Material Compatibility: Corrosion and ESC Overview

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Environmental Decontamination

Typical hospital room – high touch surfaces

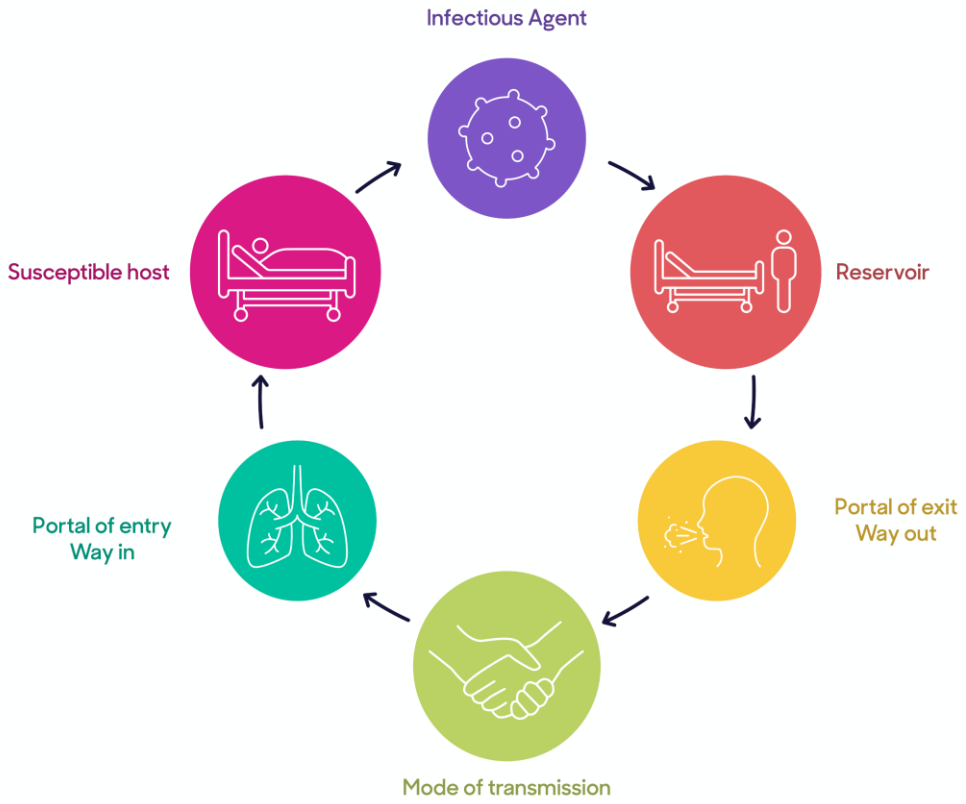
Non-invasive shared patient care equipment

As show in the CLEEN study:
Routine Disinfection of Shared medical equipment can **reduce** hospital-acquired infections by **34.5%** so having device and products which can withstand **daily cleaning** as a **minimum** is a must!

Otter J, Galletly T (2018) Environmental decontamination 3: auditing cleaning and disinfection. Nursing Times [online]; 114: 9, 25-28.

Disinfection in Clinical Practice

Disinfection is helping **break the chain of transmission.**



Highly efficacious product BUT

- Damages the surface:
  - **can create a reservoir for microbes**
  - facilitates transmission of HAIs
  - risk to patient/staff.

- **Damage to the device has increased risk and cost**
  - Increase risk of infections.
  - Cost of replacement.
  - Device failing while in use.
  - Device failing to be used as intended.

Materials Found in Surfaces

Metals
Steel (different grades)
Titanium
Brass
Copper
Aluminium
Iron

Thermoplastics
Polypropylene
Polyethylene
Polycarbonate
PMMA (Perspex)
ABS
Polystyrene
Polyvinyl chloride
POM (Acetal)
Polyphenylene oxide
Polysulfone

Other
Wood
Vinyls
Laminates
Leathers
Rubbers
Marble

Plastics – Environmental Stress Cracking (ESC)

