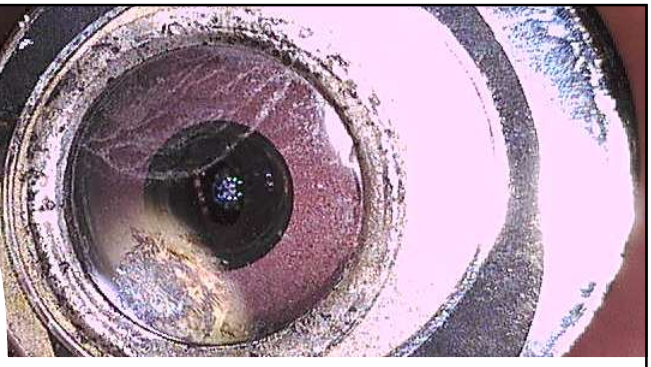
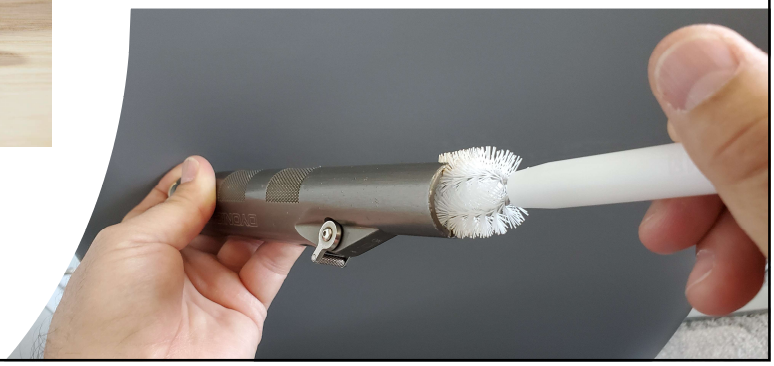
C.H.I.P. Tips (Care, Handling, Inspection, & Prevention) for the Sterile Processing Professionals





Cheron Rojo

Senior Manager of Clinical Education

Healthmark, A Getinge company

BS, FCS, CRCST, CIS, CER, CFER, CHL

1

Objectives:

Review

Review Sterile Processing tips in everyday tasks in the assembly and decontamination area.

Understand

Understand the importance of handling instrumentation and equipment within your department.

Reinforce

Reinforce the basic technical principles that are used in the Sterile processing arena

Understand

Understand the impact that standards and guidelines have in a properly functioning department within the sterile processing that process instrumentation and medical devices

2

C.H.I.P. TIP #1

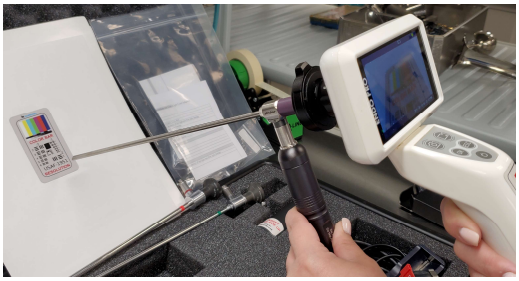
When it comes to inspecting/testing rigid-endoscopes you hold it up to the light and look for black dots?

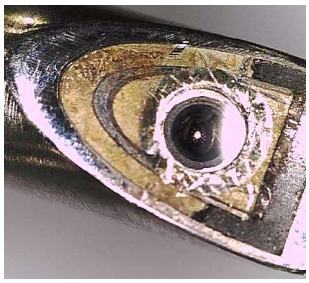
Yes, this is a common practice, but there are other methods to better accomplish this.

3

Explain the Role of Inspection and Functionality Testing for Rigid Endoscopes

- External inspection is recommended in the standards and in the IFUs.
- Internal inspection/functionality testing is recommended in the standards and in the IFUs.
- A consideration in a “Best Practice” approach.





4

Recommendation and Standards for Rigid Endoscopes

- **ANSI/AAMI 2017:**
  - "Each time a medical device is processed, it should be visually inspected for cleanliness and integrity"
  - "Enhanced inspection with magnification, borescopes, or other inspection methods to verity cleanliness and integrity may be used"

5

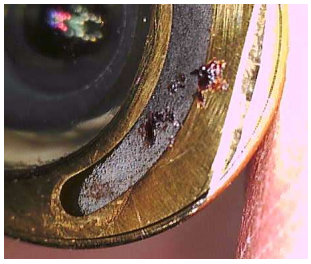
Recommendation and Standards for Rigid Endoscopes

- **FDA MAUDE Database Adverse Patient Events:**
- On **October 15, 2023**: It was reported that the "laparoscope lens seemed to be loose due to an internal failure; it would come in and out of focus and was discovered during an arthroscopy procedure with no patient harm"
- On **August 9, 2023**: It was reported that a 2.3 mm x 72 mm arthroscope had "a dark image during the procedure."
- On **May 16, 2023**: It was reported that the scope "overheated, injuring the patient with what appeared to be a thermal, first-degree burn. The telescope had gouging around the distal end, with a chipped-rod lens."
- On **May 3, 2023**: "A blurry image during the procedure was reported."

6

Examples of Instructions For Use for Rigid Endoscopes

- Under General Inspection:
  - "Hold a piece of writing at approximately 30mm from the objective cover glass."
  - "Check that the image is not cloudy, out of focus or dark."
  - "Do not use a telescope with more than 25 to 30% defective light-guide fibers.
  - "Make sure that the product has no dents, cracks, bending, or deformations, scratches, lens damages or cover glass damage."



7

Studies Surrounding the Importance of Inspection and Functionality Testing for Rigid Endoscopes

- In a 2024 published study in the international PROCESS magazine March/April issue (1-year, 5-U.S. states, 29 hospitals):
- 41 rigid endoscopes were examined (externally), 26 demonstrated integrity failures at a **63.41% failure rate**.
- Of the total 41 rigid endoscopes tested (internal), 5 exhibited integrity failures of the internal optics **12.2% fail rate**.

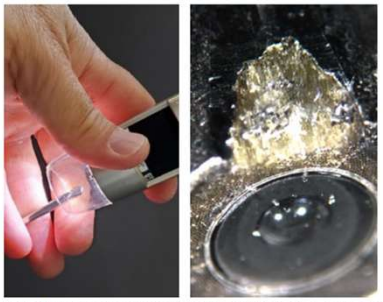
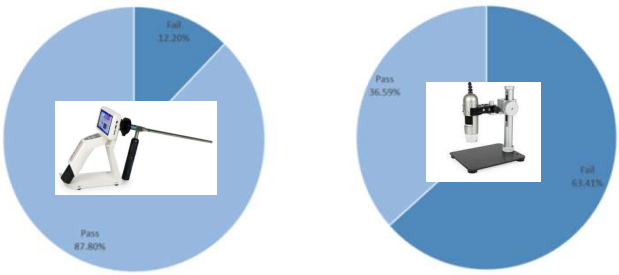


Figure 5: Enhanced magnification microscope and identified damage (exposed glass light fibers)



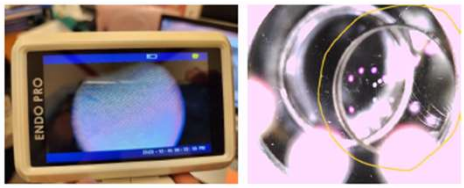


Figure 4: Endoscopic video verification tool with identified damage (dislodged lens within the rigid endoscope)

8

Studies Surrounding the Importance of Inspection and Functionality Testing for Rigid Endoscopes Continued..

