

VeriTest Process Challenge Devices

Instructions for Use

Included Products:

VeriTest Tags

VeriTest Multi

VeriTest Lumen

For best results read the entire instruction manual before using VeriTest devices.

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User assistance

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Contents

User assistance.....	2
General warnings and cautions	4
1. Purpose of the device.....	5
2. Description of the device.....	6
VeriTest Tag.....	6
VeriTest Multi Block	6
VeriTest Lumen.....	6
3. Environmental conditions that affect use	8
4. Setup instructions.....	9
4.1 Operating Instructions.....	9
4.1 VeriTest Tags.....	9
4.2 Assembly of VeriTest Multi block.....	10
4.3 Assembly of the VeriTest Lumen capsules	11
5. Cleaning process Evaluation.....	12
5.1 Cleaning Effectiveness Mapping	12
Preparation	12
Troubleshooting.....	14
5.2 Process validation	15
Troubleshooting.....	16
5.3 Process monitoring	17
Troubleshooting	18
6. Troubleshooting disclaimer	18
7. Storage	18
8. VeriTest PCDs Troubleshooting.....	18
9. Accidental Exposure	19
Eyes:	19
Skin:.....	19
Ingestion:.....	19
Inhalation:	19



General warnings and cautions



Read and understand this manual before using VeriTest family products.



Always wear gloves when handling VeriTest Tags.



VeriTest contain raw animal blood and tissue.



1. Purpose of the device



Fig 1 VeriTest PCD

VeriTest are a family of process challenge devices (PCDs) created to help evaluate effectiveness of cleaning processes for medical devices.

Modern medicine requires highly specialised and complex surgical instruments. Most of those instruments are unfortunately very difficult to clean. Consider robotic, laparoscopic and ophthalmic instruments containing features like gaps, crevices, joints and narrow lumens – as these are known to be particularly problematic.

Testing of surfaces of the instruments for the presence of is difficult since currently available methods do not allow to test both internal and external cleaning at the same time do not and provide results quickly. Because of this fact testing of actual instruments becomes troublesome and impractical from several points of view. Firstly – selecting the instruments that are representative to the entire reprocessed load and secondly assessing of particular elements of those instruments like box joint gaps or internal mechanisms of laparoscopic instruments is often impossible without disassembly and some instruments were not designed to be disassembled.

VeriTest Process Challenge Devices are a family of products specifically developed to verify cleanliness of the modern surgical instruments. VeriTest allows to evaluate narrow gap cleaning, cleaning of horizontal and vertical surfaces as well as internal cleaning of lumens.



2. Description of the device



Fig2.1 VeriTest Tag

VeriTest Tag

VeriTest family consist of VeriTest Tags and accessories like VeriTest Multi, Lumen that in combination with the Tags create particular challenges.

VeriTest Tags are small, flat strips of stainless steel or plastic with biological contamination applied to one side. VeriTest Tags were designed to be always used with accessories and never without them.



Fig2.2 VeriTest Multi Block

VeriTest Multi Block

“Multi” is a specially designed holder for VeriTest Tag used for evaluation of typical external features of medical devices that are difficult to clean.

VeriTest Tags are inserted into the holder in a specific orientation to create a box joint challenge (position 1), shadowed cleaning from underneath (position 2), cleaning from the top (position 3) and cleaning of vertical surfaces (position 4) like in a case of any three dimensional instrument.



Fig2.3 VeriTest Lumen 1

VeriTest Lumen

Hollow instrument PCDs are uniquely designed to simulate internal cleaning of lumens. Internal cleaning is an entirely different physical process to external cleaning in washers and washer disinfectors and must be evaluated independently. Internal cleaning is based on water and chemicals flowing through the lumen.



VeriTest Lumen are intended to simulate rigid scopes and are based on uniquely designed capsules that hold VeriTest Tags inside that simulate an internal wall of the lumen.

Design of the capsules ensures that water flowing through it mimics the flow through the surgical instrument.

Fig2.4 VeriTest Lumen 2



3. Environmental conditions that affect use

Washers and Washer Disinfectors that VeriTest family of PCDs is designed to evaluate use various types of chemicals in their cleaning processes. These Chemicals are an essential addition to the processes that break down contamination they however may affect some plastic materials.

