stryker®

Secur-Fit Max 127° 132°
Secur-Fit Plus Max 127°
Surgical Protocol

CuttingEdge Advantage
Hip Instrument System

Secur-Fit Max

Secur-Fit Plus Max

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Cutting*Edge* Advantage
Hip Instrument System

Table of Contents

Indications

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and,
- Treatment of nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques

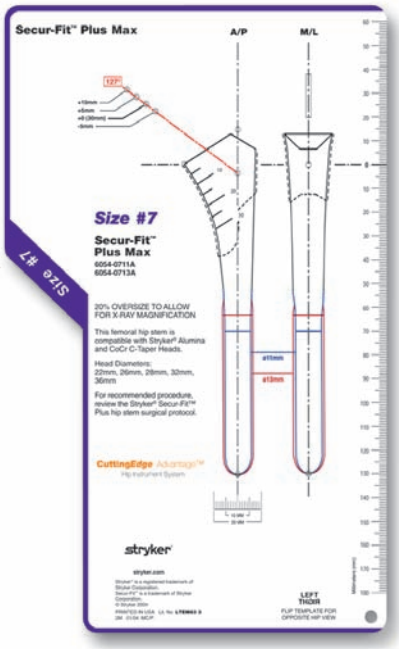
Contraindications

- Active infection or suspected latent infection in or about the hip joint;
- Bone stock that is inadequate for support or fixation of the prosthesis;
- Skeletal immaturity;
- Any mental or neuromuscular disorder that would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in post-operative care.

Warnings and Precautions

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

1



Introduction

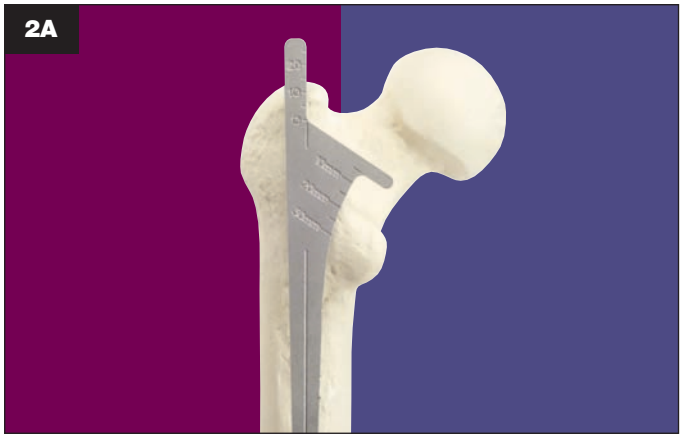
The Cutting*Edge* Advantage Instrument System is versatile, offering surgeons great flexibility and ease of use in approaching the implantation of the Secur-Fit Max and Secur-Fit Plus Max Femoral Components. Each surgeon should use the surgical approach for total hip arthroplasty with which he/she is 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 Templating

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.

2 Neck Resection

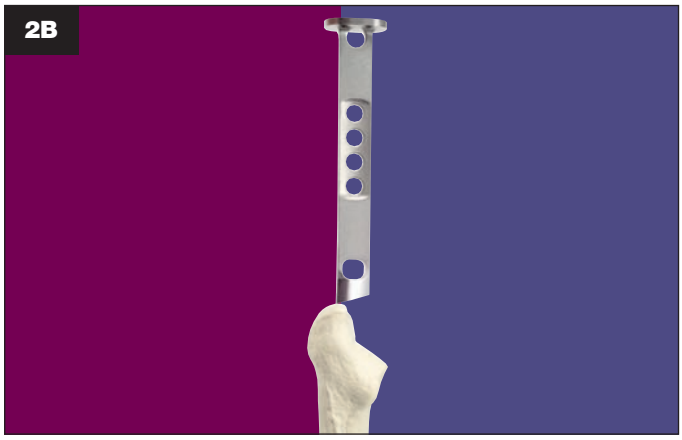
A proper neck resection level directly affects stem fit and placement. The resection should be made at a level determined during templating to restore proximal femoral head/neck length and offset. Using anatomic landmarks identified during templating, the Neck Resection Guide may be utilized for proper resection determination. The Neck Resection Guide is identical in profile to a Secur-Fit Max size #7 implant body, thus providing a means of simulating stem alignment. Care should be taken to align the axis line of the Neck 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

