**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 60 Eighth Street NE<br>Atlanta, GA 30309<br>(404)253-1161 Fax:(404)253-1202 | 2/25/2026-2/26/2026 |
| | FEI NUMBER<br>1051614 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Brad D. Wilkinson, Director of Product Management

| FIRM NAME | STREET ADDRESS |
|---|---|
| Practicon Inc | 1112 Sugg Pkwy |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Greenville, NC 27834-9077 | Repackager/Relabeler |

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.

**DURING AN INSPECTION OF YOUR FIRM I OBSERVED:**

## OBSERVATION 1

Records of risk management activities in product realization were not maintained.

Specifically, your firm failed to conduct risk management activities for the Practicon Acu-Tip Cauterizing Instrument, a Class II medical device used for stopping small bleeders in hemostasis and other similar uses. The device's Instructions for Use identify hazards under the Warning Section including inadvertent burns to patient or user, damage to adjacent tissue, and fire when exposed to oxygen-rich environments. Despite these identified hazards, your firm did not establish a FMEA to estimate and evaluate associated risks, control these risks, or monitor the effectiveness of risk controls. Your firm did not provide evidence of risk analysis documentation, risk evaluation records, or implementation of risk control measures for this device.

## OBSERVATION 2

Top management did not review the quality management system at documented planned intervals to ensure its continued suitability, adequacy, and effectiveness.

Specifically, your firm failed to conduct management reviews at planned intervals. During the inspection, management did not provide a documented procedure establishing the frequency of management review meetings, records of management review meetings, or a list of required attendees for management review meetings. Additionally, top management did not review the implementation of the Quality Management System Regulation (QMSR) to ensure the Practicon Acu-Tip Cauterizing Instrument, a Class II medical device, meets applicable regulatory requirements and product

AMENDMENT 1

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Lashawn M Elam, Investigator | X Lashawn M Elam Investigator Signed By: Lashawn M. Elam -S Date Signed: 02-26-2026 13:26:42 | 2/26/2026 |

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specifications. Furthermore, your firm has not designated a member of management as the Management Representative with defined responsibility and authority for ensuring quality management system processes are established, implemented, and maintained.

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**OBSERVATION 3**

Training has not been provided, or other actions needed taken, to achieve or maintain the necessary personnel competence.

Specifically, your firm failed to establish and maintain adequate personnel training records including records of education, training, skills, and experience for employees performing work affecting product quality and regulatory compliance. Staff responsible for handling complaints have no documented training on Medical Device Reporting found in QP1290 Medical Device Reporting. Staff responsible for receiving and packaging do not have records of training on QP1130 Packaging and Control. Also, staff responsible for inspecting finished devices, Practicon Acu-Tip Cauterizing Instrument, have no documented training on QP1090 Receiving In-Process Finished Product Acceptance. Your firm did not provide records to show that personnel performing these quality-critical functions possess the necessary training.

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## Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

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**SEE REVERSE OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Lashawn M Elam, Investigator

X Lashawn M Elam
Investigator
Signed By: Lashawn M. Elam -S
Date Signed: 02-26-2026
13:26:42

DATE ISSUED

2/26/2026

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."