Adverse Event Reporting

Adverse event reporting is an essential element to **ensure patient safety** and maintain **regulatory compliance**

⚠️ Adverse Event Definition

Death, serious injury, or malfunction related to device use

📋 Reporting Obligation

All manufacturers, healthcare facilities, and importers have reporting responsibilities

Reporting Deadlines (FDA MDR)

- **Death events:** 30 calendar days (manufacturer to FDA and user)
- **Serious injury:** 30 calendar days (manufacturer to FDA)
- **Malfunction:** 30 calendar days (manufacturer to FDA)
- **5-day report:** In case of immediate public health risk

Reporting Channels

- **USA:** FDA MedWatch, MAUDE database
- **EU:** EUDAMED, Competent Authority
- **Canada:** Health Canada MedEffect
- **Korea:** MFDS medical device adverse event reporting

📝 Report Content

Event details, device information, patient information (anonymized), investigation results

🔄 Follow-up

Submit supplementary report when additional information is found

⚠️ **Key Point:** Failure to make timely and accurate reports may result in regulatory sanctions and threaten patient safety. Establishing clear internal processes is

essential