

Virtual Case for IMDRF Adverse Event Terminology Training

Case serial: SCH-2021-04

Title: Intermittent pneumatic compression device system & leg sleeve

Patient Condition

- An 86-year-old male patient had an orthopedic surgery for femur fracture.
- The patient tried to apply the intermittent pneumatic compression device system to prevent deep vein thrombosis.

Events

- The nurse found air leaks at the tubing line (connects leg sleeve and tubing pocket). Refer to Figure (a).

Select the most appropriate IMDRF code for the above description.	
Annex A. Medical Device Problem	Annex G. Medical Device Component

Post-event management & Health effects

- The patient applied a new leg sleeve.
- No significant health complications occurred.

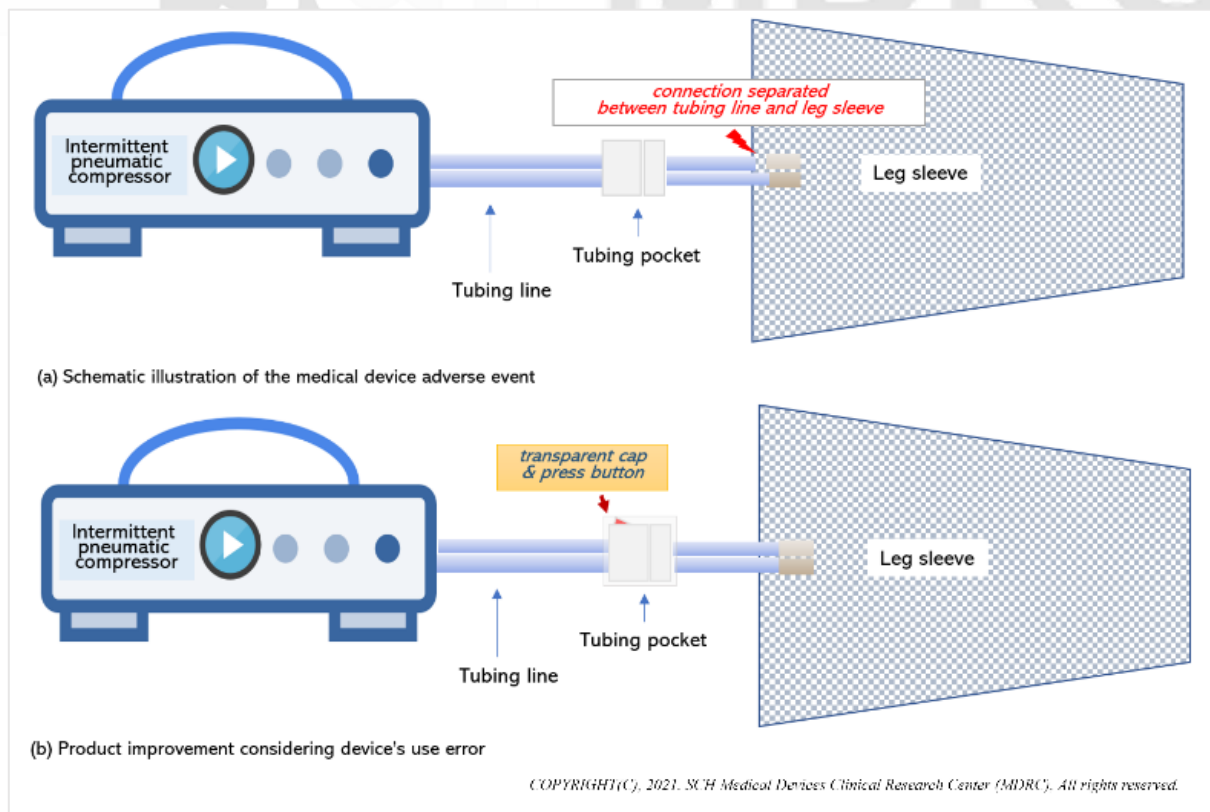
Select the most appropriate IMDRF code for the above description.	
Annex E. Clinical Signs and Symptoms	Annex F. Health Impact

Investigation (Cause, Improvements)

- Interview of patient carer: Patients put the leg sleeve on or off repeatedly for their convenience in wards.
- During that process, the patient pulled off the leg sleeve repeatedly from the tubing pocket, without holding the tubing pocket, which resulted in a tear in the tube which connects the tubing pocket to the leg sleeve.
- Added a transparent cap on the tubing pocket, which the buttons on each side of the pocket need to be pressed for the leg sleeve to be disconnected.
- This prevents patients from pulling off the leg sleeve without holding the tubing pocket. Refer to Figure (b).

Select the most appropriate IMDRF code for the above description.		
Annex B. Type of Investigation	Annex C. Investigation Findings	Annex D. Investigation Conclusion

Image



2021 SCH Medical Device CoE Training

September 1st – 17th | Online Training

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