Material Compatibility Falling Through The Cracks?: *How Disinfectants and Detergents Damage Medical Devices*

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May 21, 2024

GOV.UK

Topics

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Detergent and disinfectant wipes used on reusable medical devices with plastic surfaces – risk of degrading plastic surfaces

(All manufacturers) Ensure detergent and disinfectant wipes are compatible with the device. (MDA/2013/019)

GOV.UK (2014, accessed September 2022).

Infection Control TODAY®

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Surface Disinfection Incompatibility Does Not Support Effective Cleaning and Disinfection

May 1, 2022

By Sharon Ward-Fore, MS, MT(ASCP), CIC, FAPIC, Linda Lybert

Infection Control Today, Volume 26, Issue 4

Download RIS

The surface material and product damage caused by new advances in disinfection technology must be addressed for patient safety.

INFECTIONCONTROLTODAY.COM (2022, accessed September 2022).

HEALTHCARE SURFACES INSTITUTE

About Resources Certification

FDA recalls medical devices damaged by incompatible disinfectants

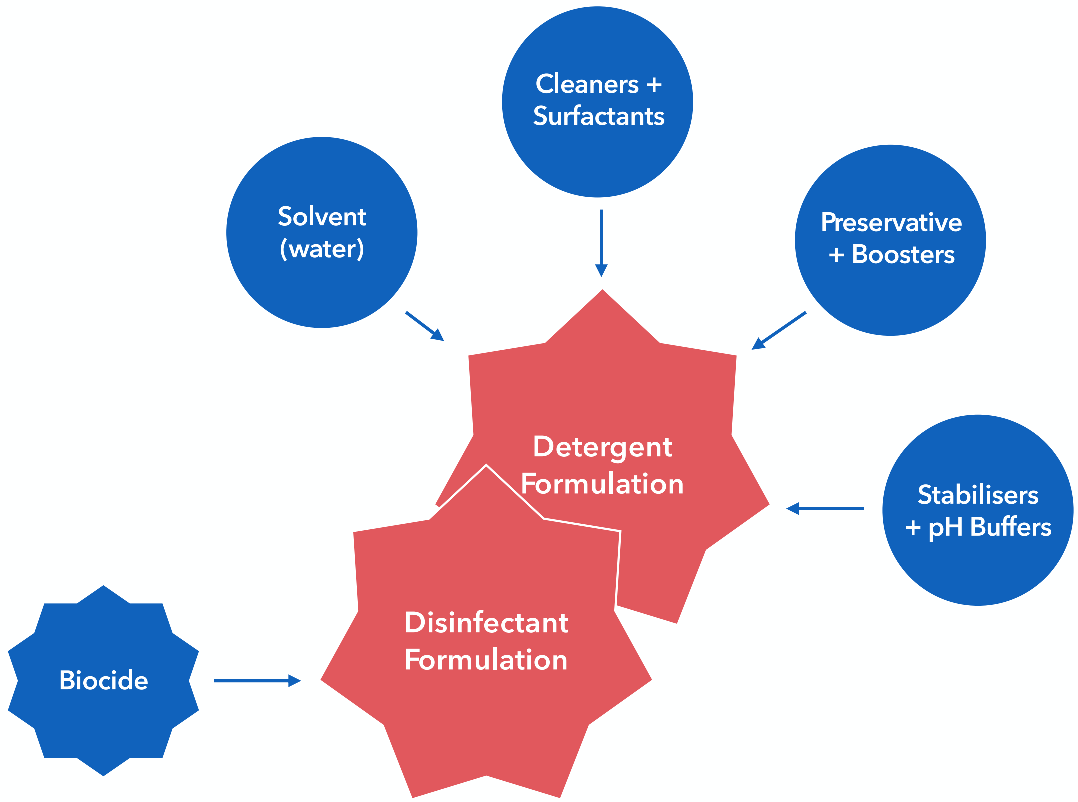
by Healthcare Surfaces Institute | Apr 27, 2022 | Cleaning & Disinfection |

HEALTHCARESURFACESINSTITUTE.ORG (2022, accessed September 2022).

EGCRI.ORG (2017, accessed September 2022).

Disinfectants and Detergents

- Disinfectants and detergents come in a variety of forms:
  - Liquids applied with a dry cloth or mop as pre-mixed solutions, tablets, granules, sprays.
  - Ready-to-use wipes.
- Disinfectant products are often not an individual biocide, but a formulation designed to (ideally) deliver a safe and efficacious product as per its intended use.



Biocides

- Chemical Biocides are used in clinical settings to inhibit or inactivate microorganisms to reduce/prevent the spread of microbes and hence infections.
- There is a broad spectrum of biocides and they can be categorised depending on their:

  - Chemical structure
  - Application
  - Mode of action
  - Spectrum of activity e.g. microbial efficacy
  - Compatibility profile

- Lots of considerations when assessing and selecting the correct biocidal product to use.

Types of Biocide

QUATs (NR_4^+)	Amines (NR_3)	
Benzalkonium chloride (BZK/ADBAC)	Chlorhexidine	
Didecyl dimethylammonium chloride (DDAC)	Dodecyl Dipropylene Triamine	
Benzethonium chloride	PHMB	
	Ethanolamine	

Other organics	Acids (H^+)	Oxidisers ([O])
Ethanol	Benzoic acid	Hypochlorite
Isopropanol	Lactic acid	Peracetic acid
Phenol	Salicylic acid	Hydrogen peroxide
Glutaraldehyde	Glycolic acid	Chlorine Dioxide

