

# PMDA Medical Safety Information

Pharmaceuticals and Medical Devices Agency



No. 62 March 2022

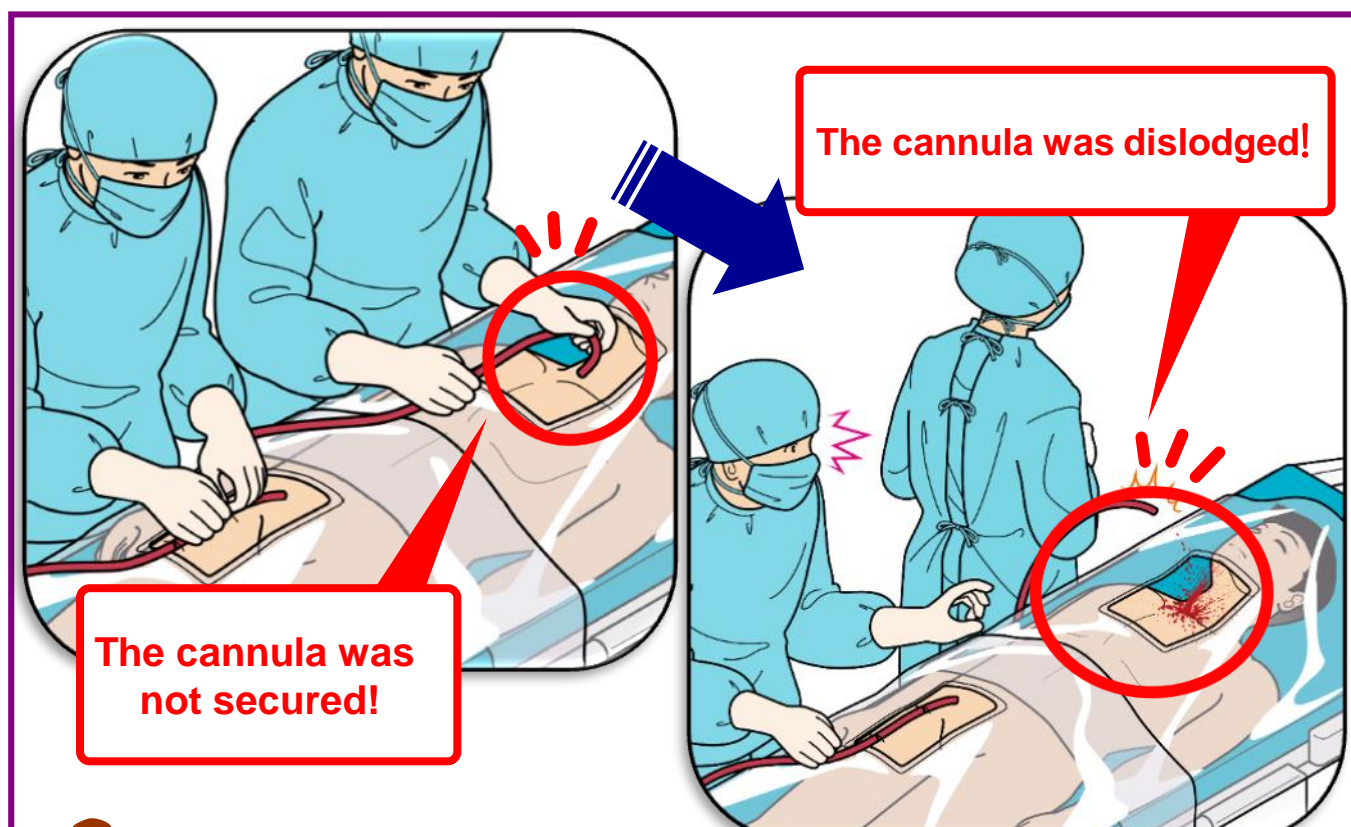
## PCPS/ECMO Cannula Accidental Removal

### POINT Key points for safe use

**(Case 1)** The cannula was removed due to insufficient cooperation between the surgeons since the surgeon who inserted the cannula and the surgeon who secured the cannula with sutures were different.

#### 1 Precautions for securing the cannula

- Share the progress of the procedures, etc.



