

# Brilliant Blue Distal Check Presented by Kimberly Todd and Linda Socha Southmedic



28/10/2014

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“Cleaning is always essential prior to disinfection or sterilization. An item that has not been cleaned, cannot be assuredly disinfected or sterilized”.

- *Public Health Agency of Canada/Health Canada*

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## Thank you

- Welcome to the “Brilliant Blue Distal-Check” Learning Annex, Westminster Room 3:30 to 4:30



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## How do we verify our instruments are clean?



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## How do we verify our instruments are clean?



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## What tools do we have to check if the instrument is clean?

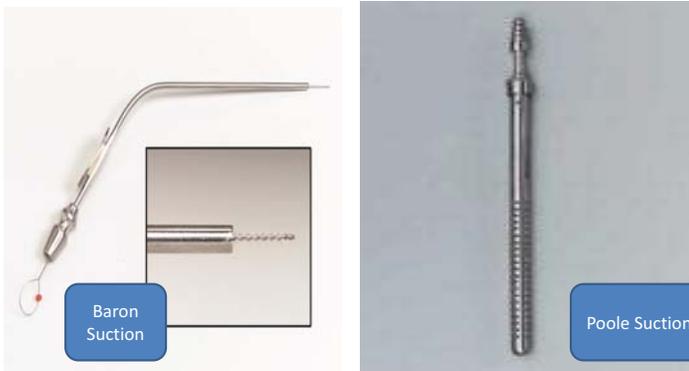


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## How do we verify our instruments are clean?



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## What tools do we have to check if the instrument is clean?



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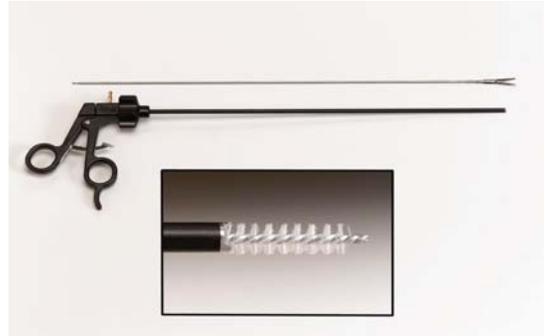
How are we checking if the channel is clean?



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How are we checking if the channel is clean?



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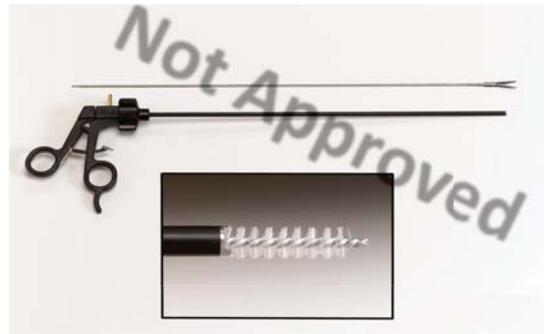
How are we checking if the channel is clean?



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How are we checking if the channel is clean?



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How are we checking if the channel is clean?



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Researchers at the University of Michigan Health System examined 350 surgery-ready suction tips. All of them contained blood, bone, tissue or rust



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How are we checking if the channel is clean?



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What do our guidelines state today?

### CSA Guidelines

- Inspection of Medical Devices:
- References in Z314.08-08: 6.2.2, 10.4.3.8, 10.7.5, 10.7.6, 10.11, 10.11.36, 10.11.7 – all excellent seven separate comments on inspection reference points

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## What do some of our guidelines state?

### C. Post-cleaning.....

- a) visually inspect all equipment/devices once the cleaning process has been completed and prior to terminal disinfection/sterilization to ensure cleanliness and integrity of the equipment/device...
- b) **Repeat the cleaning on any item that is not clean**

*Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices (PIDAC)  
February, 2010*

## **AORN: Recommendation XI Surgical Instruments should be inspected for cleanliness and proper working order after decontamination (PNDS:170)**

Inspecting instruments for sterilization before assembly of trays provides an opportunity to identify those instruments that require additional cleaning or repair before use.

*Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment, AORN, March 2002, AORN Journal*

## **Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices (PIDAC) February, 2010**

- **Practice Audits**
- i) Cleaning processes must be audited on a regular basis
- ii) A quality improvement process must be in place to deal with any irregularities/concerns resulting from the audit

