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HACTIV[®]

SURGICAL TECHNIQUE



HACTIV[®]
...since 2001.

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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 Hactiv 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 implants. For further advice please contact your local representative.

HACTIV HIP SYSTEM

The HACTIV 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 HACTIV has been widely used throughout Europe with excellent results (2).

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

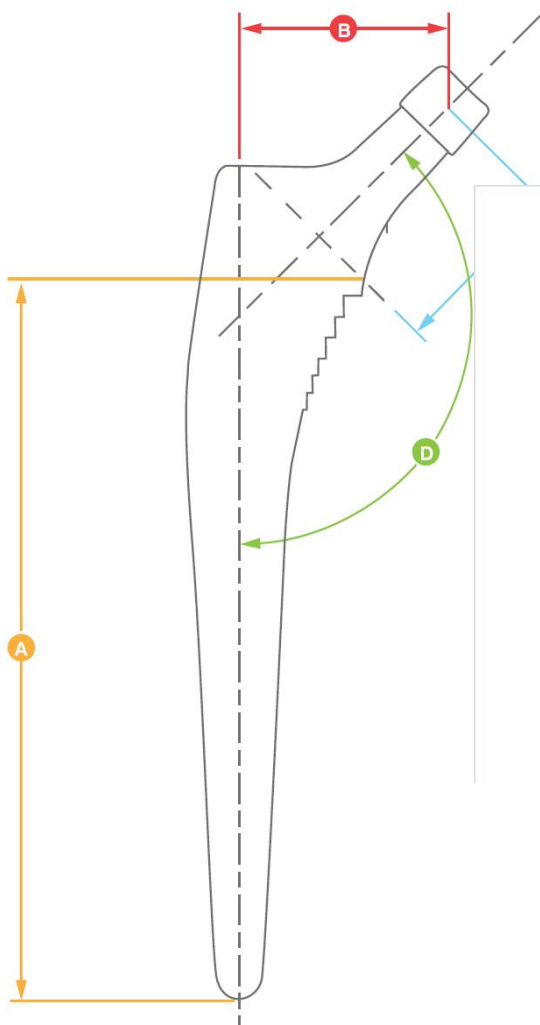
The double taper longitudinal geometry with grooves that transfer load proximally ensure that the stem remains locked against the dense bone of the calcar and greater trochanter.

Long term fixation is enhanced through bone ingrowth into the HA coating which is plasma sprayed on to the grit blasted surface of the femoral component (3).

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

The HACTIV Hip System offers stainless steel, cobalt chrome, pure alumina or composite ceramic femoral heads.

HACTIV Femoral Heads come in 22.2mm, 28mm, 32mm and 36mm and 40mm (ceramic only) sizes.



HACTIV stem dimensions

Cat N°	Stem size	A	B	C	D
		Stem length	Lateral Offset	Neck length	Neck Shaft Angle
STANDARD 135° OFFSET					
			(mm)		
H49 009	9	130	39.0	38.5	135°
H49 010	10	140	40.0	38.5	135°
H49 011	11	145	41.0	38.5	135°
H49 012	12	150	41.5	38.5	135°
H49 013	13	155	42.0	38.5	135°
H49 014	14	160	42.5	38.5	135°
H49 015	15	165	43.0	38.5	135°
H49 016	16	170	44.0	38.5	135°
H49 018	18	180	45.0	38.5	135°
H49 020	20	190	45.5	38.5	135°
LATERALIZED 128° OFFSET					
H49 L009	9	130	48.5	42.0	128°
H49 L010	10	140	49.5	42.0	128°
H49 L011	11	145	50.5	42.0	128°
H49 L012	12	150	51.5	42.0	128°
H49 L013	13	155	52.0	42.0	128°
H49 L014	14	160	52.5	42.0	128°
H49 L015	15	165	53.5	42.0	128°
H49 L016	16	170	54.0	42.0	128°

