



Professional standard for Loaner instrumentation

Standard for loaning or renting of surgical instruments

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Preface

This field norm can be used by all parties involved in the loaning or renting, the receiving, the preparation for use, the using and or dispatching of medical instruments. The field norm does not reduce the responsibility of each party and is aimed at guaranteeing the safety of patients and of staff members.

The supplier / organisation that lend / borrows the instrument, protects the receiver to whom the instruments are sent, from a risk of contamination that could lead to unsafe situations in the supplier / organisation when handling the instruments.

Version 03 is a revision of the previous field norms: versions 01 of December 1997⁽¹⁾ and 02 of November 2007⁽²⁾, drawn up by the project group Loaner Instrumentation, consisting of representatives of the Dutch Association of Experts Sterile Medical Devices (VDSMH), the Dutch Sterilization Association (CSC), the Dutch Society of Managers of Operating Theatres (NVLO), the Dutch Network of Healthcare Assortment Coordinators (LNAG) and the Dutch Federation of manufacturers, importers and traders of Medical Products (Nefemed).

In revision 03, a Program of Requirements (PoR) is added to define the requirements for sets of loaner instrumentation. In December 2007, in a meeting with representatives of the CSC and the VDSMH, the Nefemed stated that all loaner instrumentation, new and old, will meet the PoR on January 1, 2011⁽³⁾.

In version 04, November 2010, there are some small, yet important adjustments being made. Since there are longer instruments presented the maximum length of a mesh tray has been changed in 52 cm. Also the expression 'decontamination' has been removed from the text. Instead of this term the process to be executed is called by its name. No longer not only a time and temperature in the process of steam sterilization is described but a bandwidth is being mentioned.

All involved parties ensure that this field norm shall be brought to the attention of and applied within their respective focus areas. The Dutch Health Care Inspectorate has been informed about this decision.

The Project Group

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1. Introduction

Several parties are involved when instruments are rented or loaned, namely the user (e.g. the surgeon), the surgical unit (OR), the supplier, the purchasing department, the Expert Sterile Medical Devices (DSMH) and the Central Sterilization Department (CSD).

The aim of this standard is the fine-tuning of each other's wishes and possibilities. The instruments can then be at the disposal of the user at the right time, the length of stay in the hospital is kept to a minimum and the CSD can clean and sterilize the instruments in the correct way.

1.1 Definitions

Loaner instrumentation:

These are medical devices/instruments owned by a supplier and that are temporarily, usually for a small fee, loaned to an organisation. The organisation uses the medical devices for a fixed number of interventions or a period of time. If an instrument is loaned for several interventions or a longer period, a separate agreement must be made about the inspection of the functionality between uses and about repair in case of failure (who will do it and who will pay for it).

Note:

In this document, the term 'loaner instrumentation' is used for single loaner instruments and for sets of loaner instrumentation.

Organisation:

This is a hospital or any other health care facility, obtaining loaner instrumentation from a supplier for a fixed period of time or number of interventions.

Supplier:

Owner of the loaner instrumentation.

1.2 General agreement

1. The loaner instrumentation will be loaned under the express condition that the material will not be used (and has not been used) for human post-mortem examination and/or animal testing⁽⁴⁾. To prevent the transmission of, for instance, prion disease, it is prohibited to use instruments that have previously been used on animals, cadavers, and/or in the anatomical pathology laboratory⁽⁴⁾, on human beings.
2. The supplier is responsible for the maintenance of the set of loaner instrumentation if the required procedure has been observed.
3. The starting point for the procedure to be followed, are a number of criteria, defined in European⁽⁵⁾ and national⁽⁶⁾ legislation and in the guidelines and standards contained in the Dutch binder Sterilization and Sterility (*Wegwijzer Richtlijnen Steriliseren en Steriliteit*) from the Dutch standardization institute NEN⁽⁷⁾.

