White Paper of Important Gluing Techniques for PVC-Free Medical Devices

Rupendra Singh[1], Pradeep Sharma[2]

[1]Director- (Quality Assurance & Regulatory Affairs), Foxx Life Sciences
Corresponding Author Email: *rupendrachauhan0309[at]gmail.com*

[2]Manager- Quality Control, Foxx Life Sciences
Email: *rupendra.singh[at]foxxlifescience.com*

Abstract: ***Background**: Medical device PVC-free gluing procedures depend on specific bonding methods and adhesives that guarantee sterilization resistance, biocompatibility, and ISO/MDR compliance. Solvent bonding, UV-curable adhesives, and automated dispensing systems are the most efficient ways to replace PVC with TPE copolymers, polyurethane, and silicone-based adhesives. This paper examines the development of PVC-free bonding, reviews recent research, describes adhesive evaluation methodology, and discusses comparative results. **Method**: Solvent bonding: Reliable for acrylic copolymers, offering clarity and sterilisation compatibility. 1) UV-curable adhesives: Cure in 2) Polyurethane/Epoxy adhesives: Strong mechanical bonding, suitable for polyolefins. 3) Silicone adhesives: Flexible and biocompatible, preferred for tubing. 4) Automated dispensing systems: Reduce variability, improve reproducibility, and align with GMP.*

Keywords: PVC-free, Gluing process, Curing, Medical adhesives, ISO compliance

1. Introduction

Thermoplastic Elastomer (TPE) is a versatile, recyclable material combining the soft, flexible, rubber-like properties of elastomers with the easy, energy-efficient processing of plastics. TPEs are widely used in automotive, medical, consumer goods, and 3D printing applications due to their elasticity, durability, and cost-effectiveness,

Polyvinyl chloride (PVC) has long dominated the medical device industry due to its versatility and affordability. However, concerns about DEHP plasticisers, leachables, toxicity, and environmental sustainability have driven a global shift toward PVC-free alternatives such as polyolefins (PP, PE), thermoplastic elastomers (TPE), acrylic copolymers, and polyurethanes. These substrates pose distinct bonding challenges, requiring advanced gluing techniques that ensure sterilisation resistance, biocompatibility, and compliance with EU MDR 2017/745, ISO 13485, and ISO 10993 standards [1–3].2.0

2. Methodology

2.1 Material Selection

Silicone, polyolefins, TPE, polyurethane, acrylic copolymers.

2.2 Adhesive Application

- Solvent bonding via controlled exposure.
- UV-curable adhesives with LED curing devices.

2.3 Precision dispensers for epoxy/polyurethane

2.4 Silicone adhesives for tubing.

2.5 Testing Procedures

- Mechanical strength (tensile, peel).
- Biocompatibility (ISO 10993).
- Sterilisation resistance (ETO, gamma, autoclave).

2.6 Automation Integration

Assessing automated dispensing systems for ISO 13485

3. Material Overview: Thermoplastic Elastomers (TPE)

3.1 Structure and Composition

Thermoplastic Elastomers (TPEs) are **dual-phase polymers** that combine:
- **Hard thermoplastic domains** (providing rigidity and process ability).
- **Soft elastomeric domains** (providing flexibility and resilience).

This unique morphology allows TPEs to behave like rubber at service temperatures while being processed like plastics under heat.

3.2 Key Properties of TPE's

- **Phthalate-free and DEHP-free** – no plasticizer diffusion, ensuring biocompatibility.
- **Flexibility range:** Shore hardness 40A–95A (soft elastomeric feel).
- **Sterilization compatibility:** Resistant to ETO, gamma, and autoclave sterilization.
- **Low density (0.9 g/cm³):** Lightweight compared to PVC.
- **Transparency:** Suitable for medical tubing and diagnostic devices.
- **Excellent kink resistance and resilience:** Ideal for catheters and infusion sets.
- **Low drug absorption:** High chemical resistance reduces leachables.

