

4D Photopolymer Actuation: Qualification Limits for Biomedical Translation

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Statement of Significance

Published photopolymer actuators and a separately published polymeric stent do not establish a 4D biomedical device. The intersection remains an evidence gap requiring actuation, durability, sterilisation and biological evaluation of the finished article.

Keywords: 4D printing; actuation; shape memory; biomedical translation; qualification.

Abstract

Two topical sources report soft or thermoresponsive DLP actuators [1,2], while a third studies printing and post-curing of a passive polymeric stent [3]. No retained source demonstrates a vat-printed 4D actuator operating in a biological medium with blocked force or work output and cycle life. This note therefore presents qualification limits, not clinical evidence. RP-02 defines the shared evidence-to-decision and qualification method and is not reproduced here. The corrected public 4Dresyn F-HV1 TDS v1.4 was verified byte-for-byte against the controlled local copy on 21 August 2026. The product-page statement is retained only as manufacturer information and does not constitute independent evidence for biomedical actuation.

1. Evidence boundary

Rylski et al. demonstrate localized shape memory and stiffness control [1]. Miao et al. demonstrate self-sensing thermoresponsive soft actuators [2]. Bosch et al. optimise printing and post-curing parameters for polymeric stents but do not demonstrate active 4D actuation [3]. None establishes biomedical actuation in service.

2. Supported findings and gaps

- Photopolymer networks can be programmed for localized shape-memory response within defined laboratory conditions [1].
- Multimaterial DLP can produce self-sensing thermoresponsive soft actuators within the reported system [2].
- Printing and post-curing affect a passive stent's physicochemical and biomechanical properties, but this is not actuator evidence [3].
- Behaviour in biological media, blocked force, work output, fatigue, sterilisation response and finished-article biological safety remain mandatory tests rather than evidenced findings.

3. Minimum measurement and reporting set

Control	Method and minimum record	Required interpretation
Actuation	stimulus, free displacement/strain, blocked force, work and response time	Report geometry, temperature/medium and uncertainty
Durability	cycle life with predefined failure and retained output	A single reversible cycle is not durability
Biological medium	actuation and stability in the actual simulated or relevant medium	Do not transfer dry-bench performance
Sterilisation	defined applicable cycle followed by repeat actuation and chemistry/mechanics	Sterility does not establish retained function
Biological/device gate	ISO 10993-1:2025 finished-article risk-based evaluation; ISO 10993-12/-18 as applicable	No automatic clinical inference from resin or coupon data

4. Interpretation limits

This review identifies no published evidence satisfying the complete intersection of VPP 4D actuation and biomedical service. Shape recovery without load is not work capacity; a passive stent is not an actuator; and a material example is not device approval.

5. 3Dresyns implementation examples and release gate

4Dresyn F-HV1 is identified in controlled document TDS-4DRESYN-F-HV1-EN, version 1.4, August 2026. The public PDF was verified byte-for-byte against the controlled local copy on 21 August 2026. It is a manufacturer-controlled research candidate, not independent evidence of biomedical actuation. The product-page handle and legacy PDF filename contain e-hv1-elastic; this historical route identifier is not the controlled product identity, and no 4Dresyn E-HV1 Elastic product is represented.

6. Conclusions

- The retained literature supports bench actuation and passive stent processing as separate evidence domains.
- Biomedical 4D performance remains a qualification gap.
- ER-48's scientific and document-control content passed independent review. The Shopify source HTML was synchronized with TDS v1.4 and verified on 21 August 2026.

Declarations

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References

- [1] Adrian K. Rylski, Tejas Maraliga, Yudian Wu, Elizabeth A. Recker, Anthony J. Arrowood, Gabriel E. Sanoja, Zachariah A. Page. Digital Light Processing 3D Printing of Soft Semicrystalline Acrylates with Localized Shape Memory and Stiffness Control. ACS Applied Materials & Interfaces. 2023;15(28):34097-34107. <https://doi.org/10.1021/acsami.3c07172>
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- [3] A. Bosch, S. Ausellé-Bosch, C. Ponce, C. Rubio, T. Puig, J. Ciurana, A. J. Guerra. Analysis of printing and post-curing parameters to enhance physicochemical and biomechanical properties of polymeric stents produced by tubular vat photopolymerization. Progress in Additive Manufacturing. 2025;10(9):5993-6006. <https://doi.org/10.1007/s40964-025-00948-2>

Standards

ISO 10993-1:2025. Biological evaluation of medical devices - risk-management requirements and principles. <https://www.iso.org/standard/10993-1>

ISO 10993-12:2021 and ISO 10993-12:2021/Amd 1:2025. Biological evaluation of medical devices - Part 12: Sample preparation and reference materials. <https://www.iso.org/standard/75769.html>

ISO 10993-18:2020. Biological evaluation of medical devices - Part 18: Chemical characterization within a risk management process. <https://www.iso.org/standard/64750.html>

ISO 10993-18:2020/Amd 1:2022. Determination of the uncertainty factor. <https://www.iso.org/standard/82241.html>

3Dresyns. TDS-4DRESYN-F-HV1-EN, 4Dresyn F-HV1 (Flexible, High Viscosity), public version 1.4 verified byte-for-byte against the controlled local copy on 21 August 2026. The product-page handle contains the legacy identifier e-hv1-elastic and is not the controlled product identity. <https://www.3dresyns.com/products/4dresyn-e-hv1-elastic-high-viscosity-4d-resin>

3Dresyns. RP-02, Evidence-to-Decision Qualification Framework for Vat Photopolymerisation, version 0.1, 2026. Concept DOI: <https://doi.org/10.5281/zenodo.22048032>.