ORTHO DEVELOPMENT®

Entrada® Hip Stem

SURGICAL TECHNIQUE

The following is a general technique guide for the Entrada® Hip Stem. It is expected that the surgeon is already familiar with the fundamentals of Total Hip Arthroplasty and compaction broaching philosophies. Each patient represents an individual case that may require modification of the technique according to the surgeon's judgment and experience. Please refer to the Instructions for Use (IFU) for the Entrada Hip Stem for intended uses/indications, device description, contraindications, precautions, warnings, and potential risks.

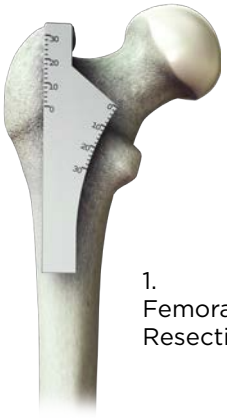
ENTRADA DESIGNING SURGEONS:

J.C. ALVAREZ, M.D.
WINTER HAVEN/SEBRING, FLORIDA

THOMAS F. CALTON, M.D.
OGDEN, UTAH

JOHN N. DIANA, M.D.
NAPA VALLEY, CALIFORNIA

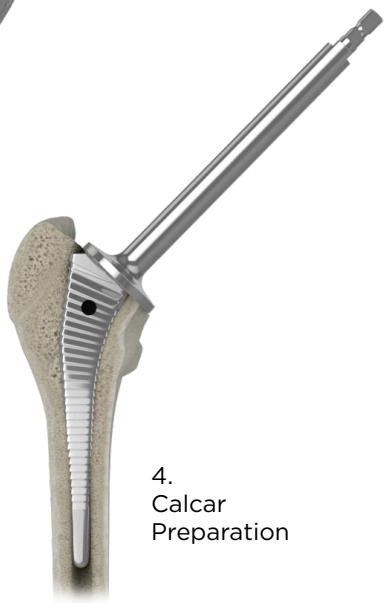
Surgical Technique Overview



1.
Femoral Neck
Resection

2.
Femoral
Preparation

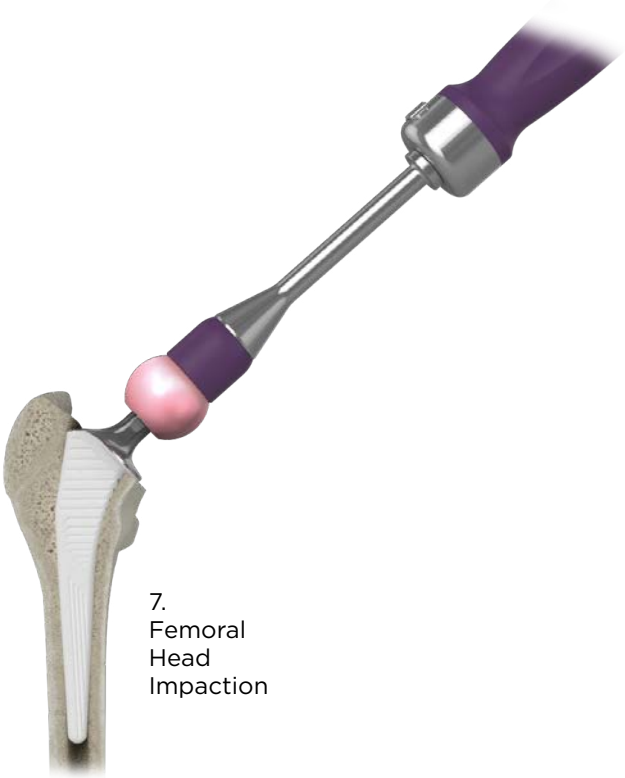
3.
Broaching



4.
Calcar
Preparation

5.
Trial
Reduction

6.
Femoral
Component
Insertion



7.
Femoral
Head
Impaction

History Refined

The Entrada Hip Stem by Ortho Development is designed with our Evolutionary Innovation philosophy of making unique refinements to the best clinically proven technologies. The stem improves upon historical design concepts revolutionized in France in 1986.

Entrada was designed by physicians who wanted a component appropriate for a majority of femoral anatomies and principled on initial mechanical stability, secondary biological integration through hydroxyapatite (HA) coating, and a true bone preserving philosophy. The stem design does not attempt to obtain cortical fit, rather compaction grafting provides a uniform stress transfer from the implant to the femur.

Historical designs demonstrate the need for better bone preservation for the small-statured patient with a short femoral neck. In worst case scenarios the initial femoral neck resection is made at the lesser trochanter to avoid limb lengthening. Entrada refines previous market designs by offering graduated neck lengths through the full range of sizes, significantly shortening the neck length in the smaller stem sizes. This offers a proportional neck length to stem size and subsequently aids in the reduction of calcar resection for bone preservation.

Entrada also addresses previous stem designs that lacked harmonious progressions causing a difficult transitioning between key sizes. Its smooth transitioning affords predictably consistent stepping, and honest graduation through broaching. The femoral stems graduate in size in 1mm increments to allow for predictable impaction grafting, offering an extensive range of sizes.

Improving upon historically proven technology and over 30 years of clinical success, Entrada is truly History Refined.

Entrada Overview

The Entrada Hip Stem integrates clinical history with improved refinements benefiting both surgeon and patient. The Entrada stem utilizes the historical combination of compaction broaching[2] and 155µm of HA coating[1] which are supported by years of clinically proven results. The improved stem has a refined neck, graduates in size in 1mm increments, and is distally shortened. Entrada's collared and collarless stems have a constant 132° neck angle, and are offered in 14 sizes in the standard neck offset, and 13 sizes in extended.

