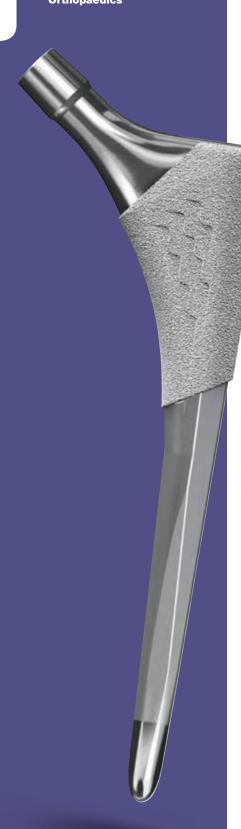
**Femoral Hip System** 

Surgical Technique **stryker**°

Orthopaedics



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#### **INDICATIONS**

Indications for use include:

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

Additional indication specific to use of Secur-Fit Advanced Hip Stems with compatible Howmedica Osteonics Constrained Liners:

When the stem is to be used with compatible Howmedica
 Osteonics Constrained Liners, the device is intended for use in
 primary or revision patients at high risk of hip dislocation due
 to a history of prior dislocation, bone loss, soft tissue laxity,
 neuromuscular disease, or intra-operative instability.

Secur-Fit Advanced Hip Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

#### **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 patients; and,
- any mental or neuromuscular disorder that would create an unacceptable risk of instability, prosthesis fixation failure or complications in postoperative care.

#### **WARNINGS AND PRECAUTIONS**

See package insert for warnings, precautions, adverse effects and other essential product information. Before using Secur-Fit Advanced Stem instrumentation, verify:

- Instruments have been properly disassembled prior to cleaning and sterilization;
- Instruments have been properly assembled post-sterilization;
- Instruments have maintained design integrity; and,
- Proper size configurations are available.

#### **Femoral Hip System**

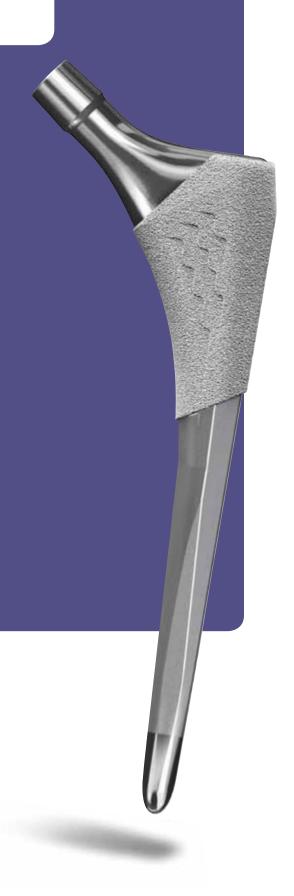
The Secur-Fit Advanced Hip Stem is intended for cementless, press-fit application. The proximal region of the stem is coated with PureFix HA over a commercially pure titanium plasma spray substrate. The Secur-Fit Advanced Hip Stem is suitable for various surgical approaches.

The total system includes:

- 16 Implants
- Size 4 and 5 in 132° offset only
- Sizes 6-12, two anatomic offset angles of 132° and 127°

The stem is designed for use with Stryker V40 femoral heads and their compatible acetabular components.

This publication sets forth detailed recommended procedures for using Stryker Orthopaedics devices and instruments. It offers guidance that you should need, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.



#### PRE-OPERATIVE PLANNING

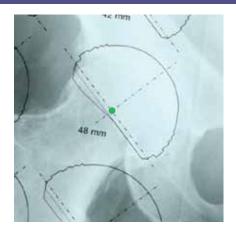


Figure 1

Pre-operative planning aids in the determination of probable implant style and size. The pre-operative planning process should take qualitative and quantitative factors (including patient bone quality, density, and morphology) into consideration in order to evaluate and select the appropriate instrument/implant system for the patient.

Place an acetabulum template over the area on the X-ray. Be sure that the cup is well centered within the acetabulum and the size fills between the tear drop and the superior rim. After templating the acetabulum for size, mark the center of rotation (represented by the green dot (Figure 1)).



Figure 2

Optimal femoral stem fit, prosthetic neck length, angle and version can be more closely evaluated with the use of pre-operative X-ray analysis. The following parameters should be determined using an A/P radiograph: Stem Size, Femoral Offset, Leg Length, Neck Angle, and Center of Rotation.

The Secur-Fit Advanced has two offset options: the standard offset 132° neck angle and the high offset 127°neck angle (Sizes 4 and 5 are available in the 132° neck angle only). Choose the Secur-Fit Advanced template for which the stem size achieves medio-lateral cortical engagement at the proximal two-thirds of the stem and recreates the desired leg length and offset (Figure 2). For both the 132° and 127° offset options, the template has markings that indicate the center of the femoral head for a range of head offset options.

