

PMDA

Medical Safety Information

Pharmaceuticals and Medical Devices Agency

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Precautions when Using Subcutaneous Ports and Catheters

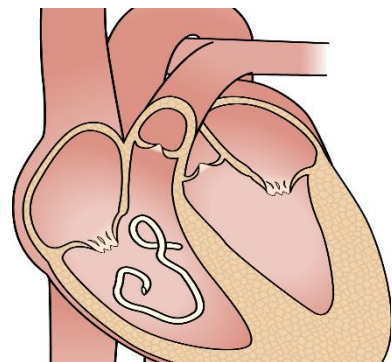
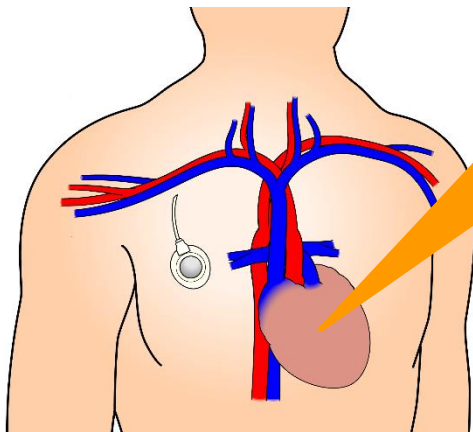
POINT

Key points to ensure safe use

1 Precautions when placing subcutaneous port and catheter

(Case 1) Drug extravasation was identified following subcutaneous port and catheter indwelling. A chest X-ray was performed and revealed fracturing of the catheter and migration of a fragment into the heart.

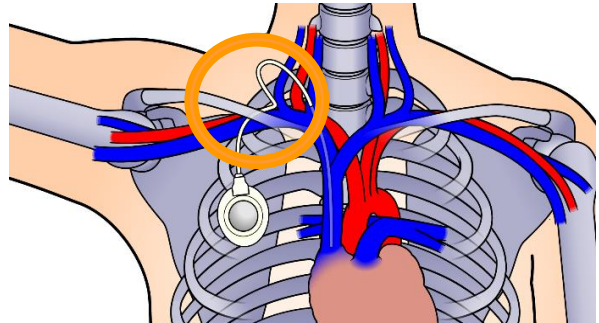
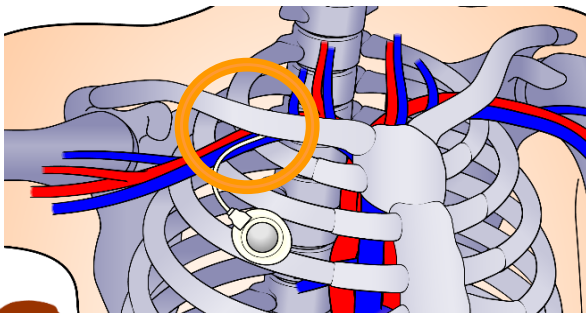
- The following factors are known causes of catheter damage. Care should be exercised when placing subcutaneous ports and catheters.



