SETTING UP A QUALITY SURGICAL INSTRUMENT PROGRAM - CARE AND HANDLING OF SURGICAL AND ENDOSCOPI C INSTRUMENTS

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OBJECTIVES
Identify the policies and procedures needed to effect a quality surgical instrument processing program
Review the inspection of surgical instruments and devices
Understand the training and competencies needed for quality instrument processing

BACKGROUND
Surgeons need surgical instruments to perform surgery
Depend on sterile processing personnel to provide instruments/devices that are
• Clean
• Functional
• Accurate
• Sterile

BACKGROUND
Most SPD personnel do not have formal training
On-the-job education limited
Learn by “trial and error”
Lack of training and understaffing contributes to errors and dissatisfaction by surgeons

EVER FEEL LIKE THIS??????

NEED
The average OR instrument inventory is $1.5 million dollars therefore, healthcare facilities MUST manage this inventory.
BACKGROUND
The core of problems between OR and SPD BEGINS with instrumentation
When a surgeon is dissatisfied they complain to the OR nurse
Repeated complaints present problems for the OR staff who have to face the surgeons each day

COSTS
Average cost for an OR/hour $3,960*
If your facility has 4 ORs and SPD causes delay of 1 hour/week per OR =
4 x 1 = 4 hours/week x $3,960 = $15,840
$15,840 x 52 weeks = $823,680/year!

*Health Care Advisory Board (2015)

BACKGROUND
Loss time in the OR = lost $$$$$$$
Average cost $1,200 per hour
Instrument problems can cost the facility thousands of dollars annually in lost revenue

BACKGROUND
Surgical instrument inventory management is recognized as an area where greater accountability and efficiencies are needed and can be derived. Effective instrument tracking systems can:
- define instrument inventories in exact dollars.
- identify instrument shortages
- identify maintenance needs
- Track repairs and their costs

NEED
The average OR instrument inventory is $1.5 million dollars therefore, healthcare facilities cannot afford NOT to manage this inventory.

INSTRUMENT QUALITY
Three rules of surgical instrument processing
# 1 – must start with quality surgical instrument
# 2 – must have policy to define process
#3 – must monitor compliance with policies
QUALITY INSTRUMENTS
No all surgical instruments created equal
Need to know where the instruments' base steel originated (US and Germany the best)
Cannot tell by looking at the instrument
Avoid using Pakistani instruments on OR sets; will contribute to corrosion and rust

QUALITY
Quality surgical instruments last longer
Have more precise detail
Less prone to corrosion

GRADES/FINISHES
Surgical grade - floor grade (Pakistani)
Floor grade lack fine detail and precision
• Break and corrode quickly
• Not suitable for OR
Finishes
• shiny - reflects light (e.g. chrome)
• dull/satin - does not reflect light
• ebonized/black - used for laser surgery

SURGICAL GRADE
OR (surgical grade) instruments have a passivation process at the end of manufacturing
Passivation “hardness” the steel to make it less corrosive to the actions of chemicals and abuse
Passivation can be accomplished by heat or chemicals
Results in the formation of a chromium oxide (protective) coating on the instrument
Floor grade instruments do not have a passivation layer

CLEANING OF INSTRUMENTS
Always obtain and follow the instrument/device manufacturer’s written instructions for cleaning, packaging and sterilization
Information should be verified each time a new device is received
Without this information, device/instrument can be damaged or not properly cleaned

CLEANING
Exposure of metals to incompatible solutions can cause a chemical and electrochemical attack called corrosion
Liquids, especially chlorides (e.g. bleach) are of concern for stainless steel
**DAMAGE TO INSTRUMENTS**

Life of an instrument - 20+ years if cared for properly

Causes of damage

- Misuse - not used as intended by design
- Abuse - dumping, stacking
- Improper cleaning, sterilization
- Chemicals/detergents (e.g. saline - chlorine bleach, blood even water!)

**PROTECTION OF INSTRUMENTS**

Specialty instruments should be placed in specialty container/tray to protect from damage.

Cost of container will be covered by minimal damage/repair instrument costs.