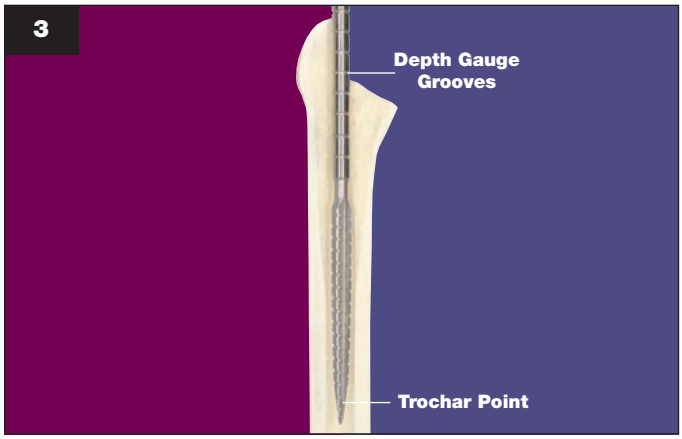
Box Chisel

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**).



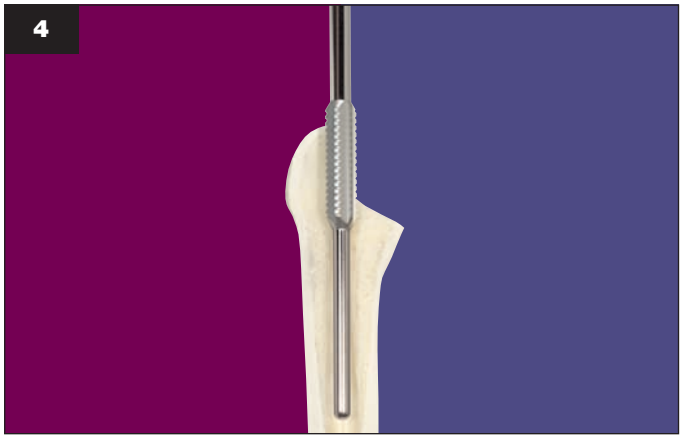
3 Opening the Femoral Canal: Axial Starter Reamer

The Axial Starter Reamer is used to enter the femoral medullary canal through the trochanteric fossa. The Starter Reamer has a trochar 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 an improperly placed or potentially undersized implant.



5 Tapered Reaming

Starting one or two sizes smaller than the templated size, insert the reamers into the canal such that the most proximal levels of the cutting flutes are 1-2mm below the desired or templated femoral neck resection level. Ream sequentially upward in size until the last Tapered Reamer achieves good contact with the cortical bone (**Figure 5A**).

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.

Note: Tapered and Cylindrical Reamers are not found in the Primary Instrument Tray and must be ordered separately. Reference page 6 for Tapered and Cylindrical Reaming Product Code information.

Cylindrical Reaming (for Secur-Fit Plus Max only)

Cylindrically reaming prepares the femoral canal to fit with the distal portion of the Secur-Fit Plus Max prosthesis. If a Secur-Fit Plus Max stem is selected, the size of the cylindrical portion of the stem is determined from pre-operative templating and is confirmed intra-operatively or by X-Ray. It is important to position the reamer laterally so that it is not pushed into varus by an overhanging trochanter.

Cylindrical reaming proceeds in 0.5mm increments until endosteal contact is achieved. A choice can be made intra-operatively to under-ream by 0.5mm or to ream line-to-line with the chosen implant size depending upon surgeon preference and/or bone quality. To ensure distal press-fit, under-ream by 0.5mm compared to the chosen implant size. When reaming line-to-line with chosen implant size, there is a potential that the distal flutes may not fully engage with the bone.

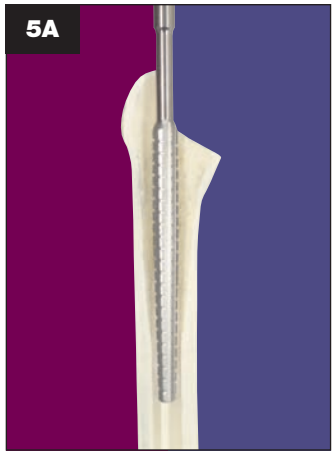
The Cylindrical Reamer is inserted such that the appropriate stem length marking intersects the most distal/medial point of the final neck resection level (**Figure 5B**). Reamers are marked in 10mm increments and should be inserted to a depth that matches or is 5mm deeper than the length of the chosen implant size (**Table 1**).

