



Specialist Orthopaedic Grouping Scheme

Groupings
06 – Specialist Orthopaedic
06.01 – ANKLE AND FOOT
06.01.01 – Ankle joint component
06.01.01.01 – Liner – fixed bearing
06.01.01.02 – Liner – mobile bearing
06.01.02 – Sinus Tarsi Implant
06.01.02.01 – Metal
06.01.03 – Ankle joint
06.01.03.01 – Talar component
CS
06.01.03.02 – Tibial component
06.01.03.03 – Tibial component, cemented/uncemented, fixed bearing
06.01.03.04 – Stem extension
06.01.04 – Replacement of other joints of the foot including articulations
06.01.04.01 – Great toe, MTP, total, metatarsal component
06.01.04.02 – Great toe, MTP, total, phalangeal component
06.01.04.03 – Great toe, MTP, total, articular insert or liner
06.01.04.04 – Great toe, resurfacing hemi articulation, metatarsal
non-metallic
06.01.04.05 – Great toe, resurfacing hemi articulation, phalangeal
06.01.04.06 – Great toe, non articulating articulation (for silastic implant replacement)
06.02 – UPPER LIMB
06.02.01 – Wrist
06.02.01.01 – Carpal component
06.02.01.02 – Radial component
06.02.01.03 – Carpal spacer
06.02.01.04 – Distal ulnar stem
06.02.01.05 – Distal ulnar head
06.02.01.06 – Tendon Spacer
06.02.01.07 – Distal Radio-Ulnar Plate
06.02.02 – Finger Joint Articulations
06.02.02.05 – Thumb, carpometacarpal – proximal component
06.02.02.06 – Thumb, carpometacarpal – distal component
06.02.02.09 – Finger, metacarpophalangeal – proximal component
06.02.02.10 – Finger, metacarpophalangeal – distal component
06.02.02.11 – Finger, interphalangeal – proximal component
06.02.02.12 – Finger, interphalangeal – distal component
06.02.02.13 – Interpositional Devices
Total
06.02.03 – Elbow

Groupings
06.02.03.01 – Distal humeral component/s
06.02.03.02 – Proximal radial stem
06.02.03.03 – Proximal radial head/neck
06.02.03.04 – Proximal ulnar component
06.02.03.06 – Elbow pin
06.02.03.07 – Accessories – bushing / insert / spool
06.02.03.08 – Accessories – circlips
06.02.03.10 – Accessories – cement restrictor
06.02.04 – Shoulder – Humeral
06.02.04.02 – Humeral component – cemented
Reverse
06.02.04.03 – Humeral component – uncemented
Reverse
06.02.04.04 – Modular humeral component – metaphyseal, cemented
06.02.04.05 – Modular humeral component – metaphyseal, uncemented
Reverse
06.02.04.07 – Modular humeral component – diaphyseal, uncemented, long (>220mm)
06.02.04.08 – Modular Humeral component – diaphyseal, cemented, short (≤220mm)
06.02.04.09 – Modular Humeral component – diaphyseal, uncemented, short (≤220mm)
06.02.04.12 – Standard humeral head
Cer
EL
06.02.04.13 – Resurfacing humeral head
EL
06.02.04.14 – Humeral cup
06.02.04.18 – Special purpose/tumour prosthesis – tumour section
06.02.04.21 – Necks/collar (modular)
06.02.05 – Shoulder – Glenoid
06.02.05.01 – Glenoid component, All poly
06.02.05.02 – Glenoid component, Metal backed
06.02.05.03 – Glenoid component & insert
06.02.05.04 – Glenoid insert
06.02.05.05 – Reverse glenoid component, Base plate, uncemented
06.02.05.06 – Glenosphere
06.02.06 – Shoulder – Accessories
06.02.06.01 – Humeral sleeve
06.02.06.02 – Humeral spacer
06.02.06.04 – Taper assembly
06.02.06.05 – Eccentric adaptor
06.02.06.06 – Definition screw / Locking Screw
06.02.06.07 – Reverse humeral tray
Metaphyseal component
06.02.06.08 – Spacer
06.03 – SKELETAL RECONSTRUCTION
06.03.01 – Intramedullary Nails
06.03.01.01 – Femoral, Proximal short (<220mm)
06.03.01.02 – Femoral, Proximal long (≥220mm)
06.03.01.03 – Femoral, Distal
06.03.01.04 – Tibial/Fibular

