



Tracking Requirements

Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requires you to track patients who have been implanted with donor human tissue or bone.

Since 1995, JCAHO has required hospitals track the implantation of all human tissues. Very recently, they have begun auditing the procedures and documentation associated with these requirements.

Market Experience

HOW LONG HAS THIS TECHNOLOGY OR PRODUCT BEEN USED CLINICALLY IN THE UNITED STATES?

HOW MANY SURGICAL PROCEDURES HAS THIS TECHNOLOGY OR PRODUCT BEEN USED IN TO-DATE?

WHAT IS THE PRODUCT'S CURRENT MARKET SHARE?

The field of osteobiologics is an emerging and evolving one. Most of the research has been conducted within the past 20 years. The past six years have seen an explosion in product commercialization. That being said, positive human experience in routine use remains a hallmark of clinical benefit. Assessing a technology's time-in-market and overall commercial success therefore also can help determine its credibility.

Bone Grafting Checklist

Product Name: _____

Yes No

Is the Product FDA approved/cleared?

If so, for what indications? _____

Is there human clinical data to substantiate efficacy?

If so, for what surgical procedures? _____

Is the data peer reviewed and published?

Have there been any adverse events with this product?

Have there been any recalls?

Has the manufacturer been served with FDA warning letters?

Are there any contraindications for this product?

How long has this product been on the market? _____

How many patients have been implanted with this product? _____

Evaluating Bone Graft Options

MAKING AN INFORMED DECISION



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Overview

Trying to understand the ever-changing osteobiologics market poses a significant challenge for hospitals and their staff. For surgeons, administrators and support staff, making sense of the seemingly endless list of manufacturers and technologies can be a formidable task.

This guide is intended to help you in assessing and evaluating the various technologies you may encounter. It is broken down into key areas with suggested questions to help you evaluate a specific product's clinical appropriateness as well as separate marketing hype from clinical fact.

FDA Clearance

IS THIS PRODUCT FDA APPROVED OR CLEARED?

WHAT PROCEDURE IS THE PRODUCT APPROVED OR CLEARED FOR? (e.g. What are the indications per the IFU?)

While all medical implants are required to be PMA approved or 510(k) cleared by the FDA, allograft tissue is not formally regulated by the FDA. At this time, allograft tissue processors follow published FDA guidelines, and highly processed (manipulated) forms of allograft, known as demineralized bone matrix (DBM), now require FDA clearance prior to marketing.

Sterility Documentation

HAS COMPREHENSIVE STERILITY DOCUMENTATION BEEN PROVIDED?

Products claimed to be sterile should have formal documentation available for your records to support these claims.

Further information on specific product recalls, incidence reports and warning letters can be found at:

RECALLS
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfred/res.cfm>

ACTIONS TAKEN IN REGARD TO FDA REGULATORY ENFORCEMENT
<http://www.fda.gov/opacom/Enforce.html>

WARNING LETTERS
<http://www.fda.gov/foi/warning.htm>

Safety

HAVE THERE BEEN REPORTED ADVERSE EVENTS WITH THE PRODUCT OR TISSUE?

HAS THE PRODUCT OR TISSUE BEEN RECALLED IN THE PAST 18 MONTHS?

HAS THE MANUFACTURING (OR PROCESSING) FACILITY BEEN SERVED WITH FDA WARNING LETTERS OR 483'S IN THE PAST 18 MONTHS? IF YES, PLEASE SPECIFY.

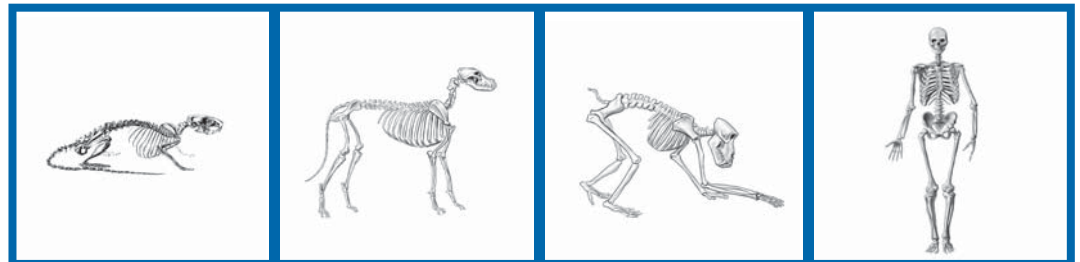
IF THE PRODUCT IS ALLOGRAFT BASED, ARE ALL THE TISSUE BANKS AND BONE PROCESSORS YOUR COMPANY HAS CONTRACTUAL RELATIONSHIPS WITH AATB CERTIFIED?

In 2006, allograft tissue came under significant scrutiny due to a series of unfortunate events involving unscrupulous tissue procurement agencies who obtained tissues without patient/family consent and falsified the data and documentation accompanying these tissues. While the majority of donor bone implanted met FDA and AATB guidelines, dozens of patients were advised that they were at higher risk for transmissible diseases such as HIV, Syphilis, and Hepatitis. The FDA recommended that doctors offer infectious disease testing for HIV, hepatitis and syphilis to patients who received the tissue.

Basic Science and Pre-Clinical Data

HAS THE PRODUCT BEEN DEMONSTRATED TO BE EFFECTIVE USING THE PRE-CLINICAL 'BURDEN OF PROOF'?

Most bone graft materials on the market, whether needed for market approval or sales promotion, have some level of demonstrated animal safety and/or efficacy. However, at this time, the FDA does not require a complete 'Burden of Proof'. The 'Burden of Proof' consists of a comprehensive series of pre-clinical studies to evaluate a technology or product's ability to form bone in a variety of defects (metaphyseal, diaphyseal, non-bony sites, and posterolateral spinal fusions) and through a hierarchical order of species (rat, dog, primate, and human).



Human Clinical Data

HAS THE PRODUCT BEEN DEMONSTRATED TO BE EFFECTIVE IN HUMAN CLINICAL STUDIES?

ARE THE STUDIES PERFORMED SUFFICIENTLY RIGOROUS TO BE RELIED UPON? (e.g. study design, controls, outcome measures, etc.)

WHICH OF THESE STUDIES CONSTITUTE NON-SPONSORED, PEER-REVIEWED RESEARCH?

ARE THE RESULTS APPLICABLE TO THE SURGICAL PROCEDURES TARGETED IN THIS FACILITY?

While preclinical data is helpful to assess the likelihood that a technology or product will work, only empirical human clinical research can provide true insight into its efficacy in humans. Independent assessment of any study is important as well. Given both the volume of new technologies and products introduced every year and the complexity of the subject matter, the availability of human clinical research is a good tool to separate the tested from the untested products.