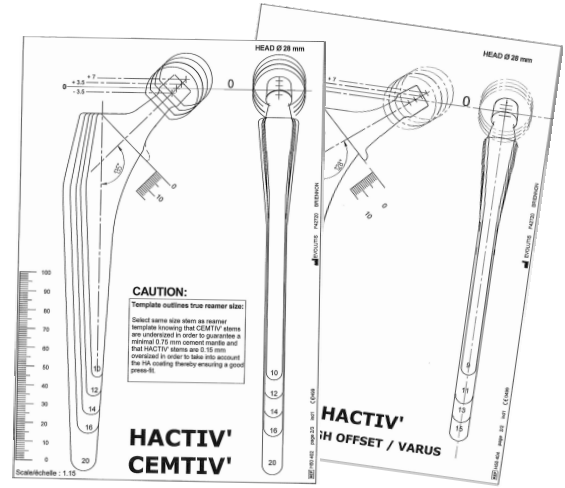
1. Vidalain JP. Corail® Stem Long-Term Results Based upon the 15-Years ARTRO Group Experience. Fifteen Years of Clinical Experience with Hydroxyapatite Coatings in Joint Arthroplasty, Ed. Springer, 217-224, 200
 2. The Norwegian Arthroplasty Register. <http://www.haukeland.no/nrl/eng/default.htm>
 3. 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.

The set of templates includes 4 sheets:

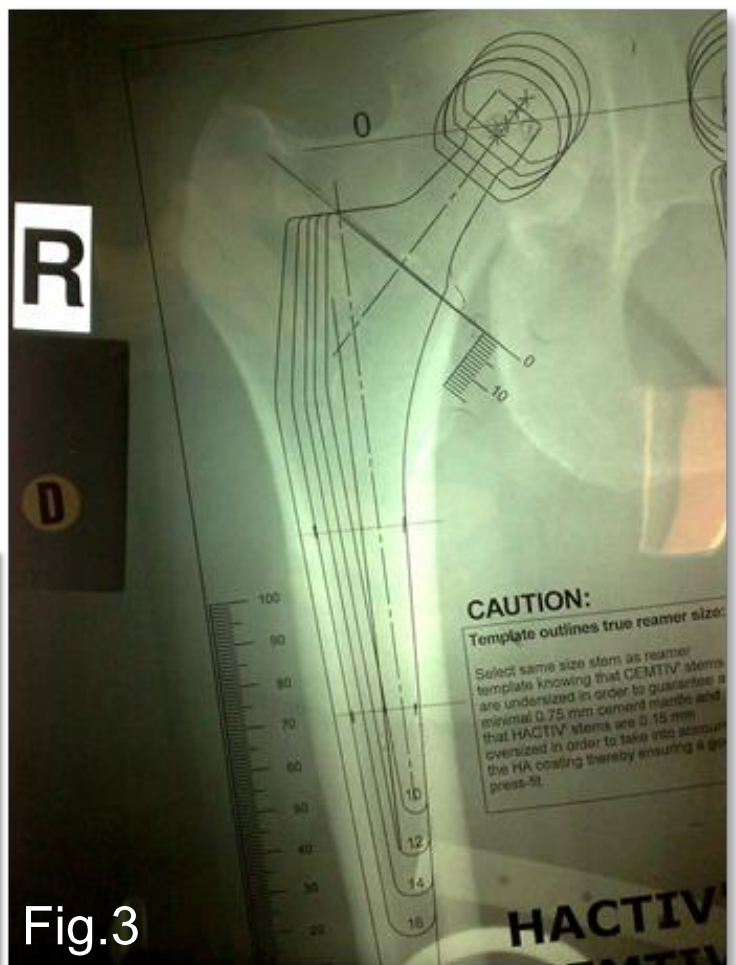
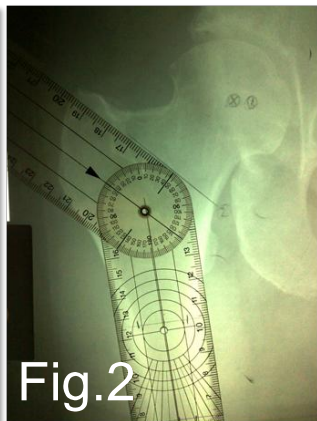
- 2 for the 135° standard version:
 - sheet 1 for sizes 9, 11, 13, 15 & 18
 - sheet 2 for sizes 10, 12, 14, 16 & 20
- 2 for 128° latero-varus version:
 - sheet 3 for sizes 9, 11, 13, 15 & 18
 - sheet 4 for sizes 10, 12, 14, 16 & 20



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.



