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Trends, material properties, and overmolding

What you need to know about TPEs for medical devices

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Aldo Zanetti— Trinseo, Business Unit Manager TPEs for Medical

Aldo Zanetti

- Trinseo business unit manager for Trinseo' s TPE products for the medical devices industry
- Involved with thermoplastics for more than 15 years.
- Experience includes compounding, packaging, and the pharmaceutical fields.
- Today works with some of the largest global OEMs in the medical and personal and baby care sectors.
- He graduated from Padua University with a MSc degree in Chemical Engineering in 1997 and graduated from the Judge Business School with a Cambridge MBA in 2006.

Agenda

- Marketplace Trends
- TPE Chemistries
- Measuring Performance
- Application & Material Types
- Overmolding Process
  - Strength
  - Measurement
  - Trouble Shooting
- Summary & Conclusion

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Trinseo and Medical Devices

- Support for the industry for nearly three decades
- Application areas: Single and Multiple Use Devices, Equipment Housings, Drug Delivery Devices, Medical Wearables
- Focused on quality and compliancy with regulatory
- requirements
- Adhere to cGMP and hold ISO 13485 certification

Trinseo and TPEs

- **Acquired Italian manufacturer API in 2017**
  - Company focused on the development and production of customized TPE compounds
  - Established in 1956
  - Broad, global customer base
- **Grew the Trinseo plastics portfolio to include soft touch plastics to complement our rigid plastics portfolio**

Global Resources

“Sometimes a Rigid Plastic Needs a Soft Touch”

Manufactured for Being Human.

Patient-Friendly Products

Drivers of Patient-Friendly Devices

Home Healthcare

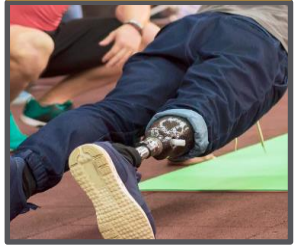
Self Treatment

FDA Guidance

Aging Population

Kid Friendly Needs

Active Disabled



Aging Population

- Need for user-friendly devices
  - Soft touch grips, or again, a user-friendly design and material enable proper use
  - Mobility, flexibility and agility are concerns

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Home Health Care

- Need for user-friendly devices
  - soft touch grips, or again, a user-friendly design and material enable proper use
  - mobility, flexibility and agility are concerns

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Active Disabled Population

- Innovations in mobility lead to active lifestyles
  - they now need to self administer and the goal is to make it easier, e.g., asthma inhalers or epi pens

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Self-Administration of Drugs

- Growth in Drug Delivery Devices
  - where devices need to be user friendly, e.g., a non slip grip or a design and material that provides helps a patient administer a treatment

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Kid-Friendly Needs

- Growth in Childhood Ailments
  - they now need to self administer and the goal is to make it easier, e.g., asthma inhalers or epi pens

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FDA Usability Guidance

- Need for patient-friendly devices
  - In 2016 the Food and Drug Administration in the US issued a Usability guidance document for Medical Device manufacturers which discusses how devices should be designed in such a way that they can be used safely, the treatment is effective, and there's no adverse impact from use, immediate or long term