- **Contributing Factors:**
  - Insufficient or lack of correct magnification to view the internal and external surfaces of rigid endoscopes.

Examples of Correct Magnification

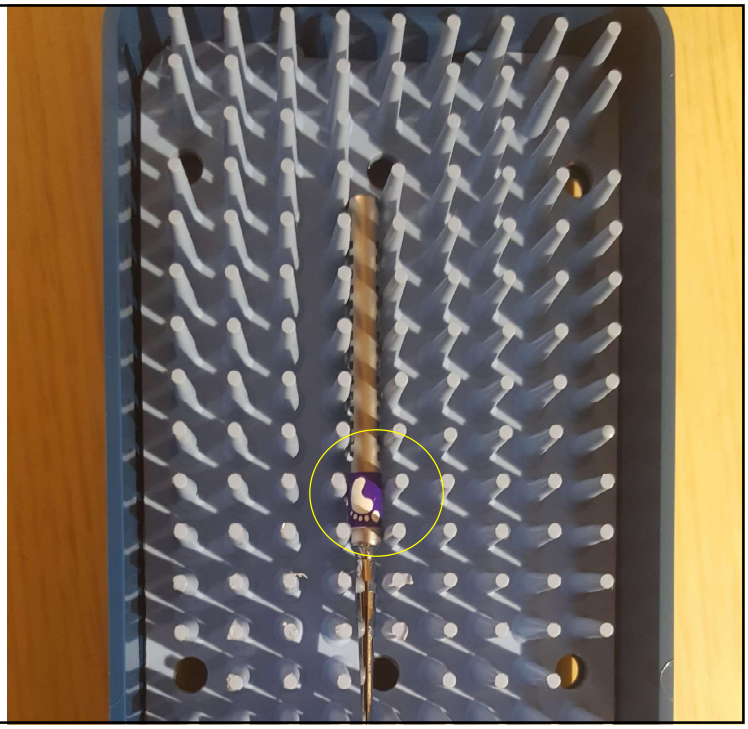
9

C.H.I.P #2

Can I use color-coding (taping) for instrumentation?

Yes

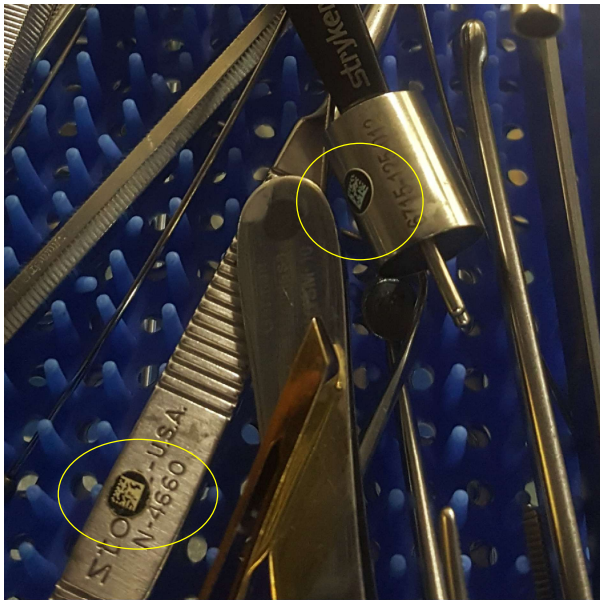
- ANSI/AAMI ST79 7.4.1 “Instrument tape and plastic dipping material, when used properly, are ways of identifying specific instruments. These types of marking products wear out over time and staff need to inspect them each time the instrument is processed, check them for wear according to the IFU of the product used, and replace them as often as needed.”



10

Key-Dotting (Instrument tracking)

- Like color-coding, but the use of a small barcode for instrument tracking
- To a specific set
- To identify for easy labeling
- Follow IFU of key-dot to apply
- Inspect every time for damage to replace



11

AST on Taping

Standard of Practice XIII

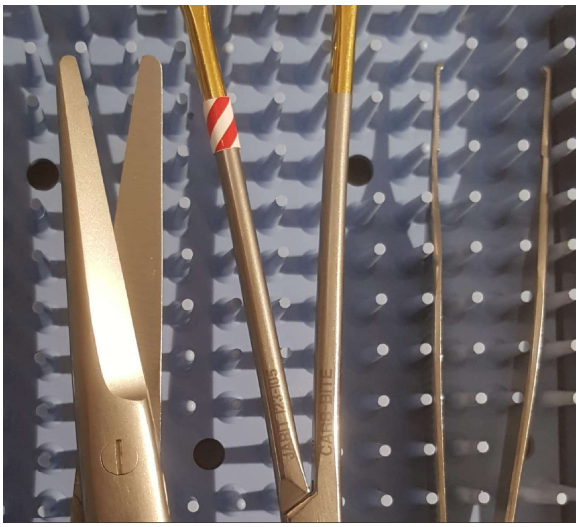
- "Manufacturer's instructions and healthcare facility policy should be followed for the use of colored tape and plastic dipping materials for the identification of specific surgical instruments."
- "Studies have confirmed that the use of colored tape does not interfere with the sterilizing agent contacting the underlying surface of the surgical instruments."

12

The Joint Commission

IC.02.02.01, EP 2

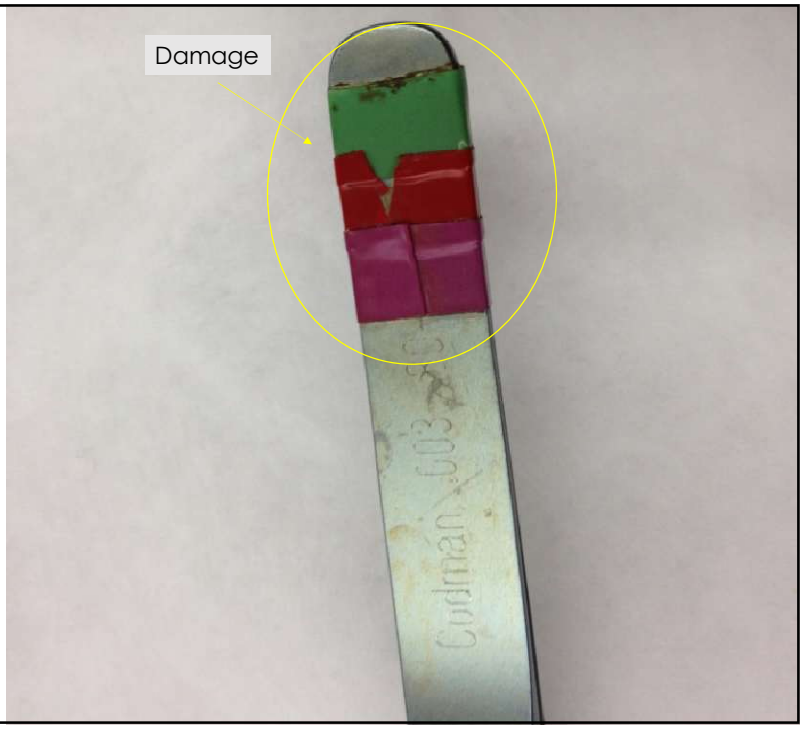
- Improperly applied or deteriorated identification tape on sterile instruments
- Instrument identification tape being used contrary to MIFU.



