smith&nephew

TANDEM° INTL

Bipolar and Unipolar Hip System

Design Rationale and Surgical Technique

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

The TANDEM Bipolar/Unipolar Hip System addresses performance from a multitude of angles. By integrating features into the product design the TANDEM Bipolar reduces wear, minimizes poly debris and maximizes range of motion.[1]*

*Based on computer modelling

Nota Bene: The technique description herein is made available to the healthcare professional to illustrate the authors' suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the patient. For more information on any product referenced herein, including indications for use, contraindications, effects, precautions and warnings, please consult the product's Instructions for Use (IFU) prior to use.

Introduction

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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.

TANDEM® INTL Bipolar Hip System

Design Features

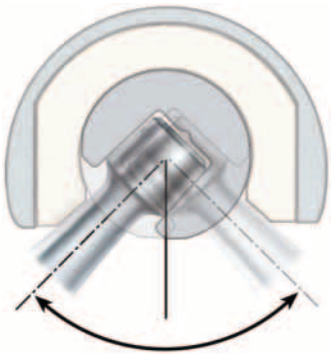
Wear Performance

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,[2] incorporating a minimum of 5mm of polyethylene in a majority of sizes. Poly thickness combined with the preassembled poly component and the anti-rotation feature is designed to minimize micromotion and thereby wear.

Unique Sterilization

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



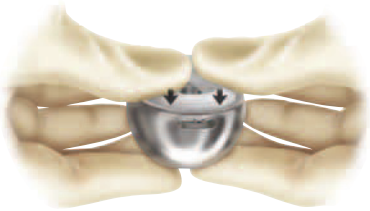
Maximum ROM

Smith & Nephew understands that range of motion (ROM) is not dependent upon neck design alone. The wide liner chamfer design of the TANDEM INTL Bipolar, which is similar to the chamfer of REFLECTION® liners, allows maximum ROM when combined with Smith & Nephew stems.[1]**

	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
** Based on computer modeling

Easy Implant Assembly



To improve efficiency in the operating room, the TANDEM® INTL Bipolar was designed for easy implant assembly,[3] 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. See Compatibility Information section for details regarding compatible femoral heads and femoral stems that can be used with TANDEM INTL Bipolar implants.

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 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.[3]

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. See Compatibility Information section for details regarding compatible femoral stems that can be used with TANDEM Unipolar implants.

The TANDEM Unipolar head is made of solid cobalt chrome. They are available in a range of OD sizes from 40-55, 57, and 61mm.

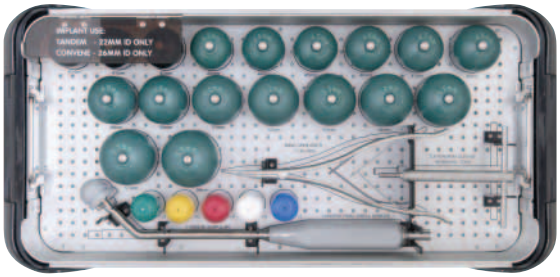
Versatile

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.[5] 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 are designed to be easily removed using the tip of the trial handle.

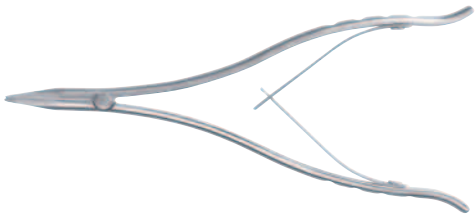
TANDEM Quick-Connect Trial Handle

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.

