ORTHO DEVELOPMENT®

Pivot® Bipolar – Solitude® Unipolar

SURGICAL TECHNIQUE

The following technique is a general guide for the instrumentation of the Pivot Bipolar® and Solitude® Unipolar systems. It is expected that the surgeon is already familiar with the fundamentals of Hip Hemiarthroplasty. 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 Pivot Bipolar and Solitude Unipolar for intended uses/indications, device description, contraindications, precautions, warnings and potential risks.

Pivot Bipolar/Solitude Unipolar Overview

The Pivot® Bipolar and the Solitude® Unipolar systems follow Ortho Development's philosophy of Evolutionary Innovation by making refinements to the best, clinically proven technologies. Pivot Bipolar and Solitude Unipolar are designed to be simple, intuitive, and share universal instrumentation.

Pivot Bipolar features a simple one-step assembly between the femoral head and the compression molded liner, reducing O.R. time.

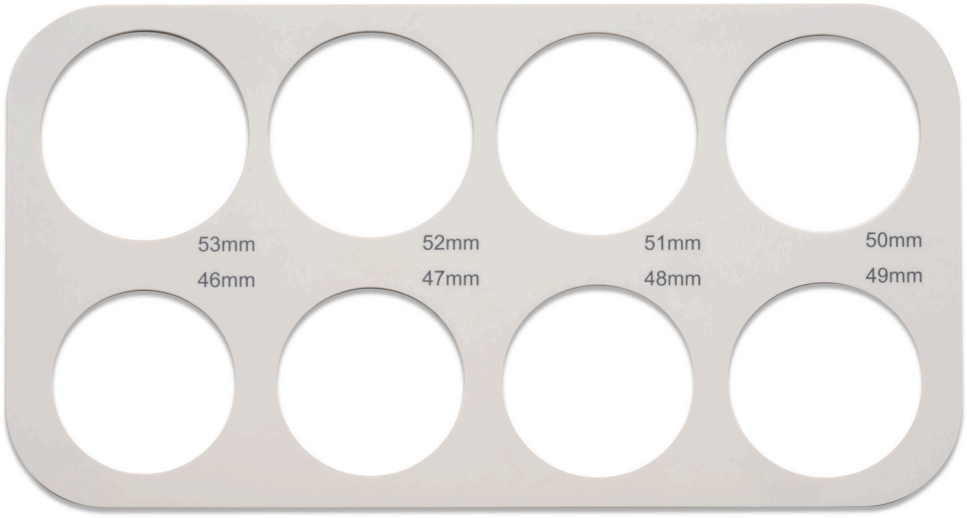
Solitude Unipolar maintains the simple one-step assembly and offers multiple size and offset options.

FEMORAL HEAD SIZE	FEMORAL HEAD OFFSETS	SHELL
22mm	-3, +0, +3, +6	38mm–45mm
28mm	-6, -3, +0, +3, +6, +9	46mm–60mm

UNIPOLAR ADAPTER OFFSETS	SHELL
-3, +0, +3, +6, +9	38mm-60mm

Figure 1:
Femoral Head Gauge

Figure 2:
Ring Gauge



1. Femoral Preparation

Please refer to the appropriate Ortho Development hip stem surgical technique for detailed instructions.

