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Standard Terminology Relating to Spinal Implants¹

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1. Scope

1.1 This terminology covers basic terms and considerations for spinal implant devices and their mechanical analyses.

2. Referenced Documents

2.1 *ASTM Standards*:²

E 6 [Terminology Relating to Methods of Mechanical Testing](#)

E 1150 [Definitions of Terms Relating to Fatigue](#)³

3. Terminology

Definitions Related to Spinal Implant Devices

anchor, *n*—components that are directly attached to the bony elements of the spine (sacrum, lamina, pedicle, vertebral body, spinous process, transverse process, the pelvis, or ribs).

band, *n*—a flexible anchor component with a noncircular cross section that connects the bony elements of the spine, pelvis, or ribs to each other or to other implant components using a knot or similar tying mechanism, forming a locked, closed loop.

bolt, *n*—an anchor component that connects to the bony elements of the spine, pelvis, or ribs by means of threads with the lead threads accommodating a nut thus sandwiching the bony element or implant component between the nut or washer and bolt head or other fixed stop.

expansion anchor, *n*— a component that forms a connection to bony element by means of a mechanism which enlarges once the component is inserted into the bony elements.

hook, *n*—an anchoring component that fastens to the spine by means of a curved blade passed under or over lamina, transverse or spinous processes or into an anatomic or surgically created notch or opening.

hook blade, *n*— that portion of a spinal hook that is placed under, over, or into a bony structure to provide attachment.

hook body—that portion of a spinal hook that connects the hook blade to the longitudinal element.

post, *n*—a non-threaded anchor component that connects to the bony elements of the spine, pelvis, or ribs by means of a non-threaded hole in the bony element.

screw, *n*—an anchor component that connects to the bony elements of the spine, pelvis, or ribs by means of threads.

staple, *n*—an anchor component that connects the bony elements of the spine, pelvis, or ribs to each other or to other implant components by using at least two interconnected posts.

wire—a single strand flexible anchor component with a circular cross section that connects the bony elements of the spine, pelvis, or ribs to each other or to other implant components. A series of wire components can be bound together to form a cable (see **cable**).

assembly, *n*—a complete implant configuration (not including spine, pelvis, ribs, or substitute material) as intended for surgical use.

component, *n*—any single element used in an assembly.

construct, *n*—a complete implant configuration attached to and including the spine, pelvis, ribs or substitute material as intended for surgical use.

¹ This terminology is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.31 on Spinal Terminology.

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² This terminology is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.25 on Spinal Devices.

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³ For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards*, Vol. 03.01, volume information, refer to the standard's Document Summary page on the ASTM website.

⁴ Withdrawn.

interbody spacer, *n*—a structure (biologic or synthetic) to replace (partially or totally) the vertebral body or intervertebral disk(s), or both.

intervertebral body fusion devices, *n*—a structure which is placed in the disc space between two adjacent vertebral bodies to provide support for eventual arthrodeses of the two adjacent vertebral bodies.

intervertebral body fusion cage, *n*—a hollow device which contains graft material.

partial replacement disc— a structure intended to restore a portion of the support and motion or a portion thereof, between adjacent vertebral bodies.

replacement disc, *n*— a structure intended to restore support and motion between adjacent vertebral bodies.

vertebral body replacement device, *n*—a structure which is designed to restore anatomic position and support to a section of spine lacking one or more vertebral bodies and intervening disc(s).

interconnection, *n*—the mechanical interface or connection mechanism between at least two components or between components and bony elements of the spine, pelvis, or ribs.

bolt interconnection, *n*—an interconnection having an implant component sandwiched between two nuts or between a nut and fixed stop.

clamp, *n*—an interconnection component whose mechanism to secure the longitudinal element is through a squeezing action.

DISCUSSION—For example, crimps, wedges, set screws.

screw interconnection, *n*—an interconnection having an implant component sandwiched between the screw head (or screw thread) and bony element or other implant components.

sleeve interconnection, *n*—an interconnection in which an implant component passes through any opening that limits motion in one or more planes.

interface, *n*—one of the two mating surfaces, lines or points of contact within an interconnection between two components, between any component and bone, or between two bony elements.

longitudinal element, *n*— a component whose long axis is parallel, or nearly so, to the long axis of the spine.

cable, *n*—a multi-strand, flexible longitudinal element designed primarily to resist axial tension loading.

hybrid longitudinal element, *n*—a longitudinal element consisting of two or more types of longitudinal elements of different size or cross-section manufactured into a single element.

plate, *n*—a longitudinal element asymmetrical in the transverse plane and designed to resist tension, compression, bending, and torsion.

rod, *n*—a longitudinal element symmetrical in the transverse plane designed to resist tension, compression, bending, and torsion.

motion segment, *n*—two adjacent vertebrae, the intervening disc, and the associated ligamentous structures.

subassembly, *n*—any portion of an implant assembly that is composed of two or more components.

subconstruct, *n*—any portion of an implant construct that is composed of two or more components including the spine, pelvis, ribs, or substitute structure.

transverse element, *n*—a component or subassembly that links longitudinal members together.

vertebral span, *n*—the number of vertebra that are spanned by the longitudinal element, including the vertebrae containing anchor components.

Definitions Related to Spinal Implant Testing Defined in Other Documents, or are Established Terminology

DISCUSSION—In certain instances, a value for moment or load can be substituted for *stress* when describing fatigue life. This is true in cases in which the actual stress values are unknown or not easily obtainable. The moment or load can be substituted when comparing devices assigned to perform the same mechanical function. The value for load or moment thus determined is subject to the same conditions as those that apply to *stress* in this terminology standard. However, whenever possible, *stress* should be the standard employed.

fatigue, *n*—the process of progressive localized permanent structural change occurring in a material subjected to conditions that produce fluctuating stresses and strains at some point or points and that may culminate in cracks or complete fracture after a sufficient number of fluctuations.

DISCUSSION—See Definitions E 1150.

fatigue life, *n*—the number of loading cycles, *N*, of a specified character that a given specimen sustains before failure of a specified nature occurs.

DISCUSSION—See Definitions E 1150

fatigue strength at N Cycles, S_n [FL⁻²], *n*—a value of stress for failure at exactly *N* cycles as determined from an *S-N* diagram. The value S_n thus determined is subject to the same conditions as those that apply to the *S-N* diagram.

DISCUSSION—The value of S_n which is commonly found in the literature is the value of S_{max} (*maximum stress*) or S_a (*stress amplitude*) at which 50 % of the specimens of a given sample could survive *N* stress cycles in which S_m (*mean stress*) = 0. This is also known as the median fatigue strength for *N* cycles (see Definitions E 1150).