Secondary Operations Part 1 - Solvent Bonding:

A versatile approach for fabricating of medical assemblies

Pooja Bajaj, PhD, Product Development Manager - Molding Compounds
Kay Bernhard, PhD, Technical Center Director - Molding Compounds
Andrew Sneeringer, Technical Marketing Specialist - Medical Molding Compounds
Maurice Biagini, Business Director - Medical Molding Compounds

Agenda

- Introduction to CYROLITE®
- Why Solvent Bonding?
- Key factors influencing the bond strength – solvents, tubing materials, polymer etc.
- Mechanical testing to measure bond strength
- Overall performance of acrylic copolymers and other medical plastics

CYROLITE® acrylic-based copolymer

CYROLITE®

ADVANCED
MEDICAL ACRYLICS

- ✓ **Leading acrylic copolymer** specifically developed for use in the Medical Device and Diagnostics Industries
- ✓ **Extensive development and application in healthcare** and labs for more than **40 years**
- ✓ **Offering eight grades with** balanced properties

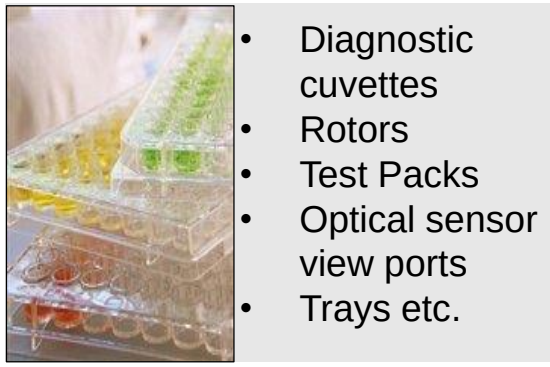
Global leader in medical grade acrylic copolymers

Business Portfolio

Infusion Therapy

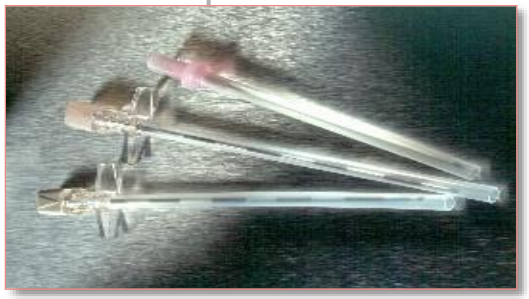
- IV connectors
- Valves
- Y Sites
- Luer Locks
- IV Filter
- Catheter accessories

Diagnostics



- Diagnostic cuvettes
- Rotors
- Test Packs
- Optical sensor view ports
- Trays etc.

Blood Management



- Separators
- Filters
- Valves
- Connectors

Medical Others

- Sterile packaging
- Respiratory components
- Ophthalmic components

Solvent bonding as a versatile fabrication technique for joining various plastic materials to medical tubing

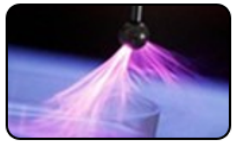
Promoting adhesion - Key fabrication strategies and factors

Strategies to promote joining between polymers

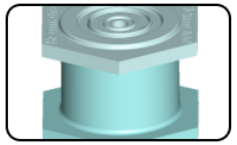
Chemical bonding by solvents or epoxy

Pressure or Temperature sensitive

Eliminating adhesives via screws, inserts, or rivets

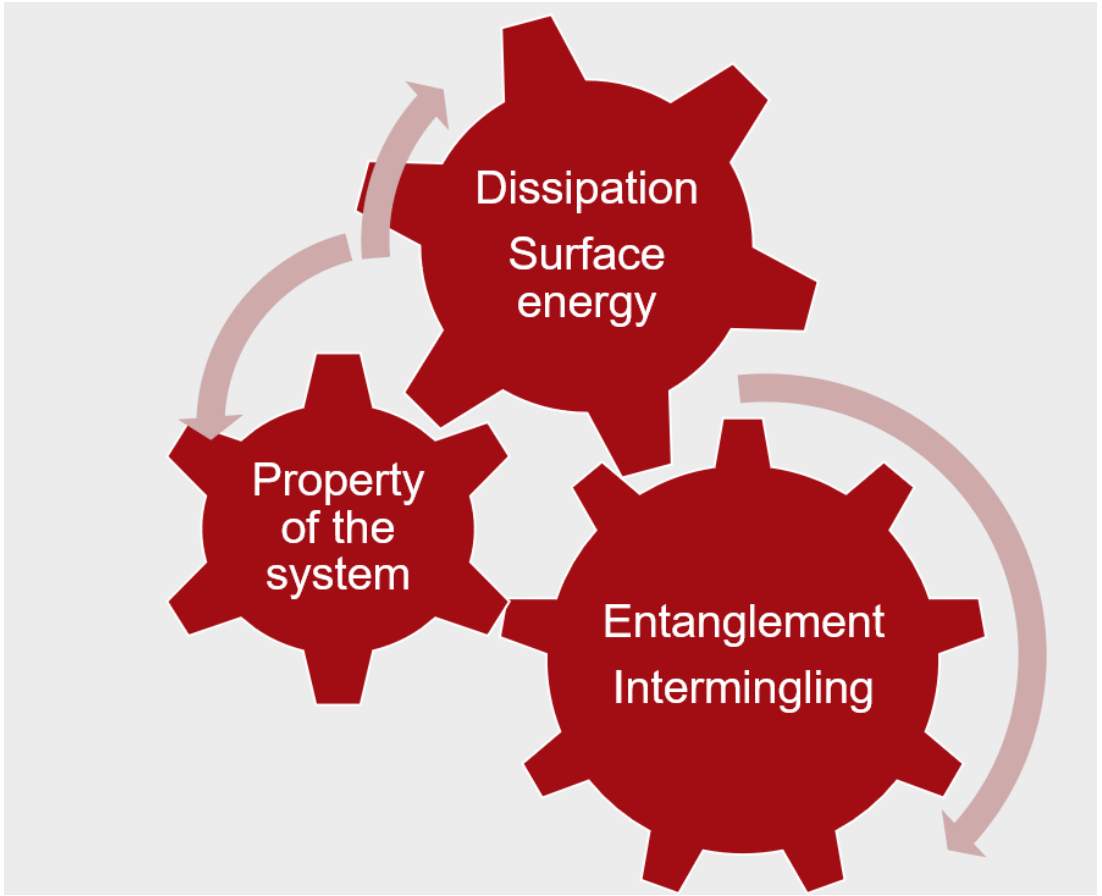


Surface modification by corona, plasma, UV, flame



Welding by ultrasonic or laser methods

What drives Adhesion?



