HYPE[®]
FEMORAL STEMS



SUPCICAL TECHNIQUE

cserf

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HYPE[®] STEM IMPLANTS RANGE

The range of HYPE° femoral stems consists of primary femoral implants available in cemented and cementless, collared or collarless versions.

4 offsets options are available: standard offset, lateralized, high offset and coxa vara configurations. Our implants are manufactured from titanium alloy (TA6V) for cementless options and from stainless steel (M30) for cemented stems.

The cementless stem features a 150 μ m thick titanium spray coating over the metaphyseal body completed by a 80 μ m thick HA⁽²⁾ coating over the whole stem surface.

Cemented stems have a highly-polished surface finish and feature a depth indicator marking. The end of the coating on cementless stems and the depth indicator for cemented stems correspond to the impaction limit of the final implants.

The HYPE range is made of the following stems:

DESIGNATION	FEMORAL STEM FAMILIES	AVAILABLE SIZES	NECK-SHAFT ANGLE CDD ⁽¹⁾
HYPE [®] SCS	Standard offset cementless stem	1 - 11	130°
HYPE® SCC	Standard offset collared cementless stem	1 - 11	130°
HYPE® SCC Mini	Mini standard offset collared cementless stem	2 - 7	130°
HYPE® ACS	Standard offset cemented stem	1 - 11	130°
HYPE [®] SCL	Lateralized offset cementless stem	2 - 10	130°
HYPE® SCLA Mini	Mini lateralized offset collared cementless stem	2 - 7	130°
HYPE [®] ACL	Lateralized offset cemented stem	2 - 9	130°
HYPE® SCHO	High Offset cementless stem	3 - 11	130°
HYPE [®] SCV	Coxa vara cementless stem	2 - 9	120°

The HYPE° femoral neck length increases proportionally between each size for all stem families except for HYPE° SCV stems (coxa vara).

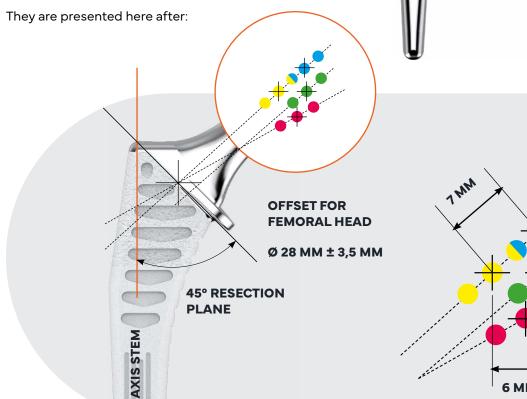
The HYPE® MINI stems are specifically designed to adapt MIS and anterior surgical approaches and are 20% shorter than HYPE® SCC and SCL stems.

1. CCD: Caput-Calllum-Diaphyseal angle 2. HA: Hydroxyapatite



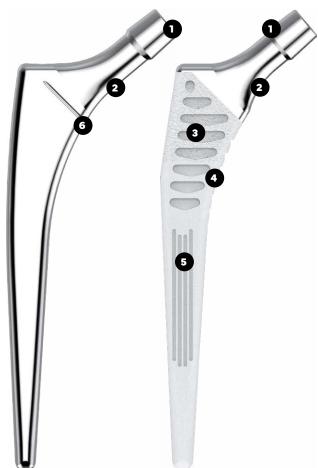
- 2 Polished narrow ovoid neck geometry
- 3 Macro-relief surface
- 4 Support ridges
- 5 Anterior and posterior longitudinal grooves
- 6 Insertion depth marking

The **HYPE** range offer several choice for the restoration of the hip joint center.

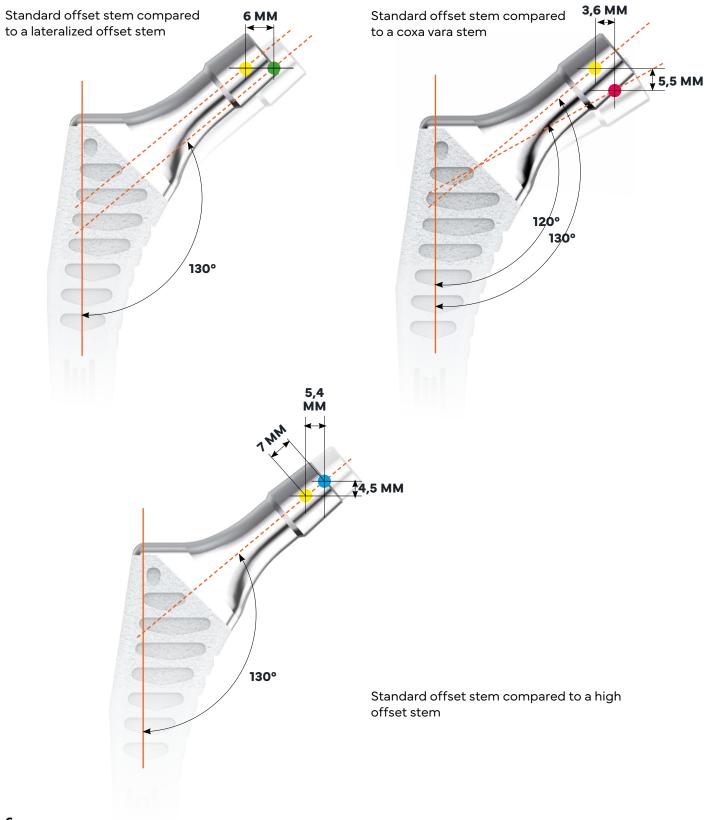


- HYPE[®] standard cementless stem (SCS - SCC - SCC MINI) HYPE® standard cemented stem (ACS)
- HYPE[®] lateralized cementless stem (SCL - SCLA MINI) **HYPE**° lateralized cemented stem (ACL)

