Biomet UK Ltd

10 Year Warranty Programme

BIOMET Europe

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Biomet Europe

Biomet Warranty Department

Six Reasons to take Advantage of the Biomet Warranty Programme

Exclusivity
Biomet is the only Orthopaedic Company that offers you a 10 year warranty in the UK.

Proven products
Initially, this Warranty programme covered the **Stanmore Hip™** and **AGC Knee®**. It has now been extended to the **Bi-Metric®** and **Taperloc®** femoral components. All four Biomet 'best in class' products come with outstanding clinical history and long-term results.

Commitment
Should warranted implants fail within 10 years at the implantation date, Biomet will provide a free of charge replacement implant for the revision operation*.

Confidence
The Biomet Warranty Programme was launched in October 1997. To date, only twelve claims for AGC and two claims for hip implants have been made.

Support
At Biomet we believe that all customer requirements should be met. That is why the Warranty complements our proven implants, to support your needs in the long term. More than orthopaedic solutions, we deliver a true first class service.

Simplicity
The Warranty procedure is simple, quick, with minimal paperwork, allowing the Biomet Clinical Warranty Department to rapidly engage a revision process if needed.

Biomet Warranty Programme - when confidence is reality

NICE
'Using the most recently available evidence of clinical effectiveness, the best prostheses (using long term viability as the determinant) demonstrate a revision rate (the rate at which they need to be replaced) of 10% or less at 10 years. This should be regarded as the current 'benchmark' in the selection of prostheses for primary Total Hip Replacement (THR).'

'The evidence used in support of any prosthesis, to establish whether or not it achieves this benchmark, should relate to data of 10 or more years follow-up from a number of centres, obtained via adequately sized, well conducted observational studies (preferably with consecutive patients from non-selected populations) or randomised controlled trials. Such evidence should have been published or be available for peer review.'

* See the Warranty condition section.

stanmore

hip replacement system

Features

- The only hip available today that retains its original geometry and surface finish with over 20 years successful clinical follow-up.
- Option of standard or straight stems, 5 stem sizes and various neck lengths to ensure best patient fit and function.
- Surgical choice of either modular or monobloc cobalt chromium femoral stems for high strength and optimal bone cement interface.
- PMMA distal centraliser to ensure stem alignment.
- Simple yet compact instrumentation.
- Proven design allows for a simple and reproducible operative technique promoting reproducible results.
- Published evidence of superior performance against the accepted “gold” standard, with a 91% stem survivorship rate at 22 years*.

BIOMET Europe

stanmore
hip replacement system

Clinical Results

"Because the Charnley and the Stanmore prostheses are both amongst the cheapest and best performing prostheses for most patients, cost minimisation and the promotion of quality can be achieved by standardising on these implants."
Effective Health Care – NHS Centre for Reviews & Dissemination. Oct 1996; Vol 2, No 2: 1-12.

"The advantages of the Stanmore and Charnley over more modern designs include their simplicity, the reproducibility of known clinical results and low cost."
Marston, RA, Cobb, AG, Bentley G. JBJS 1996; Vol 78-B: 178-184.

"We reviewed the records of the long-term outcome of 208 Charnley and 982 Stanmore (THR)… The Stanmore implant had a better survival rate before revision at 14 years (86% to 79%)… The later Stanmore implants did better than the early ones (97% to 92% at 10 years)."
Britton, AR, et al. JBJS 1996; Vol 78-B: 802-808.

"Only two hips (Stanmore and Charnley) have fifteen year results published in peer-reviewed journals."
Murray, DW, Carr, AJ, Bulstrode CJ. JBJS 1995; Vol 77-B: 520-527.

Stanmore long-term survivorship at 10 years 95%, and at 15 years 91%.
Van der Schaff, DB, Deutman, R, Mulder, TJ. JBJS 1988; Vol 70-B: 45-48.
Alsema, R, Deutman, R, Mulder, TJ. JBJS 1994; Vol 76-B: 240-244.

Survivorship was 95% at 10 years. "The average Merle d'Aubigné-Postel score was excellent up until 14 years. Patient satisfaction remained high until 22 years."

The Swedish National Hip Arthroplasty Register – 96.8% survival at 9 years.
Malchau, H, & Herberts, P. 65th AAOS, March 1998.

* The Stanmore Total Hip Replacement. A 22 year follow-up.

