The European Arthroplasty Registers and National Arthroplasty Registers

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Austria
Register activities in Europe

Annual Reports available

EAR Members

Projects and Negotiations

Initiatives
Arthroplasty Registers.....

- Are successful and recognised data sources in science and literature
- Successful in Scandinavia
- No general definition of „Register“
Definition of Arthroplasty Registers (EFORT-EAR)

- Registration of ALL primary and revision operations in a country in a central database
- Follow the Patient/Implant until it has to be revised or the patient dies or emigrates
- Definition of Revision (= Failure): At least a part of the implant has to be revised
- Focus on survival rate in the reports
Why to start an Arthroplasty Register?

Christiansen hip-prosthesis

69% survival after 6 years
Sudmann et al 1983

More than 10,000 prosthesis used in Scandinavia before the difference between Charnley and Christiansen prosthesis in single hospitals could be shown
Impact of Registers

Revision burden

- **Sweden:**
  - 1979: 18%
  - 2006: 7.7%

- **USA (AAOS)**
  - Revision burden: 1992-2002: 17.5%
Detection of inferior products

Bone-Cement: Norwegian Arthroplasty Register

B Nolan and Low Viscositii Cement brands disappeared from the market

High viscosity
Low viscosity
Boneloc

p<0.0001
Early detection major implant failure:

Norway:
Data from 1987 – 1993
- 24,408 Implants, 2907 (13%) of them cementless
- 8 different systems with > 100 Operations / Year
- 4,5 Years FUP

- Bio-Fit-stem: \( n=210; 18,6\% \) Revision rate
- Femora-stem: \( n=173; 13,6\% \) Revision rate
- PM-stem: 5,6% Revision rate
- Harris-Galante: 3,6% Revision rate
- Die 4 best performing stems <1% Revision rate

Early aseptic loosening of uncemented femoral components in primary total hip replacements. A review based on the Norwegian Arthroplasty Register
Havelin, Espehaug, Volleat, Engeseter, JBJS Br 1995, Jan 77(1): 11-17
Impact of Registers

- Rough estimation for reason of failure

Femora-stem Right-Left
Early detection major implant failure (production process):

- Example: Inter-OP-Cup event in the USA (Sulzer)

2000: Recall due to Lubricant residues on the surface
=> decreased Osteointegration
17,000 implants sold; expected revisions about 4000
725 Mio $ for reparation by the manufacturer

A small number of implants were sold in Europe (Sweden); after 30 primary implants and 5 revisions after 1.5 years => statistically significant results
### Andel reviderade per cup

Resultaten baseras på samtliga rapporterade primäroperationer (P) utförda 1999 eller senare och samtliga revisioner (R) av dessa där åtminstone aktuell komponent bytts ut.

<table>
<thead>
<tr>
<th>Nr</th>
<th>Komponent</th>
<th>P</th>
<th>R</th>
<th>Andel</th>
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<tbody>
<tr>
<td>3</td>
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<td>18</td>
<td>3</td>
<td>16,7%</td>
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<tr>
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<td>147</td>
<td>3</td>
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<td>7</td>
<td>Weber 28 mm stori. 50</td>
<td>109</td>
<td>2</td>
<td>1,8%</td>
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<tr>
<td>8</td>
<td>Allofit Ti 52/II</td>
<td>55</td>
<td>1</td>
<td>1,8%</td>
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<tr>
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<td>0,0%</td>
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<tr>
<td>17</td>
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<td>39</td>
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<td>22</td>
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<td>25</td>
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<td>0,0%</td>
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<td>26</td>
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<td>0,0%</td>
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<td>27</td>
<td>Müller Low Profile Cup 28 mm Ø 46 mm</td>
<td>17</td>
<td>0</td>
<td>0,0%</td>
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<tr>
<td>28</td>
<td>Müller Low Profile Cup 28 mm Ø 50 mm</td>
<td>17</td>
<td>0</td>
<td>0,0%</td>
</tr>
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</table>
Impact of Registers

- **Reference for surgical procedures:**

  Revision rate referring to antibiotic prophylaxis regimes
Impact of Registers

- **Decrease of the range between individual departments concerning revision rate:**

