Instructions for Use
Reusable Surgical Instruments

APTIS
Putting Ideas in Motion
CE 2862

To ensure hazards are as low as possible for patients and users, we request that you carefully observe these instructions for use. The application, disinfection, cleaning and sterilization of the medical device must only be performed by trained specialist personnel. As these devices are sold in a non-sterile state, they must be sterilized before each use.

Reusable surgical instrumentation is designed to aid the surgeon in installation, assembly, and/or removal of a surgical device. The surgical techniques for the implantation of the device describe the proper application of the reusable surgical instrumentation and should be read and understood by the surgeon prior to use. The indirect clinical benefit of the instrumentation is that they assist in the proper implantation of the Aptis prosthesis.

Materials

ASTM F 138 Stainless Steel F 316 L	ASTM A 564 Stainless Steel 17-4Ph
ASTM A 276 Stainless Steel 440C	Aluminum
Ultem™ or Radel™ Plastic	

Inspections
Before every use, the medical device must be checked for its functionality.

Damage on the surface, such as scratches, cracks, notches, grooves etc., as well as bent components, indicates the medical device must not be used. The medical device must be disposed of by the medical facility. Do not use any damaged medical devices!

Handling
The instruments must not be overstressed through twisting or levering, as this can lead to damage or to fracturing of the instruments.

Risks
If the instruments are not handled very carefully, then the following risks can occur:
- Damage of nerves, vessels and tissue
- Bleeding
- Infections

Application duration: Transient (< 60 minutes under normal conditions)

Indications

Instrumentation supplied by Aptis Medical, LLC are to be used by medical professionals only and are indicated for use with the Aptis prosthesis manufactured by Aptis Medical, LLC.

Contraindications

Instrumentation supplied by Aptis Medical, LLC are not designed, distributed, sold or intended for use other than indicated. These devices cannot be used by individuals who are not medical professionals. These devices should not be used in non-clinical or non-surgical applications.

Limited Warranty

Aptis Medical, LLC warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse, or improper handling of the product subsequent to receipt by the purchaser. Aptis Medical, LLC does not warrant the outcome of the surgical procedure.

Proper disposal of instruments

When the instruments are no longer able to be used due to wear, tear, or damage, they are to be properly disposed. Proper disposal is defined as: instruments are to be disassembled (as much as possible), the contaminations are removed, and then the instruments are sterilized once more before the disposal. Care should be taken to properly dispose of instruments with sharp or cutting edges.

Limitations on Reprocessing

Repeated processing, according to these instructions, has minimal effect on and should not compromise the performance of the Aptis instruments. End of life is normally determined by wear and damage due to use.

Instrument Care

New instruments are packaged clean, not sterile and should be assumed to be contaminated. All instruments must be cleaned and sterilized before each use.
For your safety, be familiar with the procedures for handling contaminated materials at your facility before following these instructions.

Clean instruments as soon as possible after use and avoid allowing soiled instruments to dry. Instruments should be wiped as needed with sterile surgical sponges moistened with sterile water during the procedure, to remove gross soil. Contaminated instruments must be contained during transport and should be transported in a timely manner to a location designed for decontamination.
Blood and body fluids can cause pitting of instruments and, if left to dry, can be difficult to remove. Blood, body fluids, and saline, are highly corrosive. Corrosion, rusting, and pitting occur when saline, blood, and debris are allowed to dry in or on surgical instruments. Instruments should be rinsed with water because of the corrosive nature of blood, body fluids, and saline. If blood and body fluids are not removed, they can prevent adequate sterilization, which could be an avenue for transmission of other potentially infectious materials. Dried blood and debris can be difficult, if not impossible, to remove from all surfaces during the decontamination process; therefore, subsequent disinfection or sterilization may not be achieved. Immerse or use damp towels or sponges saturated with deionized or distilled water to keep soiled instruments moist prior to cleaning. Cannulated instruments (instruments with lumens) should be irrigated with sterile water, as needed, throughout the surgical procedure to help remove residue.

