Design Rationale

smith&nephew

EMPERION◇

Modular Hip System

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Advanced simplicity

The EMPERION® Modular Hip System is the next step in hip evolution: a simpler yet more versatile hip system that delivers enhanced performance. The EMPERION Modular Hip System accomplishes this by building on a proven design concept with modern innovative technology.

The design philosophy behind the EMPERION system is based on achieving proximal loading and fixation. The system modularity allows for optimal implant sizing in those femurs with proximal/distal mismatches.

System overview

Hip anatomy varies from patient to patient. The EMPERION Modular Hip System has been designed to address the different anatomical variants that a surgeon may encounter during either primary or revision hip arthroplasty.

The EMPERION Modular Hip System has two major implant components: the 'stem' and the 'sleeve.' By mixing and matching these components, the surgeon can construct an implant that meets the needs of nearly every femoral variant that will be encountered during hip arthroplasty. Independent sizing of the proximal femur for the sleeve and the distal femur for the stem allows the surgeon to 'customize' an implant specific to the femoral anatomy. In the event of proximal and distal mismatch, the independent sizing and modularity allow for optimization of both components. Furthermore, the infinite version control of the stem allows the surgeon to align the femoral head and neck to minimize dislocation and impingement, as well as to address possible issues associated with hip dysplasia.

Stem

The EMPERION® Modular Hip System is designed with a polished cylindrical stem, optimized neck geometry, progressive offset options, distal flutes, coronal slot and a polished bullet tip. Thus, the EMPERION stem design is intended to promote stem stability while minimizing stress-shielding, micromotion, stiffness and thigh pain.

Sizing
The sizing and terminology of the EMPERION stems were planned with simplicity in mind. The instruments are designed to allow the surgeon to implant the same size stem as the last reamer used. Thus, if the surgeon reams to 15 millimeters then a size 15 stem should be implanted. Each stem is oversized by 0.5mm as compared to the final reamer size in order to achieve an appropriate press-fit. The entire technique and procedure is then based off the distal stem diameter

The EMPERION stems are available in sizes ranging from nine to 23 millimeters in two-millimeter increments. For most stem sizes, there are three stem lengths available: primary, standard revision and long revision (bowed). Each primary stem has two different offsets available. Because of the special needs in revision procedures, the revision stems are only available with the high offset option. In addition, the revision stems have a neutral proximal body option and a +10 calcar replacement option. The long revision stems have a neutral option, a +10, and a +20 calcar replacement option available. See the table on the next page for various options available for each diameter stem.

Note The primary length stems can be used in revision surgeries, if the surgeon determines it is appropriate.

Primary stem options

Distal diameter	Length (mm)	Offset options
9	140	RO, SO
11	140	SO, HO
13	150	SO, HO
15	150	SO, HO
17	160	SO, HO
19	160	SO, HO

RO = Reduced offset
SO = Standard offset
HO = High offset

13mm primary stem

Revision stem options – standard revision

Distal diameter	Length (mm)	Neck calcar options
11	180	Neutral, +10
13	190	Neutral, +10
15	190	Neutral, +10
17	200	Neutral, +10
19	200	Neutral, +10
21	200	Neutral, +10
23	200	Neutral, +10