Environmental Decontamination

Typical hospital room – high touch surfaces

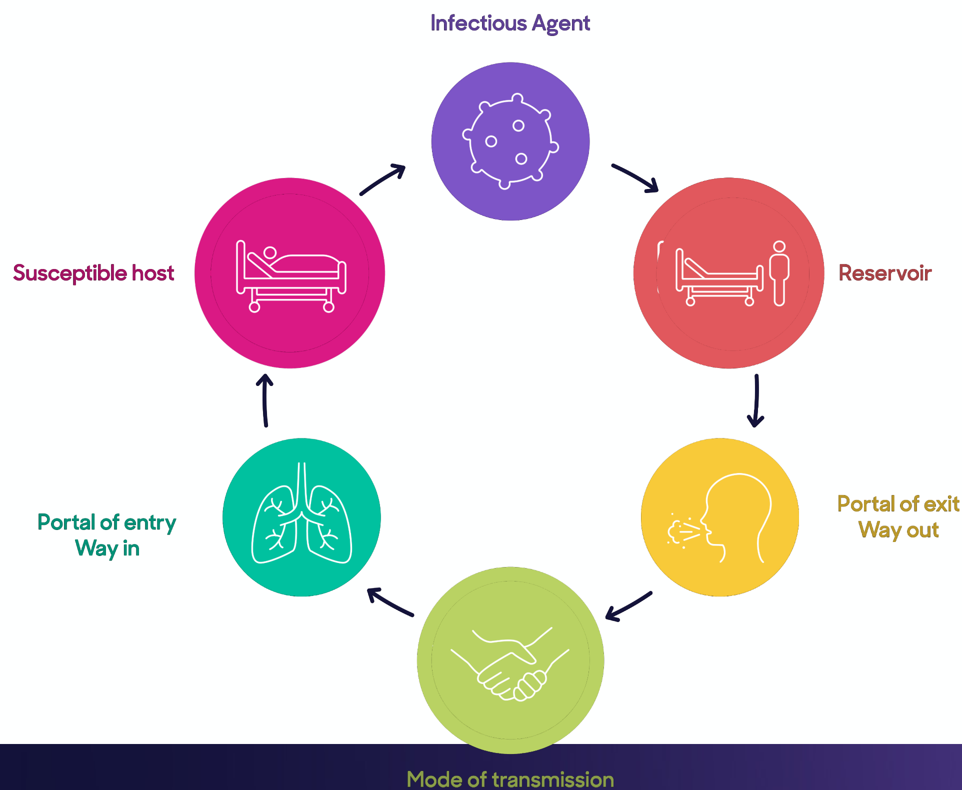
Non-invasive shared patient care equipment

Materials Found in Surfaces

Metals	Thermoplastics	Other
Steel (different grades)	Polypropylene	Wood
Titanium	Polyethylene	Vinyls
Brass	Polycarbonate	Laminates
Copper	PMMA (Perspex)	Leathers
Aluminium	ABS	Rubbers
Iron	Polystyrene	Marble
	Polyvinyl chloride	
	POM (Acetal)	
	Polyphenylene oxide	
	Polysulfone	

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.

- **Damages the surface so it's no longer safe to use**
  - risk to patient/staff
  - cost of replacement.

Some Definitions

- **Material Compatibility** - A materials resistance to damage when exposed to a chemical, in this case a disinfectant formulation.
- **Corrosion** – the deterioration of materials by chemical (or electrochemical) reaction with their environment.
- **Environmental Stress Cracking (ESC)** is premature cracking of a plastic due to the combination of:
  1. Strain – deformation on a molecular level due to stress on the plastic.
  2. ESC agents – molecules that come into contact with the plastic and can cause cracking.

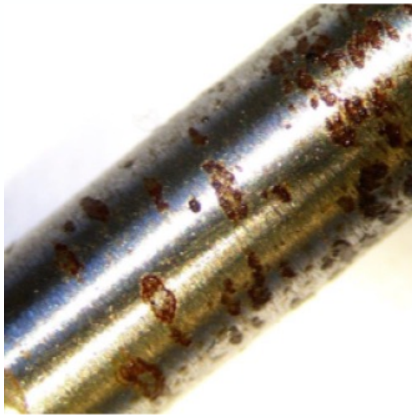
Compatibility Issues – Examples

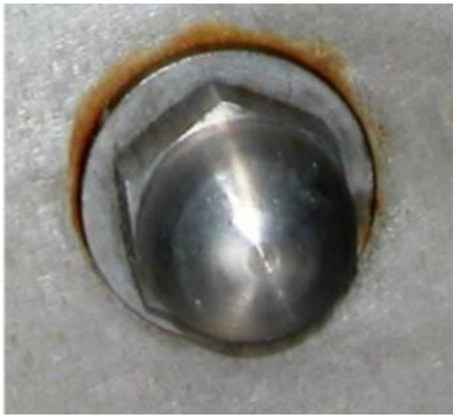
Compatibility Issues:
1) Corrosion

Corrosion – the deterioration of materials by chemical (or electrochemical) reaction with their environment.

- Plastics can corrode – but this is incredibly rare, they are inert and not very reactive.
- Metals are much more prone to corrosion, classically rust formation:

$$\text{Iron + Water + Oxygen} \rightarrow \underbrace{\text{Iron oxides + Iron hydroxides}}_{\text{Rust}}$$





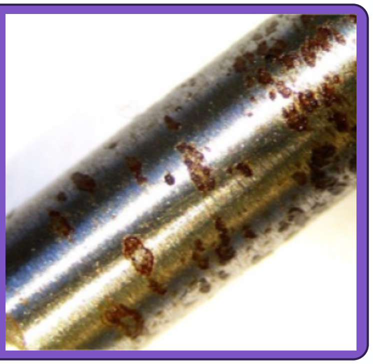
Corrosion of Steel

- Steel is a general name, there are lots of grades of steel, these importantly have **differing corrosion resistance**.
- Nearly every detergent and disinfectant uses water as a solvent, water is all that is needed to enable corrosion!
- There are different mechanisms of corrosion to consider:

1) Uniform corrosion – surface of steel is uniformly converted to rust.
2) Pitting corrosion – localised corrosion forming 'pits' from the surface down into the steel.
3) Crevice corrosion – localised corrosion in crevices which trap liquids against the surface of the steel.

1)

2)



3)

Design Choices: Steel in Devices

We can act to prevent/limit corrosion through **correct design** choices.

1. Select the correct grade/type of steel

- Avoid carbon/low alloy steel to prevent uniform corrosion
- Utilise high PREN number steel to prevent pitting corrosion
- Limit crevices at regularly cleaned/disinfected regions

2. Alloys preferred, but if using paint:

- Ensure paint is resistant to detergents and disinfectants
- Ensure paint is not going to be physically removed, this can expose poor resistance steel

Steel Type	PREN
K03	10.5-12.5
430	16.0-18.0
304	17.5-20.8
316	23.1-28.5
2202	26.5
904L	32.2-39.9

Increasing corrosion resistance.

Increasing Cr and/or Mo content.

Calculation of pitting resistance equivalent numbers (pren), *British Stainless Steel Association*. https://bssa.org.uk/bssa_articles/calculation-of-pitting-resistance-equivalent-numbers-pren/ (March 2024)

Quick Tip – Magnetism

Less corrosion resistant grades of steel are magnetic.

304 and 316 stainless steel (as well as other high alloy steels) are **not** magnetic!

Put a magnet to steel components to see if the medical device is well designed to avoid corrosion!

Not Magnetic!

Magnetic!

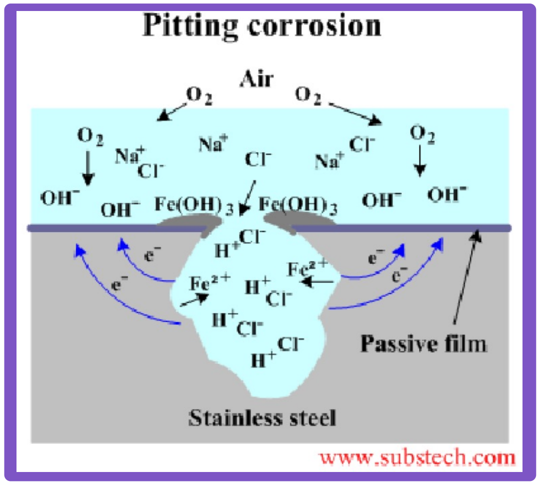
Design Choice:
Detergents & Disinfectants

We can act to prevent/limit corrosion through correct design choices.