13

How to ensure your tape is still good after time?

- Put in a Quality Check:
  - Each time an instrument is touched during assembly the tape/dipping integrity is inspected along with how the instrument looks
  - Tray audits
  - Document results



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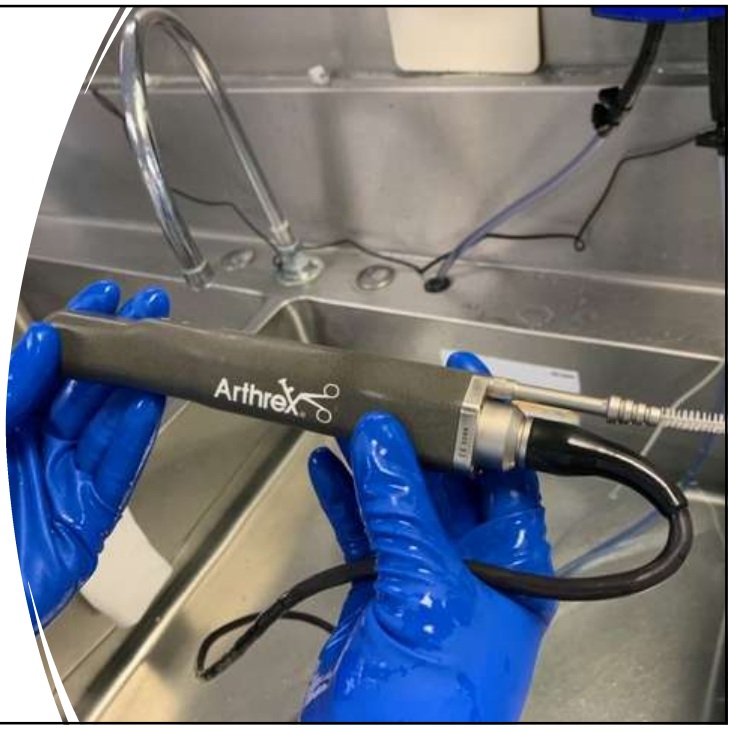
C.H.I.P. TIP #3

Are there specific cleaning brushes for certain instruments/devices? Or a brush-is-a-brush?



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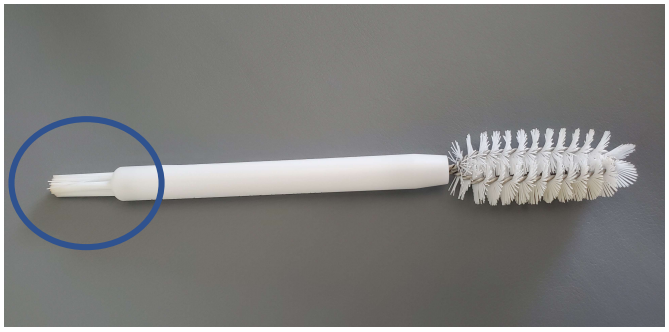

(IFU) Instructions-For-Use Smith & Nephew Dyonics Arthroscopy Shaver Handpieces

"Using the fork area brush Clean the drive fork area for a Minimum of 30 seconds".

IFU Reviewed: 07-29-22 42208 (onesourcedocs.com)

CLICK HERE Table of Contents

Cleaning, Disinfecting, and Sterilizing

Cleaning, Disinfecting, and Sterilizing

Detergents

Enzymatic detergents with a neutral pH range between 6.0 and 8.0 are recommended. Detergents with a pH outside this range can have an adverse effect or be damaging to some medical devices and containment devices. Enzymatic detergents aid in the removal of organic soil such as blood. Detergents such as Prolystica 2 or equivalent should be used at the concentration and temperature recommended by the detergent manufacturer. 1 to 4 mL/L of Prolystica 2X Concentrate Enzymatic Presoak and cleaner (neutral pH enzymatic detergents manufactured by STERIS Corporation) was used in the validation of the cleaning processes for Smith & Nephew MDU devices.

Manual Cleaning

CAUTIONS

- *Dried blood, saline, and other deposits inside the handpieces are a major cause of equipment malfunction.*
- *Do not use an ultrasonic cleaner or any other automated sterilizing or cleaning equipment other than those specifically identified in the "Cleaning, Disinfecting, and Sterilizing" section of this manual.*

1. Dispose of the blade(s) used during the operation following standard procedures for disposal of biohazardous waste.

   ⚠ **WARNING: Only Smith & Nephew DYONICS® Disposable Endoscopic Blades can be used with the DYONICS POWER II Control System. The blades are intended for single use only. Do not resterilize. Do not lubricate blades. Discard all blades after use.**

2. Disconnect the handpiece cable from the front panel by pulling back the locking collar on the connector, then unplugging it from the control unit. Do not disconnect the cable from the handpiece.
3. Place the protective cap on the connector end of the cable.
4. Set the suction control lever to the fully open position.
5. Rinse thoroughly with warm tap water for a minimum of two minutes, making sure to irrigate all features of the device.
6. Immerse the handpiece and soak for a minimum of five minutes using a neutral pH enzymatic detergent.
7. After immersion of the device into the enzymatic cleaner, agitate the device to ensure all of the air is removed from the device lumen.
8. While the unit is immersed, clean using the specified brushes from Solo Horton Brushes, Inc. (or equivalent) in Table 3.
   - (If the handpiece has controls) Using the blade port brush, scrub around the hand controls, depressing the buttons with hand during scrubbing.
   - With the suction control lever in the open position, insert the lumen brush in the device spigot (proximal end of the device) and clean the lumen using twisting and in/out movements of the brush for a minimum of 30 seconds.
   - Reinsert the lumen brush from the distal end of the device end and clean the lumen from the opposite direction using twisting and in/out movements of the brush for a minimum of 30 seconds.
   - Using the blade port brush clean the nose cavity using twisting and in/out movements for a minimum of 30 seconds.
   - Using the fork area brush clean the drive fork area for a minimum of 30 seconds.

