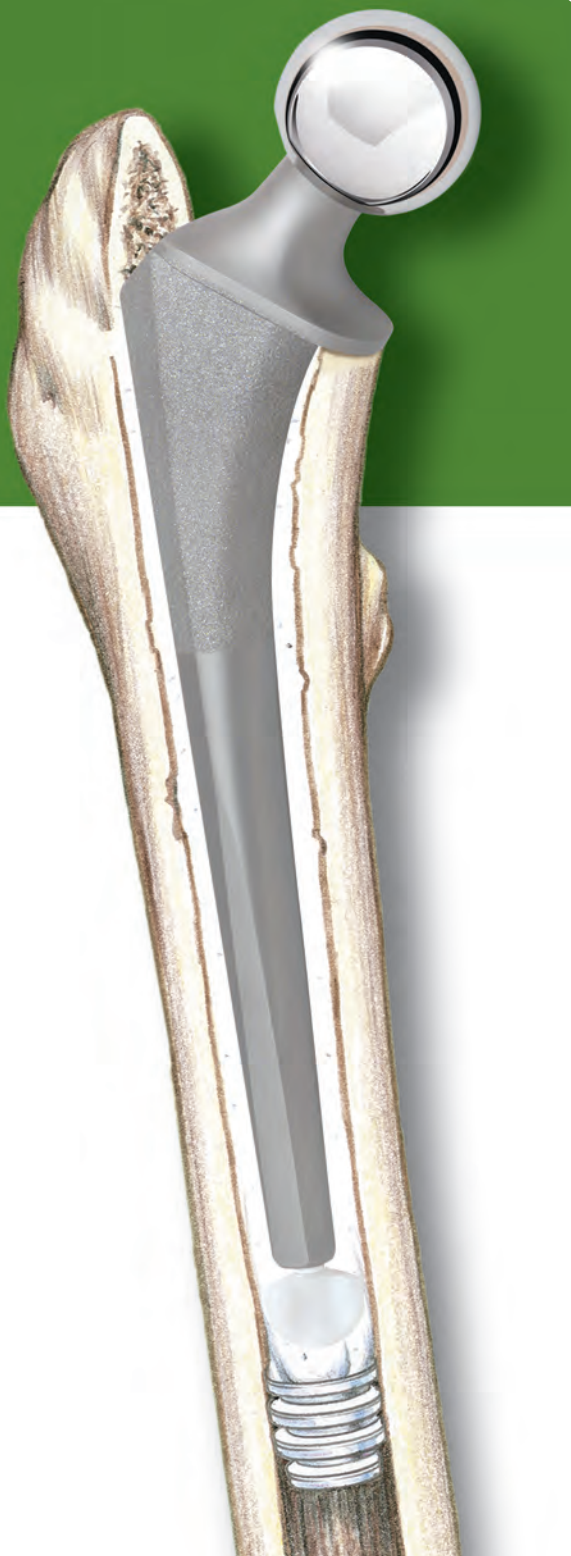
stryker

Orthopaedics

OmniFit HFx 127° 132°
Surgical Protocol



Cutting*Edge* Advantage
Hip Instrument System

- Complete
- Simple
- Adaptable

OmniFit HFx 127° 132°
Surgical Protocol

Cutting*Edge* Advantage
Hip Instrument System

Table of Contents

Indications

For use as a Bipolar Hip Replacement:
- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.
- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.
- Femoral Neck Fracture.

For use as a Total Hip Replacement:
- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Clinical circumstances that require an altered femoral resection level due to proximal fracture, bone loss, or calcar lysis.

Contraindications

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in post-operative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.

Other contraindications for use as a Bipolar/Hemi-Hip Replacement include: pathological conditions of the acetabulum which would prevent achieving adequate range of motion, appropriate head stability, and/or a well seated and supported smooth acetabular articulation of the head.

Warning and Precautions

See package insert warning, precautions, adverse effects and other essential product information.

Introduction

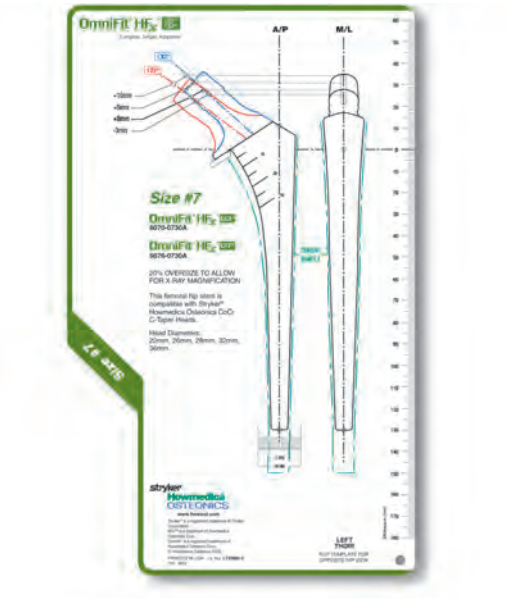
The Cutting*Edge* Advantage Instrument System is versatile, offering surgeons great flexibility and ease of use in approaching the implantation of the OmniFit HFx Femoral Hip Stems. Each surgeon should use the surgical approach for total hip arthroplasty with which he/she is most familiar.

