

EVOK®

Cementless straight
Femoral stem



Surgical
Technique

AMPLITUDE®

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EVOK® CONCEPT AND RANGE

EVOK® femoral hip system combines a comprehensive range of cementless stems based on proven designs with more than 30 years' clinical use. The system was developed by Amplitude's team of engineers in collaboration with leading surgeons from around the globe.

The stem has been launched utilizing the "Stepwise Introduction" recommended by Henrik Malchau^[1].

- Clinical pre-testing — extensively tested by Amplitude for CE marking.
- Radiostereometry (RSA) study performed on 23 stems with acceptable stability in all directions at two years with a pattern of implant stabilization that is consistent with good long term clinical outcomes^[2].
- Multicentre study performed in Australia with excellent clinical outcomes^[3].
- Registry data since 2010^[4].

First implanted in Australia in 2010 under CL2 name, EVOK® stem continues to set benchmarks for adaptability, safety, ergonomics, and simplicity with a range of unique design features that make it the system of choice for surgeons throughout the world.

EVOK® includes a simple and user-friendly instrumentation suitable for all anatomies and surgical techniques. It can easily be used for Posterior, Lateral, Anterolateral or Direct Anterior approaches.

SAFE

- Proven design, material and fixation—cementless tapered rectangular design, titanium, HA coated.
- Forged from high quality titanium by the company that has been producing this type of stem for over 30 years.
- Coated with 155 µm of HA
- Extensive mechanical testing with a focus on fatigue resistance, fretting and corrosion resistance.
- Proven two years RSA results on 23 stems and hundred of implants since 2010 on a prominent joint registry.

SIMPLE

- Comprehensive and compact range
- Ergonomic instrumentation
- Efficient tray design and layout
- Every instrument the surgeon needs and nothing he or she doesn't.

ADAPTABLE

- Three offset options (Standard, Lateralized and High Offset)
- Optimised neck geometry for range of motion and 12/14 taper
- Suitable for different anatomies and varying bone quality.

^[1] Malchau et al., *The Stepwise Introduction of Innovation into Orthopedic Surgery The Next Level of Dilemmas*, Journal of Arthroplasty Vol. 26 No. 6, (Elsevier Inc.), 2011

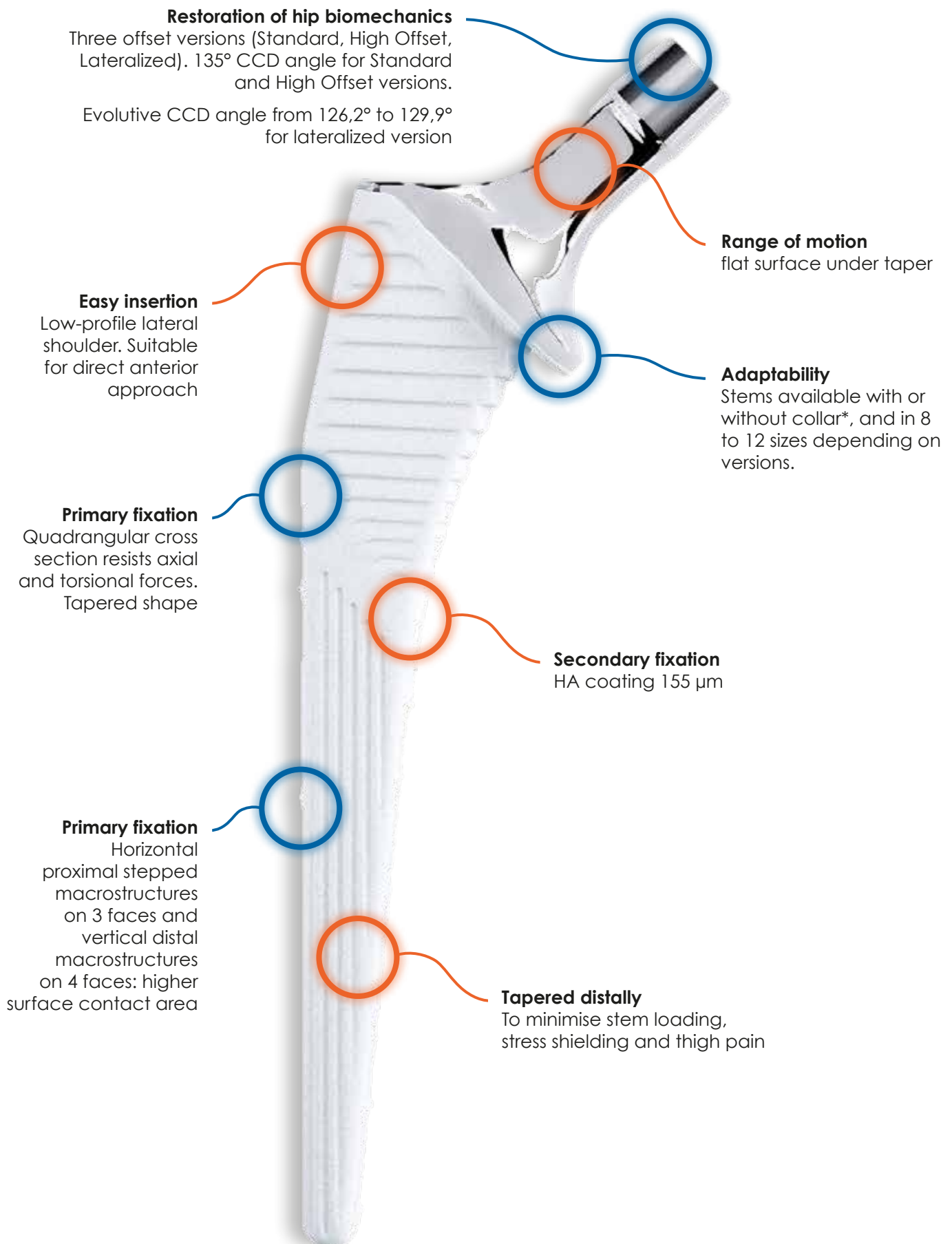
^[2] International Musculoskeletal Research Institute (data on file at Amplitude)

