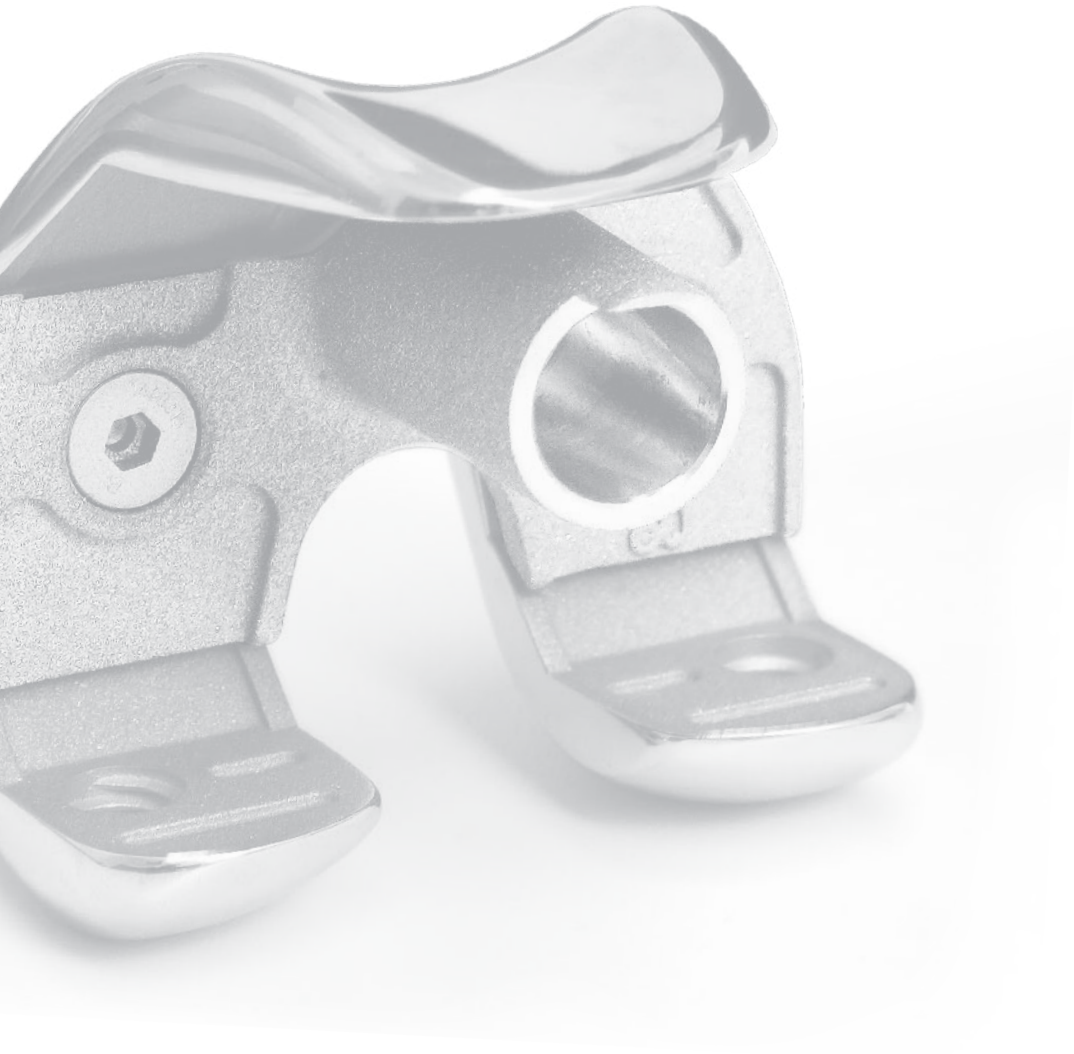
Vanguard® CR Stem Housing



Surgical Technique

Addendum to the Vanguard®
Complete Knee System

BIOMET®

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Introduction

Femoral size should have been determined before femoral bone cuts were completed using desired Vanguard® instrument platform (Premier™ Total Knee Instrumentation or Microplasty® Minimally Invasive Knee Instruments surgical techniques).