Solvent Bonding

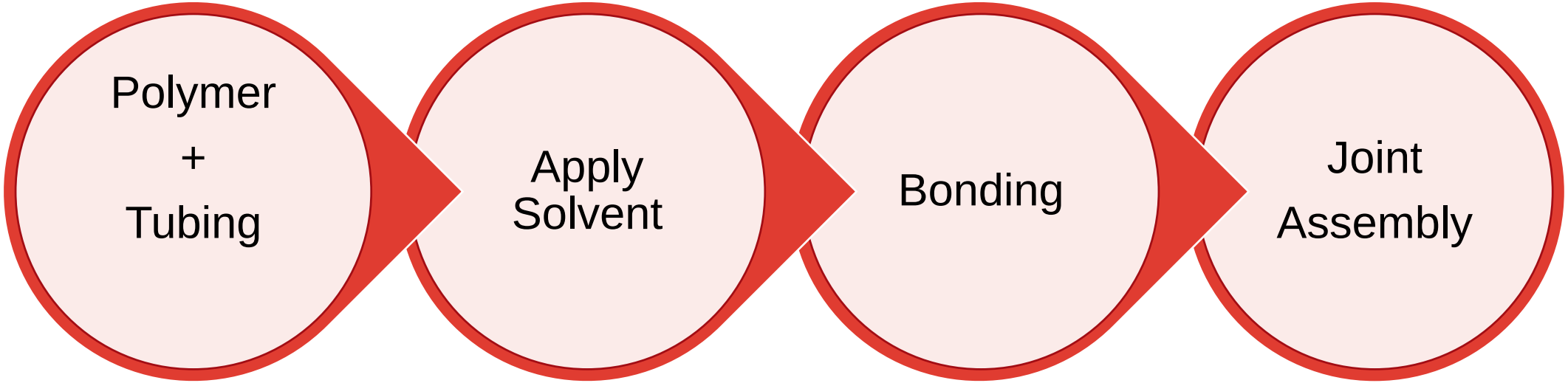
- **Motivation**
  - Solvent Bonding is an established method to connect CYROLITE® to soft tubing using compatible solvents
  - Incumbent tubing material of choice is DEHP PVC
  - Industry is seeking non-DEHP PVC and PVC-free materials due to phthalate and incineration concerns (release of dioxins)

Objective

- Improve bonding to non-DEHP PVC, PVC alternative solutions at ≥11 lb.f
- cost effective
- robust alternatives
- compliant for medical applications

- **Applications**
- Delivery systems, interconnectors, microfluidic devices

Solvent Bonding
Fabricating polymer - tubing assembly



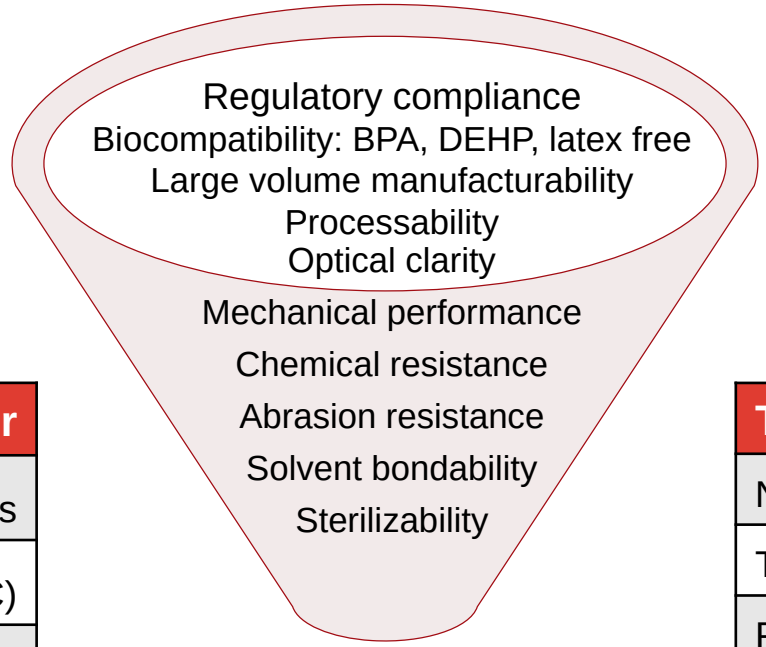
- Substrate Polymer
- Tubing material

- Solvent choice
- Solvent volume

- Temperature
- Pressure
- Processing time

- Lap joint
- Corner joint
- Edge to edge
- Tee joint

Choice of polymer and tubing material – Key considerations



Design for Performance

Substrate Polymer
Acrylic copolymers
Polycarbonate (PC)
MABS
Copolyester (PET, PBT)

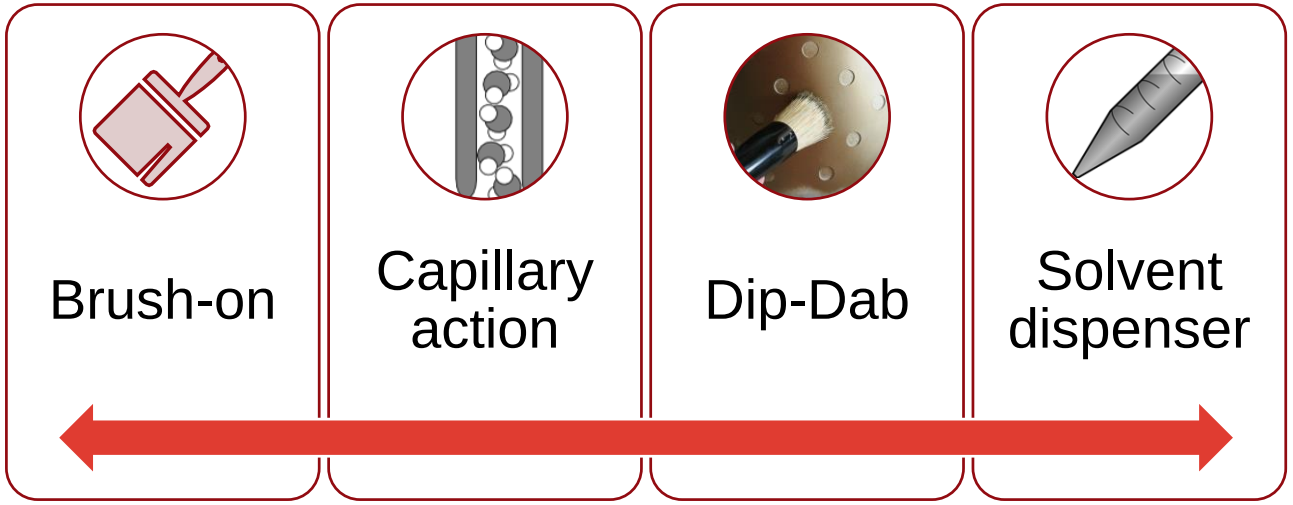
Tubing material - PVC alternatives
Non-DEHP* PVC
Thermoplastic polyurethanes (TPU)
Polyamide elastomers (TPE-A)
Styrenic block copolymers SBC (TPE-S)
Polyolefin based elastomers (TPE-O)
Copolyester elastomers (TPE-E)

**A review of alternatives to di (2-ethylhexyl) phthalate-containing medical devices in the neonatal intensive care unit. EDS Van Vliet, EM Reitano, JS Chhabra, GP Bergen, and RM Whyatt, J Perinatol. 2011, 31(8): 551–560.*