^[3] Data on file at Amplitude

^[4] Australian Orthopaedic Association National Joint Registry (data on file at Amplitude)

^[5] Khanuja et al., *Cementless Femoral Fixation in Total Hip Arthroplasty*, The Bone and Joint Surgery Inc. (Am), 2011

EVOK[®] CONCEPT AND RANGE



* High Offset stem is only available in collarless version

EVOK[®] CONCEPT AND RANGE



FEMORAL HEADS 12/14

Ceramic



Sizes
28 - 32 - 36 mm
BIOLOX[®] delta

Size	Neck length
Ø 28 mm	SN -3,5mm MN 0mm LN +3,5mm
Ø 32 mm	SN -4mm MN 0mm LN +4mm XLN +7mm
Ø 36 mm	SN -4mm MN 0mm LN +4mm XLN +8mm

Ceramic révision



Sizes
28 - 32 - 36 mm
BIOLOX[®] delta

Size	Neck length
Ø 28 mm	SN -3mm MN 0mm LN +4mm XLN +7mm
Ø 32 mm	SN -3mm MN 0mm LN +4mm XLN +7mm
Ø 36 mm	SN -3mm MN 0mm LN +4mm XLN +7mm

Metallic



Sizes
22,2 - 28 - 32 mm

Size	Neck length
Ø 22,2 mm	SN -2mm MN 0mm LN +2mm
Ø 28 mm	SN -3,5mm MN 0mm LN +3,5mm XLN +7mm
Ø 32 mm	SN -4mm MN 0mm LN +4mm XLN +7mm

Weight limitations:

Standard stem size 7 is not recommended for patients over 68 kg.
Standard stem size 8 is not recommended for patients over 85 kg.
Lateralized stem size 8 is not recommended for patients over 64 kg.
Lateralized stem size 9 is not recommended for patients over 89 kg.

EVOK[®] CONCEPT AND RANGE

Cementless femoral stems
Same intramedullary features for all stems



Standard stem



Lateralized stem

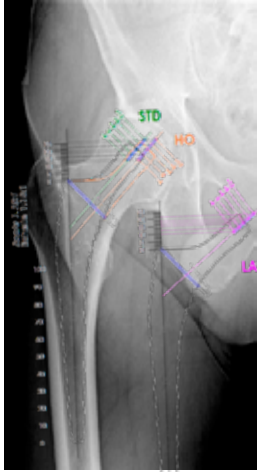


High Offset stem

SURGICAL TECHNIQUE OVERVIEW

1

Preoperative planning



2

Femoral canal preparation



3

Cancellous bone compaction (optional)

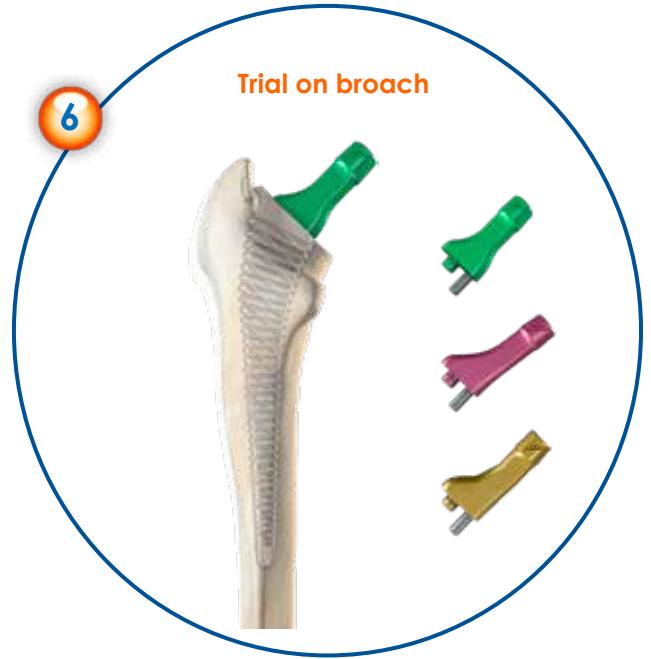
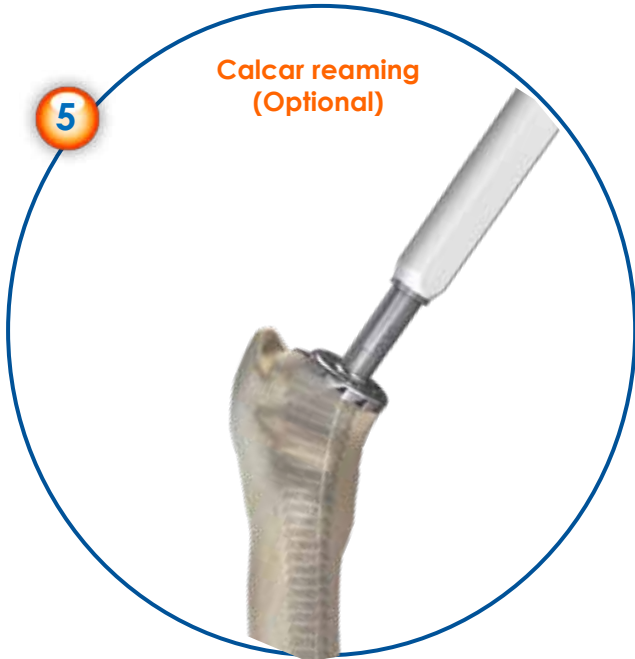


