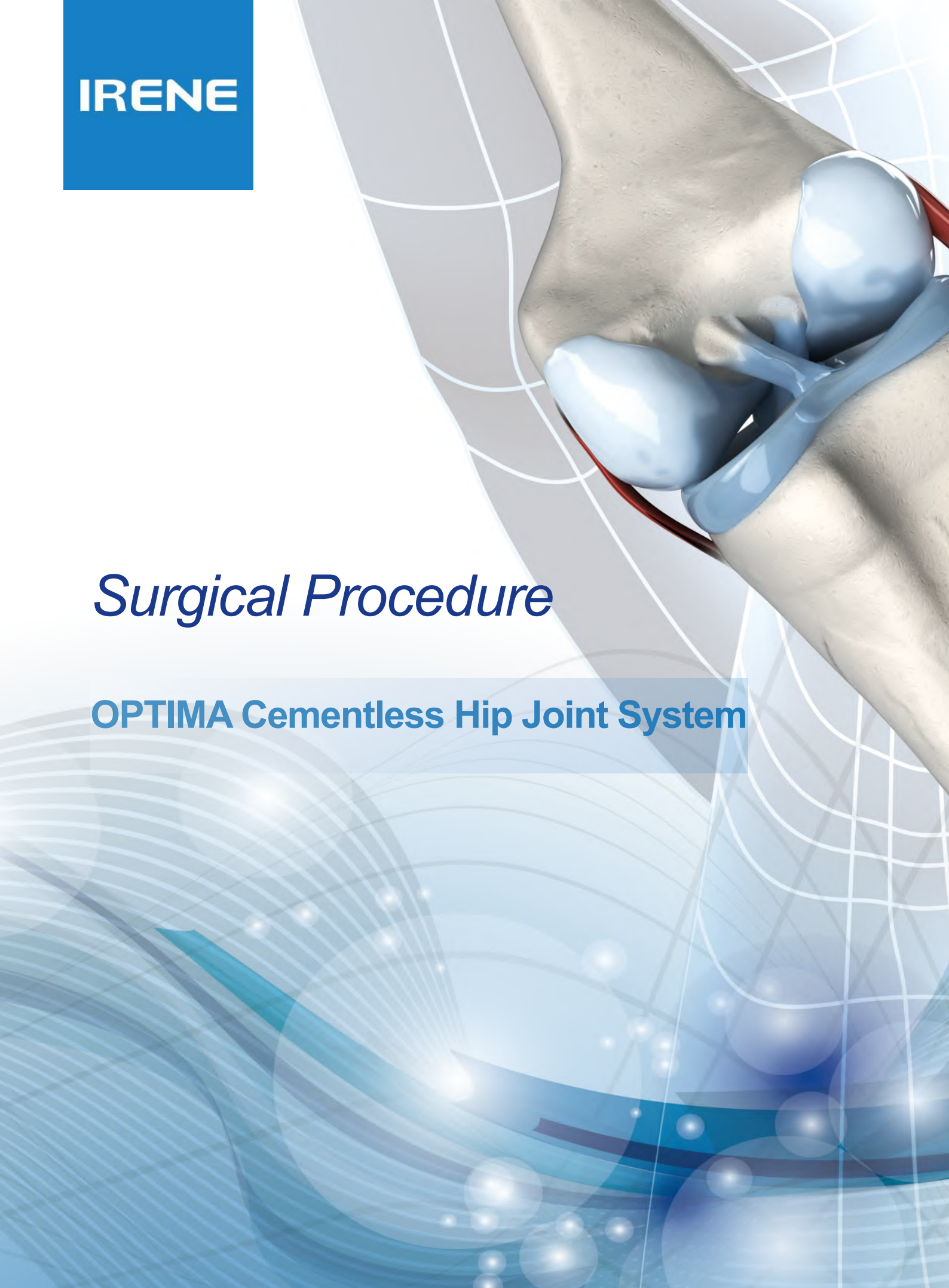


The image features a blue square in the top-left corner with the word "IRENE" in white. The background is a light blue and white grid pattern. On the right side, there is a detailed illustration of a human hip joint with a blue, cementless hip joint system. The system consists of a blue acetabular cup and a blue femoral head, which is connected to a blue femoral neck and a blue femoral shaft. The femoral head is shown in a position that suggests movement or stability. The overall design is clean and professional, typical of medical or surgical product documentation.