Catheter fragment migration

Cause 1) Pinch-off syndrome

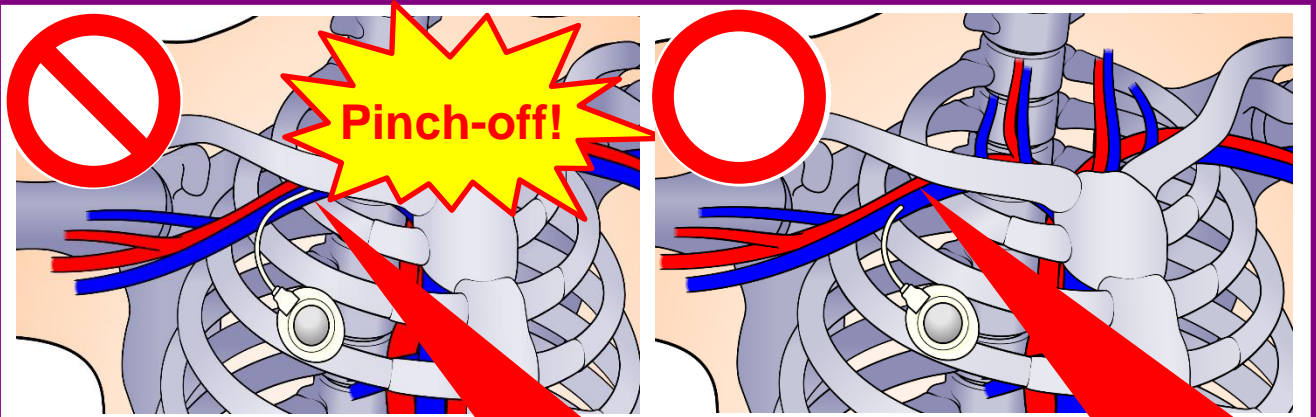
Cause 2) Catheter flexion



There have been reports of instances where damage to the catheter connected to a subcutaneous port led to extravasation of drug or migration of a fragment of the damaged catheter to heart tissue.



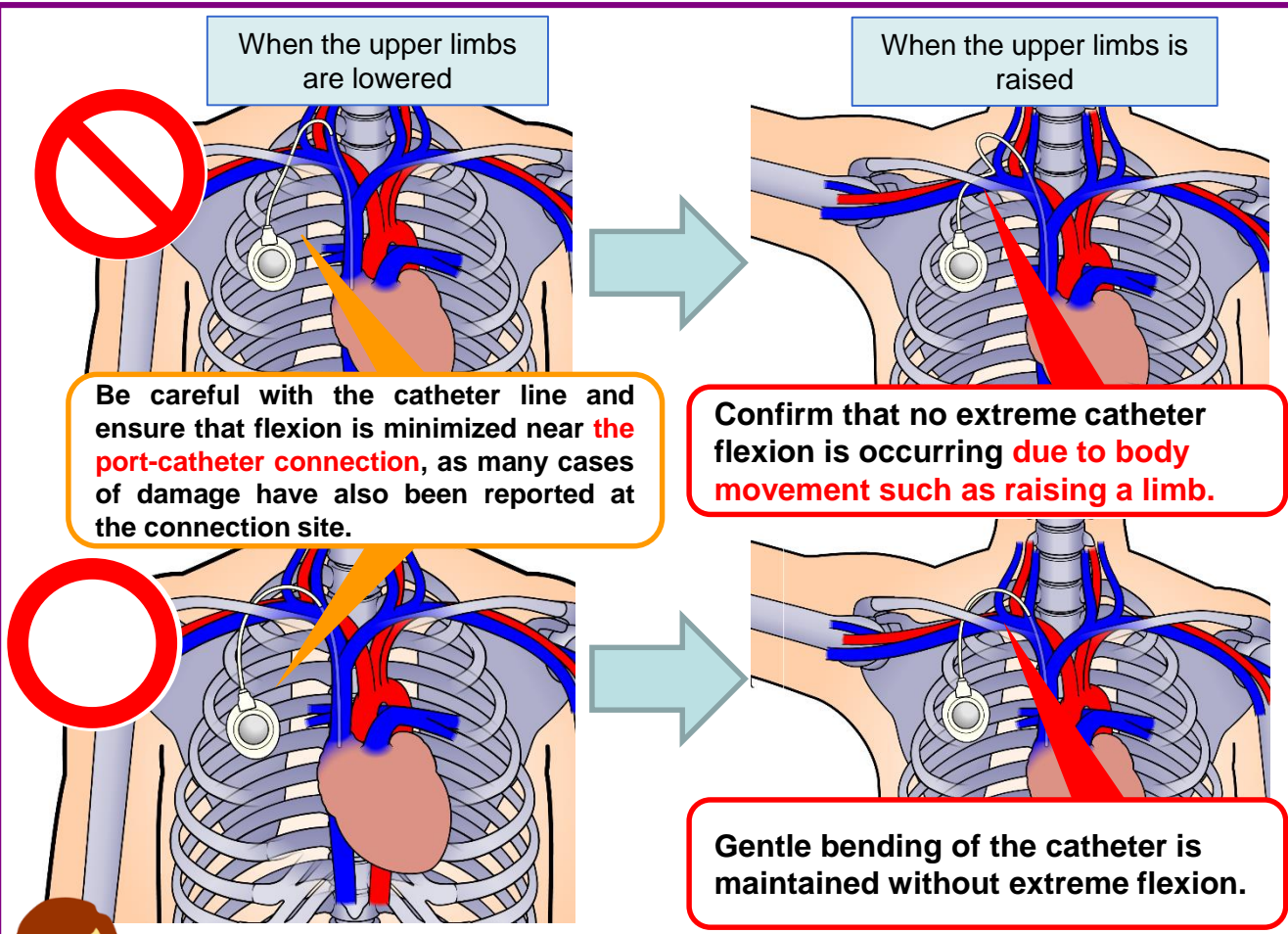
1) Precautions for the subclavian vein approach