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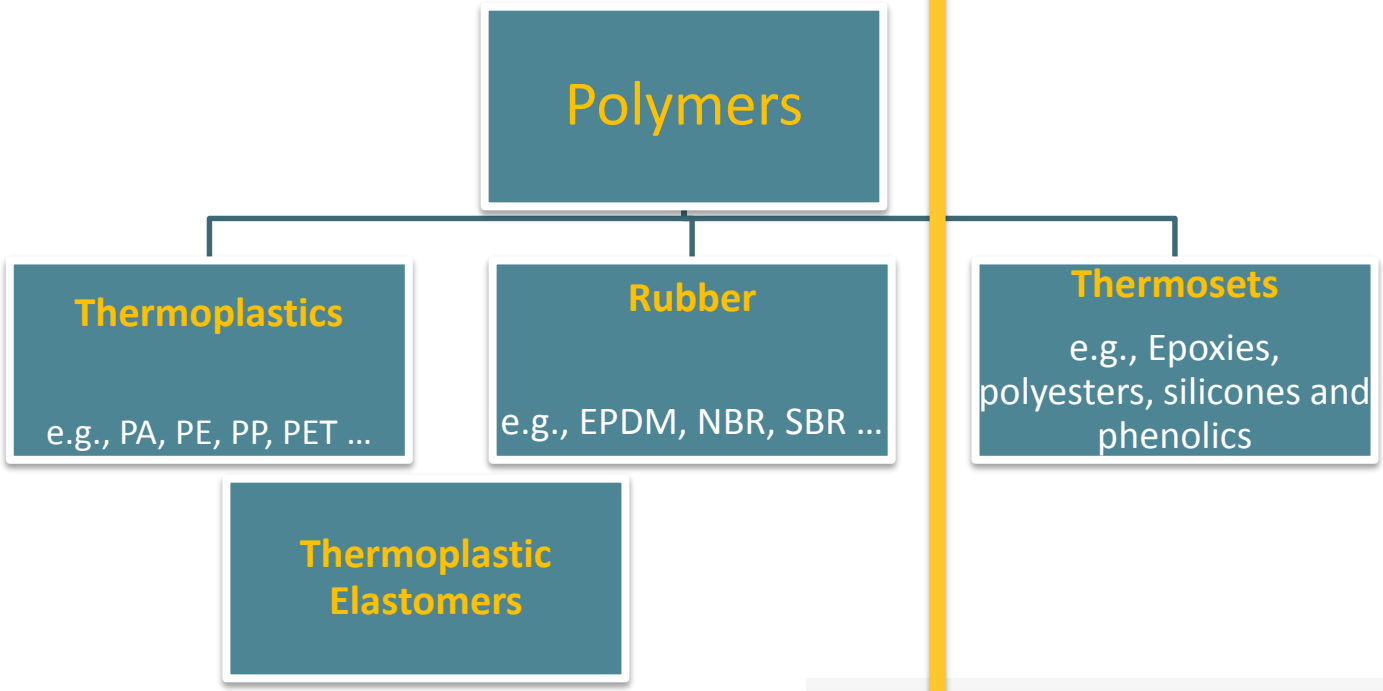
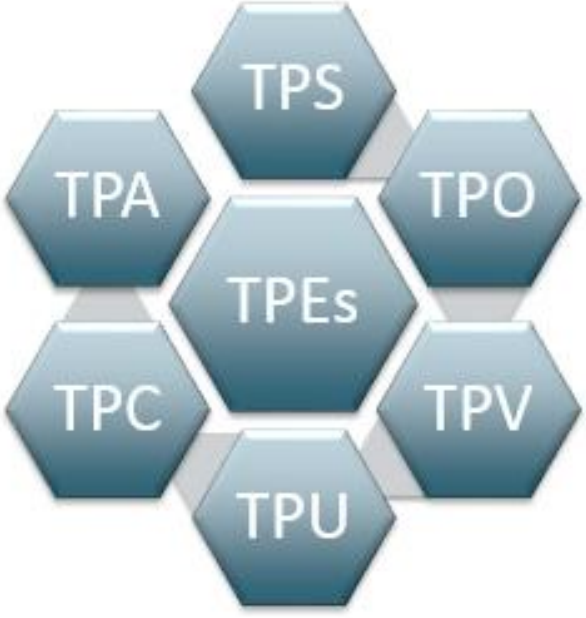
TPE Chemistries

