stryker

Orthopaedics

ACCOLADE® II

Femoral Hip System

Surgical Technique

INDICATIONS

The indications for use of the total hip replacement prostheses 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 fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of ACCOLADE II Femoral 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.

ACCOLADE II Femoral 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;
- Any mental or neuromuscular disorder that would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in post-operative care; and
- Obesity. An overweight or obese patient can produce loads on the device that can lead to failure of the fixation of the device or to failure of the device itself.

WARNINGS AND PRECAUTIONS

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

Before using ACCOLADE II 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.

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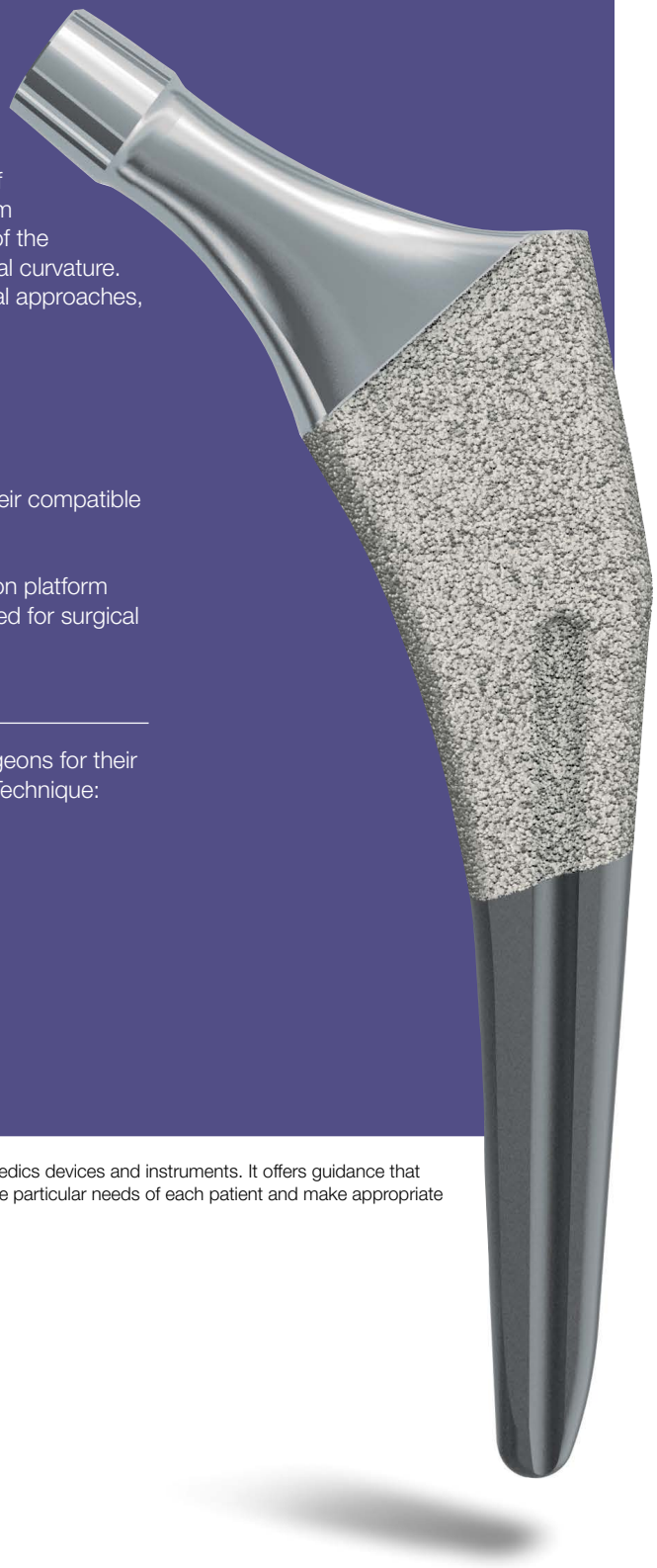
For cleaning and sterilization instructions of surgical instruments, refer to the instrument package insert.

ACCOLADE II

Femoral Hip System



The ACCOLADE II Femoral Hip System is a femoral stem that 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 Morphometric Wedge — an evolution of the tapered wedge — is characterized by its variable, size-specific medial curvature. The ACCOLADE II Femoral Hip System is suitable for various surgical approaches, including direct anterior.

The total system includes:
- 12 body sizes ranging from size 0 to size 11
- Two anatomic offset options for each size

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

The ACCOLADE II Hip System includes a broach-only instrumentation platform that accommodates all surgical approaches and has been streamlined for surgical efficiency.

Surgical Technique

Stryker Orthopaedics wishes to thank the following orthopaedic surgeons for their expertise in the development of the ACCOLADE II System Surgical Technique:

Dr. Richard Rothman
Dr. Dermot Collopy
Dr. David Jacofsky
Dr. Frank Kolisek
Dr. Art Malkani

STEP 1

PRE-OPERATIVE PLANNING

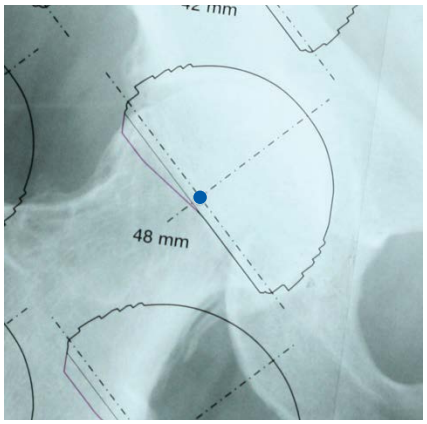


Figure 1

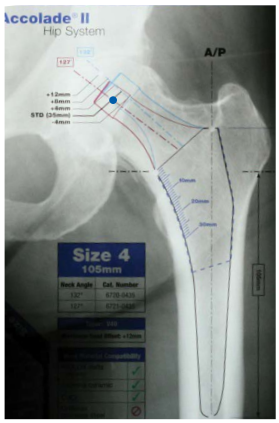


Figure 2

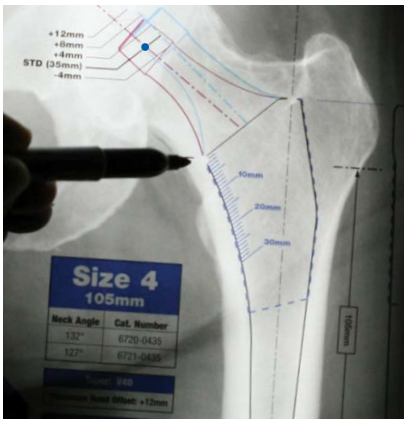


Figure 3

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 (Figure 1). 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 blue dot).

