

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 the prosthesis in each particular patient. Biomet UK Ltd is not responsible for selection of the appropriate surgical technique to be utilised for an individual patient.

Biomet Fracture Stem™ - Operative technique

Overview

Designed for cementless application, the Biomet fracture stem provides a cost effective alternative to the cemented prosthesis commonly employed in the treatment of displaced intracapsular femoral neck fractures. This cementless prosthesis has been designed specifically for use in low demand patients who may suffer from cardio-vascular problems. The use of cementless implants in these patients may significantly reduce the risk of fat embolism, operating time, expected blood loss and recovery time.

Manufactured from forged titanium alloy for improved fatigue strength and biocompatibility, the femoral stem incorporates Biomet's proven bi-planar taper wedge philosophy. Each femoral component also includes an 80 micron hydroxyapatite coating that improves the amount of ingrowth and attachment of bone and leads to a more even distribution of bone over the surface of the implant. (*Coathrup et. al. JBJS 2001:83-B118-123*)

For complete versatility, the Biomet fracture stem has been designed to accommodate all Biomet bi-polar and uni-polar components.

Bi-polar components are available manufactured from stainless steel and CoCrMo. To facilitate intra-operative flexibility all modular heads are available separately, thus allowing accurate neck length reconstruction. Modular heads are available in 22.2mm, 28mm and 32mm in various neck lengths.

Uni-polar components are available in both titanium and CoCrMo versions.

Please refer to relevant bi-polar or uni-polar operative technique for specific details.

1. Pre-operative Planning

Selection of the correct femoral component is attained through careful pre-operative planning. This can be achieved manually by means of x-ray templates, or digitally by means of a PAC system.

Manual Pre-operative Planning

The B.Fx Fracture Stem includes femoral x-ray templates in 115% magnification. These templates are positioned over the AP and Lateral x-rays to best decide the correct implant size and modular head neck length to help restore the patient's natural anatomy.



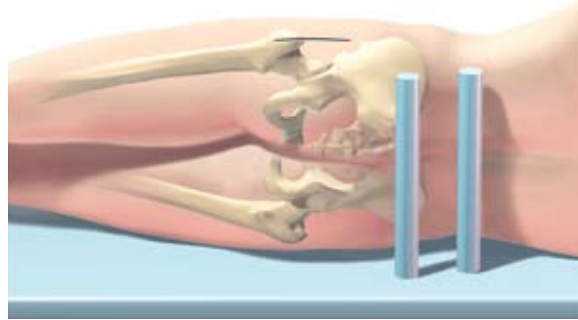
Digital Pre-operative Planning

The B.Fx Fracture Stem digital templates are available through various digital template providers. When using digital templating for a primary THR, it is necessary to use a magnification marker with a known dimension. This is required in order for the PAC system to calculate the correct magnification. As soon as the correct magnification has been determined, the PAC System can be used to best decide the correct implant size and modular head neck length required to help restore the patient's natural anatomy.



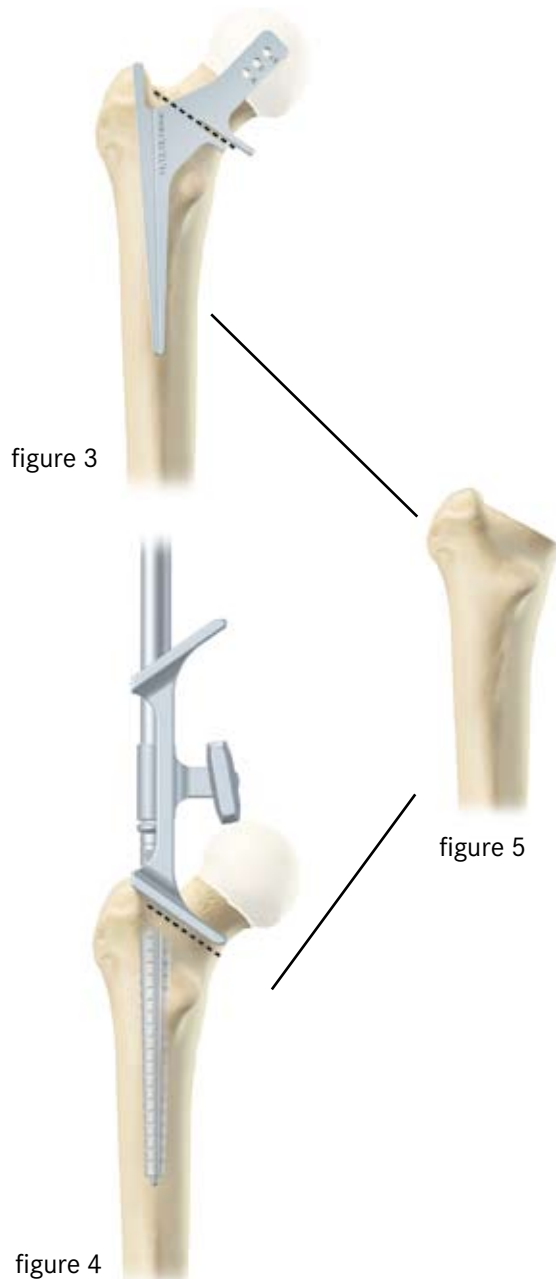
2. Surgical Exposure

The B.Fx Fracture stem femoral component can be implanted using any of the standard approaches for total hip replacement. The aim of the approach selected is to provide adequate visualisation of both the acetabulum and proximal femur.



