



Improving medical device disinfectant resistance with new housings materials

Covestro

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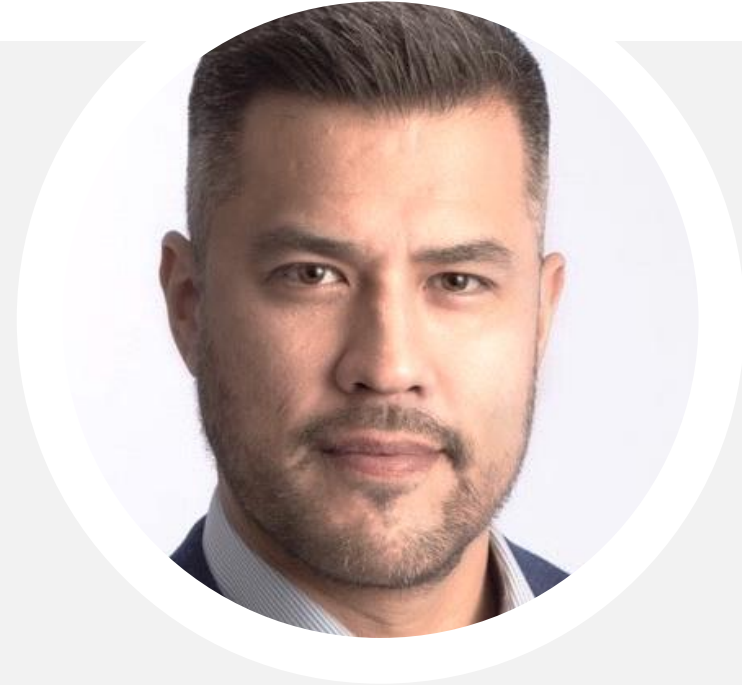
Your presenters



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Covestro – leading in the world of plastics

Strong

- €10.7 bn in sales
- ~18,000 employees¹



Useful

- Plastics, pre-products and solutions
- For many industries



Global

- ~50 production sites globally
- Close to customers and partners



Innovative

- ~1,500 employees in research and development
- 80 years of ideas and inventions




Leading polycarbonate supplier to the **Healthcare** industry

For 50 years, Healthcare OEMs have relied on our materials and industry expertise:

- *Consistency, quality and long-term reliable supply*
- *Global product availability from sites following GMP*
- *Innovative materials meeting rigorous Healthcare requirements*
- *Excellent technical and regulatory service*

Why are medical device housings important?

A circular inset image showing a close-up of a white medical device housing with a black control panel and a screen.

Housings
bring functions
like...

- “Seal device from environment”
- “Defend device against wear-and-tear”
- “Provide pleasant aesthetics”
- “Enable communication with user”
- “Prevent flames in case of short-circuit”
- “Protect user from electric shock”

Medical device housings can encounter many challenges



Aggressive disinfectants

used to prevent healthcare-associated infections (HAI's)