Instrument lumens can become obstructed with organic material. Irrigating these instruments with sterile water helps remove residue. Instrument lumens should be irrigated with sterile water, as needed, throughout the surgical procedure.

Avoid using extreme detergent concentration levels. Warm or hot water, 149°C maximum (300°F), may aid in cleaning. Ultrasonic cleaning is recommended for instruments with lumens, internal surfaces or crevices, which may be hard to clean manually.

Neutral pH cleaners (pH 6.0-8.0) are recommended for longer life of the instruments. If acidic or alkaline solutions are used, follow the manufacturer's recommendations for neutralizing the pH by rinsing with water or neutralizing agent. Highly alkaline or acidic cleaners (used in some mechanical washers) are not recommended as they will reduce the life of the instruments and may affect instrument performance. Avoid prolonged exposure to acidic or alkaline solutions and solutions containing chlorides, bromides or iodine.

Use of water-soluble lubricants is recommended for instruments with moving parts or those intended to be assembled intraoperatively to another instrument.

Check instruments thoroughly for damage. Do not use damaged instruments as they may compromise the surgical outcome. Replace damaged instruments before next use.

Manual Cleaning Instructions

Before sterilization, rinse each instrument thoroughly under running tap water until all visible soil is removed. Prepare a room temperature tap water and neutral-pH enzymatic detergent (equivalent to Enzol®) solution bath by following the detergent manufacturer's recommendations and fully immerse the instruments, allowing them to soak for a minimum of 20 minutes. Thoroughly clean and scrub each instrument manually with a clean, soft-bristled brush in the solution bath to ensure removal of any visible soil/proteinaceous material, paying particular attention to crevices and other hard to reach areas. Clean instrument lumens internally with a pipe cleaner or equivalent brush, pass completely end to end through the lumen. Perform the brushing procedure at least 4 times, each time cleaning the brush with your fingertips in the prepared detergent. Flush lumens and holes thoroughly and rinse lumens with a syringe and PURW (purified water). Rinse each instrument thoroughly using purified water for a minimum of 3 minutes.

In the same detergent bath, fully immerse and ultrasonically clean the instruments for 10 minutes. After sonication, rinse all instruments thoroughly with PURW for a minimum of 3 minutes. While immersed brush all surfaces of the device including lumens and hard to reach areas. Thoroughly flush all lumens and holes after sonication using a syringe and PURW.

Thoroughly inspect each instrument for visible soil/proteinaceous material following sonication and rinsing. Dry each instrument using a soft, clean cloth.

Thoroughly clean and visually inspect the tray and each instrument for cleanliness including internal surfaces and crevices. The tray and instruments should be re-cleaned, washed and re-inspected if not visually clean and there are any signs of foreign matter or residue.

Automated Cleaning Instructions (<u>For Metal Trays ONLY</u>)
Manual Pre-Cleaning

- Rinse each soiled instrument under running cold tap water for a minimum of one (1) minute. Thoroughly flush lumens and other difficult to reach areas.
- Prepare a detergent bath with cold tap water and neutral-pH enzymatic detergent (equivalent to Enzol®) by following the detergent manufacturer's recommendations in an ultrasonic unit. Place the instruments in the prepared detergent bath. While immersed in the detergent bath, flush lumens and brush the interior and exterior of all instruments using a soft bristled brush.
- Sonicate the instruments for 5 minutes.
- Rinse each instrument under cold running tap water for a minimum of one (1) minute. Thoroughly flush lumens and other difficult to reach areas.
- Place all instruments back in the manufacturer's provided instrument tray. Note: the tray lid must remain off the tray during the washer-disinfector cycle.
- Transfer the loaded instrument tray into a validated washer-disinfector and use the parameters below:

Stage	Recirculation Time (minutes)	Temperature	Detergent Type and Concentration (if applicable)
Pre-wash 1	1:00	Cold tap water	N/A
Enzyme Wash	10:00	Hot tap water	Neutral-pH enzymatic detergent (equivalent to Enzol®) ~8 mL/L (1oz./gallon)
Wash 1	2:00	66°C (151°F) tap water	Neutral detergent (equivalent to) Valsure® Neutral Detergent ~2 mL/L (¼ oz./gallon)
Dry Time	30:00	100°C (212°F)	N/A
Motor Speed: High			

After Cleaning

- Visually inspect all instruments and trays in a well-lit area to verify that all visible soil has been removed (if the device has been used). If necessary, repeat the cycle and/or clean manually.
- Ensure the instruments are completely dry. If necessary, use single-use towelettes to remove any remaining traces of moisture.
- Visually inspect all instruments and trays in a well-lit area for any corrosion, damaged surfaces, or wear. Do not further use any damaged instrument—instead clean it of all biological substances (if necessary) and discard it in accordance with the prevailing laws and regulations.

Sterilization

This sterilization recommendation describes steam/moist heat sterilization methods. The following sterilization cycles have been shown to produce a sterility assurance level of 10^{-6} when parts have been cleaned to the instructions above. Other similar steam cycles and cleaning procedures may be used but have not been evaluated. Sterilization qualification was performed using specific equipment and procedures. Use of cycles, equipment and procedures other than those listed should be qualified by the user. Do not exceed 149°C (300°F). Do not stack trays during sterilization or load above 11 kg (25 lbs).
*Note: Instrument cases do not provide a sterile barrier and must be used in conjunction with an FDA cleared, intact steam sterilization compatible wrap to maintain sterility.

Recommended Steam Sterilization Parameters

Cycle Type	Minimum Temperature	Minimum Exposure Time	Minimum Dry Time	Note
Prevacuum Steam Sterilization	134° C	3 minutes	40 minutes	1,2
Prevacuum Steam Sterilization	132° C	4 minutes	60 minutes	3
Immediate Use Prevacuum Steam Sterilization	132° C	3 minutes	Not applicable	2,3,4

Note: Wrapped gravity steam sterilization is no longer recommended due to the extended processing time required.
[1] Sterilization parameters not for use in the United States
[2] Minimum validated time to achieve a 10^{-6} sterility assurance level (SAL)

[3] Minimum validated temperature to achieve a 10^{-6} sterility assurance level (SAL)
[4] Flash (immediate use) steam sterilization by exposure at 132°C should only be used as an emergency procedure.

For further information on the above cleaning and sterilization recommendations please contact:

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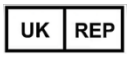
Product Complaints
Any medical professional (e.g., customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the official distributor of Aptis Medical, LLC and, where applicable, the local competent authority. Further, if any of the instrumentation ever “malfunctions” (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any Aptis Medical, LLC product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX, or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report from the distributor is requested. Before returning products which were used in a hospital environment, perform a complete processing according to these instructions. Confirmation of processing including parameters used shall be provided in the delivery note.

Meaning of the symbols

Symbol	Symbol Title	Description of Symbol
	Manufacturer.	Indicates the medical device manufacturer.
	Batch code.	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number.	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Non-sterile.	Indicates a medical device that has not been subjected to a sterilization process.
	Consult instructions for use or consult electronic instructions for use.	Indicates the need for the user to consult the instructions for use.
	Caution.	Indicates that caution is necessary when operating the device or control near where the symbol is placed, or that the current situation requires operator awareness or action to avoid undesirable consequences.
	Authorized representative in the European Community/European Union.	Indicates the authorized representative in the European Community/ European Union.
	Authorized representative in the United Kingdom	Indicates the authorized representative in the United Kingdom
	Authorized representative in Switzerland	Indicates the authorized representative in Switzerland
	Medical Device.	Indicates the item is a medical device
	CE Mark.	Signifies European technical conformity with Four Digit Notified Body Number.
	Unique device identifier	Indicates a carrier that contains unique device identifier information.