HIP

Operative Technique

ALTEON®

Tapered Wedge Femoral Stems

Primary Femoral Solutions

advita ORTHO

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ALTEON® TAPERED WEDGE FEMORAL STEM

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PRE-OPERATIVE PLANNING

TOOLS

- A/P radiograph of pelvis centered on the pubic symphysis
- Pencil that will not damage X-ray
- Straight edge
- Alteon® Short Tapered Wedge Template Set with 120 percent magnification rule
- Alteon® Tapered Wedge Template Set with 120 percent magnification rule *(Figure 1)*
- Goniometer/protractor

Traditional templating methods may be used. For an estimated determination of required offset, vertical limb length and stem size, the following detailed templating method may be used to help guide the surgeon in selecting a final implant choice.

ESTABLISHMENT OF REFERENCE POINTS

On the radiograph, a straight line is drawn across the bottom of the pelvis touching both ischial tuberosities equally. The line is extended far enough to reach each lesser trochanter. Such a line should be perpendicular to the vertically oriented pubic symphysis. If the line is not vertically oriented, it should be confirmed that the patient's pelvis was not tilted when the radiograph was taken. If the ischial tuberosities are poorly defined, the line should be drawn through the inferior portion of both obturator foramina or the inferior aspect of both teardrops. Templating is recommended to determine the unique anatomic and mechanical features of the patient, and to establish pre-operative reference points that assist in the reconstruction of the patient's natural femoral anatomy.

DETERMINATION OF LEG LENGTH

Select and position the appropriate **Alteon Tapered Wedge Template** over the X-ray so the central axis of the stem aligns with the central axis of the femoral canal and one of the available femoral head options creates the desired center of rotation. The Alteon Tapered Wedge Femoral Stems are designed for mediolateral cortical engagement within the tapered portion of the proximal femoral canal.

When the template is in the desired position, the level of the femoral neck cut and femoral head center of rotation is marked through the punch-outs provided on the template. Record the appropriate size, lateral offset (Standard or Extended), femoral head offset and level of the femoral neck resection.

Note: *For digital templating, follow the software manufacturer's instructions for use while following the preceding instructions regarding placement and implant fit.*

Note: *Templating is an important part of pre-operative preparation, and should only serve as a guide. Final decision making concerning fit, size and soft-tissue tensioning occurs in the operating room using available options of stem offset, head offset and liner configuration.*

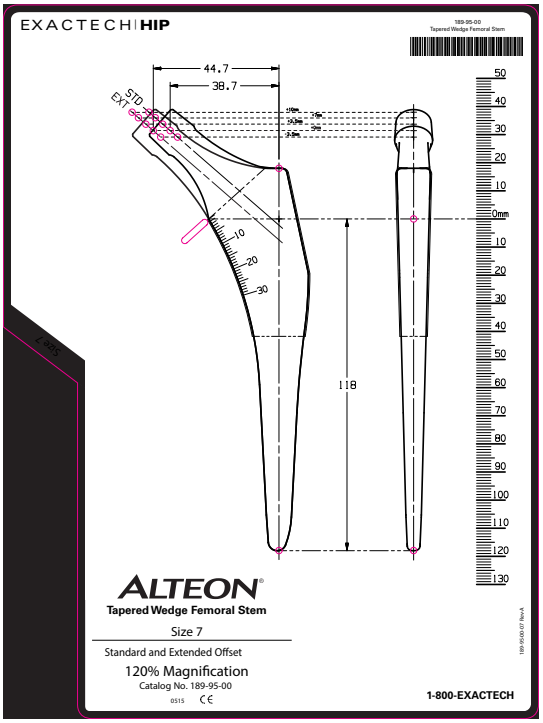


Figure 1
Alteon Tapered Wedge Stem Template

DETAILED OPERATIVE TECHNIQUE

APPROACH AND OSTEOTOMY

Figure 2
Osteotomy of the Femur

Figure 3
Opening of the Femoral Canal

APPROACH AND OSTEOTOMY

The surgical approach of choice is based upon the degree of surgical experience and preference. Align the **Osteotomy Guide** with the long axis of the femur and mark the level of the femoral osteotomy determined in the pre-operative templating exercise *(Figure 2).* Resect the femoral neck at this level in order to help re-establish the patient's limb length, lateral offset and center of rotation of the femoral head.