3. Femoral Head Removal & Neck Osteotomy

When utilising the Biomet B.Fx Fracture stem for the treatment of displaced intracapsular femoral neck fractures, it will be necessary to first excise the femoral head from the acetabulum. This is made easy by use of an Judet extractor that is threaded into the fractured femoral head and then used to manipulate the femoral head out of the acetabulum. Once the femoral head has been removed the femoral neck can be cut to the correct angle and length. This can be completed by: a) using the appropriate femoral resection templates (figure 3); or b) using the femoral resection guide in conjunction with the intramedullary reamer (figures 4 & 5).



4. Preparation of the Femur

To help avoid undersizing, varus positioning and to allow for correct alignment of the reamer and broach, it may be necessary to remove a small section of the medial cortex from the greater trochanter.

This can be achieved by one of two methods. The first involves the use of the special box chisel (Figure 6), or by using the starter drill and intra-medullary reamers (Figures 7 & 8). Whatever technique is employed, the aim is to provide a lateral starting point for the intra-medullary reamers and broaches.

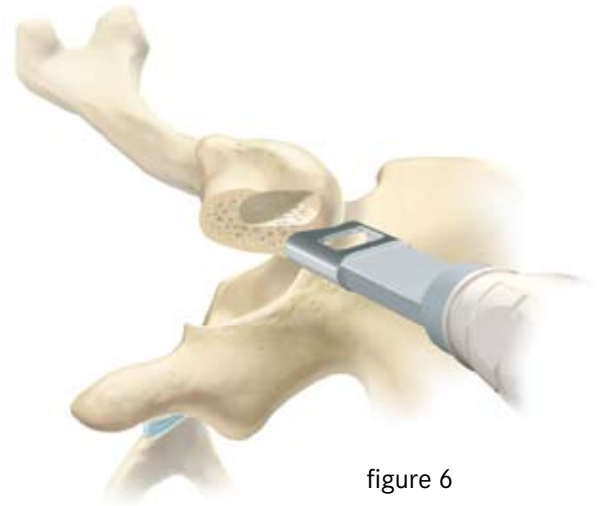


figure 6

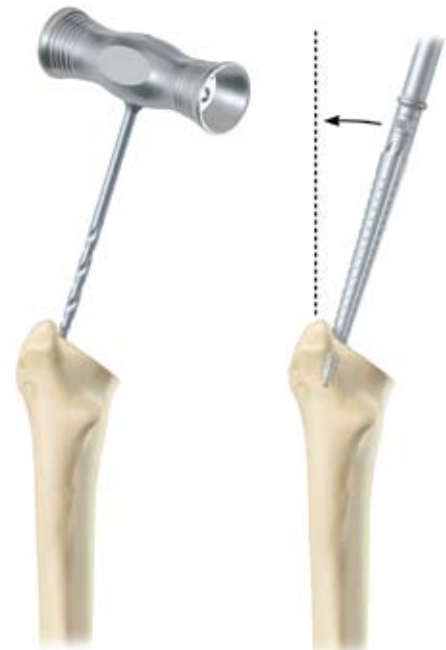


figure 7

figure 8

4a. Reaming the Distal Femur

Once the femoral canal has been located, begin reaming with the smallest tapered reamer. Subsequent reaming is then used to enlarge the intra-medullary canal until cortical chatter is encountered. (Figure 9)

Reaming should not be carried out using power tools.



