THE AGC® TRADITION™ SERIES
TIMELINE OF EXCELLENCE

1983
Biomat introduces the AGC® Total Knee System, featuring a universal femoral component, a one-piece molded, metal-backed tibial component and a dome-shaped patellar component. The AGC system is the first total knee system to offer complete component interchangeability, a deep, unconstrained patellofemoral articulation and a femoral component that incorporates the durability of a cobalt chrome articulating surface with the biocompatibility of a titanium alloy porous plasma sprayed fixation surface.

1985
Biomat designs AGC femoral components with an anatomic anterior flange and a 7° patellofemoral track. The patella-femoral articulation remains unchanged, and the universal femoral components are available in conjunction with the anatomic femora, addressing the broad needs of patients and hospitals.

1986
Biomat introduces AGC instrumentation for the femur to increase surgical flexibility.

1987
Merrill Ritter, M.D. reports preliminary 1 to 5 year clinical results showing a 98.9% survival rate for the universal AGC cruciate-retaining femoral component, molded, metal-backed tibial component and a dome-shaped patellar component. Average range of motion is 113°.

1989
The AGC Cam-and-Groove posterior-stabilized knee is introduced. This patented design addresses total knee replacement which substitutes for the posterior cruciate ligament. Today, this is the only posterior-stabilized knee that does not require any additional bone cuts from a cruciate-retaining primary knee.

1990
Biomat develops the AGC Accu-Line™ instrumentation, which increases flexibility in total knee instruments. The AGC Modular Tibial II is released and features a compressive loading polyethylene locking mechanism. This modular design helps reduce micromotion and polyethylene wear debris.

1991
Kurt Rechasinger, M.D. presents a 97% survival rate of 425 cementless AGC total knee arthroplasties at 1 to 6 years.

1992
Biomat develops the Maxim® instrument system, which is fully compatible with AGC implants. This fourth generation Biomat instrument system offers state-of-the-art technology and design in total knee surgery.

1993
Richard Worland, M.D. reports on a series of 960 cemented, PCL-retaining, primary total knees. At 1 to 7 years, the prosthesis survival rate is greater than 99% with no cases of component loosening. He also reports an overall complication rate of 3.6% and an average range of motion of 122°.

Biomat introduces Axial™ intramedullary total knee instrumentation, providing surgeons with increased operative flexibility.

1994
The Swedish Knee Study reports a cumulative survival rate of 92.5% for 2,258 AGC total knee arthroplasties at a 1 to 9 year follow-up. This multi-center, multi-surgeon study tracks all knee replacements in Sweden and demonstrates the consistency of the AGC knee’s clinical results.

1995
Merrill Ritter, M.D. presents to the Knee Society a series of 2,001 AGC cruciate-retaining total knee replacements done at three centers across the United States. At 10 years, the tibiofemoral survival rate is 98.7% with a total of six revisions for component loosening and no revisions for polyethylene failure on the tibial side. Average range of motion is 108°.

The AGC tradition continues with the introduction of the AGC Tradition High-Peel, posterior-stabilized total knee, which provides surgeons increased flexibility in the operating room. Building on the clinical success of the past 12 years, the AGC Total Knee System offers durable implants, user-friendly instrumentation and unmatched clinical results.

*U.S. Patent No. # 4,958,071

THE AGC TRADITION SERIES

Since 1983 the Biomat AGC Total Knee System has delivered clinical results that are unparalleled by other knee systems. Premier orthopaedic materials, engineered into flexible design features, provide optimal surgical latitude and consistent long-term clinical excellence:

- Molded polyethylene provides a highly consolidated, wear resistant bearing material that has shown a 98.7% tibial survival rate at 3 to 10 years clinical follow-up when used in the AGC primary total knee.¹

- Cobalt-chromium femoral articular surface offers maximum durability of the tibiofemoral and patellofemoral articulation.

- Titanium alloy porous plasma sprayed coating, which offers proven clinical biocompatibility,¹² has been in use with the AGC system since 1983.

