



 **smith&nephew**
TANDEM[®] INTL
Bipolar and Unipolar Hip System

Design Rationale and Surgical Technique



Maximizing performance from every angle

Saving time in the operating room is one of the most valuable solutions Smith & Nephew can provide surgeons. The TANDEM INTL Bipolar/Unipolar Hip System dramatically increases efficiency with an easy-to-assemble bipolar design, one-tray instrumentation and a variety of operative options.

The TANDEM INTL Bipolar/Unipolar Hip System is the most comprehensive and effective partial hip system seen on the market in years, addressing performance from a multitude of angles. By integrating superior features into the new product design, the TANDEM INTL Bipolar minimizes wear, eliminates poly degradation caused by gamma irradiation and maximizes range of motion.

Introduction

David J. Jacofsky, M.D.

Mayo Clinic, Rochester, MN

Steven H. Stern, M.D.

Clinical Associate Professor of Orthopedic Surgery, Northwestern University, Northwestern Memorial Hospital

Hemiarthroplasty of the hip involves replacement of the diseased, affected, or broken femoral head and/or neck with a prosthetic component. Hemiarthroplasty does not involve resurfacing of the acetabulum, and therefore a bipolar or unipolar prosthetic head articulates against the host acetabular articular cartilage. Avoiding the need, when appropriate, to resurface the acetabulum helps to minimize surgical trauma, operative time and dislocation risk, while preserving acetabular bone stock.

Intracapsular hip fractures may be amenable to internal fixation in appropriately chosen patients. However, many fractures of the femoral head and femoral neck are unsuitable for internal fixation due to the patient's bone quality, fracture displacement, fracture chronicity, or pre-existing patient medical comorbidities. In these situations, pain relief, mobility, and patient outcome may be best served with prosthetic replacement. In addition, certain hip pathology outside traumatic indications may benefit from hemiarthroplasty of the hip.



TANDEM INTL Bipolar Hip System

Design Features



Superior Wear Performance

The TANDEM INTL Bipolar minimizes rotational and axial movement at the liner-shell interface by incorporating a preassembled polyethylene component into the shell.

In addition, the TANDEM INTL Bipolar meets the minimum requirement for polyethylene thickness as stated by Bartel,¹ incorporating a minimum of 5mm of polyethylene in a majority of sizes. Poly thickness, combined with the preassembled poly component, provides unmatched superior wear performance.

Unique Sterilization

To reduce the potential for degradation of the polyethylene liner, the TANDEM INTL Bipolar is EtO sterilized. This patent-pending feature eliminates the susceptibility of the liner to oxidation caused by gamma sterilization.

Maximum ROM

Smith & Nephew understands that range of motion (ROM) is not dependent upon neck design alone. The wide liner chamfer of the TANDEM INTL Bipolar, which is similar to the chamfer of REFLECTION[®] liners, allows maximum ROM when combined with Smith & Nephew stems. Internal testing has shown that the TANDEM INTL Bipolar design improves ROM over competitive offerings.²



	ROM	ID (mm)	OD (mm)	Neck Offset
TANDEM INTL	82°	28	51	+0
TANDEM INTL	88°	28	59	-3
Competitor A	70°	28	60	-3*
Competitor B	68°	28	58	-3.5
Competitor C	66°	28	51	+0

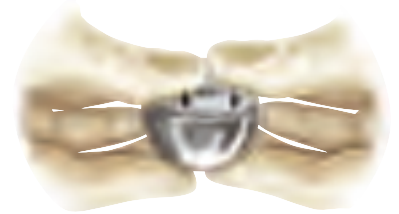
* Smith & Nephew femoral head used.

¹ Bartel, DL; Burstein, AH; Toda, MD; Edwards, DL: The effect of conformity and plastic thickness on contact stresses in metal-backed plastic implants. *J Biomech Eng.* 1985 Aug; 107(3):193-9.

² Smith & Nephew internal testing.