- 135 patients (146 prostheses) between 1975 and 1976.
- 22 year minimum follow up.
- Survival rate at 22 years for the Stanmore stem is 91%.
- "Since 1975, 11 (7.5%) of the original 146 prostheses have been revised".
  Gerritsma-Bleeker, CLE, et al. JBJS 2000; Vol 82-B: 97-102.

BI-METRIC®

TOTAL • HIP • SYSTEM

Features

- Bi-planar stem taper promotes increased proximal stress off-loading and initial implant stability and also reduces the chance of proximal bone resorption and distal hypertrophy.
- Available in 11 proportional sizes Bi-Metric standard or lateralised stems can be used for correct alignment of femur independent of leg length.
- Part of the Alliance family that comprises the largest assembly of hip implants utilising one simple, accurate and reproducible set of instruments.
- Incorporates proximal closed-pore titanium porous coating. This plasma sprayed coating allows bone to penetrate and creates a mechanical bond. It results in implant long-term fixation and minimal wear debris ingress.
- Compatible with all Biomet acetabular components.
- Forged titanium alloy for strength and biocompatibility.
- Excellent clinical survivorship of 100% at up to 13 years**.

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BI-METRIC®
TOTAL • HIP • SYSTEM

Clinical Results

**After a 5 to 13 year follow up on the Bi-Metric Porous Primary, Evans and DeLee found:
• 0% distal thigh pain
• 0% osteolysis
• 6% stress shielding
• 100% survivorship
Evans, JA, & DeLee, JC. Outcome of a Tapered, Titanium, Proximal Load-Bearing, Non-Cemented Femoral THA Component: Submitted for publication.

For over 15 years, the Bi-Metric hip stem has been delivering excellent clinical results- including stem survival of 99.3% at 10 years.
Varjonen, S, Lepistö, J, Alho, A. Cementless Hip Arthroplasty -Ten year follow-up. 3rd Domestic Congress of the European Hip Society. June 1998.

"Because no stem failed, survival analysis revealed a 100% rate of stem survival …
The longer-term results reported in this review involve a stem design that has not changed and that continues to be the choice at our institution for primary uncemented total hip arthroplasty."
Meding, JB, et al. JBJS 2004; Vol 86-A: 92-97.

Bi-Metric femoral component long-term survivorship of 98% when followed for 5-11 years.
Jacobson, S, et al. Acta Orthop Scand 2003; Vol 74: 248-252.

Excellent results from proximally HA-coated femoral stems with a minimum of 6 years follow-up. A prospective evaluation of 100 patients. "No femoral component was revised. At an average follow-up of 8 years, this proximally HA-coated femoral component showed favorable clinical and radiological outcome and excellent survivorship."
Goosen, JHM, et al. Acta Orthopaedica 2005; Vol 76: 190-197.

Total hip arthroplasty for primary osteoarthritis in younger patients in the Finnish arthroplasty register.
• Between 1991 and 2001 the Bi-Metric stem was the most commonly implanted femoral component.
• Proximally circumferentially porous-coated uncemented stems implanted between 1991 and 2001 had a 10-year survival rate of 99% with aseptic loosening as endpoint.
"The key issue for successful THA for primary osteoarthrosis in young patients is selection of the right implant. Uncemented proximally circumferentially porous and HA-coated stems appear to be the implants of choice...

Orthopedic surgeons in Finland have paid dearly for experimenting with new, undocumented implants..."
Eskelinen, A, et al. Acta Orthopaedica 2005; Vol 76: 28-41.

TAPERLOC®

Features

- Designed with a flat, wedge shaped stem for improved rotational stability and a tapered shape to allow for a gradual reduction in implant stiffness.
- Incorporate proximal closed-pore titanium porous coating. This plasma sprayed coating allows bone to penetrate and creates a mechanical bond. It results in implant long-term fixation and minimal wear debris ingress.
- Available in standard or lateral-offset option for correct alignment of the femur independent of leg length.
- Compatible with all Biomet acetabular components.
- Composed of titanium alloy for strength and biocompatibility.
- Excellent clinical survival of 98% at up to 13 years***.

BIOMET Europe

TAPERLOC®

Clinical Results

Taperloc survivorship was 99.1% at 11 years. “The present study demonstrates that excellent long-term clinical and radiological outcomes can be expected with the use of Taperloc uncemented femoral component.”
Parvizi J, Keisu KS et al. The Journal of Arthroplasty - 2004; Vol 19 Issue 2: 151-156.

