HYPE®

FEMORAL STEMS

SURGICAL TECHNIQUE

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HIP

CONTENTS

HYPE® STEM IMPLANTS RANGE

The range of **HYPE®** femoral stems consists of primary femoral implants available in cemented and cementless, collared or collarless versions.
3 offsets options are available: standard offset, lateralized, and coxa vara configurations.
Our implants are manufactured from titanium alloy (Ti6Al4V-ELI) for cementless options and from stainless steel (M30) for cemented stems.

The cementless stem features a 150 µm thick titanium spray coating over the metaphyseal body completed by a 80 µm 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® SCV	Coxa vara cementless stem	2 - 9	120°

*The **HYPE® ACS** and **ACL** are not approved for US market.

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

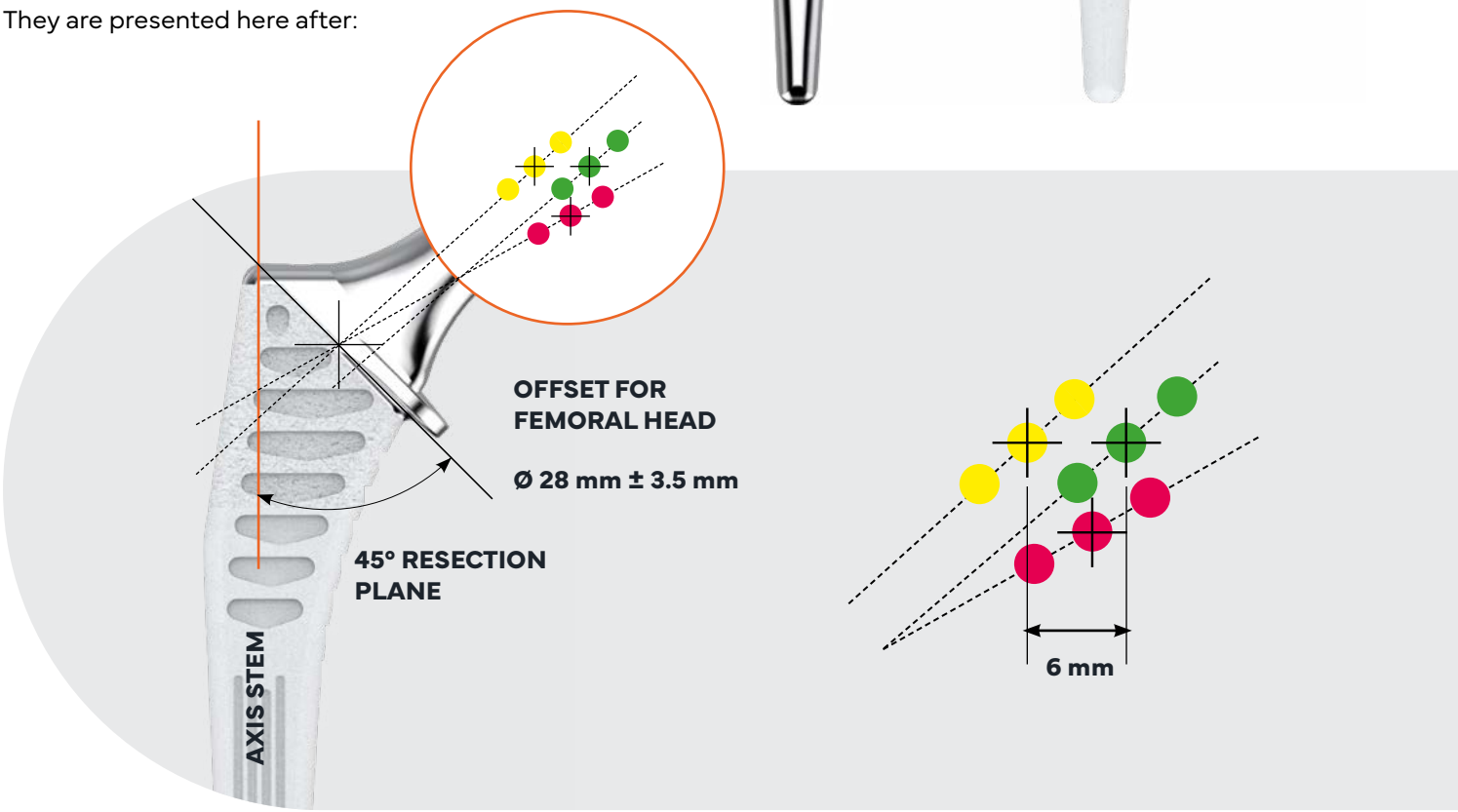
The **HYPE® MINI** stems are specifically designed to adapt MIS and anterior surgical approaches and are 20% shorter than **HYPE® SCC** and **SCL** stems.

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

1. Taper
2. Polished narrow round 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.

They are presented here after:



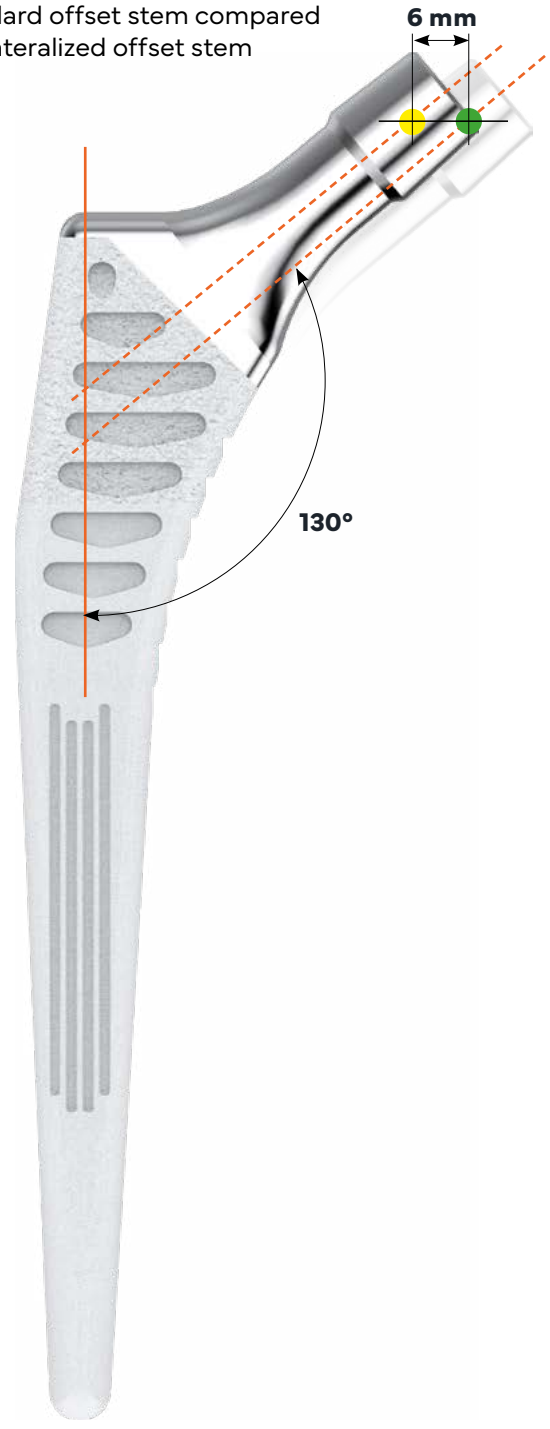
- **HYPE**® standard cementless stem (**SCS - SCC - SCC MINI**)
  HYPE® standard cemented stem (**ACS**)

- **HYPE**® lateralized cementless stem (**SCL - SCLA MINI**)
  HYPE® lateralized cemented stem (**ACL**)

