



Spine

Trauma

BioMaterials

Cement

Joint Replacement

Vanguard Knee™ Surgical **Technique**

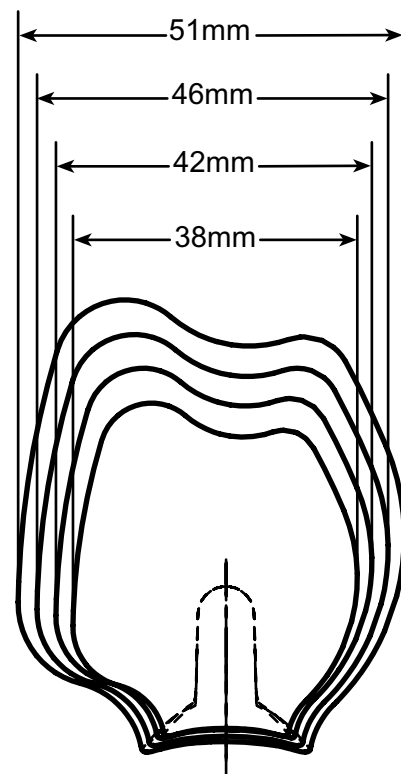
VANGUARD™ PFR

PATELLOFEMORAL REPLACEMENT SYSTEM

Vanguard™ Unicompartmental Patellofemoral Arthroplasty

Femoral Component

- Bone and ligament sparing for easier conversion to TKA
- Minimal bone resection
- Cobalt chromium alloy femoral component is available in four anatomic (L & R) sizes
- Interlok® finish with undercut pockets for enhanced cement fixation
- 3° of intraoperative rotational alignment, not constrained by anterior pegs, for optimal patella tracking
- Precise, simple, and user-friendly instrumentation



References:

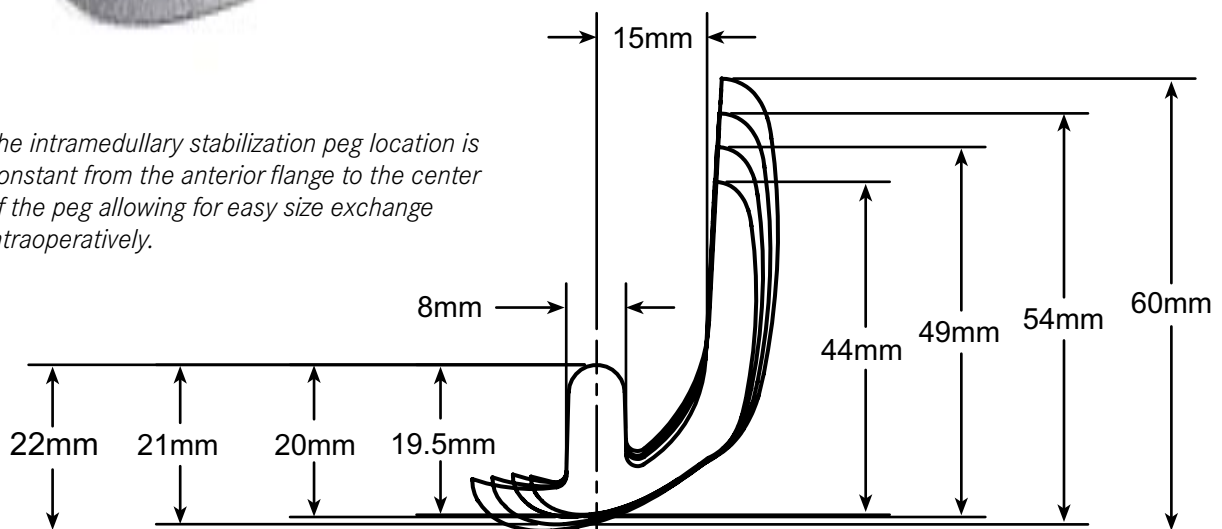
- 1 Beadling L.; Direct-Molded Components Shown to Resist Oxidation. *Orthopedics Today*, April 1997, Vol 17, No. 4.
- 2 Bankston B.; *et al.* Comparison of Polyethylene Wear in Machined Versus Molded Polyethylene. *CORR*, No. 317; 37-42.
- 3 Aglietti P.; *et al.* Patella Resurfacing in Total Knee Replacement: Functional Evaluation and Complications. *Knee Surg Sports Traumatol Arthrosc* 2001; 9 Suppl 1:S27-33.

