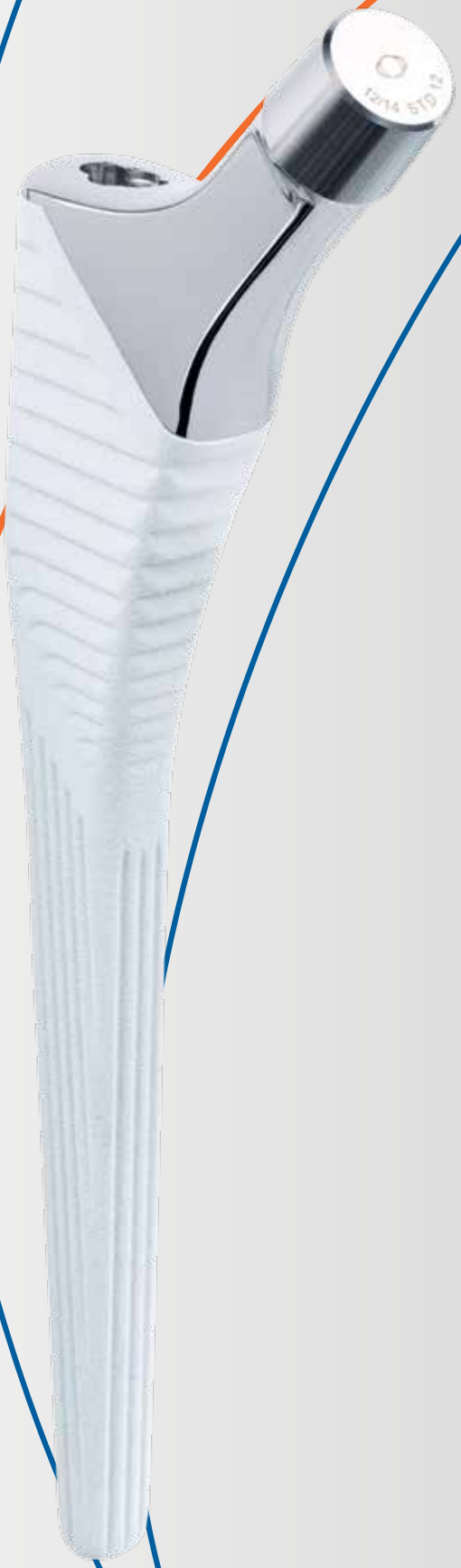
CL2® HIP SYSTEM

Surgical Technique



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AMPLITUDE is an internationally renowned orthopaedic company that has built a reputation for exceptional engineering, reliable clinical results, and cohesive collaboration with the world's leading surgeons.

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CL2® HIP SYSTEM

The CL2® 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 internationally renowned engineers in collaboration with leading surgeons from around the globe.

The stem has been launched utilising the 'Stepwise Introduction' recommended by Henrik Malchau.[1]

- Clinical Pretesting - 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 stabilisation that is consistent with good long term clinical outcomes.[2]
- Multicentre study performed in Australia with excellent clinical outcome.[3]
- Registry data since 2010.[4]

First implanted in Australia in 2010, the CL2® 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.

CL2® includes simple instrumentation suitable for all anatomies and surgical techniques. It can easily be used for Posterior, Lateral, Anterolateral or Direct Anterior approaches.

SAFE

- Proven design[4], material and fixation - cementless tapered rectangular design, titanium, Hydroxyapatite (HA) coated.
- Forged from high quality titanium by the company that has been producing this type of stem for over 30 years.[5]
- Coated with 155 microns of HA.
- Extensive mechanical testing with a focus on fatigue resistance, fretting and corrosion resistance.
- Fully validated in-house quality control on 100% of stems.
- Proven two year RSA results on 23 stems and hundreds of implants since 2010 on a prominent joint registry.[2,4]

SIMPLE

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

ADAPTABLE

- Two offset options (Standard and High) with constant neck angle.
- 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 journal of Bone and Joint Surgery Inc.(Am), 2011

