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November 3, 2015

K153203

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Navigation Instruments Premarket Notification

Dear Sir/Madam,

Globus Medical, Inc. (Globus) hereby submits this **Traditional 510(k)** to request clearance for **Navigation Instruments** that are to be used with the Medtronic StealthStation System. Stereotaxic instruments are considered Class II under panel code 84. In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act, this submission constitutes a Premarket Notification for Navigation Instruments. There have been no prior submissions for these devices. An eCopy is enclosed and is an exact duplicate of the paper copy. A draft Refuse to Accept checklist is included for convenience.

Documentation is provided to support a claim of substantial equivalence to other commercially available predicate devices, including the Medtronic Navigated Instruments (K143628, K143375, K140454). The intent to market this device and the information contained in this submission are considered proprietary, confidential, and protected from public disclosure in accordance with the provisions for confidentiality under 21 CFR §807.95 and other applicable provisions of the law.

Globus believes that the information contained in this submission is sufficient for the agency to find that the Navigation Instruments are substantially equivalent to the predicate device. If additional information is required, please do not hesitate to contact me at (b)(4) or by email at (b)(4)

(b)(4) The fax number is (b)(4)

Sincerely,

Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
Globus Medical, Inc.

#170



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Sincerely,

Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
Globus Medical, Inc.

Globus Medical 510(k) Premarket Notification

Navigation Instruments

TRADITIONAL 510(k)

Submitted to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted by:

Globus Medical, Inc.
Valley Forge Business Center
2560 General Armistead Ave.
Audubon, PA 19403

(b)(4)

Contact Name:

Kelly J. Baker, Ph.D.

(b)(4)

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II. Indications for Use

The Indications for Use Statement is provided on the next page and is suitable for publication on the FDA website. Form 3881 is provided in **Attachment D**.

III. 510(k) Summary

The 510(k) Summary is provided on page 4 and is suitable for publication on the FDA website.

Indications for Use Statement

Globus Navigation Instruments are intended to be used during the preparation and placement of Globus screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation[®] System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

510(k) Summary: Navigation Instruments

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory & Clinical Affairs

Date Prepared: November 3, 2015

Device Name: Navigation Instruments

Classification: Per 21 CFR as follows:
§882.4560 Stereotaxic Instrument
Product Code: OLO
Regulatory Class: II, Panel Code: 84

Primary Predicate: Medtronic instruments (K143628, K143375, K140454)

Purpose:

The purpose of this submission is to request clearance for the Globus Navigation Instruments for use with the Medtronic StealthStation[®] System.

Device Description:

Navigation Instruments are nonsterile, reusable instruments that can be operated manually. These instruments are intended to be used with the Medtronic StealthStation[®] System and are manufactured from stainless steel, as specified in ASTM F899.

Indications for Use:

Globus Navigation Instruments are intended to be used during the preparation and placement of Globus screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation[®] System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Performance Data:

Design validation testing was conducted to ensure the Navigation Instruments are acceptable for their intended use, ensure functionality and compatibility with

the Medtronic StealthStation® and to ensure substantial equivalence to the predicate instruments.

Basis of Substantial Equivalence:

Navigation Instruments have been found to be substantially equivalent to the predicate device with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject instruments to the predicate device. Globus Navigation Instruments are as safe, as effective, and perform equivalent to the predicate device.

IV. Device Name

Navigation Instruments

V. Registration Number

Globus Medical's FDA registration number is 3004142400.

VI. Classification Information

Per the Code of Federal Regulations, Title 21, the classification of the Navigation Instruments is as follows:

§882.4560 Stereotaxic Instrument

Product Code: OLO; Regulatory Class: II; Panel Code: 84

The classification information for the predicate Medtronic Navigated Instruments (K143628, K143375, K140454) is the same as that of subject instruments.

Form 3674 Certification of Compliance is provided in **Attachment D**.

The Navigation Instruments are not *in vitro* diagnostic devices, do not include software, and do not require EMC and electrical safety evaluation.

VII. Performance Standards

Testing was completed to ensure the functionality and compatibility with the Medtronic StealthStation System.

Form 3654 is provided in **Attachment D** for standards on testing and material referenced throughout this submission.

VIII. Proposed Labels / Labeling

See **Attachment B** for copies of the proposed package label, device specific inserts, and surgical technique manuals. The package labels are the same as previous cleared (CREO, REVERE, REVOLVE, and ELLIPSE), with new sections to reflect the Navigation Instruments. Indications for the subject device are the same as the predicate device. Navigation Instruments qualify for exemption from including directions for a layperson per 21 CFR 801 Subpart D.

IX. Description of the Device

The **predicate Medtronic Navigated Instruments** (K143628, K143375, K140454) include nonsterile/reusable and sterile/single use instruments that can be operated manually or under power. The instruments include drill bits, drill guides, taps, drivers, and probes. These instruments are designed to be used with the Medtronic StealthStation System. Medtronic instruments are manufactured from stainless steel.

The **subject Globus Navigation Instruments** are nonsterile, reusable instruments that can be operated manually. The instruments include probes, drill bits, drill guides, taps, and drivers. These instruments are designed to be used with the Medtronic StealthStation System. Navigation instruments are manufactured from stainless steel.

Subject Navigation Instruments include modified versions of instruments that are used with Globus Stabilization Systems (CREO, REVERE, REVOLVE, and ELLIPSE) and are to be used in conjunction with the Medtronic StealthStation System. The (b)(4) modification to these Globus standard instruments available is

(b)(4)



Use of the Navigation Instruments remains under the control of the surgeon; navigation allows the instrument to be tracked relative to the patient's anatomy on reconstructed images. Subject instruments include probes, drill bits, drill guides, taps, and drivers, as listed in **Attachment F**.

The (b)(4) difference between a Globus standard instrument (**Figure 1**, tap) and a Globus Navigation Instrument is (b)(4) (b)(4)

(b)(4)

(b)(4)

All subject and predicate instruments (probes, drill bits, taps, and drivers) have the same overall length (305mm)

(b)(4)



Subject Navigation Instruments will be available in the same or similar styles, diameters, and lengths as the predicate Medtronic navigated instruments. Navigation Instruments are intended for use in the preparation and placement of Globus screws (CREO, REVERE, REVOLVE, ELLIPSE), in the same manner as Medtronic Navigated Instruments. This includes probes, drill bits, taps, and drivers used to prepare the pedicles to receive screws, and drivers used to insert screws.

The StealthStation System includes hardware and software for surgical navigation using radiological patient images. The navigation system creates a translation map between all points in the patient anatomy and the corresponding points on the radiologic images of the patient. Once this map is established (registered), whenever the operator touches a point on the patient using a special tracked instrument, the system then uses the map to identify the corresponding point on the image. Instruments (with trackers) and reference frames are fitted with reflective spheres, and the camera emits light that are reflected from the spheres which signals the location of each instrument.

Figure 3 illustrates the Medtronic StealthStation System.



Figure 3. Medtronic StealthStation System

In order to track an instrument on the StealthStation, the instrument must be registered to the system using a tracker (NavLock) or a generic tracker (SureTrak Universal Tracker). NavLock is used for navigation instruments with the Stealth connection feature; SureTrak can be used to register any manual instrument. Registration must be successfully completed in order to proceed with surgery, as the system will only display registered instruments. The surgical technique describing the use of the subject Globus Navigation Instruments with the StealthStation (using NavLock trackers) is provided in **Attachment B**. Generic Class I manual surgical instruments may be registered using SureTrak trackers, however these instruments are exempt from premarket requirements and are not the subject of this submission.

Navigation Instruments are manufactured from stainless steel (ASTM F899); no color additives are used. These instruments are externally communicating devices, contacting bone and tissue for a limited (<24 hour) duration. This material has been used in similar Globus Medical instruments, and no additional biocompatibility testing is required.

A detailed comparison of subject and predicate instruments is provided below in **Table 1**.

Table 1. Detailed Device Comparison

Type	Use	Subject Globus Navigation Instruments	Predicate Medtronic Navigated Instruments	Comparison
Probes	Preparing pedicle	Straight, thoracic (small)	Straight, thoracic (small)	Same
		Length: 305mm	Length: 305mm	Same
Drill Bits	Drilling screw hole	3.5, 4.0mm diam; solid or cannulated	2.4-3.5mm diam; solid or cannulated	Similar
		Length: 305mm	Length: 305mm	Same
Drill Guides	Guiding drill or screw insertion	With adjustable stop	With adjustable stop	Same
Taps	Tapping screw hole	3.5-10.5mm diam; solid or cannulated	3.75-8.5mm diam; solid or cannulated	Similar (matches screws)
		Length: 305mm	Length: 305mm	Same
Drivers	Driving screw into pedicle	Screwdrivers, hex drivers for all screws	Screwdrivers, hex drivers for all screws	Same
		Length: 305mm	Length: 305mm	Same

Testing Summary

Validation testing was conducted on Globus Navigation Instruments compared to the Medtronic Navigated Instruments, in terms of rigidity and accuracy. The detailed test report is provided in **Attachment E**. Results show that the Globus Navigation Instruments have as rigid of a connection and are as accurate as the predicate Medtronic instruments.

Summary

Globus Navigation Instruments have been demonstrated to be substantially equivalent to the predicate Medtronic Navigated Instruments in terms of design, indications, and performance.

A summary of the comparison between the subject and predicate devices is provided in **Section X**.

X. Comparison to Commercially Available Device(s)

Table 2 below compares the subject Navigation Instruments to the predicate device.

Table 2. Overall Device Comparison Chart

Features	Subject	Predicate
Indications	<p>Globus Navigation Instruments are intended to be used during the preparation and placement of Globus screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures.</p> <p>These instruments are designed for use with the Medtronic StealthStation System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.</p>	<p>Medtronic Navigated Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures.</p> <p>Medtronic Navigated Instruments are specifically designed for use with the StealthStation System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Instruments are also compatible with the IPC POWEREASE System.</p>
Instruments		
Probes	Straight, thoracic (small) Length: 305mm	Same Same
Drill Bits	3.5, 4.0mm diameters Length: 305mm	Similar Same
Drill Guides	Adjustable stop	Same
Taps	3.5-10.5mm diameters Length: 305mm	Similar Same
Drivers	Drivers for all screws Length: 305mm	Same Same
Material	Stainless steel (ASTM F899)	Same
Biocompatibility	Stainless steel devices have a history of biocompatibility as implant material and meets ASTM specifications (F899).	Same

Features	Subject	Predicate
Performance	The performance of the Navigation Instruments supports substantial equivalence of the devices. Testing was completed to ensure the functionality and compatibility with the Medtronic StealthStation System. See Attachment E for testing summaries.	
Substantial Equivalence	<p>The subject Navigation Instruments are substantially equivalent to the predicate device based on the following criteria:</p> <ul style="list-style-type: none"> • Have the same indicated use, • Use the same operating principle, • Incorporate previously cleared device technology, • Incorporate previously cleared device material, • Have equivalent mechanical performance, and • Use the same packaging material and processes. <p>In summary, the Navigation Instruments are substantially equivalent to the predicate device.</p>	

XI. Commercially Available Device Information

The predicate Medtronic Navigated Instruments (K143628, K143375, K140454) are commercially available. See **Attachment C** for information on the predicate device.

XII. Sterilization Information

Navigation Instruments are supplied nonsterile.

Hospitals must sterilize the nonsterile instruments prior to use. Moist heat sterilization is recommended using the parameters identified in **Attachment A**. Sterilization validation was performed to ensure an SAL of 10^{-6} , as described in **Attachment A**.