SURGICAL TIP
Resect the anterior osteophytes from the acetabulum before using the Osteotomy Guide. At this point the center of the femoral head can be viewed.

OPENING OF THE FEMORAL CANAL

Use a **Box Osteotome** to remove a wedge of cancellous bone, creating a portal for entry into the femoral canal *(Figure 3).* This Box Osteotome may aid in establishing an axial position for insertion of broaches. Additional **Canal Entry Tools*** can be used to gain access to the femoral canal.

SURGICAL TIP
The Modular Box Osteotome and Canal Entry Tools are assembled with the Modular Handle prior to use. Ensure these tools properly lock into the Modular Handle.

Figure 4
Femoral Preparation

FEMORAL PREPARATION

Broach Assembly/Disassembly

Assemble the **Broach Handle** to the **Broach** by releasing the locking mechanism, mating the body of the Broach Handle to the superior aspect of the Broach and then engaging the locking mechanism. Ensure the proper respective broach is utilized based on the desire to implant either the Alteon Tapered Wedge or the Alteon Short Tapered Wedge Femoral Stem. Check for proper orientation and full engagement. Care should be taken to ensure that the assembly of the instruments is correct.

***Note:** The Canal Entry Tools are very sharp and should be handled with caution.*

Broaching

Broach up progressively, beginning with the smallest size. Insert the Broach into the femoral canal with the desired amount of anteversion. Alternate impaction and withdrawal of the Broach as the final size is approached. While referencing the femoral neck resection which was determined by pre-operative templating, impact the Broach Handle until the Broach reaches an axially-stable position.

SURGICAL TIP
Tapered Wedge users have found that sinking the Broach 3 to 4mm below the neck resection provides an indication the next size Broach will be appropriate for the femur.

Should the Broach reach an axially-stable position (no longer advances) less than 3mm below the femoral neck resection, the current size Broach has been shown to be the appropriate size for the femur. Release the Broach Handle from the Broach for trialing *(Figure 4).*

SURGICAL TIP
If resistance is encountered while preparing the desired stem size, drop down a broach size and rebroach. The Canal Entry Tools may also be used throughout the procedure to aid in positioning of the subsequent Broaches or the final implant.

***Note:** While broaching, limit the lateral bending forces applied. Excessive bending forces in the lateral direction may cause the broach post to fracture.*

Figure 5
Calcar Preparation

Figure 6
Trial Reduction

CALCAR PREPARATION (OPTIONAL)

Calcar Planing can be performed, if desired, in order to remove any bone that protrudes above the level of the impacted Broach by guiding the **Calcar Planer** onto the guidance surface feature of the Broach *(Figure 5)*.

SURGICAL TIP

The assembled Calcar Planer *(Figure 5)* is created by threading the Calcar Planer Shaft into the Calcar Planer Broach Post Adaptor which captures the Calcar Planer Blade. The assembly is tightened, or loosened, using the supplied Calcar Planer Wrench.

Note: *While calcar planing, ensure that the calcar planer blade remains parallel to the face of the broach. Excessive bending forces applied to the calcar planer tip may cause it to fracture or wear.*

Note: *The Calcar planer should be used on power, and the planing blade should be under power before clearing the calcar bone from the femur.*

TRIAL REDUCTION

Trial Component Insertion

Place the appropriate **Femoral Neck Trial** onto the guidance surface feature of the Broach. Be sure the correct size and offset (Standard or Extended) Neck Trial is chosen. Make sure when inserting the Neck Trial, the size and offset etch markings are facing laterally. Select an appropriate Femoral Head Trial and assemble for trial reduction *(Figure 6)*.

Figure 7
Final Component Placement

Trial Component Removal

Decide final components for implantation. Dislocate the hip, and remove the trial components. Reassemble the Broach Handle to the Broach and remove.

