



1. Introduction

The Cassettes are made of surgical-grade stainless steel to provide protection, storage and organization for surgical instrument. The Cassettes may be used in dental and surgical procedures and are designed to fit standard autoclaves sterilization cycles.

2. Intended use

The Cassettes are indicated to hold surgical instruments and accessories in place during sterilization cycle. These items are suitable for gravity steam and pre-vacuum steam and are intended to be used in conjunction with sterilization pouches in order to maintain sterility.

3. Intended users

For professional use only. Intended users: Dental and medical Surgeons, Dental assistants, Hygienists, Specialists in medical device reprocessing (eg employees of Central Sterile Supply Departments (CSSDs), medical end-users.

4. Contra-indication: None

5. Precaution for handling and operation

- Read these safety cautions thoroughly before use and operate the product properly.
- These indicators are to allow you to use the product safely, prevent danger and harm to you and others. These are classified by degree of danger, damage and seriousness. All indicators concern safety, be sure to follow them.

Class	Degree of Risk
 Caution	Hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.
Notice	General product specification information highlighted to avoid product malfunction and performance reduction.



Caution

- These items are not delivered in sterile condition, and shall be sterilized before use.
- Close Cassette to avoid injury caused by instrument protruding from the Cassette.
- Do not stack Cassettes in sterilization unit.
- Do not touch the product immediately after autoclaving as it could be very hot.
- Any serious incident that has occurred in relation to these items should be reported to the manufacturer and the competent authority of the Member State.

Notice

- Wrap Cassettes with legally marketed sterilization pouches.
- For effective sterilization and drying, do not stack instruments in the Cassette or do not overfill the Cassettes.
- To avoid corrosion and damages, Cassettes shall be cleaned and sterilized according to the instruction hereinafter.

6. Instruction for Use

6-1 - Cleaning

- Cassettes should be cleaned using instrument brush, detergent and water to remove visible debris from cavities (0.5% neodisher® Mediclean Forte).
- Cassettes may be cleaned in an ultrasonic cleaner with detergent and water (1% neodisher® Mediclean Forte, max. 40°C).
- Submerge Cassettes fully into ultrasonic unit and place lid on unit
- Process Cassettes for 10min.
- Following ultrasonic cleaning procedure remove Cassettes, and thoroughly rinse with warm water to remove cleaning solution. Allow items to dry before placing instruments and accessories for reprocessing as it may cause discoloration.

6.2 – Sterilization

- Once instruments and accessories have been placed inside Cassettes, wrap Cassettes with legally marketed sterilization pouches, and seal the pouch.
- Date and code item on autoclave label, and affix label on outside of the pouch.
- Place wrapped items into sterilization unit, and follow sterilizer's recommended sterilization procedures and approved local standard in force.
- Do not stack Cassettes in the sterilization unit.
- Cassettes have been tested with no adverse effects under the following condition:

Gravity Steam:

Temperature: 121°C

Exposure time: 30 minutes

Dry time: 20 minutes

Pre-Vacuum Steam:

Temperature: 134°C

Exposure time: 18 minutes

Dry time: 15 minutes

7. Maintenance

- Maximum number of admissible reuses is not provided as the service life depends on various factors, such as the manipulation undergone and treatment between uses. The best way to determine when these items should no longer be reused is to carry out a visual inspection to verify there is no evidence of deterioration.
- For best and lengthy service life, and to avoid stain, it is advisable to use demineralized water for rinsing and sterilization. Cassettes shall be allowed to properly dry before the sterilization procedure.

8. Symbol and labelling

	Lot Number		Non-Sterile		Manufacturing Date
	Catalog Number		Consult Instruction for Use		Manufacturer
	Unique Identification Number		Medical Device		Autoclavable up to 134°C
	Caution				

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