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TRACKING OF SURGICAL SPONGES IN THE OPERATING ROOM: DESIGN AND VALIDATION OF AN INNOVATIVE MEDICAL DEVICE

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During surgical procedures in operating room about 300 surgical tools (including needles, sponges, and instruments) are used. Previous studies stated that a retained surgical item in patients (gossypiboma) is one of a most critical adverse events. For the possible negative effects on patients, doctors and healthcare facilities, this event is classified as "Sentinel Event" by the Italian Ministry of Health. In hospital facilities, there are rigorous procedures and protocols for the management of instrumentation and surgical sponges during surgery. For the surgical sponges, these protocols require the recording of the initial number and the cross-counting of the sponges used and those removed by the patient at the end of surgery, in order to ensure traceability of the devices at any times. In order to provide a valuable support to this activity, a study was developed to design, implementation and testing of an automatic surgical sponges management system during surgery. The system is based on Radio Frequency Identification Technology (RFId). It's a complex hardware and software architecture that, for its intended use, is classified as a Medical Device, according to Council Directive 93/42/EEC as amended by Directive 2007/47/EC. Results obtained after *in vitro* and in vivo testing, has demonstrate that the system developed allows a significant reduction of the clinical risk in surgical practice. Hundred percent retained sponges were detected correctly, even when they were overlapped. No false positive or false negative was recorded. It was demonstrate also a reduction of the surgery times into the operating room.

THE MEDICAL STANDARD OF CARE IN CYBERMEDICINE: E-COMMUNICATION BETWEEN DOCTOR AND PATIENT

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Cybermedicine is becoming increasingly frequent around the world due to its many benefits. However, health care players are hardly aware that cybermedicine is likely to promote specific medical faults, eventually avoidable in conventional medicine. In this regard there are two dimensions that demand consideration: hazards derived from technical errors promoted by technology, on the one hand; the excessive trust the human operator has on technology, on the other hand. Both of them can easily fuel medical liability lawsuits. Therefore, the existing standard of care must be adapted to the specificities of cybermedicine. For instance, to communicate at distance with a patient - by telephone, e-mail or a website – requires proper communication rules, namely regarding security and privacy in communication, but also concerning the proper behaviour to be adopted by the health care professional. This concern is particularly relevant when the doctor never had before a personal contact with the patient, because the risk of misrepresentation is very high. In addition, within cybermedicine the doctor is required to possess particular technological skills in order to use sophisticated methods to communicate with distant patients and other health care staff, to operate complex at distance technological devices and to maintain updated the patient's health record, usually electronic health records which may be connected with different health care facilities. This presentation intends to analyse the particular rules of the cyber-standard of care and to help physicians to avoid liability law suits.