Report #	Initial Device Description	ARTG #	Date of Final Report	Clinical Event Information	Investigation Outcome	Model #	Serial #	Batch #	Lot #
19188	BHR Resurfacing Head, Size 50 - (mfr ref: W15317)	120078	23/2/09	Device implanted 02/05/2007. Patient presented with pain - diagnosed as subcapital fracture of the hip. Revision required. During this 12 month period patient also underwent hip replacement on opposite hip. Patient had resumed normal activity levels. The head linear wear is 2.70?m. The femoral component tested has an Ra of 0.014?m on the non-articulating surface. This is within specification limits for the femoral component. Similar events: The manufacturer is aware of 10 other revisions of item #74121150. Report sourced from sponsor.	Reviewed, for Trending Purposes Only				
19208	Birmingham Hip	120078	13/4/09	Patient had a Birmingham hip implanted in 2005 and had trouble from day one with pain and swelling. Patient's doctor kept reviewing her every 3 months on 'spec'. X-rays eventually showed lucency at the end of the barrel but Dr thought it was artefact and did nothing further. After one and a half years of pain, the patient was limping badly and had a 'knocking' in the hip. Dr finally ordered a CAT scan with metal suppression technology and the bone around the barrel had died. The patient was just lucky she did not fall over or the whole thing would have shattered. Dr put her on crutches and did a total hip replacement. Dr took the hip out and sent it to America to an Australian doctor who specialises in Birmingham hips. The Dr could not find the answer so sent it to the senior pathologist in America. Patient was told moths later by Dr that she was the first in the world to have this and it was caused by the Birmingham barrel design. Patient thinks that is what Dr said. Something to do with the barrel design. Patient just had a phone call from her sister. Sisters friend who had a Birmingham before her has been reviewed by his doctor every 6 months with x-rays. He had this one done and it shows the bone has died. His doctor told him that he was the first he had come across. Then why was he x-raying him? Please look into this urgently as the death of the bone can cause the bone and implant to break apart and it is hell to get the hip back together again. If the manufacturer knew about his then patient should have been told. Report sourced from patient.	Reviewed, for Trending Purposes Only				
19214	BHR Resurfacing Head (mfr# W15309)	120078	23/2/09	Device implanted 19/06/03. Revised 25/03/08 due to neck thinning and femoral loosening. Relevant medical history: AVN. The manufacturer has provided the following analysis: The maximum head linear wear is 76.78 Hm. This value is generally caused by wear, rather than manufacturing (<2 Hm). At 4 years 9 months in vivo, the linear wear rate is 16.16 Hm/year. The linear wear rate for the head is high compared to the results for previous BHR retrievals, which are in the region of 2 Hm/year. The measurements from the Coordinate Measuring Machine showed a femoral head diameter of 41.832 mm which is within specification as referenced from our product drawings. Ra is the mean departure of the profile from the reference line. The Ra must not exceed 0.05 Hm. The femoral component tested has an Ra of 0.014 Hm on the non-articulating surface. This is within the specification limits for the femoral component. The manufacturer is aware of 12 other revisions of item # 74121142. Report sourced from Sponsor.	Reviewed, for Trending Purposes Only	NA	23804		
24209	Hip Prosthesis (W16691)	120078	11/8/11	Implant Date:02/09/2008 Explant Date:02/08/2011 Following 2 years and 11 months in situ, patient underweight hip revision surgery due to pain, pseudotumor, femoral neck thinning and apparent raised cobalt ion levels. Device not returned for analysis. A review of the manufacturing records revealed no non-conformances related to the lot/batch or materials. List of other involved in the event: BHR Acetabular Cup, 74120158, 124099. Similar events: Out of 3139 BHR Resurfacing Femoral Heads implanted (74121138-74121158) since 2005 in Australia, the Sponsor is aware of 11 other similar events occurring since 2009. Report sourced from Sponsor.	Reviewed, for Trending Purposes Only	74121150	79149		

24225	BHR Resurfacing Femoral Head (mfr# W16541)	120078	10/8/11	Implant Date: 01/05/2007 Explant Date: 22/02/2011 Following 3 years and 9 months in situ, patient underwent hip revision surgery due to pain and loosening. The devices involved in this complaint have been returned and reviewed by the manufacturers Implant Developemnet Centre (IDC) in the UK. The wear patch of the acetabular cup is relatively large, extending from the bearing surface to the edge of the cup. The loosening of the cup may have contributed to the increase in size of the wear patch. Based on historic wear daa, after 3 to 4 years in vivo, the combined linear wear is expected to be in the region of around 10 - 11 um for a non-edge loaded BHR device. The maximum linear wear is: Head 13.36um; Cup - 3.36um (within the bearing surface). The devices appear to have experienced low wear. Radiographs showing the position of the components in vivo: Cup inclination = 33 degrees, Cup version = 8 degrees. The retrieval report and engineering review of the returned X-rays seems to indicate that the cup position for this case was outside of the desired parameters in the BHR surgical technique (15-20 degrees anteversion , 40-45 degrees inclination). It does appear that device orientation changes did occur, supported by the two wear patches observed on the acetabular cup and overall large wear patch on the acetabular cup. The wear report suggests that improper device loading may have existed, as supported by the secondary wear patch at the edge of the cup (possible edge-loading). In this case, it cannot be conclusively determined if the wear observed on the returned devices was the result of theimplanted condition, or a result of the loosening of the cup (possibly resulting in a changed device orientation). (See Diary)	Reviewed, for Trending Purposes Only			
24229	BHR Resurfacing Femoral Head (mfr# W16538)	120078	10/8/11	Implant Date: 01/05/2007 Explant Date: 22/02/2011 Following 3 years in situ, patient underwent hip revision surgery due to pain. The device involved in this complaint has been returned and reviewed by the manufacturers research department. The devices met manufacturing specifications. The components were visually inspected and fine scratches were observed on the bearing surfaces of the femoral head and the cup. These damages were most likely caused during revision surgery. The maximum linear wear is: Head 25.05um; Cup - 23.12um Combined 48.17um. wear of this device is high. Based on historic wear data, after 3 years in vivo, the combined linear wear is expected to be in the region of around 10um for a non-edge loaded BHR device. The position of wear on the acetabular cup shows that edge loading has occurred. This could have increased the wear for this device. Radiographs showing the position of the components in vivo: Cup inclination = 38.7 degrees, Cup version = 3 degrees. The underlying reason for revision was reported to be pain. The x-ray analysis references component positioning which is well outside the desired device orientation when compared with the BHR surgical technique. The BHR Surgical Technique/Important Medical Information indicates' Improper selection, placement, positioning and fixation of the implant components may result in early failure.' (See Diary)	Reviewed, for Trending Purposes Only	74123144	7893029		