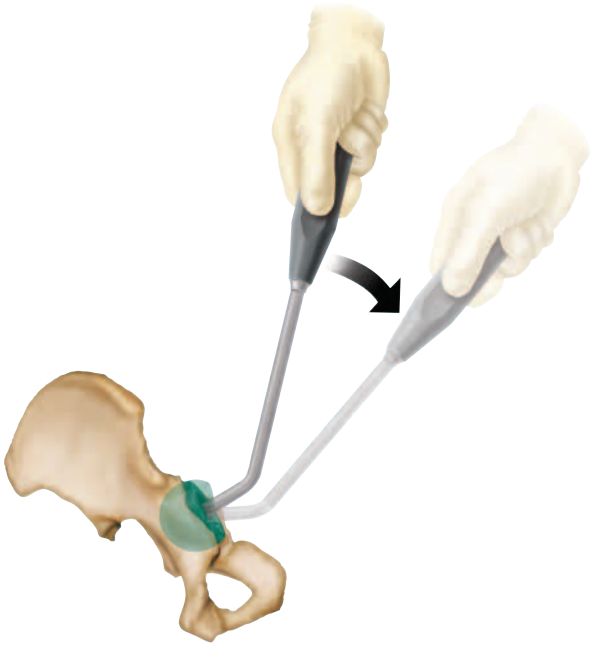


Unipolar Taper Sleeve Removal Tool

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

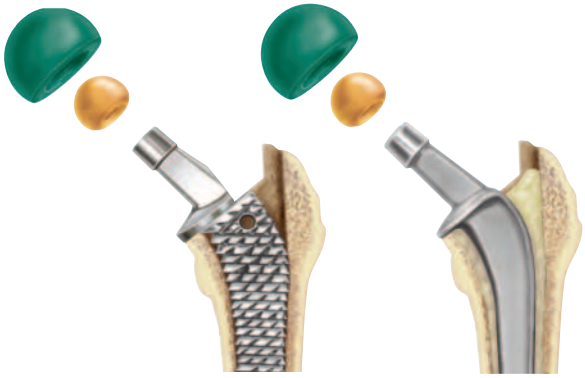


Acetabular Measurement

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 Implant

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.

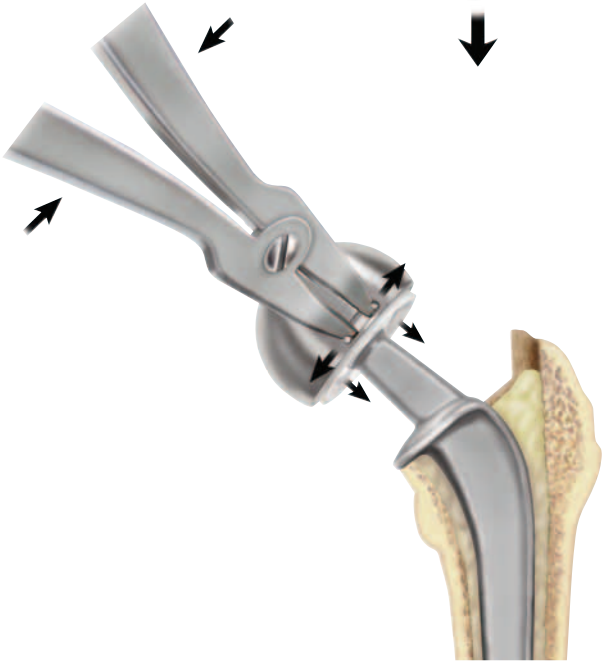
Surgical Technique

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

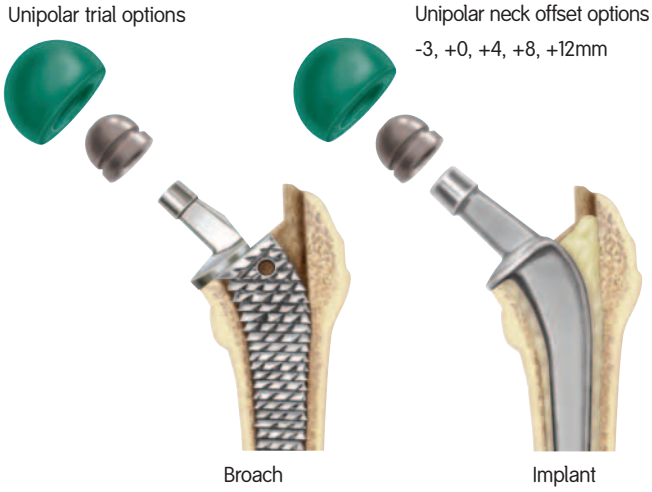
To estimate acetabular size, use preoperative templates or measure the excised femoral head with ID/OD gauge or calipers.

