CLINICAL PHYSICS

NHS
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Tom Brophy - Lead Technologist

QA of new surgical instruments
Don't accept our rejects!

Paul Srodon - Surgeon

Phil Daly - Scientist

Malcolm Birch - Clinical Physics Director

bsi. ISO 9001 Quality Management

Specialist Work Undertaken

- BBC Panorama - ‘Surgery’s Dirty Secrets’

  Uploaded on YouTube

- BBC Scotland - ‘Investigates Surgery’s Dirty Secrets’
  - Professor Brian Toft OBE PhD FRSA

    Emeritus Professor Patient Safety Coventry University and visiting professor of patient Safety Brighton and Sussex Medical School

- NHS Supply Chain

- University of Bedfordshire - Peri-operative Critical Care Team

NHS Barts Health NHS Trust

Professor Corner

National Surgical Instrument Reference Centre

(Reusable Surgical Instruments)

NHS SCOTLAND

bio-dundee

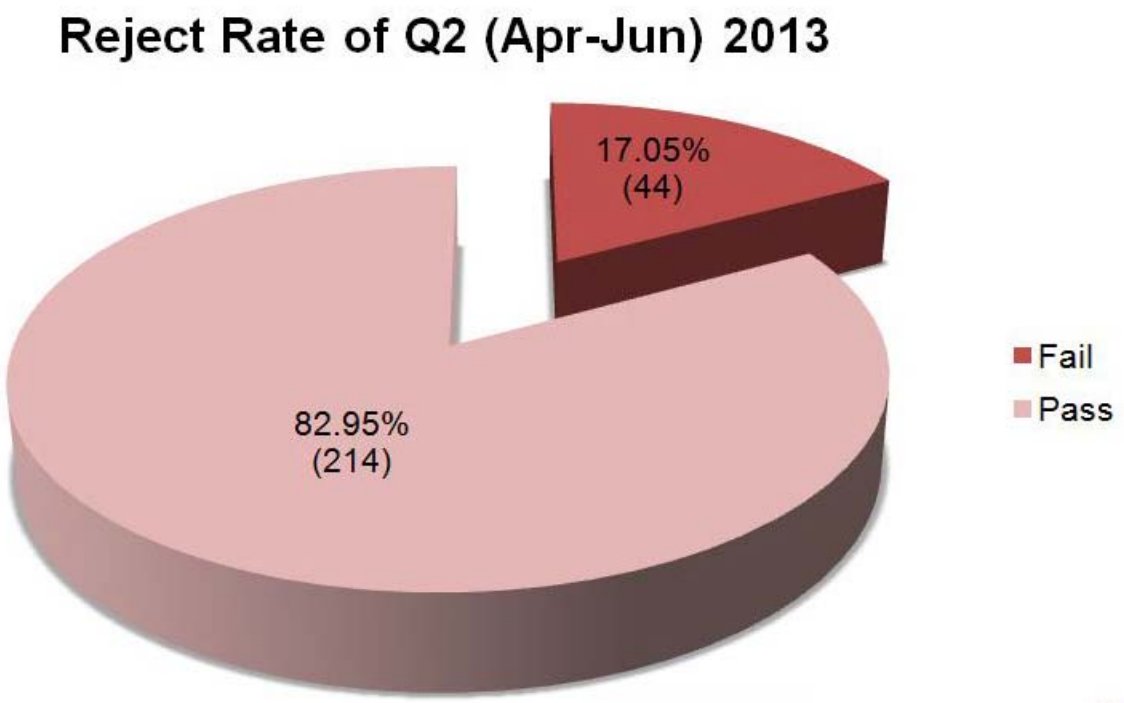
The INNOVATION PORTAL

academic expertise for Scottish business

NHS Tayside

Wendy Xu

Tayside Initial Investigation



NHS SCOTLAND
NHS Tayside
UNIVERSITY OF DUNDEE

The Beginning - Mayo Needle Holder

Research Paper

The Royal College of Surgeons of England

GENERAL SURGERY

Ann R Coll Surg Engl 2006; **88**: 000-000
Doi 10.1308/003588406X98621

Quality of surgical instruments

T BROPHY[1], PD SRODON[2], C BRIGGS[1], P BARRY[1], J STEATHAM[1], MJ BIRCH[1]

Departments of [1]Clinical Physics and [2]Vascular Surgery, Barts and the London NHS Trust, London, UK

ABSTRACT

INTRODUCTION Many surgeons will have encountered the scissors that would not cut, and the artery clip that comes off in a deep difficult location, but it would be reasonable to assume that new instruments should be of assured quality. This study reports the surprising findings of a local quality control exercise for new instruments supplied to a single trust.

MATERIALS AND METHODS Between January 2004 and June 2004, all batches of new surgical instruments ordered by the Central Sterile Supplies Department of St Bartholomew's and The Royal London Hospitals were assessed by three clinical engineers, with reference to British Standards (BS) requirements.

RESULTS Of 4800 instruments examined, 15% had potential problems. These included 116 with machining burrs and debris in the teeth of the tissue-holding regions, 71 defects of ratcheted instruments, 34 scissors with deficient cutting action, and 35 tissue forceps protruding guide pins. In addition, 254 instruments did not have a visible manufacturer's mark.

CONCLUSIONS This study demonstrates the value of local quality control for surgical instruments. This is of importance in an increasingly hazard-conscious environment, where there are concerns over instrument sterilisation, surgical glove puncture and the potential for transmission of blood-borne and prion diseases.

Research Paper

Papers

Medical Device **Decontamination** // February - April 2010 // Volume 14 // Number 3

Unretrieved Device Fragments - the clinical risk of using poor quality surgical instruments

Daly PM[1], **Brophy T**[1], **Steatham J**[1], **Srodon PD**[2], **Birch MJ**[1]
Departments of [1]Clinical Physics and [2]Vascular Surgery, Barts and The London NHS Trust, 56-76 Ashfield Street, London, E1 2BL.
Email: phil.daly@bartsandthelondon.nhs.uk

Abstract

The US Food and Drug Administration (FDA) has published a Public Health Notification advising on serious adverse events arising from fragments of medical devices left behind after surgical procedures, known as unretrieved device fragments (UDFs). There are many risks from UDFs including local tissue reaction, infection, perforation and obstruction of blood vessels and death.

One major source of UDFs is from surgical instrument failure. At Barts and The London NHS Trust, we receive a large number of poor quality newly purchased surgical instruments, with 10% of instruments failing Quality Assurance (QA) in the first 6 months of 2009. Many surgical instruments have manufacturing faults which can result in fragments becoming detached and entering the patient during surgery.

One major source of UDFs is from surgical instrument failure.[3] The following are reported examples of surgical instruments breaking and leaving behind fragments in patients:

- A 56-year-old woman had surgery on the temporomandibular joint. In the 10-year period after surgery she suffered pain, tinnitus and restricted mouth opening and a 4mm metallic foreign body was subsequently removed. The foreign body was most probably a fractured tip of a surgical awl which had been left behind in the original surgery.[4]
- A small metal fragment disassociated from an arthroscopic instrument and remained inside a patient's knee joint for 14 months, causing recurrent swelling and pain.[5]
- Conway *et al.* (1999) report that it is a well

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Clinical Service Journal

PATIENT SAFETY

Call for Trusts to review instrument quality

Experts at Barts and The London NHS Trust are campaigning to raise awareness of the risk of unretrieved device fragments posed by poor quality surgical instruments, which can lead to infection, perforation or obstruction of blood vessels, and even death.

Phil Daly and Tom Brophy from the department of clinical physics, Barts and The London NHS Trust, are urging other Trusts to follow their lead in implementing stringent quality assurance processes to ensure newly purchased instruments are fit for purpose, following research which identified quality issues in a significant number of devices.

In a bid to evaluate the scale of

'The latest reported figures show that some suppliers are continuing to sell substandard instruments, with 10% of instruments failing quality assurance tests in the first six months of 2009.'

unretrieved device fragments are reported to the FDA's Centre for Devices and Radiological Health, each year – many of which are caused by surgical instrument failure.'*

Head technician, Tom Brophy, who has over 30 year's experience of mechanical engineering, revealed that he had observed inadequate quality control procedures during visits to a significant number of manufacturing sites. However, he added that there is very little pressure on suppliers to improve performance, as so few Trusts employ dedicated expertise to perform systematic inspection of newly purchased instruments.

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Research Paper

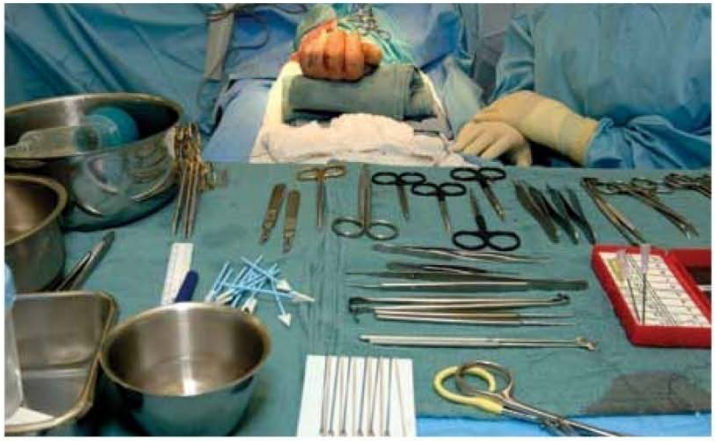
www.hospitalhealthcare.com/hhe

New surgical instruments: a question of quality

An alarming number of new surgical instruments used by the NHS and in private practice are of inferior quality and have the potential to malfunction during medical procedures

Tom Brophy
JA Pickett
PM Daly
MJ Birch
Department of Clinical Physics
Barts and The London NHS Trust
St Bartholomew's Hospital, London, UK

PD Srodon
Department of Vascular Surgery
Royal London Hospital, London, UK



When hospitals purchase surgical instruments most will assume that they are safe and reliable and that good manufacturing techniques have been used. There is also a reasonable expectation that these devices have been subjected to a rigorous quality control process.

In 1998, the Clinical Physics Department at Barts and The London NHS Trust were asked by clinical colleagues to investigate the quality of surgical instruments being

In 2000, Barts and The London NHS Trust set up its own surgical instrument quality assurance section, because we had no confidence that new instruments were undergoing a real quality control process.

