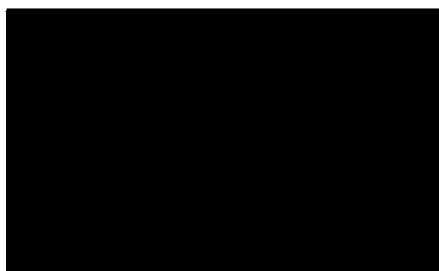


**ORTHOPAEDIC EXPERT WORKING GROUP (OEWG)
2010/3 MEETING
24 November 2010, 6.30PM EST**

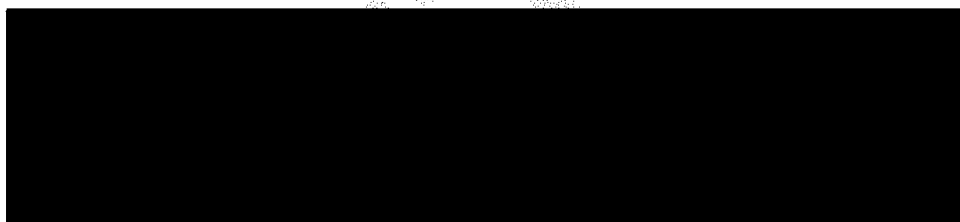
DRAFT MEETING RECORD & OUTCOMES

List of Participants:

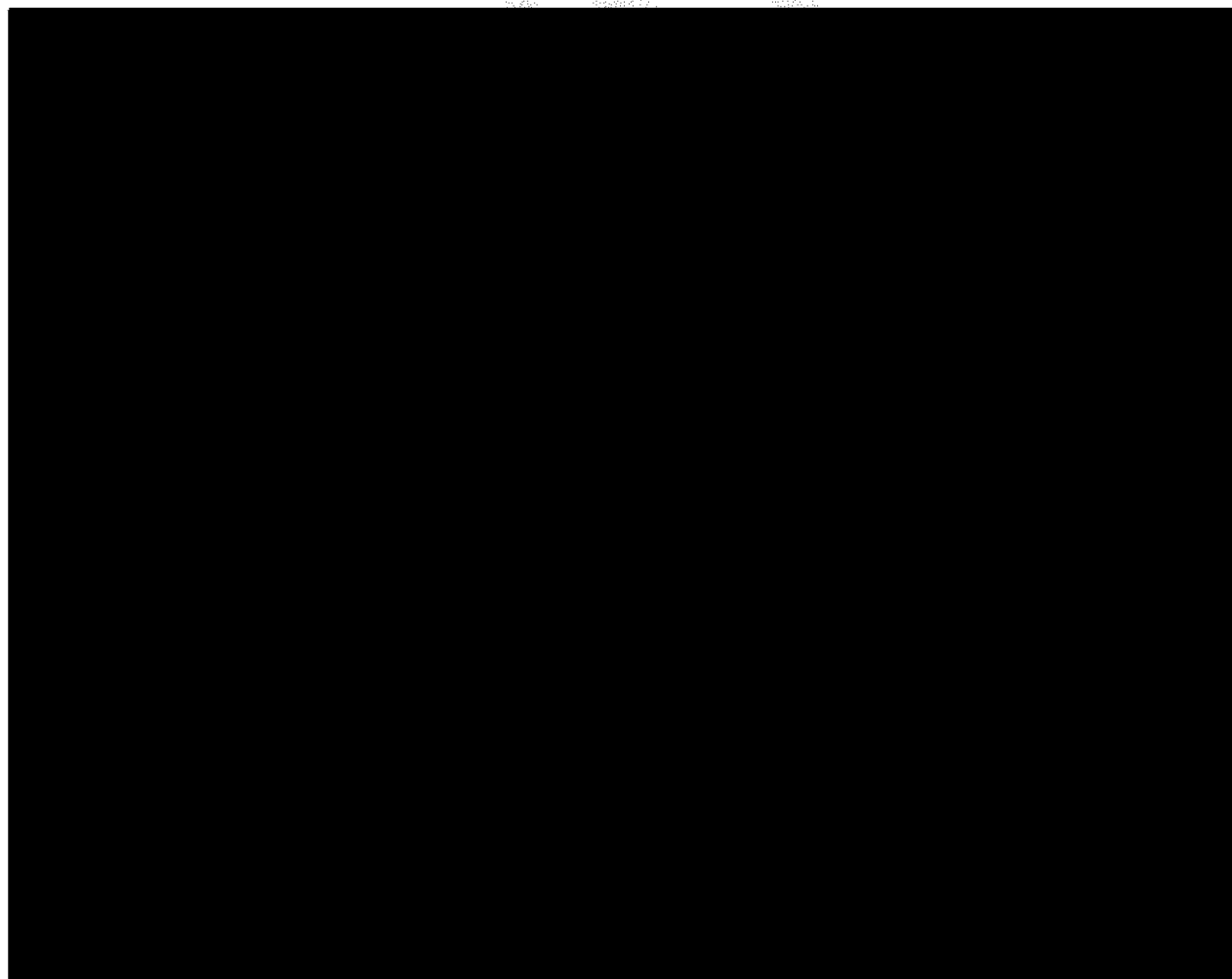
Members:

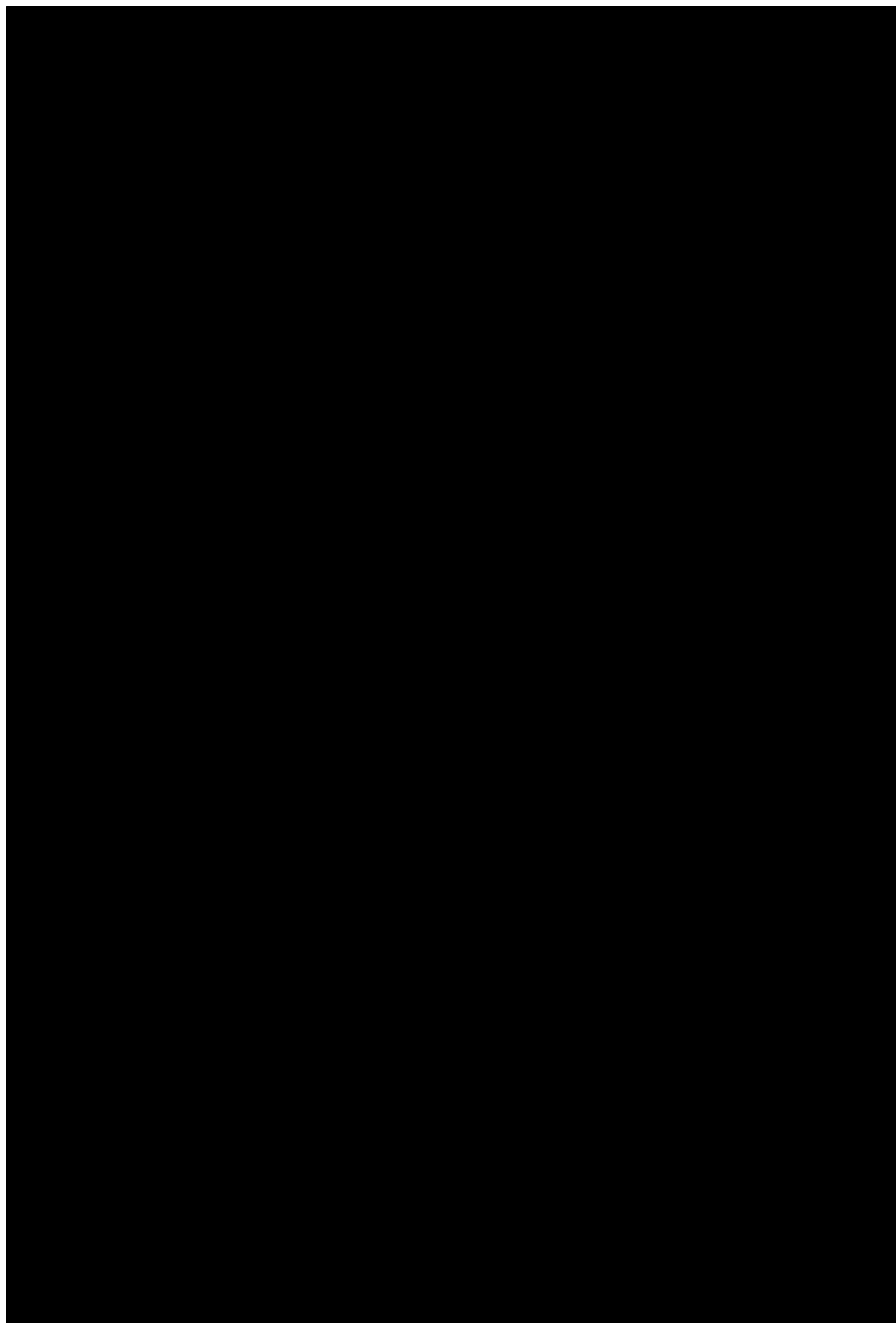


TGA advisers:



Secretariat:



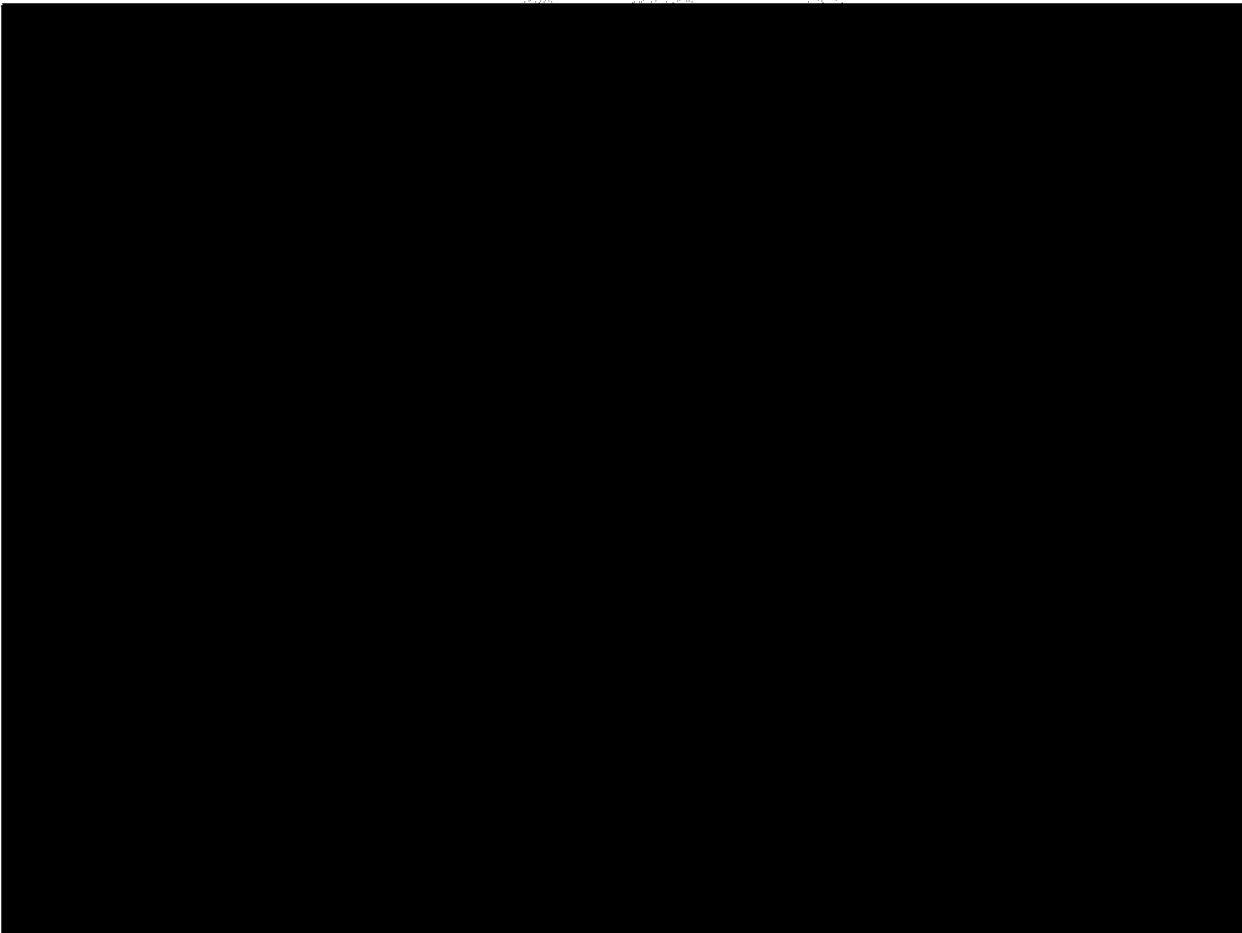


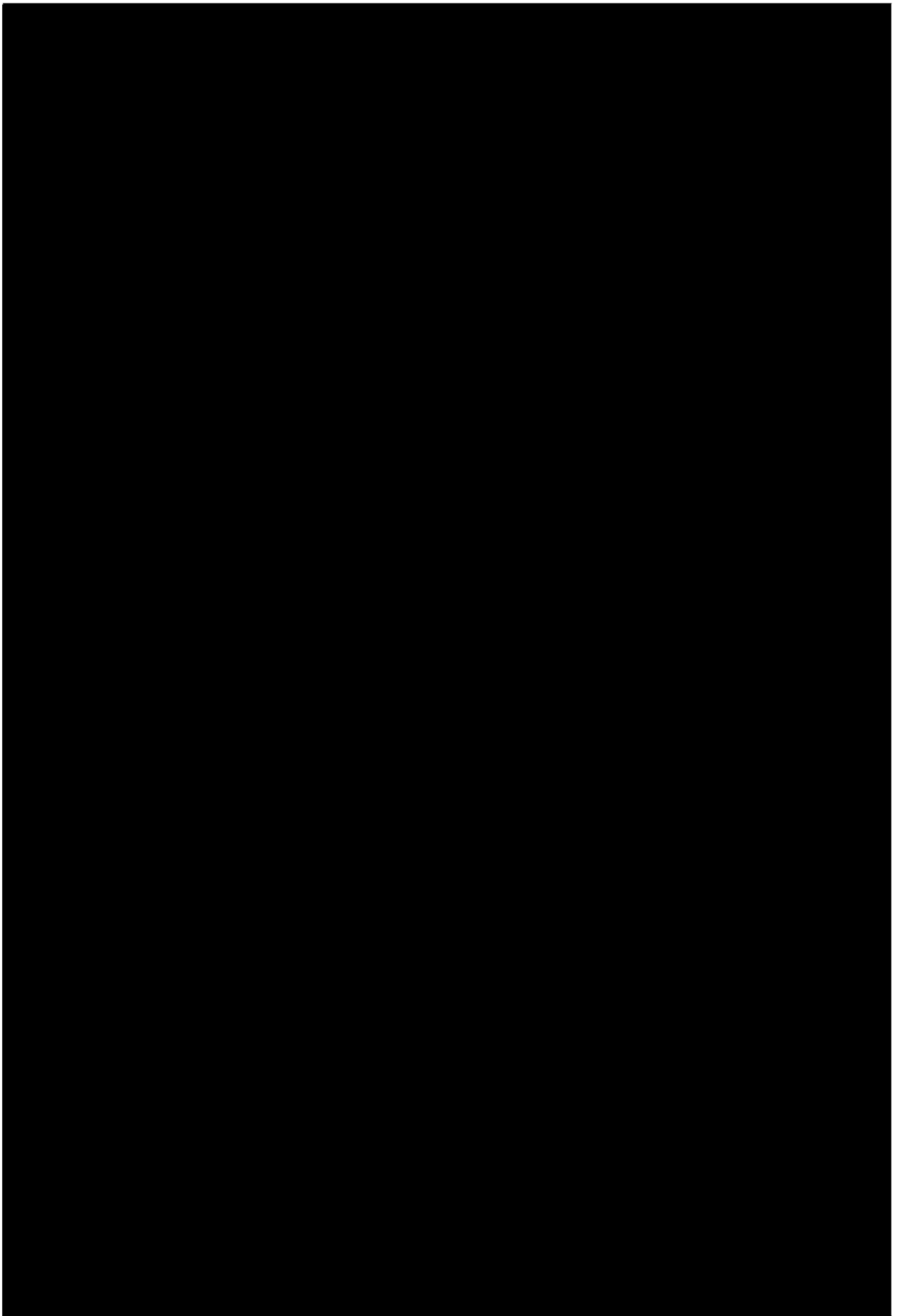


4.4 ESKA Adaptor (cementless) Femoral Stem Prosthesis

- 4.4.1 The revision rate for the Adapter (cementless) at 3 years is 5.4% compared to 2.7% for other total conventional hips. Members expressed concerns over the high revision rates and noted the poor quality response from the Company (for example the information provided by the sponsor does not relate directly to the Adaptor device).
- 4.4.2 The NJRR representative observed that the Adapter has exchangeable femoral necks which could be associated with an increased rate of revision.
- 4.4.3 A member noted that the metal bearings for this implant are made from a high carbon steel which is quite different to the materials used by similar implants made by other companies.
- 4.4.4 It was also noted that of the 567 implants there were 23 revisions and these were not common to one hospital or state indicating that the cause for revision is not surgical technique.
- 4.4.5 The NJRR representative added that, while only the cementless form of the implant was identified in 2010, the cemented form of the implant is also of concern and this indicates that the revision rates are likely to be related to implant design rather than surgical technique.

Advice: The Working Group advised that the use of the ESKA Adaptor (cementless) Femoral Stem Prosthesis should be discontinued.