Results for individual Units 1979 – 1991:

National average: 93,5% survival rate after 7 years

- 45% of the units above
- 30% at the average
- 25% below the average
Impact of Registers

• **Decrease of the range between individual departments concerning revision rate:**

Results for individual Units 1992 - 2002:

National average:
95.8% survival rate at 7 years

- 33% of the units above
- 54% at the average
- 13% below the average
Impact of Registers

- How it was possible to achieve the reduction in revision rate?
  - Surgeons focused on the best implants
    - 1979: 60 different implants on the Swedish market
    - 2001: 3 Implant (stems) have > 90% of the market’s share and all of them are in the top performer group
  - Improvement of surgical techniques by feedback
  - Autonomous by the surgeons without regulatory influence by the Public Health System
Financial Impact by a Register

- Compared to the Expenses for Revisions:

- Sweden:
  - if 40 Revisions can be „saved“ by a register it is cost effective.
  - The Register has reduced the revision burden by more than 50%
  - This is an equivalent of saving 11,630 revisions in the last 10 years
  - Direct (intrahospital) costs: 139,560,000$

= 14,000,000 $ annually for the Swedish Health Care System
How the scandinavian achieved this tremendous success?

- Active Publication of the results

- Selective Presentations to the different groups of interest.
  - Surgeons
  - Public Health System
  - Scientific Societies, Patients,..

- Assure a fair use of the figures and discussion
Reports

- General Reports published at scientific meetings, ...

- Reports referring to the national situation and (not public) reports to the single departments presenting their situation in comparison to the national average
Interpretation of Register data

- Register data are observations

- Reflect local standards
  - might lead to misinterpretation by generalisation of foreign Reports.
  - Only portuguese Register data really fit to the portuguese background

- What to do in the meantime until the Register is producing results??
Adjustment of Information from Arthroplasty Register Reports
What can I use for myself from foreign Register reports?

Figure KT5: Trends in Prosthesis Fixation – Primary Total Knee by State and Ter

The figure shows the yearly distribution for cemented, uncemented and hybrid fixation of components.
Table HT33: Primary Conventional Total Hip where the Femoral and Acetabular components were used with Cementless Fixation requiring Revision

<table>
<thead>
<tr>
<th>Femoral Component</th>
<th>Acetabular Component</th>
<th>Number Revised</th>
<th>Total Number</th>
<th>% Revised</th>
<th>Observed ‘component’ years</th>
<th>Revisions per 100 observed ‘component’ years</th>
<th>Exact 95%CI</th>
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</thead>
<tbody>
<tr>
<td>ABGII</td>
<td>ABGII</td>
<td>69</td>
<td>2396</td>
<td>2.9</td>
<td>6193</td>
<td>1.1</td>
<td>(0.87, 1.41)</td>
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<tr>
<td>ABGII</td>
<td>ABGII (shell &amp; insert)</td>
<td>7</td>
<td>544</td>
<td>1.3</td>
<td>915</td>
<td>0.8</td>
<td>(0.31, 1.58)</td>
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<tr>
<td>ABGII</td>
<td>Trident</td>
<td>23</td>
<td>876</td>
<td>2.6</td>
<td>1756</td>
<td>1.3</td>
<td>(0.83, 1.96)</td>
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<tr>
<td>Accolade</td>
<td>Trident</td>
<td>39</td>
<td>1765</td>
<td>2.2</td>
<td>2343</td>
<td>1.7</td>
<td>(1.18, 2.28)</td>
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<td>Allofit</td>
<td>20</td>
<td>848</td>
<td>2.4</td>
<td>1209</td>
<td>1.7</td>
<td>(1.01, 2.56)</td>
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<td>16</td>
<td>482</td>
<td>3.3</td>
<td>701</td>
<td>2.3</td>
<td>(1.30, 3.71)</td>
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<td>Alloclassic SL</td>
<td>Allofit</td>
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<td>1.4</td>
<td>2996</td>
<td>0.6</td>
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<td>Fitmore</td>
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<td>538</td>
<td>2.2</td>
<td>1465</td>
<td>0.8</td>
<td>(0.42, 1.43)</td>
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<tr>
<td>Alloclassic SL</td>
<td>Morscher</td>
<td>7</td>
<td>313</td>
<td>2.2</td>
<td>1018</td>
<td>0.7</td>
<td>(0.28, 1.42)</td>
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<td>CLS</td>
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<td>818</td>
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<td>1168</td>
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<td>956</td>
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<td>(0.65, 1.79)</td>
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<td>Citation</td>
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<td>1.0</td>
<td>1587</td>
<td>0.6</td>
<td>(0.23, 0.98)</td>
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</tbody>
</table>
Table HT39: Individual Primary Conventional Total Hip Prostheses with higher than anticipated revision rates either alone or in combination