13mm standard revision stem

Revision stem options – long revision

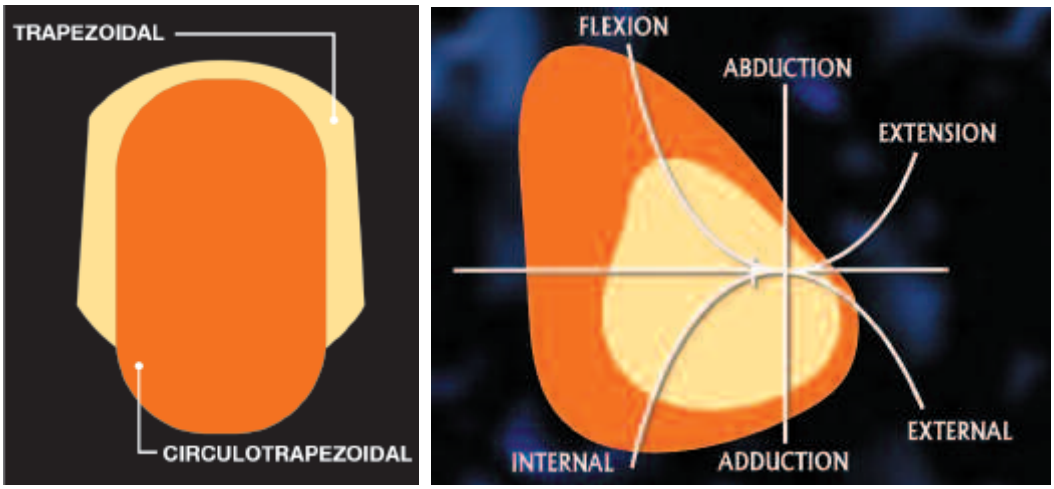
Distal diameter	Length (mm)	Neck calcar options
11	240	Neutral, +10, +20
13	250	Neutral, +10, +20
15	250	Neutral, +10, +20
17	260	Neutral, +10, +20
19	260	Neutral, +10, +20
21	260	Neutral, +10, +20
23	260	Neutral, +10, +20

13mm long revision (bowed) stem

Circulotrapezoidal neck

Optimizing neck geometry increases range of motion. The circulotrapezoidal neck on the EMPERION® stem is designed to provide a greater range of motion than a circular or a trapezoidal neck. By using more material in the medial/lateral direction where fatigue requirements are higher and less material in the anterior/posterior direction where demands are smaller, the range of motion is maximized.

The circulotrapezoidal neck was first used on the SPECTRON® Total Hip System, which has over 20 years of excellent clinical results.



Comparison of circulotrapezoidal and trapezoidal neck designs and their resultant range of motion[1]

EMPERION stem illustrating the circulotrapezoidal neck

Progressive offset

Femoral offset is an important clinical requirement to achieve optimal joint function. The advantages of increasing femoral offset after hip arthroplasty include increased range of motion, better mechanical advantages for the abductors and increased hip stability because of improved soft-tissue tension.[2]

Medialization of the femur can occur when offset is not properly restored. This can cause impingement and instability.[3] Furthermore, when offset is not restored at the time of surgery, laxity of the soft tissues can occur, thereby increasing the risk of weakness and dislocation.

EMPERION® stems incorporate two offsets for all primary stem options and a standard high offset on all revision stem options.

Stem length	Reduced offset	Standard offset	High offset*
9	30	34	–
11	–	34	40
13	–	37	45
15	–	37	45
17	–	40	50
19	–	40	50
21	–	–	50
23	–	–	50

*Revision length stems are only available in high offset.

Distal flutes

Distal flutes increase rotational stability and enhance immediate fixation of the stem. Rigid fixation and the rotational stability contribute to long-term implant success. Conversely, implant micromotion can result in loosening and ultimate failure of the prosthesis.[4]

Coronal slot

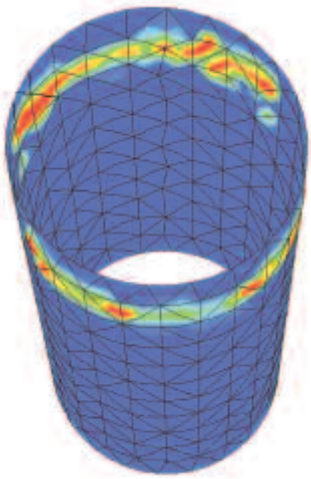
The coronal slot on the EMPERION stems helps accomplish three objectives:

- Eases stem insertion
- Reduces overall stem stiffness
- Reduces risk of femoral fracture

Studies have shown a correlation between stem stiffness and stress-shielding. The coronal slot has been incorporated into the EMPERION design to reduce stem stiffness and thereby minimize the rate of resorptive femoral remodeling and decrease thigh pain.