1. Limit contact time
- Corrosion is time dependent, less contact is better
- Aim to not overly saturate surfaces

2. Avoid ingredients which enable pitting corrosion
- Chlorine and chloride
- Excessive pH

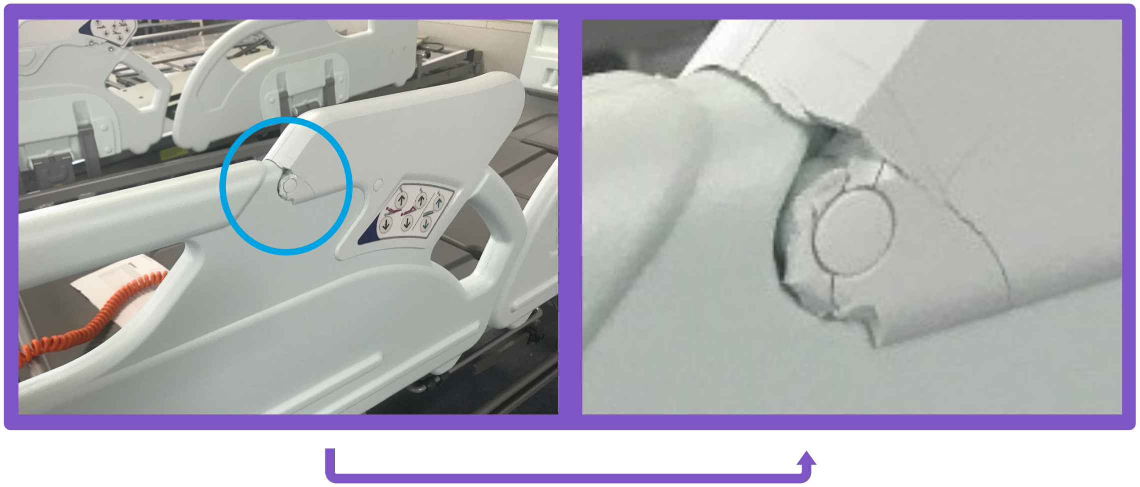
3. Test the detergent or disinfectant with metals



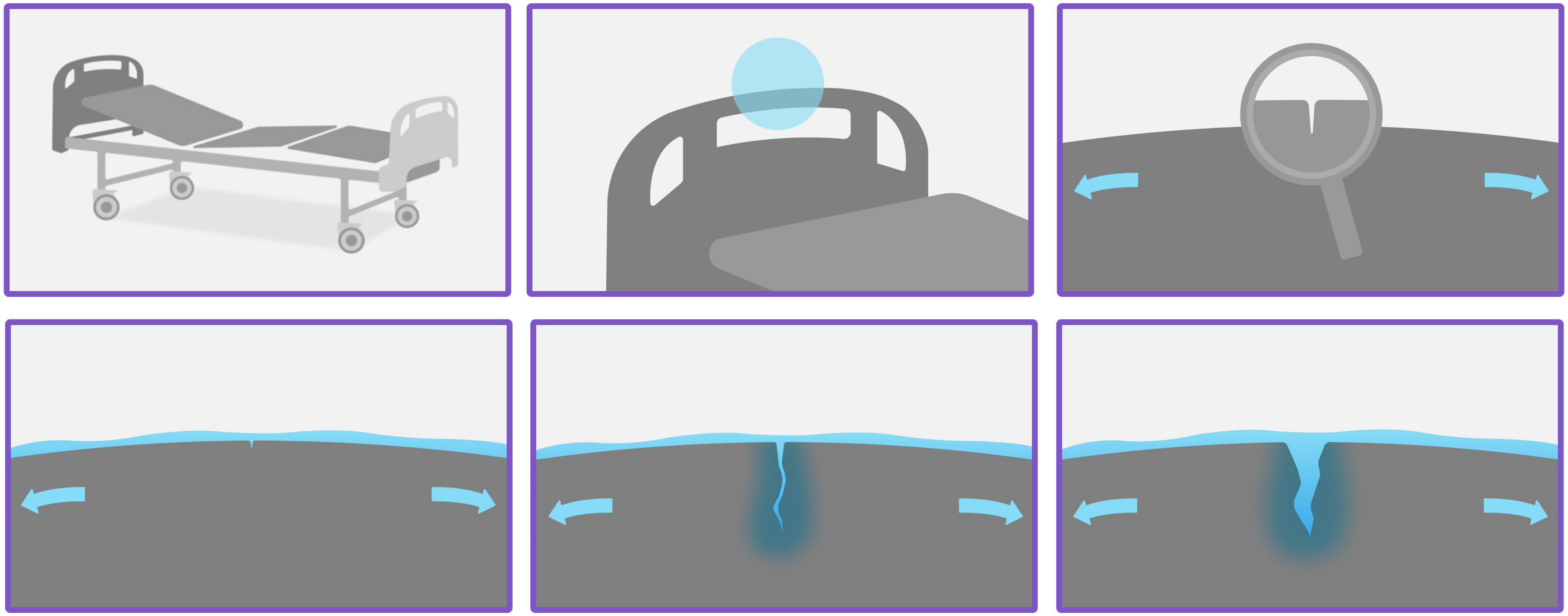
Compatibility Issues:
2) Environmental Stress Cracking (ESC)

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

1. Strain – deformation on a molecular level due to stress on the plastic.
2. ESC agents – molecules that come into contact with the plastic and can cause cracking