UV light exposure

can cause discoloration and embrittlement



Restriction of hazardous substances

including brominated flame retardants

Medical device housing key requirements



Flame
retardancy

Impact
resistance

Bio
compatibility

**Chemical
resistance**

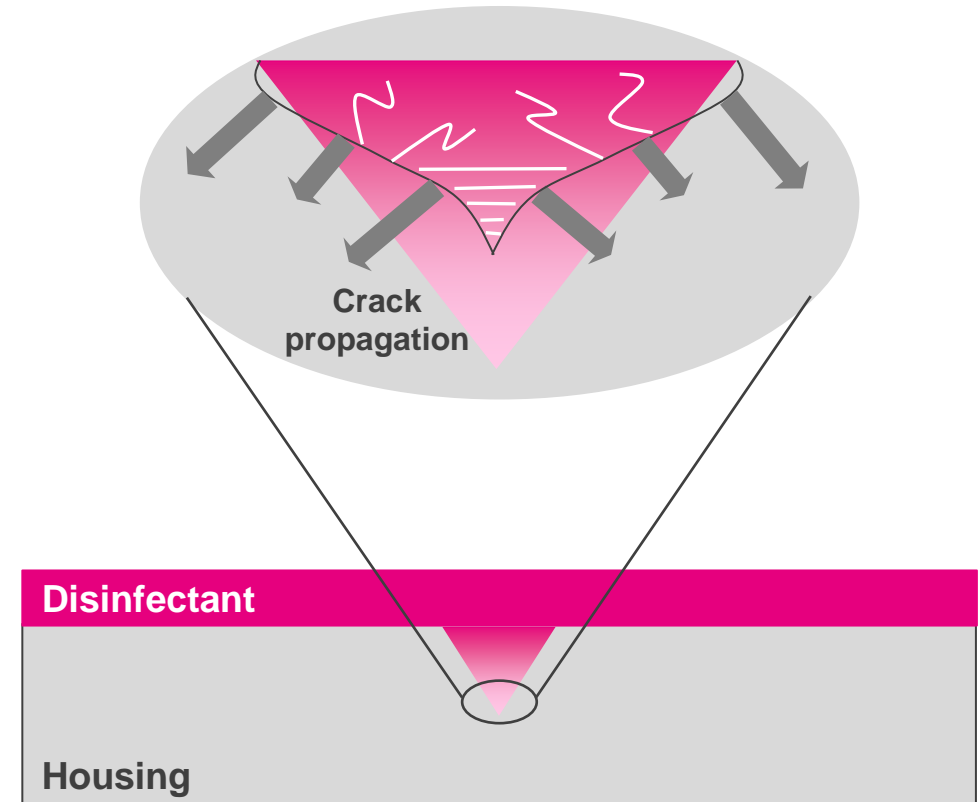
Dimensional
stability

Thermal
stability

Defining chemical resistance

Common explanations for the environmental stress cracking (ESC) mechanism

- Internal and external stress concentrations at microscopic inhomogeneities
- Chemical exposure: swelling and/or chemical attack
→ weakening of intermolecular bonds
- Growth of voids and formation of crazes
- Cracking and material failure



Chemical resistance can be understood as the capacity of a material to reduce ESC caused by the exposure to chemicals or disinfectants

Companies ask us...



“Is this material stable against chemical ‘xyz’?”

Our answer:
“It depends...”

Determining if a thermoplastic is resistant to disinfectants

A large blue circle with a white border, containing the text "Several factors are considered" in white.