Patient positioning, preparation and draping, skin incision, soft tissue dissection and hip dislocation should be performed according to the surgeon's preferred technique, making certain to adequately expose the acetabulum and the proximal femur.

1 Pre-Operative Planning and X-Ray Evaluation

Pre-operative planning aids in the selection of the appropriate implant style and size for the patient's hip pathology. Optimal femoral stem fit, prosthetic neck length, and neck offset/angle should be evaluated during pre-operative X-Ray analysis using provided templates (**Figure 1**). The appropriate proximal body and stem length should be assessed in the A/P view. Anatomic anomalies that could prevent the intra-operative achievement of the established pre-operative goals may also be detected through such planning. If needed, a lateral view may be taken to assess the femoral canal curvature.

1



2 Neck Resection

A proper neck resection level directly affects stem fit and placement. The resection should be made at a level determined during templating to restore proximal femoral head/neck length and offset. Using anatomic landmarks identified during templating, the Neck Resection Guide may be utilized for proper resection determination. The Neck Resection Guide is identical in profile to a size #7 OmniFit implant body, thus providing a means of simulating stem alignment. Care should be taken to align the axis line of the resection guide to the center axis of the femoral shaft; the scales on the lateral flange or medial radius of the guide can be used to reference the greater or lesser trochanter respectively when making the final cut (**Figure 2A**).

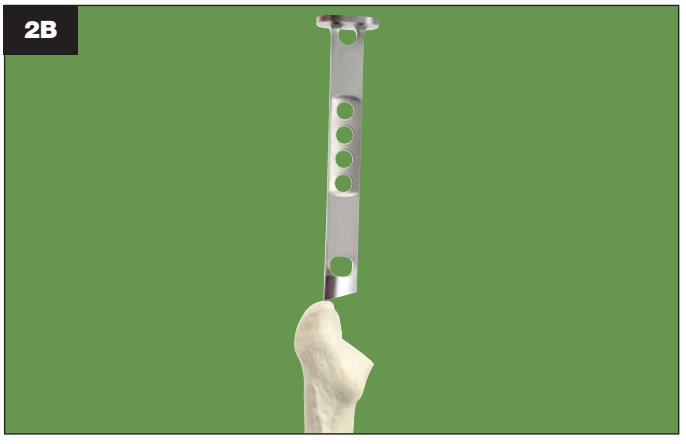
Optional Step

Box Chisel

The Box Chisel removes bone from the proximal lateral portion of the resected femoral neck to allow access to the femoral medullary canal (**Figure 2B**).

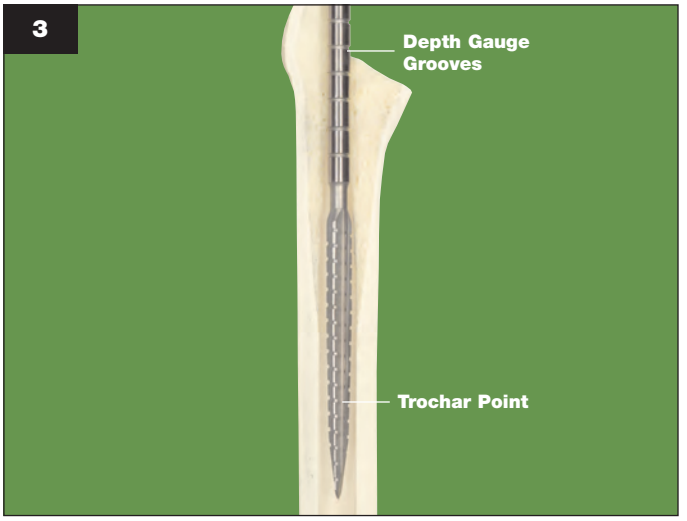
2A

2B



3 Opening the Femoral Canal: Axial Starter Reamer

The Axial Starter Reamer is used to enter the femoral medullary canal through the trochanteric fossa. The Starter Reamer has a trocar point to facilitate entry. It should be inserted to a depth such that the distal tip of the Starter Reamer is 1cm below the distal end of the final size broach. The groove, on the starter reamer shaft, is approximately in line with the intersection point of the femoral axis of the femur and the neck resection line (**Figure 3**).



4 Trochanteric Reaming

Insert the Trochanteric Reamer into the proximal area of the canal and bias the cutting teeth laterally to remove the desired amount of bone (**Figure 4**). Do not sink the reamer below the level of the trochanter. Performing this step can help facilitate the axial alignment of the broach so that it is not pushed into varus by an overhanging trochanter. Varus positioning of the implant may result in improper placement or undersizing of the implant.

