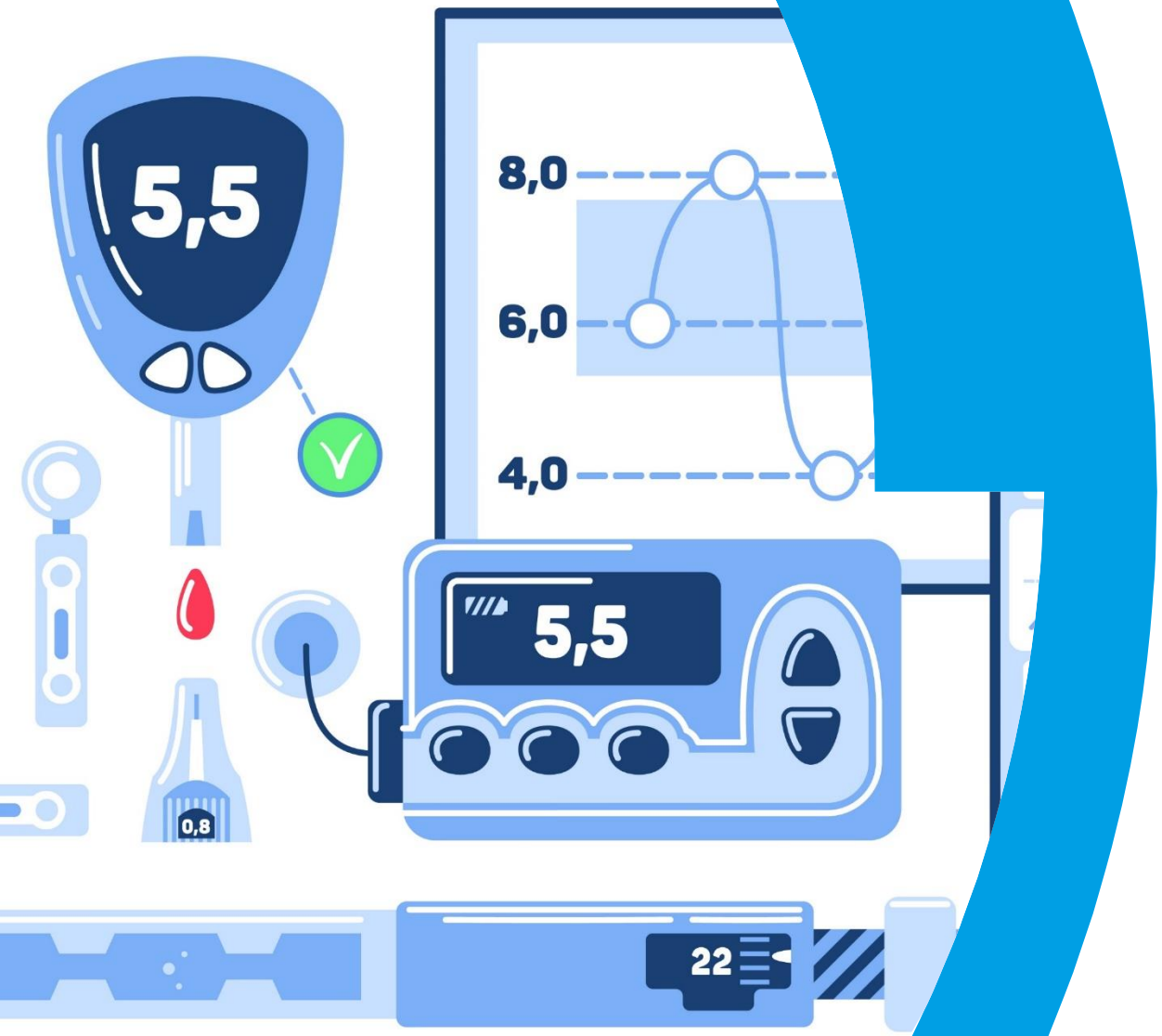

Advancing Medical Device Durability

Chemical-resistant polycarbonates in Healthcare

Introduction of our presenters...

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Covestro – leading in the world of plastics

Strong

- €14.2 bn in sales
- ~17,500 employees[1]

Useful

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

Global

- 46 production sites globally
- Close to customers and partners

Innovative

- ~1,300 employees in research and development
- 80 years[2] of ideas and inventions

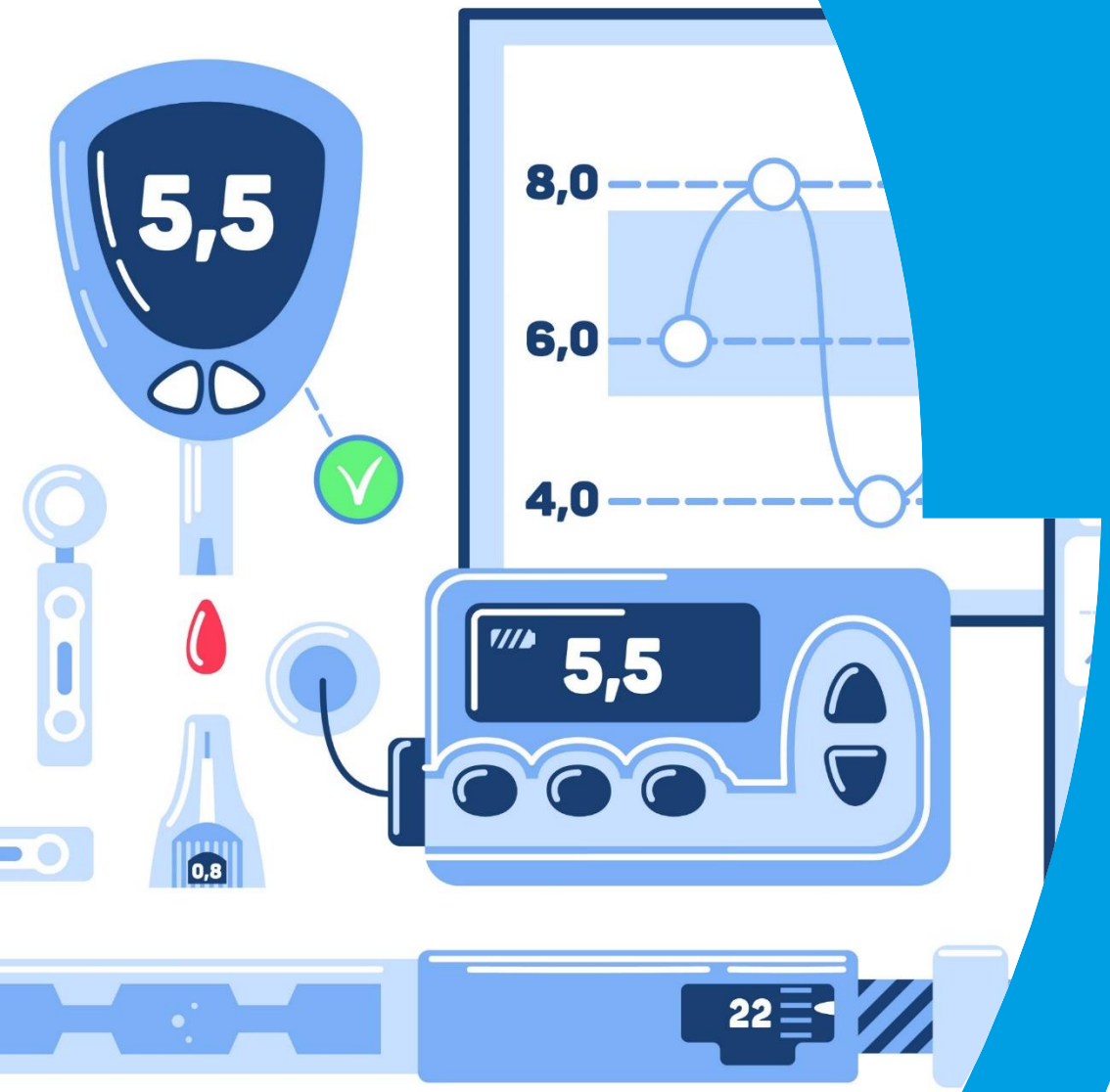
Information is based on financial results for 2024.
[1]calculated as full-time equivalent (FTE)
[2]including former legal entities