**Several factors
are considered**

Contact duration

Temperature exposure

Environment

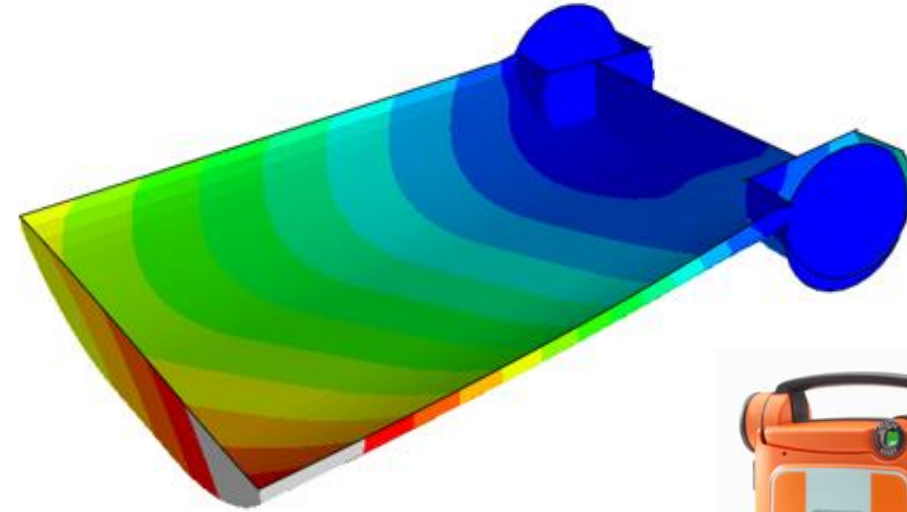
Type of disinfectant

Failure criteria

Part design

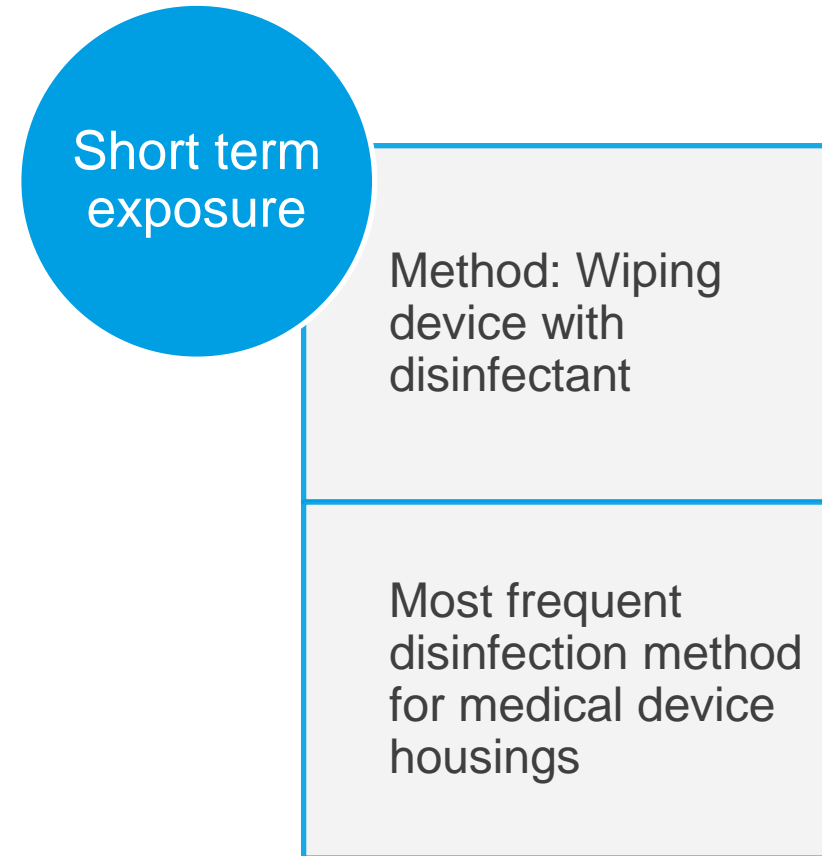
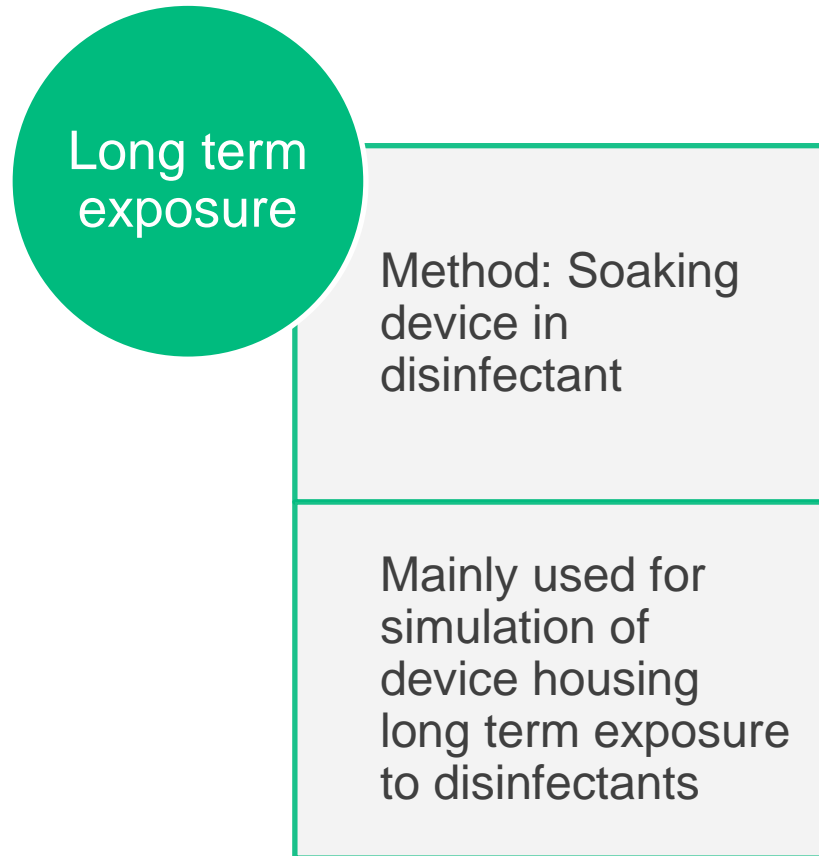
Optimizing part design to improve chemical resistance

- Reduce internal molded-in stress
- Minimize assembly stresses
- Design to limit the impact of chemicals



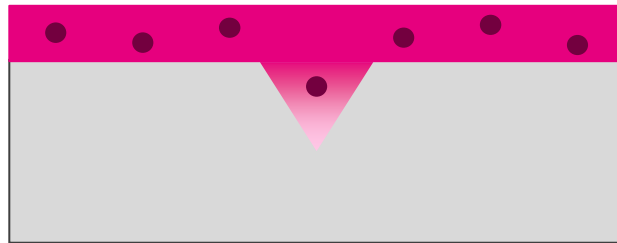
Molding simulations can aid in modeling these features prior to production

