DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139 Industry Information: www.fda.gov/oc/industry	05/04/2009 - 05/14/2009 FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: James N. Heath, President and General Manager

FIRM NAME	STREET ADDRESS
Stryker Instruments Div. of Stryker Corporation	4100 E. Milham Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kalamazoo, MI 49001	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 WE OBSERVED:

OBSERVATION 1

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated and approved according to established procedures.

Specifically,

The following processes are not fully validated:

1. The process for manufacturing the Clover Catheters and Silver Ex-Fen Catheters is not fully validated.
    a. The female luer hub component of the Clover Catheter and Silver Ex-Fen Catheters is an injection-molded part. There is evidence of dimensional failures, short shots, flash, loose foreign matter, and embedded contamination during the validation runs with injection molding operating parameters set at the minimum and maximum values. There is no documentation that these runs were repeated at revised minimum and maximum injection molding parameters to establish a range of operating parameters per the validation protocol (b) (4) . The current set-up sheet for the injection molding process used in routine production of the female luer contains the minimum and maximum injection molding parameters that were used during the failing runs. Additionally, the nominal runs performed during validation (b) (4) were not representative of actual production. The nominal runs were approximately (b) (4) long. Routine production is approximately (b) (4) .

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Charles M. Spyr, Investigator Martha Sullivan Myrick, Investigator Kimberl Lewandowski-Walker, Investigator Gary D. Urbiel Goldner, Investigator	05/14/2009

b. The extrusion process of manufacturing the tubing component of the Clover Catheter and Silver Ex-Fen Catheters has not been validated. According to personnel at Stryker Instruments, the outer diameter of the catheter tubing is the only dimension that is continuously monitored (using a (b) (4)). Other qualities of the catheter tubing, such as tensile testing, are tested using one sample at the beginning and one sample at the end of each reel.

2. The (b) (4) bonding process of the glass restrictor to the male luer of the Stryker Auto-Fuser PainPump is not completely validated. The documentation available at Stryker Instruments (translated from (b) (4)) involves a number of limited test runs to determine a range of operating parameters. There is no documentation of runs being performed at the nominal parameters as part of process validation representing routine production to determine the stability of the (b) (4) bonding process when run over time. There is no documentation that any destructive cross-sectional examination of the quality and (b) (4) bond of the glass restrictor to the male luer connector was performed. The (b) (4) bonding process was identified as the root cause of a Stryker Auto-Fuser infusion pump that was found to over-infuse by (b) (4).

OBSERVATION 2

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically,

(b) (4) complaints received by the firm between January 23, 2009 and February 18, 2009 reported leakage of oil or a black oil, substance, or material from the surgical instrument into either the sterile field or the patient wound during a surgical procedure. These complaints have not been reported as MDR's. For example:

a. PER # (b) (4) of January 23, 2009 reported:
   i. (b) (4) ."
   ii. "(b) (4) ."

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139 Industry Information: www.fda.gov/oc/industry	05/04/2009 - 05/14/2009 FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: James N. Heath, President and General Manager

FIRM NAME	STREET ADDRESS
Stryker Instruments Div. of Stryker Corporation	4100 E. Milham Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kalamazoo, MI 49001	Medical Device Manufacturer

b. PER #(b) (4) of January 27, 2009 reported:
   i. "(b) (4) [redacted] ."
   ii. "..(b) (4) [redacted] ..."

c. PER (b) (4) of February 5, 2009 reported, "(b) (4) [redacted] ."

d. PER (b) (4) of February 17, 2009 reported, "(b) (4) [redacted] ."

e. PER #(b) (4) of February 18, 2009 reported:
   i. "(b) (4) [redacted] ."
   ii. "..(b) (4) [redacted] ."

OBSERVATION 3

Potential suppliers and contractors were not sufficiently evaluated and selected on the basis of their ability to meet specified requirements.