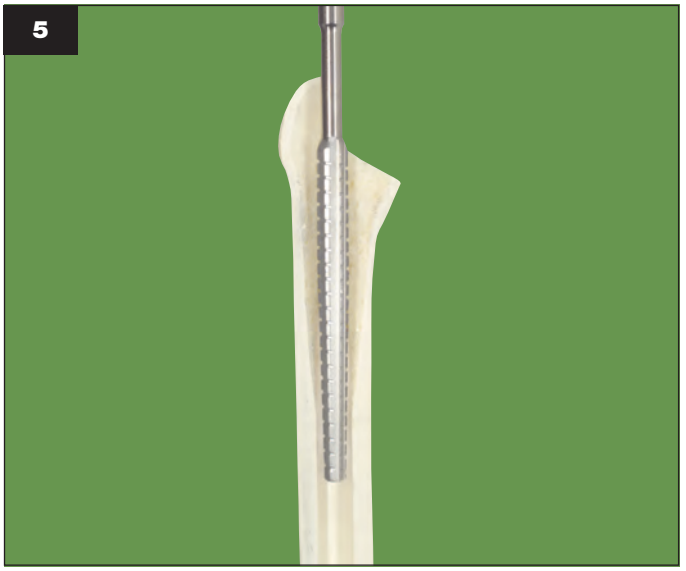
5 Tapered Reaming

Starting with a size one or two smaller than the templated size, insert the reamers into the canal such that the most proximal level cutting flutes are 1-2mm below the desired or templated femoral neck resection level. If using a Press-Fit Application, ream sequentially upward in size until the last tapered reamer achieves good contact with the cortical bone (**Figure 5**).

Note: Though the fully toothed broaches may facilitate preparation of the femoral implant without the use of tapered reamers, a narrow/tight diaphyseal shaft (e.g. champagne flute femur) may result in broach resistance in the distal canal. If resistance is encountered, tapered reaming is recommended to minimize potential for distal femoral fractures. The option to skip any reaming step is at the discretion of the surgeon.

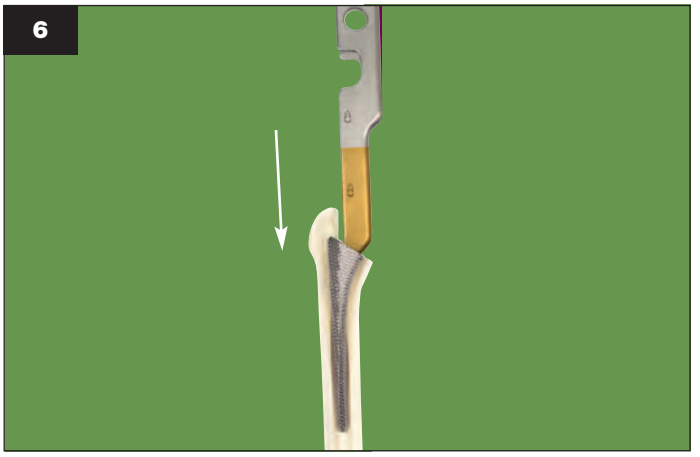
Surgeon Tip: Aggressive tapered reaming can lead to significant reduction of cancellous bone leading to premature loosening at the bone cement interface. Every effort should be made to broach only using cementation of the femoral stem and limited taper reaming should be reserved for those rare cases of narrow/tight diaphyseal shafts where an appropriate sized small broach has been passed.

Note: Tapered Reamers are not found in the Primary Instrument Tray and must be ordered separately. Reference page 9 for tapered reaming tray product code information.



6 Broaching the Femur

Assemble the Broach to the Broach Handle. Starting with the smallest Broach, advance sequentially upward approaching the templated size until a stable snug-fit is obtained. Care should be taken to lateralize the proximal portion of the Broach in order to maintain axial alignment of the Broach and implant (**Figure 6**).

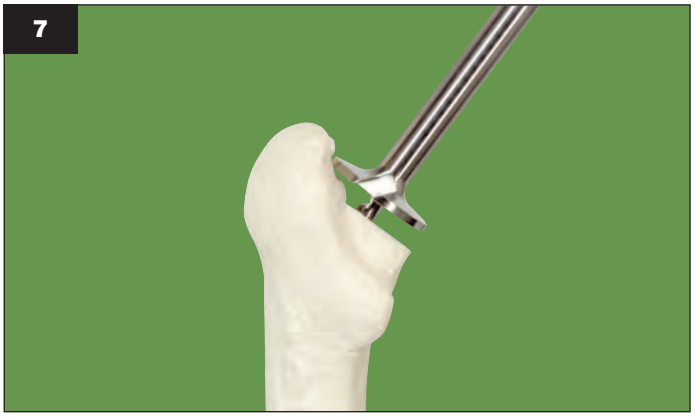


7 Calcar Planer

Leaving the final Broach seated in the femoral canal (**Figure 7**), gently guide the Calcar Planer over the Broach post (see note below) and initiate power prior to contacting the femur. Slowly advance the Calcar Planer toward the Broach to plane the femur. Planing will continue until the positive stop on the Planer contacts the Broach face.

Note: In the event that the Broach post is seated completely below the resection plane (thus preventing engagement with the Calcar Planer), the Broach should be removed and the resection re-cut at a slightly lower level. The surgeon should then re-insert the final Broach ensuring a stable and snug fit.

Caution: Failure to operate the Calcar Planer in accordance with the instructions above may result in damage to the femur.