- HYPE[®] coxa vara cementless stem (SCV)
- HYPE® high offset cementless stem (SCHO)

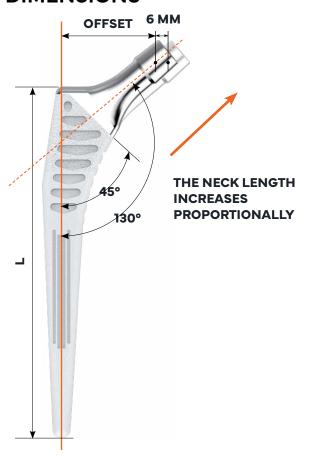


HYPE[®] STEM IMPLANTS RANGE



HYPE® STANDARD AND LATERALIZED CEMENTLESS STEM

DIMENSIONS



SIZE	L (MM)	OFFS	ET (MM)
		STEM	STEM
1	125	38	/
2	130	39	45
3	140	40	46
4	145	41	47
5	150	42	48
6	155	43	49
7	160	44	50
8	165	45	51
9	170	46	52
10	175	47	53
11	180	48	/

STANDARD OFFSET



	STANDARD STEM	REFERENCE
	HYPE° SCS 1	RM12000001
	HYPE® SCS 2	RM12000002
	HYPE° SCS 3	RM12000003
	HYPE® SCS 4	RM12000004
	HYPE [®] SCS 5	RM12000005
	HYPE® SCS 6	RM12000006
U	HYPE® SCS 7	RM12000007
scs	HYPE® SCS 8	RM12000008
) S	HYPE° SCS 9	RM12000009
	HYPE° SCS 10	RM12000010
	HYPE° SCS 11	RM12000011

	STANDARD COLLARED STEM	REFERENCE
0000	HYPE® SCC 1	RM12100001
	HYPE® SCC 2	RM12100002
	HYPE® SCC 3	RM12100003
	HYPE® SCC 4	RM12100004
	HYPE® SCC 5	RM12100005
	HYPE® SCC 6	RM12100006
	HYPE® SCC 7	RM12100007
သင္သ	HYPE® SCC 8	RM12100008
Š	HYPE® SCC 9	RM12100009
	HYPE® SCC 10	RM12100010
	HYPE° SCC 11	RM12100011

LATERALIZED OFFSET



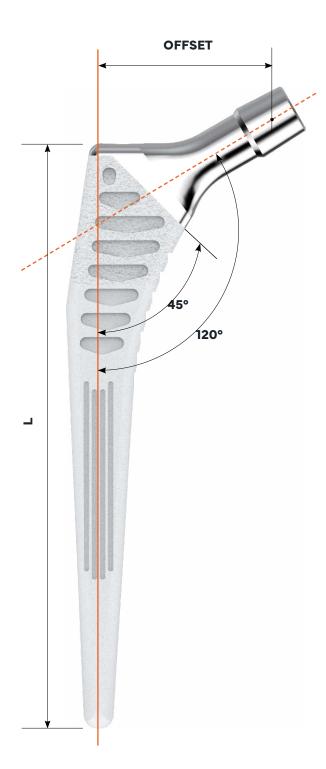
	LATERALIZED STEM	REFERENCE
1000	HYPE° SCL 2	RM12200002
	HYPE® SCL 3	RM12200003
	HYPE® SCL 4	RM12200004
	HYPE® SCL 5	RM12200005
1 U	HYPE® SCL 6	RM12200006
SCL	HYPE® SCL 7	RM12200007
6	HYPE® SCL 8	RM12200008
	HYPE® SCL 9	RM12200009
	HYPE° SCL 10	RM12200010

MATERIALS

• Stem: Titanium alloy (TA6V) • Coating: 150 µm Titanium spray + 80 µm Hydroxyapatite

HYPE® COXA VARA CEMENTLESS STEM

DIMENSIONS



NB: neck length is constant for	or a	ali sizes
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SIZE	L (MM)	OFFSET (MM)
2	130	42,9
3	140	44
4	145	44,8
5	150	45,6
6	155	46,4
7	160	47,2
8	165	48
9	170	48,8

COXA VARA



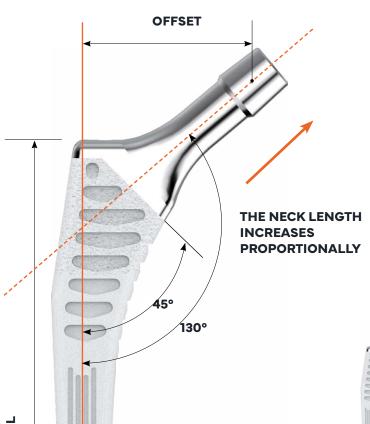
	COXA VARA STEM	REFERENCE
	HYPE [®] SCV 2	RM12400002
	HYPE° SCV 3	RM12400003
	HYPE® SCV 4	RM12400004
	HYPE® SCV 5	RM12400005
V	HYPE® SCV 6	RM12400006
scv	HYPE® SCV 7	RM12400007
	HYPE® SCV 8	RM12400008
	HYPE® SCV 9	RM12400009

MATERIALS

- Stem: Titanium alloy (TA6V)
- Coating: 150 μm Titanium spray + 80 μm Hydroxyapatite

