MEMORANDUM

Wright Medical Technology, Inc.
5677 Airline Road Arlington, TN 38002
www.wmt.com

Date: 8 November 2013

To: Jeremy Powell, Project Manager, NICE

From: [redacted] Post-Market Surveillance Engineering Manager, Wright Medical

Re: Comments on Appraisal Consultation Document (ACD)

Dear Mr. Powell,

Below you will find Wright Medical Technology's comments on the ACD related to the Multiple Technology Appraisal of total hip replacement and resurfacing arthroplasty for the treatment of pain or disability resulting from end stage arthritis of the hip (Review of technology appraisal guidance 2 and 44).

Regards,

[redacted]

[redacted] | Post-Market Surveillance Engineering Manager
Wright Medical Technology, Inc. | Clinical Affairs
Office: 901.867.4148 | Fax: 901.867.4190
[redacted]
www.wmt.com | ***Create Motion.®***

Wright Medical's Comments on the Appraisal Consultation Document

The "Appraisal consultation document – Arthritis of the hip (end-stage) hip replacement (total and resurfacing arthroplasty (Rev TA2, TA 44)," released in October 2013, posed the following questions to consultees:

1) Has all of the relevant evidence been taken into account?

2) Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

3) Are the provisional recommendations sound and a suitable basis for guidance to the NHS?

Wright Medical's response:

1) Has all of the relevant evidence been taken into account?

It appears that key pieces of clinical evidence for Wright Medical's CONSERVE® Plus resurfacing device, PROFEMUR® and ANCA-FIT™ total hip Arthroplasty (THA) devices were not considered. Please refer to the "Clinical Results" section below.

2) Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

Refer to the "Clinical Results" section below.

3) Are the provisional recommendations sound and a suitable basis for guidance to the NHS?

One of the preliminary recommendations reported in the ACD is that THA and resurfacing are recommended if the devices have an established 95% survivorship at 10 years follow-up. This value may not be appropriate in all clinical studies or patient populations, as a variety of non-device related factors can affect survivorship. These factors include infection, improper patient selection, surgical technique, brand mismatch, patient compliance, contraindications, etc. Furthermore, it remains unclear whether 95% survivorship applies to all evidence, taken as an average or can be applied selectively to specific pieces of evidence.

Clinical Results

Clinical Results for CONSERVE® PLUS Resurfacing:

The published survivorship data for the CONSERVE® PLUS resurfacing device is summarized in Table 1 below. The values highlighted in bold fall beneath the NICE benchmark of 90% survivorship at 10 years follow-up.

Table 1: CONSERVE® PLUS resurfacing survivorship

Device	Study	Reported Patient Follow-Up					
		3-Yr	3.5-Yr	5-Yr	7-Yr	8-Yr	10-Yr
CONSERVE® Plus (First 100 resurfacings)	Amstutz et al. [1]			93.9%			**88.5%**
CONSERVE® Plus (ideal patients)	Amstutz et al. [2]					99.7%	99.7%
CONSERVE® Plus (risk factor patients)	Amstutz et al. [2]					91.7%	**84.8%**
CONSERVE® Plus (one-stage bilateral patients)	Amstutz et al. [3]					83.1%	
CONSERVE® Plus (two-stage bilateral patients)	Amstutz et al. [3]					97.0%	
CONSERVE® Plus (acetabular only)	Hulst et al. [4]			99.6%			98.3%
CONSERVE® Plus (Osteonecrosis patients)	Amstutz et al. [5]	97.5%		95.7%		93.9%	
CONSERVE® Plus (Non-Osteonecrosis patients)	Amstutz et al. [5]	98.4%		95.4%		93.4%	
CONSERVE® Plus (Male Patients)	Amstutz et al. [6]			96.5%			
CONSERVE® Plus (Female Patients)	Amstutz et al. [6]			93.2%			
CONSERVE® Plus	Langton et al. [7]			99.6%			
CONSERVE® Plus + Corin Cormet	Sayeed et al. [8]				100%		
CONSERVE® Plus (IDE study results)	Amstutz et al. [9]			95.2%			
CONSERVE® Plus	Vail et al. [10]	96.5%					
CONSERVE® Plus (First 400 resurfacings)	Amstutz et al. [11]		96.75%				