Key Features Include:

- Full HA coating (155µm) combined with compaction broaching promotes early osteointegration and long-term fixation
- Multi-tapered proximal body and rounded trapezoidal cross-section contribute to axial and rotational stability
- Progressive neck lengths allow intraoperative flexibility in the majority of femoral neck geometries
- Extended offset delivers direct lateralization without affecting leg length
- Tapered collar enhances visualization during insertion
- Stepped geometry converts circumferential stresses into compression loads
- Vertical grooves aid in axial and rotational stability
- Optimized lateral shoulder enables ease of insertion in a variety of approaches

The Entrada Stem is compatible with Ortho Development's Acetabular Shell Systems. The Stem has a 12/14 taper and is compatible with CoCr Femoral Heads and BIOLOX®delta Ceramic Femoral Heads available through Ortho Development. Please refer to the appropriate surgical techniques for more information.

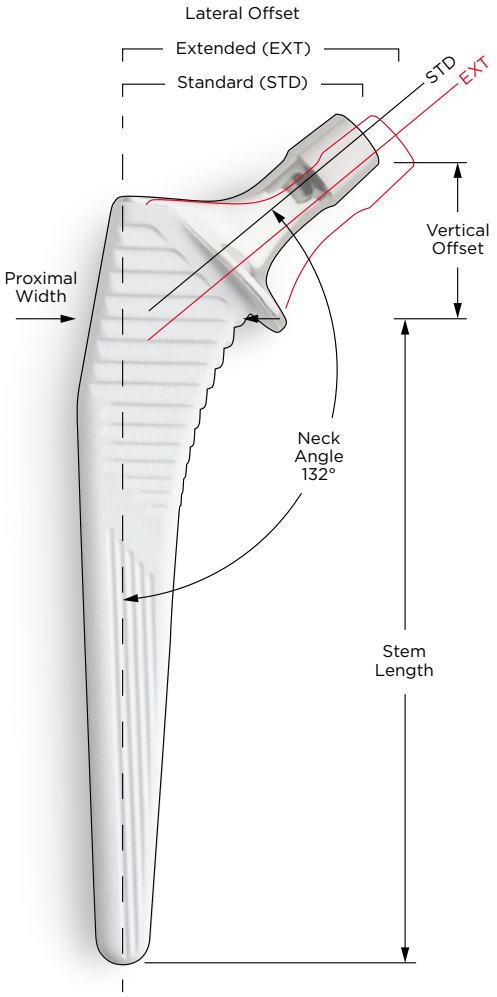
1. Preoperative Planning

Preoperative planning is essential to prepare for many different situations that may arise during Total Hip Arthroplasty. The preoperative planning phase should include patient history, physical exam, and standardized radiographs. Use magnification markers to verify magnification. The A/P radiograph should be used to plan for stem size, femoral head center of rotation, and femoral offset. Once measurements are made, the neck resection level may be marked for verification during surgery.

In creating a compaction grafted envelope, it is not uncommon for the stem to be 1-2mm away from the cortex.

For patients with dense femoral bone and narrow femoral canals in Dorr Type A and Dorr Type B femora, flexible reaming prior to broaching is an appropriate consideration. In cases where it is not obvious if flexible reaming is necessary, flexible reaming can be performed following initial broaching of the femoral canal. Begin flexible reaming 2mm under the preoperatively planned stem size then increase reaming diameter in 0.5mm increments until proper broach stability is achieved.

Flexible intramedullary reaming in these situations allows the distal portion of the femoral broach and the implant to advance distally. This may ultimately allow for better proximal fixation by achieving a more optimally sized implant based off of the preoperative planning.



ENTRADA

SIZE	LENGTH	PROXIMAL WIDTH	LATERAL OFFSET		OFFSET DIFFERENCE	VERTICAL OFFSET
			STANDARD	EXTENDED		
8	95	24.3	34.9	N/A	N/A	29
9	100	25	35.3	42.3	7.0	29
10	105	26	35.9	42.9	7.0	29
11	110	27	36.4	43.4	7.0	29
12	115	28	37.0	44.0	7.0	29
13	120	29	38.6	46.6	8.0	30
14	125	30	40.3	48.3	8.0	31
15	130	31	42.0	50.0	8.0	32
16	135	32	43.6	51.6	8.0	33
17	140	33	45.3	53.3	8.0	34
18	145	34	45.8	53.8	8.0	34
19	150	35	46.4	54.4	8.0	34
20	155	36	46.9	54.9	8.0	34
21	160	37	47.4	55.4	8.0	34