Administration (FDA) published a Public Health Notification advising on serious events that arose from fragments of medical devices being left behind after surgical procedures. These fragments are

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Health Estate Journal

Instrument decontamination

Vigilance vital to ensure high standards

With effective surgical instrument decontamination critical to ensuring that harmful pathogens are not passed from patient to patient, and, for example, an acknowledged risk that human brain degenerative diseases such as vCJD, Alzheimer's disease, and Parkinson's disease, may be transmitted from person to person via contaminated instruments, an IHEEM seminar in Birmingham recently examined effective device decontamination, and the quality of surgical instruments generally, with some found to be defective even when unpacked straight from the factory. Among leading experts to pass on valuable guidance at the seminar, titled 'Dirty Little Secrets 2', and held at the Hilton Birmingham Metropole Hotel, was Tom Brophy, lead medical engineering technologist at Barts Health NHS Trust. As *HEJ* editor, Jonathan Baillie, reports, he gave an interesting follow-up to a presentation he made on the same topic at an earlier IHEEM 'Dirty Little Secrets' seminar in February 2012.

Manufacturers' Literature

Standards to which Manufacturers or Suppliers of Surgical Instruments must comply

Medical Device Directive 93/42/EEC

British Standards 5194 : Part 1 : 1991 Specification for stainless steel / International Standard 7153-1 1991.
British Standards 5194 : Part 2 : 1989 Specification for instruments with pivot joints.
British Standards 5194 : Part 3 : 1985 Specification for dissecting forceps.
British Standards 5194 : Part 4 : 1985 Specification for scissors, shears and other jointed instruments.

International Standards 7740-1985 Instruments for surgery - Scalpels with detachable blades - Fitting dimensions.

International Standards 8319-1:1996 Orthopaedic instruments - Drive Connectors - Part 1: Keys for use with hexagon socket heads.

International Standards 8319/2-1986 Orthopaedic instruments - Drive Connectors - Part 2: Screws for single slot heads, screws with cruciate slot and cross-recessed head screws.

Instruments must comply with all the relevant British Standards or International Standards.

Note: Tungsten Carbide needle holders inserts, if soldered should have no blow holes in the solder.
In the result of no formal standards instruments must fulfil the requirements of their intended use.

No Formal Standards

- In the result of no formal standards instruments must fulfil their intended use.

- Associated equipment shall be marked with registered trade mark.

Quality Assurance Procedures applied to Surgical Instruments at Barts and The London (1)

Instruments will be inspected in accordance with British and International Standards

- All Instruments will be inspected by normal vision.
- Devices that include teeth, serrations and prongs will be inspected to ensure sharp edges, burrs and manufacturing debris have been removed with the aid of a x15 Eye Glass.
- If a problem is discovered, further evaluation may be required using a x60 Microscope.
- Any medical device that is a risk to patient safety must comply with the above requirements.

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Quality Assurance Procedures applied to Surgical Instruments at Barts and The London (2)

- Instruments that include Tungsten Carbide Inserts, will be inspected using a Microscope with a magnification up to x60 to ensure the inserts are soldered correctly, and free from fractures.

- Batch inspection is carried out:

  1-24 = **100%** **25-50** = **50%** **50-75** = **30%** **75-99** = **20%** **100-up** = **15%**

- If any failures occur during inspection, a 100% inspection will be carried out.

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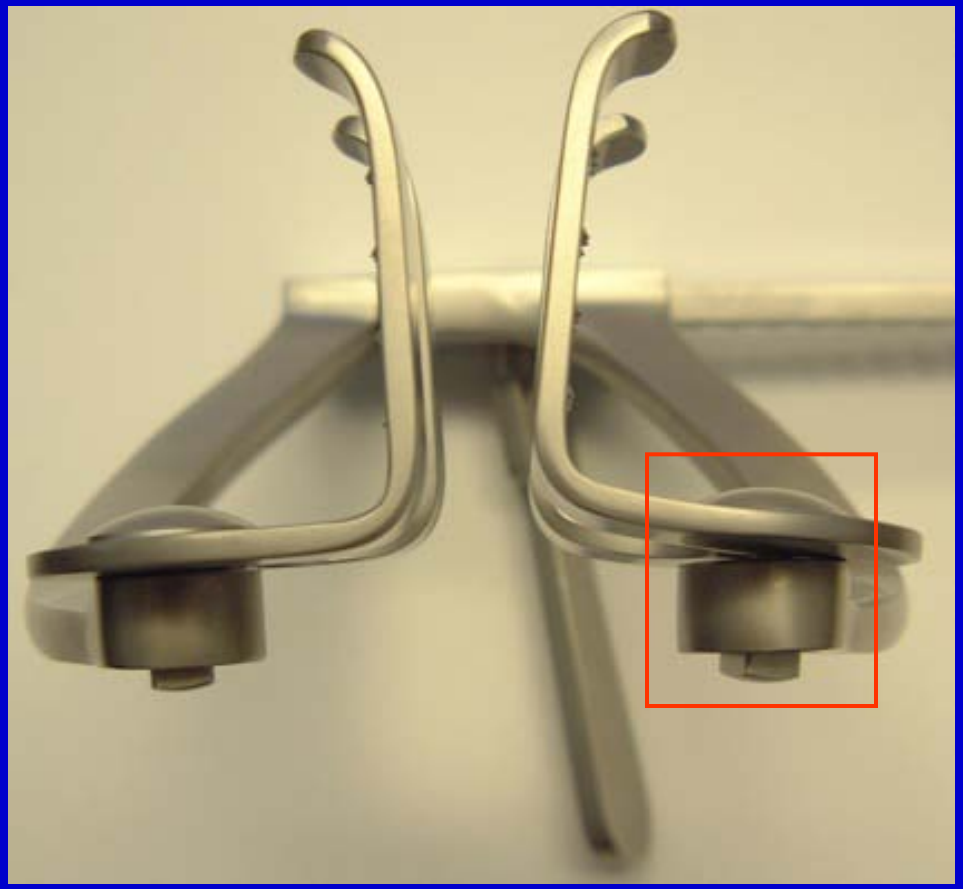
Defective Instruments

- No manufacturer's mark - no traceability.
- Fracture material may be inserted into patients.
- Soldering faults may provide niches for retention of blood and tissue.
- Forceps guide pins protruding on jaw closure - may cause glove puncture.
- Artery forceps with deficient ratchets and scissors not cutting properly.
- Visible corrosion.
- Previously used and contaminated.

Roberts Artery Forceps Ratchet not holding

Sellors Rib Spreader Blade not secure



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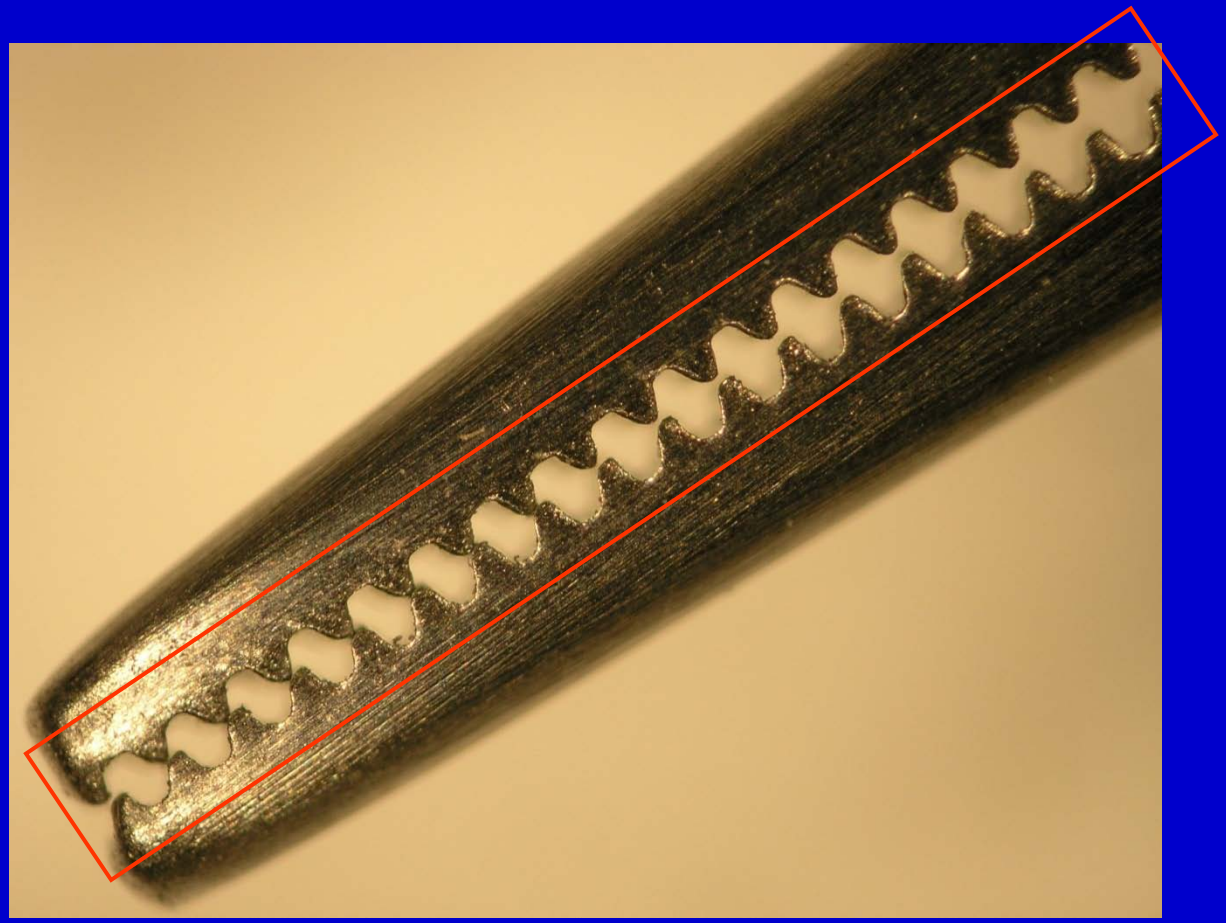
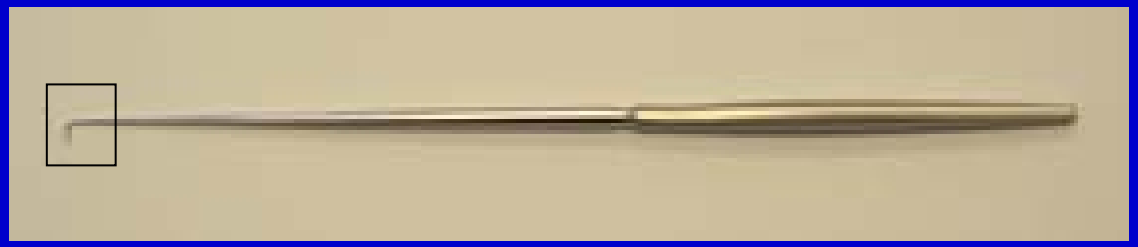
Potts Smith Dissecting Forceps Jaws not meshing