24230	BHR Resurfacing Femoral Head	120078	12/8/11	Implant Date: 25/02/2009 Explant Date: 25/01/2011 Hip resurfacing following 2 years in situ for pain and patient discomfort. The devices returned and reviewed met manufacturing specifications. The wear noticed in the retrieval report is very unlikely to be related to any manufacturing involved process, but rather a factor of the patient's implanted condition or activity, and is slightly higher than the expected wear for well-oriented BHR devices for 2 years of implantation (for the larger femoral head wear patch and cup combination). The maximum linear wear is: Head 5.08um (Wear patch 1) and 7.97 um (Wear patch 2), Cup 3.52um. However, without further information from the reporter, we cannot determine with certainty the reason for the patient's secondary wear patch. The retrieval report and engineering review of the returned X-rays seem to indicate that the cup position for this case was slightly outside of the desired parameters in the BHR surgical technique (15-20 degrees anteversion, 40-45 degrees inclination). There were no abnormalities noticed during visual inspection or retrieval analysis by IDC. Additionally, this is the first complaint against both lots involved in this complaint. As such, there is no evidence to indicate that this is an on-going or repeat complaint against the device batches involved. Other Devices: BHR Acetabular Cup, 74122150, 124099 Similar Events: 3139 BHR Resurfacing Femoral Heads have been implanted (74121138-74121158) since 2005 in Australia. The sponsor is aware of 9 revisions due to pain as the primary indication since 2009. Report sourced from Sponsor	Reviewed, for Trending Purposes Only			

24444	Hip Prosthesis (Mfrs#W16588)	120078	1/9/11	Implant Date: 13/10/2006 Explant Date: 08/04/2011 Following 4.5 years in situ, patient had revision hip surgery due to loose femoral head. Wear analysis was performed using a Redlux 3D profiler. The maximum linear wear is: Head: 5.77 m (angle from pole: 35.5Â¿, arc length: 14.2 mm) The volumetric wear is: Head: 1.25 mm3 Based on historic wear data, after 4 to 5 years in vivo, the linear wear of a head is expected to be in the region of 6.71 to 7.59 m for a non-edge loaded BHR device (articulating within the bearing surface of the joint). Radiographs are showing the position of the components whilst in vivo. The date on which the radiograph was taken was the 7th April 2011. Cup version (radiographic) = 18Â¿ Cup inclination (radiographic) = 32 Â¿ The specified parameters in the BHR surgical technique are 15-20Â¿ anteversion and 40-45Â¿ inclination. Cup inclination in this case is outside specification. There were 3,149 BHR Resurfacing Femoral Heads (74121138-74121158) implanted since 2005 in Australia. The Sponsor is aware of 72 revisions for a varied range of reasons. Report sourced by Sponsor.	Reviewed, for Trending Purposes Only	74121146	N/K		
24532	Hip Prosthesis (mfr# W16718)	120078	14/9/11	Implant Date:N/K Explant Date:25/08/2011 According to the surgeon, the patient had apparently asymptomatic left BHR resurfacing. The patient suspected and worried that he had higher than average amounts of metal ions in blood maybe relating to the implant. The patients asked the doctor to revise the BHR device and insert the total hip instead. Explanted device appeared to be well vascularised with good boney ongrowth. Metal ion levels were noted as being normal. Further analysis not possible as the device was not returned. Patient outcome: N/K. Revised with another manufacturer's implant system. Similar events: The Sponsor is unaware of any other events where a resurfaced hip has been revised as a prophylactic measure. Report sourced from Sponsor.	Reviewed, for Trending Purposes Only	N/K	N/K		
24547	Birmingham Hip Prosthesis	120078	15/9/11	In April 2010, I received a Birmingham hip replacement. After visiting my Rheumatologist, on 16th March 2011 relating to my accelerated arthritis and chronic pain throughout my entire body, she recommended that I contacted my orthopaedic surgeon as she was concerned with my condition. At this time, accelerated levels of Cobalt were noted in my blood test. My Daughter/Carer returned from holidays and noted alarming deteriation in my general health. The doctor requested x-rays and blood tests. The result showed a Cobalt level 4 times the acceptable level. X-rays showed dark areas (worn) in the hip. In consultation with the doctor, I was booked in for a Revision on 4th April 2011. Immediately after this procedure I asked for the results. There was Puss everywhere and Metallic Debris. He assured me that they had spent considerable time removing all foreign matter. Due to unfavourable media reports on the Johnson & Johnson De Pys prosthesis, I asked my doctor about the Birmingham prosthesis. He assured me it was the Rolls Royce product and not to be compared to the Johnson & Johnson. I did not expect the Birmingham to fail after only 6 months, with having all the symptoms similar to the Johnson & Johnson. The revision has hopefully saved me from more serious consequences. The revision so far has been successful, with the exception of a dislocation 4 weeks after the operation. Most of the pain, sweats, exhaustion and tinnitus have diminished and I am hopeful for further improvement. However, unfortunately my blood count continues to drop and I am now anaemic. After the AMA approving the J & J and subsequent failings, do we now have a re-occurrence with the Birmingham. I do not understand how your deoartments with knowledge of the Johnson and Johnson fiasco, has not undertaken investigations on the Birmingham prosthesis. Report sourced from user.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	U/K	U/K		

24566	BHR Resurfacing Femoral Head - (mfr ref: C25946)	120078	19/9/11	Implant Date: N/K. Explant Date: 13/09/2011. Patient underwent hip revision surgery due to pain, femoral neck thinning, mass on ultrasound and apparent raised metal ion levels. Analysis results: The device not returned for analysis. Without the device, we are unable to confirm product numbers and batch numbers. The x-rays have been withheld at the request of the surgeon. Other devices involved: BHR Acetabular Cup, model - N/K, ARTG 124099. Similar events: Of 4489 BHR resurfacing procedures in Australia since 2005, 97 were revised for a wide range of reasons. Report sourced from sponsor.	Reviewed, for Trending Purposes Only				
24584	BHR Resurfacing Femoral Head - (mfr ref: W16708)	120078	23/9/11	Implant Date: Approx 9 years ago. Explant Date: 18/08/2011. Patient reported high cobalt and chromium metal ion blood levels, aching joints, headaches and lethargy. Also reported developing cold urticaria and tinnitus. In 2010, the patient reportedly underwent arthroscopic synovectomy to remove the abnormal tissue around the hip joint. Nearly 9 years post hip resurfacing, the patient underwent revision surgery to a ceramic-on-ceramic total hip replacement. The device was not returned to the manufacturer for analysis. The patient has elected to have the retrieved devices independently analyzed. Other devices involved: BHR Acetabular Cup, 74120144, 124099. Similar events: Of 3169 BHR resurfacing femoral heads (74121138-7412158) implanted in Australia since 2005, 72 were revised for a wide range of reasons. Report sourced from sponsor.	Reviewed, for Trending Purposes Only	74121138			
24586	Acetabular Cup HAP - (mfr ref: W16643)	124099	19/9/11	Implant Date: Feb 2006. Explant Date: June 2011. Following approximately 5.5 years in situ, patient underwent revision surgery. Patient dislocated hip 12 months prior to revision and has had pain since. Patient had personal delays to the revision surgery over this period. Surgeon believes there was a wear issue. In addition, stained bursa tissue was excised during revision. Report sourced from sponsor.	Reviewed, for Trending Purposes Only	74120150	50230		
24591	BHR Resurfacing Femoral Head - (mfr ref: W16684)	120078	21/9/11	Explant Date: 19/07/2011. Hip resurfacing revised following 5.5 years in situ for continued pain and apparent increased cobalt ion levels. At the time of surgery there was increased fluid and inflammatory tissue. Analysis results: The analysis of the explanted devices was limited due to only the femoral head being returned to the manufacturer. The acetabular cup was withheld by the surgeon. The analysis report describes the visual inspection and wear analysis results of a retrieved BHR femoral head. Wear analysis was performed using a Redlux 3D profiler. The maximum linear wear is: Head: 29.52 m (angle from pole: 26.82 Â¿, arc length from pole: 11.66 mm). The volumetric wear of the Head is: 11.16 mm3. Wear of this device is high. Based on historic wear data, after 5 to 6 years in vivo, the maximum linear wear is expected to be in the region of 9 to 10 m for a non-edge loaded BHR head (articulating within the bearing surface of the joint). Any potential for edge loading could not be determined without the acetabular cup. As the radiographs have been withheld by the surgeon, version and inclination for the device could not be determined. The femoral head returned and reviewed met manufacturing specifications. No quality, production or design failures have been noted in the investigation of this device. Other devices involved: BHR Acetabular Cup, Model 74120156, ARTG 124099. Similar events: Out of 3139 BHR Resurfacing Femoral Heads implanted (74121138 - 74121158) since 2005 in Australia, the Sponsor is aware of 9 other similar events occurring since 2009.	Reviewed, for Trending Purposes Only	74121150	51838		