8 Trial Reduction

Using the Broach, Trial Neck, and Trial Head assembly, perform a trial reduction to judge component positioning, leg length and hip stability (range of motion and laxity) before the final components are implanted. Select a Cutting*Edge* Advantage Trial Neck, 132° (Silver) or 127° (Gold), that has the same base neck length as the planned implant size, see **Table 1** and **Figure 8A**.

Table 1: Broach to Implant Sizing

Stem Size	132° Neck Length	127° Neck Length	Broach Size For Press-Fitting	Broach Size For Cementing
5	25mm	25mm	PF 5	PF 7/C5
6	25mm	25mm	PF 6/C4	PF 8/C6
7	30mm	30mm	PF 7/C5	PF 9/C7
8	30mm	30mm	PF 8/C6	PF 10/C8
9	35mm	35mm	PF 9/C7	PF 11/C9
10	35mm	35mm	PF 10/C8	PF 12/C10
11	40mm	N/A	PF 11/C9	PF 13/C11

PF = Press Fit C = Cemented

Next, select the appropriate plastic C-Taper Trial Head. Refer to **Table 2** for head diameters and head offsets combinations (**Figure 8B**).

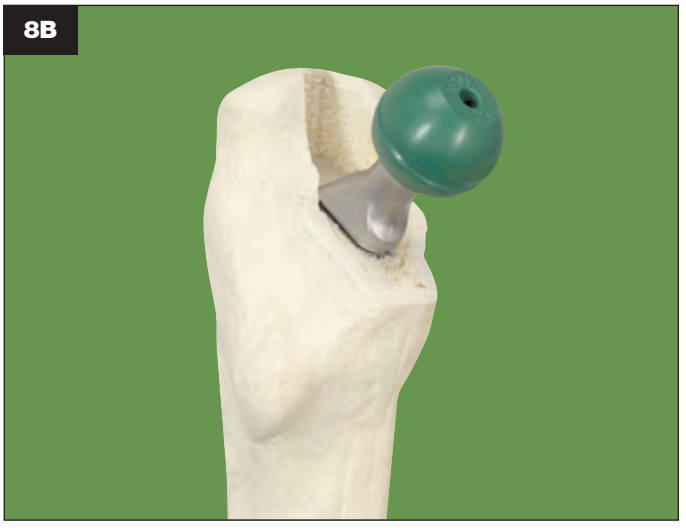
Table 2: Head Diameters and Offsets

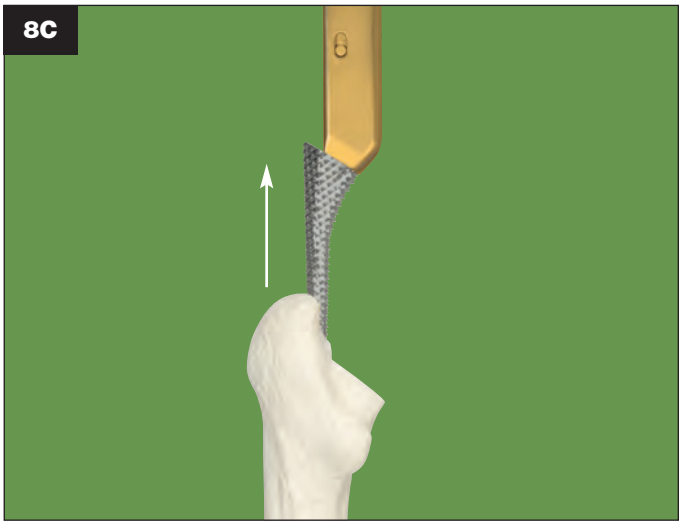
Trial Head Offsets	C-Taper Trial Head Diameters						
	22mm	26mm	28mm	32mm	36mm	40mm	44mm
-5mm				X**	X**	X**	X**
			*				
-3mm			X	*	*	*	*
-2.5mm		X	X	X	X	X	X
0mm	X	X	X	X	X	X	X
+2.5mm	X	X	X	X	X	X	X
+5mm	X	X	X	X	X	X	X
+7.5mm	X	X	X	X	X	X	

* Use only with neck lengths 30mm or longer.

** Use only with neck lengths 35mm or longer.

Head offset is adjusted until leg lengths are equal. Joint stability can be checked by telescoping the leg and performing a full range of motion. If the hip is unstable or dislocates, either a 127° or 132° hip implant can be considered to achieve adequate offset. Upon confirmation of the selected component, remove the trial head and trial neck, and re-assemble the broach handle. Remove the broach with the help of the slotted mallet to preserve the integrity of the established cavity (**Figure 8C**).