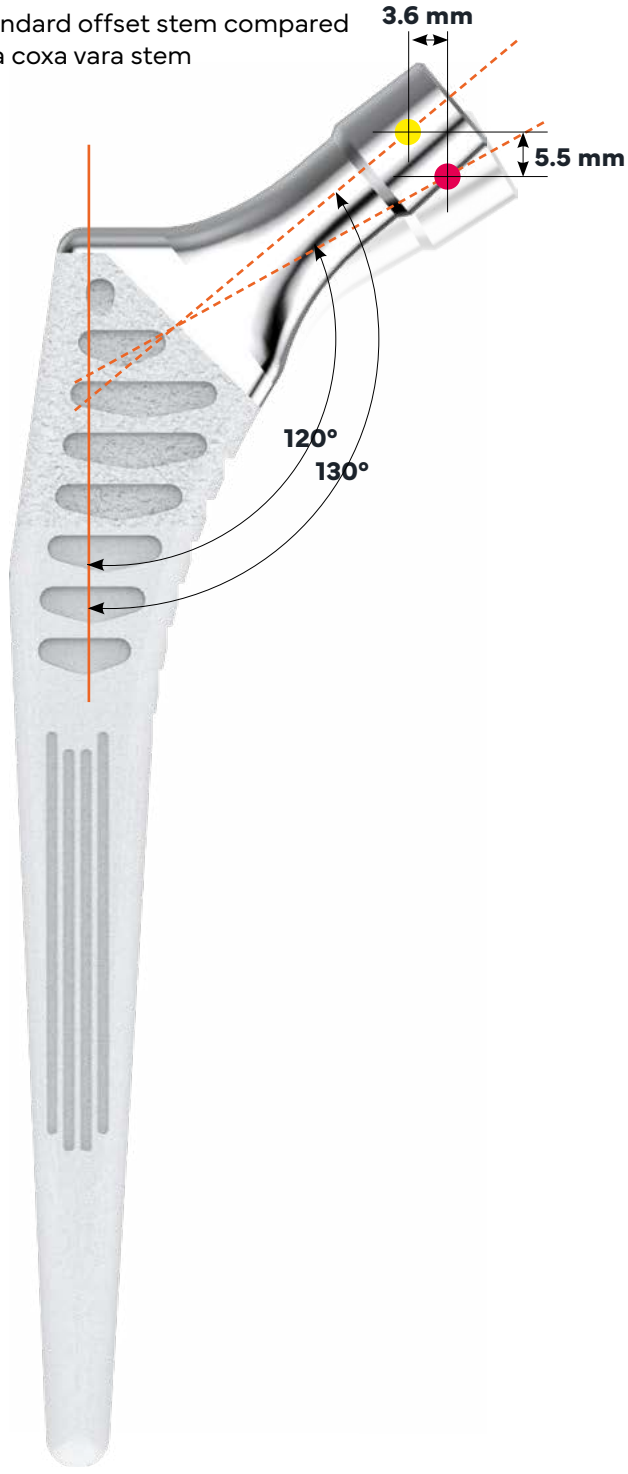
- **HYPE**® coxa vara cementless stem (**SCV**)

HYPE® STEM IMPLANTS RANGE

Standard offset stem compared to a lateralized offset stem

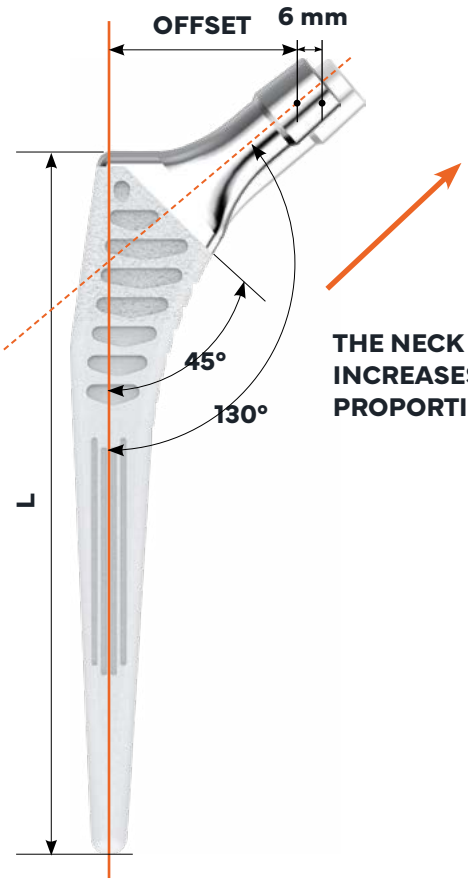


Standard offset stem compared to a coxa vara stem



HYPE® STANDARD AND LATERALIZED CEMENTLESS STEM

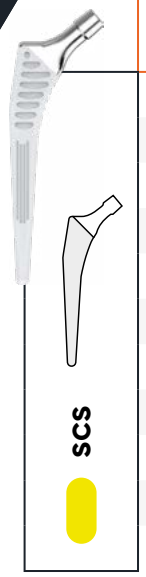
DIMENSIONS



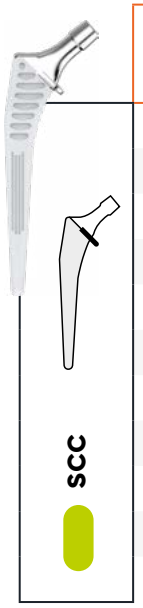
THE NECK LENGTH INCREASES PROPORTIONALLY

SIZE	L (mm)	OFFSET (mm)	
		STANDARD STEM	LATERALIZED 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

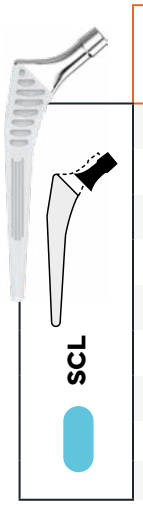


STANDARD STEM	REFERENCE
HYPE® SCS 1	RM22000001
HYPE® SCS 2	RM22000002
HYPE® SCS 3	RM22000003
HYPE® SCS 4	RM22000004
HYPE® SCS 5	RM22000005
HYPE® SCS 6	RM22000006
HYPE® SCS 7	RM22000007
HYPE® SCS 8	RM22000008
HYPE® SCS 9	RM22000009
HYPE® SCS 10	RM22000010
HYPE® SCS 11	RM22000011



STANDARD COLLARED STEM	REFERENCE
HYPE® SCC 1	RM22100001
HYPE® SCC 2	RM22100002
HYPE® SCC 3	RM22100003
HYPE® SCC 4	RM22100004
HYPE® SCC 5	RM22100005
HYPE® SCC 6	RM22100006
HYPE® SCC 7	RM22100007
HYPE® SCC 8	RM22100008
HYPE® SCC 9	RM22100009
HYPE® SCC 10	RM22100010
HYPE® SCC 11	RM22100011

LATERALIZED OFFSET



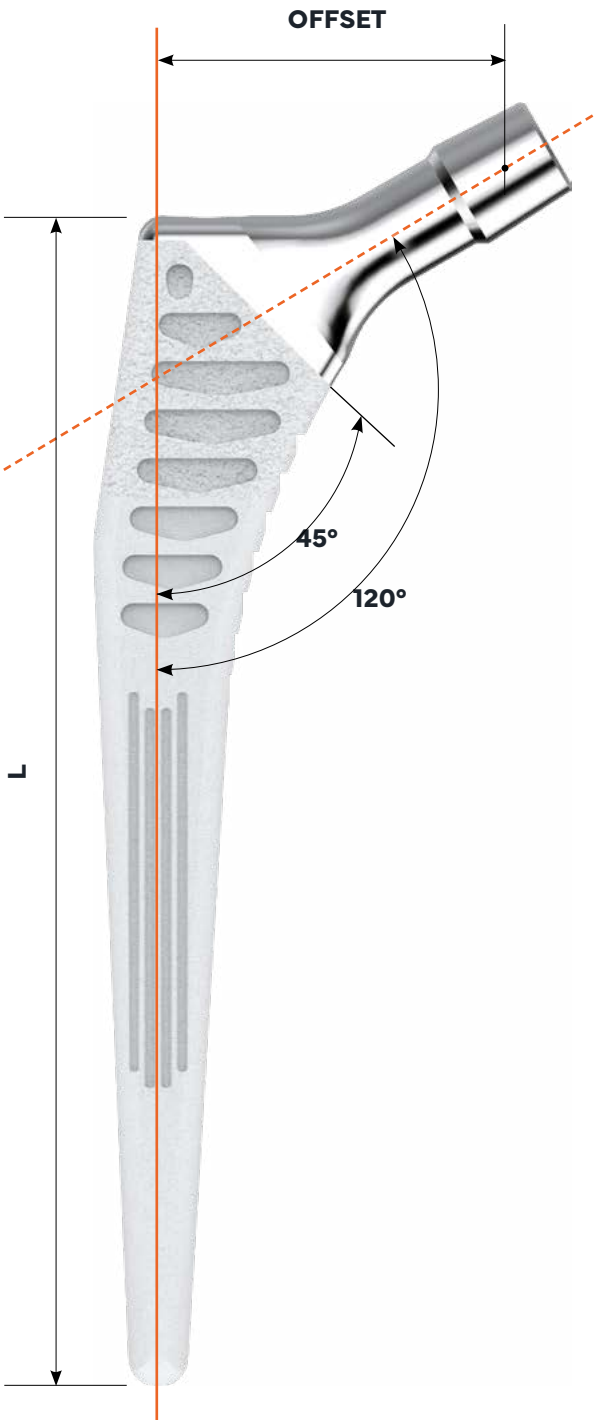
LATERALIZED STEM	REFERENCE
HYPE® SCL 2	RM22200002
HYPE® SCL 3	RM22200003
HYPE® SCL 4	RM22200004
HYPE® SCL 5	RM22200005
HYPE® SCL 6	RM22200006
HYPE® SCL 7	RM22200007
HYPE® SCL 8	RM22200008
HYPE® SCL 9	RM22200009
HYPE® SCL 10	RM22200010

