





The Juveno™ Femoral Stem has evolved from a traditional tapered wedge design to one with size-specific medial curvature geometry and an anatomically proportional neck designed to optimize fit for each patient's native anatomy. 1,2,3



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This publication is presented to demonstrate recommended procedures for using b-ONE™ ORTHO Corp. devices and instruments. b-ONE™ ORTHO Corp., as the manufacturer of this device, does not practice medicine and cannot recommend this or any other surgical technique for use on a specific patient. The choice of the appropriate surgical technique is the responsibility of the surgeon performing the operation.



System Overview

The Juveno[™] Femoral Stem is a tapered wedge femoral stem that is intended for cementless, press-fit fixation. The Juveno[™] femoral stem has evolved from a traditional tapered wedge design to one with size-specific medial curvature geometry and an anatomically proportional neck designed to allow the surgeon to optimize fit for each patient's native anatomy. ^{1,2,3}

The proximal geometry is circumferentially coated with a porous plasma spray technology that features an optimal porosity and pore size to encourage osseointegration.^{4,5,6} The Juveno™ femoral stem is also available with a bioactive hydroxyapatite layer to accelerate bone remodeling and promote long-term fixation.^{7,8,9}

The versatile stem design incorporates a reduced proximal lateral shoulder, a lateral distal relief, and an overall shorter stem length compared to traditional designs to allow for ease of insertion when performing various surgical approaches.

The Juveno™ Femoral Stem is prepared for using a broach-only system, comprised of simple, intuitive instruments designed to optimize operative workflow and efficiency. Instrumentation carriers are designed to seamlessly stack into rigid containers or can be processed individually to accommodate hospital protocol or preference.



THE JUVENO™ HIP SYSTEM INCLUDES:

- 11 femoral stem sizes ranging from size 1 to 11
- Standard offset (132°) and High offset (127°) neck options for each stem size.

The Juveno[™] femoral stem is designed for use with b-ONE[™] 12/14 Femoral Heads and their compatible acetabular components. b-ONE[™] Femoral Head implants are available as cobalt chrome (CoCr) or BIOLOX® *delta* (ceramic).

REFERENCES:

- 1. Issa, K et al. Radiographic Fit and Fill Analysis of a New Second-Generation Proximally Coated Cementless Stem Compared to its Predicate Design. Journal of Arthroplasty (2013). http://dx.doi.org/10.1016/j.arth.2013.04.029
- 2. Wuesternann T, Bastian A, Parvizi J, Nessler J, Kolisek F. A novel tapered hip stem design optimized for femoral fit in a wide array of bone types. 2011 EFFORT.
- 3. Faizan et. al. "Development and Verification of a Cementless Novel Tapered Wedge Stem for Total Hip Arthroplasty." Journal of Arthroplasty 30 (2015) 235-240.
- 4. b-ONE TM-00080
- 5. Kanuja et. Al. "Cementless Femoral Fixation in Total Hip Arthroplasty." The Journal of Bone & Joint Surgery. 93(5):500-509, Mar 2011.
- 6. Bobyn, J.D. et al. The Optimal Pore Size for the Fixation of Porous-surfaced Metal Implants by the Ingrowth of Bone. Clinical Orthopaedics and Related Research. (150): 263-70, 1980
- $7. Chambers \ et \ al.\ "Hydroxyapatite-Coated Tapered Cementless Femoral Components in Total Hip Arthroplasty." The Journal of Arthroplasty. Vol. 22 No. 4 Suppl. 1 2007. The Arthroplasty of Arthroplasty$
- 8. Frayssinet, P. et al. (1995) "Natural History of Bone Response to Hydroxyapatite-Coated Hip Prostheses Implanted in Humans," Cells and Materials: Vol. 5: No. 2, Article 2.
- 9. Herrera, A. et. Al. (2015). Clinical Study: Cementless Hydroxyapatite Coated Hip Prostheses. BioMed Research International. 2015. 13 pages. 10.1155/2015/386461.



Indications & Contraindications

INDICATIONS

The b-ONE™ Total Hip System is intended for primary or revision total hip replacement in skeletally mature patients with a severely disabled hip joint and/or hip damage due to the following conditions:

Osteoarthritis, traumatic arthritis, avascular necrosis of the femoral head, noninflammatory degenerative joint disease (NIDJD), slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant. Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis and congenital dysplasia; treatments of nonunion, acute traumatic fracture of the femoral head or neck; failed endoprosthesis, femoral osteotomy, or Girdlestone resection; and fracture-dislocation of the hip.