Chemical resistance depends on disinfectant contact duration

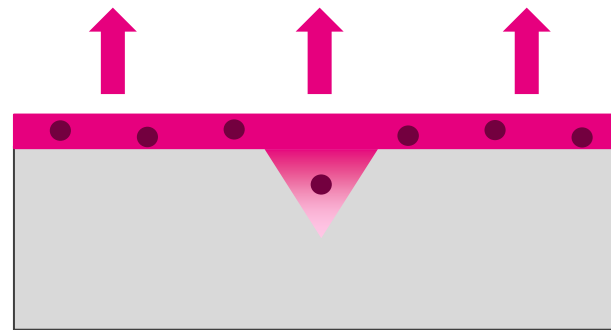


Understanding short term exposure to disinfectants

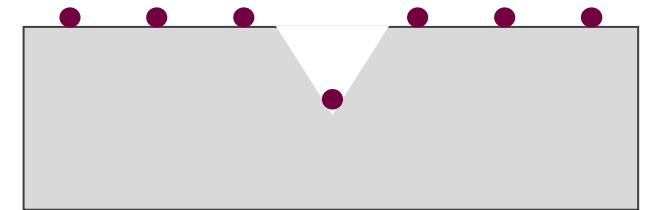
When disinfecting using the wiping method, the composition of the disinfectant will change over time



Disinfectants are a complex mixture of water, active ingredients, and 'inactive' ingredients like detergents, solvents, fragrances, etc.

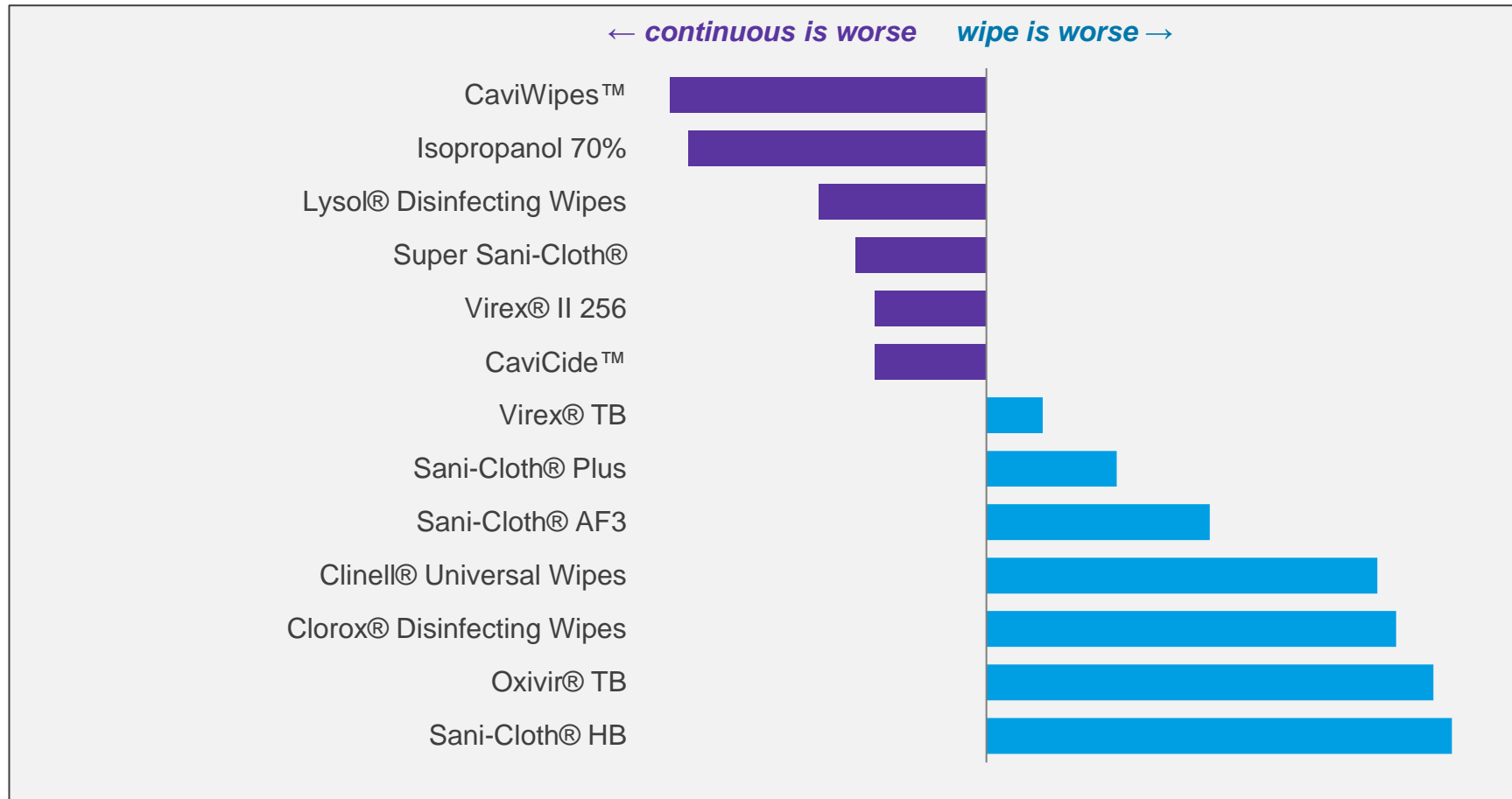


The main solvent will evaporate quickly, resulting in accumulation of low volatility components on the housing surface






















Typically, no additional washing occurs after wiping with disinfectant resulting in a long contact exposure to the low volatility components

Comparing soaking and wiping methods



* Covestro Internal testing: Sum of cracking scores for 16 different materials.