Where TPEs Fit In

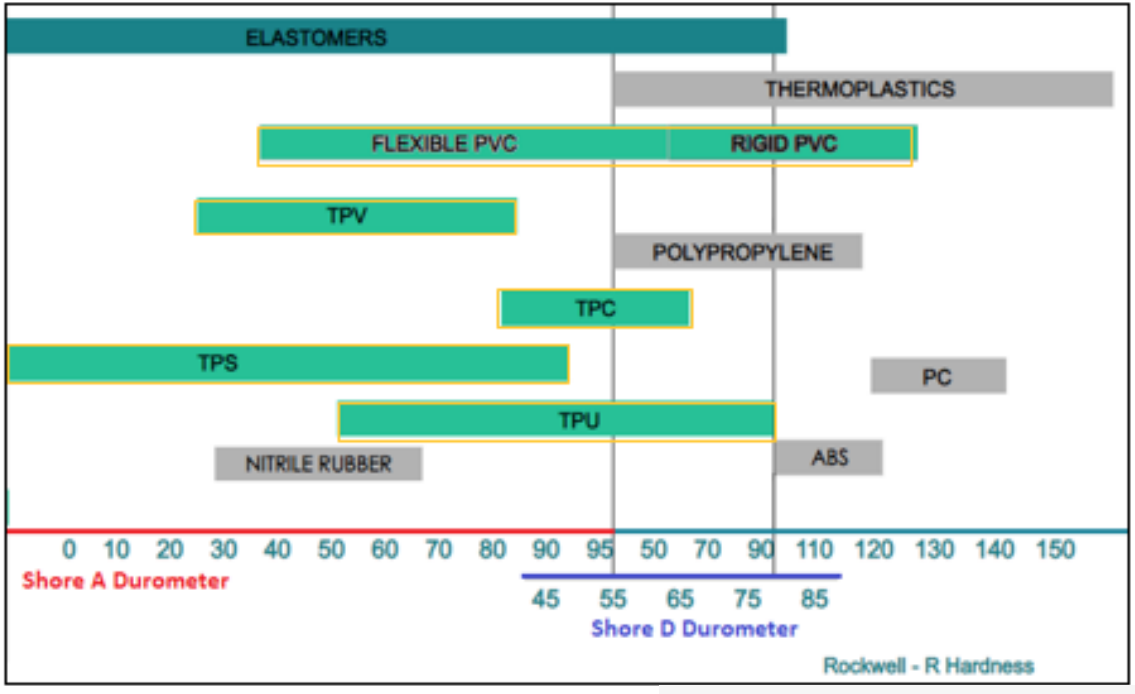


Six Thermoplastic Elastomer (TPE) Chemistries



- Materials are used for injection molding, extrusion, soft touch overlays and semi-rigid applications
- The TPE material used in overmolding applications depends on the rigid material substrate:
  - Non polar (PP)
  - Polar (PC, PC/ABS, ABS)
- Key metrics in TPEs:
  - Hardness – measured by a Shore durometer
  - Adhesion strength – measured in N/mm

Performance Comparison



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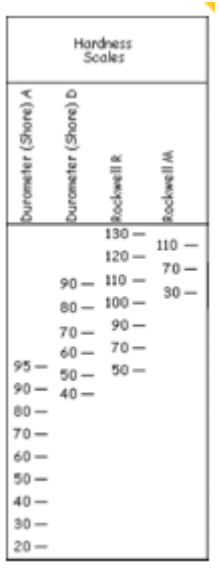
Measuring Performance In the Lab

