Cemented Hip Portfolio

Focus on:
C-STEM™ AMT and
MARATHON™ Cemented Cup
Cemented prosthesis are engineered to be a reliable method of hip replacement.

Alongside our cementless portfolio, cemented prostheses can offer surgeons and payers a total solution to treat their patients whilst providing cost effective treatment.
What’s our portfolio?

**VALUE**
- CORAIL® Cemented
- ELITE Plus Ogee Cemented Cup

**PREMIUM**
- C-STEM AMT/ C-STEM original
- MARATHON XLPE Cemented Cup

**REVERSE HYBRID**
- CORAIL® Cementless
- MARATHON XLPE Cemented Cup

**HYBRID**
- C-STEM AMT
- PINNACLE® Cementless Acetabular Cup

Latest ODEP ratings can be found at www.odep.org.uk
C-STEM original design concepts

- Reduced distal tip dimension
- Polished finish
- Reduced lateral shoulder
- Long medial bearing surface
Loading of the hip joint
The answer – load transfer through a triple taper

- Cobra Flange from the CHARNLEY® and extend it down the length of the implant
- 3rd Taper - runs from the lateral shoulder to the medial apex
- Generates proximal load transfer
- Third taper works with two more conventional tapers and overall stem geometry to increase stability
  - Axially
  - Torsion

1. Starke, G. An assessment of the C-STEM II femoral component. FRD/UCT Centre for research in computational and applied Mechanics, University of Cape Town, South Africa
The Triple Taper – a little more detail

• The 3 tapers are:
  • Taper 1 - M/L (Coronal)
  • Taper 2 – A/P (Saggittal)
  • Taper 3 - M/L Horizontal)

• Tapers 1+2
  • Axial stability

• Taper 3
  • Increased proximal M/L dimension
  • Designed for increased calcar loading
C-STEM Triple Tapered Concept

- 3rd Taper behaves as an “Ovoid” wedge resisting the varus “fall over” seen with contemporary stem designs

- Load is shared
  - medial to the anterior and posterior
  - more even circumferential loading

- A-P shear force creates hoop stresses

- The wedged cross section results in lesser sub surface fatigue
Summary of C-STEM original concept

• Proximal loading to protect and maintain femoral bone

• Improved axial and torsion stability

• Reduces cement mantle stresses

• Restoration of natural biomechanics

• Even cement mantle

• Optimal load transfer in the proximal femur resulting in positive postoperative bone remodelling

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C-STEM original – the World Wide View

• Positives
  • High acceptance of C-Stem principles
  
  • Favourable response to report of positive bone re-modelling
    • Journal of Arthroplasty papers

  • Increased World Wide acceptance of polished tapered stems
    • market segment growing

C-STEM original – the World Wide View

• Concerns
  • Consistent requests for higher offsets from some markets
  • 9/10 taper was a barrier to acceptance in major markets
  • Question mark over rotational stability\(^4\) (paper updated in 2014 which shows that C-Stem “didn’t” migrate - **Continuous distal migration and internal rotation of the C-stem prosthesis without any adverse clinical effects** Bone Joint J 2014;96-B:604–8. Received 28 November 2013;)
  • Difficult to get the correct rotation as you cannot see the shoulder (cement covering)

C-STEM AMT

- Same intra-medullary geometry
- Raised shoulder and broader M/L body
- 12/14 ‘articuleze’ mini-taper (AMT)
- Narrower A/P neck geometry
- Deep medial profile
- Greater differentiation between standard and high offset
- Continued to be made from Hi Nitrogen, cold forged Stainless Steel (Same as original C-STEM)
Geometry

12/14 articuleze mini-taper (AMT)

Increased rotational stability\(^5\)

Identical body sizes: use same broaches as C-STEM

Raised Lateral Shoulder

Size 4 HO

Size 4

5. Data on file: DHF A457 (Range of motion for C-STEM AMT)
Taper & Neck improvements

- Optimized 12/14 mini taper
  - Completely captures head
  - All head sizes and options available
  - Less inventory

- Improved neck geometry
  - Flattened A/P Geometry
  - Designed to reduce A/P impingement
  - Increased ROM possibility
  - Proportionally Offset
Biomechanics & offset