Tip

Richard Rothman, M.D.
Templating is an important aspect of pre-operative planning, but it should only serve as a guide. Final decision making concerning fit, size, and soft-tissue tensioning occurs in the operating room.

The ACCOLADE II has two offset options: the standard offset 132° neck angle and the high offset 127° neck angle. Choose the ACCOLADE II template for which the stem size achieves medio-lateral cortical engagement at the proximal two-thirds of the stem and recreate 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 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. 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 of 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.

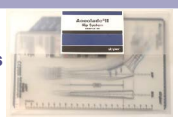
Once the final estimated stem size and position is determined, the neck resection level should be noted (Figure 3). This will be used as a reference during intra-operative neck resection.

Tip

David Jacofsky, M.D.
The templated stem size and neck resection level may have to be adjusted if leg length cannot be managed solely by changing the head offset or neck angle.

Templates

ACCOLADE II
Acetate Templates
Lit# LTEM105



Acetate templates include 20% magnification.

STEP 2

FEMORAL NECK RESECTION

Figure 4

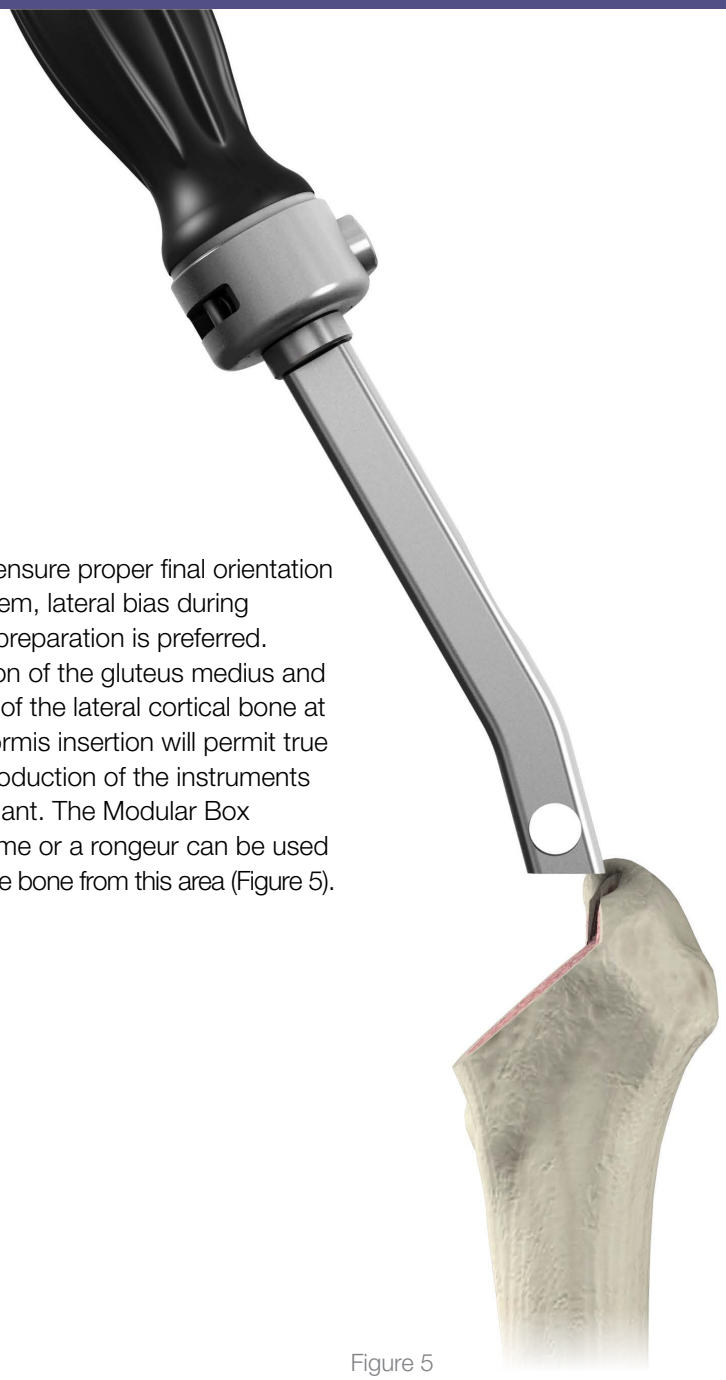
A proper neck resection level directly affects the final placement and fit of the femoral stem. By using the anatomic landmarks referenced during pre-operative x-ray templating, the pre-planned neck resection is made with an oscillating saw and with the aid of the Neck Resection Guide. The guide helps the surgeon to determine the correct stem orientation and placement. After careful pre-operative templating, the guide is placed on the anterior/posterior aspect of the exposed proximal femur and the planned femoral neck cut is marked using a marking instrument of choice. Care should be taken to align the body of the guide with the axis of the femoral canal (Figure 4).

Instrument

Neck Resection Guide
1020-1100

STEP 3

PREPARING THE FEMORAL CANAL



To help ensure proper final orientation of the stem, lateral bias during implant preparation is preferred. Retraction of the gluteus medius and removal of the lateral cortical bone at the piriformis insertion will permit true axial introduction of the instruments and implant. The Modular Box Osteotome or a rongeur can be used to remove bone from this area (Figure 5).

Figure 5

Tip

Art Malkani, M.D.
Remove the lateral cortical bone at the piriformis fossa to obtain ideal proximal fit and to minimize the risk of undersizing and/or varus placement of the femoral component.

Instruments

Modular Box Osteotome
1601-1210

Orthonomic Modular Handle
1020-2900

Mallet
1120-1000

Figure 6

The ACCOLADE II Hip System is a broach only system. While use of an axial starter reamer is needed, use of cylindrical reamers is not necessary to prepare the femoral canal. The Axial Starter Reamer is used with the T-Handle to open the femoral canal and to aid in determining the orientation of the femoral axis. The tapered design allows for access to the canal and is graduated along the flutes, which helps provide a reference during insertion into the canal. Advance the Axial Starter Reamer into the femoral canal to a depth at which the first graduation mark is aligned with the medial aspect of the neck resection (Figure 6).

Slight lateral pressure on the reamer during operation will aid in preparing the femoral canal in the neutral orientation of the implant.

Note

Care should be taken not to sink the starter reamer below the first graduation mark to allow for proper press fit of the implant.