Hardness

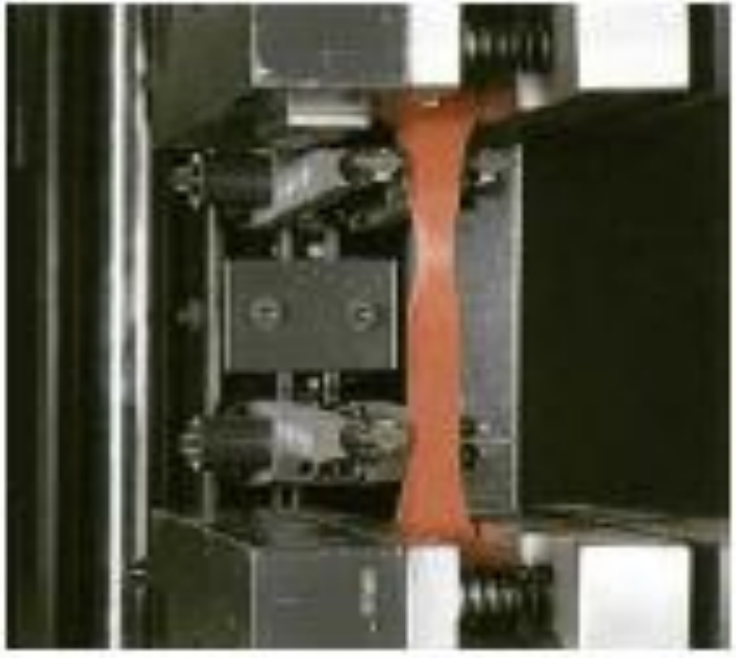
- Hardness acc. to ASTM D2240 (DIN 53457 / ISO 868)
  - Either Shore A or Shore D
    0 = total penetration / 100 = no penetration



Durometer	Use	Indentor
A	Used for softer materials.	1.25 mm, 35°, 0.79 mm
D	Used for harder materials.	1.25 mm, 30°, 0.1 mm Radius

Tensile

- Tensile acc. to ASTM D638 (ISO 527-2)
  - Ey = f (ε) - ε = 100% and 300% (MPa)
  - σ @ rupture (MPa)
  - ε @ rupture (MPa)



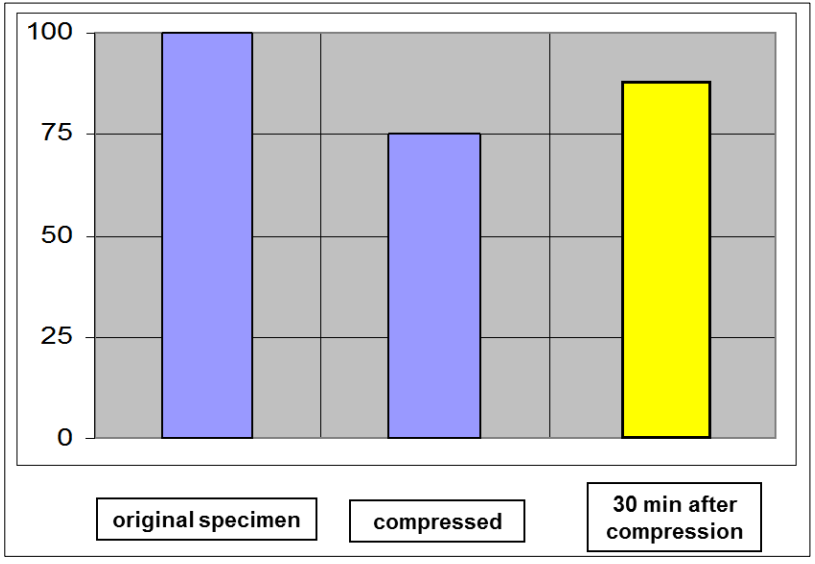
Compression Set

- Two methodologies **A** and **B** according to ASTM
  - **A** = compression set under **constant force**

    (1.8KN) - $C_A = [(t0 - ti) / t0] * 100$

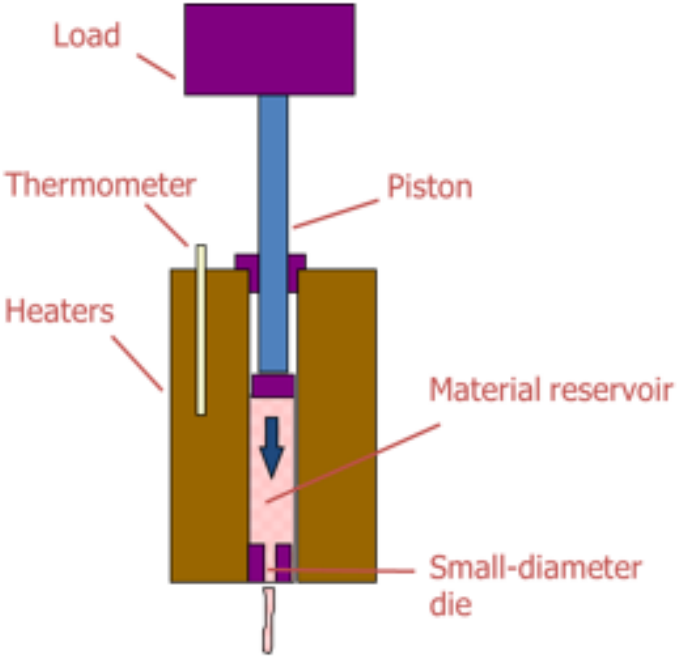
  - **B** = compression set under **constant deflection**