IRENE

Surgical Procedure

OPTIMA Cementless Hip Joint System

TianJin ZhengTian Medical Instrument Co., Ltd.
A Company of NATON Medical Group

Facility

Add: 318, Jingyi Road, Airport Economic Zone, TianJin 300308, P.R.China
Website: <http://www.irene-ortho.com/>

Customer Services

Add: Bldg 1-C, Yonyou Software Park, No. 68 Beiqing Road, Haidian District,
Beijing, 100082, China
Website: <http://www.natongroup.com/>
Tel: +86 10 8229 2929

IRENE® is the registered brand name of TianJin ZhengTian Medical Instrument Co., Ltd.
DIAMOND™, OPTIMA™, NAVIGATOR™, PLATINUM™, Kylin™ and ACUTEC™ are
registered trademarks of TianJin ZhengTian Medical Instrument Co., Ltd.
Copyright ©2014 Naton Medical Group, or its affiliates. All rights reserved.

CONTENT

OPTIMA Cementless Hip Joint System

Product Features	1
Indications	4
Product Specification	5
Preoperative Preparation	7
Surgical Procedure	9
Instrument Specification	15

Product Features:

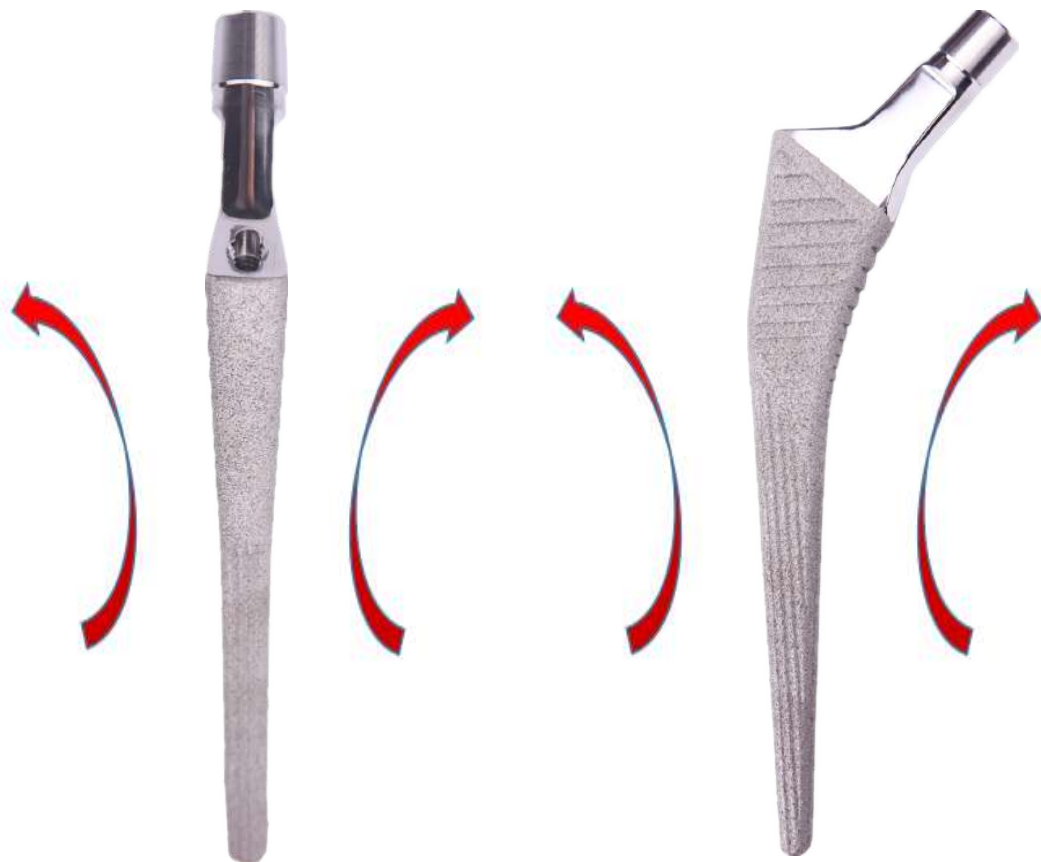
- Double Taper Design

Suitable for various femur types

Preserve more cancellous bones

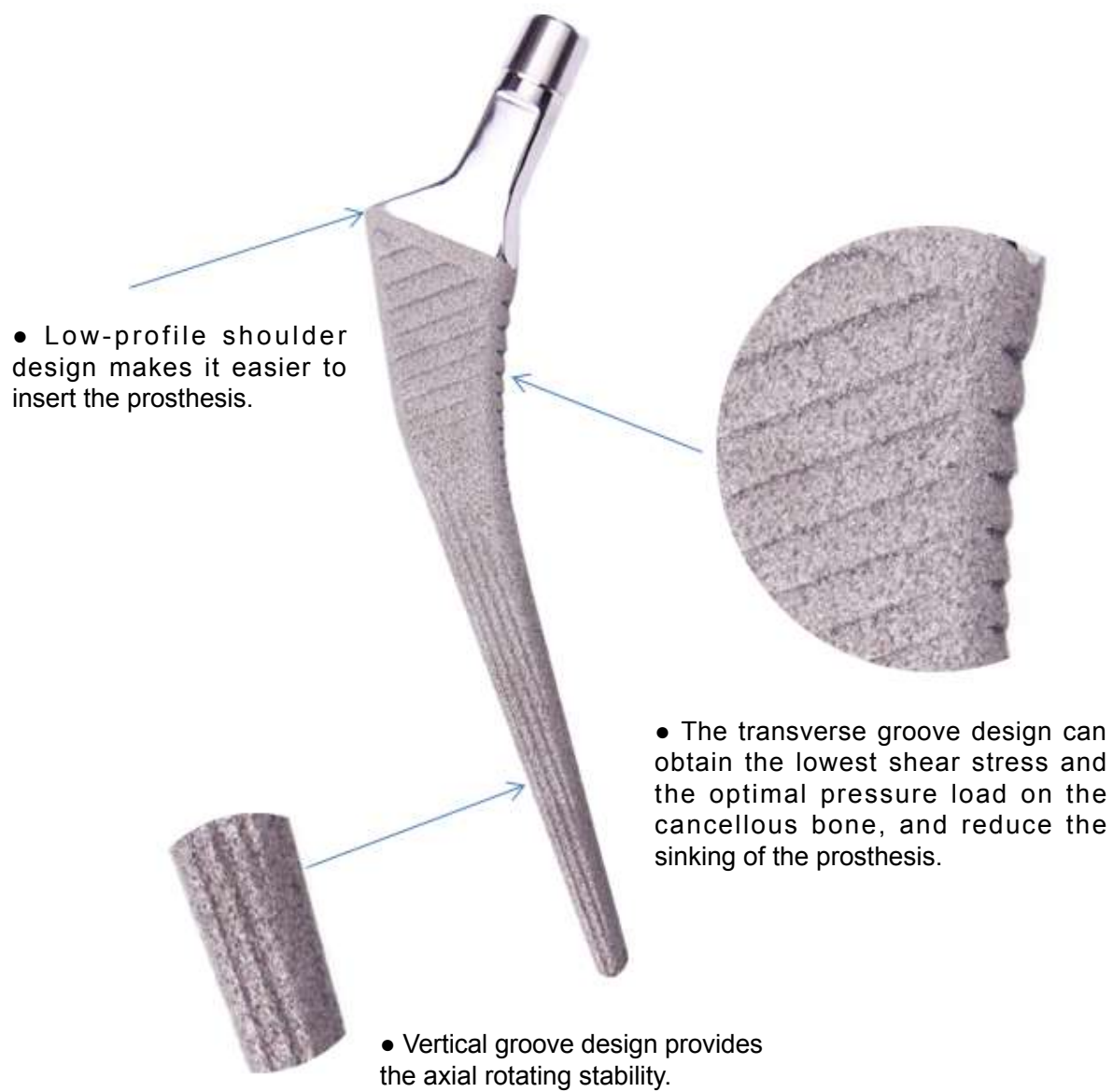
Preserve the blood transport of the endometrium

Good mode of bone remodeling



- The screw hole on the upper part of the prosthesis is designed to facilitate the removal of the prosthesis for revision surgery.





