Spinal Grouping Scheme

Groupings
13 – Spinal
13.01 – Bone Screws
13.01.01 – Pedicle, Monoaxial
Cannulated
Closed
Complex
Integrated Locking Mechanism
With cap/cover plate
13.01.02 – Pedicle, Polyaxial
Cannulated
Complex
Integrated Locking Mechanism
Integrated Locking Mechanism, Cannulated
Shank
13.01.03 – Standard
Cannulated
Closed
Complex
Dual Thread
Expansion Screw / Expansion Head Screw
13.02 – Accessories for bone screws and connector components
13.02.01 – Nut/Set Screw/Locking Screw
13.02.02 – Collar/Sleeve
13.02.03 – Cap/Cover Plate
13.02.04 – Cap/Cover Plate, Complex
13.02.05 – Block/Screw head
13.02.06 – Cross Link Rod
13.02.07 – Hook/Clamp/Plate
13.02.08 – Sublaminar Cable
Complex
13.03 – Connector
13.03.01 – In-Line
Modular-adjustable
13.03.02 – Offset
13.03.03 – Transverse (Rod-to-Rod)
13.03.03.01 – Fixed
13.03.03.02 – Adjustable

Groupings
13.04 – Hook
13.04.01 – Hook
Integrated Locking Mechanism
13.05 – Plate
13.05.01 – Integral Fixation
13.05.01.01 – Cervical
>55mm
13.05.01.02 – ThoracoLumbar / Lumbar / Lumbosacral
13.05.02 – No Integral Fixation
13.05.02.01 – Cervical
>55mm
>55mm, Complex
Complex
13.05.02.02 – ThoracoLumbar
13.05.02.03 – Occipital
13.05.02.04 – Lumbosacral / Sacral
13.05.02.05 – Laminoplasty Plate
Bilateral laminoplasty plate
13.06 – Rod
13.06.01 – Standard
Dual Diameter
Shaped
13.06.02 – Telescoping
13.06.03 – Dual Unit
13.06.03.01 – Thoracolumbar
13.06.03.02 – Occipital
13.06.04 – Composite Rod & Cap
13.06.05 – Rod, Percutaneous Controlled Expansion
13.07 – Plate-Rod
13.07.01 – Plate Rod
13.08 – Washer/Staple
13.08.01 – Washer
13.08.02 – Staple
Complex
13.09 – C-Ring
13.09.01 – C-Ring
13.10 – Fusion Cage
13.10.01 – Interbody, Integral Fixation
13.10.01.01 – Cervical
13.10.01.02 – ThoracoLumbar / Lumbar
13.10.02 – Interbody, No Integral Fixation
13.10.02.01 – Cervical
Complex
13.10.02.02 – ThoracoLumbar / Lumbar

Groupings
Paired
13.10.03 – Facet Joint
13.11 – Disc Replacement
13.11.01 – System
13.11.01.01 – Cervical
13.11.01.02 – Lumbar
13.11.02 – End Plate
13.11.03 – Core
13.11.04 – Replacement Nucleus
13.12 – Vertebral Body Replacement
13.12.01 – Telescoping Cage
13.12.01.01 – Integral Fixation
13.12.01.02 – No Integral Fixation
Cervical
ThoracoLumbar
13.12.01.03 – End Plate
13.12.02 – Stackable Cage
13.12.03 – Mesh
13.12.04 – Mesh, End Plate
13.12.05 – Non Stackable Cage, other
13.13 – Interspinous Fixation
13.13.01 – Interspinous Fixation Device
13.14 – Sacroiliac Joint Fixation
13.14.01 – Sacroiliac Joint Fixation Device
13.15 – Annular closure/reconstruction
13.15.01 – Annular closure/reconstruction device

SUFFIXES AND DEFINITIONS FOR SPINAL

The **vertebral level** (Occipital, cervical – Occiput to T4, thoracic/lumbar – T1 to sacrum and ilium)**,** the **surgical approach** (anterior v. posterior) and **composition** of the device (metal v. synthetic) may be considered as a differentiating factor in design by virtue of size and composition.

Fixation covers hardware devices that mechanically join or affix two or more vertebrae together. Fixation includes not only devices which attach to the spine (eg. screws and hooks) but to other metal devices (eg. rods and connectors) to form a framework.

