Safety challenges in arthroplasty – Patient‘s Views

Dieter Wiek, EULAR Vice President, representing PARE

EFORT Implant & Patient Safety Initiative
Inauguration Workshop
21 January 2020

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The three pillars of EULAR

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PARE (People with Arthritis and Rheumatism in Europe):
36 Member Organisations

My Personal Story

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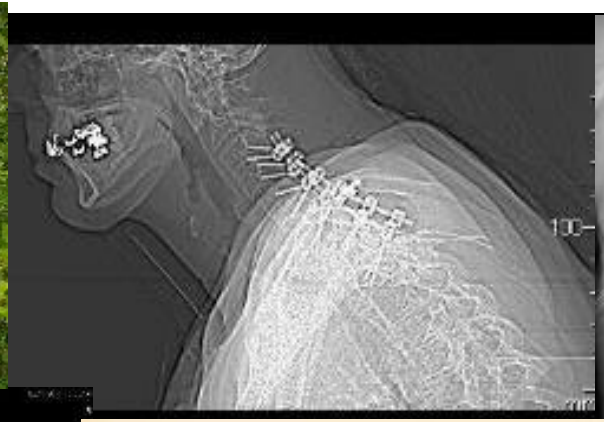
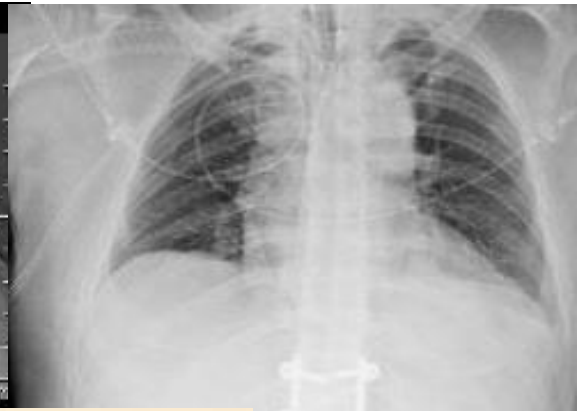
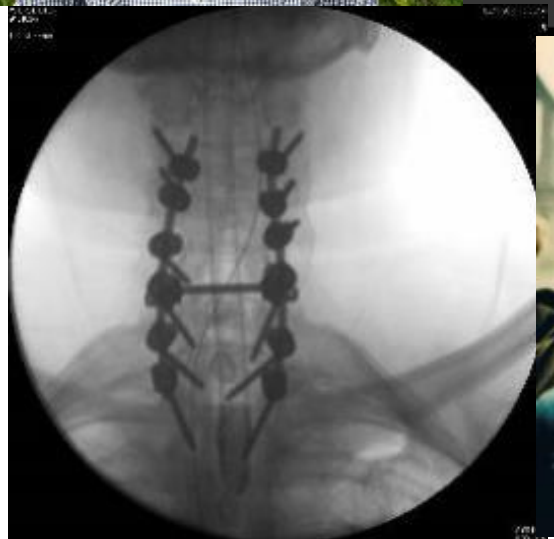
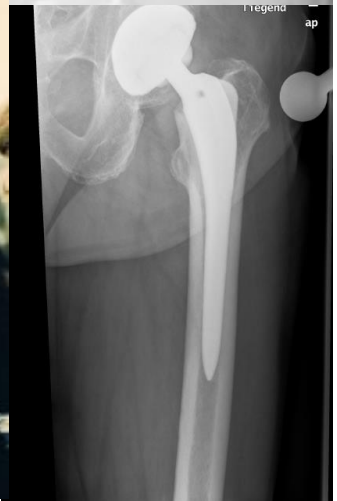








MDR - a relevant topic for patients with RMDs?

- Rheumatoid Arthritis patients: reconstructive surgeries are common, but - due to new therapies and disease management surgeries - decrease
- Ankylosing Spondylitis patients: total hip arthroplasty to manage pain, restore function and mobility, but medication/therapies have reduced the need
- Hip arthroplasty in Germany per 100 000 inhabitants

2005	2010	2017
254	283	309

Why regulations on medical devices and in vitro diagnostics are important for patients

Patient Safety

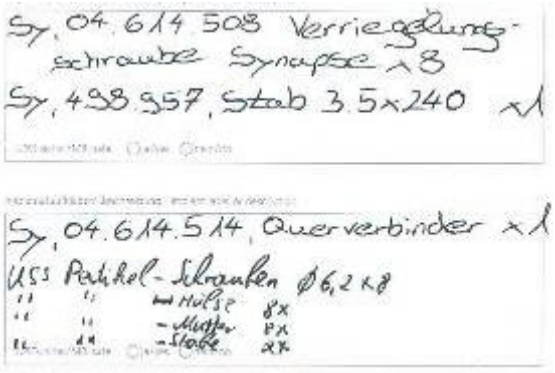
- Assessment procedure for all medical devices
- Assessment for higher risk categories by notified bodies
- Clinical investigations for higher risk categories
- Market surveillance activities ensure patient safety after market authorization

