Bone dowels and putty, heart valves, skin, cartilage, and tendon grafts—these are a few of the array of tissues used in surgery.

What do you need to know to manage tissues safely and appropriately?

OR Manager posed some frequently asked questions to Joel Osborne, vice president for quality assurance and regulatory affairs for the Musculoskeletal Transplant Foundation (MTF; www.mtf.org), a nonprofit organization that recovers, processes, and distributes tissues.

Q Do you have suggestions on meeting the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requirements for tissue handling?

Osborne: JCAHO’s standard for tissues has been moved from the hospital accreditation manual to QC.5.300 in the 2004 Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing. Under federal regulations, laboratories must be surveyed every 2 years.

Your hospital may not choose JCAHO for its laboratory accreditation. But if it does, tissue storage and handling will be evaluated during JCAHO’s laboratory survey. If your hospital stores tissues in the OR, the surveyors would review your compliance with the tissue standards at that time. In general, the QC.5.300 standard requires the organization to use standardized procedures to acquire, log in, and store tissue. This includes transporting and storing tissue according to the source’s written directions; monitoring temperatures for refrigerators and freezers; monitoring alarms and backups; and keeping records to show tissues were stored at the required temperatures.

Q How should frozen tissues be stored?

Osborne: This is covered in the standards of the American Association of Tissue Banks (AATB, www.aatb.org), the major voluntary accrediting body for tissue banks. According to AATB, frozen and cryopreserved tissue should be stored at –40º C or colder. For short-term storage (up to 6 months), tissue should be stored at –20º C to –40º C. After 6 months, grafts must be transferred to temperatures of –40º C or colder, used, or discarded. AATB also recommends that tissues not be stored in freezers where food and drinks are stored.

Q Should frozen and freeze-dried tissue be stored in the OR or elsewhere in the facility?

Osborne: There is no right or wrong answer. It depends on what works best for your organization. In some institutions, the blood bank is the ideal place because it handles blood components, which are similar to tissues. Others decide the OR is the best place.

Q Must frozen tissue be thawed before use?

Osborne: Review the package insert to see what is recommended. We advise keeping a copy of the package insert on file so users can refer to this information. Tissue banks usually recommend thawing and rehydrating frozen and freeze-dried tissue. This is important because frozen tissue is brittle.

Q If our freezer goes down, what can be done with the tissue?

Osborne: We get these calls frequently, particularly after a weekend or holiday. Keep in mind that tissues should be kept under the conditions recom-
mended by AATB. If those conditions cannot be met, the tissue may have to be discarded. Also refer to the package insert.

We strongly recommend that freezers used for storing tissues have an alarm system that will go off in an area that is manned 24 hours a day. That is something a lot of people overlook.

You should also have a backup plan in case a freezer fails. You should either have access to another freezer in the facility or access to dry ice where the tissue can be stored until the freezer is repaired or replaced.

**Q** Are we required to report adverse events with tissue, such as infections?

Osborne: Currently, the Food and Drug Administration (FDA) does not have a reporting requirement as they do for medical devices. AATB standards state that infections attributed to a tissue graft should be reported to public health authorities as well as the tissue bank. We strongly recommend that facilities report adverse events immediately to the tissue bank. In some states, such as California, that is required.

The FDA may require reporting in its final “good tissue practices” (GTP) rule, which is expected shortly and is likely to be effective in 2005. In its draft rule, the FDA proposed that tissue banks be required to track tissues from the donor to the recipient. If that is included in the final rule, tissue banks will need to set up a mechanism with health care facilities to make sure facilities have systems to track tissues to the recipient.

The death in 2001 of a 23-year-old Minnesota man who received a contaminated knee allograft pointed out the need for reporting. Without mandatory reporting, there is no way to determine how many infections may be occurring because of tissue transplants, though the number is thought to be small.

**Q** When vendors bring tissues into the hospital, how can we be assured the tissues have been stored under the proper condition?

Osborne: Some tissue banks use sales reps as their delivery agents, as they would FedEx or UPS, with the understanding they are not storing the tissue. With some grafts, the temperature is critical, so you should ask, “How did you store this tissue during transport?”

**Q** Are patients with latex allergy at risk from tissue transplants?

Osborne: Most tissue banks can issue a document saying their packaging materials are latex free. But people involved in tissue recovery and processing typically wear latex gloves, and the industry can’t guarantee that latex particles are not transferred to tissues. Tissue handlers prefer latex gloves because of the dexterity.

