Fioniavet / Bjebto ApS
C/O Coworking Plus ApS
Kochsgade 31D
DK-5000 Odense C
Denmark

Instruction for Use

Reusable Surgical Instruments

This instruction is valid for reusable surgical instruments. Please read the whole document and packing information before start using the products.

Symbols

Symbol	Explanation
	Keep instrument dry according to packing information
	Lot No / Batch Code
	QR-code to this document

Safety Information

To assure the correct use of the products, basic safety measure should always be followed including the warning and cautions listed below.

Warnings & Cautions

- Stainless Steel surgical instruments cannot be inserted into the physiological saline (NaCL Solution), because longer contact causes corrosion such as a pitting corrosion and stress corrosion.
- 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.
- 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).
- 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.
- The long, narrow cannulas, blind holes and complex parts require a special attention when cleaning.
- Sterilising parameters apply only to surgical instruments which are sufficiently cleaned.
- Sterilization parameters apply only to well-assembled, maintained, calibrated and complying equipment for reprocessing in accordance with ISO-15883-1 and 17665
- Lifetime of the surgical instruments is determined by the wear and tear and damage due to their usage

Fioniavet / Bjebto ApS
C/O Coworking Plus ApS
Kochsgade 31D
DK-5000 Odense C
Denmark

- Repeated cycles of cleaning, disinfecting and sterilization have minimal impact to the surgical instruments.

Generally
The products are a very high-quality instruments, and 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.
The surgical instruments are supplied NON-STERILE.

Product category according to EU Regulation
Not regulated. For veterinary use only.

Unpacking

Please follow this process for a good result:

1. 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.
2. Place the covers into the waste sorted in accordance local regulation
3. It is necessary to return the instrument to the manufacturer for re packing and control in case of impair packaging.
4. Dispose the package according to the recycling symbols and local regulations.
5. Perform cleaning, disinfection and sterilization according to the regulation before first use. Please see below.
6. Clean the sterilized surgical instruments as soon as possible after their usage.

Place of Use

7. Wipe the blood and any remaining tissues form the surgical instruments during the surgery before they are allowed to dry to the surface.
8. Rinse the surgical instruments with opening by the sterile or purified water before the impurities and / or remaining tissues are allowed to dry inside.
9. 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.
10. The surgical instruments should be covered with the drape dampened in the sterile or purified water to avoid drying of blood or debris.
11. Surgical instruments use in Veterinary Hospitals, Clinics and Ambulatory Practices.

Fioniavet / Bjebto ApS
C/O Coworking Plus ApS
Kochsgade 31D
DK-5000 Odense C
Denmark

Storage and Transport

12. Soiled surgical instruments must be transported separately from the clean ones to avoid their contamination.

Preparation for cleaning

13. 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.
14. Remove the sharp removable parts of the surgical instruments prior the manual cleaning or place them onto separated tray.
15. 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.

Manual Cleaning and Disinfection

16. 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. Remove the surgical instruments form the disinfecting agent and rinse under water after the expiration of recommended time.
18. 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.
19. FioniaVet does not prescribe the use of a specific detergent and disinfection.
20. 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.
21. Remove the washing agent under tap water after the expiration of recommended action time.

Fioniavet / Bjebto ApS
C/O Coworking Plus ApS
Kochsgade 31D
DK-5000 Odense C
Denmark

Automatized Cleaning and Disinfection

22. 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.
23. We recommend washing the surgical instruments before sterilization using automatic washers with thermal disinfection.
24. Place the instruments into the disinfection agent carefully to avoid moving of them freely during washing process or their overlapping which could damage their surface.
25. FioniaVet does not prescribed the use of a specific detergents and disinfectant.
26. The washing agent and disinfectant must be used in accordance with the instructions of the manufacturer. Keep prescribed concentration, temperature, water quality and action time when using.

Thermal Disinfection

27. Disinfect at a minimum temperature of 90° C for at least 5 minutes in case of cleaning in washer.

Drying

28. If drying cycle is not included in the manual washer: dry each surgical instrument properly.

Check

29. FioniaVet instruments have to be checked after treatment and before sterilizing for:
    - 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.
30. 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 damaged, 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 sales representative.

Fioniavet / Bjebto ApS
C/O Coworking Plus ApS
Kochsgade 31D
DK-5000 Odense C
Denmark

Maintenance

31. Maintenance and cure are usually performed before the test function. Maintenance and care mean a targeted application of the preservative onto the surgical instruments into the joints, hinges or threads and sliding surface, e.g. at the staples, scissors, punches after a thorough cleaning and disinfection. This 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.
32. A dismantled surgical device should be assembled prior to sterilization unless otherwise indicated.
33. The manufacturer only is entitled to perform service interventions.

Packaging

34. 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.
35. 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.
36. Pack individual surgical instruments, for which FioniaVet storage is not available into the sterilization bags that meet the requirements of ISO 11607.

Sterilization

37. Sterilized cleaned and disinfected surgical instruments only.
38. 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 310kPa for the surgical instruments.
39. 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.

Storage

40. 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.

Fioniavet / Bjebto ApS
C/O Coworking Plus ApS
Kochsgade 31D
DK-5000 Odense C
Denmark

Other Information

41. The process of washing with thermal disinfection has been verified by FioniaVet. In case of use of some other methods of the washing procedure than recommended, FioniaVet does not guarantee the results. When using some other method of washing than recommended, FioniaVet recommends this process to be validated by the supplier of such washing facility.
42. FioniaVet 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.
43. FioniaVet has validated method of dry heat sterilisation for the representative of the WORST- CASE SURGICAL PRODUCTS.
44. 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 FioniaVet 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.

Disposal of the Surgical Instrument

45. 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.
46. Damaged surgical instruments are disposed of after decontamination, washing and drying as a potentially hazardous waste / Medical waste.

Specification in general for all instruments

Material	Steel
EU regulation	Not regulated: For veterinary use only.
Standards	ISO 15883-1:2006 Washer-disinfectors — Part 1: General requirements, terms and definitions and tests ISO 11607-1:2019 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
Sterilization	No
Contact information	**Fioniavet / Bjebto ApS** C/O Coworking Plus ApS Kochsgade 31D DK-5000 Odense C Denmark Email: bjerning@fioniavet.com