SURGICAL TIP

The Broaches and Neck Trials include design features to ensure only the designated size Broach will mate with the corresponding Neck Trial.

FINAL COMPONENT PLACEMENT

Final Stem Insertion

Select the appropriate femoral stem and impact using the desired Stem Inserter ensuring correct rotational alignment, version and depth. Shorter stems, like the Alteon Short Tapered Wedge, may have a tendency to align in a varus/valgus orientation during insertion and care should be taken to ensure neutral alignment. If necessary, allow the bone to adapt to the implant as it is being impacted *(Figure 7)*. Another trial reduction can be performed with the final femoral stem and Femoral Head Trial.

Femoral Head Impaction

For CoCr heads: Clean and dry the taper of the femoral stem. Place the selected femoral head component onto the taper of the femoral stem and secure it using the Femoral Head Impactor. Apply one or several moderate strikes of the mallet on the Femoral Head Impactor in alignment with the head axis to affix the femoral head to the stem taper.

For Biolox®delta ceramic heads: Clean and dry the taper of the femoral stem. Confirm stem/head compatibility and confirm that the stem and head taper are free of damage. Fit the selected femoral head component onto the stem taper by exerting slight axial pressure on the head component while simultaneously twisting until fully seated. Place the polymer-faced Femoral Head Impactor on the pole of the femoral head and tap gently with a mallet in alignment with the head axis to secure the taper connection. Consult the Instructions for Use accompanying the ceramic femoral head for all installation instructions and warnings.

For Biolox®OPTION heads: After assuring the tapers are clean and dry, assemble the metal adapter and the femoral head per the instructions for use accompanying the Biolox®OPTION components. Clean and dry the taper of the femoral stem. Inspect the stem taper to determine its condition is undamaged or acceptable per the instructions for use accompanying the Biolox®OPTION components. Fit the selected femoral head component onto the stem taper by exerting slight axial pressure on the head component while simultaneously twisting until fully seated. Place the polymer-faced Femoral Head Impactor on the pole of the femoral head and tap gently with a mallet in alignment with the head axis to secure the taper connection. Consult the Instructions for Use accompanying the Biolox®OPTION component for all installation instructions and warnings.

SURGICAL TIP

The **Stem Inserters** and Femoral Head Impactor are assembled with the **Modular Handle** prior to use. Ensure these tools properly lock into the Modular Handle.

Final Reduction

Reduce the hip and perform a final check of leg length, range of motion and stability.

IMPLANT REMOVAL

If it is necessary to intraoperatively remove a prosthesis, the **Stem Extractor** may be assembled to the Broach Handle to facilitate removal.

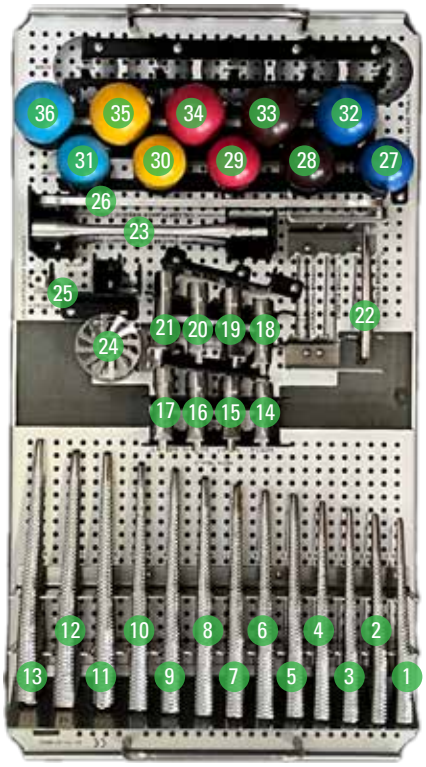
SURGICAL TIP

The **Anterior Extractor** must remain aligned with the mid-plane of the Femoral Stem so that it locks onto the neck flats. Should the Anterior Extractor disassociate from the neck of the Femoral Stem, confirm the Anterior Extractor is aligned with the mid-plane of the Femoral Stem.

