Manufacturing of Surgical Instruments

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Brief History

- **Prehistory** – Objects such as bones, ivory, bamboo and stones were used to remove foreign material from wounds.

- **Classical Age** – Surgeons used forceps, scalpels, speculums and other instruments made from iron, bronze or gold, which they believed had healing properties.

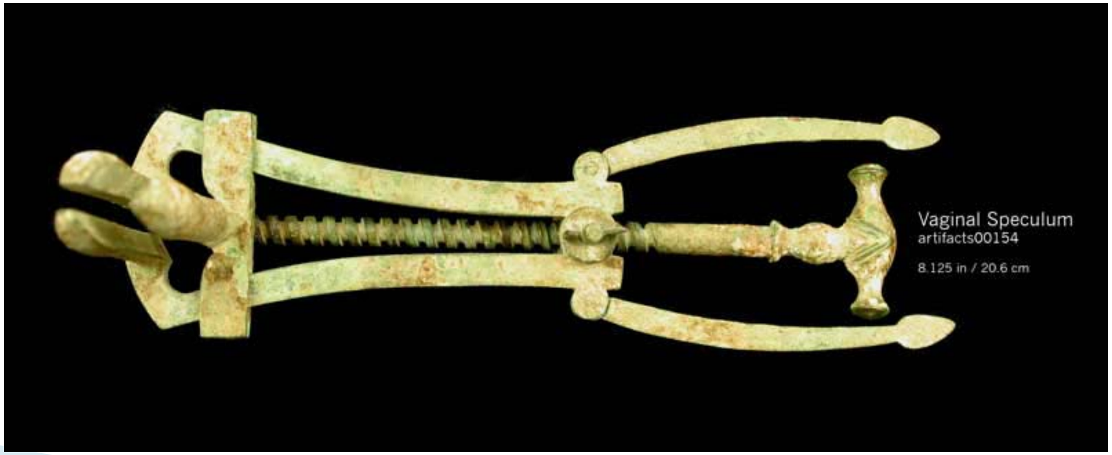
- **Scientific Revolution** – From the 17th–19th centuries, new anatomical knowledge led to the development of tools for specific functions. Steel and nickel plated instruments became common.

- **20th Century** – The invention of stainless steel made surgical instruments cleaner and safer. New materials and products such as rubber tubes, catheters, titanium and disposable blades become common.

- **Today** – Surgeons have already begun using high tech tools of the future, including lasers, water jets and computer guided instruments

Historical Pictures

- Elevators
- Forceps
- Vaginal Speculum



Why is quality manufacturing of surgical instruments important?

- High quality processes and technology leads to increased safety and reproducibility

Operating Room Environment

- Human life is at risk
- Patients expect and deserve world class healthcare
- Instruments are an extension of the surgeons hands
- Quality
- Functionality

Quality philosophy

Quality parameters in R&D

Co-operation with expert clinical consultants world-wide

Definition of optimal design, materials and dimensions with respect to:

- The application for which the instrument is intended
- National and international standards (DIN - ISO - ASTM)
- Quality standards

General demands on surgical instruments

Cutting instruments
(e.g. scissors, scalpels, chisels)

- Corrosion resistant
- Precise cutting
- Extreme hardness
- Highly resistant to wear; cutting edges stay sharp longer

Non-cutting instruments
(e.g. clamps, forceps, hooks)

- Corrosion resistant
- Highly flexible
- Optimal hardness
- Spring hardness

Training Philosophy

Technicians should be experts, having extensive training and experience .

Training periods covering:

- Grinding
- Milling
- Polishing
- Producing instruments that meet standards

Training modalities:

- Training by certified master craftsmen / instructors
- Experience passed on through apprenticeship process