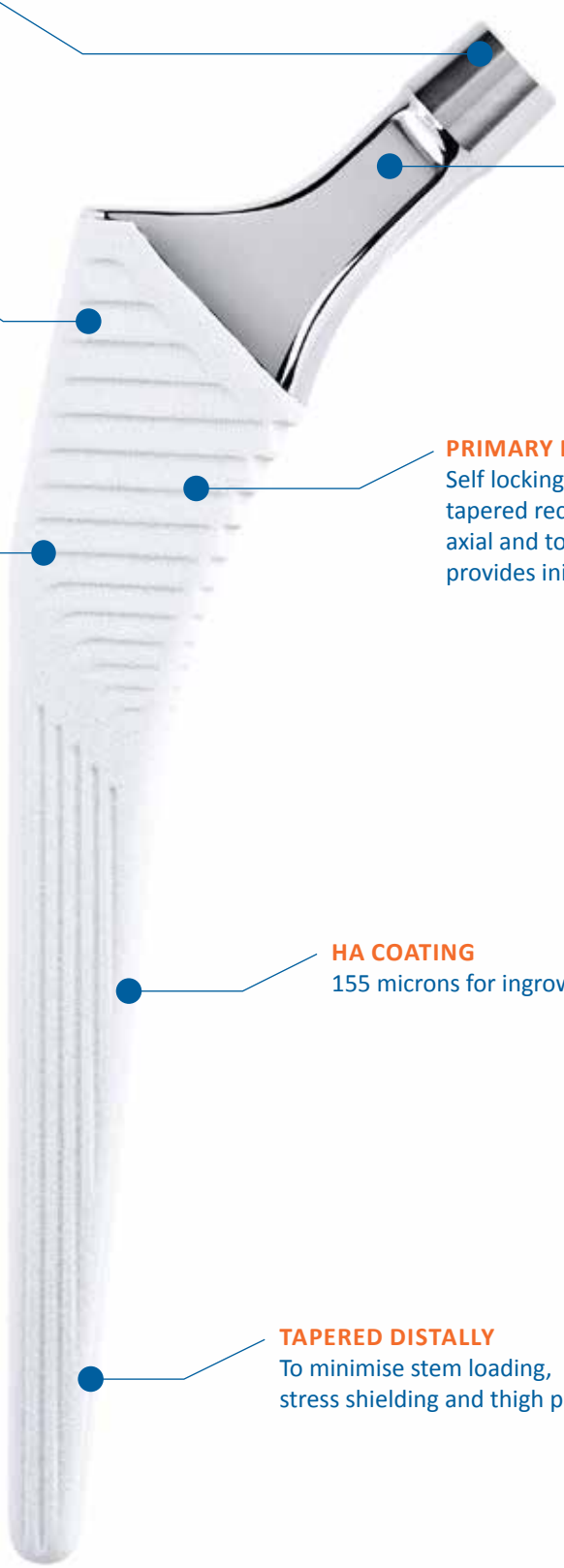
RESTORATION OF HIP BIOMECHANICS
Two offset versions - Standard and High. 135° CCD angle.

FLAT SURFACE
Under taper to maximise range of motion.

LOW PROFILE LATERAL SHOULDER
For ease of insertion and reduced risk of GT fracture.

PRIMARY FIXATION
Self locking metaphyseal fit and tapered rectangular shape resists axial and torsional forces and provides initial rotational stability.

HORIZONTAL PROXIMAL STEPPED MACROSTRUCTURES
For high surface contact area and increased stability/ ingrowth potential.



HA COATING
155 microns for ingrowth.

TAPERED DISTALLY
To minimise stem loading, stress shielding and thigh pain.

SURGICAL TECHNIQUE OVERVIEW

1 PRE-OPERATIVE PLANNING

- Assess quality of radiograph.
- Identify anatomical landmarks.
- Identify acetabular and femoral biomechanical points and optimise implant positioning.

2 SURGICAL APPROACH

- The CL2® 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 visualisation of the acetabulum and proximal femur.

3 FEMORAL NECK RESECTION

- Identify anatomical landmarks (LT, PF, GT).
- Determine the neck cut level during pre-operative planning.
- Mark the cutting plane level onto the bone with reference to the anatomical landmarks.
- Take care to protect the soft tissues and greater trochanter 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.

4 FEMORAL CANAL IDENTIFICATION & PREPARATION

- Insert the smallest T-handle reamer into centre of the femoral canal.
- Remove hard bone along the medial side of the greater trochanter with the box chisel.
- Leave cut bone within the proximal canal for compaction.

5 CANCELLOUS BONE COMPACTION

- Create a regular rectangular cross-section cavity in line with femoral axis using the most appropriate method for the patient's bone quality - Dorr A, Dorr B or Dorr C.

6

BROACHING

- Compact bone gently to create a rectangular cross sectional cavity with axial and rotational stability.
- Starting at size 7, increase broach size until axial stability is obtained.
- Check rotational stability and leave the last broach in the femur.

7

CALCAR REAMING

- With the broach in place, position the appropriate calcar reamer in line with the broach spigot.
- Ream gently and slowly until you reach the broach and achieve a flat surface, taking care to protect the soft tissues in this area.

8

NECK & HEAD TRIAL

- With the final broach still in place, attach the trial neck and head to restore the planned offset and leg length.
- Test range of motion, joint stability, leg length, and offset, then remove the head, trial neck and broach from the femur.