Specifically,

The completeness and adequacy of process validations for processes which cannot be fully verified by inspection and testing is not fully assessed during supplier evaluations. For example:

1. The supplier evaluation process for the approval of the contract manufacturer of the Stryker Auto-Fuser PainPump indicates that a functional team evaluated the (b) (4) bonding process of the glass restrictor to the male luer connector. The documentation available at Stryker Instruments (translated from (b) (4)) involves a number of short test runs to determine a range of operating parameters. There is no documentation that any destructive cross-examination of the (b) (4) bond of the glass restrictor to the male luer connector was performed during process validation to assess the quality and regularity of the bond. In spite of this lack of documentation, the functional team approved the validation documents from the contract manufacturer. The (b) (4) bonding process was identified as the root cause of a Stryker Auto-Fuser PainPump that over-infused by (b) (4)%.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Charles M. Spyr, Investigator Martha Sullivan Myrick, Investigator Kimberl Lewandowski-Walker, Investigator Gary D. Urbiel Goldner, Investigator	05/14/2009

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139 Industry Information: www.fda.gov/oc/industry	05/04/2009 - 05/14/2009 FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: James N. Heath, President and General Manager

FIRM NAME	STREET ADDRESS
Stryker Instruments Div. of Stryker Corporation	4100 E. Milham Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kalamazoo, MI 49001	Medical Device Manufacturer

2. The supplier evaluation process for the contract manufacturer of the Clover Catheter and Silver Ex-Fen Catheters included a review of the validation documentation for the injection molding of the female luer and extrusion process of the tubing. There is evidence of dimensional and other failures during the assessment of worst-case operating parameters for injection molding during the process validation. There is no evidence that the worst-case operating parameters were re-assessed and the worst-case runs were repeated with revised operating parameters. The nominal runs were not representative of actual production during injection molding, since the runs were approximately (b) (4) in duration and (according to Stryker Instruments personnel) normal production is approximately (b) (4). Personnel at Stryker Instruments approved the supplier in spite of the failures during the worst-case operating parameter runs and the short performance qualification runs.

OBSERVATION 4

Procedures for addressing the identification, evaluation, and investigation of nonconforming product were not defined.

Specifically,

1. There have been at least (b) (4) complaints alleging failure of the Stryker Auto-Fuser infusion pump to infuse medication since July of 2008. Of these complaints, six Stryker Auto-Fuser infusion pumps were tested at Styker Instruments for flow rate. However, the test was performed either using the pump alone or the pump with a catheter, but not with resistance at the end of the pump tubing or pump/catheter combination as would occur when the Stryker Auto-Fuser is used as intended and a catheter is implanted in the body. The testing that was performed at Stryker Instruments of returned Stryker Auto-Fuser infusion pumps is not representative of the actual use of the product. There is no documented procedure for conducting failure analysis of the Stryker Auto-Fuser infusion pumps or a requirement that the failure analysis be representative of the actual intended use.

2. According to risk assessment (b) (4) Stryker Instruments personnel discovered on March 10, 2009 that Stryker Auto-Fuser infusion pump kits were erroneously accepted into inventory at Stryker Instruments using the contract manufacturer's peel and burst testing of the sterile packaging. Stryker Auto-Fuser infusion pump kits in inventory were placed on hold and peel and burst testing was performed by Stryker Instruments. Peel and burst testing performed at

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139 Industry Information: www.fda.gov/oc/industry	05/04/2009 - 05/14/2009 FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: James N. Heath, President and General Manager

FIRM NAME	STREET ADDRESS
Stryker Instruments Div. of Stryker Corporation	4100 E. Milham Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kalamazoo, MI 49001	Medical Device Manufacturer

Stryker Instruments showed failing results for (b) (4) lots in inventory that passed peel and burst testing at the contract manufacturer. Four lots that failed peel and burst testing were shipped to customers. One lot (0812201629) that failed peel and burst testing that shipped to customers identified by Stryker Instruments prior to the initiation of this inspection. The shipment of portions of three additional lots (0902201024, 0812201229, 0812201929) that failed peel and burst testing that shipped to customers was discovered as a result of this inspection. There is a lack of established procedures to fully evaluate the extent of lots involved in non-conformances.