After a mean clinical and radiographic follow-up of 9.8 years, all femoral components were stable, with no evidence of progressive radiolucency or osteolysis.
“This study demonstrated that excellent long-term clinical and radiographic outcomes can be expected after the use of an uncemented proximally porous-coated tapered femoral component.”
Parvizi, J, et al. JBJS 2004; Vol 86-A: 783-786.

Taperloc survivorship was 92% at 10 year follow-up.
The Swedish National Hip Arthroplasty Register, 2002.

In a two to eleven year follow-up there were no Taperloc revisions in octogenarians.
Keisu, KS, et al. JBJS 2001; Vol 83-A: 359-363.

“…there has been no evidence of mechanical failure of a cementless femoral component at a mean follow-up of 8 years… Uncemented femoral fixation with this component design in rheumatoid patients appears to be a promising treatment.”
Keisu, KS, et al. The Journal of Arthroplasty 2001; Vol 16:415-421.

***98% survival of the Taperloc femoral component at up to 12.5 years.
“These results indicate that excellent fixation and minimal lysis can be achieved with an uncemented femoral component in young and active patients...”
McLaughlin, JR, & Lee, KR. Clinical Orthopaedics & Related Research 2000; Vol 373: 153-163.

Taperloc survivorship was 96% at 10 years. ”In our series, the results using the Taperloc femoral component are excellent, with revision for aseptic loosening at ten years in only 1% .”
McLaughlin, JR, & Lee, KR. JBJS 1997; Vol 79-B: 900-907.

Excellent 5 to 8 year results. Out of 105 hip replacements just one femoral revision was performed to aid an acetabular revision. “Component design features were thought to be critical to the excellent performance of the femoral component…”
Hozack, WJ, et al. Clinical Orthopaedics & Related Research 1996; Vol 333: 217-225.

AGC
Total Knee System

Features

- ArCom® compression molded polyethylene provides a highly consolidated bearing material with an increased resistance to wear.
- Unique monobloc tibial component design avoids the possibility for generation of wear debris between the bearing and the tibial baseplate.
- Full interchangeability of femoral, tibial and patellar components allows independent sizing, meeting the specific anatomical demands of the individual patient.
- Cobalt chromium femoral articular surface for maximum durability of the tibiofemoral and patellofemoral articulation, reduces the potential for wear and loosening of the implant.
- Titanium alloy plasma sprayed porous coating for cementless fixation, or Interlok™ finish for cemented use offer proven clinical biocompatibility, and have been in use with the AGC system since 1983.
- A deep, wide trochlear groove articulates with the dome shaped patellar compartment, creating a congruent and forgiving patellofemoral joint.
- Wide femoral condyles provide line contact with the articulating surfaces, reducing the contact stresses.
- Published long-term survivorship of over 98% at 10 years and 15 years.

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AGC
Total Knee System

Clinical Results

The Swedish Knee Arthroplasty Register – A nationwide study of 30,003 knees 1976-1992. Total number of AGC knees 3,436; Clinical follow-up 7 years; Cumulative survival rate 97.5%.
Knutson, K, et al. Acta Orthopaedica Scandinavica 1994; Vol 65: 375-386.

Long term results of a Total Joint Arthroplasty – Results of a 15 year follow-up on a nationwide registration programme in Finland. 988 AGC knees showed a clinical survival rate at 7 years of 96.7%.
Paavolainen, P, et al. The Finnish Arthroplasty Register 1980-1994.

In one hospital, 1162 AGC knees were inserted by 66 surgeons between 1987 and 1993.
16 of the AGCs have been revised giving a survival rate of 98.6% at up to 7 years.
Half (8) of these revisions were for infection.
Murray, DW, & Frost, SJ. JBJS 1998; Vol 80-B: 426-431.

"…98% survival rate at 10 years" – in a multi-centre study.
Ritter, MA, et al. Clinical Orthopaedics & Related Research 1995; Vol 321: 79-85.

Reduced potential for fatigue crack initiation in knee tibial components. "Calcium stearate-free…is better consolidated."
Schmidt, MB, & Hamilton, JV. 42nd AORS, Atlanta, Feb 1996.

"Which primary total knee replacement? A review of currently available TKR in the United Kingdom."
Liow, RYL, & Murray, DW. Annals of the Royal College of Surgeons of England 1997; Vol 79: 335-340.

"The AGC posterior cruciate sparing total knee replacement: Fifteen years experience."
Ritter, MA. AGC 15 Year Anniversary Meeting, Royal College of Physicians, London, June 1999.