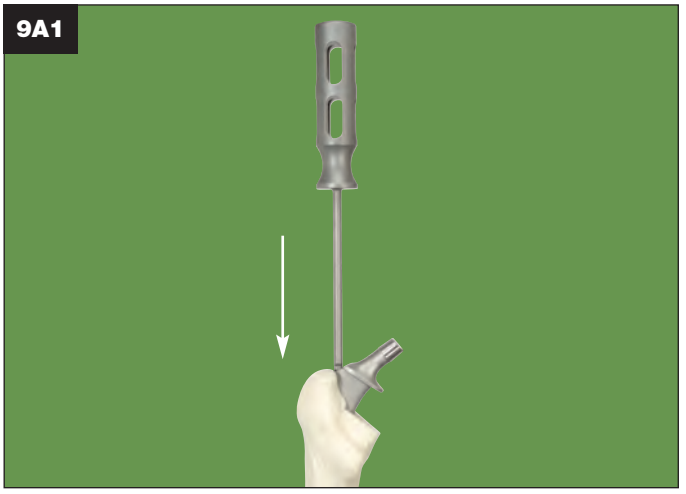
For Press-Fit Applications Only

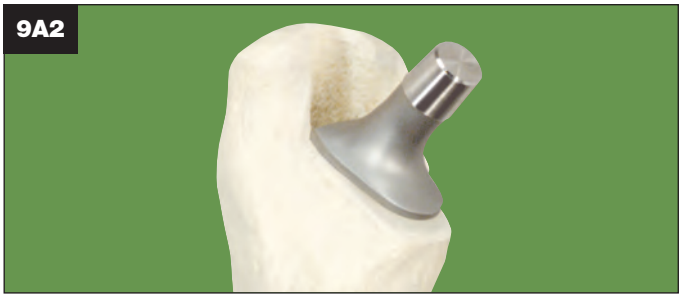
9A Femoral Stem Insertion

Introduce the stem into the femoral canal axially with a manual force until resistance is encountered. In order to assist in aligning and seating the stem, the OmniFit HFx inserter/pusher (1020-2300) should be used. A mallet is then used to seat the hip stem into the canal (**Figure 9A1**) until a stable snug-fit is attained (**Figure 9A2**).

Caution: The surgeon should NOT attempt to continue impacting the femoral component if visual and auditory clues indicate that the resting position of the femoral component has been reached. This is true even if the femoral component is proud in reference to the level of the broach trial. Further impaction may result in fracture of the femur.

Continue to step 13 for head assembly.





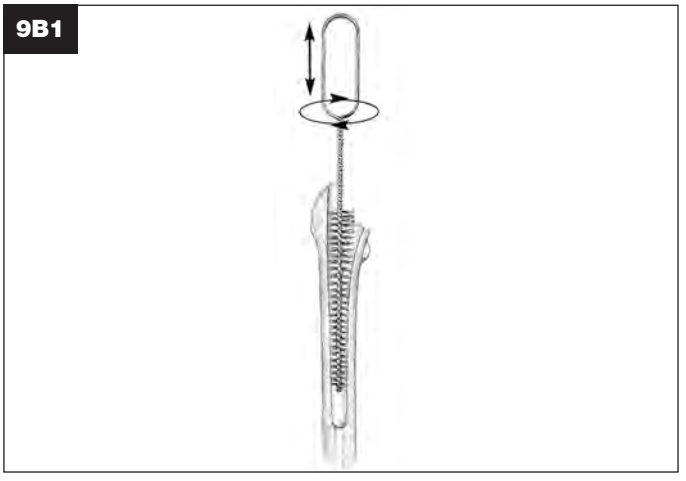
For Cemented Application Only (Steps 9B through 11)

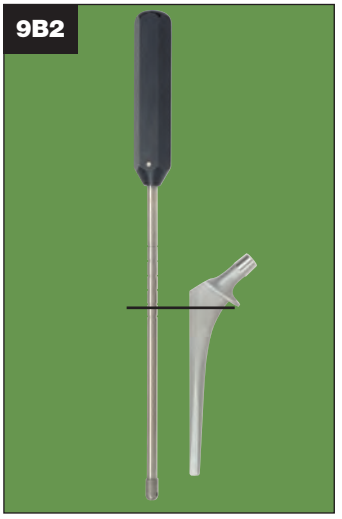
9B Cleaning the Canal and Cement-Plug Insertion

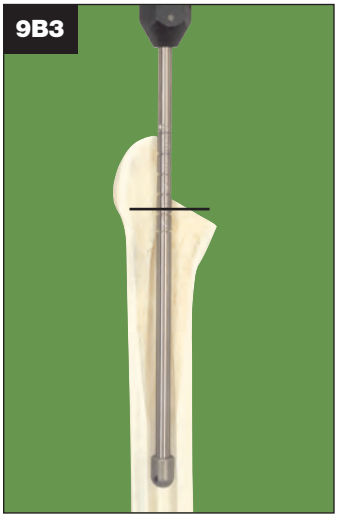
The established principles and methods for preparing the intermedullary canal for cementing should be meticulously applied. The practice of bristle brushing followed by pulsatile lavage provides an effective method for cleaning the canal of loose cancellous bone and trapped debris prior to Cement-Plug insertion (**Figure 9B1**). An optional Universal Cement-Plug and a sized Cement-Plug are available.

To determine the proper depth of the cement plug the selected stem is placed alongside the Cement-Plug Inserter, leaving at least 2cm between the shoulder on the threads of the instrument and the stem tip. The engraved groove closest to the medial aspect of the stem calcar is used as a reference for the depth of insertion (**Figure 9B2**).