The predicted change in leg length and offset is determined by the relative positioning of the center of rotation markings on the femoral and acetabular components. For example, if a given femoral component center of rotation

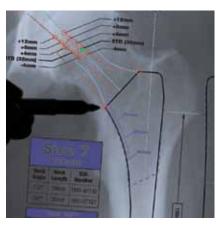


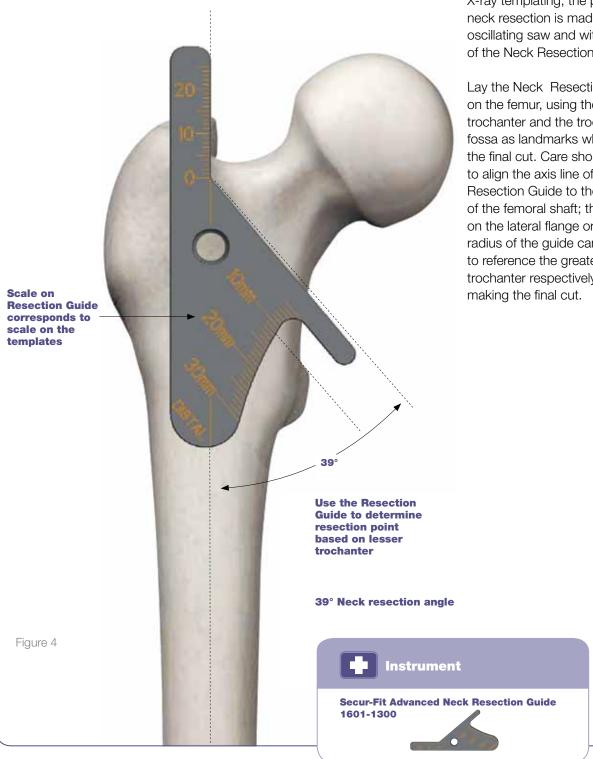
Figure 3

marking is superior to the center of rotation marking of the acetabular component, leg lengthening is predicted. The desired change in leg length is determined by the radiographic leg length inequality that was previously determined with an A/P bilateral film. If 8mm of leg lengthening is required in order to equalize the leg lengths, the center of rotation marking of the femoral component should be positioned 8mm superior to the center of rotation marking on the acetabular component. The stem size and head offset that most closely meets this goal is chosen. The predicted change in offset is also considered by comparing the relative medial/ lateral position of the center of rotation markings of the femoral and acetabular components. The templates should be used to estimate the final components that most closely restore the normal offset of the patient's hip.

Once the final estimated stem size and position is determined, the neck resection level should be noted (Figure 3). This will be used as a reference during intra-operative neck resection.



#### **FEMORAL NECK RESECTION**



A proper neck resection level directly affects the final placement and fit of the femoral stem. By using the anatomic landmarks referenced during pre-operative X-ray templating, the pre-planned neck resection is made with an oscillating saw and with the aid of the Neck Resection guide.

Lay the Neck Resection Guide on the femur, using the lesser trochanter and the trochanteric fossa as landmarks when making the final cut. 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

PREPARING THE FEMORAL CANAL





Tig

A clear-out hole has been placed on the back of the Box Osteotome that allows bone chips to be removed using a curette or other OR instruments in an action that does not require a force to be directed at the cutting surface.



Instruments

Modular Box Osteotome 1601-1210



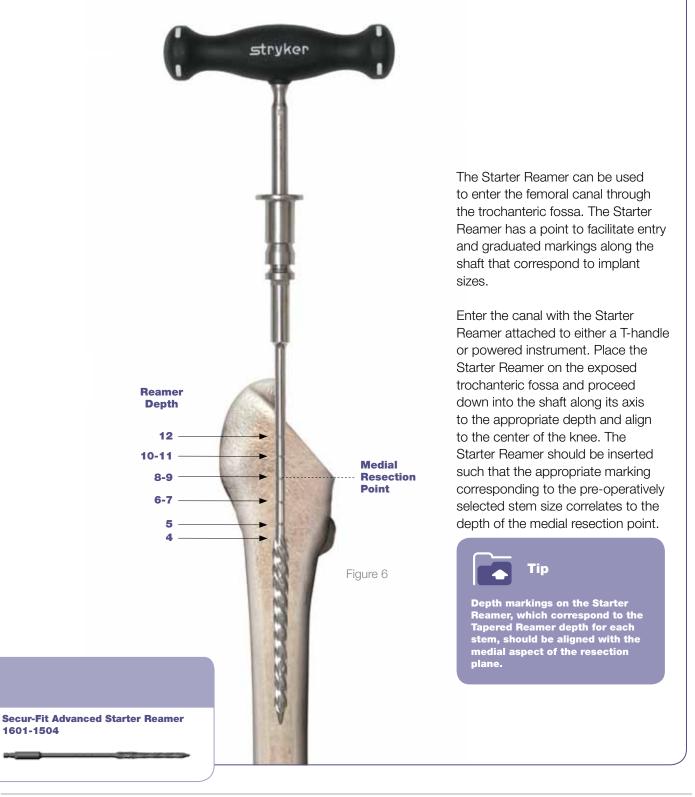
Orthonomic Modular Handle 1020-2900



**Orthonomic T-Handle** 



#### **DISTAL REAMING**



#### TROCHANTERIC REAMING



**TABLE 1:** Recommended Trochanteric Reamer Sizes

STEM SIZE	TAPERED REAMER
7-9	Standard Trochanteric Reamer
10-12	Large Trochanteric Reamer

