


Orbital Implant Introducer – Instructions For Use

	CAUTION: consult accompanying documents.		This Product is sold: Non- Sterile.
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INSTRUCTIONS - Point of use

- Following use, the instrument should be cleaned of excess soil using a disposable cloth/paper wipe as soon as possible.
- The instrument should be kept moist to prevent soil from drying on the instrument.
- **WARNING:** Do not soak instruments in solutions containing chlorine or chlorides as these may cause corrosion and damage the instrument.

Automated Cleaning and Thermal Disinfection

WARNING: Do not process microsurgical instruments in an automated washer unless it has a delicate cycle.

1. Follow the instructions of the washer manufacturer.
2. Use only neutral pH cleaning solutions.
3. If gross soiling is evident on the instrument manual pre-cleaning with a neutral pH cleaning solution may be necessary.
4. Ensure that any hinged instruments are open and that instruments with lumens can drain effectively. Where the washer has provisions for lumen adaptors these should be employed for lumened instruments.
5. Place the instruments in suitable carriers such that they are not subject to excessive movement or contact with other instruments.
6. Process the instrument according to the conditions indicated below. The cleaning times and conditions may be adjusted based on the amount of soiling present on the instrument. The following conditions were validated using a neutral pH detergent (Getinge Neutrawash) and a severe organic soil challenge (Biomedical Instrumentation and Technology 2007;41(4):324-331).

Phase	Time	Temperature
Pre-Wash	3 minutes	30°C (86°F)
Wash ¹	10 minutes	40°C (104°F)
Wash ¹	10 minutes	30°C (86°F)
Rinse	3 minutes	30°C (86°F)
Heated Final Rinse	50 minutes at 80°C (176°F) or 10 minutes at 90°C (194°F) ²	
Drying	By observation - Do not exceed 110°C (230°F) ³	

¹Neutral pH detergent: Adjust concentration according to the detergent manufacturer's directions regarding water quality and the extent of instrument soiling.

²Minimum exposure conditions for thermal disinfection.

³As cleaning frequently involves mixed instrument loads, the efficacy of drying will vary based on the equipment and the nature and volume of the load being processed. Therefore, the drying parameters must be determined by observation.

7. Following processing carefully inspect the instrument for cleanliness, any evidence of damage, and proper operation. If visible soil remains on the instrument following processing it should be reprocessed or manually cleaned.

Disinfection

Due to the potential for residual chemicals to remain on the instrument and cause an adverse reaction it the use of liquid chemical disinfectants or sterilants with instruments is not recommended. See Automated Cleaning and Thermal Disinfection above for procedures for thermal disinfection of instruments in an automated washer/disinfector. Carefully dry the instrument with a lint free surgical wipe or blow the instrument dry with micro filtered forced air.

Manual Cleaning

1. Disassemble the instrument as applicable and inspect the instrument for damage or corrosion.
2. Pre-rinse the instrument by holding it under cold running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary depending on the size and extent of soiling of the instrument.
3. Place the instrument into a suitable clean basin filled with fresh neutral pH cleaning solution prepared according to the directions of the solution manufacturer. Use only cleaning solutions that are labeled for use with medical devices or surgical instruments. Ensure that the instrument is fully immersed in the cleaning solution. The following conditions were validated using a neutral pH detergent (Steris ProKlenz NpH) and a severe organic soil challenge (Biomedical Instrumentation and Technology 2007;41(4):324-331).
4. Using a soft cleaning brush gently scrub all surfaces of the instrument while keeping the instrument submerged in the cleaning solution for at least 5 minutes. Clean the instrument until all visible soil has been removed.
5. Rinse the instrument by holding it under cold running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary depending on the size of the instrument and the amount of soil.
6. Place the instrument in an ultrasonic bath filled with fresh neutral pH cleaning solution and sonicate for 5 minutes. Use only cleaning solutions that are labeled for use with medical devices or surgical instruments. Ensure that the instrument is fully immersed in the cleaning solution. Do not overload the ultrasonic bath or allow instruments to contact one another during cleaning. Do not process dissimilar metals in the same ultrasonic cleaning cycle.
7. The cleaning solution should be changed before it becomes visibly soiled. The ultrasonic bath should be drained and cleaned each day it is in use or more frequently if visible soiling is evident. Follow the instructions of the manufacturer for the cleaning and draining of the ultrasonic bath.
8. Repeat steps 4-6 as necessary if visible soil remains on the instrument.
9. Rinse the instrument by holding it under warm (27°C – 44°C; 80°F – 111°F) running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary depending on the size of the instrument.
10. Immerse the instrument in clean basin containing fresh deionized or distilled water and soak the instrument for at least three minutes.
11. Perform a final rinse of the instrument with sterile distilled or deionized water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water.

Maintenance, Inspection and Testing

Following cleaning inspect the instrument to ensure that all visible soil has been removed and that the instrument operates as intended.

Packaging

Package the instrument in a suitable sterilization pouch or instrument tray.

Sterilization

Orbital Implant Introducer may be sterilized by the following moist heat (steam) sterilization methods:

- Prevacuum High Temperature Autoclave: 274°F (134°C) for 3 minutes; wrapped.
NOTE: As per ANSI/AAMI ST79:2010 and A1:2010 270°F (132°C) for 4 minutes and 275°F (135°C) for 3 minutes are acceptable minimum cycle times for dynamic-air-removal steam sterilization cycles.
- Standard Gravity Autoclave: 250°F/15.2 psi (121°C/104.8kPa [1.048 bar]) for 30 minutes; wrapped.
- High Speed (Flash) Autoclave: 270°F/27.1 psi (132°C/186.8kPa [1.868 bar]) for 10 minutes; unwrapped.
 - Flash sterilization processing should be reserved for emergency reprocessing only and should not be employed for routine sterilization processing of the instrument. Flash sterilized items should be used immediately, and not stored for later use. See ANSI/AAMI ST79:2010 and A1:2010 and your institution's policies for restrictions regarding the use of flash sterilization.
- High Vacuum (Pre-vacuum) Autoclave: 274°F/30.0 psi (134°C/206.8kPa [2.086 bar]) for 3 minutes.

Storage

Following sterilization processing packaged instruments may be stored in a clean area free of temperature and humidity extremes in accordance with your institution's policies.

LIMITATIONS ON REPROCESSING

Reprocessing according to the instructions provided below should not adversely affect the functionality of instruments. The useful life of the instrument is determined by wear and damage during use.