MATERIALS

- Stem : Titanium alloy (Ti6Al4V-ELI) ISO 5832-3 • Coating: 150 µm Titanium + 80 µm Hydroxyapatite

HYPE® COXA VARA CEMENTLESS STEM

DIMENSIONS



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

NB: neck length is constant for all sizes

COXA VARA

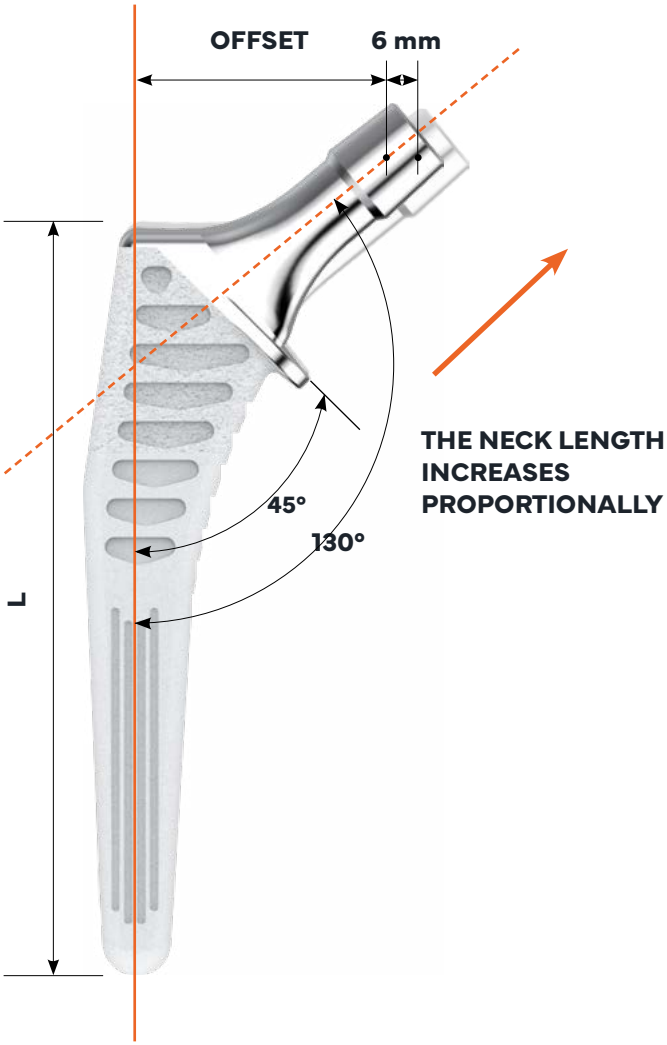
COXA VARA STEM	REFERENCE
HYPE® SCV 2	RM22400002
HYPE® SCV 3	RM22400003
HYPE® SCV 4	RM22400004
HYPE® SCV 5	RM22400005
HYPE® SCV 6	RM22400006
HYPE® SCV 7	RM22400007
HYPE® SCV 8	RM22400008
HYPE® SCV 9	RM22400009

MATERIALS

- Stem: Titanium alloy (Ti6Al4V-ELI) ISO 5832-3
- Coating : 150 µm Titanium + 80 µm Hydroxyapatite

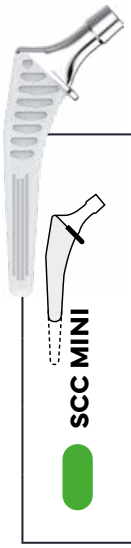
HYPE® MINI STANDARD AND LATERALIZED CEMENTLESS STEM

DIMENSIONS



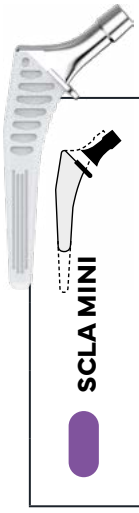
SIZE	L (mm)	OFFSET (mm)	
		STANDARD COLLARED MINI STEM	LATERALIZED COLLARED MINI STEM
2	104	39	45
3	112	40	46
4	116	41	47
5	120	42	48
6	124	43	49
7	128	44	50

STANDARD OFFSET



STANDARD COLLARED MINI STEM	REFERENCE
HYPE® SCC 2 Mini	RM22600002
HYPE® SCC 3 Mini	RM22600003
HYPE® SCC 4 Mini	RM22600004
HYPE® SCC 5 Mini	RM22600005
HYPE® SCC 6 Mini	RM22600006
HYPE® SCC 7 Mini	RM22600007

LATERALIZED OFFSET



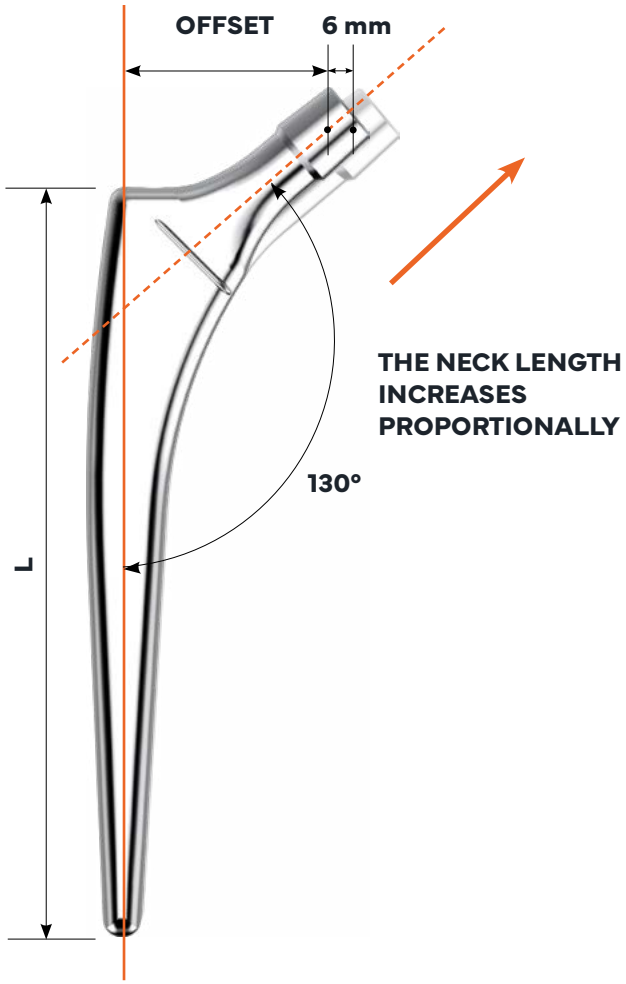
LATERALIZED COLLARED MINI STEM	REFERENCE
HYPE® SCLA 2 Mini	RM22700002
HYPE® SCLA 3 Mini	RM22700003
HYPE® SCLA 4 Mini	RM22700004
HYPE® SCLA 5 Mini	RM22700005
HYPE® SCLA 6 Mini	RM22700006
HYPE® SCLA 7 Mini	RM22700007