Axial Starter Reamer
1020-1200

Orthonomic T-Handle
1101-2200

STEP 4

BROACHING

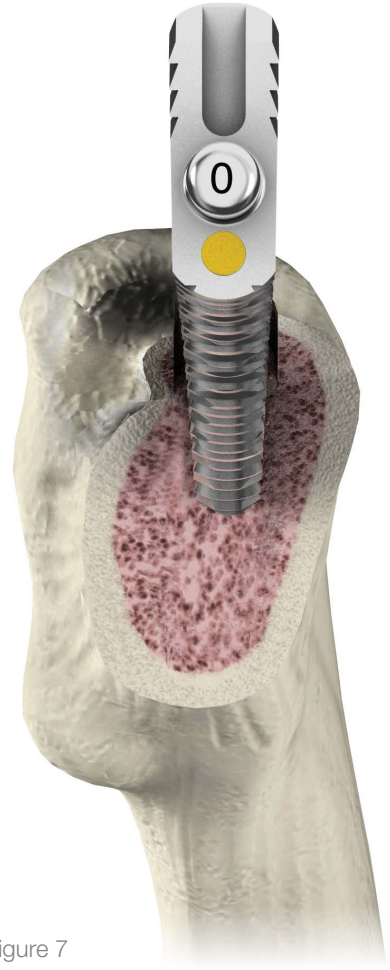


Figure 7

Broaching is then performed beginning with the size 0 broach. The broach should be oriented to the long axis of the oblong shape created by the neck resection (Figure 7).

Note

ACCOLADE II broaches can be properly identified in several ways.

1) **The broach size is engraved into a square pocket on both the anterior and posterior sides of the broach.**
2) **The size is marked on the top of the broach post.**
3) **The distal lateral tip of the broach is polished.**
4) **1020-52xx part number**

Note

Accolade and ACCOLADE II broaches cannot be used interchangeably.

Tip

Art Malkani, M.D.
During broaching, place lateral bias on the broach to fill the proximal femur and minimize undersizing the implant.

Figure 8

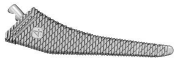
Sequentially broach upward in size until the proper size is achieved. The surgeon's clues to a firm fit and final size include 1.) changing pitch of sound that results from mallet blows to the broach handle; 2.) increased resistance to forward advancement; 3.) lack of further motion.

Two grooves on the anterior and posterior surfaces of the broach act as a point of reference to help the surgeon visualize the broach advancing into the femur (Figure 8).

Instruments

Offset Broach Handle
1020-1460

ACCOLADE II Broach
Size 0-11
1020-52xx



Mallet
1120-1000

Relying only on the neck resection height alone for final seating height may lead to improper sizing and inadequate component fixation.

The final broach should seat firmly against medial and lateral cortical bone (Figure 9).

Tip

Frank Kolisek, M.D.
If the broach and/or stem stops above or below the original neck resection, leg length and soft-tissue tensioning must be re-assessed during intra-operative trialing. Do not force the broach and/or stem to the resection level. This will increase the risk of proximal femur fracture.

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.

Calcar Planer - Standard
1020-1111

Figure 9

For good fixation of the implant, it is important that axial alignment of the broach is maintained at all times in the canal. Generally, the broach rotation is self-aligning.

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.

Tip

Frank Kolisek, M.D.
Pre-operative templating serves as a guide. Don't keep hitting the broach harder just because you have not reached the size that was templated.

OPTIONAL STEP

Figure 10A

Assemble the Calcar Planer to the reamer power adaptor. Guide the Calcar Planer over the broach post ensuring the Calcar Planer is axially aligned with the post and is stable. Initiate power prior to contacting the femur and slowly advance the Calcar Planer toward the broach using continuous power until the positive stop on the Calcar Planer contacts the broach face and the bone is removed (Figure 10A). Failure to operate the Calcar Planer in accordance with these instructions may result in damage to the femur.

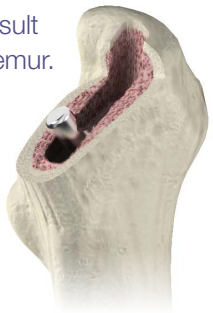


Figure 10B

In the event that the Calcar Planer cannot fully engage the broach post (Figure 10B), remove the broach and perform a new neck resection at a lower level. Alternatively, a larger broach size should also be considered.

STEP 5

TRIAL REDUCTION

TIP

Richard Rothman, M.D.
Start with a standard offset (132°) neck trial. If the leg lengths are equal, but soft tissues are lax, move to a 127° degree neck trial.

Select a Neck Trial which has the same base neck length and angle as the planned implant size. This can be determined in two ways.

1. Match the color indicator located on top of the Neck Trial taper to the color indicator on top of the broach (Figure 11).

2. The table below indicates the correct neck length for each size stem and the corresponding color code. The size of the broach directly corresponds to the size of the implant.

STEM SIZE	NECK TRIAL LENGTH/COLOR
0, 1	27mm/Yellow
2, 3	30mm/Blue
4, 5, 6	35mm/Green
7, 8, 9	37mm/Black
10, 11	40mm/Red