figure 9

4b. Broaching the Proximal Femur

Starting with the smallest broach available, attach the broach to the broach handle as shown (figure 10) and begin preparing the proximal femur (Figure 11). The broaches have been designed to follow the prepared distal canal. It is also important to ensure the broach is orientated so that the medial/lateral axis of the broach is parallel with that of the anatomic medial/lateral axis of the femoral neck, as this will determine the angle of anteversion for the implanted femoral component. Sequentially larger broaches are then used until either complete stability is achieved, or the stem size selected during pre-operative planning has been reached. The angled surface of the femoral broach should then be level with the resected femoral neck (figure 12). A calcar trimmer can then be used to plane the calcar flush with the angled surface of the broach. (Fig 13)



figure 10

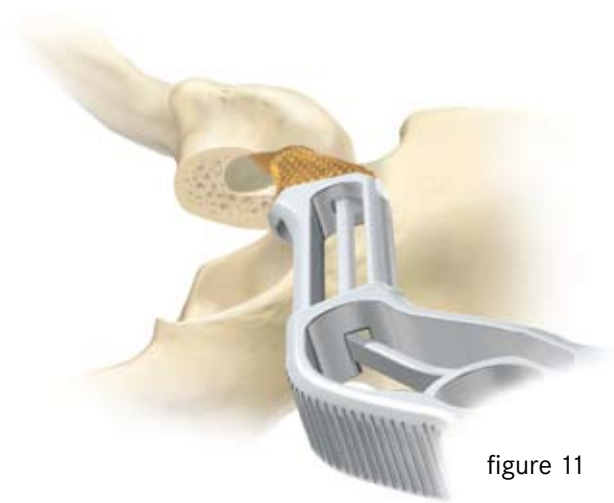


figure 11



figure 12



figure 13

5. Trial Reduction - Broach

For cementless implants the final broach used corresponds with the femoral component to be implanted. (i.e. 13mm broach = 13mm implant)
With the final broach in position, the trial neck can be secured into place (Figure 14).



figure 14

6a. Trial Reduction - Bi-Polar Component

Before a trial reduction can take place, the appropriate offset trial modular head is first attached to the trial neck (Figure 15). The correct diameter trial bi-polar shell is placed onto the trial femoral head and the joint is assessed for joint stability and leg length (Figure 16). Trial modular heads are available in numerous offsets, so it may be necessary to repeat the trial reduction process until joint stability and the desired leg length has been achieved. Please refer to relevant bi-polar operative technique for specific details.



figure 15



figure 16

6b. Trial Reduction - Uni-Polar Component

Before a trial reduction can take place, the appropriate offset trial uni-polar head is first attached to the trial neck. Trial uni-polar modular components are available in numerous offsets, so it may be necessary to repeat the trial reduction process until joint stability and the desired leg length has been achieved (Figure 17 & 18). Please refer to relevant uni-polar operative technique for specific details.



figure 17



figure 18

Once the trial reduction has been completed, carefully remove the trial components from the broach. The broach handle is then re-attached to the broach and the complete assembly carefully removed from the femur to avoid enlarging the prepared canal. **To promote the in-growth of bone into the hydroxyapatite coating, irrigation and drying of the femoral canal is not recommended.**

7. Femoral Component Insertion

When implanting a cementless implant, the definitive implant is equivalent to the last broach used. (ie. 13mm broach = 13mm implant)

Select the desired stem and attach it to the inserter handle (Figure 19). The stem is then impacted until the collar is flush with the rim of the planed calcar (Figure 20). The inserter handle is then removed.



figure 19



figure 20

8. Trial Reduction - Implant

If desired, a further trial reduction can be completed after the implantation of the femoral stem and prior to placement of the definitive modular head and bi-polar or uni-polar component (Figure 21 & 22). This is important because the femoral component may not in every instance seat exactly to the same depth as the broach and planed calcar. If this is the case, then it is recommended that a further trial reduction is carried out.



figure 21



figure 22

9a. Final Reduction – Bi-Polar Component

Prior to final reduction the definitive modular head and bi-polar shell must be assembled to the implanted femoral component. The first stage of this process is to assemble the appropriate diameter and offset modular head onto the femoral component taper. This is accomplished by placing the modular head onto a clean femoral component taper with hand pressure only. Alternatively, a combination of hand pressure and a twisting motion can be used. The modular head is finally seated in position by means of a gentle tap utilising the femoral head impaction device and mallet (Figure 23). Once the modular head is secured in position, the bi-polar component is assembled as per instructions in the relevant bi-polar operative technique.



figure 23



figure 24

9b. Final Reduction – Uni-polar Component

Prior to final reduction the definitive uni-polar component must be assembled to the implanted femoral component. This is accomplished by placing the modular uni-polar head onto a clean femoral component taper with hand pressure only. Alternatively, a combination of hand pressure and a twisting motion can be used. The modular head is finally seated in position by means of a gentle tap utilising the femoral head impaction device and mallet (Figure 25).



figure 25

Modular heads of any kind should never be heavily impacted onto the trunnion as this may cause damage to highly polished surface of the modular head.

Once the correct modular femoral head and bi-polar shell or uni-polar component has been attached to the femoral component, the hip joint can safely be reduced (Figure 26).



figure 26

10. Component Removal

Should a Biomet B.Fx Fracture stem ever require removal, included in the implant removal tray are two special instruments. These are the modular head removal instrument and the stem removal instrument.

