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CREATEUR FABRICANT



Surgical Technique

Evolutis MOTION INSIDE

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Disclaimer

This document is intended to be read only by experienced orthopaedic surgeons familiar with the application of hip arthroplasty, and by individuals related to or acknowledged by Evolutis company.

This publication is intended as the recommended procedure for using the Evolutis STEMSYS® Hip System. It offers guidance only. EVOLUTIS is the manufacturer of the device. As such and claiming no medical skill, EVOLUTIS does not recommend a specific use of a product or a technique. Each surgeon should consider the particular needs of the patient and make appropriate adjustments where necessary. For any additional information related to the products, the indications and contra indications, the warnings and precautions of use, and the adverse effects, please refer to the INSTRUCTION FOR USE leaflet included in the packaging of the implants. For further advice please contact your local representative.

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### 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).

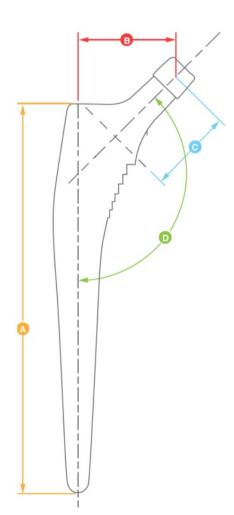
The basis of the design is a trapezoidal proximal and mid section that provides immediate rotational stability and optimal metaphyseal fit.

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 migration of wear particules, 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

		Α			В	С	D	
Standard Implant 135°								
Size	Ti HA	Length	НА	Length	Offset	Length	NS Angle	
5120	Ref. Code	(mm)	Ref. Code	(mm)	(mm)	(mm)		
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 017	160	H73 017	180	44,9	38.5	135°	
20	H45 018	170	H73 018	190	45,3	38.5	135°	
			Latera	lized Impla	nt 128°			
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	50,4	42.0	128°	
18	H45 L018	160	H73 L018	180	51,1	42.0	128°	
20	H45 L020	170	H73 L020	190	52,0	42.0	128°	

<sup>1.</sup> 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. The collar is drawn in dotted lines.

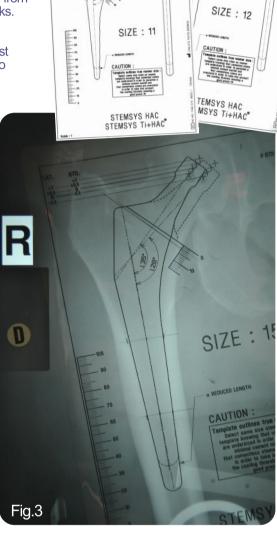
Templating time aims at anticipating on the size and neck angle best adapted to the patient, and to identify the neck resection level and to measure the resection level with reference to the lesser trochanter.

The templating steps are:

- Draw the center of diaphysis line (Fig.1)
- Draw the 45° angle resection line 1cm above the 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 the prosthetic head identical or slightly medial to the center of femoral head.
- Re-measure the level of the femoral neck resection relatively to the lesser trochanter.







ž ž

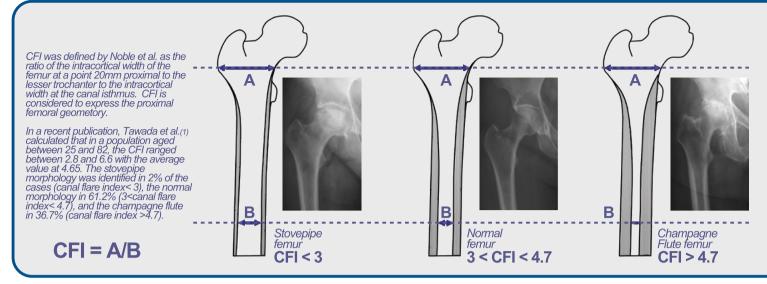
### Important notice

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.



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.

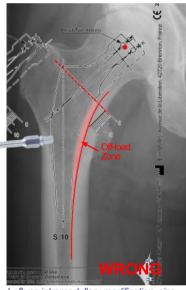
- Normal femurs (3 < CFI < 4.7) are indicated for cemented or cementless fixation of a standard primary stem where the main stability will be achieved in the femoral metaphysis section.