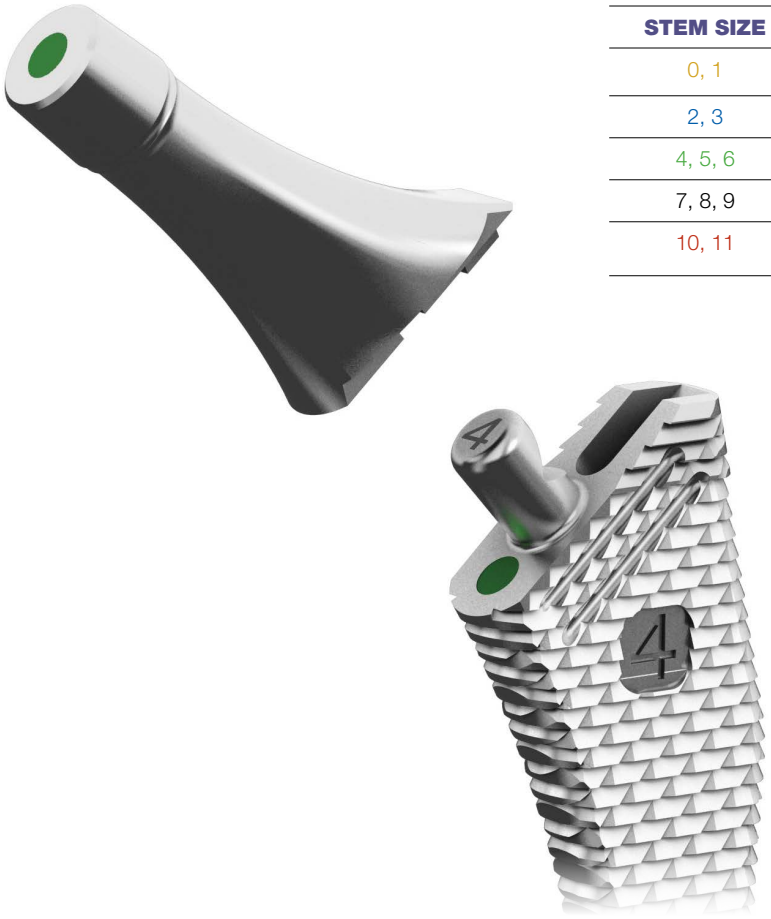


Figure 11

Instruments

132° Neck Trial
1020-32xx

127° Neck Trial
1020-27xx

ACCOLADE II Broach Size
0-11
1020-52xx

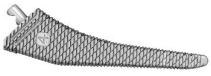


Figure 12

Assemble the Neck Trial onto the broach. Next, assemble a V40 Head Trial onto the Neck Trial (Figure 12). Femoral heads come in multiple offsets and are different for each femoral head implant material (see table at right.) 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

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

V40 Head Trial
6264-x-xxxR

Tip

Richard Rothman, M.D.
Remember, pre-operative templating serves as only a guide. Final sizing, leg length, and offset are determined intra-operatively.

Tip

Dermot Collopy, M.D.
After trial reduction and prior to removing the broach, tap on the broach a few more times to see if it will advance. Due to the visco-elastic properties of the bone, the bone could relax during the trialing process. If the broach does advance, retrial and make adjustments accordingly.

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

STEP 6

IMPLANTING THE STEM

OPTION 1

Thread the Modular Threaded Stem Inserter into the drive hole on the proximal face of the stem (Figure 13). 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.

Figure 13

OPTION 2

The ACCOLADE II Femoral 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 14). 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 disassociating from the inserter.

Note: *The Modular Offset Quick Connect Stem Inserter cannot be used with the Size 0 and Size 1 ACCOLADE II. Misuse could lead to instrument failure.*

OPTION 3

The ACCOLADE II Femoral Stem can also be inserted by hand and then impacted into the bone using the Modular Stem Impactor. 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.

Tip

Dermot Collopy, M.D.
If the stem hangs up due to impingement of the Modular Threaded Stem Inserter against the overhanging tip of the greater trochanter, remove the threaded stem inserter leaving the stem in place and use the Modular Stem Impactor to fully seat the stem.

Instruments

Modular Threaded Stem Inserter
1020-1800

Modular Offset Quick Connect Stem Inserter
1020-1860

Modular Stem Impactor
1020-1870

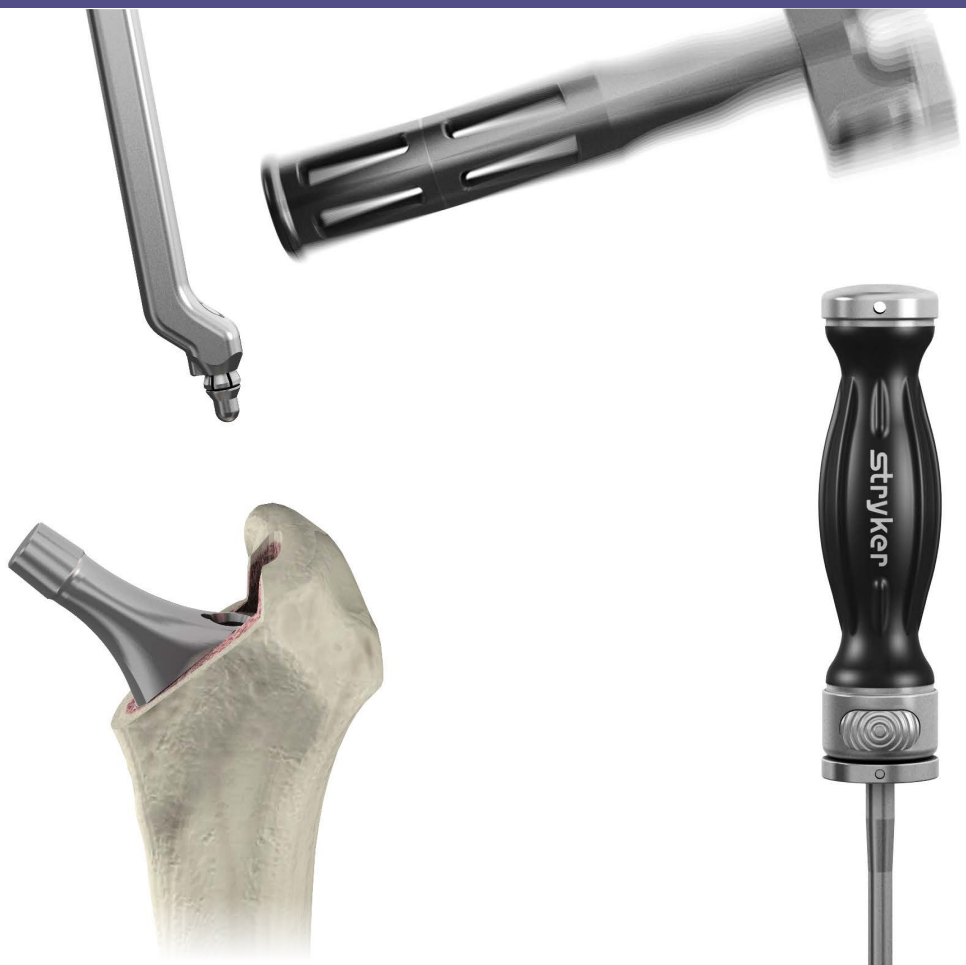


Figure 14

Figure 15

A Mallet is then used to seat the stem into the canal (Figure 15).

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 and additional broaching can be performed. If the stem inserter is contacting the greater trochanter during insertion, continued impaction could lead to a fracture.

Tip

Frank Kolisek, M.D.
Prior to any impaction using the Mallet, the implant should always be inserted into the femoral canal until it stops. This aids in positioning the implant in the same orientation that was broached, preventing the stem from being forced into a different position.