**CORROSION**

Stainless steel corrosion usually appears as surface blemishes (roughness/rust)

Creates difficulties for cleaning, disinfection and sterilization

Can indicate locations where future device failure can occur

**SPECIALTY CONTAINERS**

**BLOOD INSIDE BOX LOCK**
**CORROSION**

Stainless steel can corrode by
- Pitting
- Crevice corrosion
- Stress corrosion cracking (SCC) also known as hydrogen cracking

**CORROSION**

In early stages, effects just cosmetic
If allowed to continue device failure can occur
Corrosion interferes with proper cleaning and can inhibit the disinfection/sterilization process
Improper cleaning can cause corrosion

**CREVICE CORROSION**

Found in box locks and other “tight” spaces
Appears as a red rust
Caused by blood and other soils in box locks and other locations

**PITTING**

Caused by exposure to blood, chloride or bromide containing solutions
Highly localized corrosion of stainless steel
Results in shallow to deep localized defects
Looks like black holes (pits) on surface of instrument
Cannot be repaired, replace as soon as possible

**STAINING OF INSTRUMENTS**

Blue stains - caused by liquid chemicals (e.g. acid glutaraldehyde)
Purple-black - usually due to exposure to ammonia
- Many cleaning compounds have ammonia
- May not be rinsed properly
- Maybe residual boiler ammine residue
STAINING VS SPOTTING

Can determine if it is a spot by rubbing with an eraser; a spot will be removed.

RUSTING OF INSTRUMENTS

If good quality stainless steel probably residue is baked on blood
Do not sterilize plated instruments (e.g. Pakistani) with stainless instruments – can cause rusting to occur
May also be caused by high iron content in water

WANT THIS USED ON YOU???

HOW TO PROTECT INSTRUMENTS

At end of case, place instruments in specific container
If protective container, place items in designated location to protect from damage in transport
Do not stack unless in rigid container
Apply enzyme foam product to keep soils moist

HOW TO PROTECT INSTRUMENTS

Protect delicate items and items with fine/sharp tips
Place heavier items on bottom and lighter items on top
Separate scopes from instruments
COMPETENCIES
All individuals handling surgical instruments and devices need to be knowledgeable in the care, handling and processing of surgical instruments.

TESTING OF INSTRUMENTS
Surgical instruments are the extension of the surgeon's hands. Must work as intended when needed.

INSPECTION
NEED LIGHTED MAGNIFICATION. ONE AT EACH WORKSTATION.
INSPECT FOR:
MAGNIFICATION FACILITATES INSPECTION
NEED AT LEAST 5X MAGNIFICATION FOR NON-OPTHALMIC INSTRUMENTS.
USE OF BOROSCOPES TO VERIFY LUMEN CLEANLINESS

QUALITY INSPECTION
Are all the parts present?
Does the instrument work as intended?
Is there damage to the instrument?
Cleanliness in box lock, jaws, serrations?
Functionality; e.g. stiffness?
Sharpness of scissors
In good condition; rusting? Pitting?
Corrosion? Plating missing?

CHECK INSTRUMENTS FOR STIFFNESS

TESTING RATCHETS HOLD
CLOSE ON FIRST RATCHET TAP FINGER RINGS ON END OF TABLE JAWS SHOULD NOT POP OPEN
**TESTING OF SHARPS**

Check for dull spots on cutting edge
Chips in cutting edge
Dents
Sharpness
  • Use Theraband to test scissors

**TESTING SCISSORS**

**CRACKED BOX LOCK**

**INSPECTION OF INSTRUMENTS**

Self retaining retractors - inspect that ratchets hold
Inspect that joints are not stiff
Verify all parts present
Inspect for rust, pitting, cracked box lock, etc.
Demagnetization of CVT/eye instruments

**CHECK PLATED INSTRUMENTS**

Check for chips in metal
Sharp edges
Worn spots
Plating flaking off
Should this be sterilized????

**CHROME PLATING LOSS**

The plating of chrome-plated instruments should be checked to ensure that it is not cracked or missing.

Instruments with missing or cracked plating cannot be effectively cleaned or sterilized because the surface of the instrument is no longer intact.

These instruments should not be used, but rather sent for repair.)
**TESTING OF NEEDLE HOLDERS**
Checks jaws for burs, worn edges, cracked or missing TC inserts
Check box lock for cracks
Close jaws, should not be able to see through the tip
Can also place suture needle in jaws and try to pull through when closed on second ratchet

**VERIFY T/C INSERTS PRESENT**

**INSPECTION OF FORCEPS**
Make sure tips approximate
Teeth present
Check for rough edges
Checks for cracks – especially in joint
Are serrations clean?

**CHECK TIPS APPROXIMATE**

**INSPECTION OF HAND HELD RETRACTORS**
If self-retaining, does the retention mechanism work?
If a pair, do they match exactly? Sharp? Blunt? # prongs?