We are not aware of any incidents where patients have had a reaction to latex as a result of a tissue transplant, and we are not aware of any reports in the literature. That does not mean there haven’t been cases that are unreported. But unless there is an issue related to latex in tissue, I am not sure the industry will make changes.

**Q** Should patients who are receiving a tissue transplant give informed consent?

Osborne: We believe informed consent is something facilities should consider, similar to the consent given for blood transfusions. In some cases, patients are not aware they are receiving a tissue transplant. Whether the consent should be obtained by the hospital or the physician has not been determined. We are not aware of lawsuits involving failure to seek consent from tissue recipients.

**Q** Does a hospital have to register as a tissue bank if it shares tissue with another facility?

Osborne: According to the FDA’s registration rule for tissue banks, which was finalized in 2001, hospitals are not required to register if they simply store and
transplant tissue. If your facility is transferring tissues to other hospitals or surgery centers, it is best to check with the FDA. The FDA is concerned about traceability. If you are sending tissue to another facility and are not able to trace the tissue, that would be a big issue.

I understand that soft tissues such as knee allografts cannot be sterilized. Is that a safety issue for patients?

Osborne: The processing of tissue is a balancing act. Tissue banks must balance the biological and biomechanical function of the tissue against the processing, which may destroy those characteristics. Especially with soft tissues such as tendons and ligaments, maintaining the structure and function is a major issue. At MTF, soft tissues are processed aseptically rather than sterilized. These aseptic processes are performed in clean-room environments and employ various types of antibiotics, detergents, and other agents to reduce the risk of bacterial contaminants. The FDA requires that tissue banks validate their processes so tissue is not contaminated or cross-contaminated.

The importance of validated processes was illustrated in the Minnesota case. The tissue bank that provided the graft did not have an adequate procedure for culturing the tissue at the time of recovery. The investigation also found that the processing agents used can interfere with the microbiological tests performed on the tissue. That is a part of validation—to ensure the chemicals used do not interfere with the final culture results.

The new GTP rule will give the FDA more authority to inspect tissue processing.

Should we be culturing tissue prior to implant?

Osborne: There are different opinions. You should abide by what your organization recommends. MTF does not recommend culturing tissues. The reason is that many facilities, if they don’t have adequate procedures, may actually contaminate the tissue when attempting to culture it. The more you manipulate the tissue, the greater the risk of contaminating the tissue.

What’s the safety record for tissue transplants?

Osborne: Overall, the safety record has shown tissue transplants are very safe. There have been isolated cases of bacterial contamination and disease transmission. There are over 800,000 units of tissue transplanted a year. If there was a safety issue, you would see far more cases. Unfortunately, the majority of the incidents reported were from one tissue bank.

How actively is the FDA inspecting tissue banks?

Osborne: There are over 1,000 facilities registered with the FDA. A list of registered facilities is at www.fda.gov/cber/tissue/tisreg.htm.

Of those facilities, the last report was that the vast majority of processing facilities have been inspected at least once. In most cases, FDA is routinely inspecting facilities about every 2 years. 
Advice for selecting a tissue bank

Points to consider:

• Is the tissue bank accredited by the American Association of Tissue Banks? A list of accredited banks is at www.aatb.org.

• Is the tissue bank registered with the Food and Drug Administration, as required by regulation? A list of FDA-registered banks is at www.fda.gov/cber/tissue/tisreg.htm. Some states also require registration, including California, New York, Florida, and Maryland.

• Is the tissue bank ISO certified? This is not required, but meeting this international standard indicates that the bank is routinely inspected and has an active quality monitoring system.

• What is the surgeon’s preference?

• What type of tissue processing method is used? How does the bank ensure tissues are not contaminated and cross-contaminated? How are these processes validated, as required by the FDA?

• What is the availability of tissues? Some tissues are in high demand, such as those used in sports medicine. Can you obtain these when you need them?

• What is the tissue bank’s safety track record? Has the bank had any recalls? Has it had safety-related inspections? Has it received any FDA warning letters?

• What have been the clinical results of tissues from the bank? Much of this information is anecdotal but can be helpful.

• What are the processing fees? Tissues may not be bought or sold, but tissue banks charge processing fees, which vary.

• What type of packaging is used? How easy is the packaging to use in the OR while maintaining aseptic technique?

• How good is the service? Does the bank have a well-informed person available to answer questions?