Figure 7

**BROACH ONLY OPTION** 

Medial Resection Point

The fully toothed Broaches may facilitate preparation of the femoral canal without the use of Tapered Reamers. However, 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. If the Broach does not seat at the desired height, ream upward until the Broach seats at the desired height. The option to skip any reaming step is at the discretion of the surgeon.

lateral proximal cortical bone. This will further assist in establishing proper axial alignment. The Trochanteric Reamer is available in standard and large sizes. The Reamer should be inserted to a depth such that the distal end of the cutting flutes aligns with the medial resection point. Each Trochanteric Reamer is designed to prepare for three stem sizes. See **Table 1.** 

Select and use the appropriate Trochanteric Reamer to remove

#### **OPTION**

For Sizes 4-6, the standard Trochanteric Reamer is optional and to be used according to surgeon's discretion.

<u>Instruments</u>

Orthonomic T-Handle 1101-2200



Secur-Fit Advanced Standard Trochanteric Reamer 1601-1531 Secur-Fit Advanced Large Trochanteric Reamer 1601-1532 Secur-Fit Advanced 2 For 1 Tapered Reamer Size 5-6 1601-1556

#### **TAPERED REAMING**

Reamers are used to prepare the canal distally where dense cortical bone exists, thereby aiding in broaching. The Tapered Reamer should be inserted such that the appropriate marking corresponding to the stem size correlates to the depth of the medial resection point.

See **Table 2** for a list of recommended reamer sizes for each stem.

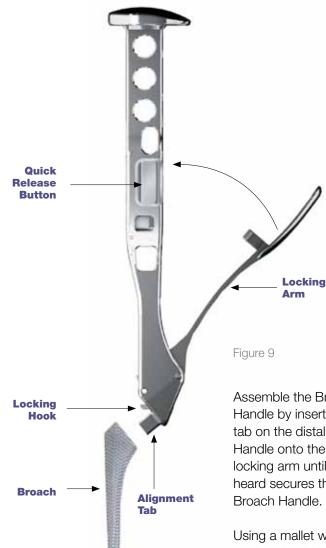
**TABLE 2:** Recommended Tapered Reamer Sizes

STEM SIZE	TAPERED REAMER	
4	*Starter reamer may be used	
5	5-6	
6	5-6	
7	7-8	
8	7-8	
9	9-10	
10	9-10	
11	11-12	
12	11-12	



Secur-Fit Advanced 2 For 1 Tapered Reamer Size 7-8 1601-1578 Secur-Fit Advanced 2 For 1 Tapered Reamer Size 9-10 1601-1590 Secur-Fit Advanced 2 For 1 Tapered Reamer Size 11-12 1601-1512

#### **BROACHING**



Assemble the Broach to the Broach Handle by inserting the alignment tab on the distal end of the Broach Handle onto the Broach. Closing the locking arm until an audible click is heard secures the Broach onto the Broach Handle.

Using a mallet with short, controlled strokes, begin broaching and sequentially broach up until the desired size is reached. Throughout broaching, continue to ensure neutral alignment of the broach to the long axis of the femur.

Correct fit will be denoted by a change in pitch, tactile resistance, or when the broach ceases to advance. Verify a secure fit and ensure that

the broach has axial and rotational stability. With proper cortical contact, the broach should not twist or move relative to the femur. If there is movement, a larger size broach may be needed.

Generally, if a broach sinks below the level of the neck resection, advance to the next larger broach. If the neck resection is deemed higher than desired, remove the broach and perform a new neck resection at a lower level.

Upon reaching the final size and depth of the broach, detach the broach handle from the broach, leaving the broach fully seated in the femoral canal.



Instruments

Secur-Fit Advanced Broach Handle 1601-1100



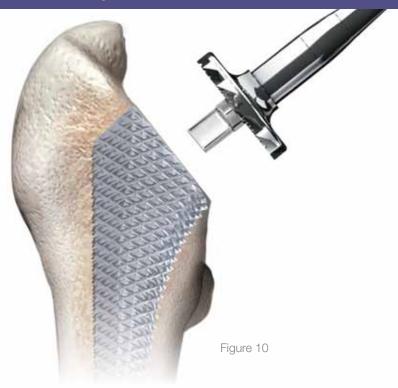
Secur-Fit Advanced Low Profile Broach Handle 1601-3100



Secur-Fit Advanced Broach Size 4-12 1601-10XXA



#### **OPTIONAL STEP: CALCAR PLANING**





#### CAUTION

Proper insertion depth of the broach in the canal is achieved when it seats tightly within the canal based on visual and auditory clues. The surgeon's clues to confirm implant fixation include increased pitch of sound with blows to broach handle and increased resistance to advancement. Reliance only on the neck cut may lead to improper sizing, inadequate component fixation, and femoral fracture.