- Full interchangeability of femoral, tibial and patellar components allows optimal independent component sizing.

- A deep, wide trochlear groove articulates with a dome-shaped patellar component, creating a congruent and forgiving patellofemoral joint.

- Wide femoral condyles reduce contact stresses.

- Cruciate-retaining and posterior-stabilized implant options increase intraoperative surgical latitude.

The Swedish Knee Study demonstrates the consistent, long-term clinical results of the AGC Total Knee System. Orthopaedic surgeons across Sweden implanted 2,258 AGC primary total knees and reported a 97.0% survival rate at 1 to 9 years. These results were unattained by other competitive knee systems.

The porous coated devices depicted in this brochure are marketed for use with bone cement in the United States.
AGC TRADITION UNIVERSAL, CRUCIATE-RETAINING FEMORAL COMPONENTS

Meeting the specific needs of patients and hospitals, the AGC Tradition anatomic femoral component shares the same sizing and bone cuts as the universal cruciate-retaining femoral, and features the following:

- Anatomic anterior flange enhances femoral bone coverage.
- A deep, wide 7° patellofemoral groove allows for anatomic patellar articulation.
- Titanium alloy porous plasma sprayed coating option for superior biocompatibility.
- Interlok finish option for enhanced cement fixation.

All AGC cruciate-retaining and cruciate-substituting femoral components are implanted with reference to the posterior condyle. Each component has a posterior condyle thickness of bone and utilizes the same trochanteric plug hole, making an interchangeable femoral sizing change as easy as treating femoral cutting guides. Patellar referencing, combined with a consistent femoral containment thickness, allows for joint line restoration in both flexion and extension.

Porous Surface

Aglo Surface

Common A-P bar geometry between all AGC Tradition and Barnett Maxim femoral components allow for flexibility and convenience in the operating room.

Features of the AGC universal cruciate-retaining femoral component:

- Universal components eliminate the need for left and right specific implants, reducing inventory.
- Cobalt chromium alloy femoral components create a durable articulating surface.
- Five sizes of AGC Tradition universal femoral components are available from 55 to 75mm in 5mm increments.
- Interlok® surface for enhanced fixation.
The AGC Tradition Cam-and-Groove posterior-stabilized total knee is the only implant that offers complete intraoperative flexibility between cruciate retaining and cruciate substituting with no additional bone cuts. The posterior-stabilized Cam-and-Groove femoral component articulates on the same one-piece molded, metal-backed tibial component that is used in cruciate-retaining applications. This combination makes the AGC Cam-and-Groove posterior-stabilized femoral component an economical and inventory-efficient posterior cruciate substituting option.

Features include:

- **Cam-and-Groove mechanism** resists posterior subluxation and has been shown to be twice as strong as the normal posterior cruciate ligament.  
- **Anatomic femoral components** are available in both porous and Interlok fixation options.

The AGC Tradition Cam-and-Groove posterior-stabilized femoral component achieves stability against posterior tibial subluxation through a unique Cam-and-Groove mechanism. This posterior-stabilized design requires no additional bone cuts.
AGC TRADITION ARCOM® MOLDED, METAL-BACKED TIBIAL COMPONENTS

With a cumulative survival rate of 98.7% up to 10 years, this tibial component offers the ultimate in both clinical performance and value.

Design features include:

- Full compatibility with all AGC Tradition Series femoral components.
- Porous and Interlok fixation options.
- A 3.6mm metal baseplate maximizes polyethylene thickness throughout the articulating area while maintaining superior base plate strength.
- One-piece design minimizes the opportunity for micromotion between the tray and polyethylene, as well as subsequent debris generation.
- Molded articular geometry eliminates machine lines on the polyethylene articular surface and the potential for debris generation caused by machine line cold flow.

The ArCom bearing surface is directly molded to the CoC baseplate during the manufacturing process, minimizing the potential for under-side bearing micromotion. Unlike many competitive modular designs, no raised peripheral locking mechanism is utilized; therefore, the AGC Tradition molded components maintain consistently thick polyethylene at the periphery and throughout the articulating area.