MATERIALS

- Stem: Titanium alloy (Ti6Al4V-ELI) ISO 5832-3
- Coating: 150 µm Titanium spray + 80 µm Hydroxyapatite

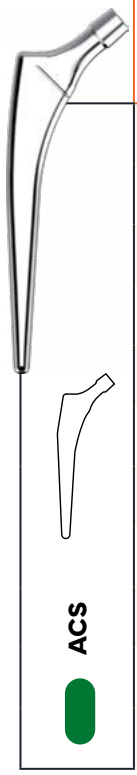
HYPE® STANDARD AND LATERALIZED CEMENTED STEM

DIMENSIONS



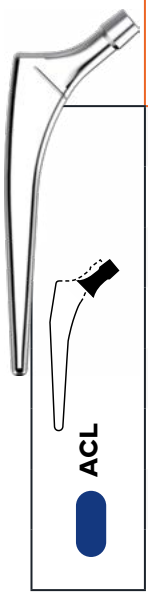
SIZE	L (mm)	OFFSET (mm)	
		STANDARD STEM	LATERALIZED STEM
1	125	38	/
2	130	39	45
3	140	40	46
4	145	41	47
5	150	42	48
6	155	43	49
7	160	44	50
8	165	45	51
9	170	46	52
10	175	47	/
11	180	48	/

STANDARD OFFSET



STANDARD CEMENTED STEM	REFERENCE
HYPE® ACS 1	RM22800001
HYPE® ACS 2	RM22800002
HYPE® ACS 3	RM22800003
HYPE® ACS 4	RM22800004
HYPE® ACS 5	RM22800005
HYPE® ACS 6	RM22800006
HYPE® ACS 7	RM22800007
HYPE® ACS 8	RM22800008
HYPE® ACS 9	RM22800009
HYPE® ACS 10	RM22800010
HYPE® ACS 11	RM22800011

LATERALIZED OFFSET



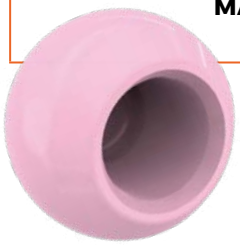
LATERALIZED CEMENTED STEM	REFERENCE
HYPE® ACL 2	RM22500002
HYPE® ACL 3	RM22500003
HYPE® ACL 4	RM22500004
HYPE® ACL 5	RM22500005
HYPE® ACL 6	RM22500006
HYPE® ACL 7	RM22500007
HYPE® ACL 8	RM22500008
HYPE® ACL 9	RM22500009

MATERIALS

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

COMPATIBLE FEMORAL HEADS & ACETABULAR CUPS

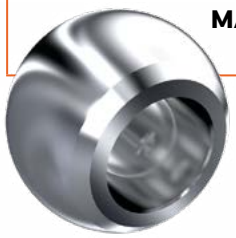
The femoral heads compatible with the HYPE® femoral stems have a 12/14 taper and are the following:



12/14 5°43

CERAMIC BIOLOX® DELTA (ISO 6474-2)

MATERIALS	Ø (mm)	REFERENCE	DESIGNATION
CERAMIC BIOLOX® DELTA (ISO 6474-2)	Ø 28	RM30660001	D28-CC (- 3.5 mm)
		RM30660002	D28-CM (0)
		RM30660003	D28-CL (+ 3.5 mm)

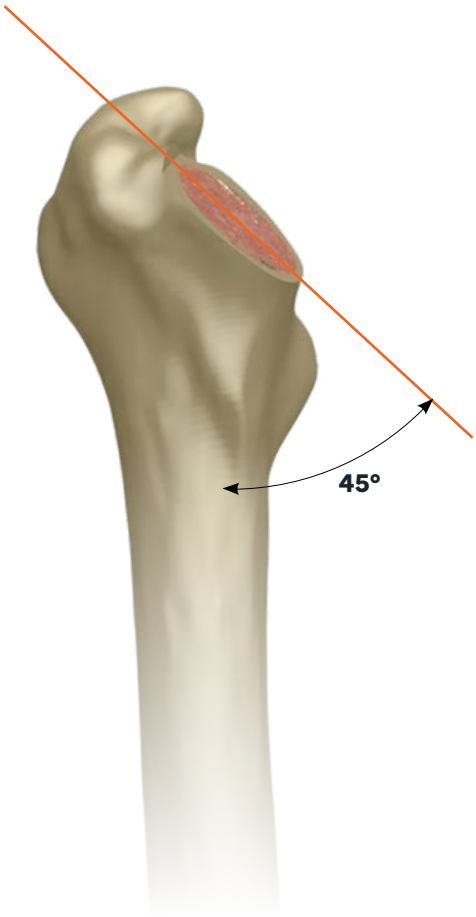


12/14 5°43

COBALT-CHROMIUM (ISO 5832-12)

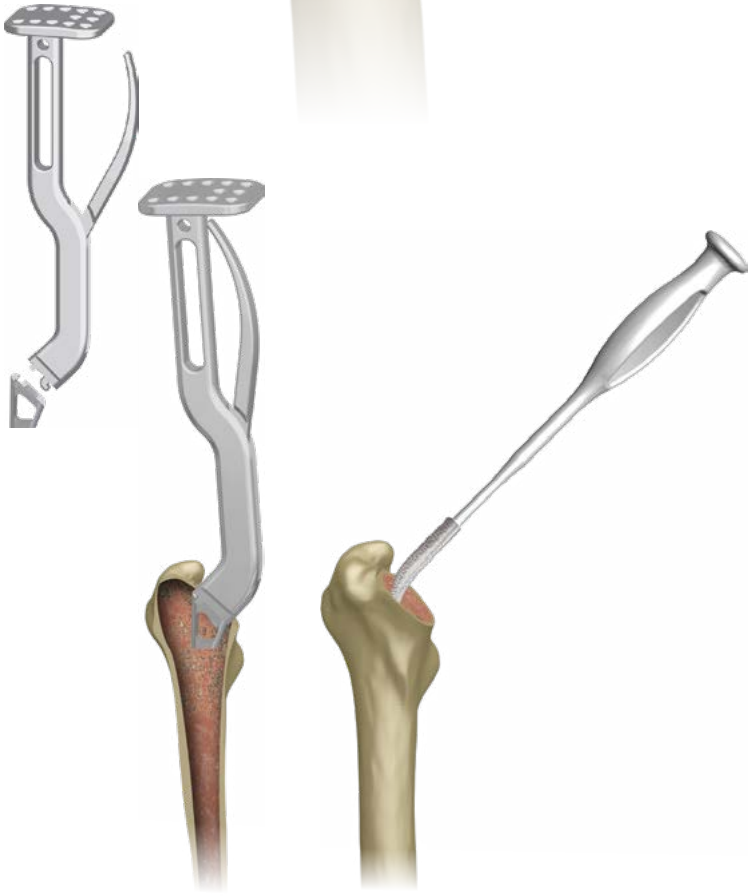
MATERIALS	Ø (mm)	REFERENCE	DESIGNATION
COBALT-CHROMIUM (ISO 5832-12)	Ø 22.2	RM30410001	C22-CC (- 2.5 mm)
		RM30410002	C22-CM (0)
		RM30410003	C22-CL (+ 2.5 mm)
	Ø 28	RM30410004	C28-CC (- 3.5 mm)
		RM30410005	C28-CM (0)
		RM30410006	C28-CL (+ 3.5 mm)

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.