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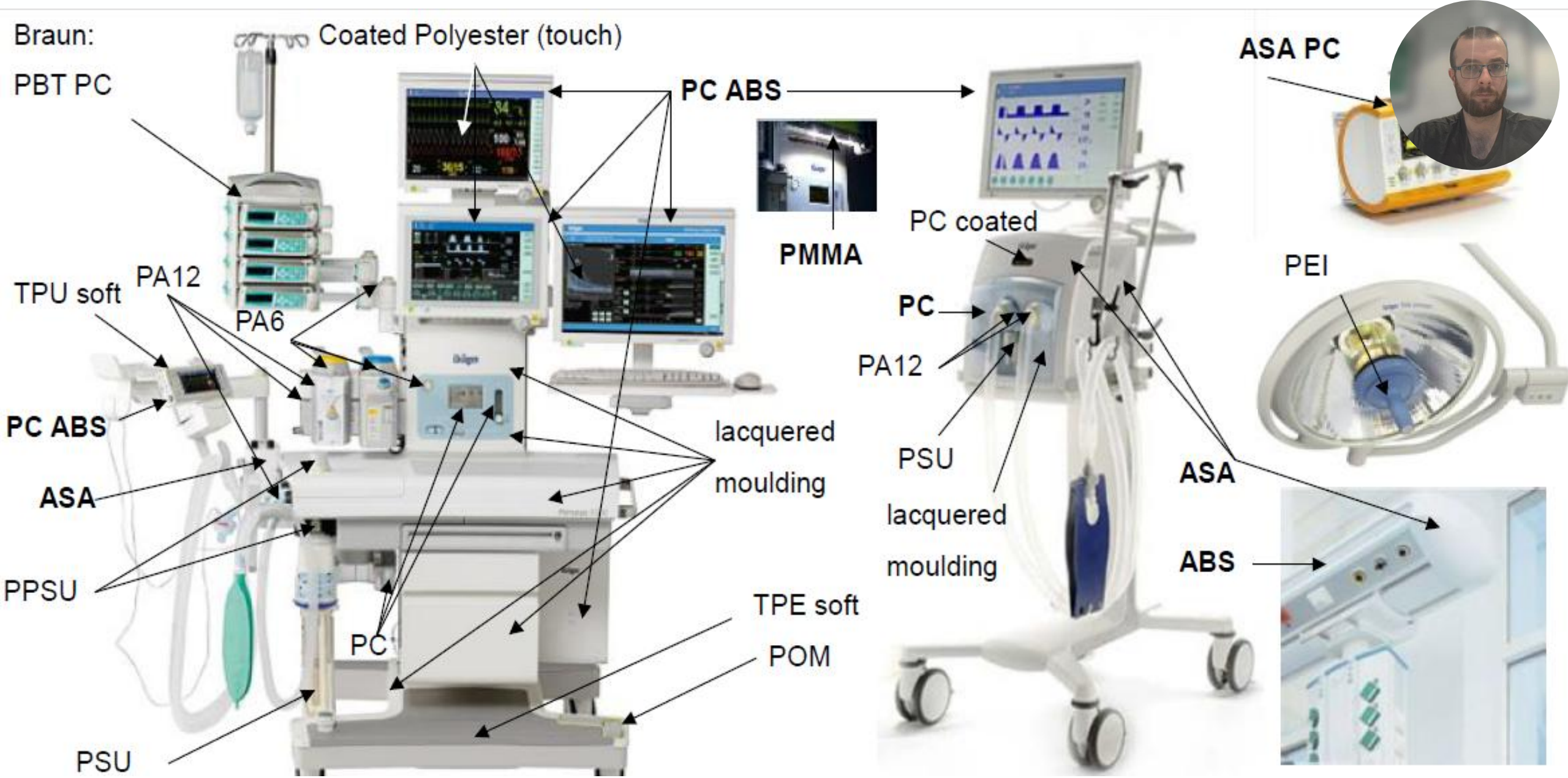
Why is ESC a Problem?

- Medical equipment, patient care equipment, high touch surfaces are generally **made of plastics**.
- Lots of **different types** and **grades** of plastics.
- The manufacturing and design of these devices often introduces **inherent strain**.
- These surfaces are **regularly cleaned and disinfected**
- Detergent and disinfection products can **contain ESC Agents**.
- ESC can cause swelling, crazing, and cracks in the plastic, resulting in **damage or device failure.**


Braun:
Coated Polyester (touch)
PBT PC
PC ABS
PMMA
TPU soft
PA12
PA6
PC ABS
ASA
PPSU
PC
PSU
lacquered
moulding
TPE soft
POM
PC coated
PC
PA12
PSU
lacquered
moulding
ASA PC
PEI
ASA
ABS

Compatibility Issues: Environmental Stress Cracking (ESC)

Environmental Stress Cracking (ESC) – the premature cracking of a plastic due to the combination of:

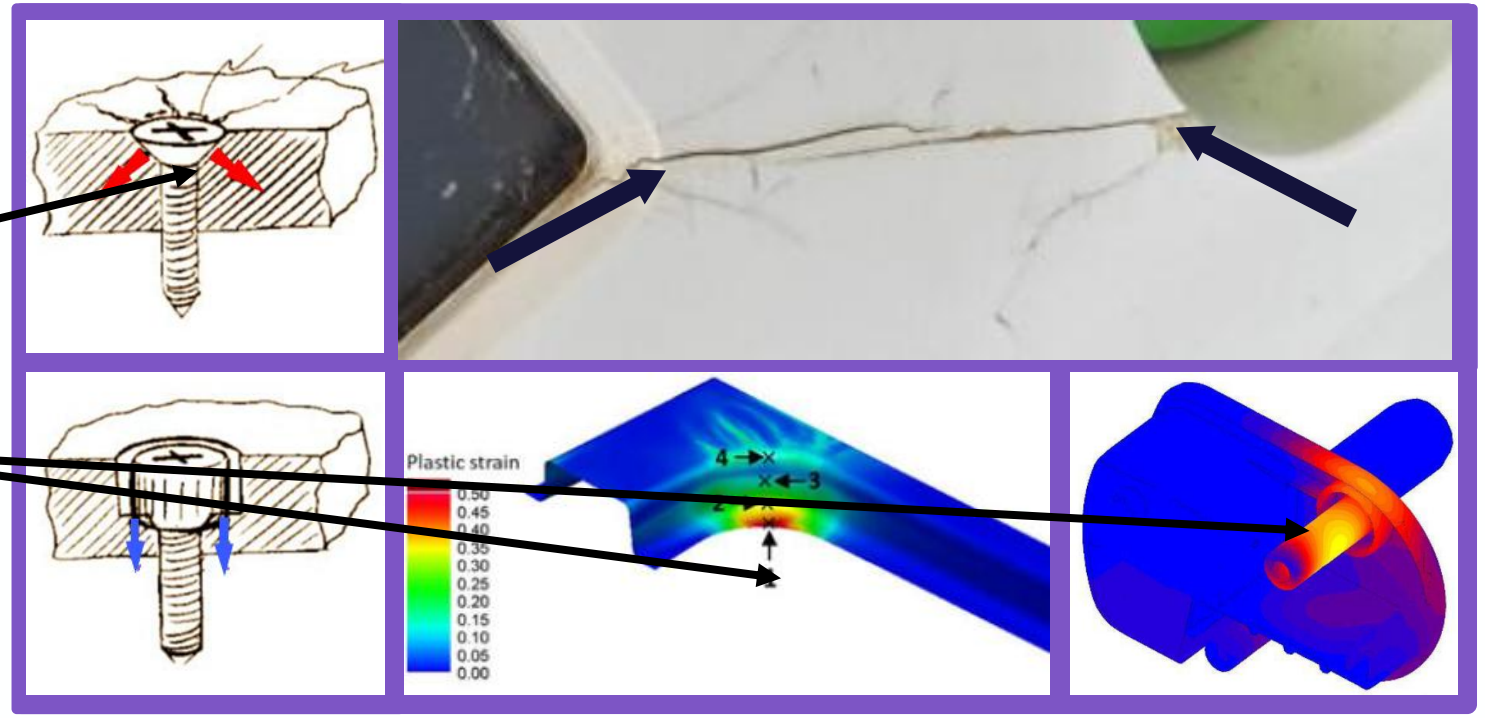
1. Strain – deformation on a due to stress applied on the plastic.
2. ESC agents – formations like detergent or disinfection that encounter the plastic and can cause cracking
3. Time – ESC can happen instantly or slowly and go unnoticed

ESC – What is Strain?

Environmental stress cracking (ESC) is the premature cracking of a plastic due a combination of **strain**, the presence of an **ESC agents** and **time** without all these ESC won't occur.

Strain is caused by a change in length or angle of a material leading to stress.