CLOSURE

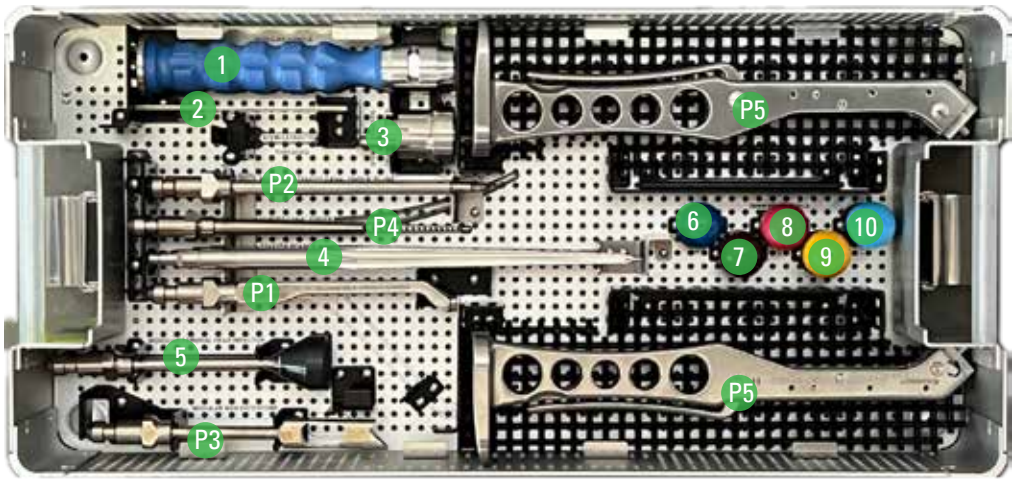
Close the wound according to the preferred method.

TRAY LAYOUT



KIT-1715TW EXACSETS ALTEON TAPERED WEDGE FEMORAL INSTRUMENTS (UPPER LEVEL TRAY)

Site	Qty	Item	Item Description
	1	01-111-01-0002	ExacSETS Hip Femoral Instrument Tray, Upper
1	1	189-12-01	Tapered Wedge Broach, Size 1
2	1	189-12-02	Tapered Wedge Broach, Size 2
3	1	189-12-03	Tapered Wedge Broach, Size 3
4	1	189-12-04	Tapered Wedge Broach, Size 4
5	1	189-12-05	Tapered Wedge Broach, Size 5
6	1	189-12-06	Tapered Wedge Broach, Size 6
7	1	189-12-07	Tapered Wedge Broach, Size 7
8	1	189-12-08	Tapered Wedge Broach, Size 8
9	1	189-12-09	Tapered Wedge Broach, Size 9
10	1	189-12-10	Tapered Wedge Broach, Size 10
11	1	189-12-11	Tapered Wedge Broach, Size 11
12	1	189-12-12	Tapered Wedge Broach, Size 12
13	1	189-12-13	Tapered Wedge Broach, Size 13
14	1	01-003-22-0104	Alteon Neck Trial STD, Size 1-4
15	1	01-003-22-0507	Alteon Neck Trial STD, Size 5-7
16	1	01-003-22-0810	Alteon Neck Trial STD, Size 8-10
17	1	01-003-22-1117	Alteon Neck Trial STD, Size 11-17
18	1	01-003-23-0104	Alteon Neck Trial EXT, Size 1-4
19	1	01-003-23-0507	Alteon Neck Trial EXT, Size 5-7
20	1	01-003-23-0810	Alteon Neck Trial EXT, Size 8-10
21	1	01-003-23-1117	Alteon Neck Trial EXT, Size 11-17
22	1	01-003-06-0006	Canal Finder, Smooth Starter Broach
23	1	01-003-04-0001	Calcar Planer, Shaft
24	1	01-003-04-0002	Calcar Planer, 1.5" Blade
25	1	01-003-04-0003	Calcar Planer, Broach Post Adapter
26	1	01-003-04-0007	Calcar Planer Wrench, Long
27	1	143-32-93	Femoral Head Trial, 12/14 32 -3.5
28	1	143-32-00	Femoral Head Trial, 12/14 32 +0
29	1	143-32-03	Femoral Head Trial, 12/14 32 +3.5
30	1	143-32-07	Femoral Head Trial, 12/14 32 +7
31	1	143-32-10	Femoral Head Trial, 12/14 32 +10
32	1	143-36-93	Femoral Head Trial, 12/14 36 -3.5
33	1	143-36-00	Femoral Head Trial, 12/14 36 +0
34	1	143-36-03	Femoral Head Trial, 12/14 36 +3.5
35	1	143-36-07	Femoral Head Trial, 12/14 36 +7
36	1	143-36-10	Femoral Head Trial, 12/14 36 +10



