DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 555 Winderley Place, Suite 200<br>Maitland, FL 32751<br>(407) 475-4700 Fax:(407) 475-4768<br>Industry Information: www.fda.gov/oc/industry | 09/02/2014 - 09/03/2014 |
| | FEI NUMBER<br>3002865793 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Bruce A. Beckstein, President

| FIRM NAME | STREET ADDRESS |
|---|---|
| MedOne Surgical, Inc. | 670 Tallevast Rd |
| CITY, STATE, ZIP CODE, COUNTRY<br>Sarasota, FL 34243-3254 | TYPE ESTABLISHMENT INSPECTED<br>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

Records of complaint investigations do not include required information.

Specifically, your records covering complaint #130002, dated 06/04/2013, and complaint #130004, dated 09/10/2013, do not accurately describe your findings in that the complaint forms, #27019B, list that the device did not malfunction although your records of the investigation do not adequately demonstrate that you found the device did not malfunction.

## OBSERVATION 2

Procedures for the acceptance of in-process product have not been adequately established.

Specifically, you have not defined, documented, and implemented acceptance criteria for the pull test conducted as part of in-process and final acceptance activities for your FlexTip Cannula, Product #3221.

## OBSERVATION 3

The device history record does not demonstrate that the device was manufactured in accordance with the device master record.

Specifically,

A. You have not adequately implemented Section 4 of your In-Process Testing procedure, SOP# 250.20.03, which requires that you repeat the Quality assurance check at approximately the halfway point of completing the process

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for lots at or exceeding (b)(4) units. For example, records for Lot# H1213, A1306, and F1306 of FlexTip Cannula devices, Product# 3221, list that the QA Check at Midpoint was conducted after production was completed.

B. You have not adequately implemented Section 12 of your written Assembly and Bonding of Tubing into Cannulas procedure in that your final acceptance activities have not included performing the destructive pull testing described in this written procedure.

## OBSERVATION 4

Acceptance activities were not adequately documented.

Specifically, your records of acceptance testing for the FlexTip Cannula device, Product# 3221, do not list the actual results of acceptance activities that were observed by the persons conducting such activities; rather, your records list only the date the acceptance activities were performed and the initials of the persons who conducted the acceptance activities. For example, your records do not list results observed from Pull Test or reslust of evaluation for Length covering the devices you have manufactured.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Joshua J. Silvestri, Investigator | 09/03/2014 |

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## Observation Annotations

Observation 1: Promised to correct within 30 days.
Observation 2: Promised to correct within 60 days.
Observation 3: Promised to correct within 60 days.
Observation 4: Under consideration.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
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| | Joshua J. Silvestri, Investigator | 09/03/2014 |