Product Indications:

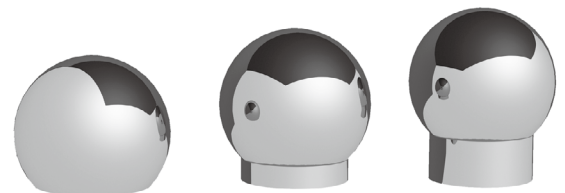
The OPTIMA Cementless Femoral Stem is Indicated for the primary total hip or hemi-arthroplasty.

OPTIMA™ Cementless Femoral Stem**Material:** Titanium Alloy (Ti6Al4V)**Matching Instrument:** B10000 Instrument Set for OPTIMA Cementless Stem System/B11000 Instrument Set for DIAMOND Bipolar System

Ref No. (Sterile)	Code	Stem Length (mm)	Distal Diameter (Φ)	Neck Angle	Offset (mm)	Taper
T25310008	8#	115	5.7	135°	38	12/14
T25310009	9#	130	5.1	135°	38.5	12/14
T25310010	10#	140	5.5	135°	39.5	12/14
T25310011	11#	145	6.5	135°	40	12/14
T25310012	12#	150	7.5	135°	41	12/14
T25310013	13#	155	8.4	135°	41.5	12/14
T25310014	14#	160	9.1	135°	42	12/14
T25310015	15#	165	10.0	135°	43	12/14
T25310016	16#	170	11.2	135°	43.5	12/14

DIAMOND™ Co-Cr-Mo Femoral Head**Material:** Co-Cr-Mo

Ref No. (Sterile)	Head Diameter (Φ)	Cervical Length (mm)
C32112400	24	0 (Standard)
C32112403	24	3.5
C32112801	28	1.5
C32112805	28	5 (Standard)
C32112808	28	8.5
C32112812	28	12
C32112815	28	15.5



CAUTION: DIAMOND™ Co-Cr-Mo Femoral Head cannot be used with femoral stems made of stainless steel.

DIAMOND™ Cementless Acetabular Cup

Material: Shell: Titanium Alloy(Ti6Al4V)
Liner: Polyethylene (UHMWPE)

Ref No. (Sterile)	Code	Outer Diameter (Φ)	Inner Diameter (Φ)
T27410044	44#	44	24
T27410046	46#	46	24
T27410048	48#	48	28
T27410050	50#	50	28
T27410052	52#	52	28
T27410054	54#	54	28
T27410056	56#	56	28
T27410058	58#	58	28
T27410060	60#	60	28



Note: 1. A standard package of DIAMOND™ Cementless Acetabular Cup includes one shell and one liner.
2. Inner diameter of DIAMOND™ Cementless Acetabular Cup corresponds with the diameter of its compatible head respectively.

DIAMOND™ Cementless Acetabular Cup Screw

Material: Titanium Alloy(Ti6Al4V)

