The new EU MDR – lessons learned from the past

Engaging with the new EU regulatory landscape for medical devices.

Challenges & opportunities



Brussel, Belgium April 6, 2018



Per Kjaersgaard-Andersen

Associate Professor Section for Hip and Knee Replacement, Vejle Hospital, Denmark

1. Vice-president, EFORT





Past challenges

- Christiansen hip prosthesis
- Boneloc cement
- MoM bearings
- Modular neck in THA

Not to forget

- Design problems
 - Ceramic inlay with elevated metal rim
 - Stable fixation of coatings
- Instruments
 - Safely use for surgeons and patients
 - Fit the final implant (tolerance)

Goals in EFORT

 Support safe and timely treatment of all patients in the European Orthopaedic Community

 In the world of <u>multiple implant options</u>, EFORT support and will ask to be involved in initiatives to guide colleagues and authorities in selecting the best and most safe implant solution for our patients

Goals in EFORT

 EFORT therefore look for initiatives to improve patients treatment – and to reduce complexity when judgment of a given implant is needed

 EFORT welcome all initiatives where patients safety is in front.