All Entrada stem dimensions and offsets are in millimeters

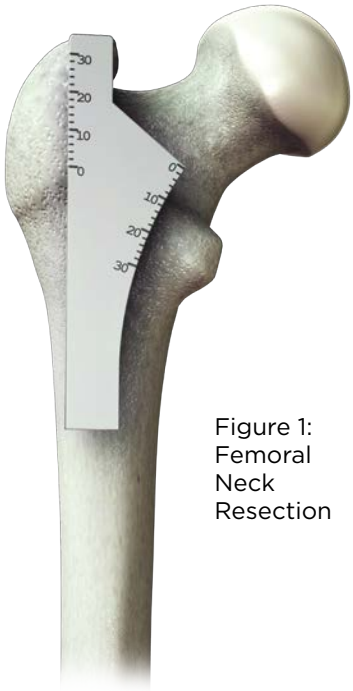


Figure 1: Femoral Neck Resection

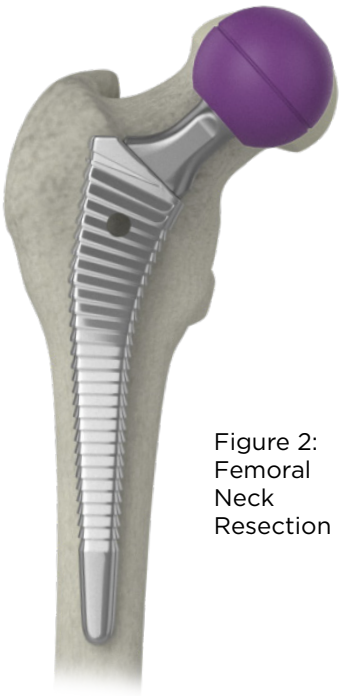


Figure 2: Femoral Neck Resection

Figure 3: Femoral Preparation

2. Surgical Exposure

Exposure is achieved through a variety of methods based on surgeon preference and patient anatomy. Instrumentation is provided to facilitate various approaches including the Direct Anterior, Anterolateral, and Posterolateral.

3. Femoral Neck Resection

The Neck Resection Guide may be used to mark the desired neck resection level (Figure 1). The neck resection level may also be confirmed by using the preoperative templates. The point of the femoral neck resection should be marked with electrocautery that corresponds to both preoperative templating and intraoperative measurements.

Alternatively, assemble the Broach, Neck Trial, and Femoral Head Trial (Figure 2) that correspond to the templated implant size. Place the construct on the femur, verify the center of the rotation and the resection level. Resect the femoral head with an oscillating saw.

Figure 4:
Chili Pepper
Broach

Figure 5:
Starter
Broach

Figure 6:
Broaching

4. Femoral Preparation

Use the Box Osteotome to open the femoral canal posterior to, and lateral of, the piriformis fossa to establish version (Figure 3). It is appropriate to begin parallel to the posterior cortex of the femur to achieve appropriate version. A rongeur may be used prior, to ease the insertion of the Box Osteotome.

To verify the correct entry and direction of the femoral canal, the Modular Rasp Canal Finder may be utilized.

If further lateralization is required, the Chili Pepper Broach (Figure 4) can aid the lateralization of the Starter Broach (Figure 5).

Begin sequential broaching with the smallest Entrada compaction broach. Advance the Broach down the medullary canal paying close attention to anteversion and alignment (Figure 6). The final Broach should sit level with the neck resection.

If the neck resection is correct and the Broach is rotationally unstable or settles below the level of the templated neck cut, the next larger size broach should be selected. Once the rotationally stable Broach is seated at the level of the neck resection, remove the Broach Handle leaving the Broach in place (Figure 7).

Note: It is recommended that rotational stability be checked once the broach has stopped advancing. Repeated verification of rotational stability prior to reaching the final broach size should be avoided, as it can disrupt the cancellous bone envelope.

Figure 7:
Final
Broach

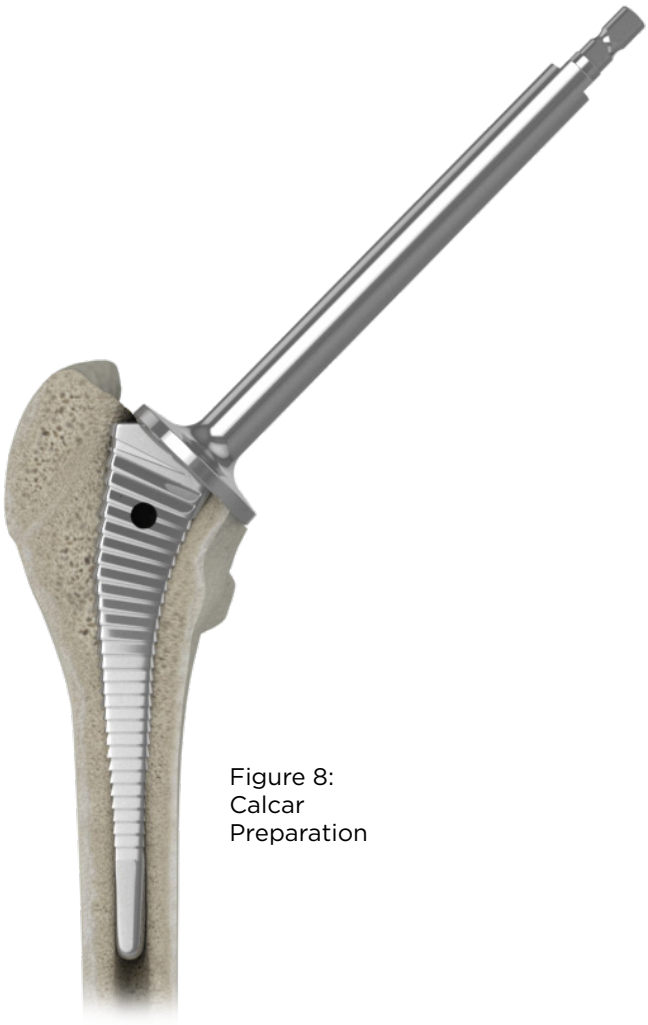


Figure 8:
Calcar
Preparation

5. Calcar Preparation

The Entrada Hip Stem is offered in both collared and collarless options. Calcar planing is optional for the collarless stem.

If a collared stem is used, place the Calcar Planar over the post of the fully seated Broach. To prevent the Calcar Planar from binding, engage the power prior to making contact with the bone.