Groupings	
06.03.01.05 – Humeral	
	Gth
06.03.01.06 – Arthrodesis knee	
06.03.01.07 – Arthrodesis ankle	
06.03.01.08 – Flexible/paediatric	
06.03.01.09 – Radial/Ulnar	
06.03.01.10 – Dynamic distraction – electronic	
06.03.01.11 – Arthrodesis Other	
06.03.01.13 – Arthrodesis	
	Interphalangeal
06.03.01.14 – Calcaneal	
06.03.02 – Intramedullary Nail Accessories	
06.03.02.01 – Intramedullary nail lag screw	
	Com
	Comp
06.03.02.02 – Reconstruction screw	
	CN
06.03.02.03 – Set screw/Locking bolt	
06.03.02.04 – End caps and extension caps	
06.03.03 – Plates	
06.03.03.01 – Standard (screw size $\geq 4.5\text{mm}$) ≤ 6 holes	
	Com
	Com, LK
	Com,VAL
	LK
	VAL
06.03.03.02 – Standard (screw size $\geq 4.5\text{mm}$) ≥ 7 to ≤ 15 holes	
	Com
	Com, LK
	Com,VAL
	LK
	VAL
06.03.03.03 – Standard (screw size $\geq 4.5\text{mm}$) ≥ 16 holes	
	Com
	Com, LK
	LK
	VAL
06.03.03.04 – Small (screw size 2.71mm – 4.49mm) ≤ 6 holes	
	Com
	Com, LK
	Com, VAL
	LK
	VAL
06.03.03.05 – Small (screw size 2.71mm – 4.49mm) ≥ 7 to ≤ 15 holes	
	Com
	Com, LK

Groupings
Com, VAL
LK
VAL
06.03.03.06 – Small (screw size 2.71mm – 4.49mm) ≥ 16 holes
Com
Com, LK
LK
VAL
06.03.03.07 – Mini (screw size ≤2.7mm) ≤ 6 holes
Com
Com, LK
Com, VAL
LK
VAL
06.03.03.08 – Mini (screw size ≤2.7mm) ≥ 7 to ≤ 15 holes
Com
Com, LK
Com, VAL
LK
VAL
06.03.03.09 – Mini (screw size ≤2.7mm) ≥ 16 holes
Com, LK
Com, VAL
LK
VAL
06.03.03.10 – Dynamic – Hip ≤ 6 holes
Com
Com, LK
06.03.03.11 – Dynamic – Hip ≥ 7 to ≤ 15 holes
Com
Com, LK
06.03.03.12 – Dynamic – Hip ≥ 16 holes
Com
Com, LK
06.03.03.13 – Dynamic – supracondylar ≤ 6 holes
Com
Com, LK
06.03.03.14 – Dynamic – supracondylar ≥ 7 to ≤ 15 holes
Com
Com, LK
06.03.03.15 – Dynamic – supracondylar ≥ 16 holes
COM
06.03.03.16 – Periarticular – Clavicle plate ≤ 6 holes
LK
VAL
06.03.03.17 – Periarticular – Clavicle plate ≥ 7 to ≤ 15 holes
LK
VAL
06.03.03.18 – Periarticular – Clavicle plate ≥ 16 holes
LK
06.03.03.19 – Periarticular – Humerus ≤ 6 holes

