DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	6/22/2026-7/6/2026* FEI NUMBER 3001237365

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sergio Finkielsztein, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Marine Polymer Technologies	461 Boston St Ste B5
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Topsfield, MA 01983-1234	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product were not documented.

Specifically, your firm failed to follow its written procedure, QS-005-012, Deviations and Non-conformances, to log, evaluate, and track nonconforming products. Instead of generating mandatory Non-conformance Reports, your firm utilized an uncontrolled "Return of Product Form" managed by the Accounting Department to process physical product deficiencies. Since the previous inspection conducted on 07/19/21, a total of 16 Return Authorizations were noted as having non-conforming product received back as returns and disposition decisions made to either destroy or return to inventory without documented rationale.

OBSERVATION 2

Procedures for timely complaint handling have not been documented.

Specifically, your firm failed to follow complaint handling procedures QS-002-011 and CS-008-007 to

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Thomas Siebertz, Investigator	X Thomas Siebertz Investigator Signed By: THOMAS J. SIEBERTZ -S Date Signed: 07-06-2026 12:09:32	7/6/2026

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ensure that post-market product deficiencies related to Syvek hemostasis patches, MRDH severe bleeding patches, and Talymed wound care patches such as short shelf-life, distribution failures, and transit losses were documented within your formal QMS. You documented 16 instances of issues including returned goods, damaged product, and short expiration dates reported by customers between 2021 and 2025. Because these were not identified as complaints, you did not follow your complaint handling procedure including reviewing and evaluating the complaints, tracking and maintaining records of complaints, initiating a CAPA (if needed), and determining if the complaint is reportable.

OBSERVATION 3

Changes to quality management system processes were not controlled in accordance with requirements and evaluated for their impact on the quality management system and the medical devices produced.

Specifically, your firm failed to follow procedures for change control documented in QS-014-009, Change Control. Since the previous inspection conducted in 2021, at least (b) (4) changes were completed: a new (b) (4) Barcode Verifier used across (b) (4) products was purchased and installed to replace an old piece of equipment; and the packaging to the Syvek Exel Kit was modified to ensure packaging integrity throughout transit. These were not documented and evaluated prior to implementation according to your change control procedure and omitted from the change control log. Furthermore, management stated that no changes have been made since the previous inspection. The documentation required by your procedure to track and evaluate changes was also not available upon request.

OBSERVATION 4

Appropriate records of personnel training were not adequately maintained.

Specifically, records of training for personnel responsible for intaking feedback and complaints were not available for training required by your procedures. For example, your accounts receivable employee who is involved in product returns as a result of complaints/feedback was trained on complaint handling (CSF-008-007) in 2018, 2019, and 2020. There have been (b) (4) updates to the procedure since 2020 and no

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additional training has been documented. Additionally, for your (b) (4) sales representatives who interface directly with customers, (b) (4) no records of training on customer complaints since 2011 and (b) (4) (b) (4) received training twice on customer complaints since 2011 despite there being (b) (4) updates to the customer complaint procedure. Your procedure also requires sales representatives, customer service, and the customer complaint coordinator to be trained at least (b) (4)

***DATES OF INSPECTION**

6/22/2026(Mon), 6/23/2026(Tue), 6/24/2026(Wed), 6/25/2026(Thu), 6/26/2026(Fri), 6/29/2026(Mon), 6/30/2026(Tue), 7/06/2026(Mon)

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

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EMPLOYEE(S) SIGNATURE
Thomas Siebertz, Investigator

X Thomas Siebertz Investigator Signed By: THOMAS J. SIEBERTZ -S Date Signed: 07-06-2026 12:09:32

DATE ISSUED
7/6/2026

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."