24611	BHR Femoral Head (Mfrs#W16620)	120078	21/9/11	Explant Date: 18/05/2011 Following approximately 7 years in situ, patient underwent hip resurfacing revision surgery due to femoral neck fracture. The analysis report describes the visual inspection and wear analysis results of a retrieved BHR femoral head and acetabular cup. Wear analysis was performed using a Redlux 3D profiler. The maximum linear wear is: Head: 26.41 m (angle from pole: 36.7Â¿, arc length: 14.7 mm) Cup: 41.21 m Combined: 67.62 m The volumetric wear is: Head: 6.94 mm3 Cup: 1.89 mm3 Combined: 8.83 mm3 Wear of this device is high. Based on historic wear data, after 7 years in vivo, the combined linear wear is expected to be in the region of 16 m for a non-edge loaded BHR device (articulating within the bearing surface of the joint). The position of wear on the acetabular cup shows that edge loading has occurred. This could have caused the increased wear for this device. Radiographs show the position of the components whilst in vivo as: Cup inclination (radiographic) = 42Â¿ Cup version (radiographic) = 30Â¿ These measurements are outside of the desired device orientation when compared with the BHR surgical technique (specified as 15-20Â¿	Reviewed, for Trending Purposes Only	74122152	N/K		
24623	Hip Prosthesis (Mfrs#W16657)	120078	30/9/11	Explant Date: 26/06/2011 Following 2 years and 8 months in situ, patient underwent hip resurfacing revision surgery due to posterior buttock pain. The analysis report describes the visual inspection and wear analysis results of a retrieved BHR femoral head and acetabular cup. Wear analysis was performed using a Redlux 3D profiler. The maximum linear wear is: Head: 11.70 m (angle from pole: 36.69 Â¿, arc length from pole: 17.22 mm) Cup: 11.55 m Combined: 23.25 m The volumetric wear is: Head: 2.73 mmÂ¿ Cup: 0.98 mmÂ¿ Combined: 3.73 mmÂ¿ Wear of this device is high. Based on historic wear data, after 2 to 3 years in vivo, the combined linear wear is expected to be in the region of 9 to 11 m for a non) edge loaded BHR device (articulating within the bearing surface of the joint). The position of wear on the acetabular cup shows that edge loading has occurred. This could have caused the increased wear for this device. Radiographs showing the position of the components whilst in vivo show: Cup inclination (radiographic) = 43Â¿ Cup version (radiographic) = 2Â¿ The BHR surgical technique measurements specify desired device orientation as 15-20Â¿ anteversion and 40-45Â¿ was well outside the specified parameters. Mfr/Sponsor aware of other similar events: Of 3,169 BHR femoral heads (74121138 -74121158) implanted in Australia since 2005, 72 were revised for a wide range of reasons.	Reviewed, for Trending Purposes Only	74121154	51420		
24626	Hip Prosthesis (Mfrs#W16665)	124099	30/9/11	Implant Date: 16/07/2009 Explant Date: 05/07/2011 Following 2 years in situ, patient underwent revision surgery due to pain, mass on ultrasound and apparent elevated CoCr levels. Report sourced from Sponsor	Reviewed, for Trending Purposes Only	74122152	O7EW11827		

24650	Hip Prosthesis (mfr# W16638)	124100	19/9/11	Explant Date:30/05/2011 Primary hip replacement was revised after approximately 3 years in situ due to pseudotumor. The analysis report describes the visual inspection, wear analysis and scanning electron microscopic (SEM) examination results of a retrieved BHR femoral head and acetabular cup. Wear analysis was performed using a Redlux 3D profiler and a Talyrond 290 roundness machine. SEM examination was performed using a QUANTA 600 electron microscope. The maximum linear wear is: Head: 31.96 m (angle from pole: 34.5Â¿, arc length: 16.2 mm) Cup: 23.60 m Combined: 55.56 m The volumetric wear is: Head: 15.33 mmÂ¿ Cup: 3.91 mmÂ¿ Combined: 19.24 mmÂ¿ Wear of this device is high. Based on historic wear data, after 3 years in vivo, the combined linear wear is expected to be in the region of 11 m for a non;edge loaded BHR device (articulating within the bearing surface of the joint). The position of wear on the acetabular cup shows that edge loading has occurred. This could have caused the increased wear for this device. Linear wear profile for the sleeve of the femoral head is also shown. The measurement was taken 5 mm from the distal rim, where the maximum wear was 29.16 m. The position of the components whilst in vivo were: shown in Cup inclination (radiographic) = 56Â¿ Cup version (radiographic) = 11Â¿ The specified parameters in the BHR surgical technique are 15-20Â¿ anteversion and 40-45Â¿ inclination. (See Diary)	Reviewed, for Trending Purposes Only	74121254	50471		
24652	BHR Hip Prosthesis (mfr# W16582)	124099	19/9/11	Implant Date:20/04/2010 Explant Date:05/04/2011 Following 1 years in situ, patient underwent revision surgery due to groin pain and alleged elevated CoCr metal ion levels. Report sourced from Sponsor.	Reviewed, for Trending Purposes Only	74122150	08KW19377		
24661	Hip Prosthesis (mfr# C26654)	124100	12/10/11	Implant Date:13/02/2007 Explant Date:04/10/2011 Following approximately 4 years and 8 months in situ, patient underwent revision surgery due to mass on ultrasound and alleged elevated cobalt and chromium levels. The retrieved devices are to be analyzed by an independent laboratory at the surgeon's request. Results or devices may not be available to the manufacturer for further analysis. Radiographs have been withheld at the request of the surgeon. Primary hip replacement revision surgery performed to replace the acetabular cup and femoral head component. Femoral stem left in situ. Other devices: BHR Acetabular Cup, 74120158, 124099 Similar events: The Sponsor is aware of a total of 376 BHR Modular Heads (74121238-74121258) implanted in Australia, and 19 revisions occurring for a wide range of reasons. Report sourced from Sponsor.	Reviewed, for Trending Purposes Only	74121250	68228		

24754	Hip Prosthesis (Mfr# W16692)	124100	19/10/11	Implant Date: 22/11/2005 Explant Date: 09/08/2011 Following 5 years and 8 months in situ, patient underwent revision surgery due to pain, mass on ultrasound and alleged elevated cobalt levels. The report describes the visual inspection and wear analysis results of a retrieved BHR modular head and acetabular cup. Wear analysis was performed using a Redlux 3D profiler. The maximum linear wear is: Head: 14.20 m (angle from pole: 27.07Â¿, arc length from pole: 9.88 mm) Cup: deformed so wear measurement was unreliable The volumetric wear is: Head: 3.35 mmÂ¿ Cup: deformed so wear measurement was unreliable Based on historic wear data, after 5 to 6 years in vivo, the linear wear is expected to be in the region of 7 to 10 m for a non-edge loaded BHR head (articulating within the bearing surface of the joint). The roundness profile for the taper from the Talyrond Roundness Machine was taken at a depth of 10mm from the proximal taper rim. The maximum deviation of the roundness was measured to be 11.11 m which is within the manufacturing tolerance range. No radiographic analysis was possible as the X-rays were withheld by the surgeon. Inclination and anteversion of the implanted devices could not be confirmed. List of other devices involved in the event: BHR Acetabular Cup, 74120148, 124099. Similar events: The Sponsor is aware of 376 BHR Modular Heads (74121238-74121258) implanted in Australia since 2005, and 19 revisions occurring for varied reasons. This product range is no longer sold in Australia. Report sourced from Sponsor.	Reviewed, for Trending Purposes Only	74121242	50654		