HYPE® HIGH OFFSET CEMENTLESS STEM

DIMENSIONS



SIZE	L (MM)	OFFSET (MM)
3	140	45
4	145	46
5	150	47
6	155	48
7	160	49
8	165	50
9	170	51
10	175	52
11	180	53

HIGH OFFSET



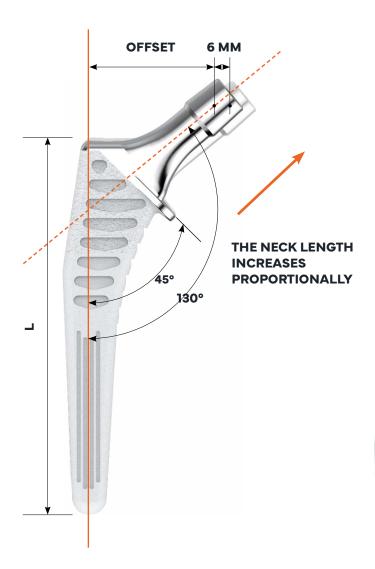
	HIGH OFFSET STEM	REFERENCE
0000	HYPE® SCHO 3	RM12300003
	HYPE® SCHO 4	RM12300004
	HYPE° SCHO 5	RM12300005
	HYPE° SCHO 6	RM12300006
	HYPE° SCHO 7	RM12300007
	HYPE° SCHO 8	RM12300008
зсно	HYPE° SCHO 9	RM12300009
	HYPE® SCHO 10	RM12300010
	HYPE® SCHO 11	RM12300011

MATERIALS

- Stem: Titanium alloy (TA6V)
- Coating: 150 µm Titanium spray + 80 µm Hydroxyapatite

HYPE® MINI STANDARD AND LATERALIZED CEMENTLESS STEM

DIMENSIONS

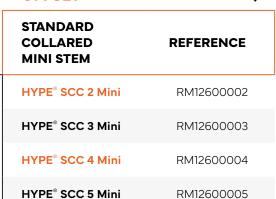


SIZE	L (MM)	OFFSET (MM)	
		STANDARD COLLARED MINI STEM	LATERALIZED COLLARED MINI STEM
2	104	39	45
3	112	40	46
4	116	41	47
5	120	42	48
6	124	43	49
7	128	44	50

STANDARD OFFSET

HYPE® SCC 6 Mini

HYPE® SCC 7 Mini







RM12600006

RM12600007

	LATERALIZED COLLARED MINI STEM	REFERENCE
	HYPE® SCLA 2 Mini	RM12700002
SCLAMINI	HYPE [®] SCLA 3 Mini	RM12700003
	HYPE® SCLA 4 Mini	RM12700004
	HYPE [®] SCLA 5 Mini	RM12700005
) S	HYPE® SCLA 6 Mini	RM12700006
	HYPE [®] SCLA 7 Mini	RM12700007

MATERIALS

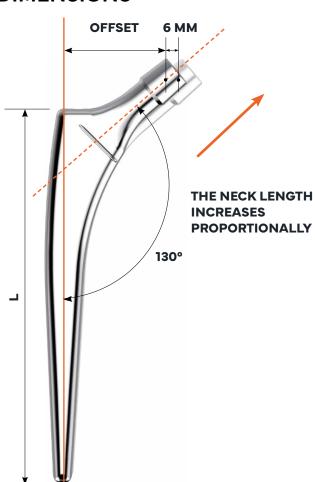
- Stem: Titanium alloy (TA6V)
- Coating: 150 µm Titanium spray + 80 µm Hydroxyapatite

HYPE® STANDARD AND LATERALIZED CEMENTED STEM

STANDARD OFFSET



DIMENSIONS



SIZE	L (MM)	OFFSET (MM) STANDARD LATERALIZI STEM STEM	
1	125	38	/
2	130	39	45
3	140	40	46
4	145	41	47
5	150	42	48
6	155	43	49
7	160	44	50
8	165	45	51
9	170	46	52
10	175	47	/
11	180	48	/

	STANDARD CEMENTED STEM	REFERENCE
	HYPE® ACS 1	RM12800001
	HYPE® ACS 2	RM12800002
	HYPE® ACS 3	RM12800003
	HYPE® ACS 4	RM12800004
	HYPE® ACS 5	RM12800005
	HYPE® ACS 6	RM12800006
	HYPE® ACS 7	RM12800007
	HYPE® ACS 8	RM12800008
	HYPE® ACS 9	RM12800009
	HYPE® ACS 10	RM12800010
	HYPE® ACS 11	RM12800011

LATERALIZED OFFSET



	LATERALIZED CEMENTED STEM	REFERENCE
	HYPE® ACL 2	RM12500002
	HYPE® ACL 3	RM12500003
	HYPE® ACL 4	RM12500004
	HYPE® ACL 5	RM12500005
	HYPE® ACL 6	RM12500006
ACL	HYPE® ACL 7	RM12500007
	HYPE® ACL 8	RM12500008
	HYPE® ACL 9	RM12500009

MATERIALS

• Stem: highly-polished stainless steel ISO 5832-9

COMPATIBLE FEMORAL HEADS

The femoral heads compatible with the HYPE° femoral stems have a 12/14 taper and are the following:

MATERIALS	Ø мм	REFERENCE	DESIGNATION
		RM30650001	D28-CC (- 3,5 mm)
	Ø 28	RM30650002	D28-CM (0)
12 0		RM30650003 D28-CL (+ 3,5 mr	D28-CL (+ 3,5 mm)
12 ^{ហូ} 14 ^ដ	Ø 32	RM30650004	D32-CC (- 4 mm)
CERAMIC		RM30650005	D32-CM (0)
BIOLOX [®] DELTA		RM30650006	D32-CL (+ 4 mm)
		RM30650008	D36-CC (- 4 mm)
	Ø 36	RM30650009	D36-CM (0)
		RM30650010	D36-CL (+ 4mm)

