Biologically Oriented Prostheses

BIOPRO

Femoral Head Revision

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Indications & Contraindications

INDICATIONS FOR USE

The BioPro Femoral Heads are indicated for use for significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis; revision of failed femoral head replacement, cup arthroplasty, or other hip procedures; proximal femoral fractures, avascular necrosis of the femoral head; non-union of proximal femoral neck fractures; other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities. The BioPro hip system (PSL) is for cemented and non-cemented use.

CONTRAINDICATIONS

• Improper stem, acetabular cup, or liner construct that would militate against femoral head fixation and articulation.
• Foreign body sensitivity to metals specifically cobalt chrome. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

WARNINGS AND PRECAUTIONS

While total hip arthroplasty components are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.
In using joint replacement implants, the surgeon should be aware of the following:

- The correct selection of the modular implant components is extremely important. The potential for success in joint replacement is increased by the selection of the proper size, shape and design of the implant. Joint replacement prostheses require careful seating and adequate bone support, and should be restricted to limited functional stress. The surgeon is to be thoroughly familiar with the implants, instruments, and surgical procedure prior to performing surgery.
- In selecting patients for joint replacement surgery, the following factors can be of extreme importance to the eventual success of the procedure:
    1. The patient's weight. An overweight or obese patient can produce loads on the prosthesis, which can lead to failure of the prosthesis. This becomes a major consideration when a small prosthesis must be used.
    2. The patient's occupation or activity. If the patient is involved in an occupation or activity, which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device or both.
    3. A condition of senility, mental illness or alcoholism. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions, leading to failure or other complications.
    4. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
    5. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, total joint replacement can only be considered a delaying technique or temporary relief.
- The correct handling of the implant is extremely important. Care must be taken to protect mating surfaces and polished bearing surfaces from nicks and scratches which could become the focal point for failure. Do not tamper with the implant as contouring or bending of the implant may reduce its service life and may cause immediate or eventual failure under load.
- Standard cleaning procedures cannot be relied upon to remove contamination from porous coating.
- A surgical implant should not be reused. Even though a used implant may appear undamaged, it may have small defects and internal stress patterns, which may lead to failure. Use only new prosthesis of the current design.
- Re-sterilization of the device is not recommended.
- The modular head and neck components must be firmly seated to prevent disassociation. Scratching of modular heads and tapers should be avoided. Repeated assembly and disassembly of the head or neck components could compromise a critical locking action. The head or neck components should be changed only when clinically necessary. The interfaces should be clean and free from debris prior to assembly.
- Bone excision should be limited to the amount necessary to accommodate the implants. Prior to closure, the surgical site should be thoroughly cleaned of bone chips, bone cement or other detritus that may cause a third body wear problem. Range of motion should be checked for impingement or instability.
- Postoperative care is important. The patient should be instructed on the limitations of these devices and should be cautioned regarding load-bearing, ranges of motion, and activity levels permissible. Excessive physical activity and trauma affecting the replaced joint have been implicated in premature failure by loosening, fracture and/or wear of the prosthesis implant. Early load-bearing should be carefully controlled. The patient should be advised to report any related pain, decrease in range of motion, swelling, fever, and unusual incidences.
- Range of motion is decreased with the use of the skirted +10.5mm offset head.

ADDITIONAL CONSIDERATIONS FOR CERAMIC HEADS

Femoral Heads are only for use with BioPro System femoral stems. No other ceramic heads should be used with these hip stems. Other considerations for the ceramic heads include the following:

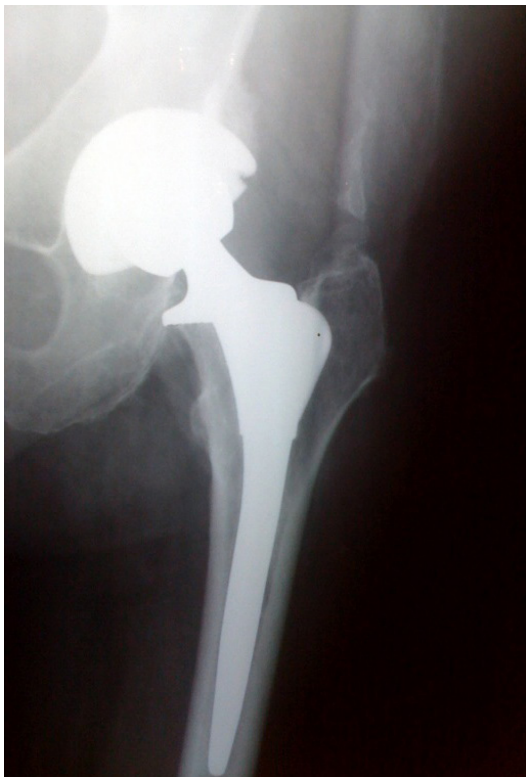
- The ceramic head must not be sterilized on the hip stem.
- The ceramic heads should not be resterilized.
- The stem cone and head bore should be dry and free of contamination.
- The ceramic head should not be implanted if the head, or the cone of the stem, are possibly damaged.
- The ceramic head should be placed on the stem neck gently while keeping the head and neck in alignment, and then firmly attached by sharply hitting the head with a soft plastic hammer.
- Ceramic heads are contraindicated for use with anything other than an UHMWPE cup or a metal backed UHMWPE cup.

Implant Identification

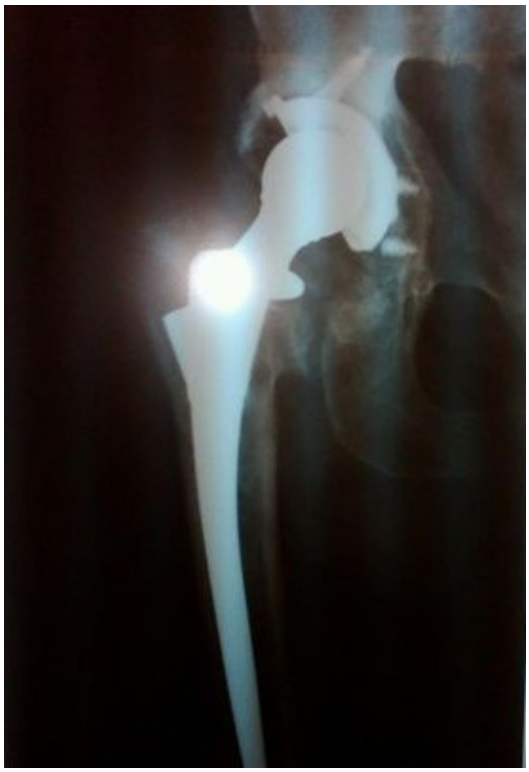
The BioPro PSL Hip femoral prosthesis was first implanted in 1987 and was designed as the next generation of the DePuy HPS. These femoral components have a major difference in the shape and location of the lateral fin that can be identified when viewing the radiographs. The PSL's fin is placed more proximally than that of the HPS and is rounded rather than the sharp pointed shape of the HPS. The trunnions are different on these two prosthesis and femoral heads are not interchangeable.

BioPro still supports revisions of the PSL Hip System. The implant has its own unique trunnion taper, and will need to be replaced with a BioPro Femoral Head. We do also offer cup inserts for cases that only require a poly exchange. Please contact BioPro and forward a copy of the radiographs to orders@bioproimplants.com if you are unsure of the manufacturer of the femoral component.

BioPro PSL



DePuy HPS



BioPro Cup Options

BioPro does not supply cup replacements, however, we do offer poly inserts if an exchange is being performed.

Cox Comb Cup

Providence Cup

Rimmed Cup

Surgical Technique

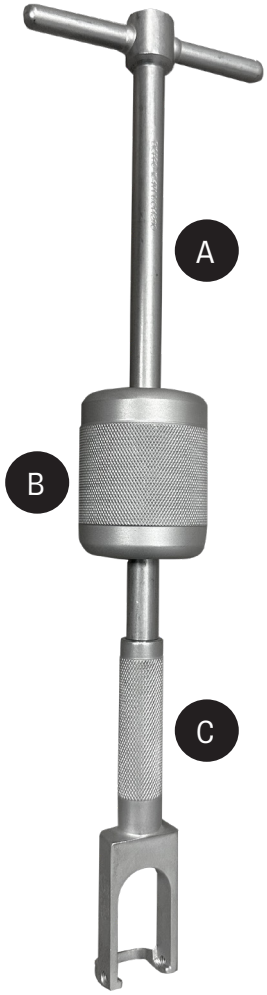
Step One
Once access to the implant is achieved, dislocate the femoral components from the acetabulum. With the femoral head of the implant exposed, place the femoral head remover under the femoral head component as shown in image above. Two femoral head removers are provided, one for Large Trunnion Stems and one for Small Trunnion Stems. Ensure the rounded edges of the head remover face the stem. Using a mallet or hammer, tap the femoral head remover to lift the femoral head off of the stem.