4. Sterilization of loaner instrumentation must meet the requirements of the Dutch Decree on sterilized medical devices in hospitals (*Besluit gesteriliseerde medische hulpmiddelen in ziekenhuizen*⁽⁸⁾) or the Dutch Decree on contract sterilization medical devices (*Besluit sterilisatiebedrijven medische hulpmiddelen*⁽⁹⁾).
5. Every medical device needs to be CE marked⁽⁵⁾.
6. According to the *Medical devices directive*⁽⁶⁾; annex 1, article 13.6, every medical device that can be reused must be supplied with “information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.”. The content of the information to be supplied must meet the requirements given in EN ISO 17664⁽¹⁰⁾.
7. In case the supplied devices need to be cleaned, disinfected, and sterilized before use, they shall not cause any risk for the patient and/or the staff, if the instructions are being followed correctly.
8. If the washer disinfector(s) in the CSD of the institution annually successfully is (are) validated, it is permitted to return the loaner instruments to the supplier after use in the hospital and after cleaning and disinfection in the CSD department. If there is no (recent) validation report available to show that the instrument can be cleaned and disinfected effectively in the available washer disinfector, sterilization must be the final step. If the procedure can not be performed within the own organisation, or if for a different reason the required procedure cannot be performed, it is necessary to consult the supplier.
9. Cleaning, disinfection and sterilization takes place under responsibility of the Expert Sterile Medical Devices (DSMH). He/she will also assess whether the instruments have been adequately supplied and can be cleaned, disinfected, and sterilized within the process (equipment) available to the organisation.

2. Procedure within the organisation

1. The request for a “loan order” by the client, addressed to the Purchasing Department, should be in accordance with the applicable procedure of the organisation. This order comes with a request for the terms & conditions of the supplier and the documentation needed by the OR and the CSD.
2. The client within the organisation (user, surgeon, OR, etc.) will inform the CSD about the loaner instrumentation that has been ordered, the time the loaner instrumentation will be delivered to the CSD, the date and possible time it will be used in the OR, and the date it will be collected by the supplier.
3. The client within the organisation should not plan the intervention until the conditions for an adequate processing in the CSD can be met, and if an explicit arrangement has been made about the moment of delivery to the user / the OR.
4. The client ensures that, as soon as the information about the loaner instrumentation is received, this information will be forwarded to the CSD.

5. The client receives and checks the loaner instrumentation at a by the organisation pre-determined location and sees to a timely delivery of the set and its accessories to the CSD.
6. Cleaning, disinfecting, and sterilization will be performed at the CSD.
7. The CSD ensures of a timely delivery of the sterilized loaner instrumentation to the user / OR.
8. The user / OR will deliver the loan instrument back to the CSD directly after use.
9. The CSD sees to it that the loaner instrumentation is cleaned and disinfected as soon as possible (see chapter 1.2 section 8).
10. The CSD returns the cleaned, disinfected and/ or sterilized loaner instrumentation (see chapter 1.2 section 8) to a location, pre-determined by the organisation and known to the supplier, so the supplier can collect it.

3. Responsibilities

When loaner instrumentation is provided, it should always be expected to be supplied for the first time, and the instrument will include all the necessary documentation. In order to keep the length of stay of the loaner instrumentation within the organisation as short as possible, it is recommendable to provide the necessary information (hard copy or digital) before delivery of the instrument. This concerns only documentation of the current loaner instrumentation. Please, refer to appendix 1 Program of Requirements.

The length of stay within the organisation shall be limited to 4 days: 1-2 working days for the processing on the CSD, 1 OR day (= user day) and 1 day for preparation of the return shipment.

The CSD needs at least 24 hours (1 working day) to prepare the loaner instrumentation for the OR. When the loaner instrumentation is sent back to the CSD immediately after the intervention, the loaner instrumentation will be ready for shipment to the supplier within 1 working day, including the Declaration of Decontamination. The length of stay within the organisation also depends on the duration of the intervention and the extent of the loaner instrumentation set, and how time-consuming its processing is.

The loaner instrumentation must be delivered at the CSD at least 24 hours (1 working day) before the scheduled intervention, in closed transport packaging accompanied by the necessary documentation (see appendix 1 Program of Requirements).

