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CREATEUR FABRICANT

Stemsys®

Surgical Technique

Evolutis
MOTION INSIDE

TABLE OF CONTENT

STEMSYS® HIP SYSTEM

The STEMSYS® uncemented primary femoral component is a fully HA coated titanium alloy stem, designed for immediate mechanical stability and long term biological fixation (1).

Made in France by the group originally responsible for the manufacture of one of the most clinically successful hip designs internationally, the STEMSYS® is the ultimate evolution of an implant widely used throughout Europe with excellent results (2).

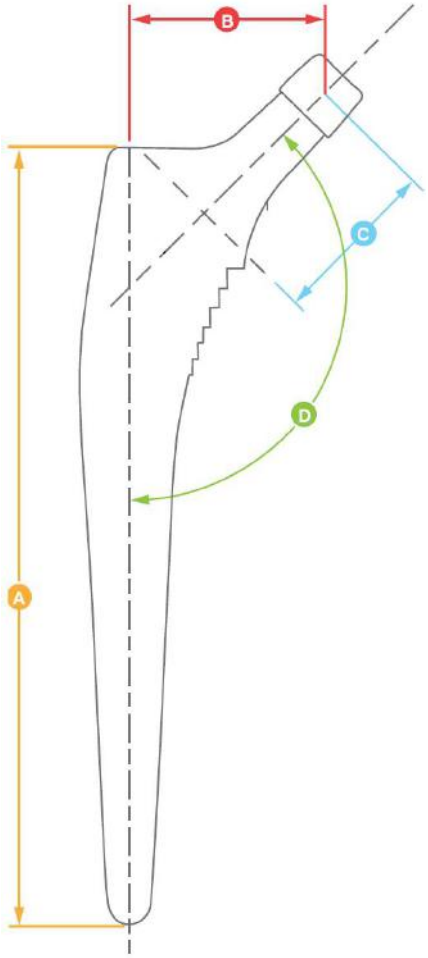
The basis of the design is a trapezoidal proximal and mid section that provides immediate rotational stability and optimal metaphyseal fit.

The double taper longitudinal geometry with grooves that transfer load proximally ensures that the stem remains locked against the dense bone of the calcar and greater trochanter.

Long term fixation is enhanced through bone ingrowth into the dual coating of HA and porous titanium plasma.

Physiological loading of the calcar region and trabecular ingrowth to the dual coating also prevent the ingress of particulate matter, reducing the potential for osteolysis.

The STEMSYS® Hip System offers stainless steel, cobalt chrome, or composite ceramic femoral heads. STEMSYS® Femoral Heads come in 22.2mm, 28mm, 32mm and 36mm diameters.



STEMSYS® stem dimensions

	A				B	C	D
Implants 135° STANDARD *Implants*							
Taille *Size*	Ti HA *Cat N°*	Longueur *Length* (mm)	HA *Cat N°*	Longueur *Length* (mm)	Offset	Longueur col *Neck length*	*NSA* Angle CCD
7	**H45 007**	110	**H73 007**	110	35,1	35	135°
8	**H45 008**	115	**H73 008**	115	36,0	35	135°
9	**H45 009**	120	**H73 009**	130	37,5	35	135°
10	**H45 010**	125	**H73 010**	140	39,4	38.5	135°
11	**H45 011**	130	**H73 011**	145	40,4	38.5	135°
12	**H45 012**	135	**H73 012**	150	41,5	38.5	135°
13	**H45 013**	140	**H73 013**	155	41,9	38.5	135°
14	**H45 014**	145	**H73 014**	160	42,4	38.5	135°
15	**H45 015**	150	**H73 015**	165	43,1	38.5	135°
16	**H45 016**	155	**H73 016**	170	43,9	38.5	135°
18	**H45 018**	160	**H73 018**	180	44,9	38.5	135°
20	**H45 020**	170	**H73 020**	190	45,3	38.5	135°
Implants 128° LATERO-VARUS *Implants*							
9	**H45 L009**	120	**H73 L009**	130	45,2	42.0	128°
10	**H45 L010**	125	**H73 L010**	140	46,2	42.0	128°
11	**H45 L011**	130	**H73 L011**	145	47,0	42.0	128°
12	**H45 L012**	135	**H73 L012**	150	48,1	42.0	128°
13	**H45 L013**	140	**H73 L013**	155	48,4	42.0	128°
14	**H45 L014**	145	**H73 L014**	160	49,0	42.0	128°
15	**H45 L015**	150	**H73 L015**	165	49,8	42.0	128°
16	**H45 L016**	155	**H73 L016**	170	50,6	42.0	128°