- 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).

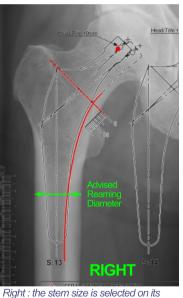
In a Champagne Flute intra-femoral morphology, the anticipated size of implant will be based on the metaphyseal adaptation of the implant to the femur, and the surgeon should consider adapting (reaming) the diameter of the isthmus to the distal dimension of the stem.



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).



raight. The stern size is selected on his ability to fill the metaphyseal space and to rest on the medial cortex. The reaming diameter should be measured at the level of the stern where the template becomes larger than the canal. In this example of a 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.





### approx. 10 à Fig.4 Fig.5

### Resection of the Femoral Neck

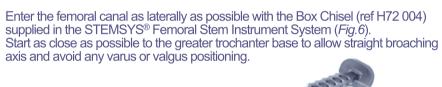
The osteotomy of the femoral neck is approx. 10 to 15mm above the lesser trochanter at an angle of 45° to the neutral axis of the femur or parallel to the intertrochanteric line (Fig.4).

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.

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

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



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 - optional), 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).



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

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

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 (note: except for the antero-lateral broach handles where one of each side is supplied in the instrument tray)

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.



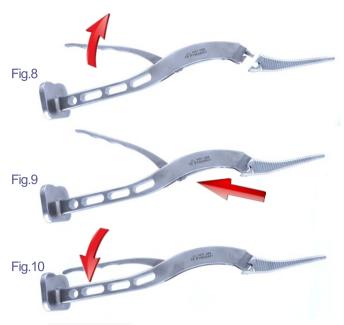
Fig.6

Fig.7



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.



### 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 while not being 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).





### **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.

CE & H50 004 P17100128

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

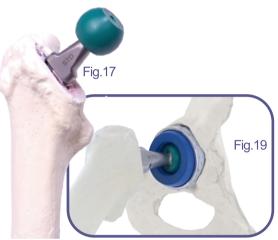


Introduce the optional calcar reamer (ref H72 330) in the proximal hole of the broach and ream until the bone cut is even with the upper side of the broach (Fig.14).



### Fig.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!

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.



Reduce the hip using the head pusher tip adapted on the stem impactor (H38 022) (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.



Fig.21a

Fig.20

### 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).

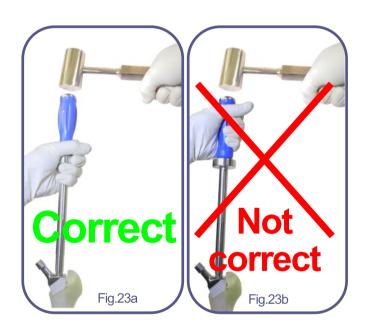
Adapt the threaded stem holder and its outer body on the STEMSYS implant taking care to adjust the teeth of the outer body (*Fig.21a*) to the corresponding slot on the implant (*Fig.21b*). Thightly screw the stem holder to the implant (*Fig.22*).



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).



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 the impaction can be finalized using the Stem Orienting impactor (H01 029 - Fig.24).