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.

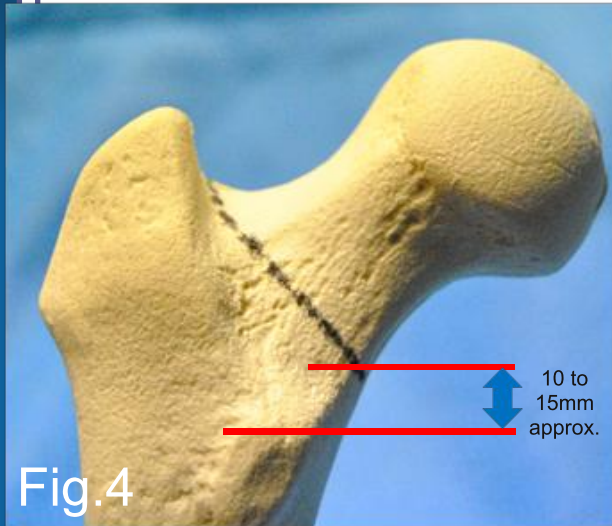
The skin incision and muscle detachment will depend on the approach chosen.

The HACTIV instrument system is custom adapted on demand to your surgical approach.

Broach handles either for postero-lateral, antero-lateral, or anterior approaches are available.

SURGICAL STEPS

Femoral Neck Resection



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. The femoral head is then removed.

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.



Opening the Canal

Enter the femoral canal as laterally as possible with the Box Chisel supplied in the HACTIV Femoral Stem Instrument System (Fig.5 & 6).



Start as close as possible to the greater trochanter base to allow straight broaching axis and avoid any varus or valgus positioning.

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, awl or gouge curette (not supplied with the instrument set) is introduced deep into the femoral canal to prepare and determine the axis (Fig.7).



SURGICAL STEPS

Assembly/dissassembly of broach handle

For cleaning purposes, the broach handle is easily dismantled and re assembled and entirely modular. Only 3 parts.

Important notice : the 3 parts of the broach handle are manufactory adjusted to each other. When re-assembling check that all 3 parts show the same id. number.



Instructions for disassembly:

Pull the trigger as high as possible by introducing a finger deeply into the eyelet.
The ratchet assembly should come away freely from the trigger.
Spread the ratchet assembly to 45° and remove it from the handle body.
Remove the trigger from the handle body.

Instructions for re-assembly:

Introduce the trigger into the handle body as shown (Fig.8).
Introduce the ratchet assembly into the handle body, checking that the channels are aligned with the corresponding ridges into the handle body (Fig.9), push the rod until contact (Fig.10).
Engage the ratchet assembly while pulling the trigger up (Fig.11).