<table>
<thead>
<tr>
<th>Femoral Component</th>
<th>Acetabular Component</th>
<th>Hazard Ratio</th>
<th>P Value</th>
<th>Total Number</th>
<th>% Revised</th>
<th>Observed ‘component’ years</th>
<th>Revisions per 100 observed ‘component’ years</th>
<th>Exact 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cementless</td>
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<tr>
<td>Alloclassic</td>
<td>Fitmore</td>
<td>2.16</td>
<td>0.004</td>
<td>482</td>
<td>3.3</td>
<td>701</td>
<td>2.3 (1.2, 3.4)</td>
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<tr>
<td>Esop</td>
<td>Altas</td>
<td>2.93</td>
<td>0.020</td>
<td>81</td>
<td>4.9</td>
<td>96</td>
<td>4.2 (0.1, 8.2)</td>
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<tr>
<td>Margron</td>
<td>*</td>
<td>3.01</td>
<td>&lt;0.001</td>
<td>563</td>
<td>7.3</td>
<td>1289</td>
<td>3.2 (2.2,4.2)</td>
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<tr>
<td>Profemur</td>
<td>*</td>
<td>7.39</td>
<td>&lt;0.001</td>
<td>134</td>
<td>6.0</td>
<td>103</td>
<td>7.8 (2.4,13.2)</td>
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<tr>
<td>Revitan</td>
<td>*</td>
<td>2.57</td>
<td>0.048</td>
<td>83</td>
<td>6.0</td>
<td>184</td>
<td>2.7 (0.3, 5.1)</td>
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<td>**</td>
<td>Artek</td>
<td>3.40</td>
<td>&lt;0.001</td>
<td>158</td>
<td>15.2</td>
<td>667</td>
<td>3.6 (2.2,5.0)</td>
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<tr>
<td>**</td>
<td>Delta</td>
<td>4.78</td>
<td>0.011</td>
<td>136</td>
<td>2.9</td>
<td>79</td>
<td>5.0 (0.1, 10.0)</td>
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<td>**</td>
<td>EDF-Plus</td>
<td>2.00</td>
<td>0.020</td>
<td>560</td>
<td>2.1</td>
<td>567</td>
<td>2.1 (0.9, 3.3)</td>
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<td>**</td>
<td>Inter-Op</td>
<td>5.13</td>
<td>0.001</td>
<td>27</td>
<td>22.2</td>
<td>111</td>
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<td>**</td>
<td>Lineage</td>
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<td>0.003</td>
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<td>492</td>
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<td>**</td>
<td>SPH Blind</td>
<td>2.12</td>
<td>&lt;0.001</td>
<td>714</td>
<td>5.3</td>
<td>1897</td>
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<td>Charnley LPW</td>
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<td>7.9</td>
<td>313</td>
<td>2.2 (0.6,3)</td>
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<tr>
<td>H Moos</td>
<td>Mueller</td>
<td>14.62</td>
<td>&lt;0.001</td>
<td>19</td>
<td>36.8</td>
<td>66</td>
<td>10.6 (2.7,1)</td>
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</table>
Figure HT21-28: Cumulative percentage revision of prostheses that have been identified.
Detail Evaluation Alloclassic

- Group Alloclassic consists of a mixture of Alloclassic SLO and SLL (- at primary Operations!!)