With the variety of commercially available chemicals, it is not possible to test for compatibility of PCDs with all existing chemicals. Whenever there is suspicion of detrimental effect on VeriTest components – PCDs should not be used.

In case a detrimental effect is observed on VeriTest components in the form of chemical damage, cracking, discolouration etc. PCDs must not be used thereafter and particular chemical should be reported to Aseptium Limited.



4. Setup instructions

Aseptium's PCDs consist of VeriTest Tags that are always used in conjunction with accessories like VeriTest Multi (Fig4.a) and Lumen (Fig4.b).

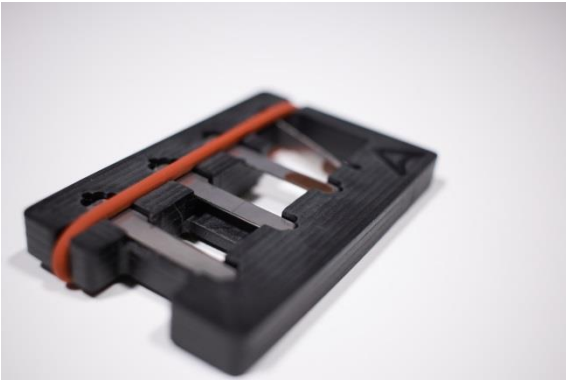


Fig4.a VeriTest Multi



Fig4.b VeriTest Lumen

Always wear protective gloves when handling VeriTest Tags. A pair of small forceps may be used to help with handling of the Tags.

4.1 Operating Instructions

VeriTest PCDs are used to simulate real surgical instruments and hence there are made from various materials and use different accessories to address the most challenging features of medical devices in respect to cleaning. Therefore the entire product family should be used instead or alongside other surgical instruments to evaluate processes.

VeriTest Multi is used to verify cleaning performance of cleaning by spray arms or ultrasonics while VeriTest Lumens are specifically addressing the problem of internal cleaning of lumens, tubes and channels. These processes are independent and require unique approaches.

4.1 VeriTest Tags

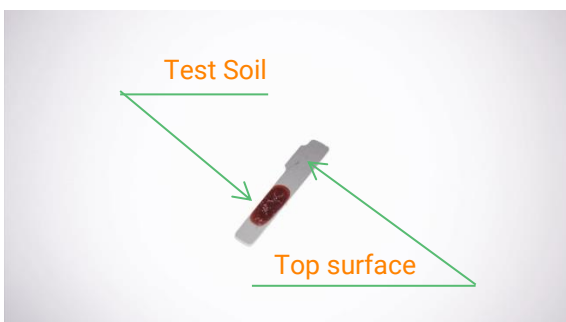


Fig4.1 VeriTest Tag soil position and tag orientation.

VeriTest Tags are hermetically packed in silver packaging foil that helps to extend their shelf life. In order to extract them from the packaging do the following:

1. Cut/tear the packaging carefully
2. Pull out the VeriTest Strip
3. Bend and twist the tag until the joining tab breaks. **DO NOT DAMAGE THE TEST SOIL!**



4.2 Assembly of VeriTest Multi block

VeriTest Multi is a block designed to hold VeriTest Tags in a certain orientation (Positions 1-4).

1. Load tag(s) in the correct orientation.
2. Fit the silicon band to hold the tag(s) securely in-place. Note that VeriTest tags will fit the VeriTest Multi Block in one orientation only for each recess.
3. VeriTest Multi Block PCD ready to use.

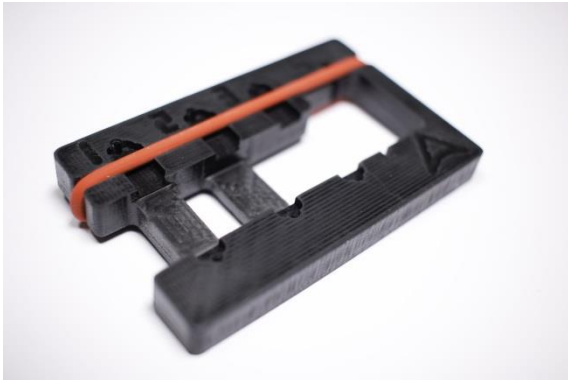


Fig4.2.1 VeriTest Multi Block

Photo on the left shows a VeriTest Multi Block with Tags and annotation to positions of particular cleaning challenges:

1. Box joint and narrow gaps
2. Shadowed areas cleaned from underneath
3. Top surface
4. Vertical side surface

For best result use four tags simultaneously.