Two studies presented survivorship values less than 90% at 10 years follow-up. Amstutz et al. reported 88.5% survival for their first 100 CONSERVE® Plus resurfacings [1]. It should be noted that these patients were implanted during the surgeon's "learning curve" phase and prior to the creation of the strict patient selection criteria now used for resurfacing. Additionally, the 88.5% survival at 10 years is greater than the survivorship reported for all hip resurfacings in the 10th Annual Report of the National Joint Registry of England and Wales (NJR) [12]. The second study with survivorship less than 90% at 10 years follow-up was also published by Amstutz et al. [2]. The patients in this study were considered "risk factor" patients as they had small femoral head sizes (<46 mm) and femoral head defects greater than 1 cm. The authors described ideal patients as having femoral heads greater than 46 mm and femoral head defects less than 1 cm.

Clinical Results for Wright Total Hip Arthroplasty (Mid to Long-Term Follow-Up)

The published mid to long-term survivorship data for the PROFEMUR® and ANCA-FIT™ total hip THA devices is summarized in Table 2 below.

Table 2: PROFEMUR® and ANCA-FIT™ THA survivorship

Device (Manufacturer)	Study	Type(Follow-Up)[a]	Any[b]	Mod Neck[c]	Aseptic stem loosening[d]	Stem Revision[e]
PROFEMUR® R (WMT)	Sakai et al. [13]	Cuml[f](14.5)	100%	100%	-	-
ANCA-FIT™ (WMT)	Traina et al. [14]	KM[g] (11)	-	96.80%	-	96.80%
ANCA-FIT™ (WMT)	Traina et al. [15]	KM[g] (11)	97.5%	-	-	-
PROFEMUR® R (WMT)	Koster et al. [16]	KM[g] (10)	93.90%	-	95.90%	-
PROFEMUR® E/E+ (WMT)	Omlor et al. [17]	KM[g] (10)	94%	99%	-	100%
PROFEMUR® R (WMT)	Koster et al. [18]	KM[g] (9)	94.30%	-	95.60%	-
ANCA-FIT™ (WMT)	Traina et al. [19]	KM[g] (9)	95.7% (HHCR) 100% (ACR)	-	-	-
ANCA-FIT™ & Apta (WMT & Adler Ortho)	Traina et al. [20]	KM[g] (9)	-	-	96.80%	-
ANCA-FIT™ (WMT)	Traina et al. [21]	KM[g] (8)	-	-	-	97.50%
PROFEMUR® R (WMT)	Artiaco et al. [22]	KM[g] (7)	-	-	-	96.60%
ANCA-FIT™ (WMT)	Antonietti et al. [23]	KM[g] (5)	98.60%	-	-	-
ANCA-FIT™ (WMT)	Blakey et al. [24]	KM[g] (5)	97.50%	-	99%	-

a. 'Type(Follow-Up)': description of survivorship calculation used & the respective follow-up time
b. 'Any' refers to the endpoint of any hip revision
c. 'Mod Neck' refers to the endpoint of revised for modular neck related reasons
d. 'Aseptic stem loosening' refers to the endpoint of revised for aseptic stem loosening
e. 'Stem Revision' refers to the endpoint of revised for stem stem related reasons
f. 'Cuml' refers to a cumulative survivorship calculation (1 minus revision rate)
g. 'KM' refers to the Kaplan-Meier method for survivorship calculation