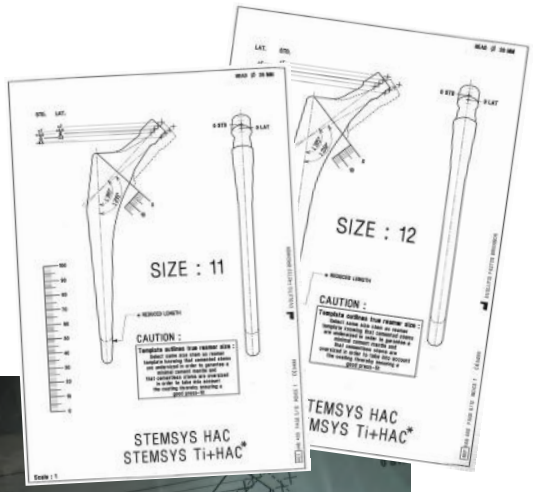
1. Vidalain JP. Corail® Stem Long-Term Results Based upon the 15-Years ARTRO Group Experience. Fifteen Years of Clinical Experience with Hydroxyapatite Coatings in Joint Arthroplasty, Ed. Springer, 217-224, 200
2. The Norwegian Arthroplasty Register. http://www.haukeland.no/nrl/eng/default.htm
3. Frayssinet, P.; Hardy, D.; Hanker, J. and Giammara, B.: Natural History of Bone Response to Hydroxyapatite-Coated Prostheses Implanted in Humans. Cells and Materials, Vol. 5, No. 2, 1995: 125-13

TEMPLATING and APPROACH

Preoperative templates will be delivered to your hospital together with the instrument set.
Digital templates for the STEMSYS® stems are also available for the MEDICAD (*https://www.medicad.eu/en/*), ORTHOVIEW (*https://www.materialise.com/en/medical/orthoview*), or SECTRA (*https://medical.sectra.com/solutionarea/orthopaedics/*) softwares.

The set of templates includes 1 sheet for each size of stem ranging from size 7 to size 20. Each sheet figures standard and latero-varus necks.

Templating time aims at anticipating on the size and neck angle best adapted to the patient, and to identify neck resection level and measure reference of cut level to the lesser trochanter.



The templating steps are:

- Draw center of diaphysis line (*Fig.1*)
- Draw 45° angle resection line 1cm above lesser trochanter (*Fig.2*)
- Juxtapose the template on the x-ray trying to match (*Fig.3*):
  - The medial curve of the stem to the inner medial cortical bone
  - The resection line parallel to the 45° resection line
  - The center of prosthetic head identical or slightly medial to the center of femoral head.

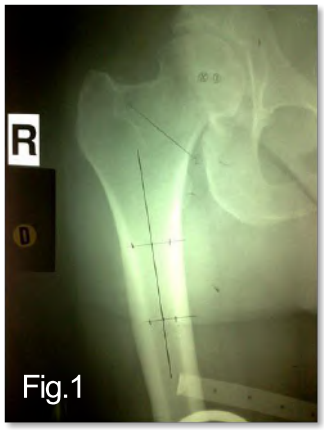


Fig.1

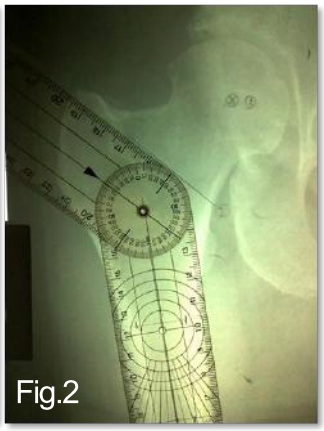


Fig.2

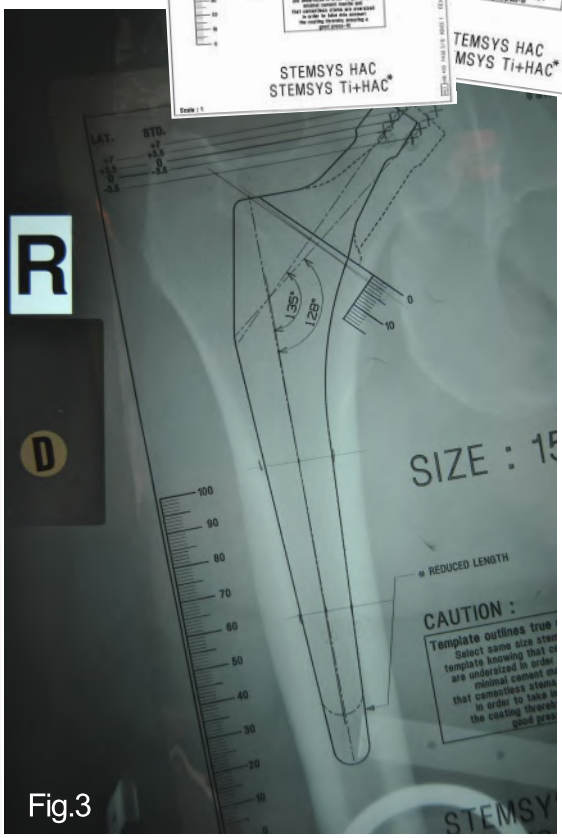


Fig.3

Important notice

Adjusting the primary fixation mode to the CFI (*Canal Flare Index*)

The Stemsys® femoral implants are most often used in their cementless variant. In these cases, they provide reproducible and satisfactory functional and longevity results.
STEMSYS® implants are designed for primary fixation in the femoral metaphyseal zone, and their fixation must be primarily obtained in contact with the patient's metaphyseal bone, and possibly metaphyso-diaphyseal, so as to respect the natural load areas of the proximal femur and avoid a by-pass of the forces through the implant and secondary bone stress-shielding.