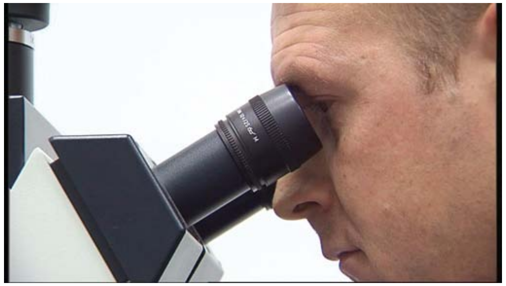
Training Philosophy

Raw Materials

All instruments begin with raw materials

Shape and dimensions checked

Raw Materials



Grain structure is visually inspected

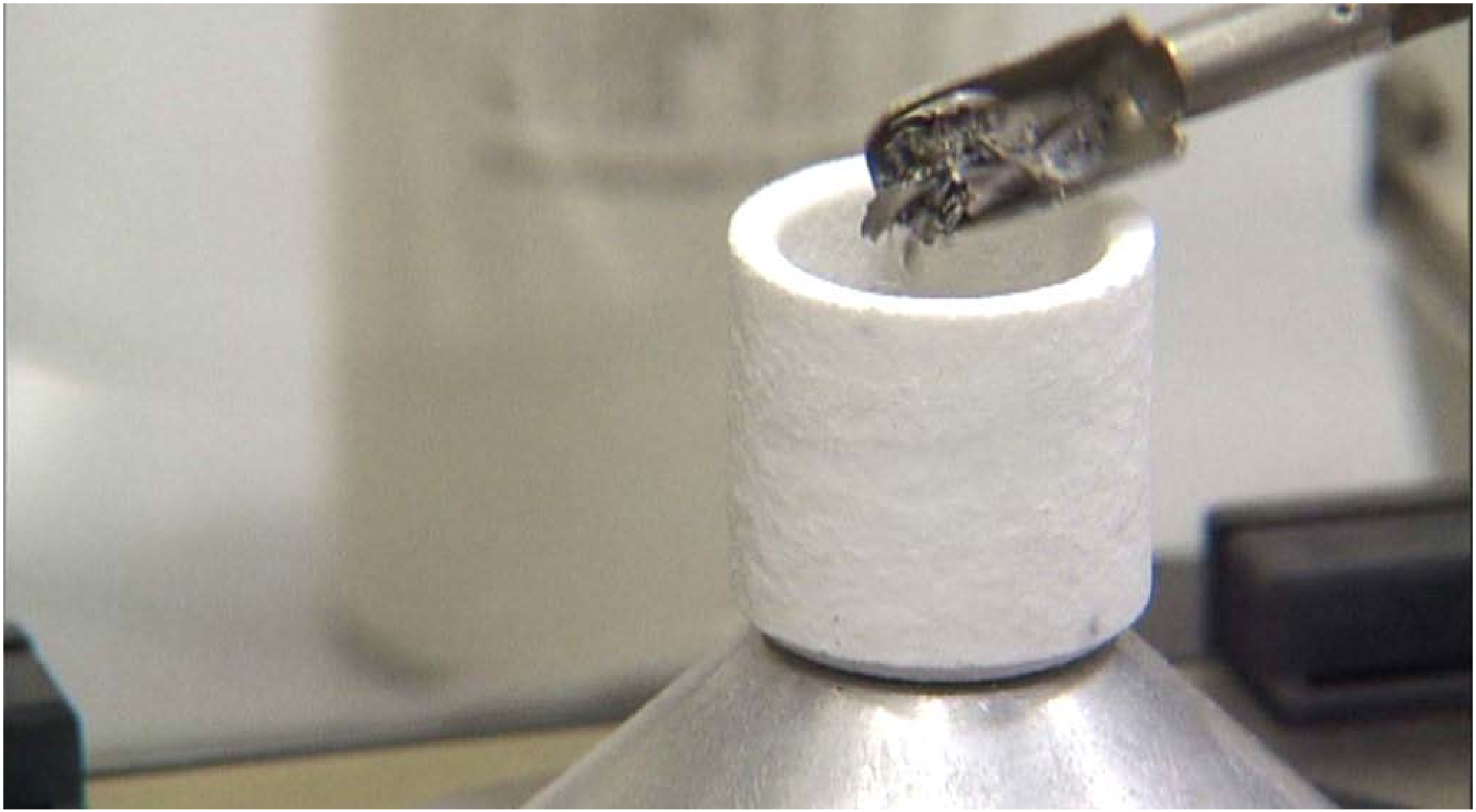
Unacceptable

Acceptable

Raw Materials

Composition is analyzed (carbon & chromium)