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

* Including former legal entities, for more details see History of Covestro | Covestro



Agenda

- Chemical resistance basics
- Testing parameters and material innovations
- Materials portfolio for healthcare devices
- Summary

Chemical attack on plastics

Basics

Examples of incompatible polymer-chemical interactions:

- **Solvation -** The chemical can dissolve the plastic
  - ABS plastic with Acetone
- **Plasticization -** Similar to solvation, but is present in small amounts
  - Polyethylene glycol with PLA
- **Chain scission (e.g. hydrolysis) -** The chemical can break bonds in the chain
  - Sodium hydroxide with polyesters or polycarbonates

Avoiding incompatible combinations is a first-line strategy

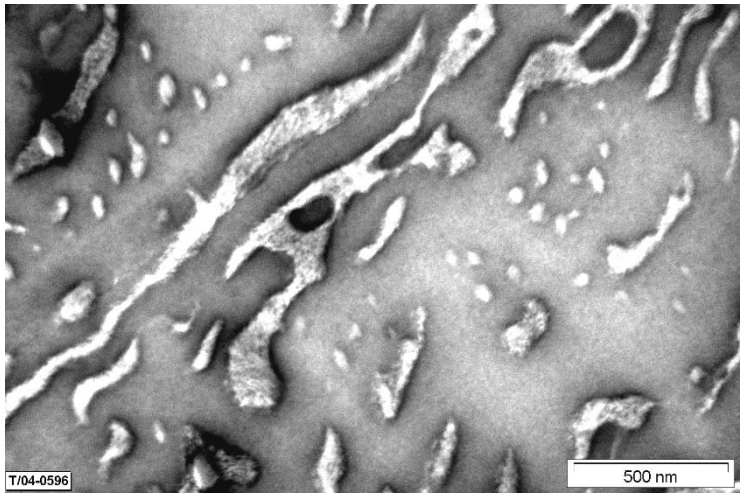
Choosing materials with better chemical resistance

Molecular weight

- Higher molecular weights deliver higher performance and better chemical resistance

Blends

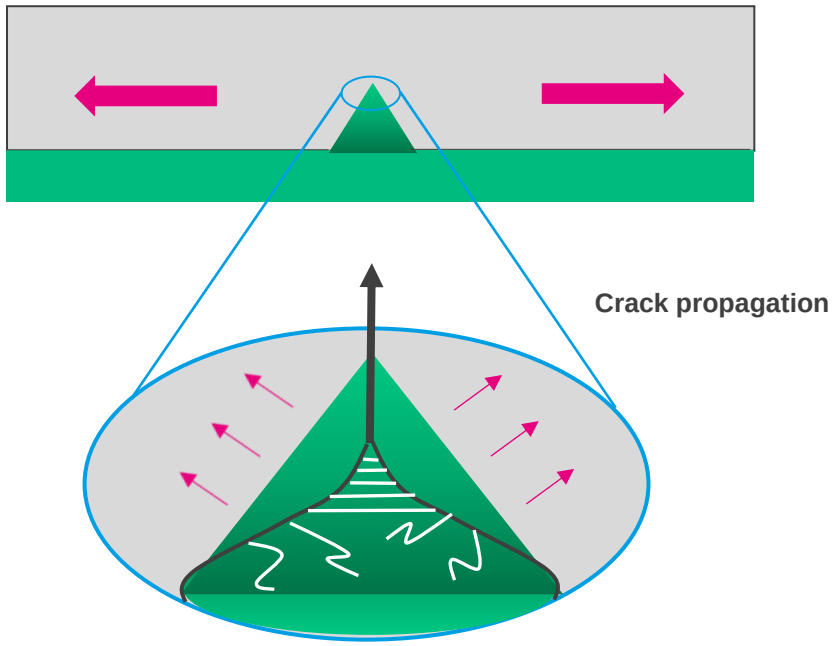
- Blending polycarbonate often brings benefits to chemical resistance
- PC+polyester provide synergistic combination of properties and chemical resistance through semi-crystallinity



Makroblend® PC+PBT

Understanding the importance of chemical resistance can help choose materials

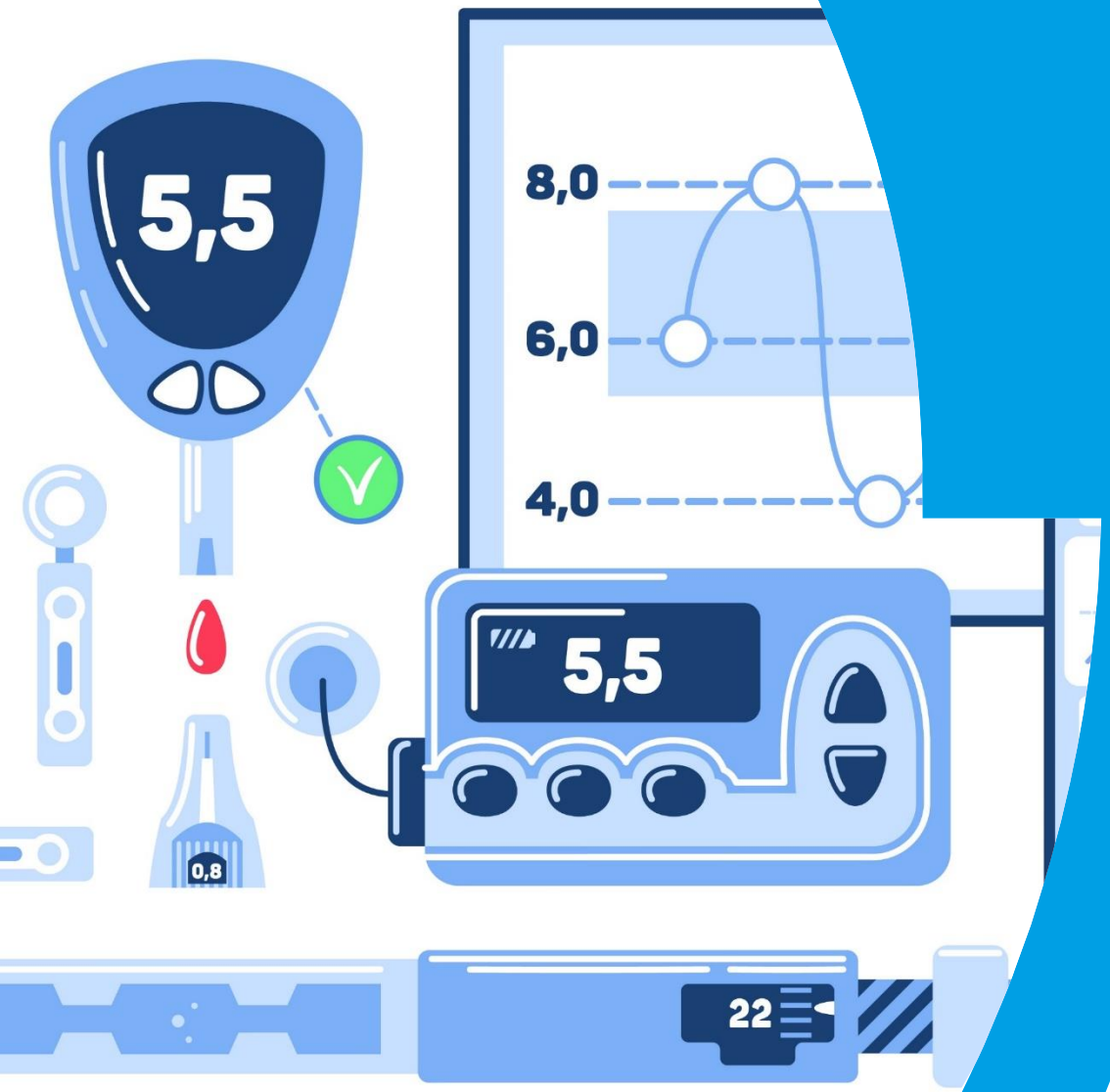
Chemical attack on plastics is accelerated by stress and voids