Advance the Calcar Planar to the level of the Broach (Figure 8). Preparation of the calcar will allow the stem collar to sit flush on the calcar.

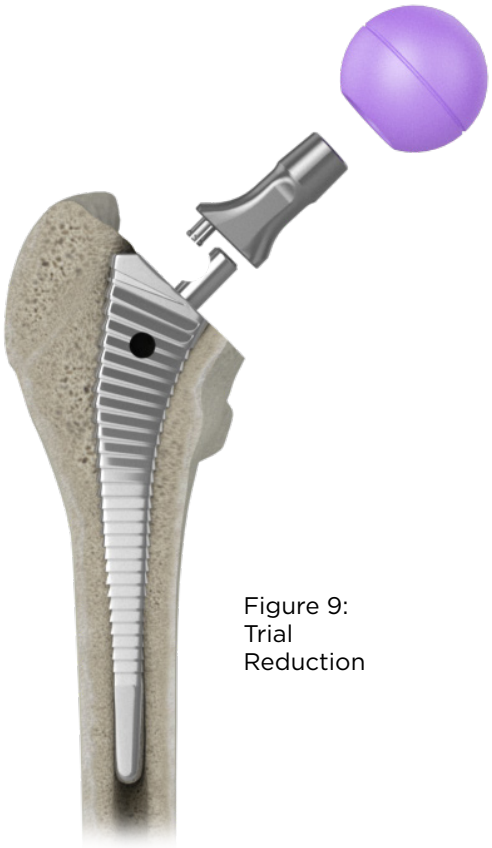


Figure 9:
Trial
Reduction

Figure 10:
Trial
Reduction

6. Trial Reduction

The Entrada Hip Stem offers Neck and Head Trials allowing the surgeon to assess range of motion, leg length, joint stability and component position.

Based on planned leg length and acetabular liner compatibility, attach the appropriate Femoral Head Trial to the Neck Trial (Figure 9). The Neck Trial can now be attached to the Broach and the hip reduced (Figure 10). Perform a range of motion and stability assessment of the hip. If necessary, change the offset, neck length, and acetabular liner until stability of the hip and desired leg length is achieved.

Note: If available, intraoperative flouroscopy may be used to verify lateral offset and positioning.

Dislocate the hip and remove the Head and Neck Trial, taking note of the final sizes chosen. Irrigation of the wound may be performed just prior to removing the broach thereby protecting cancellous bone and marrow contents from removal. Attach the Broach Handle to the Broach and remove it from the femur. Verify the size of the last Broach used for selection of the Entrada Final Implant.

Figure 11: Femoral Implant Placement

Figure 12: Femoral Implant Insertion

7. Femoral Component Insertion

Select the Entrada Implant that corresponds to the final broach size and place it by hand into the femoral canal until it stops (Figure 11). This will help to position the Implant into the orientation prepared by the Broach. When inserting by hand, the Entrada Stem should generally stop one finger breadth above the calcar resection level.

Connect the Modular Impactor to the selected Modular Stem Inserter. Place the Inserter into the Implant and insert the implant into final position with moderate blows to the Impactor (Figure 12). Excessive or heavy force should not be needed to seat the Implant, and may result in femoral fracture.

Note: In a collared stem application it is ideal to have the collar sit flush onto the femoral neck resection, while maintaining full rotational and axial stability. Occasionally the distal aspect of the stem may bind in the narrow area of the femoral isthmus prior to achieving the optimal cancellous bone envelope proximally. In those situations, distal reaming with a flexible reamer may be considered.

Note: A final trial reduction may be performed with the Trial Femoral Head before final implantation.