Figure 3:
Align
scallops

Figure 4:
Insert

Figure 5:
Rotate
to lock

Figure 6:
Pull back
to detach

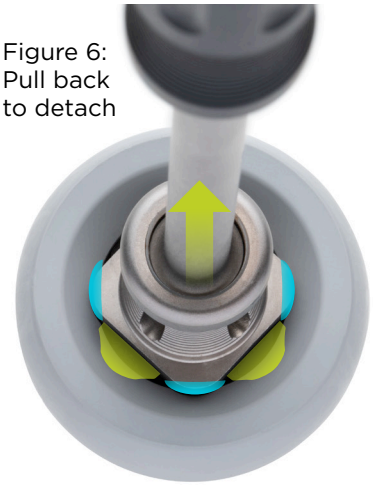


Figure 7:
Rotate to
align scallops

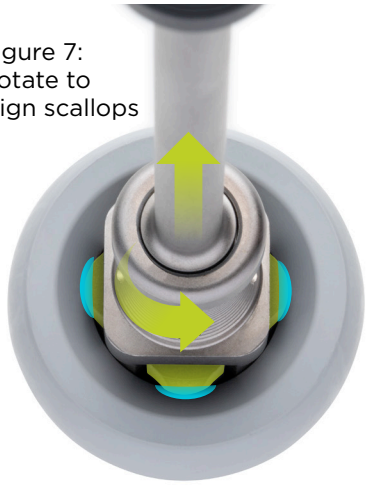


Figure 8:
Pull to
release

2. Acetabular Preparation

Femoral head size may be estimated through preoperative templating. The resected femoral head may be measured intraoperatively using the Femoral Head Gauge (Figure 1), and/or the Ring Gauge (Figure 2).

Once the appropriate size has been determined, select the corresponding Shell Trial. Attach the Shell Trial to the Shell Trial Handle by aligning the scallops (Figure 3). Insert the Shell Trial Handle into the Shell Trial (Figure 4), then rotate the handle clockwise 90° to lock into place (Figure 5). There will be an audible "click" when the Shell Trial is locked in place.

Insert the Shell Trial into the acetabulum to evaluate size. Change the size of the Shell Trial up or down until the desired fit is achieved. Shell Trials are available from 38mm-60mm in 1mm increments. Detach the Shell Trial by pulling back on the sleeve at the end of the Handle (Figure 6), then rotate the handle counter clockwise to line up the scallops (Figure 7). Pull to release (Figure 8).

Figure 9: Align scallops

Figure 10: Rotate to capture

Figure 11: Insert removal tool

Figure 12: Rotate to align scallops

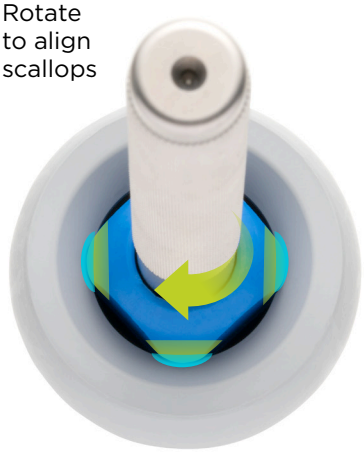


Figure 13: Pull to release

3. Trial Reduction

Pivot Bipolar System

Using the previously determined Shell Trial, select the appropriate Femoral Head Trial. Using the Femoral Head Removal Tool align the flat surfaces of the Femoral Head with the scalloped Shell Trial (Figure 9). Insert the Femoral Head Trial into the Shell Trial, then rotate a quarter turn (Figure 10), capturing the Femoral Head Trial to prevent dislocation during trial reduction.

Pivot Bipolar Shells from 38mm–45mm are compatible with 22mm Femoral Heads, and 46mm–60mm Shells are compatible with 28mm Femoral Heads. Please refer to the table below to determine sizing options:

Once the Bipolar trial is assembled, place it onto the femoral neck trial. With the trial components in place, reduce the hip and perform a range of motion and stability assessment. If necessary, change the femoral head offset until stability and desired leg length are achieved. Using the Femoral Head Removal Tool (Figure 11), disengage the Femoral Head Trial from the Shell Trial by rotating clockwise a quarter turn until scallops line up (Figure 12), and pull to release (Figure 13).

FEMORAL HEAD SIZE	FEMORAL HEAD OFFSETS	SHELL
22mm	-3, +0, +3, +6	38mm–45mm
28mm	-6, -3, +0, +3, +6, +9	46mm–60mm

Figure 14:
Prongs
face head

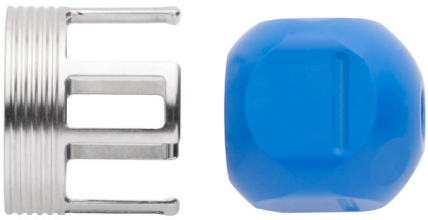


Figure 15:
Snap into
notches

Figure 16:
Locked in

Solitude Unipolar System

For Solitude Unipolar: Using the Shell Trial determined during Acetabular Preparation, prepare the Unipolar Trial by sliding the Unipolar Trial Adapter over the Femoral Head Trial. For proper assembly, the prongs of the Trial Adapter will face toward the Femoral Head Trial (Figure 14) and snap into the notches (Figure 15) on the Femoral Head Trial to lock (Figure 16). Once assembled, insert the Head Trial into the Shell Trial. The Unipolar Trial Adapter prevents the Head Trial from articulating within the Shell Trial to replicate a Unipolar component.