Setting Medial-Lateral Position

Use a 3.5mm hex driver in the upper right hand corner of the Vanguard® stem housing reamer guide to set the appropriate femoral size (Figure 1). Attach the medial-lateral (M/L) wing, ensuring that the correct side is facing out. Place the stem housing reamer guide flush with the anterior cortex and distal femur. Determine the appropriate M/L position (Figure 1a). Pin the stem housing guide in place using 1/8in pins through the anterior plate. Remove the M/L wing and snap the stem housing reamer guide bushing into place (Figure 2).

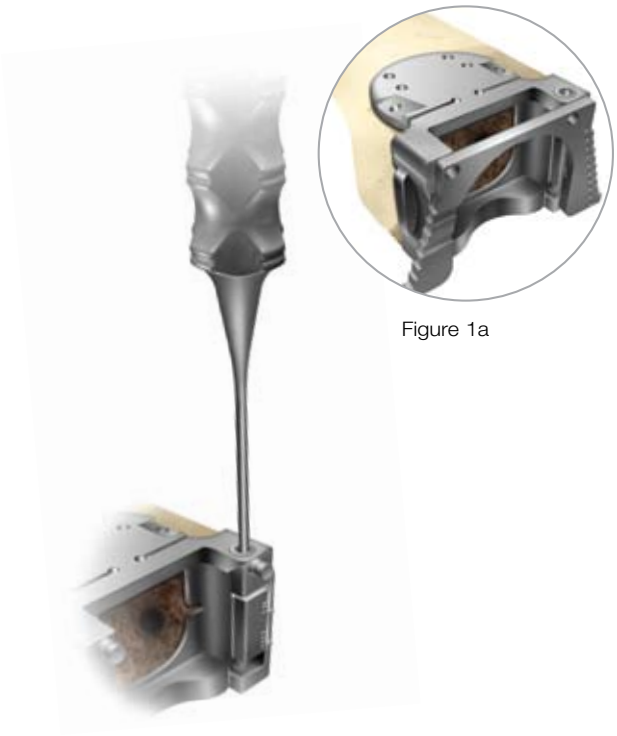

Figure 1a

Figure 1

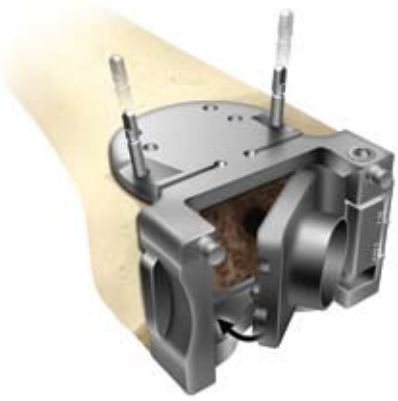

Figure 2

This surgical technique is utilized by Edward McPherson, M.D. Biomet as the manufacturer of this device, does not practice medicine and does not recommend this device or technique. Each surgeon is responsible for determining the appropriate device and technique to utilize on each individual patient.

Reaming

Ream the intramedullary canal with the 10mm diameter reamer. Align the reamer with the matching sized bushing and sequentially increase diameter until diaphyseal cortical contact is achieved (Figure 3a).

For diameters under 18mm, the stem housing reamer must be used to complete bone preparation (Figure 3).

Figure 3a

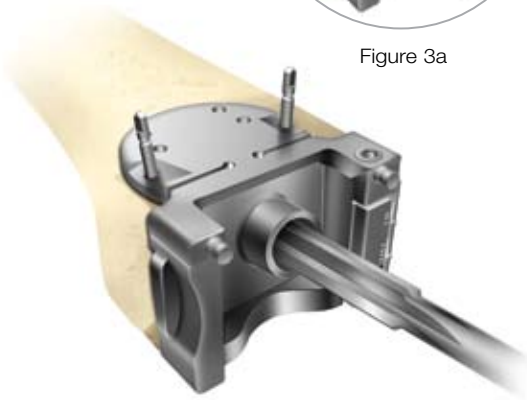

Figure 3

Distal Cut

Re-cut the distal femur (+5mm) to accommodate the stem housing attachment plate, using the slot on the anterior side of the Vanguard® stem housing reamer guide (Figure 4).