Fig.21b



### 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).

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



Fig.26



### 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-out the stem.

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

### Guidance for revision of a ceramic head

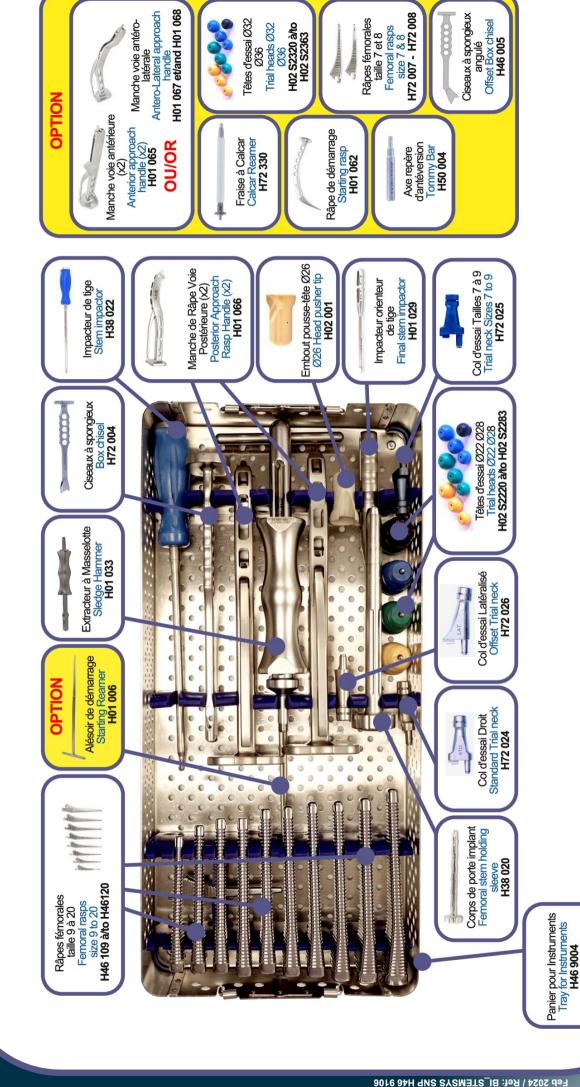
If the ceramic femoral head needs to be replaced due to **hip dislocation or replacement of a worn liner**, the connection taper of the femoral stem needs to be thoroughly examined before reimplanting a new ceramic head. If the taper appears to be scratched or damaged, a new ceramic head should not be implanted, and a metal head should be preferred.

If the ceramic femoral head needs to be replaced due to **the breakage of the head or of the ceramic liner**, the general guidance is to consider that both ceramic components and both femoral stem and acetabular cup need to be replaced. Exceptionally: if the breakage affects only one of the two ceramic components, and after thorough inspection of the connection taper (complete absence of scratches), the replacement of the ceramic component alone can be considered.



## STEMSYS Posterior Approach Abord postérieur

# Ref: H46 9106



STEMSYS Cementless Sans ciment										
Cementless dual coating Porous Ti + HA						Cementless	HA coating		Cemented	
		Double revête	ment Ti + HA			Hydrox	yapatite		Cime	entée
	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.	Standard	<i>Lateralized</i> Latéralisée
size /taille 7	H45 007 (1)	H45 C007 (1)			H73 007 (1)	H73 C007 (1)				
size /taille 8	H45 008 (3)	H45 C008 (3)			H73 008	H73 C008				
size /taille 9	H45 009	H45 C009	H45 L009 (3)	H45 LC009 (3)	H73 009	H73 C009	H73 L009	H73 LC009	H45 S009 (2)	H45 SL009 (2)
size /taille 10	H45 010	H45 C010	H45 L010	H45 LC010	H73 010	H73 C010	H73 L010	H73 LC010	H45 S010	H45 SL010 (2)
size /taille 11	H45 011	H45 C011	H45 L011	H45 LC011	H73 011	H73 C011	H73 L011	H73 LC011	H45 S011	H45 SL011
size /taille 12	H45 012	H45 C012	H45 L012	H45 LC012	H73 012	H73 C012	H73 L012	H73 LC012	H45 S012	H45 SL012
size /taille 13	H45 013	H45 C013	H45 L013	H45 LC013	H73 013	H73 C013	H73 L013	H73 LC013	H45 S013	H45 SL013
size /taille 14	H45 014	H45 C014	H45 L014	H45 LC014	H73 014	H73 C014	H73 L014	H73 LC014	H45 S014	H45 SL014
size /taille 15	H45 015	H45 C015	H45 L015	H45 LC015	H73 015	H73 C015	H73 L015	H73 LC015	H45 S015	H45 SL015
size /taille 16	H45 016	H45 C016	H45 L016	H45 LC016	H73 016	H73 C016	H73 L016	H73 LC016	H45 S016	H45 SL016
size /taille 18	H45 018	H45 C018	H45 L018	H45 LC018	H73 018	H73 C018	H73 L018	H73 LC018	H45 S018	
size /taille 20	H45 020		H45 L020	H45 LC020	H73 020	H73 C020	H73 L020	H73 LC020	H45 S020	