Solvent application methods
Fabricating polymer - tubing assembly

Apply Solvent

Variables
- Solvent choice
- Solvent volume



Simple

Cost - effective

Strength of bond depends on compatibility

ESCR in amorphous polymers

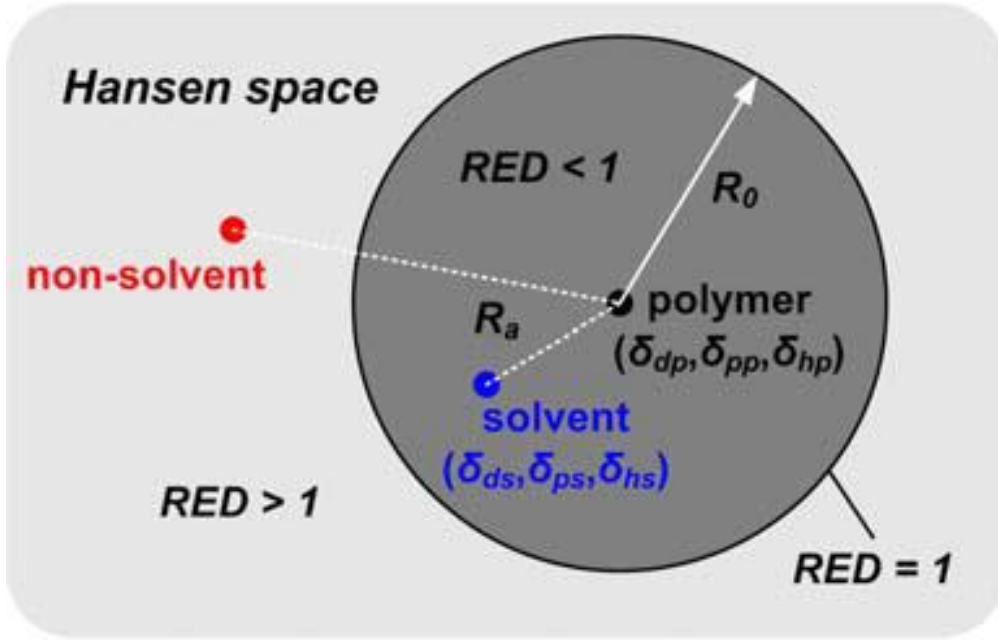
Extended drying times depending of solvent volatility

How does a solvent influence bonding?
Polymer compatibility - Hansen solubility parameter

Solubility parameters derived from the cohesive energies of polymer and solvent based on:

- *δd, dispersion bonds*
- *δp, polar bonds*
- *δh, hydrogen bonds*

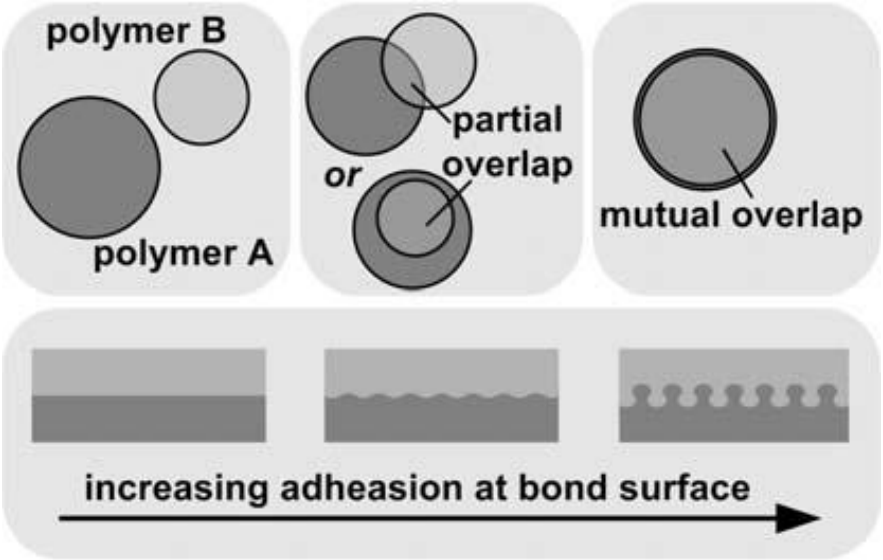
- Ra = distance between solvent and polymer
- The smaller the distance Ra between solvent and polymer, the more the solvent will be able to dissolve the polymer
- Relative energy difference RED = R_a/R_o



Schematic illustration of the Hansen space for a polymer and solvent compatibility

Solvent compatibility

*Solvents
[1]Cyclohexanone (CH)
[2]Methylene Chloride (MC)
Tetrahydrofuran
Toluene
Ethyl Acetate
90:10 CH (Cyclohexanone) / Methyl Ethyl Ketone (MEK)
Methyl Ethyl Ketone
Acetone

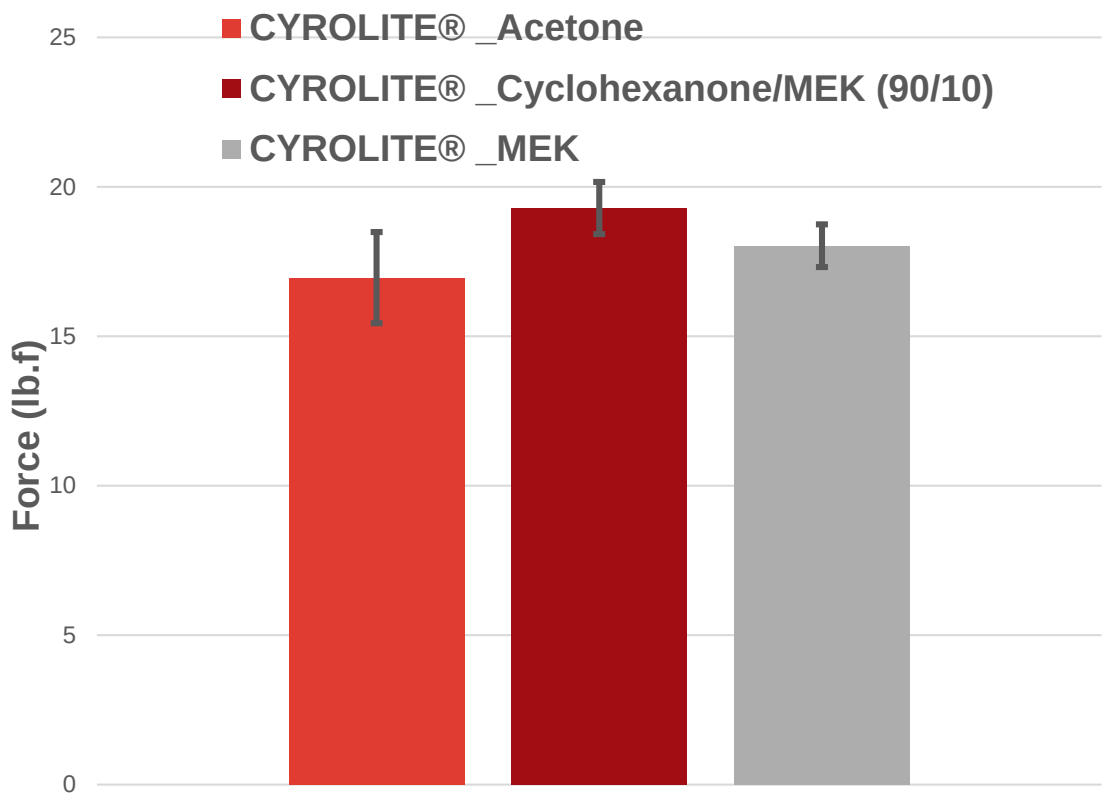


**Degree of overlap of spheres in Hansen space correlates with solvent - polymer compatibility*

1. 100% CH is reported to cause stress cracking in medical plastics
2. MC is reported to be carcinogenic, mutagenic and banned in many countries

