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CREATEUR FABRICANT

Stemsys® MI

Surgical Technique

Evolutis
MOTION INSIDE

STEMSYS® MI hip system

The STEMSYS® MI uncemented primary femoral component is a fully coated porous Ti + HA alloy stem, designed for immediate mechanical stability and long term biological fixation.

The STEMSYS® MI is a shortened variant of the STEMSYS® primary stem for hemi or total hip arthroplasty. The shortened length of STEMSYS® MI facilitates the introduction of the stem in true anterior surgical apporaches to the hip, and reduces the invasiveness of the implant into the intramedullar bone.
The basis of the design is being based on the well-known trapezoidal proximal and mid section that provides immediate rotational stability and optimal metaphyseal fit.

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

The range of sizes of the STEMSYS® MI includes 10 sizes (from size 9 to 20) and 2 cervico-diaphyseal neck angles for standard (135°) or latero-varus (128° + 3.2mm) anatomical adaptation.

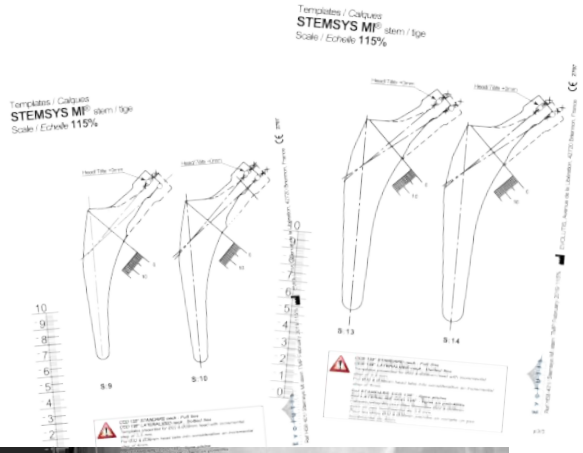
The STEMSYS® MI Hip System offers stainless steel, cobalt chrome, or composite ceramic femoral heads. STEMSYS Femoral Heads come in 22.2mm, 28mm, 32mm and 36mm sizes.

Table of contents

Templating and Approach

Pre-operative templating templates will be delivered to your hospital together with the instrument set.
Digital templating is also available on the mediCad digital templating platfrom.

The set of templates includes 1 sheet for each 2 sizes of stem ranging from size 9 to size 20 (5 sheets).
Each sheet figures standard and latero-varus necks.
Templates are available in 86%, 100%, 115% and 120% magnification ratio. Please inform your local distributor of your referred magnification ratio.



Templating aims at anticipating on the best size of the implant with respect to the primary fixation mode (see important notice below), estimate the neck angle best adapted to the patient, and to identify the neck resection level with reference to the lesser trochanter.

The templating steps are:

- Draw centre of diaphysis line (Fig.1)
- Draw 45° angle resection line and calculate the distance (in mm) to 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 centre of prosthetic head identical or slightly medial to the centre of femoral head.

