Description and application

Carefully read these instructions for use (IFU) – hereinafter referred to as 'instructions' – prior to using the device.

These instructions are supplied by 'NTOC medische techniek B.V.' hereinafter referred to as 'NTOC', and its subsidiary companies and other affiliated companies. NTOC designs and manufactures cassettes (with fixation) to facilitate the decontamination, sterilisation and transport of reprocessable devices (within a health institution). These cassettes are referred to as 'NTOC cassette' or abbreviated to simply 'cassette'.

The purpose of these instructions:
- to describe the components of which the cassette consists, and how they can be used in combination with the devices in the cassette;
- to issue instructions on the handling and reprocessing of the cassette;
- to issue instructions for inspection and maintenance to determine when a cassette and/or component has reached the end of its lifetime and must be replaced.

The intended purpose of the cassette:
- to facilitate the reprocessing of devices in the cassette by fixing the devices as efficiently as possible using the minimal contact concept;
- to protect the devices in the cassette against damage that can occur during reprocessing, transport and storage within the health institution;
- to promote a clear overview of the devices in the cassette.

Characteristics:
- Cassettes have an open structure for optimal cleaning and steam penetration, and are produced from stainless steel and/or polymer materials.
- The cassettes are accessories of the devices in the cassette such as surgical instruments and/or implants, referred to in these instructions as 'devices'.
- The cassette configuration may consist of a cassette possibly with additional removable cassettes and/or components that can together be configured to form a single set.
- Cassettes and components are available in different dimensions and types, each characterised by a different shape.
- Cassettes and components with fixation may be placed on the market as a set or individually. These are considered as accessories to the devices in the cassette and shall bear the label: 'NTOC cassette' and alternative name 'instrument cassette'.

Definitions:
- Cassette configuration: cassette including components, if any, specifically designed for specific (combinations of) devices of a particular type and manufacturer. A cassette configuration is seen as a variant of the cassette family.
- Component: components including inlays, screw racks, lids and auxiliary bins.
- Fixation: the clamp or contact point to hold the devices in the cassette.
- Reprocessing: a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device. The cleaning and disinfection process is further referred to in these instructions as the 'decontamination process'.
- Minimal contact concept (MCC): fixation of the devices in the cassette with a minimum number of contact points.

Demarcation
- For the reprocessing of the devices, other than the cassette and accompanying components, the instructions from the manufacturer of the devices in the cassette will prevail.
- These instructions describe the actions that must be taken for the reprocessing of the cassette and the devices placed and/or fixed in the cassette. The instructions for this cassette and/or the components relate only to the contact/interaction made by the NTOC cassette at the fixation point with the external surface of the devices in the cassette.
- The cassettes and/or components are suitable for internal transport within the health institution (for example transport between operating theatre and central sterilisation department).
- Users are qualified personnel such as staff of the operating theatre and/or central sterilisation department who may be assumed to have basic knowledge of handling of the devices in the cassette. They must be trained in hospital policy and procedures according to the currently applicable guidelines and standards.

Instructions are subject to change. The most recent version of these instruction is always available online (via the website of NTOC) and may be sent by email and/or post free of charge, on request. In the event of any doubt about the meaning or translation of the text of these instructions, the English text takes precedence.

Preparation for decontamination

Putting into service
- Prior to the first use, remove all original packaging such as protective material, bags, polystyrene and cardboard.
- Handles, if any, must be folded away with due caution to prevent damage during internal transport. When replacing handles, account must also be taken of any components of the cassette and devices (with accompanying hoses) in the cassette.
- When supplied, the cassettes are NON STERILE. NTOC cassettes are suitable for reprocessing. Decontamination and sterilisation must be carried out prior to putting into service.

After use
- After use in the operating theatre, as far as possible remove any visible contamination or surgical residue with a damp or lint-free cloth.
- The time between contamination with surgical residues and the reprocessing will have a negative influence on the success of the reprocessing. In addition, long-term exposure to contamination can result in corrosion. It is recommended that the cassette including components and devices in the cassette be reprocessed as quickly as reasonably practical after use in the operating theatre.

Reprocessing of devices in the cassette
- Devices must be reprocessed according to the instructions issued by the manufacturer of the device.
- Devices that can be disassembled must be disassembled according to the instructions from the manufacturer, prior to reprocessing.
- After the decontamination process, the disassembled devices must be reassembled and returned to the correct position in the cassette. Components must also be stored in the intended storage location.

Decontamination

Manual pre-cleaning

General comments
- Exclusively manual cleaning of the cassette and accompanying components is not recommended. Automated decontamination will deliver a better and more reliable final result. If the cassette and/or components are only manually cleaned, the health institution must ensure that the manual cleaning delivers the same results as the validated machine cleaning.
- If manual cleaning is a process stage in the standard procedure of the health institution, the devices from the cassette and/or components must be removed and separately cleaned according to the instructions from the manufacturer. Heavily contaminated cassettes may be manually pre-cleaned (without the instruments) according to the processing method described below.