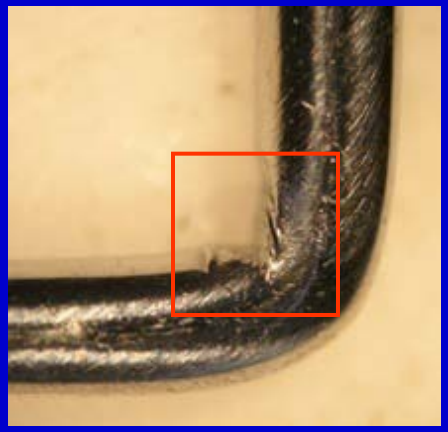


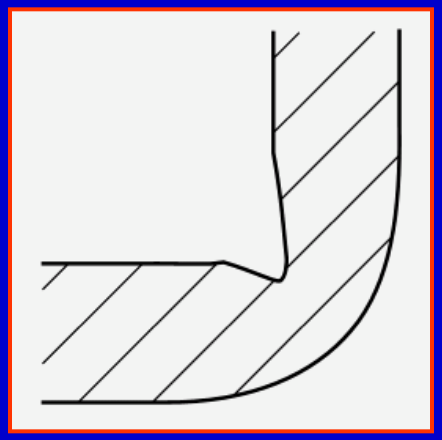
Blalock Hook Right Angle

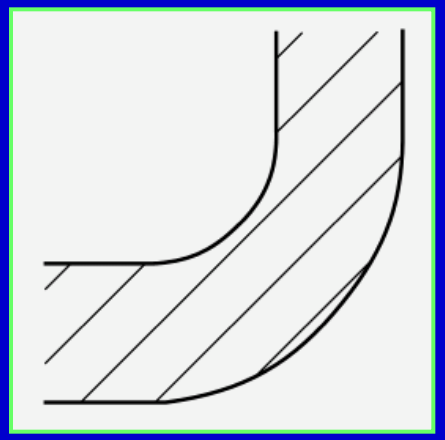


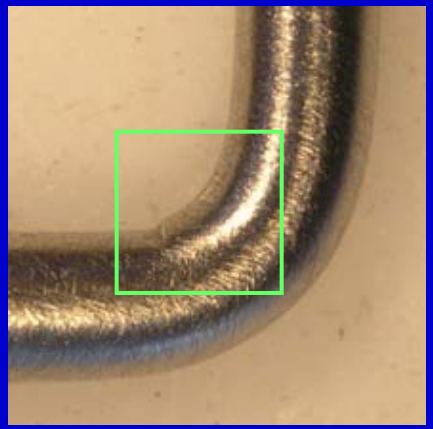
Bad Example

Good Example









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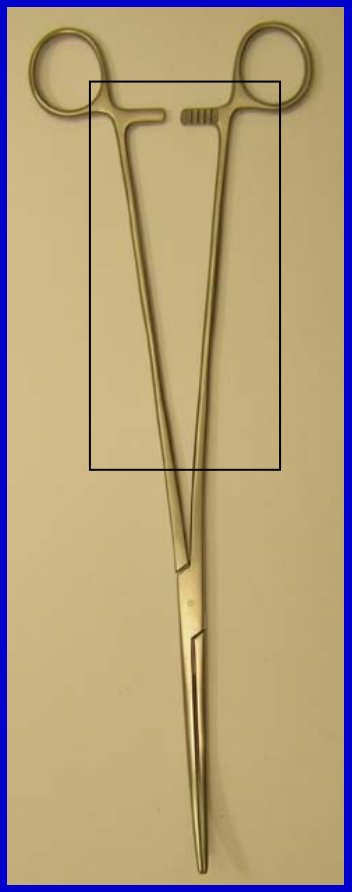
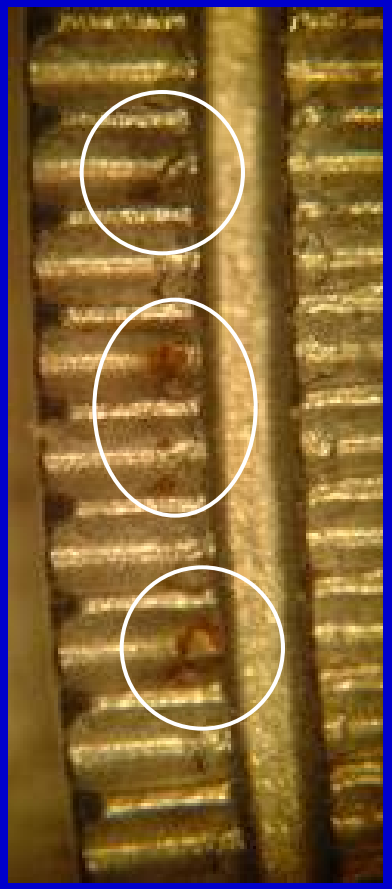
12 inch Crafoord Forceps Bodge