Orthonomic Modular Handle
1020-2900

Mallet
1120-1000

* Fung, Y.C, (1993). Biomechanics: Mechanical Properties of Living Tissues (2nd ed.). pp.500-519

STEP 7

FINAL REDUCTION

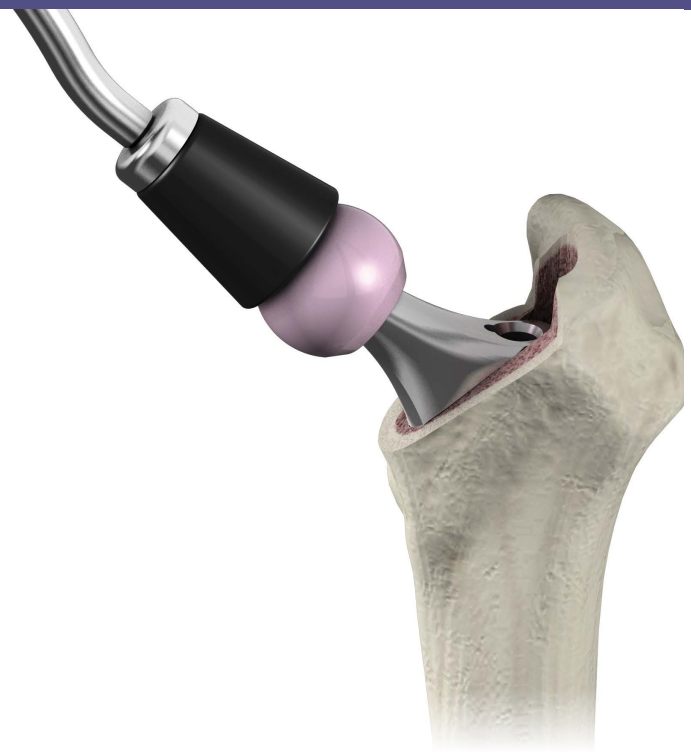


Figure 16

Prior to final head assembly, neck length / head offset selection may be re-evaluated using a V40 Head Trial. Place the Head Trial onto 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 laparatomy 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 two moderate impactions using the Modular Head Impactor (Figure 16).

Verify the head is secure on the trunnion after head impaction by applying traction to the head and confirming stability on the trunnion. If necessary, the head can be removed utilizing the head disassembly instrument.*

Relocate the femoral head into the acetabular cup and re-check the hip biomechanics. The surgical site is then closed according to surgeon preference.

** If a ceramic head is placed on the trunnion and then removed, it must be replaced with a V40 cobalt chrome head or a V40 Titanium Adapter Sleeve (17-0000E) and a C-Taper ceramic head.*

If the stem must be removed, utilize the Modular Threaded Stem Inserter.

OPTIONAL STEP

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

Catalog No.	Offset (mm)	Taper
6519-T-025	-2.5	V40
6519-T-100	+0	V40
6519-T-204	+4	V40

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.

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 strikes using the Head Impactor (6626-0-140). Care must be taken to avoid excessive impact forces when assembling the Ceramic Head to the sleeved femoral component.