Processing method
- Soak heavily contaminated parts of the cassette and/or components prior to cleaning, or rinse them in order to release dried contaminants and/or surgical residues.
- Remove any large contaminants and/or surgical residues with a soft brush and/or water jet with tap water.
- Pay particular attention to removing all contaminants and/or surgical residues from all difficult to reach parts of the cassette and/or components such as hinges, locks and rims. Activate all moving parts during cleaning.
- Visually inspect the cassette, components and devices for cleanliness. Repeat the cleaning and inspection process until no further contaminants and/or surgical residues are visible.
- The cassette and/or components are suitable for immersion in warm tap water and cleaning in an ultrasonic cleaning device. NTOC has not validated the efficiency of the cleaning in an ultrasonic bath.
  If using an ultrasonic bath, you are advised to follow the instructions from the manufacturer of the ultrasonic device in respect of the correct cleaning solution for ultrasonic devices.

Automated (machine) cleaning and thermal disinfection

General
- Decontaminate the cassette and/or components, irrespective of whether they have been used or have come into contact with blood or physiological saline solution.
- The washer disinfector must comply with the requirements of the ISO 15883 standard.
- Consult the instructions from the manufacturers of the washer-disinfector and of the devices in the cassette and use an automated cleaning cycle validated by the health institution.
- Use of cleaning agents with a pH value of 9-11 is recommended unless otherwise specified by the manufacturer of the device or by national legislation.
- Chlorine ions in surgical residues, chlorine and iodine ions from saline solutions and tinctures of iodine, can lead to (pitting) corrosion. Tap water may also contain chlorine ions or other minerals that may leave marks on the surface of the stainless steel. Avoid these marks by using demineralised water. Remove any marks that do occur using a non-abrasive stainless steel cleaner.
- Components that can be removed from the cassette such as the inlay and screw rack must be cleaned and disinfected separately from the cassette.
- If possible or applicable, lids must be removed from the cassettes prior to the decontamination process.
- See the table 'Recommended decontamination cycle parameters' for the recommended duration, temperature, water quality and cleaning and disinfection agent.

Processing method
- If the cassette and/or component contain a flushing connection (for example a lumen connection or lumen block), the device must be positioned correctly 'in front of' or 'connected to' the flushing connection. In addition, the flushing connection must be connected to the flushing port(s) of the washer disinfector, according to the instructions from the manufacturer of the washer disinfector. Machine cleaning using a flushing connection does not replace the instructions as described by the manufacturer of the device. It is the responsibility of the health institution to ensure that the desired result is achieved for the device in the cassette, by connection to a flushing connection after completion of the decontamination process as described in the instructions for the device.
- Devices must be removed from the fixation and placed on top of the fixation in such a position that they can drain effectively during the decontamination process. The user must fully understand that contaminated devices cannot be cleaned effectively at the position of the fixation point.
- If circumstances make it impossible to decontaminate the devices ON the fixation, so they are decontaminated while IN the fixation, the user must ensure that the devices are visually clean on the fixation points. All (pre-)cleaning steps must also have been followed prior to submission to the sterilisation process, according to the instructions from the manufacturer of the devices.

Drying
- If cassettes and/or components are not sufficiently dry after decontamination, the drying time can be extended.
- Thoroughly dry the cassette and/or components inside and out, in order to prevent corrosion and defects.
- Use a clean, soft, lint-free cloth to prevent damage to the surface.
- Pay particular attention to difficult to reach parts such as hinges and locking mechanisms or areas where moisture can accumulate. Open and close the moving parts so that all areas are reached.
- Dry all hollow parts such as lumens and cannulas using an air gun with compressed air of guaranteed quality.
- See the table 'Recommended decontamination cycle parameters' for the recommended drying temperature and drying time.

Recommended decontamination cycle parameters

Cycle	Duration (minutes)	Temperature	Water quality	Cleaning disinfection agent
Pre-cleaning	1 min	Cold	Tap water	N/A

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CE

Cleaning	According to the instructions from the manufacturer of the cleaning agent	According to the instructions from the manufacturer of the cleaning agent	Hot and cold tap water	Alkaline cleaning agent according to the instructions from the manufacturer
Rinsing	1 min	Cold	Demineralised water	N/A
Thermal disinfection	5 min	> 90 °C	Demineralised water	N/A
Drying	10 min	110 °C	N/A	N/A

Used decontamination cycle parameters				
Cycle[1]	**Duration (minutes)**	**Temperature**	**Water quality**	**Cleaning disinfection agent**
Pre-cleaning	1 min	Cold	Tap water	N/A
Cleaning	5 min	56 °C	Hot and cold tap water	Dr. Weigert Neodisher MediClean Forte
Rinsing	1 min	Cold	Demineralised water	N/A

Inspection and maintenance

Inspection

The cassette and/or components must be visually inspected prior to every use and between decontamination and sterilisation.