Step Two
Utilize the acetabular liner remover to remove the liner from the acetabular shell. If the acetabular liner is not a BioPro component, the surgeon should use the manufacturers recommend removal method. The acetabular shell can be removed by the surgeon's method of choice.

Step Three
Using the femoral head trials provided, assemble the trial to the stem. If range of motion and leg length are acceptable, proceed to final implantation. If not, choose another femoral head trial to provide the desired result.

If the stem was implanted in the late 1980's or early 1990's, it may have a large trunnion. Large trunnion trials are provided as well as large trunnion femoral heads, which are only available in cobalt chrome, 28mm or 32mm.

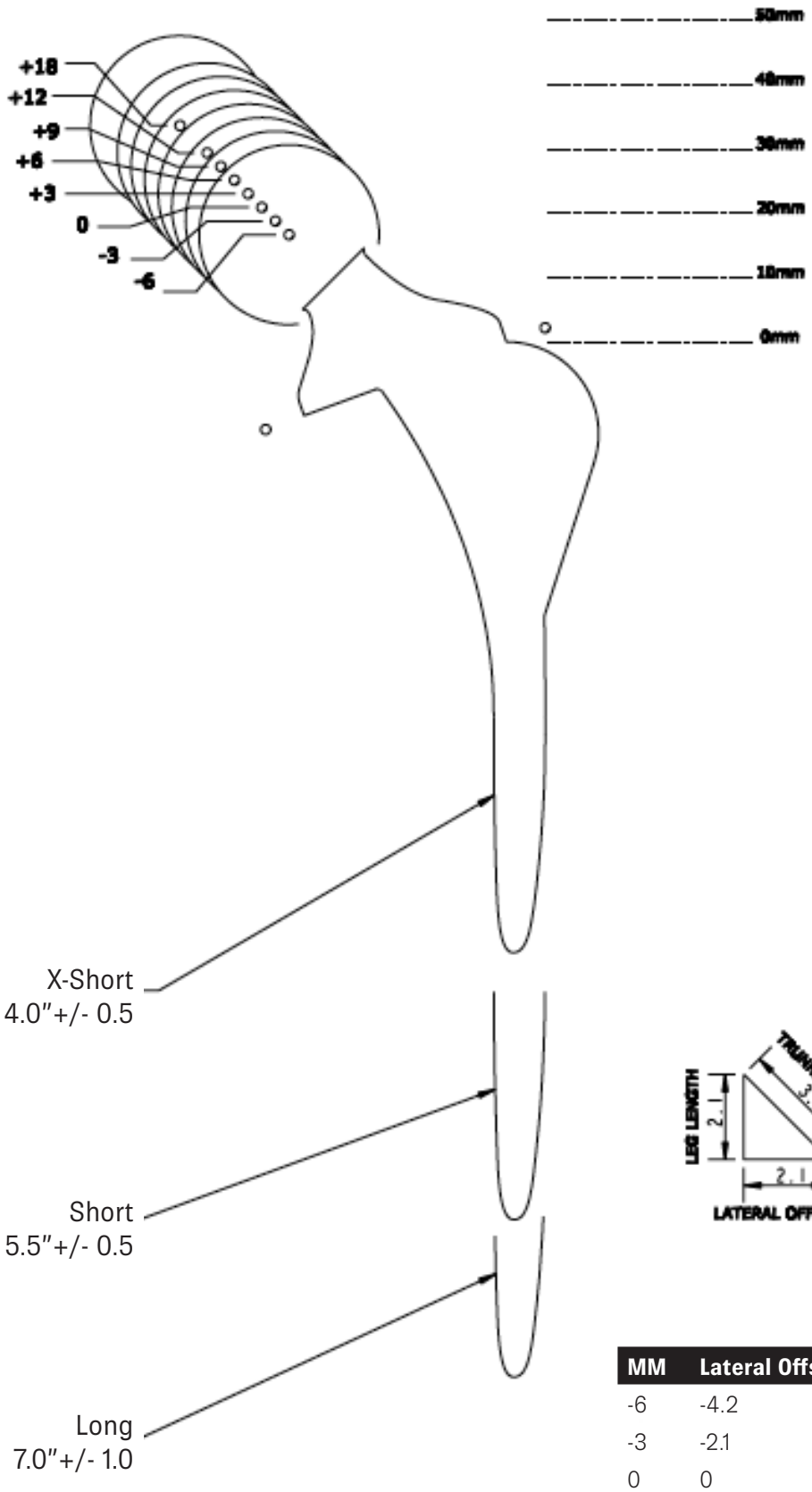
BioPro small trunnion femoral heads are available in 28, 32 and 36mm in cobalt chrome. Additionally, we have limited availability of 28 and 32mm in ziralloy ceramic. See implant ordering for additional details.