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 6A**).

Optional Step
Calcar Planer

Leaving the final Broach seated in the femoral canal (**Figure 6B**), 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.



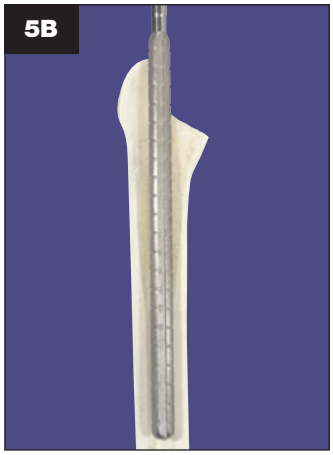
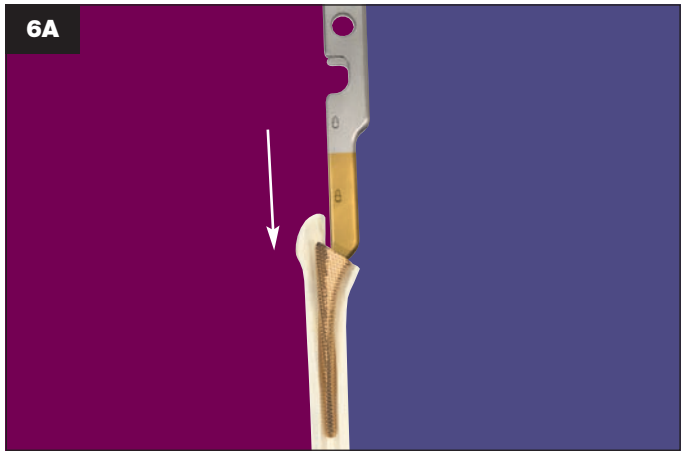


Table 1: Cylindrical Reamer Sizing (for Secur-Fit Plus Max only)

Stem Size	Distal Diameter (mm)	Final Cylindrical Reamer (mm)	Cylindrical Reamer Minimum Depth of Insertion (mm)
5	9	8.5 or 9.0	110
5	11	10.5 or 11.0	110
6	10	9.5 or 10.0	120
6	12	11.5 or 12.0	120
7	11	10.5 or 11.0	130
7	13	12.5 or 13.0	130
8	12	11.5 or 12.0	140
8	14	13.5 or 14.0	140
9	13	12.5 or 13.0	150
9	15	14.5 or 15.0	150
10	14	13.5 or 14.0	160
10	16	15.5 or 16.0	160
11	15	14.5 or 15.0	170
11	17	16.5 or 17.0	170
12	16	15.5 or 16.0	170
12	18	17.5 or 18.0	170
13	17	16.5 or 17.0	170
13	19	18.5 or 19.0	170
14	18	17.5 or 18.0	170
14	20	19.5 or 20.0	170



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.

7 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 (**Table 2** and **Figure 7A**).

Table 2: Broach and Neck Trial Sizing

Stem Size	132° Neck Length (mm)*	127° Neck Length (mm)	Broach Size For Press-Fitting
4	25	N/A	PF4
5	25	25**	PF5
6	25	25	PF6/C4
7	30	30	PF7/C5
8	30	30	PF8/C6
9	35	35	PF9/C7
10	35	35	PF10/C8
11	40	40	PF11/C9
12	40	40	PF12/C10
13	40	40	PF13/C11
14	40	40**	PF14/C12

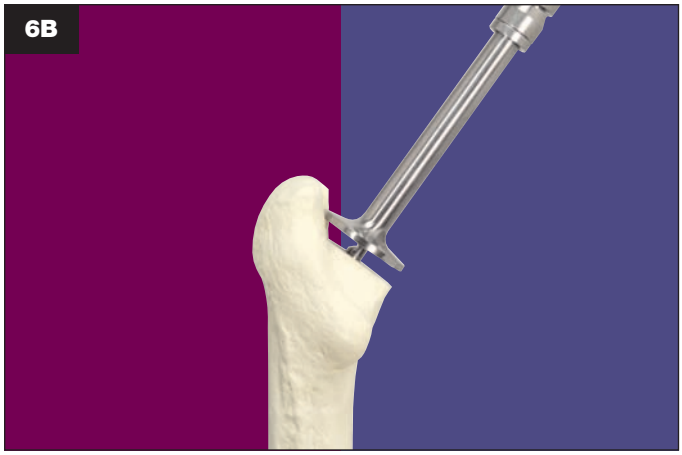
*Secur-Fit Plus Max is not available in 132° neck angle.
**Available on Secur-Fit Plus Max only.

