Biomet UK Ltd

10 Year Warranty Programme
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.
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*.
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.”

“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).”

“Only two hips (Stanmore and Charnley) have fifteen year results published in peer-reviewed journals.”

Stanmore long-term survivorship at 10 years 95%, and at 15 years 91%.

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.

* 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”
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**.
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.


"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."


Bi-Metric femoral component long-term survivorship of 98% when followed for 5-11 years.


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.”


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…"

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***.
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."

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."

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.

"…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."

***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…”

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%.”

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…”
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.
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%

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%.

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.

"...98% survival rate at 10 years" – in a multi-centre study.

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.”

“The AGC posterior cruciate sparing total knee replacement: Fifteen years experience.”

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.”

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.”
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...

Hospital registers with Clinical Warranty Dept, Biomet UK Limited who supply Surgeon with warranty registration forms

Patient has operation

Surgeon completes warranty registration form

Hospital files warranty registration form in Patient’s records

In the event of a revision procedure...

Call to Clinical Warranty Dept about a revision

Clinical Warranty Dept supply a claim form

Surgeon completes claim form and attaches original registration form

Surgeon sends documents to Clinical Warranty Dept

Clinical Warranty Dept validate registration

Completed claim form and original warranty registration

Registration valid?

IF YES

Claim Form

IF NO

Clinical Warranty Dept inform Surgeon

Process Ends

Clinical Warranty Dept inform Surgeon

Clinical Warranty Dept inform Customer Services

Customer Services supply revision implant to Surgeon

Process ends
Warranty Product Listing

AGC Knee

<table>
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<tr>
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<th>V2 Interlok™ Femoral Components</th>
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The following V2 Porous Femoral Components are only included when used with an AGC tibial implant given in the above listing.

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| 155416 | 152739 | 152749 |
### Stanmore Hip

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### Bi-Metric Hip®

Cementless Modular Femoral Components

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### Taperloc Hip®

Cementless Modular Femoral Components

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