ESC Mechanism

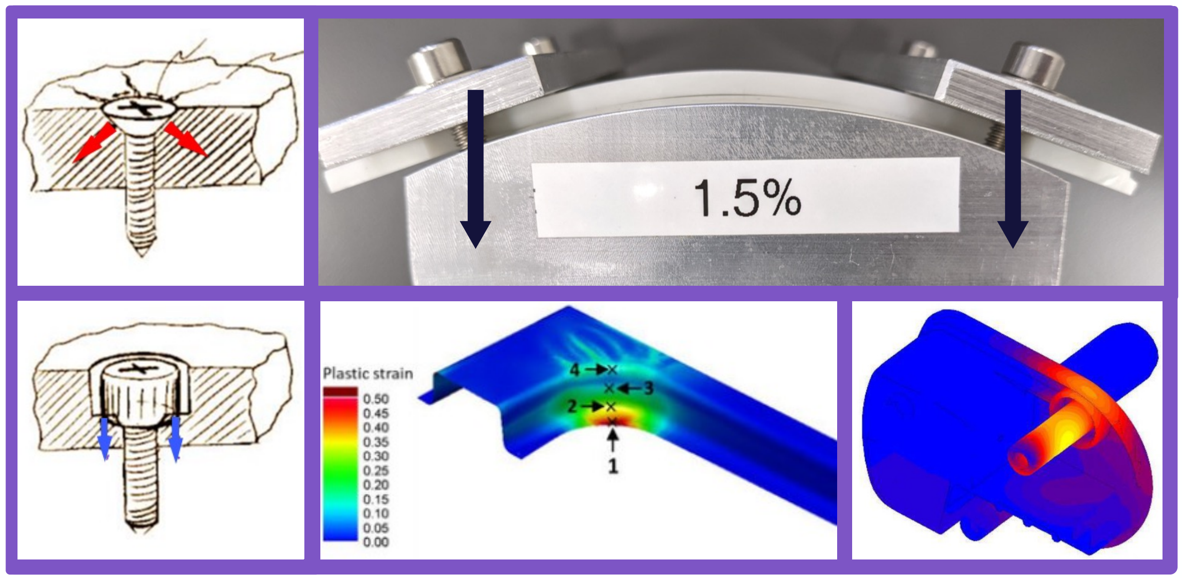


ESC – Strain

Environmental stress cracking (ESC) is the premature cracking of a plastic due to the combination of strain and the presence of molecules known as ESC agents.

1. Strain

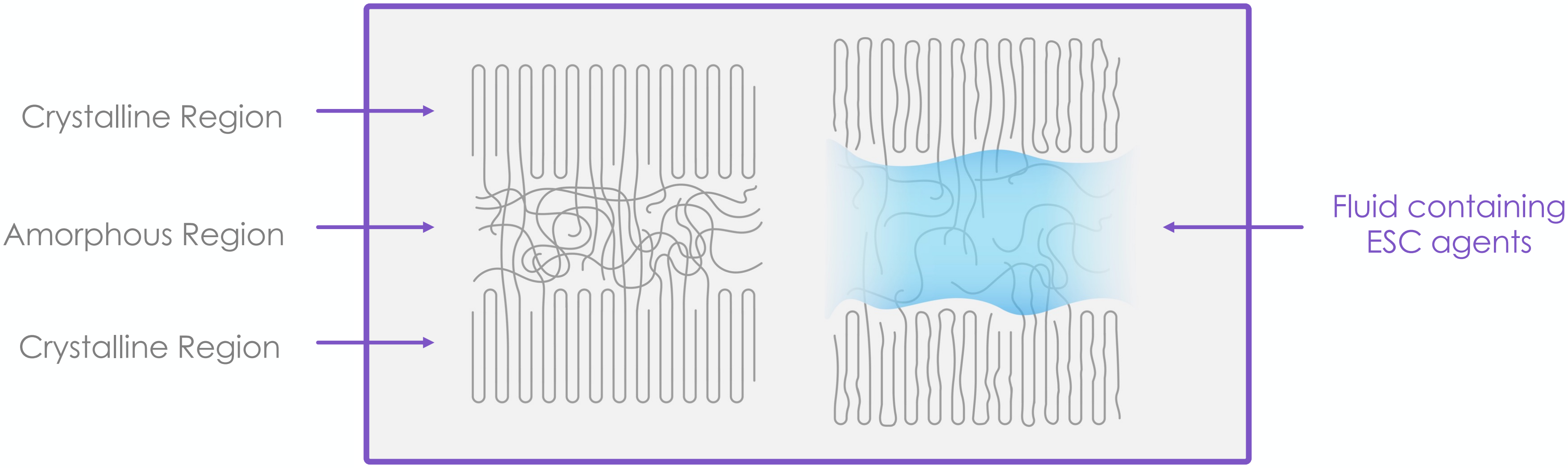
- Dimensionless deformation caused by a change in length or angle of a material – a stress.
- External stresses – operator, other parts, screws
- Internal strain resulting from manufacture.



ESC - ESC Agents

2. ESC Agent

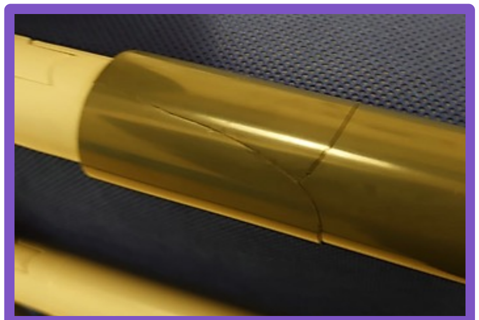
- Molecules with favourable interactions with polymers resulting in weakening and eventually stress cracking.
- Ingredients within a detergent or disinfectant formulation could be ESC agents.



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 of these devices often introduces inherent strain.
- These surfaces are regularly cleaned and disinfected as part of infection prevention practices.
- The cleaning and disinfectant products can contain ESC Agents.
- ESC can cause swelling, crazing, and cracks in the plastic, resulting in damage or device failure.

Thermoplastics
Polypropylene
Polyethylene
Polycarbonate
PMMA (Perspex)
ABS
Polystyrene
Polyvinyl chloride
Polyoxymethylene (POM)
Polyamide
Polysulfone