Fig.1

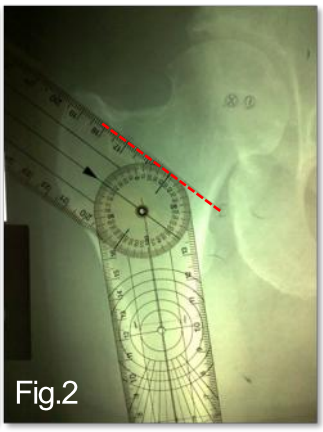


Fig.2

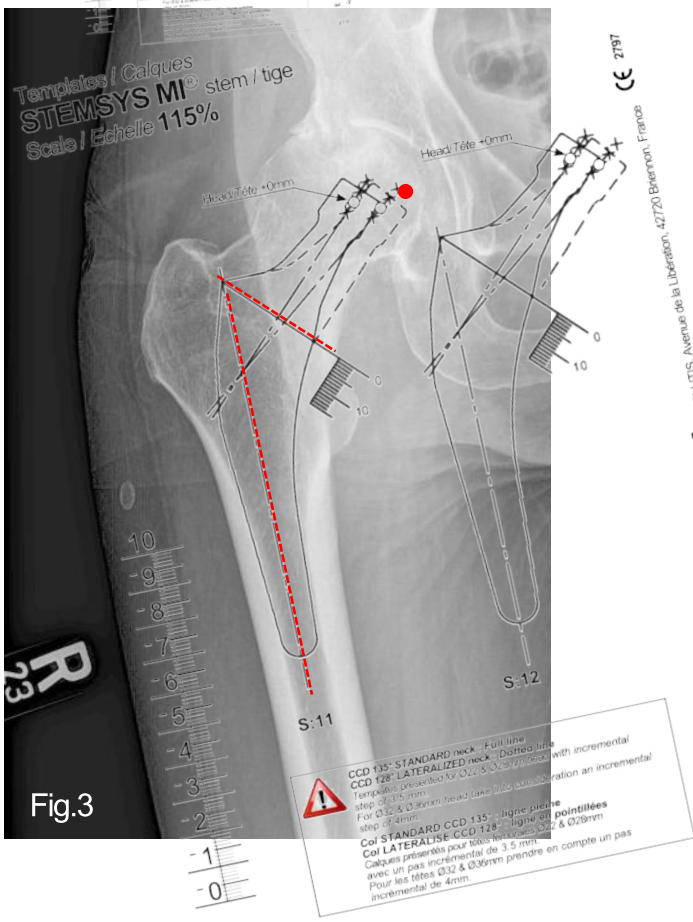


Fig.3

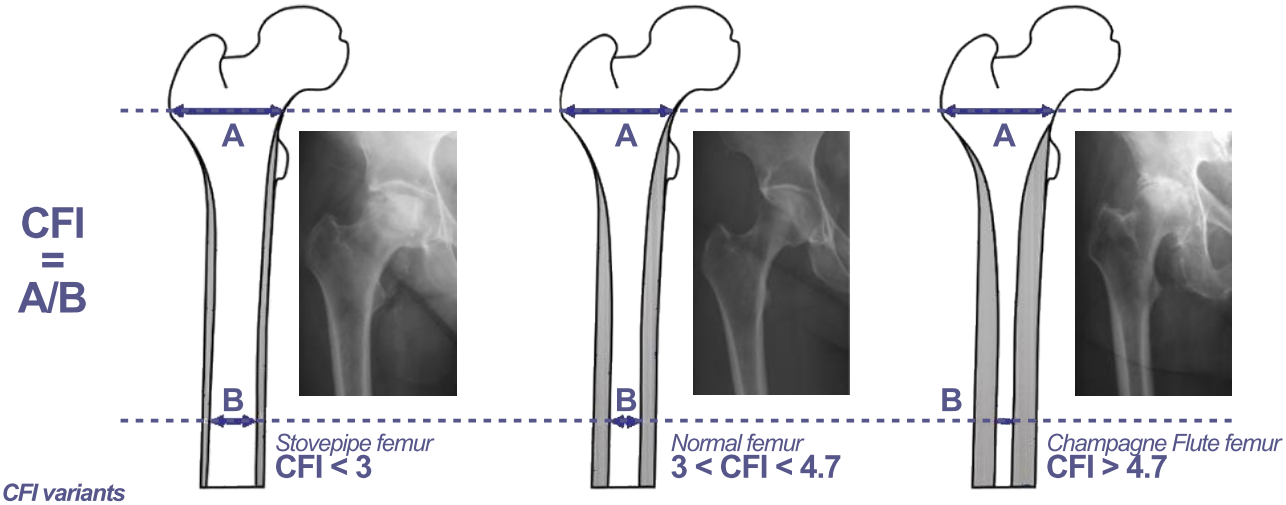
The surgical approach is at the discretion of each surgeon and should be chosen based upon the circumstances of the patient and the surgeon's preference.
Preference will dictate whether an anterolateral, lateral, or posterolateral approach is made.
The skin incision and muscle detachment will depend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

The STEMSYS® MI instrument system can be custom adapted to your surgical approach.
Broach handles for postero-lateral, antero-lateral, or anterior approaches are available.
Please ensure that the instrumentation provided for the surgery corresponds to the surgical approach that will be performed.

Important notice

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

STEMSYS® MI is the shortened variant of the conventional Stemsys® femoral stem.
Although it can be associated to any surgical approach for minimally invasive purposes, it has been developed to facilitate the introduction of the stem when implanting a total hip through an anterior surgical approach to the hip.
As a consequence of this specific use, the Stemsys® MI is more often used for younger patients than for the conventional length Stemsys® and may require a specific surgical adaptation when considering implantation in the high Canal Flare Index (CFI) femoral morphologies specific to the younger population of patients.



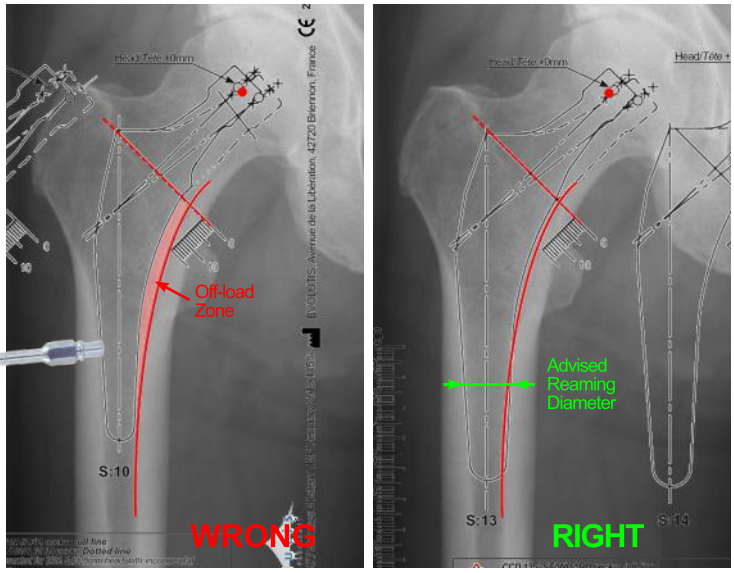
CFI variants

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).

When templating the surgery pre-operatively, the surgeon should be aware that the primary fixation mode of the femoral stem will vary depending on the CFI of each patient. The STEMSYS® MI implants are designed for fixation in the metaphyseal bone, but in femurs with high CFI, primary fixation may not be proximal due to the significant flare of the intramedullary space, and become more distal, 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.
The surgical procedure is described in page 6.

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.

(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.

Surgical steps

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 intramedullary 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 templating.

The resection is made with an oscillating saw blade.
The femoral head is then removed.

Note: in anterior approach procedures of stiff hips it may be necessary to cut a slice of the femoral neck to facilitate removal of the femoral head.

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

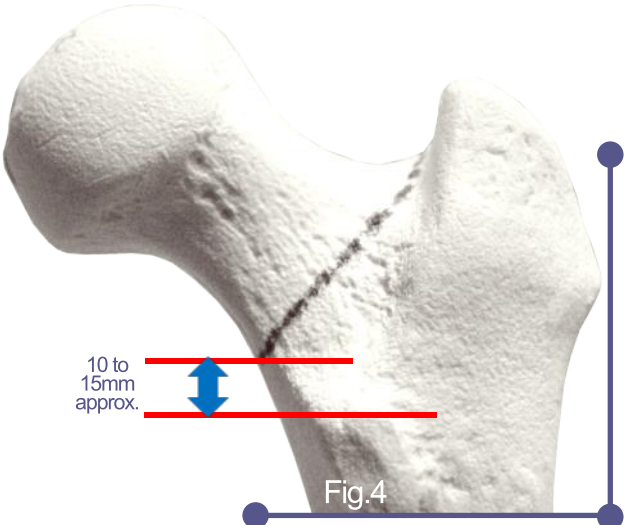


Fig.4

Opening the intramedullary canal

Enter the femoral canal as laterally as possible with the Box Chisel supplied in the STEMSYS® Femoral Stem Instrument set (*Fig.5*).

Start as close as possible to the greater trochanter base to allow straight broaching axis and prevent 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.6*).