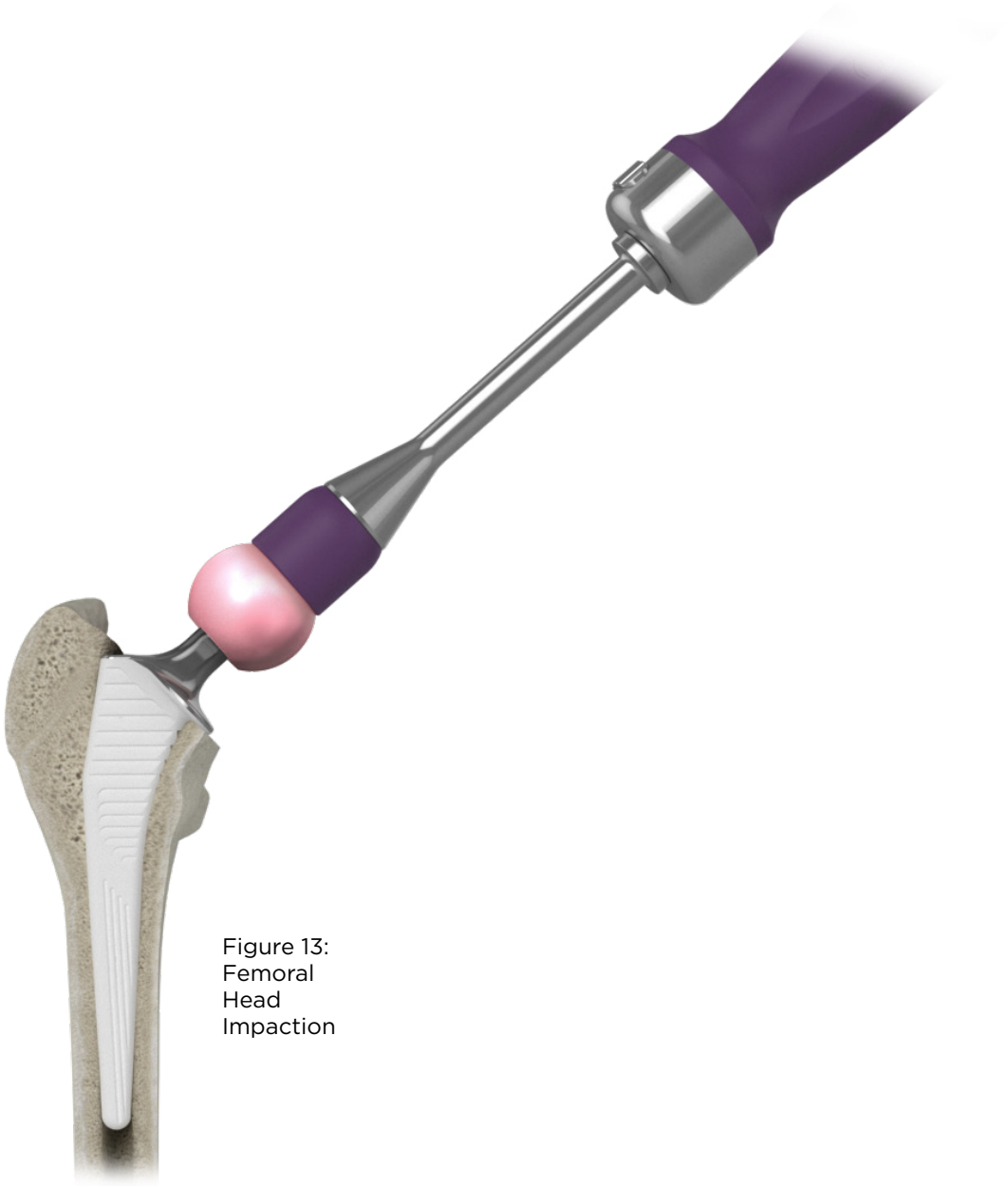


Figure 13:
Femoral
Head
Impaction

Select the Femoral Head Implant that corresponds to the last Femoral Head Trial used. Before impacting the Femoral Head Implant ensure the Implant taper is clean and dry. Place the Femoral Head onto the stem trunnion. Connect the Modular Femoral Head Impactor to the Modular Impactor and seat the Femoral Head with light taps of the Mallet (Figure 13). Reduce the hip and take it through full range of motion. After taking the hip through full range of motion, and the desired result is achieved, close the wound in a standard fashion.

1 Vidalain JP. Twenty-year results of the cementless Corail stem. Int Orthop 2011;35:189-94.

2 Vidalain JP (2011) 25-year ARTRO Results: A Special Vintage from the Old World. In: Vidalain JP et al; The CORAIL Hip System: A Practical Approach Based on 25 Years of Experience. Springer; pg 94-101.

ENTRADA COLLARED STD EXT. KIT-510-1000-02

ITEM #	DESCRIPTION
510-0208	Entrada Collared Hip Stem 8 STD
510-0209	Entrada Collared Hip Stem 9 STD
510-0210	Entrada Collared Hip Stem 10 STD
510-0211	Entrada Collared Hip Stem 11 STD
510-0212	Entrada Collared Hip Stem 12 STD
510-0213	Entrada Collared Hip Stem 13 STD
510-0214	Entrada Collared Hip Stem 14 STD
510-0215	Entrada Collared Hip Stem 15 STD
510-0216	Entrada Collared Hip Stem 16 STD
510-0217	Entrada Collared Hip Stem 17 STD
510-0218	Entrada Collared Hip Stem 18 STD
510-0219	Entrada Collared Hip Stem 19 STD
510-0220	Entrada Collared Hip Stem 20 STD
510-0221	Entrada Collared Hip Stem 21 STD
510-1209	Entrada Collared Hip Stem 9 EXT
510-1210	Entrada Collared Hip Stem 10 EXT
510-1211	Entrada Collared Hip Stem 11 EXT
510-1212	Entrada Collared Hip Stem 12 EXT
510-1213	Entrada Collared Hip Stem 13 EXT
510-1214	Entrada Collared Hip Stem 14 EXT
510-1215	Entrada Collared Hip Stem 15 EXT
510-1216	Entrada Collared Hip Stem 16 EXT
510-1217	Entrada Collared Hip Stem 17 EXT
510-1218	Entrada Collared Hip Stem 18 EXT
510-1219	Entrada Collared Hip Stem 19 EXT
510-1220	Entrada Collared Hip Stem 20 EXT
510-1221	Entrada Collared Hip Stem 21 EXT

ENTRADA COLLARLESS STD EXT. KIT-510-0000-02

ITEM #	DESCRIPTION
510-0008	Entrada Collarless Hip Stem 8 STD
510-0009	Entrada Collarless Hip Stem 9 STD
510-0010	Entrada Collarless Hip Stem 10 STD
510-0011	Entrada Collarless Hip Stem 11 STD
510-0012	Entrada Collarless Hip Stem 12 STD
510-0013	Entrada Collarless Hip Stem 13 STD
510-0014	Entrada Collarless Hip Stem 14 STD
510-0015	Entrada Collarless Hip Stem 15 STD
510-0016	Entrada Collarless Hip Stem 16 STD
510-0017	Entrada Collarless Hip Stem 17 STD
510-0018	Entrada Collarless Hip Stem 18 STD
510-0019	Entrada Collarless Hip Stem 19 STD
510-0020	Entrada Collarless Hip Stem 20 STD
510-0021	Entrada Collarless Hip Stem 21 STD
510-1009	Entrada Collarless Hip Stem 9 EXT
510-1010	Entrada Collarless Hip Stem 10 EXT
510-1011	Entrada Collarless Hip Stem 11 EXT
510-1012	Entrada Collarless Hip Stem 12 EXT
510-1013	Entrada Collarless Hip Stem 13 EXT
510-1014	Entrada Collarless Hip Stem 14 EXT
510-1015	Entrada Collarless Hip Stem 15 EXT
510-1016	Entrada Collarless Hip Stem 16 EXT
510-1017	Entrada Collarless Hip Stem 17 EXT
510-1018	Entrada Collarless Hip Stem 18 EXT
510-1019	Entrada Collarless Hip Stem 19 EXT
510-1020	Entrada Collarless Hip Stem 20 EXT
510-1021	Entrada Collarless Hip Stem 21 EXT

