

Position Statement

Innovation and Novel Technologies in Orthopaedic Surgery

This Position Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Orthopaedic surgeons are at the forefront of new procedures and technologies to optimize patient care in an evidence-based approach. Examples include augmentation of fragility fracture fixation with calcium phosphate, the use of advanced alloys, interface bearing surfaces, nanotechnology coatings, additive manufacturing for total joint replacement for arthritic disorders, and navigation and robotic assisted correction and stabilization of major musculoskeletal degenerative diseases and deformities. These innovations have revolutionized patient care. Many of these technologies were gradually introduced after extensive preclinical basic science and applied research studies followed by limited surgeon or institutional clinical trials. Other innovations have been initiated by surgeons based on empiric knowledge and then refined over many years.

Currently, new devices, combination products, pharmaceuticals, biologics and surgical procedures are being introduced and marketed at an increasing rate. Although many of these innovations have undergone comprehensive preclinical and clinical evaluation through rigorous regulatory review and marketing approval with labeling indications, some are being used in an "off-label" manner with unstructured physician oversight. Many device submissions, however, are cleared through the 510(k) process by identifying a similarly built 'predicate' which has its advantages and disadvantages. Surgeons need to be aware that even though a product is marketed in the US, having undergone regulatory review with the FDA, there may be lack of data or uncertainty around the long-term safety and efficacy profile of these products. Therefore, the importance of a detailed conversation with your patient and or caregiver regarding a novel device procedure, must never be undervalued.

The American Academy of Orthopaedic Surgeons (AAOS) believes surgeons have an obligation to offer their patients the most efficacious, safe and cost-effective non-surgical and surgical treatments available. Members should be cognizant of the scientific basis for the different treatment options offered to their patients, including the benefits and risks of an operation, device, biologic, or pharmacologic intervention. These facts should be discussed with the patient in an open manner where the patient feels no hindrance to asking questions. In addition, the surgeon and team should be proficient in the use of this new treatment in concert with its labeled indications for use and safety and efficacy data, so that the overall outcome is optimized and likelihood of adverse events is minimized to the best of available evidence at the time of the intervention. This is important not only for patient consent, but also to preserve the sanctity of the physician-patient relationship and trust that we are beholden to as physicians and surgeons. Furthermore, it is essential that appropriate training methods

for surgeons be available and completed for the safe and effective use of new technology.

Innovation in surgical procedures and technologies is important to continued progress in our specialty. Surgeons have a great opportunity to play a major role in this regard. In collaboration with hospitals, device and drug manufacturers, patients, payers, governmental agencies and other interested parties, surgeons can facilitate the introduction of new technologies to help ensure that the best possible treatment options are reaching the patient. At the same time, it is incumbent upon our specialty to track the clinical outcomes and adverse events associated with these new technologies using open readily-accessible databases, registries, and other methodologies to ensure that our patients and society in general realize the benefits of these innovations, and avoid undue risks.

American Academy of Orthopaedic Surgeons®.

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