Easy Implant Assembly

To improve efficiency in the operating room, the TANDEM INTL Bipolar was designed for easy implant assembly, requiring no tools to assemble the bipolar component. The simple and quick assembly requires less than five pounds of finger pressure.



More Options

The TANDEM INTL Bipolar implants are designed to work with either 22 or 28mm femoral heads, depending on the outer diameter shell size. The 22mm femoral heads are offered in four neck lengths, ranging from +0 to +12mm. Available in six neck lengths, the 28mm ranges from -3 to +16mm.

The TANDEM INTL Bipolar is available in a variety of sizes, increasing operative options. The implants are offered in 38-42mm outer diameter sizes which use a 22mm inner head. The 28mm inner heads are coupled with the 43-55, 57, and 59mm sizes.

Unsurpassed Mechanical Strength

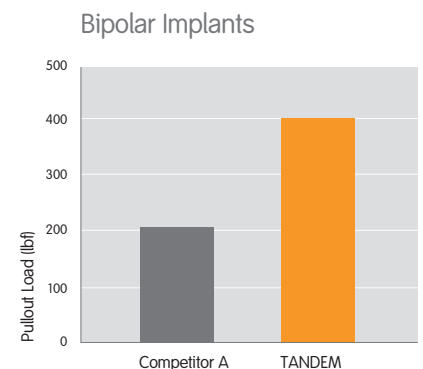
The strength characteristics of the TANDEM INTL Bipolar are superior to that of competitive designs. Internal testing shows that the TANDEM INTL Bipolar has average maximum pullout strength of 400 lbf. with a 28mm femoral head, which exceeds or meets the strength of tested competitive designs.²

Positive Eccentricity

The positive eccentricity in the TANDEM INTL Bipolar design aligns the femoral head with the joint reaction force of the body. The amount of eccentricity is varied based on inner and outer diameter dimensions of the bipolar component.

Biocompatible Material

The TANDEM INTL Bipolar is cast and machined out of standard cobalt-chrome material, a wear resistant and biocompatible material that has been used for years in medical device implants.



TANDEM Unipolar Hip System

Design Features

Flexibility

The TANDEM Unipolar provides a complete, yet streamlined, option for surgeons whose preference in partial hip replacement is a unipolar endoprosthesis.

The TANDEM Unipolar can be used with a variety of Smith & Nephew stems, providing independent sizing of the acetabulum and femur. If needed, this allows re-establishment of proper soft tissue tensioning and revision without stem removal.

Wear Resistant and Biocompatible

The TANDEM Unipolar head, made of solid cobalt chrome, a wear resistant and biocompatible material, is available in a range of OD sizes from 40-55, 57, 59, and 61mm.

Versatile

To achieve proper joint restoration, the taper sleeves are provided in five neck lengths ranging from -3 to +12mm.



TANDEM Instrumentation

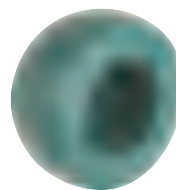
One-Tray Instrumentation

The simple, one-tray instrumentation design incorporates two trialing techniques into one system. Maximizing efficiency in the operating room, this design facilitates fast and easy trialing for either procedure.



TANDEM Trial Shells

Designed for dimensional stability, TANDEM Trial Shells perform accurately after repeated sterilization. In addition, the interchangeability of the femoral head trials (included in the femoral instrument set) and unipolar conversion sleeves with the trial shells increases the versatility of the instruments. The trial shells are also threaded for surgeons who prefer to perform a "suction" test.



TANDEM Unipolar Conversion Sleeves

TANDEM Unipolar Conversion Sleeves allow easy conversion of the trial shells into a unipolar trial quickly and efficiently. The sleeves snap directly into the trial shell and can be easily removed using the tip of the trial handle.