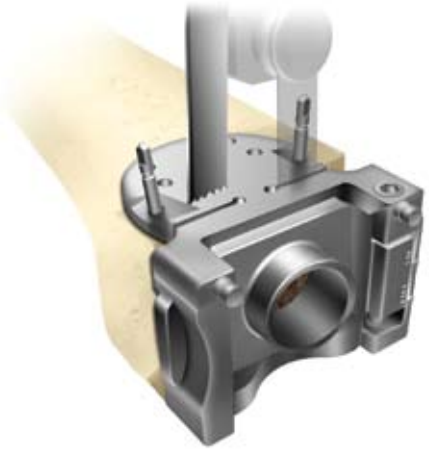

Figure 4

Drilling For Femoral Lugs (Optional)

The Vanguard® CR stem housing will allow for pegs to be placed into the distal femur. If peg use is desired, utilize the distal peg guide. Begin by setting the canal guide for a left or right femur. Place the canal guide into the prepared femur to orient the guide M/L. Ensure that the posterior feet are flush with the posterior bone. Tighten the thumb screw of the canal guide (Figure 5). Use a ¼in drill through the holes in the distal peg guide. If posterior augments are required, a trial can be threaded onto the distal peg guide.

Trial Reduction

Select the correct size trial CR stem housing and adjust the position of the bolts by aligning the black line to the correct size as indicated by the color coded dot (Figure 6). Thread the selected trial stem onto the CR stem housing trial. Attach the housing trial to the trial femoral component and complete the trial reduction.

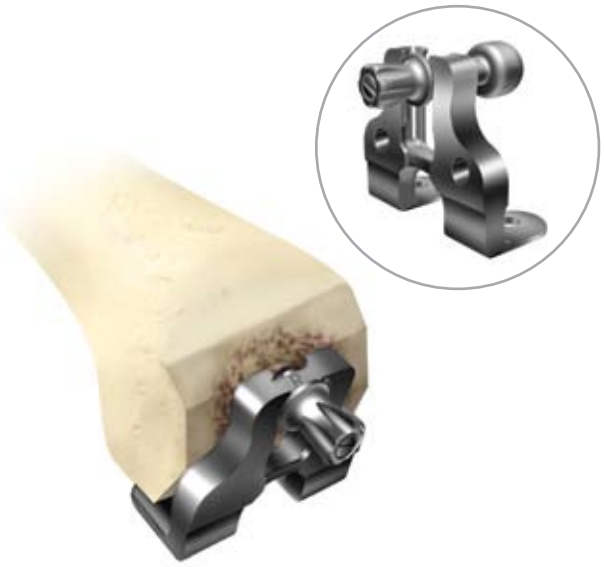

Figure 5

Figure 6

Implant Assembly

Impact the stem onto the CR stem housing. Insert the locking screw and tighten. Bolt the stem housing to the femoral component using the two supplied bolts (Figures 7 and 8).

Optional: If you desire femoral pegs, select the 5mm Vanguard® augment pegs and attach the CR stem housing construct to the femoral component.