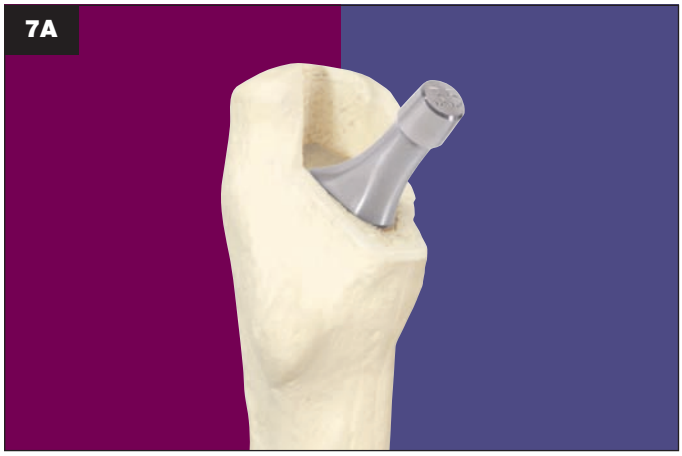
Next, select the appropriate plastic C-Taper Trial Head. Refer to (**Table 3**) for head diameter and head offset combinations (**Figure 7B**).

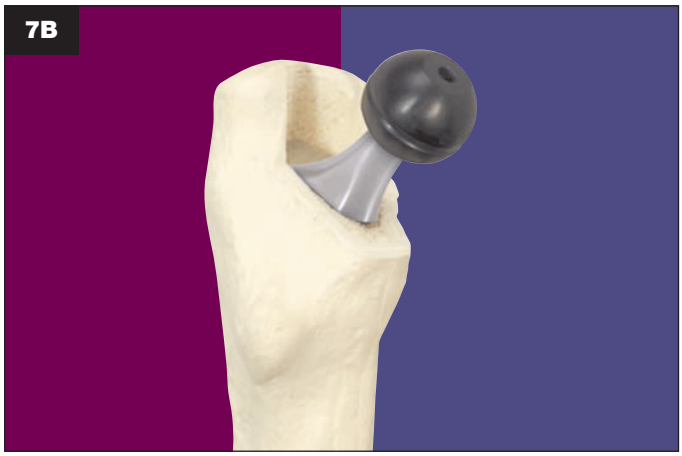
Table 3: Head Diameters and Offsets

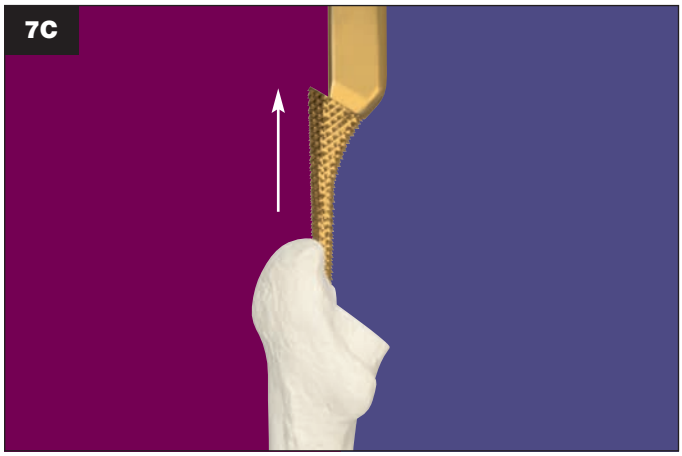
Trial Head Offsets	C-Taper Trial Head Diameters							
		22mm	26mm	28mm	32mm	36mm	40mm	44mm
	-5mm				X	X	X	X
	-3mm			X				
	-2.5mm		X	X	X	X	X	X
	0mm	X	X	X	X	X	X	X
	+2.5mm	X	X	X	X	X	X	X
	+5mm	X	X	X	X	X	X	X
	+7.5mm	X	X	X	X	X	X	
	+10mm	X	X	X	X	X	X	

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° (Secur-Fit Max only) hip implant can be considered to achieve adequate offset. Upon confirmation of the selected components, 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 7C**).





