



The Intraoperative Gamma Probe for Sentinel Node Biopsy: A Critical Medical Product

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Clinical Image

Gamma probes, used for intraoperative detection of Technetium ^{99m}-marked Sentinel Lymph Nodes (SLN) for several malignancies including melanoma are critical medical products from hygienic perspective. They enter sterile body cavities and confer a great risk of surgical site infection if the sterile coverage ruptures and the unsterile instrument gets into contact with the operation field.

Guidelines e.g. the Center for Disease Control "Guideline for disinfection and sterilization in Healthcare facilities" state that such probes should be purchased as single-use sterile devices, or **multi-use probes should be sterilized for each procedure** Figure 1a [1]. Infection prevention is essential in order to ensure safe operation procedures for the patients. The situation is similar to that of intraoperative use of ultrasound probes [2]. A wide range of gamma probe systems is available for SLN detection; however, all models share the same hygienic handicap. A proper hygiene, handling and disinfection of gamma probes is essential for proper functionality and avoidance of potential cross-contaminations which might endanger the patient's health. **Unfortunately, most probes operate with high-voltage current and thus steam sterilization, ethylen-dioxide, hydrogen peroxide gas plasma or liquid chemical sterilants cannot be used because they destroy the probe's electrical detection system** [3]. Therefore each surgical unit has to build its own concept for intraoperative probe handling; we have no established standard so far and there are no published surveys evaluating the potential gamma probe cross-contamination risks. In order to assess the status quo in Germany, we conducted a questionnaire-based study via the German Society for Dermatosurgery (DGDC) network in 2015. Thirty-eight dermatosurgery units returned our questionnaire designed to assess the hygienic details regarding intraoperative usage of gamma probes as well as contamination risk.

The survey revealed that in 66% of the hospitals internal SOP's regulated the intraoperative hygienic use of the probes for intraoperative purposes, while 34% of the hospitals have no such protocol Figure 2a. Almost all centers (97.4%) were aware of the probe's hygienic requirements as depicted in Figure 2b. **Among the 38 clinics, 70.3% use not sterilized gamma probes covered in a sterile plastic protection cover** Figure 1b and Figure 2c 21.6% use not sterilized probes with

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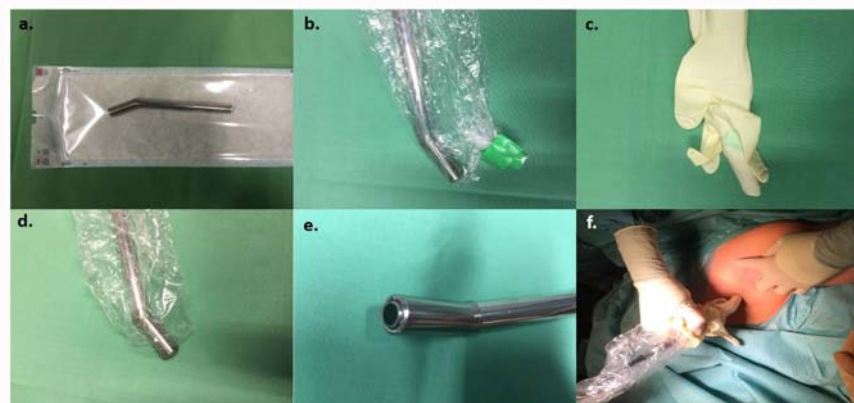


Figure 1: Hygienic use of gamma probe in intraoperative setting. a. Model of sterilized probe; b. Not sterilized gamma probe with foil protection cover; c. Not sterilized gamma probe, with protection cover and sterile glove; d. Cover perforation; e. Defect probe head; f. Intraoperative use of gamma probe, with protection cover and sterile glove.