Figure 7

Figure 8

Vanguard® CR Stem Housing

Implants

Product	Part Number	Description	Size
	**183077**	Vanguard® CR Stem Housing	55 Left
	183078	Vanguard® CR Stem Housing	57.5 Left
	183079	Vanguard® CR Stem Housing	60 Left
	183080	Vanguard® CR Stem Housing	62.5 Left
	183081	Vanguard® CR Stem Housing	65 Left
	183082	Vanguard® CR Stem Housing	67.5 Left
	183083	Vanguard® CR Stem Housing	70 Left
	183084	Vanguard® CR Stem Housing	72.5 Left
	183085	Vanguard® CR Stem Housing	75 Left
	183086	Vanguard® CR Stem Housing	80 Left
	183087	Vanguard® CR Stem Housing	55 Right
	183088	Vanguard® CR Stem Housing	57.5 Right
	183089	Vanguard® CR Stem Housing	60 Right
	183090	Vanguard® CR Stem Housing	62.5 Right
	183091	Vanguard® CR Stem Housing	65 Right
	183092	Vanguard® CR Stem Housing	67.5 Right
	183093	Vanguard® CR Stem Housing	70 Right
	183094	Vanguard® CR Stem Housing	72.5 Right
	183095	Vanguard® CR Stem Housing	75 Right
	183096	Vanguard® CR Stem Housing	80 Right
	**183097**	Vanguard® CoCr Augment Bolt (Replacement)	
	**184296**	Vanguard® Augment Peg	5mm

Vanguard® CR Stem Housing

Instrumentation

Product	Part Number	Description	Size
	**32-483070** **32-483071** **32-483072** **32-483073** **32-483074** **32-483075**	Vanguard® Trial CR Stem Housing Vanguard® Trial CR Stem Housing Vanguard® Trial CR Stem Housing Vanguard® Trial CR Stem Housing Vanguard® Trial CR Stem Housing Vanguard® Trial CR Stem Housing	55–62.5 Left 65–70 Left 72.5–80 Left 55–62.5 Right 65–70 Right 72.5–80 Right
	**32-483076**	Vanguard® Stem Housing Reamer Guide	
	**32-483077** **32-483078** **32-483079** **32-483080** **32-483081** **32-483082** **32-483083** **32-483084**	Vanguard® Stem Housing Reamer Guide Bushing Vanguard® Stem Housing Reamer Guide Bushing Vanguard® Stem Housing Reamer Guide Bushing Vanguard® Stem Housing Reamer Guide Bushing Vanguard® Stem Housing Reamer Guide Bushing Vanguard® Stem Housing Reamer Guide Bushing Vanguard® Stem Housing Reamer Guide Bushing Vanguard® Stem Housing Reamer Guide Bushing	10mm 12mm 14mm 16mm 18mm 20mm 22mm 24mm
	**32-483085**	Vanguard® Stem Housing Wing	
	**32-483086**	Vanguard® Stem Housing Reamer with Stop	18mm
	**32-483087**	Vanguard® Stem Housing Guide for Pivot Drill	
	595315	Instrument Case	

VANGUARD CR STEM HOUSING

INSTRUCTIONS FOR USE

WARNING!!: The surgeon must have a thorough knowledge of the medical, surgical and mechanical aspects concerning the use of this product, and should read these instructions carefully before using it.

PRODUCT DESCRIPTION

The CR Vanguard stem housing comprises a central body fixed to a Vanguard CR femoral component by two fixing screws (included in the product packaging). The central body also has a space for securing an intramedullary femoral stem with a fixing screw (included in the stem packaging).

Both components (the central body and fixing screws) are made of a chrome-cobalt-molybdenum alloy.

The Vanguard CR stem housing can only be used with CR Femoral Components of the Vanguard Knee system and with Intramedullary Femoral Stems from the Maxim Knee system.

INDICATIONS

Total knee arthroplasty in the following cases; osteoarthritis, traumatic arthritis, rheumatoid arthritis, correction of functional deformities, and replacement techniques when other treatments have failed.

CONTRAINDICATIONS

a) Absolute contraindications

1. Infection or inflammation of the knee joint.
2. Distant foci of infection that could lead to spreading to the prosthesis through the bloodstream.
3. Rapid progression of primary or metastatic tumours, or bone metastasis, as shown by destruction of bone mass or bone absorption that is evident in the X-ray.
4. Patients with immature skeletons.
5. Patients who are hypersensitive or allergic to any of the product components indicated on the unit container label.

b) Conditions increasing the risk of failure

1. Uncooperative patients or those with neurological disorders, senile patients, patients with mental illnesses, alcoholic patients or drug addicts, patients unable to follow the surgeon's advice.
2. Marked bone loss, severe osteoporosis or reviews for which the prosthesis cannot be properly secured.
3. Patients with metabolic disorders that could reduce bone formation or cause bone loss.
4. Osteomalacy.
5. Pathological obesity.
6. Poor prognosis for wound healing (e.g. bedsores, terminal diabetes, serious protein deficit, and or/ malnutrition).