MATERIALS		Ø ММ	REFERENCE	DESIGNATION
	12 0 Ø 22.2 14 STAINLESS STEEL (ISO 5832-9) Ø 28		RM30100001	122-CC (- 2,5 mm)
		Ø 22.2	RM30100002	122-CM (0)
			RM30100003	122-CL (+ 2,5 mm)
			RM30100005	128-CC (- 3,5 mm)
		Ø 28	RM30100006	128-CM (0)
			RM30100007	128-CL (+ 3,5 mm)

COMPATIBLE **ACETABULAR CUPS**

The HYPE® range of femoral stems is compatible with the following acetabular cups:









HYPE®



NOVAE® STICK









NOVAE® COPTOS TH

^{*} only with HYPE® ACS and HYPE® ACL femoral stems

SURGICAL TECHNIQUE

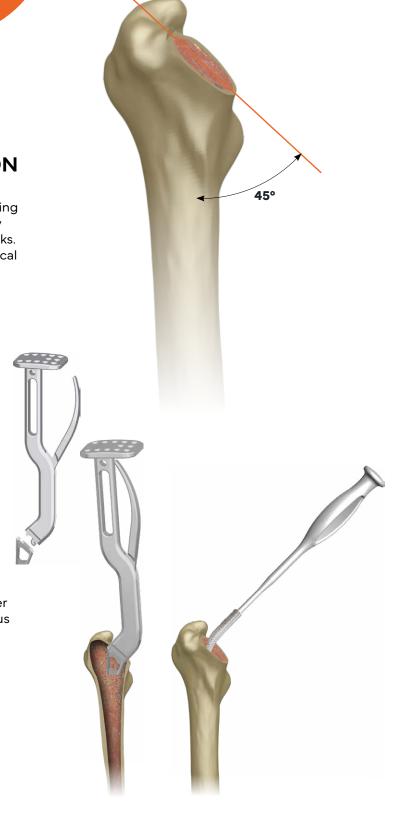
1 FEMORAL NECK RESECTION

The level of the femoral neck resection is determined during preoperative planning using radiographic templates then intraoperatively confirmed based on the anatomical landmarks. The osteotomy should be 45° to the anatomical axis of the femur.

2 GREATER TROCHANTER AND METAPHYSEAL PREPARATION

A small size broach or a bone chisel can be used to enter the femoral canal and remove medial bone in the area of the greater trochanter.

Care must be taken when broaching the inner part of the greater trochanter to prevent varus positioning of the subsequent broaches and final implant.



INSERTION DEPTH MARKING

3 BROACHING

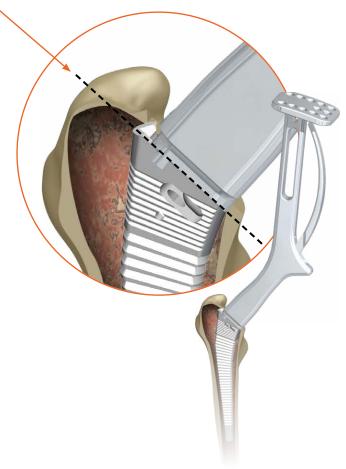
The HYPE® broaches are connected to the appropriate broach handle designed for postero-lateral, antero-lateral or anterior surgical approaches. Proximal cancellous bone compaction is then performed up to the neck resection plane.

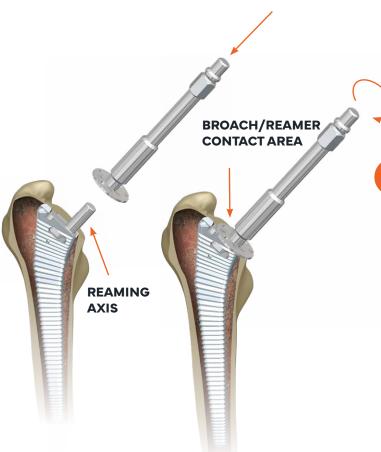
The junction between the broach and the broach handle is the limit of impaction of the broach, and it corresponds to the limit of impaction of the final implant.

Specific broaches are available for **HYPE**° Mini (Standard and Lateralized) stems.

An alignment rod may be assembled to the handle to assess anteversion.

The broach that provides proper rotational stability indicates the definitive implant size.