Place the Unipolar trial construct onto the femoral neck trial. With the trial components in place, reduce the hip and perform a range of motion and stability assessment. If necessary, change the femoral head offset until stability and desired leg length are achieved.

4. Final Component Insertion

Pivot Bipolar System

Once the femoral stem is implanted, trial reduction may be performed again to check for leg length, stability, and range of motion. Based on the trial reduction, select the appropriate Pivot Bipolar and Femoral Head final implants. Clean and dry the neck and trunnion of the stem. Place the Femoral Head onto the stem by hand. Lightly tap the Femoral Head Impactor with a mallet until the Femoral Head is fully seated. Gently push the Bipolar onto the Femoral Head by hand until fully seated.

Solitude Unipolar System

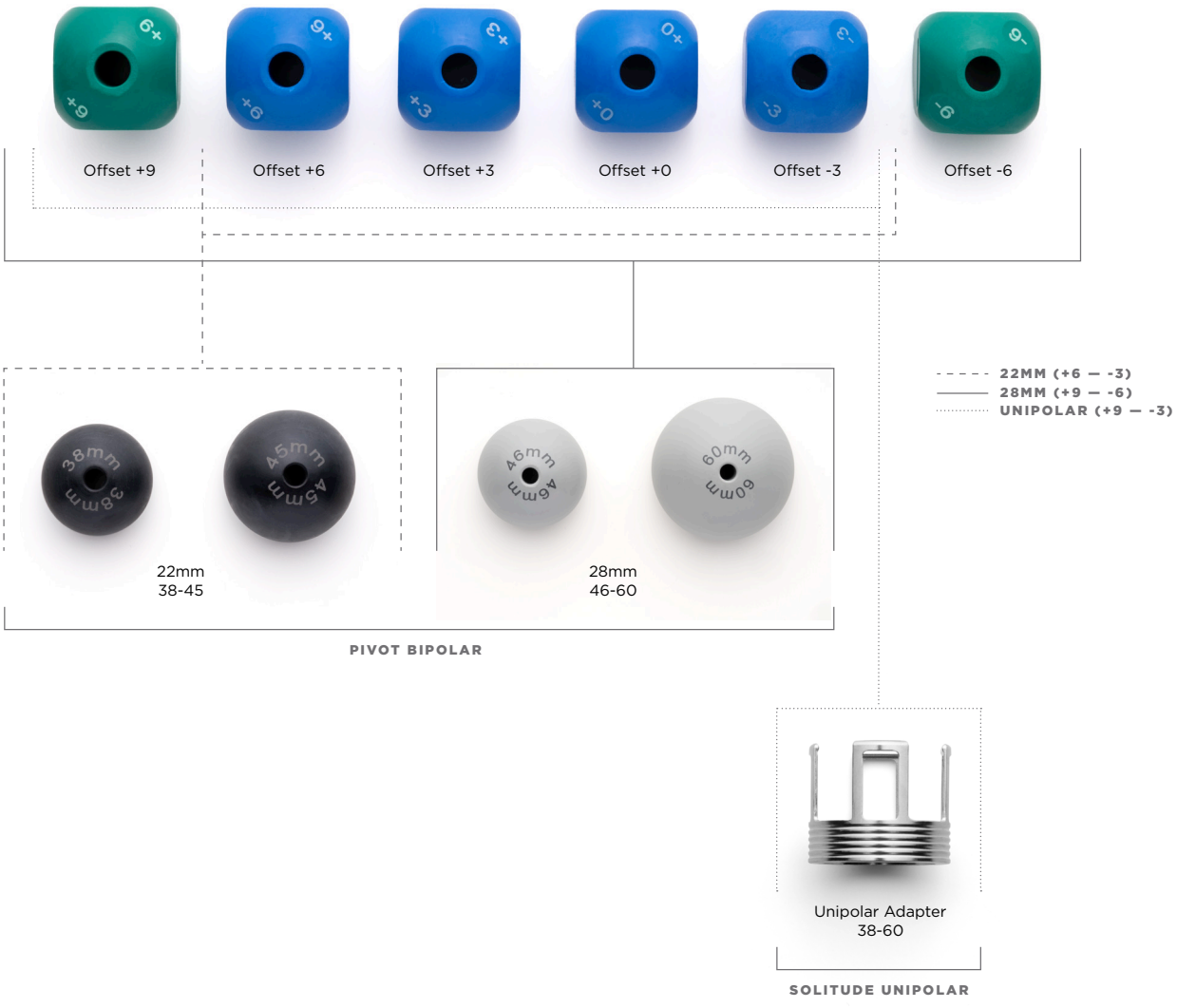
Once the femoral stem is implanted, trial reduction may be performed again to check for leg length, stability, and range of motion. Based on the trial reduction, select the appropriate Solitude Unipolar and Adapter final implants. Clean and dry the neck and trunnion of the stem. Place the Unipolar Adapter onto the stem by hand. After the Adapter is in place, gently push the Solitude Unipolar onto the Unipolar Adapter by hand until fully seated. Use the Head Impactor to fully seat the Unipolar assembly onto the femoral stem.

Note: The Pivot Bipolar and Solitude Unipolar Systems are unable to be disassembled intraoperatively. If a change in size is required, remove the assembly from the femoral stem and repeat the Implant Trialing and Final Component Insertion steps.

5. Hip Reduction

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.

Compatibility Chart



SOLITUDE UNIPOLAR SHELL

ITEM #	DESCRIPTION
132-0038	Solitude Unipolar 38mm
132-0039	Solitude Unipolar 39mm
132-0040	Solitude Unipolar 40mm
132-0041	Solitude Unipolar 41mm
132-0042	Solitude Unipolar 42mm
132-0043	Solitude Unipolar 43mm
132-0044	Solitude Unipolar 44mm
132-0045	Solitude Unipolar 45mm
132-0046	Solitude Unipolar 46mm
132-0047	Solitude Unipolar 47mm
132-0048	Solitude Unipolar 48mm
132-0049	Solitude Unipolar 49mm
132-0050	Solitude Unipolar 50mm
132-0051	Solitude Unipolar 51mm

ITEM #	DESCRIPTION
132-0052	Solitude Unipolar 52mm
132-0053	Solitude Unipolar 53mm
132-0054	Solitude Unipolar 54mm
132-0055	Solitude Unipolar 55mm
132-0056	Solitude Unipolar 56mm
132-0057	Solitude Unipolar 57mm
132-0058	Solitude Unipolar 58mm
132-0059	Solitude Unipolar 59mm
132-0060	Solitude Unipolar 60mm
132-1200	12/14 Solitude Unipolar Adapter +0mm
132-1203	12/14 Solitude Unipolar Adapter +3mm
132-1206	12/14 Solitude Unipolar Adapter +6mm
132-1209	12/14 Solitude Unipolar Adapter +9mm
132-1230	12/14 Solitude Unipolar Adapter -3mm

PIVOT BIPOLAR SHELL

ITEM #	DESCRIPTION
133-2238	Pivot Bipolar 22x38mm
133-2239	Pivot Bipolar 22x39mm
133-2240	Pivot Bipolar 22x40mm
133-2241	Pivot Bipolar 22x41mm
133-2242	Pivot Bipolar 22x42mm
133-2243	Pivot Bipolar 22x43mm
133-2244	Pivot Bipolar 22x44mm
133-2245	Pivot Bipolar 22x45mm
133-2846	Pivot Bipolar 28x46mm
133-2847	Pivot Bipolar 28x47mm
133-2848	Pivot Bipolar 28x48mm
133-2849	Pivot Bipolar 28x49mm

ITEM #	DESCRIPTION
133-2850	Pivot Bipolar 28x50mm
133-2851	Pivot Bipolar 28x51mm
133-2852	Pivot Bipolar 28x52mm
133-2853	Pivot Bipolar 28x53mm
133-2854	Pivot Bipolar 28x54mm
133-2855	Pivot Bipolar 28x55mm
133-2856	Pivot Bipolar 28x56mm
133-2857	Pivot Bipolar 28x57mm
133-2858	Pivot Bipolar 28x58mm
133-2859	Pivot Bipolar 28x59mm
133-2860	Pivot Bipolar 28x60mm