3.1 Supplier

The supplier is responsible for the functionality of each instrument and checks it before shipment.

The supplier is responsible for the loaner instrumentation being delivered at the agreed time, intact, complete, and clean, and provided with all the necessary documents (see appendix 1 Program of Requirements).

As soon as the supplier knows which loaner instrumentation will be delivered, the CSD is being informed by the client.

It is important that the supplier documents the history of the loaner instrumentation (which instruments to which organisation, including the date and the decontamination form), so that the organisation can gain insight into the history, should they request it.

At delivery of the loaner instrumentation to the organisation, the supplier declares that the instruments have been decontaminated. In this case, he cannot make use of the declaration released by a previous user, as the supplier and the receiver are the parties involved, not the previous users.

3.2 Client (user, surgeon, OR, etc.)

The client orders the loaner instrumentation in time and informs the CSD. The official name of the loaner instrumentation, as used by the supplier, will be used when ordering and in all means of communication.

The completeness of the shipment will be checked by the client, unless otherwise agreed within the organisation. The client is responsible for the transport of the loaner instrumentation and its documents to the CSD, unless the procedure of the organisation says that delivery should be made directly to the CSD.

On return of the loaner instrumentation, the client is responsible for the packaging of the complete instrument set with all its documents, and in the same way as it was delivered.

3.3 Central Sterilization Department

The CSD is responsible for the processes in the CSD and sees to it that the loaner instrumentation is being cleaned, disinfected, sterilized, and delivered in time to the user / OR.

If the cleaning and disinfection processes have undergone their yearly validation, it is sufficient for the return shipment to the supplier to clean and disinfect the loaner instrumentation. If there is no (recent) validation report available to show that the instrumentation can be cleaned and disinfected effectively in the available washer disinfectant, the instrumentation must be sterilized after cleaning and disinfection.

The CSD sees to it that the loaner instrumentation is ready in time for the return shipment and that the loaner instrumentation is accompanied by a completely filled out Declaration of Decontamination.

4. Clarification of the Program of Requirements

Appendix 1 contains the Program of Requirements for loaner instrumentation (PoR). In this chapter, the main issues of the PoR are explained.

The criteria for loaner instrumentation are specified in the PoR. The PoR is in accordance with the Evaluation Criteria for new Recirculating Medical Devices ⁽¹¹⁾.

The PoR is mainly aimed at the supplier. Nevertheless, the organisation is responsible for the loaner instrumentation and its accessories to be clean and complete when shipped back to the supplier.

The supplier as well as the organisation can call the other party to account if the loaner instrumentation is being delivered dirty or incomplete, and they are allowed to charge the related costs.

The loaner instrumentation must be accompanied by several documents (see PoR 1.2). It is recommendable to deliver the documents digitally soon after placing the order. The same goes for pictures of the loaner instrumentation. This will allow the organisation to make the necessary preparations and the CSD to create a file on the loaner instrumentation.

It is useful, for both the supplier and the organisation, that a loaner instrumentation set, besides a set description, includes a checklist, which facilitates checking the completeness of the instrument on receipt and on return.

All instruments must be CE marked. In July 2007, the Dutch Health Care Inspectorate sent out a letter⁽¹²⁾ stating that loaner instrumentation placed on the market before June 14, 1998, and being part of a set, does not have to be CE marked. "Loaner instrumentation being placed on the market as a procedure pack need to be CE marked, when not all individual included parts are CE-marked and does not need to be CE marked as a pack, if all included medical devices are CE-marked".

