

Item Description:
Item Number:



INNOMED, INC.

CE Resuable Non Sterile Instruments



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Instructions for Use

Intended Use

Innomed instruments consist of manual surgical instruments and positioners intended for use in surgical procedures. Instruments and positioners should be used by healthcare professionals only in their intended design. Use of these instruments in other than their intended purpose may result in damage to the instrument or may adversely affect the patient.

General Surgical Instrument Care, Handling, Maintenance, Sterilization, Cleaning, and Disinfection

Special instructions apply for the proper care and handling of instruments to ensure longevity.

- Visually inspect instruments before cleaning for cracks and chipped areas.
- Check instruments for smooth action, jaw alignment, and signs of wear.
- Do not autoclave chrome plated instruments with stainless steel instruments.
- Do not use a multipurpose detergent to wash or soak your instruments. Use a specifically compounded low-suds detergent with a neutral pH. A sponge, cloth, or scrub brush can be used to thoroughly clean the instruments. Never use steel wool or abrasives for cleaning.
- Never use an acid rinse or expose bleach to stainless steel instruments.
- Rinse cleaned instruments with clean water to remove any detergent before sterilization.

Detergents designed for surgical instruments are specifically formulated to remove protein, organic debris and blood. The neutral pH balance will not damage stainless steel or tungsten carbide inserts. The solution is gentle enough for manual (hand) as well as ultrasonic cleaning.

Sterilization of instruments may be accomplished by steam autoclave. Time and temperature parameters required to steam sterilize vary according to type of sterilizer. Refer to the sterilizer manufacturer's instructions and guidelines. The following guidelines are recommended times and temperatures for stainless steel instruments:

| | |
|----------------------|---------------|
| Sterilizer Type: | Prevacuum |
| Minimum Temperature: | 132 °C/ 270°F |
| Full Cycle Time: | 4 minutes |
| Dry Time: | 30 minutes |

The following guidelines are recommended times and temperatures for instruments made of aluminum:

| | |
|----------------------|---------------|
| Sterilizer Type: | Prevacuum |
| Minimum Temperature: | 132 °C/ 270°F |

Full Cycle Time: 4 minutes
 Dry Time: 30 minutes

The following guidelines are recommended times and temperatures for instruments made of delrin:

Sterilizer Type: Prevacuum
 Minimum Temperature: 132 °C/ 270°F
 Full Cycle Time: 4 minutes
 Dry Time: 20 minutes

The following guidelines are recommended times and temperatures for instruments made of CF PEEK:

Sterilizer Type: Prevacuum
 Minimum Temperature: 132 °C/ 270°F
 Full Cycle Time: 4 minutes
 Dry Time: 20 minutes

Automated Cleaning Cycle

Validated Parameters for Stainless Steel, Aluminum, Delrin, Silicone and CF PEEK

- 1) Disassemble the instrument (s) if applicable.
- 2) Load the instruments in the washer so that the design features are exposed to cleaning.
- 3) Devices capable of holding liquid should be load such that the design feature can drain.
- 4) Ensure washer is filled with dunnage to simulate a full load.

The following guidelines are recommended for cleaning. Other automatic cleaning solutions that can be used are Neodisher®, Mediclean Forte®, Thermosept®.

| Phase | Time (MM:SS) | Temp. (°C) | Detergent |
|-------------|--------------|--------------|-----------|
| Prewash | 2:00 | Cold Water | |
| Wash | 3:00 | 60+/-5°C | Enzol® |
| Rinse | 0:15 | 60+/-5°C | |
| Final Rinse | 1:00 | 80+/-5°C-DIW | |
| Dry Time | 6:00 | ≥ 80°C | |

Manual Cleaning

Validated parameters for Stainless Steel, Aluminum, Delrin, Silicone and CF PEEK

- 1) Disassemble the instrument (s) if applicable.
- 2) Rinse the instruments under running, cold water to remove gross soil. Actuate the articles during rinsing.
- 3) Prepare the cleaning solution Enzol® by using 22.2 mL detergent + 3,785 mL tap water.
- 4) Immerse the instruments in prepared Enzol® solution for one (1) minute.
- 5) Prepare Valsure® Neutral solution by using 5.5 mL + 3,785 mL tap water and place in ultrasonic bath.
- 6) Transfer the instruments to the ultrasonic bath and allow to sonicate while fully immersed for 15 minutes.
- 7) After sonication, while the instruments are in Valsure® Neutral solution, scrub the articles thoroughly using a soft-bristled brush (Spectrum M-16 or equivalent). Give the particular attention any hinges, crevices, and hard to reach areas. Actuate instruments while brushing.
- 8) Rinse the instruments for one (1) minute under running deionized water (DI) until all traces of the cleaning solution is removed. Give particular attention to any cannulations, blind

holds, hinges, joints, and other hard to reach areas. Actuate instruments during rinsing.

9) Flush any cannulations, blind spots, joints, or other hard to reach areas with 50 mL DI water. Perform the flush two (2) more times for a total of three (3) times.

10) Dry the instruments with a clean, lint free cloth.

11) Visually inspect each instrument for soil. If any remains, repeat the procedure.

Automated Thermal Disinfection

Validated parameters for Stainless Steel

Automated thermal disinfection can be accomplished by using the A₀ method; 5 minutes @ 90°C.

Manual Disinfection

Validated parameters for Stainless Steel

1) Ensure minimum effective concentration (MEC) of Cidex® OPA using Cidex OPA test strips.

2) Equilibrate a water bath of Cidex® OPA to 20°C.

3) Fully immerse the instruments in Cidex® OPA solution and wipe the surface of the test instruments with sterile lint free cloths.

4) Flush any cannulations, blind holes, hinges, joints, and other hard areas with a minimum of 25mL for each hard reach area. Actuate the instruments while flushing.

5) Allow the instruments to soak for 45 minutes.

6) Thoroughly rinse the instruments the test articles by fully immersing them in pure water, agitating, and allowing them to set for a minimum of one (1) minute.

7) Flush any cannulations, blind holes, hinges, joints, and other hard to reach areas with a maximum of 50 mL of water. Perform this flush four (4) more times for a total of five (5) times.

8) Dry the instruments using a sterile lint-free cloth.

Lubricants

Specific lubricants designed for surgical instruments are an excellent investment for long term protection. Besides lubricating moving parts, lubricants also inhibit rust, discoloration and corrosion. Used in a regular instrument care program the proper lubricant helps reduce instrument wear. A 30 to 60 second soaking, prior to autoclaving is adequate to insure protection. Some of the advantages are: prevents frozen box locks by dissolving organic debris, does not interfere with steam autoclaving, provides a protective coating to your instruments, reducing repair costs, it's non-toxic, and it inhibits rust and discoloration.

Instrument Storage

It is recommended that all instruments are stored in a clean, dry environment. Devices supplied sterile must remain in unopened packaging. Do not use if packaging is damaged or opened.

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