Calcar planing creates a final resection plane and angle to optimize stem fit. There are two calcar planers in the set (standard, large). Select the size that fits the cut surface of the neck. Each calcar planer includes a spring-loaded alignment tab that provides controlled alignment and engagement with the broach.

Initiate power prior to contacting the femur and slowly advance the Calcar Planer toward the broach. Align the tab within the broach body and press down to plane the calcar to desired level. Failure to operate the Calcar Planer in accordance with these instructions may result in damage to the femur.

Secur-Fit Advanced Calcar Planer, Standard 1601-1400



Secur-Fit Advanced Calcar Planer, Large 1601-1420



Select a neck trial which has the same stem size and angle as the planned implant size. This can be determined in three ways.

- Match the stem size indicated on the face of the neck trial trunnion with the inserted broach
- Match the neck angle with desired stem angle based on the 127° trials being gold, and the 132° trials being silver
- 3. Match the neck angle indicated on the distal portion of neck with the desired stem angle

The table below indicates the correct neck length for each size stem. The size of the broach directly corresponds to the size of the implant.

**TABLE 3:** Secur-Fit Advanced Neck Trials and Neck Lengths (mm)

STEM SIZE	NECK LENGTH (mm) 127° (GOLD)	NECK LENGTH (mm) 132° (SILVER)
4		26
5		26
6	28	26
7	32	30
8	32	30
9	36	34
10	36	34
11	40	38
12	40	38

Secur-Fit Advanced Monolithic Neck Trial, 132 Degree (Silver) 1601-XX132 Secur-Fit Advanced Monolithic Neck Trial, 127 Degree (Gold) 1601-XX127

#### **SELECTION OF V40 HEAD TRIAL ON TRIAL NECK**



Figure 13

Assemble the Neck Trial onto the broach by hand. Ensure that the engraving on the superior edge of the neck is visible, and the flat lateral edge of the neck trial is aligned with the flat lateral edge of the broach. Next, assemble a V40 Head Trial onto the Neck Trial by hand.

Femoral heads come in multiple offsets and are different for each femoral head implant material (see Table 4). For this reason, final head material should be chosen prior to trial reduction. Offsets add or subtract from the base neck length of the implant and help to achieve the desired leg length and offset.

Perform a trial reduction of the hip. Upon confirmation of the selected components, remove the trial head and trial neck, and reassemble the broach handle to the broach. Remove the broach from the femoral canal. The final broach size determines the correct implant size.





#### Note

Ensure that the broach cavity and V40 trunnion are clear of debris prior to assembling the neck and head trials.

**TABLE 4:** Head Compatibility

HEAD	HEAD SIZE	HEAD OFFSETS
	22	+0, +3, +8
	26	-3, +0, +4, +8, +12
	28	-4, +0, +4, +8, +12
CoCr V40	32	-4, +0, +4, +8, +12
	36	-5, +0, +5, +10
	40	-4, +0, +4, +8, +12
	44	-4, +0, +4, +8, +12
	28	-2.7, +0, +4
Alumina V40	32	-4, +0, +4
	36	-5, +0, +5
Alumina C-Taper	28	-2.5, +0, +5
(when used with C-Taper Sleeve –	32	-2.5, +0, +5
catalog # 17-0000E)	36	-5, +0, +5
delta BIOLOX V40	28	-4, -2.7, +0, +4
	32	-4, +0, +4
	36	-5, -2.5, +0, +2.5, +5, +7.5
delta BIOLOX C-Taper	28	-2.5, +0, +2.5, +5
(when used with C-Taper Sleeve –	32	-2.5, +0, +2.5, +5
catalog # 17-0000E)	36	-5, -2.5, +0, +2.5, +5, +7.5
	28	-2.5, +0, +4
delta BIOLOX Universal Taper (when	32	-2.5, +0, +4
used with Universal Taper Sleeve-	36	-2.5, +0, +4
catalog #6519-T-XXXX)	40	-2.5, +0, +4
	44	-2.5, +0, +4



#### Note

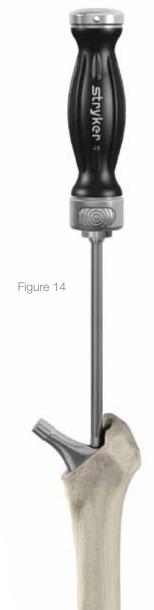
Head Trials with an "R" suffix are made from a radiopaque material, making them visible on an X-ray.