The starting rasp (ref. H01 062) specifically designed for anterior approach is then introduced to remove proximal cancellous bone in the metaphysis and in the greater trochanter to facilitate the introduction of the first broach in the axial direction (Fig.7).


Fig.5


Fig.6


Fig.7

Surgical steps

Specific step for high CFI femoral morphologies

Proportionally to a conventional stem, the STEMSYS® MI femoral stem is more often used for younger patients with high canal flare index (CFI) femoral morphology.
When facing a case where the femoral CFI is ≥ 4.7 (read important notice page 5), it is advised to ream the femoral diaphysis to prevent from an excessively tight distal fixation of the stem.

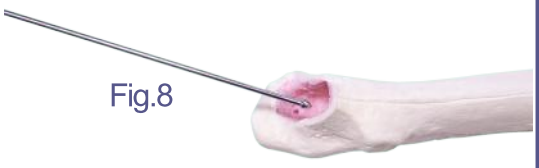


Fig.8

1) Templating step should have identified the high CFI case and calculated the required reaming diameter (page 5)
2) Introduce the reaming guide wire into the diaphysis (Fig.8)
3) Slide the smaller diameter reaming head on the flexible shaft
4) Introduce the head and shaft on the guide wire (Fig.9)
5) Connect the power tool to the flexible shaft
6) Ream the diaphysis at the minimum depth indicated in table 1
7) Increment the reaming heads up to the reaming diameter indicated for the templated femoral size in table 1 (Fig.10)

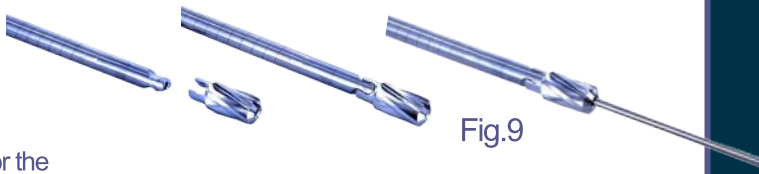


Fig.9

	A-A width 30mm from tip	Reaming diameter	Reaming depth
Size 9	11.9	Ø12	7 cm
Size 10	12.5	Ø12.5	8 cm
Size 11	13.6	Ø13.5	8.5 cm
Size 12	14,3	Ø14.5	9 cm
Size 13	15,5	Ø15.5	9.5 cm
Size 14	16	Ø16	10 cm
Size 15	17	Ø17	10 cm
Size 16	17,5	Ø17.5	10.5 cm
Size 18	19	Ø19	11 cm
Size 20	20,1	Ø20	12 cm

Table 1: Diameter and depth of reaming
Depth measured from medial level of cut
*For **information purpose**.*
Should be adapted during templating procedure, read page 3.

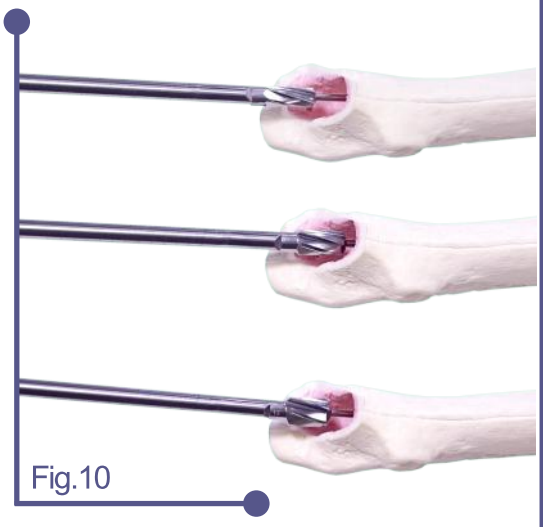


Fig.10

Choice of broach handle

The STEMSYS® MI system offers the choice broach-handles adapted to the surgical approach of the operator.
Broach handles are available for the posterior approach (H01 066), for the true direct anterior approach (DAA) (H01 065), and for the anterolateral approach (H01 067 and H01 068).

This surgical technique describes the use with an anterior approach H01 065 handle and broaches in "female" connection.

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 steps remain the same.

Surgical steps

Preparation of the femoral canal

Open the locking lever of the broach handle (*Fig.12*).
Engage the broach into the broach handle (*Fig.13*).
Close the locking lever to ensure rigid assembly of the broach (*Fig.14*).
Start broaching.

STEMSYS MI broach range: sizes 9 to 20

Fig.12

Fig.13

Fig.14

Start with the smallest broach and increment sizes one at a time until axial and rotational stability are achieved.

The surgeon chooses the anteversion of the broaches in line with the orientation of the femoral neck, usually about 15°.
An optional Tommy bar (ref.: H50 004) can be inserted in the proximal tranverse hole of the broach handle to help controlling anteversion.

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 axialy and in rotation when the handle twisted or rotated (*Fig.15*).

To disengage the broach from the handle, pull the locking lever and remove the handle from the broach.

Leave the last broach in situ for trialling (*Fig.*16).

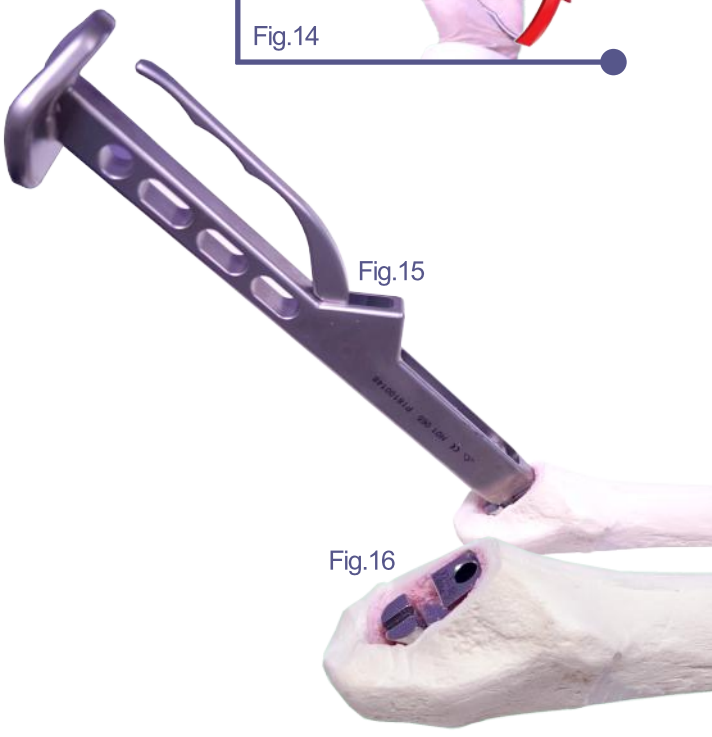


Fig.15

Fig.16

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

Introduce the optional calcar reamer (H72 330) on the broach and ream until bone level is even with broach (*Fig.*17).