WARNINGS

a) *Implant resistance and load:* Although these types of devices have a high success rate, they cannot be expected to support the same high levels of activity, load, resistance and longevity as those of a healthy bone. The load caused by bone support and the activity levels will determine the prosthesis service life. It is advisable to carry out regular controls following surgery.

b) *Adequate selection of the implant:* The adequate selection of the size, shape, and design of the prosthesis will increase its possibilities of success. The implant requires careful setting with adequate fixation to bone.

The Vanguard CR stem housing can only be used with CR Femoral Components from the Vanguard Knee system and with Intramedullary Femoral Stems from the Maxim Knee system.

c) *Critical factors in selecting the patients:*

1. Occupation or activity: if the patient's occupation or activity involves making efforts with the knee, the resulting force could cause a failure in the fixing and/or implanting. The implant will not restore function to the level of a healthy bone, and patients should not be given false expectations.
2. Senility, mental illness or alcoholism: these conditions, among others, could cause the patient to ignore certain limitations and precaution in using the implant, with the risk of failure or other complications.
3. Hypersensitivity to foreign bodies: in the event of suspecting the presence of hypersensitivity to metals, the appropriate allergy tests will be performed before placing the implant.

PRECAUTIONS

a) *Sterile, disposable product:* The product is marketed sterilized by gamma radiation. It cannot be implanted after the expiry date shown on the label. The implant must not be re-sterilized by the user.

Furthermore, the implant should not be reused under any circumstances, since although it may appear to be intact, it may have minor defects, microscopic flaws or internal stress points that could cause it to break due to fatigue or fail due to the application of direct or indirect static or dynamic loads or other undesirable types of functioning.

b) *Handling the implant:* The implant must be handled with care, using the special instrument designed for implanting it, otherwise faults could occur in the finish of its surface or other faults that eventually cause the device to fail.

Should it be necessary to remove the implant, the user must treat it as biological waste and arrange for its disposal pursuant to internal hospital procedures.

c) *Instructions and information for the patient:* The surgeon must instruct and inform the patient regarding the limitations of the implant so that the patient can take the necessary precautions as regards supporting weight and load, to ensure healing is complete. The patient must be warned that failure to abide by the post-surgical instructions could lead to the implant being broken or moving more than it should, in which case review surgery will be necessary to remove it.

Furthermore, the surgeon should advise the patient regarding the composition of the implanted product which is describe on the unit container label, for the patient to notify this during subsequent diagnostic tests such as magnetic resonance imaging.

d) *Surgical technique:* The implant must be used by surgeons who are very familiar with and experienced in the surgical technique and post-surgical care of the patient. To obtain more information, a special surgical technique is available to the surgeon.

POTENTIAL ADVERSE EVENTS

1. No consolidation or delayed consolidation.
2. Fracture, loosening or sinking of the prosthesis.
3. Sensitivity to metals or reactions to foreign bodies.
4. Loss of bone density due to the transfer of load.
5. Pain, discomfort or strange sensations due to the presence of prosthesis.
6. Injuries to the nerves, soft tissues or blood vessels caused by surgical trauma.
7. Fracture of bone structures.
8. Bone necrosis.
9. Bleeding.
10. Infection.

CAUTION:

Federal law (USA) restricts this device to sale by or on the order of a physician.

ADDITIONAL INFORMATION

For further information, please contact the nearest BIOMET representative or distributor.

For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the package insert herein and Biomet's website.

BIOMET® ORTHOPEDICS

One Surgeon. One Patient.™

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