#### **IMPLANTING THE STEM**



#### **OPTION 1**

The Secur-Fit Advanced Stem can be inserted by hand and then impacted into the bone using the Modular Stem Impactor (Figure 14). The Modular Stem Impactor has a spherical tip, which is placed onto the drive hole of the stem. This instrument allows for off-axis impaction of the stem. The Modular Stem Impactor does not connect to the stem, and, therefore, can only be used for final impaction of the stem.



#### **OPTION 2**

The Secur-Fit Advanced Stem can also be inserted using the Modular Offset Quick Connect Stem inserter. Place tip of the inserter into the drive hole of the stem taking care to align the version tab on the inserter with the slot in the stem (Figure 15). The quick connect design provides the inserter with a stable spring connection, but it does not provide a mechanical lock. Therefore, this assembly should be handled with care, as excessive shaking or motion may result in the stem dis-associating from the inserter.

#### **OPTION 3**

Thread the Modular Threaded Stem Inserter into the drive hole on the proximal face of the stem (Figure 16). The inserter should be fully threaded and secured to the stem prior to impaction to prevent damage to the threads on the implant or the instrument. Using the inserter, the stem should be inserted into the femoral canal until it stops.









Prior to implanting the final stem and femoral head, check the implants for potential damage. Ensure that the final stem matches the last broach used. Use the markings on the face of the stem trunnion to verify the stem size and taper type. A mallet is then used to seat the stem into the canal with short, controlled strokes.

The surgeon should NOT attempt to continue impacting the femoral component if visual and auditory clues indicate that the stem is firmly seated in the canal. These clues, rather than the broach seating level, should be used to determine the final seating height of the implant. Continued aggressive impaction could lead to femoral fracture. In the event that dense bone is encountered intra-operatively and compounding anatomical factors are present, the seating of the implant may not be consistent with the level of the broach due to the viscoelastic nature of the femoral bone. If the final seating height is undesirable, the implant can be removed using the Modular Threaded Stem Inserter (option 3) and additional broaching can be performed. If the stem inserter is contacting the greater trochanter during insertion, continued impaction could lead to a fracture.



Figure 16

#### **Final Implant Trunnion**





#### CAUTION

If the stem inserter is contacting the greater trochanter during insertion, continued impaction could lead to a fracture. The surgeon should consider using an alternate impactor.

FINAL REDUCTION



Prior to final head assembly, neck length/head offset may be re-evaluated using a V40 Head Trial. Place the Head Trial on to the stem neck taper and reduce the hip. Leg length equality and proper soft tissue tension are evaluated. Remove the Head Trial and dry the implant trunnion with a laparotomy sponge or sterile towel.

Select the appropriate corresponding V40 Femoral Head (CoCr, Alumina Ceramic, BIOLOX *delta* Ceramic) or sleeve and place it onto the dry trunnion of the femoral stem with a slight twist. Impact the head with moderate impactions using the Modular Head impactor.

Verify the head is secure on the trunnion after head impaction by applying traction to the head and confirming stability on the trunnion.

When selecting a BIOLOX *delta* Universal Taper Ceramic Femoral Head for implantation with the Secur-Fit Advanced Stem, use of a V40 Universal Adaptor Sleeve is necessary. After completing the trialing process, intraoperatively assemble the Adaptor Sleeve to the Femoral Stem manually. The Universal Adaptor Sleeve must be fully seated on the Stem trunnion before the Head is assembled.

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.



#### Note

Ensure that the V40 taper is clean prior to assembling the head trial or head implant



#### **WARNING**

In no instance should any attempt be made to preassemble the Adaptor Sleeve inside the BIOLOX delta Universal Ceramic Head. Intraoperatively assemble the BIOLOX delta Universal Taper Ceramic Head onto the sleeved Femoral Stem and set with moderate blows using the Stem Head Impactor (1104-1000). Care must be taken to avoid excessive impact forces when assembling the Ceramic Head to the sleeved femoral component.



#### WARNING

Any debris that is potentially generated must be fully lavaged prior to wound closure.

**TABLE 5:** Universal Adaptor Sleeves – Titanium

CATALOG NUMBER	OFFSET (mm)	TAPER
6519-T-025	-2.5	V40
6519-T-100	+0	V40
6519-T-204	+4	V40



Instruments

Orthonomic Modular Handle 1020-2900



V40 Head Trial 6264-x-xxxR



Head/Neck Impactor 1601-1700



#### **OPTIONAL STEP: EXTRACTION**



A surgeon should use his or her preferred surgical exposure and technique to conduct the revision surgery adequately. A surgeon should also refer to the subsequent product's surgical technique and instructions for use to understand all appropriate warnings, indications, contraindications, and product compatibility.