- 2 offsets per size – standard & high

- Direct lateralisation
  - Favors offset over length
  - No impact on leg length
  - Adds 6 mm to sizes 1 - 3
  - Adds 8 mm to sizes 4 - 8

- Constant 130 degree neck angle

- Proportional through size
Proximal-Distal Placement Options

• Can be implanted at three levels
• Provides 3 different leg lengths
• There are STD and high offset stems
• Multiple neck lengths depending on choice of modular head
C-Stem AMT Line Extension & refresh

- Implant portfolio completion – 6 revision stems, 3 Asian and a CDH stem added to the range.

- Instrument upgrades
  - Box osteotome
  - Curved non-retaining inserter handle
  - Depth marked broaches and trial necks
  - New trial stems

- Tray upgrades
  - InCement revision tray
  - Core kit to serve 90%+ patients
  - Streamlined kit to reduce COGs and increase hospital acceptance
New additions to C-STEM AMT range

4 Small C-STEM AMT Implants - 1 CDH & 3 ‘A’ sizes
1570-24-095 C-STEM AMT CDH Standard Offset
1570-24-091 C-STEM AMT Size 1A Standard Offset
1570-24-092 C-STEM AMT Size 2A Standard Offset
1570-24-093 C-STEM AMT Size 3A Standard Offset

6 Revision C-STEM AMT Implants
1570-24-087 C-STEM AMT Long 2 Standard Offset
1570-24-088 C-STEM AMT Long 3 Standard Offset
1570-24-089 C-STEM AMT XL205 3 Standard Offset
1570-24-094 C-STEM AMT XL240 3 Standard Offset
1570-24-085 C-STEM AMT Long 2 High Offset
1570-24-086 C-STEM AMT Long 3 High Offset

- Size 2 & 3 180 mm long stems in std and high offset
- Size 3 205 mm XL, 240 XL std offset stems
C-STEM Instrument additions

- Trial stems
  - Ability to trial a stem during InCement procedure
  - Ability to trial during revision surgery

- Simple to use height adjuster
  - More intuitive use during surgery
  - Easy placement

258003086  C STEM AMT STEM TRIAL 2 LONG S
258004086  C STEM AMT STEM TRIAL 2 LONG H
258003087  C STEM AMT STEM TRIAL 3 LONG S
258004087  C STEM AMT STEM TRIAL 3 LONG H
258005087  C STEM AMT STEM TRIAL 3 XL205
258006087  C STEM AMT STEM TRIAL SIZE 3 XL 240
258001010  C STEM AMT VERSION PIN
C-STEM Instrument additions

• Improved depth markings on broach and trial necks
  • Designed to improve ability of surgeon to gauge appropriate depth of insertion and therefore the most appropriate leg length
C-STEM Instrument additions

- Modular box osteotome
  - Reduces size and weight

- Curved non-retained inserter handle
  - Benefits of original straight inserter
  - Avoids greater trochanter during insertion

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<tr>
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</tr>
<tr>
<td>252200504</td>
<td>STEM INTRODUCER (curved/non-retained)</td>
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</table>
C-STEM Instrument additions

Improved Introducer Handle
Instruments (Pre 2017)

Leg length adjuster

Broach with +5mm Leg Length Adjuster

Broach with Neutral Position Leg Length Adjuster

Broaching levels of the central hole markers (determined during pre-operative templating)
Tray layout refresh

- Reduce our cost to serve our customer
- Improve proficiency of tray and instrument use in and out of theatre
- Reduce the instrument sterilisation costs for our customer
- Reduce instrument and tray workflow pressure on hospital nursing staff
InCement Revision

Key Value Proposition

DePuy Synthes InCement revision system is a clinically proven conservative approach that reduces complexity, reduces risk of fracture, bone loss, blood loss and surgery time and reduces cost\(^6,7,8,9\), whilst utilising a 10A* ODEP rated primary cemented stem. This system is provided for in a single tray reducing the number of trays needed for a case whilst increasing the opportunity to target competitor surgeons.

