Risk Management for Instrumentation

Jennifer Grainger

Patients worried about gangrene, septicaemia and tetanus.

Patient Concerns today

Hepatitis B

HIV

CJD

Hepatitis C

Fact One

“If an item can not be thoroughly cleaned it can not be sterilised.”

Fact Two

“The only monitoring of cleaning is by visual inspection.”

Changes that have occurred

- Advances in technology
- Development of new surgical technique.
- Development of new and complex instrumentation.
  - Variety of materials
  - Lumens
  - Movable parts
- Better patient outcome but greater challenge for re-processing

Instrument Development

"Typically, surgeons are the ones who recognise the need of a particular instrument, and then call upon the expertise of engineers to develop it. Here, however, the engineers developed the surgical instrument to solve a particular problem."

"Robot-assisted brain surgery a reality"
www.sciforums.com

Critical Incidents

"In sterilising a critical incident that can put patients at risk occurs through a breakdown or error in either the cleaning or sterilisation phase of the process."

Patients told of contamination

By **Janice Harris**

MID Western Area Health has contacted 18 people who underwent hip surgery at Orange Base Hospital and Orange Private Hospital after reports of a contamination scare over surgical equipment.

Head of Mid-Western Area Health's public health unit Dr Janine Liddle said all former patients of both hospitals who had surgery involving the instrument had been asked to contact their general practitioner so that blood tests can be carried out.

The 18 Orange hospital patients were among a group of about 200 in the State who have been identified as being at risk after a piece of equipment used to hammer in the stainless steel hip prosthesis to the thigh was found to contain congealed blood.

The discovery was made at the Orange Base Hospital on July 18.

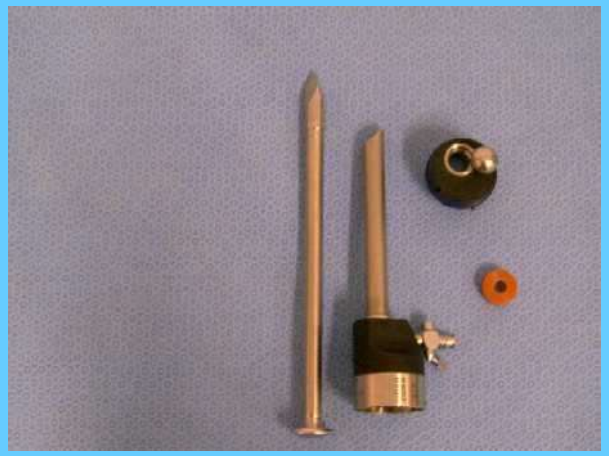
A spokesperson for the Orange orthopaedic surgeon who had previously used the equipment which has now been withdrawn, said patients listed for hip surgery would not experience delays and alternate equipment would be utilised.

OTTAWA, April 28, 2004 — As a result of an alert issued by Health Canada, The Ottawa Hospital (TOH) has reviewed the use of a surgical instrument called an acetabular reamer, particularly with regards to cleaning and sterilisation procedures.

Headlines

- Patients at risk of CJD from surgical instruments
- Over 3000 patients were recalled in Northern Ireland following concerns about inadequate disinfection of 15 endoscopes.
- Risk of transmission of infection because of inadequate decontamination.

Difficult to clean equipment




zimmer


Central Coast Health – CSSD


Central Coast Health – CSSD

Problem with Complex instruments

"If we can not see the surface area of an item it's unlikely we can clean it and we certainly can not inspect it!"

Risk Assessment Matrix

Degree of Cleaning Difficulty	Degree of Contact				
	Enters wound with force	Impacts item that enters wound	Enters wound	Supports component that enters wound	External to wound
Complex or movable parts and/or cannot dismantle	1	1	1	2	3
Complex or movable parts partially dismantles	1	1	1	3	4
Complex or movable parts and Dismantles	2	2	3	4	5
Simple item no complex or movable parts	4	5	6	6	6

Risk Control Action Plan

Set/Kit Name:

Item	Cat No	Risk	Concern	Control Measure
Sizing Guide	136	1	Multiple moving parts & doesn't dismantle	Ensure all parts are moving freely & after initial hand wash rinse and soak in enzymatic solution, rinse and ultra-sonic for 4 minutes then place in batch washer for final wash.

Issues for the future

- Consideration given to cleaning and sterilisation during instrument design.
- Clear and comprehensive cleaning and sterilising instructions from manufacturers.
- Cleaning systems keep pace with instrument development.

Thank you

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