There are instruments to manage the extraction of a Secur-Fit Advanced Stem in both intraoperative and revision situations. The instrument to use is the McReynolds Distal Stem Adaptor (6260-4-090) and McReynolds Driver (6869-1-000, 6869-2-000, 6869-3-000) from the Restoration Modular Instrument System.



#### **WARNING**

A surgeon must take care to avoid applying excessive force to the stem while exposing the joint during revision surgery.



#### **WARNING**

A surgeon must take care in assessing stability so as to not fracture the bone or create any debris. Any debris that is potentially generated must be fully lavaged prior to wound closure.

McReynolds Distal Stem Adaptor 6260-4-090



McReynolds Driver 6869-1-000, 6869-2-000.

6869-2-000, 6869-3-000

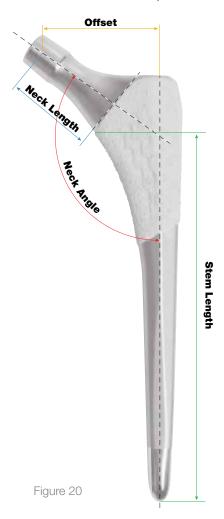


#### **IMPLANTS**

**TABLE 6:** Secur-Fit Advanced Stem Offset Table

STEM	CATALOG NUMBER	NECK ANGLE	STEM SIZE	STEM LENGTH (mm)	NECK LENGTH (mm)	FEMORAL OFFSET WITH +0mm HEAD (mm)	DISTAL TIP DIAMETER* (mm)
	1601-06127	127	6	120	28	37.2	6.9
	1601-07127	127	7	130	32	41.5	7.4
C	1601-08127	127	8	136	32	42.4	8.1
Secur-Fit Advanced 127°	1601-09127	127	9	142	36	46.9	8.9
7107011000 121	1601-10127	127	10	148	36	48.1	9.7
	1601-11127	127	11	155	40	52.6	9.7
	1601-12127	127	12	160	40	53.7	10.7
	1601-04132	132	4	110	26	31.5	5.1
	1601-05132	132	5	115	26	32.5	6.0
	1601-06132	132	6	120	26	33.6	6.9
0 5	1601-07132	132		130	30	37.5	7.4
Secur-Fit Advanced 132°	1601-08132	132	8	136	30	38.4	8.1
Auvanceu 152	1601-09132	132	9	142	34	42.6	8.9
	1601-10132	132	10	148	34	43.8	9.7
	1601-11132	132		155	38	47.9	9.7
	1601-12132	132	12	160	38	49.0	10.7

<sup>\*</sup> The distal diameter is taken at the location where the stem transitions from a square cross-section to a circular cross-section





#### WARNING

- +5mm heads are the maximum head offset allowed for the size 4.
- +12mm heads are the maximum head offset allowed for the size 5-12 stem.

**TABLE 7:** Secur-Fit Advanced Compatible Femoral Heads

HEAD	HEAD DIAMETER (mm)	OFFSET (mm)
V40 BIOLOX delta	28	-4.0, -2.7, +0, +4.0
V40 BIOLOX delta	32	-4.0, +0, +4.0
V40 BIOLOX delta	36	-5, -2.5, +0, +2.5, +5, +7.5
Universal Taper, BIOLOX delta Head	28, 32, 36, 40, 44	
Universal Taper Sleeves – V40 stems		-2.5, +0, +4
V40 CoCr	22	+0, +3, +8
V40 CoCr	26	-3, +0, +4, +8, +12
V40 CoCr	28	-4, +0, +4, +8, +12
V40 CoCr	32	-4, +0, +4, +8, +12
V40 LFIT CoCr	22	+0, +3, +8
V40 LFIT CoCr	26	-3, +0, +4, +8, +12
V40 LFIT CoCr	28	-4, +0, +4, +8, +12
V40 LFIT CoCr	32	-4, +0, +4, +8, +12
V40 LFIT CoCr	36	-5, +0, +5, +10
V40 LFIT CoCr	40	-4, +0, +4, +8, +12
V40 LFIT CoCr	44	-4, +0, +4, +8, +12
Alumina V40 Head	28	-2.7, +0, +4
Alumina V40 Head	32	-4, +0, +4
Alumina V40 Head	36	-5, +0, +5
C-Taper Alumina	28, 32	-2.5, +0, +5
C-Taper Alumina	36	-5, +0, +5
C-Taper BIOLOX delta	28, 32	-2.5, +0, +2.5, +5
C-Taper BIOLOX delta	36	-5, -2.5, +0, +2.5, +5, +7.5
Unitrax V40 Head	38, 40-56, 58, 61	+0
Unitrax V40 Monolithic Adaptor		-4, +0, +4, +8, +12
V40/C-Taper Adaptor Sleeve		