What is InCement Revision

Supporting growth

**What**
- Utilise well fixed cement mantle
- Remove old stem
- Clean and re-cement new stem

**Why**
- Less expensive implants costs
- Quicker & easier to do in elderly
- Increasing Publications show improved results
- Fits with new tariff introductions
- One of the fastest growing revision areas
InCement Revision

- There is a growing trend for InCement Revisions
- Proportion of the existing cement mantle to be left in-situ
- The “Revision” stem (usually a primary size 1 or 2 Std or HO) is then cemented within the existing mantle
- Cement mantle removal can result in
  - Substantial blood loss
  - Femoral perforation
  - Femoral fracture
  - Loss of bone stock
  - Increase in operation time
- By avoiding cement removal the surgeon is able to reduce those problems associated with cement mantle removal
InCement Revision

- Key InCement Revision steps are:
  - Old stem removal
  - Remove loose proximal cement
  - Trial stem/head combination
  - Cement in new stem

1. Stem Removal
2. Check Cement Integrity
3. Trialling
4. Cementation
5. C-STEM AMT Introduction
6. Final Reduction
InCement Revision

• Independent/standalone tray for InCement only

• Contains the main instruments required for an InCement procedure
  • Disposable chisels and handle
  • Slap hammer
  • Trial stems and heads
  • Stem inserter & head impactor

• Able to target new & competitive customers
PORTFOLIO

Don’t sell one, sell them all
What’s our portfolio?

VALUE

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How
Need to sell portfolio?

PREMIUM
A premium solution for surgeons who value cemented constructs
C-STEM AMT / C-STEM original MARATHON

REVERSE HYBRID
Believe in our proven cementless stem but want cup positioning and low wear of our cemented cups
CORAIL Cementless MARATHON

HYBRID
Want cementless cup fixation but believe cemented stems are a better option than cementless in some patients
C-STEM AMT PINNACLE
C-STEM AMT Conclusions

• C-STEM AMT founded in C-STEM heritage

• C-STEM AMT system able to compete

• Visitation centres

• Key opinion leader group

• 10A* ODEP rating
C-STEM™ Surgical Technique

Post 2017
Objectives – Understand:

• The sequence of steps in the C-STEM Surgical technique

• Good cement technique and its importance
Pre-operative Templating

- Templates are provided to determine both Implant size & neck resection level
- Consideration should be given to restoration of leg length and soft tissue balance during pre-op planning
Neck Resection

• Once the femoral head is exposed, align the neck resection guide against the long axis of the femur.* Determine the resection level by aligning the top of the guide with the tip of the greater trochanter or by referencing a measured resection level above the lesser trochanter.

• Confirm the resection level with the preoperatively templated plan. Mark the resection line using diathermy. Resect the femoral head. The collarless stem enables proximal and distal adjustment regardless of neck resection level; however, orientation of the cut should be perpendicular to the neck axis in both planes in order to avoid impingement of the medial stem against the medial neck.

*Please note that the CDH stem has a CCD angle of 125° (a resection angle of 55°).
The rest of the C-STEM AMT size range have a CCD angle of 130° (a resection angle of 50°)
Opening the femoral canal

Clearing the Anatomical Calcar

• In order to achieve an optimal cement mantle, clear the anatomical calcar (the cortical condensation overlying the endosteal entry into the lesser trochanter) using an osteotome or curette. Avoid excavating the lesser trochanter.

Femoral Alignment

• Attach the Canal Probe to the T-Handle. Introduce the probe into the femoral canal, maintaining neutral orientation.

• The C-STEM AMT Hip System is designed as a broach-only system, to maximise the strength of the bone / cement interface.
Metaphyseal Preparation

Femoral Broaching

- Attach a broach – two sizes smaller than the size determined during pre-operative templating – to the broach handle. Carefully impact the broach down the long axis of the canal in neutral orientation.

- Diamond tooth broaches should not be introduced aggressively. When using the posterolateral approach, incorporate 5-15° of anteversion
Broaching Levels

- Ensure that any remaining superolateral femoral neck is cleared to avoid varus stem placement.

- Sequentially increase the size of the broach until the final broach is fully seated in the femur with the upper surface of the broach level with the neck resection level, or at the level determined during pre-operative templating.