The b-ONE™ Total Hip System is intended for cementless use only. b-ONE™ Total Hip System components are not intended for use with other total hip systems.

CONTRAINDICATIONS

- Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implants materials.
- Severe osteoporosis or osteopenia may prevent adequate fixation and thus preclude the use of these or any other orthopedic implants.
- Conditions that may place excessive stresses on bone and implants, such as severe
 obesity or pregnancy are relative contraindications. The decision to use these devices
 in such conditions must be made by a physician taking into account the risks versus the
 benefits to the patient.
- Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during body healing and may be at a higher risk of implant failure.
- Using a BIOLOX®delta head in combination with a prosthesis stem left in situ in a revision surgery is contraindicated. A BIOLOX®delta head must only be used with a brand-new, unused, and undamaged stem taper.
- Any condition not described in the Indications for Use.

Refer to the package insert for important product information, including, but not limited to, indications, contraindications, warnings, precautions, and adverse effects.



Templating

Preoperative planning supports the determination of appropriate stem style, size, level of femoral neck resection, and proper head and stem offset combination. Qualitative and quantitative factors such as patient bone quality, density, and morphology should be considered to select the appropriate implant system for the patient. Preoperative templating should serve only as a quide.

Preoperative templating requires quality radiographs with known and correct magnification. The desired magnification for all imaging should be 20% magnification to correspond with the b-ONE™ x-ray templates, with x-ray magnification calibration used whenever possible. Generally, proper radiographs include a single anteroposterior (A/P) radiograph of the pelvis as well as A/P and lateral radiographs of the affected hip to show the proximal one-third of the femur. A/P views with the limbs in 15 degrees of internal rotation are preferred.

The following templating technique assumes the patient has a normal, symmetrical pelvis.



FIGURE 1: A/P RADIOGRAPH OF THE PELVIS



Assess Preoperative Leg Length

First note any possible hip flexion contracture which could make the leg appear short on x-ray. Use clinical evaluation with radiographic analysis to determine intraoperative leg length management.

Beginning with the A/P of the pelvis, draw a reference along the inferior border of the ischial tuberosities, ensuring the line extends beyond the medial cortices of the femurs. Alternatively, a reference line through the inferior aspect of the teardrop landmarks can be used. Then mark a reference point on each femur, such as the most proximal aspect of each lesser trochanter. Measure the distance between the reference line and each femoral reference point. The difference between the two measurements will indicate leg length discrepancy. Often, a line parallel to the reference line is drawn through each femoral reference point to assist with this measurement. This is shown below in Figure 2.



FIGURE 2: ASSESSING PREOPERATIVE LEG LENGTH

The solid line is the reference line connecting the inferior aspect of the ischial tuberosities.

The dashed line is parallel with the reference line and indicates the superior aspect of the right femoral lesser trochanter.

The dotted line is parallel with the reference line and indicates the superior aspect of the left femoral lesser trochanter.

The difference between the two measurements will indicate a leg length discrepancy. In this example, the right hip is 4mm shorter than the left hip.



Template Acetabulum

Overlay the acetabular template on the x-ray, ensuring that the medial border of the cup lies adjacent to the ilioischial line, and the inferior border of the cup is at the inferior aspect of the teardrop. The cup should be positioned with an abduction angle of 30-50 degrees. Mark the center of rotation (COR) of the acetabular component, as indicated by the "X" in **Figure 3**.



FIGURE 3: ACETABULAR TEMPLATE OVERLAY PLACED OVER X-RAY



Template Femur

The Juveno[™] femoral stem has two offset options: the standard offset 132° neck angle and the high offset 127° neck angle. The Juveno[™] template has markings that indicate the center of the femoral head for the range of head options for each femoral neck offset option. Choose the appropriate stem size that achieves mediolateral cortical engagement at the proximal two-thirds of the stem and recreates the desired leg length and offset.