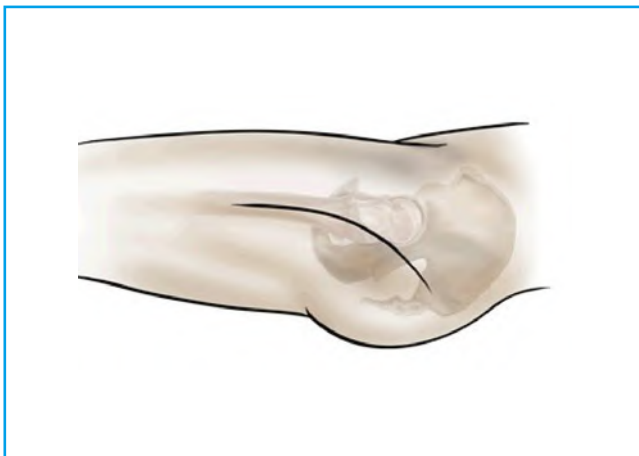
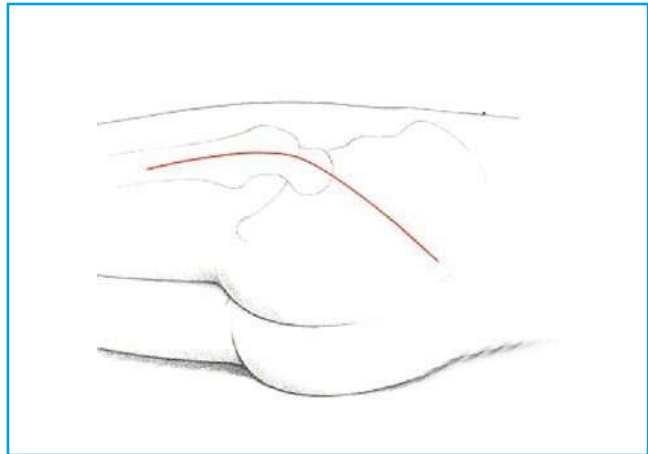
Ref No. (Sterile)	Specifications (Diameter×Length,mm)
T35006520	Φ6.5×20
T35006525	Φ6.5×25
T35006530	Φ6.5×30
T35006535	Φ6.5×35



Note: A standard package of DIAMOND™ Cementless Acetabular Cup Screw includes 1 pcs of screw.

Patient Position**(Using posterior approach)**

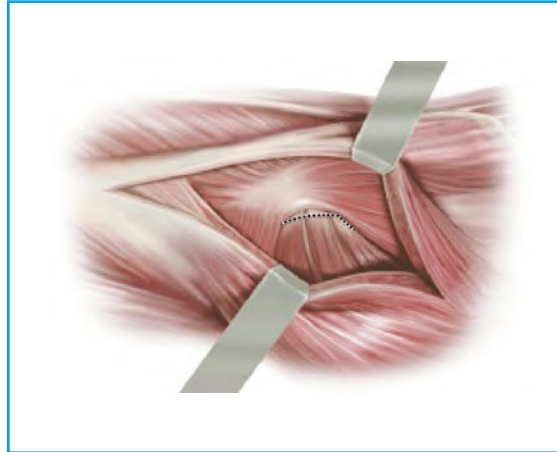
Place the patient in lateral position with the pathological leg on top. Place a mat under the axilla and restraint the patient from moving without obstructing limb circulation.

**Surgical Approach**

Make a 10cm incision from the end of posterior superior iliac spine running in the direction of the fibers of the gluteus maximus, extending to the posterior margin of greater trochanter then running down in the direction of long axis of femur for about 5cm.

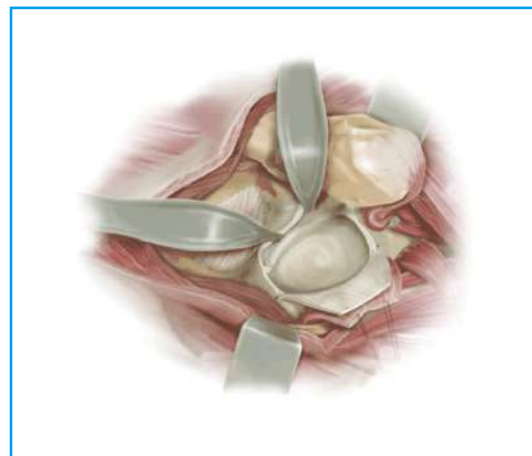
Surgical Procedure

Cut open the skin and underlying tissue then expose the external rotators. Take caution to protect the sciatic nerve.



Straighten the affected leg and detach the external rotators from greater trochanter, exposing the posterior joint capsule.

Dissect or resect the capsule at the rim of acetabulum and intertrochanter.