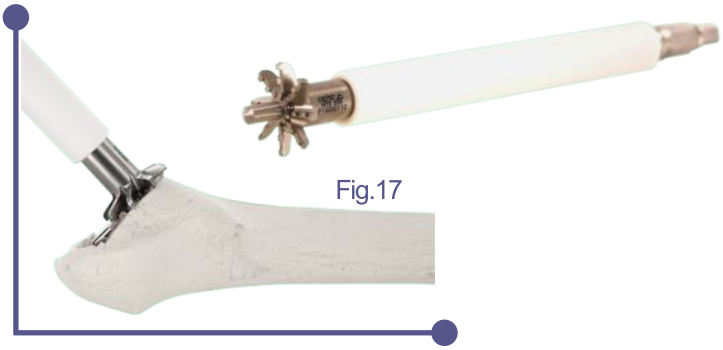


Fig.17

Surgical steps

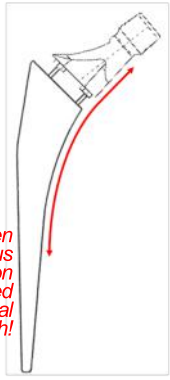
Trial reduction

Leaving the final broach in place, remove the broach handle. Attach the appropriate neck and head trials (*Fig.18 & 19*).

Trial necks are available in standard 135° (straight) or latero-varus 128°+3.2mm offset versions.

Fig.18

Fig.19



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

Head trials are delivered in standard instrument sets in 28mm (-3.5, 0, +3.5, +7), 32mm (-4, 0, +4) and 36mm (-4, 0, +4) diameters. For 22.2mm trials, and for extra-short and extra-long in 32mm and 16mm, complementary head trials need to be requested.

Unless otherwise specified, select the GREEN trial head of the diameter corresponding to the acetabular cup.
The trial heads are coloured according their length:
- YELLOW is short,
- GREEN is standard,
- BLUE is long,
- BLACK is extra-long.

Position the trial head on the Morse taper of the trial neck (*Fig.20*).

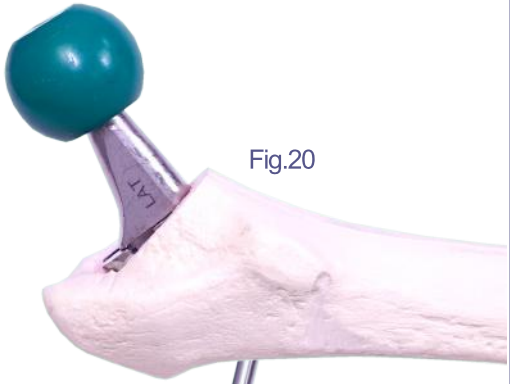


Fig.20

Reduce the hip using the head pusher tip (*Fig.21*).

Fig.21

Assess stability through the full range of motion (*Fig.22*).

Repeat the trial reduction with different lengths of trial heads as required.

Fig.22

Surgical steps

Insertion of the final stem

When the correct stability has been achieved, re-attach the broach handle and remove the broach from the femoral canal (*Fig.23*).

Fig.23

Push the threaded stem holder through the outer body of the stem holder until thread appears out of the sleeve (*Fig.24*).

Fig.24

Fig.25

Adapt the threaded stem holder and its outer body on the STEMSYS® MI implant taking care to adjust the teeth of the outer body to the corresponding slot on the implant *(Fig.25)*.
Firmly screw the stem holder to the implant. The conical end of the outer body associated to a firm screwing enables the surgeon to control rotation while introducing the implant into the femur.

Fig.26a

Fig.26b

The operator controls the rotation of the implant when holding the stem impactor at the junction between the blue handle and the thumb wheel of the outer body (Fig.*26a*).

Holding the blue handle of the stem impactor alone does not allow proper rotation control of the implant as the assembly can be unscrewed (Fig.*26b*).

Fig.27

The definitive **cementless implants** are impacted using the stem impactor (H38 022) + holding sleeve (H38 020) assembly and a hammer (*Fig.27*).

The definitive **cemented implants** are introduced into the femoral canal by hand with the final stem impactor (H01 029) (*Fig.28*).

Final stem impactor H01 029

Fig.28

Surgical steps

Placement of the femoral head and final reduction of the hip joint

Before positioning the definitive femoral head, clean the morse taper carefully: first wash with water then dry with swab.

Tap lightly to fix the femoral head onto the femoral morse taper using the head pusher (*Fig.*29).

Stem impactor H38 022 + Head Pusher tip H02 001

Ensure manually that the femoral head is firmly secured.