XIII. Determination of Substantial Equivalence

[ref. The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications (July 28, 2014)]

**New device (Globus Navigated Instruments) is compared to Yes
legally marketed predicate device (Medtronic Navigated
Instruments [K143628, K143375, K140454])?**

Do the devices have the same intended use? Yes

**Does new device have same technological characteristics, e.g. No
design, materials, etc.?**

**Do the different technological characteristics of the devices No
raise different questions of safety and effectiveness?**

Are the methods for evaluating acceptable? Yes

Do the data demonstrate substantial equivalence? Yes

“Substantially Equivalent Determination” Yes

Attachment A: Sterilization Information

Navigation Instruments are supplied nonsterile.

Nonsterile instruments have been validated following ANSI/AAMI/ISO 17665-1, Sterilization of Health Care Products – Moist Heat, to ensure an SAL of 10^{-6} . The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, “Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.”

Sterilization for NONSTERILE instruments is recommended as follows:

<u>Method</u>	<u>Cycle Type</u>	<u>Temperature</u>	<u>Exposure Time</u>	<u>Drying Time</u>
Steam	Pre-vacuum (Wrapped)	132°C (270°F)	4 minutes	30 minutes

Navigation Instruments are comprised of stainless steel and are provided nonsterile, like several other Globus instruments (CREO, REVERE, REVOLVE, and ELLIPSE instruments). The material is well-known, and Globus has an extensive history of marketing nonsterile stainless steel instruments with no expiration date and no special storage requirements.

Attachment B: Proposed Labels/Labeling

- a. Device Label**
- b. Device Specific Inserts**
CREO, REVERE, REVOLVE, and ELLIPSE inserts with new sections highlighted for convenience
- c. Surgical Technique Manual**
New technique guide to supplement existing CREO, REVERE, REVOLVE, and ELLIPSE technique guides

Stainless steel and its associated standard is well-known and well-established. There is no regulation that specifically requires material grades to be listed on package labels. The same level of description (stainless steel) has been consistently used in Globus labeling cleared by FDA, including in CREO, REVERE, REVOLVE, and ELLIPSE Systems.

a. Device Label

DRAFT PACKAGE LABELING

	 Manufactured and/or Distributed by Globus Medical 2560 General Armistead Avenue Audubon, PA 19403
CREO	REF 6123.1220 Polyaxial Screwdriver NONSTERILE MATERIAL: Stainless Steel LOT XXXXXXXX Qty: 1
See Insert for Labeling Limitations	
	
CAUTION: FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN	

b. Device Specific Inserts

**IMPORTANT INFORMATION ON
THE CREO[®] STABILIZATION SYSTEM**

GLOBUS MEDICAL *DI179A*

GLOBUS MEDICAL, INC.
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
Customer Service 1-866-456-2871

DESCRIPTION

The CREO[®] Stabilization System consists of rods, hooks, monoaxial screws, uniplanar screws, polyaxial screws, reduction screws, locking caps, t-connectors, head offset connectors, trans-iliac connectors, staples, and associated manual surgical instruments. Implants are available in a variety of sizes to accommodate individual patient anatomy. CREO[®] implants mate with 4.75mm, 5.5mm, and 6.35mm diameter rods. In addition, CREO[®] 5.5 Threaded screws and locking caps mate with 6.0mm diameter rods. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws, hooks, and t-connectors are intended for posterior use only. Staples are intended for anterior use only. Rods and monoaxial screws may be used anteriorly or posteriorly. Locking caps are used to connect screws or hooks to the rod and trans iliac connectors.

The most common use of this screw, hook, and rod system in the posterior thoracolumbar and sacral spine is two rods, each positioned and attached lateral to the spinous process via pedicle screws and/or lamina, pedicle or transverse process hooks.

The most common use of this screw, hook, and rod system in the anterior thoracolumbar spine is one rod, positioned and attached to the vertebral bodies via monoaxial screws through an appropriate size staple.

Screws and hooks attach to the rods using a locking cap with an inner set screw. The size and number of screws are dependent on the length and location of the rod. Screws are inserted into a pedicle of the thoracolumbar and/or sacral spine. Screws may be used with a staple. The type and number of hooks are also dependent on the location in the spine needing correction and/or stabilization. Hooks are attached to the laminae, pedicles, or transverse process of the posterior spine.

T-connectors are modular components designed to connect the two rods of a construct and act as a structural cross member. The rod-clamping set screws secure the t-connectors to the rods. Additional set screws secure the adjustable cross members at the desired length. Additional connectors may be used to connect two rods, and are also secured using set screws.

CREO[®] Stabilization System S-rods and unit rods are specifically excluded for use in adolescent idiopathic scoliosis patients.

CREO[®] implants are composed of titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F1537 and F138. Rods are also available in commercially pure titanium, as specified in ASTM F67. Screws are also available with hydroxyapatite (HA) coating per ASTM F1185. Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium, titanium alloy, or cobalt chromium-molybdenum alloy implants.

The CREO[®] System includes manual surgical instruments manufactured from stainless steel, as specified in ASTM F899. Navigation Instruments are nonsterile, single use instruments that can be operated manually, that are intended to be used with the Medtronic StealthStation[®] System.

INDICATIONS

The CREO[®] Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and for pediatric patients (CREO[®] 4.75 only). These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis). When used as an adjunct to fusion, the CREO[®] Stabilization System is intended to be used with autograft and/or allograft.

In addition, the CREO[®] Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CREO[®] 4.75 Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The CREO[®] 4.75 Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation in skeletally mature patients, the CREO[®] Stabilization System rods may be connected to the REVERE[®] Stabilization System (5.5mm or 6.35mm rod), REVERE[®] 4.5 Stabilization System (4.5mm rod) or ELLIPSE[®] Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. In order to achieve additional levels of fixation in pediatric patients, the CREO[®] Stabilization System rods may be connected to the REVERE[®] 4.5 Stabilization System using corresponding connectors. Refer to

the REVERE[®], REVERE[®] 4.5, or ELLIPSE[®] system package insert for instructions and indications of use.

Globus Navigation Instruments are intended to be used during the preparation and placement of CREO[®] screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation[®] System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

WARNINGS

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative disc disease, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- changes to spinal curvature,
- neurological injury, and
- vascular or visceral injury.

The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

Components of this system should not be used with components of any other manufacturer.

The components of this system are manufactured from titanium alloy, pure titanium, stainless steel and cobalt chromium-molybdenum alloy. Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical and functional reasons.

ADDITIONAL WARNINGS FOR PEDIATRIC PATIENTS

The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients not skeletally mature that undergo spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities (“crankshaft phenomenon”) due to continued differential growth of the anterior spine.

Pediatric patients may be at increased risk for device-related injury because of their smaller stature.

PRECAUTIONS

The implantation of screw, hook and rod systems should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting screw diameter and length, and hook size.

The CREO[®] Stabilization System includes 4.75 implants intended for use with a 4.75mm rod, 5.5 implants intended for use with a 5.5mm rod, and 6.35 implants intended for use with a 6.35mm rod. CREO[®] 5.5 Threaded screws and locking caps are also intended for use with a 6.0mm rod.

Surgical implants are SINGLE USE ONLY and must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

The CREO[®] Stabilization System has not been evaluated for safety and compatibility in the MR environment. The CREO[®] Stabilization System has not been tested for heating or migration in the MR environment.

Based on fatigue testing results, when using the CREO[®] Stabilization System, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

ADDITIONAL PRECAUTIONS FOR PEDIATRIC PATIENTS

The implanting surgeon should consider carefully the size and type of implants most suitable for the pediatric patient’s age, size, weight and skeletal maturity.

Since pediatric patients may have additional growth potential following implant surgery, the likelihood of a subsequent removal and/or revision surgery is greater than in adult patients.

CONTRAINDICATIONS

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

Use of these implants is contraindicated in patients with the following conditions:

1. Active systemic infection, infection or inflammation localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Prior fusion at the level(s) to be treated.
3. Severe osteoporosis, which may prevent adequate fixation.
4. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
5. Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
6. Any patient not willing to cooperate with postoperative instruction.
7. Any condition not described in the indications for use.
8. Fever or leukocytosis.
9. Pregnancy.
10. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood count (WBC), or a marked left shift in the WBC differential count.
11. Any case not needing a fusion.
12. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
13. These devices must not be used for pediatric cases or where the patient still has general skeletal growth.
14. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
15. Any case that requires the mixing of metals from two different components or systems.

16. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
17. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING AND USE

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion (i.e. rust, pitting), discoloration, excessive scratches, notches, debris, residue, flaking, wear, cracks, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

Any implant that has not been used, but has become soiled, should be handled according to hospital protocol. Any implant with evidence of damage, residue, debris, or other defects should not be used, and should be returned to Globus Medical.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol[®] (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol[®] (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments may be available sterile or nonsterile. HA-coated implants are only available sterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6} . Sterile products are packaged in a heat sealed, double foil pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants and instruments that become nonsterile or have expired packaging are considered nonsterile and may be sterilized according to instructions for nonsterile implants and instruments below, with the exception of HA-coated implants, which cannot be resterilized and should be disposed of according to hospital protocol.

Nonsterile implants and instruments have been validated to ensure an SAL of 10^{-6} . The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in² total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 minutes	30 minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (U.S.A) Law Restricts this Device to Sale by or on the order of a Physician.

**IMPORTANT INFORMATION ON
THE REVERE® STABILIZATION SYSTEM**

GLOBUS MEDICAL *DI107A*

GLOBUS MEDICAL, INC.
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
Customer Service 1-866-456-2871

DESCRIPTION

The REVERE® Stabilization System consists of rods, hooks, monoaxial screws, uniplanar screws, polyaxial screws, reduction screws, locking caps, t-connectors, offset housing clamps, head offset connectors, trans iliac connectors, sacral sacral and sacral-iliac plates, staples and staple plates, and associated manual surgical instruments. Screws and rods are available in a variety of sizes to accommodate individual patient anatomy. REVERE® implants mate with 5.5mm diameter rods; REVERE® 6.35 implants mate with 6.35mm diameter rods. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws, hooks, and t-connectors are intended for posterior use only. Staples and staple plates are intended for anterior use only. Rods and monoaxial screws may be used anteriorly or posteriorly. Locking caps are used to connect screws or hooks to the rod, trans-iliac connectors and sacral-iliac plates.

The most common use of this screw, hook, and rod system in the posterior thoracolumbar and sacral spine is two rods, each positioned and attached lateral to the spinous process via pedicle screws and/or lamina, pedicle or transverse process hooks.

The most common use of this screw, hook, and rod system in the anterior thoracolumbar spine is one rod, positioned and attached to the vertebral bodies via monoaxial screws through an appropriate size staple.

Screws and hooks attach to the rods using a locking cap with an inner set screw. The size and number of screws are dependent on the length and location of the rod. Screws are inserted into a pedicle of the thoracolumbar and/or sacral spine. The type and number of hooks are also dependent on the location in the spine needing correction and/or stabilization. Hooks are attached to the laminae, pedicles, or transverse process of the posterior spine.

T-connectors are modular components designed to connect the two rods of a construct and act as a structural cross member. The rod-clamping set screws secure the t-connectors to the rods. Additional set screws secure the adjustable cross members at the desired length. T-connectors from the PROTEX® system may be used with 6.5mm, 6.0mm or 5.5mm rod systems. REVERE® t-connectors may only be used with 5.5mm rods; REVERE® 6.35 t-connectors may only be used with 6.35mm rods. Additional connectors may be used to connect two rods, and are also secured using set screws.

REVERE® hooks and t-connectors, and 5.5mm or 6.35mm diameter rods may be used with the BEACON® Stabilization System.

REVERE[®] screws and locking caps may be used with the TRANSITION[®] Stabilization System. Specifically, REVERE[®] polyaxial (solid, cannulated and dual outer diameter) screws and monoaxial screws 6.5mm diameter and larger, and 35mm length and larger, may be used with the TRANSITION[®] implant assemblies.