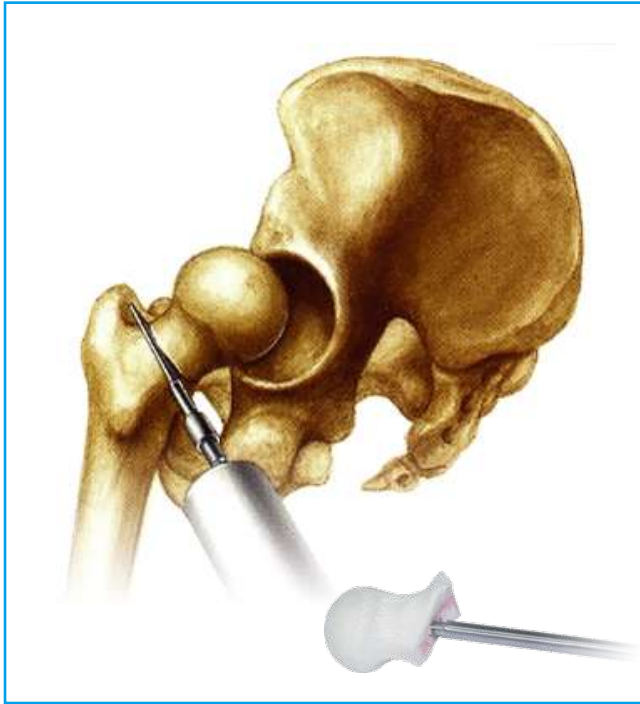
1. Dislocation of the Hip Joint

Dislocate the hip joint with a combination of movements of internal rotation, flexion and adduction.

2. Femoral Head Resection

Determine the resection level by aligning the top of the neck resection guide with the tip of the greater trochanter or by referencing a measured resection level 1-1.5cm above the lesser trochanter.



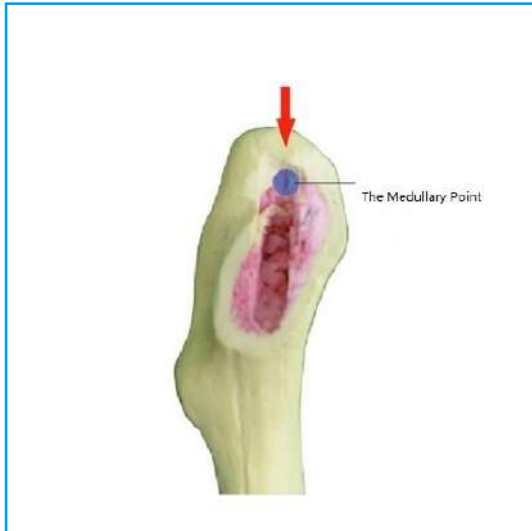


Mark the resection line using the electrocautery, then make a vertical osteotomy.

3. Femoral Preparation Medullary Canal Opening

Open the medullary canal using the Box Osteotome at the junction of the femoral neck and the greater trochanter.



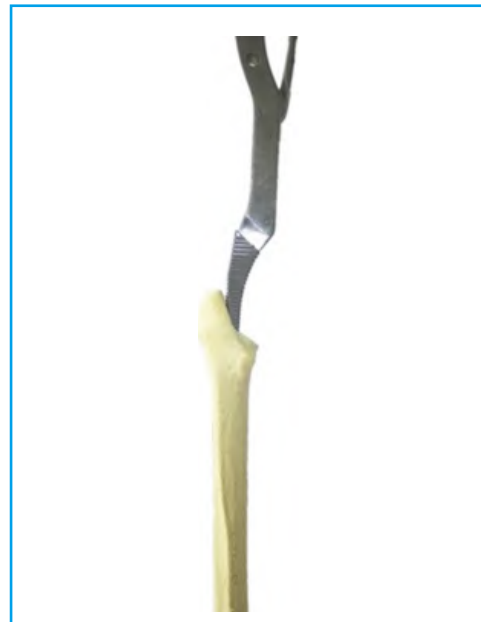


4. Femoral Canal Preparation

The correct medullary point and direction should be located in the anterior margin of the piriform fossa and along the medullary cavity direction, which is very important for the correct placement of the femoral prosthesis.

5. Femoral Broaching

Connect the Broach to the Broach handle, beginning with the smallest size, broaching should continue until complete stability is achieved with the last size broach.