Assembly and disassembly of broach handle



Fig.8



Fig.9



Fig.10

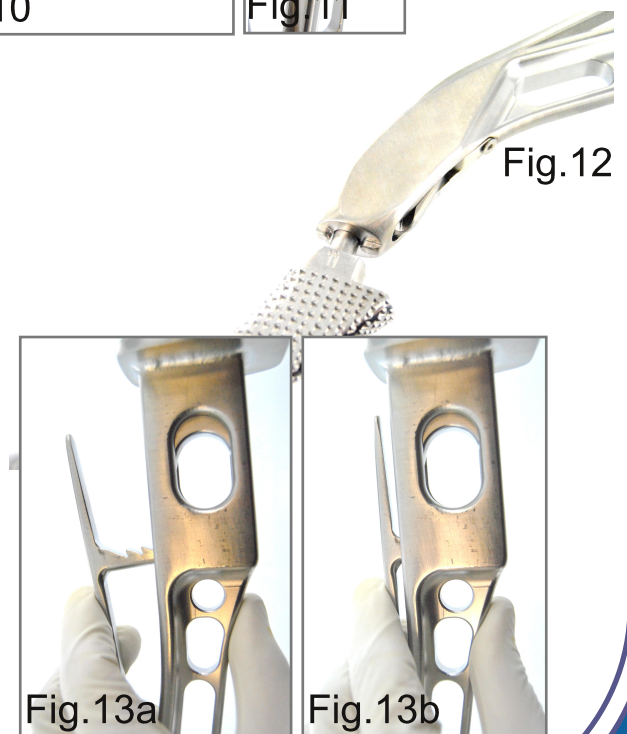


Fig.11

Engagement of broaches onto the broach handle

The instrumentation is equipped 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.

Engage the broach into the broach handle (Fig.12).
Tighten the ratchet up until the last stop to ensure rigid assembly (Fig 13 a & b).
Start broaching.



SURGICAL STEPS

Femoral Canal Preparation

Start with the smallest broach (Fig. 14) and increase in size one at a time until axial and rotational stability is achieved.

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

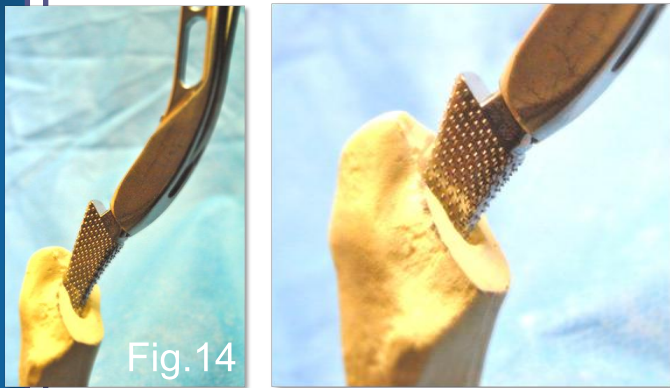


Fig.14

Height and rotation control

An optional Tommy bar (ref.: H50 004) can be inserted in the proximal transverse hole of the broach handle (Fig. 15a) to help controlling anteversion.

The height control -related to the pre-operative planning or to the summit of the GT- is achieved by positioning a pin wire (optional S01 003) in the grooved-mark of the broach handle (Fig. 15b).



Fig.15a

Fig.15b



Fig.17

Fig.16

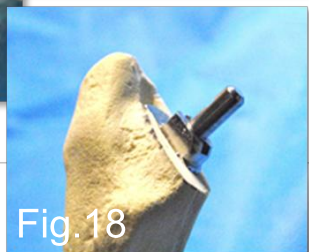


Fig.18

The aim is for the implant to sit tightly in compacted cancellous bone and not to be in direct contact with the cortex.

Each broach should be impacted to the level of the osteotomy, and the final broach – which determines the actual implant size – seated at this level. It should be stable axially and in rotation when the handle twisted or rotated (Fig. 16).

To disengage the broach from the handle, pull the trigger (Fig. 17) and remove the broach.

Remove the broach handle and leave the last broach in situ for trialling (Fig. 18).