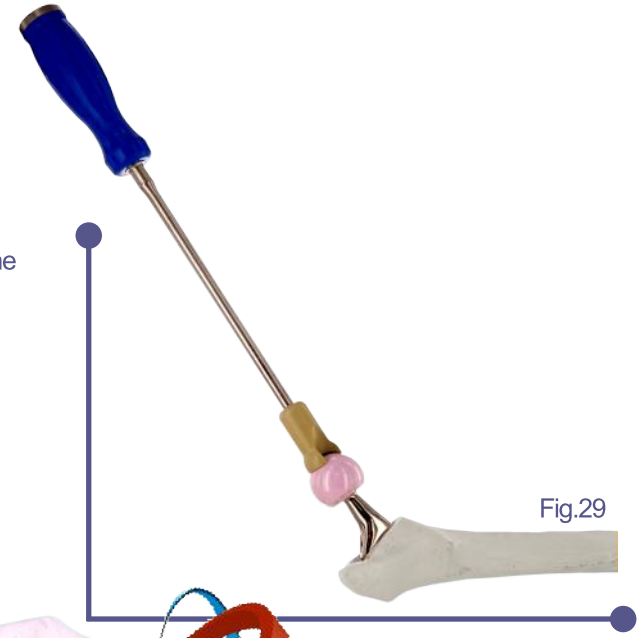


Fig.29

The hip joint is finally reduced.
Final mobilization (flexion-extension, internal-external rotation, abduction) before wound closing will confirm stability and function of the arthroplasty (*Fig.30*).

Fig.30

Revision procedure: removal of head and stem

The removal of the head is realized with the head pusher tip (Fig.31).

For the removal of the stem attach the stem impactor + holding sleeve to the sledge hammer (H01 033), then to the femoral stem.

In case of well osteointegrated stem, the surgeon should take care to detach the bone to stem interface before hammering.
In case of cemented stem, the surgeon should begin by detaching the stem from the cement mantle with specifically supplied scissors.

Fig.31

Hammer the stem out of the femur (*Fig.32*).

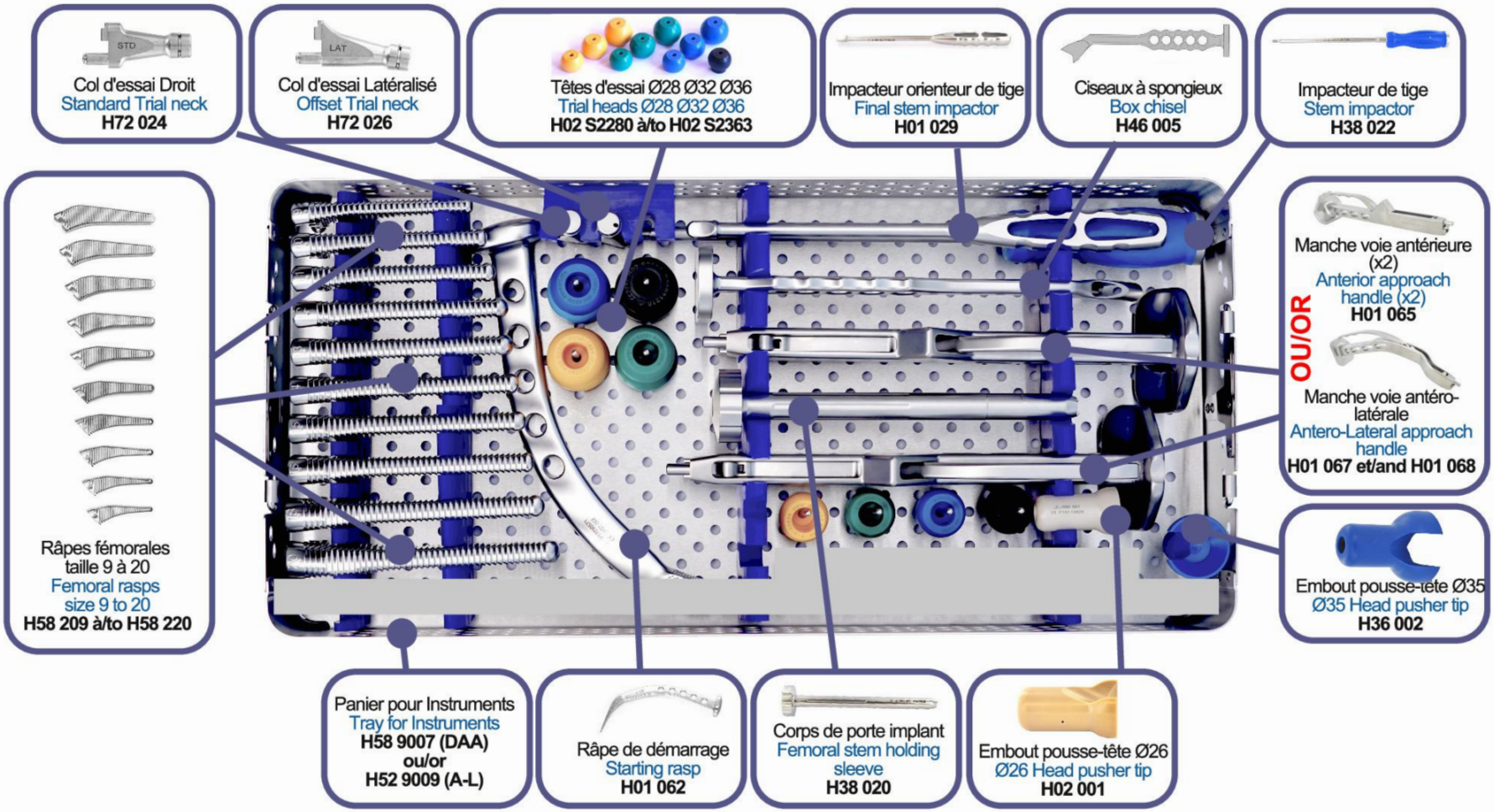
Fig.32

Notes :

Instrumentation SNAPSHOT

Ref : H58 9107 and H58 9109

STEMSYS MI Direct Anterior and Antero-Lateral



Col d'essai Droit
Standard Trial neck
H72 024

Col d'essai Latéralisé
Offset Trial neck
H72 026

Têtes d'essai Ø28 Ø32 Ø36
Trial heads Ø28 Ø32 Ø36
H02 S2280 à/to H02 S2363

Impacteur orienteur de tige
Final stem impactor
H01 029

Ciseaux à spongieux
Box chisel
H46 005

Impacteur de tige
Stem impactor
H38 022

Râpes fémorales
taille 9 à 20
Femoral rasps
size 9 to 20
H58 209 à/to H58 220

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

Embout pousse-tête Ø35
Ø35 Head pusher tip
H36 002

Panier pour Instruments
Tray for Instruments
H58 9007 (DAA)
ou/or
H52 9009 (A-L)