4

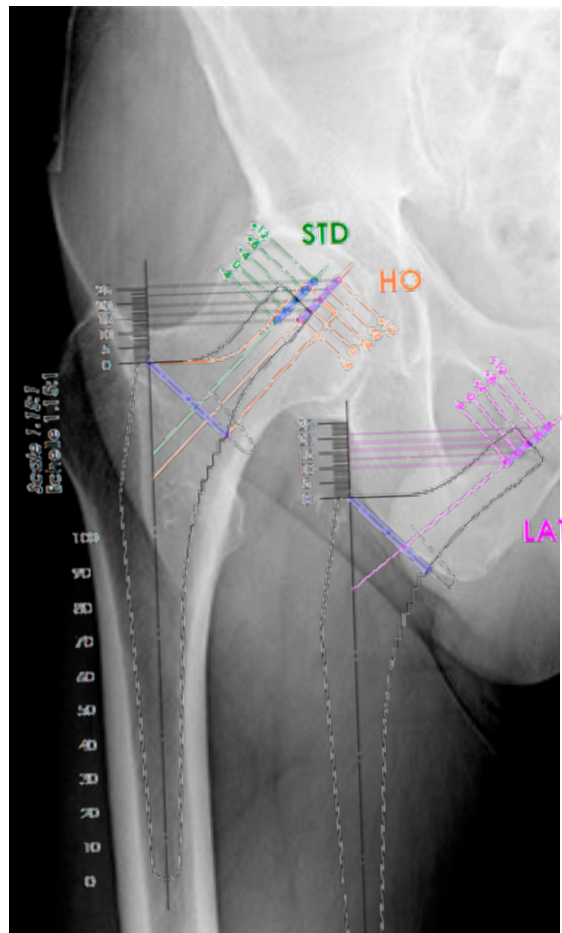
Broaching



SURGICAL TECHNIQUE OVERVIEW



PRE-OPERATIVE PLANNING



STEP 1 : ASSESS QUALITY OF RADIOGRAPH

Obtain an adequate AP pelvis X-ray centred on the pubis with attention the following:

- Pelvis rotation — the symphysis should project centrally through the middle of the sacrum. You should be able to see both of the obturator foramen equally sized and shaped.
- Pelvic flexion — Sacrococcygeal joint to upper symphysis should be approximately 30-50mm. It will be increased if the pelvic was tilted forwards, or decreased if the pelvis was tilted back at the time of the X-ray.
- Femoral rotation — Both femora should be internally rotated by 15-20 degrees. You should be able to see 2 ± 3 mm of the lesser trochanter.
- Quality of the image is acceptable, and is at expected magnification.

REMINDER

The purpose of this surgical technique description is to provide instructions on how to use the instrumentation properly. The surgeon is fully responsible for choosing and performing the approach and surgical technique.

NOTE

Templates are provided at scale 115%. Other magnifications and digital templates are available on request.

PRE-OPERATIVE PLANNING

STEP 2 : IDENTIFY ANATOMICAL LANDMARKS

You should be able to identify the following landmarks on the radiograph:

- Femoral head centres for both femora—centre of rotation
- Femoral shaft axis
- Tear drops

STEP 3 : IDENTIFY ACETABULAR AND FEMORAL BIOMECHANICAL POINTS AND OPTIMISE IMPLANT POSITIONING^[1]

Acetabulum

- Mark the tear drops and draw a straight line between them.
- Measure the distance from the inter tear drop line to the Lesser Trochanter or other fixed landmark on each side. Note the difference between the indicated and contra-indicated side in order to assess leg length inequality.
- Rest dome line of the acetabula template on the medial wall. The inferior cup should sit just below the tear drop at the inferior acetabulum. Mark the new acetabular centre. Make the inclination about 45 degrees and note the component size.

Femur

- Compare the normal and abnormal sides.
- Template the normal side first. This is of particular importance if the femoral head is deformed.
- Template the indicated side, and note the neck osteotomy level, stem size and new femoral head centre.
- The implant size should allow adequate shaft filling while leaving 1 to 2 mm space between the implant and cortical walls.
- The offset of the stem and neck cut level should allow a proper restoration of lower limb length and abductor's lever arm (femoral offset).
- Mark and measure neck resection level to use as a reference intra-operatively.
- Check and adjust neck length to restore leg length.

^[1] Scheerlinck T., *Primary hip arthroplasty templating on standard radiographs — A stepwise approach*, Acta Orthop. Belg., 2010

