

SURGICON (PVT) LTD

USER MANUAL

(Reusable Surgical Instruments)

These are a very high quality instruments, its proper handling and use are described below. To keep hazards from patients and users as possible. We ask you to follow the instructions carefully. The application, disinfection, cleaning and sterilization of instruments may be carried out by trained specialists.

Warning:

- 12.1. Stainless Steel surgical instruments cannot be inserted in to the physiological saline (NaCl Solution), because longer contact causes corrosion such as a pitting corrosion
And stress corrosion.
- 12.2. Cleaning solution in which hydrogen peroxide is added and/ or solutions for cleaning
With higher alkalinity may lead to a change in colour. This could cause damage to the
Identification of the surgical instruments.
- 12.3. It is necessary to avoid a usage of the alkaline solutions and the hydrogen peroxide
Solution and the use of oxygenated water when washing the surgical instruments with
The carbide parts (e.g. Needle Holder).
- 12.4. Do not use abrasive cleaning materials such as steel wool or abrasive detergents to
The surgical instruments. If possible, always clean the surgical instruments and sieves
In the washing and disinfecting facility for surgical instruments according to the
Standard ISO 15883-1.
- 12.5. The long, narrow cannulas, blind holes and complex parts require a special attention
When cleaning.
- 12.6. Sterilising parameters apply only to surgical instruments which are sufficiently cleaned,
- 12.7. Sterilization parameters apply only to well- assembled, maintained, calibrated and
Complying equipment for reprocessing in accordance with ISO-15883-1 and 17665

Standards.

- 12.8. The surgical instruments are supplied NON –STERILE.
- 12.9. Remove the surgical instruments from its packaging before first use and remove Covers form the sharp ends. These covers are not intended to be sterilized. Place The covers into the waste sorted in accordance with the catalogue of waste – 18 01 07 – chemicals that do not contain hazardous substances. It is necessary to Return the instrument to the manufacturer for re packing and control in case of impair Packaging. Dispose the package according to the recycling symbols.
- 12.10. Perform cleaning, disinfection and sterilization according to the regulation before First use (points 16.-24. Of these instructions).
- 12.11. Clean the sterilized the surgical instruments as soon as possible after their usage.
13. Restrictions on re - usage.
 - 13.1. Lifetime of the surgical instruments is determined by the wear and tear and damage Due to their usage.
 - 13.2. Repeated cycles of cleaning, disinfecting and sterilization have minimal impact to the Surgical instruments.

INSTRUTIONS.

14. Place of Use.
 - 14.1. Wipe the blood and any remaining tissues form the surgical instruments during the Surgery before they are allowed to dry to the surface.
 - 14.2. Rinse the surgical instruments with opening by the sterile or purified water before the Impurities and / or remaining tissues are allowed to dry inside.
 - 14.3. Soiled surgical instruments have to the separated from the clean ones to avoid Contamination of unused surgical instruments, staff and surroundings. Contaminated Surgical instruments must be separated from medical waste.

14.4. The surgical instruments should be covered with the drape dampened in the sterile or Purified water to avoid drying of blood or debris.

14.5. Surgical instruments use in Operation Thither, Hospitals and Clinics

15. Storage and Transport.

15.1. Soiled surgical instruments have to be transported separately from the clean ones to Avoid their contamination.

16. Preparation for cleaning.

16.1. Open the surgical instruments with toothed or threaded latches and hinges. Separate The pointed and sharp surgical instruments. Wipe the oil form the locks using a cloth At the new surgical instruments. A larger amount of oil in the locks of the new surgical Instruments could lead to the formation of spots on the surgical instrument. Surface After sterilization.

16.2. Remove the sharp. Removable parts of the surgical instruments prior the manual Cleaning or place them onto separated tray.

16.3. Disassembled or loosen all connections before processing of the surgical instruments. You will get further detailed information about the dismantling of the surgical Instrument form your sales representative of Surgicon.

17. Cleaning and Disinfection – Manuel

17.1. Place surgical instruments into the washing agent carefully to avoid moving of them Freely during washing process are their overlapping which could damage their surface

17.2. Remove the surgical instruments from the disinfecting agent and rinse under water After the expiration of recommended time.

17.3. Wash the surgical instruments manually. Remove coarse dirt mechanically big brush in Fresh cleaning and disinfection solution in and ultrasonic bath, and rinse under tap Water.

17.4. SURGICON company does not prescribe the use of a specific detergent and Disinfection.

17.5. The washing agent and disinfectant have to be used in accordance with the instruction Of the manufacturer. Keep prescribed contraction, the temperature, water quality and Action time when using.

17.6. Remove the washing agent under tap water after the expiration of recommended Action time.

18. Cleaning and disinfection – Automatized

18.1. The validated machine cleaning and disinfection procedure must always be preferred To manual cleaning because of the higher safety of the process. A good cleaning is also A requirement for successful sterilization.

18.2. We recommend washing the surgical instruments before sterilization using automatic Washers with thermal disinfection.

18.3. Place Surgicon instruments into the disinfection agent carefully to avoid moving of Them freely during washing process or their overlapping which could damage their Surface.