24783	Hip Prosthesis (Mfr# W16672)	124099	26/10/11	Explant Date: 11/07/2011 Following 5 years and 10 months in situ, the patient needed revision surgery due to continued pain. It is understood from the surgeon that the acetabular cup was placed in a less than optimal position. In addition, the stem was placed in a less than optimal version. The patient began to experience pain in the affected side. The surgeon also noticed a fracture in the tip of the grater trochanter. The analysis report describes the visual inspection and wear analysis results of a retrieved BHR femoral head and acetabular cup. Wear analysis was performed using a Redlux 3D profiler and a Taylor Hobson Talyrond 290 Roundness Machine. The maximum linear wear is; Head: 175.59 m (angle from pole: 35.88Â¿, arc length from pole: 13.10mm) Cup: 412.90 m Combined: 588.49 m The volumetric wear is; Head: 89.62 mm3 Cup: 39.42 mm3 Combined: 129.04 mm3 Wear of this device is very high. Based on historic wear data, after 5 to 6 years in vivo, the combined linear wear is expected to be in the region of 15 to 17 m for a non-edge loaded BHR device (articulating within the bearing surface of the joint). The wear of this device was approximately 35 times higher than that generated by a non edge loaded BHR device. The position of wear on the acetabular cup shows that edge loading has occurred. This could have caused the increased wear for this device. The roundness profile of the taper of the femoral head is shown at 6 mm from the distal taper rim. The maximum deviation from the roundness profile was 4.68 m, which is within manufacturing tolerances. (See Diary)	Reviewed, for Trending Purposes Only	74120150	50230		

24784	Hip Prosthesis (Mfrs#W16679)	120078	26/10/11	Explant Date: 20/07/2011 Hip resurfacing revised following 7 years insitu due to pain and BHR head lossening. Minimal metal debris and change tissue. Cup well fixed. The analysis report describes the visual inspection and wear analysis results of a retrieved BHR femoral head and acetabular cup. Wearanalysis was performed using a Redlux 3D profiler. The maximum linear wear is: Head: 13.92 m (angle from pole: 25.89Â¿, arc length from pole: 9.33 mm) Cup: 3.83 m (angle from pole: 31.73Â¿, arc length from pole: 11.64 mm) Combined: 17.75 m The volumetric wear is: Head: 3.46 mm3 Cup: 0.77 mm3 Combined: 4.23 mm3 Based on historic wear data, after 6 to 7 years in vivo, the combined linear wear is expected to be in the region of 17 to 19 m for a non-edgeloaded BHR device (articulating within the bearing surface of the joint). The position of wear on the acetabular cup shows that the femoral head was articulating within the bearing surface of the cup. Radiographs show the position of the components whilst in vivo: Cup inclination (radiographic) = 43Â¿ Cup version (radiographic) = 19Â¿ Note: The orientation angles for this device are for reference only, due to perspective distorted images taken of the original radiographs. The BHR surgical technique measurements specify desired device orientation as 15-20Â¿ anteversion and 40-45Â¿ inclination. List of other devices involved in the event: BHR Acetabular Cup, 74120150, 124099 Mfr/Sponsor aware of other similar events: Out of 3139 BHR Resurfacing Femoral Heads implanted (74121138 - 74121158) since 2005 in Australia, the Sponsor is aware of 6 other similar	Reviewed, for Trending Purposes Only	74121142	N/K		
24802	BHR Resurfacing Femoral Head - (mfr ref: C27209)	120078	24/10/11	Implant Date: 08/02/2005. Explant Date: 18/10/2011. Following approximately 6 years and 8 months in situ, patient underwent hip revision surgery due to pain, apparent raised metal ion levels, and low level fluid collection visible on ultrasound. Analysis results: The retrieved implants are being analyzed by an independent laboratory at the request of the surgeon. Analysis of the anteversion and inclination of the implanted devices is not possible and the radiographs have been withheld by the surgeon. Other devices involved: BHR Acetabular Cup, 74120156, 124099. Similar events: Out of 3,176 BHR Resurfacing Femoral Heads implanted (74121138 - 74121158) since 2005 in Australia, 72 were revised for a wide range of reasons. Report sourced from sponsor.	Reviewed, for Trending Purposes Only	74121150	34923		
24933	BHR Resurfacing Femoral Head	120078	18/11/11	BHR resurfacing, which was in situ since 3rd August 2007, was revised to total hip replacement. The patient presented in February 2008 with squeaking and pain, and in May 2011 presented with a catching and locking feeling. On 26th May 2011 patient's serum cobalt levels were 0.44 umol/l. On 24th June 2011 patient's serum cobalt levels were 0.22 umol/l and chromium 0.47 umol/l. There was evidence of metallosis at the time of revision.	Reviewed, for Trending Purposes Only				
25023	BHR Resurfacing Femoral Head	120078	16/2/12	Following nearly 3 years and in situ, patient underwent hip revision surgery due to pain, stiffness and femoral head collapse. Surgeon suspected AVN (Avascular Necrosis).	Reviewed, for Trending Purposes Only	74121154	82948		

				To make a very long story as short as I can, from approximately two months after this operation my husband started to feel unwell with constant low grade fevers and soreness in his hip region. We saw the surgeon who did the operation three times but he insisted there was nothing wrong with the hip, even when there was fluid/pus oozing out of the scar two years later, he just said keep on taking painkillers!! No further investigation was ordered. This surgeon is a Professor!! My husband continued to feel unwell during the past four years but as the surgeon said there was nothing wrong what could we do? He was unable to partake in any activity so just sat around putting on weight. Eventually we went to see the partner of the surgeon who did the original operation who sent my husband for tests and then told us that 'revision' surgery was needed. This operation has now taken place at great cost to us ($5121 was demanded by the surgeon to be paid 3 days prior to the operation, otherwise the surgery may be re-scheduled). I am aware that other surgeons will not have anything to do with these â€˜faulty hipsâ€™ so we had no alternative but to pay the money which we can still afford. The so called â€˜revision surgeryâ€™ to replace faulty hips must be costing the Government (Medicare) also the health insurance companies a fortune. My point to you is: Is the TGA aware of these faulty prosthesis? I did phone the company who made these replacement hips but the person there said to see the Doctor!! Why were these faulty prosthesis approved by the TGA in the first place? What can we do to recoup some of the money this â€˜revisionâ€™ surgery is costing us? I did phone the TGA in Canberra and the very nice lady sent me a form to fill out re: these faulty hips but I was unable to complete the form as it needed part numbers etc. Which we would have no way of finding. We are just ordinary people (now retired) who have worked and paid tax all our lives so where do we go from here after enduring four years of ill health because of a faulty prosthesis which never should have been approved for use by the TGA in the first place. I am aware that no one can bring back the past four years of ill health but would like to know what steps we, the gullible public (eg. Us) can take. As	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert				
25137	Birmingham Hip Prosthesis	124099	19/12/11	this was not a Johnson and Johnson prosthesis we canâ€™t join the class action which is in progress at the moment. Although from what I have read					
25164	BHR Resurfacing Femoral Head	120078	22/12/11	Following approximately 4 years and 2 months in situ, patient underwent hip revision surgery due to pain, apparent raised metal ion levels and mass on ultrasound.	Reviewed, for Trending Purposes Only	74121146	76298		
25185	BHR Resurfacing Femoral Head	120078	23/12/11	Following approximately 6 years in situ, patient underwent hip revision surgery due to pain, apparent raised metal ion levels, pseudotumor and changes to femoral neck.	Reviewed, for Trending Purposes Only	74121146	76298		
25191	BHR Resurfacing Femoral Head	120078	23/2/12	Following 2 years and 4 months in situ, patient underwent hip revision surgery due to pain.	Reviewed, for Trending Purposes Only	74121150	08EW16934		
25230	BHR (unknown specific product name)		9/1/12	Following unknown period of time in situ, patient underwent hip revision surgery due to pain and apparent metal sensitivity. Prior to experiencing pain and metal sensitivity symptoms, patient reported 5 years of pain-free good functioning BHR hip. Smith & Nephew representative was not present at the revision surgery.	Reviewed, for Trending Purposes Only				
