

PEROPERATIVE LOSS OF THE STERILE STATE OF A UNIQUE SURGICAL INSTRUMENT:

A PRACTICAL TOOL FOR DECISION-MAKING

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INTRODUCTION OBJECTIVE

For some expensive or seldom used reusable medical devices, only one model is available in our hospital, making accidental peroperative loss of sterile state an acute problem. The aim of this work was to develop a check-list to guide surgical teams' decision-making when this occurs.

METHODS

A multidisciplinary group, associating the Infection Control and Prevention, Surgical Coordination and Sterilization Departments, used a stepwise clinical path methodology. Three decision-making steps were identified:

- surgical and instrumental alternatives,
- sterilization alternatives,
- postoperative actions.

The check-list includes medical risk analysis at every step.

RESULTS

When a one-of-a-kind instrument accidentally loses its sterile state, first must be considered its replacement (by an identical or equivalent device from another box or another surgical unit), then a change (or postponement) of surgical procedure. Surgical and anesthesiological risks are evaluated and checked, and if no alternative can be found the process moves on to consider sterilization options. These are either manual cleaning followed by sterilization or, if a four-hour wait is impossible, management by the surgical unit using a degraded process of thorough manual cleaning followed by high-level disinfection with peracetic acid. Finally, whatever solution was chosen, the check-list is consigned to the patient's medical record and clinical follow-up is mandatory at 6 and 12 months post-operative. The incident must be reported to the hospital's Risk Management Department.

CHECK LIST: WHAT TO DO IN CASE OF PEROPERATIVE LOSS OF STERILE STATE OF A UNIQUE REUSABLE MEDICAL DEVICE?

RMD = Reusable Medical Device. Concerns neither single-use devices nor implantable devices.

REQUIRED INFORMATIONS

DATE: _____	PATIENT LABEL
OPERATING ROOM: _____	
HEALTH SUPERVISOR: _____	
SURGEON: _____	
ANESTHETIST: _____	
OPERATING ROOM NURSE: _____	
TYPE OF SURGERY: _____	
NAME OF THE SURGICAL BOX: _____	SURGICAL BOX LABEL
NAME OF THE SURGICAL INSTRUMENT: _____	

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STEP 1/4: ALTERNATIVES ANALYSIS

- Does the RMD exist as a satellite instrument? YES NO
- Is there an identical surgical box available? (*) YES NO
- Is there another surgical box containing the RMD in the operating room? (*) YES NO
- Is there another surgical box containing the RMD in another operating room? (*) YES NO
- Is it possible to use an equivalent but not identical RMD? (**) YES NO
 - Is it available in the same surgical box? YES NO
 - Does the equivalent RMD exist as a satellite instrument? YES NO
 - Is there a surgical box containing this RMD in the operating room? (*) YES NO
 - Is there a surgical box containing this RMD in another operating room? (*) YES NO

If you answered NO to each item, go to step 2.

(*) The search of the RMD in other surgical boxes can be realized with the help of the sterilization unit's managers.
(**) The choice of the equivalent RMD will be at the discretion of the surgical team.

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STEP 2/4: ANALYSIS OF THE SURGERY RISK

If you answer NO, go to the next question.

- Did the surgery start? (incision) YES NO
- Can the surgery be changed? (change of surgical procedure) YES NO
- Can the surgery be postponed? YES NO
- Can the anesthesia be extended? YES NO
If yes, how long? _____
- Risks related to:
 - Postponement: _____
 - Longer duration of the surgery: _____

Risks are evaluated and checked by surgical and anesthesiological teams: YES NO

Name, grade and signature: _____

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STEP 3/4: DEGRADED OPTIONS

In case of absolute necessity (only one model of RMD available in hospital, postponement and change of surgical procedure impossible), it will be possible to perform the following actions:

Priority 1: Management by the sterilization unit (at least 4h):
Manual cleaning followed by sterilization

- During the opening hours of the sterilization unit ;
- Inform the sterilization unit's managers of sending this RMD by phone call ;
- Attach a copy of this check-list to RMD.

Priority 2: Management by the surgical unit:
Manual cleaning followed by high-level disinfection (without sterilization)

- Manual cleaning: Double immersion in detergent-disinfectant (ANIOSYME DD1) + brushing (mechanical action) ;
- Rinsing with sterile water and drying with sterile compresses ;
- Immersion in peracetic acid (ANIOXYDE 1000) ;
- Rinsing with sterile water and drying with sterile compresses.

CHOSEN SOLUTION: Sterilization Disinfection

Name and signature of the surgeon: _____

STEP 4/4: ACTIONS TO ACHIEVE FOLLOWING THE SURGERY

- Declaration of the incident to the hospital's Risk Management Department via the dedicated application.
- Traceability of the decision in the patient's medical record = archiving of this document.
- Scan this document and addition to the computerized patient's medical record.
- Risk analysis to complete.
- Patient information.
- Clinical follow-up at 6 and 12 months post-operative.

DISCUSSION CONCLUSION

This check-list enables a haste-free, systematic decision-making process, allowing careful risk analysis at every step. The ultimate degraded option of manual cleaning and high-level disinfection is an improvement on currently observed practices. However, provisions must be made to insure the procedure is not resorted to for readily available instruments or single-use or implantable devices. Indeed, our check-list applies only to reusable medical devices. Analysis of incident reports should help finding long-term solutions to recurring issues (for example: purchase of instruments).