The modular head removal instrument locates either side of the taper and exerts a tensile force to eject the femoral modular head (Figure 27).

The stem removal instrument again locates either side of the taper and combined with a slide hammer can exert sufficient force to facilitate removal of the femoral stem (Figure 28).

It is important to note that the stem removal instrument must be used in conjunction with flexible osteotomes to sufficiently loosen the stem. Failure to break the bone/implant or cement/implant interface may result in a fractured femur.



figure 27



figure 28

Ordering Information

Implants

B.Fx™ Fracture Stems - Biomet Type 1 Taper (T1)

Catalogue No.	Description
650-0457	B.Fx Fracture Stem 7mm x 115mm (T1)
650-0459	B.Fx Fracture Stem 9mm x 125mm (T1)
650-0461	B.Fx Fracture Stem 11mm x 135mm (T1)
650-0463	B.Fx Fracture Stem 13mm x 145mm (T1)
650-0465	B.Fx Fracture Stem 15mm x 155mm (T1)
650-0467	B.Fx Fracture Stem 17mm x 165mm (T1)

Scan™ CoCrMo Modular Femoral Heads (T1)

Offset (mm)	Articulation Diameter (mm)	
	22.22	28.0
-6.0	-	SCAN-0650
-5.0	SCAN-0657	-
0	SCAN-0658	SCAN-0652
+6.0	-	SCAN-0654

Biomet CoCrMo Modular Femoral Heads (T1)

Offset (mm)	Articulation Diameter (mm)	
	28.0	32.0
-6.0	163660	163667
-5.0	-	-
-3.0	163661	163668
0	163662	163669
+3.0	163663	163670
+6.0	163664	163671
+9.0	163665	163672
+12.0	163666	163673

Scan™ Stainless Steel Bi-Polar Components

Articulation Diameter (mm)	Internal Diameter (mm)	
	22.22	28.0
38.0	SCAN-03822	-
40.0	SCAN-04022	-
42.0	SCAN-04222	-
44.0	SCAN-04422	-
46.0	-	SCAN-04628
48.0	-	SCAN-04828
50.0	-	SCAN-05028
52.0	-	SCAN-05228
54.0	-	SCAN-05428
56.0	-	SCAN-05628
58.0	-	SCAN-05828
60.0	-	SCAN-06028

Scan™ Bi-Polar components are designed for use with Scan™ Modular Femoral Heads

Biomet CoCrMo Bi-Polar Components

Articulation Diameter (mm)	Internal Diameter (mm)	
	28.0	32.0
41.0	165206	-
42.0	165208	-
43.0	165210	-
44.0	165212	165312
45.0	165214	165314
46.0	165216	165316
47.0	165218	165318
48.0	165220	165320
49.0	165222	165322
50.0	165224	165324
51.0	165226	165326
52.0	165228	165328
53.0	165230	165330
54.0	165232	165332
55.0	165234	165334
58.0	165240	165340
61.0	165246	165346

Biomet Bi-Polar components are designed for use with Biomet Modular Femoral Heads

Ordering Information

Instrumentation

Instrumentation

Catalogue No. Description

31-600325	Scan 22.22 & 28mm St Stl Bi-Polar Instrument Tray
31-601270	Scan Bi-Polar Modular Head Press
31-600302	Scan 22.22 & 28mm St Stl Bi-Polar X-Ray Templates 115% Mag.
31-600326	Biomet 28mm CoCr Bi-Polar Instrument Tray
31-600305	Biomet 28mm CrCo Bi-Polar X-Ray Templates 115% Mag.
31-600327	Biomet 32mm CoCr Bi-Polar Instrument Tray
31-600308	Biomet 32mm CoCr Bi-Polar X-Ray Templates 115% Mag.
31-600485	B.Fx Fracture Stem General Instrument Tray
31-600487	B.Fx Fracture Stem I/M Reamer & Rasp Tray
31-600323	B.Fx Fracture Stem X-Ray Templates (T1) 115% Mag.
31-600005	Biomet Fem Hd and Stem Removal Instr. Tray



Scan™ 22.22 & 28mm St Stl Bi-Polar Instrument Tray



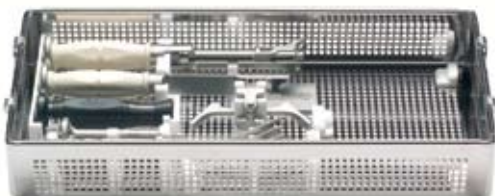
Biomet 28mm CoCr Bi-Polar Instrument Tray



B.Fx™ Fracture Stem I/M Reamer & Rasp Tray



Biomet 32mm CoCr Bi-Polar Instrument Tray



B.Fx™ Fracture Stem General Instrument Tray



Biomet Fem Hd and Stem Removal Instrument Tray



Bi-Polar Modular Head Press