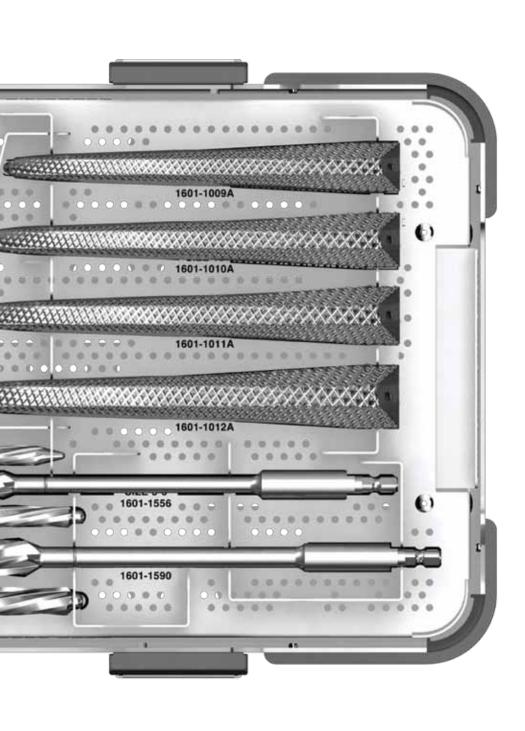
 TABLE 8: Secur-Fit Advanced Compatible Acetabular Components

TABLE OF COCAL LIC MANAGED COMPANION MOSTABANA C
Trident X3 Acetabular Inserts
Trident Crossfire Elevated Rim Liners
Trident Crossfire Poly Liners, 10° or 0° profile
Trident Crossfire Eccentric Poly Liners, 10° or 0° profile
Trident Poly Liners, 10° or 0° profile
Trident Eccentric Poly Liners
Trident Constrained Insert
Crossfire Series II Inserts (2041C, 2042C, 2043C, S2301, S2302)
Series II Inserts, and Series II Eccentric Inserts
Constrained Liner
Series I Inserts
System 12 Inserts (Standard and Crossfire)
All Poly Cup
Trident All Poly Cup
Crossfire Trident All Poly Cup
UH1
Centrax Bipolar
PCA Acetabular Insert
Precision Acetabular Components
Trident N <sub>2</sub> /Vac Polyethylene Inserts
Trident Hemispherical Solid Back Shells
Trident Hemispherical PS HA
Trident Hemispherical Shells (AD and AD-HA)
Trident PSL HA Solid Back Shells
Trident Hemispherical Cluster Shells
Trident PSL HA Cluster Shells
Trident Hemispherical Multi-Hole Shells
Tritanium Acetabular Shell System
Trident Porous Titanium Acetabular Components
Restoration ADM
MDM
Exeter X3 RimFit Cup