SURGICAL APPROACH

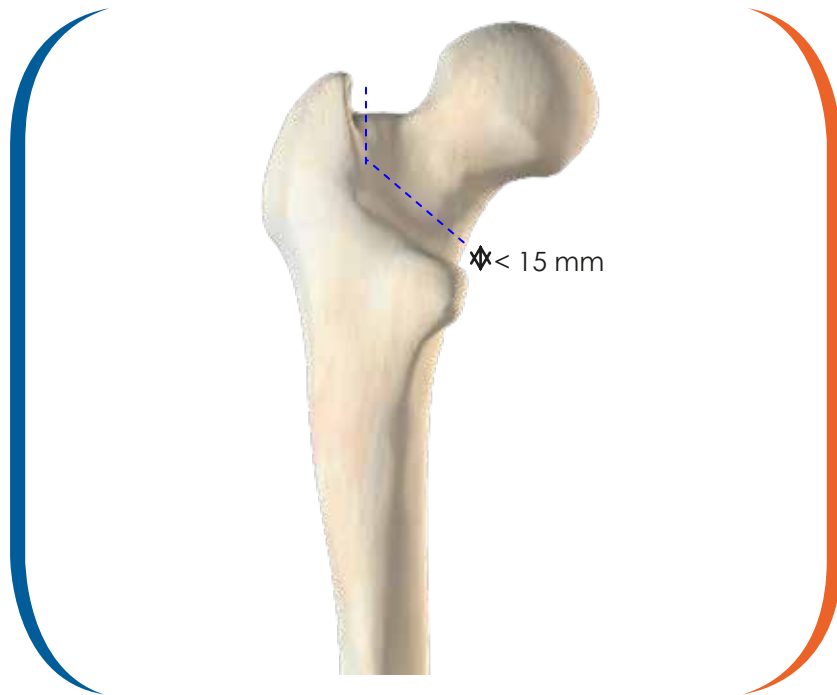
EVOK[®] femoral stem may be implanted using:

- Any of the traditional surgical approaches.
- Any of the contemporary, less-invasive approaches including direct anterior (on or off table).

The requirement of any approach is adequate visualization of the acetabulum and proximal femur.

- 360 (degree) view of the rim, floor, transverse acetabular ligament and other landmarks for correct cup positioning.
- Direct view down the femoral canal and the calcar in order to prepare the canal correctly and minimize / identify intra-operative fractures.
- Clear view of the greater and lesser trochanters to reduce incidence of fracture and measure leg length.

FEMORAL NECK RESECTION



Identify anatomical landmarks, lesser trochanter (LT), piriformis fossa, greater trochanter (GT).

Determine the neck cut level during pre-operative planning. In most cases the distance from the neck cut to the LT is less than 15 mm.

Mark the cutting plane level onto the bone with reference to the anatomical landmarks.

Take care to protect the soft tissues and GT during neck cut. In some cases, where the cut is lower, a second vertical cut is made at the base of the neck and GT.

NOTES

- The neck can be cut before or after dislocation, and its level can be slightly above what was planned as final adjustments can be made later with the calcar reamer.
- A broach aligned with the femoral diaphysis can enable you to confirm the proper orientation of cut.
- The neck cut should be 45 degrees to the axis of the stem.