Femoral Head Implants

BIOLOX®DELTA FEMORAL HEADS 28MM–36MM KIT: 136-2000-02:
BIOLOX®DELTA FEMORAL HEADS 40MM KIT: 136-4000-02:

ITEM#	DESCRIPTION
136-2800	Delta Femoral Head 28mm +0
136-2813	Delta Femoral Head 28mm +3
136-2830	Delta Femoral Head 28mm -3
136-3200	Delta Femoral Head 32mm +0
136-3213	Delta Femoral Head 32mm +3
136-3216	Delta Femoral Head 32mm +6
136-3230	Delta Femoral Head 32mm -3
136-3260	Delta Femoral Head 32mm -6
136-3600	Delta Femoral Head 36mm +0
136-3613	Delta Femoral Head 36mm +3
136-3616	Delta Femoral Head 36mm +6
136-3630	Delta Femoral Head 36mm -3
136-3660	Delta Femoral Head 36mm -6
136-4000	Delta Femoral Head 40mm +0
136-4013	Delta Femoral Head 40mm +3
136-4016	Delta Femoral Head 40mm +6
136-4019	Delta Femoral Head 40mm +9
136-4030	Delta Femoral Head 40mm -3
136-4060	Delta Femoral Head 40mm -6

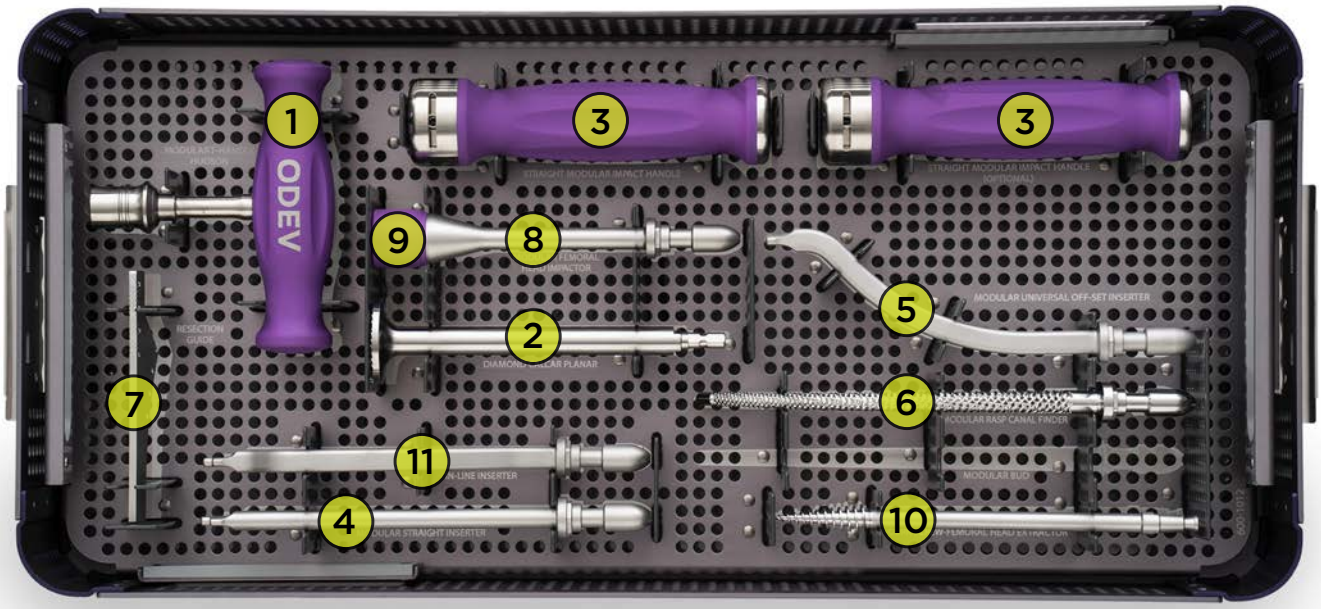
COCR FEMORAL HEADS KIT-138-1000-02:

ITEM#	DESCRIPTION
138-2800	CoCr Femoral Head 28mm +0
138-2803	CoCr Femoral Head 28mm +3
138-2806	CoCr Femoral Head 28mm +6
138-2809	CoCr Femoral Head 28mm +9
138-2830	CoCr Femoral Head 28mm -3
138-2860	CoCr Femoral Head 28mm -6
138-3200	CoCr Femoral Head 32mm +0
138-3203	CoCr Femoral Head 32mm +3
138-3206	CoCr Femoral Head 32mm +6
138-3209	CoCr Femoral Head 32mm +9
138-3230	CoCr Femoral Head 32mm -3
138-3260	CoCr Femoral Head 32mm -6
138-3600	CoCr Femoral Head 36mm +0
138-3603	CoCr Femoral Head 36mm +3
138-3606	CoCr Femoral Head 36mm +6
138-3609	CoCr Femoral Head 36mm +9
138-3630	CoCr Femoral Head 36mm -3
138-3660	CoCr Femoral Head 36mm -6
138-4000	CoCr Femoral Head 40mm +0
138-4003	CoCr Femoral Head 40mm +3
138-4006	CoCr Femoral Head 40mm +6
138-4009	CoCr Femoral Head 40mm +9
138-4030	CoCr Femoral Head 40mm -3
138-4060	CoCr Femoral Head 40mm -6