Râpe de démarrage
Starting rasp
H01 062

Corps de porte implant
Femoral stem holding sleeve
H38 020

Embout pousse-tête Ø26
Ø26 Head pusher tip
H02 001

OPTIONS

H72 330	Fraise à Calcar Ø33	Calcar Reamer Ø33
H02 S2220	Tête d'essai Ø22 -2	Trial head Ø22 -2
H02 S2221	Tête d'essai Ø22 +0	Trial head Ø22 +0
H02 S2222	Tête d'essai Ø22 +2	Trial head Ø22 +2
H02 S2323	Tête d'essai Ø32 +8	Trial head Ø32 +8
H02 S2363	Tête d'essai Ø36 +8	Trial head Ø36 +8

OPTIONS

Têtes d'Alésage Ø7,5 à 17,0mm
Reaming heads Ø7.5 to 17.0mm
Q.507-7.5 à/to Q.507-17

Arbre d'alésage flexible (x2)
Flexible Reaming Shaft (x2)
Q.507.01L et/and Q.597.02L

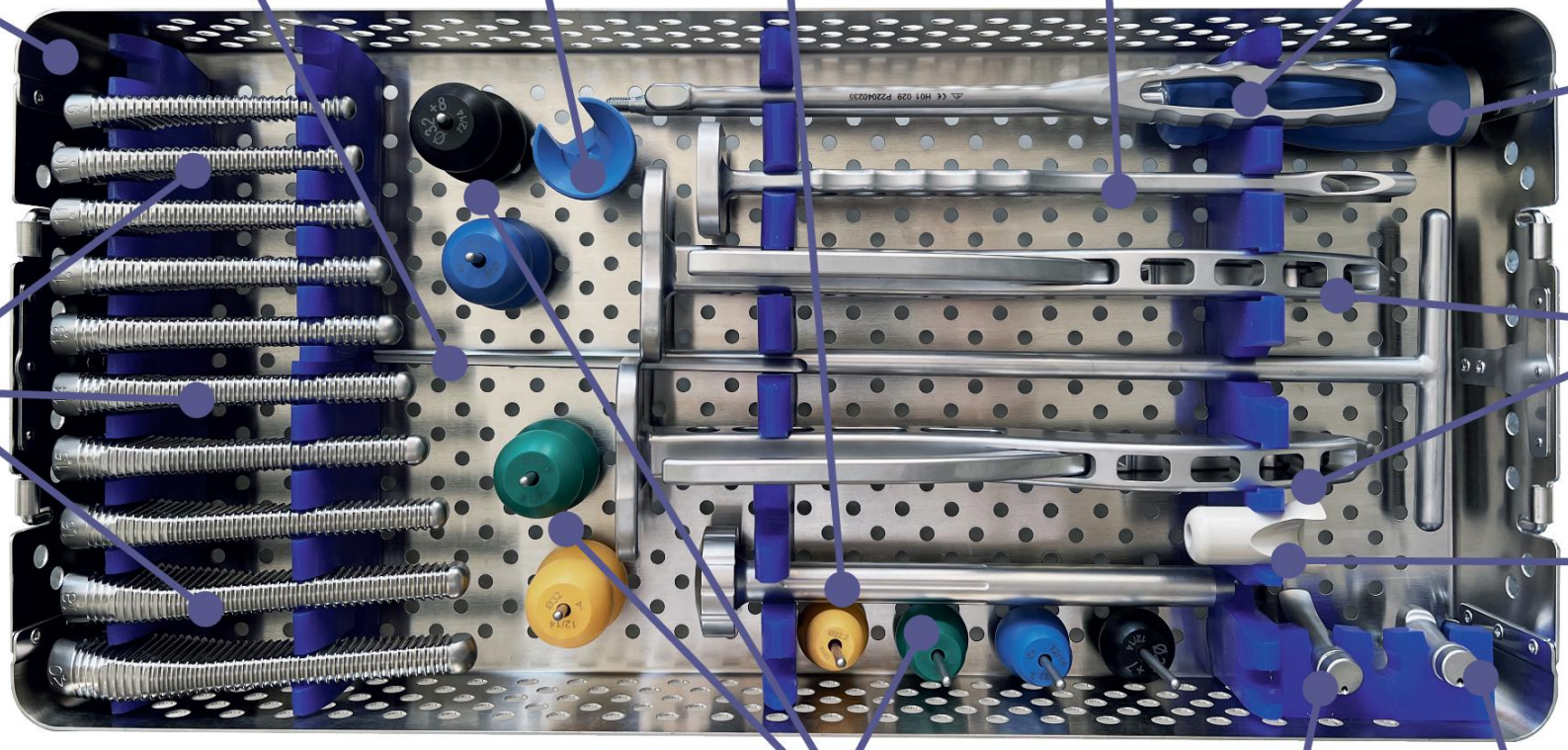
Tige Guide embout Olive 950mm
Guide Rod with ball tip 950mm
Q.507.05

Mar 2023 / Ref: BI_STEMSYS MI SNP H58 9107 & H58 9109

Instrumentation SNAPSHOT

Ref : H58 9110

STEMSYS MI Posterior Approach



Alésoir de démarrage
Starting Reamer
H01 006

Embout pousse-tête pour têtes Ø36mm
Head pusher tip for heads Ø36mm
H36 002

Corps de porte implant
Femoral stemholding sleeve
H38 020

Ciseaux à spongieux
Box chisel
H72 004

Impacteur orienteur de tige
Final stem impactor
H01 029

Panier pour Instruments
Tray for Instruments
H58 9007

Impacteur de tige
Stem impactor
H38 022

Râpes fémorales taille 9 à 20
Femoral rasps size 9 to 20
H58 209 à/to H58 220

Manches voie postérieure (x2)
Posterior approach handle (x2)
H01 066

Embout pousse-tête pour têtes Ø28 et 32mm
Head pusher tip for heads Ø28 and 32mm
H02 001

OPTIONS

Têtes d'Alésage Ø7,5 à 17,0mm
Reaming heads Ø7.5 to 17.0mm
Q.507-7.5 à/to Q.507-17