Groupings	
	LK
	VAL
06.03.03.20 – Periarticular – Humerus ≥ 7 to ≤ 15 holes	
	LK
	VAL
06.03.03.21 – Periarticular – Humerus ≥ 16 holes	
	LK
	VAL
06.03.03.22 – Periarticular – Radius ≤ 6 holes	
	LK
	VAL
06.03.03.23 – Periarticular – Radius ≥ 7 to ≤ 15 holes	
	LK
	VAL
06.03.03.24 – Periarticular – Radius ≥ 16 holes	
	LK
	VAL
06.03.03.25 – Periarticular – Ulna ≤ 6 holes	
	LK
	VAL
06.03.03.26 – Periarticular – Ulna ≥ 7 to ≤ 15 holes	
	LK
	VAL
06.03.03.27 – Periarticular – Ulna ≥ 16 holes	
	LK
	VAL
06.03.03.28 – Periarticular – Hand-phalangeal	
	VAL
06.03.03.29 – Periarticular – Pelvis ≤ 6 holes	
	LK
06.03.03.30 – Periarticular – Pelvis ≥ 7 to ≤ 15 holes	
06.03.03.31 – Periarticular – Pelvis ≥ 16 holes	
	LK
06.03.03.32 – Periarticular – Femur ≤ 6 holes	
	LK
	VAL
06.03.03.33 – Periarticular – Femur ≥ 7 to ≤ 15 holes	
	LK
	VAL
06.03.03.34 – Periarticular – Femur ≥ 16 holes	
	LK
	VAL
06.03.03.35 – Periarticular – Fibula ≤ 6 holes	
	LK
	VAL
06.03.03.36 – Periarticular – Fibula ≥ 7 to ≤ 15 holes	
	LK
	VAL
06.03.03.37 – Periarticular – Fibula ≥ 16 holes	
	LK
	VAL

Groupings	
06.03.03.38 – Periarticular – Tibia ≤ 6 holes	
	LK
	VAL
06.03.03.39 – Periarticular – Tibia ≥ 7 to ≤ 15 holes	
	LK
	VAL
06.03.03.40 – Periarticular – Tibia ≥ 16 holes	
	LK
	VAL
06.03.03.41 – Periarticular – Calcaneal ≤ 6 holes	
	LK
06.03.03.42 – Periarticular – Calcaneal ≥ 7 to ≤ 15 holes	
	LK
	VAL
06.03.03.43 – Periarticular – Calcaneal ≥ 16 holes	
	VAL
06.03.03.44 – Periarticular – Foot	
	LK
	VAL
06.03.03.45 – Periarticular – Cable plate (hook/grip) ≤ 6 holes	
06.03.03.46 – Periarticular – Cable plate (hook/grip) ≥ 7 to ≤ 15 holes	
06.03.03.48 – Periarticular – Cable plate with integrated cables – 2 or less, ≤ 6 holes	
06.03.03.49 – Periarticular – Cable plate with integrated cables – > 2, ≤ 6 holes	
	LK
06.03.03.50 – Cable plate with 1 or more cables, ≤ 6 holes	
06.03.03.51 – Cable plate with 1 or more cables, ≥ 7 holes to ≤ 15 holes	
06.03.04 – Screws	
06.03.04.01 – Standard (≥4.5mm)	
	CN
	CN,DT
	CN,DT,LK
	CN,LK
	DT
	DT,LK
	LK
06.03.04.02 – Small (2.71mm – 4.49mm)	
	Breakoff
	Breakoff, DT
	CN
	CN,DT
	CN,DT,LK
	CN,LK
	DT
	DT,LK
	LK
06.03.04.03 – Mini (2.01 – 2.7 mm)	
	Breakoff
	Breakoff, CN
	CN
	CN,DT
	CN,DT,LK