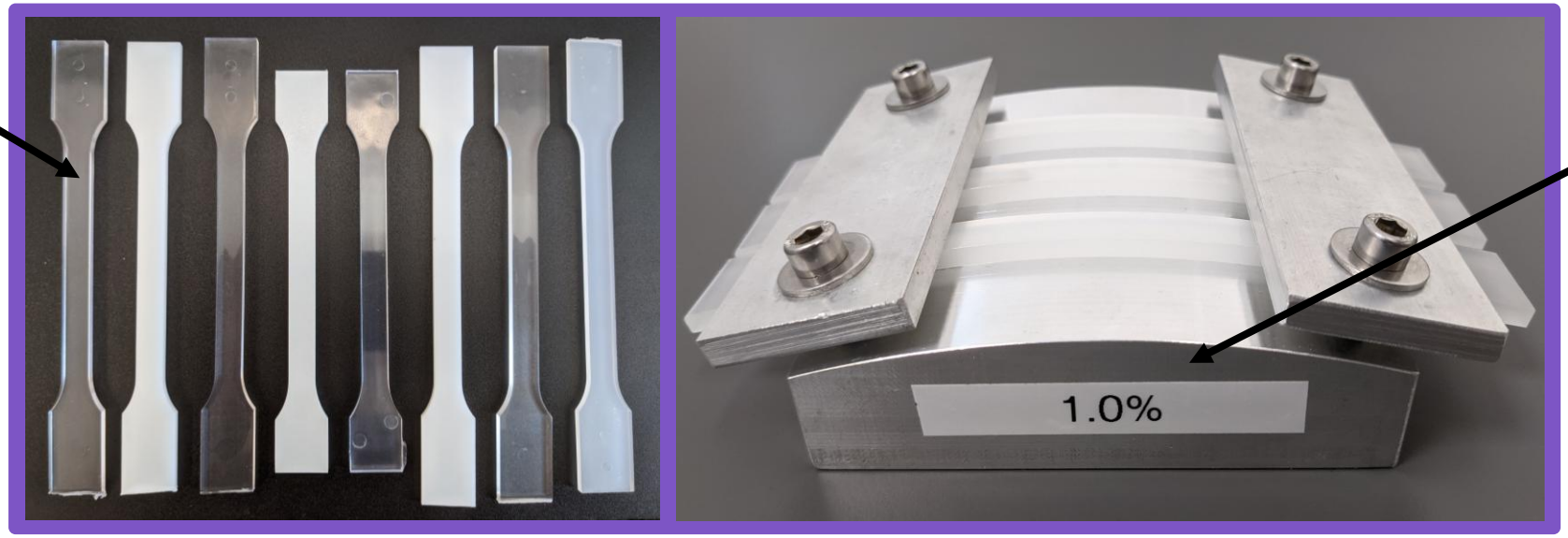
- External/environmental – Operator, other parts, screws or even leaning on a device
- Inherent/residual – Results from manufacture or design



ESC Testing

- Test standards ISO 22088:2016 part 3 or ASTM D543 Practice B.
- This is achieved using a 'strain jig', holding "dog bones" over a specific bend.
- Can be different levels of strain 0.5% (residual strain), 1.0% (push fittings), 1.5% (screw/poor design).
- Once the "dog bones" is under strain it is exposed to a test fluid – detergent or disinfectant formulation.