TANDEM Quick-Connect Trial Handle

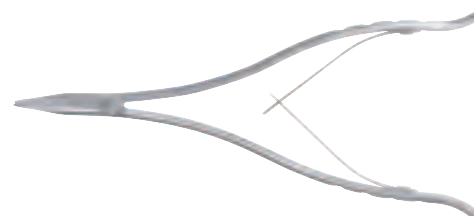
The TANDEM Quick-Connect Trial Handle (pictured) is designed to allow the trial shells to snap off quickly for a more efficient procedure and provides more visibility inside the wound.

A straight threaded trial handle is also available for surgeons who prefer additional security in their trialing technique.



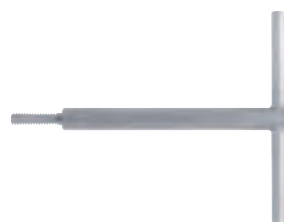
Ring Spreader

The Ring Spreader is used to disassemble the bipolar when there is a need to change femoral head neck lengths or for the removal of the bipolar component.



Unipolar Taper Sleeve Removal Tool

The Unipolar Taper Sleeve Removal Tool threads into the top portion of the taper sleeve and is used to release the taper sleeve from the stem neck.



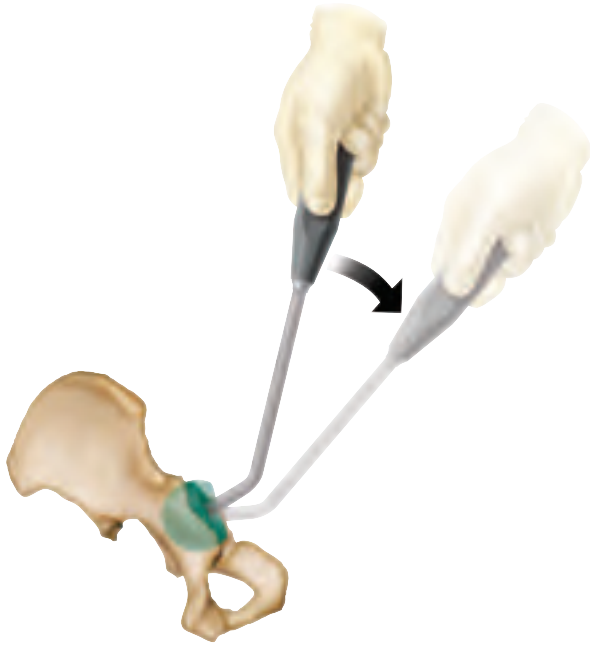
TANDEM INTL Bipolar Hip System

Surgical Technique

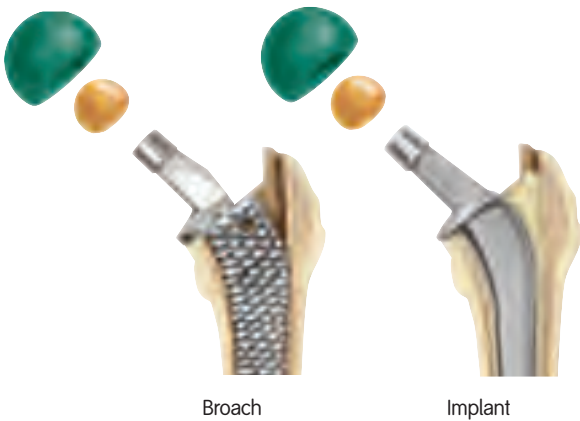
Acetabular Measurement

To estimate acetabular size, use preoperative templates or measure the excised femoral head with ID/OD gauges or calipers.

To determine implant size, acetabular measurement can be performed with TANDEM Trial Shells and the quick-connect trial handle. A straight threaded trial handle is also available.



Bipolar trial options



Broach and Implant Trialing

Follow the surgical technique for the Smith & Nephew femoral component to be used. Neck length trialing can be performed using TANDEM Trial Shells and 28mm trial femoral heads (included in the femoral instrument set).

Trialing can be performed off either the broach (using the appropriate trial neck) or the implant. Based on preoperative templating, select a trial head neck length and perform a trial reduction. Continue adjusting the trial femoral head neck length until proper leg length and joint stability are achieved.