STEMSYS Revision Révision									
	Fe	ndue		errouillage dis	stal		Vis de verro	ouillage	
	Collarless Sans collerette	Collared Avec collerette	Collared Avec collerette	L 260mm	L 320mm		<i>Length</i> Longueur	<i>Ref.</i> Réf.	
size /taille 10	H45 R010	H45 RC010					Ø6/4.5 lg.20mm	H15 SC6020	
size /taille 12	H45 R012	H45 RC012	H45 R112	H45 R112L	H45 R112XL <sup>(3)</sup>		Ø6/4.5 lg.25mm	H15 SC6025	
size /taille 14	H45 R014	H45 RC014	H45 R114				Ø6/4.5 lg.30mm	H15 SC6030	
size /taille 16	H45 R016	H45 RC016	H45 R116				Ø6/4.5 lg.35mm	H15 SC6035	
size /taille 18	H45 R018	H45 RC018	H45 R118				Ø6/4.5 lg.40mm	H15 SC6040	
size /taille 20	H45 R020	H45 RC020	H45 R120						

(1) Not validated for patients exceeding 50kgs	
(110lbs) and do not use with femoral head ≥ +7mm	7
(2) Not validated for patients exceeding 70kgs	
(154lbs)	

(10-files)
(3) Not validated for patients exceeding 75kgs
(165lbs) and do not use with femoral head ≥ +7mm

Femoral Heads Têtes fémorales						
<i>Diameter</i> Diamètre		Stainless steel Acier Inox	Cobalt-Chromium Chrome-Cobalt	Composite Ceramic DELTA®	Composite Ceramic ElecPlus®	
	S	H11 1220	H10 1220	-	-	
Ø22	M	H11 1221	H10 1221	-	-	
	L	H11 1222	H10 1222	-	-	
	XS	H11 1279	H10 1279	-	-	
	S	H11 1280	H10 1280	H14 C1280	110230	
Ø28	M	H11 1281	H10 1281	H14 C1281	110240	
	L	H11 1282	H10 1282	H14 C1282	110250	
	XL	H11 1283	H10 1283	-	11.795	
	S	H11 1320	H10 1320	H14 C1320	110260	
Ø32	M	H11 1321	H10 1321	H14 C1321	110270	
W3Z	L	H11 1322	H10 1322	H14 C1322	110280	
	XL	H11 1323	H10 1323	H14 C1323	110291	
	S	-	H10 1360	H14 C1360	110300	
Ø36	M		H10 1361	H14 C1361	110310	
	L	-	H10 1362	H14 C1362	110320	
	XL	-	H10 1363	H14 C1363	110330	

Instrumentation Sets Instrumentations Ancillaires							
Surgical Approach							
Posterior approach / Abord postérieur	H01 066	H46 9104	H46 9106				
Direct Anterior Approach / Abord Antérieur Direct	H01 065	H46 9104	H46 9106				
Lateral Approach / Abord Latéral	H01 067 & H01 068	H46 9105	H46 9107				
Revision basis / Base de Révision	H01 009		H46 9108				
Slotted complement / Complément révision fendue			H46 9101				
Distal locking complement / Complément révision ve	verrouillée		H46 9109				

H01 067 H01 065 H01 066 H01 009

Materials:
Cementless stems: Titanium alloy TA6V according ISO5832-3 + gritblasted or Calcium Hydroxyapatite or T40 titanium + Calcium Hydroxyapatite
Cemented stems: High nitrogen content stainless steel according ISO5832-9
Femoral heads: High nitrogen content stainless steel according ISO5832-9 or Co-Cr according ISO5832-12 or Composite Ceramic according ISO6474-2
Vacuum packaging. Gamma ray sterilised

**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.