KIT-1715TW EXACSETS ALTEON TAPERED WEDGE FEMORAL INSTRUMENTS (LOWER LEVEL TRAY)

Site	Qty	Item	Item Description
	1	01-111-01-0001	ExacSETS Hip Femoral Instrument Tray, Lower
	1	10-321-00-0001	Instrument Tray Lid, Full Size
1	1	01-001-00-0001	Handle, Modular Generic
2	1	189-00-00	Wedge Osteotomy Guide
3	1	01-003-10-0001	Stem Exactor, Trunnion
4	1	01-003-07-0001	Starter Reamer
5	1	01-001-03-0001	Head Pusher, Modular Low Profile
6	1	143-28-93	Femoral Head Trial, 12/14 28 -3.5
7	1	143-28-00	Femoral Head Trial, 12/14 28 +0
8	1	143-28-03	Femoral Head Trial, 12/14 28 +3.5
9	1	143-28-07	Femoral Head Trial, 12/14 28 +7
10	1	143-28-10	Femoral Head Trial, 12/14 28 +10

OPT-1715P SHOWN

Site	Qty	Item	Item Description
P1	1	01-001-01-0001	Stem Inserter, Modular Straight
P2	1	01-001-01-0003	Stem Inserter, Modular Threaded
P3	1	01-001-05-0001	Box Osteotome, Modular Straight
P4	1	01-001-06-0001	Canal Finder, Modular Straight Blunt

OPT-189P SHOWN

Site	Qty	Item	Item Description
P5	2	01-003-02-0003	Broach Handle, Straight

OPTIONAL KITS

OPT-1715A

Qty	Item	Item Description
1	01-001-01-0002	Stem Inserter, Modular Offset
1	01-001-05-0003	Box Osteotome, Modular Offset
1	01-003-06-0003	Canal Finder, Curved Blunt

OPT-189A

Qty	Item	Item Description
2	01-003-02-0001	Broach Handle, Curved - Single Offset

OPT-189DO

Qty	Item	Item Description
1	01-003-02-0004	Broach Handle, Dual Offset - Left
1	01-003-02-0005	Broach Handle, Dual Offset - Right

OPT-1489STWD

Qty	Item	Item Description
1	01-101-01-0030	Alteon Wedge Broach Instrument Tray - Half Size
1	10-322-00-0001	Instrument Tray Lid, Half Size
1	189-13-01	Short Tapered Wedge Diamond Broach, Size 1
1	189-13-02	Short Tapered Wedge Diamond Broach, Size 2
1	189-13-03	Short Tapered Wedge Diamond Broach, Size 3
1	189-13-04	Short Tapered Wedge Diamond Broach, Size 4
1	189-13-05	Short Tapered Wedge Diamond Broach, Size 5
1	189-13-06	Short Tapered Wedge Diamond Broach, Size 6
1	189-13-07	Short Tapered Wedge Diamond Broach, Size 7
1	189-13-08	Short Tapered Wedge Diamond Broach, Size 8
1	189-13-09	Short Tapered Wedge Diamond Broach, Size 9
1	189-13-10	Short Tapered Wedge Diamond Broach, Size 10
1	189-13-11	Short Tapered Wedge Diamond Broach, Size 11
1	189-13-12	Short Tapered Wedge Diamond Broach, Size 12
1	189-13-13	Short Tapered Wedge Diamond Broach, Size 13

