

Bipolar II™ Cap

Hemi-Arthroplasty Hip System



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Device Description

Bipolar II Cap –

Bipolar II can be used in hemi-arthroplasty which is indicated in the case of femoral neck fracture, trauma, and the early-stage avascular necrosis when the acetabulum remains intact.

INDICATIONS

U2 Bipolar Implant is intended for use in combination with UNITED Femoral System for cemented or cementless hemi-arthroplasty. This device may be used for the following conditions:

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia.
2. Inflammatory degenerative joint disease such as rheumatoid arthritis.
3. Correction of function deformity.
4. Revision procedures where other treatments or devices have failed.
5. Treatment of nonunion, femoral neck, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Please refer to the package inserts for important product information, including, but not limited to contraindications, warnings, precautions, and adverse effects.



Product Overview

- Metal surface roughness of $Ra \leq 0.02 \mu\text{m}$ exceeds the ISO Standard of $Ra \leq 0.5 \mu\text{m}$

Highly Polished Surface

- Designed to reduce the wear of the acetabulum

Anti-rotation Design

- Minimizes micromotion between the cap and the PE liner

Outer Beveled Lip Design

- Allows for easy reduction

One-piece Assembly with Simple Locking Ring Mechanism

- Designed to allow surgical efficiency while maintaining strength

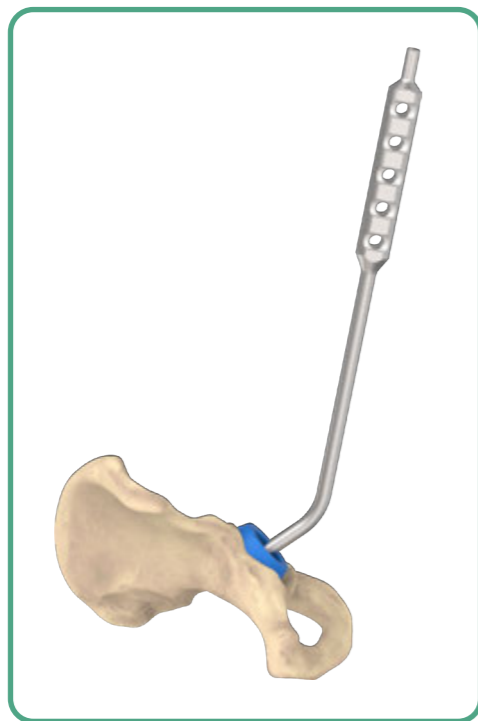
- Minimum polyethylene thickness of 5 mm

Bipolar II Cap and Femoral Head Compatibility Chart

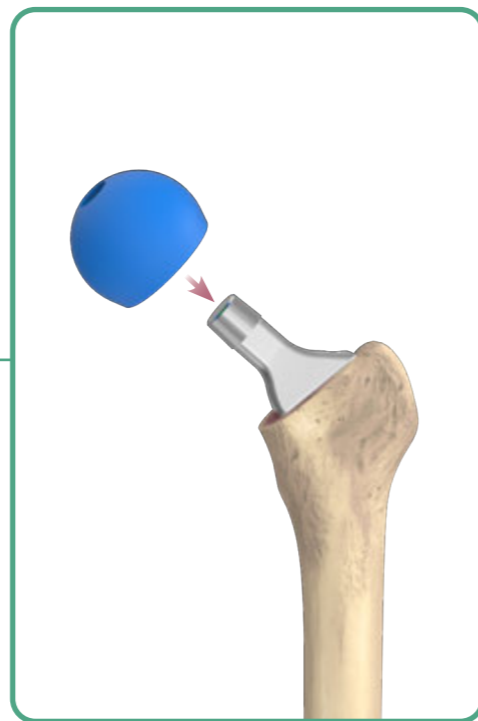


Outer Diameter	Head size
38 mm	22 mm
39 mm	
40 mm	
41 mm	22 or 26 mm
42 mm	
43 mm	28 mm
44 mm	
45 mm	
46 mm	
47 mm	
48 mm	
49 mm	
50 mm	
51 mm	
52 mm	
53 mm	
54 mm	
55 mm	
56 mm	
58 mm	
60 mm	