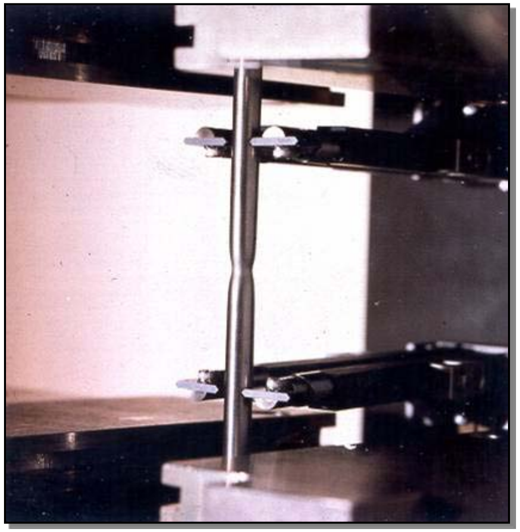
Raw Materials



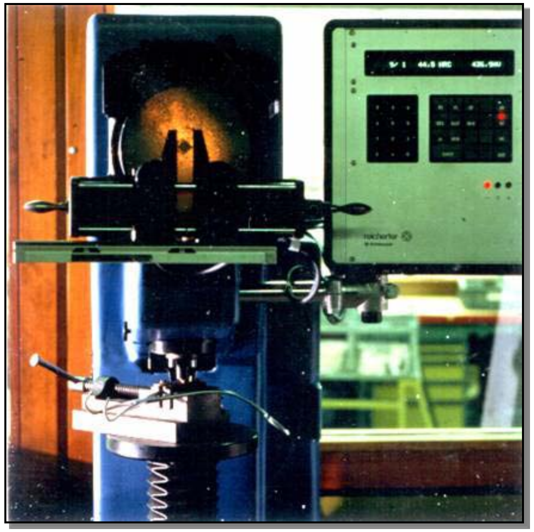
Raw Materials

Mechanical properties analyzed

- flexibility and hardness measured in relation to specific instrument functions

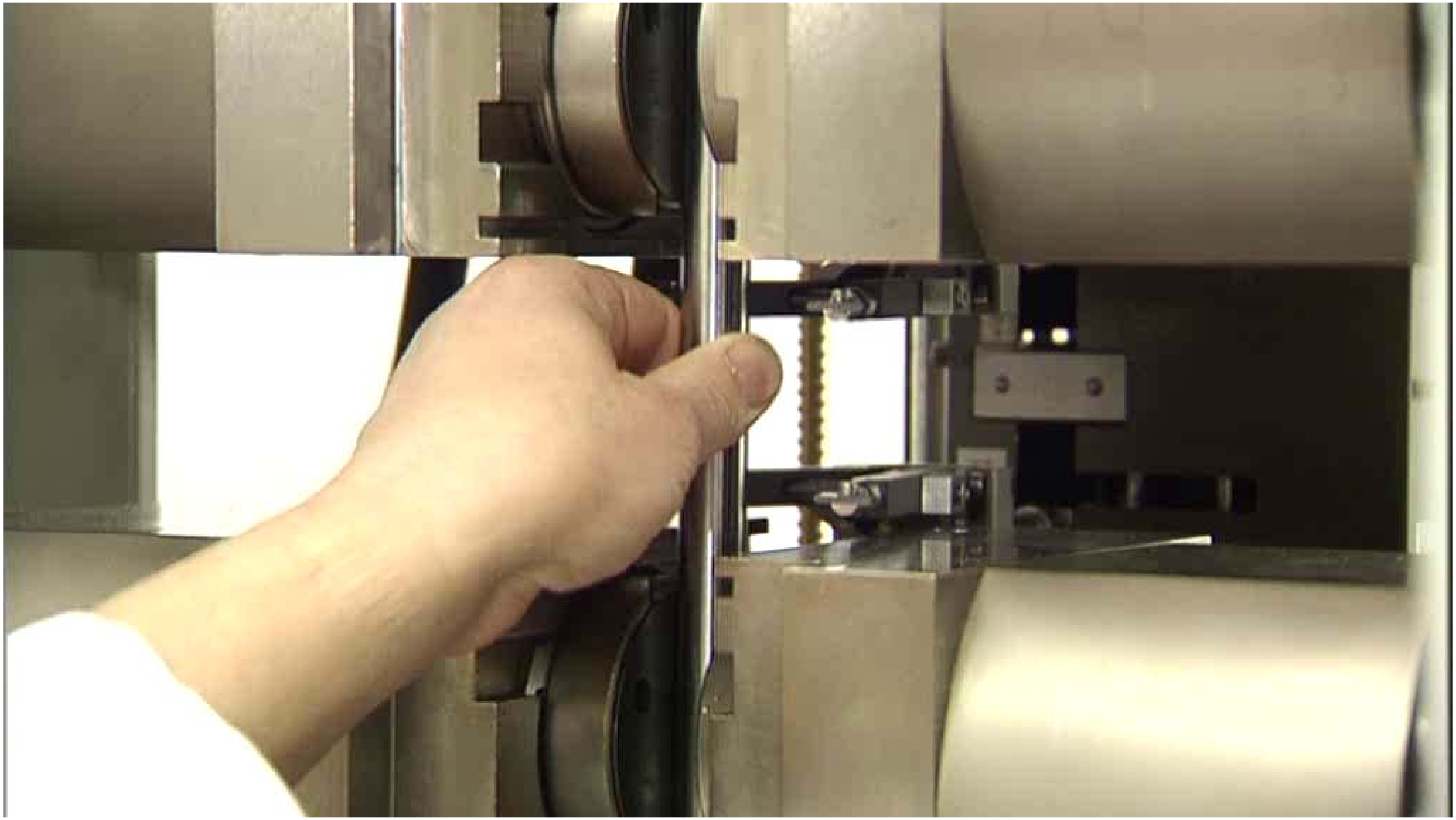


Ductility analysis



Hardness analysis

Raw Materials



Raw Materials

- Splitting machines are used to cut up the materials

- Raw material have different forms:

- Square bars
- Round bars
- Flat bars

Instrument Forging

- Drop hammer
- Basic form of an instrument created from dies

- Forging is done in three processing steps:

- Bending
- Rough forging
- Final forging

Instrument Forging

Rough forging

Final forging

Instrument Forging

Instrument Forging

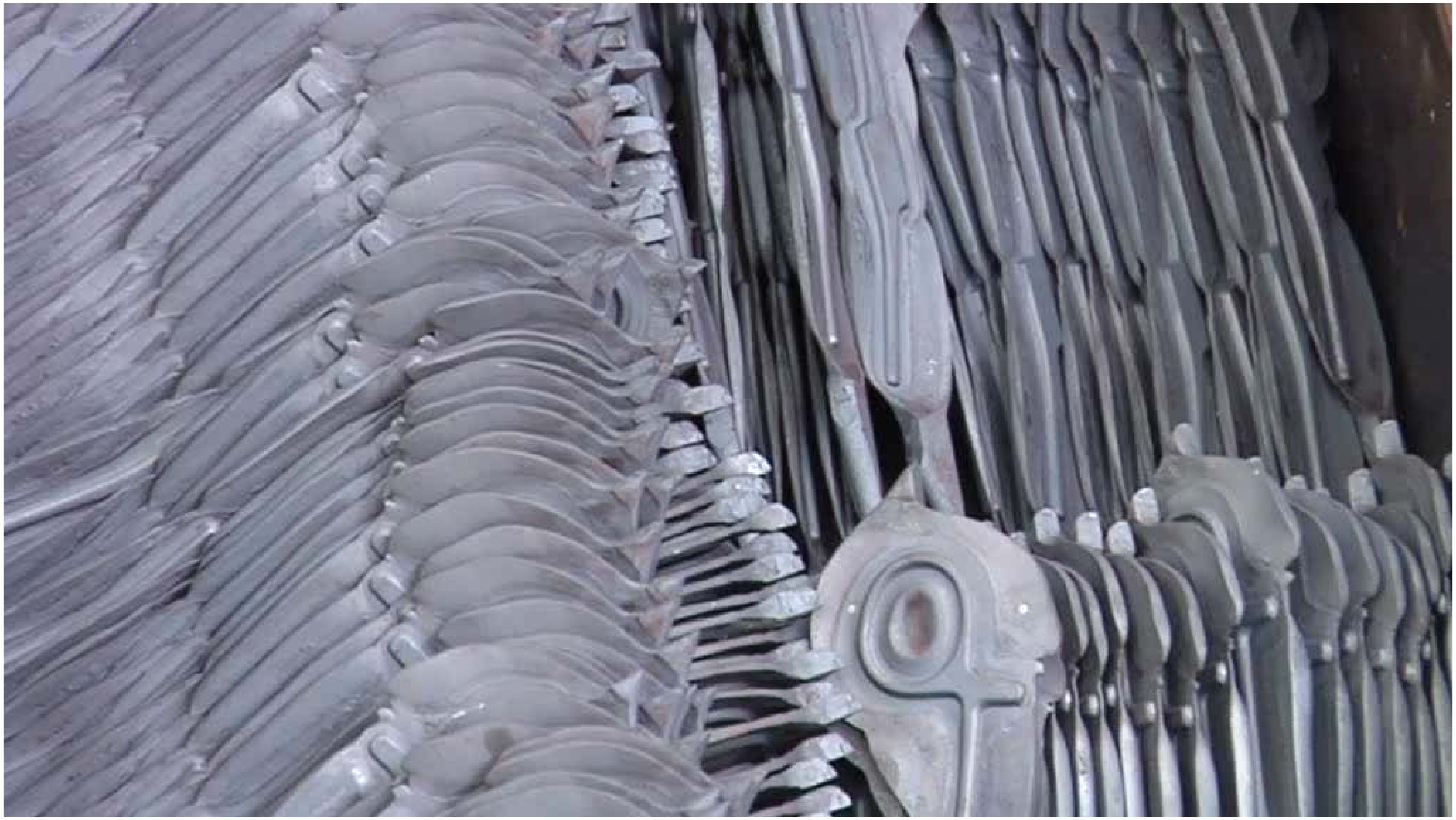
- Dies are produced to specific standards
- Replaced after determined utilization
- Steel properties:

– Temperature resistant
– Toughness
– Insensitive to notching

Instrument Forging

- Forged raw parts
- Deburring – removal of excess material
- Dulling – blasting with quartz sand to remove scale
- Adjustment
- Raw parts inspection – based on design specifications

De-burring Process



Raw Parts Inspection

Temperature Is Important

- The temperatures of the forging process cause the steel to become very “soft”
- Drilling, milling etc. is only possible with “soft steel”
- Annealing process must take place

Heat Treatment

Forging	1382 ℉ – 1922 ℉
Annealing	790 ℉
Hardening	1868 ℉ – 1958 ℉

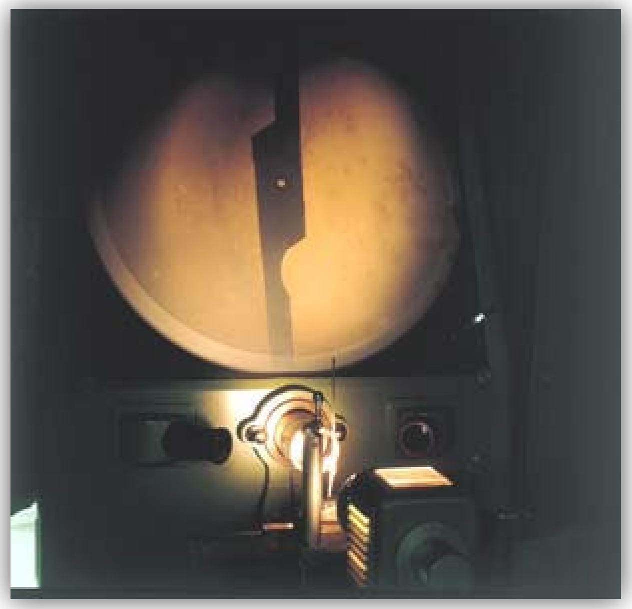
Important:
Observing the heat treatment process times – warm up time, holding time and cooling time.