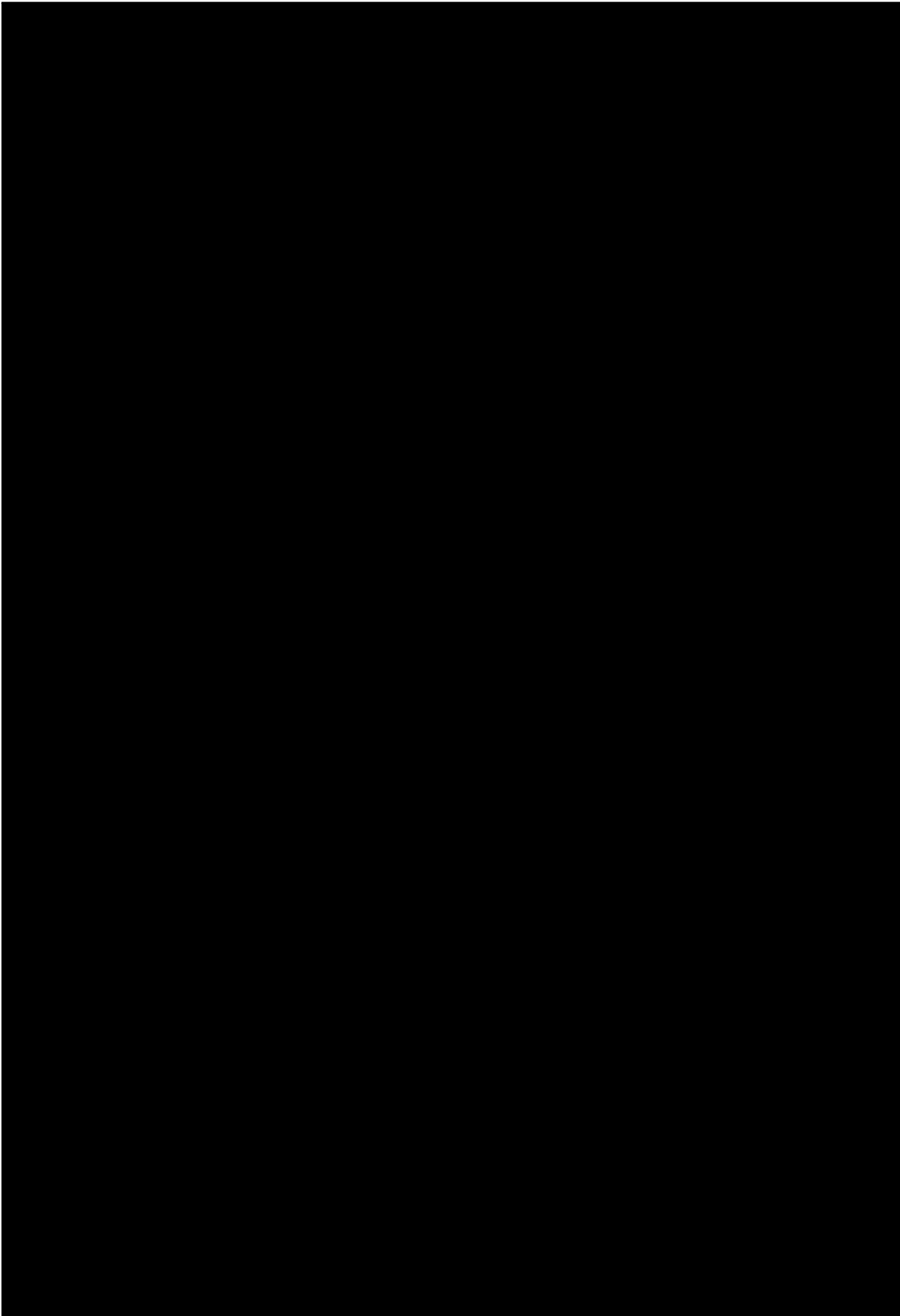


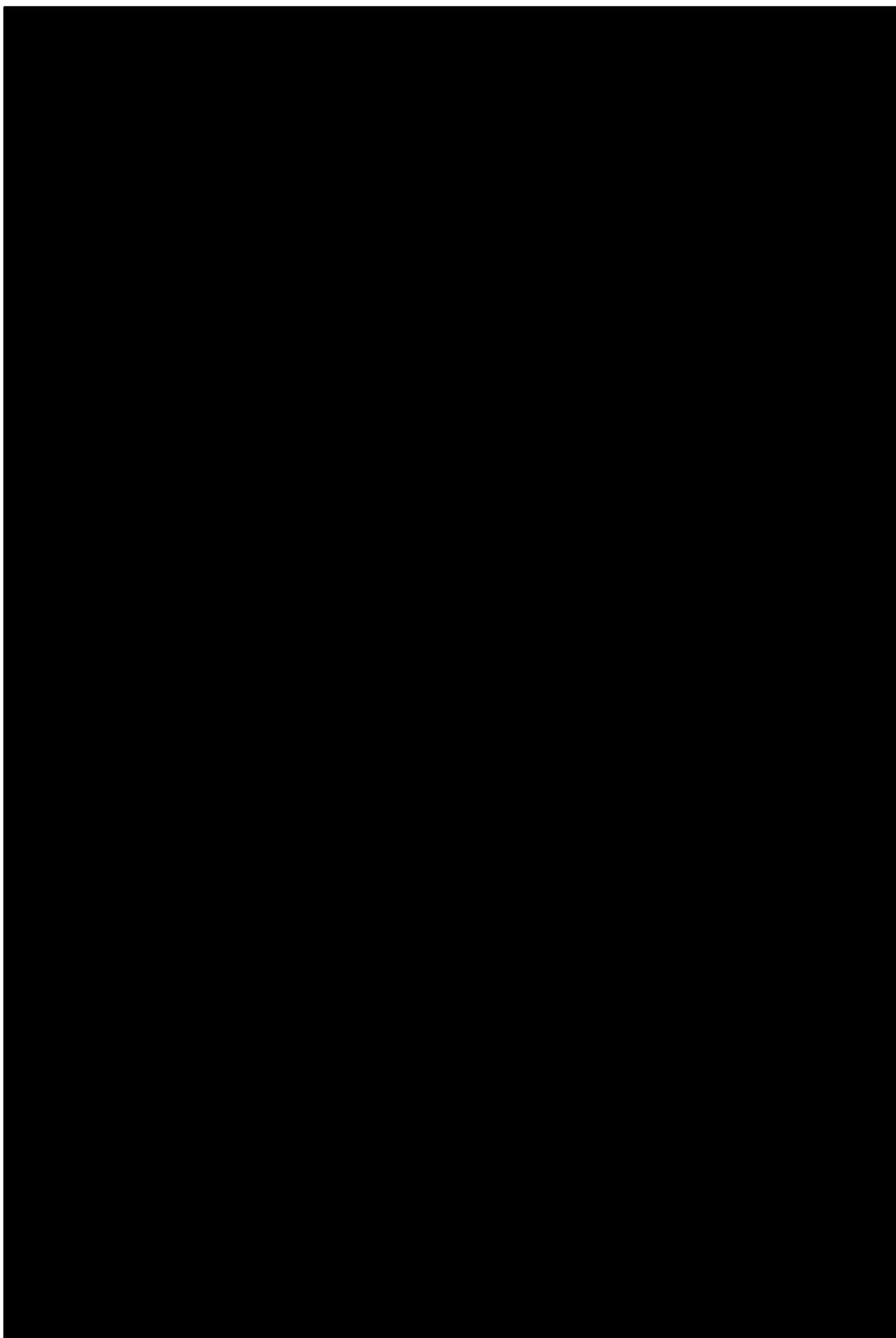


4.9 ESKA Bionik Resurfacing Femoral Head when used in conjunction with the Bionik Acetabular Component

- 4.9.1 Members noted that this implant it as a resurfacing device where only 175 were implanted. 6 out of the 9 revisions were for Femoral and Acetabular, and 3 revisions were for Acetabular only.
- 4.9.2 Members discussed the metal-on-metal bearing options and the expertise of surgeons using these prostheses. Members agreed that the Company's response was inadequate and requested that the TGA raise concerns about the data provided with the Company.
- 4.9.3 The TGA drew the members' attention to the summary of the Company's response. In its summary the Sponsor asserts that none of the revisions reported in the NJRR against the Bionik implant are related to the design of the implant. ESKA has also provided papers and citations as evidence of implant performance elsewhere in the world, but the revision rates reported in the literature provided appears to be higher – sometimes much higher than the revision rate reported by the NJRR for this implant.
- 4.9.4 The TGA asked the Working group to comment on the observation made in one of the papers supplied by the Company – neck shaft angles must be greater than 130° - Whether this affects all similar implants and whether this is commonly known in the orthopaedics field. A member confirmed the importance of the neck shaft angle and that this is commonly known. However, in this case the design of the femoral head does not lend itself to ease of use and the stem is noticeable smaller in diameter and therefore more difficult to seat with accurate alignment. This fact in combination with the implants being metal on metal is a cause for concern.

Advice: For the reasons outlined above, the Working Group advised that the use of the ESKA Bionik Resurfacing Femoral Head when used in conjunction with the Bionik Acetabular Component is of concern. Consideration should be given to the discontinuation of this implant combination.





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