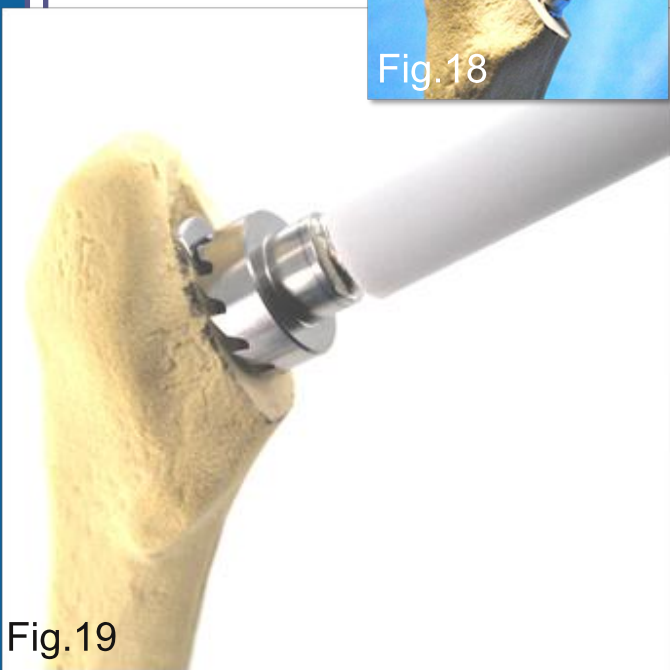


Fig.19



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

Introduce optional calcar reamer on broach tip and ream until bone level is even with broach (Fig. 19).

SURGICAL STEPS

Trial Reduction

Leaving the final broach in place and remove the broach handle.

Attach the appropriate neck and head trials (Fig.20 & 22).

Trial necks are available in standard (straight) or latero-varus versions (Fig.21).



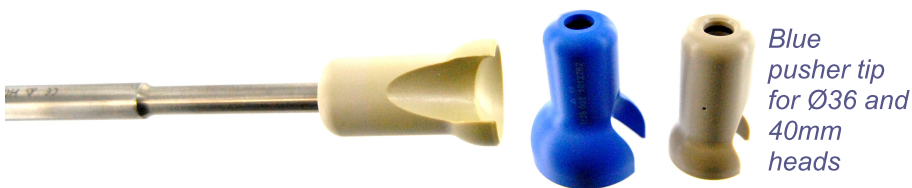
Straight trial neck (left)
Latero-varus trial neck (right)

Head trials are delivered in standard instrument sets in 28mm (-3.5, 0, +3.5, +7) and 32mm (-4, 0, +4) diameters.

For 36 and 40mm trials, complementary head trials and impactor tip need to be requested.

Reduce the hip using the head pusher tip fitted on the spherical tip impactor (Fig.23).

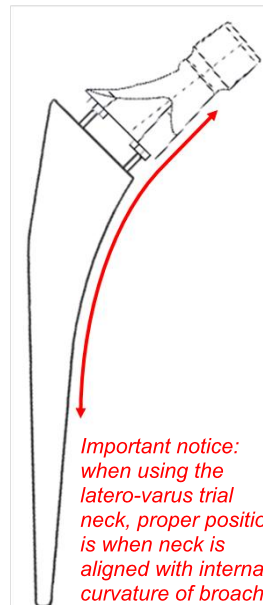
Standard head pusher tip is adapted to Ø28 and 32mm heads. For Ø36 and 40mm heads optional pusher tip (ref H36 002) need to be requested.



Blue pusher tip for Ø36 and 40mm heads

Assess stability through the full range of motion (Fig.24).

Repeat the trial reduction with different trial heads as required.



Important notice: when using the latero-varus trial neck, proper position is when neck is aligned with internal curvature of broach!