The rods are composed of titanium alloy, commercially pure titanium, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F67, F1537 and F138. All other REVERE[®] implants are composed of titanium alloy, stainless steel, or cobalt chromium molybdenum alloy, as specified in ASTM F136, F1295, F138, and F1537. The screws are available with or without hydroxyapatite (HA) coating, as specified in ASTM F1185. Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium, titanium alloy, or cobalt chromium molybdenum.

The REVERE[®] System includes manual surgical instruments manufactured from stainless steel, as specified in ASTM F899. Navigation Instruments are nonsterile, single use instruments that can be operated manually, that are intended to be used with the Medtronic StealthStation[®] System.

INDICATIONS

The REVERE[®] Stabilization System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, the REVERE[®] Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used as a posterior non-pedicle screw fixation system, the REVERE[®] Stabilization System is intended for the treatment of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis, Scheuermann's disease), fracture, pseudarthrosis, tumor resection, and/or failed previous fusion. Overall levels of fixation are T1-sacrum/ilium.

When used as an anterolateral thoracolumbar system, the REVERE® Stabilization System is intended for anterolateral screw (with or without staples or staple plates) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

Globus Navigation Instruments are intended to be used during the preparation and placement of REVERE® screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

WARNINGS

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative disc disease, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- neurological injury, and
- vascular or visceral injury.

Components of this system should not be used with components of any other manufacturer.

The components of this system are manufactured from titanium alloy, commercially pure titanium, stainless steel and cobalt chromium molybdenum alloy. Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical and functional reasons.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

PRECAUTIONS

The implantation of screw, hook and rod systems should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting screw diameter and length, and hook size.

The REVERE[®] Stabilization System includes 5.5mm REVERE[®] implants intended for use with a 5.5mm rod and REVERE[®] 6.35 implants intended for use with a 6.35mm rod.

Surgical implants are SINGLE USE ONLY and must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

The REVERE[®] Stabilization System has not been evaluated for safety and compatibility in the MR environment. The REVERE[®] Stabilization System has not been tested for heating or migration in the MR environment.

Based on fatigue testing results, when using the REVERE[®] Stabilization System, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

CONTRAINDICATIONS

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

PACKAGING

REVERE[®] implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness, and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the implants from the packaging using aseptic technique.

The instruments may be provided non-sterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to surgery.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol[®] (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.

6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare EnzoI[®] (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

REVERE[®] implants and instruments are provided sterile or nonsterile. HA-coated implants are only available sterile.

REVERE[®] sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6} . Sterile products are packaged in a heat sealed double pouch or container/pouch. The expiration date is provided on the package label. These products are considered sterile unless the packaging has been opened or damaged.

Nonsterile REVERE[®] implants and instruments have been validated to ensure SAL of 10^{-6} . The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.

- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in² total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For REVERE implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 minutes	30 minutes

For REVERE implants and instruments provided NONSTERILE in REVERE ADDITION Graphic Cases and Trays, sterilization is recommended (wrapped only) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 minutes	70 minutes + 30 minute cooling time

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

IMPORTANT INFORMATION ON THE REVOLVE® STABILIZATION SYSTEM

GLOBUS MEDICAL *DI141A*

GLOBUS MEDICAL, INC.
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
Customer Service 1-866-456-2871

DESCRIPTION

The REVOLVE® Stabilization System consists of rods, polyaxial screws, monoaxial screws, uniplanar screws, fracture screws, locking caps, t-connectors, and associated manual surgical instruments. Screws and rods are available in a variety of sizes to accommodate individual patient anatomy. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Screws are available with or without hydroxyapatite coating. The most common use of this screw and rod system in the posterior thoracolumbar and sacral spine is two rods, each positioned and attached lateral to the spinous process via pedicle screws.

Screws attach to the rods using a locking cap with an inner set screw. The size and number of screws are dependent on the length and location of the rod. Screws are inserted into a pedicle of the thoracolumbar and/or sacral spine. T-connectors are modular components designed to connect the two rods of a construct and act as a structural cross member. The rod-clamping set screws secure the t-connectors to the rods. Additional set screws secure the adjustable cross members at the desired length. REVERE® t-connectors may be used with 5.5mm REVOLVE® rods.

REVOLVE® rods are composed of titanium alloy or cobalt chromium molybdenum (CoCr) alloy as specified in ASTM F136, F1295 and F1537. All other REVOLVE® implants are manufactured from titanium alloy as specified in ASTM F136 and F1295. Screws are available with or without hydroxyapatite (HA) coating, as specified in ASTM F1185.

Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium, titanium alloy or CoCr alloy implants.

The REVOLVE® System includes manual surgical instruments manufactured from stainless steel, as specified in ASTM F899. Navigation Instruments are nonsterile, single use instruments that can be operated manually, that are intended to be used with the Medtronic StealthStation® System.

INDICATIONS

The REVOLVE® Stabilization System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with

degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, the REVOLVE[®] Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/iliac.

Globus Navigation Instruments are intended to be used during the preparation and placement of REVOLVE[®] screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation[®] System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

WARNINGS

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative disc disease, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

- Device component fracture,
- Loss of fixation,
- Non-union,
- Fracture of the vertebrae,
- Neurological injury, and
- Vascular or visceral injury.

Components of this system should not be used with components of any other manufacturer.

The components of this system are manufactured from titanium alloy. Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical and functional reasons.

PRECAUTIONS

The implantation of screw, hook and rod systems should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting screw diameter and length, and hook size.

The REVOLVE[®] System is a 5.5mm rod system. All implants in this system are intended for use with a 5.5mm rod.

Surgical implants are SINGLE USE ONLY and must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

The REVOLVE[®] Stabilization System has not been evaluated for safety and compatibility in the MR environment. The REVOLVE[®] Stabilization System has not been tested for heating or migration in the MR environment.

For optimal implant performance, when using the REVOLVE[®] Stabilization System, the physicians/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

CONTRAINDICATIONS

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or

products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare EnzoI[®] (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.

8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzo[®] (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6} . Sterile products are packaged in a heat sealed, double foil pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged.

Nonsterile implants and instruments have been validated to ensure an SAL of 10^{-6} . The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in² total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.

- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 minutes	30 minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

**IMPORTANT INFORMATION ON
THE ELLIPSE[®] OCCIPITO-CERVICO-THORACIC
SYSTEM**

GLOBUS MEDICAL, INC.
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
Customer Service 1-866-456-2871

GLOBUS MEDICAL *DI137A*

DESCRIPTION

The ELLIPSE[®] Occipito-Cervico-Thoracic Spinal System consists of 3.5mm jointed, straight and pre-bent rods, tapered rods, polyaxial screws, hooks, locking caps, t-connectors, lateral connectors, parallel connectors, in-line connectors, rod-to-rod connectors, rod extension clamps and occipital plates. CAPITOL[™] screws and rods are also available as components of the ELLIPSE[®] system. The implants are composed of titanium alloy (per ASTM F136, F1472, or F1295), stainless steel (per ASTM F138) or cobalt chromium molybdenum alloy (CoCr) (per ASTM F1537). Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical and functional reasons.

ELLIPSE[®] constructs may be connected to CREO[®], REVERE[®], BEACON[®], PROTEX[®], or PROTEX[®] CT constructs using corresponding connectors.

The ELLIPSE[®] System includes manual surgical instruments manufactured from stainless steel, as specified in ASTM F899. Navigation Instruments are nonsterile, single use instruments that can be operated manually, that are intended to be used with the Medtronic StealthStation[®] System.

INDICATIONS

ELLIPSE[®] Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

Globus Navigation Instruments are intended to be used during the preparation and placement of ELLIPSE[®] screws during spinal surgery to assist the surgeon

in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

CONTRAINDICATIONS

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

WARNINGS

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic spine secondary to degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Possible adverse effects which may occur and may require additional surgery include: failed fusion or pseudarthrosis leading to implant breakage; allergic reaction to implant materials; device fracture or failure; device migration or loosening; loss of fixation; vertebral fracture; decrease in bone density; pain, discomfort, or abnormal sensations due to the presence of the device; injury to nerves, vessels, and organs; venous thrombosis, lung embolism and cardiac arrest; and death.

The components of this system are manufactured from titanium alloy, stainless steel or cobalt chromium alloy. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Mixing of implant components of titanium or cobalt chromium with stainless steel is not recommended, for metallurgical, mechanical and functional reasons.

Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis, or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

Use this device as supplied and in accordance with the handling and use information provided below.

PRECAUTIONS

The implantation of posterior screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this posterior screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative planning for implant of cervical posterior screw implants should include review of radiographs, CT and/or MRI imaging to evaluate the patient's anatomy, transverse foramen and the course of the vertebral artery. If any findings would compromise the placement of posterior screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

The implants are for single use only. Surgical implants must never be reused. An explanted metal implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Correct handling of the implant is extremely important. Contouring of metal implants should be avoided where possible. If contouring is necessary, or allowed by design, the surgeon should avoid sharp bends, reverse bends, or bending the device at a screw hole. The operating surgeon should avoid any notching or scratching of the device when contouring it. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must have the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

For optimal implant performance, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

ELLIPSE[®] implants have not been evaluated for safety and compatibility in the MR environment. ELLIPSE[®] implants have not been tested for heating or migration in the MR environment.

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments and instrument trays and cases must be cleaned, as described in the CLEANING section below.

HANDLING

All implants, instruments, and instrument trays and cases should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged products should not be used, and should be returned to Globus Medical.

CLEANING

Instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable. All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The products should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments and instrument trays and cases after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare EnzoI[®] (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare EnzoI[®] (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6} . Sterile products are packaged in a heat sealed, double foil pouch. The expiration date is provided on the package label. These products are considered sterile unless the packaging has been opened or damaged.

Nonsterile implants and instruments have been validated to ensure an SAL of 10^{-6} . The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is

the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in² total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 minutes	30 minutes

Do not stack trays during sterilization. These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

c. Draft Surgical Technique Manual

SURGICAL TECHNIQUE MANUAL

Introduction

The Globus Navigation Instruments are manual surgical instruments that may be used in conjunction with the Medtronic StealthStation Navigation System. This technique describes how to register Globus Navigation Instruments to the Stealthstation.

Preliminary Setup

- Turn on StealthStation and log in
- Select “SYNERGY SPINE” to start setup for spine navigation.
- Select the desired surgeon profile from the “SURGEON PROFILE” tab.
- Select the desired procedure from the “SELECT PROCEDURE” tab.
- Ensure that all necessary equipment (monitors, O-arm, etc.) are connected to the StealthStation

Patient Reference Setup

- There are several reference frame options available to accommodate the preferred access to the patient: the Percutaneous Reference pin, the Open Spine clamp, the Thoracic Spine Clamp, and the Mast Clamp. Install the desired patient reference frame according to the manufacturer’s instructions.
- Attach 4 reflective spheres onto the patient reference frame.