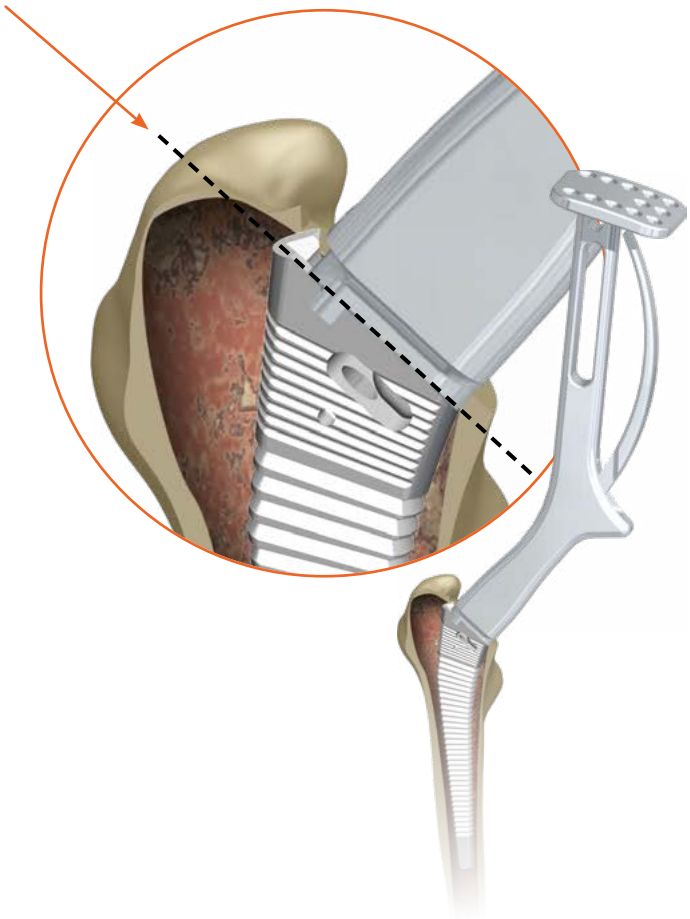
3 BROACHING

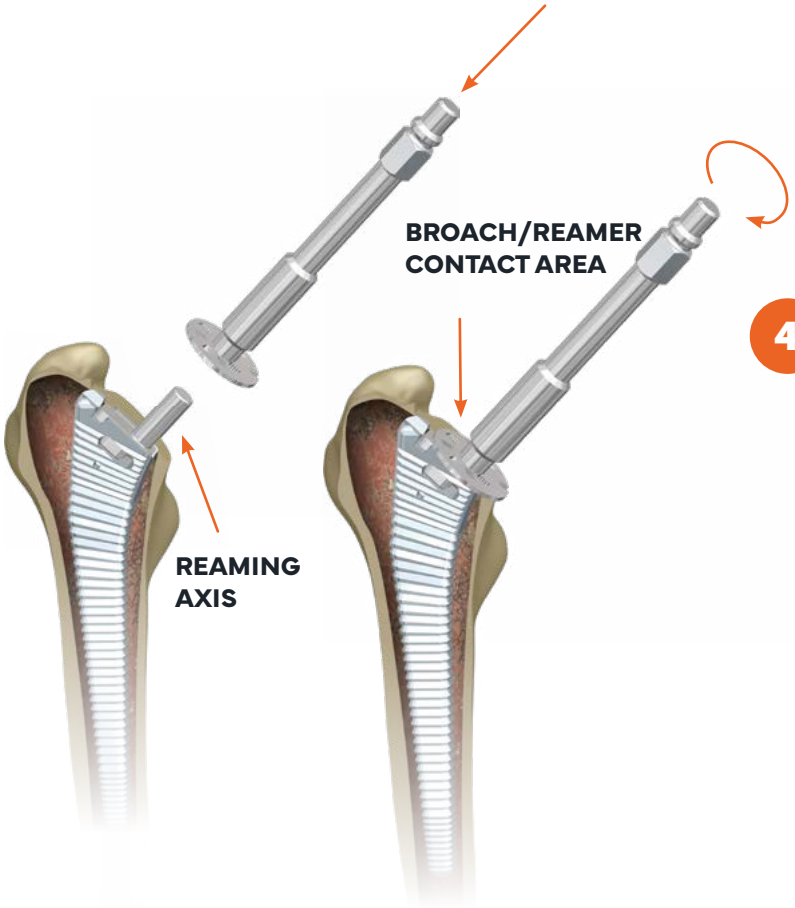
The **HYPE**® broaches are connected to the appropriate broach handle designed for postero-lateral, antero-lateral or anterior surgical approaches. Proximal cancellous bone compaction is then performed up to the neck resection plane.

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 **HYPE**® stem to assess hip joint centre.

HYPE® trial neck tip
sizes 1 to 11
COEH 1 TO 11

HYPE® standard
trial neck body
COEH STD

HYPE® trial neck tip
sizes 1 to 11
COEH 1 TO 11

HYPE® lateralized
trial neck body
COEH LAT

Coxa Vara trial neck
COE SCV

Trial reduction with trial necks

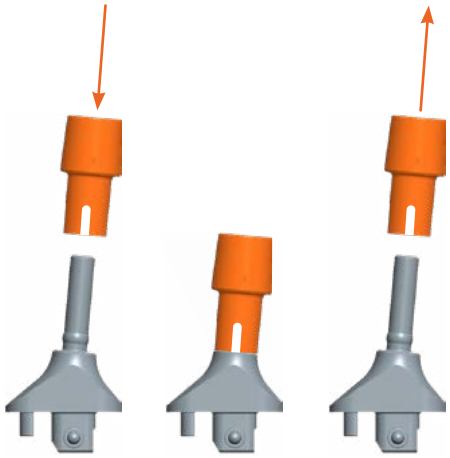
The plastic neck and the specific baseplate to the desired trial must be assembled.

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

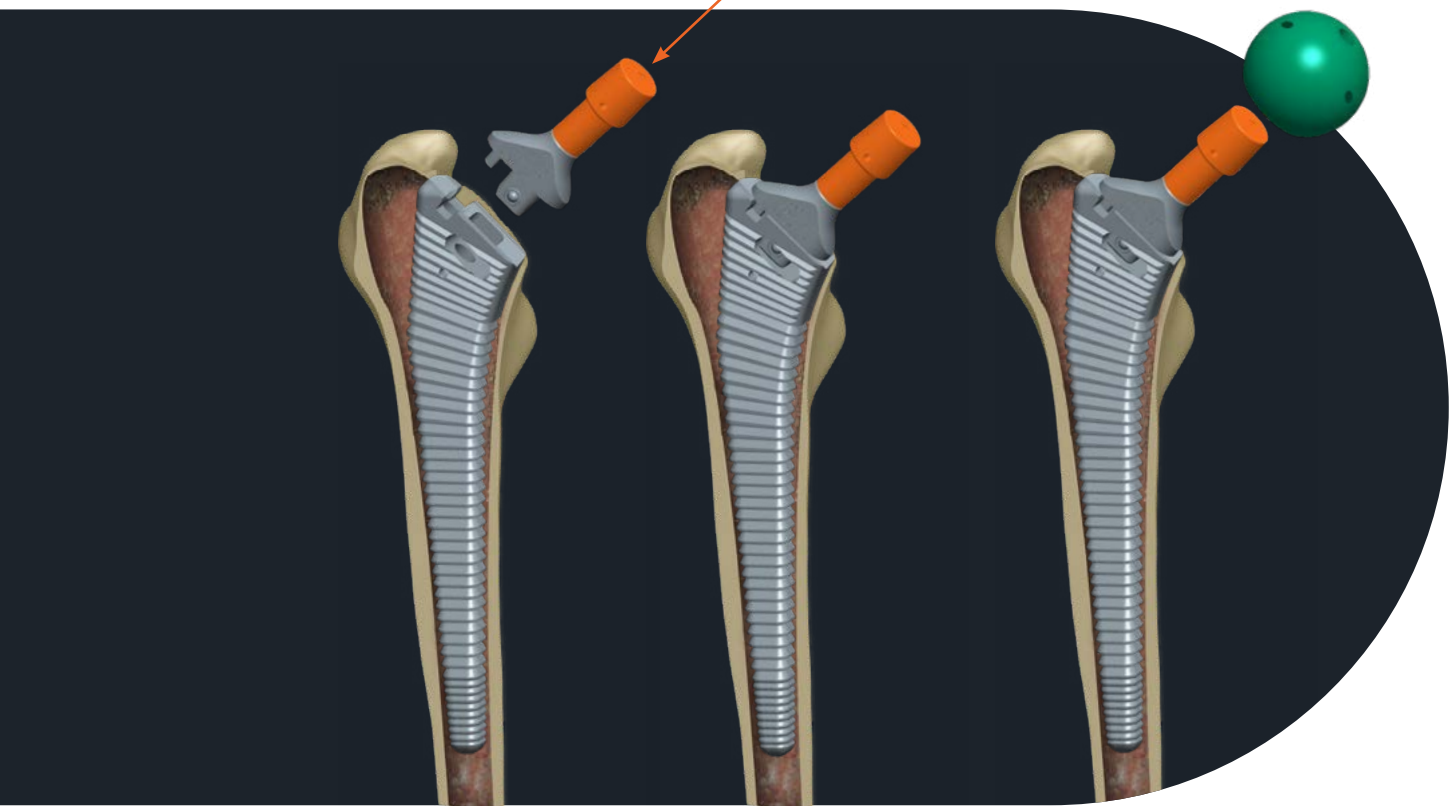
Trial heads can be used to check joint stability at this stage.