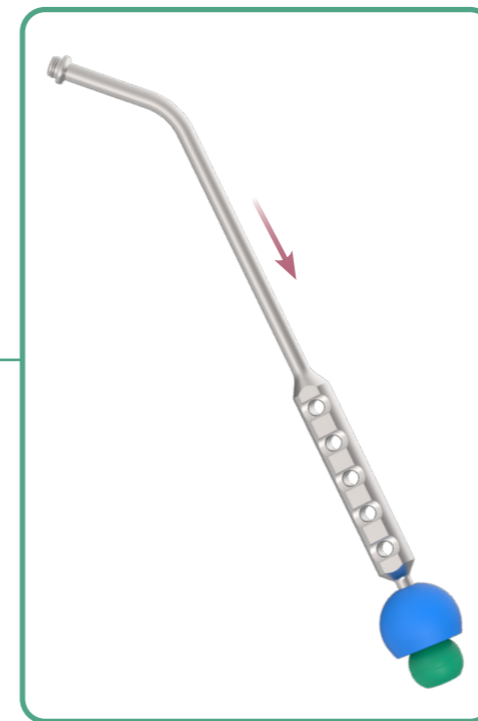
Surgical Overview



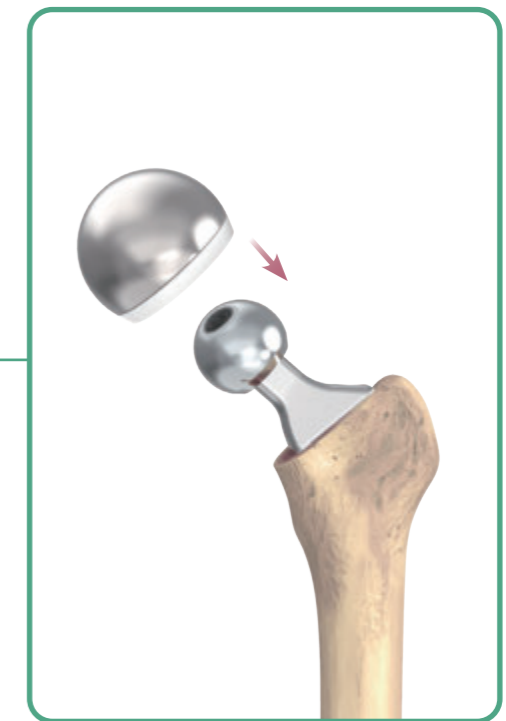
A. Size the Acetabulum



B. Trial Assembly and Reduction



C. Trial Disassembly



D. Implant Assembly

A. Size the Acetabulum

Use the preoperative template or measure the excised femoral head to estimate acetabular size.

Assemble the **Bipolar Trial** to the **Bipolar Trial Handle** to measure the acetabular size. Ensure the **Bipolar Trial** fits in the patients' acetabulum.

The Bipolar II Cap is available in 1 mm increments from 38 mm to 56 mm, and 2 mm increments from 56 mm to 60 mm.