Arbre d'alésage flexible (x2)
Flexible Reaming Shaft (x2)
Q.507.01L et/and Q.597.02L

Tige Guide embout Olive 950mm
Guide Rod with ball tip 950mm
Q.507.05

Têtes d'essai Ø28 Ø32 Ø36
Trial heads Ø28 Ø32 Ø36
H02 S2280 à/to H02 S2363

Col d'essai Droit
Standard Trial neck
H72 024

Col d'essai Latéralisé
Offset Trial neck
H72 026

OPTIONS

H72 330	Fraise à Calcar Ø33	Calcar Reamer Ø33
H02 S2220	Tête d'essai Ø22 -2	Trial head Ø22 -2
H02 S2221	Tête d'essai Ø22 +0	Trial head Ø22 +0
H02 S2222	Tête d'essai Ø22 +2	Trial head Ø22 +2
H02 S2323	Tête d'essai Ø32 +8	Trial head Ø32 +8
H02 S2363	Tête d'essai Ø36 +8	Trial head Ø36 +8

Mar 2023 / Ref: BI_STEMSYS MI SNP H58 9110

www.evolutisfrance.com / Evolutis, 11 Place des Tuiliers, 42720 Briennon, France. Tel : +33. (0)477.60.79.99 – Fax : +33. (0)477.60.79.90

Instrumentation SNAPSHOT

Ref : Q.507 + 507.05M

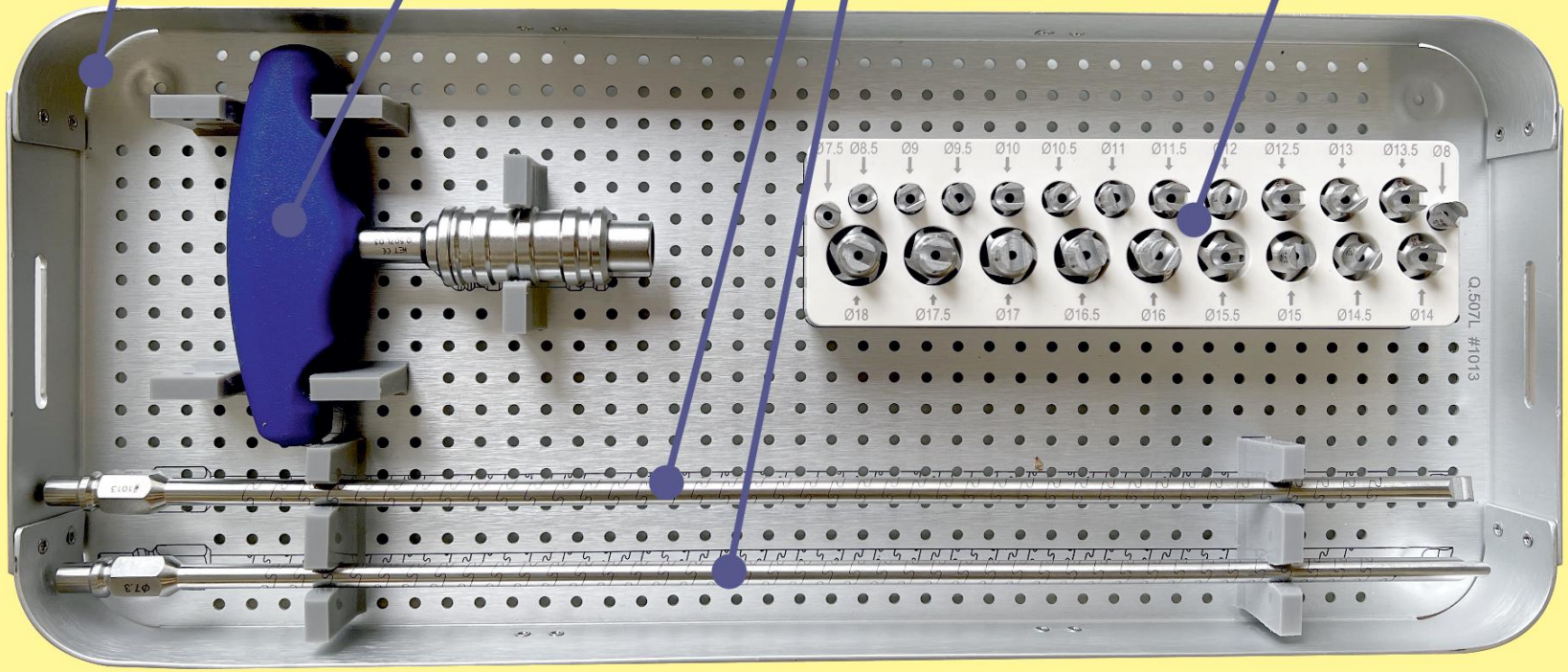
STEMSYS MI Flexible Reamers Kit

Panier pour Instruments
Tray for Instruments
Q.507L

Poignet en T raccord AO
T-Handle for Reamer shaft with AO connection
Q.507.03L

Arbre d'alésage flexible (x2)
Flexible Reaming Shaft (x2)
Q.507.01L et/and Q.597.02L

Têtes d'Alésage Ø7,5 à 18,0mm
Reaming heads Ø7.5 to 18.0mm
Q.507-7.5 à/to Q.507-18