Survivorship of the AGC total knee prosthesis was 95% at 11 years.
"We suggest that the reason for the success of the implant derives from design features as well as the materials used in the manufacture of the components."
Emerson, RH, Higgins, LL, Head, WC. The Journal of Arthroplasty 2000; Vol 15: 418-423.

The overall survival rate of the AGC total knee prosthesis was 96.6% at 8 years. Infection was the major cause for failure and if infection was excluded the survival rate was 99%.
"This knee arthroplasty follow-up analysis shows excellent midterm results.
There has been minimum modification since its 1983 launching. Therefore, the long-term study results suggest that results will remain constant."
Alemparte, J, et al. The Journal of Arthroplasty 2003; Vol 18: 420-425.

Warranty Conditions

- In order to take advantage of the warranty, the customer must comply with the warranty procedure.
- This warranty is limited to primary operations undertaken in the United Kingdom, Isle of Man, the Channel Islands and Eire (“the Territory”) where subsequent revision surgery is also undertaken within the Territory.
- This warranty protects the implant and is therefore not hospital or NHS dependent.
- This warranty will be invalid if the warranty product has been used in conjunction with the product of any other manufacturer, excluding bone cement. This warranty will be invalid if the warranty product has been used in conjunction with any other product, including bone cement, which is undergoing a trial or any other regulatory process or if the warranty product has been implanted using a trial procedure or using tools or implements which are themselves undergoing a trial.
- Even though one part of an AGC knee™ replacement is included in the warranty product listing, it will not be covered by the warranty unless it is used as part of either a “Two Part Knee” (Group A) or a “Three Part Knee” (Group B), in conjunction with other AGC implants included in the warranty product listing. For example, an AGC using a cementless tibial component or a polyethylene patella, used with a femoral or tibial component not included in the warranty product listing, will not be covered by the warranty.
- If a Stanmore™ femoral component is used in conjunction with a Biomet UK Limited acetabular cup (other than a Stanmore™ acetabular cup), then the warranty will not extend to cover the Biomet UK Limited acetabular component.
- If a Bi-Metric® or Taperloc® implant is used in conjunction with a modular head manufactured by a non Biomet company, then the warranty will not cover the stem. The warranty does not apply to Biomet modular heads.
- To qualify under this warranty the product must be implanted before the last sterile date stated on the packaging.
- This warranty cannot be varied or extended in any manner by any employee or agent of Biomet UK Limited.
- Biomet UK Limited reserves the right to withdraw this warranty at any time. If the warranty is withdrawn, Biomet UK Limited will honour all warranty products that have been implanted prior to withdrawal of the warranty. The withdrawal of this warranty will not constitute the basis for any claims whatsoever against Biomet UK Limited.
- This warranty is subject to and shall be construed in accordance with the law of England and Wales.

Nature of this Warranty

By this Warranty

Biomet UK Limited undertakes that subject to adherence to the “warranty procedure” and the terms of this warranty, Biomet will provide to any party replacing any of the “warranty products” in revision surgery the choice of an appropriate “replacement product” free of charge should the “warranty product(s)” have failed within the “warranty period”.

This warranty is provided without any admission of liability. Biomet UK Limited acknowledges that a small percentage of warranty products may fail during normal use without any defect in the product. This warranty is given in recognition of that acknowledgement and does not provide any warranty of percentage survival for that period. Further the warranty does not confer any rights other than those expressly set out in this document and does not cover any claims for consequential loss or damage. This warranty is offered as an extra benefit and does not affect your statutory rights.

Warranty Products

The products covered are:

1. AGC® implants in groups “A” and “B”:

   A -”Two part knee” - A combination of an Interlok™ (cemented) or porous (cementless) primary femur and an Interlok™ (cemented) tibia.
   B -“Three part knee” - An “A” combination of implants, plus an all polyethylene cemented patella.
   (NB: All products must be listed in the warranty document. Any other combinations of AGC implants will not be covered by the warranty).

2. Primary Stanmore™ femoral components, both monobloc and modular, Stanmore acetabular Cup and modular head.

3. Primary standard and lateralised Bi-Metric® femoral components, porous coated, Type 1 or 12/14 taper.

4. Primary standard and lateralised Taperloc® femoral components, porous coated, Type 1 or 12/14 taper.
   (Refer to full product listing at the end of this document).

Warranty Period

The warranty period is ten years from the date of implantation of the warranty product in a primary operation.