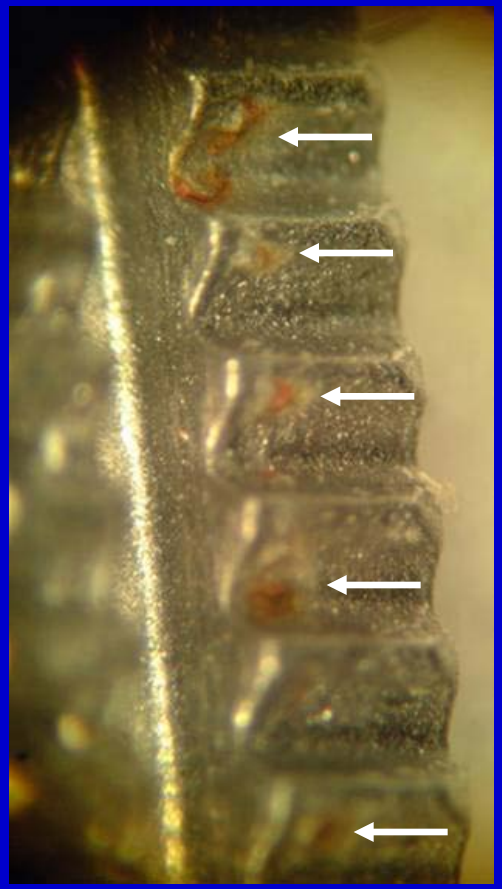


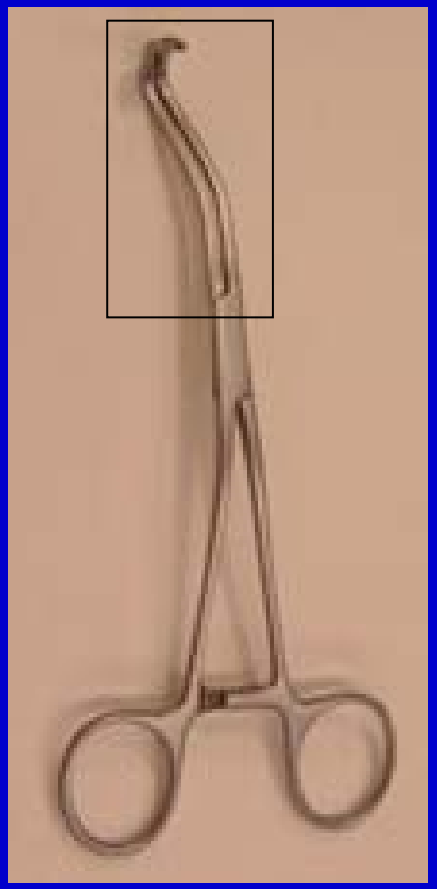




Cooley Clamps Rust

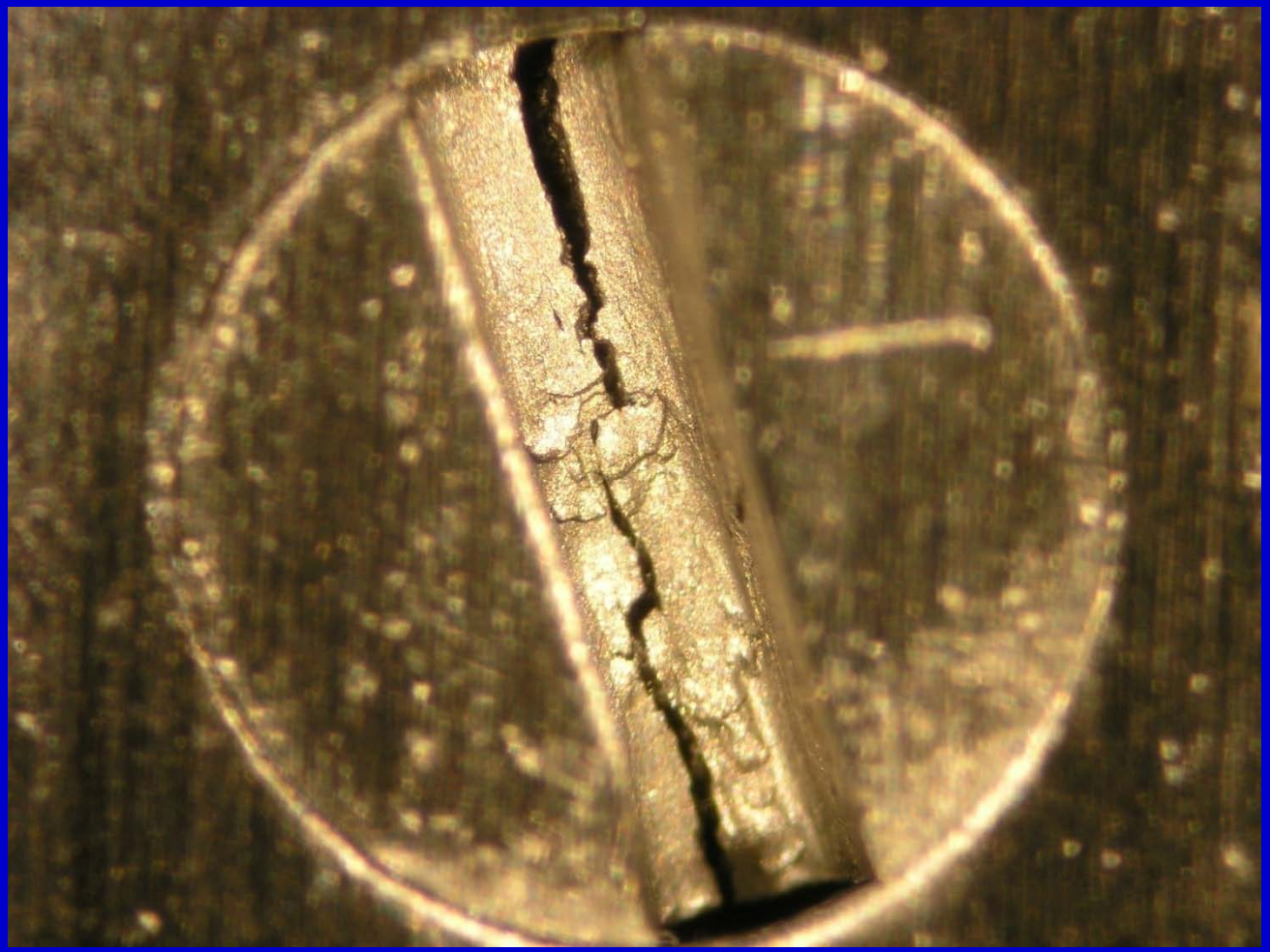




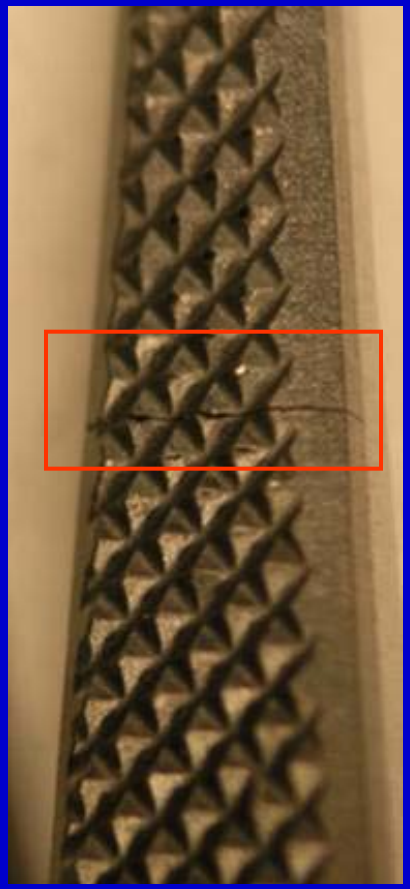


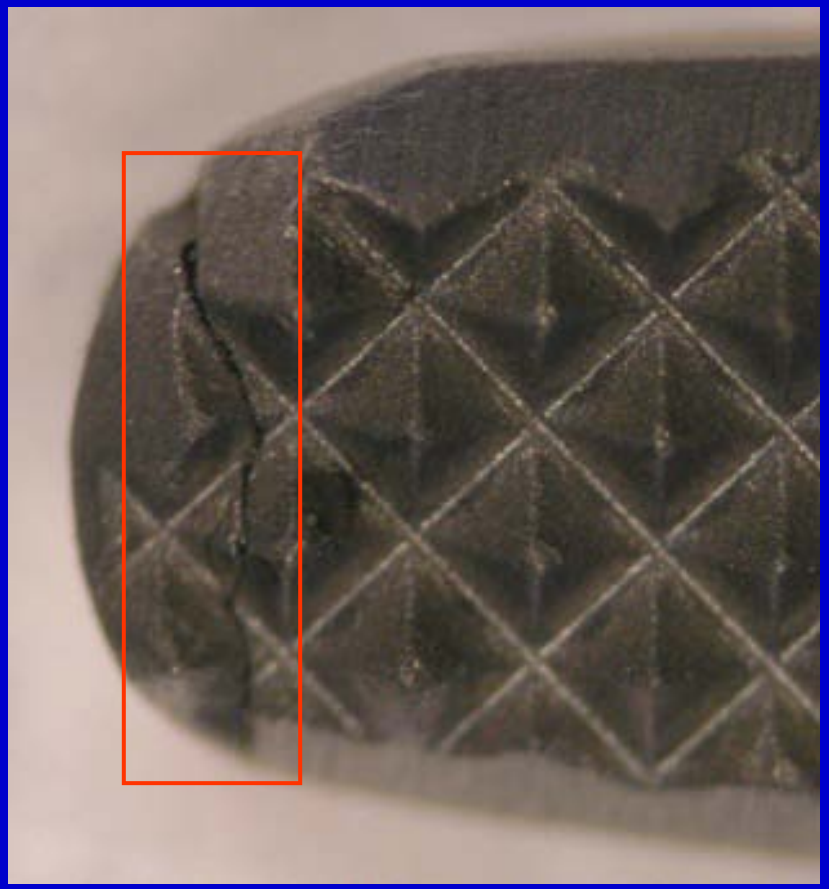
Knife Corneal Desmarres Medium Corrosion

Scissors Joint screw fracture

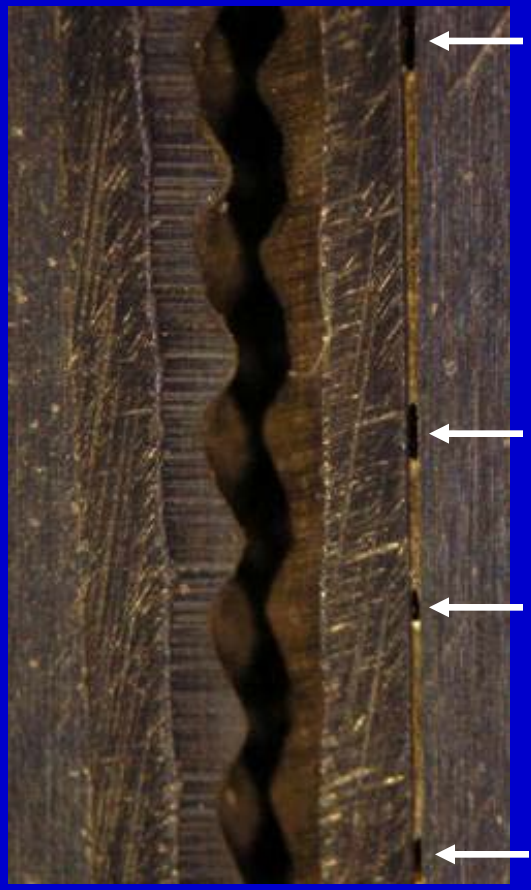


Needle Holders Soldering void - fractures



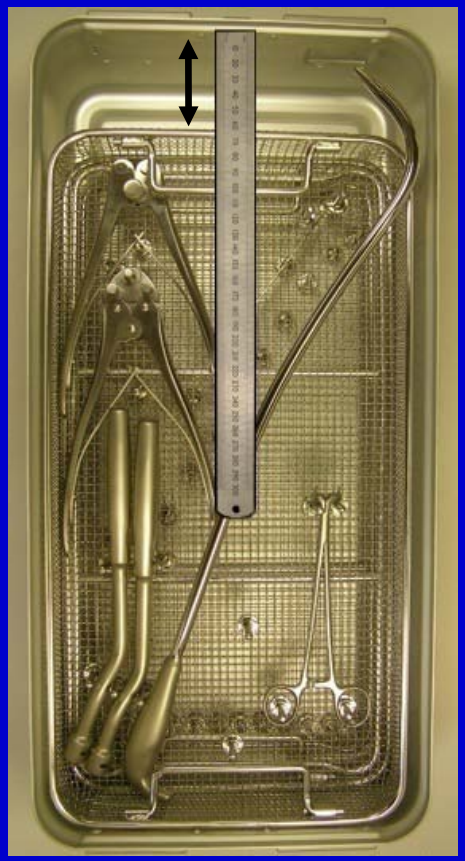


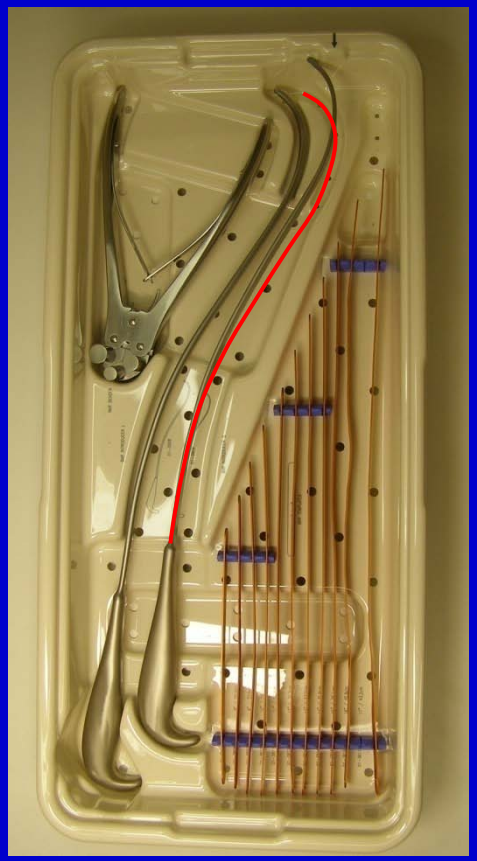
Derf Needle Holder Small Soldering - Void



Castroviejo Needle Holder Good Example

Sterilisation Containers





Bad Example

Good Example

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Burrs, Fractures, Voids, Rough Surface Finishes

- All trap potentially infectious tissue debris.
- Most of this would be removed by sterilization but there is a danger that new types of infection transmitted by protein ‘Prion disease’ might survive this.