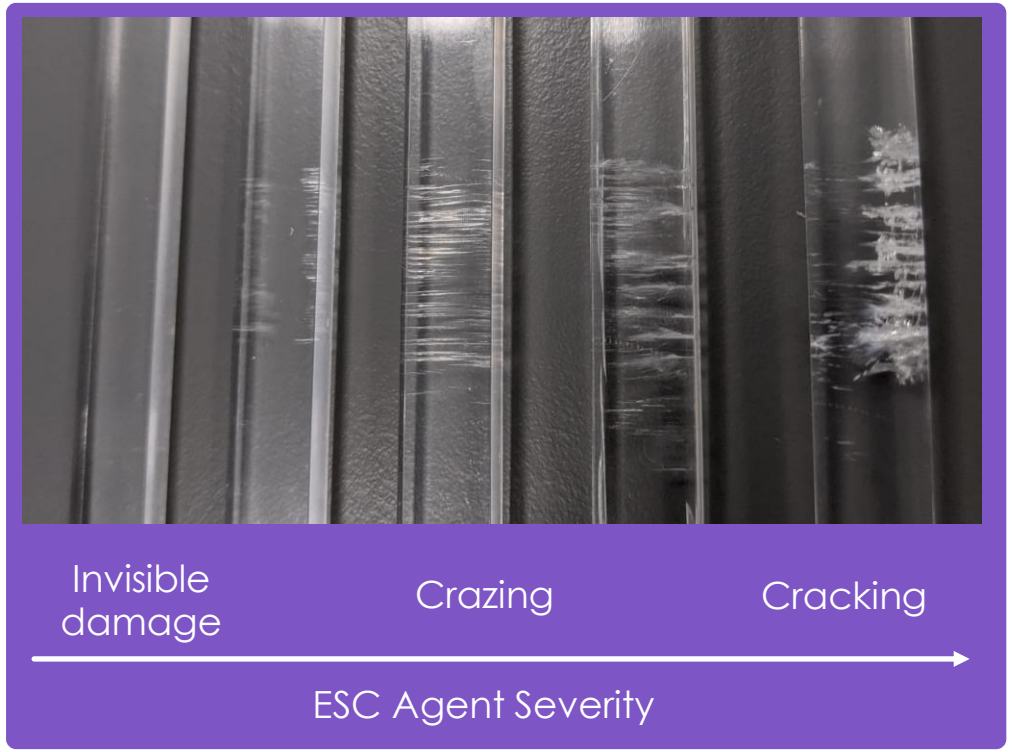
Dog bones



Strain Jig

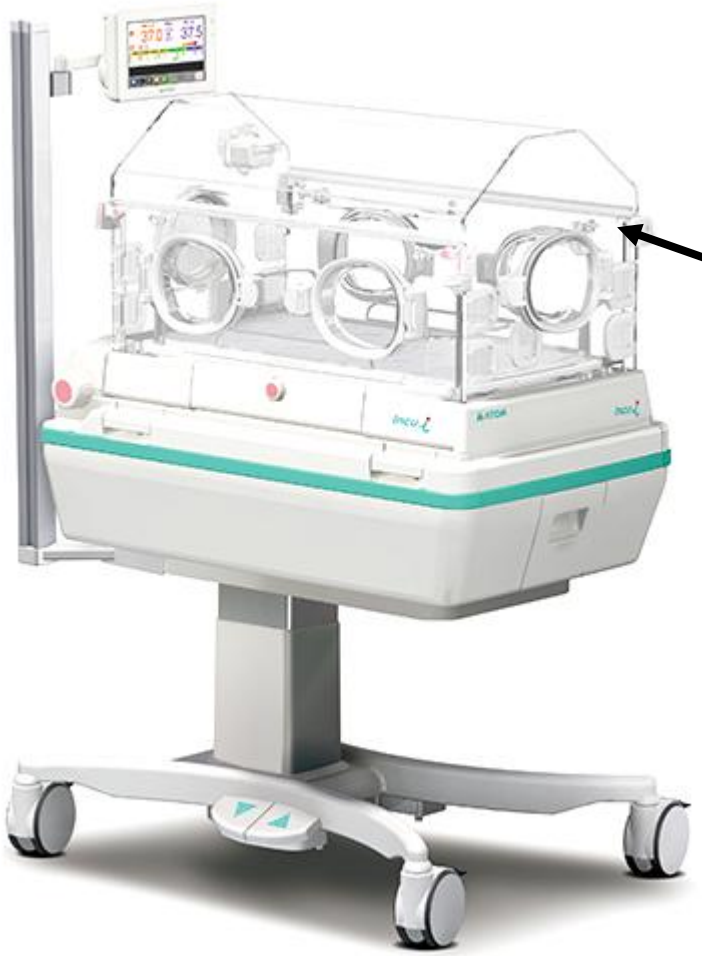
ESC Testing

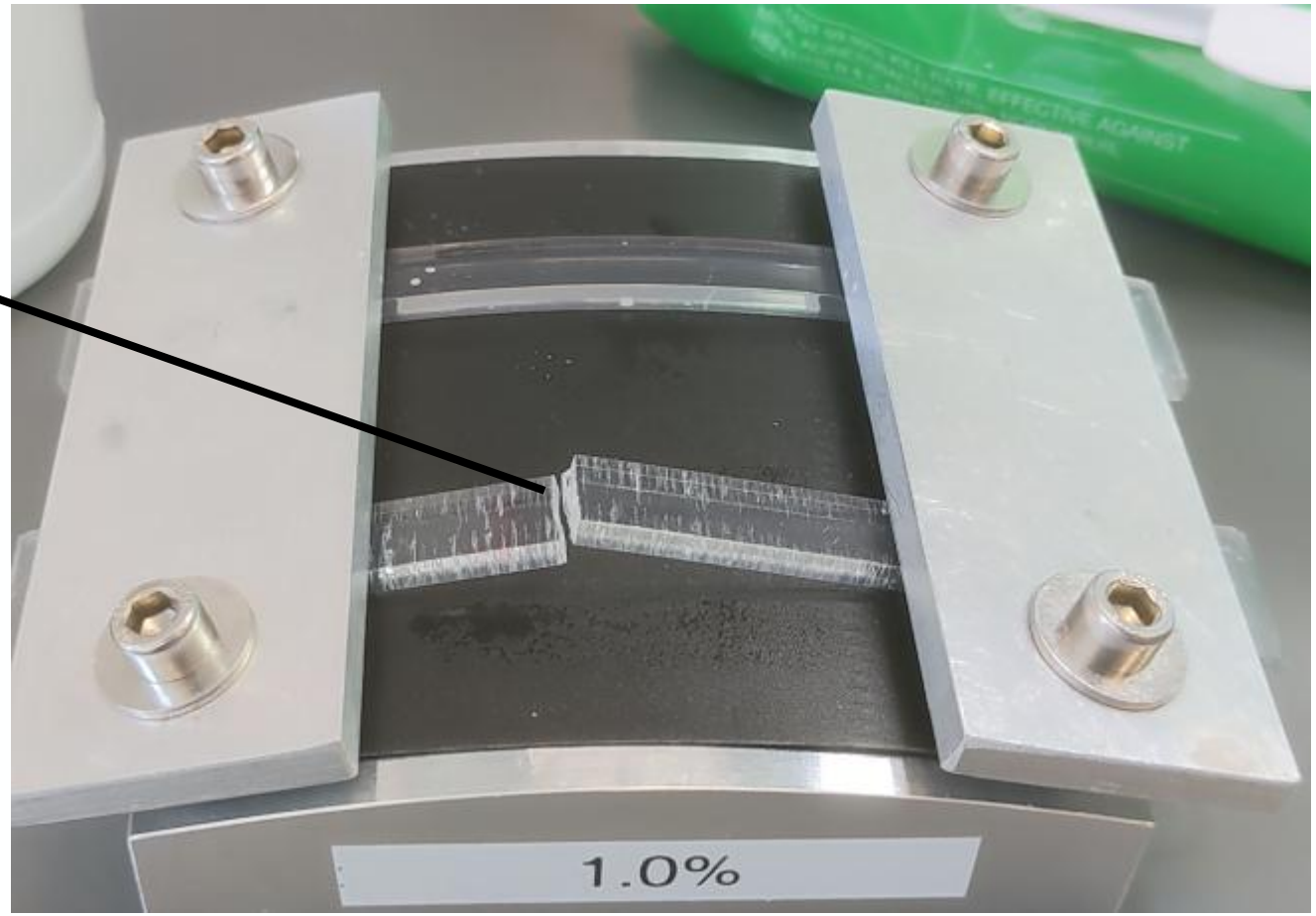
- During and after the exposure period we check for crazing and cracking.
- Environmental stress cracking goes through stages of crazing to cracking depending on the severity of the ESC agent.
- Sometimes the ESC effect can be small and there can be invisible damage.