Our existing portfolio for medical device housings

Makrolon® 2458	Makrolon® 2858	Bayblend® M850 XF	Makroblend® M525	Bayblend® M301 FR	Bayblend® FR3010	Makroblend® M4000 FR
 Tough	 Tough	 Tough	 Tough	 Tough	 Tough	 Tough
	 Chemical Resistant		 Chemical Resistant			 Chemical Resistant
 Skin Contact Biocompatible	 Skin Contact Biocompatible	 Skin Contact Biocompatible	 Skin Contact Biocompatible	 Skin Contact Biocompatible		 Skin Contact Biocompatible
				 Flame Retardant	 Flame Retardant	 Flame Retardant

*We realized we needed materials which would combine
all required housings properties into one with next generation flame retardants*

“So, we developed...”



Makroblend[®] M5005 FR and **Makrolon[®] M6011 FR** offer superior chemical resistance against aggressive disinfectants, next generation flame retardancy, skin contact biocompatibility and global availability.

Count on Makroblend® M5005 FR & Makrolon® M6011 FR



Monitoring equipment



Infusion pumps



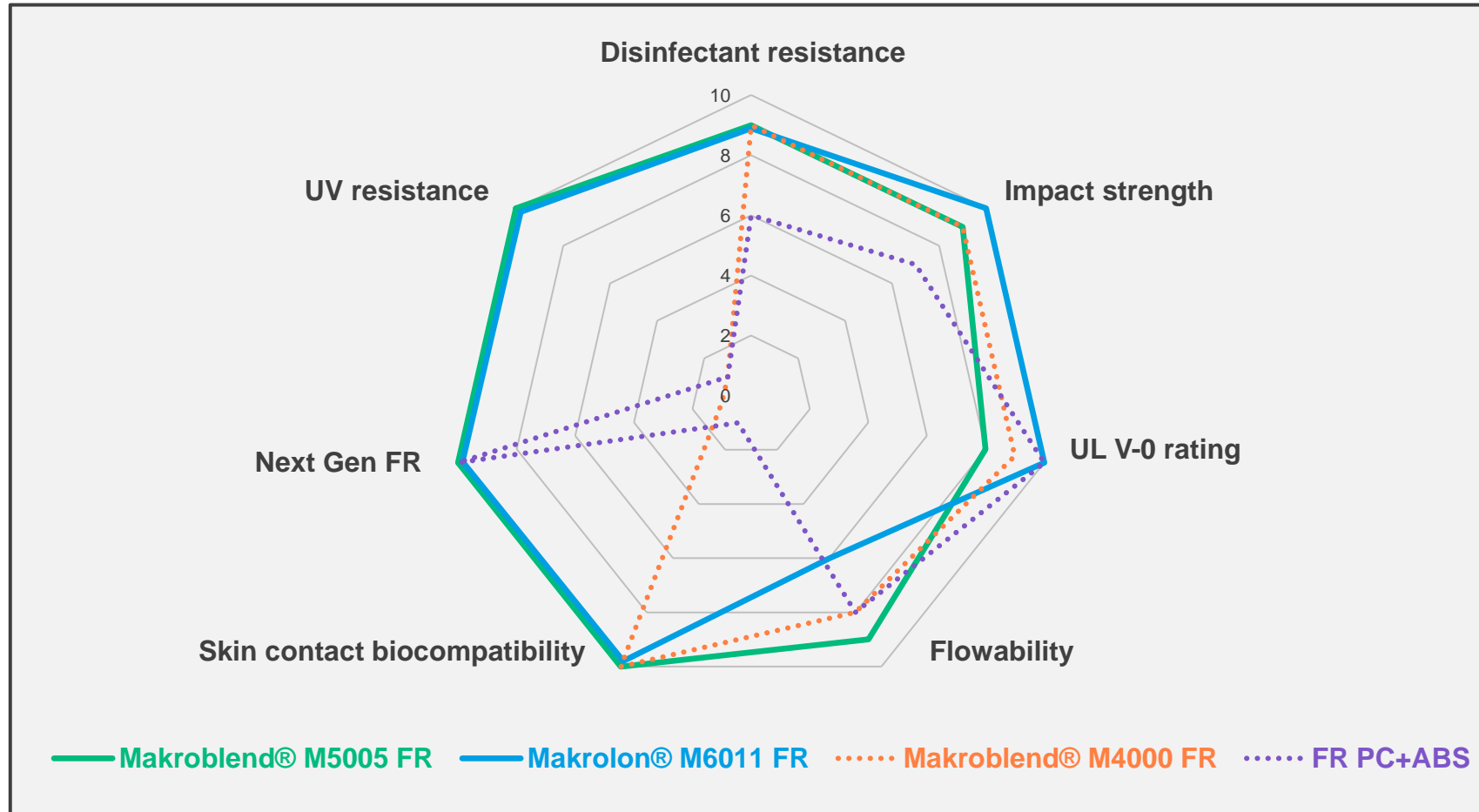