- **Process ability:** Compatible with extrusion, injection molding, blow molding, and thermoformin

3.3 Medical-Grade TPE Applications

- **MELIFLEX XT:** Infusion sets, urology catheters, suction catheters, drainage tubing, port tubing for bags.
- **MELIFLEX XM:** Drip chambers, stoppers, plungers, connectors, soft grips.
- **Other commercial grades:** CAWITON, THERMOLAST K/M, Mediprene, Kraton, Hytrel, Dryflex, Sofprene, Tuftec, Laprene.

3.4 Processing Methods

- **Extrusion & Injection Molding:** Primary methods for tubing and connectors.
- **Over molding & Co-molding:** Enables integration with rigid substrates.
- **3D Printing:** Emerging distributed manufacturing applications.
- **Secondary processes:** Welding, bonding, and UV curing for assembly.

3.5 Regulatory Advantages

- **ISO 10993 compliance:** Biocompatibility testing.
- **ISO 13485 alignment:** Manufacturing process control.
- **EU MDR 2017/745:** PVC-free mandate for safer medical devices.

a) Adhesive Application:

- Solvent bonding via controlled exposure.
- UV-curable adhesives with LED curing devices. Precision dispensers for epoxy/polyurethane.
- Silicone adhesives for tubing.

b) Testing Procedures:

- Mechanical strength (tensile, peel).
- Biocompatibility (ISO 10993).
- Sterilisation resistance (ETO, gamma, autoclave).
- Optical clarity evaluation.

c) Automation Integration

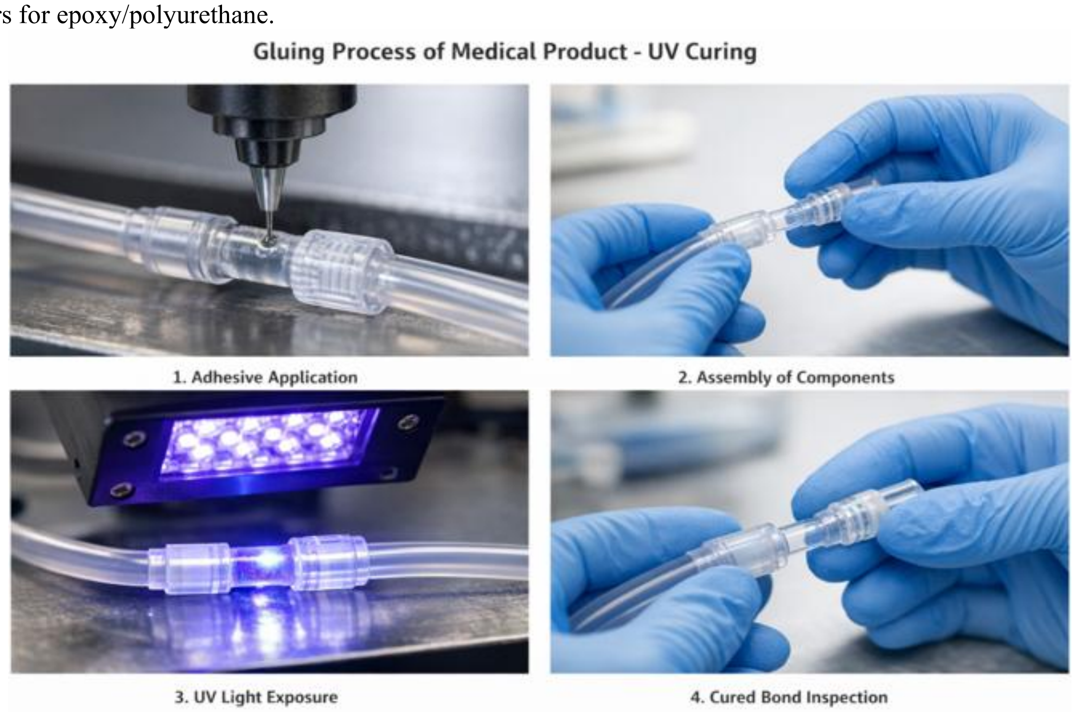
Assessing automated dispensing systems for ISO 13485 compliance.

- TPE materials that come from the block copolymers group include CAWITON†, MELIFLEX, THERMOLAST K†, THERMOLAST M†, Chemiton, Arnitel, Hytrel, Dryflex†, Mediprene, Kraton, Pibiflex, Sofprene†, Tuftec† and Laprene†. † indicates styrenic block copolymers (TPE-s).