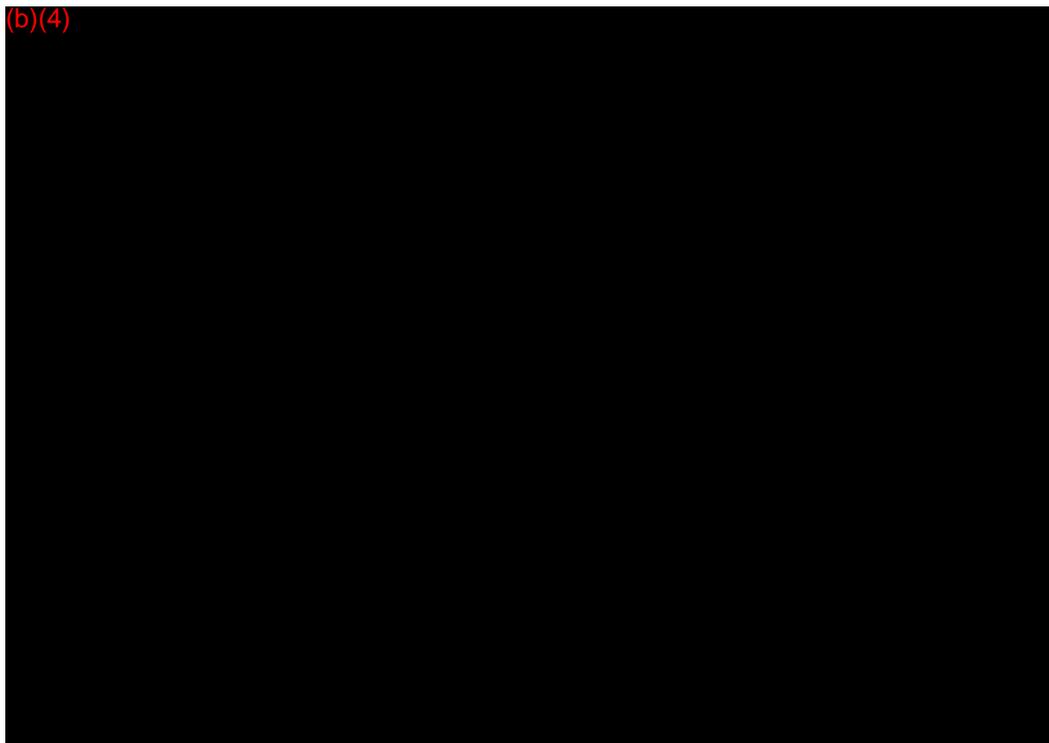
Instrument Setup

- On the “VERIFY INSTRUMENTS” tab on the StealthStation, add one NavLock tracker for each instrument being used in the surgery by selecting it from the “ADD/REMOVE INSTRUMENTS” window. Assign the tracker to an instrument by choosing one of the following from the dropdown menu:
 - Screwdrivers: select “Standard Driver”
 - Taps: select “XXmm Tap”, with XX representing diameter.
 - Straight pedicle probes: select “Straight Pedicle Probe”
 - Thoracic pedicle probe: select “Thoracic Pedicle Probe”
 - Drill bits: select “XXmm Tap” with XX representing diameter
- Attach each NavLock tracker to its assigned instrument. Do not place NavLock trackers onto instruments that have not been assigned.
- Attach 4 reflective spheres to each NavLock tracker.

Registering Instruments to the StealthStation

- Aim the camera in the direction of the patient reference frame. Use the Tracking View window to confirm that the reference frame and trackers are in range and can be tracked by the system (**Figure 1**). Blue dots indicate successful tracking and yellow dots indicate

blocked/malfunctioning spheres (**Figure 2**). The blue triangle indicates how close/far the camera is from the reference frame.



- Place the distal tip of each instrument, one at a time, into the divot on the patient reference frame (**Figure 3**). Hold the instrument as perpendicular to the reference frame as possible.
- Successful registration is indicated on the instrument tool card on the VERIFY INSTRUMENTS tab (**Figure 4**). The card transitions from blue to green once registered, and an audible notification is heard.
- If registration is unsuccessful, the card remains blue and an audible notification plays. Ensure sterile spheres are clean and that both the instrument and reference frame are visible in the tracking view. Repeat steps until the instrument is successfully registered.



Figure 3. Instrument registration

(b)(4)

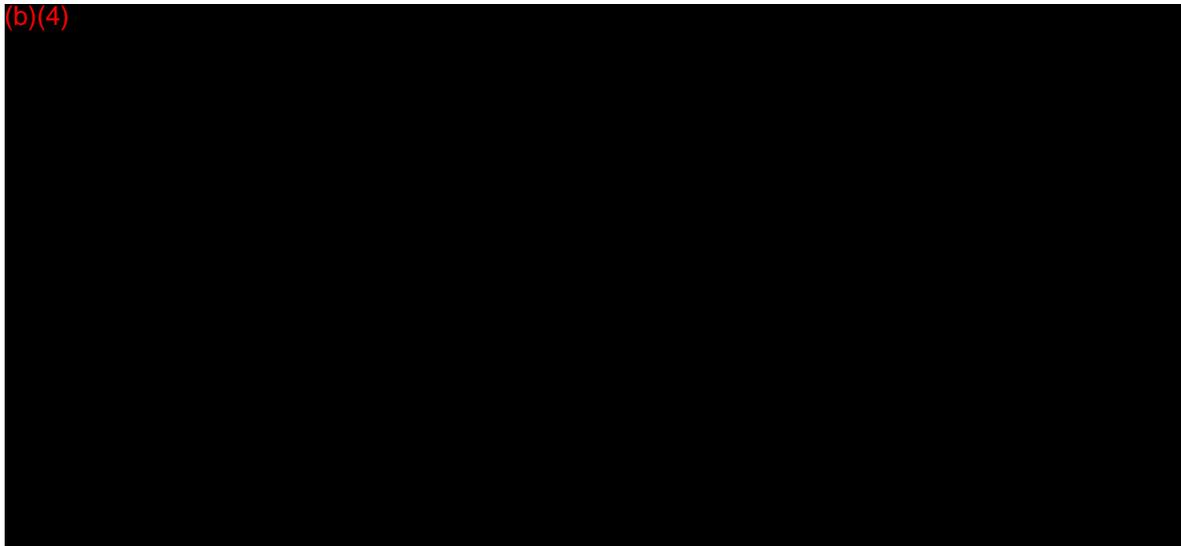


Figure 4. Instrument registration-instrument tool card display

Acquiring Scans

- After installing patient reference frame, obtain 3D CT images of the desired anatomical area.
- Transfer images to the StealthStation

Navigating Instruments

- Perform surgery as indicated by the surgical technique for the corresponding implant system (CREO, REVERE, REVOLVE, or ELLIPSE).



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
Mr. Tejas Patel
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

February 12, 2015

Re: K143628

Trade/Device Name: Navigated VERTEX SELECT[®] Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 19, 2014
Received: December 22, 2014

Dear Mr. Patel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 Mr. Tejas Patel

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K143628

Device Name

Navigated VERTEX SELECT® Instruments

Indications for Use (Describe)

Medtronic Navigated Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Medtronic Navigated Instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Instruments are also compatible with the IPC® POWEREASE™ System.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

December 19, 2014

I. Company: Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, TN 38132
Telephone Number: (901) 396-3133

Contact: Tejas Patel
Regulatory Affairs Specialist
Telephone number: (901) 396-3133
Email: tejaskumar.r.patel@medtronic.com

II. Proprietary Trade Name: Navigated VERTEX SELECT® Instruments

Common Name: Stereotaxic Instrument, Navigated Screwdriver, Navigated Tap, Navigated Drill Bit

Classification Name: Stereotaxic Instrument (21 CFR 882.4560)

Classification: Class II

Product Code: OLO

III. Predicate Device:

Navigated CD HORIZON® SOLERA® Screwdrivers and Taps (K140454, S.E. 05/22/2014)

This predicate has not been subject to a design-related recall. This predicate is the primary predicate for this submission.

No reference devices were used in this submission.

IV. Device Description:

The Navigated VERTEX SELECT® Instruments are both non-sterile, reusable and sterile, single use instruments that can be operated manually or under power. These instruments are intended to be used when implanting components of the VERTEX® Reconstruction System. The Navigated VERTEX SELECT® Instruments are also compatible with the StealthStation® and IPC® POWEREASE® Systems.

V. Indications for Use:

Medtronic Navigated Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely

locating anatomical structures in either open or minimally invasive procedures. Medtronic Navigated Instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Instruments are also compatible with the IPC® POWEREASE® System.

VI. Comparison of the Technological Characteristics with the Predicate Device:

The Navigated VERTEX SELECT® Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery and are specifically designed for use with the StealthStation® System. Identical to the predicates, the Navigated VERTEX SELECT® Instruments attach to the NavLock™ Tracker, which allows for optical navigation of the surgical instruments. These devices have similar designs as the predicate devices and incorporate the same design features to enable navigation and use with the IPC® POWEREASE® System, when desired. Like the predicate devices, the subject Navigated VERTEX SELECT® Instruments are also made from stainless steel.

The following technological differences exist between the subject and predicate devices:

- The Navigated VERTEX SELECT® Instruments are intended to be used with VERTEX® Reconstruction System screws whereas the predicate Navigated CD HORIZON® SOLERA® instruments are intended to be used with the CD HORIZON® SOLERA® screws.
- The subject devices include a sterile drill bit while the predicate devices do not.
- The subject Navigated Taps & Drill Bits have a single lead threadform as compared to the dual lead threadform of the predicate Navigated Taps.

The instrument modifications detailed in this submission have no impact on the technological characteristics of either the existing instruments or the StealthStation® and IPC® POWEREASE® Systems.

VII. Performance Data:

Testing was completed to ensure the functionality and compatibility with the identified Medtronic products. The following table summarizes the performance testing completed:

Test	Description
Navigation Accuracy Analysis	Confirmed navigated instrument accuracy
Anatomical Simulated Use	Confirmed instrument functionality under expected use conditions

Navigation Simulated Use	Confirmed navigation system functionality under expected use conditions
CAD Model Evaluation	Verified that the CAD models are accurately reflected in the application software
Implant/Instrument Mating Conditions	Verified that the instruments can be assembled with the appropriate devices according to their intended use
Spine Tools Package Functional Testing	Verified that the Spine Tools package has met the required interface needs of the spine application software

VIII. Conclusions

The Navigated VERTEX SELECT® Instruments have been shown through comparison and testing to be substantially equivalent to the identified predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
Ms. Becky Ronner
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

February 13, 2015

Re: K143375

Trade/Device Name: CD HORIZON[®] Spinal System, Medtronic Navigated Reusable
Instruments

Regulation Number: 21 CFR 888.3070

Regulation Name: Pedicle screw spinal system

Regulatory Class: Class III

Product Code: NKB, OSH, MNH, MNI, KWP, KWQ, OLO, HBE

Dated: January 16, 2015

Received: January 20, 2015

Dear Ms. Ronner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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Page 2 Ms. Becky Ronner

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K143375

Device Name

CD HORIZON® Spinal System

Indications for Use (Describe)

The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications as an adjunct to fusion.

With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON® Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD HORIZON® SPIRE™ Plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: degenerative disc disease (as previously defined), spondylolisthesis, trauma, and/or tumor.

In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX® Reconstruction System with the VERTEX® rod connector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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Indications for Use

510(k) Number (if known)

K143375

Device Name

Medtronic Navigated Reusable Instruments

Indications for Use (Describe)

Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Reusable Instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Reusable Instruments are also compatible with the IPC® POWEREASE™ System.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) SUMMARY

MEDTRONIC Sofamor Danek USA

January 2015

Submitter:	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person	Becky Rommer Senior Regulatory Affairs Specialist Direct Telephone: (901)399-2757
Date Prepared	November 21, 2014
Common Name	Bone Screws, Rods, Set Screws, Extenders, and Drivers
Device/Trade Name	1. CD HORIZON® Spinal System 2. MEDTRONIC NAVIGATED REUSABLE INSTRUMENTS For use with StealthStation® and IPC® POWEREASE™ Systems
Regulatory Class, Regulation Number, Regulation Name, and Device Product Code	1. CD HORIZON® Spinal System <ul style="list-style-type: none"> • Class III • 21 CFR 888.3050 Spinal Interlaminar Fixation Orthosis; KWP • 21 CFR 888.3060 Spinal Intervertebral Body Fixation Orthosis; KWQ • 21 CFR 888.3070 Pedicle Screw System; MNH, MNI, NKB, OSH 2. MEDTRONIC NAVIGATED REUSABLE INSTRUMENTS For use with StealthStation® and IPC® POWEREASE™ Systems <ul style="list-style-type: none"> • Class II • 21 CFR 882.4560 Stereotaxic Instruments; OLO • 21 CFR 882.4310 Drills, Burs, Trephines & Accessories (Simple, Powered); HBE
Predicate Devices	1. CD HORIZON® Spinal System <ul style="list-style-type: none"> • K142847 CD HORIZON® Spinal System (S.E.

