

Bone Graft Substitutes Containing Recombinant Proteins or Synthetic Peptides in Patients Under Age 18: FDA Safety Communication - Reports of Serious Injuries

AUDIENCE: Pediatrics, Plastic Surgery, Dentistry, Orthopedic Surgery, Neurosurgery

ISSUE: FDA is aware of healthcare providers using bone graft substitutes containing recombinant proteins or synthetic peptides in patients under age 18. Reports of serious injuries, such as excess bone growth, fluid accumulation, inhibited bone healing, and swelling, have increased the FDA's concern.

While these types of events are similar to those seen in patients over age 18, they are of more concern in patients under age 18 because of their overall smaller size and because their bones are still growing. Any product that affects bone growth could have the potential to negatively impact skeletal development by altering normal bone formation and growth, especially if implanted near open growth plates.

BACKGROUND: The FDA considers bone graft substitutes containing recombinant proteins or synthetic peptides high-risk (Class III) medical devices. Before marketing the products, manufacturers are required to submit a premarket approval application (PMA) that includes clinical data supporting safety and effectiveness. The FDA has not evaluated their safety and effectiveness in patients under age 18.

RECOMMENDATIONS:

- FDA recommends against routine use of these products in patients under age 18 because their safety and effectiveness has not been reviewed or approved for use in this population.
- Consider alternatives such as autograft bone, allograft bone, and bone graft substitutes that do not contain recombinant proteins or synthetic peptides before using bone graft substitutes containing recombinant proteins and synthetic peptides in patients under age 18.
- Carefully consider the benefits and risks before using these products in any patient. If considered the best or only option, inform parents/guardians and patients about the risks and benefits of using the product when discussing surgical options.
- Closely monitor patients under age 18 for adverse events and if necessary, refer them to the appropriate healthcare provider for corrective treatment. Adverse events may include problems with skeletal development, excess growth of other tissues, and tissue swelling or fluid accumulation that could put pressure on adjacent organs or tissues.

See the [FDA Safety Communication](#) for additional recommendations for parents, guardians, and patients.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178