



# CS QUESTIONS · CS ANSWERS

## Handling explants; insulated instrument

by Ray Taurasi



SUBMIT YOUR QUESTIONS  
email: [editor@hponline.com](mailto:editor@hponline.com)  
phone: (941) 927-9345 ext. 202

**Q** I run a predominately orthopedic surgery center and was wondering how other facilities handle explants. We have patients who come in for hardware removal and request to keep their hardware. I feel that this is a biohazard and would like input of other ASC's regarding their policy, as I am updating ours.

**A** There is no universal standard or regulation on this practice. In my experience the decision and process is left to each hospital to decide and develop a policy. There are many concerns and issues to address when developing a policy for returning explants to patients. It is suggested that a task force or committee be established, bringing together the required expertise to develop a sound and rational policy. Representation on the committee may include surgeons, peri-operative staff, infection control, epidemiology, risk management, legal affairs, manufacturer, sterile processing, pathology and materials management. Each committee rep or group of reps should investigate issues related to their area of expertise. The following list contains some of the concerns and issues you will need to address:

- Reprocessing of implants method of cleaning, decontamination and sterilization for each type of explants
- Personal safety, injury risk assessment associated with explants to be processed and returned to patient
- Identify which explants can and cannot be returned to patients
- Quality Assurance of reprocessing efficacy
- Packaging and labeling of device for sterilization and return to patient
- Adherence to any biohazard handling or labeling in accordance with federal, state and local regulations
- Who rightfully has ownership rights to the explant
- Issues involving past, current or future implant recalls – and compliance to FDA regulations – e.g., tracking, ownership, reporting, return to manufacturer

- Compliance with FDA and/or other regulatory mandates relating to disbursement and distribution of such devices
- Maintenance of required documents and manifestoes for tracing purposes
- What other records will hospital create and maintain
- Who, when, where and how will explants be returned to patient

Reference:  
February 2012 • AORN Journal Vol. 95, Issue 2, Pages 288-296

**Q** We recently had an incident in our OR where a surgical technician claimed he got a minor shock from a piece of electrical equipment. Now our safety officer and risk manager have been conducting inspections of everything including the cleaning and maintenance of electrical patient care equipment. They reviewed our processing procedures for powered surgical instruments, drills, shavers, etc. While everything seemed to be fine they suggested that I might want to get more information on the life of and efficacy of the insulation on surgical instruments. We have never had any problems with these instruments so it's not something that has ever concerned me. My staff is very attentive, inspects all surgical instruments thoroughly, and uses a lighted magnifier when necessary. I really don't know what more we could do. What do you suggest?

**A** Any damage such as breaks, cracks, or holes in the insulation along the shaft or other areas of a medical device may allow the electrical current to leak and cause electrical shocks or burns to the patient, surgeon or other members of the surgical team. The insulation on medical devices can wear thin with age and usage. Mishandling and improper usage can also cause damage to the insulation. Compromises in the insulation could provide an avenue for the unintended passage or electrical current to an unprotected area of tissue in the surgical

incis  
ous l  
Ve  
is cri  
tion  
How  
not b  
Ther  
instr  
with  
figur  
throu  
delet  
of th  
of al  
shou  
with  
devis  
cessi  
the r  
world  
that  
tions  
AAB  
ough  
devis  
App  
whic  
perf  
shou  
that  
the r  
and l

Fi  
Ray  
tions  
decal  
nolog