Step Six:
If stem removal is required, assemble the T-handle (A), slap hammer (B) and the stem retractor (C).

Step Seven:
Slide the retractor assembly onto the hip stem as shown in figure above.

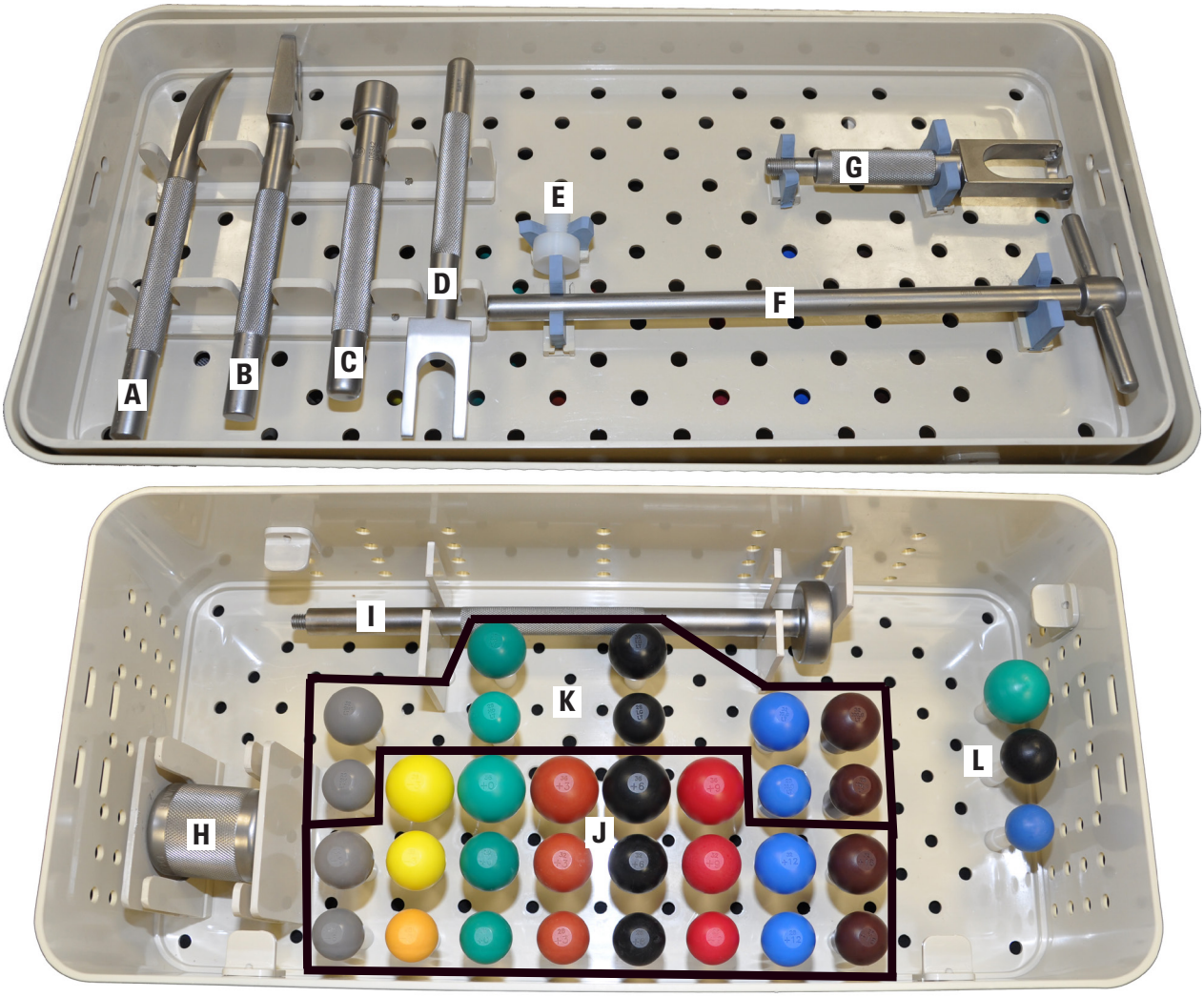
Step Eight:
Forcefully slide the slap hammer superiorly to remove the stem from the femur.