    (25%) - $C_B = [(t0 - ti) / (t0 - tn)] * 100$



Melt Flow Rate

- Melt ***F***low Rate (MFR) or Melt ***V***olume Rate (MVR) acc. to ASTMD1238 (ISO 1133)
  - The testing conditions are most commonly reported as temperature/load (i.e. 190°C/2.16 kg) reported in g/10mn



Abrasion Test

- Abrasion Resistance (Rotary Drum Abrader) acc. to DIN 53516 (ISO 4649)
  - Applying coarse paper to a substrate under pressure via a rotating cylinder.
  - The specimen weight is measured before and after.
  - Results typically expressed in terms of volume loss of the substrate in mm^3.

A Quick Glance Reference

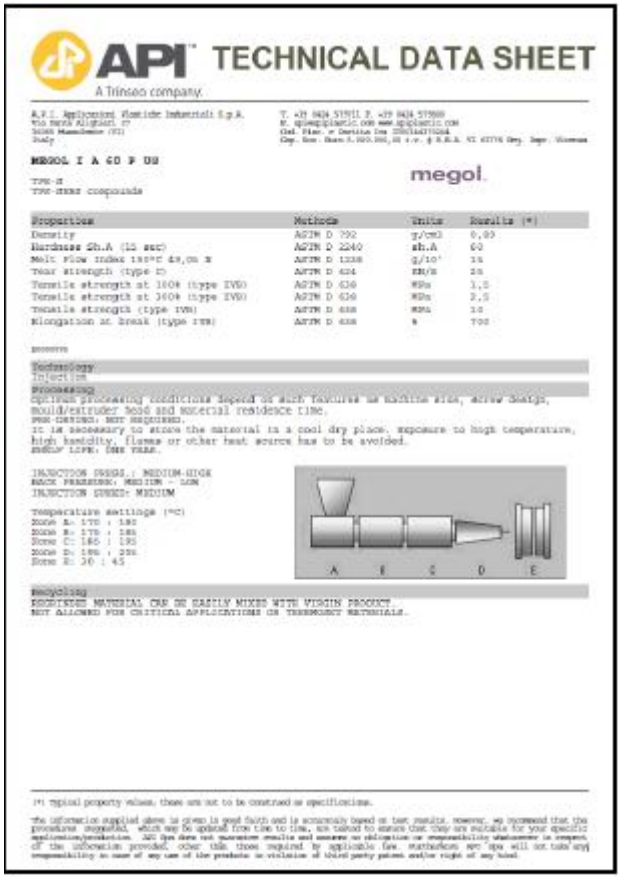
Technical Data Sheet

MEGOL I A 60 P UG

megol

TPE-S
TPS-SEBS compounds

Properties	Methods	Units	Results (*)
Density	ASTM D792	g/cc	0,89
Hardness Sh.A (15 sec)	ASTM D2240	sh.A	60
Melt flow index 190°C 49.05N	ASTM D1238	g/10'	15
Tear strength (type C)	ASTM D624	KN/m	25
Tensile strength at 100% (type IVB)	ASTM D638	MPa	1,5
Tensile strength at 300% (type IVB)	ASTM D638	MPa	2,5
Tensile strength (type IVB)	ASTM D638	MPa	10
Elongation at break (type IVB)	ASTM D638	%	700



Applications and Material Types

Application Examples

TPEs can be used in applications alone or over-molded using co-injection or insert-molding technology.