Simon Herrlich et al. "Solvent Bonding of a Drug Delivery Device by Using Hansen Solubility Parameters" Proceedings of the 8th International Conference on Multi-Material Micro Manufacture
Dwivedi AM. Residual solvent analysis in pharmaceuticals. Pharmaceutical Technology. November (2002) 42

CYROLITE® GS-90
Bond strength to non-DEHP PVC using compatible solvents



*Hansen Solubility Parameter δ ((MJ/m^3)$^{1/2}$)			
Substrate Polymer	δD	δP	δH
Acrylics	18.1	8.4	3.1

*Hansen Solubility Parameter δ ((MJ/m^3)$^{1/2}$)			
**Solvents	δD	δP	δH
Cyclohexanone	17.8	8.4	5.1
Methyl ethyl ketone	15.9	8.7	5.1
Acetone	15.5	10.4	6.9

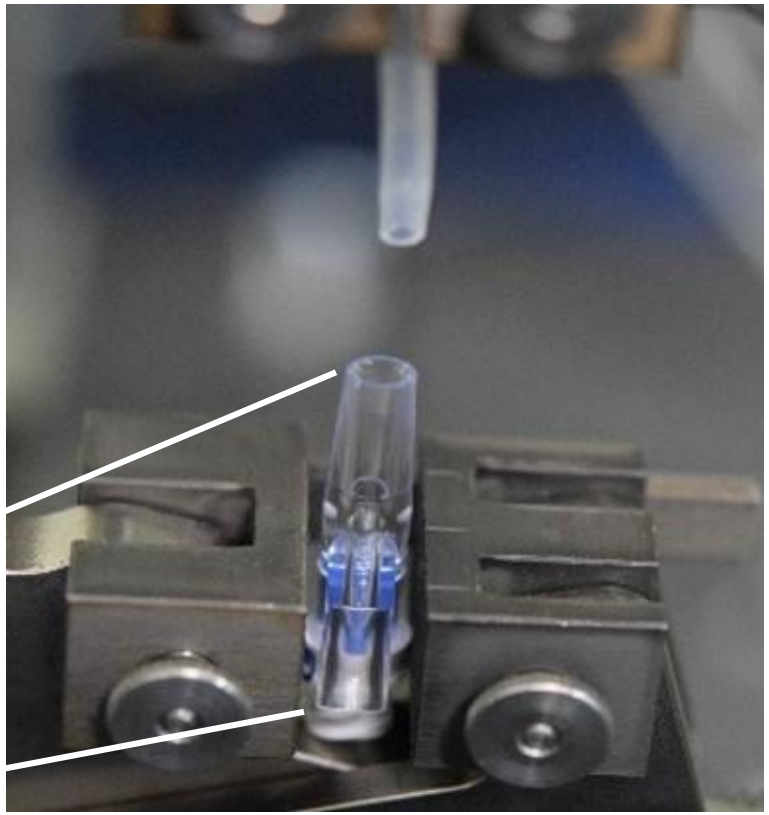
*Dispersion forces, δD ((MJ/m^3)$^{1/2}$)
Dipolar intermolecular force, δP ((MJ/m^3)$^{1/2}$)
Hydrogen bonds, δH ((MJ/m^3)$^{1/2}$)

**Handbook of Solvents, Volume 1 - Properties (2nd Edition)*
***Dwivedi AM. Residual solvent analysis in pharmaceuticals. Pharmaceutical Technology. November (2002) 42*

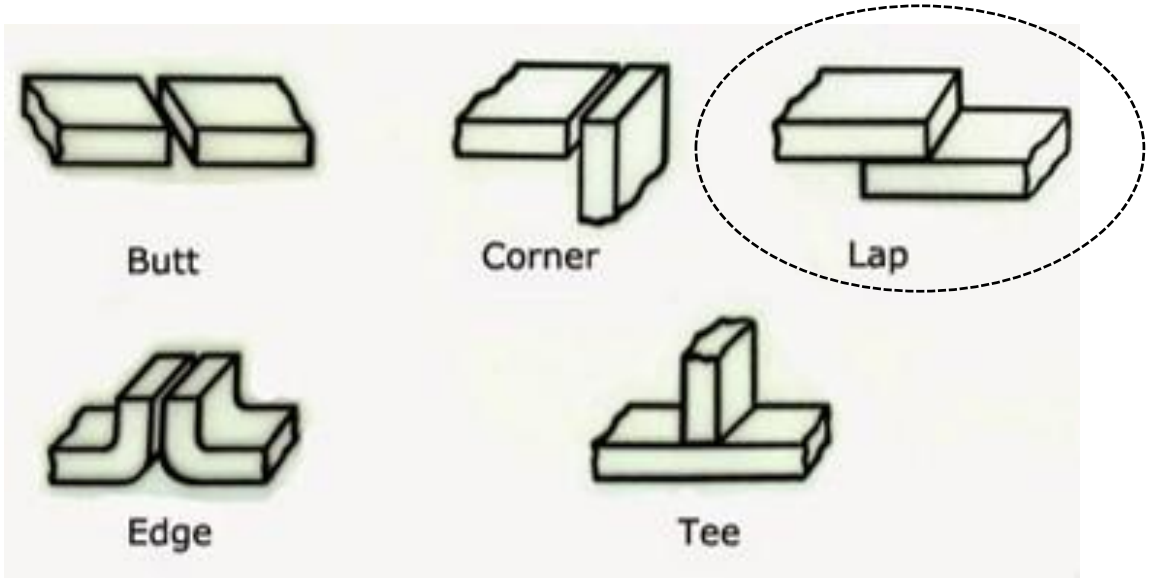
Solvent bonding
Fabricating CYROLITE® GS-90 - tubing assembly