COCR FEMORAL HEAD

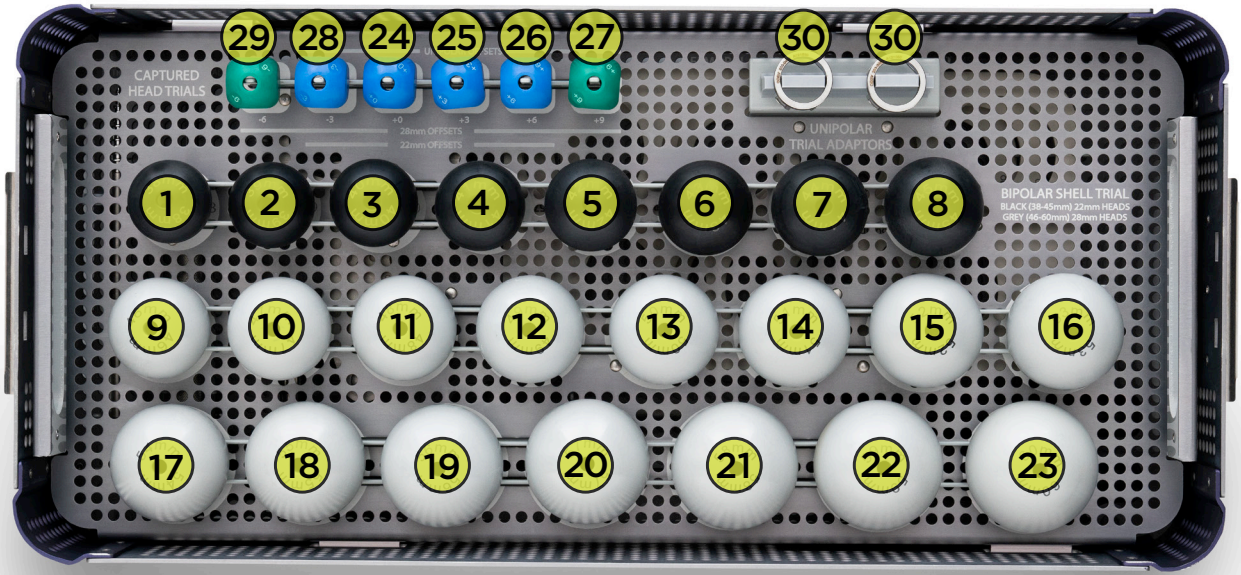
ITEM #	DESCRIPTION
138-2200	12/14 CoCr Femoral Head 22mm + 0
138-2203	12/14 CoCr Femoral Head 22mm +3
138-2206	12/14 CoCr Femoral Head 22mm +6
138-2230	12/14 CoCr Femoral Head 22mm -3
138-2800	12/14 CoCr Femoral Head 28mm +0

ITEM #	DESCRIPTION
138-2803	12/14 CoCr Femoral Head 28mm +3
138-2806	12/14 CoCr Femoral Head 28mm +6
138-2809	12/14 CoCr Femoral Head 28mm +9
138-2830	12/14 CoCr Femoral Head 28mm -3
138-2860	12/14 CoCr Femoral Head 28mm -6