- If the final seating position does not match the pre-operatively templated position, the leg length adaptors can be used to set the broach at neutral or +5 mm positions for trial reduction.
Calcar Planing

• Since the C-STEM AMT Stem is a collarless stem, it can be positioned proximally or distally to the neck cut. Therefore, calcar planing is not mandatory; however, it is advisable in order to facilitate seating the actual prosthesis to the same level as the broach. Position the centre hole of the planer over the broach trunnion and plane the bone until it is level with the proximal surface of the broach.

• Because the CDH stem has a CCD angle of 125° (rather than 130° like the rest of this range), calcar planing SHOULD NOT be used with the CDH broach.
Trial Reduction

Femoral Neck Trial Assembly

• Attach the appropriate neck segment to the broach.

• If the femoral neck resection level is correct for proper leg length restoration, but there is still inadequate soft tissue abductor muscle tension, consider a high offset neck segment.

• Use a combination of neck segment and trial head sizes to restore joint stability with an adequate range of motion

Broach Removal

• Remove the broach using the broach handle. Clean the canal to remove loose cancellous bone using a curette.
Inserting the Cement Restrictor

- Use pulsatile lavage to clear the femoral canal of debris and open the interstices of the bone.

- Use the stem restrictor trial based on the size determined from pre-operative templating to establish the correct size. Attach the correct size of trial cement restrictor to the cement restrictor inserter and insert the trial to the planned depth.

- Check that it is firmly seated in the canal.

- Remove the trial and replace it with the corresponding restrictor implant. Insert the PE cement restrictor implant at the same level as the restrictor trial.
Distal Centraliser

Attaching the Void Centraliser

- Using the centraliser trials, select the C-STEM void centraliser that corresponds to the diameter of the femoral canal (C-STEM Void Centralisers increase in 2 mm increments from 10 - 20 mm).

- After selecting the right size of centraliser, slide it firmly over the distal tip of the stem and push the end over the tip of the stem, observing the correct orientation of one of the fins with the lateral edge.
Opening the femoral canal

• Start at the distal part of the femoral canal and inject the cement in a retrograde fashion, allowing the cement to push the nozzle gently back, until the canal is completely filled and the distal tip of the nozzle is clear of the canal.

• Continually inject cement during the period of Pressurisation. Use the Femoral Prep Kit curettes to remove excess bone cement. Implant insertion can begin when the cement can be pressed together without sticking to itself.
DePuy Synthes Cement

The SMARTMIX™ CEMVAC® Vacuum Mixing System Prefilled with SmartSet (G)HV Bone Cement

The SMARTMIX CEMVAC Vacuum Mixing System
Femoral Stem Implantation

• Introduce the implant in line with the long axis of the femur. Its entry point should be lateral, close to the greater trochanter.

• During stem insertion maintain thumb pressure on the cement at the medial femoral neck ensuring the stem is in the middle of the prepared cavity.

• In terms of implantation depth, the stem is “neutrally” seated when the middle marking on the stem is level with the neck resection. The additional lines allow the implant to be raised or to increase or decrease leg length, without adjusting the offset.
Femoral Head Impaction

• Once the cement has completely set, place the trial head on the implant and perform a final trial reduction.

• Remove the trial head and irrigate and thoroughly clean and dry the taper to remove any fluid or particulate debris.

• Twist and push the definitive head onto the taper using the head taper, then impact firmly with head impactor.

• Reduce the hip to carry out a final assessment of joint mechanics and stability.

Closure

• Closure is based on the surgeon’s preference and the individual case. The repair should be tested throughout the hip range of motion.
Summary

• The sequence of steps in the C-STEM Surgical Technique ✓

• Good cement technique and its importance ✓
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MARATHON™ XLPE Cemented Cup
Cemented Cup History

• Wrightington Hospital – Sir John Charnley
• 1962 – Charnley Cemented cup
• 1972 – LPW introduced to improve resistance to dislocation
• 1977 – PIJ- Flange to assist cement pressurisation
• 1982 – OGEE- Anatomic shaping of the flange
• 2008 – MARATHON XLPE - Improved wear performance

