

From: [REDACTED] Nicola [DPYGB]
To: [REDACTED] Sally [DPYGB]
Sent: 6/4/2008 8:25:06 AM
Subject: FW: BIG ASR Design Change
Attachments: ASR review.ppt

I agree with Mary.....this is massive.

I plan to take Andrew along for training purposes and with a view that he can share some of the fallout. Hope this is ok.

Thanks,

Nicola

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

From: [REDACTED] t, Mary [DPYGB]
Sent: 04 June 2008 08:51
To: [REDACTED], Alistair [DPYGB]; [REDACTED] Tony [DPYGB]; [REDACTED] Kathy [DPYUS]; [REDACTED] Michael [DPYUS]; [REDACTED] Polly [DPYUS]; [REDACTED] n, James [DPYGB]; [REDACTED] Richard [DPYGB]; [REDACTED] t, Philip [DPYGB]; [REDACTED] Nicola [DPYGB]; [REDACTED] Paul [DPYGB]; [REDACTED] Nick [DPYGB]; [REDACTED] George [DPYGB]; [REDACTED] Lindsay [DPYGB]; [REDACTED] Amy [DPYUS]; [REDACTED] Bernard [DPYUS]; [REDACTED] Bernice [DPYUS]; [REDACTED] Lawrence [DPYUS]; [REDACTED] [DPYGB]; [REDACTED] Janice [DPYGB]
Cc: [REDACTED] Neville [DPYGB]
Subject: ASR II PCT meetings - Tues 3pm (int) or 10 am Warsaw

Hi,

We are looking to change the ASR cup design. ASR was launched in International late 2003. The WW bearings team have defined a need to update the cup design based on clinical literature and changes in the international market. I have pulled together a summary of the aims of the project ahead of the PCT meeting on Tuesday 10 June. The ASR brand is currently about \$80m WW and should be well over \$100m in 2009 with the US launch of resurfacing.

This is a massive project - particularly if the up graded design needs to be swapped with the current cup. We have about 1500 instruments sets WW with implant inventory to match. In the US this is a PMA product. As a PCT we have to lead this decision process and financial implications.

One goal is to add gription (remove HA), PSM technology (reduce ion release) and increase the bearing surface. As yet we have not defined if we want to repeat the ASR clinical trials.

I would like to present PACE gate 1 on the 9th July at the PACE review as I think this will help define many aspects of the project. Particularly around US/Int launch plans and inventory management plans. The file is in agile PACE-100385. If we need money to support write off we need to have ball park figures for this meeting.

As the June PACE review was cancelled due to the 'needs based assessment requirements' we have circulated the scorecard to the WW team.

Bryan Overbury will be the project manager from 1st July.

I appreciate your support in assessing and implimenting this challenging, but, exciting projected aimed at maintaining our position leaders in high performance bearings.

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Please call/contact me if you have any questions.

Best wishes,

Mary

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[REDACTED]



ASR cup II

ASR cup II

Next generation ASR cup


Release: 5 years post ASR launch

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Cup positioning - issues

- All large head MOM manufactures are now recommending cup position of between 35-45 deg. Some KOLs even recommend revision if post operative x-ray is >55deg.
 - High inclination causes high wear
 - Effect of anteversion is beginning to be seen
 - Patient tolerance varies
 - Sensitivity
 - Joint tension
 - Femoral position
- Some clinical issues
 - Tissue masses
 - Groin pain/ anterior bulge of head Psoas tension or tissue reaction around psoas
 - Fluid in joint
 - Low cell count, cream fluid
 - Darker fluid causes necrosis

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up loosening?

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Cup design

- ASR best in class at 45deg
 - Lubrication combine with fixation
 - Low profile (lower ROM/risk of impingement)
- ASR is weaker where cup inclination is >55deg (~15% cases)
 - Mainly female
 - Mainly small sizes
- Modify the design to give 10deg more tolerance to inclination. This benefits all patients
 - Re-launch as ASR II



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Cup alignment system (for information only)

This is a separate project to address same issue

- Aim to address needs of the surgeon
- VOC to review where the surgeons are
 - What is important? What are you satisfied with?
 - Expect 3 areas – reaming, alignment, insertion
 - Address – what is the target?
- Aim to reduce the number of cups that are inserted at inclination >55deg
 - To be used with all bearings - MOPe, MOM, COM, COPE, COC



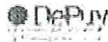
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ASR Prioritization (defined by WW bearing team).
We need to deliver area in black.

Phase 1 ASR Upgrade 2009:

- Cup redesign – Remove locking channel/increase bearing surface, add Gription (no HA), PSM treatment (cleaning process?).
- Relaunch new ASR story (timing TBD)



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Design/operations

- New cup – Leeds design and expected Leeds manufacture (TBC by S. Corbett)
- Cup positioning instruments – Leeds design and external purchase (TBC by GSC)
- Cup introducer – France design and external purchase (TBC by GSC)



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Cost

		cost make	US	Int	Warehouse	total sets	USD \$k	
999800073	ASR ACET IMPACTOR & TRL	£297.35	400	1000	2	1403	\$879	2.11 exchange rate
ASR0002	ASR Ace Imp. Holder Kit (8mm)	\$1,045.00	400	1000	62	1462	\$1,528	
ASR0004	ASR Ace Imp. Holder Kit (Med)	\$1,828.75	400	1000	79	1479	\$2,705	
ASR0005	ASR Ace Imp. Holder Kit (Lg)	\$783.75		800	215	1015	\$790	guess
E11111312	ASR XL curved cup impactor	\$1500?						
Total \$k								

300 data check Sept checked

Implants		ICP USA (USD)	ICP UK (GBP)	US	Int	Warehouse	USD \$k	
10 sizes	10 sizes	1324.55	892.75	400	1000	40	\$9,806	2.11 exchange rate
4 sizes	4 sizes	1324.55	892.75		800	40	\$1,702	guess
Total \$k								
30% write off		4 large sizes particularly						

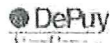
- Implant value confirmed by GSC
- Instrument numbers confirmed by N. Wilcoxon/L. Horner
- Instruments would have to be replaced with new design
- ASR 300/US resurfacing/ASR plus not included in costs
 - 600 sets (\$5M, \$1.5M write off)
- Cups HA coated – cost incurred to strip HA and recoat under new part number.
- 11.3rad inc std cost. Could be like aspheric heads.
- 0.7 rad – std cost

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Who authorises spend?

PCT aims

- SC – circulated in absence of PACE 3 June
- Gate 1 – 8th July 08 – PACE- 100385
 - This should set
 - Regulatory implications (MOM, gription, PSM)
 - Class III (int)
 - Cups for XL heads – class III 510k - US
 - Cups for resurfacing – PMA - US
 - Costs – as yet no one has defined who pays?
 - Start to define exchange program
 - Patent clearance
 - Reimbursement – should be unchanged.
- Please start to complete the templates



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