Virtual Case for IMDRF Adverse Event Terminology Training

Case serial: SCH-2024-01-07

Title: Silicone Gel Breast Implant

Patient Condition

- A 43-year-old woman underwent primary breast augmentation surgery with breast implants.
- During surgery, a 4cm inframammary incision was made and the breast implant was placed under the pectoralis major muscle.

Events

- The patient continued complaining of pain and swelling at the surgical site even after 4 weeks.

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

- An ultrasound revealed that malposition of the left breast implant. Revision surgery was performed to remove of existing breast implant and replace new implant.

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 requested to return the device to investigate the root cause. But, it was not returned. The manufacturer interviewed the surgeons and analyzed their product records. Similar cases in previous adverse event reporting were found regarding the product. Conclusively, it was reported as a known adverse event of the device, although it is difficult to determine the exact cause.

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

Image