## What have I been told?

- **The environment where cleaning/decontamination is performed should:**
  - a) Be distinctly separate from areas where clean/disinfected/sterile devices are handled or stored;
  - b) Have restricted access from other areas in the setting;
  - c) Ensure one-way work flow of staff and medical devices;
  - d) Have adequate space for the cleaning process and storage of necessary equipment and supplies;
  - e) Have surfaces that can be easily cleaned and disinfected;
  - f) Have slip-proof flooring that can withstand wet mopping and hospital-grade cleaning and disinfecting products; and
  - g) Have easy access to hand hygiene facilities.
- Decontamination work areas shall be physically separated from clean and other work areas to control traffic flow and to isolate contaminants generated during the stages of cleaning. Walls or partitions should be cleaned regularly and be constructed of materials that can withstand cleaning and disinfection.<sup>53</sup>
- **Decontamination sinks:**
  - a) Shall be designed and arranged to facilitate soaking, washing and rinsing of devices with minimal movement or delay between steps;
  - b) Should be adjacent to waterproof counter tops and a backsplash;
  - c) Shall not have an overflow;
  - d) Should be at a height that allows workers to use them without bending or straining;
  - e) Shall be large enough to accommodate trays or baskets of instruments;
  - f) Shall be deep enough to allow complete immersion of larger devices and instruments so that aerosols are not generated during cleaning; and
  - g) Should be equipped with water ports for the flushing of instruments with lumens, if appropriate.
- Hand hygiene facilities shall be located in all personnel support areas and at all entrances to, and exits from, the decontamination area. Hand hygiene facilities should include:
  - a) Accessible hand washing sinks with hands-free controls, soap dispensers and paper towels; and/or
  - b) Alcohol-based hand rub (ABHR).
- **As the clean side does not meet these requirements and are not under negative pressure as designated it cannot be done there.**

## Challenges

- New staff – where were they certified, their qualifications?
- New instruments – Did the manufacturer train the staff on reprocessing their instrument. Do you have a copy of the IFU that is accessible? Does the manufacturer provide a **VALIDATION** of their cleaning process?
- Accreditation – if you were audited or there was a linked HAI, are you able to document your process and have records of on going audits?

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## What's new in the tool box today...



Southmedic  BEST MANAGED COMPANIES

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## Challenges

- What is the verification process in your facility?
- How do you record or verify the cleaning process has been done properly?
- How do you confirm in lumened instruments where visualization cannot be accomplished that they are clean?

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### MED7910 – Brilliant Blue Distal-Check

brilliantBLUE  
distalcheck

For fast detection of protein residues on complex instruments

Use Brilliant Blue Distal Check for the detection of protein residues left behind on complex surgical instruments.



## MED7910 – Brilliant Blue Distal-Check

### Features and Benefits:

- No swabbing! – easy to use
- Fast results in 10 seconds
- Protein detection range 5 – 50 micrograms
- Instant – accurate protein residue indication test
- Clear colour change
- No incubation required
- No electronics required



## MED7910 – Brilliant Blue Distal-Check

For fast detection of protein residues on complex instruments



- 1 Kit includes:
  - 25 x Tests per box
  - 48 x kits per case
  - 16 Cases per pallet

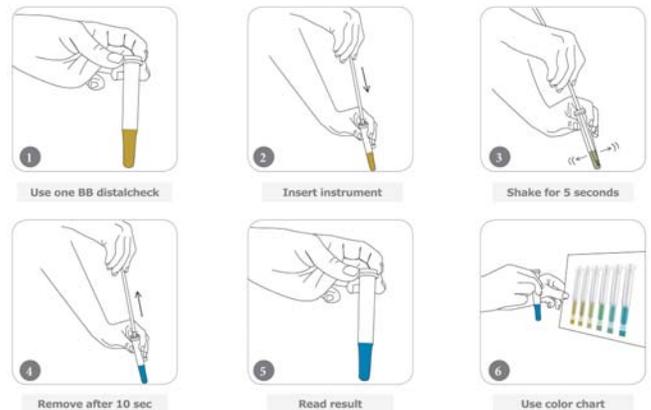
## MED7910 – Brilliant Blue Distal-Check

### Conformance to standards:

- EN ISO 15883-1:2009  
Please refer to Annex C
- CFPP 01-01 part D  
“The development path for the guidance recognises the current work in the piloting of high sensitivity post decontamination protein qualification tests.” CFPP recommends to follow ACDP TSE Risk Management Subgroup recommendations, as “It is evident that the ninhydrin test for prion detection does not work and cannot be used to monitor the WD.”
- ANSI/AAMI ST79:2010/A3:2012 – 7.5.3.3  
“It is imperative that all traces of blood, body fluids and debris be removed during the wash phase of a mechanical cleaning equipment cycle. Failure to do so could result in undetected bioburden that could pose a risk to employee health or result in patient infection.”

## MED7910 – Brilliant Blue Distal-Check

### Instructions for use:



### MED7910 – Brilliant Blue Distal-Check

#### Miscellaneous:

- Test should be made minimum 1 time per week (per washer)
- Storage conditions: Refrigerated 2-8°C
- CE marked (Class I)
- Diagnostic dye-binding solution
- Shelf life: 6 months non-refrigerated / 24 months refrigerated
- Results in 10 seconds
- Vial cap is clear in colour and contains “dust cap” to prevent contamination

### ScopeCheck / InstruCheck

Residual Protein is not always visible, so a swab plus chemical interpretation is required

V3504095	Valisafe Scope Check Standard Kit
V3505005	Valisafe Scope Check 2.8mm
V3505010	Valisafe Scope check 1.9mm
V3505013	Valisafe Scope Check 3.7mm



1 Ug result in 10 seconds (no incubation required)

### Protein Residue testing – ScopeCheck / InstruCheck

For fast detection of protein residues on Standard instruments / Endoscope channels.