Groupings
CN,LK
DT
DT,LK
LK
06.03.04.04 – Micro ($\leq 2.0\text{mm}$)
Breakoff
Breakoff, DT
CN
CN,DT
CN,DT,LK
DT
DT,LK
LK
06.03.04.05 – Dynamic
06.03.04.06 – Screw Washers
06.03.04.07 – Screw post/peg
06.03.04.08 – Screw Accessories – Nuts
06.03.04.09 – Screw Accessories – Locking Nuts / Insert
06.03.04.10 – Screw Accessories – Caps
06.03.05 – Surgical Accessories
06.03.05.01 – Pins and Wires, diameter $\leq \varnothing 1.6\text{ mm}$
06.03.05.02 – Pins and Wires, diameter $> \varnothing 1.6\text{ mm}$
AB
COM
OL
TH
06.03.05.03 – Cables
06.03.05.04 – Cables – with in-built locking device
06.03.05.05 – Cables – with >1 locking device
06.03.05.06 – Wire forms (including washers/screws) – all sizes
06.03.05.07 – Cerclage bands
06.03.05.08 – Locking device for wires/cables
06.03.05.09 – Hook/Grip for wires/cables
06.03.05.10 – Grooved Button for wires/cables
06.03.05.11 – Wedges
06.03.05.12 – Chest Wall Reconstruction Plates
Modified
06.03.05.13 – Chest Wall Reconstruction Plate Accessories
06.03.06 – Staples
06.03.06.01 – Staples
COMP
MI
MM
06.03.07 – Soft Tissue Fixation Devices
06.03.07.01 – Anchor only (without suture), dart or arrow
AB
06.03.07.02 – Small Anchors ($\leq 2.3\text{ mm}$) with suture
AB
MI
06.03.07.03 – – Medium Anchors (2.4 mm – 3.9 mm) with suture
AB

Groupings	
06.03.07.04 – Large Anchors (≥ 4.0 mm)) with suture	
	AB
06.03.07.05 – Button/thread/tape or Button/thread/button	
06.03.07.06 – Button	
06.03.07.07 – Interference Screw ($\pm$ sleeve)	
	AB
	AB, HA
06.03.07.08 – Screw/Pin/Post	
	AB
06.03.08 – Soft Tissue Substitute	
06.03.08.02 – Non-biological	
06.03.08.03 – Non-biological cartilage substitute	
	$\leq 10\text{mm}$
06.03.11 – External Fixateurs	
06.03.11.02 – Frame Complete – Monoplanar & Modular Frames	
	CDD
	Mini
	Small
	Small, 3D, CDD
	Small, CDD
06.03.11.03 – Frame Component – Monoplanar, Clamp	
	3D
	Mini
	Small
06.03.11.04 – Frame Component – Monoplanar, Body	
	CDD
	Small, CDD
06.03.11.05 – Frame Component – Monoplanar, Adaptor	
06.03.11.06 – Frame Component – Full Circular Ring	
06.03.11.07 – Frame Component – Partial Circular Ring	
06.03.11.08 – Frame Component – Circular Coupling Device	
06.03.11.09 – Frame Component – Circular Frame Strut Device	
	3D
06.03.11.10 – Frame Component – Foot Plate	
06.03.11.11 – Frame Component – Circular Frame, Nuts & Spacers	
06.03.11.12 – Frame Component – Coupling Device	
	CDD
	Mini
	Small
06.03.11.13 – Frame Component – Rods	
	Mini
	Small
	Standard
06.03.11.14 – Frame Component – Pins	
06.03.11.15 – Frame Component – Pin Clamp Assembly	
	3D
	Small
06.03.11.16 – Frame Component – Pin Clamp Assembly Post	
	Small
06.03.11.17 – Articulating Hinge	
	CDD

