MATHYS European Orthopaedics

Medical and Legal Aspects of Serious Implant Failure

Strategy of the Company

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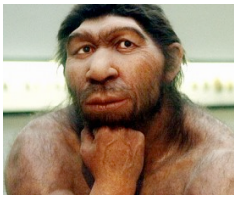
Preservation in motion

A surgeon with a clinical problem

- Did I make a stupid mistake? Better not talk about it.
- It will go wrong again if I don't report it



ISO 14971: Risk Management
„reasonably foreseeable misuse"

Topics

1. How can we **prevent** serious incidents?
2. What do we expect from **you surgeons** when an incident occurs?
3. What does the **company** do after an incident?

Ti/CaP-coating

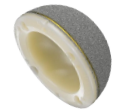
ceramys®

vitamys®

RM-coating

Smart design

New material technologies



→ Innovative new implant solutions

The Importance of Vigilance Reporting

Medical Device Regulation (MDR, May 2020)

Risk Management (ISO 14971)

Active and continuously

Clinical Evaluation

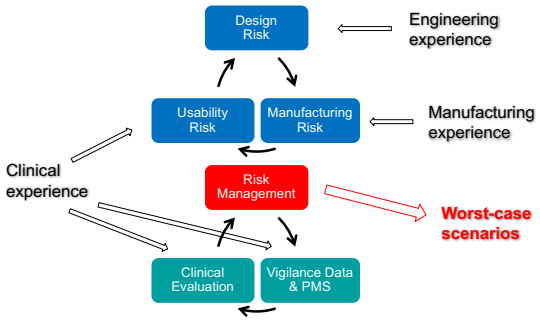
Vigilance Data & PMS

In case of deviation:

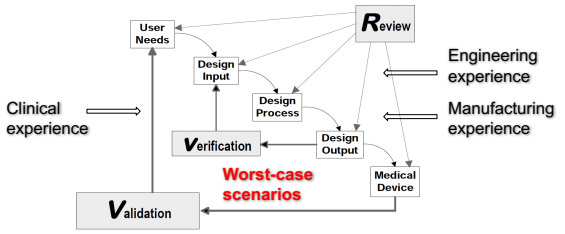
Benefit-Risk-Assessment

Corrective Actions (CAPA, etc.)

Risk Management based on Experience



«V & V»: Validation and Verification



Development of medical devices is **based on experience**!
Part of the experience comes from users (surgeons).

Medical and Legal Aspects of Serious Implant Failure

What to do after a serious adverse event

Preservation in motion

Examples of Incidents

- Inaccuracy in **labelling**, instructions for use and promotional materials
- **Damage** detected in instrument or implant prior/after surgery
- **Malfunction** of an instrument during surgery
- Difficulties with the **Surgical Technique** during surgery
- Clinically relevant increase (> 10 min.) in the **duration** of a surgical procedure
- **Premature revision** of an orthopaedic implant ("premature" = shorter than the expected useful life, i.e. <10 years after implantation)
- A condition that requires significant prolongation of **hospitalisation**

Complaint Handling by Surgeon

- **Notify your sales rep immediately!**
  OR
- Notify the Vigilance Department of Mathys Ltd Bettlach (vigilance@mathysmedical.com)
  OR
- Notify the Competent Authority

- **Provide information** for the vigilance form
  - Description of incident (when, where, how)
  - X-Rays or photos (anonymised)
  - Surgical report
  - Damaged device or explant → Patient consent! (art.nr., lot nr. etc.)

Explant Handling

- Polymer

- Metal

- Ceramic

- **Mechanical cleaning** in an automatic cleaning and disinfection unit (without manual steps, do not remove evidence!)
- **Disinfection in 70% alcohol** solution during one hour (e.g. 70% isopropyl (IPA) or ethanol solution)

For metal & ceramic:

- *Sterilisation in autoclave permitted*

- Shipping to Mathys (individually packed) or collection by sales rep.

Complaint Handling by Company

1. Open **vigilance case «PSxxxx»** (anonymised)
   - Check if information is sufficient
2. Assess incident and find **root cause**
   - Perform additional analyses if needed
3. If **patient harm** cannot be ruled out:
   - Perform a HHE (Health Hazard Evaluation)
   - Decide on CAPA and/or FSCA (Field Safety Corrective Action)
4. Write **final report**
5. Give **feed-back** to surgeon (if demanded)

Legal obligation

Report to Authorities by Company

- In case of **serious incident**
  - IF: Event led, or might have led, to **death or serious health deterioration** of patient or user (permanent impairment of body function, serious patient harm, revision surgery)
  - AND: Manufacturer's device is suspected to be contributory **cause** of the event
  - *NOT IF: expected side-effects which are clearly documented in the product information*
- In case of **FSCA** (recall or field safety notice)

famhp

swissmedic

European Commission

Medical Device Regulation (MDR, May 2020)

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Take-home Message

Preservation in motion

Conclusions

1. An incident is – although not desired – **an important source of information to improve quality of care.**
2. Vigilance data allows us to:
   - Recognise trends
   - Take corrective actions
   - Initiate FSCA (recall or safety notice)
   - Improve products
   - Increase safety for users & patients

3. **The more you report, the more we learn**. Explants are a valuable source of information about the function of the implant.