Fig.20



Fig.21

Latero-Varus trial neck



Fig.22

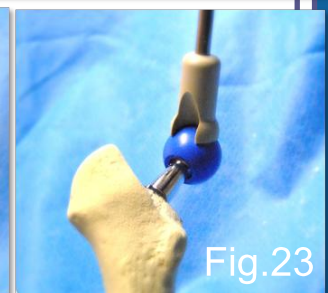


Fig.23

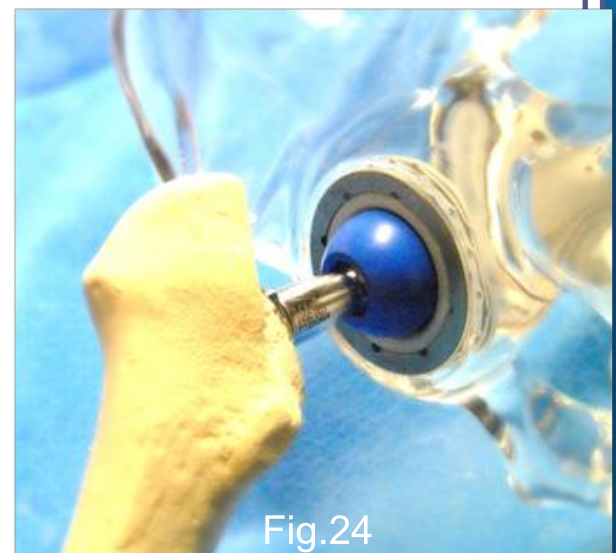


Fig.24

Stem Insertion



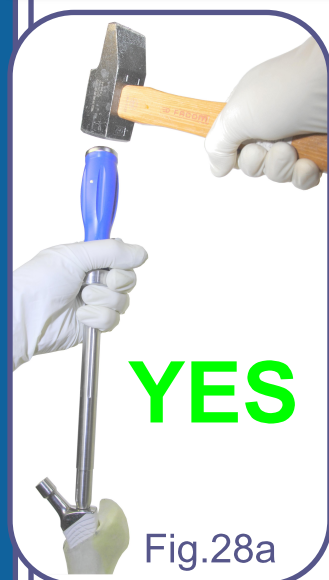
When correct stability has been achieved, re-attach the broach handle and remove the broach from the femoral canal (Fig.25).

Push the threaded stem holder through the outer body of the stem holder until thread appears out of the sleeve (Fig.26).



Fig.26

Adapt the threaded stem holder and its outer body on the STEMSYS implant taking care to adjust the teeth of the outer body to the corresponding slot on the implant (Fig.27 a). Firmly screw the stem holder to the implant (Fig.27b). The conical tip of the outer body associated to a firm screwing enables the surgeon to control rotation while introducing the implant into the femur.



YES

Fig.28a



NO

Fig.28b



Fig.27a



Fig.27b

The operator controls the rotation of the implant when holding the stem holder at the junction between the blue handle and the thumb wheel of the outer body (Fig.28a).

Holding the blue handle of the stem holder alone does not allow proper rotation control of the implant as the assembly can be unscrewed (Fig.28b).

The definitive cemented implants are introduced into the femoral canal by hand. The cementless stems are impacted using the definitive stem impactor and a hammer (Fig.29).

Final impactation with the optional spherical tip impactor (Fig.30) does not influence anteversion.



Fig.27 Fig.29

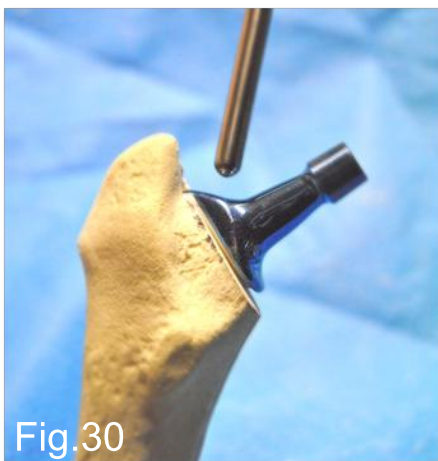


Fig.30

SURGICAL STEPS

Trial Femoral head on final stem

Once the stem has been implanted, perform a final trial reduction with a trial head (Fig.29).

Reduce the hip using the head pusher fitted on the spherical tip impactor.

Assess stability through the full range of motion.



Femoral Head Insertion and reduction

Before positioning the definitive femoral head, clean the Morse taper carefully by hand (first with water then dry).

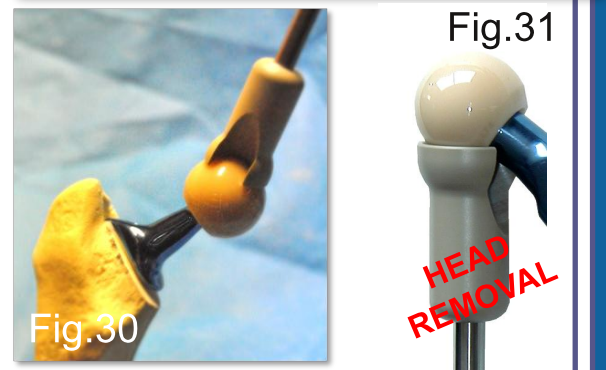
A femoral head with 12/14 taper is mounted with a light rotational movement, and rotated further with axial force until it is seated firmly.