Optimize part and mold design

- Reduce molded-in stress via molding parameters and subsequent annealing
- Avoid application of external stress upon assembly
- Limit areas where chemicals may concentrate
  - Connection areas (e.g. seams, screw sockets)
  - Surface structures (e.g. cavities, pores)
  - Voids from sample preparation (e.g. notches)

Stress-reduction and prevention of voids significantly improves compatibility



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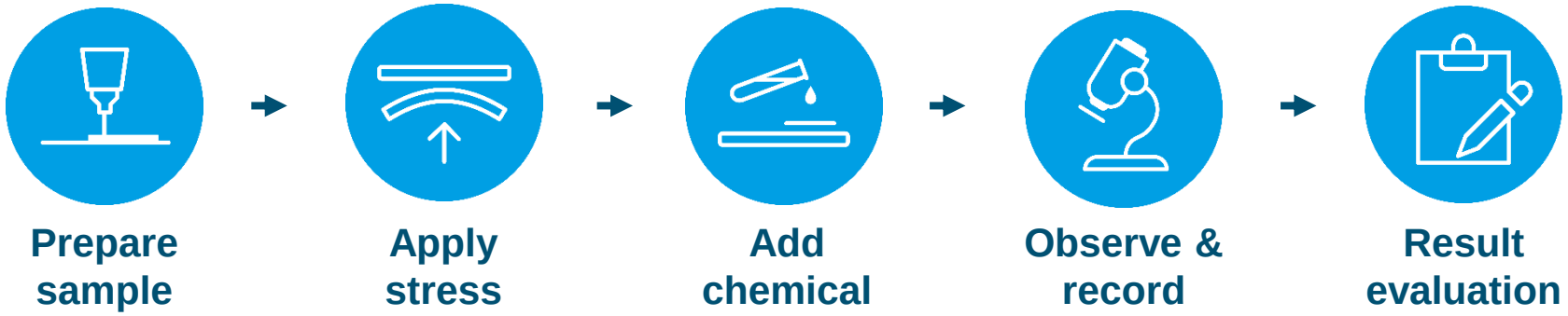
Testing for Environmental Stress Cracking (ESC)

Typical workflow



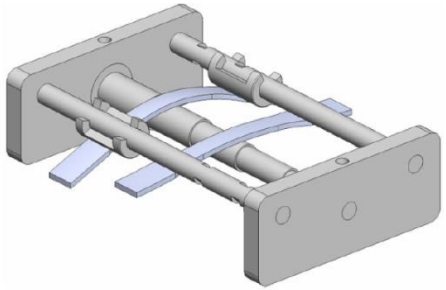
The ESC test workflow analyzes the impact of a certain chemical (disinfectant) to a material sample under applied stress.

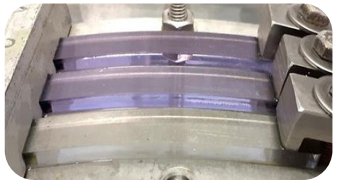
Application of defined conditions helps assess severity of attack, and compare material performances

Wiping versus immersion tests*

- Wiping better represents actual method of disinfecting housing materials
- Classical “immersion” test method with tensile bars on strain fixtures may miss cases where wiping gives worse results

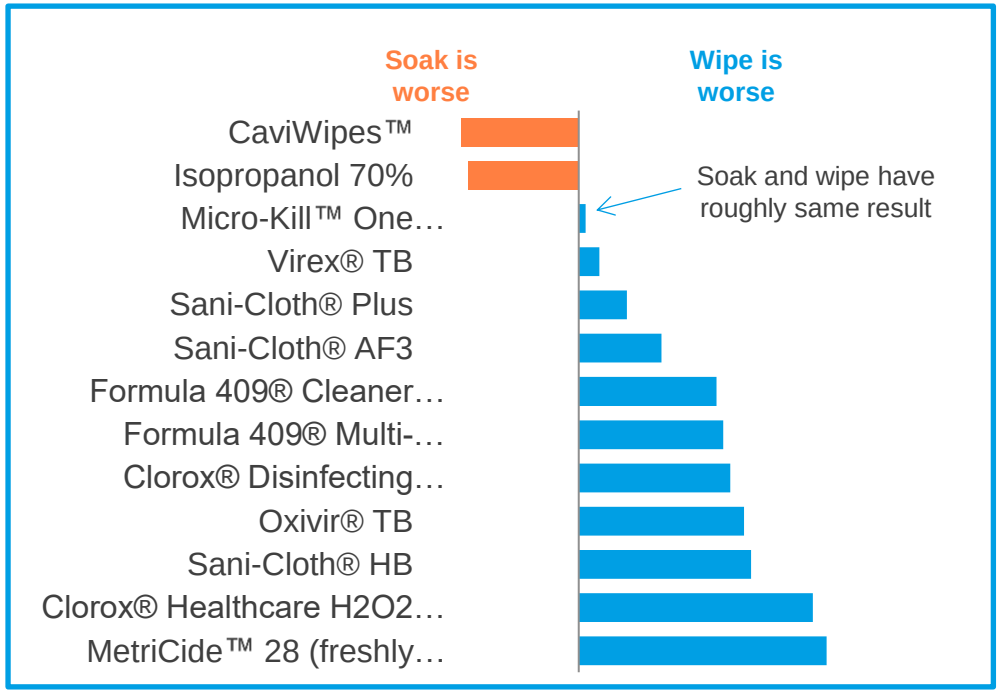
Tensile Bars / Strain Fixture





1% Strain
10x Wipe Cycles Over 24hr

Comparison of test results from wiping vs immersion test with various housing materials. Results based on property retention[1]