FEMORAL CANAL IDENTIFICATION AND PREPARATION

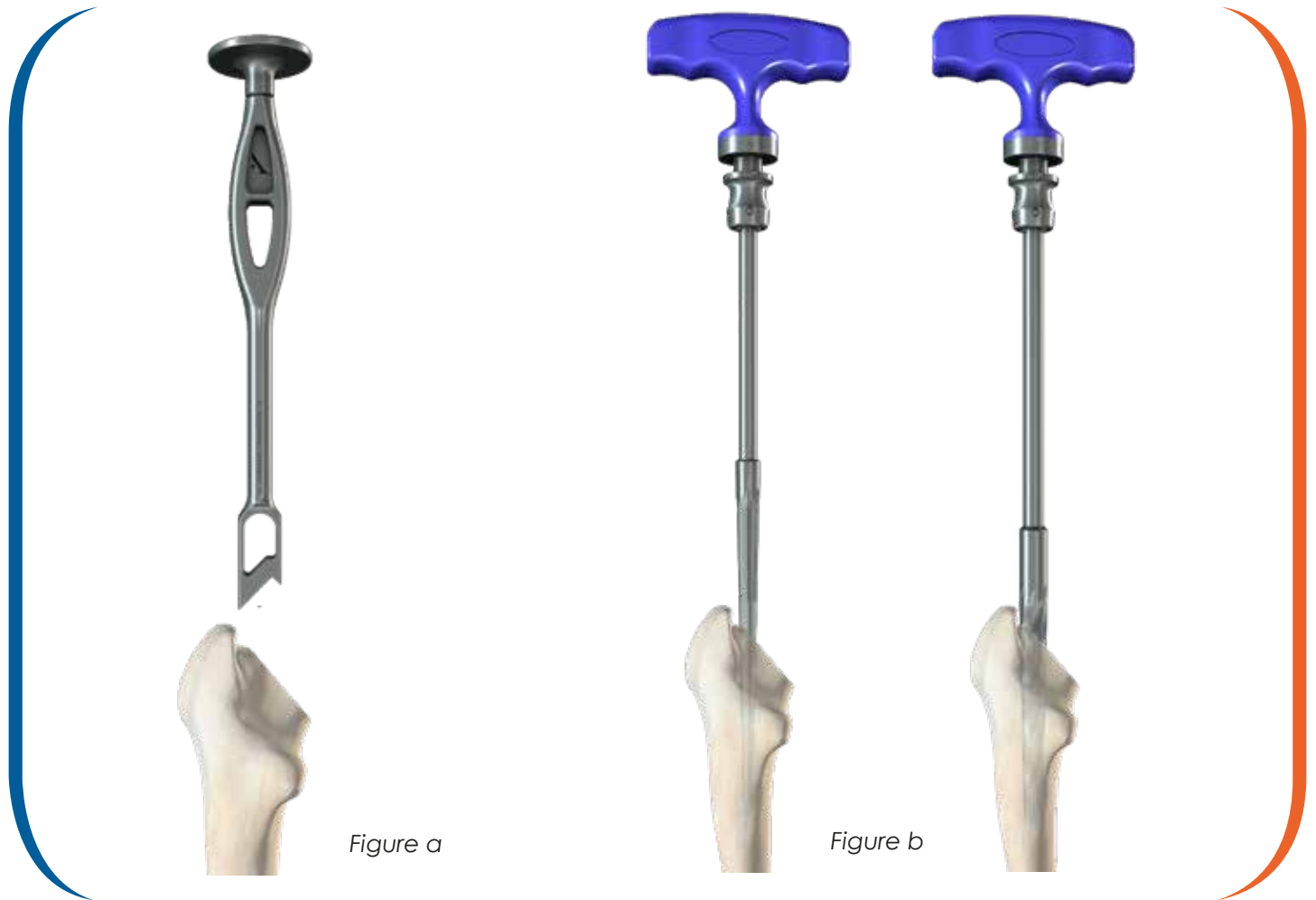


Figure a

Figure b

Canal Identification

In order to help ensure adequate orientation of the stem, lateral bias during implant preparation is preferred. Retraction of the gluteus medius and removal of the lateral cortical bone at the piriformis insertion will permit true axial introduction of the instruments and implant. Use the box chisel (*Figure a*) to start preparing the metaphyseal area by removing cortical bone, passing close to the medial side of the greater trochanter at its junction with the neck.

Keep the box chisel in line with the canal and the planned anteversion of the stem.

Canal Opening

Assemble the reamer of the smallest diameter with the T-handle reamer-holder. Push both components down into the femoral canal to prepare it for broaching, making sure to stay in the femoral shaft axis (*Figure b*).

If needed, repeat the previous step with the largest reamer.

METAPHYSEAL CANCELLOUS BONE COMPACTION (OPTIONAL)



Use the bone compactor to compact the proximal cancellous bone. This will preserve as much bone stock as possible.

Create a strong compacted bone envelope of cancellous bone, avoiding direct stem contact with the cortical bone if possible.

Create a regular rectangular cross-section cavity in line with femoral axis. Bone quality will determine how this is achieved.

NOTE

Bone compactor is designed to have the same metaphyseal size as a size 7 broach

BROACHING



EVOK[®] broaches are designed to compact bone only, rather than remove bone. They are not sharp cutting broaches.

The aim of this step is to compact bone gently to create a rectangular cross sectional cavity with axial and rotational stability.

Broaching is performed beginning with the size 7 broach. The broach should be oriented in line with the femoral axis and planned anteversion, staying lateral. The natural anatomy of the proximal femur will dictate anteversion. It is not advised to alter this natural position.

The progressive preparation is continued using broaches of increasing sizes, until good rotational and axial stability are achieved. The depth corresponds to the junction between the broach handle and broach.

In order to prevent any varus position, attention must be paid to introduce broaches in the anatomical axis, with a lateral bias.

Size of the last broach is usually the same as the size templated. Leave the last broach in the femur and remove the broach handle.

NOTES

The broach / broach handle junction corresponds to the extra / intra-medullary boundary on the final stem.

If at any time a broach does not insert easily, check that the broach is not held up laterally or distally, removing some lateral bone with the box chisel may help.

If rotational and axial stability cannot be obtained, consider using a cemented stem.

CALCAR REAMING (FOR COLLARED STEMS)



Calcar reaming is performed for several reasons:

- To define the correct insertion level.
- To remove prominent proximal bone at the neck that may reduce range of motion or create impingement.
- For collared stems in order to allow calcar loading.

Leave the last broach in the femur and remove the broach handle.

Assemble the calcar reamer that matches the chosen stem size with the surgical hand-piece or with the motor :

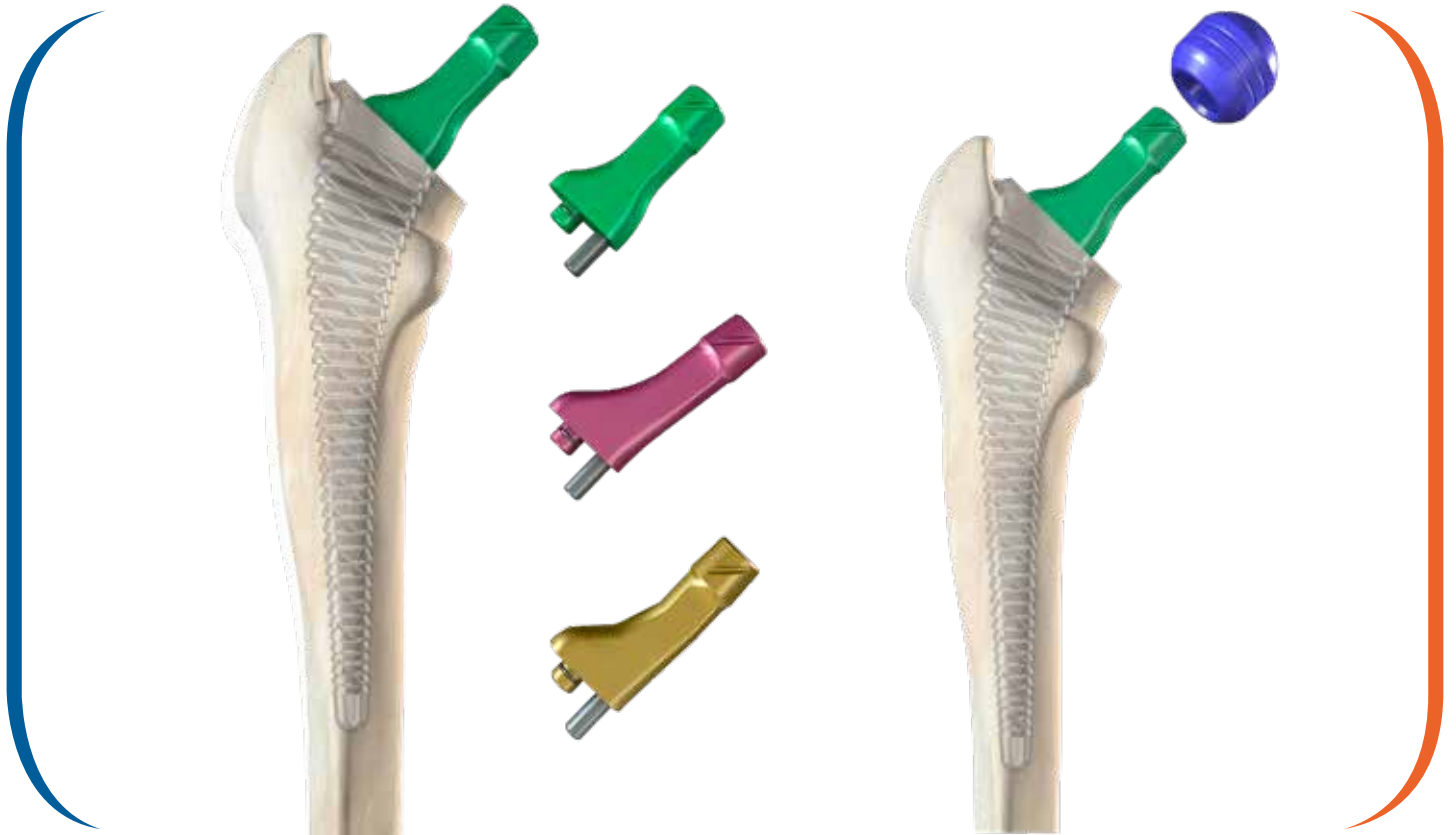
- For stems sizes 7 to 12 - 13, use calcar reamer diameter 30 mm
- For stems sizes 12 - 13 to 20, use calcar reamer diameter 35 mm

