

Allograft Tissue Recall (12/05)

The Food and Drug Administration (FDA) is notifying the public of its investigation of human tissue recovered by Biomedical Tissue Services, Ltd (BTS) of Fort Lee, NJ and sent to tissue processors. Some of this tissue (e.g., human bone, skin, tendons) may have been implanted into patients from early 2004 to September 2005. The tissue was recovered by BTS from human donors who may not have met FDA donor eligibility requirements and who may not have been properly screened for certain infectious diseases. Of special interest to periodontists are LifeCell Corporation, which produces Alloderm for BioHorizons, Inc., and Totugen Medical Inc, which produces Puros for Zimmer Dental. No adverse reactions related to these tissues have been reported at this time and the FDA and the Centers for Disease Control (CDC) believe the risk of infection from these tissues is low. It is important to determine whether the allograft material is from the recalled lots. Dentists and physicians who have obtained tissue affected by the recall should have been notified by now.