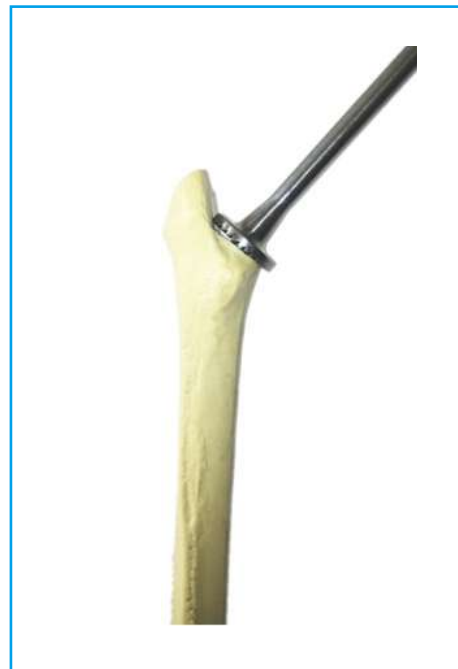


NOTE:

If it is difficult into the medullary cavity, recommend use Tapered Canal Probe grind bones

6. Calcar Planing

When the Broach cannot go forward and reach the axial stability, it can stop impact. The size of the required prosthesis can be determined at this point. (The Stem size = The Broach Size). Leave the correct broach in the medullary cavity and removed the handle, use Calcar Handle to mill Femoral osteotomy.

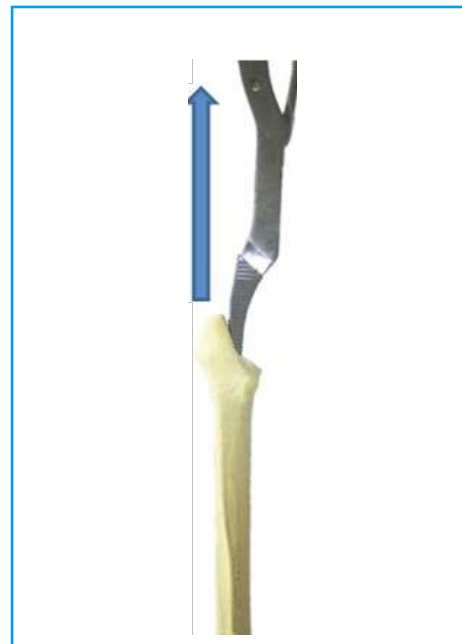




7. Trial Reduction

Assemble the corresponding trial head and trial neck segments with the broach. Perform trial reduction to evaluate joint stability. There should be no dislocation or impingement. (Hip Flexion 90°, adduction 20°, internal rotation 30°.)

The dislocation of the hip, carefully remove the broach from the medullary cavity, pay attention not to expanded the medullary cavity to keep the surface of the compression of cancellous bone in good condition & promote bone growth, it is not recommended to flush the medullary cavity.





8. Prosthesis Insertion

Choose the femoral stem corresponding to the broach and assemble it with the stem inserter. Insert the stem into the femoral canal while maintaining the correct anteversion. Advance the stem into position with moderate blows from the mallet.

9. Femoral Head Impaction

A final trial reduction is carried out to confirm joint stability and range of motion. Confirm the size of head, fully flush the hip and wipe clean the neck of prosthesis.