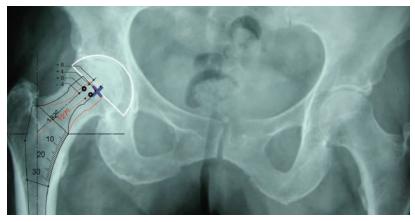


FIGURE 4: JUVENO™ FEMORAL STEM TEMPLATE

The change in leg length and offset will be predicted by the relative position of the femoral head center of rotation (COR), indicated on the Juveno™ femoral template, with respect to the acetabular COR previously marked (X) on the x-ray. For example, as shown in Figure 4, the +8mm femoral head COR for either stem offset lies superior to the acetabular COR (X), and thus will lengthen the limb. Selecting a femoral head COR that lies inferior to the acetabular COR (X) will predict a shortening of the limb. The change in offset is also predicted by comparing the relative medial/lateral position of the head COR and acetabular COR.

The desired change in leg length and offset is determined by the radiographic leg length inequality and clinical evaluation previously determined.

Once the stem size and offset that most closely meets this goal is determined, mark the anticipated neck resection level. This will be used as a reference during intra-operative neck resection.



STEP TWO | FEMORAL RESECTION

Resect the Femoral Neck

The neck resection level affects the final fit and placement of the stem. The Neck Resection Guide can aid in marking the appropriate neck resection level by placing it on the anterior/posterior aspect of the exposed femur, with the centerline aligned with the axis of the femoral canal. Care should be taken to reference the anatomic landmarks determined during preoperative templating, as well as visual inspection in relation to the lesser trochanter prior to making the cut. The neck resection will typically lie approximately 10mm above the lesser trochanter. After the femoral resection is marked, the resection is made with an oscillating saw. To remove the femoral head, a Corkscrew is available and can be connected to the modular T-Handle or power.

Typically after the femoral head is removed, the acetabulum Is prepared for the acetabular component before proceeding to the femoral preparation (see b-ONE Primary Acetabular System Surgical Technique, b1LIT-00002).



INSTRUMENTS



8819003000 Femoral Resection Guide



8819055000 T-Handle



8819040000 Corkscrew



STEP THREE | FEMORAL PREPARATION

Access the Femoral Canal



Position the leg to provide the best exposure for the preparation of the femoral canal. Connect the Modular Box Chisel to the Axial Handle, and impact with the Mallet to initiate entry into the femoral canal. Ensure the orientation of the Box Chisel reflects the desired anteversion which is typically 10-15 degrees.



Connect the Starter Reamer to the T-Handle, or power, and create a pathway into the medullary canal.

NOTE: To minimize the risk of varus stem placement or undersizing of the femoral prosthesis, remove adequate bone from the lateral aspect of the canal with the Starter Reamer, Box Chisel, or a rongeur.

INSTRUMENTS



8819035000 Modular Box Chisel



8819036000 Axial Handle



8819014000 Starter Reamer



8819055000 T-Handle



STEP THREE | FEMORAL PREPARATION

Broaching

Begin broaching with the smallest available Broach. The Broach size can be identified on the Broach.

The Broach Handle is designed for easy attachment to the Broach by extending and closing the lever handle. Be sure to orient the Broach in the correct version and pay special attention to the varus/valgus and anterior/posterior placement of the Broach. With the Mallet, deliver solid impacts to the strike plate on the Broach Handle to advance the Broach.

Sequentially increase the size of the Broach until adequate fill is achieved. The final Broach should sit firmly on medial and lateral cortical bone. Increased resistance to advancement and change in pitch during impaction serve as clues to achieving adequate size. In general, if the Broach sinks below the level of resection, advance to the next size unless the resection is deemed higher than desired.

Two grooves on the anterior and posterior aspect of the Broach act as reference marks to aid in visualizing the Broach advancing into the femur. The proximal groove approximates the level of advancement for standard bone, while the distal groove serves as a reference for poorer bone quality.

Leave the final Broach in the femoral canal and remove the Broach Handle to proceed with calcar planing (optional) or trialing.



INSTRUMENTS



88190420XX Juveno Broaches 8819090000 Straight Broach Handle OR



Straight Broach Handle, Trigger Style



8819022000 Mallet



STEP THREE | FEMORAL PREPARATION

Calcar Planing (optional)

Calcar planing may be performed but is not required as this is a collarless prosthesis. If calcar planning is desired, attach the Calcar Planer to power, ensuring the power setting is set to ream. Advance the Calcar Planer over the broach post, confirming alignment and stability. Power should be initiated prior to contacting bone. Slowly advance the Calcar Planer on continuous power until the stop engages the Broach post and adequate bone is removed.

