

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

DISTRICT ADDRESS AND PHONE NUMBER 22215 26th Ave SE Suite 210 Bothell, WA 98021 (425) 302-0340 Fax: (425) 302-0404	DATE(S) OF INSPECTION 12/8/2015-4/15/2016*
	FEI NUMBER 3001239271

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Katerie D. Chapman , Senior Vice President and Hospital Administrator

FIRM NAME Virginia Mason Medical Center	STREET ADDRESS 1100 9th Ave
CITY, STATE, ZIP CODE, COUNTRY Seattle, WA 98101-2756	TYPE ESTABLISHMENT INSPECTED User Facility

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 WE OBSERVED:

OBSERVATION 1

MDR event files do not contain or reference all adverse event information in the possession of the reporting entity, including documentation of the deliberations and decision making process used to determine if an event was or was not reportable.

Specifically,

a) Your facility indicated that 39 patients who had undergone ERCP procedures were found to harbor a multidrug-resistant E coli. Your facility also identified that this same multidrug-resistant E coli was found to be growing on duodenoscopes used during these ERCP procedures. There is no documentation available showing these events were reviewed for reportability to the manufacturer.

b) Patient Safety Alert **b(6)** was opened on **b(6)** regarding a patient needing emergency repair surgery of a failed patch angioplasty after the patient had a left carotid endarterectomy. There is no documentation available showing this adverse event was reviewed for reportability to the manufacturer.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Stephen R Souza, Investigator Sharon I Gundersen, Investigator Christopher S Genther, Investigator	DATE ISSUED 4/15/2016
	<input checked="" type="checkbox"/> Stephen R Souza Stephen R Souza Investigator Signed by: Stephen R. Souza -S	

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The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility.

Specifically, on **b(3)b(6)**, an **b(3)** was surgically removed from a patient due to the **b(3)** migrating and bowel obstruction in the patient. Patient Safety Alert **b(3)b(6)** regarding this **b(3)** removal was reported on **b(3)**. On **b(3)** a FDA mandatory report draft was completed. The Mandatory MedWatch report to the manufacturer, dated **b(3)**, states the initial report to manufacturer was done in **b(3)** by **b(3)** via telephone report. There is no documentation available showing all information required on the FDA Form 3500A or electronic equivalent was submitted to the manufacturer prior to the **b(3)** Medwatch report.

OBSERVATION 3

An authorized FDA employee was not permitted to copy MDR required records during reasonable times.

Specifically, during the inspection of your facility a MedWatch report, dated **b(3)**, was provided to us regarding a product problem with **b(3)**. Your firm indicated that Patient Safety **b(3)b(6)** contains information relating to this event. Your firm allowed us to review but refused to provide a copy of Patient Safety **b(3)b(6)**.

OBSERVATION 4

Written MDR procedures have not been implemented .

Specifically, the Clinical Policy and Procedure Manual Patient Safety for Medical Device User Reporting, Procedure Section 5b documents the requirement to report information that “that reasonably suggests that a device may have caused or contributed to a serious injury of a patient” to the FDA within 10 work days after becoming aware of the information and to the manufacturer if known.

a) On **b(3)b(6)** an **b(3)** was surgically removed from a patient due to the **b(3)** migrating and bowel obstruction in the patient. Patient Safety **b(3)b(6)** regarding this **b(3)** removal was reported

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on b(3) . On b(3) a FDA mandatory report draft was completed. The Adverse Event Determination Team met on b(3) and decided this event is reportable to the FDA and manufacturer. The Mandatory MedWatch report to the manufacturer and the Voluntary MedWatch report to the FDA was submitted on b(3) .

b) Patient Safety b(3)b(6) was opened in response to a media story regarding the dislodging of b(3) b(3) . Medical records were reviewed and Virginia Mason found they removed a b(3) b(3) from a patient on b(3) b(6) . The Determination Team Decision Tool was completed for the Determination Team meeting on b(3) but a reportability determination was not decided during the b(3) meeting. The Determination Team met on b(3) and agreed to submit a voluntary MedWatch report regarding this patient. This MedWatch was submitted to the FDA on b(3) .

Annotations to Observations

Observation 1: Not annotated
 Observation 2: Not annotated
 Observation 3: Not annotated
 Observation 4: Not annotated

***DATES OF INSPECTION**

12/08/2015(Tue),12/09/2015(Wed),12/10/2015(Thu),12/11/2015(Fri),12/21/2015(Mon),12/22/2015(Tue),1/04/2016(Mon),1/05/2016(Tue),1/07/2016(Thu),1/19/2016(Tue),1/20/2016(Wed),1/21/2016(Thu),3/01/2016(Tue),3/24/2016(Thu),4/12/2016(Tue),4/15/2016(Fri)

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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."