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**Infuse is a bone cement cleared for adults 18 and over. It has known risks for children, because they are still growing.**

**What happens if it is used on babies?**

# 2-year old treated with Infuse at St Louis Children's Hospital

2008 published case report



# Hailey, Infuse in Cincinnati Children's Hospital, 2010



# Current Insufficient FDA Warning

## **Product:**

Certain recombinant proteins and synthetic peptides mimic **bone growth substances** normally found in the body and may be added to a carrier or scaffold to be used as bone graft substitutes. Once combined, these products are surgically implanted in a patient with a bone defect to promote new bone growth or to replace or heal existing bone.

The FDA has approved these products for orthopedic and dental use only in patients over the age of 18 who are done growing (skeletal mature). The labeling for each product provides the specific indications for use.

**These products are not approved for any use in patients under the age of 18 who are still growing (skeletally immature).**

# Current FDA Warning (cont'd)

## **Recommendations:**

The 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.

# Current FDA Warning (cont'd)

## Recommendations (cont'd):

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.

[Report to the FDA](#) if you become aware of a patient experiencing an adverse event associated with the use of recombinant proteins or synthetic peptides.