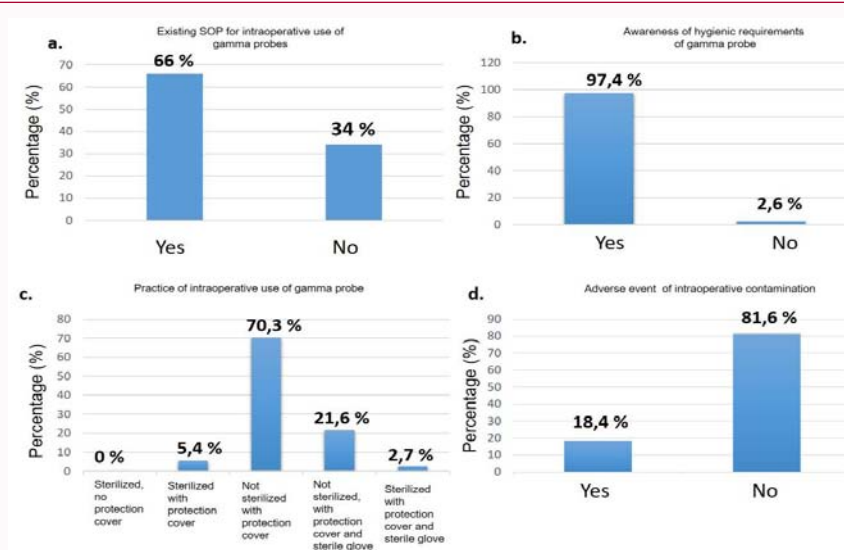


Figure 2: Results of the questionnaire-based study regarding standard hygienic measures of intraoperative use of gamma probes as well as contamination risk. a. Existing SOP for intraoperative use of gamma probes: in 66% of the hospitals, the SOP regulates the intraoperative hygienic use of the gamma probes, while 34% of the hospitals do not have such protocols; b. Awareness of hygienic requirements: 97,4% of the centers are aware of the hygienic requirements and function control of the probe; c. Practice of intraoperative use of gamma probe: 70,3% of the clinics use not sterilized probes in sterile plastic cover, 21,6% use a double sterile coverage of the probe, 5,4% sterilize the probe and use a sterile cover while only 2,7% use sterile probes with double sterile covering; d. Adverse event of intraoperative contamination: no cases of perforation in 81,4% of clinics, while 18,4% admit to have had cases of intraoperative perforation of the covering.

sterile protection cover and sterile glove Figure 1c. Only 5.4% of the departments sterilize the gamma probe and use a sterile protection cover during surgery, while 2.7% use a sterile probe with sterile protection cover and sterile glove. Concerning potential cover perforation and wound contamination (Figure 1d) 81.6% of clinics reported no such event so far. **However, 18.4% experienced intraoperative perforation, leading to intraoperative contact of the probe with tissue and blood** Figure 2d. There was no intraoperative report of radioisotopic gamma probe contamination, an incident that would render the probe useless for the detection procedure. The survey revealed clearly that in order to secure sterility, usually a sterile protective plastic foil cover is used [4]. The connection between collimator sleeve and sterile cover is closed with sterile adherent tape. After surgery, the cover is removed and disposed of; however, after cover removal, the probe handling could potentially result in smear infections and contaminations (HBV, HCV, HIV, MRSA etc) [4]. Furthermore, **in case of intraoperative perforation, the probe head can be contaminated with blood and wound fluid. Thus there is also a risk of pathogen transmission between patients if the heads cannot be cleaned accordingly. Furthermore, the head must always be checked for material integrity as collimators might break into parts increasing the risk of cover perforation** Figure 1e. There are reports regarding cases of hepatitis B/C transmission from inadequately decontaminated transoesophageal echocardiography probes or endocavitary ultrasound, i.e. devices with similar critical hygienic status and use [5,6]. Therefore sentinel probes should be sterilized between patients, and if not possible, at least disinfected [1,7]. In Germany the use of impregnated wipes for manual disinfection is a widespread strategy and often the sole option for sentinel probes, however it is sometimes not properly performed. A study revealed that up to 21% of ultrasound probes remain contaminated after disinfection with such wipes [8]. Our survey shows that there is no general protocol for intraoperative use of gamma probes and every commercially available probe has distinct

hygienic measures. Intraoperative cover perforation represents an important contamination source for patients; hence we recommend the usage of a double sterile coverage during surgery (sterile covering + sterile glove) to diminish this risk Figure 1f. Taken together, this survey shows that wound contamination with the sentinel probe is a rare event, but nevertheless the need for staff education regarding handling gamma probes exists. Each centre needs compulsory guidelines for processing such critical products in perioperative setting in order to prevent potential infection transmission and ensure the patients' safety.

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