Diagnostic equipment



Automated external defibrillators

For electromedical device housings that require improved resistance to harsh disinfectants, UV light and environmental stress cracking

Makroblend® M5005 FR & Makrolon® M6011 FR enhance our portfolio by providing the **best overall balance** of properties



Makroblend® M5005 FR & Makrolon® M6011 FR provide **chemical resistance** to aggressive disinfectants

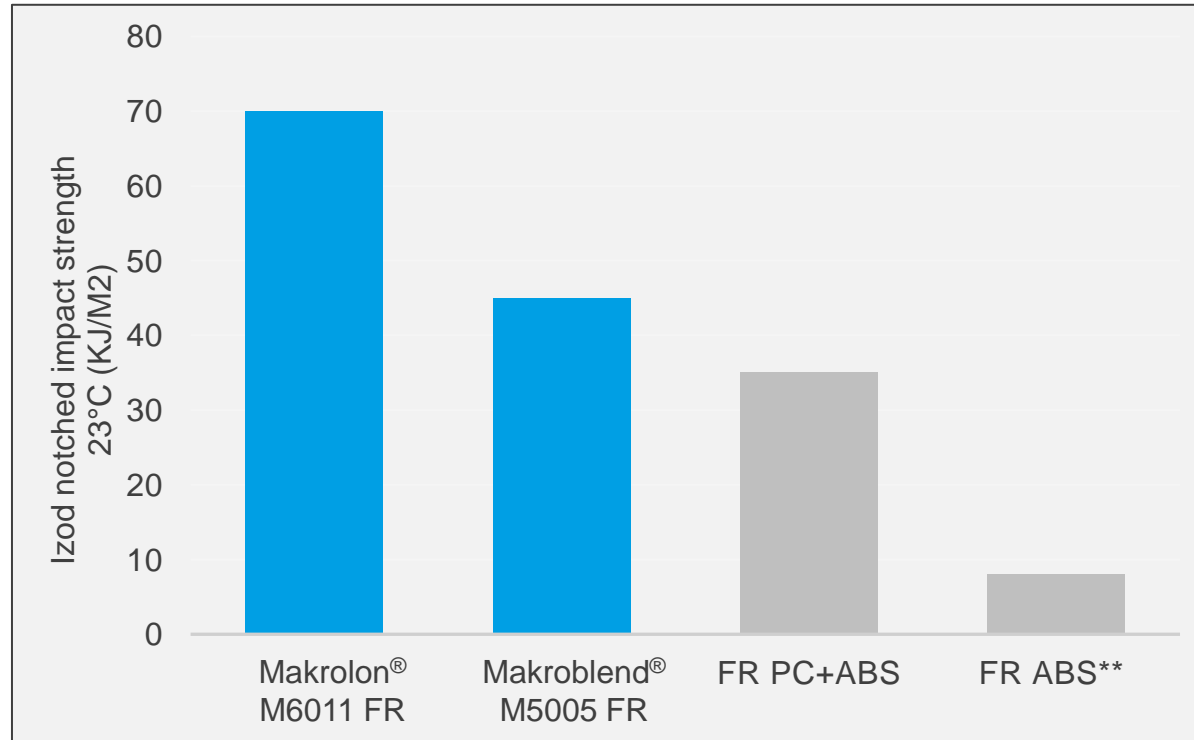


	Makroblend® M5005 FR	Makrolon® M6011 FR	Makroblend® M4000 FR	FR PC+ABS
CaviCide™	R	R	R	R
Clorox Healthcare® Bleach Germicidal Wipes	R	R	R	R
Lysol® Disinfecting Wipes (Lemon & Lime)	R	R	R	R
Opti-Cide3® Surface Wipes	R	R	R	R
Oxivir® Tb	R	R	R	N
Sporicidin®	R	R	R	R
Super Sani-Cloth® Germicidal Wipes	R	R	R	R
Sani-Cloth® HB	L	L	L	N
Virex® II 256	R	R	R	R

● "resistant": passed evaluation at 1.0% strain
 ● "limited resistance": passed evaluation at 0.6% strain, failed at 1.0% strain
 ● "not resistant": failed evaluation at 0.6% strain