Biomet ArCom[®] Patellar Components

- Biomet patellar components are manufactured from ArCom[®] polyethylene, which has shown superior wear properties.^{1,2}
- Choice of one-peg and three-peg fixation models in four sizes for increased flexibility and optimal patient sizing.
- A true dome patella design is more forgiving to rotational stresses and misalignment.³



The intramedullary stabilization peg location is constant from the anterior flange to the center of the peg allowing for easy size exchange intraoperatively.



Indications/ Contraindications*

The Unicompartmental Patellofemoral Prosthesis is indicated for use in patients with osteoarthritis in the patellofemoral joint, a history of patellar dislocation or patellar fracture, and in patients with failed previous surgery where pain, deformity, or dysfunction persists. Both cruciate ligaments must be intact. The tibiofemoral joints should be well preserved, with an intact meniscus and full thickness of articular cartilage.

Patellofemoral replacement is contraindicated in patients with active infection and in all forms of inflammatory arthritis. The procedure is contraindicated in patients with mental or neuromuscular disorders that do not allow control of the knee joint or without soft tissue integrity to provide adequate stability of the joint. Patients whose weight, age or activity level might cause extreme loads leading to early failure might be considered inappropriate for patellofemoral replacement.



Disclaimer

Biomet UK Ltd., as the manufacturer of this device, does not practice medicine and does not recommend any particular surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and utilising the appropriate techniques for implanting prosthesis in each individual patient.

Biomet UK Ltd, is not responsible for selection of the appropriate surgical technique to be utilised on an individual patient.

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Exposure

A midline skin incision is made longitudinally from above the patella to a point just medial to the tibial tubercle. The joint capsule and synovia are opened using a standard median parapatella incision (figure 1). Evert the patella laterally to expose the patellar facet and excise the lateral facet as necessary. Remove any osteophytes in the trochlear groove with rongeurs or an osteotome.

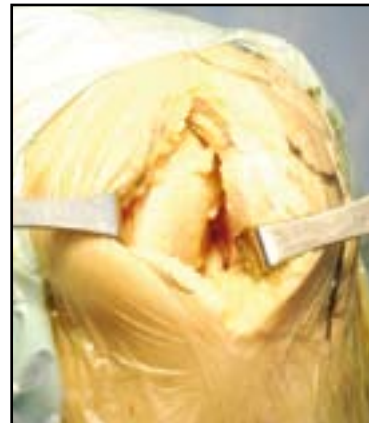


figure 1

Femoral Preparation

Reduce the joint and observe the articulation of the patella as the knee is flexed, so as to identify the centerline of both the patella and the patellargroove.

Bring the knee into 90° of flexion and retract the patella laterally. A 6mm hole is made in line with the femoral shaft using the 6mm step drill (figure 2). The canal location is approximately 1 cm above the insertion of the posterior cruciate ligament. Slight toggling of the drill upon entering will help center the intramedullary rod and provide additional venting of the medullary canal.



figure 2

Insert the the PFR IM rod impactor onto the fluted rod. Slowly insert the fluted intramedullary rod into the isthmus, engaging the fins into the femoral canal (figure 3). Remove the IM rod impactor, leaving intramedullary rod in the isthmus.



figure 3

Insert the PFR alignment guide block onto the fluted rod with the arrow pointing towards the knee (figure 4).

Position the alignment guide block so that it approximates the distal femur, (figure 5) and insert the PFR alignment rod into the alignment guide block.

Using the handles and anterior prominence, adjust rotation manually using Whiteside's line and the epicondylar plane in both the sagittal and transverse plane (figure 6). Lock the alignment guide block into place on the fluted rod with the small knob. Remove the PFR alignment rod.



figure 4



figure 5



figure 6

Insert the femoral resection guide into the alignment block bringing the stylus into contact with the anterior femur (figure 7). Depending on exposure, the guide may be placed on the medial or lateral side of the joint; whichever allows best access to make the anterior cut.