Surgical Tool Handle

Soft Closure Caps

Medical Patches

Equipment Housings

Infusion Drip Chambers

Drug Delivery Devices

Oxygen Masks and Nebulizers

Wearable Health and Fitness Trackers

Resin classifications

- Food Contact Grades

- Skin Contact Grade (SK)

- Medical Grades (MED)

Food Contact

- No biocompatibility testing
- cGMP compliant
- Regional food contact compliance

Skin Contact Grades

-Limited ISO 10993 biocompatibility tests

-cGMP compliant

MED Grades

-Full battery of ISO 10993 biocompatibility tests

-cGMP compliant

-Extended MED NOC

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Overmolding

Overmolding

What is it?

Plastic overmolding is a process in which a thermoplastic elastomer is molded over another material to form one part.

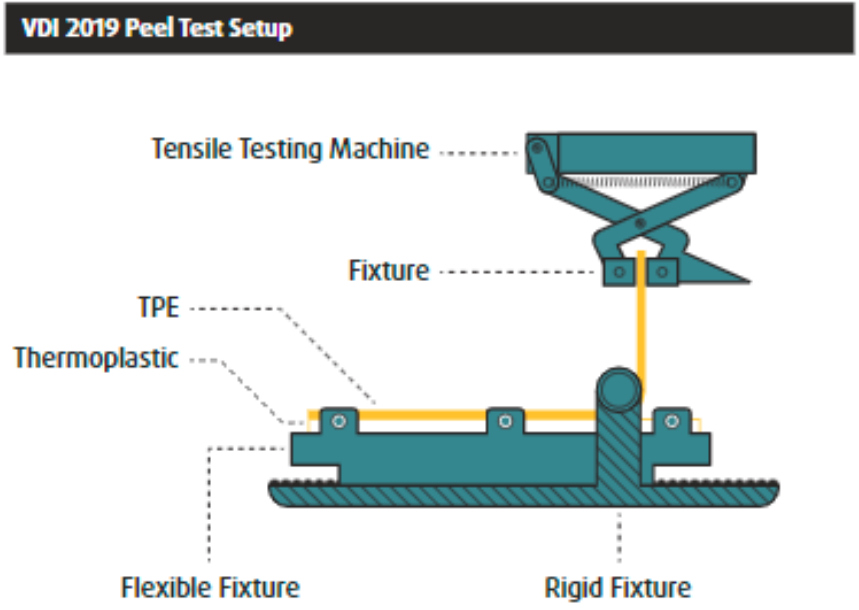
Why is it Important?

Plastic overmolding technology is employed for a wide range of **aesthetic and functional** purposes in many industries and applications, such as Medical Devices, Appliances, Electronics, Consumer, and Automotive products and components.