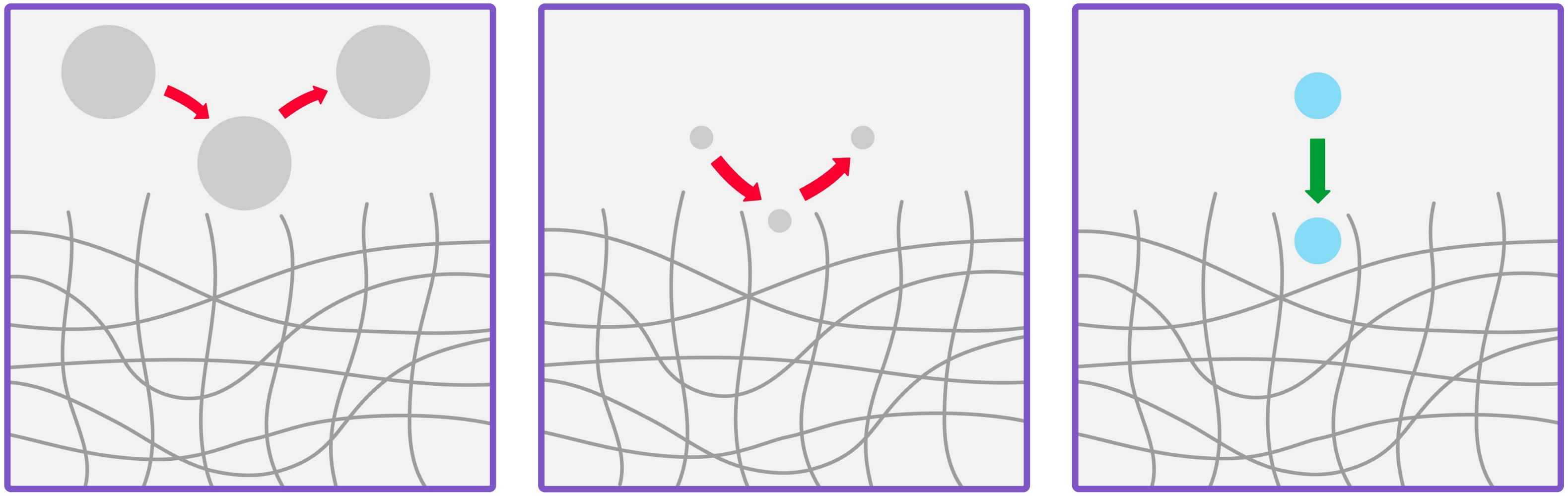


ESC Video Example

ESC Predictions

ESC agents differ greatly in severity.

- *Water itself is an ESC agent!* Just typically a very mild one…
- Some typical trends: both very large and very small molecules are typically quite mild.



- Intermolecular interactions are key to the ESC effect.

Ward et al (1991), Polymer, 32 :12,2172-2178. Hulme et al (2014) Life prediction of polymers for industry, accessed 09/2022

ESC Predictions

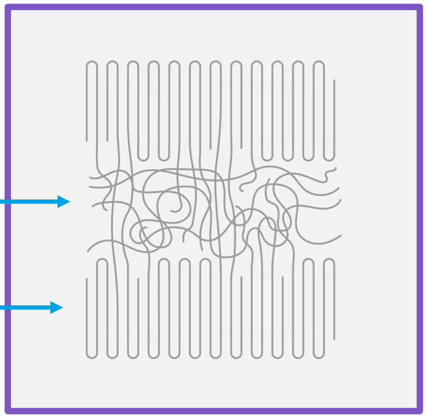
We can make predictions about the capabilities of an ESC agent.

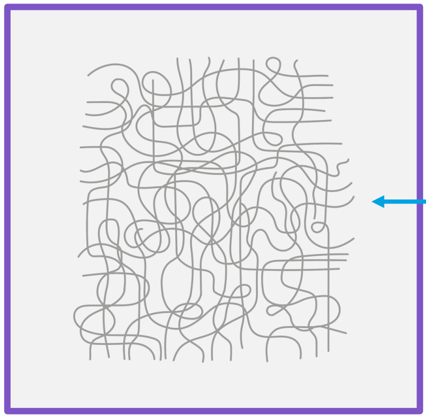
- Looking at disinfectant formulations – many molecules, many potential ESC agents.
- Polymer type is massively important, amorphous polymers more prone to ESC than semi-crystallines.

Semi-Crystalline Polymer

Amorphous Region

Crystalline Region





Amorphous Polymer

Fully Amorphous

- External factors such as temperature can affect the rate of ESC.
- There is a massive amount of variability to ESC, the only way to really know is to do some testing!

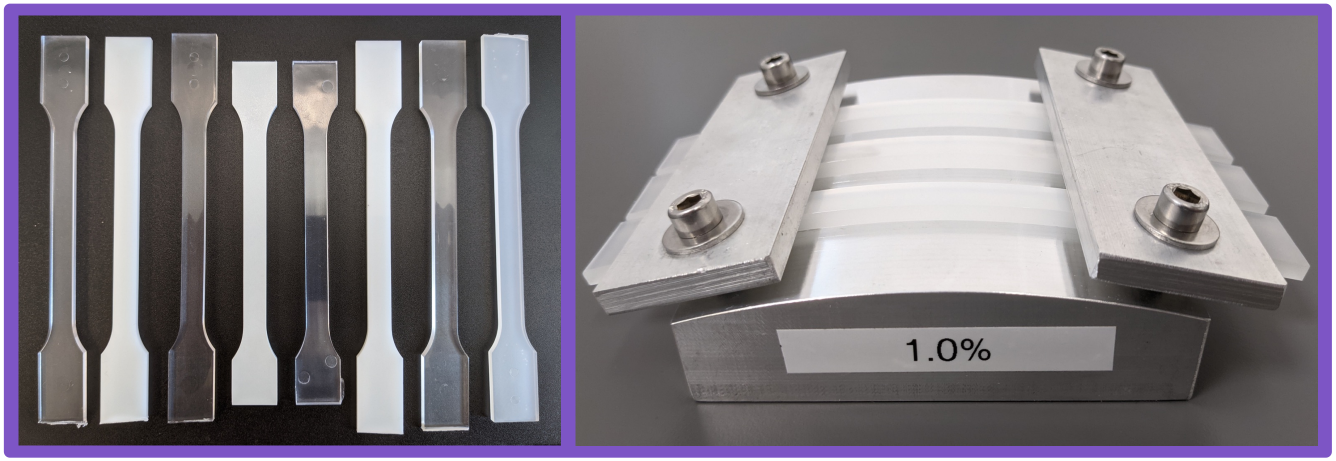
Ward et al (1991), Polymer, 32 :12,2172-2178. Hulme et al (2014) Life prediction of polymers for industry, accessed 09/2022

Standards For Evaluating Material Compatibility of Plastics and Environmental Stress Cracking (ESC)

- ASTM D543-21(2021) - Standard Practices for Evaluating the Resistance of Plastics to Chemical Reagents
  - Practice A – Immersion
  - **Practice B - Mechanical Stress and Reagent Exposure under Standardized Conditions of Applied Strain**
- ISO 22088:2016 - Determination of resistance to environmental stress cracking (ESC)
  - Part 1: General guidance
  - Part 2: Constant tensile load method
  - **Part 3: Bent strip method**
  - Part 4: ball or pin immersion method
  - Part 5: Constant tensile deformation method
  - Part 6: Slow strain rate method