	<p>10/27/2014) Primary Predicate</p> <ul style="list-style-type: none"> • K091974 CD HORIZON® Spinal System (S.E 9/2/2009) • K113529 CD HORIZON® Spinal System (S.E 2/9/2011) • K132639 CD HORIZON® Spinal System (S.E 11/25/2013) • K102555 CD HORIZON® Spinal System (S.E 11/17/2010) • K141605 CD HORIZON® Spinal System (S.E 7/14/2014) <p>2. MEDTRONIC NAVIGATED REUSABLE INSTRUMENTS For use with StealthStation® and IPC® POWEREASE™ Systems</p> <ul style="list-style-type: none"> • K140454 Navigated Instruments (S.E 5/22/2014) <p><i>The predicates have not been subject to a design related recall.</i></p>
<p>Description of Device</p>	<p>1. The CD HORIZON® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK® plates, staples and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. The subject devices include:</p> <ul style="list-style-type: none"> • Bone screws • Rods • Set Screws • Extender • Extender Cap • Accessories, case, caddies trays, and lids which may be used to transport and sterilize the subject implants and instruments. <p>The subject CD HORIZON® Spinal System device will be available in similar sizes as the predicate systems.</p> <p>2. MEDTRONIC NAVIGATED REUSABLE INSTRUMENTS For use with StealthStation® and IPC® POWEREASE™ Systems</p> <p>Medtronic Navigated Reusable Screwdriver is a spine preparation instrument made of high grade stainless steel. This instrument was specifically designed for use in procedures where the use of stereotactic surgery may be</p>

	<p>appropriate. Placing Medtronic single-use sterile spheres on each of the NavLock™ Tracker passive stems allows a Medtronic computer-assisted surgery system such as the StealthStation® Image Guidance System to track the instruments in the surgical field.</p> <p>Medtronic Navigated Reusable Screwdriver is compatible with various Medtronic spinal implant systems. This screwdriver is also compatible with Medtronic’s IPC® POWEREASE™ System when connected to the POWEREASE™ Driver.</p>
<p>Indications for Use</p>	<p>1. CD HORIZON® Spinal System</p> <p>The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.</p> <p>Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications as an adjunct to fusion.</p> <p>With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.</p> <p>When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON® Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis,</p>

	<p>kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.</p> <p>The CD HORIZON® SPIRE™ Plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: degenerative disc disease (as previously defined), spondylolisthesis, trauma, and/or tumor.</p> <p>In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX® Reconstruction System with the VERTEX® rod connector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use.</p> <p>2. MEDTRONIC NAVIGATED REUSABLE INSTRUMENTS For use with StealthStation® and IPC® POWEREASE™ Systems</p> <p>Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Reusable Instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR-based</p>
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	<p>model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Reusable Instruments are also compatible with the IPC® POWEREASE™ System.</p>
<p>Comparison of Technological Characteristics with the Predicate Devices:</p>	<p>1. CD HORIZON® Spinal System</p> <p>The CD HORIZON® Spinal System has the same fundamental technology, cobalt chrome, titanium and stainless steel material as the predicate devices. The predicate and subject devices are intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic lumbar and/or sacral spine.</p> <ul style="list-style-type: none"> • K142847 CD HORIZON® Spinal System (S.E. 10/27/2014) (Primary Predicate) • K091974 CD HORIZON® Spinal System (S.E 9/2/2009) • K113529 CD HORIZON® Spinal System (S.E 2/9/2011) • K132639 CD HORIZON® Spinal System (S.E 11/25/2013) • K102555 CD HORIZON® Spinal System (S.E 11/17/2010) • K141605 CD HORIZON® Spinal System (S.E 7/14/2014) <p>2. MEDTRONIC NAVIGATED REUSABLE INSTRUMENTS For use with StealthStation® and IPC® POWEREASE™ Systems</p> <p>The subject Medtronic Navigated Reusable Instrument for use with StealthStation® and IPC® POWEREASE™ Systems has the same fundamental technology and stainless steel material as the predicate devices. The predicate and subject devices are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Reusable Instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Reusable Instruments are also compatible with the</p>

	<p>IPC® POWEREASE™ System.</p> <ul style="list-style-type: none"> • K140454 Navigated CD HORIZON® Instruments (S.E 5/22/2014)
<p>Performance Data:</p>	<p>The following performance data were provided in support of substantial equivalence.</p> <p>Biocompatibility</p> <p>The biocompatibility evaluation for the CD HORIZON® Spinal System devices was conducted in accordance with FDA’s Draft Guidance for Industry and FDA Staff “Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” issued April, 23, 2013.</p> <p>The subject CD HORIZON® Spinal System bone screws, rods, and set screws are permanent implants and will be classified as permanent , >30 day body contact according to with FDA’s Draft Guidance for Industry and FDA Staff “Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”. The subject bone screws are manufactured from identical materials as the predicate devices, in accordance with the following ASTM standards:</p> <ul style="list-style-type: none"> • ASTM F1537 – Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloys for Surgical Implants • ASTM F67 – Specification for Unalloyed Titanium for Surgical Implant Applications • ASTM F136 – Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications <p>The subject rods are manufactured from identical materials as the predicate devices, in accordance with the following ASTM standards:</p> <ul style="list-style-type: none"> • ASTM F1537 – Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum

Alloys for Surgical Implants

The subject set screws are manufactured from identical materials as the predicate devices, in accordance with the following ASTM standards:

- **ASTM F136** – Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications

The CD HORIZON® Spinal System extender, Extender Cap and screwdriver are external communicating devices and are classified as limited, up to 24 hours of body contact according to with FDA’s Draft Guidance for Industry and FDA Staff “Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”. These instruments are manufactured from the same medical grade stainless steel as the predicate devices in accordance with the following ASTM standards:

- **ASTM F899** – Standard Specification for Wrought Stainless Steel for Surgical Instruments
- **ASTM A564** – Standard Specification for Hot-Rolled and Cold Finished Age-Hardening Stainless Steel Bars and Shapes
- **ASTM A693** – Standard Specification for Precipitation-Hardening Stainless and Heat-Resisting Steel Plate, Sheet and Stripe
- **ASTM A276** – Standard Specification for Stainless Bars and Shapes

The case, caddies trays, and lids used to for shipment and sterilization of instruments are manufactured from aluminum and/or radel and/or polypropylene with the brackets securing the instruments into the case/tray made of silicone and/or nylon coated stainless steel and/or polypropylene and are not patient contacting and do not require biocompatibility testing.

	<p>Cobalt Chrome, Commercially Pure Titanium, Titanium Alloy, and medical grade stainless steel have a long history of safe and effective use in spinal surgery and biocompatibility testing is not required and not testing was conducted.</p> <p>Mechanical Testing In accordance with, Guidance for Industry and FDA Staff – Spinal System 510(k)’s”, Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices. It was determined that subject devices do not represent a new worst case. Engineering rationales were used to demonstrate substantial equivalence.</p>
<p>Conclusion:</p>	<p>Based on the risk analysis, test results, and additional supporting documentation provided in the pre-market notification, the subject CD HORIZON® Spinal System is substantially equivalent to the following predicates:</p> <ul style="list-style-type: none">• K142847, K091974, K113529, K132639, K102555, K141605 <p>The MEDTRONIC NAVIGATED REUSABLE INSTRUMENTS are substantially equivalent to the following predicate:</p> <ul style="list-style-type: none">• K140454

K140454

510(k) Summary

MAY 22 2014

February 2013

- I. Company:** Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, TN 38132
Telephone Number: (901) 396-3133
- Contact:** Regina Holmes
Sr. Regulatory Affairs Specialist
Telephone: (901) 399-3101
Fax: (901) 346-9738
- II. Proprietary Trade Name:** Navigated CD HORIZON® SOLERA® Screwdrivers and Taps
- III. Common Name:** Stereotaxic Instrument, Navigated Screwdriver, Navigated Tap
- IV. Classification Name:** Stereotaxic Instrument (21 CFR 882.4560)
- V. Classification:** Class II
- VI. Product Code:** OLO, HBE
- VII. Product Description:**
The Navigated Screwdrivers and Taps are non-sterile, reusable surgical instruments that can be operated manually or under power. These instruments are intended to be used when implanting CD HORIZON® Spinal System devices. The Navigated Screwdrivers and Taps are also compatible with the StealthStation® and IPC® POWEREASE™ Systems.
- VIII. Indications for Use:**
Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Medtronic Navigated Reusable Instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Reusable Instruments are also compatible with the IPC® POWEREASE™ System.

IX. Identification of Legally Marketing Devices (Predicate Devices)

- NAVIGATED CD HORIZON® SOLERA® SCREWDRIVERS, TAPS, ILIAC TAPS, LEGACY™ TAPS (K124004)
- IPC® POWEREASE™ System (K111520, K123270)

X. Comparison of the Technological Characteristics:

The Navigated Taps and Screwdrivers are intended to be used during the preparation and placement of Medtronic screws during spinal surgery and are specifically designed for use with the StealthStation® System. Identical to the predicates, the Navigated Screwdrivers and Taps attach to the NavLock™ Tracker, which allows for optical navigation of the surgical instruments. These devices have similar designs as the predicate devices and incorporate the same design features to enable navigation and use with the IPC® POWEREASE™ System, when desired. Like the predicate devices, the subject Navigated Taps and Screwdrivers are also made from stainless steel.

The instrument modifications detailed in this submission have no impact on the technological characteristics of either the existing instruments or the StealthStation® and IPC® POWEREASE™ Systems.

XI. Discussion of the Performance Testing

Testing was completed to ensure the functionality and compatibility with the identified Medtronic products. The following table summarizes the performance testing completed:

Test	Description
Navigation Accuracy Analysis	Confirmed navigated instrument accuracy.
Anatomical Simulated Use	Confirmed instrument functionality under expected use conditions.
Navigation Simulated Use	Confirmed navigation system functionality under expected use conditions.
CAD Model Evaluation	Verified that the CAD models are accurately reflected in the application software.
Implant/Instrument Mating Conditions	Verified that the instruments can be assembled with the appropriate devices according to their intended use.
Spine Tools Package Functional Testing	Verified that the Spine Tools package has met the required interface needs of the spine application software.

XII. Conclusions

The Navigated Screwdrivers and Taps have been shown through comparison and testing to be substantially equivalent to the identified predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 22, 2014

Medtronic Sofamor Danek USA, Incorporated
Ms. Regina Holmes
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K140454

Trade/Device Name: Navigated CD HORIZON® SOLERA® Screwdrivers and Taps
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO, HBE
Dated: February 20, 2014
Received: February 24, 2014

Dear Ms. Holmes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Ms. Regina Holmes

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K140454

Device Name
Navigated CD HORIZON® SOLERA® Screwdrivers and Taps

Indications for Use (Describe)

Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Medtronic Navigated Reusable Instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Reusable Instruments are also compatible with the IPC® POWEREASE™ System.