Trial Removal

To remove the femoral trial head from the trial shell, insert the tip of either trial handle into the outer portion of the threaded hole of the trial shell.

Femoral Head Selection

For instrument simplicity, all bipolar trialing utilizes 28mm trial femoral heads.

A 22mm femoral head must be used with a 38-42mm OD. A 28mm femoral head requires 43mm and larger ODs.

TANDEM INTL Bipolar Selection

OD	ID Trial	ID Implant
38, 39mm	n/a	22mm
40-42mm	28mm	22mm
43-55mm	28mm	28mm
57, 59mm	28mm	28mm

Bipolar Assembly

The bipolar component (shell and liner) is packaged in one box. Place the appropriate diameter femoral head, corresponding to the outer diameter and appropriate neck length, into the preassembled metal-polyethylene bipolar shell.

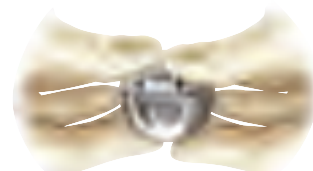
Place the polyethylene top-locking ring over the femoral head.

Making sure the poly ring is not tilted, ease the poly locking ring into the shell. **Using finger pressure, gently press down on the poly lock ring until an audible click is heard.**

The poly locking ring should be flush with the metal shell.



“Click”



TANDEM INTL Bipolar Hip System

Surgical Technique



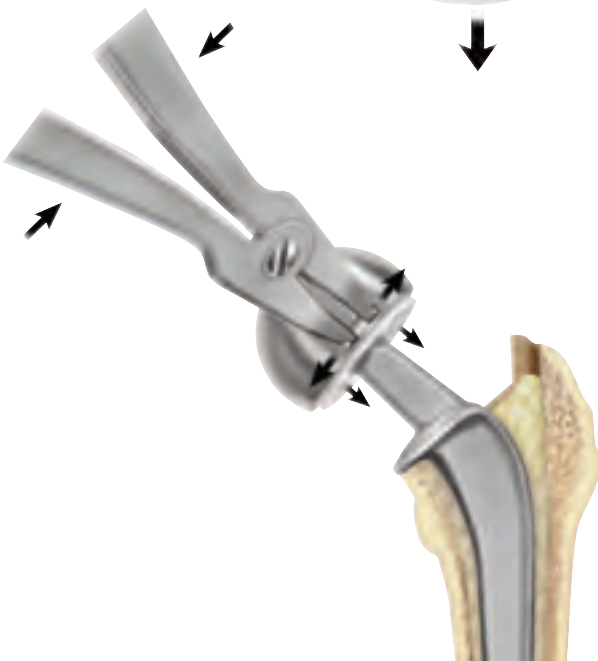
Implant Assembly

Clean and dry the stem taper. Place the fully assembled bipolar onto the stem taper and tap with the femoral head impactor until secure.



Bipolar Disassembly: Back Table

Holding the assembled bipolar over a clean, secure surface, place the tip of the ring spreader into the disassembly slot of the bipolar component. By squeezing the handles of the ring spreader, the inner snap ring will expand, allowing the top poly ring to disengage. If necessary, gently shake the component until the poly ring is disengaged and the femoral head is released.



Bipolar Disassembly: *In Vivo*

Place the tip of the ring spreader into the disassembly slot of the bipolar component. Squeezing the handles of the ring spreader, slightly push in to release the retaining ring. While holding the retaining ring open, gently lift the bipolar metal shell until the top poly ring is disengaged.

TANDEM Unipolar Hip System

Surgical Technique

Acetabular Measurement

To estimate acetabular size, use preoperative templates or measure the excised femoral head with ID/OD gauge or calipers.

To determine implant size, acetabular measurement can be performed with TANDEM Trial Shells and the quick-connect trial handle. A straight threaded trial handle is also available.



