

From: [REDACTED]
To: [REDACTED]
Subject: RE: BHR Joint applications- MRI safety information [SEC=UNCLASSIFIED]
Date: Wednesday, 13 April 2016 10:58:46 AM
Attachments: [image003.png](#)
[image004.png](#)
[image005.png](#)

Dear [REDACTED]

I can confirm that the manufacturer has indicated that it has no immediate plan to add the conditional MR symbol to the label for the reason stated.

Regards

[REDACTED]

From: [REDACTED]
Sent: Wednesday, 13 April 2016 10:53 AM
To: [REDACTED]
Subject: RE: BHR Joint applications- MRI safety information [SEC=UNCLASSIFIED]

Dear [REDACTED]

Thanks for your email. Based on our phone conversation can you confirm that the manufacturer has no immediate plans to add the 'MR' symbol to the label as the current label includes the



'caution' symbol that directs the user to the IFU which contains extensive information on the use of the implant in the MR environment.

Kind Regards

[REDACTED]

From: [REDACTED]
Sent: Monday, 11 April 2016 9:04 AM
To: [REDACTED]
Subject: RE: BHR Joint applications- MRI safety information [SEC=UNCLASSIFIED]

Good morning [REDACTED]

Regrettably, no. I would suggest that you proceed on the basis which you outlined to me in our recent telephone conversation.

Kind regards

[REDACTED]

From: [REDACTED]
Sent: Friday, 8 April 2016 1:23 PM
To: [REDACTED]
Subject: RE: BHR Joint applications- MRI safety information [SEC=UNCLASSIFIED]

Hi [REDACTED]

Has there been progress on the MR labelling issue with the manufacturer ?

Thanks

[REDACTED]

From: [REDACTED]
Sent: Monday, 21 March 2016 5:14 PM
To: [REDACTED]
Subject: RE: BHR Joint applications- MRI safety information [SEC=UNCLASSIFIED]

Dear [REDACTED]

I have referred your enquiry below, to the manufacturer and shall revert to you upon receipt of a response.

In relation to the TGA's request to include a reference to "metal on metal" in the applications, I have today amended the Functional Descriptions as follows:

Acetabular Cup Changes

-

A sterile porous press-fit cobalt-chrome alloy (Co-Cr) hemispherical acetabular cup ~~intended to be used~~ in metal on metal articulation with a cemented femoral head component. The outer surface of the cup has a single layer of integrally-cast Co-Cr beads on the outer surface that are coated with hydroxyapatite (HA). The acetabular cup is supplied with a disposable polyethylene impactor cap wired to the cup with disposable introducer cables. ~~Following~~ After sequential reaming of the acetabulum, the cup is impacted into place.

Now:

A sterile porous press-fit cobalt-chrome alloy (Co-Cr) hemispherical acetabular cup used in metal on metal articulation with a cemented femoral head. The outer surface of the cup has a single layer of integrally-cast Co-Cr beads on the outer surface that are coated with hydroxyapatite (HA). The acetabular cup is supplied with a disposable polyethylene impactor cap wired to the cup with disposable introducer cables. After sequential reaming of the acetabulum, the cup is impacted into place.

Femoral Head Changes

-

A cemented sterile cobalt-chrome alloy (Co-Cr) stemmed femoral head resurfacing component ~~intended to be used~~ in metal on metal articulation with a cementless acetabular component. The femoral head central stem is parametric and varies proportionally with the external diameter. There are 6 equally spaced internal recesses intended to provide antirotational locking for the cement mantle. ~~Following~~ After resection of the femoral head and using low viscosity cement, the resurfacing component is impacted into place.

Now:

A cemented sterile cobalt-chrome alloy (Co-Cr) stemmed femoral head resurfacing component used in metal on metal articulation with a cementless acetabular component. The femoral head

central stem is parametric and varies proportionally with the external diameter. There are 6 equally spaced internal recesses intended to provide antirotational locking for the cement mantle. After resection of the femoral head and using low viscosity cement, the resurfacing component is impacted into place.

I have resubmitted both of the applications.

Kind regards



Regulatory Affairs Co-ordinator

Smith & Nephew Pty Ltd

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www.smith-nephew.com

From: [REDACTED]
Sent: Monday, 21 March 2016 1:50 PM
To: [REDACTED]
Subject: BHR Joint applications- MRI safety information [SEC=UNCLASSIFIED]

Dear [REDACTED]

I refer to the following joint applications:

- Application ID: DV-2014-DR-19876-1; Submission ID: DA-2015-02876-1; UPI: BIRMINGHAM HIP Resurfacing Femoral Head
- Application ID: DV-2015-DR-03198-1; Submission ID: DA-2015-02877-1; UPI: BIRMINGHAM HIP Resurfacing HAP Coated Acetabular Cup

As you are aware, following the review of the MRI safety data for the BHR devices, the TGA

clinical reviewer requested the inclusion of the  symbol on the label.

In your response of 14 January 2016, you have indicated that the MRI safety information is contained on a leaflet supplied with the device and there is insufficient space of the label to incorporate the information which needs to be imparted.

Based on your response can you clarify if the manufacturer does not intend to include the



symbol on the label.

Kind Regards

[REDACTED]

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