Type of Use (Select one or both, as applicable)

- Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

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Ronald P. Jean -S

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PRAStaff@fda.hhs.gov

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Attachment D: Forms

The following forms are included in this attachment:

- Form 3881 – Indications for Use
- Form 3674 – Certification of Compliance
- Form 3654 – Standards Data Report for 510(k)s
 - ASTM F899 – Stainless Steel

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

Device Name

Navigation Instruments

Indications for Use (Describe)

Globus Navigation Instruments are intended to be used during the preparation and placement of Globus screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter Globus Medical		2. Date of the Application/Submission Which This Certification Accompanies 11/03/2015	
3. Address		4. Telephone and Fax Numbers (Include country code if applicable and area code)	
Address 1 (Street address, P.O. box, company name c/o) Valley Forge Business Center		(Tel): 610-930-1800	
Address 2 (Apartment, suite, unit, building, floor, etc.) 2560 General Armistead Avenue		(Fax): 610-930-2042	
City Audubon	State/Province/Region PA		
Country USA	ZIP or Postal Code 19403		

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Navigation Instruments

See attached list of names, classification, model numbers (part #s)

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

IND
 NDA
 ANDA
 BLA
 PMA
 HDE
 510(k)
 PDP
 Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number (If number previously assigned)

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes (See instructions for additional information and explanation)
- A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.
- B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.
- C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

CERTIFICATION STATEMENT / INFORMATION (Continued)

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(j)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. (Add continuation page as necessary.)

NCT Number(s): _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name Kelly J. Baker, Ph.D.	Title Senior Vice President, Regulatory and Clinical Affairs
-------------------------------	---

12. Address

Address 1 (Street address, P.O. box, company name c/o) Valley Forge Business Center	
Address 2 (Apartment, suite, unit, building, floor, etc.) 2560 General Armistead Avenue	
City Audubon	State/Province/Region PA
Country USA	ZIP or Postal Code 19403

13. Telephone and Fax Numbers

(Include country code if applicable and area code)

(Tel): 610-930-1800 x1670

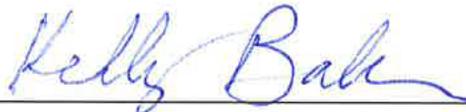
(Fax): 610-930-2042

14. Date of Certification

11/03/2015

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative (Sign)

Sign



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The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Attachment to Form 3674

Part #	Description	Classification
6123.1002	3.5mm Head Positioner Hex Driver, G11	Class II
6123.1003	3.5mm Hex Driver, Shaft, G11	Class II
6123.1004	Holding Sleeve Assembly, G11	Class II
6123.1008	3.5mm Hex Driver, Self-Retaining, G11	Class II
6123.1020	Pedicle Probe, Straight, G11	Class II
6123.1026	Pedicle Probe Thoracic, Straight, G11	Class II
6123.1045	4.5mm Tap, G11	Class II
6123.1050	5.0mm Tap, G11	Class II
6123.1055	5.5mm Tap, G11	Class II
6123.1065	6.5mm Tap, G11	Class II
6123.1075	7.5mm Tap, G11	Class II
6123.1085	8.5mm Tap, G11	Class II
6123.1101	Screwdriver, G11	Class II
6123.1102	Low Profile Screwdriver, G11	Class II
6123.1150	5.0mm Cannulated Tap, G11	Class II
6123.1155	5.5mm Cannulated Tap, G11	Class II
6123.1165	6.5mm Cannulated Tap, G11	Class II
6123.1175	7.5mm Cannulated Tap, G11	Class II
6123.1185	8.5mm Cannulated Tap, G11	Class II
6123.1202	Drill Guide with Adjustable Stop, 6-50mm, G11	Class II
6123.1204	3.5mm Drill Bit, G11	Class II
6123.1206	4.0mm Drill Bit, G11	Class II
6123.1220	Polyaxial Screwdriver, G11	Class II
6123.1225	Screwdriver, 2.5mm Hex, Self Retaining, G11	Class II
6123.1226	Pedicle Probe, Straight, G11	Class II
6123.1235	3.5mm Tap, G11	Class II
6123.1240	4.0mm Tap, G11	Class II
6123.1405	10.5mm Cannulated Tap, G11	Class II
6123.1406	Driver, Self-Retaining, G11 (CREO)	Class II
6123.1410	4.75 Driver, G11 (CREO)	Class II
6123.1414	5.5 Driver, G11 (CREO)	Class II
6123.1495	9.5mm Cannulated Tap, G11	Class II
6134.1440	Screwdriver, 30mm reduction, G11 (CREO MIS)	Class II
6134.1445	Screwdriver, 10mm reduction, G11 (CREO MIS)	Class II

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM F899 Standard Specification for Wrought Stainless Steels for Surgical Instruments

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #8-343

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>
³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>
⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>
⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ASTM F899 Standard Specification for Wrought Stainless Steels for Surgical Instruments		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER ALL	SECTION TITLE ALL	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRASStaff@fda.hhs.gov</p> </div> <div style="width: 35%; text-align: right;"> <p><i>"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."</i></p> </div> </div>		

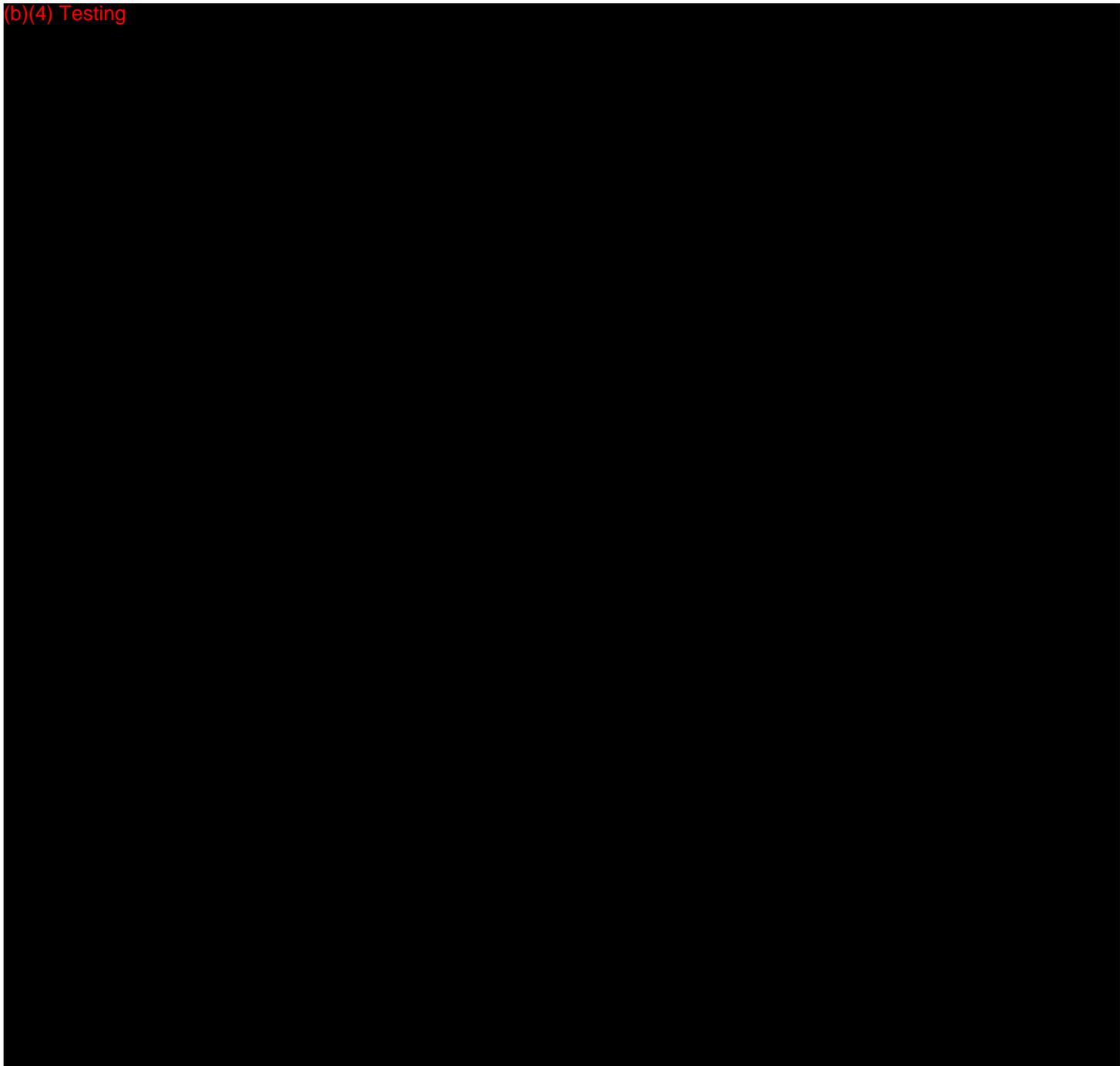
Attachment E: Test Report

Validation testing of Navigation Instruments is provided in this attachment.



TEST REPORT

(b)(4) Testing



**Attachment F: Standard Table of Components,
Confidential Engineering Drawings**

510(k) clearance is requested for the following Navigation Instruments part numbers, as listed in **Table 1**. Confidential engineering drawings are included.

Table 1. Standard Table of Components

Part #	Description
6123.1002	3.5mm Head Positioner Hex Driver, GI1
6123.1003	3.5mm Hex Driver, Shaft, GI1
6123.1004	Holding Sleeve Assembly, GI1
6123.1008	3.5mm Hex Driver, Self-Retaining, GI1
6123.1020	Pedicle Probe, Straight, GI1
6123.1026	Pedicle Probe Thoracic, Straight, GI1
6123.1045	4.5mm Tap, GI1
6123.1050	5.0mm Tap, GI1
6123.1055	5.5mm Tap, GI1
6123.1065	6.5mm Tap, GI1
6123.1075	7.5mm Tap, GI1
6123.1085	8.5mm Tap, GI1
6123.1101	Screwdriver, GI1
6123.1102	Low Profile Screwdriver, GI1
6123.1150	5.0mm Cannulated Tap, GI1
6123.1155	5.5mm Cannulated Tap, GI1
6123.1165	6.5mm Cannulated Tap, GI1
6123.1175	7.5mm Cannulated Tap, GI1
6123.1185	8.5mm Cannulated Tap, GI1
6123.1202	Drill Guide with Adjustable Stop, 6-50mm, GI1
6123.1204	3.5mm Drill Bit, GI1
6123.1206	4.0mm Drill Bit, GI1
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6123.1226	Pedicle Probe, Straight, GI1
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6123.1240	4.0mm Tap, GI1
6123.1405	10.5mm Cannulated Tap, GI1
6123.1406	Driver, Self-Retaining, GI1 (CREO)
6123.1410	4.75 Driver, GI1 (CREO)
6123.1414	5.5 Driver, GI1 (CREO)
6123.1495	9.5mm Cannulated Tap, GI1
6134.1440	Screwdriver, 30mm reduction, GI1 (CREO MIS)
6134.1445	Screwdriver, 10mm reduction, GI1 (CREO MIS)



FDA/CDRH/DCC

JAN 06 2016

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Valley Forge Business Center
2560 General Armistead Avenue Audubon, PA 19403
Phone: 610.930.1800 Fax: 610.930.2042
Order Fax: 610.930.2041
www.globusmedical.com

January 5, 2016

K153203/S1

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-002
Attn: Michel Janda, LCDR, USPHS

Re: K153203/S1 Navigation Instruments

Dear Mr. Janda,

This submission is in response to the request for additional information sent December 31, 2015. The original questions are identified in bold, and the responses are identified in standard font. An eCopy is enclosed and is an exact duplicate of the paper copy.

Globus believes that the information contained in this response is sufficient to address the deficiencies. Please feel free to contact me at (b)(4) or (b)(4) if you have further questions regarding this response or this submission. Our fax number is (b)(4)

Sincerely,

Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
Globus Medical, Inc.