3. Supplier Non-Conforming Product Report, NC ID (b) (4), indicates that a Stryker Auto-Fuser infusion pump, part number 0580-002-016, was found to over-infuse by (b) (4) during a flow-rate test performed at Stryker Instruments. The infusion pump is manufactured by a contract manufacturer. Investigation by the contract manufacturer indicates that the over-infusion was due to an irregular bond of the glass restrictor to the male luer connector, which allowed the fluid to bypass the restrictor. There is no documentation that the contract manufacturer performed any additional flow-rate testing using fluid on Stryker Auto-Fuser infusion pumps in stock to determine the extent of the failure of the (b) (4) bonding process or that Stryker Instruments personnel requested an evaluation of the Stryker Auto-Fuser PainPumps in stock at the contract manufacturer.

OBSERVATION 5

Procedures were not established for reviewing sampling methods for adequacy for their intended use.

Specifically,

1. Procedure (b) (4) (b) (4) " states in (b) (4) . The sampling plan used during incoming inspection at Stryker Instruments for peel and burst testing of the sterile packaging of the Stryker Auto-Fuser infusion pumps corresponds (approximately) to (b) (4) . However, the packaging validation documentation supplied by the contract manufacturer of the Stryker Auto-Fuser infusion pumps is not complete because it contains only subjective qualities of the seal for the sterile packaging using limited production runs to determine a range of operating parameters. The peel and burst testing validation at the contract manufacturer of the Stryker Auto-Fuser infusion pumps has not been approved by Stryker Instruments as of the date of this inspection. Additionally, various lots

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Charles M. Spyr, Investigator Martha Sullivan Myrick, Investigator Kimberl Lewandowski-Walker, Investigator Gary D. Urbiel Goldner, Investigator	05/14/2009

of sterile packages that passed peel and burst testing at the contract manufacturer of the Stryker Auto-Fuser infusion pumps were found to fail peel and burst testing when the lots were re-tested at Stryker Instruments.

2. There are no established procedures for the re-assessment of the applicability of sampling plans when non-conformances are discovered.

OBSERVATION 6

The design was not validated using production units under actual or simulated use conditions.

Specifically,

There is no documentation that design validation for the Clover Lumen Catheter (Tr (b) (4) of 11/09/05) and the Maestro dynamic seal (Tr (b) (4) of 6/1/06) was performed on initial production units or their equivalents.

OBSERVATION 7

Employees have not been adequately trained.

Specifically,

Sales representatives and other individuals responsible for customer service are not adequately trained regarding complaint handling. For example:

1. Complaint PER (b) (4) alleges that the Stryker Auto-Fuser infusion pump did not infuse. The sales representative received the infusion pump from the customer, but discarded it rather than returning it to Stryker Instruments for evaluation. The opportunity for Stryker Instruments to perform failure analysis was lost.

2. Complaint PER (b) (4) alleges that the Stryker Auto-Fuser infusion pump did not infuse. The sales representative was contacted three times to determine if the product is being returned. The sales representative did not respond.

3. Complaint PER (b) (4) alleges that the tubing connected to the Stryker Auto-Fuser infusion

pump was blocked, preventing medication from being infused to the patient. The sales representative was contacted to determine if the product is being returned. The sales representative did not respond.

4. Complaint PER (b) (4) alleges that the Stryker Auto-Fuser infusion pump did not infuse. The complaint was received by customer service. The complainant is listed as the patient. The customer (the medical center who purchased or otherwise received the Stryker Auto-Fuser infusion pump) is listed on the complaint, but there is no patient (complainant) information included in the complaint, such as the patient's name, address, telephone number, or surgical procedure for which this infusion pump was used. The sales representative was not informed by the customer of an issue with the pump. The opportunity for Stryker Instruments to receive the infusion pump from either the patient or customer in order to perform failure analysis was lost.

5. Complaint PER (b) (4) alleges that the Stryker Auto-Fuser infusion pump did not infuse. The sales representative was contacted by Stryker Instruments complaint handling personnel as to the return status of the pump. The sales representative did not respond and the product was not returned to Stryker Instruments for failure analysis.

6. Complaint PER (b) (4) alleges that the Stryker Auto-Fuser infusion pump did not infuse and there was blood in the tubing. The complainant is the patient. The complaint was received by customer service on October 27, 2008. An e-mail was sent to the sales representative on December 22, 2008 regarding the return of the pump. The sales representative did not respond. The opportunity for Stryker Instruments to receive the infusion pump from either the patient or customer in order to perform failure analysis was lost.