25259	BHR Acetabular Cup	124099	24/10/11	Following 7 years and 2 months in situ, patient had revision hip surgery due to pain and femoral neck thinning.	Reviewed, for Trending Purposes Only	74120150			
25261	BHR Resurfacing Femoral Head	120078	9/10/11	Following approximately 5 years and 11 months in situ, patient underwent hip revision surgery due to pain, pseudotumor, femoral neck thinning and apparent raised cobalt ion levels.	Reviewed, for Trending Purposes Only	74121142			
25282	BHR Resurfacing Femoral Head	120078	28/10/11	Following approximately 3 years and 9 months in situ, patient underwent hip revision surgery due to pain, apparent raised metal ion levels, and fluid collection visible on ultrasound.	Reviewed, for Trending Purposes Only	74123144	07JW13442		
25306	BHR Acetabular Cup	124099	28/10/11	Following 1 year and 1 month in situ, patient underwent revision hip surgery due to pain as a result of the "flipped" loose acetabular cup.	Reviewed, for Trending Purposes Only	74120160	97315		
25307	BHR Acetabular Cup	124099	28/10/11	Following 9 years and 7 months in situ, patient had revision hip surgery due to pain, mass on ultrasound and apparent increased cobalt ion levels.	Reviewed, for Trending Purposes Only	74120150	7437		
25965	BHR Resurfacing Femoral Head	120078	8/3/12	Following 6 years in situ, patient underwent hip revision surgery due to femoral neck fracture.	Reviewed, for Trending Purposes Only	74121146	54295		
26153	BHR Resurfacing Femoral Head	120078	23/3/12	Following approximately 7 years and 10 months in situ, patient underwent hip revision surgery due to pain, apparent mass on ultrasound, elevated metal ion levels and femoral neck thinning.	Reviewed, for Trending Purposes Only	74121142	32595		
26195	Resurfacing Femoral Head	120078	29/3/12	Following approximately 3 years and 2 months in situ, patient underwent hip revision surgery due to femoral neck thinning, effusion on ultrasound and elevated metal ion levels.	Reviewed, for Trending Purposes Only	74121142	81848		
26611	Resurfacing Femoral Head	120078	27/4/12	Following 6 years and 1 month in situ, patient underwent hip revision due to groin pain. It has been noted at the revision that the femoral component had collapsed into varus but there was no macroscopic loosening of the stem. There was some metallosis staining of the capsular soft tissues.	Reviewed, for Trending Purposes Only	74121146	52998		
27057	BHR Resurfacing Femoral Head	120078	14/6/12	Following approximately 4 years and 10 months in situ, patient underwent hip revision due to the femoral neck fracture.	Reviewed, for Trending Purposes Only	74123144	9157		
28271	BHR Acetabular Cup	124099	30/8/12	Following almost 5 years in situ, patient underwent hip revision surgery. Patient was doing well until 3 months ago when acetabular shell shifted. At revision surgery the surgeon noted mass and slurry behind the acetabular shell.	Reviewed, for Trending Purposes Only	74120156			

28311	Birmingham hip replacement	68178	3/9/12	in 2011 symptoms of cobalt toxicity- i.e. constant peeling of hands and feet, eye/ vision changes , bowel changes , pain posterior joint, and presence of pseudotumour post hip joint. Cobalt levels increased to approx 180 over a period of time. Constant peeling of hands and feet eventually led me to get testing of cobalt levels. Other symptoms were present for 6 to 9 months or so . Prosthesis removed in Jan 2012, and a different hip replacement put in . Cobalt levels dropped significantly over next 3 femonths or so, Now levels are normal again.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	120148		50406 047	
28686	BHR Resurfacing Femoral Head	120078	20/9/12	Following approximately 4 months in situ, patient underwent hip resurfacing revision surgery due to femoral neck fracture.	Reviewed, for Trending Purposes Only	74121150	11KW06636		
28895	BHR Acetabular Cup	124099	16/10/12	Following approximately 7 years and 9 months in situ, patient underwent hip revision surgery. Hip had been mostly asymptomatic, however surgeon had concerns over patient's increasing blood metal ion levels. CT scans showed cystic lesions and small soft tissue mass behind the cup, but they have not increased over time.	Reviewed, for Trending Purposes Only	74120152			35266
29024	BHR Acetabular Cup	124099	25/10/12	Following approximately 4 years in situ, patient underwent revision surgery due to pain. A pre-op x-ray has shown the acetabular cup has rotated. Implanted November 2008.	Reviewed, for Trending Purposes Only	74120156	82432		
29051	BHR Resurfacing Femoral Head	120078	26/10/12	Following approximately 4 years and 8 month in situ, patient underwent hip resurfacing revision surgery. The surgeon is unwilling to share his reasons for revision with us and has not allowed our representative to attend the case.	Reviewed, for Trending Purposes Only	74121150			
29359	BHR Resurfacing Femoral Head	120078	14/3/13	Following approximately 4 years and 1 month in situ, patient underwent hip resurfacing revision surgery due to pain and fluid accumulation.	Reviewed, for Trending Purposes Only				
29367	BHR Acetabular Cup	124099	12/2/13	Following approximately 7 years and 3 months in situ, patient underwent hip revision surgery for pain and apparent elevated metal ion levels. Acetabular and femoral neck lesions/cysts were visible on x-ray.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	120148	35156		
29369	BHR Acetabular Cup	124099	18/8/12	Following approximately 8 years in situ, patient underwent revision surgery due to implant loosening. Implant date: 2004.	Reviewed, for Trending Purposes Only	74120160	32521 058		
29916	BHR Resurfacing Femoral Head	120078	18/7/13	Following approximately 3 years in situ, patient underwent hip resurfacing revision surgery due to a pseudotumor and apparent elevated metal ion levels.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74121146			80983
29985	BHR Resurfacing Femoral Head	120078	18/4/13	Following unknown period of time in situ, patient underwent hip resurfacing revision surgery due to pain and apparent increased blood metal ion levels.	Reviewed, for Trending Purposes Only	74121146			51339
30109	BHR Resurfacing Femoral Head	120078	16/4/13	Following approximately 5 years and 5 months in situ, patient underwent hip resurfacing revision surgery due to pain and AVN.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74121142	51827		
30451	BHR Resurfacing Femoral Head	120078	22/3/13	Following approximately 7 years in situ, patient underwent hip resurfacing revision surgery due to lysis.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	121146			34534 057
30529	BHR Resurfacing Femoral Head	120078	2/4/13	Patient underwent hip resurfacing revision surgery following a non-union of fractured neck of femur.	Reviewed, for Trending Purposes Only	N/K	N/K	N/K	N/K
30708	BHR Resurfacing Femoral Head	120078	14/6/13	Following almost 3 years in situ, patient underwent hip resurfacing revision surgery due to pain and AVN.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74121150			95972
31200	BHR Resurfacing Femoral Head	120078	13/6/13	Following 3 years and 10 months in situ, patient underwent hip resurfacing revision surgery due to pain.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74123148			08GW17733
31211	BHR hip prosthesis	120078	13/6/13	A report has been received that approximately 18 months ago patient underwent hip revision surgery due to pain.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert				
31593	BHR Acetabular Cup	124099	26/7/13	Following approximately 8-9 years in situ patient underwent hip revision surgery due to loosening of the cup.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	N/K	N/K		N/K
31854	BHR Resurfacing Femoral Head	120078	23/8/13	Patient underwent hip resurfacing revision surgery.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	N/K	N/K	N/K	N/K
31923	BHR Resurfacing Femoral Head	120078	11/3/14	Following approximately 6 years in situ, patient underwent hip resurfacing revision surgery due to elevated metal ion levels.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74121150			51508