Replacement Products

In the event of a claim under this warranty, Biomet UK Limited will supply free of charge to the hospital/surgeon undertaking the revision surgery a replacement product of the hospital/surgeon's choice for use in the revision surgery. Such replacement product will be limited to products usually held by Biomet UK Limited at that time. For the avoidance of doubt, any replacement product will not be covered under the terms of the warranty.

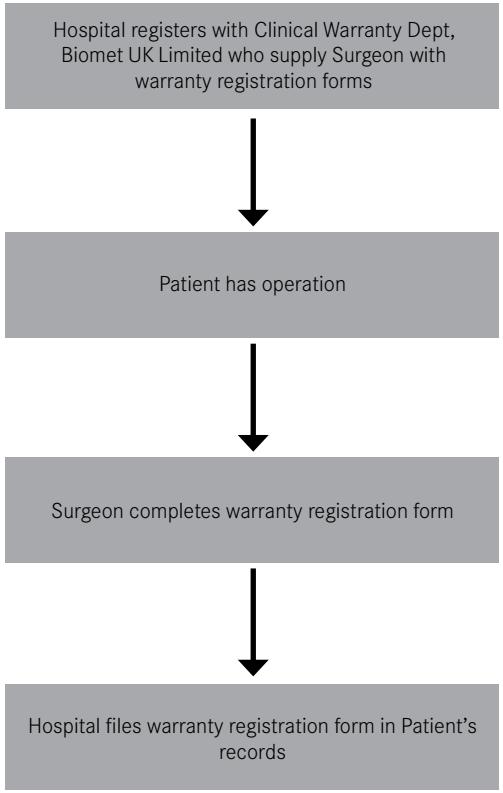
Exclusions

This warranty will be invalid if:

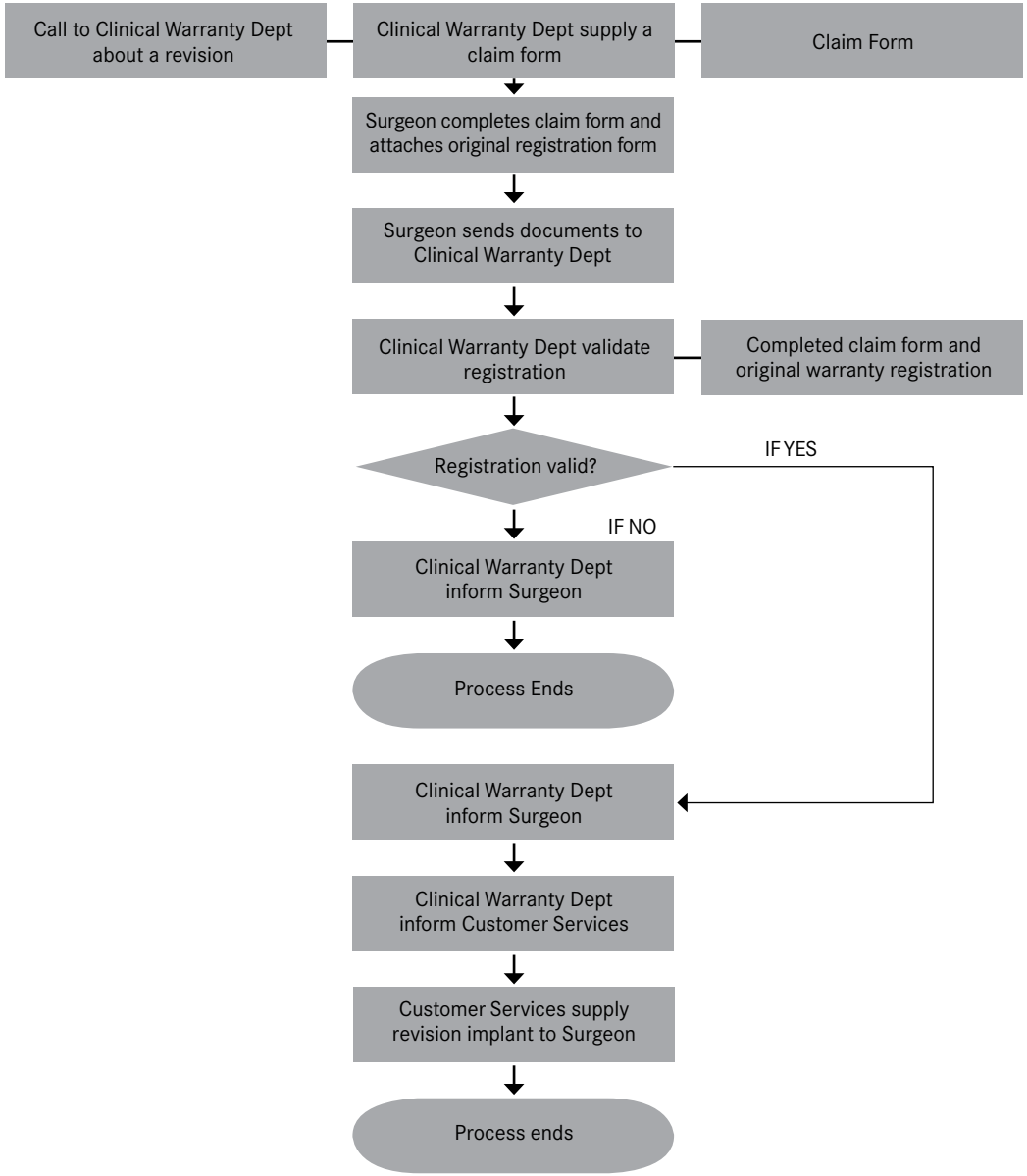
- The patient suffers at the time of the operation from a pre-existing condition that would normally preclude the implantation of a primary hip or knee replacement. This would include osteomyelitis, osteomalacia, alcoholism, Parkinson's disease, cachexia, CDH, spasticity, peripheral neurological disorders, severe obesity, psychiatric disorders and dementia.
- There is post operative trauma to the area of the warranty product, including falls and other traumatic events.
- The warranty product has been altered or modified.