Handpiece REF	Lumen Brush	Blade Port Brush	Fork Area Brush
72200616, 72200617, 72200872	Brush 1	Brush 2	Brush 3
72201500, 72201503	Brush 4	Brush 5	Brush 3

Table 3: Brush Identification

Brush 1: Bristles: Nylon, 2.0" area length, 0.25" diameter (no taper), 14.00" minimum length
Solo Horton Brushes, Inc. PN 86-0002-14ST, or equivalent*

Brush 2: Bristles: Nylon, 2.25" area length, 0.75" diameter (tapered to 0.50"), 6.00" minimum length
Solo Horton Brushes, Inc. PN 86-1234-0006, or equivalent*

Brush 3: Bristles: Nylon, 0.75" area length, 0.5" diameter (with ferrule), 6.00" minimum length
Solo Horton Brushes, Inc. PN 86-0340-1206, or equivalent*

Brush 4: Bristles: Nylon, 1.75" area length, .156" diameter (no taper), 14.00" minimum length
Solo Horton Brushes, Inc. PN 86-0134-14ST, or equivalent*

Brush 5: Bristles: Nylon, 1.75" area length, 0.5" diameter (tapered to 0.25"), 6.00" minimum length
Solo Horton Brushes, Inc. PN 86-0212-1234, or equivalent*

* Equivalent must include bristle material, bristle area length, and bristle diameter as specified.

9. Scrub crevices and around hinged/mating surfaces with the blade port brush.
10. Rinse thoroughly with warm tap water for a minimum of 30 seconds, making sure to irrigate all features of the device. Ensure that the suction control lever is opened and closed repeatedly while rinsing the device lumen.

Manual Cleaning Verification

1. After cleaning, inspect devices under normal lighting to ensure that all visible soil has been removed.
2. If not visibly clean, repeat cleaning and reinspect. For difficult-to-view areas, 3% hydrogen peroxide may be applied (bubbling is evidence of the presence of blood).

   Note: Rinse instruments thoroughly with warm tap water following any hydrogen peroxide testing.

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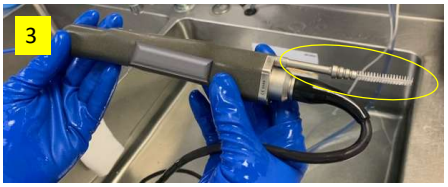
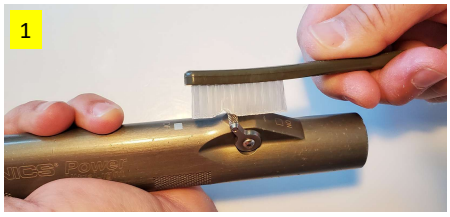
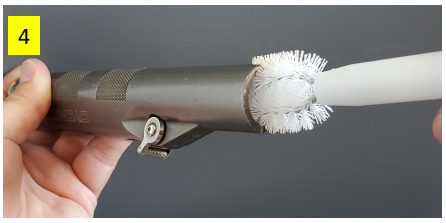
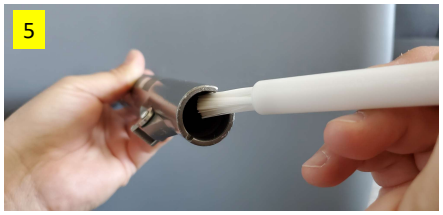
How Many Cleaning Brushes do Need for A Shaver?









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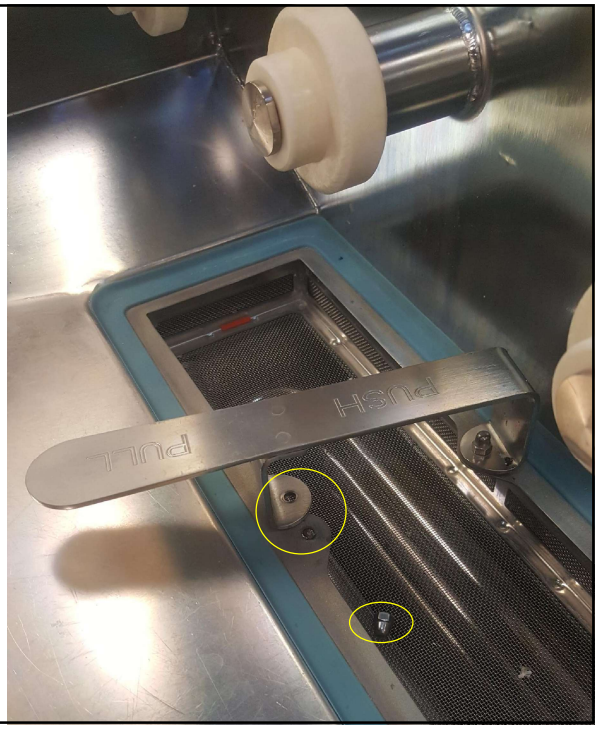
C.H.I.P Tip #4

Why must I clean screens in my washer or cart washer all the time? I don't have time to clean, and the next shift will do it!

- Daily, each shift, or as needed
- Reduce issues with sprayers and spray arms, and the water pump



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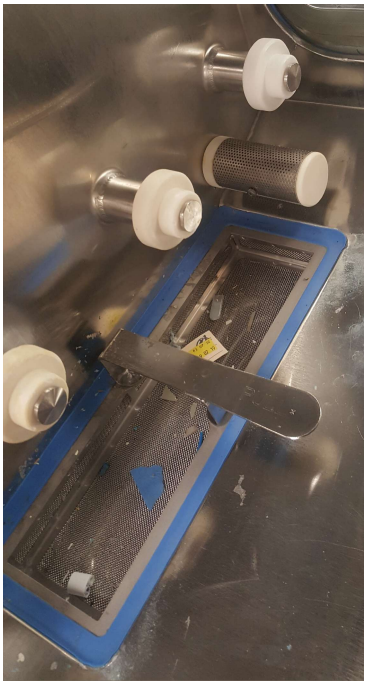


Example of an IFU for a Washer Disinfector

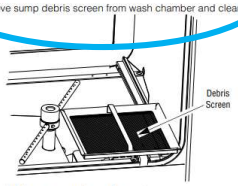
"6.1 Cleaning Procedures: Suggested Frequency, As Required".

6.2 Daily Cleaning

⚠ WARNING – SLIPPING HAZARD To prevent slips, keep floors dry. Promptly clean up any spills or drippage. For spills or drippage of detergents or other chemicals, follow safety precautions and handling procedures set forth on detergent or chemical label and/or Material Safety Data Sheet (MSDS).

Each day, clean washer as follows:

1. After the last cycle of the day, allow unit to cool.
2. Open unload side door.
3. Remove sump debris screen from wash chamber and clean.



4. Rinse debris screen under running water.

NOTE: Always clean debris screen while it is still wet, before foreign matter dries.

