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## QUESTION 7: What can be done with a prosthesis that has been dropped on the floor or allowed to come into contact with a non-sterile portion of the operating room?

**RECOMMENDATION:** Cleaning, re-sterilization and reuse of dropped prostheses or implants is not permitted in most hospitals and should not be performed. Only in extremely rare circumstances, such as the use of a custom implant, a dropped prosthesis may be decontaminated and sterilized.

**LEVEL OF EVIDENCE:** Consensus

**DELEGATE VOTE:** Agree: 90%, Disagree: 8%, Abstain: 2% (Super Majority, Strong Consensus)

### RATIONALE

The creation and maintenance of an aseptic environment has a direct influence on patient outcomes in general and the incidence of subsequent surgical site infections/periprosthetic joint infections (SSIs/PJIs) in particular. One of the measures for preventing SSIs is to provide surgical instruments and implants that are free of contamination at the time of use [1]. This is particularly important when an implant such as a joint prosthesis is being left behind in the body. Prior studies have shown that as little as 100 bacteria gaining access to a surgical field that involves the use of an implant is sufficient to lead to infection [2,3]. The number of bacteria needed to result in infection in the absence of an implant was much higher [4,5]. Thus, the presence of a foreign material, such as an implant, is a strong risk factor for subsequent SSIs/PJIs [4,5]. Due to this, extreme care should be exercised in ensuring that the prosthesis being implanted in joints are completely sterile and devoid of any bacteria [6].

There are strict regulatory requirements for implant sterilization, which is usually the last step in manufacturing of these prostheses [7]. Most manufacturers use high dose gamma irradiation to achieve the required sterility of implants manufactured for use in humans [6]. Implants being opened from their package are thus believed to be absolutely sterile. Dropping an implant on the floor results in contamination of the implant by microorganisms that can potentially lead to a subsequent infection. Sterilization of the dropped implants in the hospital using autoclave does not meet the regulatory requirements and very likely leads to presence of residual bacteria or their cell walls “exotoxins” [8]. Thus, this practice is not considered to be acceptable by hospitals and local health authorities.

Different sterilization methods, such as steam, dry-heat, ethylene oxide, formaldehyde or ionizing radiations result in a different effect on the biomaterial surface and their subsequent behavior in vivo [9]. Titanium (Ti) has been widely used as an implant material due to its biocompatibility and excellent corrosion resistance. In order to enhance osseointegration of dental and orthopaedic implants made of Ti, many surface modification strategies have been pursued, focusing on the important role of the biomaterial surface properties [6].

Annunziata et al. evaluated the effects of the argon plasma treatment on different Ti implant surfaces previously exposed in vitro to bacterial contamination. They found that the argon plasma technology could be efficiently used to decontaminate/sterilize previously contaminated Ti implant surfaces [7], however, they did not evaluate any possible adverse effect of sterilizing method on implant characteristics. Park et al. evaluated the effect of cleaning and sterilization on Ti implant surface properties and cellular response. In their study, different methods for Ti sterilization that included autoclaving, gamma irradiation, oxygen plasma, and ultraviolet were used [6]. The study indicated that recleaning and resterilized Ti

implant resulted in surface alterations that could potentially affect the osseointegration of the surface and other biological behavior of the biomaterial in vivo.

Based on the latter study, we conclude that resterilization of dropped components in a hospital setting could lead to detrimental alteration of the biomaterial surface of the implant being used and adversely affect the in vivo behavior of the implant. Thus, and whenever possible, a new implant should be used to replace the dropped implant. If this is not possible, the dropped implant needs to be processed very carefully to remove all potential microorganisms on the surface [10]. This may include chemical cleansing of the implant with bactericidal agents such as chlorhexidine or povidone iodine. The purpose of cleaning is to remove or reduce visible soils, blood, proteins and debris [11]. To resterilize the implant, it should be subjected to steam-heat, as irradiation method for sterilization is not available in hospitals. Flash sterilization is not recommended [1]. The wound should also be copiously irrigated with antiseptic solution, such as aqueous povidone iodine, prior to the use of the dropped implant.

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