#### **INSTRUMENTATION**

1601-5005 Secur-Fit Advanced Femoral Preparation Tray 5900-8114 Case

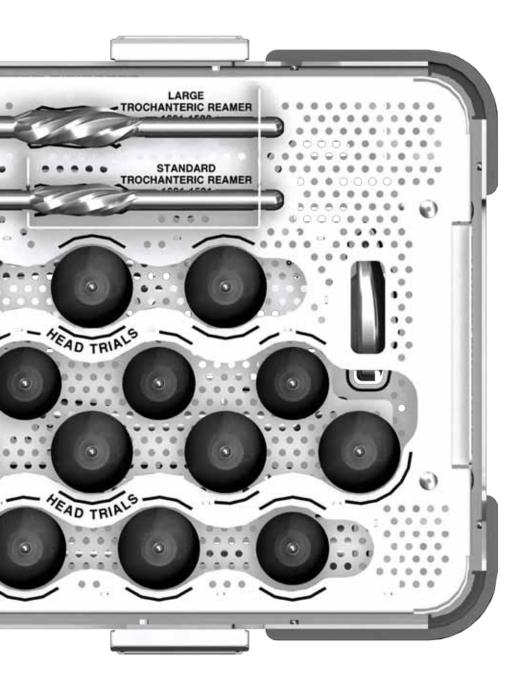




#### **INSTRUMENTATION**

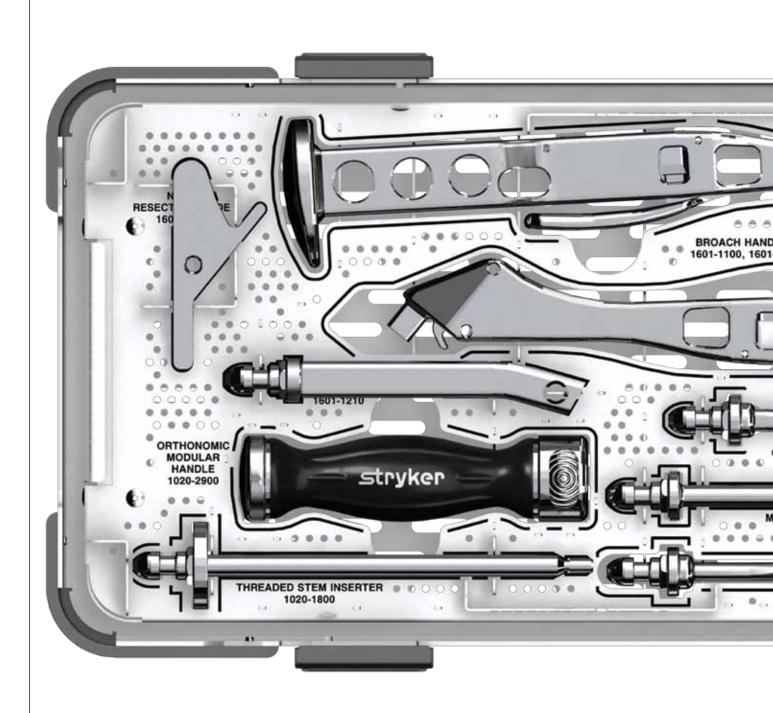
1601-5006 Secur-Fit Advanced Procedural Tray 1

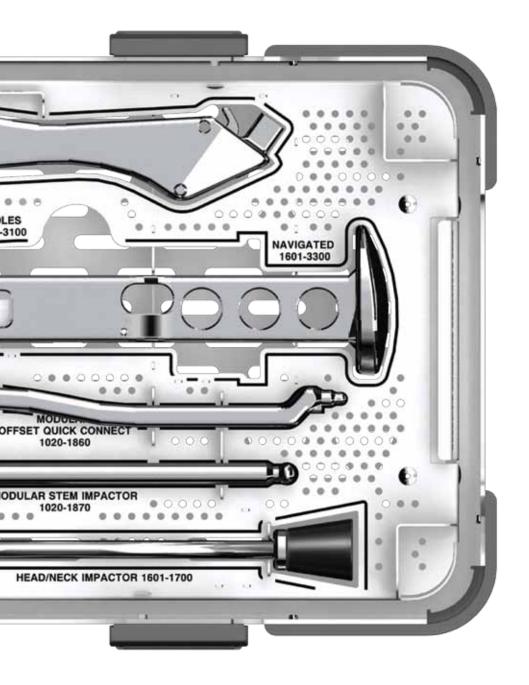




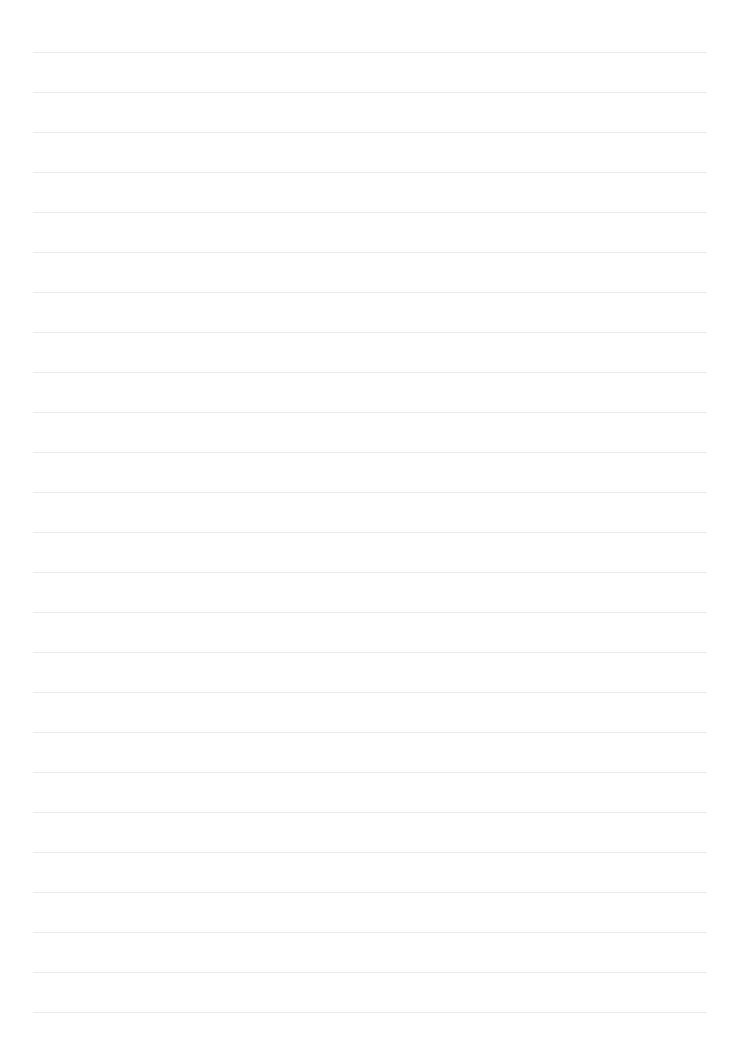
INSTRUMENTATION

1601-5007 Secur-Fit Advanced Procedural Tray 2





NOTES		





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