Tap lightly to fix the femoral head onto the femoral Morse taper using the head pusher fitted on the spherical tip impactor (Fig.30).

Ensure the femoral head is firmly secure.

If ever the femoral head need to be removed, use the head pusher and tap the femoral head from bottom to top (Fig.31).

The joint is then reduced and manipulated to retest stability and function (Fig.32).



Removal of femoral stem

In case removal of stem is required (intraoperative complication or revision), attach slap-hammer to the stem inserter (Fig.33), 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 bone to stem interface before hammering.



REFERENCES

Implants HACTIV® Implants

Description	Taille Size	Réf. Cat N°	Description	Taille Size	Réf. Cat N°
HACTIV 135° std HAP/Cementless *	7	H49 007	HACTIV 128° lat-var HAP/Cementless	9	H49 L009
HACTIV 135° std HAP/Cementless *	8	H49 008	HACTIV 128° lat-var HAP/Cementless	10	H49 L010
HACTIV 135° std HAP/Cementless	9	H49 009	HACTIV 128° lat-var HAP/Cementless	11	H49 L011
HACTIV 135° std HAP/Cementless	10	H49 010	HACTIV 128° lat-var HAP/Cementless	12	H49 L012
HACTIV 135° std HAP/Cementless	11	H49 011	HACTIV 128° lat-var HAP/Cementless	13	H49 L013
HACTIV 135° std HAP/Cementless	12	H49 012	HACTIV 128° lat-var HAP/Cementless	14	H49 L014
HACTIV 135° std HAP/Cementless	13	H49 013	HACTIV 128° lat-var HAP/Cementless	15	H49 L015
HACTIV 135° std HAP/Cementless	14	H49 014	HACTIV 128° lat-var HAP/Cementless	16	H49 L016
HACTIV 135° std HAP/Cementless	15	H49 015	HACTIV 128° lat-var HAP/Cementless *	18	H49 L018*
HACTIV 135° std HAP/Cementless	16	H49 016	HACTIV 128° lat-var HAP/Cementless *	20	H49 L020*
HACTIV 135° std HAP/Cementless	18	H49 018			
HACTIV 135° std HAP/Cementless	20	H49 020			
HACTIV 135° Cimentée/Cemented	9	H49 S09	HACTIV 135° std. HAP avec/with coll.	9	H49 C09
HACTIV 135° Cimentée/Cemented	10	H49 S10	HACTIV 135° std. HAP avec/with coll.	10	H49 C10
HACTIV 135° Cimentée/Cemented	11	H49 S11	HACTIV 135° std. HAP avec/with coll.	11	H49 C11
HACTIV 135° Cimentée/Cemented	12	H49 S12	HACTIV 135° std. HAP avec/with coll.	12	H49 C12
HACTIV 135° Cimentée/Cemented	13	H49 S13	HACTIV 135° std. HAP avec/with coll.	13	H49 C13
HACTIV 135° Cimentée/Cemented	14	H49 S14	HACTIV 135° std. HAP avec/with coll.	14	H49 C14
HACTIV 135° Cimentée/Cemented	15	H49 S15	HACTIV 135° std. HAP avec/with coll.	15	H49 C15
HACTIV 135° Cimentée/Cemented	16	H49 S16	HACTIV 135° std. HAP avec/with coll.	16	H49 C16
			HACTIV 135° std. HAP avec/with coll.	18	H49 C18