Loading VeriTest Multi blocks:

Four VeriTest Tags can be loaded into the VeriTest Multi Block. Tags fit the Block in one orientation only – the side tab makes them asymmetrical and prevents from loading them the wrong way round:

Positions one and two are loaded face down (top surface with test soil down). Position three face up and position four face to the left. For each position slide the tag under the orange silicone band using tweezers or by hand as per Fig 4.2.2.

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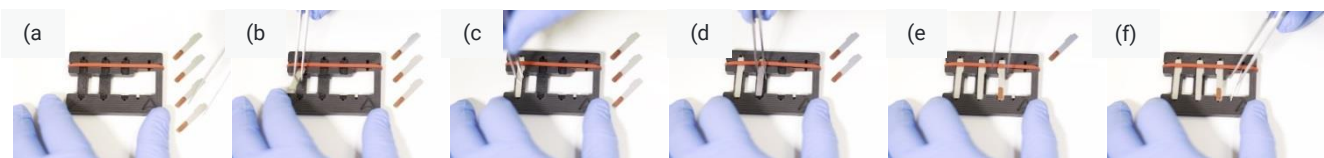


Fig 4.2.2 VeriTest Multi loading.



4.3 Assembly of the VeriTest Lumen capsules

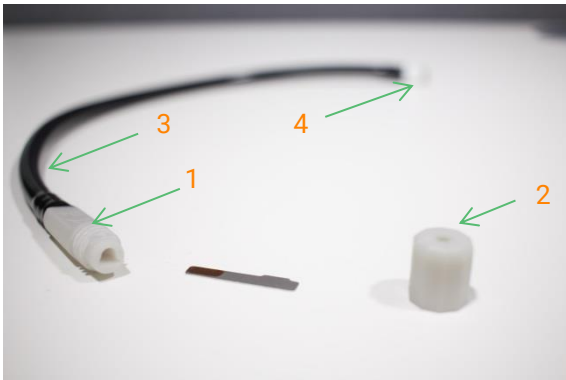


Fig4.3.1. VeriTest Lumen

Similarly to VeriTest Multi all VeriTest Lumen capsules are designed to work with the VeriTest Tags.

VeriTest Lumen consist of:

1. Capsule
2. Screw-on Cap
3. Lumen channel
4. Connector

Steps to follow to place a VeriTest Tag in the Capsule:

1. Unscrew the cap counter clockwise
2. Insert the VeriTest tag into the cavity in such way that only a small fraction of its length sticks out. Tags can be fully inserted only one way round where the top surface with the test soil faces the inside of the cavity and blank side faces the only internal flat wall.
3. Screw on the Cap tight until a resistance is felt. Do not overtighten the cap as it may be difficult to unscrew after the process.

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Loading VeriTest Lumen

VeriTest Lumen come in different sizes corresponding with the size of channels they evaluate. Loading procedure is the same for each size. Capsules are designed such that VeriTest tags fit only one way round. Use tweezers or load it by hand.

To load the VeriTest Lumen capsule unscrew the cap, insert a new VeriTest Tag fully into the cavity (the back of VeriTest Tag always fits against the flat side of the capsule cavity wall) and crew the cap tight by hand. Do not use excessive force as it may be difficult to remove the tag after the process.

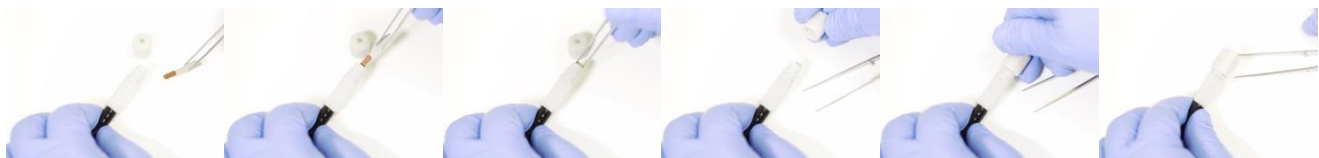


Fig 4.3.2. VeriTest Lumen Loading.