- Relatively small sample, 15 Revisions

- Almost all Revisions within the first year
• Questions:
  - Case mix Faktor?
  - Surgical influence?

• Implant related problem????????

• Not everything what´s significant is relevant

• Accurate Analyses by Register staff is recommended and essential to give the „customer surgeon“ the possibility for proper consequences
Implant tracking - Example

- Omnifit-Cup in Romania: Most Popular Implant in Romania

- Omnifit-Cup in Sweden: Release from the Market due to poor performance (62% survival rate at 10 years)

- ?????????? What’s this?
Omnifit-Cup

- Sweden

- Romania
Omnifit-Cup

• 6 different versions of this cup

• Not possible to specify simply by the product name

• Dilution in Studies, assessment and scientific discussions?

• Sufficient information and lack of specification might lead to unsecure feeling by surgeons and/or patients
Value of Datasets
• **EUPHORIC**: (EUropean Public Health Outcome Research and Indicators Collection)

• Methodological Research project by the European Commission (DG SANCO)
• Comparison Register and Metaanalyses of peer reviewed literature.

• Revision Rate (Revisions per 100 observed component years)

• Implants with sufficient publications in both datasets
Ankle Replacement
Metaanalysis STAR Ankle Replacement

- 42 Publications (Medline)
- 23 with survival rate data (1187 Cases)

of these

- 6 Studies from Author´s group (>25%) (212 Cases)
- 17 Independent Studies (975 Cases)
STAR Ankle Replacement

Revisionsraten
Studien vs. Register

\[ \text{Prozent (\%)} \times \text{Jahre} \]

Studies from the author’s group

Studies > 30 Cases

N= 531
1993 - 2005
Revisions: 101 (22%)

N= 259
1994 - 2004
Revisions: 40 (15,4%)

N= 202
2002 - 2005
Revisions: 14 (7%)
## STAR Ankle Replacement

<table>
<thead>
<tr>
<th></th>
<th>FUP</th>
<th>Revision Rate</th>
<th>Primary cases</th>
<th>Revision cases</th>
<th>Observed component years</th>
<th>Revisions per 100 observed component years</th>
<th>CI</th>
<th>Factor Difference Register-Studies</th>
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<td>1018.50</td>
<td>0.88</td>
<td>0.47-1.67</td>
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<td>13.35</td>
<td>1049</td>
<td>140</td>
<td>4658.11</td>
<td>3.01</td>
<td>2.55-3.54</td>
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<td>Pooled clinical studies</td>
<td>4.60</td>
<td>12.08</td>
<td>1233</td>
<td>149</td>
<td>5677</td>
<td>2.62</td>
<td>2.24-3.07</td>
<td>1.56</td>
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<td>Pooled Register Data</td>
<td>4.01</td>
<td>16.41</td>
<td>579</td>
<td>95</td>
<td>2321.2</td>
<td>4.09</td>
<td>3.36-4.98</td>
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</table>
Other Ankle Replacements

• Pappas-Büchel:
  – Author is underestimating the Register revision rate by a factor of 14.31
  – Clinical studies (from the US) are underestimating the revision rate by a factor of 7.45

• Agility:
  – Author is underestimating the Register Revision rate by a factor of 2.43
  – Independent Studies are overestimating the benchmark by a factor of 1.66
  – Pooled data near to the Register Benchmark
Boneloc

BONELOC CEMENT GUN
Boneloc

- In favour of the product
- Technical studies or no statement
- Negative to the product

![Graph showing the percentage of NOT REVISED for different years (1991, 1995, 2000, 2003) with a p-value of 0.0001.]