Insert the feeler gauge through the cutting slot to meet the stylus at the anterior cortex (figure 8). This is a secondary check to make sure the implant will sit flush on the anterior cortex.

Stabilize the rotation of the guide with a quick release drill bit through the pinhole on the guide and the stylus (figure 9). Re-confirm alignment of the guide with Whiteside's line.



figure 7



figure 8



figure 9

Anterior Femoral Cut

Make the anterior cut through the slot in the resection guide using an oscillating saw with a 12mm x 0.054 inch sawblade (figure 10). The saw blade should emerge from the bone at the tip of the stylus.

Remove the femoral cutting guide and the fluted rod using the pin and nail puller, which may be attached to the slap hammer extractor if necessary (figure 11).

After completion of the anterior femoral cut, use the conical rasp to remove any articular cartilage remaining in the trochlear groove. Round off the intracondylar portion of the cut edge that will contact the corresponding portion of the implant. Remove any intracondylar osteophytes (figure 12).



figure 10



figure 11



figure 12

Sizing of the Femoral Component

To determine the correct size of the femoral component, start with a medium trial to judge the contour and fit. The intracondylar portion of the trial should fit flush and its articular surface should be prominent by 1mm. This will allow the patellar component to articulate with the femoral component without contacting the normal femoral condyles during flexion (figure 13).



figure 13

Patellar Preparation

The border of the patella is excised of soft tissue down to the insertion of the quadriceps and patellar tendons. The maximum thickness of the patella is then measured with the patellar caliper prior to making any cuts (figure 14). The patellar resection is performed utilizing any cutting or milling technique desired. Resect only as much patella as will be replaced with the patella implant.



figure 14

Patellar Preparation, Continued

Place the appropriate one or three peg patella drill guide onto the patella and drill the peg hole(s) with the stop drill (figure 15).

Trial Reduction

Trial patellar and femoral components are inserted, pinning the femoral trial on the medial side only (figure 16) and the knee reduced and put through a full range of motion (figures 17a & 17b).

The thickness of the patella with the trial in place is again measured with the patellar caliper and compared to the thickness measured before the resection was made. If the final thickness is too great, the trials are removed and additional bone resected.



figure 15

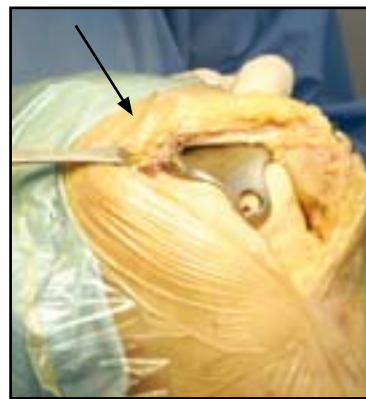


figure 16



figure 17a



figure 17b

Drill for Femoral Peg

When a satisfactory trial reduction has been completed, attach the bushing to the femoral trial and drill the peg hole with the appropriate 8mm step-drill (figure 18). Remove all trial components and select the implant components, which correspond to the sizing of the final trial components used.

Implantation

The anterior femoral surface may be roughened by multiple small drill holes made with the optional cement key drill or an 1/8 in. drill bit. Prior to the application of bone cement, all resected surfaces must be thoroughly cleaned with a pressurized lavage and thoroughly dried. It is advisable to use a suctioning device to remove debris and liquid trapped in the chambers of the trabecular bone. Meticulous bone preparation and cementing techniques are critical to the success of the procedure.

The bone cement is mixed and the final components are cemented into place using a standard cementing technique. The femoral component is impacted until it is fully seated using the femoral impactor. The patellar cementing clamp is applied to the patella to sustain compression while the cement is curing.

Excess cement is cleared from the edges of the components with a curette, taking care not to damage the articulating surfaces of the implants (figure 19). A final check of the range of motion should be carried out with the patella reduced and the joint inspected for any remaining cement or debris.

Closed suction drainage tubes may be inserted, if desired. The wound is closed in the usual manner.