Tubing to CYROLITE® Y-site connection

Joint Assembly

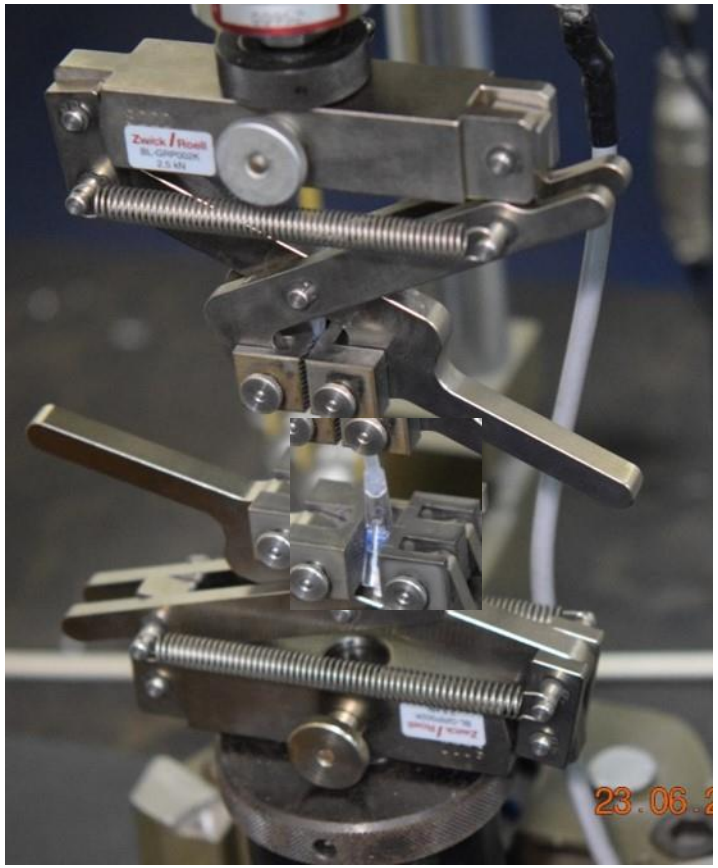


Joining assemblies

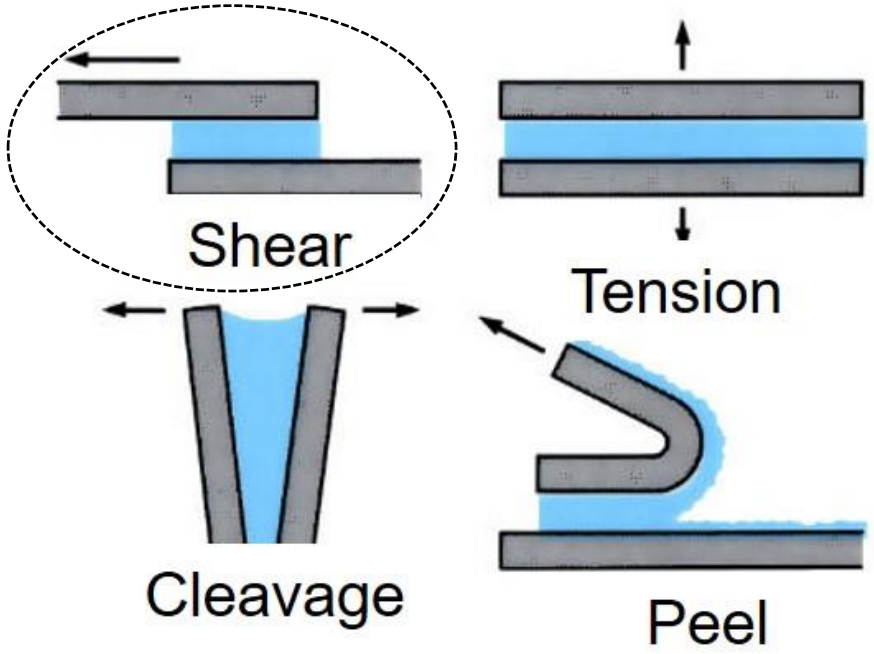


Solvent bonding
Fabricating CYROLITE® GS-90 - tubing assembly

Tubing to CYROLITE® GS-90 Y-site connection



Mechanical tests - Measure of bond strength



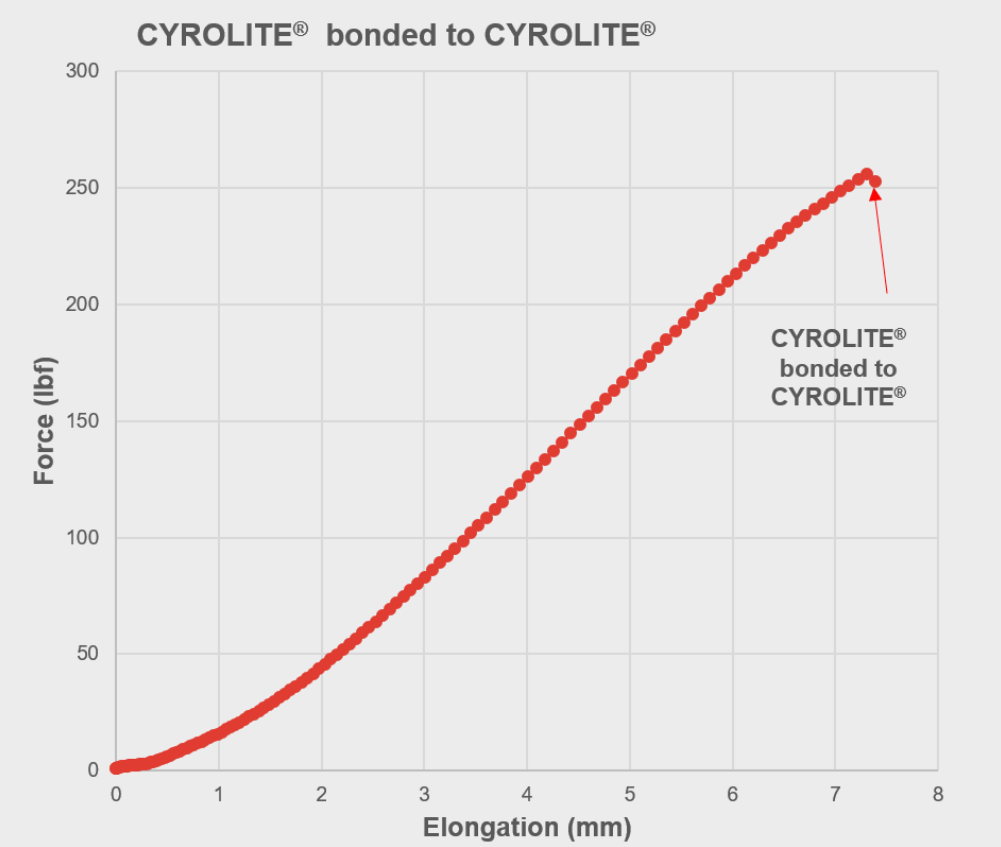
Solvent bonding – Experimental parameters

Polymer	CYROLITE® GS-90	PC	MABS	
Tubing	non-DEHP PVC	TPU	Polybutene	Silicone
*Solvent	CH/MEK (90:10)			
Bonding time	7 days			
Mechanical Test	Lap shear pull strength	Tube to CYROLITE® GS-90		

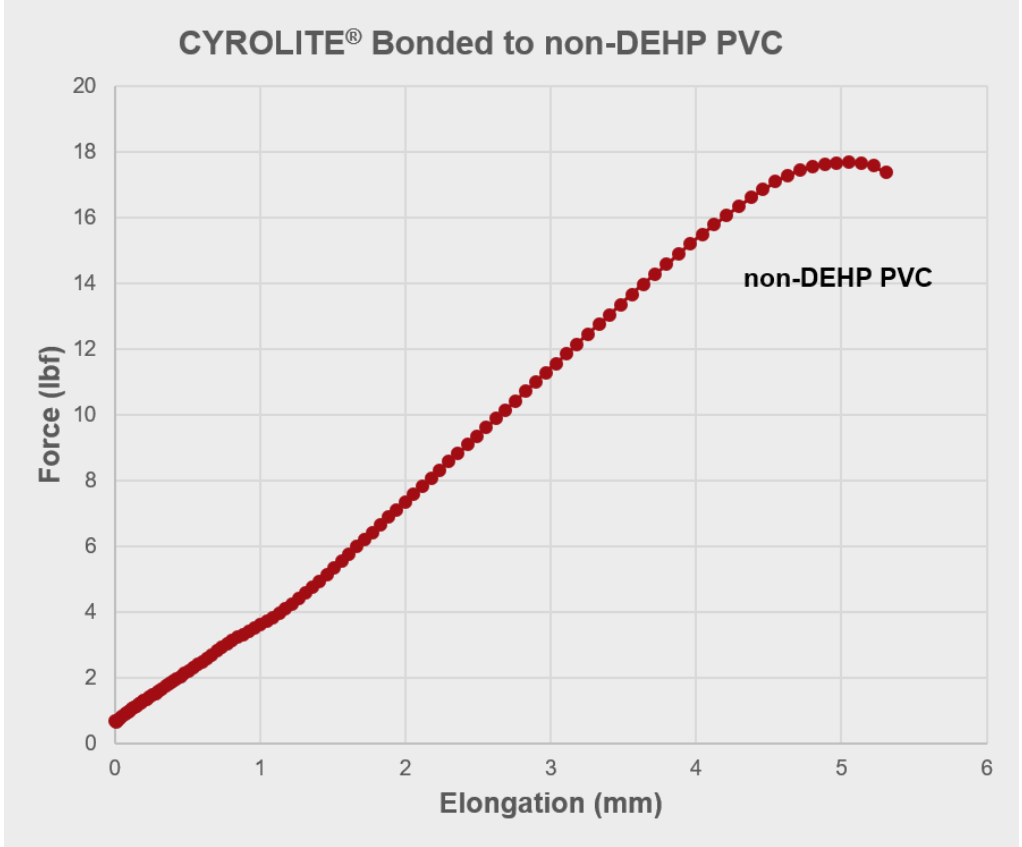
*Solvents
Current
90:10 CH (Cyclohexanone) / Methyl Ethyl Ketone (MEK)

CYROLITE® GS-90 shows strong bond strength to self and non-DEHP PVC to using Cyclohexanone/MEK (90/10)

CYROLITE® GS-90 to CYROLITE® GS-90

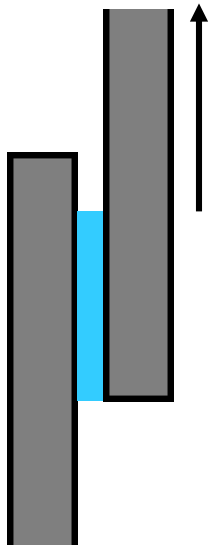


CYROLITE® GS-90 to non-DEHP PVC

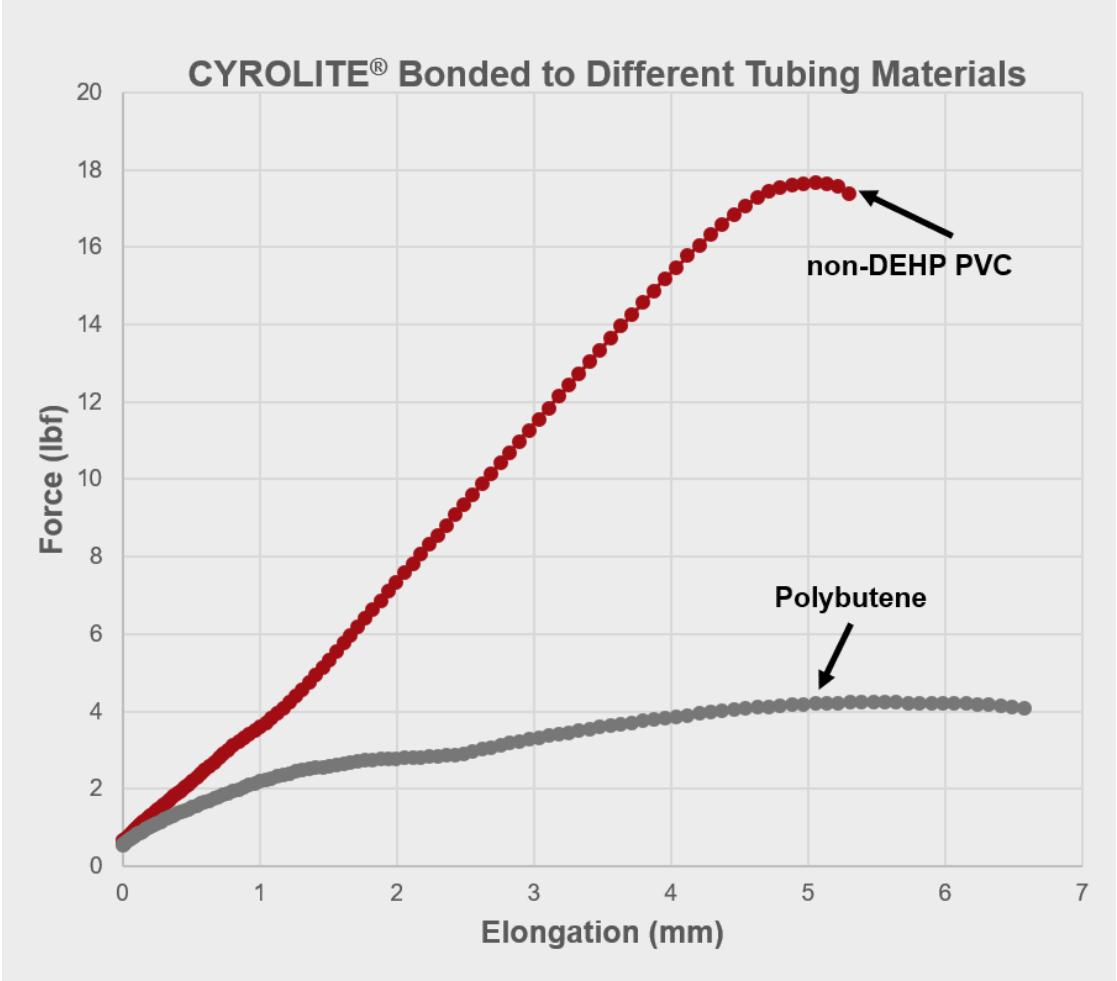


Lap shear pull strength at 20inch/min (500mm/min)