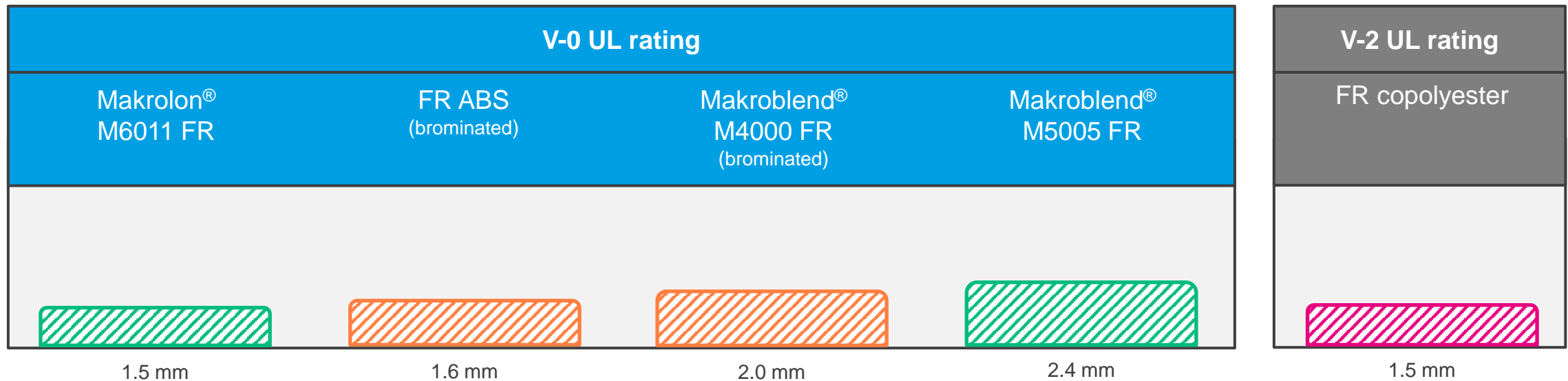
Covestro Internal Data. Method: ISO 527 tensile specimens were held at fixed flexural strains of 1.0% and 0.6% and wiped 10 times at ≥30 minute intervals with 24 hours total exposure to strain. Pass criteria: (1) no visible cracking upon close inspection, (2) tensile yield strength fully retained: >98%, and (3) yield behavior preserved with >10% nominal strain at break


Makroblend® M5005 FR & Makrolon® M6011 FR for **durable** electromedical devices



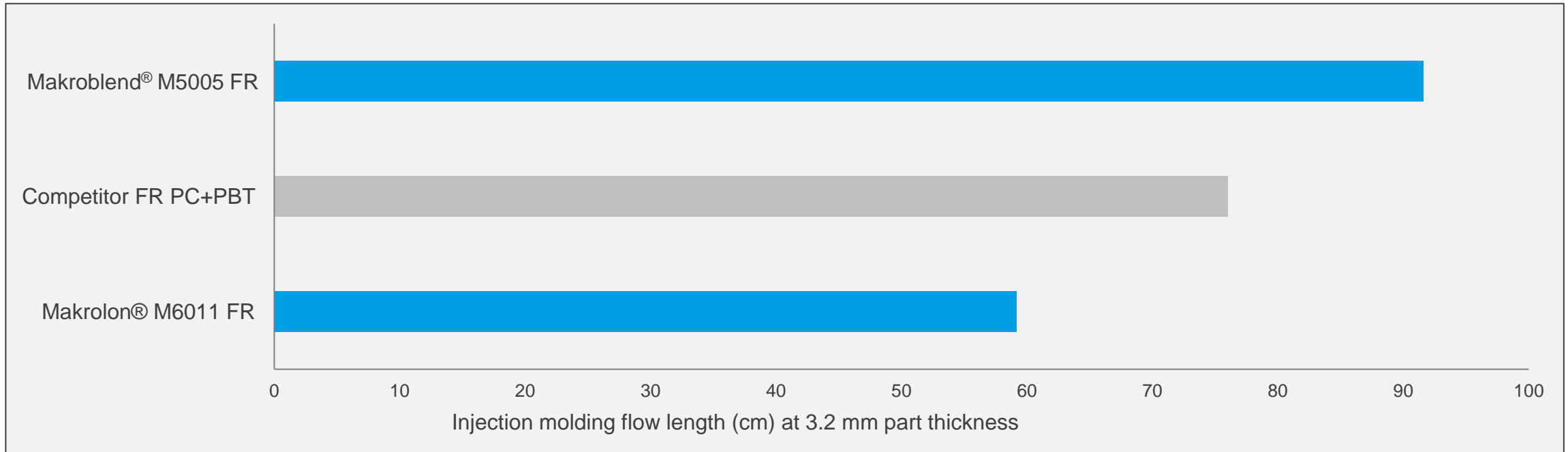
Makroblend® M5005 FR & Makrolon® M6011 FR provide **higher impact strength** than FR ABS