Entrada Hip Stem Instrument Trays

610-9000 ENTRADA BASIC TRAY

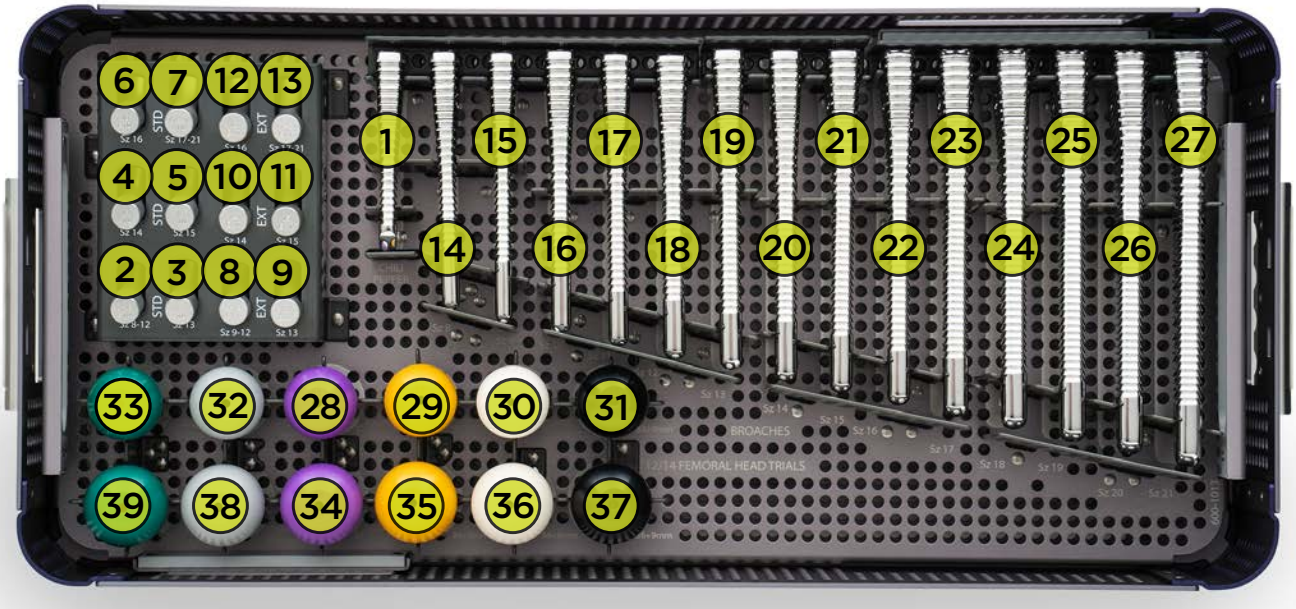
NUMBER	ITEM#	DESCRIPTION	QTY
1	610-1100	Modular T-Handle Hudson	1
2	800-0001	Diamond Calcar Planar	1
3	610-1000	Straight Modular Impact Handle	2
4	610-1006	Modular Straight Inserter	1
5	610-1007	Modular Universal Off-Set Inserter	1
6	610-1010	Modular Rasp Canal Finder	1
7	201-0000	Femoral Neck Resection Guide	1
8	610-1013	Modular Femoral Head Impactor	1
9	610-1019	Femoral Head Impactor	1
10	201-0018	Femoral Head Extractor	1
11	610-1015	In-Line Inserter	1
	600-1012	Entrada Basic Insert	1
	600-0001	Standard Single Level Instrument Case	1
	600-0000	Instrument Case Lid	1



610-9001 ENTRADA BROACH TRAY

NUMBER	ITEM #	DESCRIPTION	QTY
1	610-1009	Entrada Chili Pepper	1
2	610-4001	Entrada Neck Trial STD Size 8-12	1
3	610-4002	Entrada Neck Trial STD Size 13	1
4	610-4003	Entrada Neck Trial STD Size 14	1
5	610-4004	Entrada Neck Trial STD Size 15	1
6	610-4005	Entrada Neck Trial STD Size 16	1
7	610-4006	Entrada Neck Trial STD Size 17-21	1
8	610-4007	Entrada Neck Trial EXT Size 9-12	1
9	610-4008	Entrada Neck Trial EXT Size 13	1
10	610-4009	Entrada Neck Trial EXT Size 14	1
11	610-4010	Entrada Neck Trial EXT Size 15	1
12	610-4011	Entrada Neck Trial EXT Size 16	1
13	610-4012	Entrada Neck Trial EXT Size 17-21	1
14	610-0008	Entrada Broach Size 8	1
15	610-0009	Entrada Broach Size 9	1
16	610-0010	Entrada Broach Size 10	1
17	610-0011	Entrada Broach Size 11	1
18	610-0012	Entrada Broach Size 12	1
19	610-0013	Entrada Broach Size 13	1
20	610-0014	Entrada Broach Size 14	1
21	610-0015	Entrada Broach Size 15	1