Thermoplastic Polyolefin tubing to CYROLITE® GS-90 shows weak bond strength using Cyclohexanone/MEK (90/10)

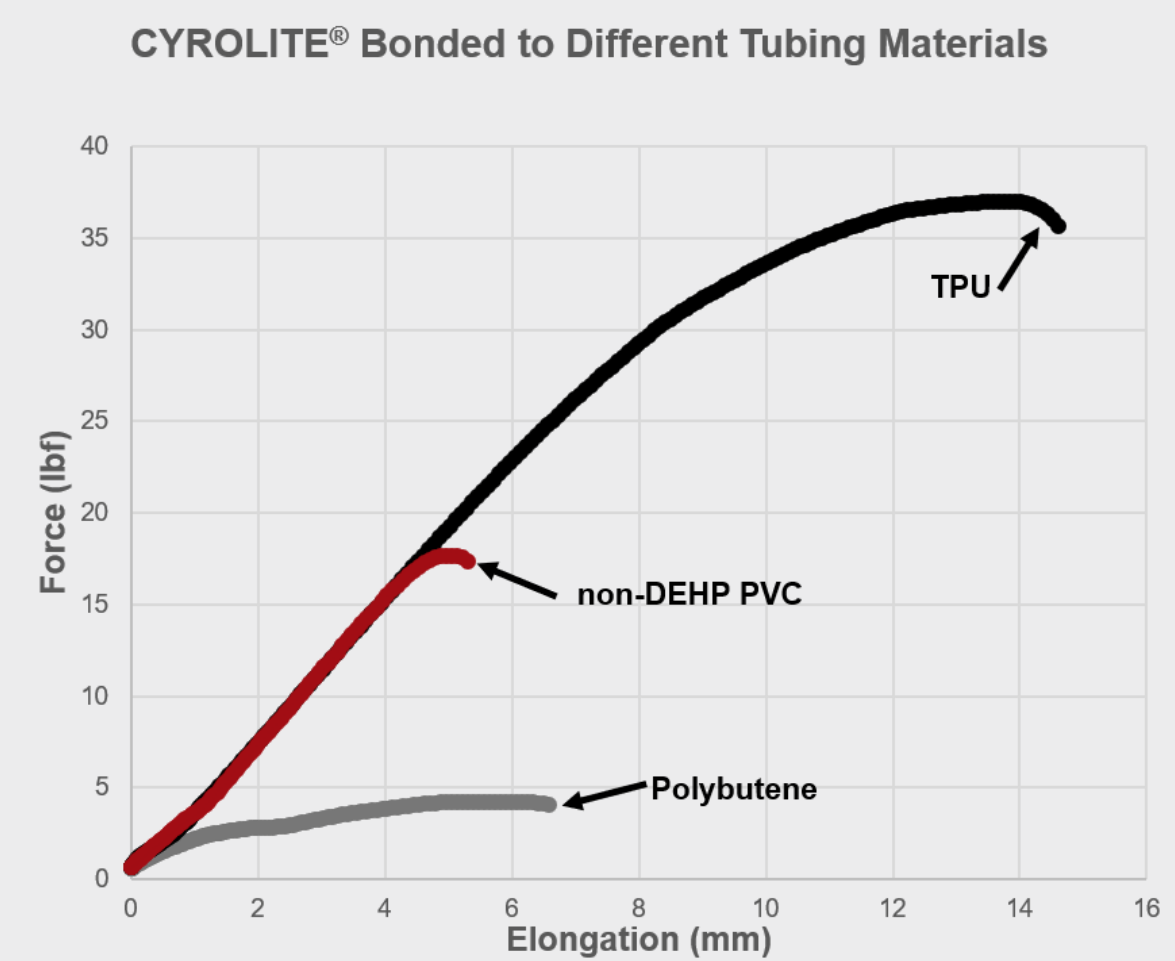


Lap shear pull strength at 20inch/min (500mm/min)



- Similar behavior is experienced with PC and MABS

Thermoplastic Polyurethane (TPU) tubing to CYROLITE® GS-90 shows excellent bond strength using Cyclohexanone/MEK (90/10)



- Similar behavior is experienced with PC and MABS

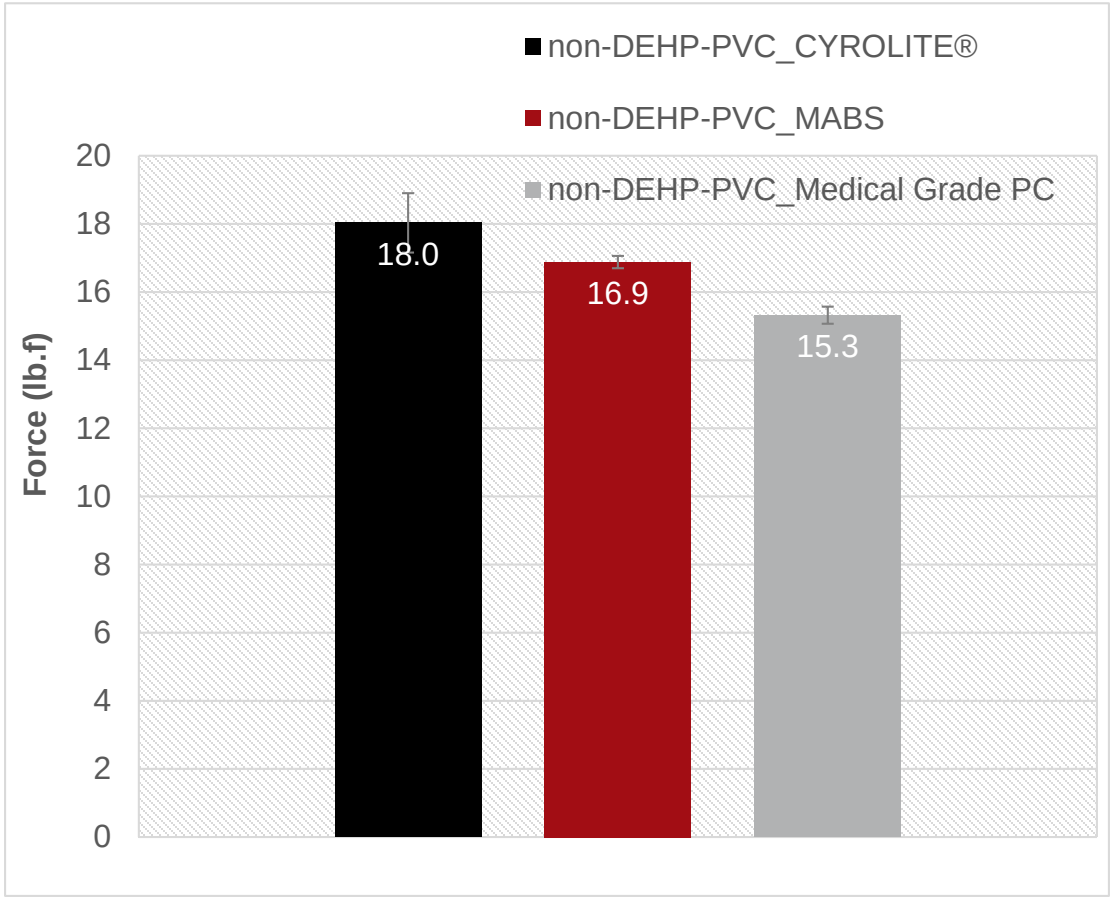
*Hansen Solubility Parameter δ ((MJ/m³)^1/2)			
Substrate Polymer	δD	δP	δH
Acrylics	18.1	8.4	3.1