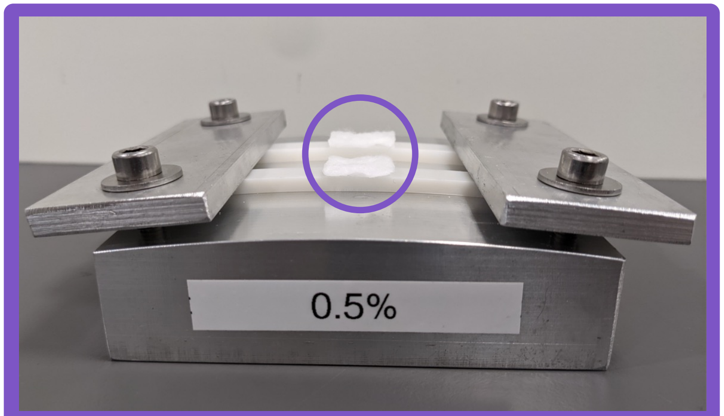
ESC Testing

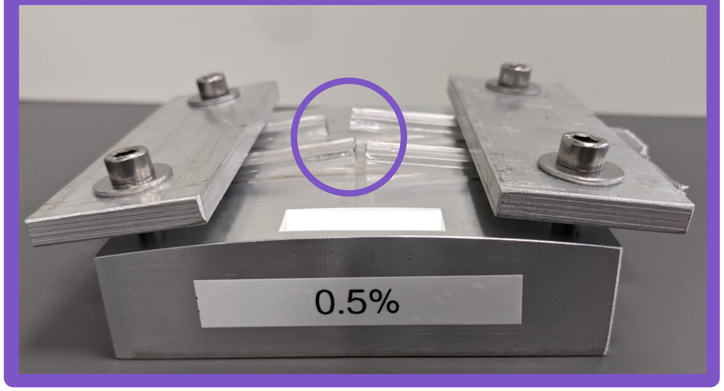
- Test standards ISO 22088:2016 part 3 or ASTM D543 Practice B.
- Both standards require applying a **constant strain to a thermoplastic.**
- Flexural strain is constant and simple to apply and test.
- This is achieved through the use of a 'strain jig', holding test specimens over a specific bend.
- Can be different levels of strain 0.5%, 1.0%, 1.5% most common.



ESC Testing

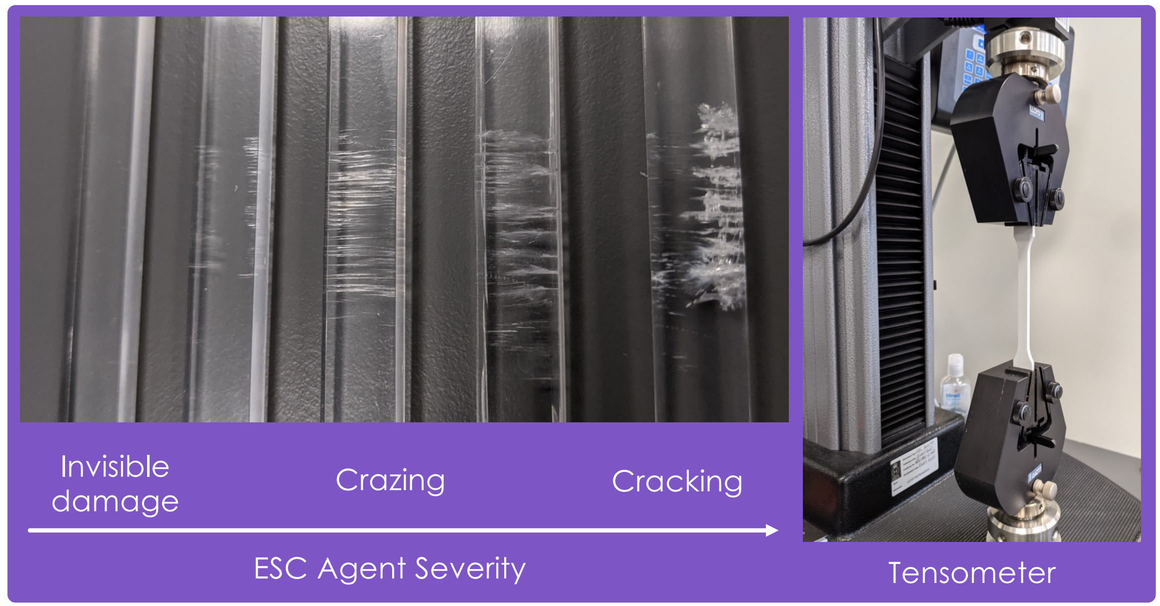
- Once the test specimen is under strain it needs to be exposed to a test fluid – detergent or disinfectant formulation.
- The entire apparatus can be immersed – requires lots of liquid.
- Easier alternative is to use a wet patch exposure.
- This involves placing cotton wool on the test specimen and regularly reapplying the formulation to saturation.
- Looking for cracking of specimens within the exposure period – this can differ but usually 7 days!



