

From: Blount, Sharon
Sent: Wednesday, April 09, 2003 4:22 PM
To: Adjodha, Michael E
Cc: Mulry, Kevin P; Runner, Mary S.; Betz, Bob
Subject: Adverse Reports on Tr-Calcium Phosphate Dental device

Michael,

After reviewing the adverse reports that were sent by Dr. Janie Fuller, the following adverse report only applied to Tri-Calcium Phosphate:

Event Date: 28-Jun-2002
Adverse Event: Problem
Report Date:28-Jun-2002
Event Location: unknown
Manufacturer: Synthes
Product Code: LYC- Bone Filling Augmentation Material
Device Type:Calcium Phosphate Compound

Event Description:*RPTR is concerned that a new medical compound used in filling bone voids may accelerate blood clot formation if it escapes from bone into the venous circulation. While conducting preliminary experiments to design a toxicity study of this product, Norian SRS MFG by Synthes, RPTR has observed an effect which may result in complications when this product is used un humans. Norian is a calcium phosphate compound. It is used in filling bone gaps in fractures of the proximal tibia and distal radius and in filling cranial defects. When RPTR injected it into the venous circulation of a pig, it created a large thrombus. RPTR also measured the effect of different doses of Norain on clotting time for blood obtained from one human volunteer. Larger concentrations of Norian decreased clotting time. RPTR is concerned that if this material is distributed in the venous circulation in humans, it may result in accelerated Thrombus formation.*

I hope that this is helpful.

Respectfully submitted by: Sharon L. Blount
Date: April 9, 2003