Groupings	
Mini	
06.03.11.18 – Upper body kit	
06.03.11.19 – Lower body kit	
06.03.11.20 – Simple fixture kit – Lower body (Uniplanar)	
06.03.12 – Internal Fixator	
06.03.12.01 – Elbow	
06.03.14 – Bone Cement	
06.03.14.01 – Cement only	
06.03.14.02 – Cement with Antibiotic	
06.03.14.03 – Cement with Complex Delivery System	
06.03.14.04 – Cement with Antibiotic and Complex Delivery System	
06.03.14.05 – Accessories – Restrictors	
06.03.15 – Bone Graft Substitute	
06.03.15.01 – Ceramic, 0-5cc	
	AUG
	CDS
06.03.15.02 – Ceramic, >5cc – 10cc	
	AUG
	CDS
06.03.15.03 – Ceramic, >10cc – 20cc	
	AUG
	CDS
06.03.15.04 – Ceramic, >20cc	
	AUG
06.03.15.06 – Demineralised Bone Matrix, 2 – 5cc	
06.03.15.07 – Demineralised Bone Matrix, >5cc – 10cc	
06.03.15.08 – Demineralised Bone Matrix, >10cc	
06.03.15.09 – Composite (Extracellular Collagen Matrix with DBM or Ceramic), 0 – 5cc	
06.03.15.10 – Composite (Extracellular Collagen Matrix with DBM or Ceramic), >5cc – 10cc	
06.03.15.11 – Composite (Extracellular Collagen Matrix with DBM or Ceramic), >10cc – 20cc	
06.03.15.12 – Composite (Extracellular Collagen Matrix with DBM or Ceramic), >20cc	
06.03.15.17 – Metal Scaffold	
06.03.16 – Meshes	
06.03.16.01 – Metallic	
	3D anatomical
06.03.16.02 – Non Metallic	
06.03.17 – Tumour / Limb Deficiency	
06.03.17.02 – Spacer	
06.03.17.04 – Central Screw	
06.03.17.05 – Healing Cylinder	
06.03.17.06 – Healing Screw	
06.03.17.07 – Fixture	
06.03.17.08 – Abutment	
06.03.17.09 – Abutment Screw	
06.03.17.10 – Oncology Humeral Stem	
06.03.17.11 – Humeral Ancharge Piece	
06.03.17.12 – Humerus Extension Piece	
06.03.17.14 – Humerus Connection Piece	
06.03.17.15 – Oncology Humeral Body	
06.03.17.16 – Wedge	
06.03.17.17 – Humerus Connecting Screw	

Groupings
06.03.17.18 – Humerus Hex Socket Bolt
06.03.17.19 – Plug Screw Axis
06.03.17.21 – Humeral Bearing
06.03.17.22 – Humeral Head/Cap
06.03.17.23 – Distal Humerus Flange
06.03.17.24 – Humeral Collar Round Smooth
06.03.17.25 – Humeral Component for use with Hemi Head
06.03.17.26 – Humeral Head Fixation Screw
06.03.17.27 – Humeral Component with Liner and re-attachment
06.03.17.28 – Humeral Collar Round Coated
06.03.17.29 – Humeral Stem
06.03.17.30 – Humeral Shaft
06.03.17.31 – Humeral Intergral Shaft & Stem Coated
06.03.17.33 – Humeral Component with Liner
06.03.17.34 – Humeral Component with Reattachment for use with Hemi Head
06.03.17.35 – Glenoid / Glensphere component
06.03.17.36 – Humeral Hemi-Head
06.03.17.37 – Femoral Stem – Uncemented
06.03.17.39 – Tibial Stem – Uncemented
06.03.17.41 – Valgus Sleeve

SUFFIXES AND DEFINITIONS FOR SPECIALIST ORTHOPAEDIC

DEFINITIONS FOR SUFFIXES

3D	Multiaxial – device features multi axis of rotational and or translational movement
AB (Completely Absorbable) (for 06.03.05.02 – Surgical Accessories – Pins, and 06.03.07 – Soft Tissue Fixation Devices [Various Subgroups])	means the Pin or Soft Tissue Fixation device (including all parts) must be made of completely absorbable material (for the avoidance of doubt, for example, soft tissue fixation anchor with eyelet to hold the suture made of PEEK is not taken as completely absorbable, although non-absorbable suture listed with completely absorbable anchor does not impact on the eligibility for suffix AB).
ABT	Antibiotic Additive
AUG	AUGMENTED with silicate
Break Off (for 06.03.04 – Screws [various subgroups])	means a screw which may be break off or snap off
CDD	Compression/Distracton/Dynamisation – device features intrinsic capacity to apply compression &/or distraction force &/or controlled dynamic force
Cer	Ceramic
CN (Cannulated Screw) (for 06.03.04 – Screws [various subgroups])	means that the screw is cannulated and is designed to be introduced over a guide wire (images of cannulation with a guidewire going through the screw must be available).