If the Calcar Planer cannot fully engage the Broach post, remove the Broach and consider either a recut of the neck resection or proceeding to the next size Broach. Failure to follow these instructions could result in damage to the femur.



INSTRUMENTS



8819019032 Calcar Planer, 32mm



8819019042 Calcar Planer, 42mm



STEP FOUR | NECK TRIAL

Neck Trial

The JuvenoTM femoral stem is designed with an anatomic proportional neck to optimize patient fit. The anatomic offset options are:

- Standard Offset (132° silver trials)
- High Offset (127° gold trials)

The neck length increases proportionally with femoral size, shown in **Chart A**. The neck trials are labeled according to corresponding femoral size.

Choose the Neck Trial with desired offset and correct size to match the final broach size, and assemble onto the broach.

STEM SIZE	NECK LENGTH
1	27mm
2, 3	30mm
4, 5, 6	35mm
7, 8, 9	37mm
10, 11	40mm

Chart A: Juveno[™] Femoral Stem Size and Corresponding Neck Length





INSTRUMENTS



88190432XX Standard Offset (132°) Neck Trials



88190437XX High Offset (127°) Neck Trials



STEP FOUR | NECK TRIAL

Head Trial

Insert the appropriate b-ONE 12/14 Taper Head Trial onto the Neck Trial. Note the femoral head offsets differ depending on the femoral head size as shown in **Chart B**.

When performing the trial reduction, it is recommended to perform the following:

- Inspect the reduction of the femoral head in the acetabular cup. The reduction should be concentric and the appropriate amount of coverage of the femoral head achieved.
- 2. Appropriate tissue tension should be assessed. Pulling the leg in a neutral position is important to obtain a true assessment of tissue tension.
- Assess stability through a full functional range of motion, checking any maneuvers that lead to instability. Note any acetabular osteophytes that may cause the hip to sublux out of the cup.
- 4. Assess leg length.

HEAD DIAMETER (MM)	HEAD OFFSET (MM)
28	-3.5, 0, +3.5, +7*
32	-4, 0, +4, +7
36	-4, 0, +4, +8

Chart B. Femoral Head Offset Options. *28mm x +7mm not available in BIOLOX® *delta* ceramic.

INSTRUMENTS



8819053XXX Head Trials



8819038000 Modular Head Impactor



8819036000 Axial Handle



STEP FIVE | IMPLANTATION

Once the final construct is determined, remove all trial components from the body. Ensure that the selected stem size matches the Broach and Neck Trial combination that was determined during the trial procedure.

The Juveno[™] femoral stem can be placed into the prepared canal by hand and seated with the femoral stem impactor. Alternatively, if a threaded insertion tool is preferred, the Stem Remover can be assembled to the Axial Handle and used as a threaded inserter.

Assemble the Stem Impactor to the Axial Handle. The Stem Impactor is a straight instrument; should an offset impactor be desired, the Offset Stem Inserter can be assembled to the Axial Handle and used as an offset stem impactor.

Note: The Offset Stem Inserter has a version control tip that mates with an indexing feature found on the prosthesis' impaction slot for sizes 3-11 only. For sizes 1-2, the Stem Impactor (straight) must be used as these sizes do not contain the indexing feature on the impaction slot.

Position the assembled impactor/inserter into the impaction slot on the superior lateral aspect of the prosthesis. Impact the impactor/inserter with the Mallet until the stem is fully seated.



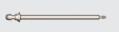
INSTRUMENTS







8819010000 Offset Stem Inserter



8819008000 Stem Remover



8819022000 Mallet



8819036000 Axial Handle



STEP FIVE | IMPLANTATION

Femoral Head

Remove the Stem Impactor. Perform the trial reduction steps with the Head Trial component on the femoral prosthesis to confirm the final femoral head implant.

The Juveno[™] Femoral Stem is compatible with all b-ONE[™] 12/14 Taper Femoral Heads. b-ONE Femoral Head implants are available as cobalt chrome (CoCr) or BIOLOX® *delta* (ceramic).

Once the final femoral head implant is selected and confirmed, remove the Femoral Head Trial. Make sure the taper of the femoral prosthesis is clean and dry.