Broach and Implant Trialing

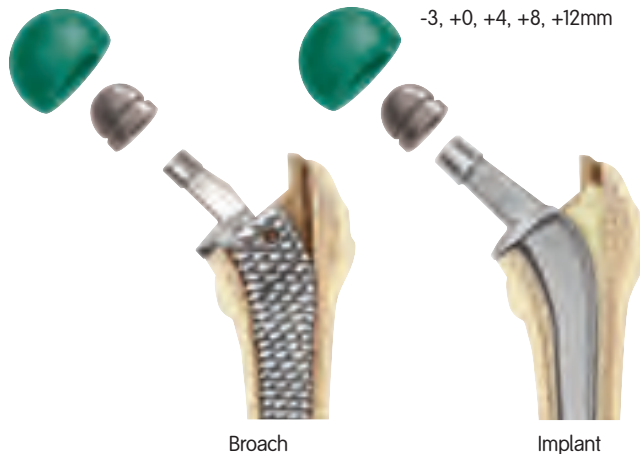
Follow the surgical technique for the Smith & Nephew femoral component to be used. Neck length trialing can be performed using TANDEM Trial Shells and TANDEM Unipolar Conversion Sleeves.

Trialing can be performed off either the broach (using the appropriate trial neck) or the implant. Based on preoperative templating, select the appropriate unipolar conversion sleeve and perform a trial reduction. Continue adjusting the unipolar conversion neck length until proper leg length and joint stability are achieved.

Unipolar trial options

Unipolar neck offset options

-3, +0, +4, +8, +12mm



Trial Removal

To remove the TANDEM Unipolar Conversion Sleeve from the trial shell, insert the tip of either trial handle into the outer portion of the threaded hole of the trial shell.



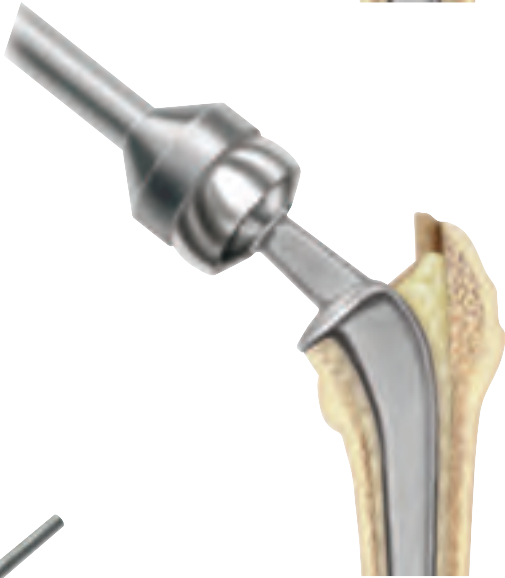
TANDEM Unipolar Hip System

Surgical Technique



Implant Assembly

Clean and dry the stem taper. Firmly place the taper sleeve on the femoral taper.



Clean and dry the taper sleeve and place the appropriate size unipolar head onto the sleeve. Impact with the femoral head impactor and mallet.

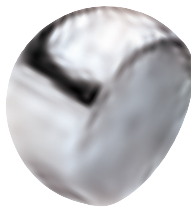


Implant Disassembly

After removing the unipolar head from the taper sleeve, thread the Unipolar Taper Sleeve Removal Tool into the top of the taper sleeve implant until it contacts the femoral taper. Continue turning until the sleeve separates from the stem.

Catalog

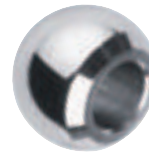
Implants



TANDEM INTL Bipolar Implant
(Cobalt Chrome/UHMWPE)



Cat. No.	Outer Diameter	Inner Diameter
7132-4038	38mm	22mm
7132-4039	39mm	22mm
7132-4040	40mm	22mm
7132-4041	41mm	22mm
7132-4042	42mm	22mm
7132-4043	43mm	28mm
7132-4044	44mm	28mm
7132-4045	45mm	28mm
7132-4046	46mm	28mm
7132-4047	47mm	28mm
7132-4048	48mm	28mm
7132-4049	49mm	28mm
7132-4050	50mm	28mm
7132-4051	51mm	28mm
7132-4052	52mm	28mm
7132-4053	53mm	28mm
7132-4054	54mm	28mm
7132-4055	55mm	28mm
7132-4057	57mm	28mm
7132-4059	59mm	28mm