Position the calcar reamer's tip into the medial hole of the broach.

Ream slowly with minimal force until stop, in order to reach a flat surface, taking care to protect the soft tissues in this area.

This step is only necessary when using a collared stem. It ensures that the underside of the collar rests on a flat surface.

TRIALS ON BROACH

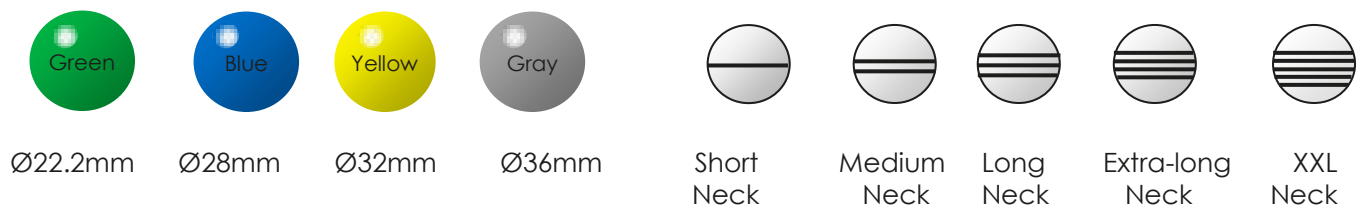


The last broach is left in position and used to position the trial neck and head selected during the pre-operative templating step.

Place the trial neck of the desired offset on the broach:

- Trial neck for **Standard** stem (green)
- Trial neck for **Lateralised** stem (pink, evolutive homothetic trial neck): select the neck that matches the stem size
- Trial neck for **High Offset** stem (yellow)

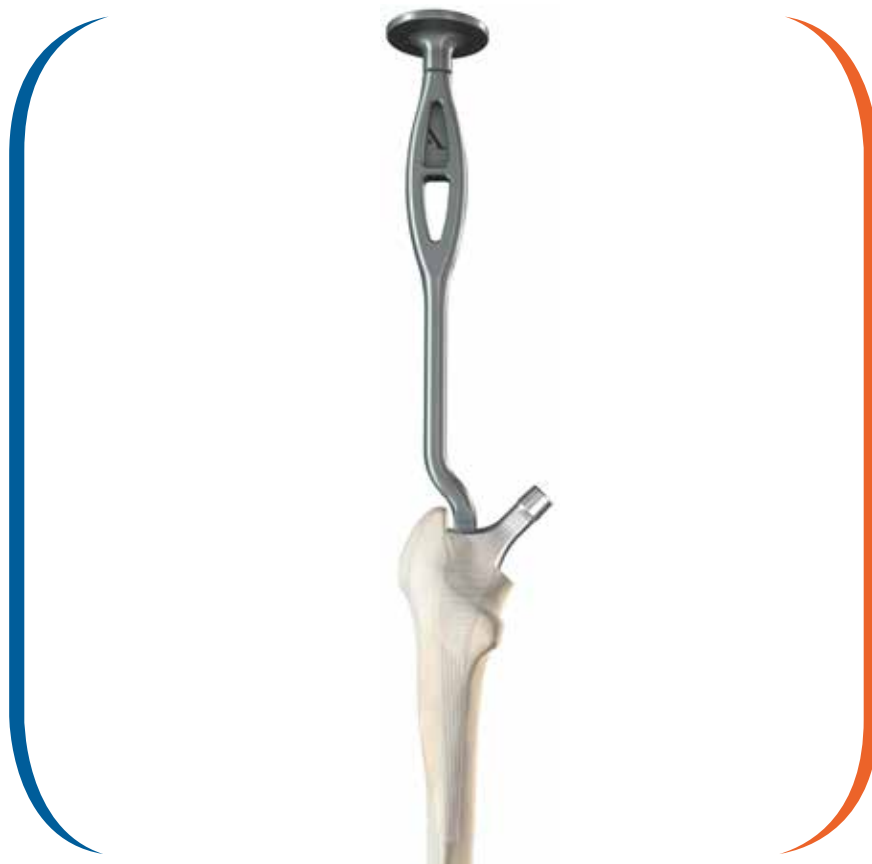
Select and place a trial head of the desired length and diameter on the neck:



Reduce the head with the head impactor. Test the range of motion, joint stability and then check the length to validate the extramedullary settings.