Risks:
Increased risk of fracture
Danger of corrosion, due to structural damage

Drilling

Drilling

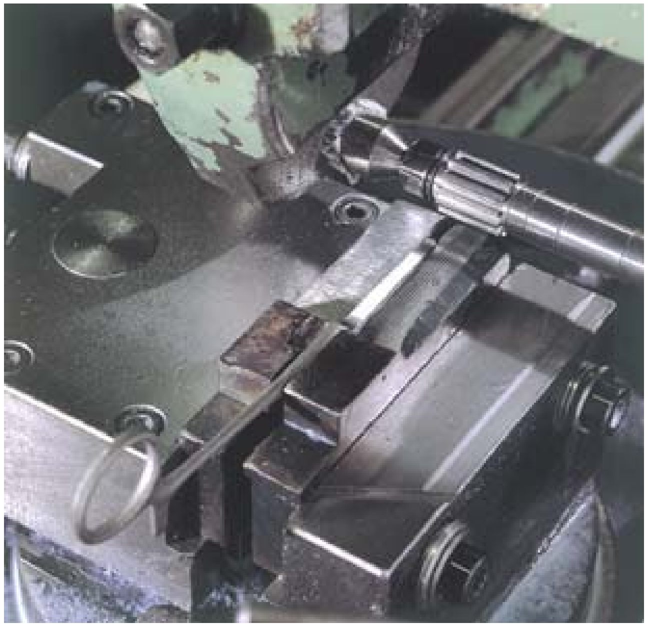
- Reference point is largely responsible for the dimensional accuracy



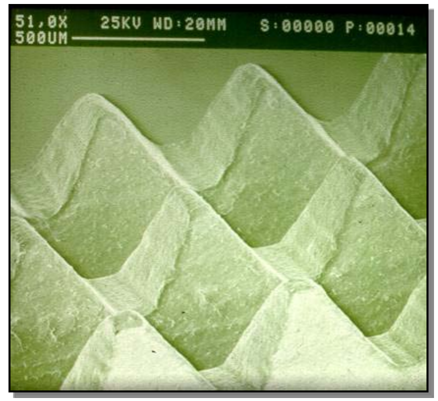
Test Projector

- Shape and dimensional checks monitor the proper completion of steps

Milling



- Jaw tooth milling
- Female and male component



• Quality Features:
- Fully formed teeth
- Smooth surface

• Poor quality

Broaching/Expanding

- Broaching the female component
- The female component of the clamp is broached using a broaching tool

- Expanding the female component

Assembling components

- Inserting the male component of the clamp into the female component

- Pressing together
- The individual parts comprising a two part instrument are intemperately connected at the joint by pressing together and riveting.

Grinding

• Profile grinding on a rough stone grinding wheel

• Profile grinding to a template
• Guarantee of an exact profile accuracy of the jaw profile and lock

Bending

- Bending an atraumatic clamp
- Distal end of clamp is bent to spec, following profile grinding

Production Inspection

- Worker self testing
- Intermediate tests of all required manufacturing steps
- Producers are verified and validated
- Random sample testing with respect to:

- Shape and dimension accuracy
- Surface quality
- Functionality

Cleaning Process

- Cleaning Unit I
- Before hardening
- Is used for washing out oil, grease and foreign material

- Cleaning Unit II
- Final cleaning takes place after instrument production is completed

Hardening Process

- Vacuum hardening
- Hardness, toughness and wear characteristics
- Increase corrosion resistance

- Advantages of the vacuum process:

- No surface reactions
- No cracking or imbrittlement
- Very little distortion

Hardening Process

Heat treatment criteria for hardening

Heating:	Uniform penetration, not too fast
If not observed:	Danger of cracking

Exact observation of **heat treatment** and **holding times** at these temperatures.

Cooling:	Observe correct speed
If not observed:	Structural damage, increased risk of fracture, reduced corrosion resistance

Surface Treatment

- Belt grinding

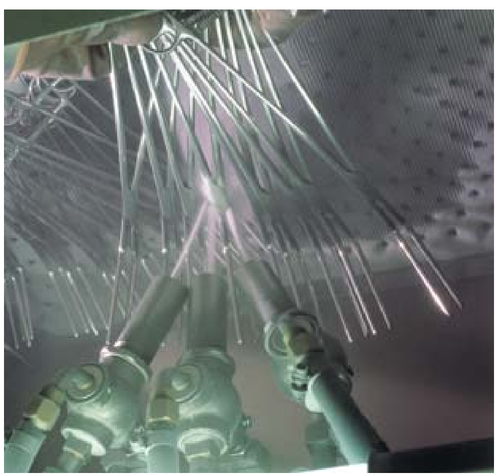
- Outside of the rings
- Branches and neck of latch
- Outside and inside of jaws
- Side of the joint