5. Cleaning process Evaluation

Process Challenge devices are an excellent tool to investigate the effectiveness of cleaning processes. Critically cleaning processes are not uniform within the washing chamber, meaning that in different positions and orientation of instruments or surfaces inside the same washing chamber will produce different results. For that reason it is essential to first locate areas of lower cleaning effectiveness - cleaning effectiveness mapping.

Once it is known in which areas in the washing chamber cleaning effectiveness is lowest those areas can be selected for consequent process validation and periodic monitoring.

5.1 Cleaning Effectiveness Mapping

The premise of chamber mapping is to assess cleaning efficiency (how well particular technology performs) of particular washer and not cleaning effectiveness of particular washing cycle. Mapping will allow for Identification of areas of lower cleaning efficiency that may be caused by malfunctions, defects, wear of components and sometimes poor design. This test verifies Operational Performance (OQ) of the equipment and will pick up such cases like differences in spray arm coverage one each level, differences between washer levels etc. It is critical to subsequent process optimisation and monitoring.

Preparation

In deluge washers, where primary cleaning action is delivered by spraying water on instruments, it is possible to reduce the number of tests require for complete mapping by applying the concept of symmetry. It assumes that cleaning efficiency will be the same on the opposite side of the symmetry plane. Typically deluge washers with centrally positioned spray arms are symmetrical against the spray arm axis making it possible to test only one half of each level (right/left or back/front).

In case of ultrasonic washers or baths, asymmetrical instrument carriers each entire level should be evaluated. It is recommended to use Stainless Steel tags only unless equipment is used predominantly for plastic instruments – in the latter case use Polymer Tags only.

Test procedure – deluge and ultrasonic washers

*for a typical deluge washer with a central spray arm configuration and ultrasonic baths and washers:

1. Remove VeriTest Tags from the packaging and mark them individually.
2. On each level of the carrier place 5 VeriTest Multi blocks and arrange them for:
 - a. Fig 5.1.1. a deluge washer with three Din basket self and as per shelf.
 - b. Fig 5.1.2. a deluge washer with two din basket shelf.
 - c. Fig 5.1.3. an ultrasonic bath/washer with rectangular chamber – Left Hand Side.
 - d. Fig 5.1.4. an ultrasonic bath/washer with rectangular chamber – Right Hand Side.

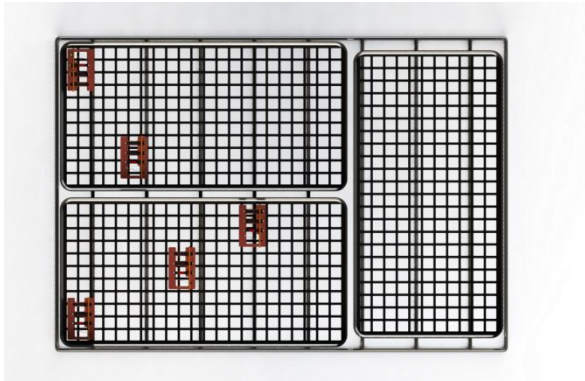


Fig 5.1.1. Setup for 3 Din Basket shelf.

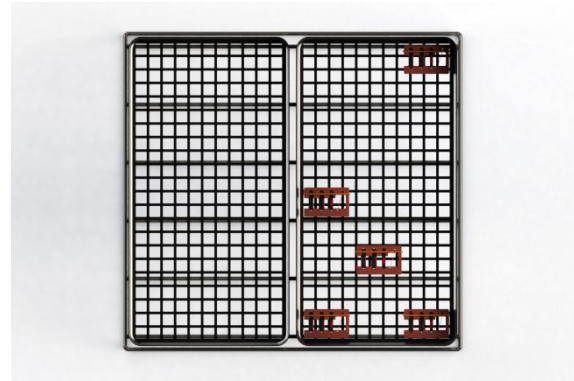


Fig 5.1.2. Setup for 2 Din Basket shelf.

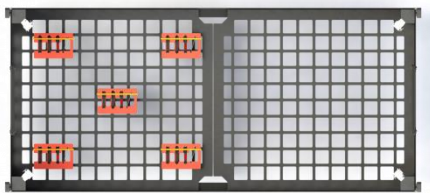


Fig 5.1.3. Setup for an Ultrasonic bath/washer Left Hand Side (LHS).