4. Processing

The two most important manufacturing methods with TPEs are extrusion and injection molding. TPEs can now be 3D printed and be economically advantageous to make products using distributed manufacturing. Compression molding is seldom, if ever, used. Fabrication via injection molding is extremely rapid and highly economical. Both the equipment and methods normally used for the extrusion or injection molding of a conventional thermoplastic are generally suitable for TPEs. TPEs can also be processed by blow molding, melt calendar thermoforming, and heat welding

4.1 Gluing & UV curing process Overview



Results

- Solvent bonding: Strong, transparent connections in acrylic copolymers.
- UV-curable adhesives: High transparency, rapid curing (<10s).
- Epoxy/polyurethane: Superior mechanical strength, sterilisation resistance.
- Silicone adhesives: Flexible, biocompatible, but lower mechanical strength.
- Automation: Increased GMP compliance, reduced variability, improved reproducibility.

POST (ETO) Sterilization Risk Assessment (FMEA) Visual and Morphological Examination

A detailed FMEA assessment shows that leakage, mechanical strength loss, extractables/leachable, cleanability, and sterilization robustness all fall within low or very-low risk categories. Whitening is confirmed to be superficial and non-structural.

Parameter	Value
Cuing Time	10Sec
UV Intensity	3.5
Leakage Test (2 Bar, Air)	All Passed
Minimum Tensile Strength (N)	41.8
Maximum Tensile Strength (N)	55.2
Average Tensile Strength (N)	47.65
Standard Deviation (N)	3.73

Category Function /Mechanical test:

- **Leakage test:** Passes the test (Tested as per standard ISO 8536-4))
- **Tensile test:** Passes the test (Tested as per standard ISO 8536-4)

5. Results

All 20 samples cured under identical conditions (10 sec cuing time, UV intensity 3.5) successfully passed leakage testing at 2 Bar air pressure. Tensile strength values ranged from 41.8 N to 55.2 N, with an average of 47.65 N and a standard deviation of 3.73 N. The narrow distribution of tensile strength demonstrates reproducibility of the curing process, while the absence of leakage failures confirms structural integrity under pressure."

Risk Assessment (FMEA) Visual and Morphological Examination

Process Step	Potential Failure Mode	Potential Effect(s)	Severity (S)	Potential Cause(s)	Occurrence (O)	Current Controls	Detection (D)	RPN (S×O×D)	Recommended Actions
UV Curing (10 sec, 3.5 intensity)	Incomplete curing	Weak tensile strength (<42 N)	7	Insufficient UV exposure, lamp degradation	3	Standard curing time, UV intensity monitoring	4	84	Periodic UV lamp calibration, increase curing time validation
Bond Integrity	Leakage at 2 Bar	Product failure in use	9	Poor adhesive spread, contamination	2	Leakage test at 2 Bar	2	36	Maintain clean bonding surfaces, improve adhesive dispensing
Mechanical Strength	Low tensile strength variation	Reduced reliability	6	Operator inconsistency, adhesive batch variability	4	Tensile testing of samples	3	72	Tighten process controls, batch qualification
Testing	False pass/fail	Incorrect quality decision	8	Equipment calibration drift	2	Regular calibration schedule	3	48	Increase calibration frequency, add secondary verification

6. Discussion

No single adhesive method is universally optimal. Selection depends on substrate type, device function, and regulatory requirements.

- **UV-curable adhesives**: Best for diagnostic instruments.
- **Epoxy/polyurethane adhesives**: Ideal for structural components.
- **Silicone adhesives**: Preferred for flexible tubing.
- **Automation**: Essential for reproducibility and ISO 13485 compliance

7. Conclusion

PVC-free gluing techniques are vital for sustainable and safe medical devices. Solvent bonding, UV-curable adhesives, and automated dispensing systems each offer unique advantages. Future research should focus on:

- Enhancing polyolefin adhesive compatibility.
- Improving sterilisation resistance of UV-curable adhesives.
- Scaling automation systems for high-volume production.
- The transition to PVC-free materials reflects both regulatory mandates and a commitment to patient safety and environmental responsibility.

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