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	03/16/2009 - 03/26/2009
	FEI NUMBER 1017294

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Gregory R. Jones, Vice President- QA/RA

FIRM NAME	STREET ADDRESS
Linvatec Corp.	11311 Concept Boulevard
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Largo, FL 33773	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

Certain indicators of nonconformities are not investigated to determine the cause of the nonconformity.

Specifically,

a) The investigation and corrective action determined for CAPA 531, initiated on 8/2/07, in response to distributor complaints of sterility seals breaches in sterile packages in June 2007, which initiated a Class II recall, was incomplete. The investigation to determine location of all pouches received from vendor determined that [redacted] of the Teflon pouches, part number P30-091-000 were unaccounted in inventory and determined to be waste without investigation. Firm failed to take corrective action to improve accountability of raw materials and components used in manufacture and packaging of sterile (b)(4) implantable devices.

b) The investigation of CAPA 742, dated 9/10/08 was incomplete in that the root cause for the failures of the Arthroknife sheath to allow full retraction of the blade determined that the machine operator was utilizing tooling improperly. Corrective action to implement additional labeling in the form of an IFU for newly processed knives and retraining of operators in proper use of tooling appears to be inadequate in that:

i.) the IFU is sent with all new products manufactured at the implementation of the corrective action, however; the IFUs were not provided to end users or distributors for previously affected processed knives.

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ii.) investigation to determine length of time operators failed to properly utilize tooling to determine full impact of process inconsistencies was not considered at the time of investigation.

(b)(4)

c) In addition, review of DHRs and processing of [redacted] a sterile stainless steel implantable wire used to stabilize mainly flat human bone after surgery revealed that tradability of raw materials was also incomplete in that prior to February 6, 2009 and implementation of SOP 05019 Rev P, not all issued [redacted] for each lot were properly documented and controlled. Management explained that in a lot of [redacted] ordered, [redacted] wires are issued to be used for tooling set-up and test before final production of the lot. Remaining wires were unaccounted for and determined to be scrapped with no documentation.

OBSERVATION 2

Acceptance procedures to ensure that specified requirements for in-process product are met were not complete.

Specifically, review of investigation and corrective action activities for CAPA 372, dated 11/30/06, which also resulted in a Class II recall of sterile product, revealed that integrity testing of sterile packaging during sealing operations fails to include the device in the package before sealing to challenge the seal of the package as finished.

(b)(4)

Firm's Sterile Packaging Seal Inspection Procedure, IP-000-238, Rev AD requires that one package from each sealer per product at the beginning and end of shift are sealed and peel tested to determine seal compliance. However; this procedure fails to include the actual [redacted] packaging surrounding the device. The package is sealed empty.

OBSERVATION 3

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 firm's labeling for sterile reusable devices includes the firm's recommended and validated steam sterilization procedure. The validation was concluded in March 1996 and filed as [redacted]

(b)(4)

Review of the IFU and validated process revealed inconsistencies. The validation required a ½ cycle validation to challenge the sterilization parameters, however; the actual time of the cycle was actually

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conducted at $^{2}/_{3}$ the time for each stage for the [redacted] processes. (b)(4)

OBSERVATION 4

There is incomplete documentation of the disposition of nonconforming product.

Specifically, review of Complaints 233067 and 233068 revealed that several complaints were received for mislabeled sterile SUD burrs. The burrs were labeled as 7.5 mm when in fact the size of the burr is 5 mm. Review of the complaint file and processing records for the lot processed determined the quality engineer assigned the complaint for investigation failed to document the non-conformance, follow-up and corrective action. The in-process inspection report in the DHR indicates that 13 samples were evaluated and passed specifications by the certified independent operator, however; the 5 mm burrs were package, distributed, sterilized and returned from the distributor without the firm's inspection procedures alerted or documenting the non-conformance.

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Observation Annotations

Observation 1: Promised to correct.
Observation 2: Promised to correct.
Observation 3: Promised to correct.
Observation 4: Promised to correct.

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	Leo J Lagrotte, Investigator	03/26/2009