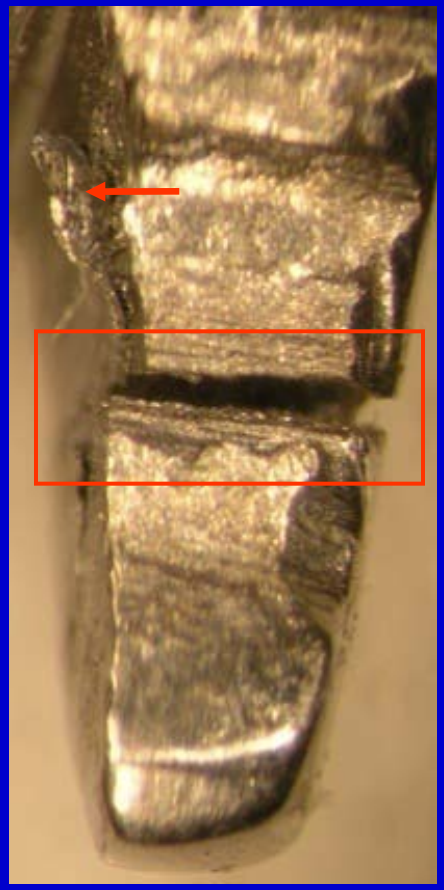
e.g. CJD (Creutzfeldt-Jakob disease).

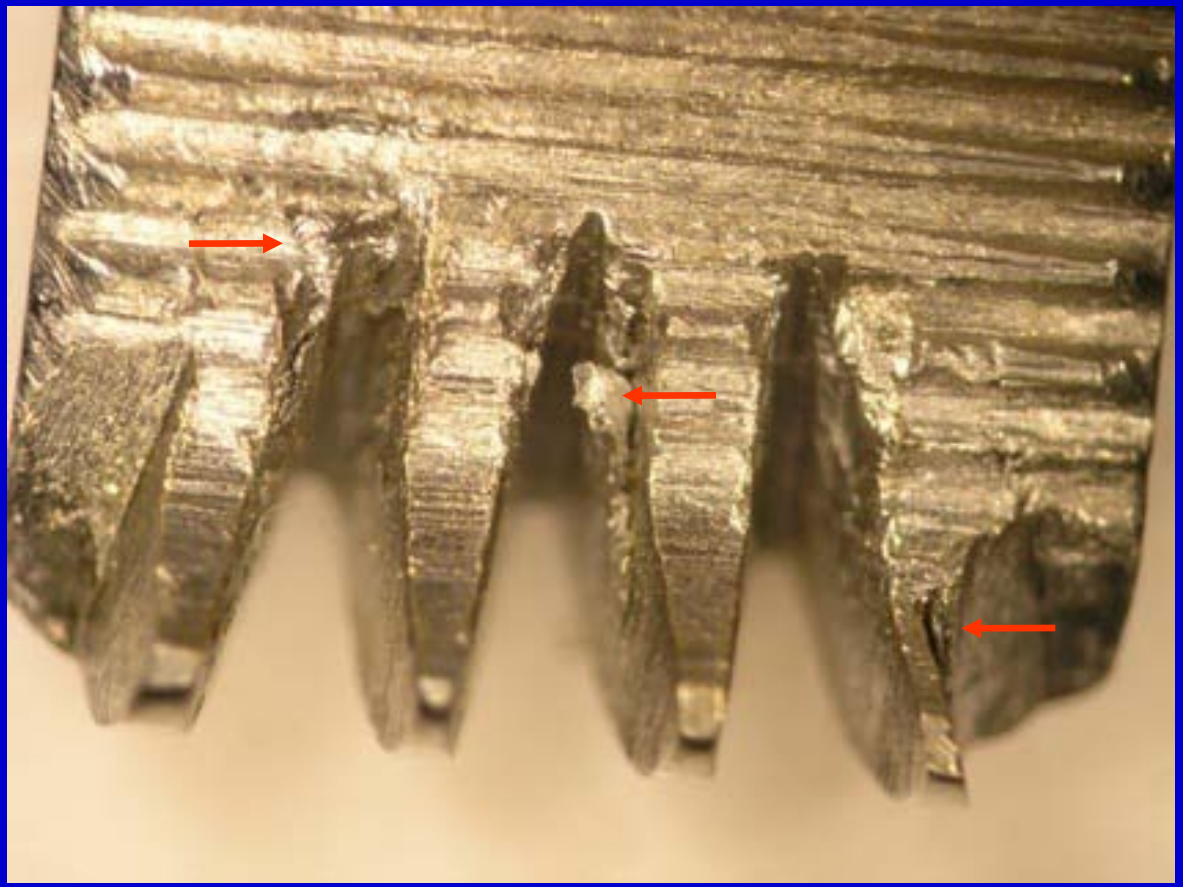
Burrs

- Burrs may become detached - debris provides a focus for infection.
  - Foreign body granuloma.
  - Foreign body embolism.
  - Weaken patient immune system.
  - MRI burns.

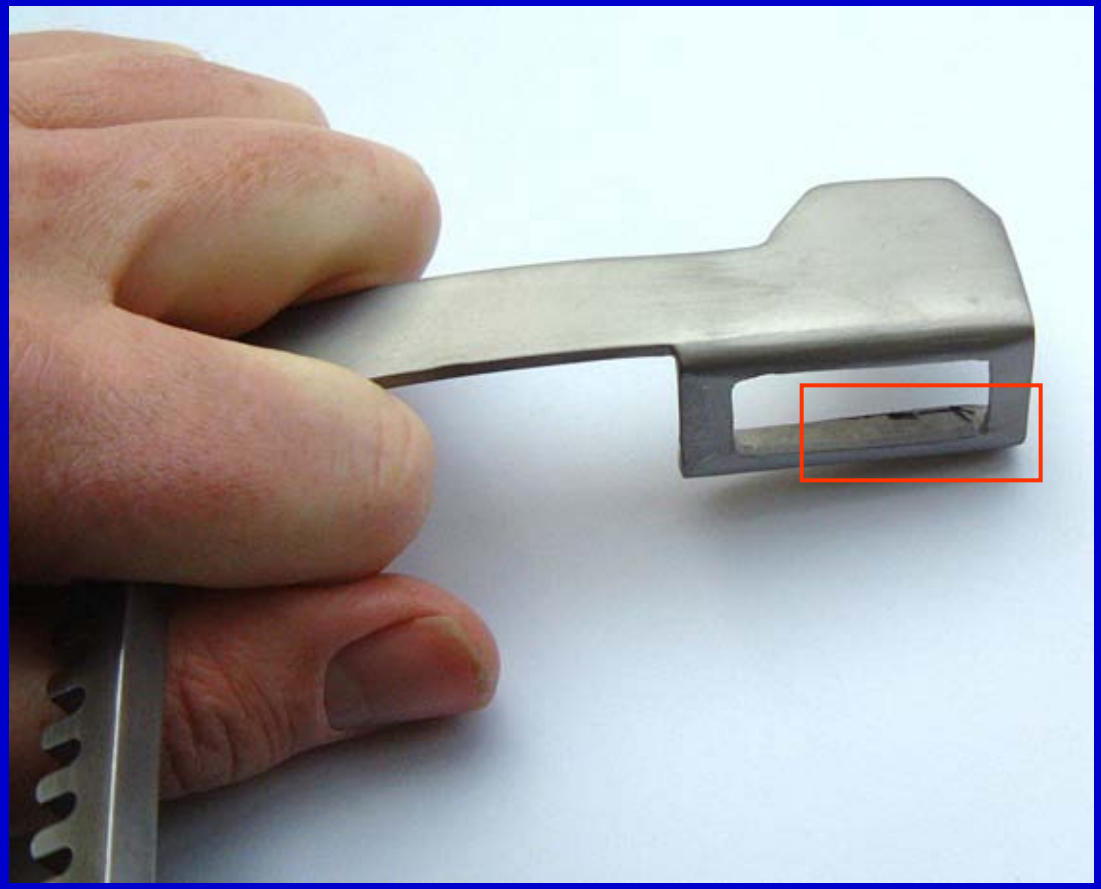
- The majority of instruments are manufactured from martensitic stainless steel which is not an implant grade.

