Virtual Case for IMDRF Adverse Event Terminology Training

Case serial: SCH-2021-06

Title: Disposable clip

Patient Condition

- A 64-year-old male patient with acute cholecystitis.
- The patient was undergoing laparoscopic cholecystectomy.

Events

- The surgeon was performing laparoscopic cholecystectomy. The first clip of the applier worked well, but when used again on the cystic duct of the gallbladder, it stopped working and there was no clip in the jaws. (* A clip applier contains 15 clips)
- The cystic duct was torn off by the squeezed jaws of the clip applier and resulted in a leak of bile juice into the peritoneal cavity.
- The surgeon replaced it with another clip applier (same lot number), which also failed to fire its clip. The surgeon was able to finish the surgery by replacing the clip applier to another manufacturer's product.

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 surgeon carried out an additional irrigation with 1 liter of normal saline to handle the contamination. The patient received appropriate medical treatment, including additional dose of antibiotics, but the fever continued. On the 5th day post-surgery, ultrasound and CT scans showed inflammation and necrotic changes of the common hepatic duct.
- The surgeon performed emergency choledocho-jejunostomy for the patient and the patient fully recovered.

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

Investigation (Cause, Improvements)

- The manufacturer's quality manager received two problematic clip appliers from the user, confirmed the products' defect, and reported the event to the regulatory authority.
- The cause analysis of the defect confirmed that it was caused by an urgent change in the production plant due to a fire at the production plant that was manufacturing the clip applier.
- The manufacturer carried out a voluntary recall for the same lot of the product.

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