Polished bullet tip

The EMPERION® stem features a polished bullet tip distal to the flutes. This design feature minimizes implant impingement against the femoral cortex and reduces stress between the implant tip and the femoral bone. Testing has shown that the polished bullet tip has less contact pressure and that pressure is distributed more uniformly than a similar stem with a blunt tip.[5]



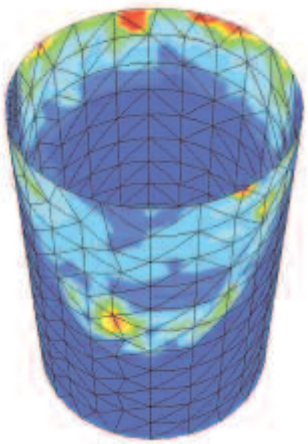


Figure 2

Figure 1

Finite element analysis of S-ROM® stem distal tip (Figure 1) with a more focal distribution of contact pressure and EMPERION stem distal tip (Figure 2) demonstrating greater distribution of contact pressure

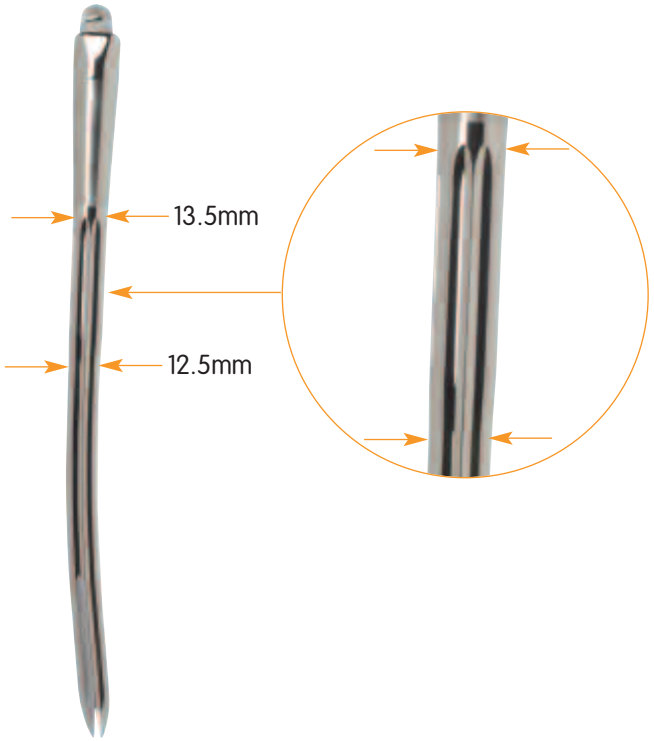
Figure 3 **Figure 4**

The distal tips of S-ROM stem (Figure 3) and EMPERION stem (Figure 4)

Bowed stem downsizing

Inserting a long bowed stem into the femoral canal is often one of the most difficult parts of a revision hip procedure. Commonly, the femur is over-reamed to help ensure that the stem can be fully seated without fracturing the femur. As a result, the stem may not fit tightly within the femoral canal and this could potentially lead to stress-shielding or stem micromotion.

The EMPERION bowed stems are uniquely designed to help minimize this problem. Starting at a point just proximal to the bow, each stem's diameter tapers down by 1mm. This design feature minimizes the need for over-reaming of the femoral bone, thereby both conserving bone and minimizing stress-shielding and micromotion.



Sleeve

Each sleeve is designed with a tapered porous surface. The outer porous coating is covered with a hydroxyapatite (HA) layer, also known as POROUS PLUS® HA.

Sizing

Although modularity increases the available intraoperative options, many times it also increases the system complexity. However, the EMPERION® Modular Hip System keeps it simple. This simplicity continues with sleeve options and terminology.

The EMPERION system has two sleeve length options available: a 40mm sleeve length (standard) and a 60mm sleeve length (tall). The tall sleeve extends further distally into the femoral canal thereby achieving fixation over a larger area that extends into the femoral diaphysis. This may be useful in revision situations where bone loss prevents adequate fixation from being achieved in the more proximal femur.

Each sleeve is referred to by two different dimensions (see diagram below): the diameter of the 'cone' of the sleeve and the size of the 'spout' of the sleeve.