Officer Tissue Forceps Fracture - Burrs

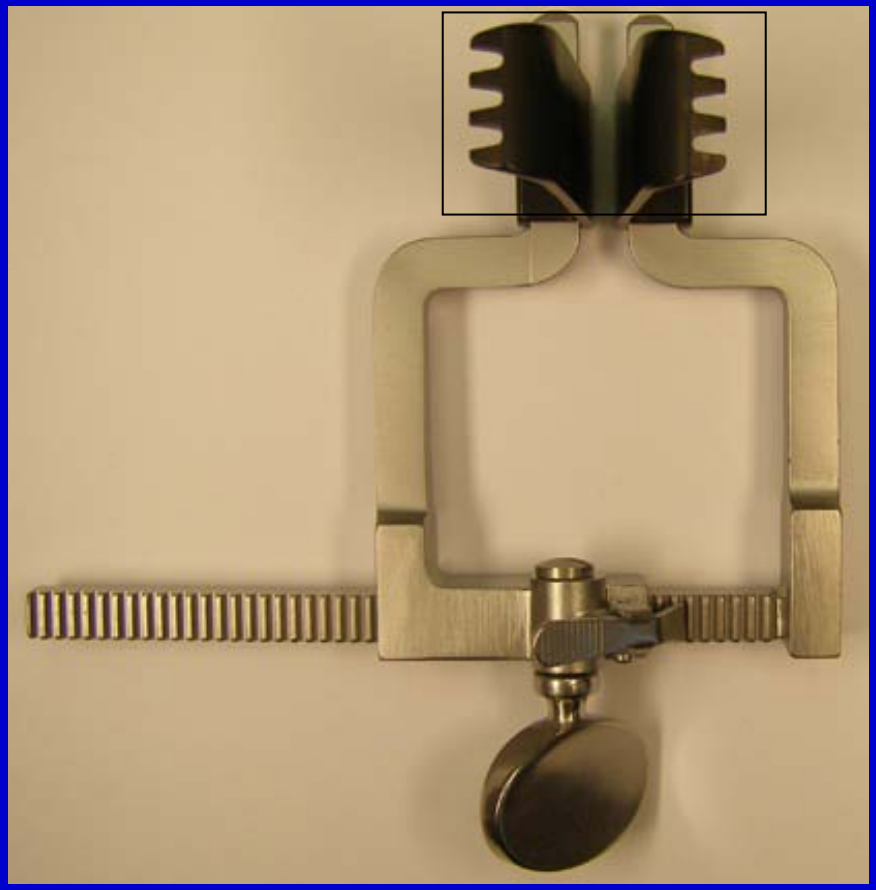




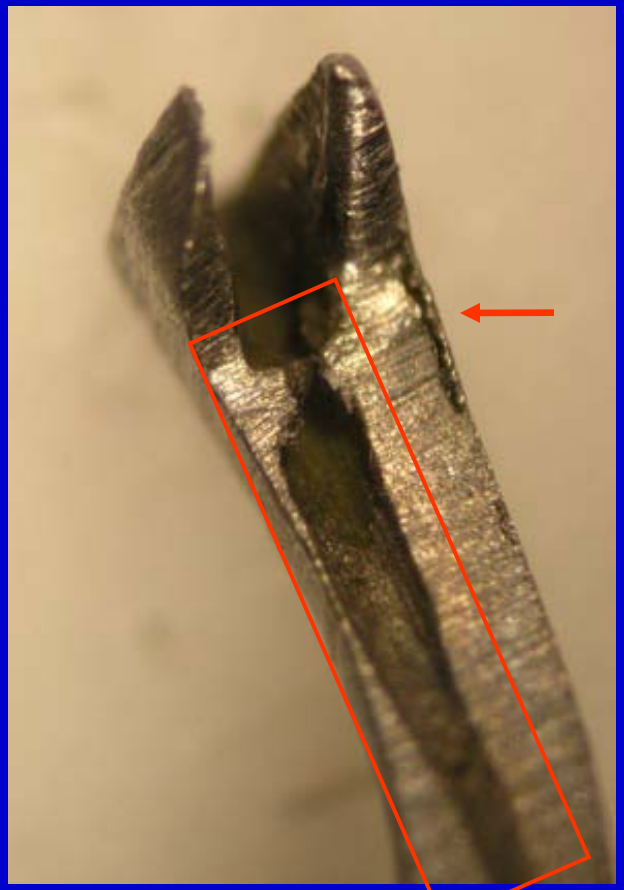
Infant Retractor Burr



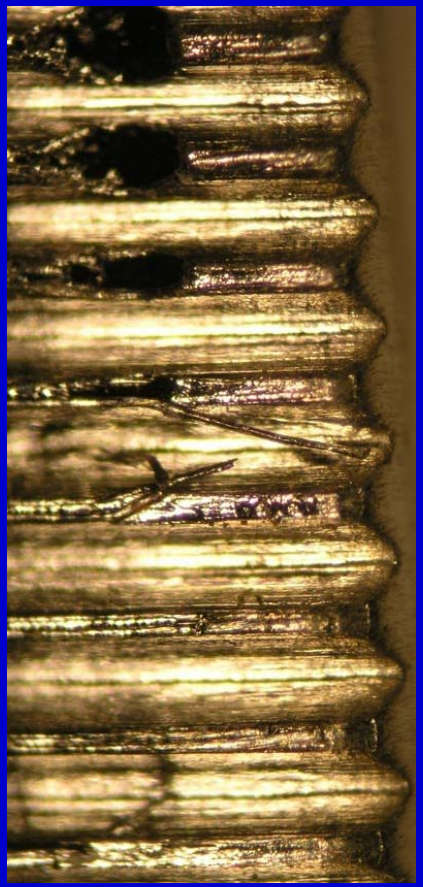
McCulloch Muscle Retractor Blades Burrs

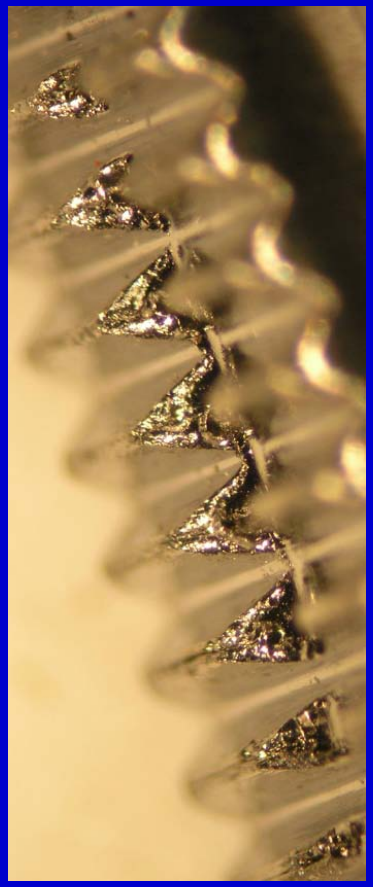


Barraquer Iris Forceps Burrs - Void



Moorfields Ophthalmic Forceps Fragments - Burrs





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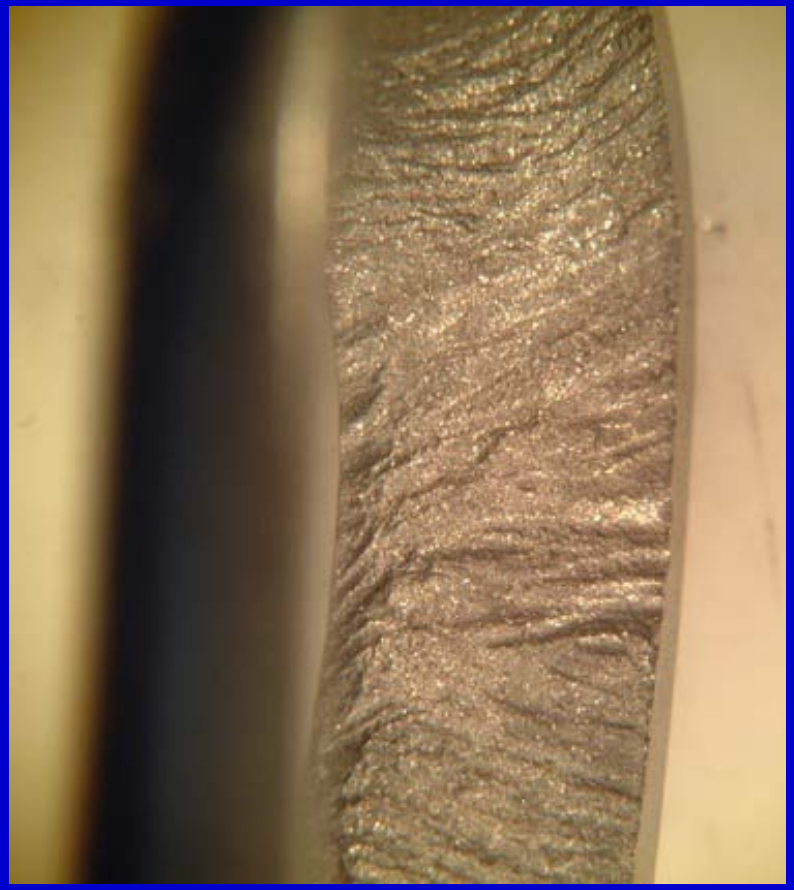
Dennis Browne Tonsil Forceps Surface finish



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Cusco Vaginal Speculums Large & Medium

Burrs

Bad example

Good example

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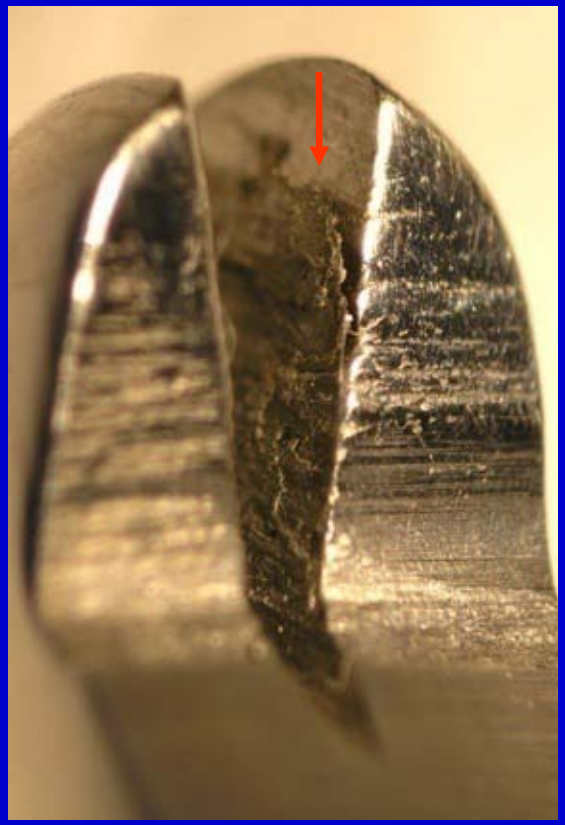
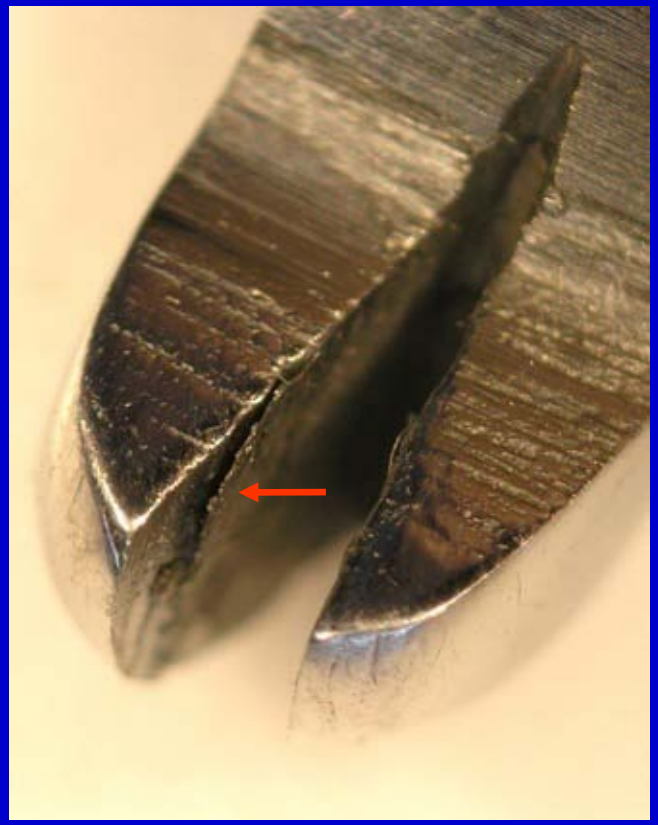
Toothed Forceps Burrs