- To test for invisible damage, we can test the tensile properties to show how “weak” a material is



ESC Video Example – Acrylic

ESC Example – Acrylic





Metals – Corrosion and Pitting

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Compatibility Issues: Corrosion

Corrosion is the oxidation of metals which can lead to a build up of corrosion product called rust.

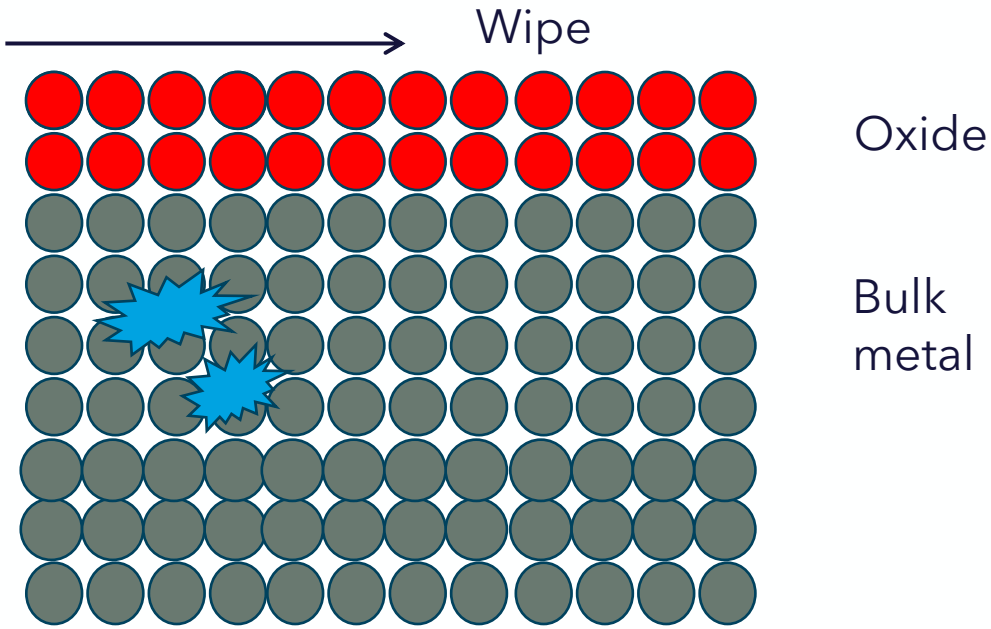
This process can be caused by several factors:

1. Surface oxide damage – The protective layer on the surface of the metal
2. Chemicals – But even water will corrode given enough time
3. Time – The age and use of the product has an impact
4. Environmental factors – Temperature and humidity have a big impact

Why is corrosion a problem?

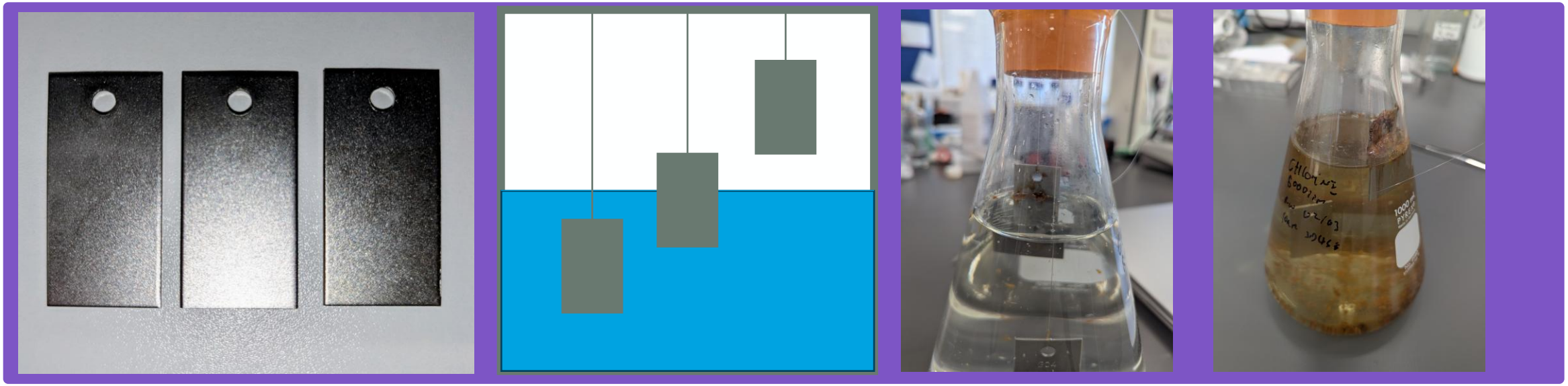
Most of the time it's cosmetic but corrosion comes in different forms:

1. **General corrosion –** This is the common form of what is seen as “rust” and is often easy to remove
2. **Pitting corrosion –** This is where material is broken down and leaves behind “Pits” which act as reservoirs



Corrosion Testing – ASTM G31

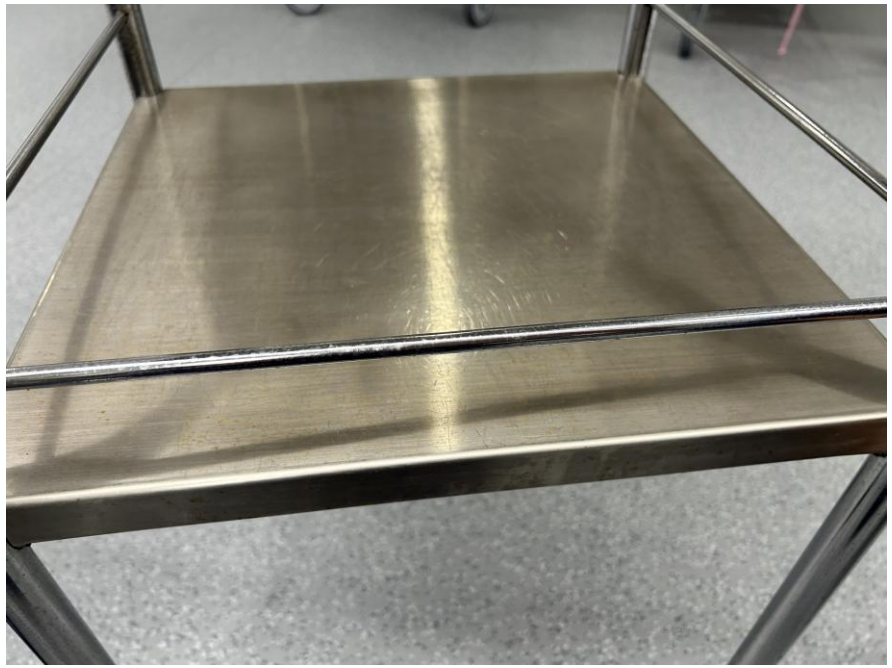
- Test standards ATSM G31 Corrosion testing
- This is achieved using a ‘Coupon’ which is a representative example of the metal tested
- Can be different levels of immersion with full (soak), partial (wipe) and suspended (environment)
- Once the test specimen is exposed to a test fluid (e.g. Chlorine) it is left for a period of one week then the corrosion rate is determined based on mass loss.



