September 13, 2012

Margaret A. Hamburg, MD
FDA Commissioner
Food and Drug Administration (FDA)
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Dr. Hamburg:

On behalf of more than 18,000 board-certified orthopaedic surgeons, the American Academy of Orthopaedic Surgeons (AAOS/Academy) thanks the FDA for the opportunity to comment on the proposed reclassification of posterior cervical screws, including pedicle and lateral mass screws, published in the July 18, 2012 Federal Register. AAOS champions the interests of patients by improving treatment options through education and research. We are dedicated to the development of sound federal health care policy that fosters patient access to the highest quality orthopaedic care.

Clinical Applications and Safety Concerns

Posterior cervical screw fixation has been practiced in the United States since late 1980’s, to treat unstable cervical spines secondary to trauma or other destructive lesions, as an adjunct to anterior fusion or repair of failed anterior fusion, reconstruction of cervical deformity, and for stabilization of congenital malformations. Screws may be applied to lateral masses at C1 and from C3-C7. Also screws can be placed into the pedicles of C2, the subaxial spine from C3 to C6, and into C7. Various devices may be attached to the screws such as plates or rods.

The goal of posterior screw fixation is to rigidly stabilize the spine to aid fusion success and to maintain alignment. Numerous studies have shown high rates of fusion success for C1-2 and subaxial spine arthrodesis with screw fixation.1-6 These devices are more successful than alternatives, such as wire fixation, which do not provide sufficient stability in most cases. Frequently, inadequate bone stock - due to its inherent size, from injury, or removal - precludes wire fixation or requires additional levels be included in fusion construct. Wire fixation requires more restrictive post-operative immobilization, such as the halo-vest, which limits patients activity and is associated with its own adverse events.
Safety concerns are relevant, when screws are placed in proximity to neurologic and vascular structures, and procedures require meticulous preoperative planning and surgical technique. The risk of screw placement varies by location (lateral mass vs. pedicle) and anatomic level. At C1, only lateral mass screws can be placed. Lateral mass screws are not indicated in C2 due to risk of vertebral artery injury, and only pedicle (or sometimes called pars) screws should be placed. In the sub-axial spine from C3-C6, lateral mass screws have had an excellent safety profile. However, placement of pedicle screws from C3-C6 has a significant risk for vertebral artery injury. The vertebral artery at C7 lies outside the vertebra, therefore both lateral mass and pedicle screws can be placed safely at this level.

The complex nature of cervical spine anatomy, the small tolerance for error in screw placement, and the significance of a neurologic or vascular injury requires extensive training for proper use of these devices. The present classification does not allow such training at hands-on cadaveric courses sponsored by industry or organizations such as the AAOS. Despite these challenges, posterior cervical screws are often used in an off-label manner to meet the needs of spine patients, with good clinical outcomes.

Off-label Use and Classification Change

In our June 2009 position statement, the Academy acknowledged the challenges for the orthopaedic surgical community to meet the needs of their patients through the use of medical products before there is approval or clearance of the labeled indications for use for a particular product. We encourage our members to carefully evaluate the risks and benefits of these applications and employ their best knowledge and judgment when selecting a treatment option for their patients.

AAOS believes that a Class II designation, along with general and special controls, provide reasonable assurance of the safety and effectiveness of posterior cervical screws, with the following limitations of labeling:
1. lateral masses of C1,
2. lateral masses from C3-C7, and
3. pedicles of C2 and C7.

AAOS does not support labeled indications for pedicle screw use in levels C3-C6.

We are committed to working, through the ASTM, International, to develop scientifically sound and clinically relevant standards for the evaluation of medical and surgical devices. AAOS looks forward to collaborating with FDA staff and other stakeholders, in this arena, to further the creation of standards that will
enhance the Agency’s ability to thoroughly and efficiently evaluate the safety and effectiveness of posterior cervical screws and other orthopaedic devices.

Conclusion

The AAOS shares the concerns of FDA in ensuring that safe and effective products enter the marketplace. We remain committed to protecting consumers and our patients, as well as encouraging that the latest technologies in safe orthopaedic devices come to the marketplace through a least burdensome, streamlined regulatory review.

If you have any questions on the AAOS comments, please do not hesitate to contact our Medical Director, William R. Martin, III, MD, at (202) 546-4430 or martin@aaos.org.

Sincerely,

John R. Tongue, MD
President, American Academy of Orthopaedic Surgeons