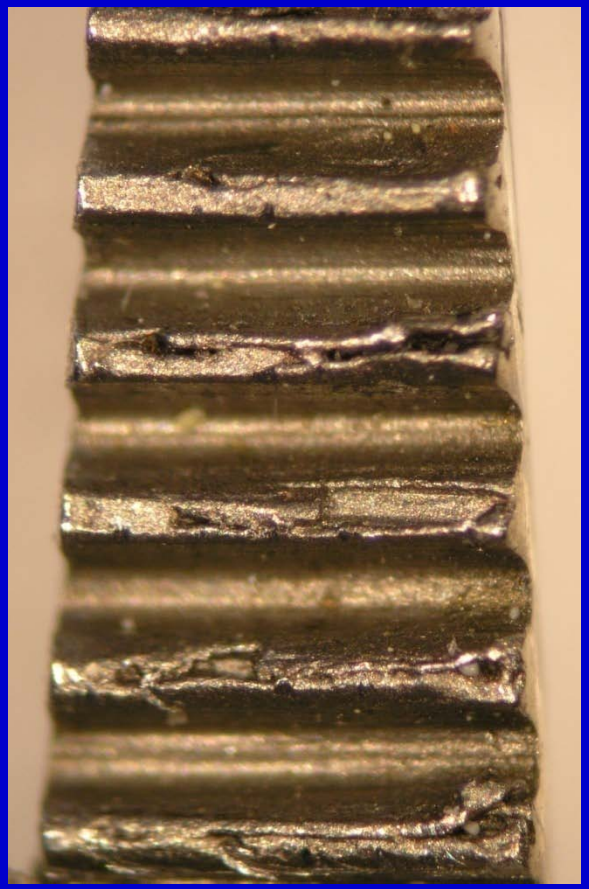


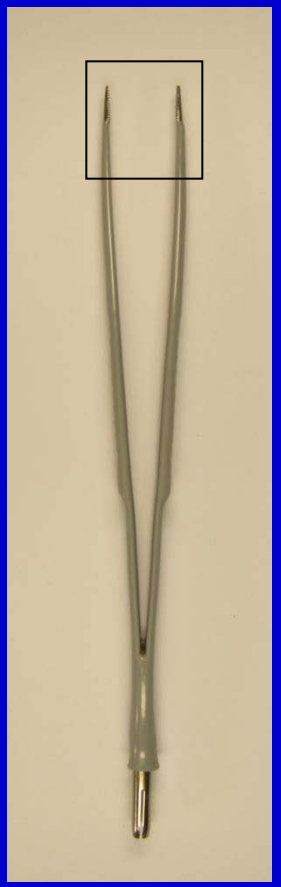
Bad examples

Good example

Monopolar Diathermy Dissecting Forceps

Serrations Shedding - Burrs



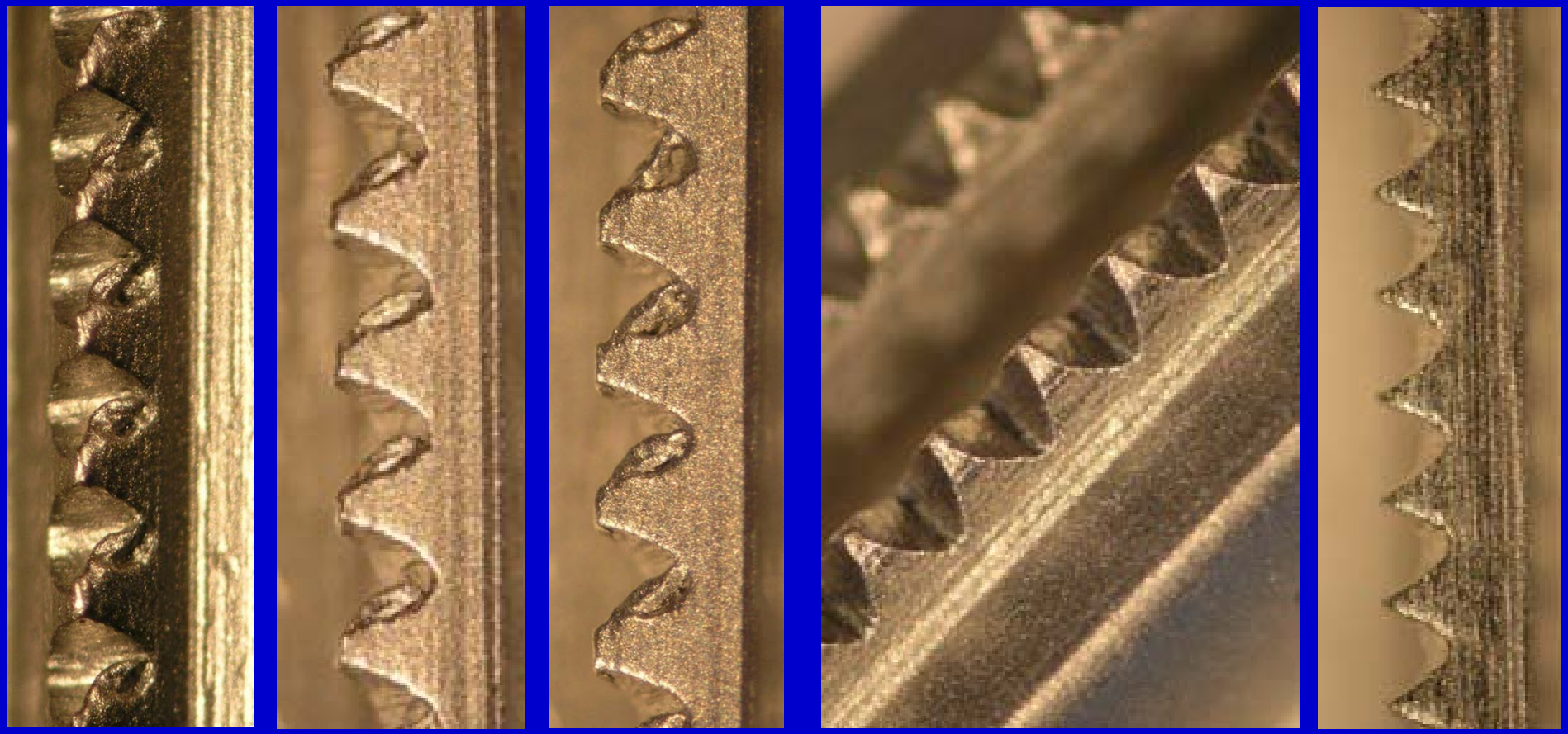


Debakey Dissecting Forceps Burrs





Debakey Coarctation Clamp Burrs



Bad examples

Good examples

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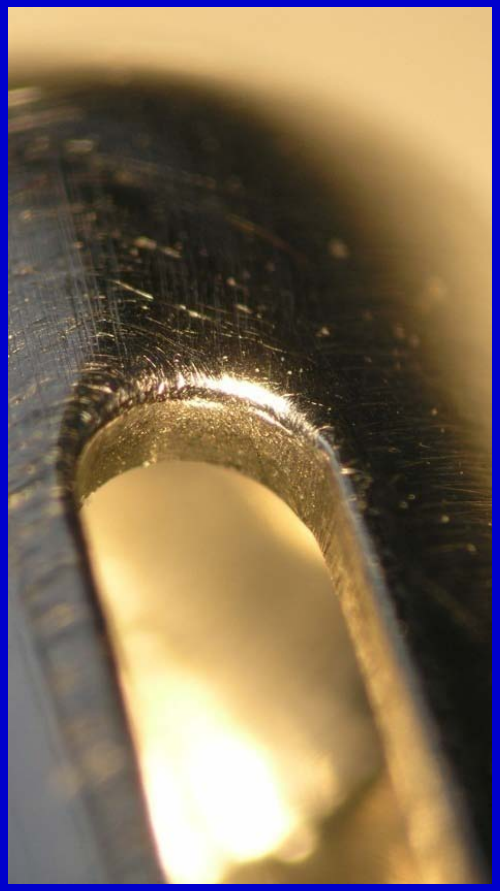
Ross Ventricular Vent Adult Burrs