Instrument

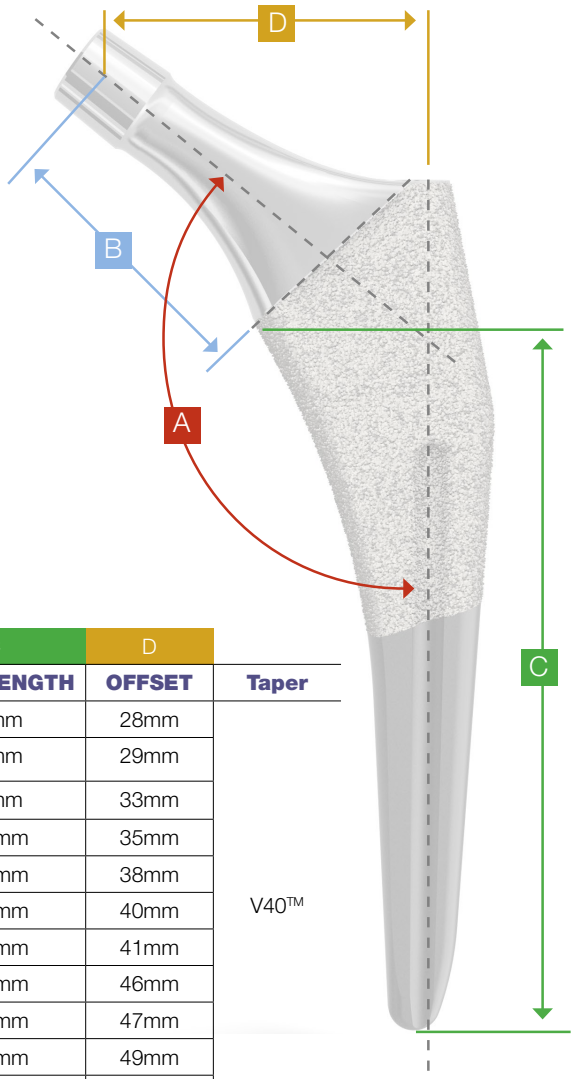
V40 Head Trial
6264-x-xxxR

Modular Head Impactor
1601-1700

Orthonomic Modular Handle
1020-2900

ACCOLADE II

IMPLANT INFORMATION

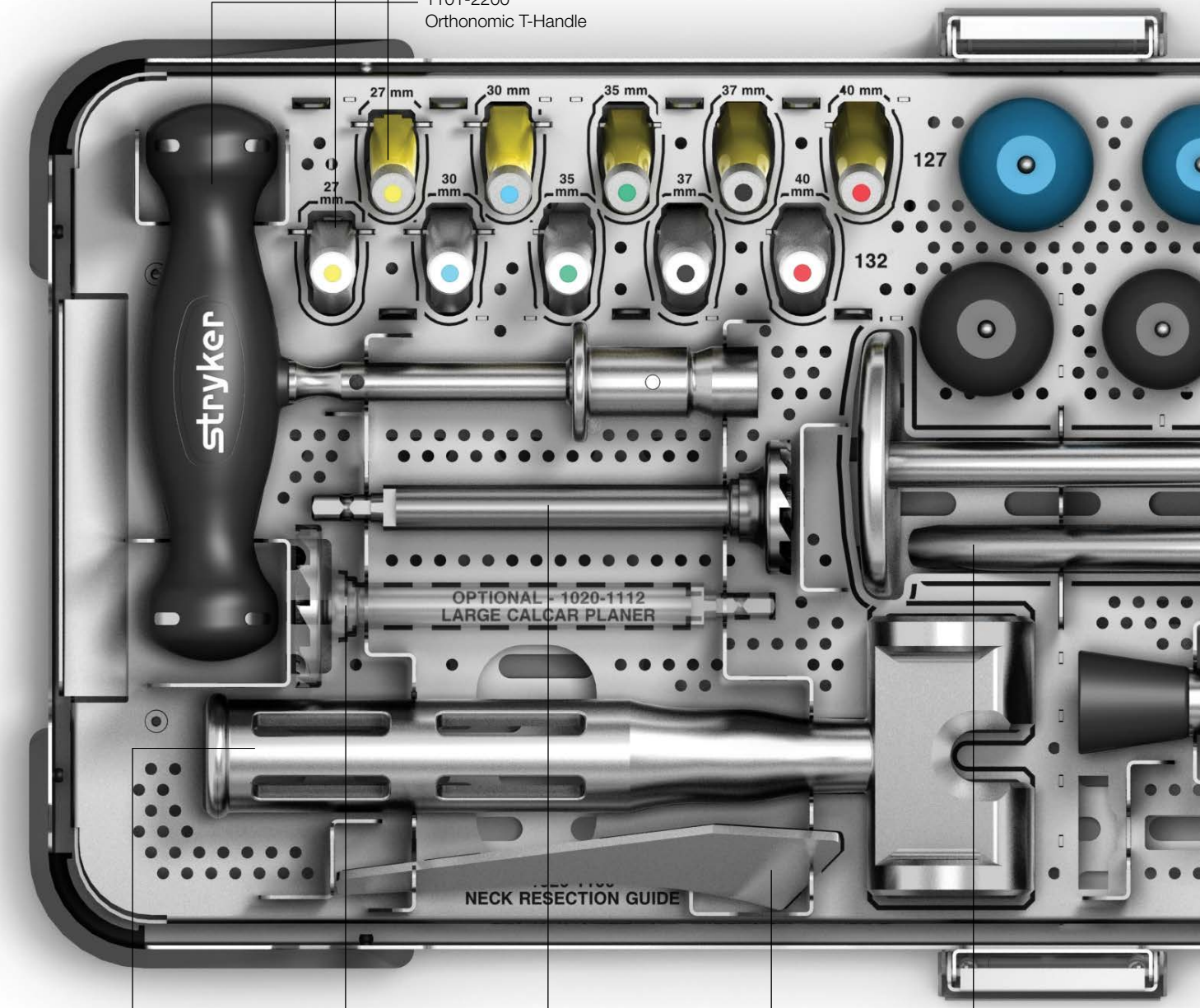


		A	B	C	D	
PART NUMBER	**SIZE**	**NECK ANGLE**	**NECK LENGTH**	**STEM LENGTH**	**OFFSET**	**Taper**
6720-0027	0	132°	27mm	93mm	28mm	V40™
6720-0127	1		27mm	96mm	29mm	
6720-0230	2		30mm	99mm	33mm	
6720-0330	3		30mm	102mm	35mm	
6720-0435	4		35mm	105mm	38mm	
6720-0535	5		35mm	108mm	40mm	
6720-0635	6		35mm	111mm	41mm	
6720-0737	7		37mm	114mm	46mm	
6720-0837	8		37mm	117mm	47mm	
6720-0937	9		37mm	120mm	49mm	
6720-1040	10		40mm	123mm	51mm	
6720-1140	11		40mm	126mm	53mm	
6721-0027	0	127°	27mm	93mm	32mm	V40™
6721-0127	1		27mm	96mm	34mm	
6721-0230	2		30mm	99mm	37mm	
6721-0330	3		30mm	102mm	38mm	
6721-0435	4		35mm	105mm	42mm	
6721-0535	5		35mm	108mm	44mm	
6721-0635	6		35mm	111mm	45mm	
6721-0737	7		37mm	114mm	50mm	
6721-0837	8		37mm	117mm	51mm	
6721-0937	9		37mm	120mm	53mm	
6721-1040	10		40mm	123mm	57mm	
6721-1140	11		40mm	126mm	58mm	