13.01 – Bone Screws

Screw is a threaded fastener, consists of a shaft, which may be cylindrical or conical, and a head. The shaft has a helical ridge or thread formed on it. The thread is essentially an inclined plane wrapped around a shaft. The thread mates with a complementary helix in the material. The material may be manufactured with the mating helix (eg a nut or tapped plate), or the screw may create it when first driven in (a self-tapping screw). The head is specially shaped to allow a screwdriver or wrench to grip the screw when driving it in. It also stops the screw from passing

right through the material being fastened and provides compression. Screws employ a wide variety of drive designs (eg. Phillips, cruciform, inset socket), each requiring a different kind of tool to drive in or extract them.

13.01.01 Pedicle Bone Screws, Monoaxial

Monoaxial screw is used for connecting vertebrae to rods in spinal surgery. It is essentially a screw with a fixed head in-line with and continuous with the shaft. The head of the screw can be locked to a rod by various screw couplings.

13.01.02 Pedicle Bone Screws, Polyaxial

Polyaxial screw is used for connecting vertebrae to rods in spinal surgery. It is essentially a screw whose spherical head is enclosed on a housing, which allows the screw head a range of motion along several different axes relative to the housing. The ball joint allows the surgeon some flexibility in placing the screws. The head of the screw (housing) can be locked to a rod by various screw couplings. Polyaxial screws include uni-planar screws which allow adjustment of the mobile screw head in the sagittal plane.

Where a polyaxial screw can be assembled from component parts, the threaded shank of the screw will be considered a Bone Screw, Polyaxial. The separate head is classed as a Coupling, Block / Clamp / Screw Head (Coupling – 2e). The separate shank and screw head will be considered together to form a polyaxial screw as a whole for the purpose of benchmarking. The sum of the benefits for the component parts is equivalent to the benefit of a polyaxial screw as a whole.

13.01.03 Bone Screws, Standard

A standard bone screw is of standard industrial design for insertion in isolation or through a hole in a device such as a plate into the underlying bone often providing fixation by compression between the screw head or bolt and the bone. Bone screws provide bone-to-bone fixation or attachment of a device to bone.

Simple screws include those of a **Schanz screw** design (rod with screw thread) that can be connected to a rod using a coupling mechanism or the screw component (alone) of a polyaxial screw when marketed as a separate component.

Bolts are cylindrical (as opposed to conical) threaded fasteners that passes through the work piece and are held in place by a nut or a threaded hole on the other side. This is a very common way of holding together temporary and permanent constructions. An unthreaded hole is known as a *clear* hole.

Suffixes identify significant design features, some of which may increase manufacturing costs or improve performance. For the purposes of classification, cannulated, dual thread and expansion screws are deemed to be complex bone screws.

- **CN (Cannulated screw)** (for subcategory 13.01 – Bone screws [Various groups]) means that the screw is cannulated and is designed to be introduced over guide wire (images of cannulation with a guidewire going through the screw or other relevant and sufficient information must be available and provided).
- A screw which is offered as a complete device and includes a **cover cap or plate** and not included separately as a *coupling* is deemed to be substantially different for the purposes of classification.
- **Dual thread screws** have different threads at each end of the screw. The different threads may have differing purposes such as threads to attach to bone at one end and a plate or other device at the other. An example is a Herbert style screw is another dual thread design for bone-to-bone fixation with compression.
- **Expansion** screw is designed with an internal bore for the subsequent insertion of a locking device such as a screw or rod which increases the diameter of the screw to increase the contact pressure and improve fixation. An expansion screw is equivalent to a modified cannulated screw but requires an additional locking (coupling) device.
- Bone screws may have an **expansion** head for the insertion of a set screw or locking screw to secure the screw in the hole of a bone plate. As such the bone plate would be deemed to have integral fixation.
- A **shank** suffix indicates the shank component of a pedicle screw construct requiring a coupling device to attach to the rod.

While the following screw features and other thread designs are acknowledged, for the purposes of classification they

are not considered to constitute significant design features.

Self-tapping is the ability of a screw to advance when turned while creating its own thread. Self-tapping screws have sharp threads that cut into bone. They are sometimes notched at the tip to aid in chip removal during thread cutting. These edges can cut their own threads as the screw is driven into bone.

Self-drilling screw is similar to a self-tapping screw, but has a drill-shaped point to cut through the material without prior drilling.

13.02 Accessories for bone screws and connector components

Couplings are the actual locking devices or mechanisms that join or secure two components of a fixation system together in a rigid or semi-rigid manner. They may connect spinal anchors such as screws or hooks or other devices to axial rods or interconnect axial rods to form a rigid or semi-rigid frame. Excluded are all clearly identifiable couplings.