Enclosed:
K153203/S1 hard copy and eCopy



Valley Forge Business Center
2560 General Armistead Avenue Audubon, PA 19403
Phone: 610.930.1800 Fax: 610.930.2042
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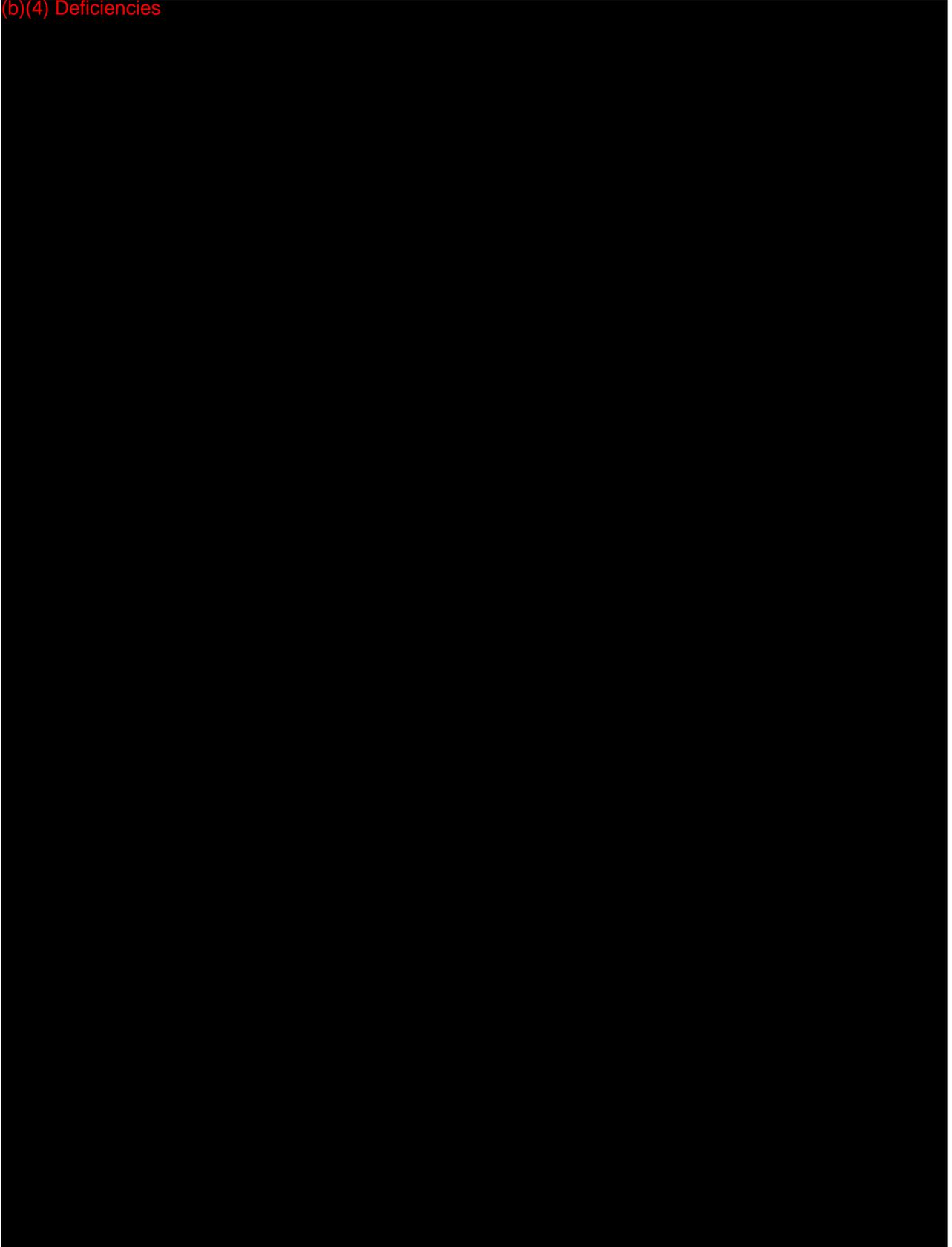
Sincerely,

Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
Globus Medical, Inc.

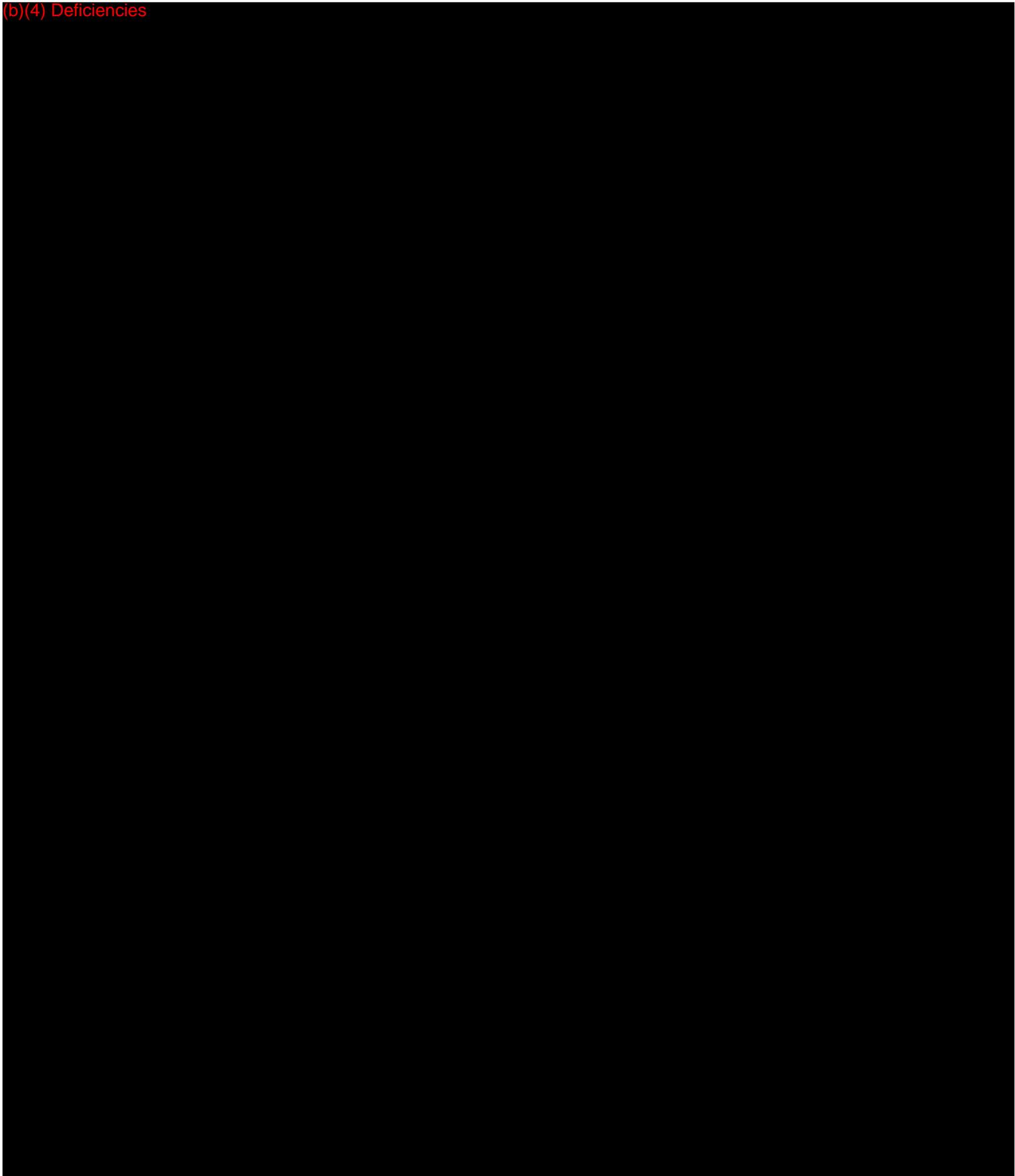
Enclosed:
K153203/S1 hard copy and eCopy

K153203 Response to Request for Additional Information Dated 12/31/15

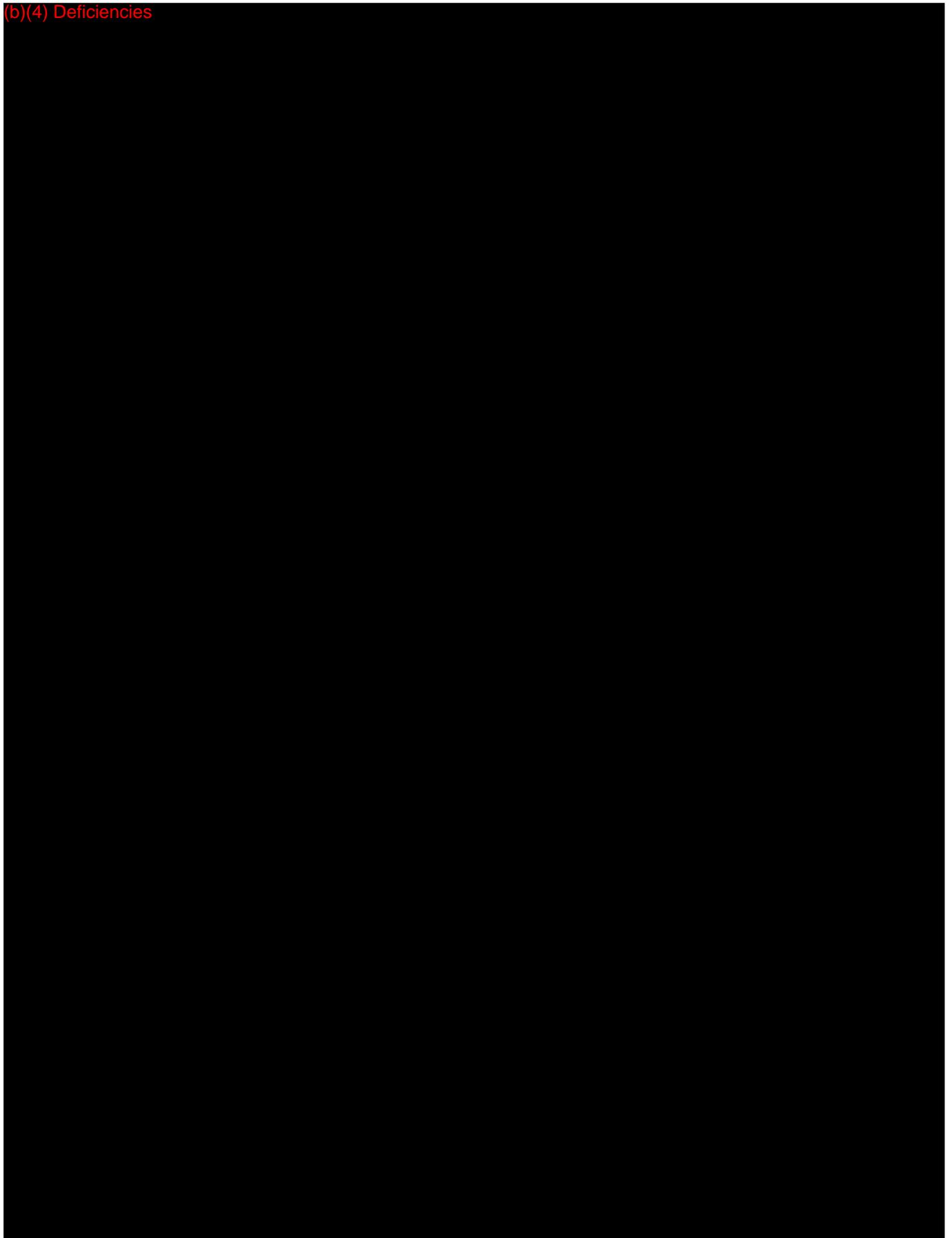
(b)(4) Deficiencies



(b)(4) Deficiencies



(b)(4) Deficiencies



(b)(4) Deficiencies



Attachment S1.1: Revised Documents

This attachment includes the following documents:

- 510(k) Summary
- Indications for Use
- Form 3881
- Surgical Technique
- PROTEX CT device specific insert

510(k) Summary: Navigation Instruments

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory & Clinical Affairs

Date Prepared: January 5, 2016

Device Name: Navigation Instruments

Classification: Per 21 CFR as follows:
§882.4560 Stereotaxic Instrument
Product Code: OLO
Regulatory Class: II, Panel Code: 84

Primary Predicate: Medtronic instruments (K143628, K143375, K140454)

Purpose:

The purpose of this submission is to request clearance for the Globus Navigation Instruments for use with the Medtronic StealthStation® System.