COM (Complex plate) (for 06.03.03 – Plates [various subgroups])	means that a plate has significant three-dimensional curvature, bend and/or rotation and may include outriggers, hooks, or steps. The plate may have holes accepting screws near the joint but is not expected to be designed for supporting or restoring the articulating surface of the joint.
LK (Locking Plate) (for 06.03.03 – Plates [various subgroups])	means that a plate must have threaded screw holes which allow threaded screw head to be locked in the plate.
COM (Complex Intramedullary Nail Accessory) (for subgroup 06.03.02.01)	means that intramedullary nail lag screw must have a spiral blade configuration.
Comp	Compression – device features intrinsic capacity to apply compression force
CS	Ceramitised surface
DT (Dual Threaded Screw) (for 06.03.04 – Screws [various subgroups])	means a screw must have at least two threads of distinctly different pitch (distance between two consecutive threads of the screw), which provide intrinsic compression within the bone.
LK (Locking Screw) (for 06.03.04 – Screws [Various Subgroups])	means that a screw must have a thread on the head of the screw which allows fixing the screw into the respective orthopaedic device's holes with corresponding thread.
DT and LK (Dual Threaded and Locking Screw) (for 06.03.04 – Screws [various subgroups])	means a screw must have at least three (3) threads, including two (2) threads of distinctly different pitch in the shaft, plus one (1) locking thread on the head of the screw (for further information, refer definitions for suffix DT and suffix LK).
HA	Hydroxyapatite coated
Mini	Applies only to External Fixateurs used on the hand and foot
MM	Memory Metal
Multiple	Multiple – applies only to Carpal component
OL	Olive Wire
Reverse	Reverse
Small	Applies only to External Fixateurs used on the upper limb
Standard	Applies only to External Fixateurs used on any long bone and pelvis
T	Tumour
TL	Telescopic – A threaded moveable rod within an outer rod that allows for revolution and lengthening movement
VAL (for 06.03.03 – Plates [various subgroups])	means that a plate has screw holes allowing Variable Angle Locking

GROUPS AND SUBGROUPS DEFINITIONS AND DESCRIPTORS

Articulating Hinge	A device that features intrinsic capacity to allow a range of movement around a central articulation
Body	Metaphyseal component
Cannulated screw	The cannulated screw can be introduced with a guide wire
Circular Frame	Ring Fixation
Circular Frame Strut	A device used in combination with circular ring fixation for limb angular and length reconstruction

Complex Delivery System	A delivery system that contains a mixing mill, with or without vacuum, and a container that becomes part of the delivery system that maintains compression and does not result in voids.
Coupling Device	A device that connects rods, pins and wires to Pin Clamps & Circular Rings
Dynamic Screw	The large sliding screw that is specifically used with a dynamic hip or dynamic supracondylar plate
External Fixateur Mini	Primarily used in hand and foot
External Fixateur Small	Primarily used in upper limb
External Fixateur Standard	Primarily used in tibia, femur and pelvis
Frame Adaptor	An adaptation device used to connect different frame types
Gth	Growth
Head	Articulating component
MI	Multi Implant
Modular Frame	Individual coupling, pin clamp and rod fixation
MRI	Magnetic Resonance Imaging safe (to be included in description)
Neck	Modular (including cone/sleeve)
Orthopaedic plates (various subgroups)	Subgroups in the group 06.03.03 for the orthopaedic plates are to be determined based on the total number of holes (including slots) in the plate (in the shaft and in the distal or proximal joint end of the plate, as applicable) that are intended to accept a screw; and the largest outer thread diameter of the screw holes is used for the purposes of defining the subgroup for the plates.
Periarticular Orthopaedic plates (for group 06.03.03 – Plates [various subgroups for Periarticular plates])	The plates specifically designed to support and reconstruct the articulating joint surface (images of the plates in situ in connection with the respective joint are required to be available).
Pins and Wires	means pointed orthopaedic implants that are grouped according to diameter of the device
Pin Clamp Assembly	A device that connects multiple pins to coupling devices & rods
Revision	A revision component must be clearly designed to be used in revision and/or difficult primary arthroplasty situations. These components must be suitably different from a primary implant to justify a revision suffix. The very fact that an implant may be used in a revision situation does not necessarily mean that it will be granted a revision suffix
RL	Radiolucent (to be included in description)
Screw post/peg	Predominantly smooth device with a terminal thread for fixation
Stem	Diaphyseal component
TH	Threaded Rod (to be included in description)
Total	This subgroup is for finger joint articulations that cannot be classified specifically as thumb/finger, carpometacarpal/interphalangeal, and proximal/distal.
Unilateral Frame	A single sided one piece device