Suffixes identify different types of locking devices.

13.02.01 Nut

Nut is a type of hardware fastener with a threaded hole. Nuts are variably shaped to permit tightening with a wrench. Along with a bolt, nuts are designed to capture and fasten objects together. Without the nut the bolt would slide out. Nuts are classified under bone screw couplings.

13.02.01 Accessories for bone screws and connector components Nut/Set Screw/Locking Screw

Nut/Set Screw/Locking Screw means that set screw, locking screw or grub screw are the devices used to secure a rod within a bone pedicle screw, hook, or connector, or other components of a fixation spinal system, preventing loosening due to vibration or loading. The set screw passes through a threaded hole in the outer object (bone screw, hook, or connector) and is tightened against the inner object (rod) to prevent it from moving relative to the outer object. It exerts clamping force through the bottom tip that projects through the hole. Set screws employ a wide variety of drive designs including headless (designed to be inserted flush with or below the surface of the work piece) and break-off set screws (having a drive designed to snap-off or detach flush with the surface of the hook or screw when designated in-built torque force is reached). Set screws designed to be used with pedicle screws are grouped to be listed in group 13.02.01. However, set screws, designed and intended to be part of and be used with spinal connectors, are required to be listed with the respective connector (refer groups 13.03 – Connector).

13.02.02 Collar or sleeve

Collar or sleeve is a tubular device for insertion over a rod as part of a multi-component locking system.

13.02.03 Cap or Cover plate

Cap or Cover plate is a component of a locking mechanism that overlies two linked components of a fixation system to hold them in position. The locking plate or cap is secured firmly in place with an additional set screw or locking screw. An example is a plate or cap which holds a rod in the saddle of a pedicle bone screw in a non-rigid manner with an additional locking screw to secure the rod, pedicle bone screw and locking cap or plate rigidly in the final position. Similarly, bone plates may be attached to bone with standard screws which are secured to the bone plate with and overlying locking plate secured to the bone plate by a set screw or locking screw.

13.02.04 Cap/Cover Plate, Complex

Complex Cap/Cover Plate include all required components.

13.02.05 Block

Block is a device used to hold two or more system components tightly together and to prevent movement or separation. Screw Head: Where a polyaxial screw can be assembled from component parts, the threaded shank of the screw will be considered a Bone Screw, Polyaxial – System (1b.1). The separate head is classed as a Coupling, Block / Clamp / Screw Head. The separate shank and screw head will be considered together to form a polyaxial

screw as a whole for the purpose of benchmarking. The sum of the benefits for the component parts is equivalent to the benefit of a polyaxial screw as a whole.

13.03 – Connector

Connector is a device designed to join various implants together to form a framework. Set screws and Locking Screws, designed and intended to be part of and be used with spinal connectors, are required to be listed together with the respective connectors.

13.03.01 In-line

In-line connector allows coaxial connections of two rods either as an end-to-end connection or side-by-side dominos.

13.03.01 Connector In-Line, Suffix: Modular-adjustable

In-Line Connector modular-adjustable is required to be modular (compared with the usually solid/mono rectangle or bridge shaped devices) allowing relative mobility, adaptability, and range of motion.

13.03.02 Offset

Offset connector allows a non-axial (indirect) connection of a bone anchor such as a screw or hook to an axial or longitudinal device (rod).

13.03.03 Transverse (Rod-to-Rod)

Transverse (Rod-to-rod) connector means a device for the interconnection of two parallel axial devices (rods) to form a rectangular framework for the attachment of bone anchors.

Subgroups identify different types of Transverse Connector.

13.03.03.01 Connector Transverse Fixed

Fixed transverse (rod-to-rod) connector means a transverse connector that has a non-adjustable solid one piece bridge, although the connecting hooks at either end of the bridge may be adjustable.

13.03.03.02 Connector Transverse Adjustable

Adjustable transverse (rod-to-rod) connector means a transverse connector that must have a bridge that consists of more than one piece/component and these components can be adjusted horizontally and/or rotated or angulated to lengthen or shorten or change the shape of the bridge as needed. Adjustable Connectors have screw holes that allow for screws placement for fixation of the components.