**CURETTES AND RONGEURS**
Check edges are free of nicks and burrs
Visually inspect edges to identify any damaged surfaces
INSTRUMENT TESTING

Gouges
- Edges should be free of nicks and burrs
- Visually inspect edge for damage to the cutting surface

Pituitary Rongeurs
- 3/4 of the jaws should make a firm imprint onto an index card

TESTING

Cervical biopsy punches
- Should cut cleanly through 2 layers of facial tissue without tearing or snagging

OPHTHALMIC INSTRUMENTS

Require special care and handling
Inspect with a microscope if possible
Diamond blades require special attention
Some must be sterilized with the blade RETRACTED to prevent damage. Need to check IFU

MARKING INSTRUMENTS

If instrument tape or dipping was used
- Verify sterilant can penetrate (written technical data from manufacturer)
- Verify tape not coming off, flaking
- Verify integrity of dipped surfaces
These methods must be maintained properly
NO ENGRAVING!

INSTRUMENT TAPE IN POOR CONDITION

POWER EQUIPMENT

Follow the power equipment manufacturer’s IFUS for lubrication and sterilization.
Inspect hoses and power cords for damage. If present, replace.
If recommended by the manufacturer, lubricate power equipment according to the device manufacturer’s instructions; use only the lubricant recommended by the manufacturer.
If recommended, test power equipment following the power equipment manufacturer’s instructions for testing of equipment.
Disassemble prior to sterilization. Loosely coil hoses.
POWER EQUIPMENT

Use a lint free tray liner or surgical towel validated for use in steam sterilization cycles between coils of hose to permit steam penetration between coils.
Sterilize in cycle, temperature, pressure and exposure time as directed by the device manufacturer.
If SPD is not equipped to perform the testing it should be the responsibility of the OR.
The correct pressure, in (psi) should be set while equipment is operating and/or as determined by the device manufacturer.

LUBRICATION

- Only use water soluble lubricants
- Check with instrument manufacturer regarding lubrication; most recommend its use after each cleaning
- Sonication removes chromium oxide layer; lubricant will help to re-apply during steam sterilization
- Always allow to air dry
- Check for use life; not microbicidal; will have to date container if manually lubed
- Check water quality recommended if lubricant must be diluted

LUBRICATION

Instrument lubricants should be specifically designed for their intended use and compatible with the processing method being used.
The lubricant manufacturer should provide evidence to support material compatibility and biocompatibility (e.g., lack of cytotoxicity) of the lubricant for its intended use (e.g., following sterilization).
Lubricants should be used according to the device manufacturer’s instructions.

INSTRUMENT REPAIRS

Need quality repair service
Select service with approval of OR and Materials Management
Evaluate service, contact references
On-site repairs preferred
Establish preventive maintenance for sharps
Track repairs

NEW/REPAIRED INSTRUMENTS

When new instruments received:
- check if correct instrument
- check for damage
- clean before placing in storage
Repaired instruments
- check repair and thoroughly clean before placing in storage
During storage, ratchets should be kept open to avoid excessive pressure on the box lock, which can damage the instrument
INSTRUMENT LOSS

All instruments must be accounted for during all phases of use:

• OR
• SPD

Should be counted at end of ALL cases for inventory control (AORN)

INSTRUMENTS IN LAUNDRY

INSTRUMENTS IN SYRINGE CONTAINERS!

ENDOSCOPIC INSTRUMENTATION

2 categories

Rigid (e.g. TMJ-laparoscopic, arthroscopic
  • Will only discuss these

Flexible (bronchoscopes, colonoscopes, etc.)

RIGID SCOPE

4 BASIC PARTS - RIGID SCOPE

Objective lens:
  • located at the distal tip of the rigid endoscope
  • Determines the viewing angle – forward, oblique, lateral, or retrograde.

Telescope:
  • The optical element in a rigid endoscope is commonly called a telescope.
  • The most expensive and fragile part of the endoscope
  • Provides both the image and the light that allows the image to be viewed.
  • A fiber optic light cable and power source transmit light through illumination fibers distributed around the lens train.
4 BASIC PARTS - RIGID SCOPE

Light post:
- The light post allows attachment of the light cable to the telescope.

Eyepiece: Also called the ocular lens
- remains outside of the patient’s body.
- The physician may either view images directly, or attach a camera to the eyepiece and view the images on a video monitor.