ACCOLADE II

INSTRUMENTATION

1020-9001 **Basic Tray**
1020-9000 Single Tray Case



1020-2727
127°, 27mm Neck Trial

1020-2730
127°, 30mm Neck Trial

1020-2735
127°, 35mm Neck Trial

1020-3227
132°, 27mm Neck Trial

1020-3230
132°, 30mm Neck Trial

1020-3235
132°, 35mm Neck Trial

1101-2200
Orthonomic T-Handle

1120-1000
Mallet

Optional
1020-1112
Calcar Planer - Large

1020-1111
Calcar Planer - Standard

1020-1100
Neck Resection Guide

1020-1460
2 x Offset Broach Handle

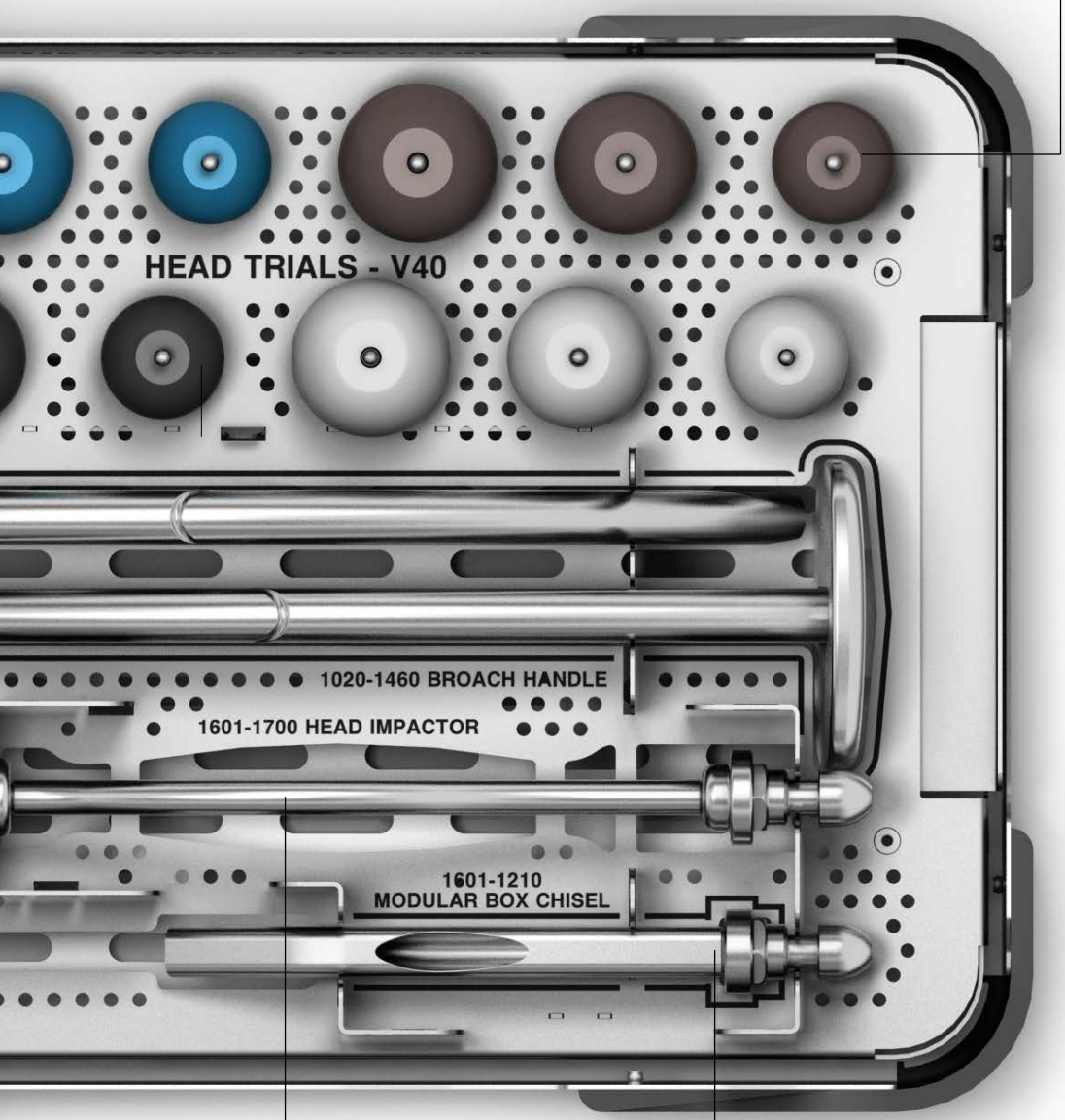
Optional
1440-1460
2 x Straight Broach Handle