13.04 – Hook

Hook is a general term for mechanical devices with an inwardly-bent or curved narrow tipped free end for anchorage to bone and the other end secured to a rod or connector. A free end of the hook is a bone anchorage device for grabbing designated parts of the spine. Fixation to the spine is achieved by compression of the hook to the bone at the site of attachment. Hooks used in the assembly of a transverse connector are not included in this group as they are not anchor devices but couplings.

13.05 – Plate

Plate refers to a thin, flat metallic (or other semi-rigid composition) sheet of uniform thickness and generally although not necessarily of uniform width. Plates can be attached to the underlying spine with screws or bolts inserted through clear hole in the plate. The screws are free to toggle somewhat in the holes and fix the plate by compression between the head of the screw and the underlying bone. Alternatively the plate may have holes with machined internal threads, intended for the insertion of a matching screw held in place by the locking of the threads.

13.05.01 Plate, Integral Fixation

Integral fixation of a plate implies that bone screws used to attach the plate to bone are fixed in a rigid or semi-rigid manner to the plate (in its free form) either by screw threads which interlock with threads manufactured into the plate or where the head of the bone fixing screws are locked into position by a set screw, plate or other complex coupling device (excludes a simple locking nut). This does not include designs where the screws “lock” into the plate by a jam fit of the screw head unless the expansion head is locked with a set screw or similar mechanism.

13.05.02 Plate, No Integral Fixation

No Integral Fixation implies an unthreaded hole in the plate through which a screw or bolt can be inserted into the underlying bone for fixation. The screw does not attach to the plate via any locking mechanism in a manner that holds the screw in a set position when the assembled fixation device is in a free standing form.

Suffixes are to identify plate variations. Cervical Plate > 55mm: identifies cervical fusion plates for fixation of more than 55mm in length.

13.06 – Rod

A rod is a straight (sometimes curved), slender bar to which can be attached a number of objects (hooks, screws, or connectors) to secure fixation to the spine or other objects to form a framework.

130.6.01 Rod, Standard

Standard rods are constructed of metal and have a smooth surface to allow sliding. The rod may be preshaped or can be shaped with rod benders. Metal rods are considered rigid and non-flexible.

13.06.02 Rod, Telescoping

Telescoping rods are cannulated to take a standard rod internally while allowing free piston-type movement between the two rods. These rods are specifically used in the treatment of a growing child with spinal deformity. They allow periodic surgical distraction and therefore lengthening of the composite rod.

13.06.03 Rod, Dual Unit

Dual rod is a U-shaped rod having parallel rods interconnected at one end by a 180 degree curve in the rod.

Flexible rods by design or composition can temporarily deform (flex) within the length of the rod to a variable degree when under strain. Flexible rods include those of non-metallic (synthetic) composition. Axial rods of pedicle non-fusion stabilization devices are considered flexible plates. Rods with an integral universal joint component are considered flexible rods.

Suffixes – can be used for standard rods.

Dual diameter: This implies that there are two diameters within the single rod thus allowing axial fixation from the cervical to the thoracic spine.

Shaped: Implies that the rod is preshaped (other than purely curved / prebent / dual unit) for a designed purpose. This includes S-shaped or any other shaped rods and eye rods.

13.07 – Plate-Rod

Plate-rod is a single piece device with a plate at one end attached to a rod at the other end.

13.08 – Washer/Staple

13.08.01 Washer

A washer is a flat disc with a hole through it for placement beneath a nut or screw to distribute pressure.

13.08.02 Staple

Staple is a metal washer or plate with barbs used to secure the washer or plate to bone. A screw or bolt can be inserted through the hole in the washer into the underlying bone. It provides increased security to the fixation to tangential forces on the screw or bolt. The suffix *complex* can be used.

13.09 – C-Ring

C-ring is C-shaped blocking device, the shape of an incomplete circle, which can be placed over a rod to which the device can be fixed by an interference screw. The device prevents movement of a mobile attachment to the rod in one direction.

13.10 – Fusion Cage
Includes any component of a spinal fixation system not classified under any of the above headings.

Interbody devices are blocks or braces inserted in conjunction with the procedure of interbody fusion. They are of variable design and composition and fit or inter-positioned between vertebral bodies after removal of the disc. They are usually retained in place by interference or press fit, being jammed between the vertebrae. Their retention in place is achieved by friction rather than by any other means of fastening. Friction that holds the parts together is often greatly increased by compression and the integrity of the spacer relies on the tensile and compressive strengths of the material(s). They are used in conjunction with a bone graft which if successful will secure permanent secure bony fixation.