Cosmetic vs Problematic

Cosmetic

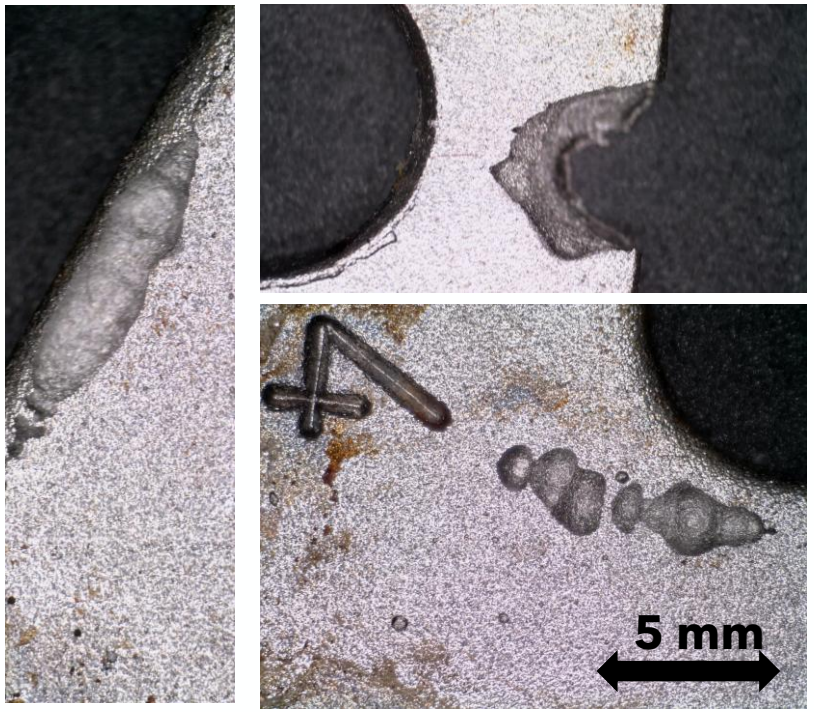
Surface level corrosion often called “Tea staining”



Can be removed and cleaned no loss in function

Problematic

Pitting which causes loss of material and leads to reservoir forming (Damaging)



Can’t be removed and cleaning is compromised and loss of function

Material compatibility approvals

User and patient

Cleaning & Disinfectant Product Manufacturer

Medical Device Manufacturer

Collaboration and transparency is key

1. It is easy for the above to blame each other – **not helpful!**
2. We need to **collaborate** in this space for better designed **cleaning products and devices** on both sides to prevent these issues – **Not just one side**
3. GAMA Healthcare are eager for collaborations to share our testing expertise and knowledge to approve or disapprove our products for medical devices but manufactures need to hear from you– **you can help be a bridge for better products!**

GAMA's collaborative efforts have supported **over 50 OEM** with testing our products for compatibility and want to test as many devices as possible to support our users at no cost.
For testing or materials support contact: Info@gamahealthcare.com or compatibility@gamahealthcare.com

Conclusions

Compatibility is not always easy as there is a lot to consider:

1. The material being disinfected "What material is it being used on?"
2. The chemistry of the formulation "What is it being cleaned with?"
3. The environment "Where is it? Does it have high strain?"
4. How often its used and cleaned "How often is it used?"

Robust testing:
"How was the product tested, was it done to standard and with the real world in mind?"

While corrosion and ESC are common these are but two issues in hospitals the effects are wide-reaching. Understanding and collaborating to prevent damage not only protects expensive equipment but also protects lives.

Protecting patients starts with protecting their equipment

We help **prevent infections** to **save** and **improve lives**.

Thank you.

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