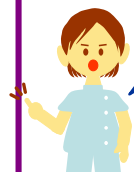
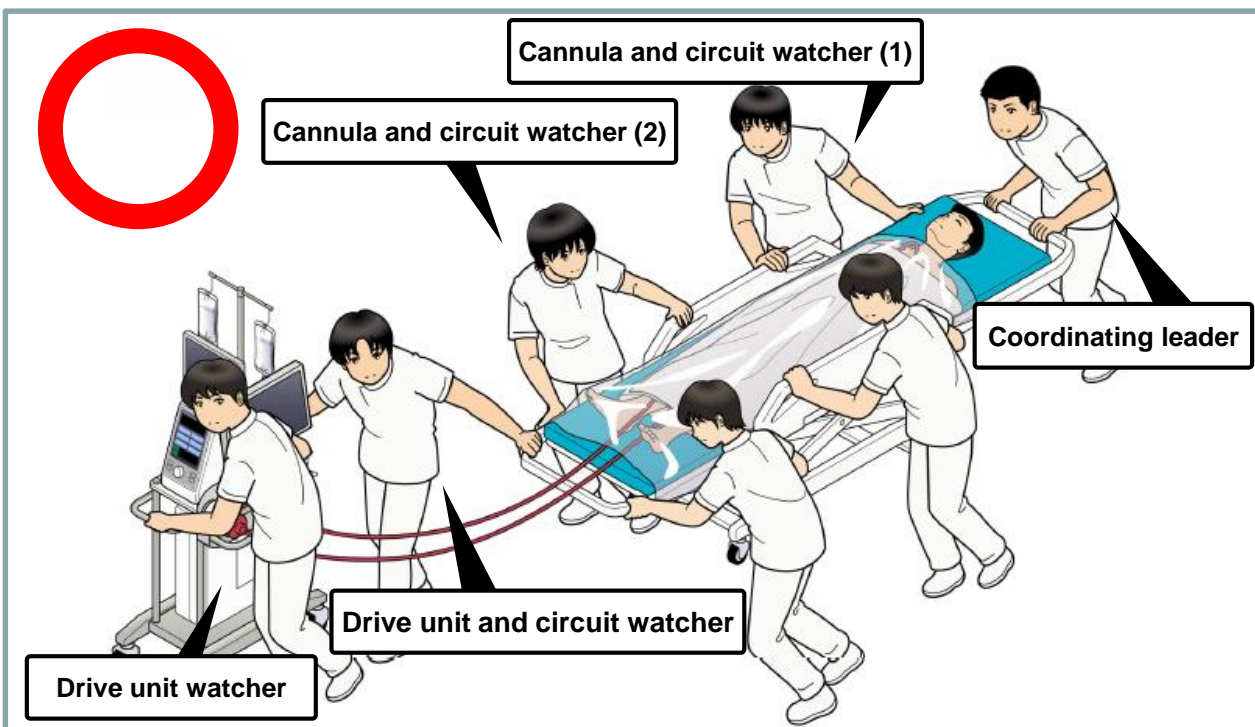
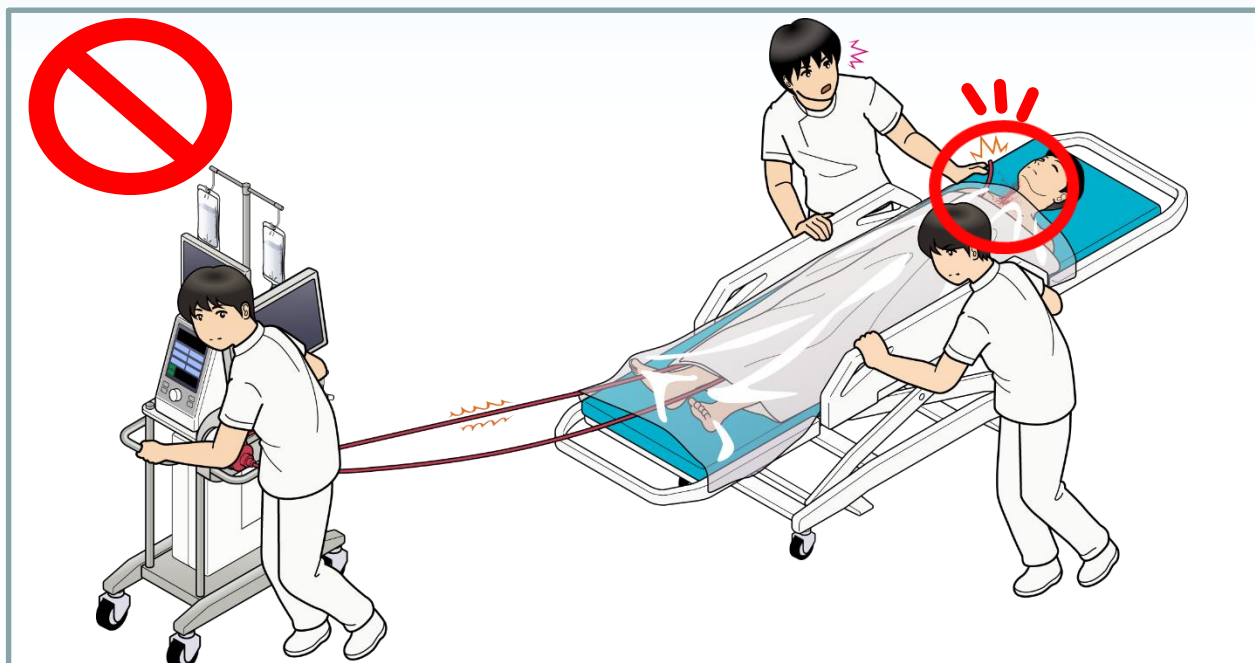
After completion of the cannula insertion and initiation of assisted circulation, the cannula may move due to its weight, etc., so decide the procedure in advance to prevent dislodgement such as holding the cannula until it is secured with sutures.