9

FINAL STEM IMPACTION

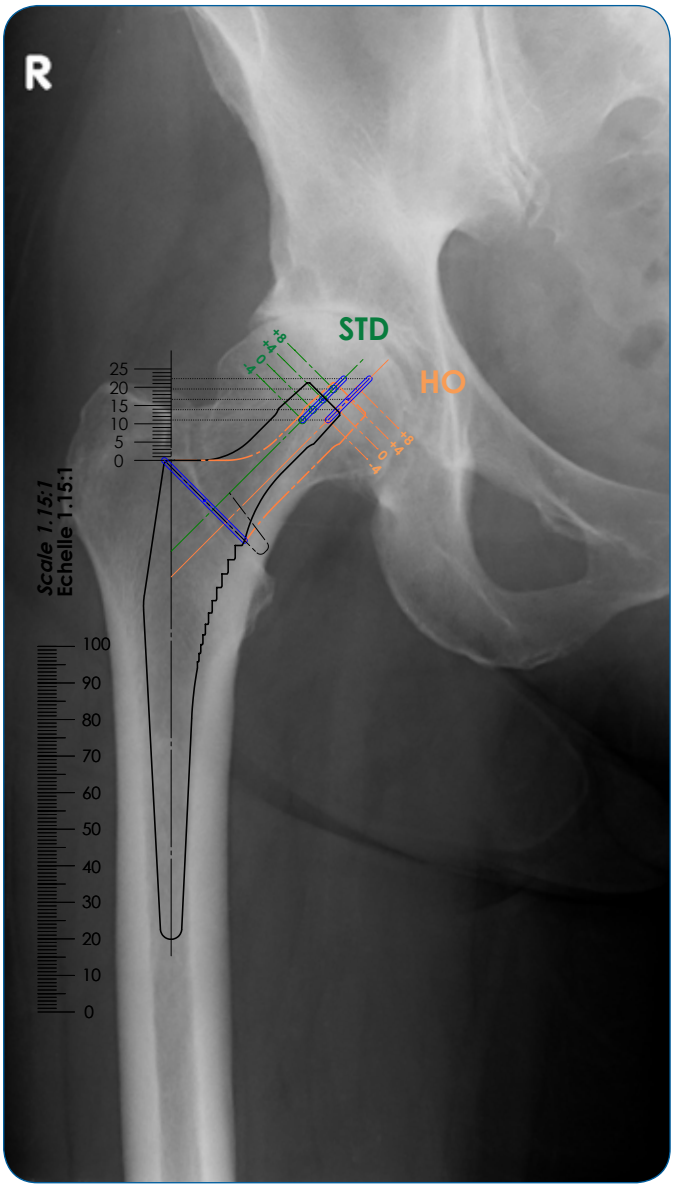
- Gently impact the appropriate CL2® Stem until the HA border marking the appropriate depth is reached and the stem is stable.
- Remove the stem impactor.
- Place a trial head on the stem and reduce the joint to help confirm the head neck length.

10

HEAD IMPACTION

- Clean and dry the stem taper, inspecting for damage or contamination.
- Position the femoral head in the axial direction of the stem taper using a slight turning motion.
- Lock the femoral head on the stem taper.
- Tap the impactor with hammer in the axial direction of the stem taper to ensure the femoral head is seated firmly.

1 PRE-OPERATIVE PLANNING



STEP 1: ASSESS QUALITY OF RADIOGRAPH

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

- Pelvic 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 pelvis was tilted forwards, or decreased is the pelvis was tilted back at the time of x-ray.
- Femoral rotation – Both femora should be internally rotated by 15-20 degrees. You should be able to see 2+/-3mm of the lower trochanter.
- Quality of the image is acceptable, and is at the expected magnification~115%.

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 acetabular 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 40 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 femoral shaft filling while leaving 1 to 2mm 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

2 SURGICAL APPROACH

THE CL2® STEM MAY BE IMPLANTED USING:

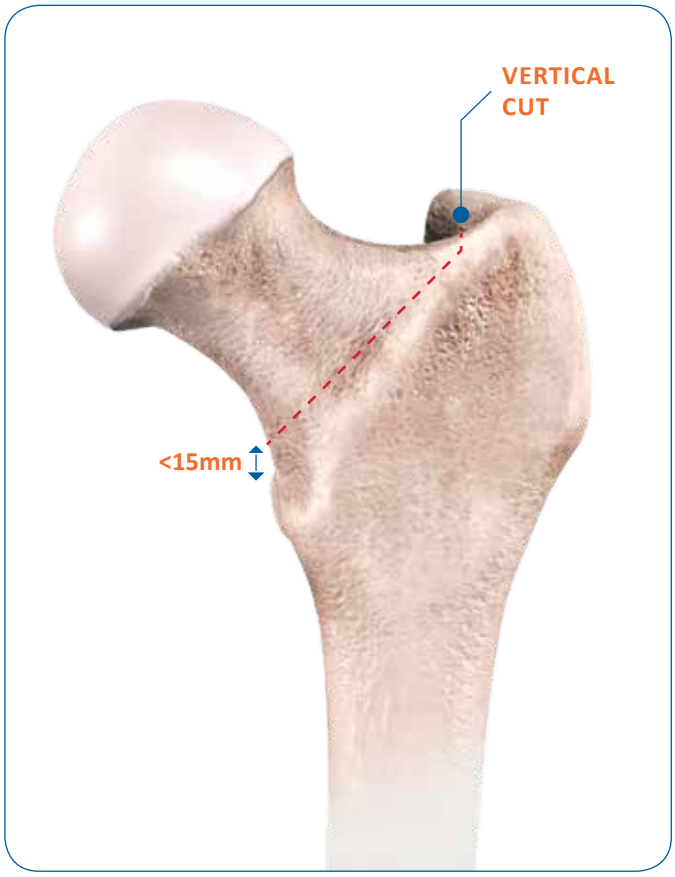
- Any of the traditional surgical approaches.
- Any of the contemporary, less-invasive approaches including direct anterior (on or off table).