Adhesion: A Physical Blending Process

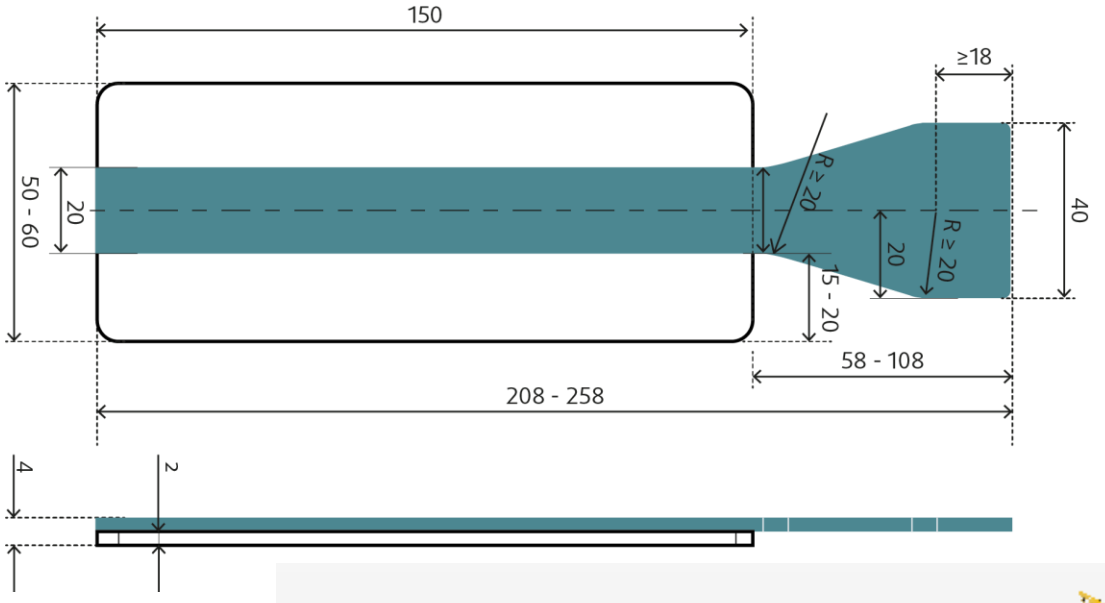
The VDI Standard

- The VDI 2019 standard measures the adhesion between materials. API was part of the team of engineers that developed this global standard that is now used cross industry
- Focused on developing, designing, and processing TPEs and rigid plastics in overmolding and measuring adhesion (N/mm)



Peeling Test

- To define and describe consistently the bond strength between a TPE and a thermoplastic rigid substrate
- To offer a systematic peeling test procedure
- To standardize data reporting
- The peel strength is in N/mm followed by one or two letters indicating the peeling behavior



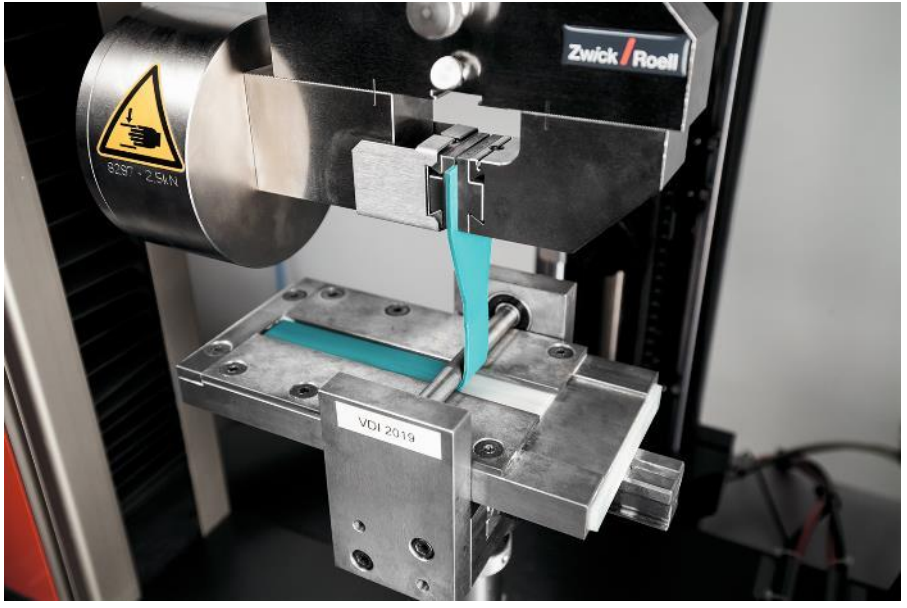
Two Main Types of Failures

Adhesive failure

The TPE peels from the substrate (Material Strength > Peel Strength).

Cohesive failure

The TPE material breaks before it peels from the substrate (Material Strength < Peel Strength).