References

[1] Lavigne, T., et al., *The John Charnley Award: The functional outcome of hip resurfacing and large-head THA is the same: a randomized, double-blind study.* Clin Orthop Relat Res, vol. 468, pp.326-36, 2010.
[2] Vendittoli, P.A., et al., *A prospective randomized clinical trial comparing metal-on-metal total hip arthroplasty and metal-on-metal total hip resurfacing in patients less than 65 years old.* Hip Int, vol. 16 Suppl 4, pp.73-81, 2006.
[3] Amstutz, H.C., et al., *The effect of patient selection and surgical technique on the results of Conserve(R) Plus hip resurfacing--3.5- to 14-year follow-up.* Orthop Clin North Am, vol. 42, pp. 133-42, vii, Apr 2011.
[4] Amstutz, H.C., et al., *Are There Benefits to One- versus Two-stage Procedures in Bilateral Hip Resurfacing?* Clin Orthop Relat Res, vol. 469, pp. 1627-34, Jun 2011.
[5] Hulst, J.B., et al., *Survivorship of Conserve(R) Plus monoblock metal-on-metal hip resurfacing sockets: radiographic midterm results of 580 patients.* Orthop Clin North Am, vol. 42, pp. 153-9, vii, Apr 2011.
[6] Amstutz H.C. and M. J. Le Duff, *Hip resurfacing results for osteonecrosis are as good as for other etiologies at 2 to 12 years.* Clin Orthop Relat Res, vol. 468, pp. 375-81, Feb 2010.
[7] Amstutz, H.C., et al., *Sex as a patient selection criterion for metal-on-metal hip resurfacing arthroplasty.* J Arthroplasty, vol. 26, pp. 198-208, Feb 2011.
[8] Langton, D.J., et al., "Adverse reaction to metal debris following hip resurfacing: the influence of component type, orientation and volumetric wear," J Bone Joint Surg Br, vol. 93, pp. 164-71, Feb 2011.
[9] Sayeed, S. A., et al., *Hip Resurfacing in Patients Who Have Osteonecrosis and are 25 Years or Under.* Clin Orthop Relat Res, vol. 469, pp. 1582-8, Jun 2011.
[10] H Amstutz H.C. and M. J. Le Duff, *Eleven Years of Experience With Metal-on-Metal Hybrid Hip Resurfacing: A Review of 1000 Conserve Plus.* J Arthroplasty, vol. 23 (6 Suppl 1), pp. 36-43, 2008.
[11] Amstutz, H.C., et al., *Socket Position Determines Hip Resurfacing 10-Year Survivorship.* Clin Orthop Relat Res, Apr 18 2012
[12] 10th Annual Report of the National Joint Registry of England and Wales (NJR)
[13] Sakai, T., et al., *A modular femoral neck and head system works well in cementless total hip replacement for patients with developmental dysplasia of the hip.* J Bone Joint Surg Br, 2010. 92(6): p. 770-6.
[14] Traina, F., et al., *Sex differences in hip morphology: is stem modularity effective for total hip replacement?* J Bone Joint Surg Am, 2009. 91 Suppl 6: p. 121-8.
[15] Traina, F., et al., *Modular neck prostheses in DDH patients: 11-year results.* J Orthop Sci, 2011. 16(1): p. 14-20.
[16] Koster, G. and T.A. Walde, *[Revision arthroplasty of the hip: modularity of neck and metaphyseal components].* Orthopade, 2009. 38(3): p. 238-47.
[17] Omlor, G.W., et al., *A stature-specific concept for uncemented, primary total hip arthroplasty.* Acta Orthop, 2010. 81(1): p. 126-33.
[18] Koster, G., T.A. Walde, and H.G. Willert, *Five- to 10-year results using a noncemented modular revision stem without bone grafting.* J Arthroplasty, 2008. 23(7): p. 964-70.
[19] Traina, F., et al., *The influence of the centre of rotation on implant survival using a modular stem hip prosthesis.* Int Orthop, 2009. 33(6): p. 1513-8.
[20] Traina, F., et al., *Outcomes of total hip replacement in patients with slipped capital femoral epiphysis.* Arch Orthop Trauma Surg, 2012.
[21] Traina, F., Baleani, M., Viceconti, M., Toni, A. *Modular neck primary prosthesis: experimental and clinical outcome.* in *71st AAOS Annual Meeting*. 2004. San Francisco.
[22] Artiaco, S., et al., *Clinical experience in femoral revision with the modular Profemur R stem.* Hip Int, 2011. 21(1): p. 39-42.
[23] Antonietti, B., et al., *Anatomic cementless total hip arthroplasty with ceramic bearings and modular necks: 3 to 5 years follow-up.* Chir Organi Mov, 2003. 88(3): p. 259-65.
[24] Blakey, C.M., et al., *Mid-term results of the modular ANCA-Fit femoral component in total hip replacement.* J Bone Joint Surg Br, 2009. 91(12): p. 1561-5.