4 CALCAR REAMING (COLLARED STEM)

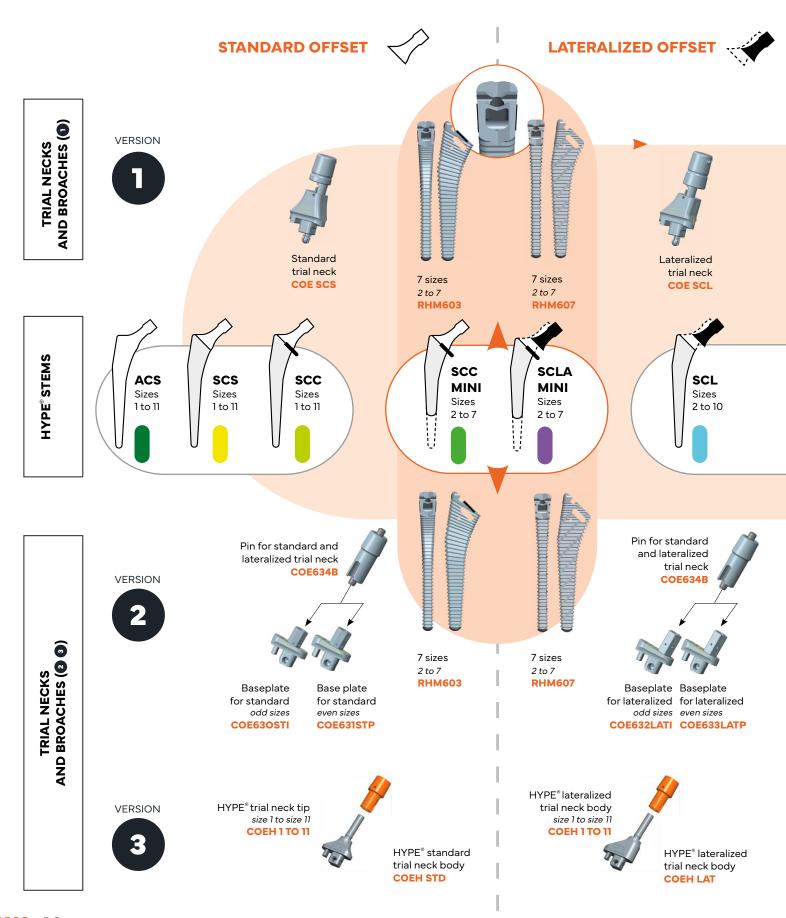
Initiate power to the reamer mounted onto the broach then ream until the reamer/broach are in contact.

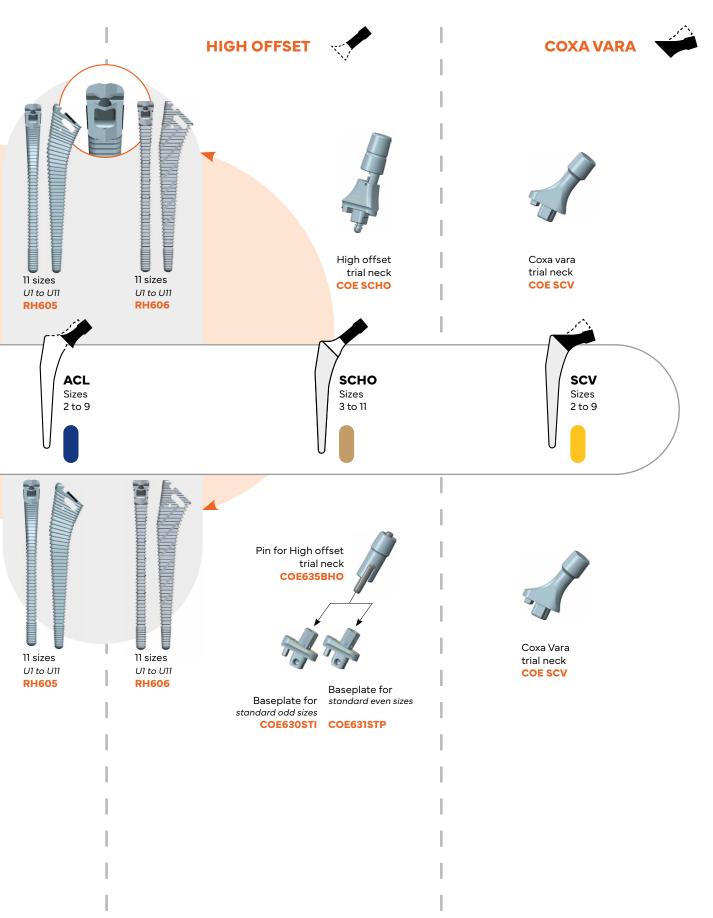
Reaming should allow the upper surface of the broach to sit level with the femoral resection plane.

The calcar reamer should normalize the resection plane for collared stems.

5 TRIAL REDUCTION WITH FINAL BROACH

With the last broach in situ and in order to do the trial reduction, trial necks are required for Standard, Lateralized, Coxa vara or **HYPE**° high offset stem to assess hip joint centre. Three different versions of trial necks exists. Hereafter you will find the details of those three versions and their broach compatibility:





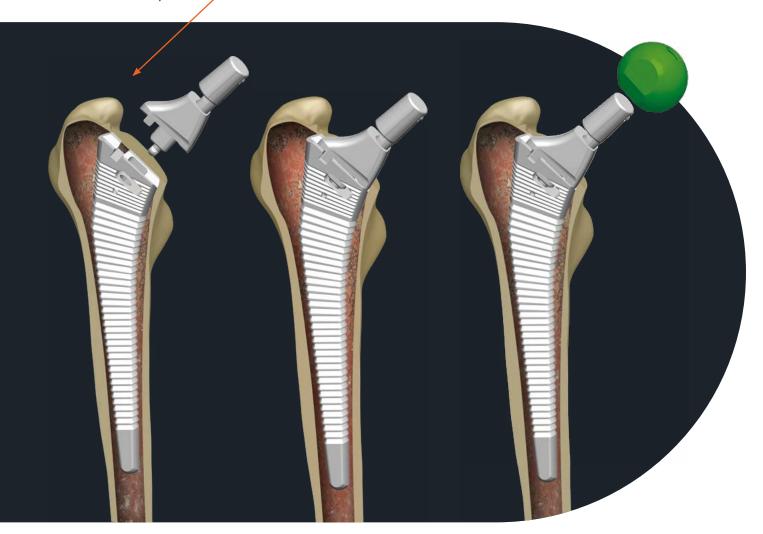
TRIAL REDUCTION WITH FINAL BROACH (CONTINUING)

Trial reduction with trial necks - 1st version

The taper should be firmly pushed up to the stop to achieve correct length and proper neck locking.

