

Protract™ Hip Stem

Surgical Protocol and Product Specifications



Protract™ Hip Stem



Introduction

With emphasis on maximum stability and ease of use, the StelKast Protract-Hip System provides the surgeon with a comprehensive system that offers standard and lateralized offsets to allow soft tissue balancing without compromising leg length. The Protract stems are made of forged titanium with a proximal surface coating of plasma spray or plasma spray/hydroxyapatite. The circumferential coating on the proximal geometry of the stem provides up to 0.5mm interference fit per side. The distal stem is slotted to better match the elasticity of the isthmic femur. Distal flutes provide additional rotational stability. The Protract stem is implanted using a combination of progressive reaming and broaching to achieve proximal fit and distal fill.

Preoperative Planning

Preoperative planning is established by using the StelKast Protract templates. To allow for magnification in the radiographs the StelKast templates are oversized by 18%. The femoral component is sized to the isthmic femur and the medullary canal to obtain the optimal fill. The template is also used to determine the level of the neck cut.

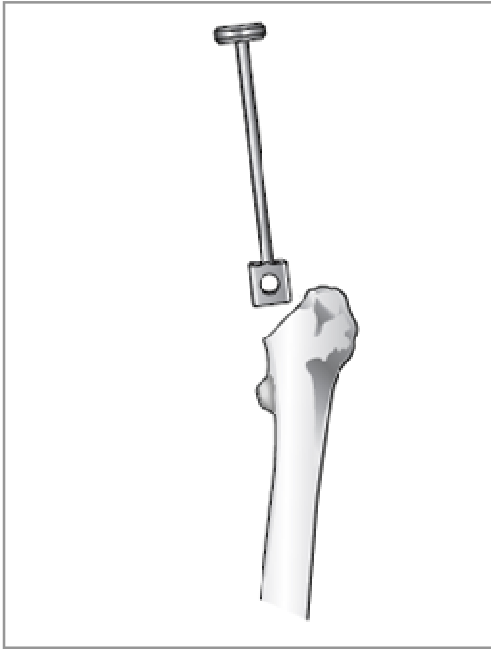


Figure 1
Box Chisel to Expose the Proximal Femur

Femoral Neck Cut

The femoral neck cut can be made at the level of the preoperative plan, however, it is strongly advisable to allow a minimum cut of 15mm from the superior aspect of the lesser trochanter. Too short of a neck cut will compromise the proximal fill of the implant and too high of a neck cut will interfere with access to the acetabulum. An intended overshoot of the neck cut can be corrected with the calcar reamer at the time of broaching.

The level of the neck cut can be marked using either the osteotomy guide or a metric ruler. The guide is positioned in line with the femoral shaft. To improve visualization for positioning, the guide is transparent. An electrocautery is used to mark the desired cut. The saw blade is positioned perpendicular to the neck to avoid an oblique cut in the AIP plane.

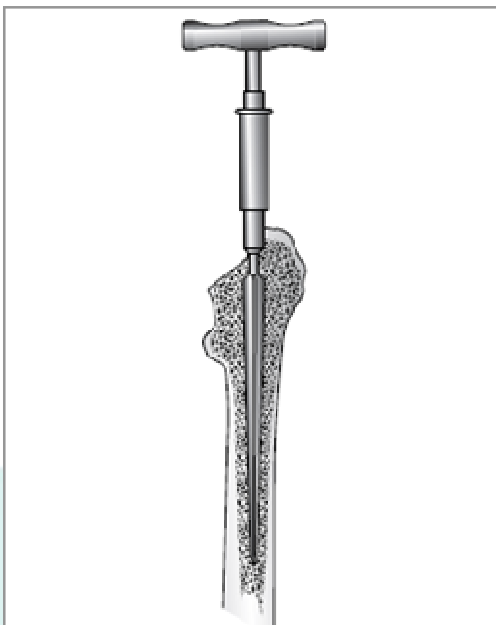


Figure 2
Starter Reamer to Locate the Femoral Canal

Femoral Preparation

The soft tissue remnants of the piriformis fossa are removed by dissection and the Protract box chisel is used to clear the superolateral aspect of the femoral neck to gain access to the femoral canal (Figure 1). A T-handle awl is used to locate the femoral canal (Figure 2).