**(Case 2)** When moving a patient by the stretcher, the stretcher and the drive unit became separated, and the cannula was removed.

## 2 Precautions when transferring and moving

- When transferring or moving, decide a coordinating leader or staff assignment in advance.

### Distance to the drive unit

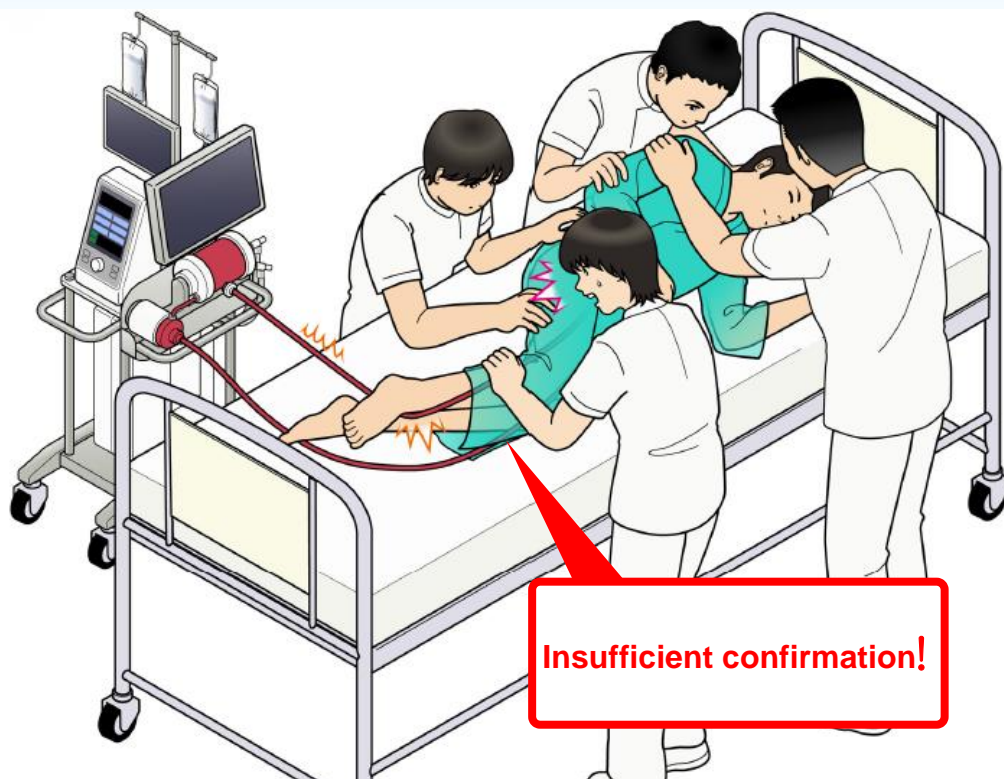


In order to avoid cannula removal during transfer or moving, decide the roles and perform simulation for troubles, etc. in advance.

**(Case 3)** When changing the body position, the cannula was pulled and came out about 10 cm.

### 3 Precautions when changing the body position

- When changing the body position, communicate verbally and check the position of the cannula and the placement of the circuit.



**Insufficient confirmation!**



**There have been reports of instances that led to severe symptoms such as bleeding and hypotension due to accidental dislodgement of the cannula.**

The Ministry of Health, Labour and Welfare (MHLW) issued a notification concerning training program on ECMO and ventilator related to PMDA Medical Safety Information No.62

● Administrative Notice dated April, 1, 2021

Implementation of the Training Program for Medical Personnel Responding to Critically Ill Patients with COVID-19

#### 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 Law on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices.

\* 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.

Access to the most up-to-date safety information is provided via the PMDA Medi-navi service.



Contact: Division of Medical Safety and Report Management

TEL +813-3506-9486  
E-mail [iryo-anzen@pmda.go.jp](mailto:iryo-anzen@pmda.go.jp)