Upper/or lower limb kit	A completely self-standing product. Must contain all instruments and devices for inserting the External Fixateurs for upper/and or lower limb.
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GLOSSARY OF TERMS – BONE CEMENTS AND BONE GRAFT SUBSTITUTES

Bone Cements (PMMA)

Bone cements are composed of polymethylmethacrylate and may be used to: fill a space in bone and provide structural integrity and strength; fill a space and provide an adhesive function between a prosthesis and bone and more recently; to restore vertebral height and strength in osteoporotic vertebral fractures. They are non-osseous and are not resorbable. Bone cements are offered in two components of varying volumes which when mixed together form a solid bone cement.

Bone Cement Additives

Bone cements may be provided with premixed antibiotic additive (usually but not restricted to aminoglycosides) of varying strengths.

Bone Cement Delivery Systems

Complex mixing or delivery systems are complex with respect to design, method of use and manufacture. They contain a mixing mill, with or without vacuum, and a container that becomes part of the delivery system that maintains compression and does not result in a void. They are integral to the delivery of the bone cement, e.g. some percutaneous vertebroplasty kits, and are disposable and single use. The complex system should provide a clinical benefit with use of the bone cement with increased efficacy and safety.

As a result of the HTA Review, Simple mixing or delivery systems do not warrant a higher benefit amount and therefore a Simple Delivery System (SDS) suffix is no longer available.

Bone Graft Substitutes

Surgeons involved in bone repair, reconstruction and fusion may encounter bone defects and or instability which are unlikely to heal with fixation alone. Autograft though considered the 'gold standard' has well recognized limitations and allograft may not provide the solution. Synthetic and or biologically active substances are increasingly used as substitutes alone or in combination with traditional bone graft material. Bone substitutes are described as osteoconductive if it promotes bone formation along their surface when placed in bone and osteoinductive if they induce new bone formation.

Bone substitutes are grouped according to their predominant composition.

1. Ceramics (eg Calcium phosphate and hydroxyapatite compounds), which are osteoconductive
2. Metal scaffolds, which are osteoconductive
3. Demineralised bone matrix, which are osteoconductive
4. Composite products which are Extracellular Collagen Matrix with ceramic or demineralised bone matrix, which are osteoconductive
5. Biologically active bone inductors, such as bone growth factors (eg bone morphogenetic proteins) which are osteoinductive.

Bone substitutes are presented as pastes, granules, pellets or as a block or preformed implant which may provide some structural integrity and in varying volumes which the grouping system recognizes.

Bone substitute may require a delivery system which can be classified as simple or complex.

All delivery systems are considered simple unless their design, manufacture, composition or use is complex. The system should be disposable and provide a clear clinical benefit in safety, ease of use and efficacy of the product.

Augmented bone graft substitutes (suffix AUG)

The AUG suffix means that the ceramic bone graft substitute has to be AUGMENTED with silicate.