When trialing for the Sized Cement-Plug, the Cement-Plug Trial must be fully threaded onto the Inserter prior to the test insertion. Proper fit is determined by the Trial which fits snugly in the canal when inserted to the reference depth or until mild resistance is encountered based on surgeon preference (**Figure 9B3**).







10 Distal Cement Spacer and Cemented Stem Insertion

The Distal Cement Spacer is designed to be inserted into the corresponding hole in the distal end of the cemented stem. During implant insertion, the Universal Distal Cement Spacer will assist in positioning the stem in the neutral axis of the cement-filled femoral canal (**Figure 10**).

Caution: Do not twist the PMMA spacer in the stem as it will score and possibly fracture.

Note: If the decision has been made not to utilize the Distal Cement Spacer, then it is recommended that the distal stem hole be plugged with a small amount of unpolymerized PMMA, prior to insertion.

Note: Cylindrically reaming to the minimum size Distal Spacer is optional. However, if a larger than minimum size Distal Spacer is planned, then cylindrical reaming of the distal femoral canal may be required and should be accomplished prior to plugging the canal.

Surgeon Tip: If possible, reaming should be avoided to minimize the risk of removing cancellous bone, which is necessary for fixation.

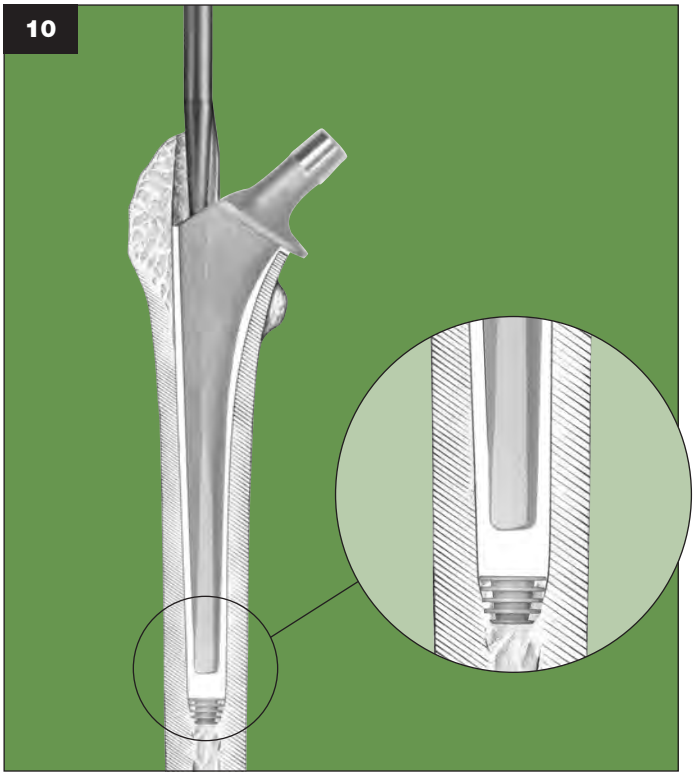
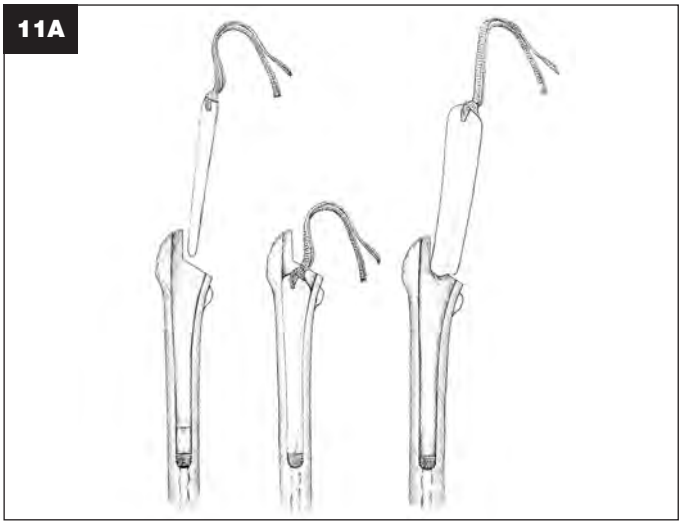


Table 3: Cement Spacer Sizing

Stem size	Minimum Size PMMA Cement Centralizer
5	8mm
6	9mm
7	10mm
8	11mm
9	11mm
10	12mm
11	13mm