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

The Coxa-Vara trial neck is monobloc. There is no plastic neck to assemble. Present the neck directly to the broach and push to obtain right length and lock it.



Push Clip Pull



6 STEM INSERTION

Cementless stem

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

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

Cemented stem (not approved for US market)

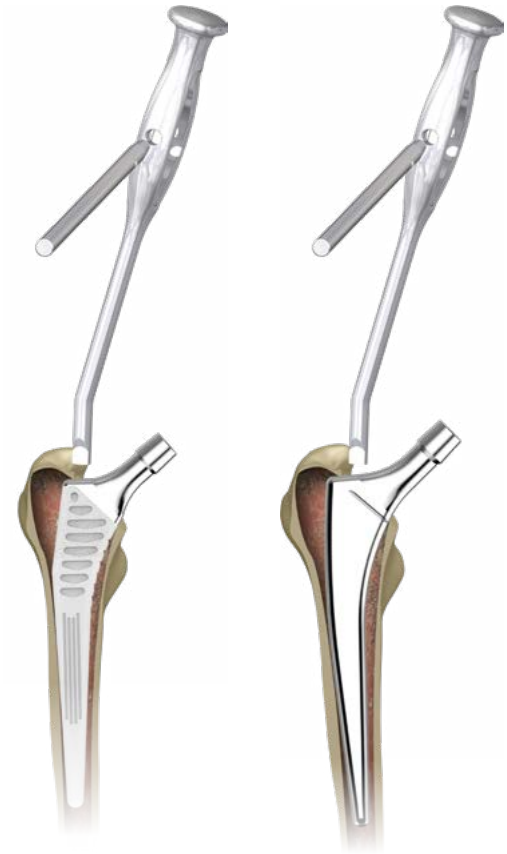
The stem is progressively inserted into the cement mantle by applying manual pressure.

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.



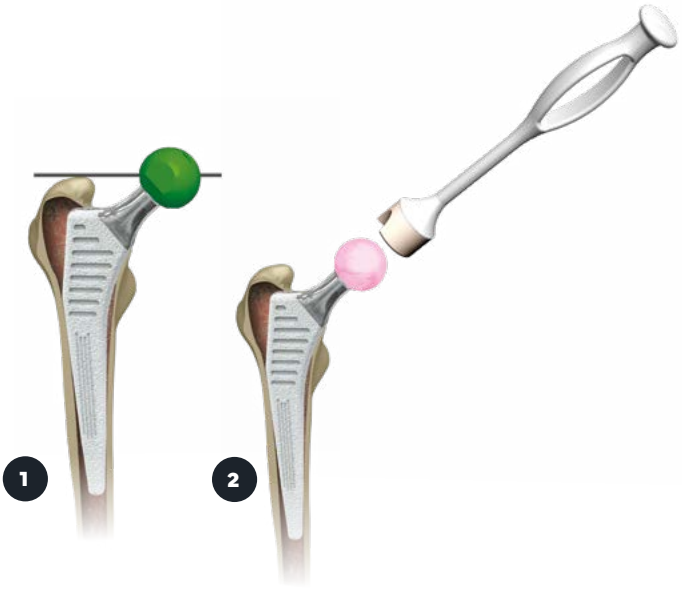
7 FEMORAL HEAD INSERTION

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 can 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 and lateralized 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

The clamp is assembled to the stem taper (the taper flat surface abuts against the bottom of the clamp), tighten the nut using the alignment guide then connect the broach handle.

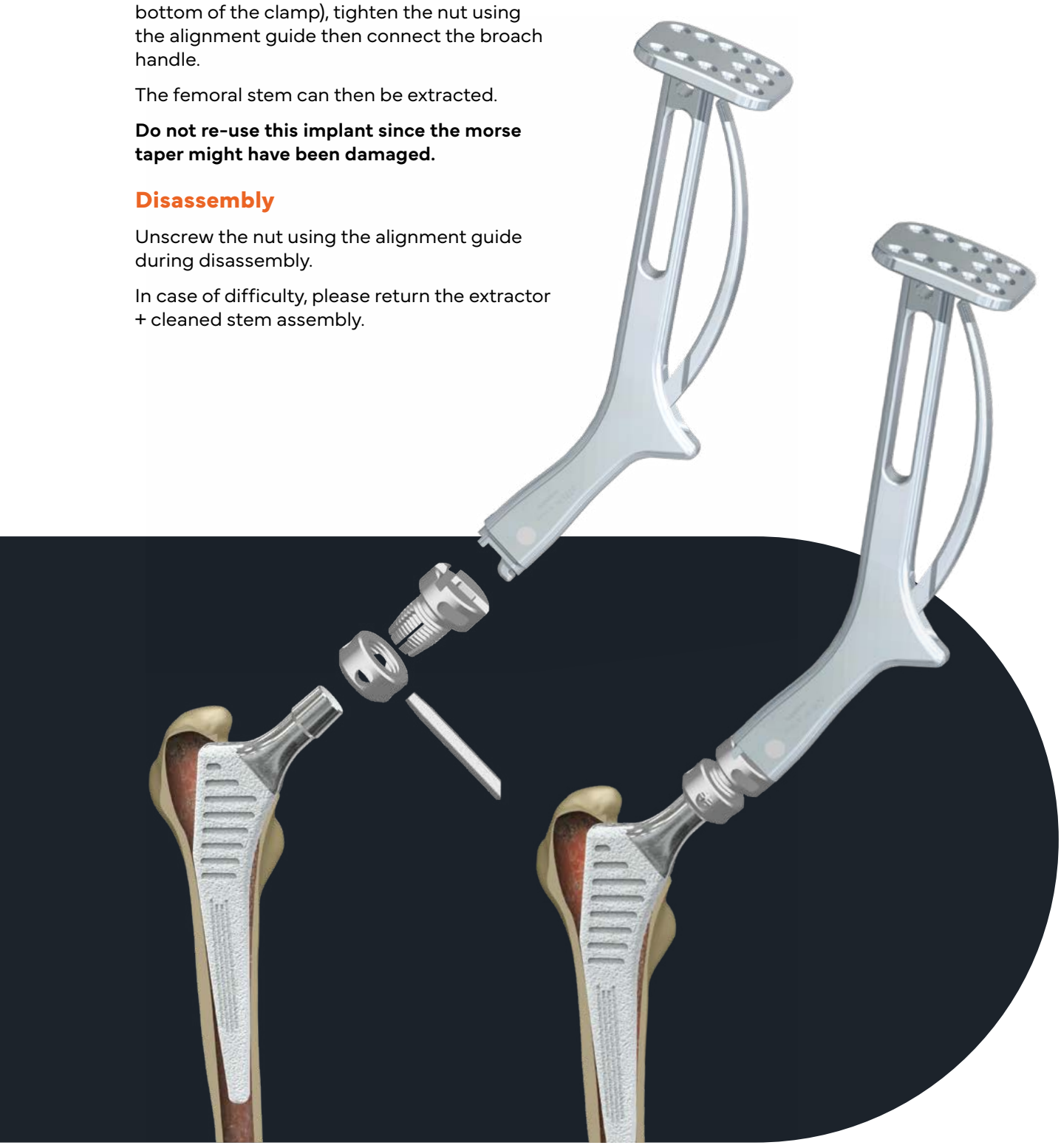
The femoral stem can then be extracted.