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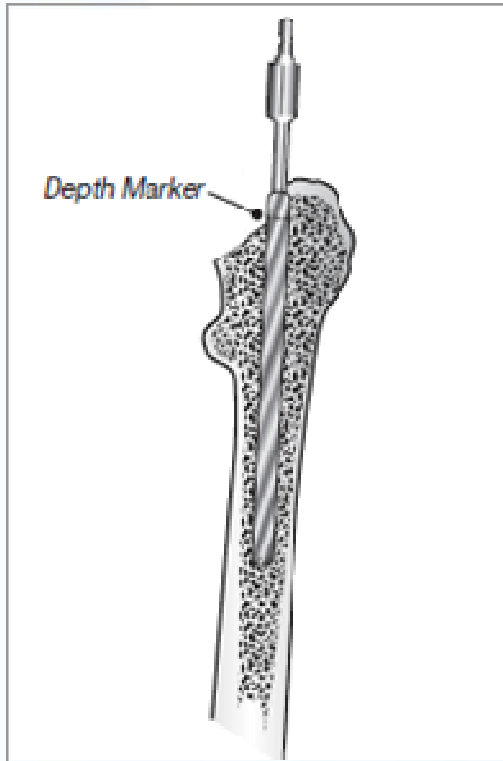


Figure 3
Sequential Reaming of the Femoral Canal

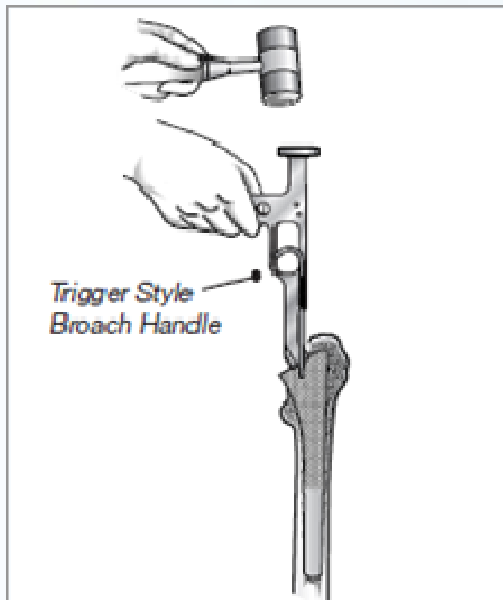


Figure 4
Broaching of Femoral Canal

Reaming

Sequential femoral reaming begins with the 9mm femoral reamer. The tendency toward varus positioning of the reamers is avoided by applying lateral pressure. The reamer is advanced into the canal so that the depth marker aligns with the medial neck cut (Figure 3). The size of the reamer is increased until a "chatter" is felt or heard from the isthmic femur. To avoid aggressive reaming of the canal, stop at one size less than templated and begin broaching. Should the broach not provide satisfactory rotational stability, it is removed and the isthmic femur is reamed to the next larger size. This iteration between broaching and reaming will assure maximal proximal fit and distal fit of the implant.

Broaching

The proximal femur is shaped into the correct configuration of the implant beginning with the smallest broach. Broaching is continued sequentially with each new broach being seated into the proximal femur until the broach size corresponds to the last femoral reamer size. When resistance is encountered the broaching process should continue by tapping the broach in and out until full cortical seating is obtained. The broach is checked for rotational stability when it is seated tightly just below the neck cut (Figure 4). If motion is detected the implant size is too small to be rotationally stable and the next larger femoral reamer and broach should be used. Ideally, templating will provide the appropriate size of implant. However, final sizing is determined intraoperatively.

