



AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS CONGRESS OF NEUROLOGICAL SURGEONS

Position Paper on The Use of Bone Dowels from "Human Tissue"

Introductory Statement

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), representing over 4,500 neurological surgeons in the United States offer the following position regarding the use of human tissue for the production of bone dowels:

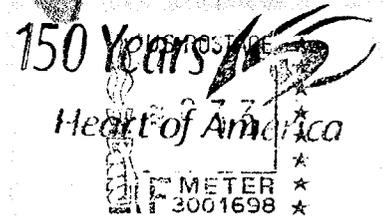
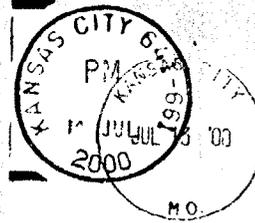
- 1) Use of human bone products (processed and pre-shaped) for spine surgery has a long history of documented safety and efficacy.
- 2) Appropriate regulations for infectious disease testing, donor screening and record keeping already exist.
- 3) The use of processed and pre-shaped bone products has been clinically proven to enhance patient care and improve outcomes.
- 4) Any change in the classification of human bone dowels from its current status of tissues to that of a medical device would decrease availability of these products to physicians and their patients.
- 5) The overall effect of any reclassification of these products from human tissues to medical devices could have dramatic and unpredictable implications on utilization of all other human tissues, with widespread negative impact on patient care.

Furthermore, it is the position of the AANS and the CNS that human bone dowels currently fall within the definition of "minimally processed tissue" and therefore meets the proposed criteria for regulation as "tissue".

Finally, any effort to reclassify human bone dowels from "tissue" to "medical devices" would appear to be contrary to the previously stated intent of the Federal Register notice regarding registration of human tissue-based products (63 FR 26744, May 14, 1998) in which it was stated that a primary goal of registration was "improved protection of the public health **without the imposition of unnecessary restrictions on research, development, or the availability of new products**".

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