- Final grinding
  Definition: *Mechanical – chemical process using ceramic rocks to smooth the rough instrument surfaces.*

Surface Treatment

- Electro polishing

  Definition: *Electromechanical removal to smooth and passovate rough component surfaces.*



- Compressed air treatment with very fine glass beads

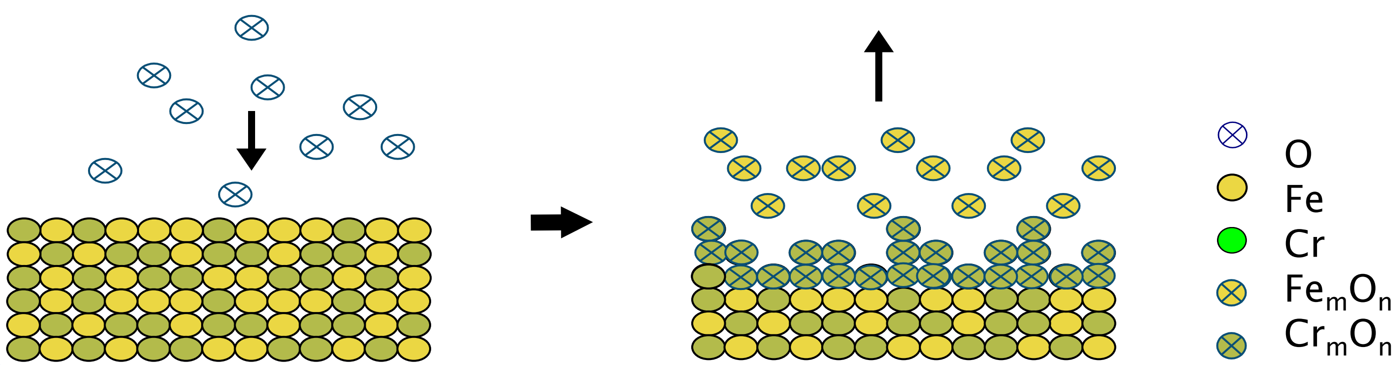
Passivation

What happens during chemical passivation

Organic Acids react with Fe (Iron)

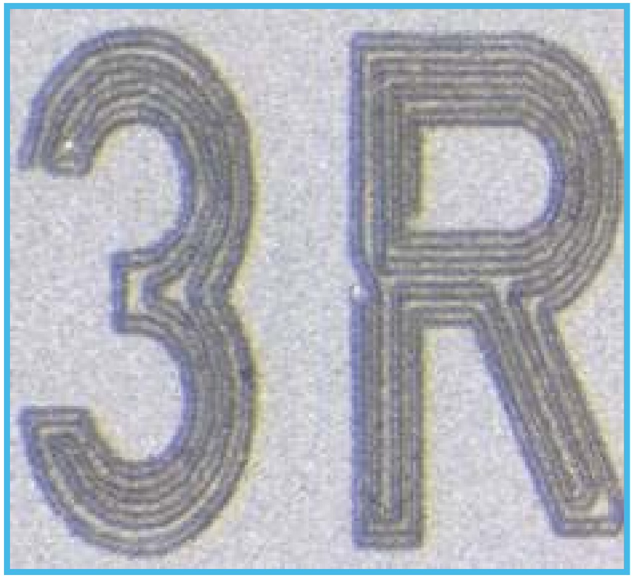
- Oxidation to Fe_mO_n and Chromiumoxide Cr_mO_n
- Fe_mO_n is solved from the surface
- Cr_mO_n remains and builds a protective layer

Thickness of the layer: 2 – 5 nm



Passivation Process

Instrument Marking



Laser marking

Etching

Summary

Producing quality instruments is a complex and technical process, which is 70% - 75% hand crafted.

The following must be taken into account during the manufacturing process:

- Choice of materials
- Utilizing correct materials for different instruments
- Forging the raw parts
- Heat treatment
- Surface treatment
- Passivation
- Instrument Marking

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Thank you for your kind attention!!

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