AGC TRADITION MODULAR TIBIAL COMPONENTS

The AGC Tradition modular tibial components utilize a unique compressive locking mechanism that reduces polyethylene micromotion and maintains full polyethylene thickness peripherally as well as beneath the tibial articulating area. Tibial trays include both porous and Interlok fixation options, and block and wedge augmentations are available to fill bone defects. Other features include:

- Nine medial-lateral tibial sizes, based on the anatomic work of Mench and Amstutz, provide optimal bone coverage.
- Molded ArCom bearing inserts eliminate machine lines on the articulating surface and reduce the potential for wear particles.
- Porous coated modular baseplates utilize circumferential porous coating and accept up to four 6.5mm cancellous bone screws.
- Modular stems are locked by a Morse taper and a screw thread that create a cold weld to secure the stem and plate.

License includes U.S. and foreign patent rights.
Simplicity, consistency and flexibility have made the AGC system's patellofemoral articulation clinically successful for 12 years. The AGC femoral's deep, wide and unconstrained trochlear groove allows the Biomet dome-shaped patellar component to travel without restriction and in correct anatomical alignment, while maintaining a line contact into flexion.

Biomet patellar components are manufactured from ArCom polyethylene, which provides the consistent consolidation of molded polyethylene and shows superior wear properties to that of extruded bar polyethylene.1

Features of Biomet patellar components include:

- **31, 34 and 37mm patellar component diameters** provide optimal patient sizing.

- **Choice of one-peg and three-peg fixation modes** are available for increased flexibility.

- **Three distinct instrumentation options** allow for flexibility and control of patellar bone thickness. Biomet patellar components can be inset or onset as the surgeon desires.

Unlike competitive modified dome and anatomic patellofemoral articulations, the AGC system maintains a line contact if the extensor mechanism tracks normally, as well as when the extensor mechanism tracks laterally.
THE AGC TRADITION HIGH-POST POSTERIOR-STABILIZED FEMORAL COMPONENTS

The AGC Tradition High-Post femoral component offers a posterior-stabilized option that enhances knee kinematics by inducing femoral rollback. Tradition High-Post femoral components require one additional bone cut, making the transition to cruciate-substituting simple. Design features of the AGC Tradition High-Post component include:

- Complete interchangeability between High-Post femoral, tibial, and biometer patellar components, allowing flexibility in component sizing.
- Universal anterior flange reduces inventory.
- Cobalt chromium alloy provides durable articulation.
- Interlok fixation surface enhances cement mantle integrity.

The AGC Tradition High-Post posterior-stabilized component provides anatomic rollback and an optimal range-of-motion.

THE AGC TRADITION ARCOM HIGH-POST POSTERIOR-STABILIZED TIBIAL COMPONENTS

Orthopaedic bearing materials made of compression molded polyethylene have shown superior wear properties over extended time polyethylene.* Like all AGC Tradition bearing materials, the AGC Tradition High-Post tibial component utilizes the proven durability of ArcCom polyethylene. The fixed, 3.6mm metal baseplate allows for uniformly thick polyethylene. Thick polyethylene has been shown to distribute loads evenly and increase an implant’s durability.**

Other features of the Tradition High-Post posterior-stabilized tibial component include:

- Clinically proven molding process eliminates machine lines in the articulating surfaces, providing a smooth articulating area, while potentially reducing wear debris.
- Posterior lipped tibial component adds anterior/posterior stability.
- Central tibial eminence, which substitutes for the posterior cruciate ligament to produce anatomic femoral rollback.
- Fixed I-beam stem offers component stability.
- Interlok surface provides enhanced cement fixation.