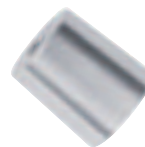
12/14 Taper Femoral Heads
(Cobalt Chrome)

Cat. No.	Outer Diameter	Neck Length
7130-2200	22mm	+0mm
7130-2204	22mm	+4mm
7130-2208	22mm	+8mm
7130-2212	22mm	+12mm
7130-2803	28mm	-3mm
7130-2800	28mm	+0mm
7130-2804	28mm	+4mm
7130-2808	28mm	+8mm
7130-2812	28mm	+12mm
7130-2816	28mm	+16mm



TANDEM Unipolar Implant
(Cobalt Chrome)

Cat. No.	Outer Diameter
12-6640	40mm
12-6641	41mm
12-6642	42mm
12-6643	43mm
12-6644	44mm
12-6645	45mm
12-6646	46mm
12-6647	47mm
12-6648	48mm
12-6649	49mm
12-6650	50mm
12-6651	51mm
12-6652	52mm
12-6653	53mm
12-6654	54mm
12-6655	55mm
12-6657	57mm
12-6659	59mm
12-6661	61mm

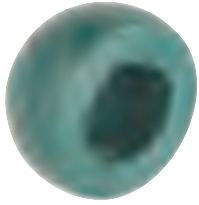


TANDEM Unipolar 12/14
Taper Sleeves

Cat. No.	Neck Length
7132-6603	-3mm
7132-6600	+0mm
7132-6604	+4mm
7132-6608	+8mm
7132-6612	+12mm

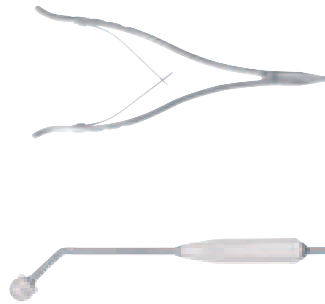
Catalog

Instruments



TANDEM Trial Shells

Cat. No.	Outer Diameter
7136-3040	40mm
7136-3041	41mm
7136-3042	42mm
7136-3043	43mm
7136-3044	44mm
7136-3045	45mm
7136-3046	46mm
7136-3047	47mm
7136-3048	48mm
7136-3049	49mm
7136-3050	50mm
7136-3051	51mm
7136-3052	52mm
7136-3053	53mm
7136-3054	54mm
7136-3055	55mm
7136-3057	57mm
7136-3059	59mm



Ring Spreader

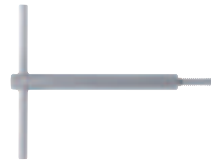
Cat. No. 7136-2802

TANDEM Quick-Connect Trial Handle

Cat. No. 7136-2803

TANDEM Straight Threaded Trial Handle (Not Shown)

Cat. No. 7136-2804



Unipolar Taper Sleeve Removal Tool

Cat. No. 11-6608

TANDEM Unipolar Conversion Sleeves



Cat. No.	Description
7136-7903	-3mm



7136-7900	+0mm
-----------	------



7136-7904	+4mm
-----------	------



7136-7908	+8mm
-----------	------



7136-7912	+12mm
-----------	-------



TANDEM Instrument Tray

Cat. No. 7136-2805



TANDEM Instrument Set

Cat. No. 7131-1002

TANDEM CoCr Bipolar
Implant Set (Not Shown)

Cat. No. 7131-9933

TANDEM CoCr Unipolar
Implant Set (Not Shown)

Cat. No. 7131-9916

Orthopaedics

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

www.smith-nephew.com

Telephone: 1-901-396-2121
Information: 1-800-821-5700
Orders/Inquiries: 1-800-238-7538