

STARMED ENGINEERING (PVT) LTD

INSTRUCTIONS USER MANUEL

(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 from 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 impaired 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 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.

INSTRUCTIONS.

14: Inspection

14.1. All instruments must be inspected prior to first use and after each subsequent use, to check proper function, bent or damaged parts as well as surface damaged (cracks, nicks, pitting etc.) if any of these present the instruments should not be used.

14.2. Application: Starmed Instruments are produced as standard equipment in an operational setting for general surgery. The selection of appropriate instruments for each procedure is the responsibility of the attending physician. It is also their responsibility that surgical staff have sufficient knowledge and experience to handle

surgical instruments.

14.3. Handling and Use: Sterilized instruments should only be used for their intended purpose

They should not be twisted or overstressed by leverage as this may result in damage
And breakage of the instruments.

14.4. Risks: Improper handling of surgical instruments can result in injury and or infections.

15. Place of Use.

15.1. Wipe the blood and any remaining tissues from the surgical instruments during the
Surgery before they are allowed to dry to the surface.

15.2. Rinse the surgical instruments with opening by the sterile or purified water before the
Impurities and / or remaining tissues are allowed to dry inside.

15.3. Soiled surgical instruments have to be separated from the clean ones to avoid
Contamination of unused surgical instruments, staff and surroundings. Contaminated
Surgical instruments must be separated from medical waste.

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

15.5. Surgical instruments use in Operation Theater, Hospitals and Clinics

16. Storage and Transport.

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

17. Preparation for cleaning.

17.1. Holding/Pre-Sock: Never allow blood, tissue and debris to dry onto instruments
Surface. If rinsing and decontamination process are not immediately available, pre-treat
Instruments or hold them in a neutral PH pre-sock enzymatic solution after patient use
But prior to actual cleaning's soon as possible, rinse, disinfection and clean your
Instruments as follows.

- 17.2. Rinse: Immediately after, remove organic materials by rinsing instruments under Warm (not hot) running water. This rinse should remove most debris. Do NOT process Dissimilar metals (stainless steel, copper, chrome plated) together.
- 17.1. 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.
- 17.2. Remove the sharp. Removable parts of the surgical instruments prior the manual Cleaning or place them onto separated tray.
- 17.3. 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 Surgeon.

18 Cleaning and Disinfection – Manuel

- 18.1. **Cleaning:** All blood fluids and tissue must be completely removed from an instruments Prior to sterilization. Irrespective of the cleaning method used always observe the
- i) Use only PH (7) or mild alkaline enzymatic cleaners and detergents.
 - ii) Always use distilled water of final rinse.
 - iii) Dissimilar metal instruments must be separated,
 - iv) Do not let "Sharp" (Scissors, knives etc.) touch each other during the cleaning process.
 - v) All the instruments with hinges, box locks, ratchets, etc. must be processed in an open position.
- 18.2. **Manuel Cleaning:**
- i) Soaking instruments in an enzymatic cleaner bath is an effective way of removing organic materials.
 - ii) Make sure to follow the cleaning agent manufacturer's instructions carefully.
 - iii) Ensure that all spaces and recesses are completely filled with cleaning solution

and no air pockets exist.

iv) Maintain a solution temperature of 20 C to 10 C during the soaking process.

v) Use a stiff nylon brush. DO NOT use steel wool or wire brushes. Brush delicate instruments carefully and if possible separately from general instruments.

vi) After scrubbing rinse instruments thoroughly in demineralised water to remove Cleaning solution. While rinsing, open and close hinged instruments, such as Scissors, to ensure the hinged areas are rinsed out and no debris remain.

vi) Change solution frequently.

18.3. Ultrasonic Soaking & Cleaning:

i) This is widely recognized as being the most effective method of cleaning instruments. However, extreme care must be taken when using this method to prevent damage Being caused to instruments. Check that your selected detergent can be safely used With your ultrasonic cleaner.

ii) Process instruments as per the manufacturers recommended cleaning cycle NEVER-LONGER.

iii) Upon completion of the cycle, remove the instruments IMMEDIATELY and rinse with demineralised water.

18.4. After Cleaning:

i) Inspection each instruments for the proper function and condition.

ii) Make sure instruments surfaces are visibly clean and free from stain.

iii) Separate all dissimilar metals prior to sterilization.

iv) Allow instruments to air dry

18.5. 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

18.6. Remove the surgical instruments from the disinfecting agent and rinse under water

After the expiration of recommended time.

18.7. 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.

18.8. STARMED company does not prescribe the use of a specific detergent and disinfectant.

18.9. 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.

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

19. Cleaning and disinfection – Automatized

19.1. 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.

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

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

19.4. STARMED company does not prescribed the use of a specific detergents and Disinfectant.

19.5. 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.

20. Thermal Disinfection.

20.1. Disinfect at a minimum temperature of 90 degrees for at least 5 minutes in case of

Cleaning in washer.

21. Drying;

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

Properly.

22. Check:

22.1. STARMED 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 a fore mentioned defects.

22.2. 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 of have dull blades. Discard

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

Functionality, please contact your STARMED sales representative.

23. Maintenance.

23.1. Maintenance and cure 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, punch

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.

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

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

24. Packaging:

24.1. 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.

24.2. 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.

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

25. Sterilization

25.1. Sterilized cleaned and disinfected surgical instruments only.

25.2. 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.

25.3. 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.

26. Storage

- 26.1. 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.

27. Other Information

- 27.1. The process of washing with thermal disinfection has been verified by Starmed Company. In case of use of some other methods of the washing procedure than Recommended, Starmed Company does not guarantee the results. When using some other method of washing than recommended, Starmed company recommends this process to be validated by the supplier of such washing facility.
- 27.2. The STARMED 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.
- 27.3. The STARMED company has validated method of dry heat sterilisation for the Representative of the WORST- CASE SURGICAL PRODUCTS.
- 27.4. 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 Starmed 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.

28. Disposal of the Surgical Instrument

28.1. 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.

28.2. Damaged surgical instruments are disposed of after decontamination, washing and

Drying as a potentially hazardous waste according to the catalogue of waste-group 18-
Medical waste.

CAUTION: Disinfected Instruments are NOT sterile. Never expose stainless steel instruments to bleach or other corrosive chemicals. Exposure to bleach may result in instruments surface pitting and void all manufacturer warranties.

Special Note for the Tungsten Carbide Instruments:

- Starmed Instruments that contain tungsten carbide(TC) can be easily identified by their distinctive gold coloured handles.
- DO NOT use solutions that contain benzyl ammonium chloride (BAC) to clean TC instruments. The BAC will soften and destroy the TC inserts.
- Use detergents and lubricants that are PH neutral (7) only. High PH will break down the carbide and will deteriorate prematurely. Low PH will begin to break down the weld materials that adheres the Tc to the stainless steel and the carbide will lose hardness.

NOTE: caring for your instruments by following these cleaning, maintenance, and sterilization guidelines will ensure trouble-free functionality and increase the longevity of your Starmed Instruments.



QA/RA Manager

Date: 09/11/2020