

From: [REDACTED] Annemiek [MEDNL]
To: [REDACTED] Bridget [JNJIE]; [REDACTED] Magnus [DPYGB]
Sent: 6/28/2006 9:02:57 AM
Subject: ASR --> problem with ASR-study!

Dear both,

We experienced a little surprise with our ASR Steering Committee meeting yesterday..

As you know, dr. [REDACTED] has suffered some problems with the ASR lately. He has reported his problems with moving cups, as was discussed with Magnus. Although he seemed satisfied with the discussion, he is still convinced that two moving cups are not explained what happened and that this might be an ASR-problem more then caused by his own surgical technique. The third was sent to Magnus on which he is awaiting the results of research on that cup. Recently, dr. [REDACTED] saw two patients in his practice with heavy pain complaints (ASR was placed one year ago). He did not see any significant problem that might have caused these problems. What he did see is high concentrations of metal ion-levels in the blood. I contacted Magnus and asked dr. [REDACTED] to send all relevant information, so that is running.

However, yesterday dr. [REDACTED] made an official statement during the meeting for the ASR-study. He declared that with his experience with BHR and ASR, his results show a significance in failure rate for ASR. Also he discussed his problems and mentioned the last two patients. Then he mentioned that so far he will NOT use ASR anymore for this reason. He is awaiting the results from DePuy and needs a reassuring proof, before he will start again. This is our key opinion leader in the Netherlands, responsible for 100 ASR's per year. We suspect that Finsbury with ADEPT hip (via Oudshoorn distributor) is trying to get [REDACTED] as KOL, so we know there are commercial/financial issues playing on a personal level with dr. [REDACTED]. However, this is a huge problem for us, as all other ASR users will listen to dr. [REDACTED].

My request to you is as follows:

- Could you please help me in writing a sound statement that what dr. [REDACTED] is experiencing is NOT what we see globally?
- Could you advise me in using the correct literature (publications in journals) to provide reassurance to our other ASR-users?
- Could you please advise me in what strategy is best to follow here? (we need our reps to discuss with the doctors, provide an official DePuy statement and provide them with written proof of the ASR-success; what else can I do?)

Thanks in advance and looking forward to discuss this with you!

Regards,
Annemiek

-----Original Message-----

From: [REDACTED] Bridget [JNJIE]
Sent: dinsdag 27 juni 2006 12:55
To: [REDACTED], Annemiek [MEDNL]
Subject: RE: Literature



Hi Annemeik,

The "Proceedings of the Inst. of Med Engineers; Part H: Journal of Engineering in Medicine; 220 no 2", is very powerful and although our customers do not subscribe to this it would be of benefit to present a Clinical Matrix with the abstracts from all of the articles quoted by Magnus.

I have attached some papers that I have copies of but as you know due to copyright laws we cannot distribute these without paying the publishers,

Thanks,
Bridget.

<< File: Morlock et al. IMECHE 2006.pdf >> << File: [REDACTED] Index.pdf >> << File: Lessons learned from

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early clinical experience and.pdf >>

—Original Message—

From: [REDACTED] Annemiek [MEDNL]
Sent: 27 June 2006 09:20
To: [REDACTED] Bridget [JNIE]
Cc: [REDACTED] Magnus [DPYGB]
Subject: Literature

Hi Bridget,

Can you please help me?

I am looking for the most relevant literature publications on ASR, or resurfacing in general since January this year. I would like to get some more attention for ASR on our current users joining the ASR-study and would like to inform our non-users on the current status on ASR/resurfacing.

Also, we would like to include information on the cup migration. This is becoming a huge rumour in the field, because of our competitors activities. I will use the two articles that Magnus has sent to me, but would also prefer to use some data from clinical relevant journals, instead of only an engineering reference (maybe from Dr. [REDACTED]).

We will ask a journalist to write a review on these articles and distribute this with an ASR look-and-feel on print.

Second: could you advise whether or not you have reprints available from the following proceedings: "Proceedings of the Inst. of Med Engineers; Part H: Journal of Engineering in Medicine; 220 no 2", or is this publication too much engineering-related for our clients?

Thanks a lot for the advice!

Regards,

Annemiek

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