Têtes Fémorales Femoral Heads

Matériau / Matériel	Taille Size	Réf. Cat N°	Matériau / Matériel	Taille Size	Réf. Cat N°
Chrome-Cobalt / Cobalt-Chromium	Ø28 -3.5mm	H10 1280	Alumine / Alumina	Ø28 -3.5mm	H14 1280
Chrome-Cobalt / Cobalt-Chromium	Ø28 +0mm	H10 1281	Alumine / Alumina	Ø28 +0mm	H14 1281
Chrome-Cobalt / Cobalt-Chromium	Ø28 +3.5mm	H10 1282	Alumine / Alumina	Ø28 +3.5mm	H14 1282
Chrome-Cobalt / Cobalt-Chromium	Ø28 +7mm	H10 1283	Céram. Composite / Composite Ceram.	Ø32 -4mm	H14 C1320
Chrome-Cobalt / Cobalt-Chromium	Ø32 -4mm	H10 1320	Céram. Composite / Composite Ceram.	Ø32 +0mm	H14 C1321
Chrome-Cobalt / Cobalt-Chromium	Ø32 +0mm	H10 1321	Céram. Composite / Composite Ceram.	Ø32 +4mm	H14 C1322
Chrome-Cobalt / Cobalt-Chromium	Ø32 +4mm	H10 1322	Céram. Composite / Composite Ceram.	Ø32 +8mm	H14 C1323
Chrome-Cobalt / Cobalt-Chromium	Ø32 +8mm	H10 1323	Céram. Composite / Composite Ceram.	Ø36 -4mm	H14 C1360
			Céram. Composite / Composite Ceram.	Ø36 +0mm	H14 C1361
			Céram. Composite / Composite Ceram.	Ø36 +4mm	H14 C1362
			Céram. Composite / Composite Ceram.	Ø36 +8mm	H14 C1363

* : sur demande spéciale / on special request

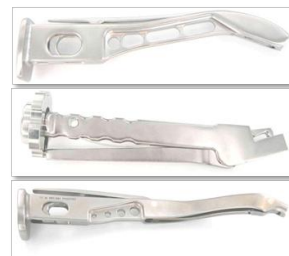
Instrumentation HACTIV® Instrument Set H50 9100

Description	Nbre. Numb. Articles	Réf. Cat N°	Description	Nbre. Numb. Articles	Réf. Cat N°
Plateau avec couvercle / Tray with Lid	1	H50 9000	Râpe Taille 9 / Broach size 9	1	H50 009
Manche porte-râpe / Broach handle	2	H01 009	Râpe Taille 10 / Broach size 10	1	H50 010
Ciseau évideur / Bone chisel	1	H01 013	Râpe Taille 11 / Broach size 11	1	H50 011
Chemise bt conique / Conical tip sleeve	1	H01 021	Râpe Taille 12 / Broach size 12	1	H50 012
Impacteur à bout sphérique	1	H01 023	Râpe Taille 13 / Broach size 13	1	H50 013
Masse coulissante / Slap hammer	1	H01 033	Râpe Taille 14 / Broach size 14	1	H50 014
Embout pousse-tête / Head pusher tip	1	H02 001	Râpe Taille 15 / Broach size 15	1	H50 015
Tête d'essai Ø28 -3.5mm Trial Head	1	H02 2280	Râpe Taille 16 / Broach size 16	1	H50 016
Tête d'essai Ø28 +0mm Trial Head	1	H02 2281	Râpe Taille 18 / Broach size 18	1	H50 018
Tête d'essai Ø28 +3.5mm Trial Head	1	H02 2282	Râpe Taille 20 / Broach size 20	1	H50 020
Tête d'essai Ø28 +7mm Trial Head	1	H02 2283			
Tête d'essai Ø32 -4mm Trial Head	1	H02 2320			
Tête d'essai Ø32 +0mm Trial Head	1	H02 2321			
Tête d'essai Ø32 +4mm Trial Head	1	H02 2322			
Impacteur de tige / Stem impactor	1	H38 022			
Col d'essai 135° standard Trial Neck	1	H50 003			
Col d'essai 128° latero-varus Trial Neck	1	H50 005			

Options	Nbre. Numb. Articles	Numb. Articles
Anterior approach broach handle	2	H01 027
Right Offset broach handle	1	H01 048
Left Offset broach handle	1	H01 049
Head pusher tip for Ø36 & 40mm	1	H36 002



Femoral broaches: choice of machined bone-compact structure (picture) or embossed spiked structure.



From top : postero-lateral, anterior approach, and lateral offset broach handle.

HACTIV®

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