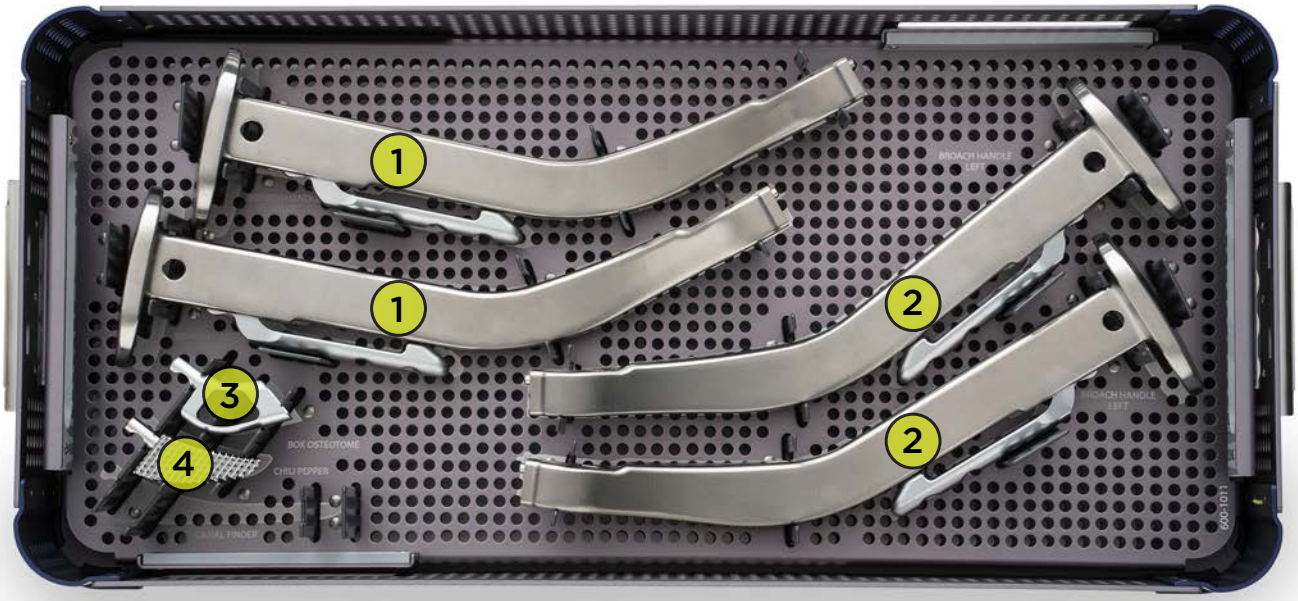
NUMBER	ITEM #	DESCRIPTION	QTY
22	610-0016	Entrada Broach Size 16	1
23	610-0017	Entrada Broach Size 17	1
24	610-0018	Entrada Broach Size 18	1
25	610-0019	Entrada Broach Size 19	1
26	610-0020	Entrada Broach Size 20	1
27	610-0021	Entrada Broach Size 21	1
28	238-0019	12/14 Femoral Head Trial 32, +0	1
29	238-0020	12/14 Femoral Head Trial 32, +3	1
30	238-0021	12/14 Femoral Head Trial 32, +6	1
31	238-0022	12/14 Femoral Head Trial 32, +9	1
32	238-0023	12/14 Femoral Head Trial 32, -3	1
33	238-0024	12/14 Femoral Head Trial 32, -6	1
34	238-0026	12/14 Femoral Head Trial 36, +0	1
35	238-0027	12/14 Femoral Head Trial 36, +3	1
36	238-0028	12/14 Femoral Head Trial 36, +6	1
37	238-0029	12/14 Femoral Head Trial 36, +9	1
38	238-0030	12/14 Femoral Head Trial 36, -3	1
39	238-0031	12/14 Femoral Head Trial 36, -6	1
	600-1013	Entrada Broach Insert	1
	600-0001	Standard Single Level Instrument Case	1
	600-0000	Instrument Case Lid	1



*Note: 32-36 Trial Femoral Heads come standard in the Entrada Broach Tray.
28 and 40 Trial Femoral Heads are available upon request

610-9002 DAA TRAY KIT

NUMBER	ITEM #	DESCRIPTION	QTY
1	201-0200	DAA Broach Handle Lt	2
2	201-0201	DAA Broach Handle Rt	2
3	201-2119	DAA Box Osteotome	1
4	201-2000	Chili Pepper Broach	1
	600-1011	DAA Insert	1
	600-0001	Standard Single Level Instrument Case	1
	600-0000	Instrument Case Lid	1

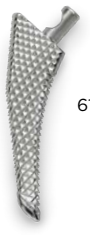


ENTRADA TOOLS

ITEM #	DESCRIPTION
610-1020	Modular BUD - Hudson (not pictured)
610-1017	Entrada Dual Offset Inserter Right
610-1018	Entrada Dual Offest Inserter Left
610-0001	Entrada Starter Cutting Broach
610-1021	Modular Neutral Offset Inserter (not pictured)

610-1017

610-1018


610-0001

Ortho Development® Corporation designs, manufactures, and distributes orthopedic implants and related surgical instrumentation—with a specialty focus on hip and knee joint replacement, trauma fracture repair and spinal fixation. ODEV was founded in 1994 and is located at the base of the Wasatch Mountains in the Salt Lake City suburb of Draper, Utah. The company has established distribution throughout the United States and Japan, along with other select international markets.

ORTHO DEVELOPMENT®

Ortho Development Corporation
odev.com

12187 So. Business Park Drive
Draper, Utah 84020
801-553-9991/fax 801-553-9993

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