If the joint range of motion or stability are unsatisfactory, redo the trials with a different trial neck and/or head length until the desired stability and range of motion are achieved.

FINAL STEM IMPACTION



Select the EVOK[®] stem that matches the size and model (Standard, Lateralised, High Offset, collared or collarless) chosen during the trials.

Manually position the stem in the prepared femoral canal.

Place the stem impactor in the impaction hole on top of the stem being implanted.

Impact the stem until adequate stability is achieved. HA border corresponds to the junction between broach and broach handle. Remove the stem impactor.

Place a trial head on this stem and reduce the joint; this will help confirm the head length and joint stability.

NOTES

The stem is 0.31 mm thicker than the space prepared with the broach to ensure a press-fit effect.

	Stable	Unstable
Over planned impaction level	Consider a shorter neck length or remove the stem. Do not continue to impact as this may result in fracture	Continue to impact gently.
Conform to impaction level	Correct position	Remove the stem and use the next size.
Under planned impaction level	Consider a longer neck length if possible or remove the stem and use the next size.	Remove the stem and use the next size.

FINAL HEAD IMPACTION



Select final femoral head that matches settings validated during trials.

> Impaction of metallic head:

Make sure the stem taper is clean, dry and undamaged, then position the head.

Use the head impactor to impact it. Reduce the joint.

> Impaction of ceramic head:

Before placing the ceramic head onto femoral stem:

- Carefully rinse and dry the stem taper.
- Meticulously inspect the stem taper and female head taper, and remove any foreign body.

Manually place the head onto stem taper by gently turning it while pushing it along the taper axis until it is firmly seated.

Use the head impactor to finalize impaction slightly. Reduce the joint.

STEM EXTRACTION (OPTIONAL)



A per-operative extraction instrumentation is available.

Remove the femoral head by tapping around the base of the head.

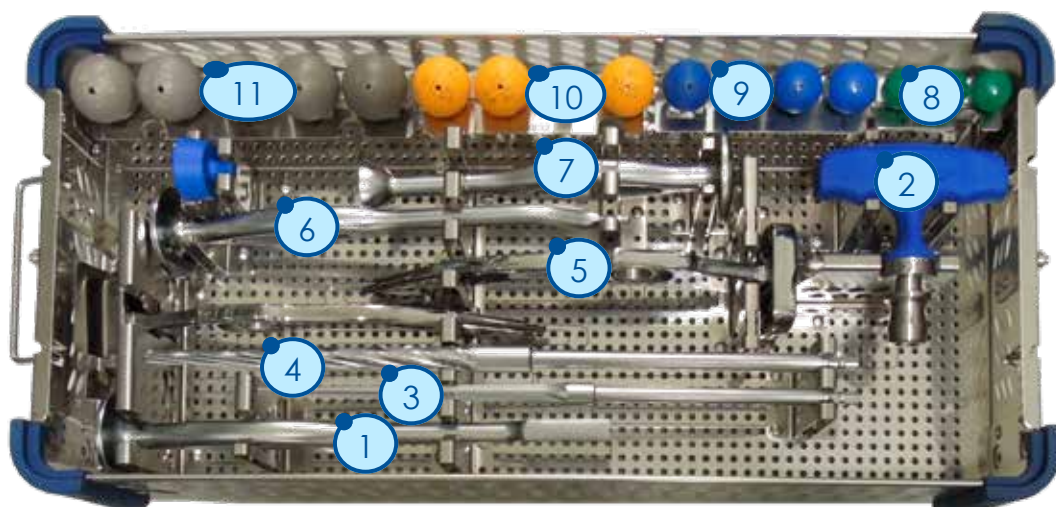
Assemble the slap hammer weight onto the slap hammer shaft and screw both components into the slap hammer tip.

Tightly screw the slap hammer tip into the upper portion of the stem and then extract it. Keep the slap hammer aligned with the stem axis during extraction.