MM	Lateral Offset
-6	-4.2
-3	-2.1
0	0
+3	2.1
+6	4.2
+9	6.4

Ordering

ITEM #	DESCRIPTION	COLLAR	MATERIAL	Lateral Offset
19003	HEAD FEMORAL 28MM-6	NO	COBALT CHROME	-4.2
19004	HEAD FEMORAL 28MM-3	NO	COBALT CHROME	-2.1
19005	HEAD FEMORAL 28MM+0	NO	COBALT CHROME	0
19006	HEAD FEMORAL 28MM+3	YES	COBALT CHROME	2.1
19007	HEAD FEMORAL 28MM+6	YES	COBALT CHROME	4.2
19008	HEAD FEMORAL 28MM+9	YES	COBALT CHROME	6.4
19130	HEAD FEMORAL 32MM-6	NO	COBALT CHROME	-4.2
19131	HEAD FEMORAL 32MM-3	NO	COBALT CHROME	-2.1
19132	HEAD FEMORAL 32MM+0	NO	COBALT CHROME	0
19133	HEAD FEMORAL 32MM +3	NO	COBALT CHROME	2.1
19134	HEAD FEMORAL 32MM+6	YES	COBALT CHROME	4.2
19135	HEAD FEMORAL 32MM +9	YES	COBALT CHROME	6.4
19053	HEAD FEMORAL 36MM -3	NO	COBALT CHROME	-2.1
19054	HEAD FEMORAL 36MM +0	NO	COBALT CHROME	0
19055	HEAD FEMORAL 36MM +3	NO	COBALT CHROME	2.1
19056	HEAD FEMORAL 36MM +6	YES	COBALT CHROME	4.2
19057	HEAD FEMORAL 36MM +9	YES	COBALT CHROME	6.4
19023	HEAD FEMORAL CERAMIC 28MM -3	NO	Ziralloy Ceramic	-2.1
19024	HEAD FEMORAL CERAMIC 28MM +0	NO	Ziralloy Ceramic	0
19025	HEAD FEMORAL CERAMIC 32MM -3	NO	Ziralloy Ceramic	-2.1
19026	HEAD FEMORAL CERAMIC 32MM +0	NO	Ziralloy Ceramic	0
19027	HEAD FEMORAL CERAMIC 32MM +3	NO	Ziralloy Ceramic	2.1
14089	HEAD LARGE TRUNION FEMORAL 28 SH LT	NO	COBALT CHROME	-4.25
14090	HEAD LARGE TRUNION FEMORAL 28 MD LT	YES	COBALT CHROME	0
14091	HEAD LARGE TRUNION FEMORAL 28 LG LT	YES	COBALT CHROME	+4.25
14094	HEAD LARGE TRUNION FEMORAL 32 SH LT	NO	COBALT CHROME	-4.25
14095	HEAD LARGE TRUNION FEMORAL 32 MD LT	YES	COBALT CHROME	0
14096	HEAD LARGE TRUNION FEMORAL 32 LG LT	YES	COBALT CHROME	+4.25



Location	Description
A	Acetabular Liner Remover
B	Regular Trunnion Femoral Head Remover
C	Femoral Head Impactor
D	Large Trunnion Femoral Head Remover
E	Impactor Tip
F	T-handle
G	Stem Retractor
H	Slap Hammer
I	Cup Impactor Handle
J	Standard Trunnion Femoral Head Trials (28mm, 32mm, 36mm)
K	Large Trunnion Femoral Head Trials (28mm, 32mm)
L	Cup Impactor Tips (28mm, 32mm, 36mm)

BIOLOGICALLY ORIENTED PROSTHESES

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Call us at 1-810-982-7777 to schedule a case today.

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