13.10.01 Interbody Fusion Cage, Integral Fixation
This group is for the interbody spacers that in addition to an interference fit are secured by either inbuilt fixation mechanism (for example, blades) or by some additional form of bone fixation (usually screws inserted through holes in the interbody spacer). There must be an intrinsic link between the cage and the fixation screws and other required devices. Interbody spacers, screws, and/or plates, used for achieving integral fixation, are required to be listed together, as a set, under the same billing code for it to be eligible for Prescribed List reimbursement under group 13.10.01.

13.10.02 Interbody Fusion Cage, No Integral Fixation
This group is for the interbody spacers that depend entirely on interference fit for stability or are secured to bone by any additional form of bone fixation such as screws that are listed on the Prescribed List separately.

13.10.03 Facet Joints
Cages which are inserted into facet joint to stabilize and facilitate a fusion are termed facet joint fusion cages. Facet Joints/fusion cages should be identified as stand alone devices or whether they are combined with additional fixation such as pedicle screws.

Suffix
Paired: Smaller cages that occupy only a small portion of the end-plate and are intended to be inserted in pairs.

13.11 – Disc Replacement
Replacement implies substitution of a diseased part of the spine with an artificial device.

Disc replacement consists of the total replacement of a painful, arthritic, worn or diseased disc with an artificial joint with artificial surfaces shaped in such a way as to allow movement between vertebral bodies.

13.11.01 System
These are total disc replacements that come as a single total device or total disc replacements that come made up from a number of component parts for assembly at the time of insertion to form a complete implant.

13.11.02 End plate
End plate is a part of a multicomponent disc replacement which attaches to the vertebral end plate to which it may be secured.

13.11.03 Core
A central part of a multicomponent disc replacement which interposes between endplates thus facilitating movement.

13.11.04 Replacement Nucleus
Nuclear replacement involves the insertion of an implant into the centre of an intervertebral disc to replace a diseased nucleus while retaining the annulus.

13.12 – Vertebral Body Replacement

Vertebral body replacement involves the substitution of a diseased segment of the spine involving vertebral body or bodies and adjacent discs with and artificial construct usually via an anterior approach. This is not a motion preserving device but serves to restore the load-bearing properties of the anterior column of the spine. These devices are usually inserted in conjunction with a bone graft.

13.12.01 Telescopic Cages

Cages allow for extending or shortening of the device at the time of insertion to ensure the best possible fit. Adjustment of the length of the device is achieved by a mechanism inbuilt in the implant. The mechanism for varying the length is an integral design of the implant.

13.12.01.01 Vertebral body, Telescoping Cage – Integral fixation

Telescoping cages with integral fixation are adjustable vertebral spacers that in addition to an interference fit, are secured by some additional form of bone fixation usually screws inserted through holes in the device.

13.12.01.02 Vertebral body, Telescoping Cage – No Integral fixation

Telescoping cages without integral fixation are adjustable vertebral spacers that depend entirely on interference fit for stability. The spacer is not secured to bone by any additional form of bone fixation such as screws.

13.12.01.03 Vertebral body, Telescoping Cage – End Plate

End Plates are flat bases or rings, separate from the cage that are attached to the ends of the adjustable vertebral body replacements to provide an increased area of weight bearing with the intention of limiting subsidence of the device into the vertebral body.

13.12.02 Vertebral Body, Stackable cages

Stackable cages are spacers which interlock when placed one upon the other. The length of the spine to be replaced can be reconstructed using an appropriate number of cages.

13.12.03 Mesh

Mesh vertebral body replacement is a tubular metal device which has surfaces of mesh design. The implant can be cut to length if necessary to accurately replace a diseased segment of spine. The lumen of the tube can be packed with bone graft. The interstices of the mesh allows for in-growth of blood vessels and possible bone generating tissue.

13.12.04 Mesh, End Plate

End Plates are separate flat bases or rings that are attached to the ends of the vertebral body replacements to provide an increased area of weight bearing thus limiting subsidence of the device into the vertebral body.

Complexity

Where a device has design, materials, composition, manufacturing process, performance, safety, effectiveness, or other characteristics, where applicable, that indicate some uniqueness of the device not included in the current list of suffixes, this will be identified with a terminal suffix code of *complex*. This indicates a possible increased cost in manufacturing, a lack of a true comparator, or a proven greater clinical efficacy and/or safety than the comparator group.