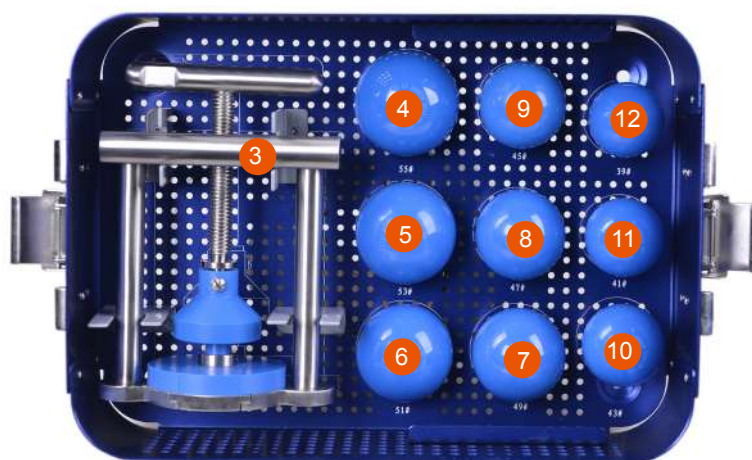
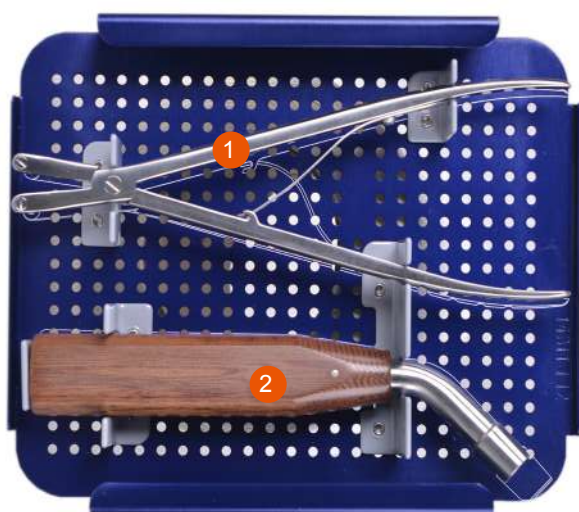
Install the femoral head, impact the femoral head using the femoral head impactor.





B10000 Instrument Set for OPTIMA Cementless Stem System

	Ref No.	Description	Specification (mm)	Qty
1	B05131	Broach for Optima Cementless Stem	16#	1
2	B05130	Broach for Optima Cementless Stem	15#	1
3	B05129	Broach for Optima Cementless Stem	14#	1
4	B05128	Broach for Optima Cementless Stem	13#	1
5	B05127	Broach for Optima Cementless Stem	12#	1
6	B05126	Broach for Optima Cementless Stem	11#	1
7	B05125	Broach for Optima Cementless Stem	10#	1
8	B05124	Broach for Optima Cementless Stem	9#	1
9	B05123	Broach for Optima Cementless Stem	8#	1
10	B08028	Hammer		1
11	B04009-1	Broach Handle		1
12	B08027	Universal T-Handle		1
13	B04009-2	Broach Handle Connector		1
14	B08001	Femoral Head Extractor		1
15	B08026	Femoral Head Impactor		1
16	B10003	Acetabular Retractor		1
17	B10001	Acetabular Retractor		1
18	B10002	Acetabular Retractor		1
19	B04001	Neck Resection Guide		1
20	B08009	Calcar Handle		1
21	B08002	Tapered Canal Probe		1
22	B05144	Calipers		1
23	B08010	Trial Femoral Head	24+0	1
24	B08011	Trial Femoral Head	24+3.5	1
25	B08012	Trial Femoral Head	28+1.5	1
26	B08013	Trial Femoral Head	28+5	1
27	B08014	Trial Femoral Head	28+8.5	1
28	B08015	Trial Femoral Head	28+12	1
29	B08016	Trial Femoral Head	28+15.5	1
30	B05122	Trial Neck		1
31	B04013-1	Stem Inserter-Handle		1
32	B04013-2	Stem Inserter-Shaft		1
33	B05120	Stem Inserter (Non-threaded)		1
34	B01002	Box Osteotome		1
	B10999	Instrument Box		1



B11000 Instrument Set for DIAMOND Bipolar System

	Ref No.	Description	Specification	Qty
1	B04021	Cling Ring Forceps		1
2	B04018	Detaching Handle		1
3	B04019	Bipolar Impactor		1
4	B08025	Trial Bipolar Head	55#	1
5	B08024	Trial Bipolar Head	53#	1
6	B08023	Trial Bipolar Head	51#	1
7	B08022	Trial Bipolar Head	49#	1
8	B08021	Trial Bipolar Head	47#	1
9	B08020	Trial Bipolar Head	45#	1
10	B08019	Trial Bipolar Head	43#	1
11	B08018	Trial Bipolar Head	41#	1
12	B08017	Trial Bipolar Head	39#	1
	B11999	Instrument Box		1



Joint System

IRENE

Reference No. VA-0060000

Version: 3.2

Copyright ©2014 Naton Medical Group, or its affiliates. All rights reserved.

Printed in China