A catheter can be severely compressed by bone and ligament tissue when the puncture site passes the contact point between the clavicle and the first rib. This may lead to catheter fragmentation.

By placing the puncture site outside the contact point between the clavicle and the first rib, the catheter will not be compressed or easily fractured as it is protected inside the blood vessel when the line passes the contact point.

2) Precautions related to catheter flexion

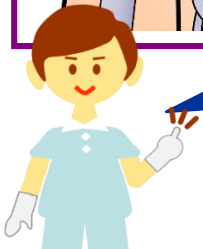


Be careful with the catheter line and ensure that flexion is minimized near the port-catheter connection, as many cases of damage have also been reported at the connection site.

Confirm that no extreme catheter flexion is occurring due to body movement such as raising a limb.

Gentle bending of the catheter is maintained without extreme flexion.

Placement of the catheter line while considering the patient's body movements and confirming such with an x-ray imaging, etc. is effective for ensuring proper catheter indwelling. Handling the catheter carefully to avoid damage when connecting it to its port is also important.

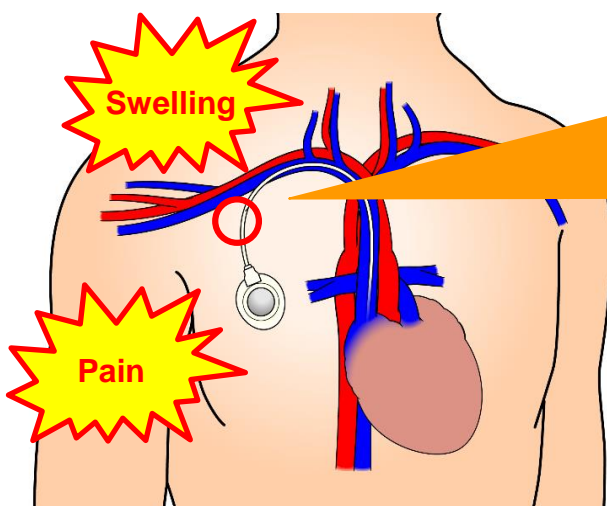


2 Precautions for after subcutaneous port and catheter placement

(Case 2) Catheter fracture was discovered 1 month after subcutaneous port and catheter placement.

(Case 3) Catheter fracture was discovered 11 years after subcutaneous port and catheter placement.

- There is a risk of catheter fracture caused by damage such as cracks resulting from physical stress due to body movement or material degradation, **regardless of the duration of catheterization.**
- Consider prompt removal of catheters from patients in whom the device is no longer needed.



Example of a fractured catheter



When a catheter is not used for a certain period of time for reasons such as suspension of drug therapy, **be sure to check the catheter periodically** to confirm there are no abnormalities such as damage. **Catheters should also be checked before resuming use.**

If a patient complains of pain or discomfort when flushing a catheter or administering a drug via catheter, when swelling is observed near the indwelling site, or when the drug is not infusing properly, it is possible that catheter cracking or blockage may have occurred. Examine the catheter using **x-ray imaging, etc.**, and **remove the catheter if any abnormalities are discovered.**

The Ministry of Health, Labour and Welfare (MHLW) issued an administrative notice, and PMDA issued investigation results in PMDA Medical Safety Information No. 57.

- Pharmaceutical and Food Safety Bureau [PFSB]/Safety Division [SD] Notification No. 0525001, dated May 25, 2011
Revision of Package Inserts of Subcutaneous Ports and Catheters

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.

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