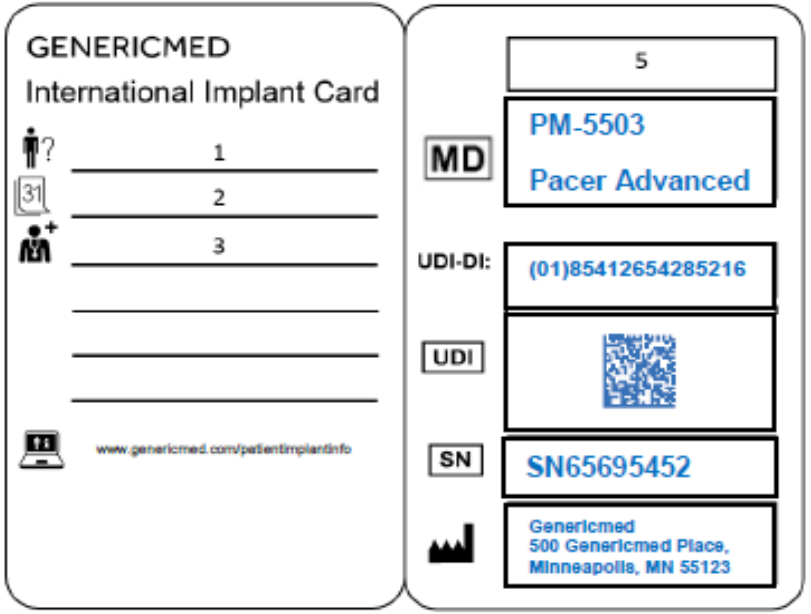
Why regulations on medical devices and in vitro diagnostics are relevant for patients

Patient Safety

- Products receive an identification number
- Electronic system to exchange information
- Monitoring of devices

The Implant Card





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Medical Products used by patients

have to be barrier-free devices with **barrier-free operating instructions** and should include

- **purpose of the product/indication**
- **permissible operating conditions/locations**
- **existing application risks and contraindications**
- **assembly and mounting instructions**

Position Paper BAG Selbsthilfe 23.09.2019

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Medical Products used by patients

have to be barrier-free devices with barrier-free operating **instructions** and should include

- **specification of the material used**
- **technical data/parameters**
- **cleaning instructions**
- **specification of the lifetime of the device**

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Security and privacy in implantable medical devices (IMDs)

- **IMDs treat, monitor, improve the medical condition**
- **IMDs incorporate communication and networking functions**
- **Great benefits for patients,**

  but also numerous risks like intentional malfunction, privacy issue due to remote detection …

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Relevance for Patients

refers to

- **usability**
- **technical safety**
- **ergonomic safety**
- **application security**
- **data protection (especially IMDs)**
- **supply security**

Current Key Issues

1. Lack of Notified Bodies that assess and certify medical devices (status 26-12-2019)

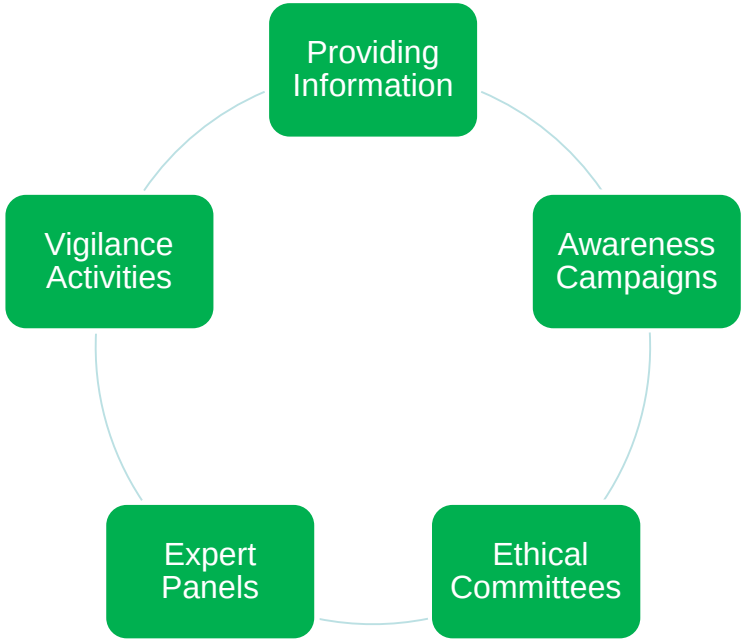
- 9 Notified Bodies designated under the EU MDR (2017/745)
  Commission 14.01.2020: 12 approved, 2 to be approved in near future
- 3 Notified Bodies designated under the EU IVDR (2017/746)

2. EUDAMED postponed, launch May 2022

- Coordination between national and European databased systems essential to avoid duplication

3. **Report of suspected cases** mandatory, but no consequences if not done

Involvement of Patients and/or Patients‘ Organisations




Thanks for your attention!