The requirement of any approach is adequate visualisation 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 minimise/identify intra-operative fractures.
- Clear view of the greater and lesser trochanters to reduce incidence of fracture and measure leg length.

3 FEMORAL NECK RESECTION

1. Identify anatomical landmarks lesser trochanter (LT), piriformis fossa, greater trochanter (GT).
2. Determine the neck cut level during pre-operative planning. In most cases the distance from the neck cut to the LT is less than 15mm (see diagram).
3. Mark the cutting plane level onto the bone with reference to the anatomical landmarks.
4. Take care to protect the soft tissues and greater trochanter 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 (see diagram).



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.**

4 FEMORAL CANAL IDENTIFICATION AND PREPARATION

CANAL IDENTIFICATION

1. Identify the femoral entry point which is normally found in the piriformis fossa on the posterior and lateral quadrant of the cut neck surface. You may need to remove a small part of the posterior cortex at the neck junction.
2. Use the smallest T-handle reamer to find the centre of the canal.
3. Push into the femoral canal to prepare it for broaching, making sure to stay in the femoral shaft axis.

CANAL OPENING

1. Prepare the metaphyseal area by removing hard bone, passing close to the medial side of the greater trochanter at its junction with the neck.
2. Keep the box chisel in line with the centre of the canal and the planned anteversion of the stem.
3. Avoid removing any additional bone and leave cut bone within the proximal canal for compaction.

5 METAPHYSEAL CANCELLOUS BONE COMPACTION

1. Create a strong compacted bone envelope of cancellous bone, avoiding direct stem contact with the cortical bone if possible.
2. Create a regular rectangular cross-section cavity in line with femoral axis. Bone quality will determine how this is achieved.

- **Dorr A** - Consider reaming diaphysis to 11 or 12mm to prevent distal stem fixation and to allow proper proximal bone compaction.
- **Dorr B** - Utilise tamp to create the correct proximal shape prior to broaching.
- **Dorr C** - The proximal cancellous bone may be soft or deficient. A tapered rectangular straight stem may be used if adequate 3-point fixation can be achieved. Be careful not to remove any bone from the proximal envelope and compact gently to avoid fracture. If this 3-point fixation is not possible, use of a cemented stem is advisable. There is a higher risk of intraoperative fracture in this group of patients.

NOTES:

- **Proximal metaphyseal bone compaction is extremely important to preserve as much bone stock as possible.**
- **Bone compactor is the same size as a size 7 broach.**

6 BROACHING

IMPORTANT:

- **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.**
- **If calcar fracture occurs, remove broach, wire calcar and then use the broach one size smaller than that which caused the fracture. If this is not rotationally or axially stable, consider using a cemented stem.**

CL2® 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.
- Broach orientation should remain in line with the femoral mechanical axis and planned anteversion, staying lateral and taking care not to fracture the calcar.
- Aggressive broaching increases the risk of femoral fracture.
- Broaches should be introduced in the desired anteversion. Typically, the femoral morphology will dictate this, however anatomic variation may make it desirable to alter the anteversion. Note: Care should be taken not to rotate the broaches.
- To prevent any varus position, be sure to introduce broaches in the anatomical axis, with a lateral bias.
- The top of the broach corresponds with the top of the HA coating on the stem.

1. Start at size 7 broach and increase progressively until axial stability is obtained.
2. If the broach can be inserted 4mm below the planned resection level, it is usually possible to go to the next size.
3. Once good axial stability is achieved, check rotational stability.
4. Leave the last broach in the femur and remove the broach handle.

7 CALCAR REAMING

Calcar reaming is performed for several reasons:

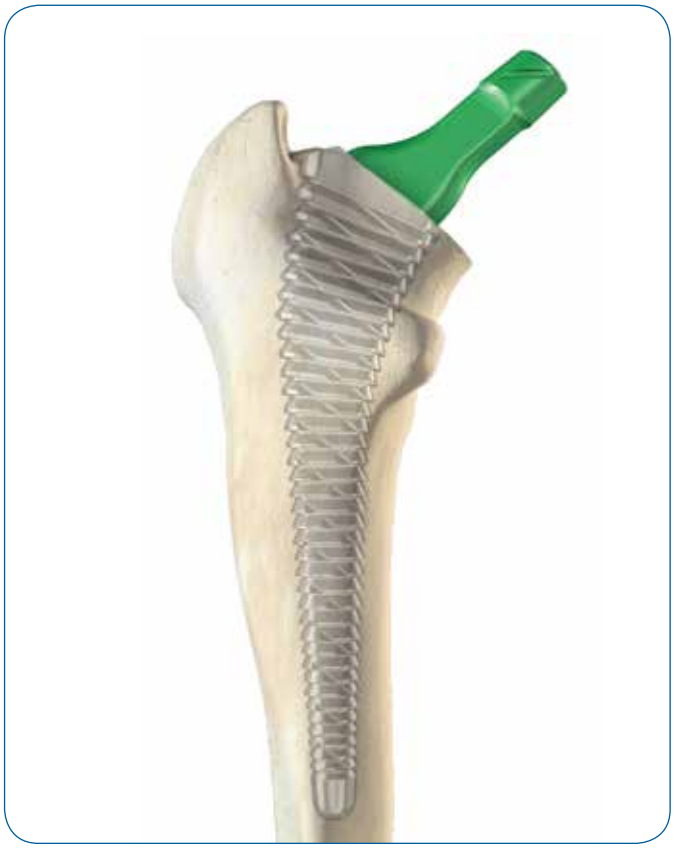
- To define the correct insertion level.
- To remove prominent proximal bone at the neck that may reduce range of motion or create impingement.

1. Ensure final broach is stable and is at the correct insertion level.
2. Choose the small calcar reamer and assemble with the surgical hand-piece.
3. Apply gently in line with the broach spigot then ream slowly with minimal force.
4. Ream until you reach the broach and achieve a flat surface, taking care to protect the soft tissues in this area.
5. User larger reamer if peripheral bone remains.

NOTE:

Use the Ø35 mm reamer for stem sizes 7 to 12-13
Use the Ø40 mm reamer for stem sizes 12-13 to 20

8 NECK AND HEAD TRIAL



1. With the final broach in place, attach the trial neck and head to restore the planned offset and leg length.
2. Assess trial joint for leg length, offset, impingement and stability.
3. Adjust the offset and neck length as needed.
4. Remove the head, trial neck and broach from the femur.

NECK LENGTH

Head Trial Diameter	Colour	Short	Medium	Long	Extra long
		1 line	2 lines	3 lines	4 lines
22.2mm	green	-2	0	+2	n/a
28mm	blue	-3.5	0	+3.5	+7
32mm	yellow	-4	0	+4	+7
36mm	grey	-4	0	+4	+8

9 FINAL STEM IMPACTION

1. Select the CL2® stem that matches the size and offset chosen during the trials.
2. The stem is 0.31 mm larger than the broach trial.
3. Manually position the stem in the prepared femoral canal within 1-2 cm of top of the HA coating.
4. Place the stem impactor in the impaction hole on top of the stem with the handle positioned away from the GT to avoid impingement.
5. Gently impact in line with the axis of the stem until the HA border marking the appropriate depth is reached and the stem is stable.
   Do not attempt to change or direct the stem anteversion.
6. Once stem is stable, remove the stem impactor.
7. Place a trial head on this stem and reduce the joint to confirm the head neck length.

NOTES:

- **If the stem is unable to be fully seated with gentle impaction, consider a shorter neck length or consider removing the stem if it is too proud. Do not continue to impact as this may result in fracture.**
- **If the stem inserts below the planned level, check for stability and check for fracture.**
- **If stable and no fracture, consider a longer neck length if possible or remove the stem and use the next size.**
- **If a fracture is evident, remove the stem, wire the fracture and reinsert the same stem to the correct level. Refer Page 19 for STEM EXTRACTION TECHNIQUE if required.**

10 HEAD IMPACTION/FINAL REDUCTION

1. It is essential to thoroughly clean and dry the stem taper.
2. Inspect the taper for possible damage and contamination with foreign material.
3. Position the femoral head in the axial direction of the stem taper using a slight turning motion on the clean and dry stem taper.
4. After correctly positioning the femoral head, it is essential that the femoral head is locked on the stem taper.
5. Tap the impactor with hammer in the axial direction of the stem taper to ensure the femoral head is seated firmly. A single hammer blow is sufficient, although several blows are permitted if necessary.

IMPORTANT:

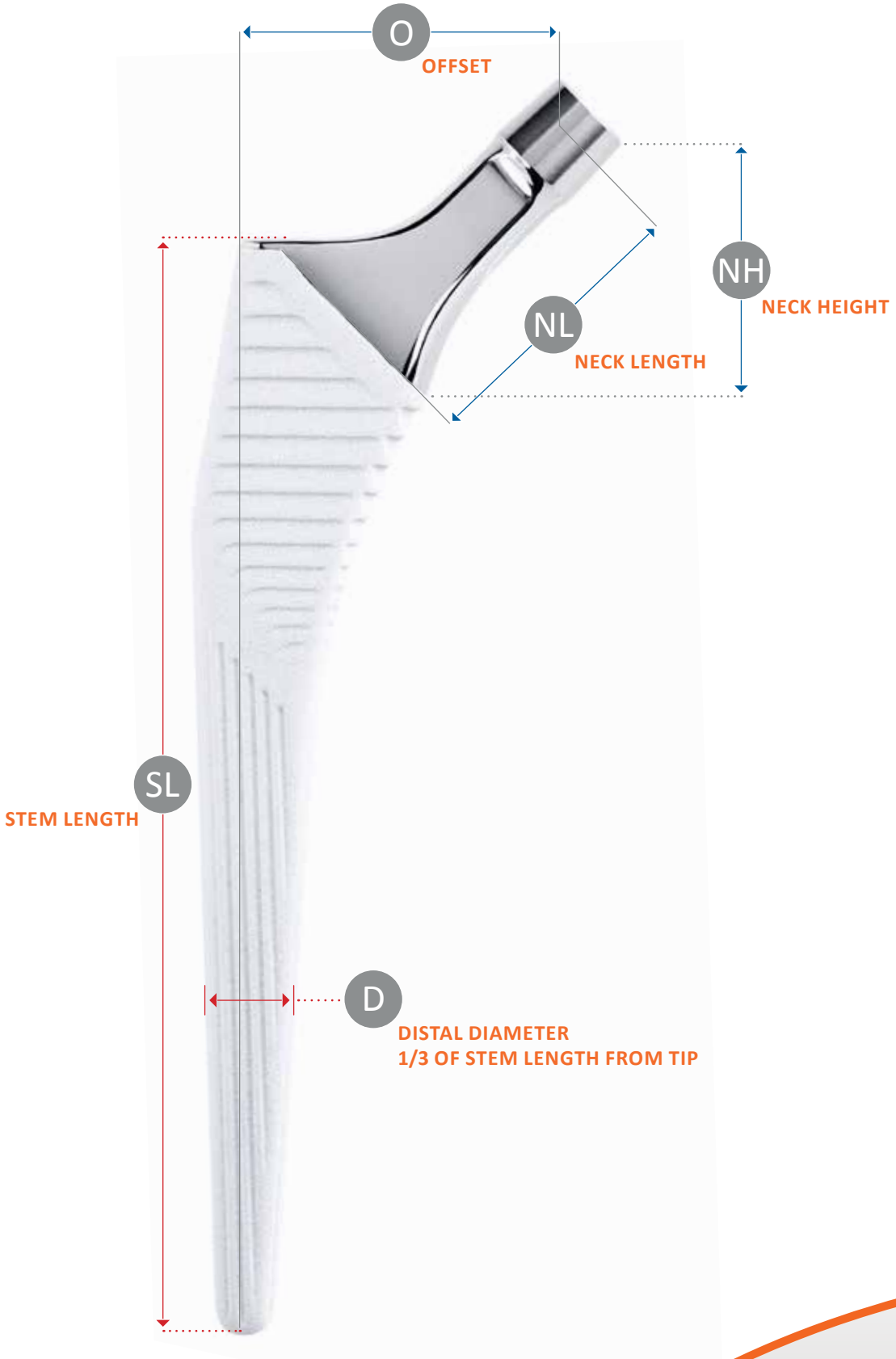
- **Never strike the femoral head directly with the hammer so as to avoid damage.**
- **During the final reduction of the femoral head into the acetabular liner, contact between the femoral head and any metal (cup or instruments) must be avoided.**

STEM EXTRACTION - IF REQUIRED

A peri-operative extraction instrument is available.

1. Assemble the slap hammer weight onto the slap hammer shaft and screw both components into the slap hammer tip.
2. 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.

IMPLANT INFORMATION



STANDARD OFFSET

SIZE	O	SL	D	NH	NL	CCD
7	37.5	111	8.9	35.9	38.5	135°
8	38.1	116	9.5	35.9	38.5	135°
9	38.8	131	9.9	35.9	38.5	135°
10	39.4	141	10.6	35.9	38.5	135°
11	40.1	146	11.6	35.9	38.5	135°
12	40.7	151	12.6	35.9	38.5	135°
13	41.4	156	13.6	35.9	38.5	135°
14	42.0	161	14.6	35.9	38.5	135°
15	42.7	166	15.6	35.9	38.5	135°
16	43.3	171	16.6	35.9	38.5	135°
18	44.6	181	18.6	35.9	38.5	135°
20	45.9	191	20.5	35.9	38.5	135°

