

Melbourne Orthopaedic Group

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Monday 8th October, 2007-10-08

RD/jw

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Mr Namal Nawana General Manager Johnson and Johnson Medical Pty Ltd. 20-24 Howleys Road Notting Hill Vic 3168

Dear Mr Nawana

I was simply appalled by your most recent communication from De Puy and signed by Arron Maree. Twelve months ago I indicated to you that the ASR was a flawed prosthesis and should be withdrawn from the market, only to be re-assured that "internal communication had demonstrated superior results". To imply that sub optional patient selection and surgical technique have contributed to the premature failure is absurd. This is a standard technique of companies to offset their responsibilities.

Prior to doing the ASR hip resurfacing I had performed probably 600 or more Birmingham hip resurfacings with none of the problems that I encountered with the ASR. X-rays were taken in the recovery room following my ASR implantations and your so called requirements were more than appropriately met. (Your representative Mr Chris Reece was privy to all these cases)

What your company appears to misunderstand is the patient grief that occurs with an imperfect implant released prematurely onto an unsuspecting orthopaedic user group. When Jonathan Lettin and I spoke some three years ago, he said that he would not let me down if I started to use Johnson and Johnson products. You in your position as General Manager can be the judge as to whether your company has succeeded. I have no wish to sign your facsimile alerting me to the safety alert notification.

The PFC Sigma RP high flexion is an untried prosthesis, although it does come from a superior performing implant. When I attempted to communicate with the product manager regarding aspects of post operative management, the subsequent email was both arrogant and most importantly ignorant of the questions that I asked. I have

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probably performed more mobile bearing knee replacements that Dr Ranawat would ever perform as he is a relatively new person to this area of knee implant surgery.

The manner of some of your sales staff in leaving the operating theatre prematurely, distinguishes them as being sales people with no more interest in the case other than "another sale knocked up".

The release of the computer guidance for ASR resurfacing was flawed as judged by myself working on this program at your offices. This is still being released with unknown consequences. Whist allowances can be made, it delivers in an imperfect way to the unsuspecting orthopaedic user group.

A recent meeting in New Zealand of the LCS knee replacement system was recorded and I received a copy of the subsequent DVD. These are of a very low standard, given the current level of DVD production of open meetings such as this. I hope that this DVD is not released to the general orthopaedic audience.

The Hylamer polyethylene was released by Johnson and Johnson and had a premature failure in the shoulder associated with its use as a glenoid implant. I stopped using this implant on the advice of friends in America and know that the implant was still being sold in Australia when it had been withdrawn in America.

The current C stem is an experimental prosthesis where changes have been made. Should I remind you of the problems with the Elite prosthesis where changes were made to the Charnley stem resulting in change to mechanics involving premature failure of the stem.

All of the above would make interesting reading in the contemporary press and I am so cross with both you and your company that this thought occurs to me. I will inform you of my decision prior to releasing this information.

Rod Dalziel F.R.A.C.S.