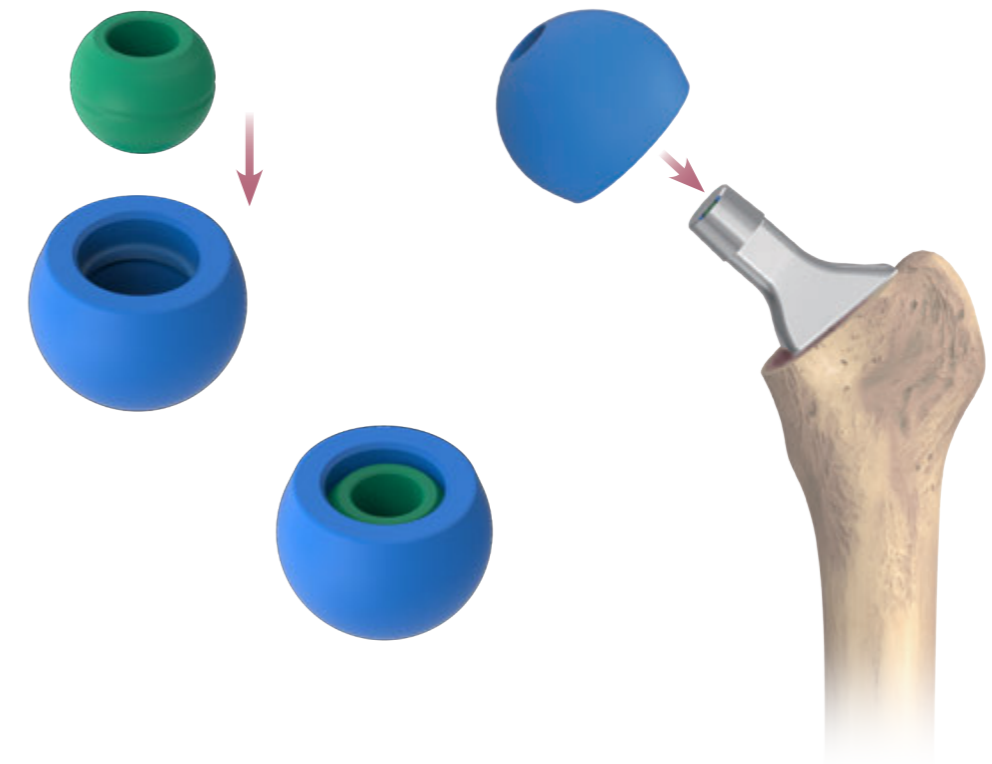
Instruments



Bipolar Trial Handle

B. Trial Assembly and Reduction

Assemble the corresponding size **Femoral Head Trial** to the **Bipolar Trial**. Connect it to the **Neck Trial** and perform the trial reduction.



Cup Trial Sizes (mm)	38, 39, 40	41, 42	43-60
Head Trial Sizes (mm)	22	22/26	28

Instruments



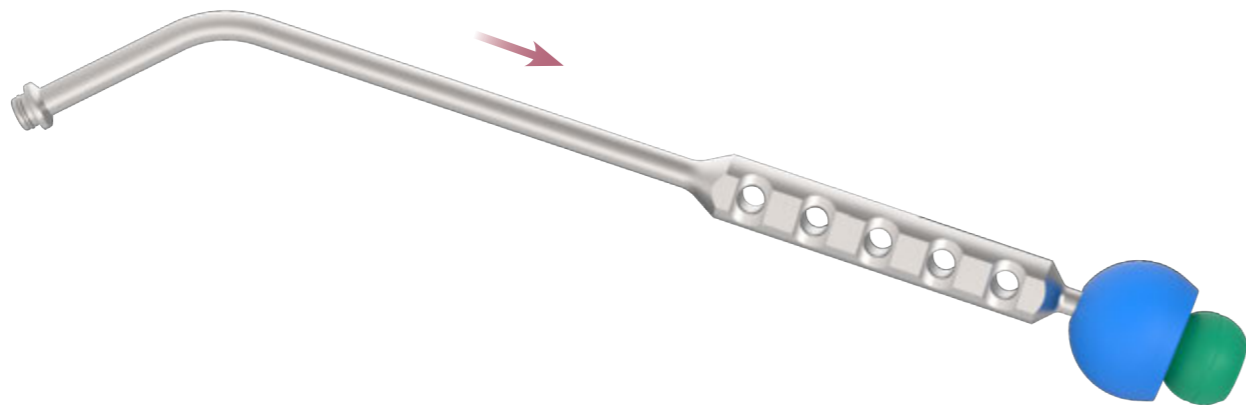
U2 Bipolar Trial



U2 Femoral Head Trial

C. Trial Disassembly

Insert the **Bipolar Trial Handle** tip into the outer portion of the threaded hole on the **Bipolar Trial** to disassemble the **Bipolar Trial** from the **Femoral Head Trial**.