18.4. Surgicon company does not prescribed the use of a specific detergents and Disinfectant.

18.5. The washing agent and disinfectant have to be used in accordance with the Instructions of the manufacturer. Keep prescribed concentration, temperature, Water quality and action time when using.

19. Thermal Disinfection.

19.1. Disinfect at a minimum temperature of 90 degrees for at least 5 minutes in case of Cleaning in washer.

2.0. Drying;

20.1 If drying cycle is not included in the manual washer: dry each surgical instrument

Properly.

21. Check:

21.1. Surgicon Instruments have to be checked after treatment and before sterilizing for the

Following:

- Cleanness.
- Any damage including corrosion, change of the colour, excessive and significant scratching, chipping, wear and cracks
- Proper functioning including the sharpness of the cutting surgical instruments, Flexion of the elastic parts of the surgical instruments, moving of the joints / joint Connections / threaded latches and other moving parts, such as handles, toothed Latches and connections.
- Missing and removed (Scraped) Numbers of the parts and wear and tear.
- Discard the surgical instruments with the fore mentioned defects.

21.2. Make sure that the surgical instruments have an intact surface and that they are

Properly adjusted and functional. Do not use the surgical instruments that are severely

Damage, have illegible marks, show the signs of corrosion or have dull blades. Discard

These surgical instruments. For more detailed instructions on the check of

Functionality, please contact your Surgicon sales representative.

22. Maintenance.

22.1. Maintenance and care is usually performed before the test function. Maintenance and

Care means a targeted application of the preservative onto the surgical instruments in

To the joints, hinges or threads and sliding surface, e.g. at the staples, scissors,

Punches after a thorough cleaning and disinfection. Dis prevents friction of a metal on

A metal. And consequent friction corrosion. The surgical instruments are being

Maintained in a

Movable state. Requirements for the preservative for the surgical instruments:
Paraffin- / white oil based, complying with the applicable European pharmacopoeia
Or the united states pharmacopoeia, Biocompatible, suitable for the steam
Sterilization and vapour - permeable the surgical instruments must not be treated
With silicon preservatives. They may complicate movement and reduce the effect of
The steam sterilization.

22.2. A Dismantled surgical device should be assembled prior to sterilization unless
Otherwise indicated.

22.3. The manufacturer only is entitled to perform service interventions.

23. Packaging:

23.1. Put the disinfected, cleaned, rinse and dry instruments in their place in a sieve. In
Addition, use a suitable sterilization packaging or a reusable hard container such as
A system of sterile barriers according to ISO 11607 standard.

23.2. It is necessary to pay attention to the protection of the surgical instruments and
Ensure that the spiky or sharp surgical instruments do not come in to contact with
Other objects whose surface could be damaged.

23.3. Pack individual surgical instruments, for which Surgicon storage is not available into
The sterilization bags that meet the requirements of ISO 11607.

24. Sterilization

24.1. Sterilized cleaned and disinfected surgical instruments only.

24.2. It is recommended to use sterilisation with wet heat in a steam sterilizer at a
Temperature of 134 C and the time of sterilization of 7 min. And pressure of 310 kPa
For the surgical instruments.

24.3. When using of hot air sterilization is recommended in a special precaution, it is
Performed in the facilities with forced air circulation at the temperature of 160 C
For 60 minutes or at the temperature of 170 C for 30 Minutes or at the temperature

Of 180 C for 20 minutes.

25. Storage

25.1. Store the packed surgical instruments in a dry clean environment without extreme Temperature and humidity, away from direct sunlight, animals, insects, dust, fungi and Chemicals.

26. Other Information

26.1. The process of washing with thermal disinfection has been verified by Surgicon Company. In case of use of some other methods of the washing procedure than Recommended, Surgicon Company does not guarantee the results. When using some other method of washing than recommended, Surgicon company recommends this process to be validated by the supplier of such washing facility.

26.2. The Surgicon company has validated the method of sterilization with the damp heat at The temperature of 134 C and the time of the sterilization of 7 min and pressure of 310 kPa for the representative of the WORST- CASE SURGICAL PRODUCTS.

26.3. The Surgicon company has validated method of dry heat sterilisation for the Representative of the WORST- CASE SURGICAL PRODUCTS.

26.4. The instructions for cleaning and sterilization are stated in accordance with the norms And standards ISO 15883, ISO 17664, ISO 17665-1. The instructions listed above have Been confirmed by the manufacturer of the surgical instruments as appropriate for The preparation of Surgicon non sterilise surgical instruments. It is the responsibility of The provider to achieve the desired outcome by preparing a product with the use of The equipment, materials and workers on the pre-site. This requires the validation and Routine the monitoring of the procedure. Likewise every deviation of the provider form These recommendations should be properly accessed in terms of the efficiency and any Possible undesired consequences.

27. Disposal of the Surgical Instrument

27.1. A Discarded surgical instrument is considered as a hazardous waste. The user is Responsible for the implementation of the measures to the safe handling and disposal Of the product.

27.2. Damaged surgical instruments are disposed off after decontamination, washing and Drying as a potentially hazardous waste according to the catalogue of waste-group 18- Medical waste.