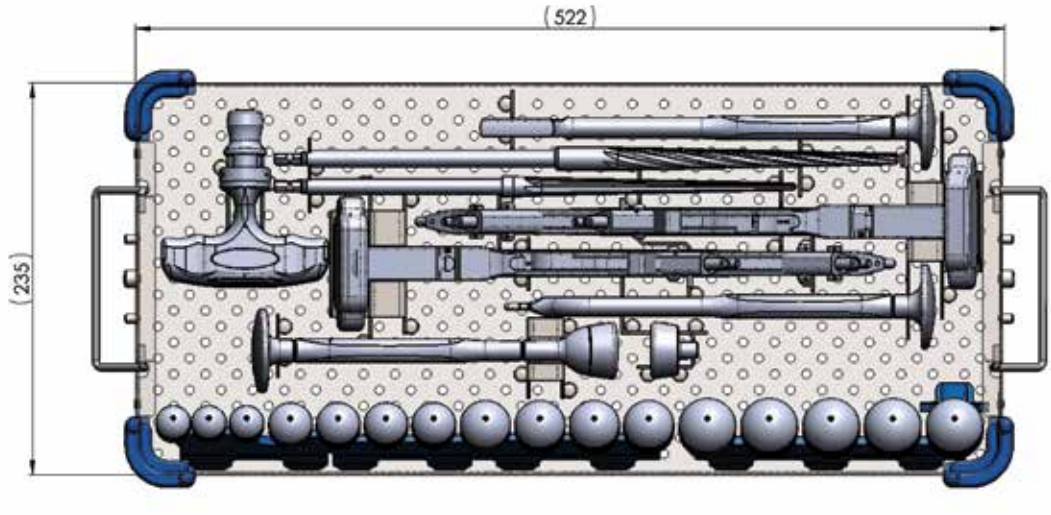
HIGH OFFSET

SIZE	O	SL	D	NH	NL	CCD
9	45.8	131	9.9	35.9	43.2	135°
10	46.4	141	10.6	35.9	43.2	135°
11	47.1	146	11.6	35.9	43.2	135°
12	47.7	151	12.6	35.9	43.2	135°
13	48.4	156	13.6	35.9	43.2	135°
14	49.0	161	14.6	35.9	43.2	135°
15	49.7	166	15.6	35.9	43.2	135°
16	50.3	171	16.6	35.9	43.2	135°

INSTRUMENTATION FOR CL2® STEM

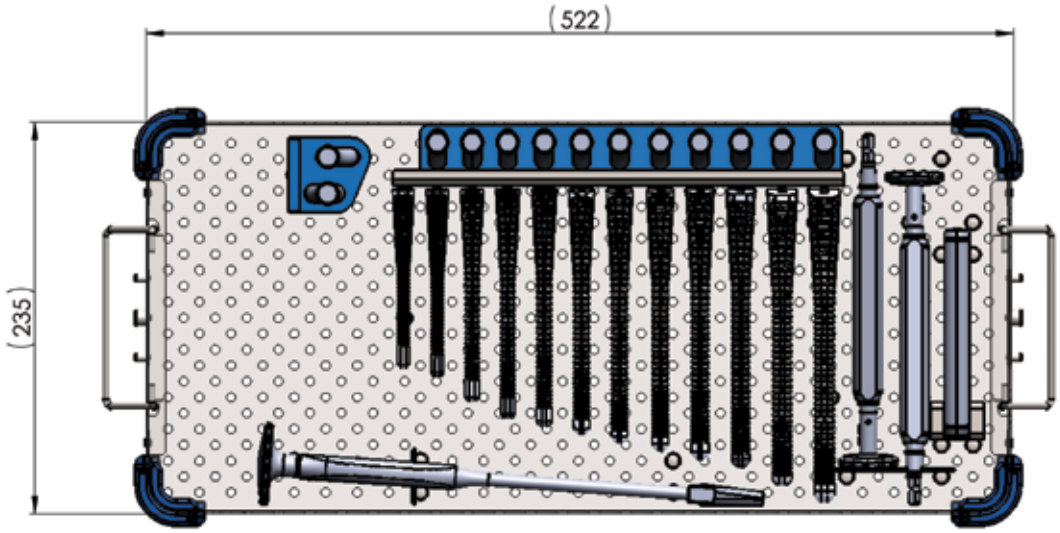
CL2® COMPRISES THREE INSTRUMENT TRAYS:

UNIVERSAL FEMORAL TRAY



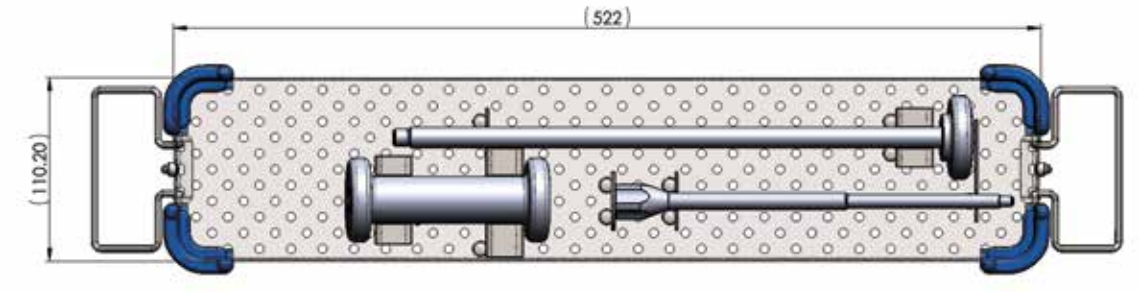
DESCRIPTION	REFERENCE	QTY
Box chisel medium size	112-042-038	1
Tapered pin reamer 4/11 mm - Zimmer/Hall connection	2-0193200	1
Tapered pin reamer 7/14 mm - Zimmer/Hall connection	2-0193300	1
T-handle - Zimmer/Hall connection	2-0192300	1
Straight broach handle	2-0194500	2
Offset stem impactor	2-0194200	1
Head impactor	112-042-045	1
Trial heads	2-01961XX	16