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.



Trial Removal

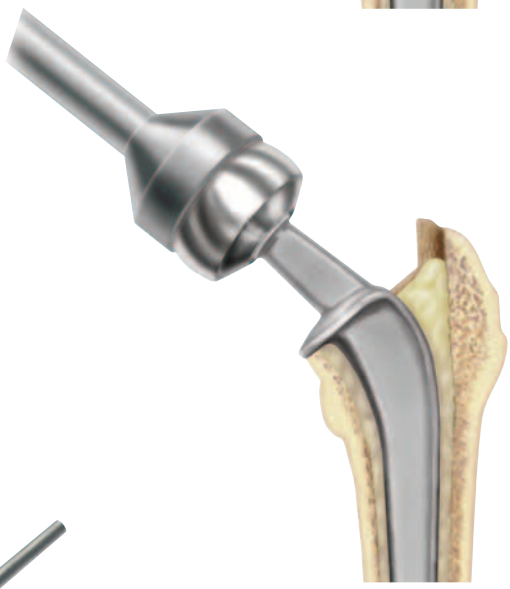
To remove the TANDEM Unipolar Conversion Sleeve from the trial shell, insert the tip of either trial handle into the outer portion of the threaded hole of the trial shell.

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
71324038	38mm	22mm
71324039	39mm	22mm
71324040	40mm	22mm
71324041	41mm	22mm
71324042	42mm	22mm
71324043	43mm	28mm
71324044	44mm	28mm
71324045	45mm	28mm
71324046	46mm	28mm
71324047	47mm	28mm
71324048	48mm	28mm
71324049	49mm	28mm
71324050	50mm	28mm
71324051	51mm	28mm
71324052	52mm	28mm
71324053	53mm	28mm
71324054	54mm	28mm
71324055	55mm	28mm
71324057	57mm	28mm
71324059	59mm	28mm

TANDEM Unipolar 12/14 Taper Sleeves

Cat. No.	Neck Length
71326603	-3mm
71326600	+0mm
71326604	+4mm
71326608	+8mm
71326612	+12mm

TANDEM Unipolar Implant (Cobalt Chrome)

Cat. No.	Outer Diameter
126640	40mm
126641	41mm
126642	42mm
126643	43mm
126644	44mm
126645	45mm
126646	46mm
126647	47mm
126648	48mm
126649	49mm
126650	50mm
126651	51mm
126652	52mm
126653	53mm
126654	54mm
126655	55mm
126657	57mm
126659	59mm
126661	61mm

12/14 Taper Femoral Heads (Cobalt Chrome)

Cat. No.	Outer Diameter	Neck Length
71302200	22mm	+0mm
71302204	22mm	+4mm
71302208	22mm	+8mm
71302212	22mm	+12mm
71302600	26mm	+0mm
71302604	26mm	+4mm
71302608	26mm	+8mm
71302612	26mm	+12mm
71302803	28mm	-3mm
71302800	28mm	+0mm
71302804	28mm	+4mm
71302808	28mm	+8mm
71302812	28mm	+12mm
71302816	28mm	+16mm

12/14 Taper Femoral Heads (OXINIUM®)

Cat. No.	Outer Diameter	Neck Length
71342200	22mm	+0mm
71342204	22mm	+4mm
71342208	22mm	+8mm
71342212	22mm	+12mm
71342600	26mm	+0mm
71342604	26mm	+4mm
71342608	26mm	+8mm
71342612	26mm	+12mm
71342803	28mm	-3mm
71342800	28mm	+0mm
71342804	28mm	+4mm
71342808	28mm	+8mm
71342812	28mm	+12mm
71342816	28mm	+16mm