- Repeat the cleaning process if visible contamination and/or surgical residues are still present.
- Inspect for damage such as corrosion (rust, pitting), dents, discolouration, excessive scratching, scale, cracking and wear.
- Excessive dosages of neutralisation agents or basic cleaners can result in chemical damage and/or fading of the laser markings on stainless steel, as a result of which they become visually or mechanically illegible.
- Inspect for deformation of sides, bottom and handles of the cassette and malfunctioning, poorly fitting components in the cassette.
- Check the dryness and free movement of moving parts, movement of hinges, connectors and locking mechanisms.
- Due to intensive use, over time, the silicone material may become slightly discoloured. This is considered a normal process and will not result in any damage to the cassette or the devices in the cassette.
- If visible damage raises doubts concerning the functioning of the cassette and/or components, it is recommended that the cassette and/or the component should no longer be used and should be removed.

Maintenance

- Maintenance of the cassette and/or components is not specifically required. The only exception is the lubrication of moving parts (such as a hinged lid) if it no longer moves smoothly. For this purpose, use a lubricant that is also suitable for lubricating reusable surgical instruments, and in respect of which suitability for inclusion in the steam sterilisation process and biocompatibility are known. After applying the lubricant, remove any excess lubricant with a single-use lint-free cloth. If lubrication is part of the automated decontamination cycle, additional lubrication is not required.
- No modifications may be made to the cassette under your own authority, but must be carried out by NTOC. Alterations or repairs carried out by persons not specifically approved by NTOC will undermine the product warranty.

Preparation for sterilisation

Assembly

- The cassette, components and devices must be thoroughly cleaned and dry before they are returned to the correct position in the cassette and/or fixation. A photograph of the cassette configuration can be supplied on request by NTOC or its distributors. After this a start can be made on packaging for sterilisation.
- Disassembled devices must be reassembled prior to sterilisation according to the instructions from the manufacturer of the devices, and then returned to the cassette.
- Numerical indications in the cassettes and/or components serve solely to indicate the correct positioning of implants in the cassette and/or component. These indications are not intended to determine the dimensions of implants, and use of these indications is at your own risk.
- When reinserting the devices, ensure in particular that the non-conductive parts (such as handles of polymer materials) of the devices do not come into contact with each other, in order to avoid a negative impact on the sterilisation parameters.
- If the lid of the cassette and/or component was removed during the decontamination process, it must be replaced on the cassette prior to sterilisation.

Packaging

- The cassettes on their own do not form a sterile barrier and must be used in combination with a sterilisation wrapper and/or sterilisation container to guarantee sterility.
- Packaging material must comply with (inter)national guidelines. In addition, the health institution must approve and validate the material.

Sterilisation

Sterilisation

- The autoclave must be installed, maintained, validated and calibrated according to the requirements of the health institution and must comply with the requirements of the ISO 17665 standard.
- Sterilisers vary in design and performance characteristics. Maintenance, cycle parameters and load must always be verified according to the instructions from the manufacturer of the steriliser and must comply with the instructions from the manufacturer of the devices in the cassette. They must also be validated by the health institution.
- National specifications must also be complied with if the parameters for steam sterilisation in those specifications are stricter or more conservative than the requirements contained in the table below.
- Other sterilisation methods may also be suitable but must be validated by the health institution itself. NTOC cannot issue any guarantees or accept any liability in this connection.
- See the table 'Recommended sterilisation parameters' for the recommended temperature, duration and drying time.

Recommended sterilisation parameters[2]			
Type cycle	**Minimum exposure temperature**	**Minimum duration**	**Minimum drying time**
Steam sterilisation[3] Fractioned pre-vacuum process	134 °C	3 minutes	10 minutes

Handling, transport, storage & disposal

Handling and transport

- It is recommended that the lid of a cassette and/or component be removed/opened with due care, only when it has been placed on a stable surface.
- The lid closing mechanism is not intended for picking up the cassette. Handles mounted on the lid are only intended for lifting the cassette out of a sterilisation container.
- If a cassette includes handles, it is recommended that they be used for inserting the cassette in and removing it from a sterilisation container and/or for moving the cassette at its intended use location.
- The cassette and/or components, whether or not containing any devices, are not designed to be reprocessed, transported and/or stored upside down or on their side.
- Cassettes are not suitable for stacking during transport and storage within the health institution.

Storage

- Packaged products must be stored in a clean and dry environment and protected against pests, extreme temperatures and extreme humidity.

Disposal

- If it is decided that the cassette and/or components must be disposed of on the basis of the already mentioned and outlined inspection points, the user is responsible for the destruction of the decontaminated cassette via the regular waste disposal channels.

