



Trends, material properties, and overmolding

## What you need to know about TPEs for medical devices

16, May, 2019

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



## 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



Mussolente, Italy

- **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



## 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



## 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





## 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





## 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

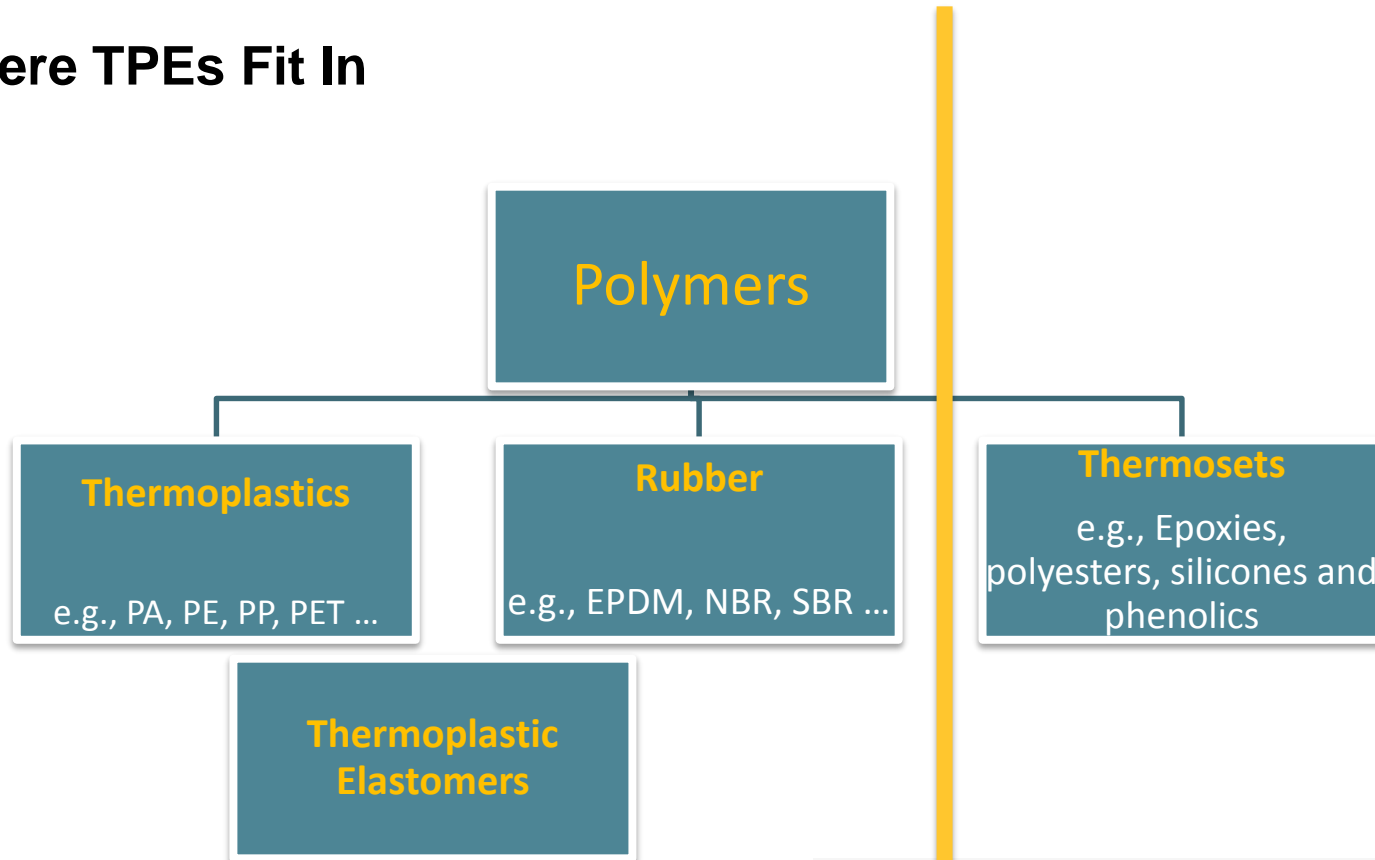


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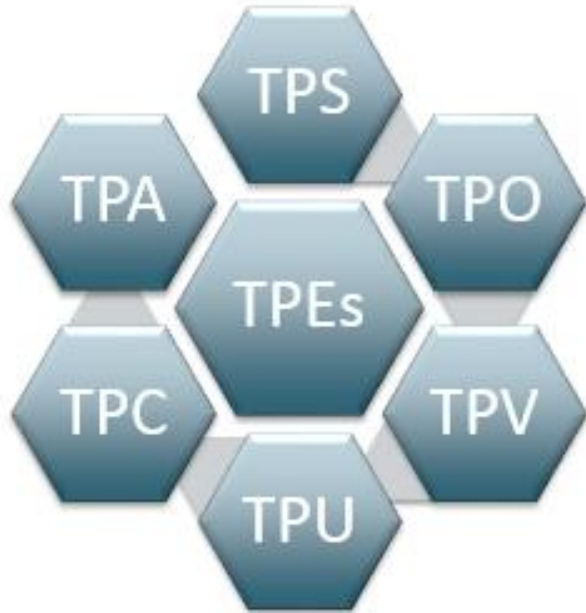
# TPE Chemistries



## Where TPEs Fit In

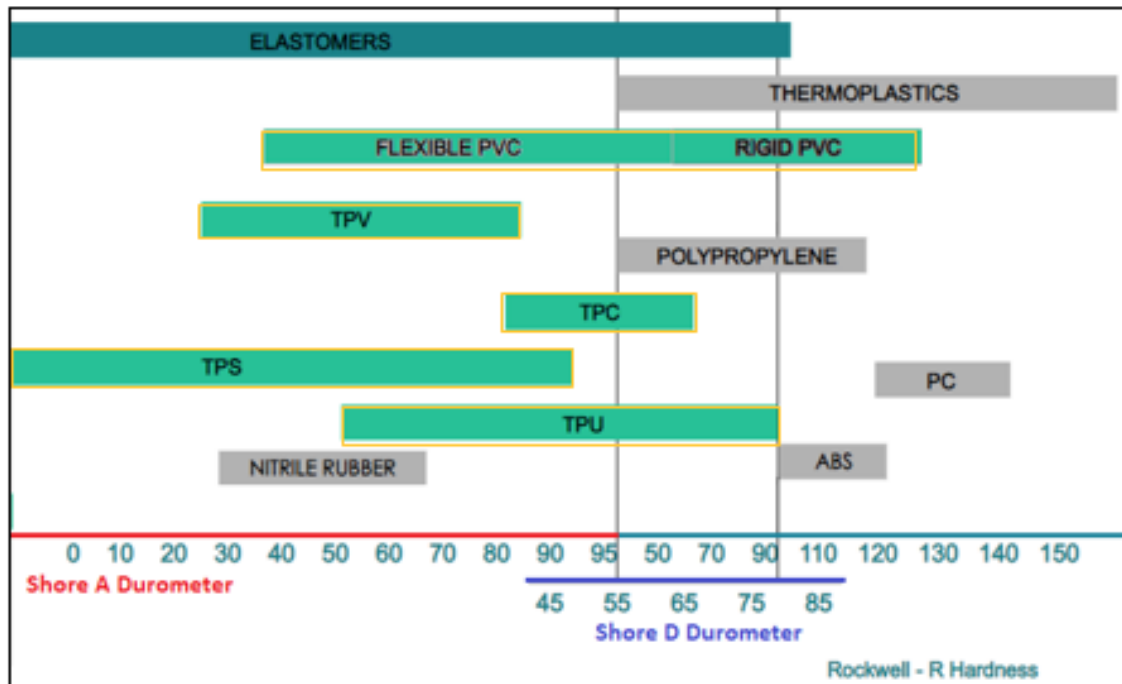


## Six Thermoplastic Elastomer (TPE) Chemistries



- 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

# Measuring Performance

## Hardness

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



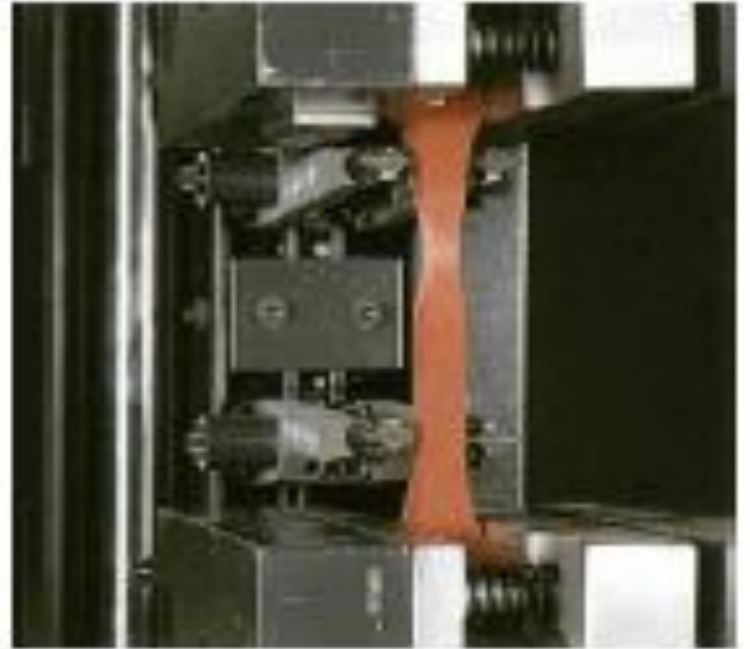
Durometer	Use	Indenter
A	Used for softer materials.	
D	Used for harder materials.	

Hardness Scales	
Durometer (Shore) A	Durometer (Shore) D
	Rockwell R
	Rockwell A
130 —	110 —
120 —	70 —
90 —	110 —
80 —	100 —
70 —	90 —
60 —	70 —
95 —	50 —
90 —	50 —
80 —	40 —
70 —	
60 —	
50 —	
40 —	
30 —	
20 —	

## Measuring Performance

### Tensile

- Tensile acc. to ASTM D638 (ISO 527-2)
  - $E_y = f(\epsilon)$  -  $\epsilon = 100\%$  and  $300\%$  (MPa)
  - $\sigma$  @ rupture (MPa)
  - $\epsilon$  @ rupture (MPa)



## Measuring Performance

# Compression Set

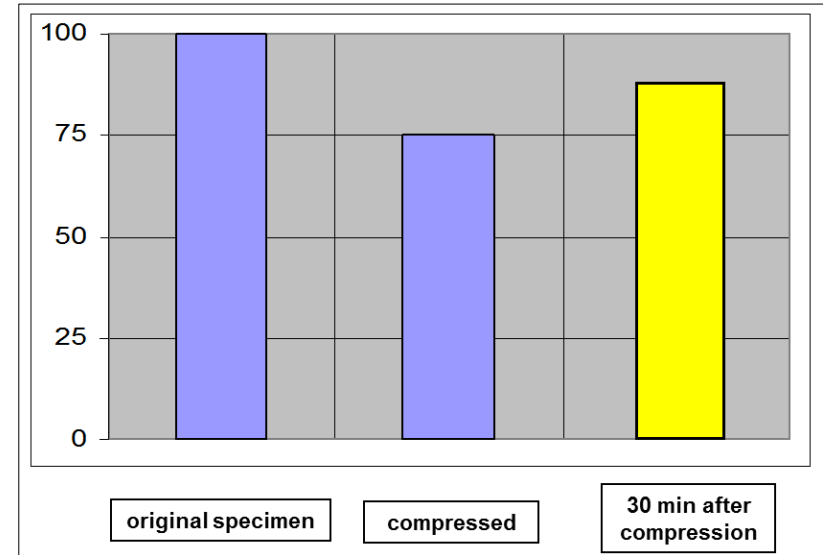
➤ Two methodologies **A** and **B** according to ASTM

- **A** = compression set under constant force

$$(1.8\text{KN}) - C_A = [(t_0 - t_i) / t_0] * 100$$

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

$$(25\%) - C_B = [(t_0 - t_i) / (t_0 - t_n)] * 100$$

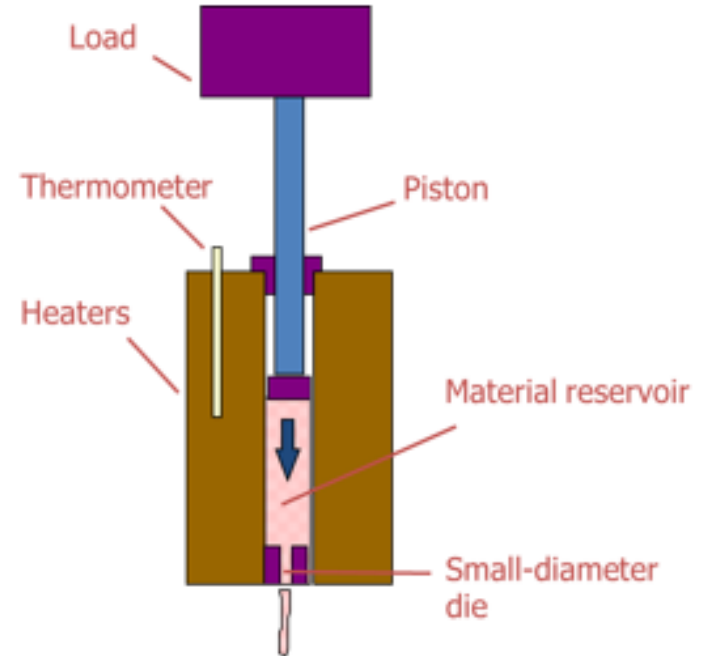




## Measuring Performance

# Melt Flow Rate

- Melt **F**low Rate (MFR) or Melt **V**olume Rate (MVR) acc. to ASTM D1238 (ISO 1133)
  - The testing conditions are most commonly reported as temperature/load (i.e. 190°C/2.16 kg) reported in g/10mn



## Measuring Performance

### 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  $\text{mm}^3$ .



## 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



## API TECHNICAL DATA SHEET

A Ingeo company.

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Cap. Soc. - Share S. 1.000.000,00 i.r.e. - p. S.A.S. n. 02776 Reg. Imp. - Verona

**MEGOL I A 60 P UG**

**megol.**

Properties	Methods	Units	Results (*)
Density	ASTM D 792	g/cm3	0,89
Hardness Sh.A (15 sec)	ASTM D 2240	sh.A	60
Melt flow index 190°C 49,05 N	ASTM D 1238	g/10'	15
Tear strength (type C)	ASTM D 624	KN/m	25
Tensile strength at 100% (type IVB)	ASTM D 638	MPa	1,5
Tensile strength at 300% (type IVB)	ASTM D 638	MPa	2,5
Tensile strength (type IVB)	ASTM D 638	MPa	10
Elongation at break (type IVB)	ASTM D 638	%	700

monomers

technology

production

processing

Optimal processing conditions depend on each feature of machine size, screw design, barrel/rotor design and material resistance time.  
PRE-HEATING NOT REQUIRED.  
It is necessary to store the material in a cool dry place, exposure to high temperature, high humidity, flames or other heat source has to be avoided.  
RECYCLE INFO: SEE PAGE.

INJECTION MOLDING / MEDIUM-HIGH

BACK FEEDING / MEDIUM - LOW

INJECTION SPEED: MEDIUM

Temperature settings (°C)

Zone A: 175 - 180

Zone B: 175 - 180

Zone C: 185 - 190

Zone D: 170 - 175

Zone E: 20 - 45



recycling

RECYCLED MATERIAL CAN BE EASILY MIXED WITH VIRGIN PRODUCT.

NOT ALLOWED FOR CRITICAL APPLICATIONS OR THROUGH MULTIPHASE.

(\*) typical property values, these are not to be construed as specifications.

The information supplied above is given in good faith and is accurately based on test results, however, we warrant that the procedure specified, which may be updated from time to time, we intend to ensure that they are suitable for your specific application. We are not responsible for any damage or loss of production or any other consequences, in consequence of the information provided, other than those required by applicable law. Furthermore, we are not liable for any responsibility in case of any use of the products or violation of third party patent, within scope of any law.



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# 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**

## A Quick Glance Reference

### Resin classifications

- Food Contact Grades



- Skin Contact Grade (SK)

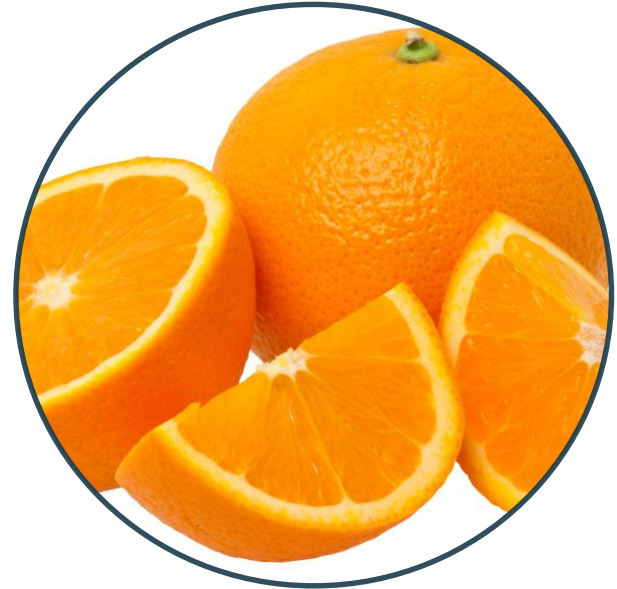


- Medical Grades (MED)



## Food Contact

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





## Skin Contact Grades

- Limited ISO 10993 biocompatibility tests
- cGMP compliant



Resins Suitable for Medical Applications

## **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.



Overmolding

## Adhesion: A Physical Blending Process

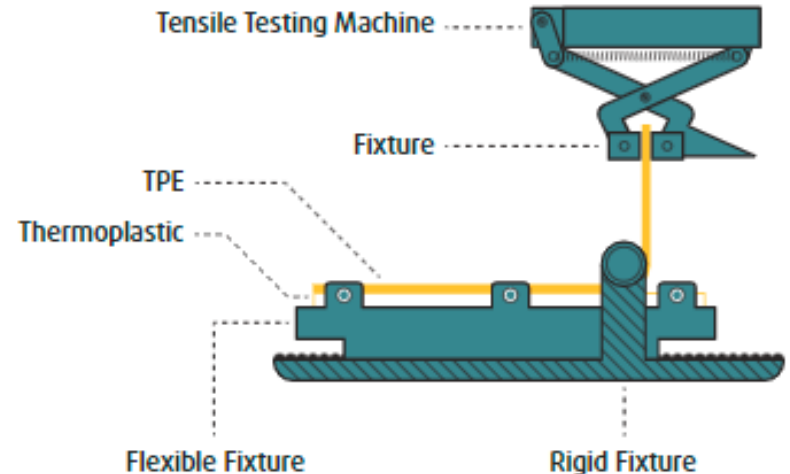


## Understanding Adhesion

### 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)

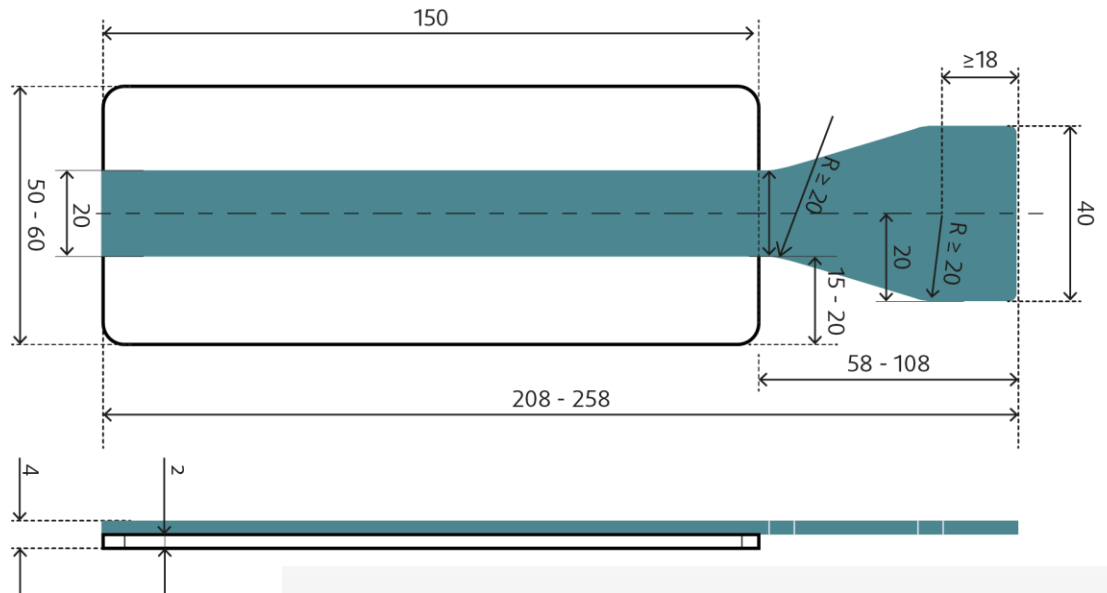
VDI 2019 Peel Test Setup



# Understanding Adhesion

## 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



# Understanding Adhesion

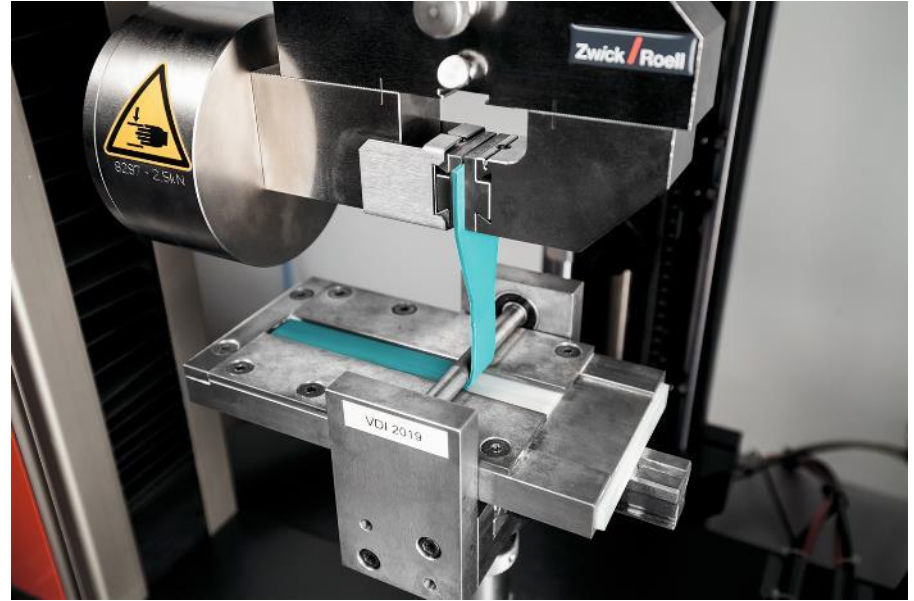
## Two Main Types of Failures

### 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

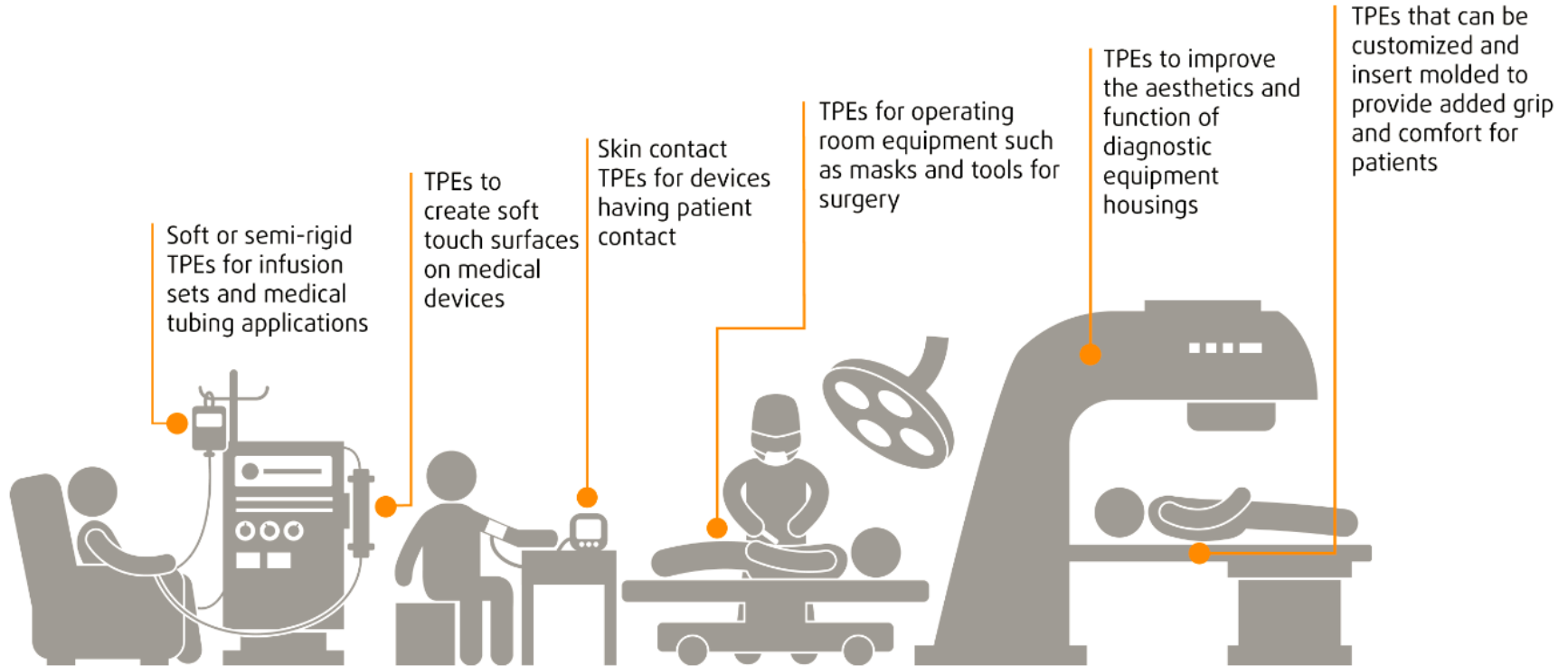




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# Summary and Conclusion

# Medical Applications for TPEs





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Thank you for  
joining the call.

## Contact

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### **Worldwide**

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