

Read these instructions carefully before use.

These instructions apply to all cassettes for medical devices offered by the private limited liability company according to Dutch law NTOC medische techniek BV, and all its subsidiaries or other affiliated companies, hereinafter referred to as 'NTOC'.

Description and scope:

The intended use of the cassettes supplied with a fixation for medical devices to be used for decontamination, sterilisation and transport (abbreviated to cassettes) is threefold;

- To guarantee the functionality of medical devices by guarding from damage during decontamination, sterilisation processes and transport.
- Optimising the clean ability of the medical devices by fixing them as spatial as possible by using the minimal contact concept.
- Promoting the overview of the medical devices and/or implants before, during and following the operation.

The term medical devices refers to medical instruments. Fixation should be taken to mean the attachment of the medical devices in the cassettes. The decontamination process comprises the cleaning and disinfection process. The decontamination process is followed in many cases by a sterilisation process. The user, in these instructions, is the person making use of the cassettes.

 **Warnings**

- **The cassettes must only be used for the purpose described above.**
- **Specific instructions from the manufacturer for the decontamination and/or sterilisation of the fixed medical devices take precedence above the information contained in this sheet.**
- **The user must be fully aware that the medical devices to be cleaned in the cassettes may be subject to other requirements and restrictions from a technical and practical point of view, such as maximum temperature, than the requirements and restrictions upon the cassettes themselves. In that case, the requirements and restrictions on the medical devices at all times take precedence.**
- **Before using the cassette, always check the content of the cassette and any engraved text and symbols.**
- **Numerical indications in the cassettes serve exclusively as an aid in correctly positioning the medical devices in the cassette. These indications are not suitable for determining the sizes of medical devices or implants. The user must at all times make certain that he uses an implant of the correct length.**
- **Medical devices must be removed from the fixation and placed on top of the fixation during the decontamination process. The user must fully understand that soiled medical devices will not be cleaned at the position of the clamping point.**
- **Following the decontamination process, medical devices must be placed back in the correct location (see enclosed photograph) in the cassette fixation. The cassette can then be introduced into the sterilisation process. If the conditions do not allow medical devices to be decontaminated on the fixation, such that they must be decontaminated in the fixation, the user must ensure that the medical devices are visually clean at the fixation points before they are placed in the sterilisation process.**
- **When fixing and removing medical devices, due care must be taken. In particular sharp medical devices can damage the fixation material as a result of which fixation material may remain behind on the medical device. The user must visually inspect the medical device following removal for any fixation material remaining on the device.**

Recommendations on decontamination and sterilisation

- During decontamination, use personal protective equipment such as gloves, mouth and nose mask and apron. In non-standard situations, follow the instructions imposed by the user.
- The cassettes are supplied non-sterile. Prior to use, cassettes must be decontaminated and sterilised.
- If treated and maintained correctly, cartridges can be reused.
- The cassettes are suitable for use in well-maintained and validated machines for decontamination and sterilisation.
- Medical devices with difficult-to-access components such as lumen and joints, etc. must therefore first be manually precleaned before the cassette containing medical instruments is placed in the mechanical decontamination process.
- The user must always ensure that the decontamination process has also delivered the required result before initiating the sterilisation process. In case of doubt, the cassette and/or the medical device in the cassette must be decontaminated again.
- Use of slightly alkaline pH detergent (pH 9-10) is recommended, unless otherwise specified by the manufacturer of the medical device. Avoid disinfectants or other containing chloride because these can have a corrosive effect on the stainless steel material. Also consult the instructions for use from the manufacturer of the washer disinfectant. The cassette is resistant to thermal disinfection at 90-95 °C and drying at 110 °C.
- Sterilisation according to current guidelines for steam sterilisers is recommended.
- The cassette is resistant to steam sterilisation at 134-137 °C and to gas plasma sterilisation with hydrogen peroxide. It is recommended that the guidelines from the manufacturer of the medical device and the steriliser are followed.
- Other sterilisation methods may also be suitable, but must be validated in advance, by the user. NTOC is unable to issue any guarantee or accept any liability for such use.

- Following decontamination and prior to sterilisation, the cassette must be wrapped in suitable packaging in accordance with the requirements imposed by the user.

Transport and storage

- The cassette is not suitable for transport and storage upside down.
- To prevent damage to instruments and packaging, it is recommended that cassettes should not be stacked during transport and storage unless the bottom of the cassette is sufficiently supported.
- A cassette with content may not weigh more than 8.5 kg.
- The cassette should be stored in a clean and dry environment.

Guarantee conditions and after care

- Prior to delivery, the cassette is subjected to strict quality standards. If defects should unexpectedly occur before, during or following use of the cassette, NTOC must be duly informed within 14 days after the defect is found.
- During normal use, according to standard decontamination and sterilisation processes, the fixation is subject to a 1-year warranty.
- To guarantee the constant quality of the cassette, no modifications should be undertaken on your own account, but must be carried out by NTOC. Alterations or repairs undertaken by persons not specifically approved by NTOC, will nullify the warranty. Cassettes requiring after care must be decontaminated and accompanied by a declaration of decontamination prior to return.
- The cassette is subject to no restrictions following repeated use, apart from normal wear. In the event of destruction, the user is responsible for the correct disposal of the cassette, via normal waste flows.

Finally

- NTOC shall under no circumstances be liable for defects arising from normal wear, incorrect and/or inexperienced use of the cassettes and/or the medical devices, inexperienced cleaning and/or the non, incorrect or late maintenance of the cassettes and/or the medical devices.
- All deliveries by NTOC are subject to our General Terms and Conditions of Sale and Delivery as deposited with the Chamber of Trade and Industry in 's Hertogenbosch under number 16076617.
- With a view to preventing damage, we would particularly request you to contact us if you have any questions and/or uncertainties about (the use of) the cassettes, prior to use. We will be delighted to assist you in every possible way.
- In the event of doubt concerning the meaning of the text, the Dutch version always takes precedence over the English.