Instruments



Bipolar Trial Handle



U2 Bipolar Trial

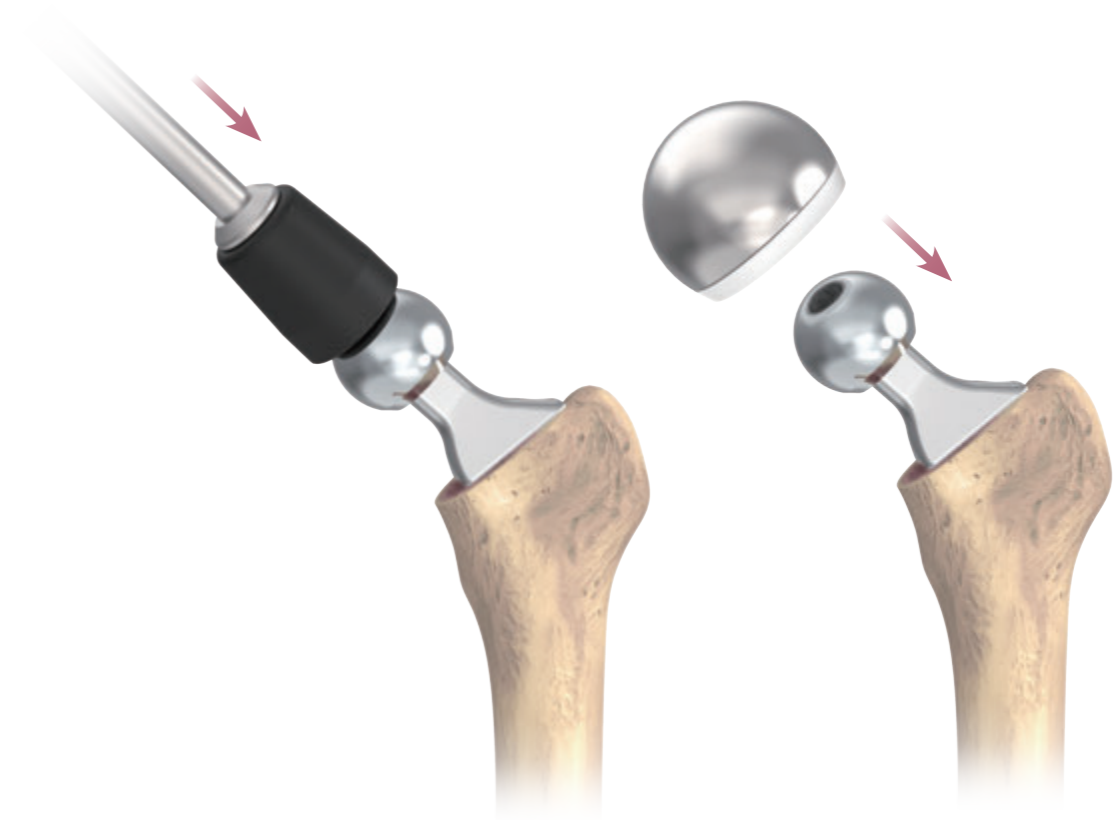


U2 Femoral Head Trial

D. Implant Assembly

Connect the **Femoral Head Impactor** to the **Universal Handle** and impact the femoral head until it is firmly seated.

Push the Bipolar II Cap onto the femoral head.