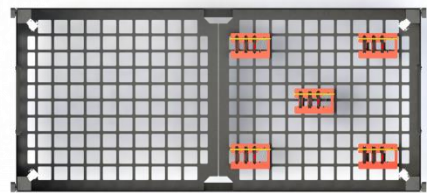


Fig 5.1.4. Setup for an Ultrasonic bath/washer Right Hand Side (RHS).

3. Note the position of each individual tag in the chamber.
4. Load the carrier in the washer and run a test washing cycle with a 25% shorter main wash (part of the cycle where primary cleaning chemical is added).
5. Unload the instrument carrier and remove the VeriTest tags from the blocks.
6. Evaluate the differences of the amount of contamination with a quantitative or semi quantitative contamination detection method. Alternatively evaluate the amount of contamination visually and note down the results. If most of the samples come out "clean" or difficult to visually interpret further reduce the cycle time until results can be clearly compared. Take photographic evidence.
7. Repeat above steps three times and compare average values. Areas identified to be of lower cleaning efficiency should be thereafter used as location for periodic monitoring.
8. Dispose of used VeriTest Tags.

Test Procedure - Hollow instruments cleaning

It is recommended that VeriTest Capsules are used simultaneously with VeriTest Multi blocks.

1. Remove VeriTest Tags from the packaging and mark them individually and load them into VeriTest Lumen Capsules.
2. Connect VeriTest Lumen PCDs to each flushing or irrigation ports (or groups of ports if there is more than one) in the machine. Connect at least first and last connector of each the group.
3. Note the position of each individual PCD in the chamber.
4. Load the carrier in the washer and run a test washing cycle with a 25% shorter main wash (part of the cycle where primary cleaning chemical is added).
5. Unload the instrument carrier and remove each VeriTest Tag from each VeriTest Lumen Capsule.
6. Evaluate the differences of the amount of contamination with a quantitative or semi quantitative contamination detection method. Alternatively evaluate the amount of contamination visually and



note down the results. If most of the samples come out “clean” or difficult to visually interpret further reduce the cycle time until results can be clearly compared. It is possible that the amount of contamination on tags removed from VeriTest Lumen Capsules will significantly differ from ones evaluated with VeriTest Multi – in that case adapt the cycle parameters to be able to evaluate internal cleaning at a similar level of accuracy. Take photographic evidence.

7. Repeat above steps three times and compare average values. Areas identified to be of lower cleaning efficiency should be thereafter used as location for periodic monitoring.
8. Dispose of used VeriTest Tags.

Troubleshooting

If considerable differences are identified in cleaning in different areas of the cleaning chamber consider the following:

For deluge washers and washer disinfectors:

1. Inspect spray arms for blockages in holes and nozzles that direct water.
2. Check whether rotation is not impeded by debris or defects. Spray arms should spin freely when spun around by hand.
3. If no issues found run a cycle and if possible measure the speed of rotation. Count the number of full rotations over a 60s period) note down and compare results. Difference between same type of spray arms should not exceed 10%.
4. If the initial results repeat and speed differs by more than 10% contact the manufacturer and request assistance. If initial results repeat and difference in rotational speed does not differ by more than 10% use the area of lowest cleaning efficiency for further process optimisation.

For ultrasonic baths and washers:

1. Consider the loading patterns and the influence of the instrument carrier and other features of the bath on the process. Repeat the exercise if no difference is noticed use areas of lower cleaning efficiency for further process optimisation and monitoring.
2. If the washing results differ considerably (i.e. very poor cleaning results in one particular area)
3. Inspect ultrasonic transducers performance (ensure the machine is switched off and where possible disconnect from power)
 - a. Inspect water level measurement
 - b. Perform functional test of ultrasonic activity (cavitation meter, thin foil test, etc.)
 - c. Repeat the test and if no difference is noticed contact the manufacturer

For internal channels (lumen) cleaning:

1. Inspect the connection to the irrigation system and the connection port for debris, cracks or visible signs leakages.
2. If filters are installed in the irrigation system inspect them for blockages.
3. Repeat the test – if separate pump is used for irrigation inspect whether the pumps turns on properly (noise/vibrations/etc)
4. Where multiple ports are available test them individually – extreme positions first (first and last ones from the row).
 - a. Use multiple PCDs if possible at the same time and compare results. If not possible ensure the consecutive cycles are exactly the same (time, temperatures etc)
5. Consider ultrasonic activity and PCD positioning within the chamber.
6. If above do not improve the result contact the equipment manufacturer.