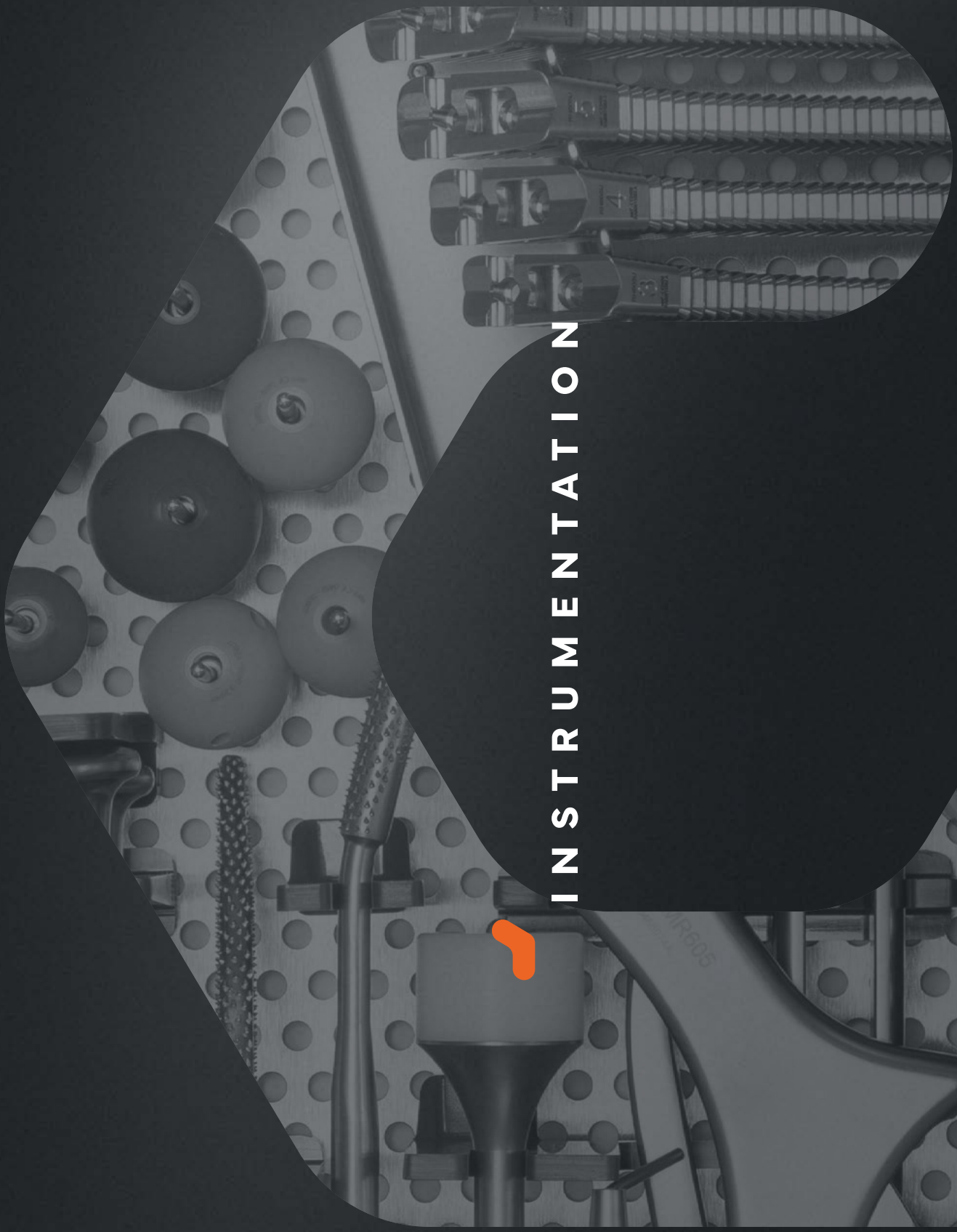
Do not re-use this implant since the morse taper might have been damaged.

Disassembly

Unscrew the nut using the alignment guide during disassembly.

In case of difficulty, please return the extractor + cleaned stem assembly.



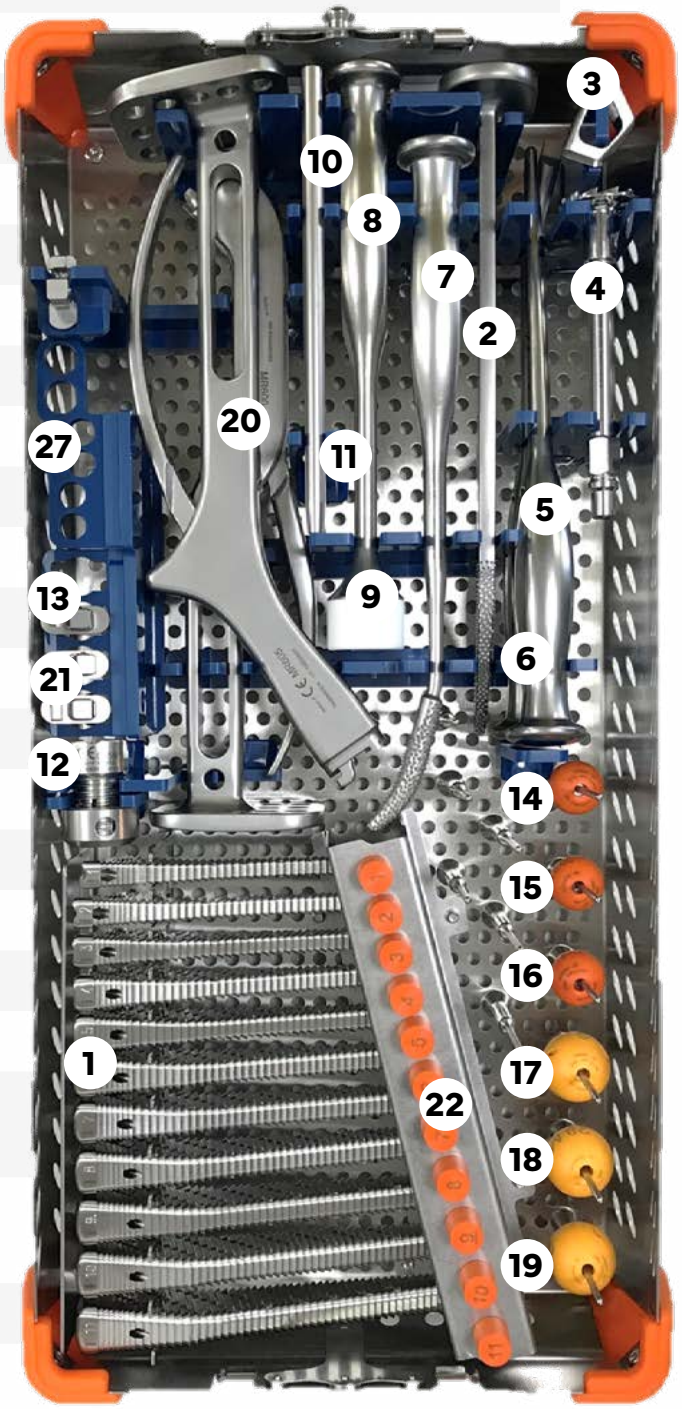


INSTRUMENTATION

HYPE® STEM

VARAHL01

N°		REFERENCE	DESIGNATION
1	OR	RH605 U1 to U11 RH606 1 to 11	HYPE® machined broach size 1 to size 11 HYPE® broach size 1 to size 11
2		RP601	Femoral preparation broach for anterior approach
3		OST600	Femoral osteotome
4		FC603 FC603 Adapter	Calcar reamer Calcar reamer adapter
5		PI600	Impaction punch
6		IP605	Angled stem impactor
7		RP602	Femoral preparation broach
8		MI605	Impaction handle
9		EI602	Impactor tip
10		OR600	Stem guide
11		OR601	Trial head guide rod
12		ET602	HYPE® stem extractor
13		COE SCV	HYPE® coxa vara trial neck
14		TE607-22.2CC	Short trial head Ø 22.2mm (-2.5)
15		TE607-22.2CM	Medium trial head Ø 22.2mm (0)
16		TE607-22.2CL	Long trial head Ø 22.2mm (+2.5)
17		TE607-28CC	Short trial head Ø 28mm (-3.5)
18		TE607-28CM	Medium trial head Ø 28mm (0)
19		TE607-28CL	Long trial head Ø 28mm (+3.5)
20	OR	MR600 MR605 MR604	Broach handle Hueter approach broach handle Anterior approach broach handle
21		COEH STD COEH LAT	HYPE® standard trial neck body HYPE® lateralized trial neck body
22		COEH 1 to 11	HYPE® trial neck tip size 1 to size 11