1020-2737
127°, 37mm Neck Trial

1020-2740
127°, 40mm Neck Trial

1020-3237
132°, 37mm Neck Trial

1020-3240
132°, 40mm Neck Trial



1601-1700
Modular Head Impactor

1601-1210
Modular Box Osteotome

6264-8-028R
28mm -4mm V40 Head Trial

6264-8-928R
28mm -2.7mm V40 Head Trial

6264-8-128R
28mm +0mm V40 Head Trial

6264-8-228R
28mm +4mm V40 Head Trial

6264-8-328R
28mm +8mm V40 Head Trial

6264-8-428R
28mm +12mm V40 Head Trial

6264-8-032R
32mm -4mm V40 Head Trial

6264-8-632R
32mm -2.5mm V40 Head Trial

6264-8-132R
32mm +0mm V40 Head Trial

6264-8-232R
32mm +4mm V40 Head Trial

6264-8-332R
32mm +8mm V40 Head Trial

6264-8-432R
32mm +12mm V40 Head Trial

6264-8-036R
36mm -5mm V40 Head Trial

6264-8-436R
36mm -2.5mm V40 Head Trial

6264-8-136R
36mm +0mm V40 Head Trial

6264-8-536R
36mm +2.5mm V40 Head Trial

6264-3-236R
36mm +4mm V40 Head Trial

6264-8-236R
36mm +5mm V40 Head Trial

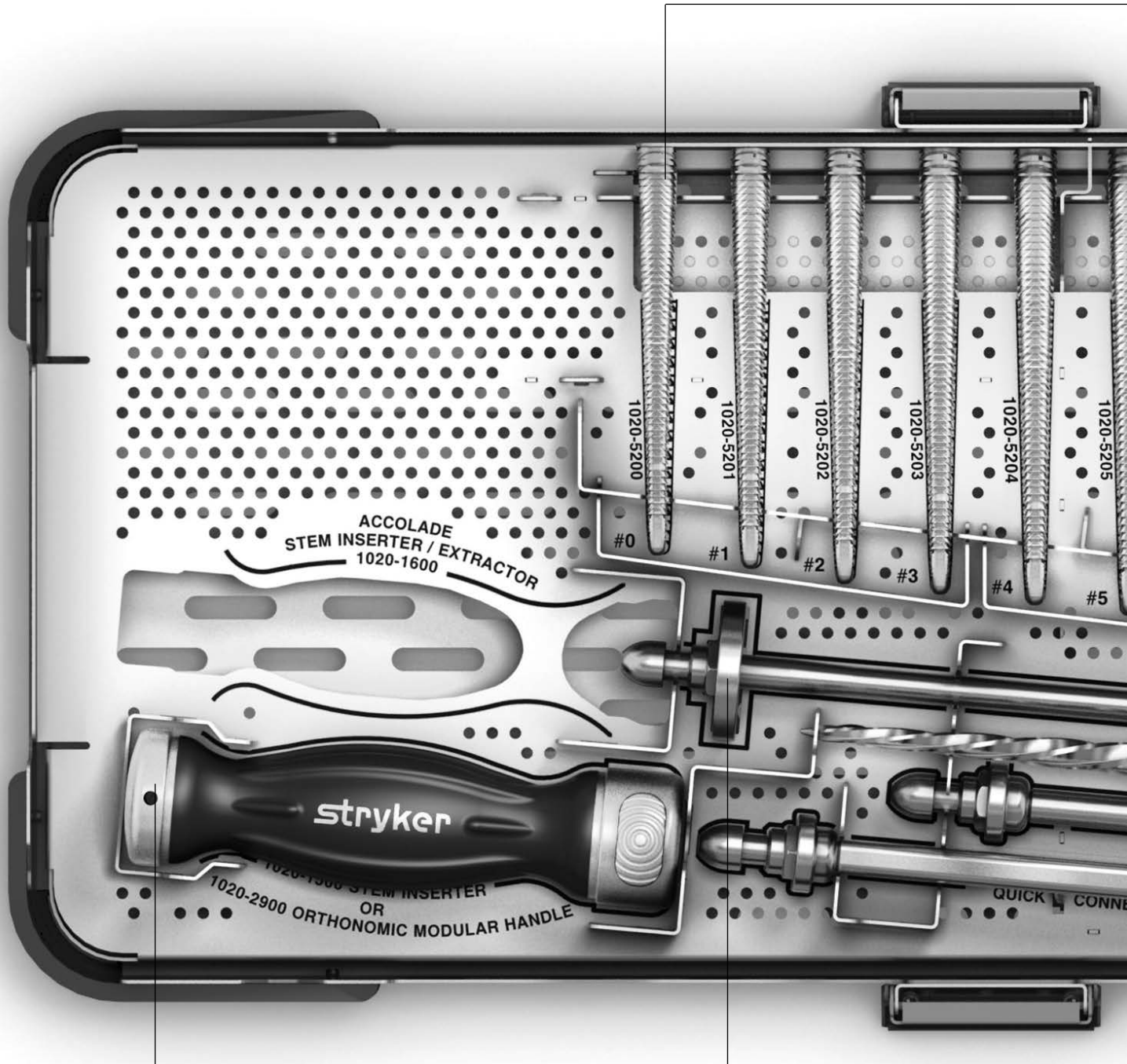
6264-8-736R
36mm +7.5mm V40 Head Trial

6264-8-336R
36mm +10mm V40 Head Trial

ACCOLADE II

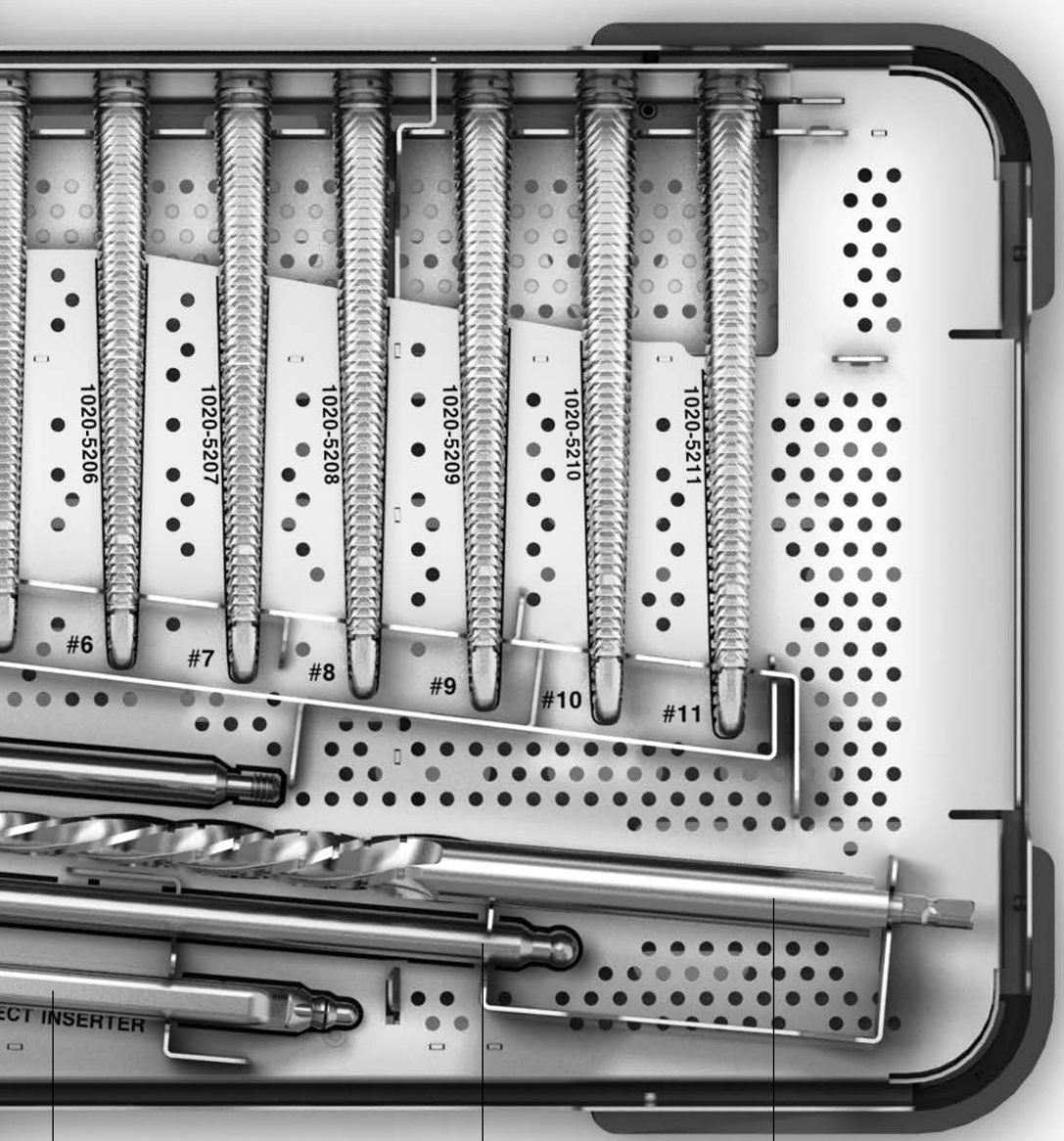
INSTRUMENTATION

1020-9002 **ACCOLADE II Broach Tray**
1020-9000 Single Tray Case



1020-2900
Orthonomic Modular Handle

1020-1800
Modular Threaded Stem Inserter



1020-5200
Size 0 ACCOLADE II Broach

1020-5201
Size 1 ACCOLADE II Broach

1020-5202
Size 2 ACCOLADE II Broach

1020-5203
Size 3 ACCOLADE II Broach

1020-5204
Size 4 ACCOLADE II Broach

1020-5205
Size 5 ACCOLADE II Broach

1020-5206
Size 6 ACCOLADE II Broach

1020-5207
Size 7 ACCOLADE II Broach

1020-5208
Size 8 ACCOLADE II Broach

1020-5209
Size 9 ACCOLADE II Broach

1020-5210
Size 10 ACCOLADE II Broach

1020-5211
Size 11 ACCOLADE II Broach

1020-1860
Modular Offset Quick Connect Stem Inserter

1020-1870
Modular Stem Impactor

1020-1200
Axial Starter Reamer

Alternate Instrument Tray Configuration

1020-9102	**General Tray**
1020-9000	Single Tray Case

1020-9101	**Accolade II Tray**
1020-9000	Single Tray Case

Refer to ACCII-B-1 for tray layouts

Stryker Orthopaedics has validated the following reusable instrument trays with Aesculap's SterilContainer™ System and with CSR wrap. Refer to LSTPI-B (Instructions for Cleaning, Sterilization, Inspection, and Maintenance of Reusable Medical Devices).

6147-0-100 Universal Lid
6147-1-101 Accolade II Basic Tray
6147-1-102 Accolade II Broach Tray

ACCII-SP-1_13060

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