5.2 Process validation

If local guidance allows for process validation with use of process challenge devices follow this procedure.

Wherever possible use washer symmetry to reduce the number of samples. Depending on the types of surgical instruments used use either stainless or polymer VeriTest Tags.

Test procedure:

*for a typical deluge washer with a central spray arm configuration and ultrasonic washers:

1. Remove VeriTest Tags from the packaging and mark them individually.
2. On each level of the carrier place 5 VeriTest Multi blocks and arrange them for:
 - a. Fig 5.2.1. a deluge washer with three Din basket shelf and as per shelf.
 - b. Fig 5.2.2. a deluge washer with two din basket shelf.
 - c. Fig 5.2.3. an ultrasonic bath/washer with rectangular chamber – Left Hand Side.
 - d. Fig 5.2.4. an ultrasonic bath/washer with rectangular chamber – Right Hand Side.

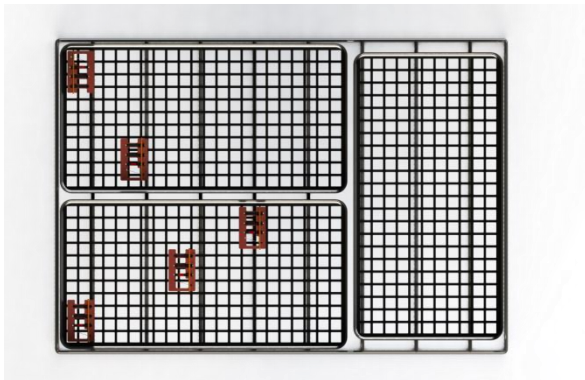


Fig 5.1.1. Setup for 3 Din Basket shelf.

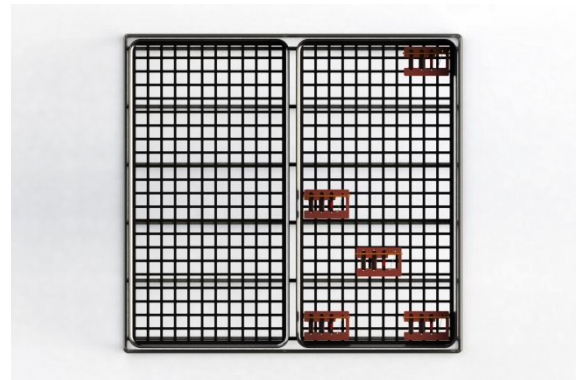


Fig 5.1.2. Setup for 2 Din Basket shelf.

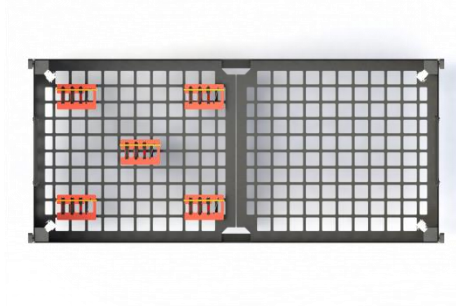


Fig 5.1.3. Setup for an Ultrasonic bath/washer Left Hand Side (LHS).

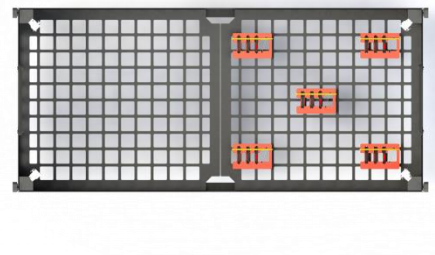


Fig 5.1.4. Setup for an Ultrasonic bath/washer Right Hand Side (RHS).

3. Note the position of each tag.
4. Load the carrier in the washer and run the cleaning process in question.
5. Unload the carrier and remove the VeriTest multi blocks and very test tags individually. Pay attention not to contaminate tags in the process.
6. Evaluate the differences of the amount of contamination with a quantitative contamination detection method to confirm it is below the imposed limit – take photographic evidence.
7. Repeat above steps three times and ensure all tags from three consecutive cycles have lower contamination levels than the imposed limit.