Catalog

Instruments

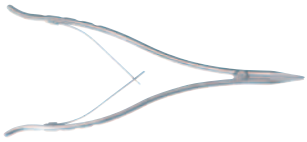
TANDEM® Trial Shells

Cat. No.	Outer Diameter
71363040	40mm
71363041	41mm
71363042	42mm
71363043	43mm
71363044	44mm
71363045	45mm
71363046	46mm
71363047	47mm
71363048	48mm
71363049	49mm
71363050	50mm
71363051	51mm
71363052	52mm
71363053	53mm
71363054	54mm
71363055	55mm
71363057	57mm
71363059	59mm

TANDEM Unipolar Conversion Sleeves

	Cat. No.	Description
	71367903	-3mm
	71367900	+0mm
	71367904	+4mm
	71367908	+8mm
	71367912	+12mm

Ring Spreader



Cat. No. 71362802

TANDEM Quick-Connect Trial Handle

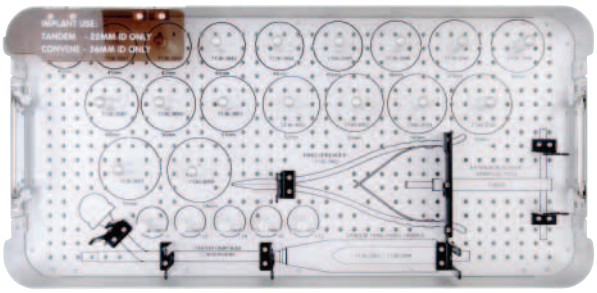
Cat. No. 71362803

TANDEM Straight Threaded Trial Handle (Not Shown)

Cat. No. 71362804

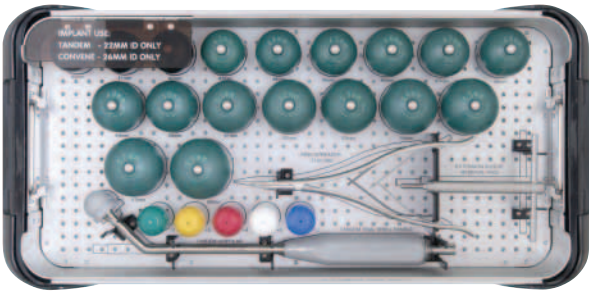
Unipolar Taper Sleeve Removal Tool

Cat. No. 116608



TANDEM® Instrument Tray

Cat. No. 71362805



TANDEM Instrument Set

Cat. No. 71311002

TANDEM CoCr Bipolar Implant Set (Not Shown)

Cat. No. 71319933

TANDEM CoCr Unipolar Implant Set (Not Shown)

Cat. No. 71319916

Implant Compatibility

TANDEM® Bipolar Hip System

Femoral Heads

Cobalt Chrome
12/14 Femoral Head

Cobalt Chrome
10/12 Femoral Head

Cobalt Chrome
14/16 Femoral Head

OXINIUM®
12/14 Femoral Head

OXINIUM
10/12 Femoral Head

Stems

SPECTRON® EF Stems
Primary and Revision

REDAPT® Stems*

ANTHOLOGY® Stems

CPCS® Stems
Cobalt Chrome
Molybdenum

POLARSTEM®
Cemented Stems*

POLARSTEM
Cementless Stems*

SL-PLUS® MIA
INTEGRATION-PLUS®
Cementless Stem**

SL-PLUS®
INTEGRATION-PLUS®
Cementless Stem*

TANDEM Unipolar Hip System

Unipolar Component

OXINIUM
Unipolar

Cobalt Chrome
Unipolar

Stems

SPECTRON® EF Stems
Primary and Revision

REDAPT® Stems*

ANTHOLOGY® Stems

CPCS® Stems
Cobalt Chrome
Molybdenum

POLARSTEM®
Cemented Stems*

SL-PLUS® MIA
INTEGRATION-PLUS®
Cementless Stem**

SL-PLUS®
INTEGRATION-PLUS®
Cementless Stem*

SL-PLUS® MIA

Taper Sleeves

Titanium
Unipolar Sleeve

Note: Please refer to your local Smith & Nephew representative to confirm the approval status in your country or region if you have any questions about how Smith & Nephew products can be used.