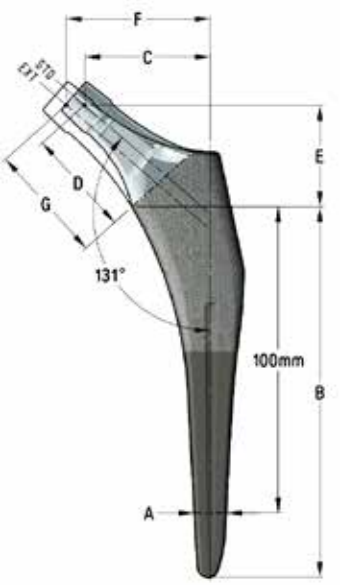
IMPLANT ORDERING INFORMATION

Stem Size	Alteon Tapered Wedge	
	Standard Offset	Extended Offset
1	188-00-01	188-01-01
2	188-00-02	188-01-02
3	188-00-03	188-01-03
4	188-00-04	188-01-04
5	188-00-05	188-01-05
6	188-00-06	188-01-06
7	188-00-07	188-01-07
8	188-00-08	188-01-08
9	188-00-09	188-01-09
10	188-00-10	188-01-10
11	188-00-11	188-01-11
12	188-00-12	188-01-12
13	188-00-13	188-01-13
14**	188-00-14	188-01-14
15**	188-00-15	188-01-15
16**	188-00-16	188-01-16
17**	188-00-17	188-01-17

Stem Size	Short Tapered Wedge	
	Standard Offset	Extended Offset
1	188-30-01	188-31-01
2	188-30-02	188-31-02
3	188-30-03	188-31-03
4	188-30-04	188-31-04
5	188-30-05	188-31-05
6	188-30-06	188-31-06
7	188-30-07	188-31-07
8	188-30-08	188-31-08
9	188-30-09	188-31-09
10	188-30-10	188-31-10
11	188-30-11	188-31-11
12	188-30-12	188-31-12
13	188-30-13	188-31-13
14**	188-30-14	188-31-14
15**	188-30-15	188-31-15
16**	188-30-16	188-31-16
17**	188-30-17	188-31-17

***These implants are not included in standard offering.*

SYSTEM SPECIFICATIONS

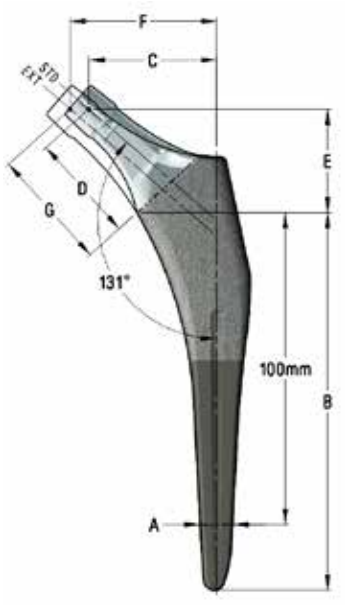


STANDARD OFFSET

Size	A	B		C					D					E				
	M to L width	Stem Length (mm)		Lateral Offset with the following head lengths (mm)					Neck Length with the following head lengths (mm)					Vertical Offset with the following head lengths (mm)				
		Tapered Wedge	Short Tapered Wedge	-3.5	0	3.5	7	10	-3.5	0	3.5	7	10	-3.5	0	3.5	7	10
1	4.5*	100	74	31.4	34.1	36.7	39.4	41.6	26.5	30.0	33.5	36.9	39.9	27.2	29.5	31.8	34.1	36.1
2	5.25*	103	75	31.9	34.6	37.2	39.9	42.1										
3	6.0*	106	76	32.4	35.1	37.7	40.4	42.6										
4	6.75*	109	77	32.9	35.6	38.2	40.9	43.1										
5	7.5	112	79	35.1	37.7	40.3	43.0	45.2	29.0	32.5	36.0	39.4	42.4	29.1	31.4	33.7	36.0	38.0
6	8.5	115	81	35.6	38.2	40.8	43.5	45.7										
7	9.5	118	83	36.1	38.7	41.3	44.0	46.2										
8	10.5	121	86	38.3	40.9	43.6	46.2	48.5	31.5	35.0	38.5	41.9	44.9	30.9	33.2	35.5	37.8	39.8
9	11.5	124	89	38.8	41.4	44.1	46.7	49.0										
10	12.5	127	92	39.4	42.0	44.7	47.3	49.6										
11	13.5	130	95	41.9	44.6	47.2	49.9	52.1	34.0	37.5	41.0	44.4	47.4	32.7	35.0	37.3	39.6	41.6
12	14.75	133	98	42.7	45.4	48.0	50.7	52.9										
13	16.0	136	101	43.7	46.4	49.0	51.7	53.9										
14**	17.25	139	104	44.7	47.4	50.0	52.7	54.9										
15**	18.5	142	107	45.7	48.4	51.0	53.7	55.9										
16**	19.75	145	110	46.7	49.4	52.0	54.7	56.9										
17**	21.0	148	113	47.7	50.4	53.0	55.7	57.9										