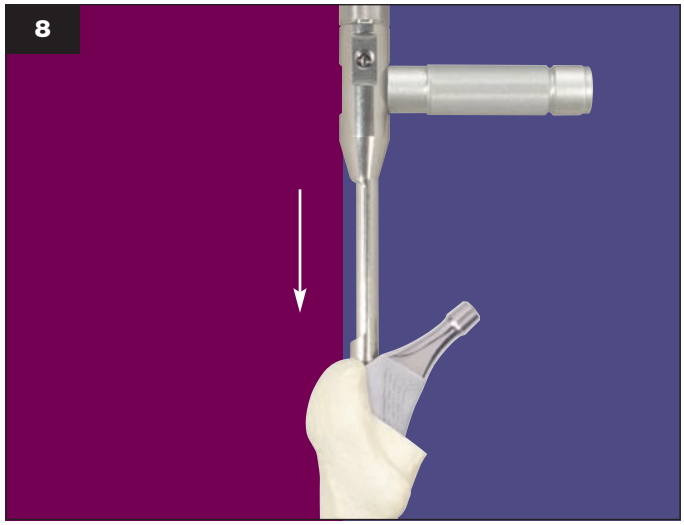




8 Femoral Stem Insertion

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 threaded Femoral Impactor can be used. A Mallet is then used to seat the hip stem into the canal (**Figure 8**) until a stable snug-fit is attained. If instrument impingement on the greater trochanter is evident, the bullet-tipped Femoral Stem Impactor may be used. ***Surgeon Tip: An alternative is to insert by hand to within 1- 1.5cm and use the blunt nose to complete insertion.***

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.

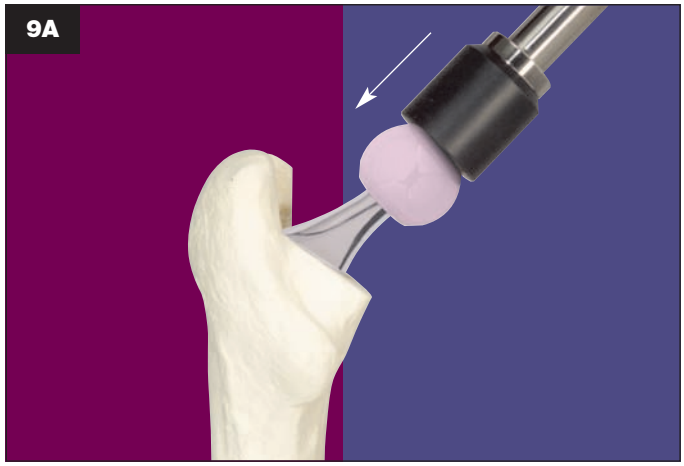


9 Head Assembly

Prior to head assembly, neck length selection may be re-evaluated using a Stryker C-Taper Trial Head. Place the 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 corresponding C-Taper Femoral Head (CoCr, Alumina Ceramic, BIOLOX *delta* Ceramic) 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 9A**).



Note: See Trident Surgical Protocols for recommended head compatibility.

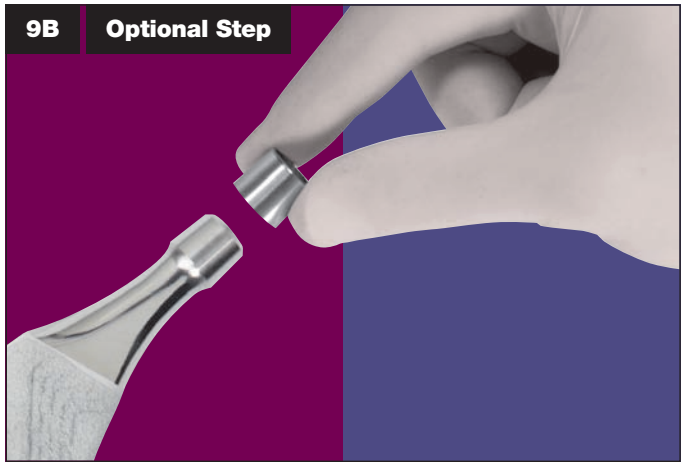
Optional Step

Note: When selecting a BIOLOX *delta* Universal Taper Ceramic Femoral Head (6519-1-0xx) for implantation, use of a Universal Adaptor Sleeve is necessary (**Table 4**).