32205	BHR Resurfacing Femoral Head	120078	19/3/14	Following approximately 6 years in situ, patient underwent hip resurfacing revision surgery due to pain and osteolysis.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74121146	N/K	N/K	N/K
32426	BHR	124100	30/10/13	Following unknown period of time in situ patient underwent hip revision surgery due to loosening.	Reviewed, for Trending Purposes Only	N/K		N/K	
32635	BHR Resurfacing Femoral Head	120078	5/3/14	Following 2 years and 7 months in situ, patient underwent hip revision surgery due to pain and large build up of fluid in the psoas.	Reviewed, for Trending Purposes Only	71423152	N/A	10LW01812	N/A
32637	BHR Acetabular Cup	124099	21/11/13	Following 4 years in situ patient underwent hip revision surgery due to acetabular cup moving out of position and alleged increase in blood metal ion levels.	Reviewed, for Trending Purposes Only	74120156		95252	

33089	BHR Acetabular Cup	124099	3/1/14	Following approximately 2 years and 10 months in situ, patient underwent hip revision surgery.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74120144	N/K		N/K
33090	BHR Acetabular Cup	124099	3/1/14	Following 1 year and 9 months in situ, patient underwent hip resurfacing revision surgery due to pain and swelling.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74120150	50051030		
33091	BHR Acetabular Cup	124099	3/1/14	Following 4 years and 10 months in situ, patient underwent hip resurfacing revision surgery due to pain and restricted range of motion.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74120156	25518 090		
33096	BHR Acetabular Cup	124099	3/1/14	It was reported that total hip revision surgery has been performed. At original implantation, the cup was inserted vertically.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74120156	28774 093		
33163	ACETABULAR CUP	124099	22/5/14	Following approximately 6 years and 3 months in situ, patient underwent hip revision due to Metal Sensitivity; Pain; ALVAL and Elevated Metal Ions.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74122152	N/A	7646002	N/A
33260	BHR RESURFACING FEMORAL HEAD	120078	3/4/14	Following approximately 4 years and 8 months in situ, patient underwent hip resurfacing revision surgery due to pain and femoral neck thinning.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74123144	N/A	08GW17726	N/A
33305	BHR Resurfacing Femoral Head	120078	6/2/14	Following approximately 4 years and 8 months in situ, patient underwent revision surgery due to unknown reason. This revision came to light after a second revision was reported to Smith and Nephew our Reference# C40760 which was reported to TGA on date 08/11/2012 (DIR# 29362).	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	N/K			N/K
33355	ACETABULAR Cup	124099	23/4/14	It was reported that "BHR revision with query ALVAL".	Reviewed, for Trending Purposes Only	74120156			12CW07364
33522	BHR Acetabular Cup	124099	1/12/14	It was reported that:"Birmingham Mid Head Resection (BMHR) was revised as the patient presented with elevated cobalt levels of 80 umol/l however was otherwise asymptomatic. The patient was reported to have an area of bone loss superior of acetabular which was bone grafted. We have reviewed the NJRR data and the current revision rate for the BHR Acetabular Cup is 0.85 revision/100 Observation years.	Reviewed, for Trending Purposes Only	74122150			08CW1603
33815	Hip Implant	124100	31/3/14	I had a Birmingham Hip Resurfacing in 2004. I was 45 years old weighed 51 kg. Except for osteoarthritis I was a healthy female. I went from hip pain pre surgery to back pain, hip pain, leg pain numbness, burning sensation, not being able to sit for more than a few minutes due to pain post-surgery, have stomach problems, memory loss, am light headed at times. I lost 10 kg in a few months. When I went back to surgeon all he said after an X-Ray was that it was perfectly aligned and that was it. In his eyes it was a success and I am sure this would have been passed on to our watchdog the TGA , and now question the statistics on success rates of bhr if relying on surgeons input. Over the years I have had bone scans, X-rays physio, acupuncture, massage, pain killers, sleeping tablets, cortisone injections etc without much success. I did send the surgeon an email 6 months after surgery describing my symptoms. He did phone me and only said it would take time...not sure what that meant. In 2011 when the J&J recall took place I went to another specialist who also said everything looked fine however could not explain my symptoms. He did however send me for a blood test and cortisone injection. Blood test showed above levels of metal although were not too high, the cortisone injection did not relieve pain. I once again gave up on going to any more medical specialists. Recently my pain has become worse, so have made another appointment to see a specialist. For the first time I will have a CT scan as well as another X ray and blood tests. (was unable to copy this in description area).	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert				
34049	BHR Acetabular Cup	124099	4/6/14	It has been reported that "patient had squeaking and increased blood metal ions after 4 years and 1 month insitu."	Reviewed, for Trending Purposes Only	74120150	89580		
34150	BHR Resurfacing Cup	124099	1/12/14	It has been reported that cup flipped out and patient noted clicking in hip when moving. We have reviewed the NJRR data and the current revision rate for the BHR Resurfacing Cup is 0.85 revision / 100 Observation years.	Reviewed, for Trending Purposes Only	74120156			

34271	Smith & Nephew Birmingham Hip Resurfacing (BHR)	124099	28/5/14	I have a left BHR is situ and have had since September 2004. Just before Christmas 2013, my GP decided to check for chromium cobalt levels which were found to be very high; cobalt 809 nmol/L and chromium 1361 nmol/L. My GP was extremely concerned at these levels and contacted colleagues for an opinion. I also contacted, who referred my case to the head of the unit at the hospital. He rang my GP to say he would be concerned about nerve damage and cardiomyopathy at these levels. I then contacted my surgeon who asked to repeat the tests, which I did that week and they came back at similar levels. My surgeon then rang me to say that the hip "has to come out" which meant a revision procedure. I was booked for the revision on May 9, but in March, I had an unrelated pelvic infection for which I was hospitalised. Under advice for treating specialists, the surgery has been delayed, which will be reviewed, in late July. The left BHR has had minimal functional problems, apart from the odd clunking and squeaking. A recent CT has shown bursal effusion and changes in the psoas. The greatest concern is the systemic chromium cobalt levels caused by the implant. My own research has revealed that the BHR has statistically performed well, particularly in men, with a large femoral head size. But it has been documented that it is no longer recommended in women, due to the often small size of the femoral head of the implant, having a greater, and unacceptable failure rate. The National Joint Registry has reported on this and would have the statistics. It has also been documented in a recent BMJ paper (Langton et al), that high levels of cobalt and chromium are a predictor of joint failure and indicate revision. The whole BHR cohort, looks statistically sound, but in women it does not. I believe this device needs to be looked at, at the gender performance level, separately to the whole cohort. I believe that this device, in some patients, is performing as badly the J & J ASR, which of course is a recalled device. I believe that cases such as mine, are being overlooked and that the BHR is misleadingly touted as being an excellent, well performing device. Contrary to that information are cases like mine, where very high cobalt and chromium levels, directly related to an implanted BHR hip resurfacing implant/device, is the sole cause for revision. This is not acceptable outcome on any level and after much consideration, I have decided to report this as an adverse medical event, which I believe warrants reporting and an further investigation. I believe that I should not have been subjected to ill health as the direct result of the implantation of this Smith & Nephew device. I urge the TGA to look at the BHR, particularly in relation to the female cohort and small femoral head size 42mm or less. Is touted as being a great device. I do believe that having very high cobalt and chromium levels, directly related to an implanted BHR hip resurfacing implant/device and having to undergo a hip revision, as the sole cause, is reportable as an adverse medical event, which warrants reporting and an investigation. I believe that I should not have been subjected to ill health as the direct result of the implantation of this device. I urge the TGA to look at the BHR, particularly in relation to the female cohort.	Reviewed, for Trending Purposes Only	Acetabular cup 50mm and femoral head 42mm	Ref cup 120150 and head 121142	N/A ?	Lot cup 32991 and head 3339
