

# GLOSSARY



510(k) clearance	Clearance from the FDA to market a medical device in the US, based on the FDA deeming the medical device to be substantially equivalent to another medical device already on the US market.
Allograft	A bone graft transplanted between genetically non-identical individuals of the same species. Allograft can be living related (harvested from femoral heads during hip arthroplasty) or cadaveric.
Aseptic loosening	Implant failure of a joint prostheses causing the prostheses (or part of the prostheses) to loosen, and the reason for which is not related to bacterial infection.
Autograft	A bone graft harvested from the patient's own skeleton, usually from the iliac crest.
Bone bank	Storage for bone and bone tissue, typically allograft.
Bone graft	Surgical replacement of damaged or missing bone tissue by transplanting other bone tissue or by using synthetic materials.
Bone graft substitute	Synthetic material used as bone grafts instead of biological bone tissue.
Bone morphogenetic protein	A group of growth factors. Bone morphogenetic proteins orchestrate tissue architecture throughout the body, especially the formation of bone and cartilage.
Bioceramic	A ceramic material that is biocompatible, i.e. can interact with biological materials such as the human body.
Bone tissue	Bone tissue is composed of bone which is cortical (compact) on the outside and cancellous (spongy) on the inside.
Bisphosphonates	A type of drugs that inhibits resorption of bone tissue,
Demineralized bone matrix	A processed form of allograft, an acid-extracted organic matrix from human bone sources.
DRG (Diagnosis-related groups)	A state or federal system for categorization and remuneration of healthcare. Originally from the US, but is now common in many countries.
Simple trauma	A physical injury caused by slipping, stumbling or a low-height fall in combination with a disease which has affected the integrity of the bone (e.g. osteoporosis or metastatic disease).
External / internal fixation	External fixation is a surgical method for stabilizing and supporting bone defects with external fixation devices. Internal fixation uses implants, e.g. plates, nails and screws, which are placed into the bone.
FDA, Food and Drug Administration	The federal medical authority in the US.
Diabetic foot infections	Foot infections due to a compromised vascular supply, neuropathy (nerve damage) and osteopathy secondary to diabetes mellitus.
Benign tumor	A tumor that lacks the ability to invade neighboring tissue or metastasize.
Hematoma	A localized collection of blood outside the blood vessels.
Hydroxyapatite (HA)	A type of calcium phosphate ( $\text{Ca}_5(\text{PO}_4)_3\text{OH}$ ) that occurs as a mineral and is the chief structural element of bone.
Health Economics and Outcomes Research (HEOR)	Scientific discipline that quantifies the economic and clinical outcomes of medical technology.
Iliac crest	The upper wing of the hip bone.
IDE (Investigational Device Exemption)	Exemption from regulatory approval in the US to conduct clinical studies on a medical device. An IDE study is thus a clinical study conducted by such exemption after approval from the FDA.
Iohexol	Radiocontrast agent used in various forms of radiology and which enhances visibility.

Callus	Bony and cartilaginous material forming a connecting bridge across a bone fracture during healing and repair.
Calcium phosphate	A family of materials and minerals containing calcium ions and phosphate ions, used in synthetic bone graft substitutes.
Calcium sulfate (gypsum)	A calcium sulfate compound, which exists in different levels of hydration ( $\text{CaSO}_4$ , $\text{CaSO}_4(\text{H}_2\text{O})_2$ and $\text{CaSO}_4(\text{H}_2\text{O})_0.5$ ) and has been used extensively in medicine, for example as material in bone regeneration.
Clinical study	Study on human participants of e.g. a medical device or a pharmaceutical.
Complex trauma	A high energy trauma typically caused by a motor vehicle accident, a high-height fall, or an industrial accident.
Host bone	The patient's own bone (bone tissue).
Malignant tumor	Cells that grow out of control and are cancerous. Cells in malignant tumors can invade nearby tissues and spread to other parts of the body.
Mesenchymal stem cells	Mature stem cells, usually harvested from the bone marrow.
Metastasis	The spread of a cancer from one organ or part of the body to another without being directly connected with it. The new occurrences of disease thus generated are referred to as metastases (mets).
Necrotic bone tissue	Dead bone tissue.
Orthobiologics	Orthobiologic products support tissue healing and restoration by harnessing regenerative potential with the body's own cells to replace or regenerate musculoskeletal structures. The applications stretch across joint reconstruction, trauma, soft tissue repair and spine.
Orthopedic	The branch of surgery concerned with conditions involving the musculoskeletal system.
Osteoblasts	Bone cells that produce bone tissue.
Osteoclasts	Bone cells that break down and resorb old bone tissue.
Osteoconduction	Osteoconduction means that a bone graft material can serve as a scaffold for new bone growth.
Osteogenesis	Osteogenesis is the process of new bone tissue production by osteoblasts.
Osteoinduction	Osteoinduction means that a bone graft material or a growth factor can stimulate the differentiation of osteoblasts, that in turn form new bone tissue.
Osteomyelitis	A bacterial infection affecting bones.
Osteoporosis	A disease characterized by reduced bone mass. This leads to increased bone fragility and risk of fracture.
Periprosthetic joint infection (PJI)	Bacterial contamination of a hip or knee prostheses with bacterial infection of the surrounding bone and joint tissue. This condition can lead to the septic loosening of a prosthesis.
pH	Numerical scale used to specify acidity of a solution.
PMA (Pre-market approval)	Market pre-approval from the FDA in the US for class III medical devices.
PMMA	Poly methyl methacrylate, often called "bone cement".
Progenitor cell	Biological cell that can advance into a specific type of cell.
Revision arthroplasty	Surgery following arthroplasty (joint replacement) to replace a worn-out prosthesis.
Sponsor	An individual, company, institution or organization, which takes responsibility for the initiation, management and/or financing of a clinical study.
Systemic / local administration	Systemic administration of a substance means that the substance is delivered through the bloodstream and is spread throughout the body. Local administration means that a substance is delivered locally to specific part of the body, e.g. a bone void.