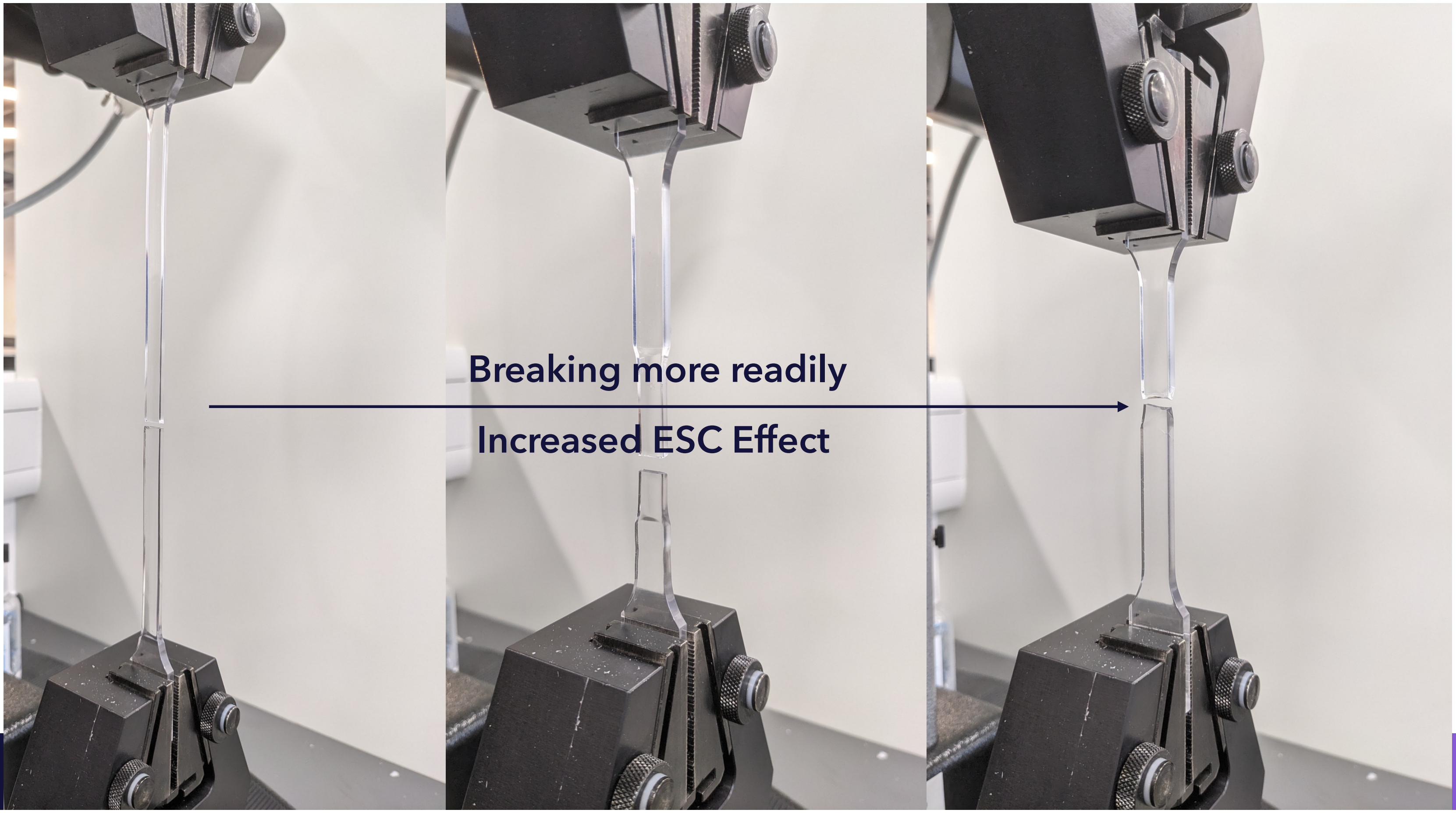


ESC Testing

- 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, the force required to pull the plastic until it breaks.



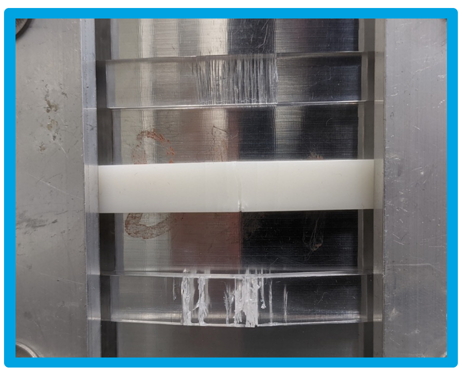
Tensile Weakening



Does the specimen crack or craze?

Yes

Severe Failure. The test liquid has a severe ESC effect at the tested strain level.



No

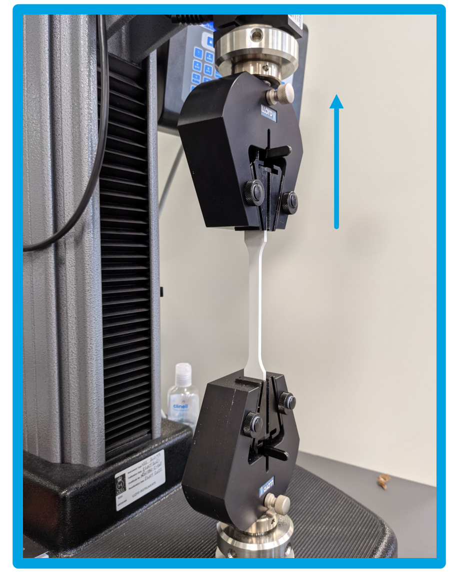
Invisible damage? Are the tensile properties weakened?

Yes

Moderate Failure. The test liquid has a moderate ESC effect at the tested strain level.

No

Pass. There is no significant ESC effect at the tested strain level.



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ESC Testing of Commercial Products

- Tested several disinfectant and detergent products from UK and Australian hospitals
- Six amorphous polymers prone to ESC and one semi-crystalline, all found in clinical settings:

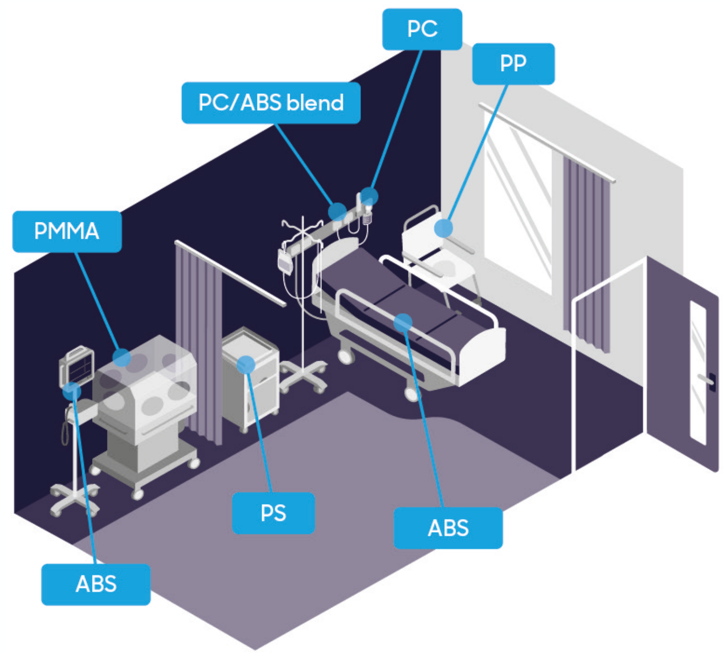
  -Polycarbonate (PC) – surgical instruments, infusion systems, blood delivery systems, hemodialysers, handles and transparent sheets.

  -ABS – valves, drug delivery systems, portable device housing and casing.

  -Polycarbonate/ABS blend – equipment housing, monitoring devices, diagnostic equipment.

  -PMMA (Perspex) – incubators and screens.

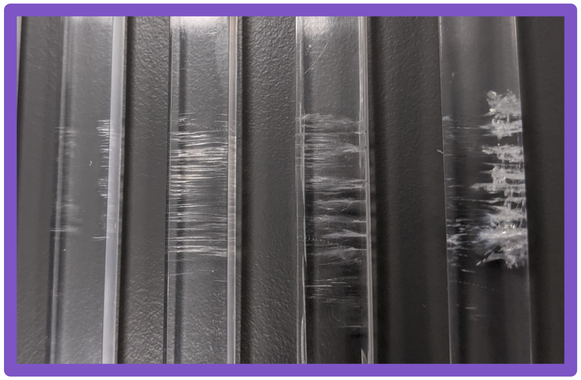
  -Polypropylene (PP) – instrument connectors, containers and surgical trays.



- Tested at 0.5% strain for 7 days at 23°C/50% RH using wet patch method.

ESC Testing Results

- To recap before sharing test results:



No crazing or cracking
AND
No weakening of
tensile properties.