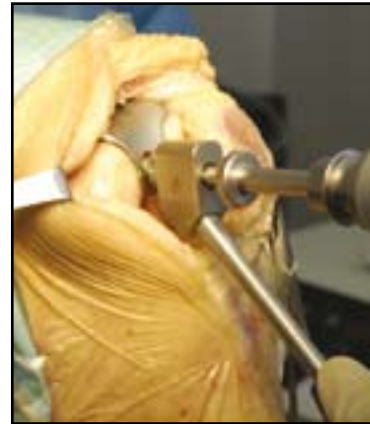


figure 18



figure 19

Ordering Information

Vanguard™ PFR Femoral Components	
Part No.	Size
11-150902	X-Small, Rt
11-150904	X-Small, Lt
11-150906	Small, Rt
11-150908	Small, Lt
11-150910	Medium, Rt
11-150912	Medium, Lt
11-150914	Large, Rt
11-150916	Large, Lt

Instrumentation

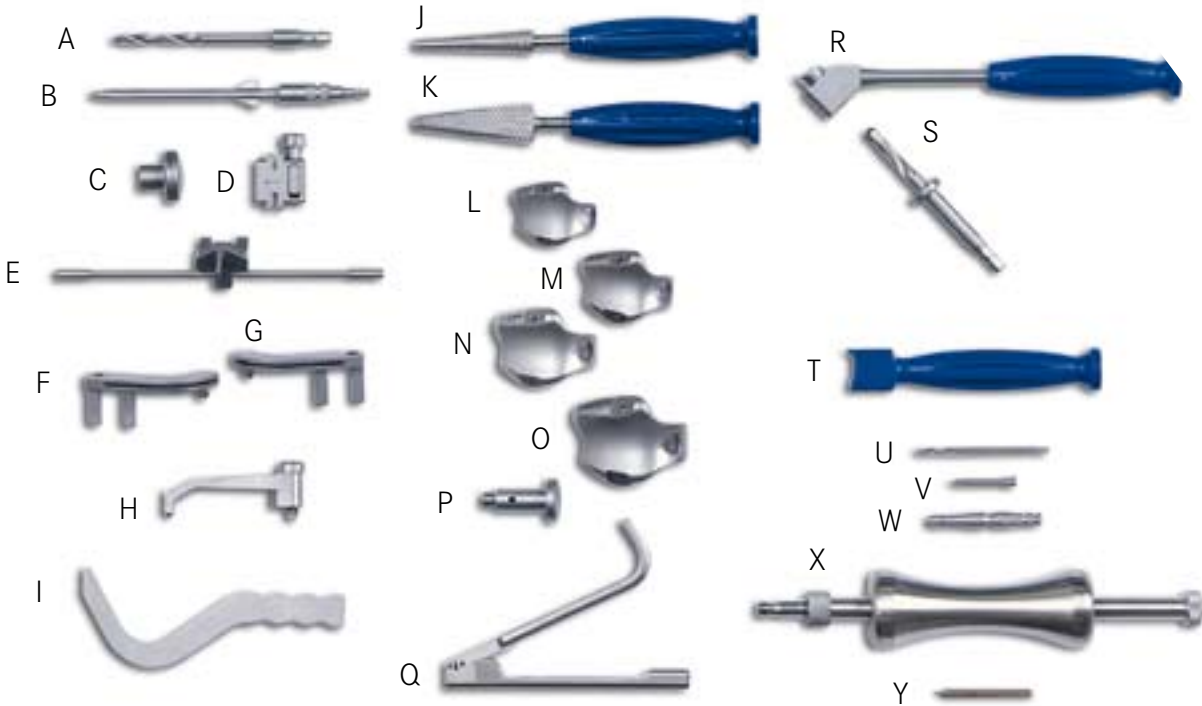
(A) PFR IM Drill 6mm		32-347599
(B) PFR IM Fluted Rod		32-347570
(C) PFR IM Rod Impactor Knob		32-347593
(D) PFR Alignment Guide Block		32-347571
(E) PFR Alignment Rod		32-347575
(F) PFR Fem Resection Guide RM/LL		32-347572
(G) PFR Fem Resection Guide LM/RL		32-347573
(H) PFR Anterior Femoral Stylus		32-347574
(I) PFR Axial Fem Anterior Feeler Gauge		32-347594
(J) PFR Small Rasp		32-347576
(K) PFR Large Rasp		32-347577
(L) PFR Femoral Trial Extra Small	Right Left	32-347580 32-347581
(M) PFR Femoral Trial Small	Right Left	32-347582 32-347583