Makroblend® M5005 FR & Makrolon® M6011 FR are based on **next generation** flame retardants with **UL V-0** rating



 Wall thickness representation

Relative flowability of our new materials



Makroblend® M5005 FR has enhanced melt flow
Makrolon® M6011 FR processes like standard polycarbonate

Makroblend[®] M5005 FR & Makrolon[®] M6011 FR are **skin contact biocompatible** per ISO 10993



Skin contact
biocompatibility per
ISO 10993

Product
stewardship

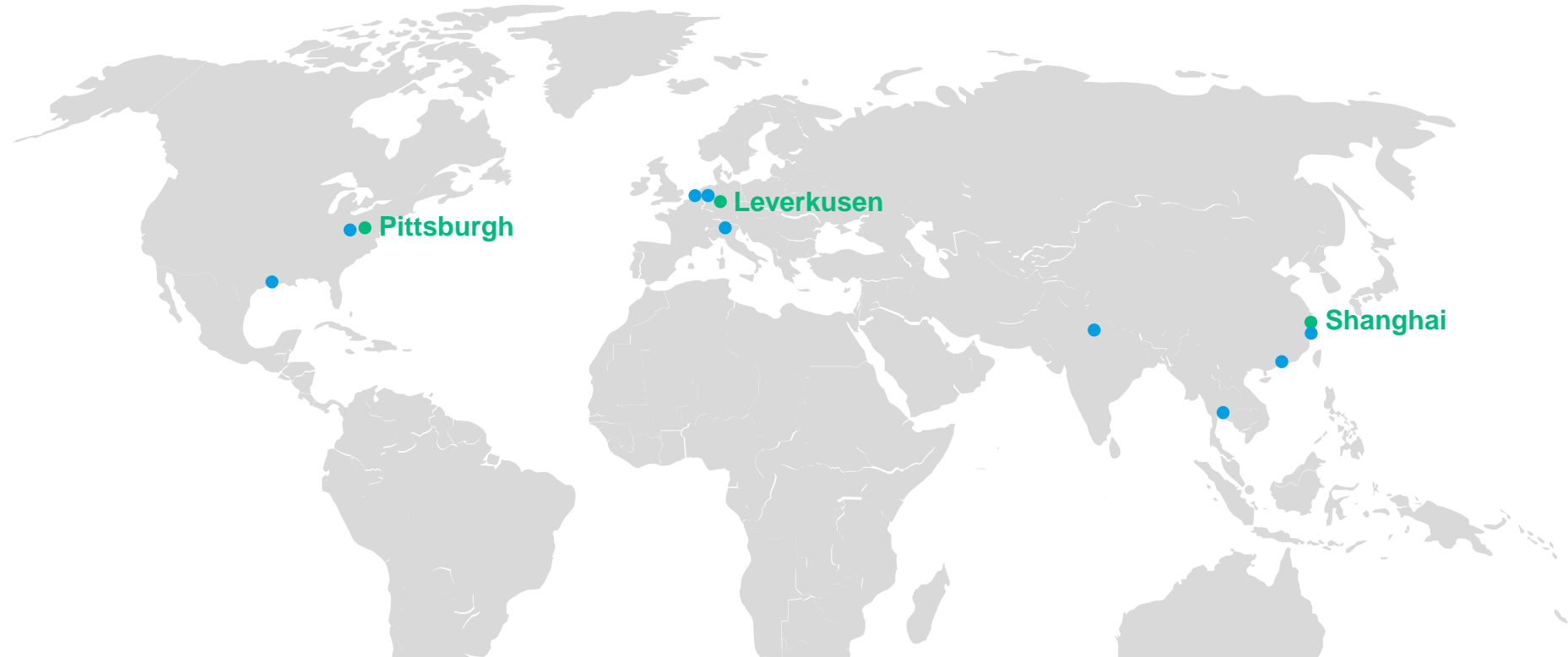
Notification of
change

FDA Device (MAF)
and Drug Master
File (DMF)
available upon
request

Manufactured at
ISO 9001 certified
sites that follow
GMP standards



You'll find us around the world ... and just around the corner



3
innovation hubs

9
production sites

We take pride in the **global consistency, quality and reliable supply** of our Healthcare polycarbonate materials

Customization available for a variety of opaque colors



Additional resources

New technical information is shared via our [Healthcare Polymers eNewsletter](#)



- Subscribe to the newsletter [here](#)
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- Click on 'Subscribe now'
- Enter your contact information
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Thank you for your participation!

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