34838	BHR Acetabular Cup	124099	16/1/15	It has been reported that patient underwent hip revision due to pain. We have reviewed the NJRR data and the current revision rate for the BHR Acetabular Cup is 0.84 revision/100 Observation years.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74120156			50281029
34928	BHR Acetabular Cup	108428	27/1/15	It has been reported that patient had hip revision due to aseptic loosening. We have reviewed that NJRR data and the current revision rate for the BHR Resurfacing Cup is 0.77 revision / 100 Observation years.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	120156			31100043
34964	BHR Resurfacing Cup	124099	14/8/14	It has been reported that patient underwent hip revision due to pain and metal ions level. We have reviewed the NJRR data and the current revision rate for the BHR Resurfacing Cup is 0.83 revision/100 Observation years.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74120160			69308
34965	BHR Resurfacing Cup	124099	14/8/14	It has been reported that patient underwent hip revision due to pain and Metal ions level. We have reviewed the NJRR data and the current revision rate for the BHR Resurfacing Cup is 0.83 revision / 100 Observation years.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74120160			77310
35142	Birmingham Hip Resurfacing Femoral Head	108428	19/2/15	It has been reported that patient underwent Hip revision due to pain and elevated metal ions. We have reviewed the NJRR data and the current revision rate for the Birmingham Hip Resurfacing Femoral Head is 0.73 revision/100 Observation years.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	121154			10720
35262	BHR Hip Prosthesis	124100	17/9/14	This was a metal-on-metal prosthesis that "failed" and needed to be removed and replaced (revision) with a 'normal' hip. Cobalt toxicity resulted from this. Hip revision in 2011. Knee replacement 2013 - subsequent health problems: - emphysema (non-smoker/husband of 46 year - also a non-smoker) - glaucoma - degenerative spinal injury - severe depression as a result of trauma and pain.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert				
35434	BHR Acetabular Cup	124099	19/3/15	It has been reported that patient underwent hip revision due to pain and Elevated Metal Ions. We have reviewed the NJRR data and the current revision rate for the BHR Acetabular Cup is 0.87 revision / 100 Observation years.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74120150			33566
35494	BHR Acetabular Cup	124099	23/3/15	It has been reported that patient underwent hip revision due to Metal ion level and Alval. We have reviewed the NJRR data and the current revision rate for the BHR Acetabular Cup is 0.87 revision / 100 Observation years.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	120162	33651	N/K	N/K
35732	BHR Resurfacing Femoral Head	120078	5/11/15	It has been reported that patient underwent hip Bilateral revision due to pain and metal ion levels. We have review the NJRR data and the current revision rate for the BHR Resurfacing Femoral Head is 0.65 revision/100 Observation years.	Reviewed, for Trending Purposes Only	74121146	N/K	N/K	N/K
36098	BHR Resurfacing Cup Acetabulum prosthesis	124099	26/8/15	It has been reported that patient underwent Hip revision due to pain. We have reviewed the NJRR data and the current revision rate for BHR Resurfacing Cup is 0.84 revision/100 Observation years.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74122154	08CW16049	N/K	N/K
36200	BHR Resurfacing Femoral Head	120078	6/10/15	It has been reported that patient underwent Hip replacement due to unknown reason. We have reviewed the NJRR data and the current revision rate for BHR Resurfacing Femoral Head is 0.81 revision / 100 Observation years.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74120156	07EW12697		

36514	BHR Acetabular Cup	124099	30/10/15	It has been reported that patient revised hip due to elevated chromium test results. We have reviewed the NJRR data and the current revision rate for the BHR Acetabular Cup is 0.86 revision / 100 Observation years. Elevated Test Results Patient underwent Revision THR 20/1/2015 for removal of BHR acetabular cup and modular head. Primary THR 21/11/2006 (see attached copy of implants used) 8/7/2013 test result: chromium nmol/L 57. 8/23/2014 test result: cobalt nmol/L 161.	Reviewed, for Trending Purposes Only	74120150 / 74121242			50822
37185	BHR Resurfacing Cup	124099	6/11/15	It has been reported that patient revised hip due to elevated metal ions. We have reviewed the NJRR data and the current revision rate for the BHR Resurfacing Cup is 1.68 revision / 100 Observation years.	Reviewed, for Trending Purposes Only	120246	1106	N/K	1106
37203	BHR Resurfacing Cup - Acetabulum prosthesis	124099	11/1/15	It has been reported that patient revised hip due to radiolucent shape in superior acetabulum. We have reviewed the NJRR data and the current revision rate for BHR Resurfacing Cup is 0.78 revison / 100 Observation years.	Reviewed, for Trending Purposes Only	74122154	N/K	N/K	09JW24717
37257	BHR resurfacing Cup, Acetabulum prosthesis	124099	6/1/15	It has been reported that patient revised hip due to pain and Metal ion levels. We have reviewed the NJRR data and the current revision rate for the BHR resurfacing Cup is 0.78 revision / 100 Observation years.	Reviewed, for Trending Purposes Only	74120152	N/K	N/K	N/K
37266	BHR Resurfacing Cup	124099	22/9/15	It has been reported that patient revised hip due to squeaking. We have reviewed the NJRR data and the current revision rate for the BHR Resurfacing Cup is 0.87 revision/100 Observation years.	Reviewed, for Trending Purposes Only	74122150	09DW22913	N/K	N/K
37747	BHR Resurfacing Head	120078	16/3/16	It has been reported that patient revised hip due to Gradual collapse of bone on lesser trochanter. We have reviewed the NJRR data and the current revision rate for the BHR Resurfacing Head is 0.69 revision / 100 Observation years.	Reviewed, for Trending Purposes Only	121142			37261
37771	BHR Acetabular Cup with impactor	124099	2/3/16	It has been reported that patient revised hip due to radiographic lesion present in acetabulum. We have reviewed the NJRR data and the current revision rate for the BHR Acetabular Cup with impactor is 0.86 revision / 100 Observation years.	Reviewed, for Trending Purposes Only	74120152	96464035	N/K	N/K
38111	BHR Resurfacing Cup - Acetabulum prosthesis	124099	6/1/16	It has been reported that patient revised hip due to osteolysis around the cup and top of the stem. We have reviewed the NJRR data and the current revision rate for the BHR Resurgacing Cup is 0.87 revision / 100 Observation years.	Reviewed, for Trending Purposes Only	74120156	N/K	N/K	N/K
38827	BHR Resurfacing Cup, Acetabulum prosthesis	124099	8/10/15	It has been reported that patient revised hip due to Osteolysis. We have reviewed the NJRR data and the current revision rate for the BHR Resurfacing Cup is 0.81 revision / 100 Observation years.	Reviewed, for Trending Purposes Only	74120152			50790
38847	BHR resurfacing Cup, - Hip Component	124099	26/9/16	It has been reported that patient revised hip due to unknown reason. We have reviewed the NJRR data and the current revision rate for the BHR resurfacing Cup is 0.81 revision / 100 Observation years.	Reviewed, for Trending Purposes Only	74120156	N/K	N/K	50696
38958	BHR Acetabular Cup w/ Impactor	124099	26/10/15	It has been reported that patient underwent hip bilateral revision due to pain and metal ion levels. We have reviewed the NJRR data and the current revision rate for the BHR Acetabular Cup w/ Impactor is 0.86 revision/ 100 Observation years.	Reviewed, for Trending Purposes Only	120152	N/K	N/K	N/K