Trial heads can be used to check joint stability at this stage.

After validation of the diameter and/or length of the neck, remove the trial head.



Trial reduction with trial necks -2nd version

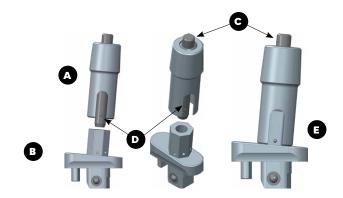
Neck assembly is to proceed according to the following instructions (and according to their compatibility as seen on previous page):

- 1 The pin A should face the neck baseplate B for proper assembly.
- 2 Press_the push-button c to unlock the ball **D** and allow insertion of the pin into the baseplate. The pin should be aligned with the selected size, engraved on the baseplate.

Once the ball is engaged into the shaft of the baseplate, release the push-button C - which must be blocked in lower position.

3 Proper locking of the pin A over the baseplate **B** is confirmed by an audible click. The push-button **c** is then released.

Present the trial neck in front of the broach, and firmly push up to the stop to achieve correct length and proper neck locking (do not push on the push-button as this will change the fixed parameters).



- A Pin for trial neck
- **B** Baseplate for trial neck
- © Push-button
- **D** Ball
- E Trial neck assembly







Trial heads can be used to check joint stability at this stage.

After validation of the diameter and/or length of the neck, remove the trial head.

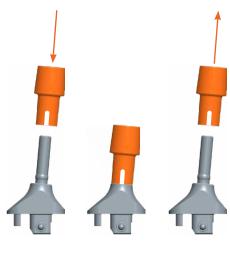
Trial reduction with trial necks - 3rd version

The plastic neck and the specific baseplate to the desired trial must be assembled.

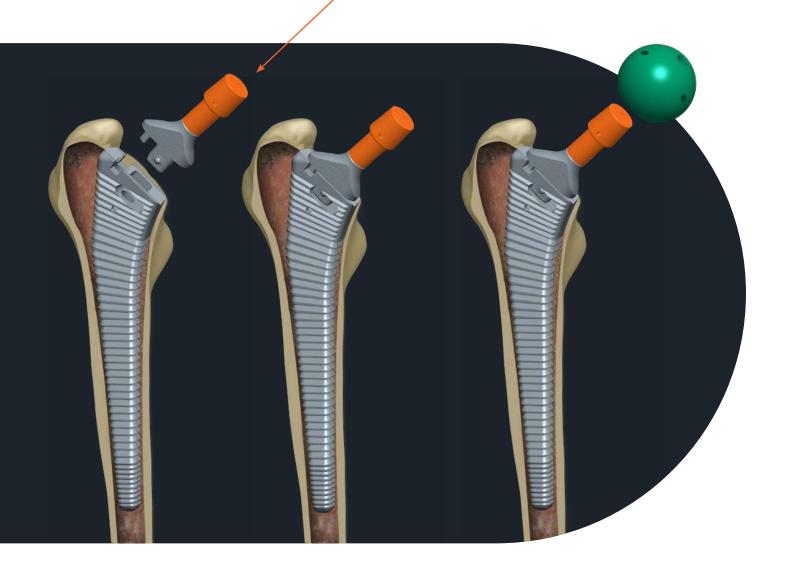
Present the assembled system in front of the rasp, push until the stop to obtain the right length and lock the neck.

Trial heads can be used to check joint stability at this stage.

After validation of the diameter and/or length of the neck, remove the trial head.







STEM INSERTION

Cementless stem

The stem is inserted and driven in the femoral canal without excessive force using the punch or angled impactor (with if needed the stem orientation device mounted on it).

Definitive impaction is obtained when the stem coating is at the level of the resection plane.

Cemented stem

The stem is progressively inserted into the cement mantle by applying manual pressure.

The constraint impactor placed into the housing (stem shoulder) helps adjust the definitive stem orientation.

The alignment rod connected to the handle will indicate stem anteversion.

The insertion depth has been reached when the depth indicator marking on the implant sits level with the osteotomy line.

The non-constraint impaction punch will maintain pressure on the stem during cement setting.

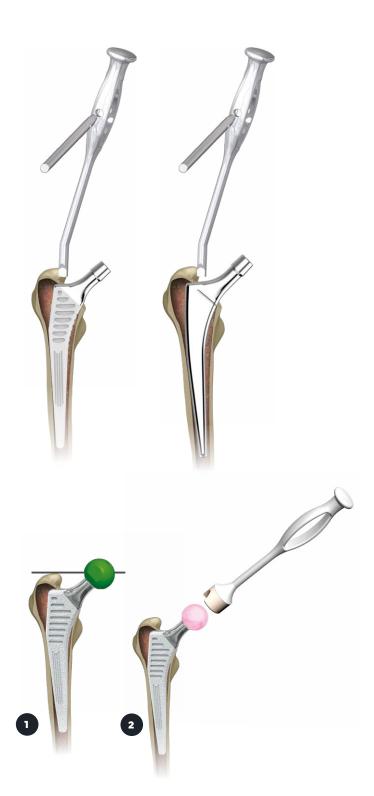


1 Trialing on implant

Trial heads can be used to check joint stability directly on the definitive stem (same trials can be performed on broach and the trial neck).

The Alignment rod for trial head be used to assess the position of the joint center, compared to the greater trochanter. Place the rod in the holes on the trial head. Nb: The identification of the joint center with the alignement rod is only valid for standard offset stems, lateralized offset stems and high offset stems.

After validation of the diameter and/or length of the neck, remove the trial head.