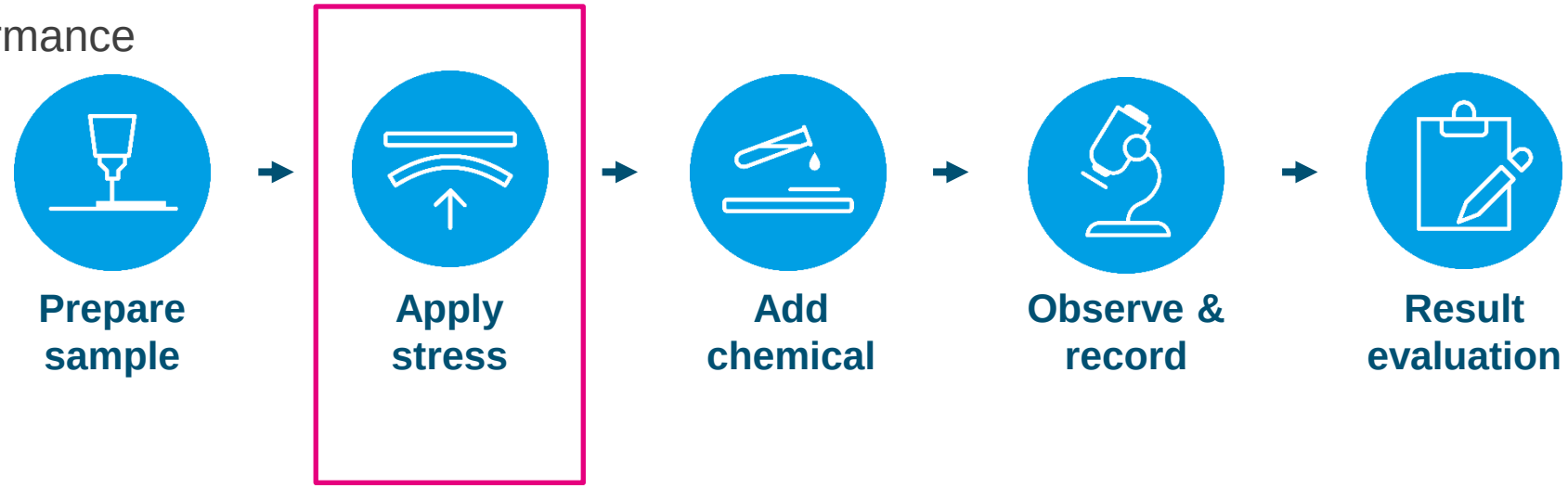
Choosing representative test criteria is essential

* source: “Chemical resistance testing of polycarbonates and blends with hospital disinfectants and cleaners “, P. Nowatzki, ANTEC 2020

Testing for Environmental Stress Cracking (ESC)

Application of stress / deformation can complicate comparison between materials:

- Rigid vs. soft materials
- Creep performance



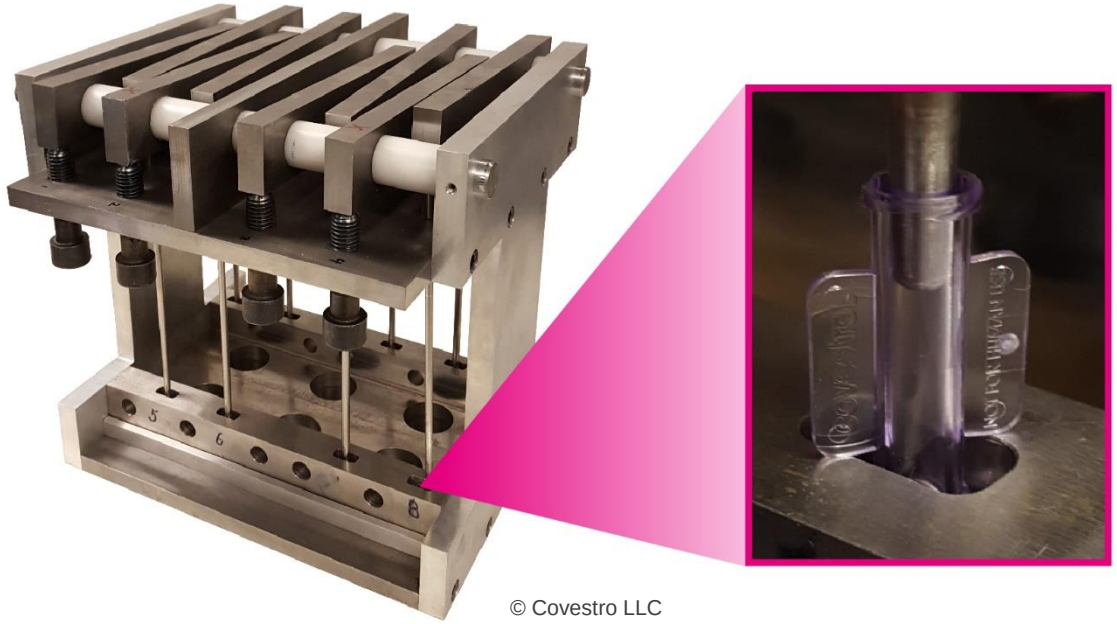
Adapting the test method to mimic the application helps identify better materials*

*based on Covestro internal test results

Test stand for IV access components*

Controlled strain testing for Luer connectors*

- Enables immersion testing of IV connectors under ***realistic loading conditions***
- Adjustable force allows ***accelerated testing***
- Capable of testing ***different geometries and sizes***



Customized, realistic tests support material innovation

*test stand for IV access components designed by Covestro

Makrolon® Rx3440 for better IV connectors

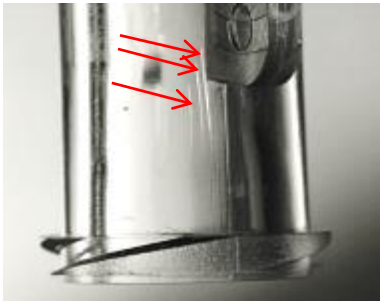
offers superior durability, reliable IV connections and oncology drug resistance*

Makrolon®

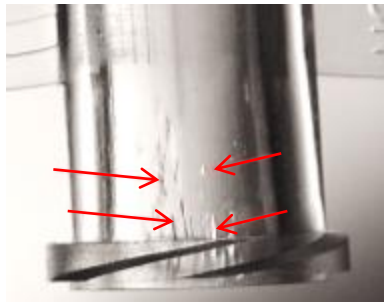
Solution	Makrolon® Rx3440	Makrolon® Rx1805	Copolyester	COC	SAN	PMMA
70% Isopropyl Alcohol	100%	88%	0%	13%	0%	0%
Etoposide simulant (Benzyl Alcohol)	94%	75%	0%	0%	0%	0%
Busulfex simulant (DMAc + PEG)	75%	63%	0%	75%	0%	0%
Taxol simulant (Castor Oil + IPA)	75%	69%	0%	0%	0%	0%

[Table displays passing percentage of female luers (no cracks) while being immersed in oncology drug simulant and subject to downward force]