*Hansen Solubility Parameter δ ((MJ/m³)^1/2)			
Tubing material	δD	δP	δH
PVC	18.7	10	3.1
TPU	18.8	10	8.2

*Hansen Solubility Parameter δ ((MJ/m³)^1/2)			
Solvents	δD	δP	δH
Cyclohexanone	17.8	8.4	5.1
Methyl ethyl ketone	15.9	8.7	5.1

CYROLITE® GS-90 bond superior to non-DEHP PVC compared to other medical plastics using Cyclohexanone/MEK (90/10)

Bond strength (lbf)



Hansen solubility parameter

*Hansen Solubility Parameter δ ((MJ/m^3)$^{1/2}$)			
Substrate Polymer	δD	δP	δH
Acrylics	18.1	8.4	3.1
MABS	18.5	3.7	3.9
PC	19.6	8.8	5.7

*Hansen Solubility Parameter δ ((MJ/m^3)$^{1/2}$)			
Tubing material	δD	δP	δH
PVC	18.7	10	3.1

*Hansen Solubility Parameter δ ((MJ/m^3)$^{1/2}$)			
Solvents	δD	δP	δH
Cyclohexanone	17.8	8.4	5.1
Methyl ethyl ketone	15.9	8.7	5.1

Title: Handbook of Polymers (2nd Edition)
Handbook of Solvents, Volume 1 - Properties (2nd Edition)

CYROLITE® GS-90 and other Medical Plastics
Solvent Bonding to non-DEHP PVC medical tubing and alternatives

Solvent compatibility to non-DEHP PVC medical tubing	CYROLITE® GS-90
Methyl Ethyl Ketone (MEK)	
Cyclohexanone/MEK 90/10	

Solvent bonding to CYROLITE® and other medical grade resins using Cyclohexanone/MEK 90/10			
Tubing materials	CYROLITE® GS-90	PC	MABS
Silicone			
Polybutene			
non-DEHP Poly Vinyl Chloride (PVC)			
*Thermoplastic Polyurethane (TPU)			

** Excellent bonding to TPU*

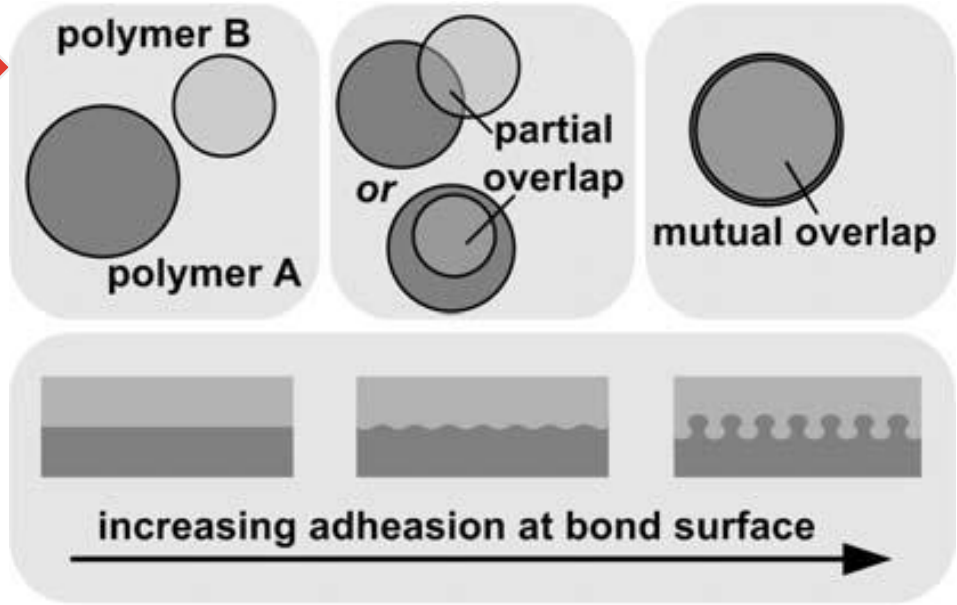
Legend	
Lap shear pull force strength	Color
Poor bond	
Good/Excellent bond	

Hansen Solubility parameter - Screening for compatibility - Substrate, tubing, solvent combinations

Substrate polymer → Tubing material → Solvents

*Hansen Solubility Parameter δ ((MJ/m^3)$^{1/2}$)			
Substrate Polymer	δD	δP	δH
Acrylics	18.1	8.4	3.1

*Hansen Solubility Parameter δ ((MJ/m^3)$^{1/2}$)			
Tubing material	δD	δP	δH
PVC	18.7	10	3.1
TPU	18.8	10	8.2
SBC	17.4	1.12	2.64
Polyamide	18.5	5.1	12.2
PTFE	14	0	0



*Hansen Solubility Parameter δ ((MJ/m^3)$^{1/2}$)			
Solvents	δD	δP	δH
Cyclohexanone	17.8	8.4	5.1
Methyl ethyl ketone	15.9	8.7	5.1

Conclusions

- Solvent bonding is a versatile technique to adhere tubing to polymer materials for medical interconnector applications
- CYROLITE® GS-90 presents a BPA-free, and latex-free bonding solution to non-DEHP PVC tubing as well as alternatives to PVC tubing
- Hansen solubility parameter as a viable tool for determining polymer (substrate-tubing) to solvent compatibility

  (reference slide 21)
- Cyclohexanone/MEK and MEK are suitable choices for optimum solvent bonding of CYROLITE® GS-90 to

  non-DEHP PVC tubing

Table 6.2. Hansen Solubility Parameters of Selected Polymers. Retrieved from https://app.knovel.com/hotlink/itble/rcid:kpHPE00024/id:kt00XREBS1/handbook-plasticizers/table-6-2-hansen-solubility Handbook of Solvents, Volume 1 - Properties (2nd Edition)

Q & A

CYROLITE®

ADVANCED
MEDICAL ACRYLICS

Roehm America LLC
299 Jefferson Road
Parsippany, NJ 07834

Röhm GmbH
Deutsche-Telekom-Allee 9
64295 Darmstadt
Germany

Roehm Chemical (Shanghai) Co., Ltd.
55 Chundong Rd. Xinzhuang Industry Park
201108, Shanghai
China

www.roehm.com
www.cyrolite.com

RÖHM
TRADITIONALLY
INNOVATIVE

COMING SOON: January 2021
Secondary Operations Part 2: Ultrasonic Welding

Visit CYROLITE on LinkedIn for updates and registration

RÖHM

TRADITIONALLY
INNOVATIVE