5. Reinstall sump debris screen.
6. Remove manifold sliding inlet and inspect for debris.

Table 6-1. Routine Maintenance - Check List (Cont'd)

Recommended frequency of inspection is indicated in the right column. Usage and utility conditions may require more or less frequent inspections.		Suggested Frequency
5.0	**EMERGENCY FEATURES**	
	Verify operation of Emergency Stop buttons (one on each side of washer; see *Section 6.7*).	2 X/year
6.0	**CHAMBER COMPONENTS**	
6.1	Perform cleaning procedures as noted in this section (see *Section 8, Daily Cleaning* and *Section 8, Weekly Cleaning*.	As required
7.0	**CHEMICALS AND INJECTION PUMPS**	
7.1	Verify pickup tube is not clogged, cracked or distorted. If damaged call STERIS or Customer's Maintenance Service.	4 X/year
7.2	Verify operation of chemical empty switches.	4 X/year
8.0	**CONVEYORS (if option is present)**	
8.1	Refer to SCS Conveyor System *Operator Manual* (P920506-634) for more detailed information about preventive maintenance.	As Required
8.2	Refer to Reliance ATS Automated Transport System *Operator Manual* (P122995-004) for more detailed information about preventive maintenance.	As Required
9.0	**FINAL TEST**	
	Verify washer/disinfector has proper labels (caution, warning, etc.).	Each Inspection

IFU Reviewed: 01-06-23

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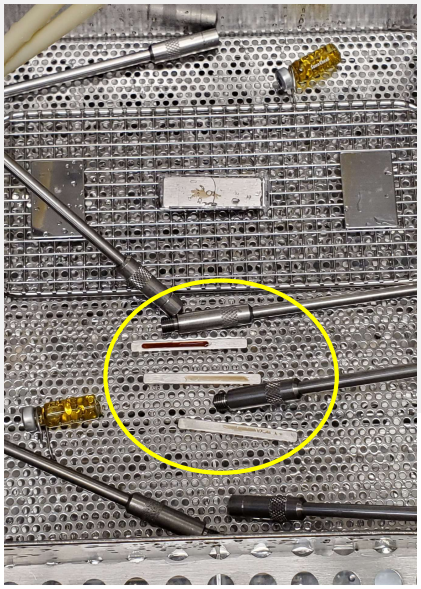

C.H.I.P Tip #5

Do I have to test the irrigation in an ultrasonic irrigator? I already run a test to test for cavitation.

Yes, Irrigation, chemistry, and temperature fails are contributing factors.

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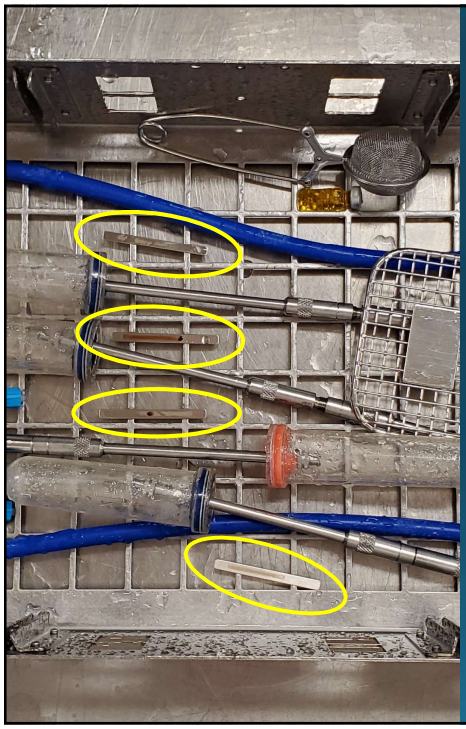

Daily Testing of all Cleaning Equipment

ANSI/AAMI ST79 2017, 13.2 Monitoring of Mechanical Cleaning Equipment:

- *"Health care personnel should perform verification testing on all mechanical cleaning equipment as part of the overall quality assurance program."*
- *"Mechanical cleaning equipment should be tested upon installation, each day that it is used, and after major repairs."*
- *"Key performance outcomes include clean surfaces and adequate fluid flow in equipment that has adaptors for lumened devices."*

ANSI/AAMI ST79 2017 ANNEX D Verification tests for Ultrasonic Cleaners

- *"Test for cavitation in ultrasonic baths"*
- *"Test for soil removal (external) in ultrasonic bath"*
- ***"Test for soil removal (internal within lumens) in ultrasonic bath"***

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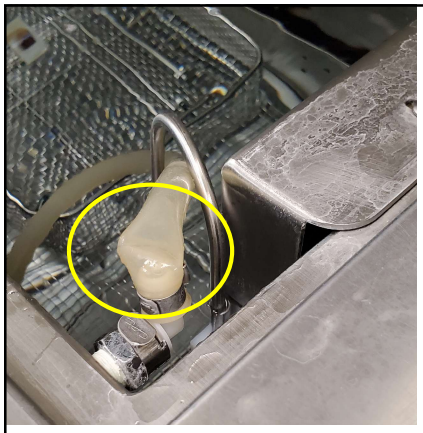
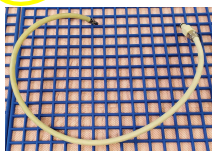


Breakdown of LumCheck and Possible Reasons for Not Passing

- **LumCheck Fails**:
  - Damaged ports
  - Damaged tubing connectors
  - Damaged/kinked tubing
  - Tubing blocked/plugged
  - Damaged/kinked main/carotid tubing to manifold
  - And……..



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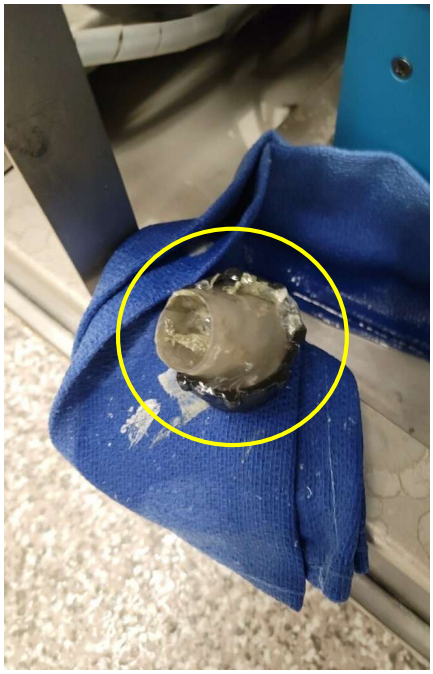
Cont…Breakdown of LumCheck and Possible Reasons for Not Passing

LumCheck Fails:

- Damaged or going bad irrigating water pump (for irrigation) e.g., pump (clogged filter) thus, no water



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C.H.I.P. Tip #6

- Do you have to inspect/test light cables? I am not aware that we have to?
- Yes, in the IFU and recommendations/standards state inspection.