**Measured diameter vs M/L width due to lateral relief.*

***These implants are not included in standard offering.*



EXTENDED OFFSET

Size	A	B		C					D					E				
	M to L width	Stem Length (mm)		Lateral Offset with the following head lengths (mm)					Neck Length with the following head lengths (mm)					Vertical Offset with the following head lengths (mm)				
		Tapered Wedge	Short Tapered Wedge	-3.5	0	3.5	7	10	-3.5	0	3.5	7	10	-3.5	0	3.5	7	10
1	4.5*	100	74	37.5	40.1	42.7	45.4	47.6	30.6	34.0	37.5	41.0	44.0	27.2	29.5	31.8	34.1	36.1
2	5.25*	103	75	38.0	40.6	43.2	45.9	48.1										
3	6.0*	106	76	38.5	41.1	43.7	46.4	48.6										
4	6.75*	109	77	39.0	41.6	44.2	46.9	49.1										
5	7.5	112	79	41.1	43.7	46.3	49.0	51.2	33.0	36.5	40.0	43.5	46.4	29.1	31.4	33.7	36.0	38.0
6	8.5	115	81	41.6	44.2	46.8	49.5	51.7										
7	9.5	118	83	42.1	44.7	47.3	50.0	52.2										
8	10.5	121	86	44.3	46.9	49.5	52.2	54.4	35.5	39.0	42.5	45.9	48.9	30.9	33.2	35.5	37.8	39.8
9	11.5	124	89	44.8	47.4	50.0	52.7	54.9										
10	12.5	127	92	45.4	48.0	50.6	53.3	55.5										
11	13.5	130	95	48.0	50.6	53.2	55.9	58.1	38.1	41.5	45.0	48.5	51.5	32.7	35.0	37.3	39.6	41.6
12	14.75	133	98	48.8	51.4	54.0	56.7	58.9										
13	16.0	136	101	49.8	52.4	55.0	57.7	59.9										
14**	17.25	139	104	50.8	53.4	56.0	58.7	60.9										
15**	18.5	142	107	51.8	54.4	57.0	59.7	61.9										
16**	19.75	145	110	52.8	55.4	58.0	60.7	62.9										
17**	21.0	148	113	53.8	56.4	59.0	61.7	63.9										

**Measured diameter vs M/L width due to lateral relief.*

***These implants are not included in standard offering.*

OPTIONAL INSTRUMENTS

ITEM	ITEM DESCRIPTION
143-22-00	Femoral Head Trial, 12/14 22 +0
143-22-03	Femoral Head Trial, 12/14 22 +3.5
143-22-07	Femoral Head Trial, 12/14 22 +7
143-22-10	Femoral Head Trial, 12/14 22 +10
143-40-93	Femoral Head Trial, 12/14 40 -3.5
143-40-00	Femoral Head Trial, 12/14 40 +0
143-40-03	Femoral Head Trial, 12/14 40 +3.5
143-40-07	Femoral Head Trial, 12/14 40 +7
143-40-10	Femoral Head Trial, 12/14 40 +10
4251-4080***	Advita Straight Anterior Broach Handle
01-003-06-0007	Canal Finder, Lateralizing Starter Broach
01-003-06-0008	Canal Finder, Toothed Starter Broach
01-003-10-0002	Stem Extractor, Threaded