Copolyester*



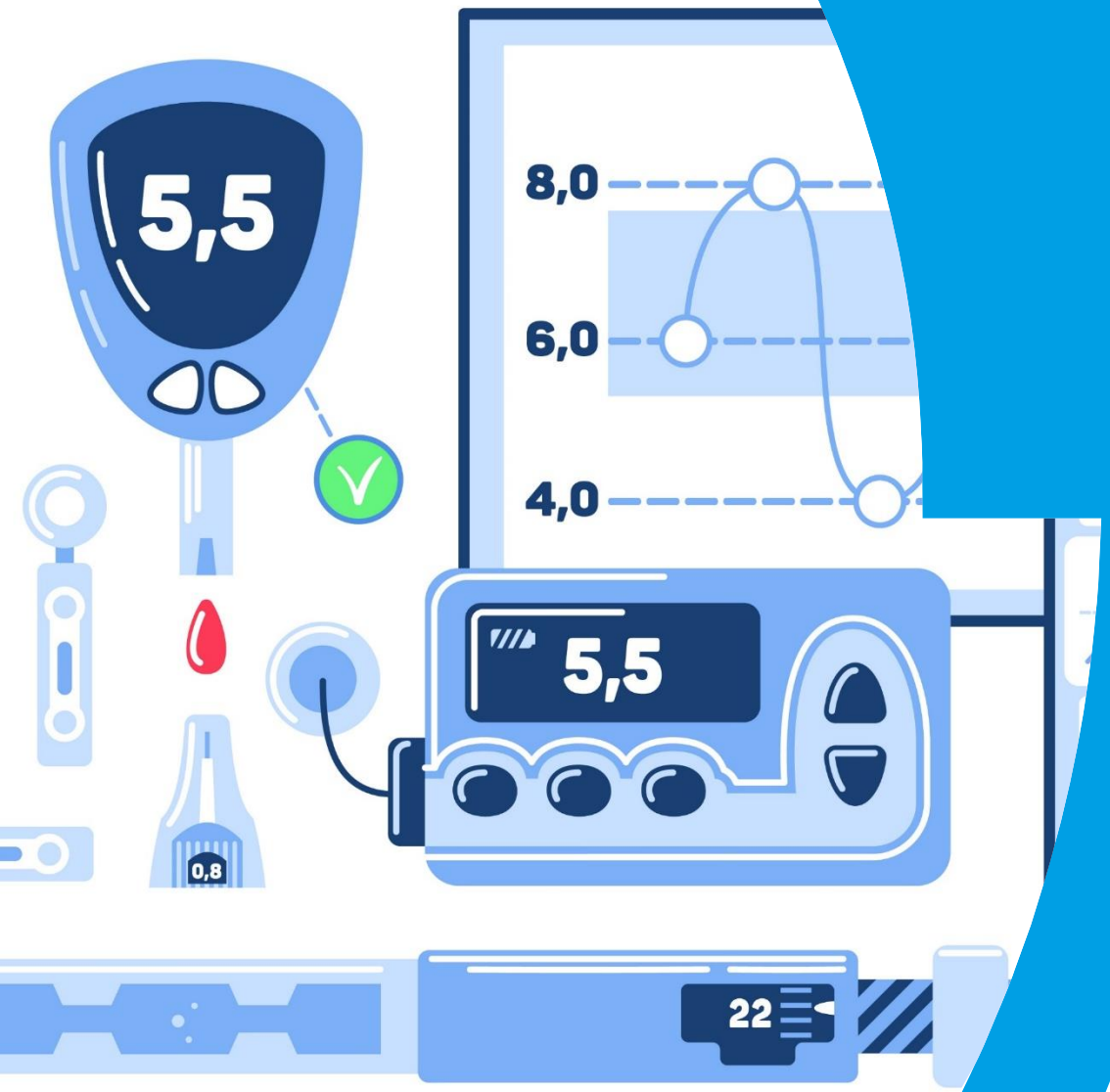
COC*



SAN*

PMMA*

*based on Covestro internal test results



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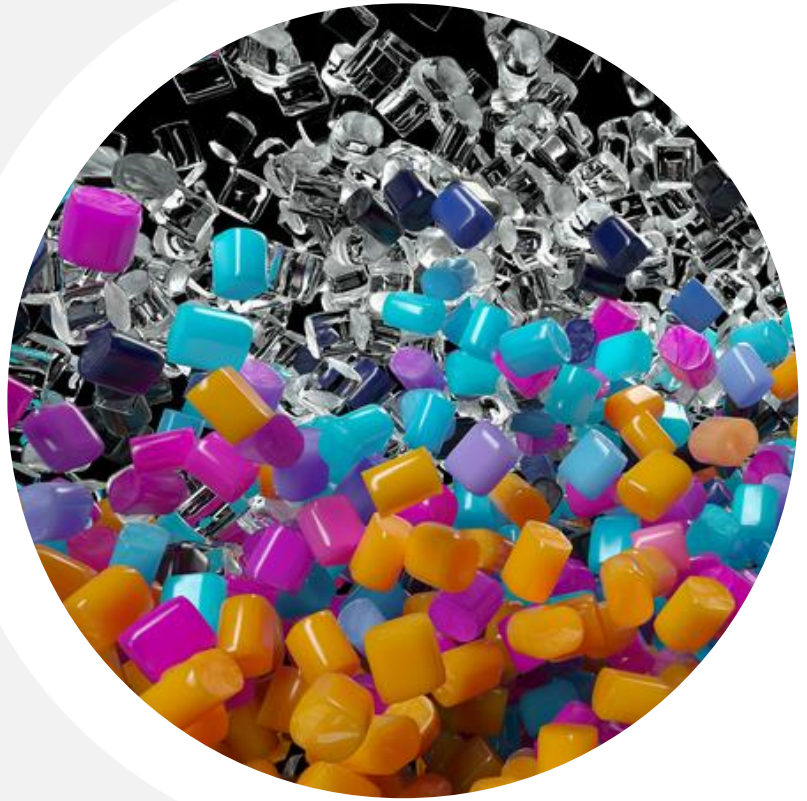
Covestro medical grades for healthcare applications

Makrolon®
polycarbonate (PC)

Bayblend®
PC+ABS

Makroblend®
PC+polyester

Apec®
Copolymers



Covestro medical grades and regulatory compliance

- Biocompatibility: ISO 10993-1 and USP Class VI for contact of 30 days or less
- Compliance to Regulation (EU) 2017/745 on medical devices and (EU) No 722/2012 regarding medical devices manufactured utilizing tissues of animal origin
- Maintenance of FDA Device (MAF) and Drug Master (DMF) File and provide letters of authorization
- Product stewardship
- Manufactured at ISO 9001 certified sites that follow GMP standards
- Supplier notification of change

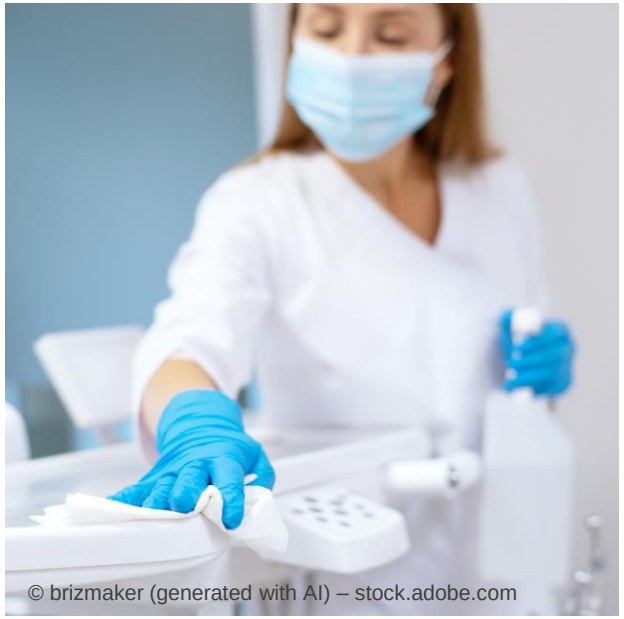
Value added services for medical devices

Drug delivery demonstrator device, photo and drawing, © Covestro Deutschland AG

Support from first drawings to mass-production

- Utilize our machine lab for design, engineering, tooling and processing support
- CAE tools for design and analysis
- Data for advanced simulations and digital design

Medical devices increasingly require more durability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Addressing HAIs