Bad Examples

Good Example

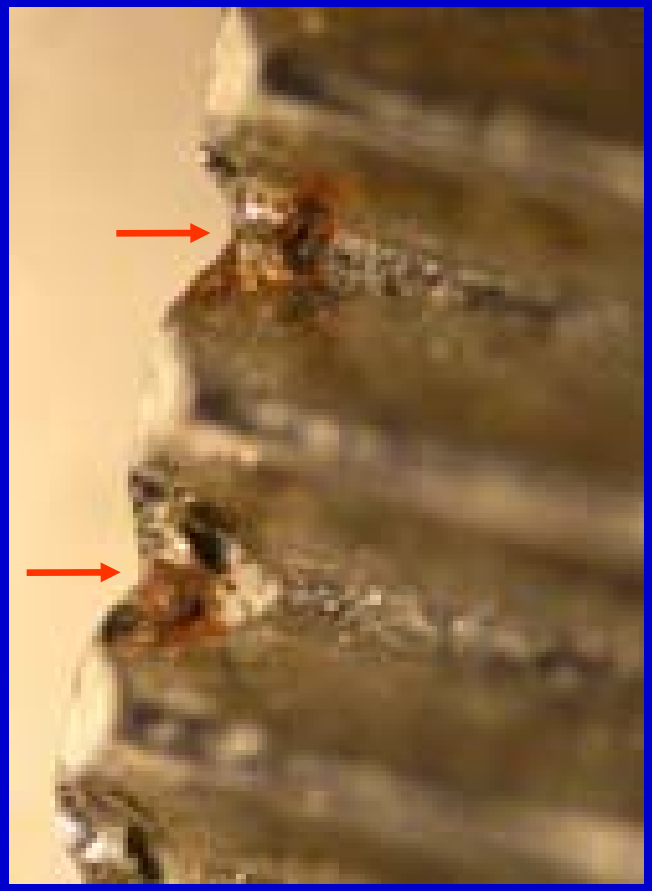
Harley Street Suction Tube Burrs

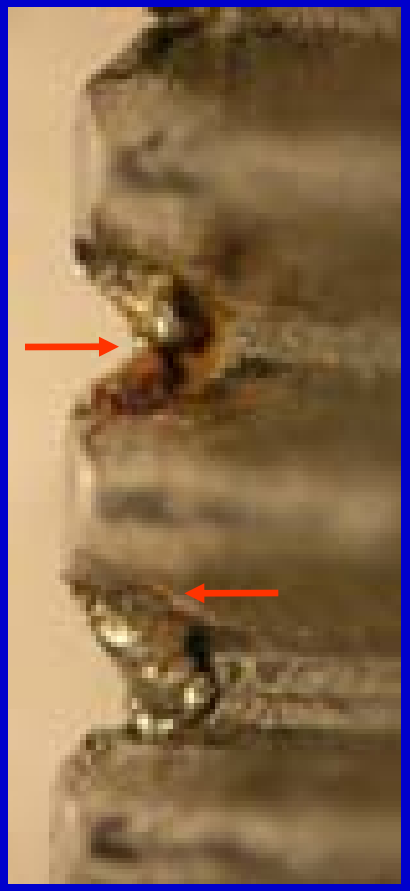
Bad Examples

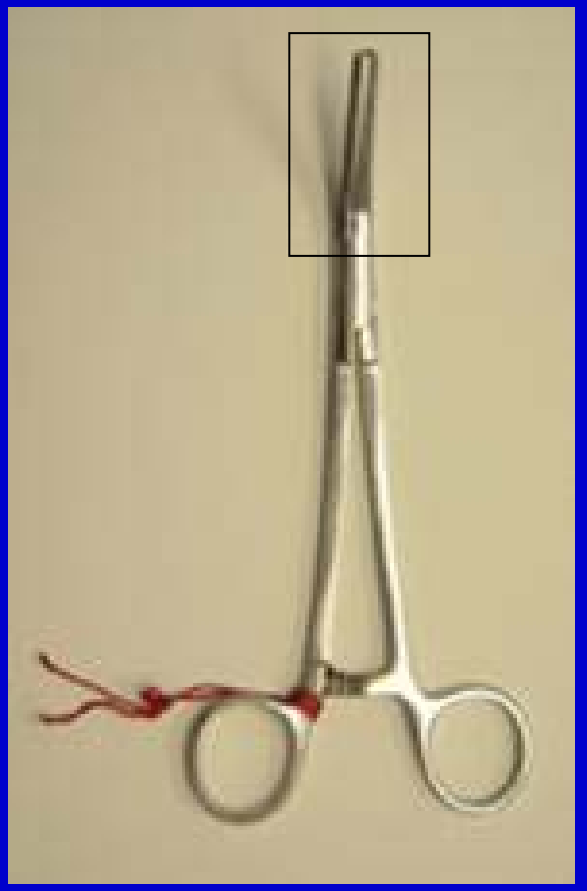


Good Example

Angled Artery Forceps Blood - in service







Spencer-Wells Artery Forceps Blood - in service

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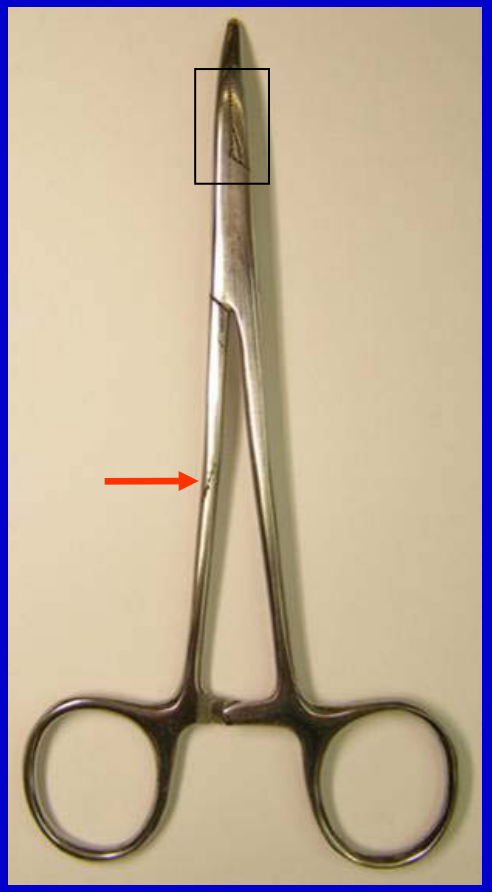
NHS Trust

Spencer-Wells Artery Forceps Blood - in service



Inspection Failure

Year 2002 18% Year 2003 16% Year 2004 11%

Year 2017 3% Year 2018 1% Year 2019 2%

In 2004 the following action was taken:

1) We supplied manufacturers/suppliers with our QA procedures.

2) Photographs taken to support written documentation.

3) Trust talks to manufacturers/suppliers.

4) Only purchasing from companies that met our QA procedures.

5) Involved in clinical trials.

Clinical Physics Workshops

Surgical Instruments Procurement - Statistical Report

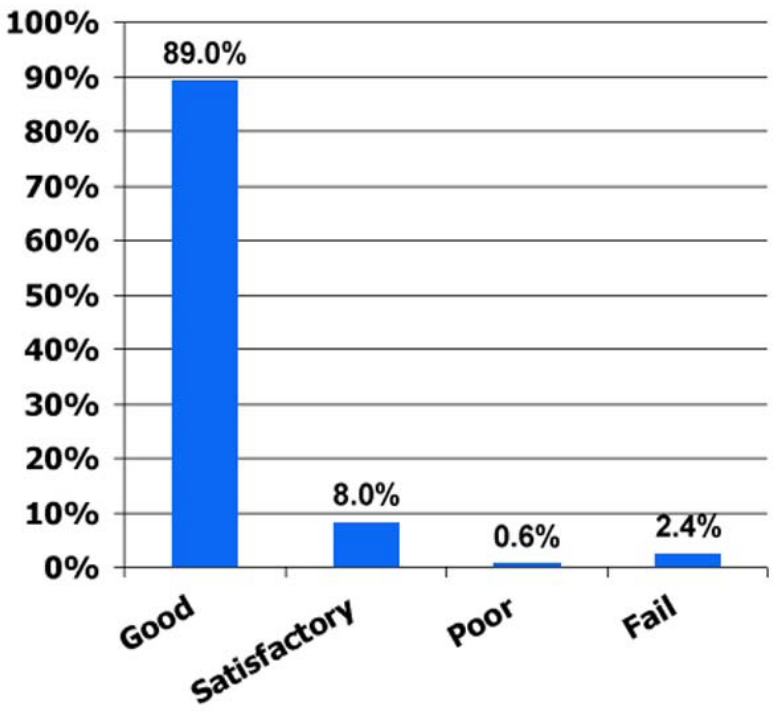
Company:

Department:

Instrument:

No. of Inst: 11811

Date: 01/01/2019 - 31/12/2019



bsi. ISO 9001 Quality Management

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Clinical Physics Workshops

Surgical Instruments Procurement - Statistical Report

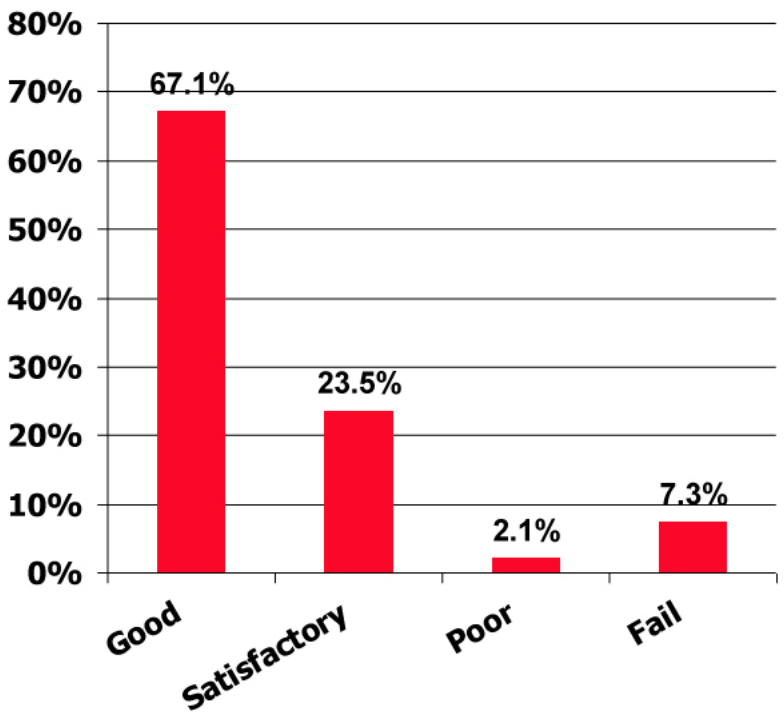
Company:

Department:

Instrument:

No. of Inst: 94850

Date: 01/02/2000 - 31/12/2019



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Reporting Failures to MHRA

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Advantage of the QA Service

- Protects patients, surgeons and SSD staff.
- Protects Trust from legal action.
- Instruments are being supplied to British Standards.
- Saves money on unnecessary replacement.

Barts Health NHS Trust is supplied with the best quality instruments in the NHS, if not the world!

What is the quality of your instruments?

I hope you don’t accept our rejects!

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CLINICAL PHYSICS

NHS
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NHS Trust

Tom Brophy

020 7377 7150

tom.brophy@bartshealth.nhs.uk