5. References

1. Field norm Loaner Instrumentation December 1997, Central Sterilisation Club
2. Field norm Loan Instrumentation November 2007, Central Sterilisation Club
3. Decision list from meeting Nefemed-VDSMH-CSC nfm.act75, December 10, 2007
4. Letter concerning Prions, Dutch Health Care Inspectorate (IGZ), June 17, 1996, reference FMT-U-963214
5. Medical Devices Directive 93/42/EEG
6. Dutch Decree on Medical Devices (Stb. 1995,243)
7. Wegwijzer richtlijnen Steriliseren en Steriliteit 301.081, NEN
8. Dutch Decree on sterilized medical devices in hospitals (Stb. 1983,281)
9. Dutch Decree on contract sterilization medical devices (Stb. 1989, 248)
10. NEN EN ISO 17664; Sterilization of medical devices - information to be provided by the manufacturer for the processing of resterilizable medical devices (2004)
11. Evaluation Criteria for New Recirculating Medical Devices - RMH, VDSMH, February 2007
12. Letter Loaner Instrumentation IGZ, July 9, 2007, reference 2007-46401/pr8/JK/cg and letter Loaner Instrumentation IGZ, July 12, 2007, reference 2007-47336/pr8/JK/cg

Appendix 1

Program of Requirements

In this PoR, 'OR' can also be replaced by 'user'.

1. Supply

- 1.1 The loaner instrumentation must be in the CSD at least 24 hours (1 working day) before the scheduled OR time, together with all the necessary documents. With new and complex loaner instrumentation the OR and the CSD must be allowed to receive the loaner instrumentation 1 or 2 days earlier.
- 1.2 The loaner instrumentation must be accompanied by an up-to-date:
 - a. Declaration of Decontamination completed by the supplier;
 - b. Description of the set per tray;
 - c. Picture per tray;
 - d. Instructions for cleaning, disinfection, and sterilization;
 - e. Instructions for the OR.
- 1.3 Documents b, c and d will be, at request, provided digitally to the CSD.
- 1.4 Only loaner instrumentation that meets this PoR of the professional standard for loaner instrumentation, will be accepted.

2. Compounds

- 2.1 Sets of loaner instrumentation come in different compounds. In that case, the supplier should indicate, before delivery to the OR and CSD, which compound is sent.
- 2.2 If an existing and known set of loaner instrumentation is or will be adapted with, for instance, (new) loaner instrumentation or otherwise, the supplier should inform the OR and the CSD beforehand.
- 2.3 A tray with contents can not be heavier than 8.5 kg.

3. Name

- 3.1 The supplier must use a univocal name in purchase orders, at delivery, and in the documentation.
- 3.2 The documents must indicate to which loaner instrumentation or set of loaner instrumentation they apply.

4. Instructions for cleaning, disinfection, and sterilization

- 4.1 The content of the processing instructions must meet NEN-EN-ISO 17664.
- 4.2 The instructions must be in comprehensible Dutch.
- 4.3 The instructions may only contain references to standards, guidelines and procedures current in the Netherlands.
- 4.4 The instructions must clearly state which instrument(s) need(s) to be disassembled and how.

5. Acceptance loaner instrumentation

- 5.1 Only visibly clean loaner instrumentation is accepted.
- 5.2 In case of dirty loaner instrumentation, the complete set will be sent back.
- 5.3 In exceptional cases , a set of loaner instrumentation with a dirty instrument will not be sent back, but the instrument will be cleaned by the CSD. The CSD will then charge these extra cleaning costs to the supplier. Refer to section 12. Claims.

6. CE marking

- 6.1 The loaner instrumentation must be CE marked ⁽¹²⁾.
- 6.2 In absence of an CE marking on an instrument, a written statement must be included, saying that the concerned loaner instrument has been CE marked, or on the outside of the set (on the tray for example) must be an indication that the total set of loaner instrumentation has been CE marked ⁽¹²⁾.

7. Reference code

- 7.1 All loaner instruments must have a legible reference code (this is the code used by the supplier). The relevant reference code must also be indicated on the pictures of the loaner instrumentation set.

8. Trays

- 8.1 The loaner instrumentation must be packed in mesh trays (no plastic trays).
- 8.2 The mesh tray may not have any sharp edges or projections .
- 8.3 The mesh tray must have a format conform DIN or ISO or derive from that format (maximum H x L x W: 48*25*10 cm respectively 46*32*10 cm). For exceptionally long instruments it is allowed to use a tray with a maximum length of 52 cm.