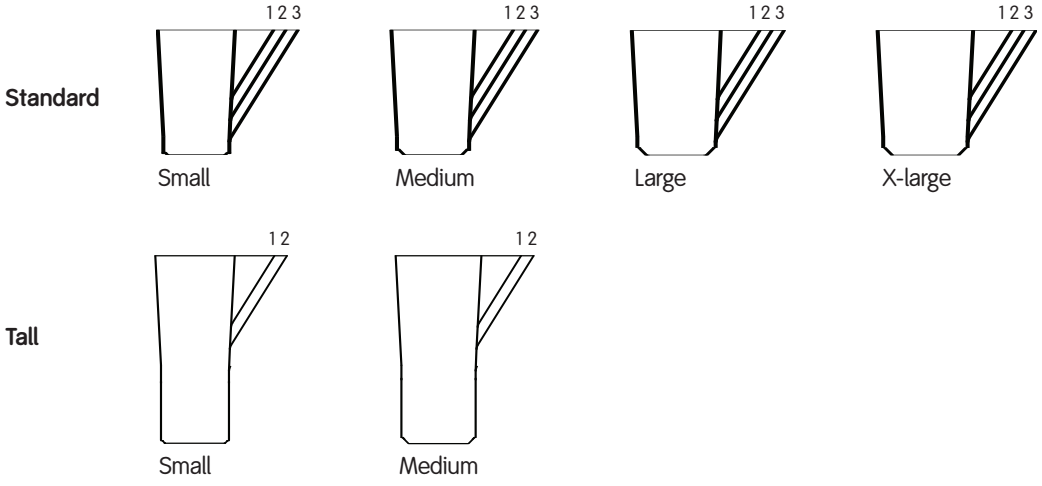
The cones come in sizes of small, medium and large. In addition, an extra-large cone is available for stem sizes 17mm and higher. There is a 2mm difference between each cone size.

The spouts come in sizes of 1, 2 and 3. There is a 4mm incremental difference between each spout size.

The combination of three cone sizes and three spout sizes results in nine different standard sleeve options for stem sizes 15mm and smaller. The fourth cone size (extra large), available for stem sizes 17mm and higher, results in a total of 12 different sleeve options available for these larger size stems.

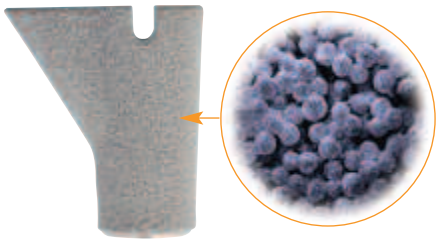
The tall sleeves have two cone sizes (small and medium) and two spout sizes (1 and 2). Thus, there are a total of four different tall sleeve options available for each revision size stem.

EMPERION sleeve options



POROUS PLUS◇ HA coating

POROUS PLUS HA coating uses RoughCoat porous coating technology with an HA application.



EMPERION sleeve with POROUS PLUS HA coating

- RoughCoat porous coating
  The sintered-bead RoughCoat porous coating, manufactured from commercially pure titanium, has demonstrated several advantages over plasma-sprayed or simple macro-textured surfaces:
  - The irregularly layered beads of the RoughCoat porous coating enhance the 3-D interlock of the prosthesis.
  - Studies have shown stems with sintered beads result in two to three times less polyethelene wear in the acetabular component than stems with plasma sprayed surfaces.[6]
  - Sintered beads have been shown to have greater bond strength than plasma-sprayed surfaces or diffusion bonded wire surfaces.[7,8,9]

  Mechanical testing has shown the optimal pore size for bone in-growth to be between 50 and 400 microns.[10] The pore size of the RoughCoat porous coating on the EMPERION◇ Modular Hip System is 200 microns.

- HA
  A 50-micron thick layer of HA is applied to the RoughCoat porous coating. A thinner HA layer can be discontinuous and cause a loss of mechanical integrity. Conversely, a thicker coating is likely to have lower attachment strength, leading to cracking and delamination under fatigue loads. The optimum thickness of HA has been shown to be 50 microns.[11,12]

Proximal taper

The proximal sleeve design incorporates a 6° taper (3° on each side). This taper improves proximal fill and enhances loading of the proximal femoral bone. In addition, the actual implant is oversized by 0.5mm compared to the area machined by the instruments, thereby providing for an interference fit and enhanced initial fixation. The interference fit and tapered sleeve geometry are designed to work together to transfer stress to the host bone and minimize bone loss from stress-shielding.

EMPERION sleeve with 3° of proximal taper on each side

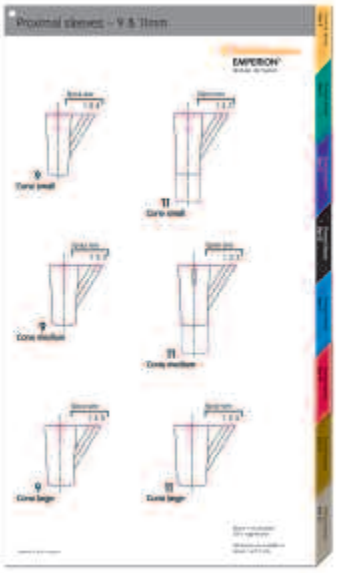
Instruments

Technique simplicity

The EMPERION® instruments and technique were designed with simplicity in mind. The EMPERION trays are clearly organized in technique order, and some trays will not need to be opened unless a specific stem size or length is required.

The EMPERION Modular Hip System also uses color-coding to help the surgical team during surgery. Each distal stem diameter has its own unique color. This same unique color is consistently referenced on templates, tray layouts, instrumentation and component packaging. This allows the operating team to easily follow the surgical technique and helps minimize instrument and implant confusion.

Distal diameter of stem (mm)	Color
9	
11	
13	
15	
17	
19	
21	
23	



Color-coded templates

Color-coded trials

Color-coded trays

Trochanteric reamer

A special reamer is designed to open the proximal femur and ensure that subsequent reaming stays lateral. Removing lateral bone is important to maintaining neutral stem placement. This proximal reamer can also be used to remove sclerotic bone.

Straight distal reamers

Straight distal reamers are available in 0.5mm increments for exact preparation of the femoral canal. Easy-to-see depth marks for both the primary and standard revision stems are designed to clearly reference off of the greater trochanter to ensure proper reaming depth. The color-coding on the reamers correlates with the recommended stem size.

Thin shaft elliptical reamers

During distal reaming for the long revision bowed stems, thin shaft elliptical reamers are used in conjunction with the straight distal reamers. The diameter of the reamed canal and the elliptical reamer are also more consistent with elliptical reamers.[12]

Proximal reamers

Special proximal reamers are available to prepare the femur for the sleeve implant. There are standard reamers available for the standard length sleeve and tall reamers for the tall sleeves. Once again, these reamers are color-coded and sized according to cone size and diameter size. Easy-to-see depth marks for each neck option (neutral, +10 and +20) clearly reference off the greater trochanter to ensure proper reaming depth.

Each reamer also has a smooth chamfer instead of a 90° lip at the proximal end of the reamer. This chamfer allows for easy withdrawal of the instrument from the femur.

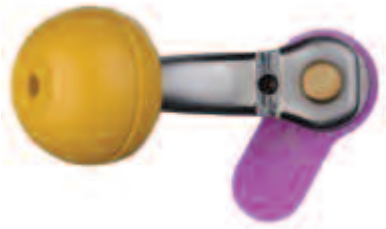
Accu-Miller

The miller is designed to more accurately prepare the spout. The locking slot maintains the relationship of the spout and cone to accurately match that of the implant sleeve.

The different parts of the miller have been clearly marked to ensure that the instrument is used with the correct components. This includes color-coded pilots, color-coded and numbered milling frames that reference the proximal reamers, and numbered locking slots to ensure proper spout size when milling.

Quick-connect trials

The trialing system for the EMPERION® system uses quick-connect technology which allows for push-button version control and easily interchangeable trial necks. The trials are also color-coded for ease of use.



Notes

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Printed in USA
45870401 06/06