Table 4: Universal Adaptor Sleeves

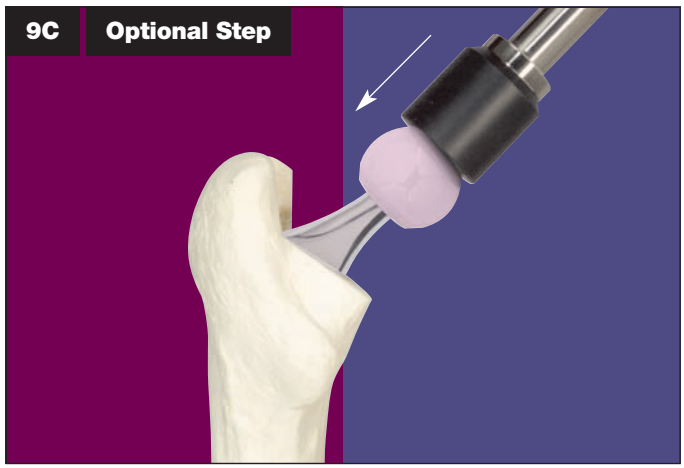
Universal Adaptor Sleeve Part Number	Taper	Stem Material Compatibility
19-0XXXT	C-Taper	TMZF, Ti64, CoCr

After completing the trialing process, intra-operatively assemble the Adaptor Sleeve to the femoral stem **manually**. The Universal Adaptor Sleeve must be fully seated on the stem taper before the head is assembled (**Figure 9B**).



Note: In no instance should any attempt be made to pre-assemble the Adaptor Sleeve inside the BIOLOX *delta* Universal Ceramic head.

Intra-operatively assemble the BIOLOX *delta* Universal Taper Ceramic head onto the sleeved femoral stem and set with two moderate blows using the Stem Head Impactor (1104-1000) (**Figure 9C**). Care must be taken to avoid excessive impact forces when assembling the Ceramic Head to the sleeved femoral component.



Catalog Information

Cutting*Edge* Advantage General Instruments

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 -3.0mm
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	Calcar Planer
1104-1000	Femoral Head Impactor
1100-1000	Cutting*Edge* Advantage Broach Handle
1120-1000	Slotted Mallet
1101-2100	T-Handle - Trigger Release
5900-0050	T-Handle - Small Trigger Release
1113-1001	Small Box Chisel
1113-1002	Medium Box Chisel
1113-1003	Large Box Chisel
1100-1500	Cutting*Edge* Advantage Neck Resection Guide

Cutting*Edge* Advantage Primary Instruments

Catalog Number	Part Description
1110-0204	Secur-Fit/OmniFit EON Broach PF4
1110-0305	Secur-Fit/OmniFit EON Broach PF5
1110-0406	Secur-Fit/OmniFit EON Broach PF6/C4
1110-0507	Secur-Fit/OmniFit EON Broach PF7/C5
1110-0608	Secur-Fit/OmniFit EON Broach PF8/C6
1110-0709	Secur-Fit/OmniFit EON Broach PF9/C7
1110-0810	Secur-Fit/OmniFit EON Broach PF10/C8
1110-0911	Secur-Fit/OmniFit EON Broach PF11/C9
1110-1012	Secur-Fit/OmniFit EON Broach PF12/C10
1110-1113	Secur-Fit/OmniFit EON Broach PF13/C11
1110-1214	Secur-Fit/OmniFit EON Broach PF14/C12
1111-1001	Small Trochanteric Reamer
1111-1002	Medium Trochanteric Reamer
1111-1003	Large Trochanteric Reamer
1101-0304	Tapered Starter Reamer
1119-0000	Femoral Stem Impactor
1119-2100	Threaded Femoral Stem Impactor/Extractor
1119-3000	OmniFit EON Inserter
1119-3100	OmniFit EON Locking Inserter
1212-0008	Canal Sizer Trial Tip (8mm)
1212-0009	Canal Sizer Trial Tip (9mm)
1212-0010	Canal Sizer Trial Tip (10mm)
1212-0011	Canal Sizer Trial Tip (11mm)
1212-0012	Canal Sizer Trial Tip (12mm)
1212-0013	Canal Sizer Trial Tip (13mm)
1212-0014	Canal Sizer Trial Tip (14mm)
1212-0015	Canal Sizer Trial Tip (15mm)
1212-0016	Canal Sizer Trial Tip (16mm)
1212-0017	Canal Sizer Trial Tip (17mm)
1212-0018	Canal Sizer Trial Tip (18mm)
1212-0019	Canal Sizer Trial Tip (19mm)
1212-0020	Canal Sizer Trial Tip (20mm)
1212-0000	Depth Gauge Handle