Note: The BIOLOX® *delta* head must only be used with a brand-new, unused, and undamaged stem taper. Prior to placement of the BIOLOX® *delta* head on the stem taper, the stem taper must be rinsed thoroughly and dried carefully. The stem taper and the inner taper of the BIOLOX® *delta* head must be inspected carefully, and any foreign bodies must be removed.

Assemble the Modular Head Impactor to the Axial Handle. The final head implant is placed on the femoral taper. The BIOLOX® delta head must be fixed on the stem taper by using slight axial pressure and twisting at the same time.

Rest the plastic end of the assembled Head Impactor against the femoral head, ensuring the Head Impactor axis is aligned with the femoral stem neck axis. Firmly impact the assembled Head Impactor with the Mallet to seat the femoral head.

CAUTION: The BIOLOX® delta head must never be struck with a mallet directly. Only the plastic end of the b-ONE Modular Head Impactor should be used.

Confirm the femoral head is secure on the femoral prosthesis by applying traction on the femoral head while confirming stability on the trunnion.

Inspect the acetabulum for any bone or soft tissue interference and then reduce the hip. The hip biomechanics should be reassessed before closure.

Closure is performed. Attention to detail during closure will improve stability and wound healing. Postoperative care is determined by surgical technique, patient factors, and surgeon preference and judgment.



INSTRUMENTS













8819011000 Stem Impactor 8819010000 Stem Inserter, Offset

8819008000 Stem Remover 8819022000 Mallet 8819038000 Modular Head Impactor 8819036000 Axial Handle

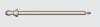
STEM REMOVAL

Stem Removal

If the stem must be removed, the impaction slot of the femoral prosthesis contains a threaded hole that mates with the Stem Remover. Clean the impaction slot and threaded hole thoroughly to ensure debris does not prevent engagement of the Stem Remover threads. Attach the Stem Remover to the Axial Handle. Thread the assembled Stem Remover into the threaded hole of the prosthesis, being careful to avoid cross-threading. Proceed to reverse impact the stem remover handle with a mallet to remove the stem.



INSTRUMENTS



8819008000 Stem Remover



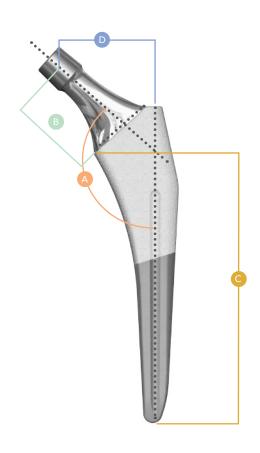
8819036000 Axial Handle



8819022000 Mallet



SIZING CHART | IMPLANTS



	А		С	D
SIZE	NECK ANGLE	NECK LENGTH	STEM LENGTH	OFFSET
1		27mm	96mm	29mm
2		30mm	99mm	33mm
3		30mm	102mm	35mm
4		35mm	105mm	38mm
5		35mm	108mm	40mm
6	132°	35mm	111mm	41mm
7		37mm	114mm	46mm
8		37mm	117mm	47mm
9		37mm	120mm	49mm
10		40mm	123mm	51mm
11		40mm	126mm	53mm

	А	В	С	D
SIZE	NECK ANGLE	NECK LENGTH	STEM LENGTH	OFFSET
1		27mm	96mm	34mm
2		30mm	99mm	37mm
3		30mm	102mm	38mm
4		35mm	105mm	42mm
5		35mm	108mm	44mm
6	127°	35mm	111mm	45mm
7		37mm	114mm	50mm
8		37mm	117mm	51mm
9		37mm	120mm	53mm
10		40mm	123mm	57mm
11		40mm	126mm	58mm



ORDERING | IMPLANTS



881000XXXX

Juveno™ Cementless
Femoral Stem with HA Coating

JUVENO™ Cementless Femoral Stem, Porous Plasma Spray + HA Coating		
SIZE	STANDARD OFFSET (132°) IMPLANT PART #	HIGH OFFSET (127°) IMPLANT PART #
1	8810003201	8810002701
2	8810003202	8810002702
3	8810003203	8810002703
4	8810003204	8810002704
5	8810003205	8810002705
6	8810003206	8810002706
7	8810003207	8810002707
8	8810003208	8810002708
9	8810003209	8810002709
10	8810003210	8810002710
11	8810003211	8810002711