*This device combination is not approved for use in the European Union
** Size 01 femoral stems are not compatible with +16 offset femoral heads or with TANDEM® INTL Bipolar implants
***10/12 not sold in the EU
†40mm and 44mm heads must be used with Ti Sleeves to convert to a compatible 12/14 taper

Smith & Nephew no longer offers 14/16 tapered stems, however the 14/16 Ti Sleeve option is offered with TANDEM Unipolar system in the event there is a revision case where the patient has a Smith & Nephew stem with a 14/16 taper and the surgeon wants to keep the stem in place.

TANDEM® Component Size Compatibility

TANDEM Bipolar System			
TANDEM Bipolar Implant assembly	**Compatible Component: Stem**	**Compatible Component: Femoral Head**	**Femoral Head Size**
TANDEM INTL Bipolar Shell (CoCr) + UHMWPE Liner **TANDEM Bipolar** Shell (CoCr)+ XLPE Liner	SPECTRON® EF Stems Primary and Revision REDAPT® Stems* ANTHOLOGY® Stems CPCS® Stems Cobalt Chrome Molybdenum POLARSTEM® Cemented Stems* POLARSTEM Cementless Stems** SL-PLUS® MIA INTEGRATION-PLUS® Cementless Stem** SL-PLUS® INTEGRATION-PLUS® Cementless Stem*	OXINIUM® 12/14 CoCr 12/14 OXINIUM 10/12*** CoCr 10/12***	22mm, 28mm
		CoCr 14/16	28mm

TANDEM Unipolar System		
Compatible Component: Stem	**Compatible Component: Unipolar Component**	**Unipolar Component Size**
SPECTRON EF Stems Primary and Revision REDAPT Stems* ANTHOLOGY Stems CPCS Stems Cobalt Chrome Molybdenum POLARSTEM Cementless Stems* SL-PLUS MIA INTEGRATION-PLUS Cementless Stem** SL-PLUS INTEGRATION-PLUS® Cementless Stem* SL-PLUS MIA	OXINIUM Unipolar	40-55mm†
	CoCr Unipolar	40-55mm†, 57mm, 59mm, 61mm
	Titanium Unipolar Sleeve 12/14	-3, +0, +4, +8, +12

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In the above tables either of the selected Bipolar Implant assemblies are compatible with any choice of listed stem and femoral head.

Notes

Reference

1. Barrack R, Thornberry R, Ries M, Lavernia C, Tozakoglou E. The Effect of Component Design on Range of Motion to Impingement in Total Hip Arthroplasty. Instr Course Lect. 2001;50:275 - 280
2. Bartel DL, Burstein AH, Toda M, Edwards D. The effect of conformity and plastic thickness on contact stresses in metal-backed plastic implants. J Biomech Eng. 1985;107(3):193-9.
3. Smith+Nephew 2003. Instrument Validation Summary. Internal Report.
4. Smith+Nephew 2002. Pull-Out, Shuck-Out, and Torsion-To-Failure Testing of the Global Bipolar Acetabular System. Internal Report. OR-02-091
5. Smith+Nephew 2002. Effect of Autoclaving on the Dimensional Stability of the Global Bipolar Trial Retainer Ring. Internal Report. OR-02-085

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Smith & Nephew representative or distributor if you have questions about the availability of Smith & Nephew products in your area.

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