8. Dispose of used VeriTest Tags.

Validation of Hollow instrument washing

If same process is intended for hollow instrument (lumen) cleaning it is critical that internal flushing or irrigation system is evaluated at the same time. Perform the following additional steps:

At point 1:

1. Remove additional tags from the packaging and mark them individually.
2. Load each VeriTest Capsule intended for the test with a new VeriTest Tag.

At point 2:

1. Connect at least one VeriTest Lumen to each connector group (If connectors are on different sides of the chamber or instrument carrier connect at least three VeriTest Lumen to each side)

Troubleshooting

If any of the VeriTest Tags after the cleaning process still contain contamination consider two scenarios.

1. Random Tag failed in one cycle out of three. Failure may be caused by:
 - a. Issue with loading (additional shadowing, Tag misplaced from the holder etc.)
 - b. Random temporary reduction of cleaning performance that may be caused by:
 - i. Blocking, intermittent or impeded rotation spray arm. Check whether all spray arms rotate freely and without noticeable resistance. Inspect spray arm nozzles for debris and blockages.
 - ii. Cleaning chemistry dosing problem. Inspect for leakages, air trapped in the system, chemical pickup tube and cycle logs to ensure equal amount of detergent was delivered.
 - c. Incoming water temperatures. In conventional washers water is often heated to the set point while washing. Depending on temperature difference of the mains water and the set point heating times will differ. Fluctuations in incoming water temperature may change overall cycle time but also lead to excessive foaming etc. In some cases temperature of pre-wash is not controlled and dictated by main cold water temperature that may also fluctuate considerably. Compare logs from all three cycles to identify significant differences.
2. Same Tags failed in all three cycles. Failure may be caused by:
 - a. Persistent issue with loading – loading tray design, issues with the carrier.
 - b. Continuous reduction of cleaning performance in particular area. May be caused by:
 - i. Stuck or slowly moving spray arm. Check free rotation on each level. Check for debris and mechanical wear.
 - ii. Inspect spray arm nozzles for debris and blockages.
 - iii. Carrier design. In some cases the carrier design itself does not allow for even distribution of pressure between spray arms and by design these will spin at different speeds – If the difference is significant it may cause performance issues. Compare different levels and identify whether the condition is permanent. If problem persists the washer may need to be revalidated with emphasis on achieving good results in areas of lower cleaning effectiveness.
 - iv. Excessive foaming. Typically affects the bottom level of the carrier where load gets covered in foam and impedes the washing action. Foaming is highly undesirable as it can reduce the head of water in the sump and cause loss of pump pressure (intermittent and continuous) and cause cavitation in the pump head. In both cases are audible as pump noise fluctuates. If machine is equipped with pressure



monitoring investigate the cycle logs for the loss of pressure. When foaming causes loss of pressure the entire chamber volume is affected.

- c. Issues with cleaning chemicals.
 - i. Check whether the right chemical is supplied and whether it is not out of date. Inspect dosing line for leaks and trapped air (especially if low quantities are dispensed).
 - ii. Check recommended detergent concentration and compare with the cycle logs.
 - iii. Check chamber temperature at which detergent is dispensed. In some cycles detergents are added while or right after water is pumped into the chamber and before washing temperature is reached. Some detergents foam excessively when used at temperatures outside the recommended range.
- d. Issues with water quality.
 - i. Quality of incoming water may vary periodically and it may influence the washing cycle. Impurities, minerals and metal content affect washing performance as they may react with cleaning detergent and lower it's effectiveness.
 - ii. Check water conductivity against one measured during cycle validation. If they differ significantly cycles may need to be optimised to new conditions and revalidated. It is advisable to install water quality monitoring system.

5.3 Process monitoring

Process monitoring with use of VeriTest Family of PCDs allows to routinely verify cleaning process effectiveness. Washing efficiency mapping should reveal in which areas in the chamber or instrument carrier surfaces of instruments are more difficult to clean. These areas should be used for routine monitoring. Additionally individual experience with washers may suggest other areas of suboptimal performance. Routine monitoring aims to pick up issues with particular cycles like failures of the equipment as well as random issues with loading, chemicals, water supply as well as occasionally cycle design. For best results it is recommended to monitor every cycle.