Unlike secondary load bearing cycles used in other machine lines, the molding process provides a smooth, durable bearing surface of highly cross-linked material with over 10 years of excellent clinical follow-up. Ultrasound machine lines reduce the potential for debris generation caused by machine line coolant flow.
THE BIOMET FAMILY OF KNEE SYSTEMS
AGC — MAXIM — FINN

Living surgeons and hospitals the flexibility to meet the needs of virtually any patient requires the cornerstone of the Biomet Family of total knees. The Family™ packages three very successful knee systems into one comprehensive approach to total knee arthroplasty. The Family utilizes common instrumentation and addresses a wide range of options and issues:

- Low-Demand Primary—Providing cost-effective, clinically documented implant designs.
- High-Demand Primary—Expanding indications.
- Posterior-Stabilized—Increasing surgical latitude.
- Constrained—Addressing complicated cases.
- Rotating Hinge—Extending salvage options.

The foundation of the Family is rooted around the long-term clinical excellence and design parameters of the AGC Total Knee. The Maxim Knee System increases the flexibility and surgical latitude of the Family by providing advancements in modularity. This, combined with the clinical success of the Finn Rotating Hinge Knee,¹ provides the most complete line of total knee implants available today.

A COMMON SET OF INSTRUMENTS TO MEET YOUR SPECIFIC NEEDS

Biomet's Family of total knees utilizes the same femoral and tibial resection instruments, providing the operating room team with precise, user-friendly instrumentation that is familiar, regardless of a patient's specific indication and implant need.

Instrument standardization reduces operating room confusion and instrument processing costs, while increasing the efficiency of the operating room team.
THE AGC TRADITION AND ARCOM POLYETHYLENE: A SOLID STORY

The long-term clinical success of molded polyethylene in the AGC tibial design spurred Biomet research and development scientists to explore polyethylene performance and improve polyethylene quality. The result of their efforts: ArCom polyethylene.

ArCom, a one-piece molded, metal-backed tibial component, is made from ArCom polyethylene. The reasons ArCom polyethylene is the polyethylene of choice are:

- Controlled compression molding manufacturing process.
- Better consolidation of polyethylene particles.
- No additional thermal cycles required.
- Pure, very high molecular weight resin.
- Resin contains no processing additives.
- Higher ultimate tensile strength.
- Inert gas packaging and sterilization environments to reduce oxidation.
- Improved resistance to degradation and discoloration.

CONSOLIDATION AND MANUFACTURING

Before ArCom, tibial bars made of extruded bar polyethylene were the standard of the industry. Ram extrusion is the most widely used manufacturing process of ultra high molecular weight polyethylene (UHMWPE). However, ram extrusion can result in non-consolidated areas within the UHMWPE bar.

THE MANUFACTURING OF UHMWPE

The two basic methods of processing polyethylene are ram extrusion and compression molding. The ram extrusion process involves melting resin into a gel, which is then forced with a ram through an extrusion die under pressure to make a polyethylene bar.

Ram Extrusion Process

Extruded Polyethylene is then packed into molding dies, heated, and compressed to achieve the desired density. This process is followed by cooling and trimming to ensure the final dimensions of the component.

The potential problems associated with ram extrusion are:

- **Problem: Residual stress**—This can occur from the inconsistent ram pressure being exerted on the gel and polyethylene flake as it is processed. Result: Bar needs to be subjected to an additional thermal cycle.
- **Problem: Additional thermal cycles are needed to remove residual stresses**—Additional thermal cycles can negatively affect the material properties of ram extruded bar stock. Result: Material oxidation and density are increased. Molecular weight is decreased and contact stresses may be increased.
- **Problem: Dead centers**—If the polyethylene resin is fed too rapidly through the ram extruder process, a dead center, or areas of non-consolidated resin, can result from incomplete heating of the resin. Result: Voids of non-consolidated areas can result.
- **Problem: Non-consolidated areas**—These areas can result in inconsistent quality of the polyethylene. Result: Voids in the material may affect wear characteristics.
- **Problem: Purity of flake depends on vendors**—Implant manufacturers have no control over extruded bar resin purity. Result: The purity of the resin used in processing can affect the final quality of extruded polyethylene stock.