11 Final Canal Preparation and Cement Delivery

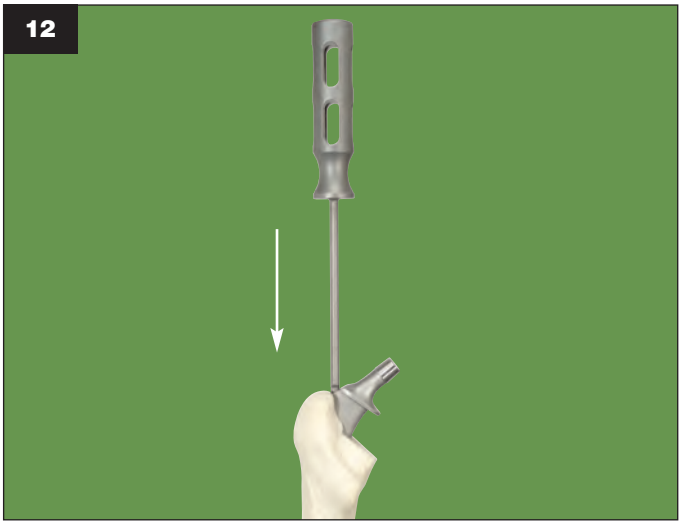
The medullary canal is thoroughly lavaged and dried with a laparatomy sponge prior to cement delivery (**Figure 11A**). A cement gun is employed to introduce doughy cement in a retrograde manner (**Figure 11B**). The distal portion of the nozzle is broken away below the conical pressurizer and the cement is pressurized with the cement gun through the pressurizer (**Figure 11C**).



12 Femoral Stem Insertion

The proximal portion of the stem can be coated with doughy cement to ensure that blood and fat do not come in contact with the stem. To assist in aligning and seating the stem, the OmniFit HFx stem inserter should be used. Introduce the assembled stem into the femoral canal with an axial force while providing a laterally directed force (**Figure 12**). The goal is to introduce the stem in neutral position with an adequate cement mantle. Remove excess cement. At final seating, the collar of the prosthesis should rest in intimate contact with the prepared neck cut.

Note: It is recommended that the distal cement spacer be coated with unpolymerized PMMA to help prevent introduction of air and cement defects.



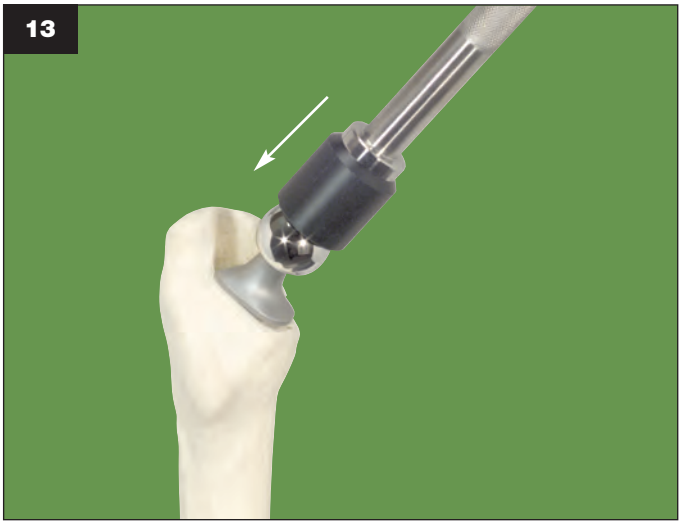
13 Head Assembly

Prior to head assembly, neck length selection may be re-evaluated using the Stryker C-Taper Trial Head. Place the C-Taper Trial Head onto the stem neck taper and reduce the hip to verify that the mechanics have not been altered due to implant seating.

Remove the Trial Head and dry the implant trunnion with a laparatomy sponge or sterile towel.

Select the appropriate Cobalt Chrome C-Taper Head size and place it onto the dry trunnion of the femoral stem with a slight twist. Impact the head with two moderate blows using the Stem Head Impactor (1104-1000) (**Figure 13**).

Note: See Trident Surgical Protocols for recommended head compatibility.



14 Wound Closure

Relocate the femoral head into the acetabular cup and re-check the laxity and range of motion. The surgical site is then closed according to surgeon preference.

Catalog Information

CuttingEdge Advantage General Instruments (1100-1400)