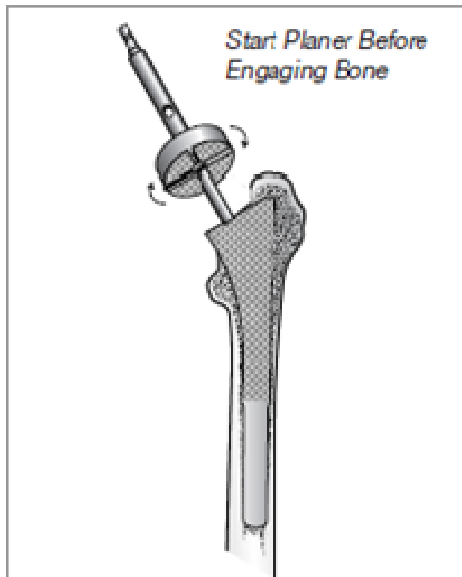


Figure 5
Calcar Planing on Broach

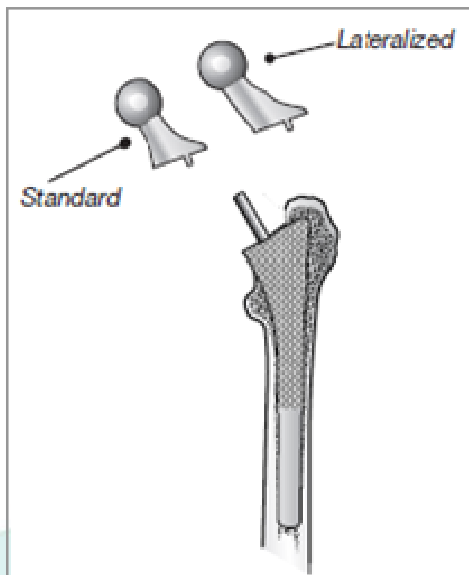


Figure 6
Trial Reduction with Broach

Once the final broach has been seated, the calcar planer is used to remove excess bone and smooth the calcar region (Figure 5).

Note: The planer should be placed on the stem of the broach advancing it slowly to plane the femoral neck, and rotating before it engages the bone.

Trial Reduction

With the broach seated in the femoral canal, the corresponding standard trial neck is placed on the broach. The selected trial head that will optimally restore stability and appropriate leg length is then placed on the trial neck and the hip is reduced (Figure 6). After the hip has been reduced, the joint is checked for range of motion, neck impingement, and soft tissue tension. If instability exists, the cause should be identified and appropriate corrections should be made. If the leg length has already been restored, then stability may be improved by using a lateral offset. The lateralized offset can be trialed on the broach by utilizing the matching lateralized trial neck. If instability is still detected, the neck length should be increased to assure soft tissue tension stability.

The position of a hooded acetabular liner may also be changed to a more posterior position if necessary. These maneuvers, however, do not compensate for a malpositioned acetabular component. If such is the case, the liner should be removed and the acetabular component changed to a more stable position.

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Figure 7
Insertion of Femoral Stem

Femoral Component Insertion

The appropriate Protract implant size will match the final broach size, which will provide an 0.5mm/side interference fit in the proximal area and line-to-line fit in the distal region. After removing the broach and irrigating the canal, the appropriate size implant in either a standard or lateralized version is selected and threaded onto the inserter. The Protract femoral component is driven and seated with light taps on the inserter until the stem no longer advances (**Figure 7**). Because of the collarless design of a press-fit stem using excessive force and/or attempting to seat a malrotated stem below the neck cut can result in a femoral fracture.

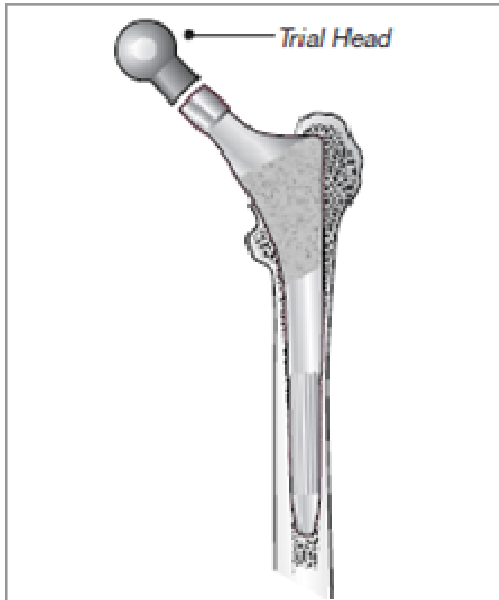


Figure 8
Final Trial Reduction of Femoral Stem

Final Trial Reduction

Final trial reduction is performed with the desired trial head (Figure 8). This provides the last opportunity to adjust the leg length and soft tissue tension of the joint. The appropriate neck length is then determined. Once the trial head is removed, the trunnion and femoral head bore should be cleaned and dried with a clean sponge. The selected femoral head implant is seated onto the trunnion with impactor (Figure 9). If a ceramic head is being implanted, the head should be placed on the stem trunnion gently while keeping the head and trunnion in alignment. The head is then firmly attached by sharply impacting the head with the plastic impactor. The hip is then reduced and the incision is closed.