PIVOT SOLITUDE CAPTURED TRIAL KIT: 233-9002 TOP LEVEL

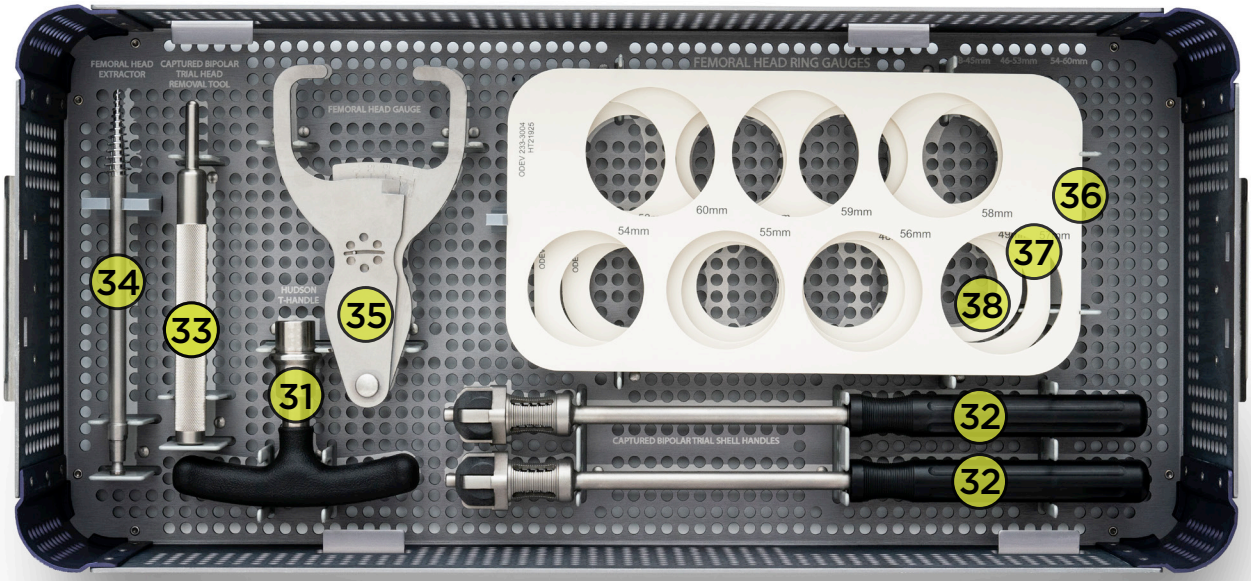
NUMBER	ITEM #	DESCRIPTION	QUANTITY
1	233-0138	Captured Bipolar Shell Trial 38mm	1
2	233-0139	Captured Bipolar Shell Trial 39mm	1
3	233-0140	Captured Bipolar Shell Trial 40mm	1
4	233-0141	Captured Bipolar Shell Trial 41mm	1
5	233-0142	Captured Bipolar Shell Trial 42mm	1
6	233-0143	Captured Bipolar Shell Trial 43mm	1
7	233-0144	Captured Bipolar Shell Trial 44mm	1
8	233-0145	Captured Bipolar Shell Trial 45mm	1
9	233-0146	Captured Bipolar Shell Trial 46mm	1
10	233-0147	Captured Bipolar Shell Trial 47mm	1
11	233-0148	Captured Bipolar Shell Trial 48mm	1
12	233-0149	Captured Bipolar Shell Trial 49mm	1
13	233-0150	Captured Bipolar Shell Trial 50mm	1
14	233-0151	Captured Bipolar Shell Trial 51mm	1
15	233-0152	Captured Bipolar Shell Trial 52mm	1
16	233-0153	Captured Bipolar Shell Trial 53mm	1
17	233-0154	Captured Bipolar Shell Trial 54mm	1
18	233-0155	Captured Bipolar Shell Trial 55mm	1

NUMBER	ITEM #	DESCRIPTION	QUANTITY
19	233-0156	Captured Bipolar Shell Trial 56mm	1
20	233-0157	Captured Bipolar Shell Trial 57mm	1
21	233-0158	Captured Bipolar Shell Trial 58mm	1
22	233-0159	Captured Bipolar Shell Trial 59mm	1
23	233-0160	Captured Bipolar Shell Trial 60mm	1
24	233-0200	Captured Bipolar 12/14 Head Trial +0 Offset	1
25	233-0203	Captured Bipolar 12/14 Head Trial +3 Offset	1
26	233-0206	Captured Bipolar 12/14 Head Trial +6 Offset	1
27	233-0209	Captured Bipolar 12/14 Head Trial +9 Offset	1
28	233-0230	Captured Bipolar 12/14 Head Trial -3 Offset	1
29	233-0260	Captured Bipolar 12/14 Head Trial -6 Offset	1
30	233-0403	Captured Bipolar Unipolar Trial Adapter	2



PIVOT SOLITUDE CAPTURED TRIAL KIT: 233-9002 BOTTOM LEVEL

NUMBER	ITEM #	DESCRIPTION	QUANTITY
31	215-0009	Hudson Large Female T-Handle	1
32	233-0401	Captured Bipolar Trial Shell Handle	2
33	233-0402	Captured Bipolar Trial Head Removal Tool	1
34	201-0018	Femoral Head Extractor	1
35	233-3001	Femoral Head Gauge	1
36	233-3002	Femoral Head Ring Gauge 38-45mm	1
37	233-3003	Femoral Head Ring Gauge 46-53mm	1
38	233-3004	Femoral Head Ring Gauge 54-60mm	1
	600-000	Instrument Case Lid	1
	233-6002	Pivot/Solitude Captured Trial Case	1



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.

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