Catalog Number	Part Description
1100-1225	127° C-Taper Trial Neck – 25mm
1100-1230	127° C-Taper Trial Neck – 30mm
1100-1235	127° C-Taper Trial Neck – 35mm
1100-1240	127° C-Taper Trial Neck – 40mm
1100-1325	132° C-Taper Trial Neck – 25mm
1100-1330	132° C-Taper Trial Neck – 30mm
1100-1335	132° C-Taper Trial Neck – 35mm
1100-1340	132° C-Taper Trial Neck – 40mm
1100-2200R	C-Taper 22mm Trial Head +0mm
1100-2225R	C-Taper 22mm Trial Head +2.5mm
1100-2205R	C-Taper 22mm Trial Head +5mm
1100-2275R	C-Taper 22mm Trial Head +7.5mm
1100-2210R	C-Taper 22mm Trial Head +10mm
1100-2697R	C-Taper 26mm Trial Head -2.5mm
1100-2600R	C-Taper 26mm Trial Head +0mm
1100-2625R	C-Taper 26mm Trial Head +2.5mm
1100-2605R	C-Taper 26mm Trial Head +5mm
1100-2675R	C-Taper 26mm Trial Head +7.5mm
1100-2610R	C-Taper 26mm Trial Head +10mm
1100-2898R	C-Taper 28mm Trial Head –3mm
1100-2897R	C-Taper 28mm Trial Head –2.5mm
1100-2800R	C-Taper 28mm Trial Head +0mm
1100-2825R	C-Taper 28mm Trial Head +2.5mm
1100-2805R	C-Taper 28mm Trial Head +5mm
1100-2875R	C-Taper 28mm Trial Head +7.5mm
1100-2810R	C-Taper 28mm Trial Head +10mm
1100-3299R	C-Taper 32mm Trial Head –5mm
1100-3297R	C-Taper 32mm Trial Head –2.5mm
1100-3200R	C-Taper 32mm Trial Head +0mm
1100-3225R	C-Taper 32mm Trial Head +2.5mm
1100-3205R	C-Taper 32mm Trial Head +5mm
1100-3275R	C-Taper 32mm Trial Head +7.5mm
1100-3210R	C-Taper 32mm Trial Head +10mm
1100-3699R	C-Taper 36mm Trial Head -5mm
1100-3697R	C-Taper 36mm Trial Head -2.5mm
1100-3600R	C-Taper 36mm Trial Head +0mm
1100-3625R	C-Taper 36mm Trial Head +2.5mm
1100-3605R	C-Taper 36mm Trial Head +5mm
1100-3675R	C-Taper 36mm Trial Head +7.5mm
1100-3610R	C-Taper 36mm Trial Head +10mm
1100-4099R	C-Taper 40mm Trial Head –5mm
1100-4097R	C-Taper 40mm Trial Head –2.5mm
1100-4000R	C-Taper 40mm Trial Head +0mm
1100-4025R	C-Taper 40mm Trial Head +2.5mm
1100-4005R	C-Taper 40mm Trial Head +5mm
1100-4075R	C-Taper 40mm Trial Head +7.5mm
1100-4010R	C-Taper 40mm Trial Head +10mm
1100-4499R	C-Taper 44mm Trial Head -5mm
1100-4497R	C-Taper 44mm Trial Head -2.5mm
1100-4400R	C-Taper 44mm Trial Head +0mm
1100-4425R	C-Taper 44mm Trial Head +2.5mm
1100-4405R	C-Taper 44mm Trial Head +5mm
1020-2700	Accolade Calcar Planar
1104-1000	Femoral Head Impactor
1100-1000	CuttingEdge Advantage Broach Handle
1120-1000	Slotted Mallet
1101-2100	T-Handle - Trigger Release
5900-0050	T-Handle - Small Trigger Release (Optional)
1113-1002	Medium Box Chisel
1100-1500	CuttingEdge Advantage Neck Resection Guide

CuttingEdge Advantage Instrument Cases

Catalog Number	Part Description
1440-0001	Single Layer Outer Case
1100-1400	CuttingEdge Advantage General Instruments Tray
1100-1402	CuttingEdge Advantage Primary Instruments Tray
1100-1403	CuttingEdge Advantage Tapered Reamer Tray
1100-1404	Cylindrical Reamer Tray (8.0-14.5mm)
1100-1405	Cylindrical Reamer Tray (15.0-20.0mm)

CuttingEdge Advantage Hip Fracture Instrument Tray (1100-1401)

Catalog Number	Part Description
1100-0305	OmniFit HFx Broach PF5
1100-0406	OmniFit HFx Broach PF6/C4
1100-0507	OmniFit HFx Broach PF7/C5
1100-0608	OmniFit HFx Broach PF8/C6
1100-0709	OmniFit HFx Broach PF9/C7
1100-0810	OmniFit HFx Broach PF10/C8
1100-0911	OmniFit HFx Broach PF11/C9
1100-1012	OmniFit HFx Broach PF12/C10
1100-1113	OmniFit HFx Broach PF13/C11
1020-2300	OmniFit HFx Stem Inserter
1212-0000	Depth Gauge Handle
1212-00XX	Omniflex™ Trial Distal Tips (XX=08-14)
1111-100X	Trochanteric Reamer
1101-0304	Tapered Starter Reamer

OmniFit HFx Hip Stems

127° Neck Angle

Catalog Number	Stem Size	Stem Length	Neck Length	Offset (+0mm)
6076-0525A	5	110mm	25mm	35mm
6076-0625A	6	120mm	25mm	36mm
6076-0730A	7	130mm	30mm	41mm
6076-0830A	8	140mm	30mm	42mm
6076-0935A	9	150mm	35mm	46mm
6076-1035A	10	160mm	35mm	47mm

132° Neck Angle

Catalog Number	Stem Size	Stem Length	Neck Length	Offset (+0mm)
6070-0525A	5	110mm	25mm	29mm
6070-0625A	6	120mm	25mm	30mm
6070-0730A	7	130mm	30mm	35mm
6070-0830A	8	140mm	30mm	36mm
6070-0935A	9	150mm	35mm	41mm
6070-1035A	10	160mm	35mm	42mm
6070-1140A	11	170mm	40mm	46mm

Instrument Case

Catalog Number	Part Description
1440-0001	Single Layer Case
1100-1400	CuttingEdge Advantage General Instrument Tray
1100-1402	CuttingEdge Advantage Primary Instrument Tray
1100-1403	CuttingEdge Advantage Tapered Reamer Tray

Notes

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A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

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