

Correspondence

Boneloc[®] cement

Sir—In a well-informed Editorial (“Boneloc[®]—the Christiansen experience revisited” *Acta Orthop Scand* 1995; 66: 205–206), Lars Linder describes the poor performance of the new bone cement, Boneloc[®]. In the “1992 Annual Report” for its shareholders, the Biomet Inc. Company announces, among the new products to be introduced on the international market, a “Boneloc[®] Bone Cement Delivery System”.

I believe that it is very important for the readers of *Acta* to know whether the Boneloc[®] bone cement, marketed in Scandinavia, is in any way associated, or even identical, with the product of the Biomet Inc. Company. This assurance is necessary to either confirm or dispel suspicions, occasionally expressed, that some American companies use the Scandinavian countries, with their excellent National Registers, as a testing ground for their products, before submitting them for approval by the FDA.

This raises another important and unpleasant question: who will compensate the patients operated on with this clearly experimental device when it fails?

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Sir—In response to your request, I welcome this opportunity to provide some comments on behalf of Biomet, which I hope will be useful.

Boneloc[®] bone cement was manufactured by Polymers Reconstructive A/S (Farum, Denmark) and distributed by Biomet Ltd. or Biomet, Inc. in countries outside of Scandinavia. In September 1990, Biomet Inc. applied for an Investigational Device Exemption (IDE) in order to obtain approval to conduct an application in the USA. Other independent distributors began distributing Boneloc[®] in Scandinavia. The FDA application, which included biological, chemical and physical testing, was approved by the FDA. A clinical trial was initiated in the USA and continues to be monitored by Biomet, Inc. To date, there have been 3 reported revisions out of 149 cases.

It is Biomet's policy to seek and obtain the appropriate approvals before distributing products in any country. Biomet does not consider the Scandinavian implant registries a “test field” for products manufactured or distributed by the Company.

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