ORDERING | IMPLANTS CONTINUED



88110XXXXX CoCr Femoral Head



39717XXXXX BIOLOX® *delta* Ceramic Femoral Head

b-ONE™ 12/14 Taper Femoral Heads			
DIAME- TER	NECK LENGTH	BIOLOX®delta CERAMIC IMPLANT PART #	CoCr IMPLANT PART #
	-3.5mm	397175445	8811028035
20	+0mm	397175455	8811028000
28mm	+3.5mm	397175465	8811028350
	+7mm	N/A	881102870S
	-4mm	397175665	8811032040
32mm	+0mm	397175675	8811032000
32mm	+4mm	397175685	8811032400
	+7mm	3971796750	8811032700
	-4mm	397179275	8811036040
36mm	+0mm	397179285	8811036000
	+4mm	397179295	8811036400
	+8mm	397164795	8811036800



ORDERING | TRAYS

PART #	DESCRIPTION
8819900100	Juveno™ Hip System Sterilization Case includes 8819900100, 8819900101, & 8819900102
8819900000	Sterilization Case, Lid
8819900101	Juveno™ Hip System Femoral General Tray
8819014000	Starter Reamer
8819019032	Calcar Planer 32mm
8819019042	Calcar Planer 42mm
8819022000	Mallet
8819035000	Modular Box Chisel
8819036000	Axial Handle
8819038000	Modular Head Impactor
8819040000	Corkscrew
8819055000	T-Handle
8819053281	Head Trial - b-ONE™ 12/14 Taper 28mm Diameter, -3,5mm Neck Length
8819053282	Head Trial - b-ONE™ 12/14 Taper 28mm Diameter, 0mm Neck Length
8819053283	Head Trial - b-ONE™ 12/14 Taper 28mm Diameter, +3.5mm Neck Length
8819053284	Head Trial - b-ONE™ 12/14 Taper 28mm Diameter, +7mm Neck Length
8819053321	Head Trial - b-ONE™ 12/14 Taper 32mm Diameter, -4mm Neck Length
8819053322	Head Trial - b-ONE™ 12/14 Taper 32mm Diameter, 0mm Neck Length
8819053323	Head Trial - b-ONE™ 12/14 Taper 32mm Diameter, +4mm Neck Length
8819053324	Head Trial - b-ONE™ 12/14 Taper 32mm Diameter, +7mm Neck Length
8819053361	Head Trial - b-ONE™ 12/14 Taper 36mm Diameter, -4mm Neck Length
8819053362	Head Trial - b-ONE™ 12/14 Taper 36mm Diameter, 0mm Neck Length
8819053363	Head Trial - b-ONE™ 12/14 Taper 36mm Diameter, +4mm Neck Length
8819053364	Head Trial - b-ONE™ 12/14 Taper 36mm Diameter, +8mm Neck Length

PART #	DESCRIPTION
8819900102	Juveno™ Hip System Femoral Broach Tray
8819003000	Femoral Resection Guide
8819008000	Stem Remover
8819010000	Stem Inserter, Offset
8819011000	Stem Impactor
8819090000	Straight Broach Handle*
8819042001	Broach, Size 1
8819042002	Broach, Size 2
8819042003	Broach, Size 3
8819042004	Broach, Size 4
8819042005	Broach, Size 5
8819042006	Broach, Size 6
8819042007	Broach, Size 7
8819042008	Broach, Size 8
8819042009	Broach, Size 9
8819042010	Broach, Size 10
8819042011	Broach, Size 11
8819043227	Neck Trial Standard Offset (132°), 27mm Length
8819043230	Neck Trial Standard Offset (132°), 30mm Length
8819043235	Neck Trial Standard Offset (132°), 35mm Length
8819043237	Neck Trial Standard Offset (132°), 37mm Length
8819043240	Neck Trial Standard Offset (132°), 40mm Length
8819043727	Neck Trial High Offset (127°), 27mm Length
8819043730	Neck Trial High Offset (127°), 30mm Length
8819043735	Neck Trial High Offset (127°), 35mm Length
8819043737	Neck Trial High Offset (127°), 37mm Length
8819043740	Neck Trial High Offset (127°), 40mm Length



^{*}Additional option available: 8819077000 Straight Broach Handle, Trigger Style





