

Information Statement

Tissue-Engineered and Cell-Based Medical Products

This Information 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.

The regulation of tissue-engineered and cell-based medical products is evolving. As a result, such products are currently under varying degrees of regulation. Because the safety and effectiveness of treatments involving less regulated tissue-engineered and cell-based medical products may not be fully known before they are available, orthopaedic surgeons should exercise caution in using these products and similar emerging technologies. For all developing technologies including those with the highest degree of regulation, the American Academy of Orthopaedic Surgeons (AAOS) supports continued long-term monitoring of outcomes for confirmation of safety and effectiveness.

Tissue-engineered and cell-based medical products are evolving treatment options for musculoskeletal conditions and diseases. The products include cells, tissues, inorganic and organic substances used alone or in combination with other factors that are manufactured, manipulated, or altered in a laboratory. They may be used for the repair, restoration or regeneration of living tissue. They also may include substances that are not found naturally in tissues or whose normal physiologic concentration has been altered. Examples of these products include bone graft substitutes or extenders, bone growth factors used alone or in combination with other products, and autologous or allograft cells for regrowth of musculoskeletal tissues.

The AAOS believes tissue-engineered and cell-based medical products should meet requirements for safe use in humans. Safety of these products involves minimal risk of unacceptable side effects or disease transmission to the recipient after implantation. Because federal regulation of tissue-engineered and cell-based medical products is evolving, it is incumbent upon orthopaedic surgeons who use these products to be familiar with known risks involved with their use and to communicate these risks to patients, as appropriate.

Knowledge of the effectiveness of therapies involving tissue-engineered and cell-based medical products may be incomplete prior to their availability to orthopaedic surgeons and their patients. Under these circumstances, orthopaedic surgeons should be familiar with the current knowledge about these products, the proposed indications for their use and the possible outcomes of the procedures. The AAOS supports the process of informed consent in the use of

these products. Orthopaedic surgeons should discuss their reasons for choosing a therapy involving these new products, alternatives, risks and benefits with their patients and the known results of their use.

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