RIGID SCOPES

Follow manufacturer’s instructions for cleaning
Brush distal end with soft bristle brush
Wipe outer surfaces of scope and accessories with gauze or soft cloth moistened with detergent solution.
Light cables - clean as above and brush both ends

Brush distal end with soft bristle brush
Wipe outer surfaces of scope and accessories with gauze or soft cloth moistened with detergent solution.
Light cables - clean as above and brush both ends

RIGID SCOPES

Can use high pressure water jets for lumens or brush and flush thoroughly
Rinse repeatedly to remove all detergents and residues
No ultrasonic cleaning for scopes - vibrations can damage lens seals and fracture optical fibers

RIGID SCOPES

Inspect all areas of scope for scratches, dents, burns, etc.
Inspect for image clarity
- hold tip of scope app. 3 inches above a nonglaring printed, white surface
- Move tip of scope progressively closer until it is app. 1/4” away
- Image should be crisp, clear

RIGID SCOPE TESTER

If image cloudy, discolored, hazy - may be caused by improper cleaning, disinfectant residue, cracked or broken lens, presence of internal moisture or external damage (shaft)
RIGID SCOPES
Store in specialty container to prevent damage
Use scope protector sleeve for TRANSPORT ONLY....
May not be validated to keep on scope for sterilization

CABLES
LOOSELY coil cables
Should be app. 8" diameter coil
Avoid tightly coiling - will damage light bindles

DAMAGE TO FIBER OPTIC CORD

DAMAGE TO CORDS
• Inspect by holding up one end to a light, look at opposite end
• If more than 15-30% black dots, insufficient light for surgeon, send for repair

LAPAROSCOPIC INSTRUMENTS
Extremely difficult to clean due to long shaft and jaw assembly
Both can trap debris
Positive pressure of insufflated abdomen can cause blood and body fluids to flow under insulation and into channels making cleaning difficult/impossible

BLOOD ON LAPAROSCOPIC INSTRUMENTS
INSPECTION

During surgery defective insulation could allow 100% of the electrical current (700°F) to flow from the defect to organs, tissue.

Smaller the crack the more dangerous - more current escapes from small hole because it is more concentrated

App. 90% of the active electrode outside surgeon’s field - problem could go unnoticed

INSPECTION

Insulated instruments require special inspection

- repeated use/sterilization can cause the layer of insulation covering the shaft to break down
- Minute tears can go unnoticed during cleaning/inspection

COMPLICATIONS

Patient complains of severe abdominal pain after several days

Can result in peritonitis and sepsis and can lead to death

INSULATION FAILURE

Occurs when there is a leak in the insulation along the shaft of the instrument, burning nearby tissue.

INSULATION FAILURES

Occur due to normal wear and tear, high voltages, the cleaning and sterilization process (flash increases damage) and contact with sharp instruments (e.g. trocars)
INSPECTION

Need comprehensive system for inspection of insulation
Insulation can get damaged from dropping the instrument, repeated sterilizations and/or placing instruments on top of other instruments, or “dumped” into a table
Insulation should last for app. 20 cases

INSPECTION

Develop policy and procedure to visually inspect insulation each time with lighted magnifying lamp
Look for cracks, holes, flaking in insulation
Follow with insulation testing equipment
Document EACH instrument tested and results

INSULATION TESTERS

Reusable – cost effective (may be able to get from instrument repair company)
Single use, sterile (for use in the OR)
Specialty instruments – monitored for defects throughout surgery

INSULATION TESTER

ROBOTIC INSTRUMENTS

Similar in design to laparoscopic instruments
Require special cleaning protocols
Can take as long as 20 minutes to clean each instrument
Must have equipment specified by the manufacturer
Need to track uses (maximum 10)

ROBOTIC INSTRUMENTS

Can only be cleaned manually (sonic permitted)
Labor intensive
Challenges to cleaning-requires special high pressure hose
Multiple vendors and models, all may have different IFUs
BLOOD AND DEBRIS HIDES INSIDE CABLES AND PORTS

SETTING UP

Begins with policies and procedures
Cannot have accountability without these
Develop a comprehensive policy and procedure for handling instruments from the OR to SPD and back to the OR
Involve OR in the process
This policy should apply to all departments whose instruments are processed in SPD

Policy Considerations:

• Specify what happens to the instruments at the end of the case?
  • Counted? (AORN supports counting at the end of ALL cases)
  • Wiped off
  • Sharps separated inside container

UNACCEPTABLE!!!

Sprayed with an enzyme foam to facilitate cleaning?

WHAT SET DO THESE BELONG TO?