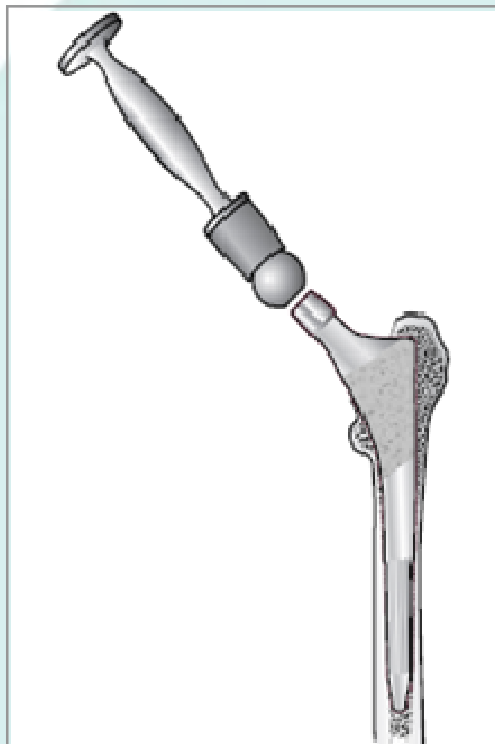



Figure 9
Final Assembly of Femoral Head

GENERAL PRODUCT INFORMATION .625

Through the advancement of partial and total hip joint replacement, the surgeon has been provided with a means of restoring mobility, correcting deformity, and reducing pain for many patients. While the prostheses used are largely successful in attaining these goals, it must be recognized that they are manufactured from metal, ceramic, and plastic materials and that any joint replacement, therefore, cannot be expected to withstand activity levels and loads as would normal healthy bone. In addition, the system will not be as strong, reliable, or durable as a natural human joint.

INDICATIONS FOR USE


Stelkast Company hip implant components are indicated  for single use only in skeletally mature individuals undergoing reconstruction of severely disabled and/or very painful joints. If cemented fixation is required for the component being used, then the respective component label will include the statement; "This device is intended for cemented use only." Stelkast Hip System components are indicated for either cemented or cementless use for reconstruction of the articulating surface of the femoral and/or acetabular portions of the hip that are severely disabled and/or very painful resulting from non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, rheumatoid arthritis, traumatic arthritis, correction of functional deformity, treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement unmanageable using other techniques. The components can be used for primary hip implant or for hip revision of a failed total hip arthroplasty.

CONTRAINDICATIONS

Stelkast Company hip implant components are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, patients without sufficient soft tissue integrity to provide adequate stability, muscle laxity or inadequate soft tissue for proper function and healing, any pathological conditions that would interfere with the performance of the system and in patients with either mental or neuromuscular disorders that do not allow control of the affected joint, and in patients whose weight, age or activity level might cause extreme loads and early failure of the system. The Biolox Delta and Zirconia ceramic heads are contraindicated for use with any other than an UHMWPE cup or metal backed UHMWPE cup

WARNINGS AND PRECAUTIONS

Familiarity with and attention to appropriate surgical technique for hip joint arthroplasty and the Stelkast implant system is essential for success of the procedure. Improper position of the components could result in dislocation. Only surgeons who have reviewed the literature regarding hip surgery and have had training in the technique should utilize the device. Patient selection is based on age, bone stock and size. The surgeon or his designee should instruct patients in the limitations of the prosthesis, and these patients should be taught to govern their activities accordingly. Patient lifestyles must be evaluated by the physician, and patient properly advised of any required modifications.

 Hip implant components must not be reused. The surgeon must not allow damage to polished bearing surfaces because this may accelerate wear of the components. Any alteration or damage to a component may reduce fatigue strength and could result in failure under load. Any prostheses so damaged must not be used. In the case of hip cup revisions in which the hip stem is not revised, ceramic femoral heads could break because of trunnion damage or mismatch. Care must be taken when ceramic heads are implanted to avoid overuse of force during seating the head on the trunnion. The stem trunnion and head bore should be dry and free of contamination prior to assembly of a ceramic head to the trunnion.