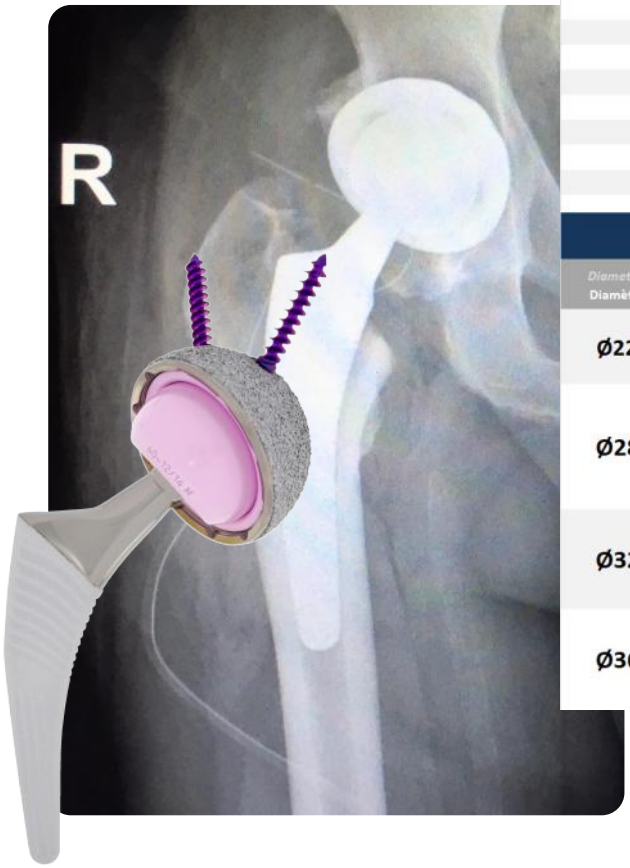


OPTION

Tige Guide embout Olive 950mm
Guide Rod with ball tip 950mm
507.05M

Notes :

Reference list

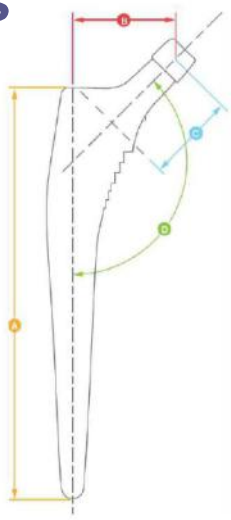


Stemsys MI Implants *Implants*		
Standard 135° **Standard**	*Size* **Taille**	*Lateral Offset 128°* **Latéro-varus**
H57 009 (2)	size 9	H57 L009 (1)
H57 010	size 10	H57 L010 (2)
H57 011	size 11	H57 L011
H57 012	size 12	H57 L012
H57 013	size 13	H57 L013
H57 014	size 14	H57 L014
H57 015	size 15	H57 L015
H57 016	size 16	H57 L016
H57 018	size 18	H57 L018
H57 020	size 20	H57 L020

Femoral Heads Têtes fémorales				
Diameter Diamètre	*Length* Longueur	*Stainless steel* Acier Inox	*Cobalt-Chromium* Chrome-Cobalt	*Composite Ceramic* Céramique Composite
Ø22	-2.0mm	H11 1220	H10 1220	-
	+0mm	H11 1221	H10 1221	-
	+2.0mm	H11 1222	H10 1222	-
Ø28	-7mm	H11 1279	H10 1279	-
	-3.5mm	H11 1280	H10 1280	H14 C1280
	+0mm	H11 1281	H10 1281	H14 C1281
	+3.5mm	H11 1282	H10 1282	H14 C1282
	+7mm	H11 1283	H10 1283	-
Ø32	-4mm	H11 1320	H10 1320	H14 C1320
	+0mm	H11 1321	H10 1321	H14 C1321
	+4mm	H11 1322	H10 1322	H14 C1322
	+8mm	H11 1323	H10 1323	H14 C1323
Ø36	-4mm	-	H10 1360	H14 C1360
	+0mm	-	H10 1361	H14 C1361
	+4mm	-	H10 1362	H14 C1362
	+8mm	-	H10 1363	H14 C1363

(1) Not validated for patients exceeding 75kgs (165lbs) and do not use with femoral head ≥ +7mm
(2) Not validated for patients exceeding 75kgs (165lbs)

STEMSYS® MI stem dimensions



		A	B	C	D
Implants 135° STANDARD *Implants*					
Taille *Size*	Refrence *Catalogue Number*	Longueur *Length*	Offset Latéral *Lateral Offset* (mm)	Longueur col *Neck length*	*NSA* Angle CCD
9	**H57 009**	95	37.5	38.5	135°
10	**H57 010**	102	38.5	38.5	135°
11	**H57 011**	106	39.5	38.5	135°
12	**H57 012**	110	40.5	38.5	135°
13	**H57 013**	114	41.5	38.5	135°
14	**H57 014**	118	42.5	38.5	135°
15	**H57 015**	122	43.5	38.5	135°
16	**H57 016**	126	44.5	38.5	135°
18	**H57 018**	134	45.5	38.5	135°
20	**H57 020**	142	46.5	38.5	135°
Implants 128° LATERO-VARUS *Implants*					
9	**H57 L009**	95	45.5	42.0	128°
10	**H57 L010**	102	46.5	42.0	128°
11	**H57 L011**	106	47.5	42.0	128°
12	**H57 L012**	110	48.5	42.0	128°
13	**H57 L013**	114	49.5	42.0	128°
14	**H57 L014**	118	50.5	42.0	128°
15	**H57 L015**	122	51.5	42.0	128°
16	**H57 L016**	126	52.5	42.0	128°
18	**H57 L018**	134	53.5	42.0	128°
20	**H57 L020**	142	54.5	42.0	128°

Dimension table for STEMSYS MI femoral implant

Notice: Instrument set content may be subject to modifications and/or adapted to the customer's needs. Consequently the item lists presented in the Snapshots in pages 12 to 14 are 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® MI implants belong to the class III implantable medical device classification. The STEMSYS® MI 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) leaflet S12 032 included in the packaging of the implant or available for download on the www.evolutisfrance.com website, as well as the surgical technique manual (H58 454) initially delivered with the instrument set, or equally available for download on the www.evolutisfrance.com website.

Materials:
Stems: Titanium alloy TA6V according ISO5832-3 coated with T40 titanium + Calcium Hydroxyapatite coating
Femoral heads: Stainless steel according ISO5832-9 or Co-Cr according ISO5832-12 or Composite Ceramic according ISO6474-2
VACUPAC Vacuum packaging. Gamma ray sterilised

CE 2797 Evolutis
10 Place des Tuiliers, 42720 Briennon, France
Tel : +33. (0)477.60.79.99 – Fax : +33. (0)477.60.79.90
www.evolutisfrance.com

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