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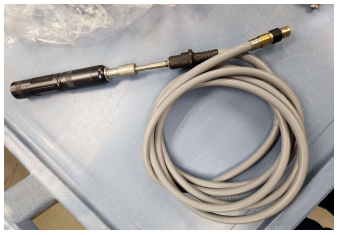
Recommendation and Standards for Light Cables

- **ANSI/AAMI 2017:**
  - "Each time a medical device is processed, it should be visually inspected for cleanliness and integrity"
  - "Enhanced inspection with magnification, borescopes, or other inspection methods to verify cleanliness and integrity may be used"



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Recommendation and Standards for Light Cables

- **FDA MAUDE Database Adverse Patient Events:**

- On **January 28, 2025,** a shaver handpiece was reported for having "Once turned on, the end of the cable sparked, and the drape caught fire."
- Lastly, on **July 5, 2023,** it was reported that "the light source unexpectedly became disconnected and burned a hole through the drapes. This resulted in 5mm diameter burn to patient's left chest."
- On **August 26, 2019,** it was reported that the "light fiber quality is poor (the fibers are dark)."

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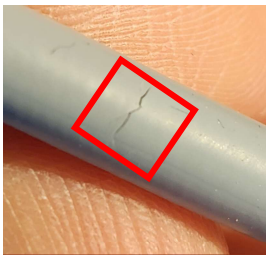
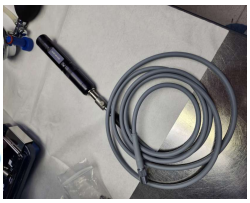
Examples of Instructions For Use for Light Cables

- Under 5.3 Expected Service Life
  - "The expected service life of the cable is 100 reprocessing cycles."
  - "Prior to each use, visually inspect the cable for damage…"
  - "and test the device function."
  - "If there is any sign of damage or malfunction, the device should not be used."





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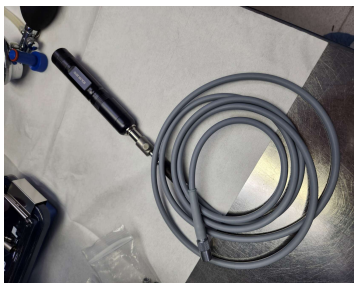
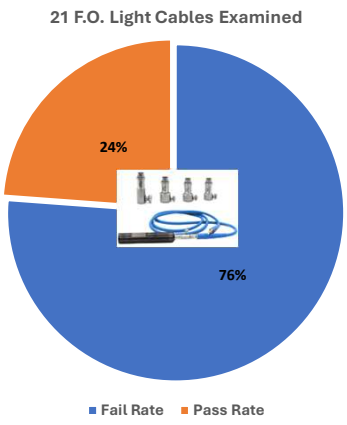
Studies Surrounding the Importance of Inspection and Functionality Testing for Rigid Endoscopes

- Preliminary 2-year Study, 2024-2025, 21 facilities across 8 different states.
- 21 F.O. light cables examined, and 16 identified with integrity failures, at a 76% failure rate.
- Determined by a 20% fail rate or higher as a failure.





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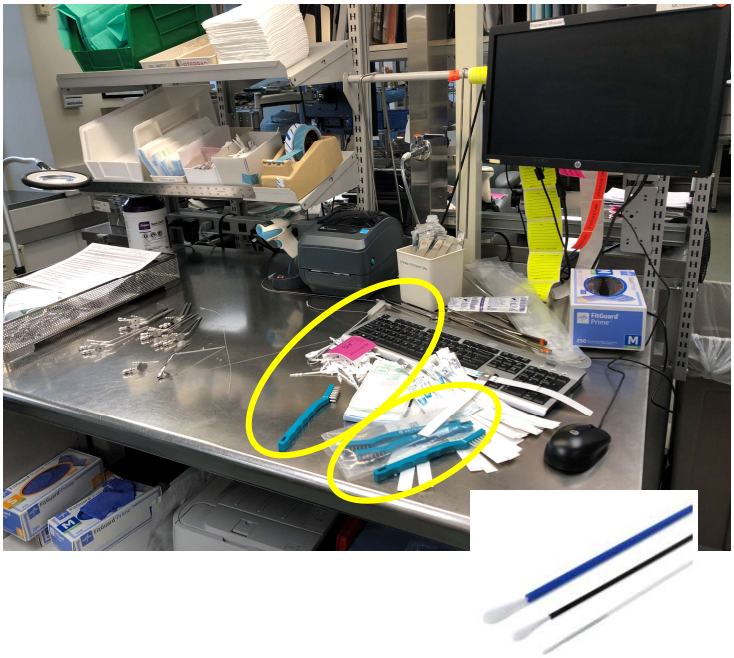
C.H.I.P #7

We use cleaning brushes on the clean side to inspect instruments and devices. Is this practice, OK?

Yes and No

- History (cleaning brushes) used on the clean side
- The IFU of cleaning brushes is to clean, not inspect BE CAREFUL ON HOW IT READS!
- The Joint Commission (hot topic)



29

C.H.I.P. Tip #8

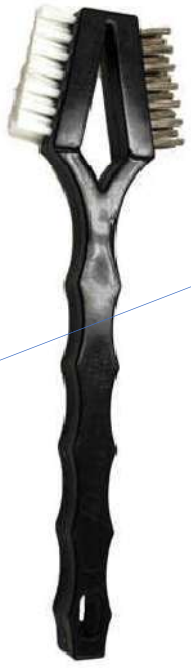
Is it ok to have wire Stainless steel/Brass brushes in the decontamination area?

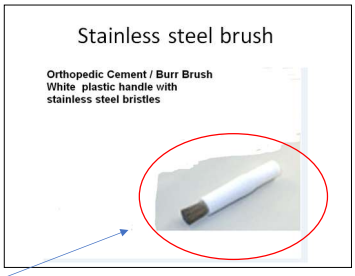
THE ANSWER IS IT DEPENDS. WHAT DOES THE IFU STATE:

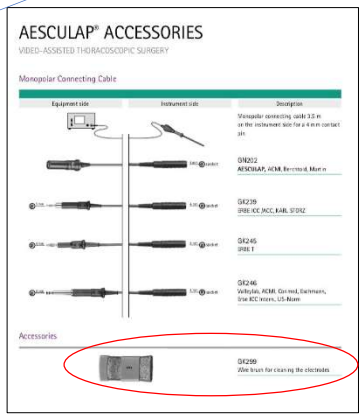
AAMI ST 79 STATES "…*USE BRUSHES AND OTHER CLEANING IMPLEMENTS INTENDED FOR USE ON MEDICAL DEVICES; BRUSHES SHOULD BE CHECKED FOR VISIBLE SOIL AND DAMAGE FOLLOWING EACH USE AND SHOULD BE FREQUENTLY CLEANED AND DISINFECTED*. ***IF THE DEVICE MANUFACTURER SPECIFIES A SPECIFIC BRUSH OR CLEANING IMPLEMENT, THE BRUSH OR AN EQUIVALENT SHOULD BE USED…***"