Use Scope Check / InstruCheck for the detection of protein residues left behind on the surface of surgical instruments / inside endoscope channels



### ScopeCheck / InstruCheck

#### Features and Benefits:

- Fast results in 10 seconds
- Conforms to BS EN ISO 15883
- Easy to use - no incubation required
- Clear colour change
- Cost effective
- For use with:
  - Endoscopes
  - WD / Ultrasonic surfaces
  - Surgical instruments

- 1 Kit includes:  
25 x Tests per box



## ScopeCheck / InstruCheck

### Conformance to standards:

- EN ISO 15883-1:2009  
Please refer to Annex C

- CFPP 01-01 part D

“The development path for the guidance recognises the current work in the piloting of high sensitivity post decontamination protein qualification tests.” CFPP recommends to follow ACDP TSE Risk Management Subgroup recommendations, as “It is evident that the ninhydrin test for prion detection does not work and cannot be used to monitor the WD.”

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## ScopeCheck / InstruCheck

### Miscellaneous:

- Test should be made minimum 1 time per week (per washer)
- Storage conditions: Refrigerated 2-8°C
- CE marked (Class I)
- Diagnostic dye-binding solution
- Shelf life: 6 months non-refrigerated / 24 months refrigerated
- Results in 10 seconds

### Instructions for use:

Gloves must be worn when using the protein kit to avoid cross-contamination. For your safety, please wear appropriate clothing and eyewear.



If the object to be tested is already wet, swab the object focusing on hinges or crevices which may be contaminated. If object to be tested is dry, simply wet the swab with sterile water before swabbing areas of interest. If test kits are stored in a refrigerator, remove them from refrigerator to stabilise at room temperature (15-25°C) before undertaking test. The kit should not be stored or used at temperatures above 25°C.



Unscrew the cap



Swirl the swab in the brown reagent for 5 seconds.



Visually inspect the reagent for colour change. If the reagent has turned a shade of blue, protein has been detected. The darker the blue colour, the more protein detected. If the reagent remains brown, protein residue has not been detected.

**NOTE:** Positive controls can be used for verification and training purposes. Use positive control to make deliberate fail which enables result comparison or use to ensure that batch has not been compromised in any way. If other swabs not supplied with the Valsafe Protein Test are used, a negative and positive control needs to be performed to exclude interferences. Vials should not be removed from the box until required for use to avoid light exposure to reagent.

## Protein Residue testing – DentaCheck

Required weekly by HTM01-05.

Confirms that the cleaning process retains the capability of removing protein.

### Features and Benefits:

- No test more sensitive
  - No incubation required
  - Enhanced accuracy
  - Easy to use
  - Cost effective
  - Clear colour change
  - Shelf life 2 years
  - Conforms to BS EN ISO 15883 & HTM 01 05
  - Accurate results within 10 seconds
- 
- For use with
    - Dental & surgical instruments



## Protein test – visual reading of chemical Interpretation



## DentaCheck

### Miscellaneous:

- Test should be made minimum 1 time per week (per washer)
- Storage conditions: Refrigerated 2-8°C
- CE marked (Class I)
- Diagnostic dye-binding solution
- Shelf life: 6 months non-refrigerated / 24 months refrigerated
- Results in 10 seconds

### Instructions for use:

Gloves must be worn when utilising the protein kit to avoid cross-contamination.  
For your safety, please wear appropriate clothing and eyewear.



1 If the object to be tested is already wet, swab the object (touching on fingers or crevices which may be contaminated). If object to be tested is dry, simply wet the swab with sterile water before swabbing areas of interest. If test kits are stored in a refrigerator, remove them from refrigerator to stabilise at room temperature (15-25°C) before undertaking test. The kit should not be stored or used at temperatures above 25°C.



2 Unscrew the cap



3 Swirl the swab in the brown reagent for 5 seconds.



4 Visually inspect the reagent for colour change. If the reagent has turned a shade of blue, protein has been detected. The darker the blue colour, the more protein detected. If the reagent remains brown, protein residue has not been detected.

**NOTE:** Positive controls can be used for verification and training purposes. Use positive control to make deliberate fail which enables result comparison or use to ensure that batch has not been compromised in any way. If other swabs not supplied with the Valsafe Protein Test are used, a negative and positive control needs to be performed to exclude interferences. Vials should not be removed from the box until required for use to avoid light exposure to reagent.

## In Summary

- Protein testing enables both routine verification of the efficacy of the cleaning process be it with or without incubation and a quality control tool in those departments where manual cleaning plays a significant role.
- Irrespective of whether you are working in a small dental clinic, an ambulator clinic or a hospital MDRD routine monitoring of your cleaning phases – both manual and mechanical are critical in providing evidence of the efficacy of your decontamination process!

## Thank you

**“In today’s healthcare system everyone is accountable for the clinical and financial outcomes produced by our actions. If you practice what we will teach you, we promise measurable positive outcomes in both areas”**

**Kimberly Todd, Environmental and MDRD Manager**

**Linda Socha, Canadian Operations Director**

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Coming Soon...

### Brilliant Blue ProTEST Pen

Ready to use rapid protein residue detection system  
for testing any surface after the cleaning process...