39177	ACETLR CUP with impactor	124099	18/1/16	We have reviewed the NJRR data and the current revision rate for the ACETLR Cup with the impactor is 0.85 / 100 Observation years.	Reviewed, for Trending Purposes Only	74120148	N/K	N/K	N/K
39461	ACETABULAR CUP HAP - Acetabulum prosthesis	124099	15/4/16	It has been reported that patient revised hip due to unknown reason. We have reviewed the NJRR data and the current revision rate for the BHR Resurfacing Cup is 0.87 revision / 100 Observation years.	Reviewed, for Trending Purposes Only	74122146	N/A	N/A	N/A
39920	ACETLR CUP HAP 54MM W/ IMPTR	124099	5/12/16	It has been reported that patient revised Hip due to increased metal ions and black fluid on hip aspiration.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74120154	N/K	N/K	N/K
39955	BHR Resurfacing Cup	124099	26/2/16	It has been reported that patient revised Hip due to Metallosis. We have reviewed the NJRR data and the current revision rate for the BHR Resurfacing Cup 0.87 revision / 100 Observation years.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74120152	30069	N/K	N/K
40301	Birmingham Hip Resurfacing	101100	23/2/16	It has been reported that patient revised Hip due to unknown reason.	Reviewed, for Trending Purposes Only	N/K	N/K	N/K	N/K
40359	BHR Acetabular Cup - Acetabulum prosthesis	124099	20/6/16	It has been reported that patient revised Hip due to metalosis and a defect in acetabular wall. We have reviewed the NJRR data and the current revision rate for the BHR acetabular Cup is 0.86 revision/ 100 Observation years.	Reviewed, for Trending Purposes Only	74120152	N/K	N/K	N/k
41377	RESURFACING FEMORAL HEAD - Prosthesis, internal, joint, hip, resurfacing	120078	7/7/16	It has been reported that patient revised hip or knee due to unknown reason. We have reviewed the NJRR data and the current revision rate for the Resurfacing Femoral Head is 0.64 revision / 100 Observation years.	Reviewed, for Trending Purposes Only	74121154	10722	N/K	N/K
42484	ACETABULAR CUP HAP SIZE 48/54 - Metallic acetabulum prosthesis	274334	14/10/16	It was reported that revision surgery performed, due to higher than normal Chromium & Cobalt levels in pathology reports. The metal head had slight wearing inside the metal liner.	Reviewed, for Trending Purposes Only	74122154	N/K	09GW24305	N/k
43744	BIRMINGHAM HIP Resurfacing Head - Prosthesis, internal, joint, hip, resurfacing	274333	20/12/16	Via notification from solicitors: Pt had Left BHR inserted 03/10/2006. Following fall on 28/02/2016 reported L. hip and knee pain. Elevated cobalt levels. Revised 27/10/2016.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74121150		50495	
43928	ACETLR CUP HAP 60MM W/ IMPTR - Metallic acetabulum prosthesis	274334	14/12/16	Bilateral BHR patient. Left hip complaint no:C-0126529. Elevated metal ion levels. No indication that the right hip is to be revised.	Reviewed, for Trending Purposes Only	74120160	N/k	26945	N/K
43966	ACETABULAR CUP HAP SIZE 48/56 - Metallic acetabulum prosthesis	274334	10/1/17	Primary implant 2003. Last 2 months of Left Hip Pain Replaced BHR left side with Synergy stem and R3 cup 58 cup 36 4+ Oxinium head.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert	74122156	N/k	8961020	N/K
43983	ACETLR CUP HAP 56MM W/ IMPTR - Metallic acetabulum prosthesis	274334	18/1/17	Revision Right Total Hip due to suspected Peri-prosthetic fracture. The implants were not able to be retrieved. Previous surgical notes not available. Original Metal on Metal Total Hip Replacement performed (estimated 13yrs ago) 56 Birmingham cup with corresponding head.	Reviewed, for Trending Purposes Only	74122156	N/k	N/K	N/K

44873	ACETLR CUP HAP 60MM W/ IMPTR - Metallic acetabulum prosthesis	274334	5/4/17	The patient had bilateral BHR surgery. He presented with bilateral groin pain and after blood testing it was found that he had elevated blood ion levels for Cobalt and Chrome. He underwent revision surgery on the right side hip, which according to surgeon is at this time is well functioning. He underwent further analysis of his blood ion levels after the revision of the right side BHR and it was found that the levels were dropping. Recently he presented to surgeon for further follow up on his revised hip and levels were again repeated and had dropped further. Although his ion levels had dropped patient continued to complain of groin pain in his left hip and requested to undertake a revision of the left hip. Wound opened and dissection made down to hip joint. No bursal collection noted. Hip joint opened. Very little black stained fluid and tissue. Osteotomy of femoral neck performed and Head removed. Acetabulum exposed and explant osteotomes used to remove cup.	Reviewed, for Trending Purposes Only	74120160	N/K	N/K	N/K
45962	ACETLR CUP HAP 56MM W/ IMPTR - Metallic acetabulum prosthesis	274334	4/7/17	Patient was revised due to pain.	Reviewed, for Trending Purposes Only	74120156	N/K	N/K	N/K
46189	BIRMINGHAM Hip Resurfacing HAP Coated Acetabular Cup - Metallic acetabulum prosthesis	274334	24/8/17	Metallosis, ongoing hip and groin pain, decreased range of motion, impaired gait / limp, reduced hip function reported.	Reviewed, for Trending Purposes Only	74120158			82939
48560	Birmingham Hip Resurfacing Acetabular Cup - Metallic acetabulum prosthesis	274334	24/1/19	Revision of right BHR cup and modular head. Stem remains implanted. Reason for revision - pain and dislocation.	Reviewed, for Trending Purposes Only	74120158			92609
50110	BIRMINGHAM HIP Resurfacing HAP Coated Acetabular Cup - Metallic acetabulum prosthesis	274334	20/12/18	Revision surgery performed due to pain and clunking of bearing.	Reviewed, for Trending Purposes Only	74122158			10764
50645	BIRMINGHAM HIP Acetabular Cup w/ Impactor	124099	30/1/19	It was reported that: Patient presents with pain around right hip with three subluxations of the hip. Serum cobalt levels elevated	Reviewed, for Trending Purposes Only	74120150			50818018
50649	BIRMINGHAM HIP Acetabular HA Porous Coated Cup w/Impactor	124099	30/1/19	It was reported that: Increased metal ions in the bloodstream.	Reviewed, for Trending Purposes Only	74120154			
53741	BIRMINGHAM Hip Resurfacing HAP Coated Acetabular Cup - Metallic acetabulum prosthesis	274334	18/3/19	Pain leading to Revision surgery	Reviewed, for Trending Purposes Only	74120156			581818 001
54105	Birmingham Hip Replacement - Prosthesis, internal, joint, hip, resurfacing	274334	29/10/18	In * I had a Birmingham Hip resurfacing done. Over the past 9 years I have had knee problems, which I had over the years a total of 5 arthroscopes. In * this year I went back to the surgeon to seek help with my knees again and was told it's arthritis. Went to Rheumatologist they organised a bone scan and it returned as a faulty BHP. I was told to see a hip surgeon, in the mean time I investigated what could possibly go wrong with it I came across the recall and hazard alert. My catalogue numbers from the operation report match your recall alert these numbers being: 74123144 and 74122150 Smith & Nephew. I am booked in to have revision hip replacement on the * and I have to pay for this out of my own pocket which I am very unhappy about. At no stage did the * Orthopaedic Group mention that there was a problem and was never notified that perhaps I should be scanned and blood tested regularly. I have been suffering leg and knee pain for over 9 years now, have had problems sleeping because of the pain, even taking strong medication didn't help.	Reviewed, for Trending Purposes Only	74122150 & 74123144			9932 & 9843
55869	Birmingham Resurfacing - Prosthesis, internal, joint, hip, resurfacing	120078	15/2/19	I was a abc current affair program on people who were suffering side effects of MoM inplants. In 2005 I had Birmingham Resurfacing of my right hip. I have had treatment for a sore lower back, sore bursar and buttock pain, plus a growth removed from near the hip joint. I have been ona chornic health care plan for approx 5 years, as I have suffered fatigue. My Dr sent me for blood tests and my Chromium levels are 378.7 and my Cobalt is 269.9. I have had no contact from the * Orthopedic Group since 2005, or contacted for follow up re blood tests.	Reviewed, for Trending Purposes Only, Field Safety Corrective Action Hazard alert				