THUS, ON STAINLESS STEEL BRUSHES, THE DESIGNED USAGE OF THIS STAINLESS WIRE BRUSH (PICTURED) IS MOSTLY FOR BONE FILES AND ORTHOPEDIC INSTRUMENTS TO HELP REMOVE CEMENT. ***IF THE IFU STATES YOU CAN USE A METAL BRUSH, THEN MAKE SURE YOUR POLICY REFLECTS ITS USE AND ONLY ON THOSE ITEMS***. THIS ALSO PERTAINS TO BRASS TYPE BRUSHES AS WELL.

d=OIP bowe_9las30oZGoF0SajFwAAAA&mediaurl=http%3A%2F%2Fi.ebayimg.com%2Fimages%2Fg%2F4D8AAOSwnDZUBvvh%2Fs-l300.jpg&exph=225&expw=300&q=stainless+medical+grade+steel+cleaning+brushes&selectedindex=101&cbir=sbi&ajaxhist=0&vt=0&eim=1,2,6&ccid=bowe%2F9la&simid=608028623119714256



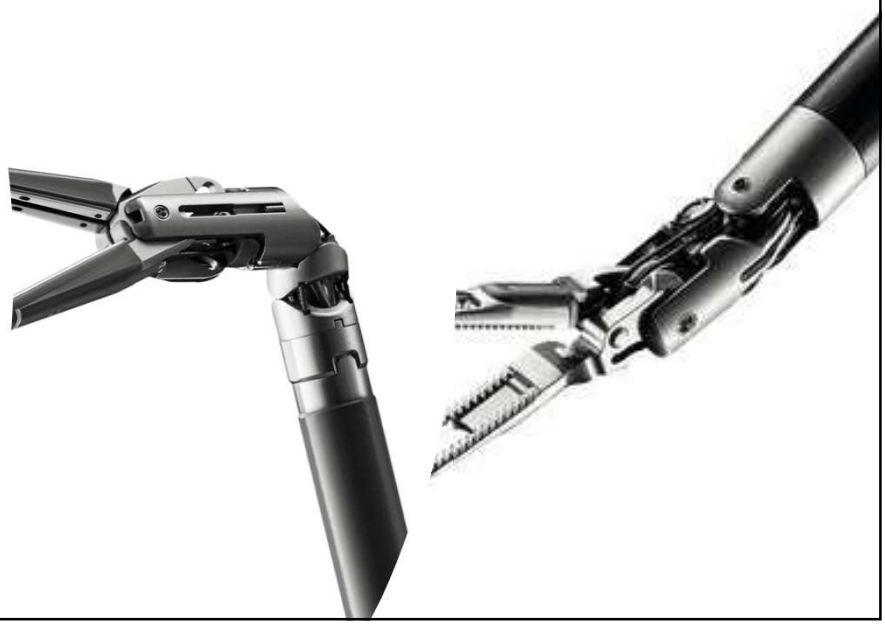




30

C.H.I.P. Tip 9

- Does INNTUITIVE state anything on inspection of their instrumentation?
- Yes, the IFU



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INTUITIVE IFU

- This would be the minimum requirement
- Not all magnification are equal
- If you pay more for the magnifier, does not mean higher magnification level.

INSTRUMENTS: DECON

Supplies needed in Decon

See the following pages for step by step instructions using the following materials:

- Large container or sink to fit instrument (27 inches or 70 cm minimum length)
- pH-neutral to mildly alkaline enzymatic solution (pH 7-11)
- Syringe with Luer tip (20 mL minimum)
- Running cold water
- Gauge monitored pressurized water (30 psi/2 bar)
- Critical water, per AAMI TIR34
- Clean nylon brush
- Flush port adapter (Luer fitting, Intuitive Surgical cleaning kit)
- Magnifying glass (4X)

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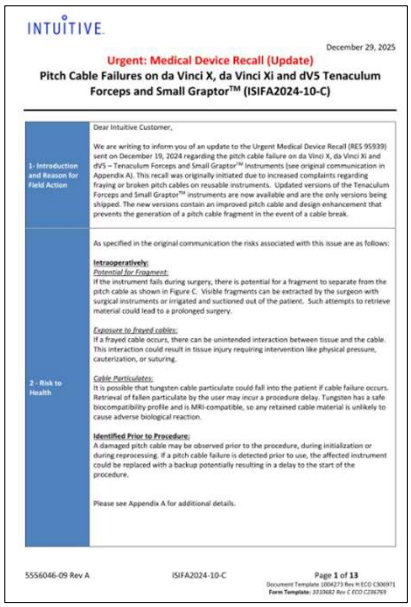
INTUITIVE Recall Statement: December 29, 2025

- Frayed pitch cables may be identified through endoscopic view.

- Define an endoscopic view: Camera on the end.



INTUITIVE

December 29, 2025

Urgent: Medical Device Recall (Update)

Pitch Cable Failures on da Vinci X, da Vinci Xi and dV5 Tenaculum Forceps and Small Graptor™ (ISIFA2024-10-C)

1- Introduction and Reason for Field Action

Dear Intuitive Customer,

We are writing to inform you of an update to the Urgent Medical Device Recall (RES 95939) sent on December 19, 2024 regarding the pitch cable failure on da Vinci X, da Vinci Xi and dV5 – Tenaculum Forceps and Small Graptor™ instruments (see original communication in Appendix A). This recall was originally initiated due to increased complaints regarding fraying or broken pitch cables on reusable instruments. Updated versions of the Tenaculum Forceps and Small Graptor™ instruments are now available and are the only versions being shipped. The new versions contain an improved pitch cable and design enhancement that prevents the generation of a pitch cable fragment in the event of a cable break.

2 - Risk to Health

As specified in the original communication the risks associated with this issue are as follows:

Intraoperatively:

Potential for Fragment:

If the instrument fails during surgery, there is potential for a fragment to separate from the pitch cable as shown in Figure C. Visible fragments can be extracted by the surgeon with surgical instruments or irrigated and suctioned out of the patient. Such attempts to retrieve material could lead to a prolonged surgery.

Exposure to frayed cables:

If a frayed cable occurs, there can be unintended interaction between tissue and the cable. This interaction could result in tissue injury requiring intervention like physical pressure, cauterization, or suturing.

Cable Particulates:

It is possible that tungsten cable particulate could fall into the patient if cable failure occurs. Retrieval of fallen particulate by the user may incur a procedure delay. Tungsten has a safe biocompatibility profile and is MRI-compatible, so any retained cable material is unlikely to cause adverse biological reaction.

Identified Prior to Procedure:

A damaged pitch cable may be observed prior to the procedure, during initialization or during reprocessing. If a pitch cable failure is detected prior to use, the affected instrument could be replaced with a backup potentially resulting in a delay to the start of the procedure.