All polyethylene components used in the AGC Tradition Series are ArCom molded polyethylene. The molded manufacturing process utilizes circumference adjustment and pressure to make highly uniform, consistent material that has very few, if any, non-consolidated areas. Additional thermal cycles are not needed with compression molding because no residual stresses are created during molding, due to the consistency of the heat, time and pressure used in the manufacturing process.

Since ArCom Tibial bearings are molded, not machined, the articular surface of the ArCom Tibial components is very smooth and free of machine lines that can roughen the articulating area. In competitive Tibial designs, these lines may cause wear and be a cause of polyethylene wear debris.

**ARCOM POLYETHYLENE UTILIZES PURE, VERY HIGH MOLECULAR WEIGHT RAW MATERIAL**

Polyethylene with a molecular weight of 3-8 million has been the industry standard in Tibial bearing surfaces and patellar components. ArCom's molecular weight approaches the high end of the scale, providing potentially better wear resistance. Studies published by Eyre and Stein have indicated that polyethylene wear is directly related to the molecular weight of the polyethylene. The higher the molecular weight, the better the wear resistance.

**HIGHER ULTIMATE TENSILE STRENGTH**

ArCom has shown a 30% increase in tensile strength compared to conventional extruded bar. Ultimate tensile strength refers to the maximum stress a material can withstand before failure. By increasing the tensile strength, ArCom helps to minimize polyethylene wear and debris generation.

**RESIN CONTAINS NO PROCESSING ADDITIVES**

Extruded bar polyethylene has been shown to have high levels of impurities that may be introduced during the extrusion process; polymer resins may be contaminated with dirt and contain stearates. Additionally, stearates (flow enhancers) can coalesce (grow) during the manufacturing process and create voids in the polyethylene. These voids, or non-consolidated areas in the polymer can lead to greater wear in the material.

ArCom polyethylene resin is stringently tested and selected from the highest quality polyethylene resin. The compression molding process also eliminates the need for stearate additives.

**ARGIN PACKAGING TO REDUCE OXIDATION**

Polyethylene demonstrates degradation caused by gamma radiation sterilization in oxygen. Sterilization of polyethylene in an inert gas environment has been shown to reduce the damage to the material. ArCom polyethylene is sterilized in an argon environment instead of an oxygenated atmosphere. Argon is a non-reactive gas which will not bond with the free radicals generated during sterilization. Polyethylene sterilized in an oxygen atmosphere creates short chains, or free radicals, which result in lower molecular weight of the polyethylene and make it more susceptible to wear. ArCom promotes the recombination and cross-linking of the polyethylene chains back to a long-chain configuration rather than short segments. Cross- linking of chains increases strength and polymer wear resistance.

**ARCOM POLYETHYLENE**

Through improved processes and controls, ArCom polyethylene is the evolution of proven UHMWPE into a superior, wear resistant polyethylene. Its properties make ArCom polyethylene the preferred choice for outstanding clinical performance in the polyethylene components of the knee.
AGC TRADITION COMPONENT MATRIX

AGC TRADITION SURGICAL OVERVIEW

Twelve years of clinical experience have evolved the AGC Tradition surgical technique into one of flexibility and simplicity. With the surgeon's preference in mind, Biomet offers both intramedullary and extramedullary instrumentation for the tibia and femur.

Step One—Either an FEM or IM tibial resection guide is used to make a flat cut perpendicular to the long axis of the tibia.

Step Two—The distal femoral resection is made, noting the distal femoral component thickness of 9mm.

Step Three—Referencing the posterior condyles, size is determined and rotation set via the distal peg holes.

Step Four—Femoral contour cuts are made using 4-in-1 contour, surface, or dual-pivot cut blocks.

Step Five—An intercondylar box resection is made (Tradition High-Post posterior stabilized only).

Step Six—The patella is prepared.

Step Seven—A trial reduction is made and tibial stem preparation is completed.

Step Eight—Components are implanted.

Biomet, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on an individual patient. The surgeon who performs any procedure is responsible for determining and selecting the appropriate techniques for each patient. Biomet is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.
REFERENCES


9. Information on file at Biomet, Inc., Warsaw, IN.


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