Components of Stelkast Company hip implants should not be used with those of another manufacturer since articular and dimensional compatibility cannot be assured, including possible femoral head taper mismatch. **Only Stelkast femoral heads should be used with Stelkast hip stems.**

Hip implant components have not been evaluated for safety and compatibility in the MR environment. Hip implant components have not been tested for heating or migration in the MR environment.


ADVERSE EVENTS

As with all hip joint implant systems, potential adverse effects include infection, loosening of the components, breakage, bending or disassembly of the components, or change in position of the components. There have been reports of sensitivity reactions to the implant components. Other potential adverse effects of hip implant joint surgery include neurovascular damage, dislocation, thromboembolic disease, acetabular pain, component failure and wear debris and other less common adverse effects. On rare occasions, amputations have been necessary.

STERILITY AND HANDLING

Each Stelkast Company hip implant component is supplied sterile in double sealed containers maintaining double sterile barriers. If the seals or containers are breached, then the component should not be used. The components are not represented to be "pyrogen-free."

Metal and ceramic parts as well as polyethylene (UHMWPE) parts and/or components containing polyethylene or polymethylmethacrylate (PMMA) are supplied exposed to a minimum of 2.5 Mrad of gamma irradiation or Ethylene Oxide sterilization and must be kept unopened in the double protective packaging until implantation. The sterilization method used is listed on the respective component label. The sterile container is to be checked for possible damage. Do not use any component if the packages have been breached.

 Resterilization by any method is ruled out.

Care should be utilized in the handling of the components to minimize contamination of the component surfaces. Do not allow porous surfaces to come in contact with cloth or other fiber releasing materials. In using cement for fixation, the surgeon should use care to ensure complete cement support on all parts of the prosthesis embedded in bone cement.

UTILIZATION AND IMPLANTATION

Selection of Stelkast Company hip implant components depends on the judgment of the surgeon with regard to the relationship to the requirements of the patient. The surgeon should become thoroughly familiar with the technique of implantation of the prostheses by: (1) appropriate reading of the literature, and (2) training in the operative skills and techniques required for hip joint arthroplasty surgery.

MATERIALS USED

The materials used are listed on the respective product label.

INFORMATION

For any further information, please contact the supplier. Please be sure to refer to the Catalog Number designated with REF

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

Protract™ Hip Stem

Product Specifications

The Protract Stem offers a press-fit option which will allow choice of standard or lateralized neck offsets while keeping a consistent leg length.

Femoral Stem

- Forged Titanium 6AL-4V
- Proximal porous coating
 - Titanium plasma spray
 - Titanium plasma spray with HA
- Polished midshaft for increased strength
- Distal flutes for rotational stability
- Coronal slot to reduce thigh pain
- Optimized neck geometry for improved ROM

Femoral Head

- Polished CoCr and Ceramic options
- 36mm, 32mm, 28mm, and 22mm diameters
- Wide range of neck lengths available



Size	STANDARD		LATERALIZED		Stem Length (mm)
	SC2659		SC2660		
	Titanium Plasma Spray		Titanium Plasma Spray		
	SC2661		SC2662		
	Titanium Plasma Spray HA		Titanium Plasma Spray HA		
	Neck Lengths (mm)	Head Offset (mm)	Neck Lengths (mm)	Head Offset (mm)	
9	26.0	31.0			110.3
10	25.5	31.0	27.6	35.0	117.9
11	29.4	35.5	33.6	43.5	125.4
12	31.2	37.5	35.4	45.5	133.0
13	30.7	37.5	34.8	45.5	140.6
14	34.0	40.5	38.1	48.5	148.2
15	35.8	42.5	40.0	50.5	155.7
16	37.7	44.5	41.8	52.5	163.3

Neck Angle = 135. degrees Note: Size 9 not available for Lateralized

Prior Part Numbers: SC2100, SC2166, SC2179 and SC2180 are not for use with Surpass™ Acetabular System or any Stelkast BIOLOX® delta Femoral Head.

www.stelkast.com



200 Hidden Valley Road | McMurray, PA 15317
 phone: (724) 941-6368 | fax: (724) 941-5987 | www.stelkast.com