9. Arrangement

- 9.1 Only 1 layer of instruments / implants is allowed per tray. An inlay that can be placed easily in one movement of the hand, may be used.
- 9.2 Instruments should only be fixated if this is required because of the overview on the tray or because of the instrument to be fixated is fragile.
- 9.3 If fixation is necessary, this should be done with as little touching as possible between the fixating material and the instrument or the implant. Other options are: a four-point fixation (or less), radial-fixation, or similar; or separated compartments with open metal strips.
- 9.4 "Bottom plates" indicating the name and the reference code of the instrument or the size of the fitting implants must be avoided.
- 9.5 Fixation with silicone mats or anything similar is not desirable.
- 9.6 The fixation must not be obstructive to the cleaning procedure.
- 9.7 The tray must not be too full; it must be filled in such a way that all instruments can be reached easily by water and detergents, and spray shadow must be avoided.

10. Implant racks

- 10.1 Implant racks must be designed in such a way that they do not have a negative effect on the cleaning or disinfecting process.
- 10.2 Implant racks must be designed in such a way that the implants do not 'swim' in the washer disinfectator .
- 10.3 Implant racks must be made of stainless steel.

11. Logistics

- 11.1 The supplier delivers the loaner instrumentation and its documents at a place chosen by the client.

12 Claims

- 12.1 If the supplied loaner instrumentation or part of it is dirty (visibly unclean) when delivered to the organisation, the supplier is responsible for a timely replacement. In case a replacement set of loaner instrumentation can not be delivered on time, cleaning and disinfection of the loaner instrumentation should be considered being done by the organisation. It is the supplier's responsibility to communicate the above mentioned situation adequately and on time. The organisation will then charge the extra costs resulting from this situation to the supplier.

Appendix 2

Cleaning, disinfection and sterilization protocol for loaner instrumentation

Name loaner instrumentation and name supplier:

Order number:

Date:

Are all lumen and joints reachable by water and detergents?	YES / NO
If NOT, to which instrument does this apply?	
Is / are the instrument(s) submersible?	YES / NO
If NOT, which instruments are not? Add instructions for manual cleaning.	
Is mechanically cleaning possible?	YES / NO
If NOT, to which instruments does this apply? Add instructions for manual cleaning.	
Is thermal disinfection possible?	YES / NO
If NOT, to which instruments does this apply? How should these instruments be disinfected? Add instructions for disinfection.	
Is ultrasonic cleaning possible (25-50 kHz)?	YES / NO
Is disassembly needed before cleaning?	YES / NO
If SO, to which instruments does this apply? Add instructions for disassembly and assembly.	
Are paraffin containing lubricants allowed?	YES / NO
Is a special operational test required?	YES / NO
If SO, to which instruments does this apply? Add instructions.	
Is / are the instrument(s) resistant to:	
acidic products (pH < 7)	YES / NO
neutral products (pH 7-10)	YES / NO
alkaline products (pH 11-12)	YES / NO
Is drying at a temperature of 110°C possible?	YES / NO
If NOT, which instrument(s) is / are not?	
The instrument(s) can be sterilized:	
with steam * 121°C at least 15 minutes (a validated process)	YES / NO
with steam * 134-137°C at least 3-3,5 minutes (a validated process)	YES / NO
gas plasma hydrogen peroxide (Sterrad®)** (a validated process)	YES / NO
differently, namely:	
* Steam sterilization in the Netherlands is always a process with fractioned pre-vacuum.	
** Gas plasma sterilization in the Netherlands is always a process with a full cycle.	

Appendix 3

Declaration of Decontamination

The undersigned declare that the set of loaner instrumentation (full name of the set or instrument):

.....
.....

with order number:

supplied to:

on (date):

has been cleaned and disinfected (see chapter 1.2, section 8)

has been sterilized (see chapter 1.2, section 8)

*tick were appropriate

and are not used for post mortem examination and / or animal testing (see chapter 1.2, section 1)

For supply:

Location: Date:

Name supplier:

Name representative:

Signature:

For return shipment:

Location: Date:

Name organisation:

Name staff member CSD:

Signature: