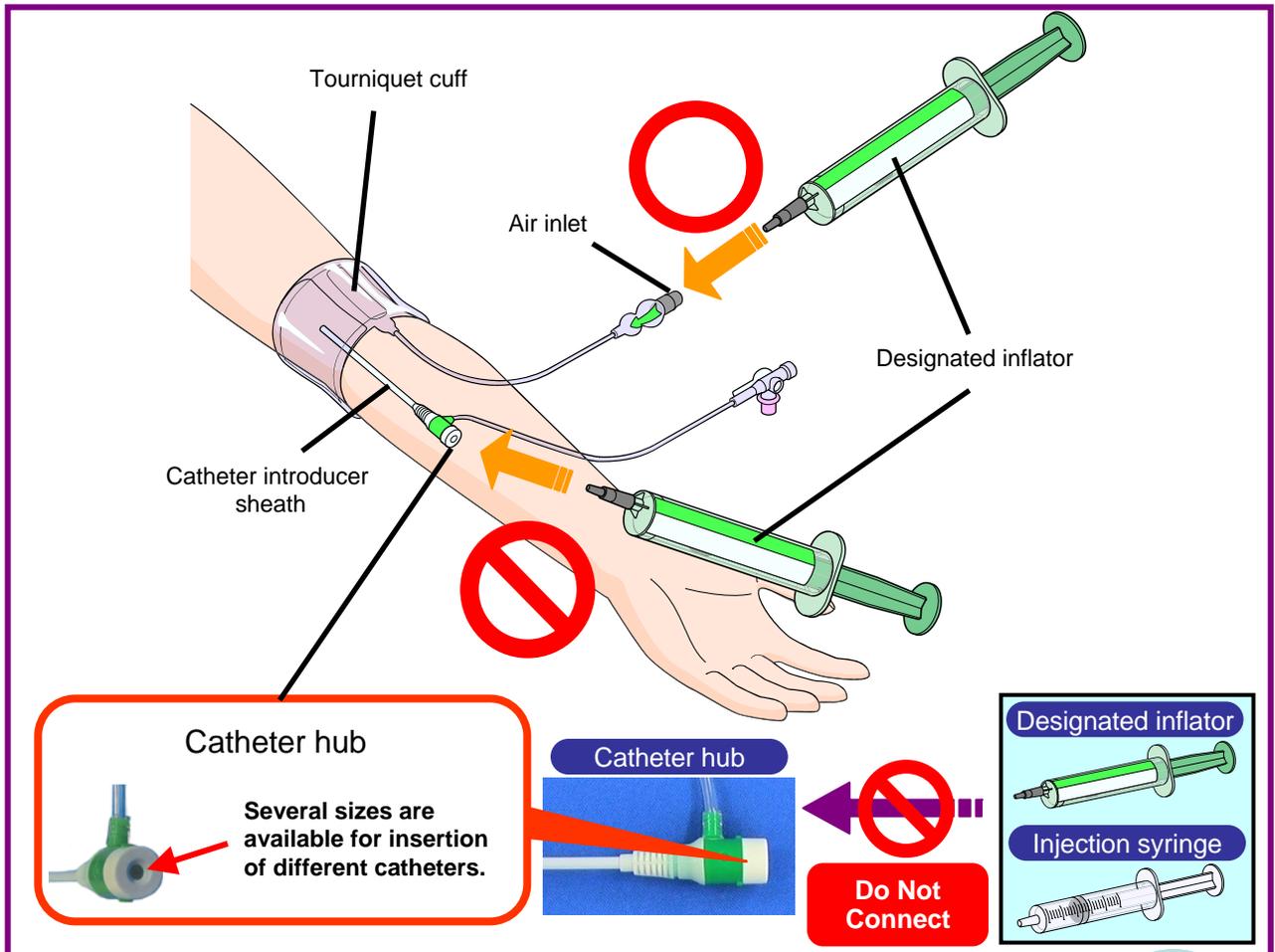


Mechanism to prevent misconnection



(Case 2) The designated inflator to apply compression was erroneously connected to the catheter hub of the introducer sheath, and air was pumped into the blood vessel.

2 Precaution when using a tourniquet cuff -2



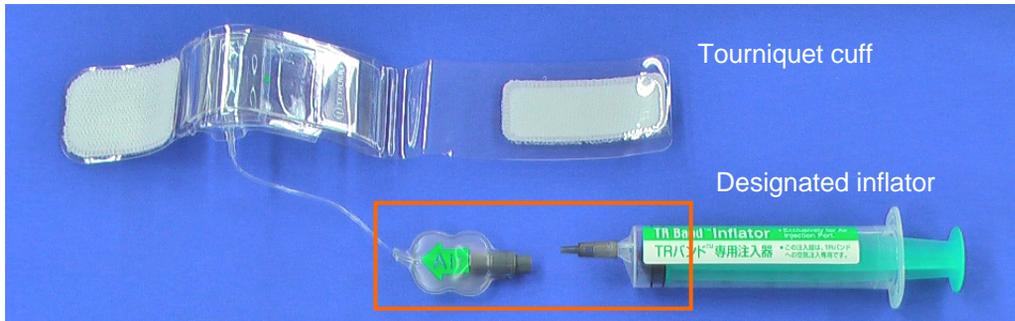
Make sure that the designated inflator is properly connected to the air inlet! Double check, even if you are using the designated inflator!!



Tourniquet cuff with built-in misconnection safeguards.

Terumo Corporation

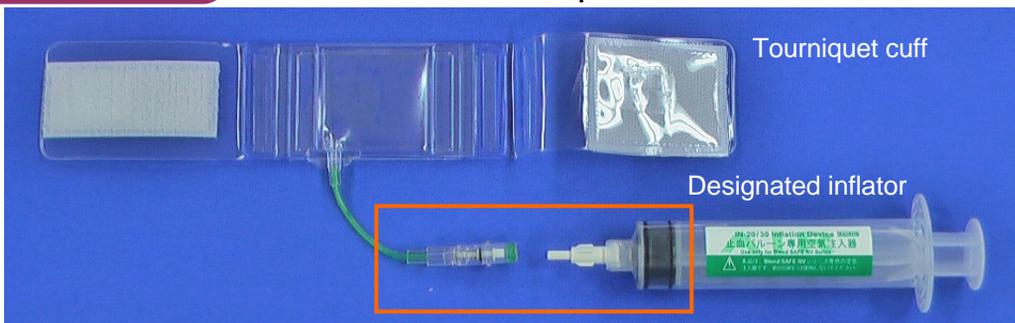
TR Band * The compression band shown is for the radial artery (wrist).



For information contact: Terumo Corporation, Call Center at 0120-12-8195

Dairin

BLEED SAFE * The compression band shown is for the radial artery (wrist).



For information contact: Dairin at 046-279-5711

Zeon Medical Inc.

XEMEX Hemostatic Device "Tometa-kun"

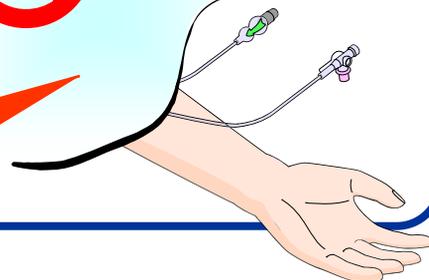
* The compression band shown is for the humeral and radial artery (wrist).



For information contact: Zeon Medical Inc, Marketing Dept. at 03-3578-7726

Even if you are using devices with built-in misconnection safeguards, **visual rechecking by more than one person is important** to make sure that the designated inflator is connected to the air inlet.

Connections are hidden under the cover and cannot be checked by a cursory glance.



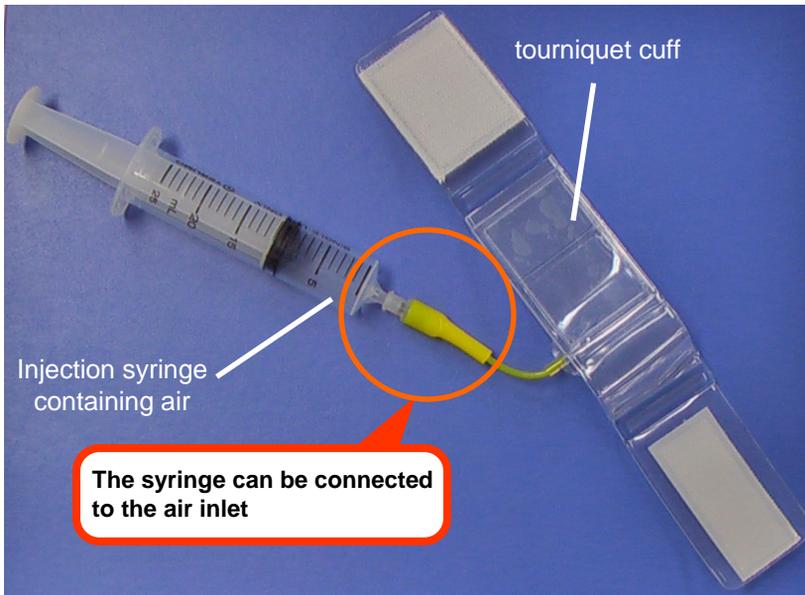
3 Request to hospitals



Old devices without misconnection safeguards are likely to be still in use at your facility. To avoid any accident, you are kindly requested to dispose of these devices as soon as you find any.

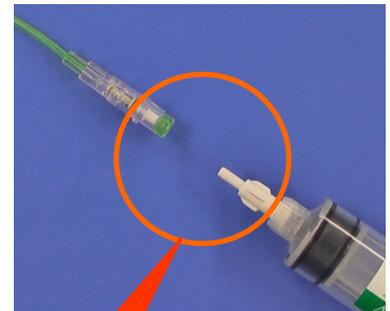
Example of old products

BLEED SAFE (old product) of Dairin



- * As shown in the picture above, old-type tourniquet cuffs were inflated using an injection syringe connected to the air inlet. Some cuffs were sold without the syringe or were supplied as a component in other medical kits. None of these cuffs are reusable, and unused cuffs are long past their expiry dates.

Example of new products with misconnection safeguards



The syringe cannot be connected to the air inlet because the shapes are different.

- * See previous page for products with misconnection safeguards.

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 endeavored to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy into 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.