Please see Appendix A for additional details.

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Appendix B: Additional Images to Identify Pitch Cable Failure

In addition to instructions provided in da Vinci X and Xi Instruments and Accessories User Manual, the following section provides additional images to help with identification of a pitch cable failure (broken and frayed).

Pitch Cable breaks may be detected visually prior to use or through the loss of instrument function during use. Frayed and broken pitch cables may also be identified through endoscopic view.

The inspection is limited to the instrument wrist and does not require magnification as shown in the pictures below. Articulation of the instrument wrist is not required but inspection of cables on both sides of the wrist is required.

1. Inspection prior to use

Prior to use, visually inspect all instruments for broken or frayed cable per Figure E, F and G below

Figure E: Example of a pitch cable fragment

Figure F: Broken Pitch Cable

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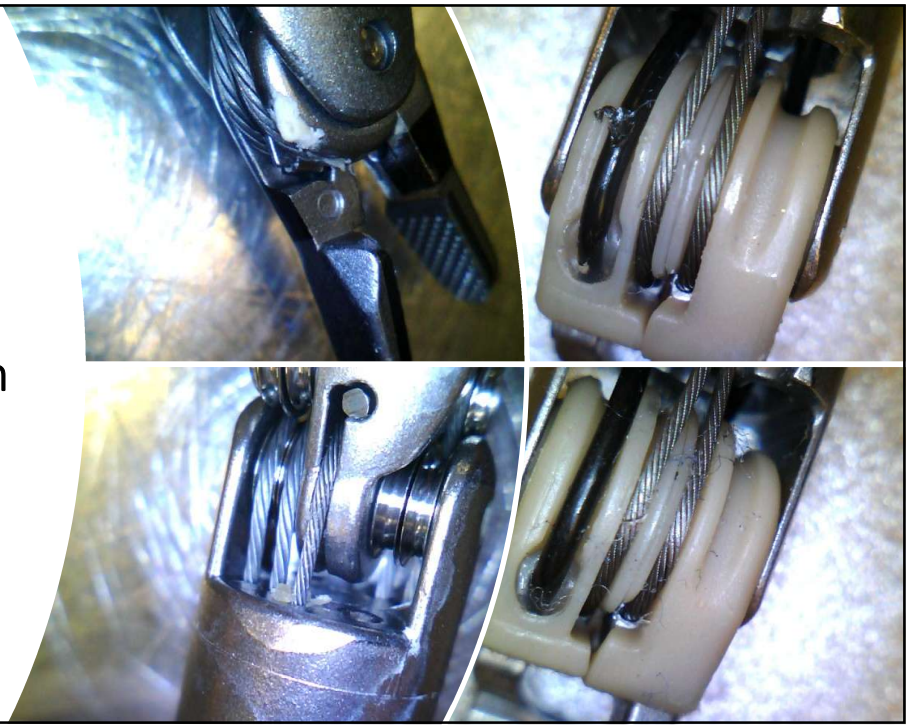
Examples of Why Inspection is Essential



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C.H.I.P. Tip #10

- When purchasing new transport containers why can't I use containers from Walmart or Target? They are a lot cheaper!
- Answer: No, non-medical grade containers are not validated to be disinfected between uses and become damaged very easily, which can cause injury to employees with sharp edges, etc.
- Harsh chemicals can be absorbed into the plastic as well

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C.H.I.P. Tip 11

- Why do we need to test our heat sealers? AAMI does not state to!
- You are correct that AAMI does not specifically address heat sealers, but equipment fail & need a functionality test & ISO.

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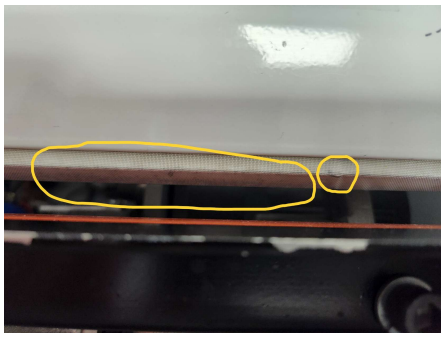
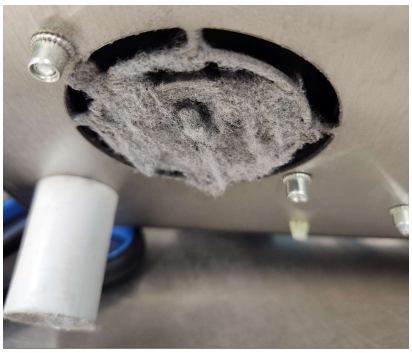
Heat Sealers are a Piece of Equipment

- IFUs can state yearly or twice a year calibrations.
- They get damaged.
- The aeration fans gets plugged.





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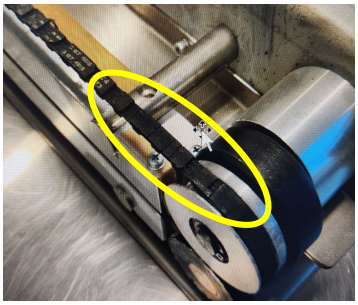
Heat Sealers are a Piece of Equipment

- More examples of damage

Teflon inside a heat-sealer



Belt damage and cracked rotating wheel

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Recommendations/Standards

- ANSI/AAMI ST79 9.5.4 "…be closed so that all pouch seals are smooth (i.e., without folds, bubbles, or wrinkles)."
- ISO 11607.2.2019 5.3 Operational Qualification, "PQ shall demonstrate the process will consistently produce preformed sterile barrier systems".
- ISO 11607.2.2019 5.4"packaging process is under control and within the established parameters during routine operation and consistently producing the specified process output".

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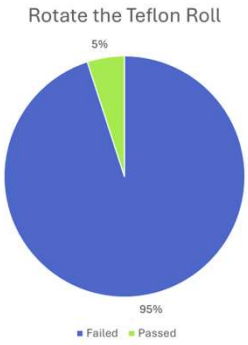
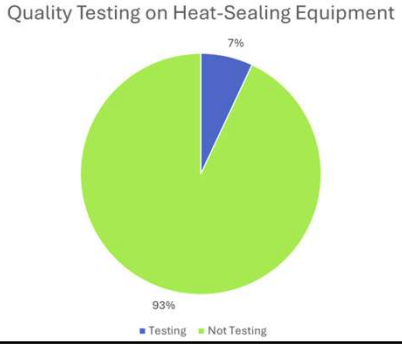
Cross-Sectional 2023 Preliminary Study on Heat Sealers

- 12-month study that was conducted from January to December 2023, across 39 healthcare facilities.
- Heat seal pouches had a 37% defect rate.
- 95% unaware of/or failed routinely to rotate the Teflon roll, per the MIFU.
- 93% facilities were not conducting required quality testing on heat-sealers in accordance with ISO.

Thank you to Ms. Elammari for the data collection.





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Thank you, Questions?

2026 Healthmark Clinical Educators

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