PCDs should be used alongside normal load.

Test Procedure

1. Identify the process for evaluation and typical instruments that it cleans to choose between the Stainless Steel and Polymer(plastic) VeriTest Tags.
2. Remove VeriTest Tags from the packaging (optionally mark them individually) and load them to VeriTest Multi block and optionally if internal cleaning is evaluated to VeriTest Lumen capsules. See Section 4.1 for detailed instructions.
3. Place VeriTest Multi block in the instrument carrier in a position identified by cleaning efficiency mapping to experience lowest cleaning efficiency – note down the position.
4. Optionally - connect VeriTest Lumen to available flushing/irrigation ports – ideally in to the same group of connectors as other instruments.
5. Load the carrier in the washer and run a cleaning process.
6. After the process unload the carrier and remove the VeriTest multi blocks and VeriTest Lumen capsules. Pay attention not to contaminate tags in the process.
7. Evaluate the amount of contamination with a quantitative contamination detection method to confirm it is below the imposed limit or in case those methods are not available perform a thorough visual inspection of the tag ensuring it is visually clean – take photographs for evidence.
8. Dispose of used VeriTest Tags.



Troubleshooting

Routine monitoring aims to pick up failures and random issues with the process. If after the process VeriTest Tags still contain excessive level of contamination inspect the following aspects:

1. Wrong cycle for the load. Some machines rely on operators choice of cycle. Reference the cycle log whether the correct cycle was executed.
2. Loading patterns. In some cases instruments or equipment can move during the washing process. this may lead to excessive shadowing, spray arm blocking.
3. Too many instruments in a single wash. At times of intensive demand there is a tendency to overload the washers beyond what they were validated to reprocess. Overloading leads to excessive shadowing but also introduces a larger amount of contamination that may lead to excessive foaming as well as lower efficiency of detergents.
4. Detergent delivery. Issues with detergent pickup from the bottle, blockages, twisted or bent delivery tubes, leakages may lead to inadequate dose of detergent may lead to lower cleaning effectiveness.
5. Wrong detergent. Especially during bottle changes it is sometimes possible to replace bottle with wrong detergent or detergent batch. Inspect whether correct detergent is present and properly installed in the machine.
6. In any of the above cases the entire load should be considered compromised and should be cleaned again unless there is a clear explanation to the issue with particular basket or even individual Tag.

6. Troubleshooting disclaimer

Cleaning cycles can be affected by multiple variables and random events. All troubleshooting contained within this document is presented as exemplary cases and these should not be the ultimate basis for any decision making. Aseptium does not accept any responsibility for following instructions contained in this document.

7. Storage

VeriTest Tags as well as accessories should be stored in a dry place at temperatures between 5°C and 25°C.

Shelf life of VeriTest Tags is 60 days from the date of manufacturing.

Due to the risk of biofilm growth inside of the VeriTest Lumen the shelf life of these accessories is reduced to 6 months from the first use.

Dispose of used/expired VeriTest Tags and Accessories into the medical waste bin. Packaging is widely recyclable.

8. VeriTest PCDs Troubleshooting

If VeriTest Tags do not seem to fit the accessories correctly check the orientation they should be used at.

If VeriTest Tags are deformed (bent, twisted) after taking them out of the packaging or if Test soil on VeriTest Tags is cracked, peels off or is covered in mould do not use them as they may damage VeriTest Multi and Lumen and produce false results.

In case VeriTest Multi orange silicone band breaks replace it with an equivalent available from the distributor. Additionally investigate the nature of the incident as it may be caused by degeneration of



material exposed to certain chemicals – if material looks cracked or porous report it to the distributor noting what chemicals were used in the process.

In case VeriTest Lumen produce positive results (dirty VeriTest Tag) and contamination looks intact or only slightly washed check the connector integrity and check for channel blockages by running it under lukewarm water from the tap – water should run freely through the PCD.

9. Accidental Exposure

In the case of accidental exposure, take the following precautionary measures:

Eyes: Immediately flush eyes with plenty of water for 15 minutes. Get medical attention if irritation persists.

Skin: Immediately wash with soap and water. Get medical attention if irritation develops.

Ingestion: Give water to drink and get medical advice.

Inhalation: Remove to fresh air. Get medical attention for any breathing difficulty.