1962 – Charnley Cemented cup

GENERAL NOTES
1. LASER MARK IN 1MM.
   HIGH CHARACTER THE FOLLOWING DETAILS:
   WHITR "DSEJ" Trade Mark
   MATERIAL
   EMBOS?ED - CATALOGUE No.
2. WHILST IN PRODUCTION OBSERVE ALL PROCEDURES AND
   INSTRUCTIONS AS SPECIFIED IN THE COMPANIES QUALITY
   MANUAL.
3. NO VISIBLE INCLUSIONS ALLOWED IN THE BODY - IT IS
   PERMISSIBLE FOR THE NON BEARING SURFACE TO HAVE
   TWO INCLUSIONS PROVING THEY ARE NO BIGGER THAN
   0.2mm x 0.4mm DIAMETER AND DO NOT AFFECT THE
   AESTHETIC FEATURES OF THE IMPLANT.
4. SURFACE FINISH Ra0.6.
5. TIR FRAr:1:
   0.015.5
   0.000 0.003
   0.000 0.003
   ANGLES 2.0°
6. THE DRAWING WAS FORMERLY
   DRAWING NUMBER 9803-02-053-153-000 REV M.
1972 – LPW introduced to improve resistance to dislocation
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1982 Ogee – Anatomic shaping of the flange
1982 Ogee – Anatomic shaping of the flange

OGEE

Dictionary entry overview: What does ogee mean?

• **OGEE (noun)**
  The noun **OGEE** has 1 sense:

  1. a molding that (in section) has the shape of an S with
  the convex part above and the concave part below

  *Familiarity information: **OGEE** used as a noun is very rare.*

Dictionary entry details

• **OGEE (noun)**
MARATHON XLPE

- Developed by Dr Harry McKellop and introduced in 1998

- MARATHON XLPE liners available for DURALOC and then PINNACLE modular cup systems

- Engh reported 83% reduction in linear wear and 77% reduction volumetric wear at 10 yrs compared with ENDURON\textsuperscript{11}

- 2008 MARATHON XLPE Cemented cups introduced after 10 year success in DURALOC and PINNACLE

What is MARATHON XLPE?

- **GUR 1050 bars Gamma irradiation at 50 kGy**
- Remelting in **vacuum** at 155°C 24hr
- Annealing 120°C 24hr
- Component machining
- Gas permeable packaging
- Gas Plasma Sterilization
MARATHON XLPE - Features

• MARATHON XLPE cross linked polyethylene

• Trimmable PIJ flange

• Fixation interface identical to proven CHARNLEY/ELITE cup

• LPW feature

• X-Ray marker wire - marker wire is provided with the cup for assembly by the end user

• Straight forward instrumentation
MARATHON XLPE - Range

Marathon™ XLPE Cemented Cup Size Range mm

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available
MARATHON XLPE Marker Wire
MARATHON XLPE cup insertion video

- MARATHON XLPE insertion by Prof Martin Stone
  - DSEM-JRC-0115-0238a
- MARATHON XLPE discussion with Prof Martin Stone
  - DSEM-JRC-0115-0238
MARATHON XLPE Cement Pressurisation
MARATHON XLPE Clinical data

- Clinical experience with MARATHON is good (ODEP 10A*). Cup survival is equivalent or better than standard ENDURON PE out to 7 years.

- Clinical wear performance confirms laboratory wear studies

- Engh et al reported a 83% reduction (linear wear) in wear of MARATHON compared to ENDURON at 10 years follow up and a reduced incidence of osteolysis [28mm CoCr head]^{10}

- Hopper et al reported a 50% reduction (linear wear) at 2-3 years clinical follow up [28mm CoCr head]^{11}

- Heisil et al showed a 70% reduction (volumetric) in patients when MARATHON was used as one half of a bilateral joint replacement (compared with enduron) [28mm CoCr head]^{12}

- Horne and Devane showed Wear of MARATHON effectively dropped to zero after the first year (0.32mm wear at 4 years compared with 0.97mm wear for ENDURON) [28mm CoCR head]^{13}

MARATHON XLPE Summary

- MARATHON XLPE material
- Easy to cut flange
- Retains CHARNLEY features
  - LPW
  - Marker wire
  - Fixation surface
- Straight forward instrumentation