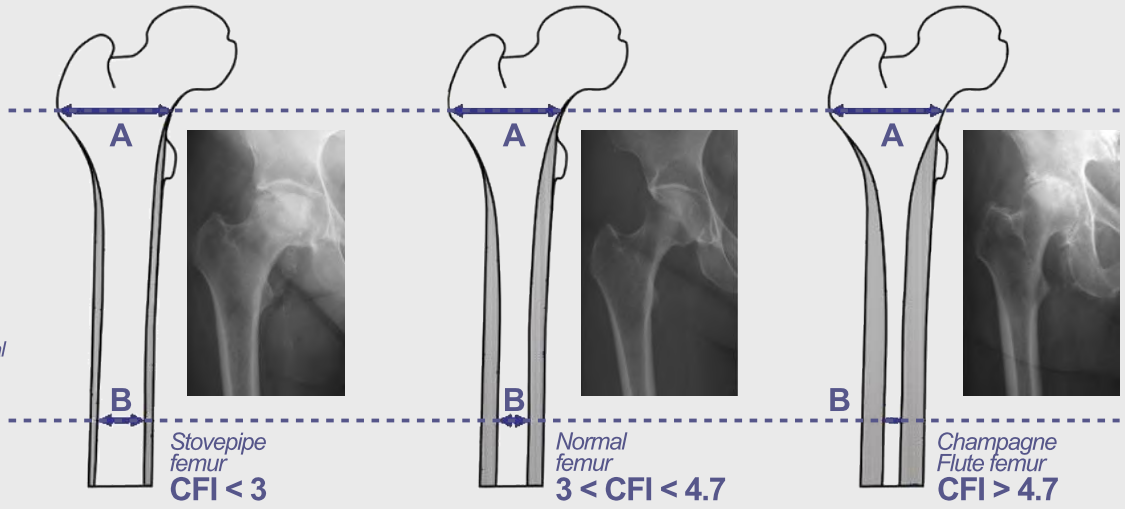
The surgeon should take into account that the primary fixation mode of the femoral stem is dependent on the canal flare index (CFI) of each patient. Pre-operative templating should identify the particular femoral morphologies for which this primary fixation mode would not be achieved. In these morphologies characterized by a high CFI, as described by Noble et al., the primary metaphyseal fixation is often compromised by the significant expansion of the proximal intramedullary space. The fixation is then obtained in the distal zone, which is to be avoided.

CFI: the 3 variants

CFI was defined by Noble et al. as the ratio of the intracortical width of the femur at a point 20mm proximal to the lesser trochanter to the intracortical width at the canal isthmus. CFI is considered to express the proximal femoral geometory.

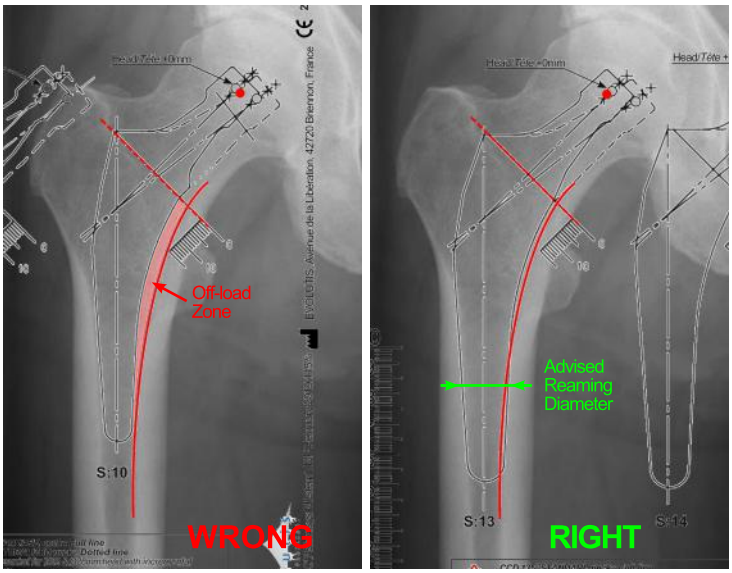
In a recent publication, Tanada et al.(1) calculated that in a population aged between 25 and 82, the CFI ranged between 2.8 and 6.6 with the average value at 4.65. The stovepipe morphology was identified in 2% of the cases (canal flare index< 3), the normal morphology in 61.2% (3<canal flare index< 4.7), and the champagne flute in 36.7% (canal flare index >4.7).