7. Complaint PER (b) (4) for false elevation readings on the SNAP II, had an awareness date listed as 3/25/2009. Review of the complaint determined that the sales rep was aware of the potential complaint on 2/26/2009. The sales rep did not forward the complaint to the appropriate personnel for investigation until 3/25/2009. This complaint led to an MDR.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139 Industry Information: www.fda.gov/oc/industry	05/04/2009 - 05/14/2009 FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: James N. Heath, President and General Manager

FIRM NAME	STREET ADDRESS
Stryker Instruments Div. of Stryker Corporation	4100 E. Milham Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kalamazoo, MI 49001	Medical Device Manufacturer

OBSERVATION 8

A validated process was not performed by a qualified individual.

Specifically,

There is no documentation of the qualification of employee retraining in the operation of the Automated Optical Inspector (AOI) machine. During original qualification on the AOI machine on 4/6/06 using known defective boards, employees had difficulty observing defect boards that were observed by the AOI machine. The Process Qualification Characterization Test Report stated all defects were identified correctly by the system, but defects were identified with abnormalities by the operators. During operations, the Quality Operators override defects observed by the AOI machine.

In addition, Disc Monitor PCB Set work order number (b) (4) passed (b) (4) visual in process inspection under IPC (b) (4) standard inspectional guidelines was released based on final inspection of 2/11/09. Defects, including backwards pressure sensors, were then discovered at Stryker Puerto Rico on the Disc Monitor PCB Set.

OBSERVATION 9

Complaint handling procedures for receiving complaints have not been implemented.

Specifically,

Corporate SOP (b) (4) dated 09/26/2008 states that patient involvement shall be documented and a rationale shall be provided if the field is unknown. This was not always completed as evidenced by:

- Complaint (b) (4) for the RF Multi Gen unit dated 5/01/2009
- PER # (b) (4) of January 6, 2009 for an Automatic High Vacuum Foot Pump (Catalog # 0206500000)
- PER # (b) (4) of March 6, 2009 for a Repair Core U Drill (Catalog # 5400100000R)
- PER # (b) (4) of April 16, 2009 for a Micro Drill Medium Straight Attachment (Catalog # 5100015250)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Charles M. Spyr, Investigator Martha Sullivan Myrick, Investigator Kimberl Lewandowski-Walker, Investigator Gary D. Urbiel Goldner, Investigator	05/14/2009

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139 Industry Information: www.fda.gov/oc/industry	05/04/2009 - 05/14/2009 FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: James N. Heath, President and General Manager

FIRM NAME	STREET ADDRESS
Stryker Instruments Div. of Stryker Corporation	4100 E. Milham Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kalamazoo, MI 49001	Medical Device Manufacturer

OBSERVATION 10

Rework and reevaluation activities have not been fully documented in the device history record.

Specifically,

Rework activities of defective electronic boards that were originally manufactured in the Stryker Board house are not always documented. Rework activities include the repair and reinspection of the boards. Work Order (b) (4) for documentation of post solder inspection shows a defective product for the reason code of wrong component. There is no written entry for the repair or reinspection of the defect.

In addition, during inspection, including both (b) (4) visual and Automated Optical Inspector (AOI) inspection, of the electronic boards, there is no documentation to show during which operation or in process inspection step defects are observed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Charles M. Spyr, Investigator Martha Sullivan Myrick, Investigator Kimberl Lewandowski-Walker, Investigator Gary D. Urbiel Goldner, Investigator	05/14/2009

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139 Industry Information: www.fda.gov/oc/industry	05/04/2009 - 05/14/2009 FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: James N. Heath, President and General Manager

FIRM NAME	STREET ADDRESS
Stryker Instruments Div. of Stryker Corporation	4100 E. Milham Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kalamazoo, MI 49001	Medical Device Manufacturer

Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Promised to correct within 30 days.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct.
Observation 5:	Promised to correct.	Observation 6:	Reported corrected, not verified.
Observation 7:	Promised to correct.	Observation 8:	Promised to correct.
Observation 9:	Promised to correct.	Observation 10:	Promised to correct.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Charles M. Spyr, Investigator
Martha Sullivan Myrick, Investigator
Kimberl Lewandowski-Walker, Investigator
Gary D. Urbiel Goldner, Investigator

DATE ISSUED

05/14/2009