Warranty Procedure

For primary procedures...



In the event of a revision procedure...



Warranty Product Listing

AGC Knee

Patella Components	V2 Interlok™ Femoral Components		V2 Interlok™ Tibial Components			
11-150820	152830	152846	158470	158490	158510	158530
11-150822	152832	152848	158471	158491	158511	158531
11-150824	152834	152849	158472	158492	158512	158532
11-150840	152836	155421	158473	158493	158513	158533
11-150842	152838	155422	158475	158494	158515	158535
11-150844	152839	155423	158477	158495	158517	158537
150820	152840	155424	158480	158497	158520	158540
150822	152842	155425	158481	158500	158521	158541
150824	152844	155426	158482	158501	158522	158542
			158483	158502	158523	158543
			158485	158503	158525	158545
			158487	158505	158527	158547
				158507		

The following V2 Porous Femoral Components are only included when used with an AGC tibial implant given in the above listing.

155411	152730	152740
155412	152732	152742
155413	152734	152744
155414	152736	152746
155415	152738	152748
155416	152739	152749

Stanmore Hip

Femoral Components		ArCom Acetabular Cups	Modular Femoral Heads	
6125-9	9125	6039-25	163653	163673
6129-9	9129	6045-25	163660	164164
6129-10	9130	6045-29	163661	164165
6133-9	164241	6045-32	163662	164166
6133-10	164242	6050-25	163663	164167
6625	164243	6050-29	163664	164168
6626	164244	6050-32	163665	164200
6629	164245	6053-25	163666	164201
6630	164251	6053-29	163667	164440
7249	164252	6053-32	163668	164441
9025	164253	165780	163669	164445
9029	164254	165781	163670	164446
9032	164255	165782	163671	164447
		165783	163672	163653

Bi-Metric Hip® Cementless Modular Femoral Components

Porous Coated T1 taper		Porous Coated 12/14 taper	
162310	650-0215	650-0280	650-1607
162251	650-0216	650-0281	650-1608
162311	650-0217	650-0282	650-1609
162252	650-0218	650-0283	650-1610
162312	650-0219	650-0284	650-1611
162253	650-0220	650-0285	650-1612
162313	650-0221	650-0286	650-1613
162254	650-0222	650-0287	650-1614
162314	650-0223	650-0288	650-1615
162255	650-0224	650-0289	650-1616
162315	650-0225	650-0290	650-1617

Taperloc Hip® Cementless Modular Femoral Components

Porous Coated T1 taper		Porous Coated 12/14 taper	
103201	11-103201	650-0580	650-0590
164400	103807	650-0319	650-0349
103203	11-103203	650-0260	650-0263
164401	103808	650-0320	650-0350
103205	11-103205	650-0261	650-0264
164402	103809	650-0321	650-0351
103207	11-103207	650-0262	650-0265
164403	103810	650-0322	650-0352
164404	103811	650-0323	650-0353
164405	103812	650-0324	650-0354

Notes

Notes

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