Instruments



Femoral Head Impactor

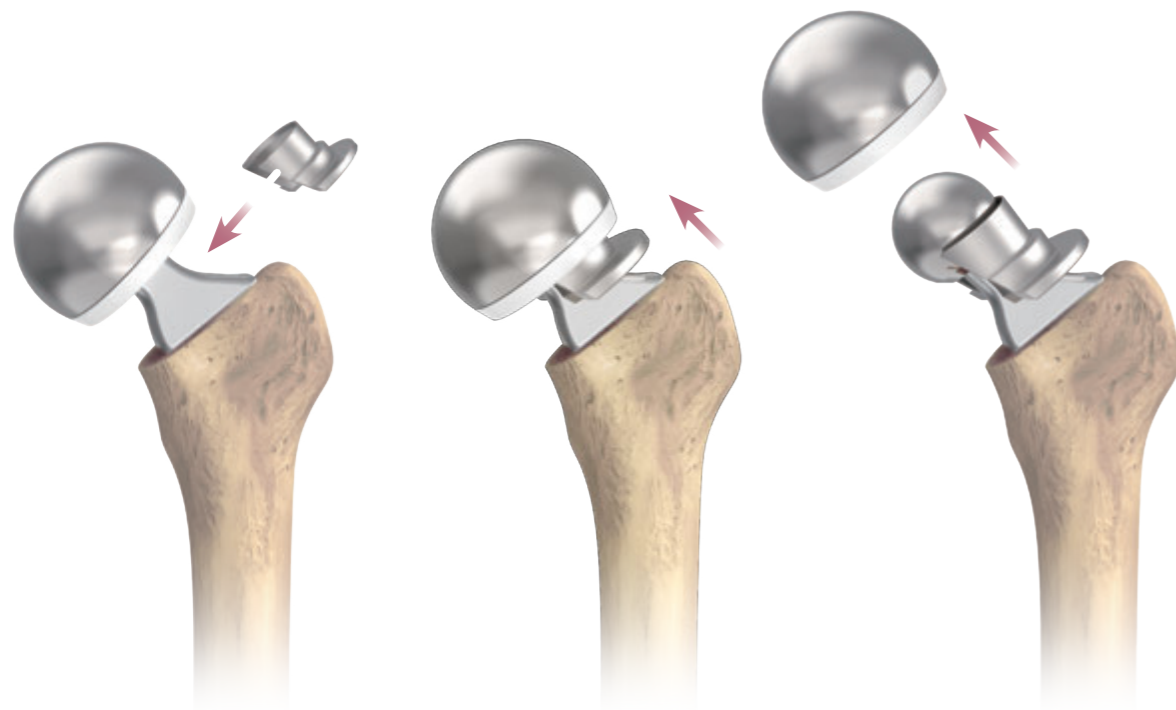


Universal Handle

Appendix

Implant Disassembly

Utilize the **Head Remover** to push the inner ring of Bipolar II Cap to disassemble the Bipolar II Cap from the femoral head.




Instruments





Head Remover

Order Information

Special Order Items

	Catalog Number	Outer Diameter	Inner Diameter
Bipolar II Cap 	1503 - 3338	38 mm	22 mm
	1503 - 3339	39 mm	22 mm
	1503 - 3340	40 mm	22 mm
	1503 - 3341	41 mm	22 mm
	1503 - 3342	42 mm	22 mm
	1503 - 3041	41 mm	26 mm
	1503 - 3042	42 mm	26 mm
	1503 - 3143	43 mm	28 mm
	1503 - 3144	44 mm	28 mm
	1503 - 3145	45 mm	28 mm
	1503 - 3146	46 mm	28 mm
	1503 - 3147	47 mm	28 mm
	1503 - 3148	48 mm	28 mm
	1503 - 3149	49 mm	28 mm
	1503 - 3150	50 mm	28 mm
	1503 - 3151	51 mm	28 mm
1503 - 3152	52 mm	28 mm	
1503 - 3153	53 mm	28 mm	
1503 - 3154	54 mm	28 mm	
1503 - 3155	55 mm	28 mm	
1503 - 3156	56 mm	28 mm	
1503 - 3158	58 mm	28 mm	
1503 - 3160	60 mm	28 mm	

Order Information

	Catalog Number	Outer Diameter (mm)		
U2 Femoral Head 	1206 - 1122	* Ø 22		+ 0
	1206 - 1322	* Ø 22		+ 3
	1206 - 1522	* Ø 22		+ 6
	1206 - 1722	* Ø 22		+ 9
	1206 - 1026	Ø 26		- 2
	1206 - 1126	Ø 26		+ 0
	1206 - 1326	Ø 26		+ 3
	1206 - 1526	Ø 26		+ 6
	1206 - 1726	Ø 26		+ 9
	1206 - 1028	Ø 28		- 3
	1206 - 1128	Ø 28		+ 0
	1206 - 1228	Ø 28		+ 2.5
	1206 - 1428	Ø 28		+ 5
	1206 - 1628	Ø 28		+ 7.5
1206 - 1828	Ø 28		+ 10	
BIOLOX® delta Ceramic Head 	1203 - 5022	* Ø 22	S	+ 1
	1203 - 5222	* Ø 22	M	+ 3
	1203 - 5422	* Ø 22	L	+ 5
	1203 - 5028	Ø 28	S	- 2.5
	1203 - 5228	Ø 28	M	+ 1
1203 - 5428	Ø 28	L	+ 4	

* The actual spherical diameter of a 22 mm metal head is 22.2 mm.
*BIOLOX® is a registered trademark of the CeramTec Group, Germany

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