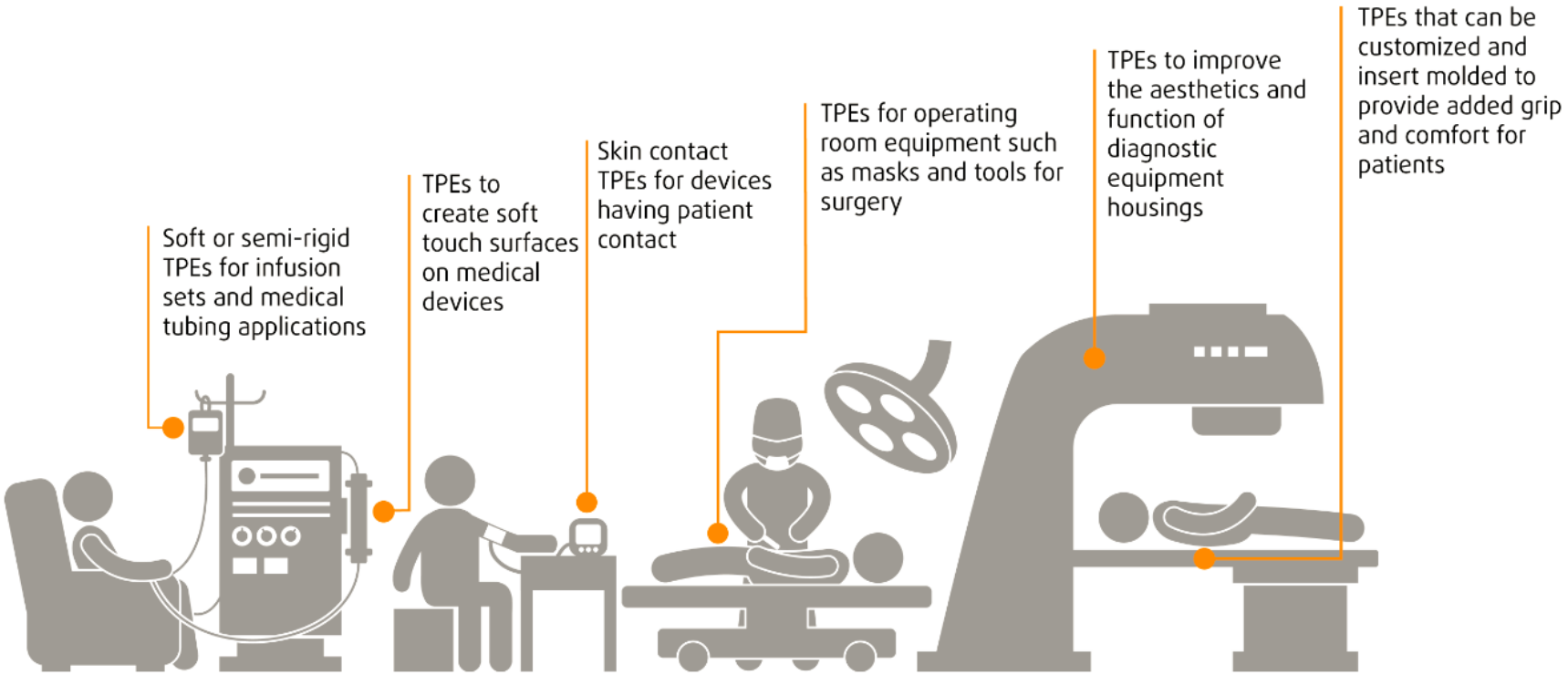
Cohesive is the more desired mode of failure

Variables Impacting Adhesion

- Chemical compatibility of the materials, including miscibility and interfacial tension, which impact physical blending
  - *TPEs need to be chemically modified to adhere to a specific substrate material such that their polarity and solubility parameters match*
- Anything that interferes with “blending”, e.g., moisture or mold release agents, will impact the chemical interactions at the interface.
- Temperature: higher temperatures result in greater bond strength
- Injection Speed: the greater the injection speed of the TPE without warping or moving the substrate the better the adhesion.
- Holding pressure and time

Summary and Conclusion

Medical Applications for TPEs



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Thank you for joining the call.

Contact

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