Device Description:

Navigation Instruments are nonsterile, reusable instruments including probes, drill bits, drill guides, taps, and drivers that can be operated manually. These instruments are intended to be used with the Medtronic Synergy Spine and Trauma StealthStation® System (v 2.1.0) and are manufactured from stainless steel, as specified in ASTM F899.

Indications for Use:

Globus Navigation Instruments are intended to be used in the preparation and placement of Globus screws (CREO, REVERE, REVOLVE, ELLIPSE and PROTEX CT Stabilization Systems) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Technological Characteristics as Compared to the Predicates:

The Globus Navigation Instruments and the predicate instruments are intended to be used with the Medtronic StealthStation® System to assist the surgeon in locating anatomical structures. These instruments have similar designs, are made from the same materials, and function in the same manner as the predicates. Performance testing shows that the Globus Navigation Instruments are substantially equivalent to the predicate instruments.

Performance Data:

Design validation testing, including rigidity, registration, and accuracy, was conducted to ensure the Navigation Instruments are acceptable for their intended use, to ensure functionality and compatibility with the Medtronic StealthStation®, and to demonstrate substantial equivalence to the predicate instruments. Rigidity testing evaluated the connection between the NavLock Tracker and the instruments. Registration testing was performed to ensure that the instruments can be registered to the StealthStation®. Accuracy testing was completed for comparison to the predicate instruments.

Basis of Substantial Equivalence:

Navigation Instruments have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject devices to the predicate devices. Globus Navigation Instruments are as safe, as effective, and perform equivalent to the predicate devices.

Indications for Use Statement

Globus Navigation Instruments are intended to be used in the preparation and placement of Globus screws (CREO, REVERE, REVOLVE, ELLIPSE and PROTEX CT Stabilization Systems) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Indications for Use

510(k) Number (if known)

K153203

Device Name

Navigation Instruments

Indications for Use (Describe)

Globus Navigation Instruments are intended to be used in the preparation and placement of Globus screws (CREO, REVERE, REVOLVE, ELLIPSE and PROTEX CT Stabilization Systems) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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PRASStaff@fda.hhs.gov

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SURGICAL TECHNIQUE MANUAL

Introduction

The Globus Navigation Instruments are manual surgical instruments that may be used in conjunction with the Medtronic StealthStation Navigation System. This technique describes how to register Globus Navigation Instruments to the StealthStation.

Preliminary Setup

- Turn on StealthStation and log in
- Select “SYNERGY SPINE” to start setup for spine navigation.
- Select the desired surgeon profile from the “SURGEON PROFILE” tab.
- Select the desired procedure from the “SELECT PROCEDURE” tab.
- Ensure that all necessary equipment (monitors, O-arm, etc.) are connected to the StealthStation

Patient Reference Setup

- There are several reference frame options available to accommodate the preferred access to the patient: the Percutaneous Reference pin, the Open Spine clamp, the Thoracic Spine Clamp, and the Mast Clamp. Install the desired patient reference frame according to the manufacturer’s instructions.
- Attach 4 reflective spheres onto the patient reference frame.

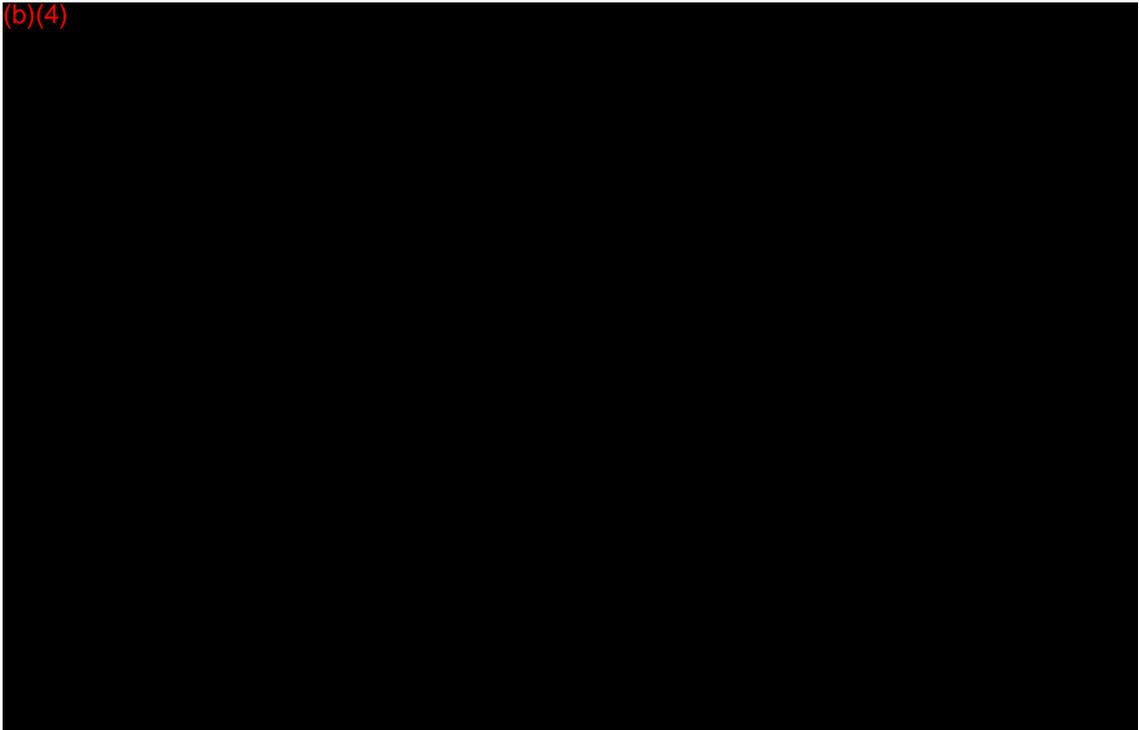
Instrument Setup

- On the “VERIFY INSTRUMENTS” tab on the StealthStation, add one NavLock tracker for each instrument being used in the surgery by selecting it from the “ADD/REMOVE INSTRUMENTS” window. Assign the tracker to an instrument by choosing one of the following from the dropdown menu:
 - Screwdrivers: select “Standard Driver”
 - Taps: select “XXmm Tap”, with XX representing diameter.
 - Straight pedicle probes: select “Straight Pedicle Probe”
 - Thoracic pedicle probe: select “Thoracic Pedicle Probe”
 - Drill bits: select “XXmm Tap” with XX representing diameter
 - **NOTE: If the desired instrument size is not available in the dropdown menu, select the next larger size. For example, for a 3.5mm drill bit, select the 3.75mm Tap.**
- Attach each NavLock tracker to its assigned instrument. Do not place NavLock trackers onto instruments that have not been assigned.
- Attach 4 reflective spheres to each NavLock tracker.

Registering Instruments to the StealthStation

- Aim the camera in the direction of the patient reference frame. Use the Tracking View window to confirm that the reference frame and trackers are in range and can be tracked by the system (**Figure 1**). Blue dots indicate successful tracking and yellow dots indicate

blocked/malfunctioning spheres (**Figure 2**). The blue triangle indicates how close/far the camera is from the reference frame.



- Place the distal tip of each instrument, one at a time, into the divot on the patient reference frame (**Figure 3**). Hold the instrument as perpendicular to the reference frame as possible.
- Successful registration is indicated on the instrument tool card on the VERIFY INSTRUMENTS tab (**Figure 4**). The card transitions from blue to green once registered, and an audible notification is heard.
- If registration is unsuccessful, the card remains blue and an audible notification plays. Ensure sterile spheres are clean and that both the instrument and reference frame are visible in the tracking view. Repeat steps until the instrument is successfully registered.



Figure 3. Instrument registration

(b)(4)



Acquiring Scans

- After installing patient reference frame, obtain 3D CT images of the desired anatomical area.
- Transfer images to the StealthStation

Navigating Instruments

- Perform surgery as indicated by the surgical technique for the corresponding implant system (CREO, REVERE, REVOLVE, ELLIPSE or PROTEX CT).

**IMPORTANT INFORMATION ON THE
PROTEX® CT OCCIPITO-CERVICO-THORACIC
SPINAL SYSTEM**

GLOBUS MEDICAL *DI105A*

GLOBUS MEDICAL, INC.
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
Customer Service 1-866-456-2871

DESCRIPTION

The PROTEX® CT Occipito-Cervico-Thoracic Spinal System consists of rods, polyaxial screws, hooks, locking caps, t-connectors, lateral connectors, parallel connectors, and occipital clamps. The implants are composed of titanium alloy (per ASTM F136, F1472, or F1295) or stainless steel (per ASTM F138). Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium or titanium alloy implants.

INDICATIONS

The PROTEX® CT Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

Globus Navigation Instruments are intended to be used during the preparation and placement of PROTEX CT screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

CONTRAINDICATIONS

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

WARNINGS

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic spine secondary to degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Possible adverse effects which may occur and may require additional surgery include: failed fusion or pseudarthrosis leading to implant breakage; allergic reaction to implant materials; device fracture or failure; device migration or loosening; loss of fixation; vertebral fracture; decrease in bone density; pain, discomfort, or abnormal sensations due to the presence of the device; injury to nerves, vessels, and organs; venous thrombosis, lung embolism and cardiac arrest; and death.

The components of this system are manufactured from titanium alloy or stainless steel. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Mixing of implant components with different materials is not recommended, for metallurgical, mechanical and functional reasons. Components of this system should not be used with components of any other system or manufacturer, unless specifically stated.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

PRECAUTIONS

The implantation of posterior screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this posterior screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative planning for implant of cervical posterior screw implants should include review of radiographs, CT and/or MRI imaging to evaluate the patient's anatomy, transverse foramen and the course of the vertebral artery. If any findings would compromise the placement of posterior screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

The implants are for single use only. Surgical implants must never be reused. An explanted metal implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Correct handling of the implant is extremely important. Contouring of metal implants should be avoided where possible. If contouring is necessary, or allowed by design, the surgeon should avoid sharp bends, reverse bends, or bending the device at a screw hole. The operating surgeon should avoid any notching or scratching of the device when contouring it. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must have the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management.

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments and instrument trays and cases must be cleaned, as described in the CLEANING section below.

HANDLING

All implants, instruments, and instrument trays and cases should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged products should not be used, and should be returned to Globus Medical.

CLEANING

Instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable. All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The products should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments and instrument trays and cases after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare EnzoI[®] (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.

8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare EnzoI® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6} . Sterile products are packaged in a heat sealed, double foil pouch. The expiration date is provided on the package label. These products are considered sterile unless the packaging has been opened or damaged.

Nonsterile implants and instruments have been validated to ensure an SAL of 10^{-6} . The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in² total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.

- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 minutes	30 minutes

Do not stack trays during sterilization. These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.