

Virtual Case for IMDRF Adverse Event Terminology Training

Case serial: SCH-2023-01-02

Title: Disposable handpiece of electro-surgical unit

Patient Condition

- A 66-year-old male patient with peritonitis accompanied by acute appendicitis.
- The patient was under laparoscopic surgery.

Events

- When the surgeon pressed the coagulation button to stop the bleeding using an electro-surgical unit (ESU), cutting occurred on the procedure area.

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

- After becoming aware of the event, the surgeon took relevant actions and completed the surgery using another handpiece of electro-surgical unit from the same manufacturer.
- The surgery took 1.5 times longer than usual. The patient recovered without any particular complications.

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

2023 SCH Medical Device CoE Training

November 1st – 24th 2023

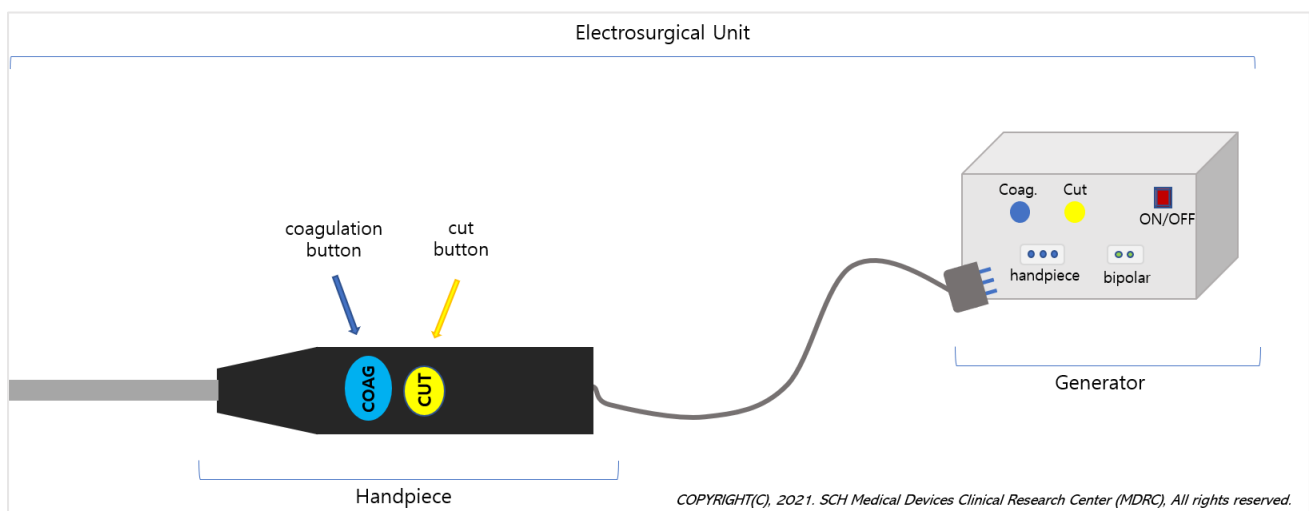
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Investigation (Cause, Improvements)

- After investigating the problematic product, the investigator from the manufacturer confirmed that the coagulation button was connected to turn on the cutting output from ESU to tip of the handpiece and vice versa.
- It is guessed that the accident occurred because the misassembled product could not be filtered out during the manufacturing inspection process. However, the nurse, who has pre-tested the handpiece could not recall whether the visual and audible display on the ESU worked accordingly with the mode of the handpiece button.
- Also, there is no routine pre-testing to check the ESU's output, because it is not feasible in practice during surgery.
- Manufacturing aspect: Re-evaluate the manufacturing process and strengthen the inspection process of the final products.
- User aspect; Audible or visual display of the ESU and ESU output to be double-checked by the assistant surgeon.

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

Image



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