FAIL

FAIL

PASS

0.5% Strain	Product 1	Product 2	Product 3	Product 4	Product 5	Product 6
Polycarbonate (Medium Viscosity)	PASS	PASS	PASS	FAIL – Cracking from 36 hours	FAIL – Cracking from 12 hours	FAIL – Cracking from 36 hours
Polycarbonate (High Viscosity)	PASS	PASS	PASS	FAIL – Cracking from 36 hours	FAIL – Cracking from 36 hours	FAIL – Cracking from 36 hours
Polycarbonate (w/ 10% Glass Fibres)	PASS	PASS	PASS	FAIL – Cracking from 120 hours	FAIL – Cracking from 120 hours	FAIL – Cracking from 80 hours
Acrylonitrile Butadiene Styrene (ABS)	PASS	PASS	PASS	PASS	PASS	FAIL – Invisible Damage
Polycarbonate/ABS Blend	PASS	PASS	PASS	PASS	FAIL – Cracking from 48 hours	FAIL – Cracking from 48 hours
Polymethyl Methacrylate (PMMA)	FAIL – Invisible Damage	FAIL – Invisible Damage	FAIL – Cracking *immediately*	PASS	FAIL – Cracking from 120 hours	FAIL – Cracking from 24 hours
Polypropylene (PP)	PASS	PASS	PASS	PASS	PASS	PASS
Primary Biocide(s)	QUATs (BZK, DDAC)	QUATS (ADEBAC, DDAC)	QUATS (ADEBAC, BZK), Isopropanol	QUAT (DDAC)	QUAT (DDAC)	QUAT (DDAC)
pH	5.2	6.1	5.6	10.8	10.5	8.8

High pH

Detergent Products

0.5% Strain	Detergent Product A	Detergent Product B	Detergent Product C
Polycarbonate (Medium Viscosity)	PASS	FAIL – Cracking from 48 hours	FAIL – Cracking from 120 hours
Polycarbonate (High Viscosity)	PASS	PASS	PASS
Polycarbonate (w/ 10% Glass Fibres)	FAIL	FAIL	FAIL
Acrylonitrile Butadiene Styrene (ABS)	FAIL – Cracking from 96 hours	FAIL – Cracking from 24 hours	PASS
Polycarbonate/ABS Blend	FAIL – Cracking from 60 hours	FAIL – Cracking from 12 hours	FAIL
Polymethyl Methacrylate (PMMA)	FAIL – Cracking from 24 hours	FAIL – Cracking from 24 hours	FAIL
Polypropylene (PP)	PASS	PASS	PASS

Design Choices: Plastics in Devices

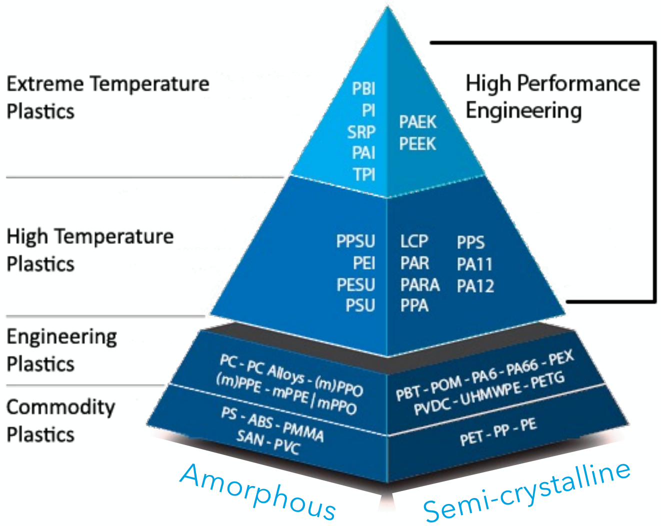
We can act to prevent/limit ESC through **correct design** choices.

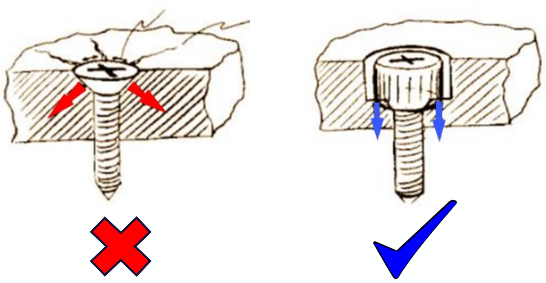
1. Select the correct polymers

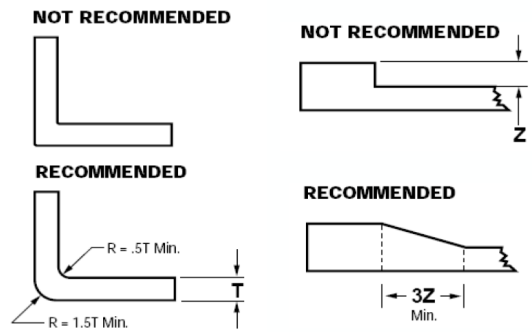
- Avoid or reduce the use of amorphous polymers
- Attempt to use higher MFI / viscosity polymer grades

2. Limit and reduce strain

- Better design screw joints
- Avoid right angles
- Maintain uniform thickness
- Optimise moulding conditions







Design Choice:
Detergents & Disinfectants

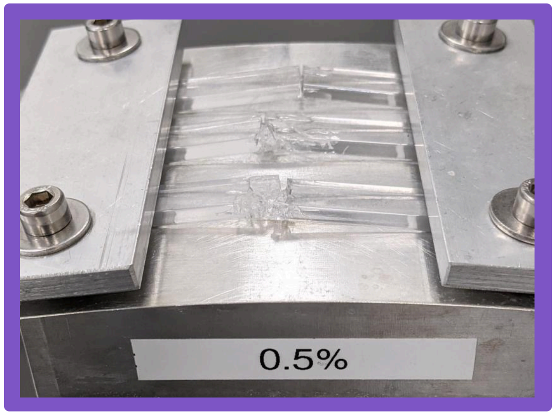
We can act to prevent/limit ESC through correct design choices.

1. Avoid known severe ESC agents
   - Alcohols for PMMA
   - Amines for PC
   - Correct surfactant choice

2. Aim for neutral pH

3. Consider all ingredients – not just biocide

4. Test the detergent or disinfectant with strained plastics.



Collaboration is Key

Cleaning & Disinfectant Product Manufacturer

Medical Device Manufacturer

- If medical devices are being damaged it is easy for the above to blame each other – not helpful!
- We need to collaborate in this space and better design on both sides to prevent these issues for our customers.
- GAMA Healthcare are keen for collaborations and to share our testing expertise to approve or disapprove our products for medical devices.

→ Reach out to j.jennings@gamahealthcare.com or compatibility@gamahealthcare.com

Compatibility Check List

<u>Disinfection Product</u>

What ingredients are in this product?

What pH is this product?

What is the application of this product?

Is it CE-marked?

<u>Surface or Device</u>

What am I disinfecting?

What material(s) are present?

Does this device have a cleaning protocol?

Has the product been tested to a standard method ASTM/ISO?

Has the disinfection product been tested against the surface or device I want to use it on?

How does this impact the IPC policy/guidelines?

Don’t forget about antimicrobial efficacy!

Thank You

Happy to take any questions, reach out to me by email j.jennings@gamahealthcare.com or on LinkedIn

www.webbertraining.com/schedulep1.php

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