Optional additional instrumentation delivered in a separated bag:

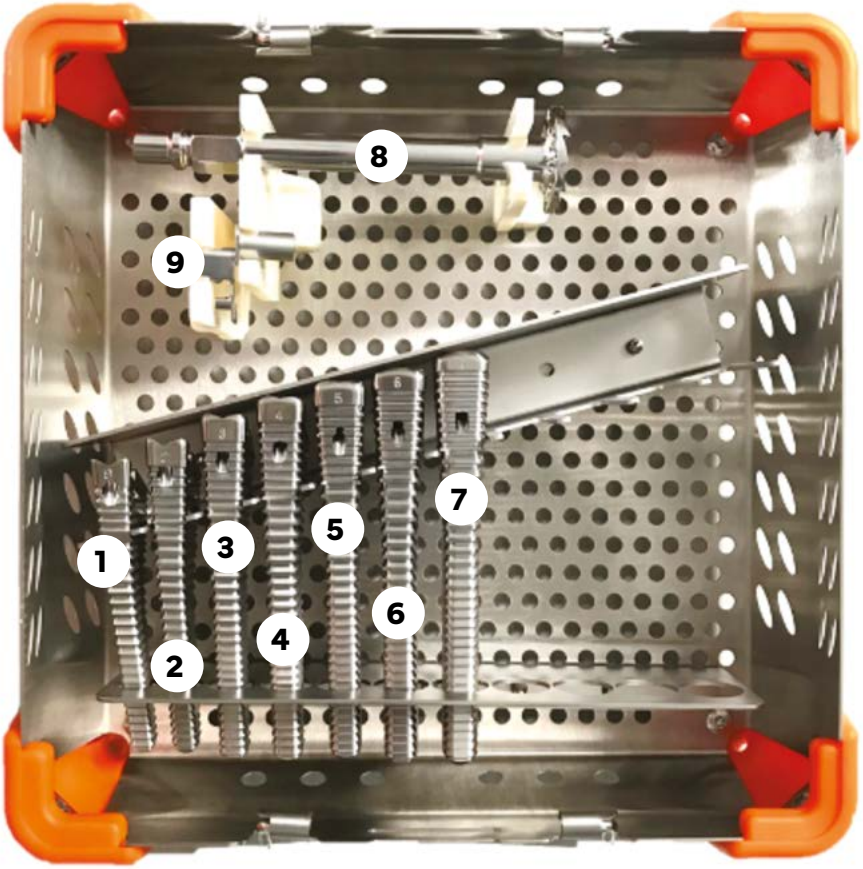
23		AR700	Conical cross reamer

INSTRUMENTATION

COMPLEMENT FOR HYPE® MINI STEMS

VARAHM01

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

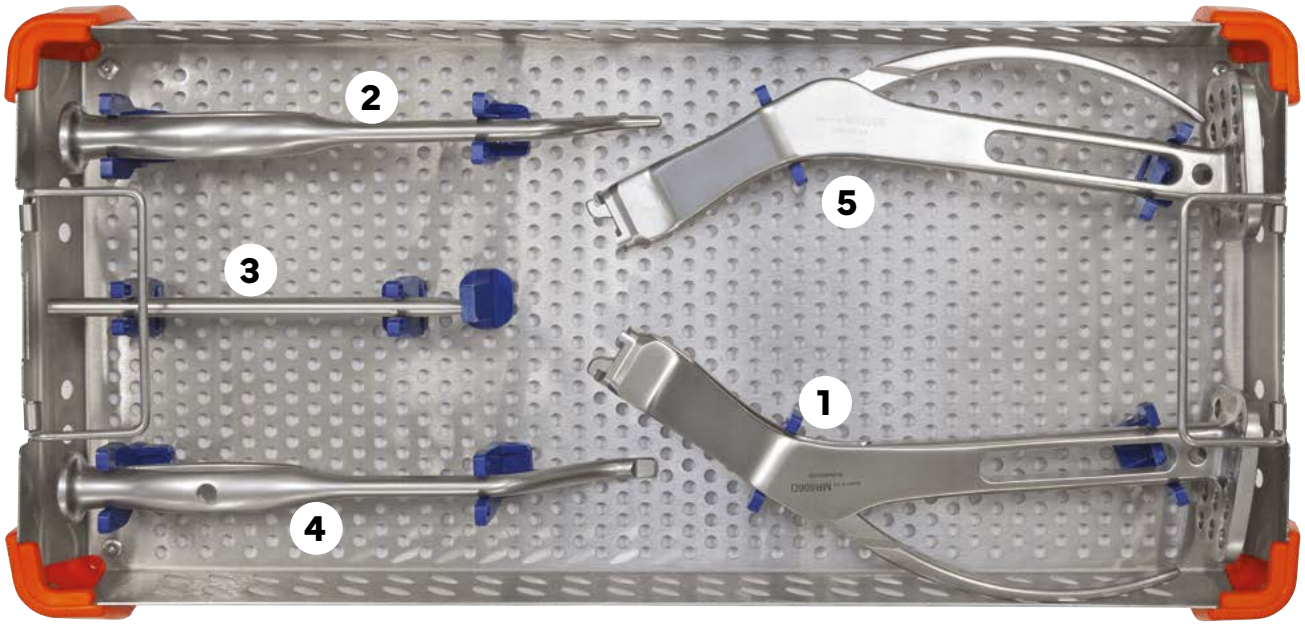


INSTRUMENTATION

HYPE® STEMS

VARALM01

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



ACCESS TO THE DIGITAL INSTRUCTION FOR USE

SERF offers, for each type of implant, dematerialized Instructions for Use (IFU) regularly updated, and easy to download and to print according to your needs.

You will find in these IFU not only the regulatory information and technical specifications of our implants, but also valuable information on indications, contraindications, and compatibilities between implants, etc.

These dematerialized instructions, provided in PDF format, are available and downloadable via two ways:

- from a QR code on the packaging of the implant, which can be read using a smartphone or tablet (requires Internet connection, 3G / 4G, WiFi ...) and an application appropriate reading (available for free download on Google Play, Apple® AppStore and Windows® Store according to the device used)
- with an Internet connection via a PC, smartphone or tablet, typing directly the URL address written near the QR code, to your usual Internet browser's,.

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

HYPE® CEMENTLESS HIP STEMS

http://doc.serf.fr/0930.pdf

HYPE® ACS & ACL

http://doc.serf.fr/0931.pdf

12/14 BIOLOX® DELTA FEMORAL HEADS

http://doc.serf.fr/0929.pdf

12/14 COBALT-CHROMIUM FEMORAL HEADS

http://doc.serf.fr/0928.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

NOTES

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Only for distribution within the USA.
Before using a SERF product, please refer to the instruction leaflet and to the surgical technique. Please refer to the labels, instructions for use and surgical technique for the complete list of indications, contraindications, risks, warnings, precautions and directions for use. For further information please contact your SERF's local distributor.

DISTRIBUTED BY

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