(N) PFR Femoral Trial Medium	Right Left	32-347584 32-347585
(O) PFR Femoral Trial Large	Right Left	32-347586 32-347587
(P) PFR Impactor Head		32-347595
(Q) Pin Insert/Extractor		32-420160
(R) PFR Drill Guide Bushing		32-347590
(S) PFR Peg Fixation Drill		32-347591
(T) PFR Femoral Impactor		32-347592
(U) Quick Release Drill 1/8"	Sterile PK/2	32-486265
(V) Bone Nail Medium		32-349218
(W) Quick Release Drill Chuck		32-467618
(X) Slide Hammer Extractor		31-473621
Instrument Case		595215
Templates		11-150930

Optional Instrumentation

(Y) Cement Key Drill	32-420661
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Instrumentation



Instruments Assembled



Case Study

A sixty-two year old female, with severe anterior knee pain from osteoarthritis of the patellofemoral joint, did not improve with conservative treatment. She underwent patellofemoral arthroplasty utilizing the Vanguard™ PFR Patellofemoral implant. The postoperative X-rays, shown here at her two-year follow-up, confirm good alignment of the components without progression of the osteoarthritis. The patient continues to be pain-free with a ROM of 0–125 degrees and ambulates without assistance.



This package insert was applicable at the time of print and is subject to change without notice. Please ensure that you review and familiarize yourself with the product insert accompanying the implant at the time of surgery.

TOTAL KNEE PROSTHESIS INSTRUCTIONS FOR USE

The advancement of Total Joint Replacement has provided the surgeon with a means to restore mobility and reduce pain in many patients.

The Total Knee Prosthesis includes a number of implants: Femoral Components, Tibial Inserts, Tibial Trays, Tibial Stems, Femoral Stems, Tibial Augmentation Blocks, Femoral Augmentation Blocks, Patellas, Tibial Locking Screws, Fixation Screws, etc.

Although these devices have a high percentage of success, it cannot be expected that they will withstand the same activity levels and loads as normal healthy bone.

In the use of total joint replacement implants the surgeon should be aware of the following:

A. The correct selection of the implant is extremely important. The potential for success in a total joint replacement is increased by the selection of the proper size, shape and design of the implant. No total joint replacement can be expected to withstand the same loads and activity levels as normal healthy bone. Total joint prostheses require careful implantation and adequate bone support and should be restricted to limited functional stresses.

B. In selecting patients for total joint replacement, the following factors can be of extreme importance for the ultimate success of the procedure:

1. Patient weight. An overweight or obese patient can overload the implanted device.
2. Patient occupation or activity. If the patient is involved in an occupation or activity that implies substantial walking, running, weight lifting or muscle strain, the resultant forces can lead to failure of the orthopedic device.
3. Senility, mental illness or alcoholism. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the device, leading to implant failure or other complications.
4. Certain degenerative diseases. In some cases, the progression of a degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the orthopedic device. In such cases joint replacement can only be considered a delaying technique or a means for providing temporary relief.
5. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection and implantation.

C. The materials used to manufacture the implants are specified on the individual labeling of each implant.

D. Correct handling of the implant is extremely important, in order to avoid defects in the surface finish, which could constitute the origin of ultimate device failure.

E. No component of the Total Knee Prosthesis should be reused. Once used, these implants must be discarded. Even if they appear undamaged, they may have small defects and stress patterns which may lead to fatigue failure.

F. Postoperative care is important. The patient should be instructed on the limitations of these devices and should be cautioned regarding load bearing, range of motion, and permissible activity levels. Early load bearing should be carefully controlled.

G. Total Knee Prosthesis are supplied sterile (gamma radiation) and should never be resterilized.

H. Specific instrumentation is available for use with the different components of the Total Knee Prosthesis, along with a description of the surgical technique.

INFORMATION: For further information, please contact the Biomet representative in your area.

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