From:

To:

Graham [DPYGB] Valentina [DPYIT] Magnus [DPYGB]

CC: Sent:

12/22/2006 12:38:10 PM

Subject:

RE: ASR LX / message from Olimpia

Dear Valentina,

Will review when it comes into the complaints system. Two points to note, high implant angle and used with a competitor stem.

Regards

Graham

---Original Message---From: Valentina [DPYIT] Sent: 22 December 2006 09:15 ham [DPYGB Davide [CRDIT] DPYIT]

Subject: ASR LX / message from Olimpia

Importance: High

Dear Graham

following our telephone conversation, let me summarise as follows:

hospital

: policlinico

surgeon

: Dr Filippo

- case

: Ix head implanted with Link stem (I have checked, on IFU is indicated to use only with DePuy stem;

on brochures I have checked this restricction is not indicated)

: the patient was revised around 1 year from surgery

: stem was mobilized

: by indication of the cup was placed vertically

: the levels of cr-co in the blood was too high

explant

: given to us for examination

(He also reports on other 2 cases under observation, again asr lx with link stem, cup well positioned, cup well positioned,

but levels or co are very high)

I asked him for further details (date of implant, date of revision, general clinical info on patient, copies of xrays to issue

a complaint form based on which I could then send explant for analyses.

does not wish to give us the requested info before we analyse the product, he requests "quality quantity analyses"

Therefore we shall enter a complaint with only data we have

Dear Davide



DEPUY000124078



can you please urgently enter in ETQ the complaint with the information we have;

we are sending to you the explant, so you can deliver it as indicated by product complaint dept

Many thanks and best wishes olimpia

Walentina Business Development Assistant

IDePuy divisione di Johnson&Johnson Medical Spa

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