Cutting*Edge* Advantage Optional Instruments

Catalog Number	Part Description
1100-1225S	Secur-Fit Max 127° C-Taper Trial Neck – 25mm
1100-1230S	Secur-Fit Max 127° C-Taper Trial Neck – 30mm
1100-1235S	Secur-Fit Max 127° C-Taper Trial Neck – 35mm
1100-1240S	Secur-Fit Max 127° C-Taper Trial Neck – 40mm
1100-1325S	Secur-Fit Max 132° C-Taper Trial Neck – 25mm
1100-1330S	Secur-Fit Max 132° C-Taper Trial Neck – 30mm
1100-1335S	Secur-Fit Max 132° C-Taper Trial Neck – 35mm
1100-1340S	Secur-Fit Max 132° C-Taper Trial Neck – 40mm

Cutting*Edge* Advantage Instrument Cases

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

Ancillary Instruments

Catalog Number	Part Description
HISH-3	3lb. Slide Hammer Handle
HISH-SHAFT	Slide Shaft
1118-6000	Head Dis-assembly Instrument

Catalog Information

Secur-Fit Max Hip Stems
127° Neck Angle

Catalog Number	Stem Size	Neck Length (mm)	Base Offset (mm)	Stem Length (mm)	Distal Tip Diameter (mm)
6052-0625S	#6	25	33	120	9.6
6052-0730S	#7	30	39	130	10.4
6052-0830S	#8	30	40	140	11.2
6052-0935S	#9	35	45	150	11.9
6052-1035S	#10	35	46	160	12.7
6052-1140S	#11	40	51	170	13.5
6052-1240S	#12	40	52	170	14.7
6052-1340S	#13	40	53	170	16

132° Neck Angle

Catalog Number	Stem Size	Neck Length (mm)	Base Offset (mm)	Stem Length (mm)	Distal Tip Diameter (mm)
6051-0425S	#4	25	29	100	8.1
6051-0525S	#5	25	29	110	8.9
6051-0625S	#6	25	30	120	9.6
6051-0730S	#7	30	35	130	10.4
6051-0830S	#8	30	36	140	11.2
6051-0935S	#9	35	41	150	11.9
6051-1035S	#10	35	42	160	12.7
6051-1140S	#11	40	47	170	13.5
6051-1240S	#12	40	47	170	14.7
6051-1340S	#13	40	48	170	16
6051-1440S	#14	40	49	170	17.2

Secur-Fit Plus Max Hip Stems
127° Neck Angle

Catalog Number	Stem Size	Base Neck Length (mm)	Base Offset (mm)	Stem Length (mm)	Distal Diameter (mm)
6054-0509S	#5	25	32	110	9
6054-0511S	#5	25	32	110	11
6054-0610S	#6	25	33	120	10
6054-0612S	#6	25	33	120	12
6054-0711S	#7	30	39	130	11
6054-0713S	#7	30	39	130	13
6054-0812S	#8	30	40	140	12
6054-0814S	#8	30	40	140	14
6054-0913S	#9	35	45	150	13
6054-0915S	#9	35	45	150	15
6054-1014S	#10	35	46	160	14
6054-1016S	#10	35	46	160	16
6054-1115S	#11	40	51	170	15
6054-1117S	#11	40	51	170	17
6054-1216S	#12	40	52	170	16
6054-1218S	#12	40	52	170	18
6054-1317S	#13	40	53	170	17
6054-1319S	#13	40	53	170	19
6054-1418S	#14	40	54	170	18
6054-1420S	#14	40	54	170	20

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.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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