INSTRUMENTATION

EVOK® INSTRUMENTATION COMMUNE

2-01999109

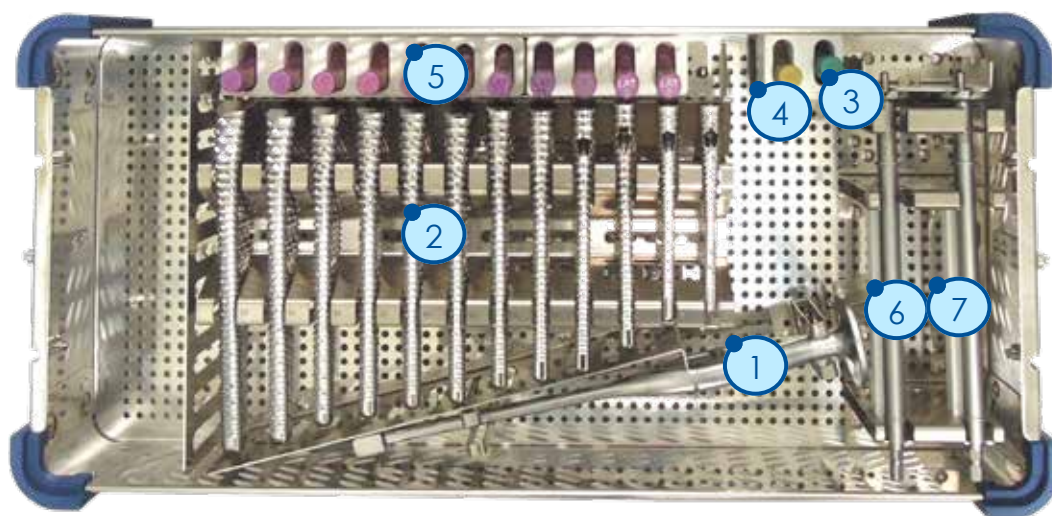


Item	Description	Reference	Qty
1	Box Chisel size Medium	112-042-038	1
2	T Handle - Zimmer-hall connection	2-0192300	1
3	Conical Reamer 4/11 mm	2-0193200	1
4	Conical Reamer 7/14 mm	2-0193300	1
5	Broach Handle	2-0103100	1
6	Offset Stem Impactor	2-0194200	1
7	Head Impactor	112-042-045	1
8	Trial Head 12/14 Ø22.2 Short, Medium and Long Neck	2-0196104 to 2-0196106	1 of each
9	Trial Head 12/14 Ø28 Short, Medium, Long and Extra-Long Neck	2-0196101 to 2-0196103 2-0196113	1 of each
10	Trial Head 12/14 Ø32 Short, Medium, Long and Extra-Long Neck	2-0196107 to 2-0196109 2-0196114	1 of each
11	Trial Head 12/14 Ø36 Short, Medium, Long and Extra-Long Neck	22-0196110 to 2-0196112 2-0196116	1 of each

INSTRUMENTATION

EVOK® INSTRUMENTATION (Suite)

2-01999110

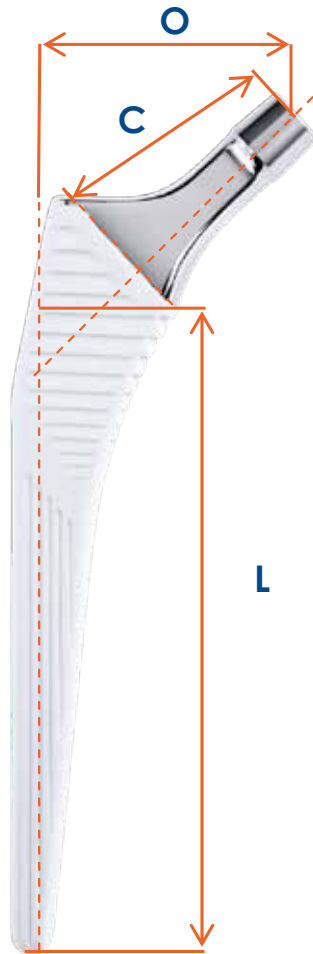


Item	Description	Reference	Qty
1	Cancellous Bone Compactor for EVOK® Femoral Stem	112-042-037	1
2	EVOK® Broach Sizes 7 to 20	2-0197407 to 2-0197420	1 of each
3	Trial Neck on Broach for EVOK® Standard Femoral Stem Compatible with all sizes	2-0194100	1
4	Trial Neck on Broach for EVOK® High Offset Femoral Stem Compatible with sizes 9 to 16	2-0194101	1
5	Trial Neck on Broach for EVOK® Lateralized Femoral Stem Sizes 8 to 20	2-0194108 to 2-0194120	1 of each
6	Calcar Reamer for Ø30 mm Femoral Stem	2-0197630	1
7	Calcar Reamer for Ø35 mm Femoral Stem	2-0197635	1



Item	Description	Reference	Qty
1	Rod for Slap Hammer	2-0102900	1
2	Slap Hammer tip for Femoral Stem	2-0103200	1
3	Slap Hammer Cylinder	2-0103300	1

VALUES



Size	Length L (mm)	Offset O (mm)			Neck length C (mm)			CCD Angle		
		STD	LAT	HO	STD	LAT	HO	STD	LAT	HO
7	91	37,5	-	-		-	-		-	-
8	96	38,1	45,9	-		41,3	-		126°	-
9	111	38,8	46,8	45,8		41,8			127°	
10	121	39,4	47,7	46,4		42,3			127°	
11	126	40,1	48,6	47,1		42,7			127°	
12	131	40,7	49,5	47,7	38,5	43,2	43,2	135°	128°	135°
13	136	41,4	50,4	48,4		43,7			128°	
14	141	42	51,3	49		44,1			128°	
15	146	42,7	52,2	49,7		44,6			128°	
16	151	43,3	53,1	50,3		45,1			129°	
18	161	44,6	54	-		45,1	-		129°	-
20	171	45,9	54,9	-		45,1	-		130°	-

NOTES

A series of horizontal dotted lines for writing notes.



Customer Service - France

Porte du Grand Lyon,
01700 Neyron, France
Tel. : +33 (0)4 37 85 19 19
Fax : +33 (0)4 37 85 19 18
E-mail : amplitude@amplitude-ortho.com

Customer Service-Export

11, cours Jacques Offenbach. Zone Mozart 2
26000 Valence, France
Tel. : +33 (0)4 75 41 87 41
Fax : +33 (0)4 75 41 87 42
E-mail : amplitude@amplitude-ortho.com

Internet : www.amplitude-ortho.com