Placed back in their respective container before return to SPD?
NOT RECOMMENDED

- Should not be separated from clean/not used instruments.
- Promotes loss

POLICY CONSIDERATIONS

Must address
- Turn around times for sets
- Need system of priority processing
- Identify tray/set
- Document when received in SPD
- Document each phase of processing from receipt to return
- Document time returned to OR

PRIORITY ALERT – PROCESSING

The following item(s) is required IMMEDIATELY.
Item(s) being sent:
The item(s) are to be: __________________
Sterilization:

Room number: __________________
Note: __________________

SPD COMPLETE

Time items received in Decontam: __________________
Received by (name): __________________
Items completed Decontamination (Time): __________________
Items completed prep/assembly by: __________________
Items placed in sterilizer by: __________________
Time in Sterilizer: __________________
Returned to OR fully decontaminated by: __________________
Returned to OR Sterilized at (time): __________________
OR Personnel accepting item(s): __________________

TURN AROUND TIMES

Need to know the processing required for items
- E.g. robotic instruments require 20 minutes of processing in Decontam (each inst).
- Affects turn around time
- Include sterilization and cooling time

INSTRUMENT INVENTORY

Need sufficient instrumentation to permit turnaround time which complies with device manufacturer’s instructions
Need sufficient time to permit items to cool correctly
- Flash sterilization increases damage to instruments by rapid expansion and contraction of metal

POLICY CONSIDERATIONS

How are instruments transported to SPD?
- Dumbwaiter/elevator?
- Picked up by SPD?
- Delivered by OR? Transporters?
What are instruments transported in?
- Case carts?
- Covered carts/bins?
POLICY
CONSIDERATIONS

What is the frequency of delivery?
- Immediately at the end of the case?
- Every ?? hours?
- When the OR calls?

What happens to the instruments when they arrive in SPD?
- Off loaded; how soon?
- Removed from rigid container (if applicable)
- Sorted

Use of manufacturer’s written instructions for processing
Instruments opened, disassembled
Lumened devices manually brushed

Procedures for specialty devices
- Powered equipment
- Robotic instruments
- Laparoscopic/endoscopic instruments

Procedures for missing/damaged instruments

SETTING UP

Get a buy-in from the OR (or other departments)
Get policy approved
In-service policy to SPD and OR personnel

TRAINING

Can use manufacturer’s videos, textbooks, catalogs
Use photo references
Make sure count sheets specific to sets
- Correct instrument name
- Correct catalog #
- Correct and complete description
- Correct quantity
- Special instructions

Table 7.2 — Example of an Instrument Count Sheet

<table>
<thead>
<tr>
<th>Item Identification</th>
<th>Item description</th>
<th>Item description</th>
<th>Item description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item 1</td>
<td>Item 2</td>
<td>Item 3</td>
<td>Item 4</td>
</tr>
</tbody>
</table>

Table 7.3 — Example of a Form to Document Missing Instruments
COUNT SHEETS

Using count sheets or tray lists promotes accountability and prevents delays in surgery because of missing instruments.

Markers with permanent, non-toxic ink should be used to write on count sheets or tray lists.

As instruments are placed on the set, enter the quantity.

Avoid placing instruments on set FIRST then “drawing a line” down the entire count sheet or entering the quantities at the end. THIS IS HOW ERRORS ARE MADE.

COUNT SHEETS INSIDE SETS

A very small FDA-sponsored study revealed little evidence of toxicity from count sheets placed inside sets (Lucas, et al., 2009), but limited types of toners and only one type of paper were used. The study did not evaluate whether debris from the paper remains on the instruments or builds up inside the sterilizer chamber. Study did recommend that methods be used to prevent transfer of ink from the count sheet to the surgical instruments or container.

COUNT SHEETS INSIDE SETS

Can use a lint free tray liner or autoclaveable bag, etc.

There is no documentation that placement of the count sheet on the outside of the container limits any toxicity concerns.

AORN GUIDELINE FOR PACKAGING (2015)

“The health care organization should weight the risks vs the benefits of placing a non-validated product (count sheet) in instrument trays against the need for inventory control and instrument count procedures.”

COUNT SHEETS

It is important for processing personnel to verify the accuracy of the number and type of instruments placed in the set.

Inaccurate counts can delay cases in the OR because of the need to obtain another set (which will increase the workload of processing personnel) or to locate a sterile replacement instrument.

The OR staff depends on processing personnel to provide them with a clean, sterile, and accurate set of instruments; otherwise, the delivery of patient care can be delayed or compromised.

SUMMARY

Instruments are extensions of the surgeon’s hands

Proper use, handling, cleaning, sterilization and maintenance can keep instruments in good working order for 20+ years

Everyone needs to know how to care for instruments
SUMMARY
Patient safety initiatives are essential
Follow device manufacturer’s instructions for cleaning, inspection and testing
Handle all instruments with extreme care
Carefully inspect insulated instruments

MOTIVATION
Need to motivate the staff to provide quality products each and every time!
Instill pride in the process and department.
Use team building strategies

CONCLUSION
Surgical Instruments high dollar investment
All personnel handling instruments must protect them from abuse and damage
Cannot afford to throw money away!

QUESTIONS?

REFERENCES