2 Femoral head impaction

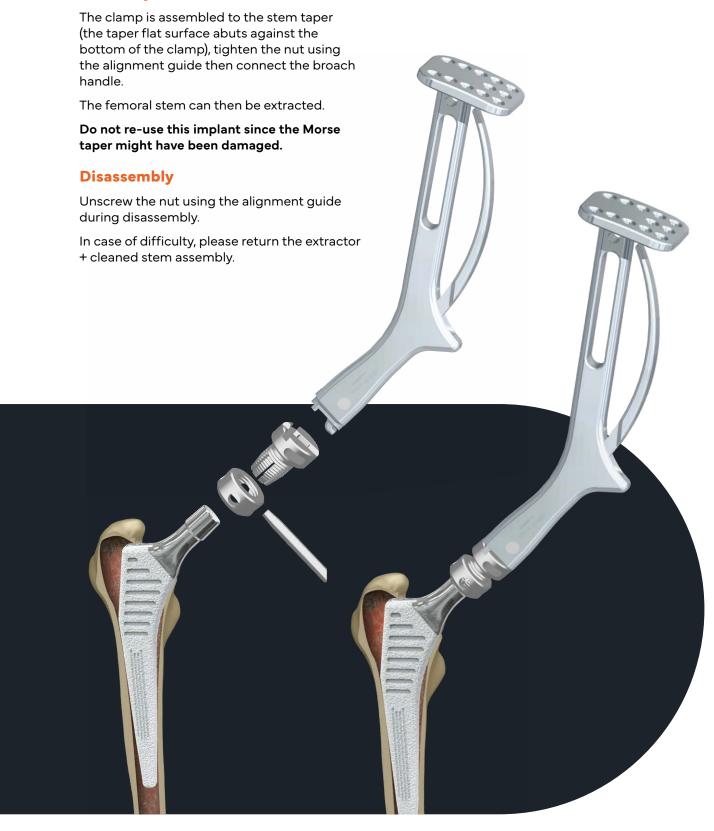
The taper should be carefully cleaned and dried.

The definitive femoral head is mounted on the stem taper with a rotational movement.

The head is firmly seated with one mallet blow on the impactor in an axial direction. The hip can then be reduced.

STEM EXTRACTION (PER OPERATIVE)

Assembly





HYPE® STEM

VARAHL01

N°		REFERENCE	DESIGNATION	
1		RH605 U1 à U10 RH606 1 à 10	HYPE® machined rasp size 1 to size 10 HYPE® rasp size 1 to size 10 / Size 11 ir	
2		RP601	Femoral preparation rasp for anterio	or approach
3		OST600	Femoral osteotome	
4	OR	FC602 Adapter FC603 Adapter	Calcar reamer Calcar reamer Calcar reamer	
_		FC603 Adapter PI600	Calcar reamer adapter	
5		IP605	Impaction punch	(10)
6 7		RP602	Angled stem impactor Femoral preparation rasp	
8		MI605	Impaction handle	8
9		EI602	Impactor tip	7
9 10		OR600	Stem guide	
11		OR 601	Trial head guide rod	(2)
11 12			HYPE® stem extractor	
		ET 602		26
13		COE SCV	HYPE® coxa vara trial neck	28
14		TE607-22.2CC	Short trial head Ø22,2mm (-2,5)	
15		TE607-22.2CM	Medium trial head Ø22,2mm (0)	
16		TE607-22.2CL	Long trial head Ø22,2mm (+2,5)	
17		TE607-28CC	Short trial head Ø28mm (-3,5)	27 9 9
18		TE607-28CM	Medium trial head Ø28mm (0)	
19		TE607-28CL	Long trial head Ø28mm (+3,5)	
20		TE607-32CC	Short trial head Ø32mm (-4)	13
21		TE607-32CM	Medium trial head Ø32mm (0)	
22		TE607-32CL	Long trial head Ø32mm (+4)	12
23		TE607-36CC	Short trial head Ø36mm (-4)	2
24		TE607-36CM	Medium trial head Ø36mm (0)	16
25		TE607-36CL	Long trial head Ø36mm (+4)	Salitation of the last of the
26	OR	MR600 MR605 MR604	Rasp handle Hueter approach rasp handle Anterior approach rasp handle	
27		COE SCS COE SCL COE-SCHO	HYPE® standard trial neck HYPE® lateralized trial neck HYPE® high offset trial neck	1
28	OR	COE630STI COE631STP COE632LATI COE633LATP COE634B COE635BHO	HYPE® odd trial neck HYPE® even trial neck HYPE® lateralized odd trial neck HYPE® lateralized even trial neck HYPE® trial neck HYPE® high offset trial neck	29
29	OR	COEH STD COEH LAT COEH 1 à 10	HYPE® standard trial neck body HYPE® lateralized trial neck body HYPE® trial neck tip size 1 to size 10	31
Opt	tion	nal additional in	strumentation included in the	tray:
		DUGOE 11	LIVDE® reaching dragge size 11	

30 OR RH605 11 HYPE® machined rasp size 11 HYPE® rasp size 11

31 COEH 11 HYPE® trial neck tip size 11

Optional additional instrumentation delivered in a separated bag:

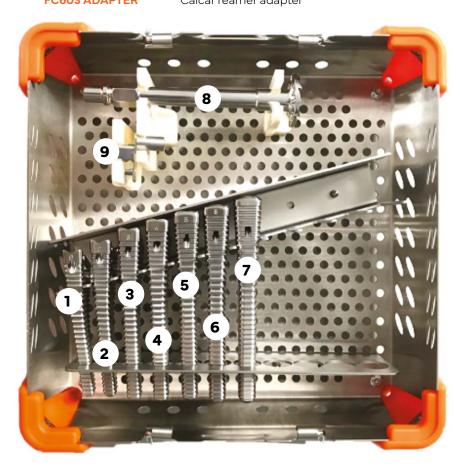
32 AR700 Conical cross reamer

INSTRUMENTATION

COMPLEMENT FOR HYPE® MINI STEMS

VARAHM01

N°	REFERENCE	DESIGNATION
1	OR RHM603 S RHM607 S	Starter machined broach for femoral
2	OR RHM603 T2 RHM607 2	Machined broach for femoral preparation size 2
3	OR RHM603 T3 RHM607 3	Machined broach for femoral preparation size 3
4	OR RHM603 T4 RHM607 4	Machined broach for femoral preparation size 4
5	RHM603 T5 RHM607 5	Machined broach for femoral preparation size 5
6	RHM603 T6 RHM607 6	Machined broach for femoral preparation size 6
7	RHM603 T7 RHM607 7	Machined broach for femoral preparation size 7
8	FC603	Calcar reamer
9	FC603 ADAPTER	Calcar reamer adapter

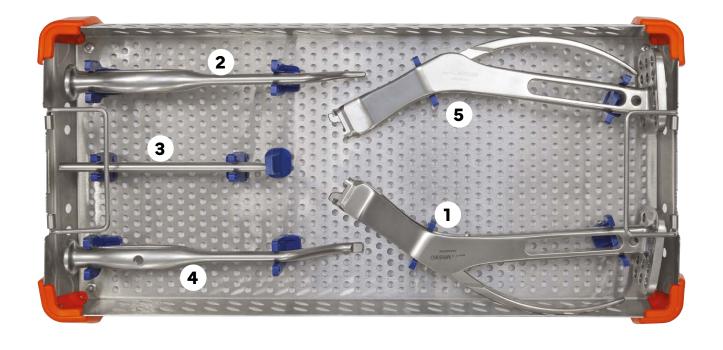


INSTRUMENTATION

HYPE® STEMS

VARALM01

N°	REFERENCE	DESIGNATION
1	MR606 D	Double curved right rasp handle
2	PIC601	Curve impaction center punch
3	OR600	Stem orientator
4	IPC604	Stem curved impactor orientator
5	MR606 G	Double curved left rasp handle



ACCESS TO THE DIGITAL INSTRUCTION **FOR USE**

For each type of implant, SERF provides you with specific, regularly updated digital Instructions for Use that can be searched, downloaded, and printed according to your needs.

A hard copy of these Instructions for Use can be sent to you within 7 calendar days, without fee, through a simple request to SERF.

In these Instructions for Use, you will find not only the regulatory information and technical features of our implants, but also valuable information on the indications, contraindications, compatibility between implants, permissible examinations and those to strictly avoid, etc.

These digital Instructions for Use, in AdobeR AcrobatR PDF format, can be accessed and downloaded in two ways:

- using a QR code on the implant's label, which can be read with a smartphone or tablet (internet connection required; 3G/4G, Wifi, etc.) and a suitable reading app (available to download for free from Google Play, AppleR Appstore and WindowsR Store depending on the model of device used)
- using an internet connection on a computer, smartphone, or tablet, by typing the URL address indicated near the QR code directly into your usual internet browser.

Here are below the QR code and URL address of the dematerialized IFU covering the range of HYPE® stems presented in this document:



HYPE® CEMENTLESS HIP STEMS



http://doc.serf.fr/0915.pdf



HYPE® **ACS & ACL**



http://doc.serf.fr/0903.pdf



METAL FEMORAL HEADS 12/14 "I"



http://doc.serf.fr/0917.pdf



CERAMIC FEMORAL HEADS (SD/D)



http://doc.serf.fr/0926.pdf

Acrobat Reader DC Operating System required

Windows

- 1.5 GHz processor or faster
- Windows Server 2008 R2 (64 bits), 2012 (64 bits), 2012 R2 (64 bits)[†] or 2016 (64 bits); Windows 7 SP1 (32 and 64 bits), Windows 8, 8.1 (32 and 64 bits)[†] or Windows 10 (32 and 64 bits)
- 1 Gb of RAM
- 380 Mb of free disk space
- 1024x768 screen resolution
- Internet Explorer 11

MacOS

- Intel processor
- Mac OS X v10.11, macOS v10.12, macOS v10.13 or macOS v10.14*
- 1 Gb of RAM
- 380 Mb free disk space
- 1024x768 screen resolution
- Safari 9.0, 10.0 or 11.0 (The plug-in for Safari is supported only by 64-bit systems with an Intel processor).

Mobile application

- Adobe Acrobat Reader: iOS, Android, Windows Phone
- Adobe Scan: iOS, Android
- Adobe Fill & Sign: iOS, Android

NOTES





Unless they are specifically identified as "not CE marked", all the medical devices mentioned in this document are CE marked in accordance with Directive 93/42/EEC and its amendments for femoral stems implants HYPE® and IIa instruments, according to Regulation (EU) 2017/745 for Ir instruments.

The medical devices mentioned in this document are class Ir, IIa, III devices. Class Ir, IIa, III medical devices are marked CE 0459 by GMED.

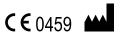
Before using a SERF product, please refer to the instruction leaflet and to the surgical technique.

Check the labels and product leaflets for the complete list of indications, contra-indications, risks, warnings, precautions, and instructions for use.

We recommend that you consult the current instructions for the product(s), which is the only document containing the information that is authentic with regard to the CE marking of the product(s).

For further information please contact SERF's local distributor.

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