DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	09/14/2009 - 09/21/2009* FEI NUMBER 3006168886

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Gary Paul Clark, Senior Vice President, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Munroe Regional Medical Centre	1500 Sw 1st Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ocala, FL 34474-4004	Medical Center

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

An MDR adverse event report was submitted on a form other than FDA Form 3500A (MEDWATCH form) or an approved electronic equivalent.

Specifically, you contacted the device manufacturer by telephone to report the event featured in Incident Report #InvP-140417, dated 07/29/09, involving a patient who suffered a torn esophagus during a procedure utilizing the EsophyX device.

OBSERVATION 2

The written MDR Procedure does not include an internal system which provides for the timely and effective identification and evaluation of events that may be subject to medical device reporting requirements.

Specifically, your Medical Device Problem Reporting procedure, Number 14, dated 12/10/08, does not include provisions to evaluate events which may be subject to MDR requirements for determining the severity of the event, in order to determine if it is reportable. Further, Incident Report InvP-140417, filed 07/29/09, was created per the requirements of the procedure and includes information that the patient suffered a torn esophagus which may have been caused by the a medical device, but your firm did not determine and document if the nature of the injury was serious.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Joshua J. Silvestri, Investigator	09/21/2009

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	09/14/2009 - 09/21/2009* FEI NUMBER 3006168886

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Gary Paul Clark, Senior Vice President, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Munroe Regional Medical Centre	1500 Sw 1st Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ocala, FL 34474-4004	Medical Center

OBSERVATION 3

The written MDR procedure does not include an internal system which provides for a standardized review process/procedure for determining when an event meets the criteria for reporting.

Specifically, your Medical Device Problem Reporting procedure, Number 14, dated 12/10/08, does not define any review process or procedures for events to determine when an event is required to be reported to FDA and/or the manufacturer. Further, Incident Report InvP-140417, filed 07/29/09, involving a patient who suffered a torn esophagus during a procedure utilizing the EsophyX device, was created per the requirements of the procedure, and your Director of Materials Management determined the event was not reportable injury was serious, although CT scans performed at your facility showed fluid leaking into the chest cavity.

OBSERVATION 4

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, your documents covering deliberations and/or decision making processes used to determine that Incident Report #InvP-140417, dated 07/29/09, involving a patient who suffered a torn esophagus during a procedure utilizing the EsophyX device, was not a reportable event are not complete and do not fully demonstrate the decision process or list the final decision.

OBSERVATION 5

The written MDR procedure does not include documentation and recordkeeping requirements for all information that was evaluated to determine if an event was reportable.

Specifically, your Medical Device Problem Reporting procedure, Number 14, dated 12/10/08, does not include documentation and recordkeeping requirements for all information that was evaluated to determine if an event was reportable.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Joshua J. Silvestri, Investigator	09/21/2009

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	09/14/2009 - 09/21/2009* FEI NUMBER 3006168886

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Gary Paul Clark, Senior Vice President, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Munroe Regional Medical Centre	1500 Sw 1st Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ocala, FL 34474-4004	Medical Center

Observation Annotations

Observations intentionally left blank.

*** DATES OF INSPECTION:**
09/14/2009(Mon), 09/15/2009(Tue), 09/21/2009(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Joshua J. Silvestri, Investigator	09/21/2009

was not tested for entrapment risk. Firm failed to send reply letter of this complaint investigation's conclusion.

(F) Firm received Complaint #4023 dated 01/05/10 which references an 18 year old patient with cerebral palsy (4 foot 4 inches tall weighing 53 lbs) fell from the Invacare bed and suffocated. Firm's complaint investigation was inadequate in that:

(i) Firm did not document good faith attempt to obtain pertinent information as to what area of the bed suffocation occurred and what mattress was used and its condition.

(ii) Firm did not determine most likely root cause. Firm did not determine if patient's size related to higher risk of entrapment and did not determine if the bed's dimensions put patient at higher risk.

(G) Firm received Complaint #4181 dated 02/11/10 which references a consumer alleges an Invacare bed system allowed his wife's head to get stuck between rail and mattress causing her suffocation. Firm's complaint investigation is adequate in that:

(i) Firm failed to document attempt to obtain pertinent information including actual user's name, contact information and patient's height/weight.

(ii) Firm did not determine most likely root cause. Firm did not attempt to determine if patient's size could relate to higher risk of entrapment. Firm did not determine if bed system's dimensions put patient at higher risk of entrapment/death.

(H) Firm received Complaint #4234 dated 02/17/10 which references that there was an alleged death of patient and entrapment with Invacare bed between the bottom of the rail and the top of the mattress. It is documented in firm's investigation that health care facility personnel stated a coroner's report indicated that the patient suffered a heart attack and then was allegedly entrapped post mortem. Firm's complaint investigation was inadequate in that:

(i) Firm failed to obtain copy of subject coroner's report.

(ii) Firm failed to obtain pertinent information including contact information for patient's family and patient's height/weight.

(iii) Firm states that non-Invacare mattress was used, however no identification of brand name/manufacturer/dimensions/condition and firm failed to send reply letter to complainant cautioning them not to use a non-Invacare mattress.

(I) Firm received Complaint #4522 dated 04/13/10 which references an Invacare bed and bed rail was allegedly involved in a bed entrapment death of a child (age 11). Firm's complaint investigation was inadequate in that:

(i) Firm did not attempt to get pertinent information regarding bed model #, mattress type/condition, patient weight/height, where the child was entrapped and whether there is a history of entrapment with this particular bed rail.