DEDICATED CL2® TRAY

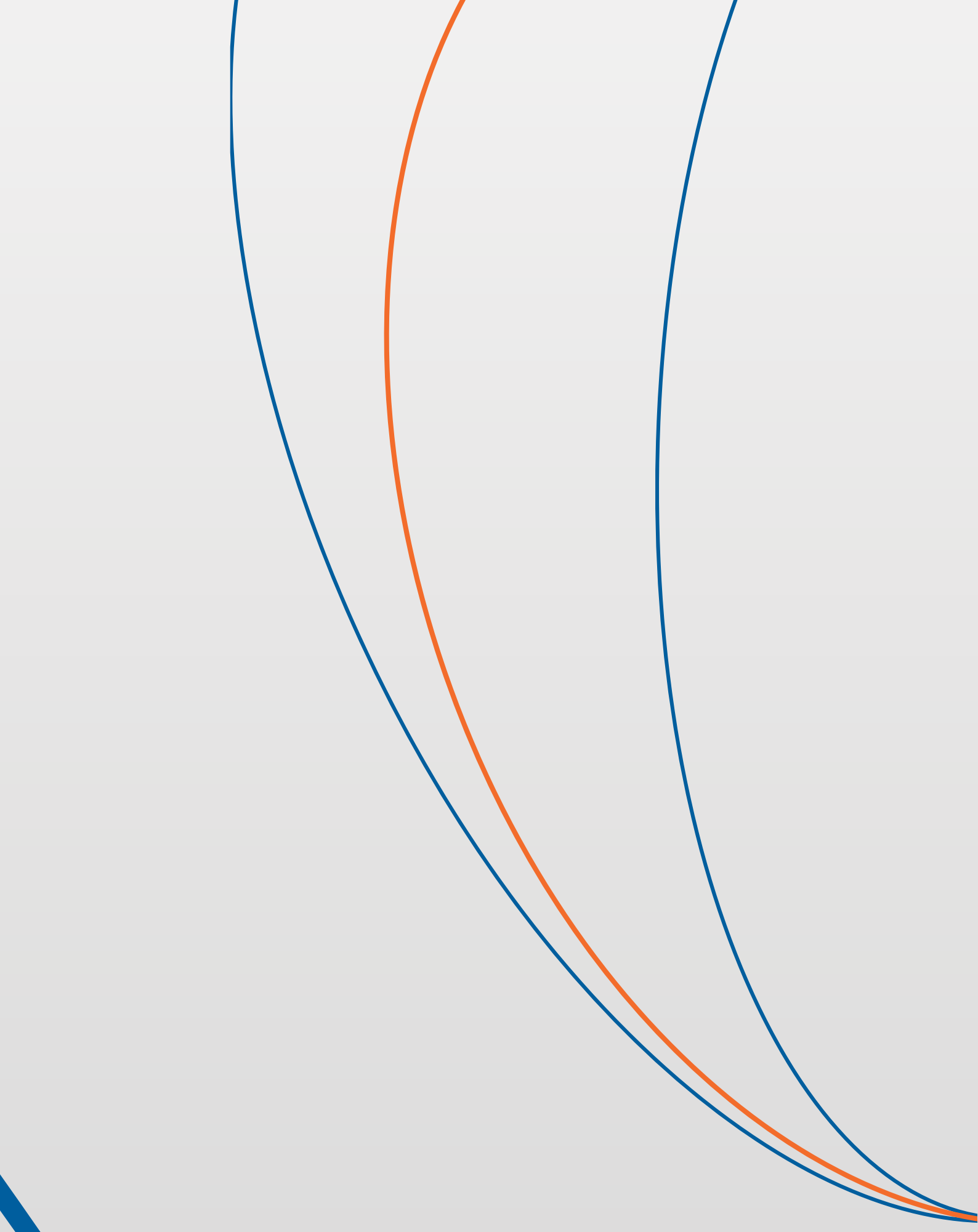


DESCRIPTION	REFERENCE	QTY
Bone compactor	112-042-037	1
Broaches – size 7 to 20	112-042-000 to 112-042-011	12
Standard trial neck	2-0129000	1
High offset trial neck	2-0129001	1
Calcar reamer Ø35 mm	2-0193135	1
Calcar reamer Ø40 mm	2-0193140	1

MINI TRAY FOR EXTRACTION



DESCRIPTION	REFERENCE	QTY
Shaft	2-0102900	1
Slap hammer weight	2-0103300	1
Slap hammer tip	2-0103200	1



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