Hospitals adopting increased disinfection protocols


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Treatments for cancer

Oncology drugs can contain aggressive solvents


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Everyday use

Wearable and reusable devices need to withstand everyday lives

Selection of Covestro grades for medical devices

Transparent

	Makrolon® 2458	Makrolon® 2858	Makrolon® Rx3440
Izod notched impact strength (23°C) [kJ/m²]	65	85	80
Flow behavior	High flow	Medium	Low
Linear thermal expansion (23 to 55°C) [10^{-4}/K]	0.65	0.65	0.65
Chemical resistance	★	★★	★★★
UL 94 Rating	V2 @<2.6 mm	V2 @ <2.4 mm	HB @ 0.75 mm
Transparency	Yes	Yes	Yes
Biocompatibility	Full	Full	Full

Source: Covestro data and measurements, please refer to Covestro technical data sheets for more information

Selection of Covestro grades for medical devices

Opaque, Non-FR

new

	Bayblend® M850 XF	Makroblend® M325	Makroblend® M525
Izod notched impact strength (23°C) [kJ/m²]	48	11	60
Flow behavior	High flow	High flow	Medium
Linear thermal expansion (23 to 55°C) [10^{-4}/K]	0.7	0.9	0.9
Chemical resistance	★	★★★	★★★
UL 94 Rating	HB @ 0.85 mm	TBD	HB @ 1.5 mm
Transparency	No	No	No
Biocompatibility	Full	Skin contact	Skin contact

Source: Covestro data and measurements, please refer to Covestro technical data sheets for more information

Makroblend® - For long service time and reusability

new

Makroblend® M325

Excellent **resistance to** many commonly used **chemicals**

Balanced flowability and toughness for **thin-wall applications**

Biocompatibility for skin contact (ISO 10993-5/-10)

Durability: long-term performance over a wide temperature range

graphics: © Emma / MonoPixel – stock.adobe.com

Selection of Covestro grades for medical devices

FR

	Bayblend® M301 FR	Makroblend® M4000 FR	Makroblend® M5005 FR	Makrolon® M6011 FR
Izod notched impact strength (23°C) [kJ/m²]	35	>30	45	70
Flow behavior	High flow	High flow	High flow	Medium
Linear thermal expansion (23 to 55°C) [10^{-4}/K]	0.76 – 0.8	0.9	0.9	0.65
Chemical resistance	★★	★★★	★★★	★★★
UL 94 Rating	V-0 @ 1.5 mm	V-0 @ 2.0 mm	V-0 @ 2.4 mm	V-0 @ 1.5 mm
Transparency	No	No	No	No
Biocompatibility	Skin contact	Skin contact	Skin contact	Skin contact

Source: Covestro data and measurements, please refer to Covestro technical data sheets for more information

Makrolon® M6011 FR – Chemical-resistance and additional FR

Makrolon® M6011 FR offers superior chemical resistance against daily chemicals, next generation flame retardancy, skin contact biocompatibility and global availability

- Izod notched impact strength of 70 kJ/m²
- V-0 in UL 94 test at 1.5mm wall thickness
- Dimensional stability: Low and isotropic CLTE

  (coefficient of linear thermal expansion)

The way towards a circular and climate neutral future

Climate neutrality as objective: Scope 1 & 2 by 2035

Net zero[1] by 2035

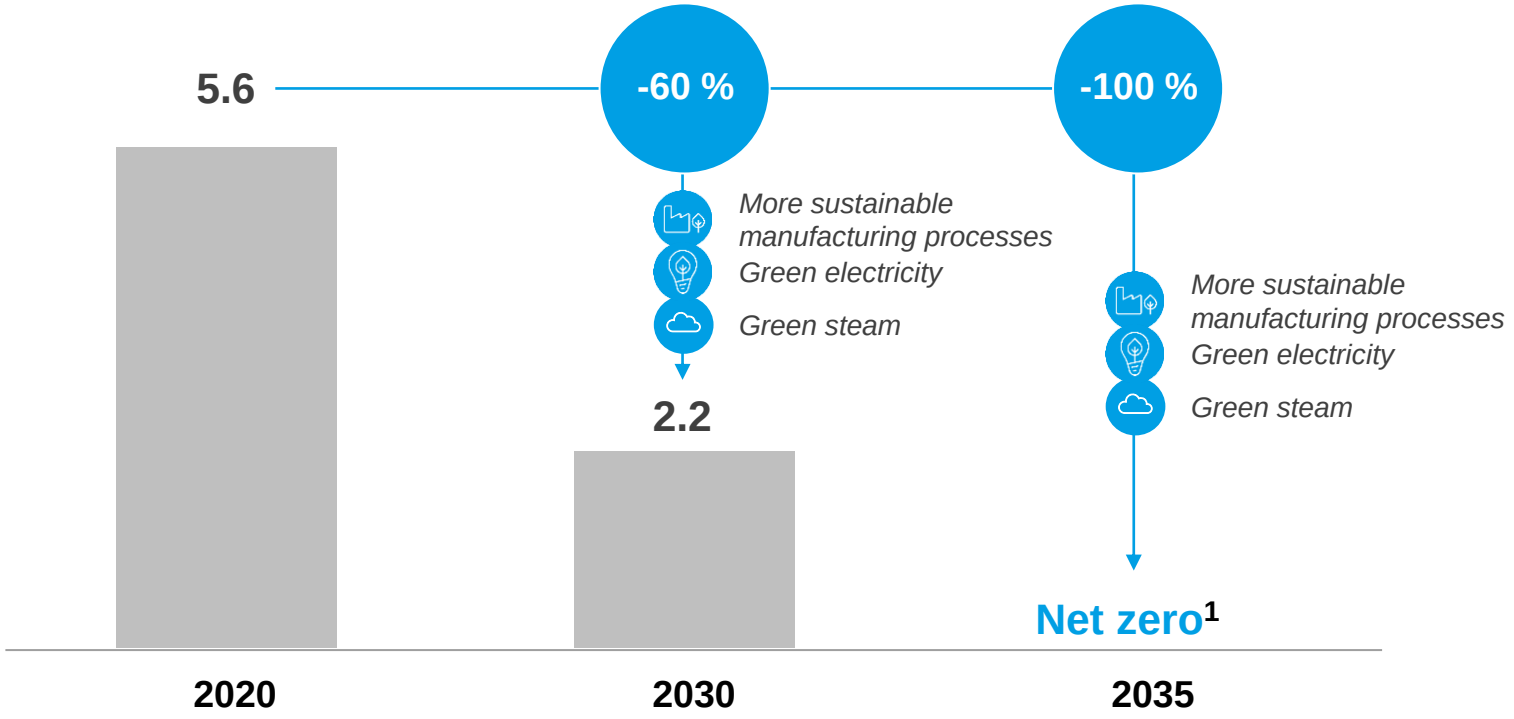
By 2035, Covestro aims for net zero for our own emissions (scope 1) and external energy sources (scope 2)

Three key levers for reduction:

- More sustainable manufacturing processes
- Green electricity
- Green steam

All efforts contribute towards the 1.5°C goal of the Paris Climate Agreement

Greenhouse gas emissions in million t, scope 1 and 2



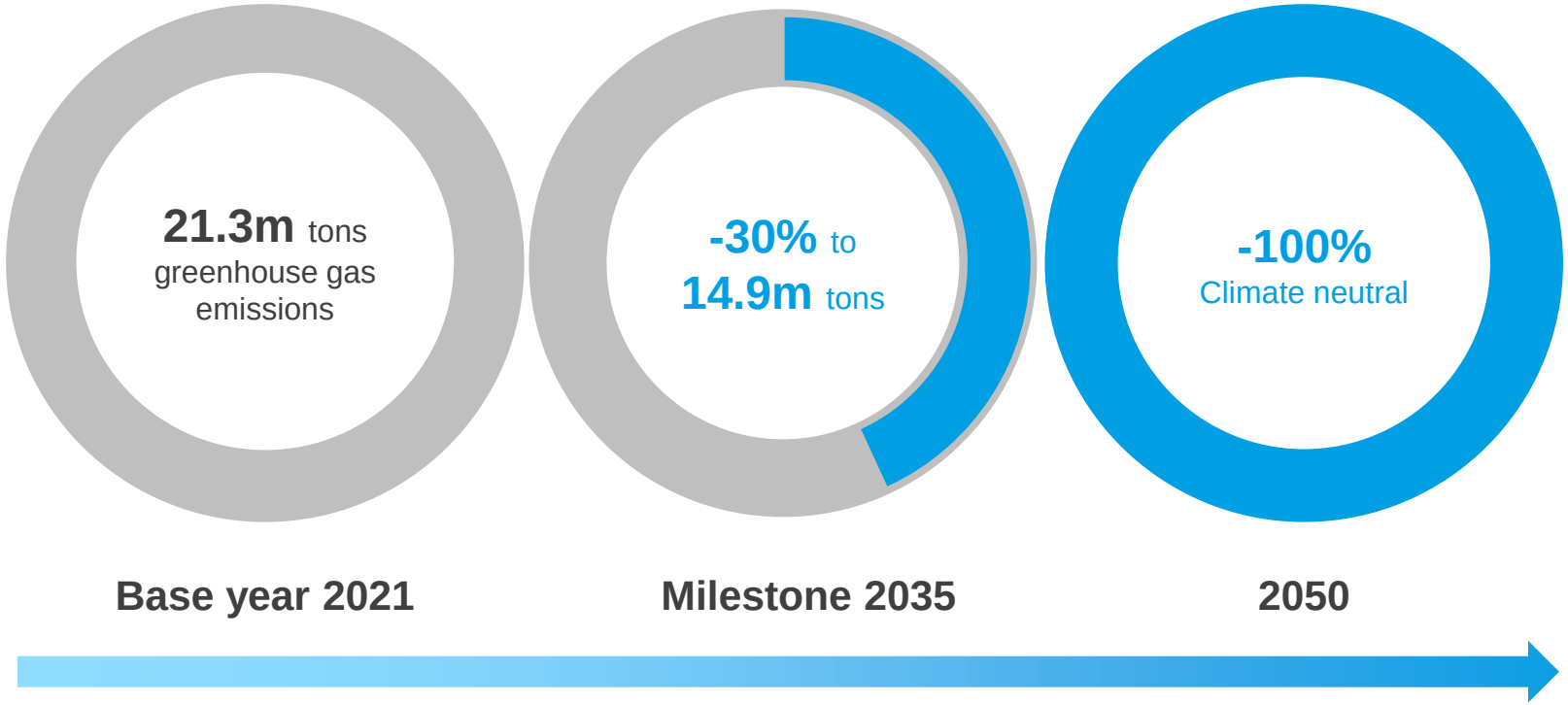
[1] Achieving net zero greenhouse gas emissions is defined as a balance between anthropogenic emissions (from own operations and energy procurement) and anthropogenic removals of greenhouse gases.

Climate neutrality as objective: Scope 3 by 2050

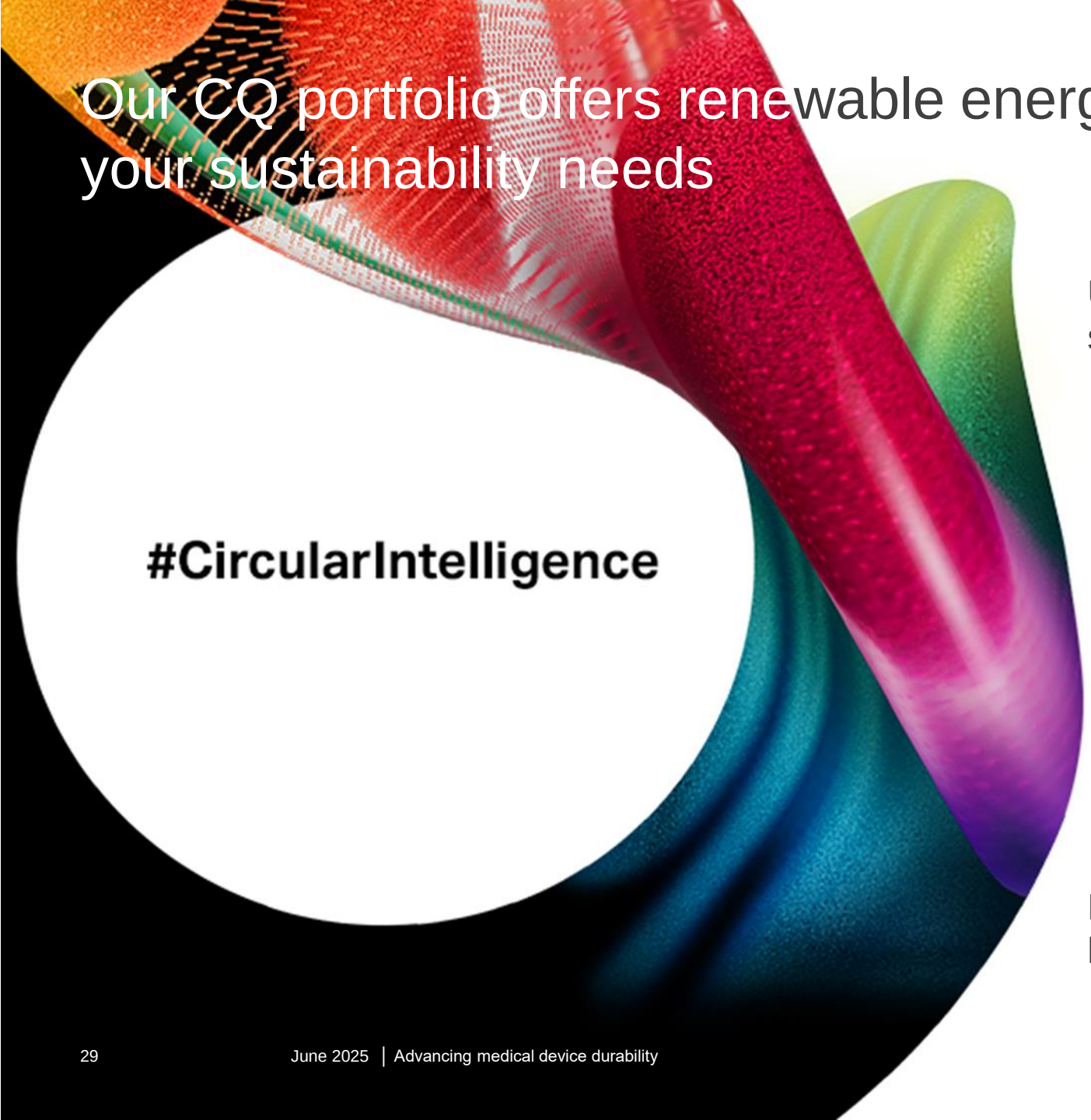
By 2050, Covestro aims for net zero emissions upstream and downstream in the value chain, so called scope 3 emissions.