Limitations and restrictions on reprocessing

The lifetime of cassettes and components will depend on a variety of factors including the method of reprocessing and handling during application. For that reason, no maximum number of applications is defined. As a rule, the end of the lifetime is determined by wear or damage through use. In the section: 'inspection and maintenance', instructions are given on how the cassette should be inspected and maintained as well as when wear or damage are considered to have taken place and when the cassette should be replaced. If used and maintained carefully and correctly, validation by NTOC[4] indicates that an undamaged, clean cassette and/or component can be reprocessed at least 250 times.

Warnings

- **The cassettes are supplied NOT STERILE.**
- **Requirements and restrictions applicable to the devices in the cassette as described in the instructions from the manufacturer, ALWAYS take precedence over the information contained in these instructions. In the event of a discrepancy between these instructions and the instructions from the manufacturer of the devices in the cassette, the instructions from the manufacturer of the device take precedence and for this specific reprocessing stage, the device must be reprocessed separately from the cassette. NTOC has not validated the instructions from the manufacturer of the devices in the cassette.**
- **Numerical indications in the cassettes and/or components serve solely to indicate the correct positioning of the implants in the cassette and/or component. These indications are not intended to determine the dimensions of implants and use of those indications is at your own risk.**
- **Devices must be removed from the fixation and placed on top of the fixation in such a position that they can drain effectively during the decontamination process. The user must fully understand that contaminated devices cannot be cleaned effectively at the position of the fixation point.**
- **If circumstances make it impossible to decontaminate the devices ON the fixation, as a consequence of which they are decontaminated IN the fixation, the user must ensure that the devices are visually clean on the fixation points and that all (pre-)cleaning stages have been followed in accordance with the instructions from the manufacturer of the devices in the cassette, prior to submission to the sterilisation process.**
- **Due care must always be observed when fixing devices in and removing them from the cassette. In particular sharp devices in the cassette can damage the fixation material as a result of which some fixation material may remain attached to the device. The user must visually inspect the device for any remaining fixation material, after removal.**
- **The use of abrasive cleaning agents, metal cleaning brushes or other abrasive agents can cause permanent damage and corrosion to the cassette.**
- **Any cassette configuration may only be used in combination with the cassette, components and devices in the cassette for which this cassette configuration was designed. The cassette configuration was not designed to be combined with other cassettes, components and/or devices or with cassettes or components not designed by NTOC.**

1 The washer disinfector is validated according to the EN ISO 15883-1 standard.
2 NTOC has validated the sterilisation process for the cassette family on the basis of a worst-case setting based on the half cycle process (1.5 min 134 °C) in accordance with the ISO 17665-1 standard (drying time of 10 minutes). The steam steriliser was validated according to the EN 285 standard.
3 Sterilisation with saturated steam. Minimum validated steam sterilisation time required to achieve a 10^{-6} sterility assurance level (SAL).
4 PMS data indicate that the NTOC cassette continues to perform after between 500 and 1000 cycles.

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	CJD and related infections - **In respect of patients at risk of Creutzfeldt-Jakob Disease (CJD) and related infections, always consult the national regulations in respect of the reprocessing of devices. This applies in particular to the various guidelines on the inactivation of prions. Also consult internal hospital policy rules and procedures and instructions from the manufacturers of cleaning and disinfection agents and equipment for clinical reprocessing. The health institution bears full responsibility.**
Responsibilities of the user	- The user is responsible for compliance with the instructions for the cassette and the devices in the cassette, thereby ensuring that the cassette and the devices in the cassette become actually clean/sterile according to the specifications described in the instructions in question. - The health institution must establish and maintain a validated process within the relevant statutory and international standards. Staff training and the competence of users within the health institution are an absolute requirement for the successful implementation of all phases of reprocessing. - Regulations issued by the health institution and the instructions from the manufacturer of the cleaning and disinfection agents with regard to protective measures must be followed during reprocessing. - In the event of problems involving the use of the cassettes, please contact NTOC or its distributors. Decontaminate products that need to be returned before shipment and provide them with a decontamination declaration. For complaints and after care in respect of the devices in the cassette, the user should contact the manufacturer of the devices. - If the user observes a serious incident relating to the cassette, this must be notified to NTOC, the manufacturer of the devices in the cassette and the competent authority of the Member State where the user is established. NTOC can be notified via the telephone number listed below or via cs@ntoc.nl.
Key to symbols	MD Medical Device UDI Unique Device Identifier QTY Quantity Distributor LOT Batch code Common NTOC BATCH number formats: - Seven characters: YYMMXXX e.g. 2001000 YY=year / MM=month / XXX= ascending number starting from 000 or - Ten characters: YYMM-XXXXX e.g. 2001-00001 YY=year / MM=month / XXXXX= ascending number starting from 00001

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