CFI = A/B



The surgeon should take adequate measures to adapt the fixation of the implant to each morphology:
- Stovepipe femurs (CFI < 3) are more indicated for cemented fixation.
- Normal femurs (3 < CFI < 4.7) are indicated for cemented or cementless fixation of a standard primary stem where the main stability will be achieved in the femoral metaphysis section.
- Champagne flute femurs are at risk of achieving the primary stability at the isthmus level, which will create unfavourable conditions of fixation both for the femur (stress-shielding of the proximal femur), and for the stem (excessive lever arm to the shaft of the implant).

In a Champagne Flute intra-femoral morphology, the anticipated size of implant will be based on the metaphyseal adaptation of the implant to the femur, and the surgeon should consider adapting (reaming) the diameter of the isthmus to the distal dimension of the stem.



Templating of a "Champagne Flute" femur:

Left: no intramedullary modification, size 10 is anticipated to block distally at the level of the isthmus, while the proximal section of the stem stays at distance of the medial cortex (area in pink).

Right : the stem size is selected on its ability to fill the metaphyseal space and to rest on the medial cortex. The reaming diameter should be measured at the level of the stem where the template becomes larger than the canal. In this example of size 13 stem, the isthmus may have to be reamed up to 16mm.

Choice of surgical approach to the hip

The surgical approach is at the discretion of the surgeon and should be chosen based upon the circumstances of the patient and the surgeon's preference.
Preference will dictate whether an anterolateral, lateral, or posterolateral approach is made.
The skin incision and muscle detachment will depend on the approach chosen.

The STEMSYS instrument system can be custom adapted to your surgical approach.
Broach handles for postero-lateral, antero-lateral, or anterior approaches are available.

(1) Tawada et al. "Measurement of the Canal Flare Index using 3D-models and the effect of the roational femur position" - Feb 2018 in Orthopaedic Proceedings (Vol. 93-B, No. SUPP_IV). CFI measures of 49 femurs (18 male, 31 female), aged on average 60.4 years ranging from 25 to 82.

Resection of the Femoral Neck

The osteotomy of the femoral neck is approx. 10 to 15mm above the lesser trochanter at an angle of 45° to the neutral axis of the femur or parallel to the intertrochanteric line *(Fig.4)*.

This may vary due to differences in the proximal femoral anatomy and should be based on preoperative planning.

The resection is made with an oscillating saw blade *(Fig.5)*.
The femoral head is then removed.

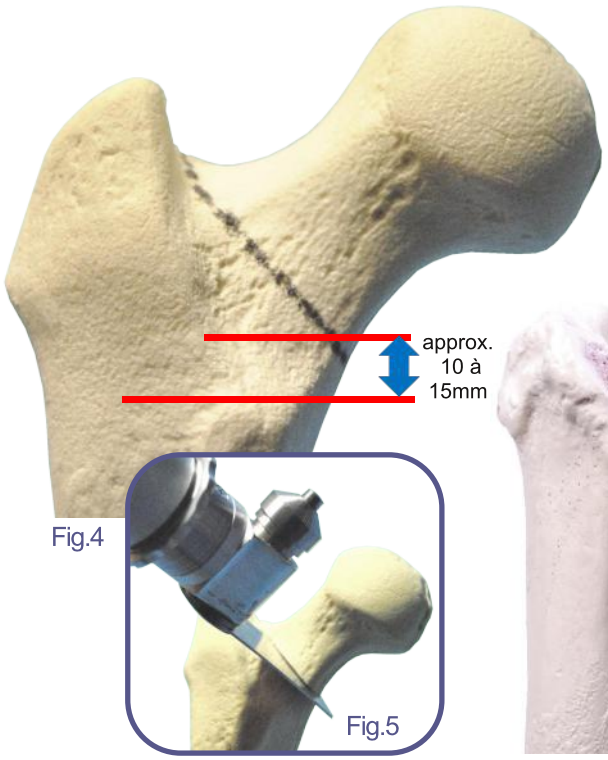


Fig.4

Fig.5

Note: if the resection is too high, it may result in a varus positioned stem.

In the case of total hip arthroplasty, preparation and implantation of the acetabular component should commence following the neck resection.

Fig.6

Fig.7

Enter the femoral canal as laterally as possible with the Box Chisel (ref H72 004) supplied in the STEMSYS Femoral Stem Instrument System (*Fig.6*).
Start as close as possible to the greater trochanter base to allow straight broaching axis and avoid any varus or valgus positioning.

H72 004

The bone block removed by the chisel can be preserved and used at a later stage, such as bone plug for cemented fixation.
A femoral reamer (ref H01 006), awl or gouge curette (not supplied with the instrument set) is introduced deep into the femoral canal to prepare and determine the intra-medullary axis (*Fig.7*).

Engagement of the broach onto the broach handle

The STEMSYS® system offers a choice of broach-handles adapted to the surgical approach of the operator.
This surgical technique describes the use with a posterior approach H01 066 handle.

Other broach handles are available for the Direct Anterior Approach (H01 065 Instrumentation sets H46 9104 or H46 9106), and for the anterolateral approach (H01 067 and H01 068 / Instrumentation sets H46 9105 or H46 9107).

In case of use of a broach handles intended for another approach, the surgeon will have to adapt this surgical technique to his practice and to his installation. Nevertheless the surgical stages remain the same.

The instrumentation is delivered with 2 broach handles.
The instrument nurse can prepare incremental sizes broaches on the second broach handle while the surgeon is broaching the femur with the first broach handle.

Open the broach handle by pulling on the lever (*Fig.8*).
Engage the broach on the tip of the broache handle (*Fig.*9).
Close the lever to ensure rigid assembly (*Fig.10*).

Start broaching.

Fig.8

Fig.9

Fig.10

Preparation of the Femoral Canal

Start with the size 9 broach *(Fig.11)* and increment sizes progressively until axial and rotational stability is achieved.
The aim is for the implant to sit tightly in compacted cancellous bone and not to be in direct contact with the cortex.

The surgeon chooses the anteversion of the broaches in line with the orientation of the femoral neck, usually about 15°.

Each broach should be impacted to the level of the osteotomy *(Fig.12)*, and the final broach – which determines the actual implant size – seated at this level.
It should be stable axialy and in rotation when the handle is twisted or rotated.

To disengage the broach from the handle, pull the lever and leave the last broach in situ for trialling *(Fig.13)*.

Fig.11

Fig.12

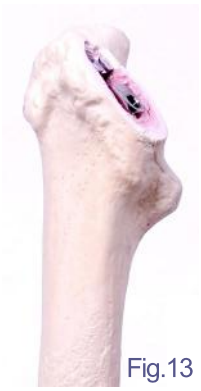
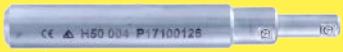


Fig.13

Anteversion control

An optional Tommy bar (ref. H50 004) can be inserted in the proximal tranverse hole of the broach handle to help controlling the anteversion of the femoral stem.



When implanting a collared stem, additional calcar preparation is required.

Introduce the optional calcar reamer (ref H72 330) in the proximal hole of the broach and ream until the bone cut is even with the upper side of the broach *(Fig.14)*.

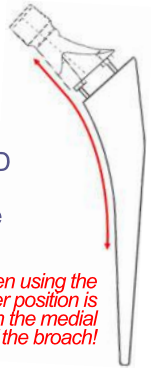
Fig.14

Fig.15

Fig.16 *Trial neck for S.7 to 9 (left)*
Standard 135° trial neck (middle)
Lateralized 128° trial neck (right)

Trial Reduction

Leaving the final broach in place, remove the broach handle.
Attach the appropriate trial neck (*Fig.15*).



Trial necks are available in short (135° for S.7 to S.9), Standard (135°) or lateralized (128°) versions (*Fig.*16).
For the STANDARD femoral stems sizes 7 to 9 designed with a shorther neck length, use the specially adapted shorter trial neck (blue: H72 016).
The femoral stem sizes 7 and 8 are not available in LATERALIZED 128° variants.
In order to acheive a trial for a LATERALIZED stem size 9, use the H72 026 LATERALIZED trial neck.

Important notice: when using the lateralized trial neck, proper position is when the neck is aligned with the medial border of the broach!

Fig.17

Place a trial head on the trial neck *(Fig.17)*.
Head trials are delivered in standard instrument sets in 22mm (-2, 0, +2) and 28mm (-3.5, 0, +3.5, +7) diameters.
For 32 and 36mm trials, optional head trials needs to be requested.

Fig.18

Reduce the hip using the head pusher tip (*Fig.*18).
The H02 001 head pusher tip is adapted to Ø22, 28 and 32mm heads. For Ø36 and 40mm heads the optional pusher tip (ref H36 002) need to be requested.

Optional blue pusher tip for Ø36 and 40mm heads

Fig.19

Assess stability through the full range of motion (*Fig.18*).
Repeat the trial reduction with different trial heads as required.

When the correct stability has been achieved, re-attach the broach handle and remove the broach from the femoral canal (*Fig.*19).

Insertion of the Final Stem

Push the threaded stem holder through the outer body of the stem holder until the screw threads appear out of the sleeve (*Fig.20*).

Fig.20

Fig.21a

Fig.21b

Adapt the threaded stem holder and its outer body on the STEMSYS implant taking care to adjust the teeth of the outer body *(Fig.21a)* to the corresponding slot on the implant *(Fig.21b)*.
Thightly screw the stem holder to the implant *(Fig.22)*.

Fig.22

The conical tip of the outer body associated to a tight screwing enables the surgeon to control the anteversion of the stem while introducing the implant into the femur.

During the introduction the surgeon should hold the stem impactor at the junction between the blue handle and the thumb wheel of the outer body (Fig.*23a*).

Holding the blue handle of the stem impactor alone does not allow proper anteversion control of the implant as the assembly can be unscrewed (Fig.*23b*).

Fig.23a

Fig.23b

In case of implantation of a cemented femoral stem, insert manually the implant into the intramedullary-canal and gradually push it to its final position.

In case a cementless femoral stem is implanted, insert manually the implant into the intramedullary-canal and hammer the impaction handle until the stem is fully seated at its correct position. Then unscrew the impaction handle.

If required te impaction can be finalized using the Stem Orienting impactor (H01 029) (*Fig.24*).

Fig.24

Fig.25

Placement of the femoral head and Reduction of the hip joint

Before positioning the definitive femoral head on the Morse taper of the stem, ensure that the Morse taper is cleaned and dried (first with water then dry).

Adjust the femoral head (12/14 taper) to the Morse taper of the stem together with a rotational movement, and rotate further with axial force until the femoral head is seated firmly.

Hammer softly to finally secure the femoral head onto the Morse taper using the head pusher (*Fig.25*).
Test-pull the femoral head to ensure it is firmly secure.

If necessary, the removal of the head is realized with the head pusher *(Fig.26)*.

Fig.26

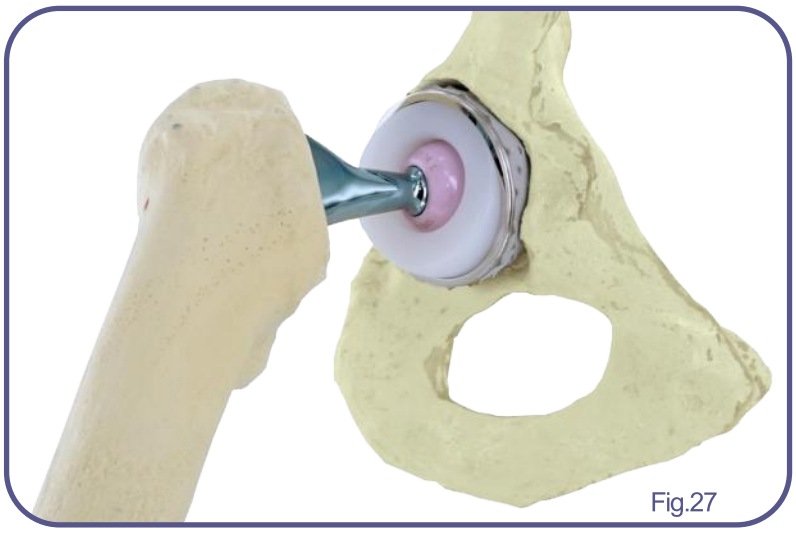


Fig.27

The hip joint is then reduced and tested for final stability and mobility (*Fig.*27).

Removal of the Femoral Stem

In case a removal of stem is required (intraoperative complication or revision), attach the sledge-hammer (Ref H01 033) to the stem inserter (*Fig.28)*, screw the stem inserter to the stem and hammer the stem out of the femur.

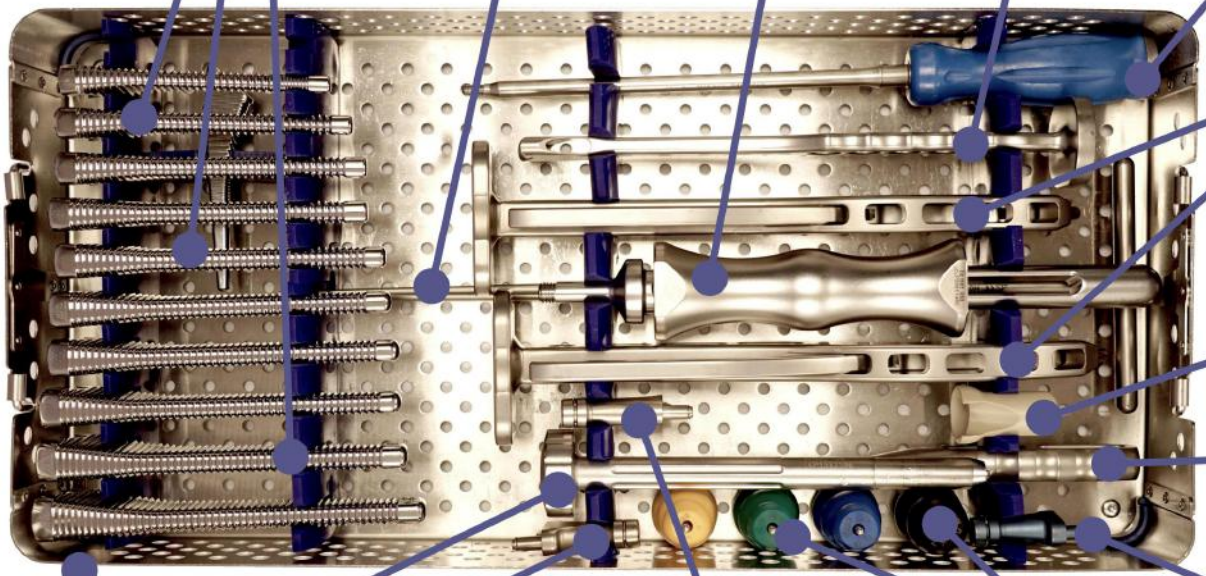
Note : in case of osteointegrated stem, the surgeon should take care to detach the bone to stem interface before hammering.

Fig.28

Instrumentation SNAPSHOT

Ref : H46 9106

STEMSYS Posterior Approach
Abord postérieur



Râpes fémorales taille 9 à 20
Femoral rasps size 9 to 20
H46 109 à/to H46120

OPTION
Alésoir de démarrage
Starting Reamer
H01 006

Extracteur à Masselotte
Sledge Hammer
H01 033

Ciseaux à spongieux
Box chisel
H72 004

Impacteur de tige
Stem impactor
H38 022

Manche de Râpe Voie Postérieure (x2)
Posterior Approach Rasp Handle (x2)
H01 066

Embout pousse-tête Ø26
Ø26 Head pusher tip
H02 001

Impacteur orienteur de tige
Final stem impactor
H01 029

Col d'essai Tailles 7 à 9
Trial neck Sizes 7 to 9
H72 026

Têtes d'essai Ø22 Ø28
Trial heads Ø22 Ø28
H02 S2220 à/to H02 S2283

Col d'essai Latéralisé
Offset Trial neck
H72 026

Col d'essai Droit
Standard Trial neck
H72 024

Corps de porte implant
Femoral stem holding sleeve
H38 020

Panier pour Instruments
Tray for Instruments
H46 9004

OPTION

Manche voie antérieure (x2)
Anterior approach handle (x2)
H01 065
OU/OR
Manche voie antéro-latérale
Antero-Lateral approach handle
H01 067 et/and H01 068

Fraise à Calcar
Calcar Reamer
H72 330

Têtes d'essai Ø32 Ø36
Trial heads Ø32 Ø36
H02 S2320 à/to H02 S2363

Râpe de démarrage
Starting rasp
H01 062

Râpes fémorales taille 7 et 8
Femoral rasps size 7 & 8
H72 007 - H72 008

Axe repère d'antéversion
Tommy Bar
H50 004

Ciseaux à spongieux angulé
Offset Box chisel
H46 005

Dec 2020 / Ref: BI_STEMSYS SNP H46 9106

REFERENCES

STEMSYS *Cementless* Sans ciment

	Cementless dual coating Porous Ti + HA Double revêtement Ti + HA				*Cementless HA coating* Hydroxyapatite			
	Standard	*Std Collared* Std à Coll.	*Lateralized* Latéralisé	*Lat Collared* Lat à coll.	Standard	*Std Collared* Std à Coll.	*Lateralized* Latéralisé	*Lat Collared* Lat à coll.
size /taille 7	* H45 007	* H45 C007			* H73 007			
size /taille 8	* H45 008	* H45 C008			* H73 008	* H73 C008		
size /taille 9	H45 009	H45 C009	H45 L009	H45 LC009	H73 009	H73 C009	H73 L009	H73 LC009
size /taille 10	H45 010	H45 C010	H45 L010	H45 LC010	H73 010	H73 C010	H73 L010	H73 LC010
size /taille 11	H45 011	H45 C011	H45 L011	H45 LC011	H73 011	H73 C011	H73 L011	H73 LC011
size /taille 12	H45 012	H45 C012	H45 L012	H45 LC012	H73 012	H73 C012	H73 L012	H73 LC012
size /taille 13	H45 013	H45 C013	H45 L013	H45 LC013	H73 013	H73 C013	H73 L013	H73 LC013
size /taille 14	H45 014	H45 C014	H45 L014	H45 LC014	H73 014	H73 C014	H73 L014	H73 LC014
size /taille 15	H45 015	H45 C015	H45 L015	H45 LC015	H73 015	H73 C015	H73 L015	H73 LC015
size /taille 16	H45 016	H45 C016	H45 L016	H45 LC016	H73 016	H73 C016	H73 L016	H73 LC016
size /taille 18	H45 018	H45 C018	H45 L018	H45 LC018	H73 018	H73 C018	H73 L018	H73 LC018
size /taille 20	H45 020		H45 L020	H45 LC020	H73 020	H73 C020	H73 L020	H73 LC020

Fracture

Gritblasted Corindonné
Std Collared Std à Coll.****
size/taille 8 ****H73 TC008
size/taille 9 ****H73 TC009
size/taille 10 ****H73 TC010
size/taille 11 ****H73 TC011
size/taille 12 ****H73 TC012
size/taille 13 ****H73 TC013
size/taille 14 ****H73 TC014
size/taille 15 ****H73 TC015
size/taille 16 ****H73 TC016
size/taille 18 ****H73 TC018
size/taille 20 ****H73 TC020

Femoral Heads Têtes Fémorales

Description	*Size* Taille	Cat. N°	Description	*Size* Taille	Cat. N°
Co-Cr / Chrome-Cobalt	Ø28 -7mm	H10 1279	*Composite* Ceramic Composite	Ø28 -3.5mm	H14 C1280
Co-Cr / Chrome-Cobalt	Ø28 -3.5mm	H10 1280	Composite Ceramic Composite	Ø28 +0mm	H14 C1281
Co-Cr / Chrome-Cobalt	Ø28 +0mm	H10 1281	*Composite* Ceramic Composite	Ø28 +3.5mm	H14 C1282
Co-Cr / Chrome-Cobalt	Ø28 +3.5mm	H10 1282	Composite Ceramic Composite	Ø32 -4mm	H14 C1320
Co-Cr / Chrome-Cobalt	Ø28 +7mm	H10 1283	*Composite* Ceramic Composite	Ø32 +0mm	H14 C1321
*** Co-Cr / Chrome-Cobalt	Ø28 +10.5mm	H10 1284	Composite Ceramic Composite	Ø32 +4mm	H14 C1322
Co-Cr / Chrome-Cobalt	Ø32 -4mm	H10 1320	*Composite* Ceramic Composite	Ø36 -4mm	H14 C1360
Co-Cr / Chrome-Cobalt	Ø32 +0mm	H10 1321	Composite Ceramic Composite	Ø36 +0mm	H14 C1361
Co-Cr / Chrome-Cobalt	Ø32 +4mm	H10 1322	*Composite* Ceramic Composite	Ø36 +4mm	H14 C1362
Co-Cr / Chrome-Cobalt	Ø32 +8mm	H10 1323	Composite Ceramic Composite	Ø40 -4mm	H14 C1400
Co-Cr / Chrome-Cobalt	Ø36 -4mm	H10 1360	*Composite* Ceramic Composite	Ø40 +0mm	H14 C1401
Co-Cr / Chrome-Cobalt	Ø36 +0mm	H10 1361	Composite Ceramic Composite	Ø40 +4mm	H14 C1402
Co-Cr / Chrome-Cobalt	Ø36 +4mm	H10 1362			
Co-Cr / Chrome-Cobalt	Ø36 +8mm	H10 1363			

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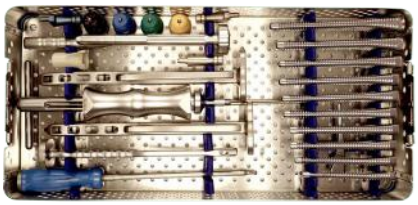
	Shiny-Polished Poli-Brillant	
	Std.	Lat.
size/taille 9	H45 S009	** H45 SL009
size/taille 10	H45 S010	H45 SL010
size/taille 11	H45 S011	H45 SL011
size/taille 12	H45 S012	H45 SL012
size/taille 13	H45 S013	H45 SL013
size/taille 14	H45 S014	H45 SL014
size/taille 15	H45 S015	H45 SL015
size/taille 16	H45 S016	H45 SL016
size/taille 18	H45 S018	

* *not validated for patients exceeding 75kgs (165lbs)*
** *not validated for patients exceeding 80kgs (176lbs)*
*** *not validated for use with 128° NSA femoral stem*
**** *indicated only for the femoral neck fracture at the elderly*

Instrumentation Sets STEMSYS

Selected STEMSYS Implant	Broach Handle	Ref. Instrumentation Set
H73 Implants **HA coated**	Posterior H01 066	**H46 9104**
	Anterior DAA H01 065	
	Lateral H01 067 & H01 068	**H46 9105**
H45 Implants **Dual Coating**	Posterior H01 066	**H46 9106**
	Anterior DAA H01 065	
	Lateral H01 067 & H01 068	**H46 9107**



***Notice**: Instrument set content may be subject to modifications and/or adapted to the customer's needs. Consequently the above item list is for indication purposes only. For an accurate list of the instrument set that has been delivered to your hospital, please refer to the delivery bill.*

Important Notice:
The STEMSYS implants belong to the class III implantable medical device classification. The STEMSYS implants are indicated in total hip arthroplasty primary procedures (THR) for the femoral component.
The surgeon is required to read the instructions for use (IFU) included in the packaging of the implant, as well as the surgical technique manual initially delivered with the instrument set, or available for download on the www.evolutisfrance.com website.

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Designed and Manufactured in France

Dec 2020 / Ref: EN_STEMSYS STC H46 (H46 451)