Four levers for reduction:

- Suppliers reduce their scope 1- and scope 2-emissions
- Selling products made from alternative raw materials
- Advancing investments projects (MAKE projects)
- A large number of different factors as a fourth lever



Our CQ portfolio offers renewable energy solutions tailored to your sustainability needs

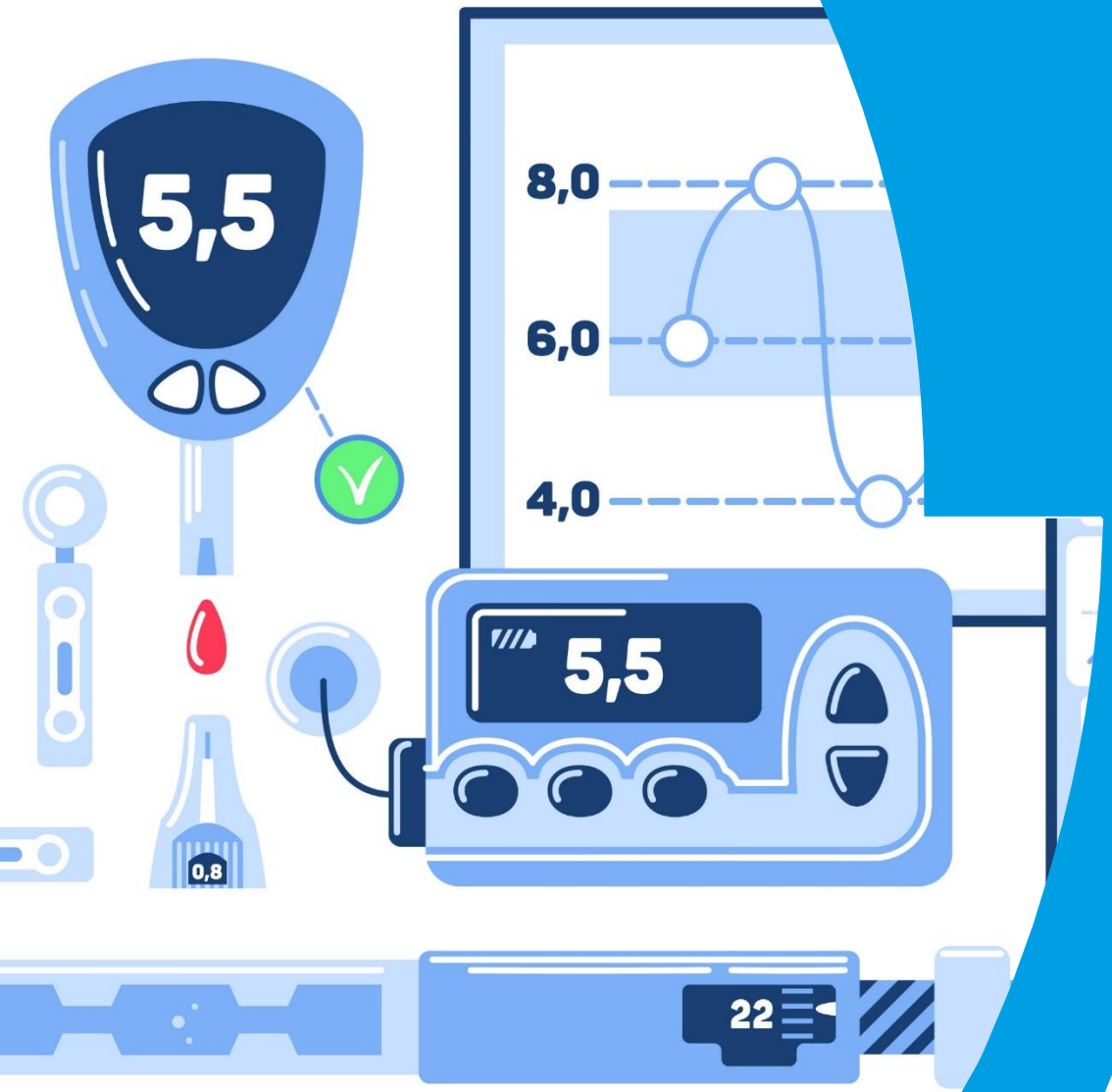


Using a mass-balance approach*, we provide sustainable alternatives across all products

- **Makrolon® RE**
- **Bayblend® RE**
- **Makroblend® RE**
- **Apec® RE**

Helping achieve climate goals while maintaining highest quality standards of Covestro.

* According to ISCC plus



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Summary

Proper selection of material, process, and disinfectants is key to meet chemical resistance requirements of an application

- Our **Application Development** team provides support

Tailored polycarbonate materials offer well-balanced properties for many healthcare devices featuring impact strength and chemical resistance:

- **Makrolon® Rx3440** for IV access components
- **Makrolon® M6011 FR** and **Makroblend® M5005 FR** for durable device housings requiring additional FR
- **Makroblend® M325** for reusable device housings


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Thank you for your attention

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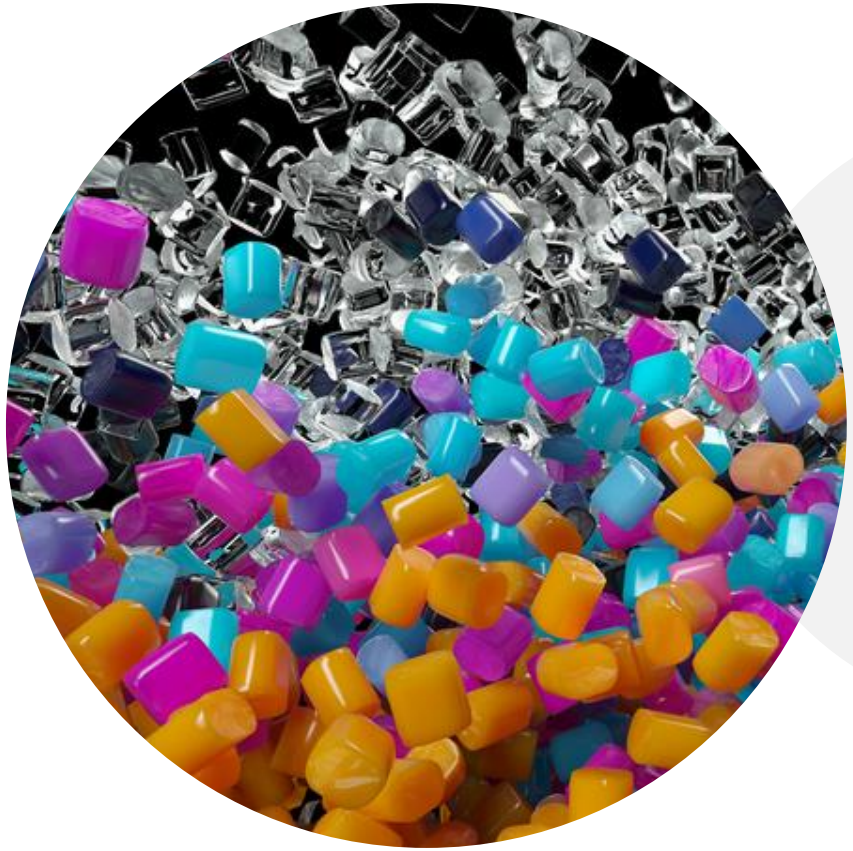

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