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EFORT – JOINT EFFORTS
Statement per Type of Publication

Number of Publication

Experimental | Clinical Studies | Reviews

- Negative
- Neutral
- Positive
Articles published

Year

Cumulative numbers


- Experimental
- Migration Analyses
- Clinical Studies
- Registers
- Reviews

Boneloc
### Boneloc

**Clinical Studies were published at a time where the failure of the product was obvious**

**Clinical Studies overestimate the real revision rate by a factor of 7,33**

<table>
<thead>
<tr>
<th></th>
<th>FUP-Periode (years)</th>
<th>Reoperation Rate [%]</th>
<th>Number primary cases</th>
<th>Observed Component years</th>
<th>Number revision cases</th>
<th>Revisions per 100 observed component years</th>
<th>Factor Difference</th>
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<td>5618,00</td>
<td>166</td>
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<td>21.71</td>
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Patella Replacement at TKA
Patella Resurfacing Clinical Literature
## Literature Overview incl. Register

<table>
<thead>
<tr>
<th></th>
<th>Follow up period</th>
<th>Revision rate [%]</th>
<th>Primary cases</th>
<th>Revision cases</th>
<th>Observed component years</th>
<th>Revisions per 100 observed component years</th>
<th>CI</th>
<th>Factor Difference to Register</th>
<th>Factor Difference Resurfacing/non Resurfacing</th>
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<tr>
<td><strong>Resurfaced Register</strong></td>
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<td><strong>Non Resurfaced Register</strong></td>
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</table>
Summary

- Statistically significant Bias in Clinical Literature
- Authors and Publications from the US have higher Bias factors
- Clinical Literature reviews can not eliminate this bias without reference to Register data
How to organise a National Register?

- Require a professional and solid data collection and evaluation centre
- Results have to be published, discussed and findings have to be considered in daily decisions
- National Orthopaedic Societies are the only forum which can achieve this.
- Registers are just as effective as the surgeons support them
Effects of Registers

3 Years, 25% Risk reduction
Effects of Registers

- Since 2000: Decrease
Register-section at EFORT-Portal

European Arthroplasty Register

European Arthroplasty Register (EAR)
http://www.ear.efort.org/

Danish Hip Arthroplasty Register
http://www.dhr.dk/ENGLISH.htm

Danish Knee Arthroplasty Register
http://www.dshk.org/DKR-frame.htm

Finnish National Arthroplasty Register
http://www.nam.fi/english/publications/

Norwegian Arthroplasty Register
http://info.haukeland.no/ncl/

Romanian Arthroplasty Register
Register-section at EFORT-Portal

Romanian Arthroplasty Register
http://www.rne.ro/site/Default.aspx

Slovakian National Arthroplasty Register
https://sor.mfn.sk/

Swedish Knee Arthroplasty Register
http://www.art.lu.se/knee/indexeng.html

Swedish National Hip Arthroplasty Register
http://www.jru.orthop.gu.se/

International Arthroplasty Register

Australian Orthopaedic Association National Joint Replacement Registry

Canadian Joint Replacement Register
http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=services_cjrt_e

New Zealand Joint Register
http://www.cdhb.govt.nz/NJR/
**EUROPEAN ARTHROPLASTY REGISTER**

Last updated: January, 26th 2005

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**NEWS**

April 12th, 2005  Organised by EAR, an Arthroplasty Register section at the EFORT Portal was launched. Aim is to collect and present worldwide Arthroplasty Register information in a user friendly way.

http://www.efort.org/1/05/01-50.asp

Feedback to this page is welcome:

Please post your message to the EAR-office by e-mail

The development of an International Register Society was decided at a meeting of the AAOS in February 2005:

EFORT-EAR supports this initiative.

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**EVENTS**

June 6th, 2005  On Monday, 6th of June, 8.00 - 10.00 a European Arthroplasty Register Symposium will be presented at the EFORT-Congress in Lisbon.

EAR will organise a hot public meeting concerning innovative documentation systems and techniques for national large scale documentation systems at the EFORT congress. Interested colleagues are invited to order information at the EAR-Coordinator.

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**EAR REPORTS**

- Basic Statements concerning Arthroplasty Registers (771 KB)
- Development of the Romanian Register (3886 KB)
- New Regulatory Requirements and related challenges in the European Union for orthopaedic medical devices (157 KB)

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**RECOMMENDED PUBLICATIONS**

- EFORT Minimal Dataset
- Basics about Arthroplasty Registers

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**CONTACT**

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EUPHORIC Results will be Published at the EFORT-Congress 2009 in Vienna