*"*** This instrument is not included in the Advita Ortho Kits but can be ordered and shipped separately, which includes its own IFU and reprocessing instructions.*

ITEM	ITEM DESCRIPTION
189-12-14	Tapered Wedge Broach, Size 14
189-12-15	Tapered Wedge Broach, Size 15
189-12-16	Tapered Wedge Broach, Size 16
189-12-17	Tapered Wedge Broach, Size 17
189-02-01	Tapered Wedge Chip Breaker Broach, Size 1
189-02-02	Tapered Wedge Chip Breaker Broach, Size 2
189-02-03	Tapered Wedge Chip Breaker Broach, Size 3
189-02-04	Tapered Wedge Chip Breaker Broach, Size 4
189-02-05	Tapered Wedge Chip Breaker Broach, Size 5
189-02-06	Tapered Wedge Chip Breaker Broach, Size 6
189-02-07	Tapered Wedge Chip Breaker Broach, Size 7
189-02-08	Tapered Wedge Chip Breaker Broach, Size 8
189-02-09	Tapered Wedge Chip Breaker Broach, Size 9
189-02-10	Tapered Wedge Chip Breaker Broach, Size 10
189-02-11	Tapered Wedge Chip Breaker Broach, Size 11
189-02-12	Tapered Wedge Chip Breaker Broach, Size 12
189-02-13	Tapered Wedge Chip Breaker Broach, Size 13
189-02-14	Tapered Wedge Chip Breaker Broach, Size 14
189-02-15	Tapered Wedge Chip Breaker Broach, Size 15
189-02-16	Tapered Wedge Chip Breaker Broach, Size 16
189-02-17	Tapered Wedge Chip Breaker Broach, Size 17
189-13-14	Short Tapered Wedge Diamond Broach, Size 14
189-13-15	Short Tapered Wedge Diamond Broach, Size 15
189-13-16	Short Tapered Wedge Diamond Broach, Size 16
189-13-17	Short Tapered Wedge Diamond Broach, Size 17
189-03-01	Short Tapered Wedge Chip Breaker Broach, Size 1
189-03-02	Short Tapered Wedge Chip Breaker Broach, Size 2
189-03-03	Short Tapered Wedge Chip Breaker Broach, Size 3
189-03-04	Short Tapered Wedge Chip Breaker Broach, Size 4
189-03-05	Short Tapered Wedge Chip Breaker Broach, Size 5
189-03-06	Short Tapered Wedge Chip Breaker Broach, Size 6
189-03-07	Short Tapered Wedge Chip Breaker Broach, Size 7
189-03-08	Short Tapered Wedge Chip Breaker Broach, Size 8
189-03-09	Short Tapered Wedge Chip Breaker Broach, Size 9
189-03-10	Short Tapered Wedge Chip Breaker Broach, Size 10
189-03-11	Short Tapered Wedge Chip Breaker Broach, Size 11
189-03-12	Short Tapered Wedge Chip Breaker Broach, Size 12
189-03-13	Short Tapered Wedge Chip Breaker Broach, Size 13

These products are manufactured by Exactech, Inc. and distributed by Advita Ortho, LLC.

For additional device information, refer to the manufacturer's Instructions for Use for information including, but not limited to, a device description, indications, contraindications, precautions and warnings. For further product information, please contact Customer Service, Advita Ortho, LLC 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (833) 4-ADVITA.

Exactech, as the manufacturer of this device, does not practice medicine and is not responsible for recommending the appropriate surgical technique for use on a particular patient. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part. These guidelines are intended to be solely informational, and each surgeon must evaluate the appropriateness of these guidelines based on his or her personal medical training and experience. Prior to use of this system, the surgeon should refer to the product package insert for information including, but not limited to, comprehensive warnings, precautions, indications for use, contraindications and adverse effects.

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