U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K113666 - 648 pages
COMPANY:	STRYKER SPINE (STRYSPIN)
PRODUCT:	ORTHOSIS, SPINAL PEDICLE FIXATION, FOR DEGENERATIVE DISC DISEASE (NKB)
SUMMARY:	Product: XIA 3 SPINAL SYSTEM
DATE REQUESTED:	Mar 22, 2016
DATE PRINTED:	Mar 22, 2016
Note:	Printed

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

June 27, 2013

Stryker Spine
% Musculoskeletal Clinical Regulatory Advisers, LLC
Mr. Glenn Stiegman
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005

Re: K113666
Trade/Device Name: Xia® 3 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, OSH, KWP, MNH, MNI
Dated: July 25, 2012
Received: August 1, 2012

Dear Mr. Stiegman:

This letter corrects our substantially equivalent letter of August 28, 2012.

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 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Erin D Keith

For

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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K113666

Device Name: XIA® 3 Spinal System

Indications for Use:

The XIA® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fustion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative disc disease (DDD) (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, and/or lordosis)
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion

The Ø5.5mm rods from the Stryker Spine Radius™ Spinal System and Ø6.0mm Vitallium Rods from the XIA® Spinal System are intended to be used with the other components of the XIA® 3 Spinal System.

When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA® 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis.

The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christy Foueren

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113666

--- REMOVE SECTIONS BELOW THIS LINE WHEN PRINTING or EMAILING to SPONSORS ----

Full Submission Number: K113666 Corrected SE

Digital Signature Concurrence Table	
Reviewer Sign-Off	-
Branch Chief Sign-Off	Ronald Jean
Division Sign-Off	Erin Keith Erin I. Keith 2013.06.27 13:08:51 -04'00'

JHP:f/t:jhp:06/18/2013:eaf:6/18/2013

Template Name: Corrected Substantially Equivalent Letter: Classified and Not Classified; v2013-04-02

510(k) Summary

AUG 28 2012

Applicant:

Stryker Spine
2 Pearl Court, Allendale, NJ 07401
Phone: (201)-760-8206 / Fax: (201)-962-4206
E-mail: tiffani.rogers@stryker.com

Contact Information:

Tiffani Rogers, Regulatory Affairs Manager
Stryker Spine
2 Pearl Court, Allendale, NJ 07401
Phone: (201)-760-8206/ Fax: (201)-962-4206
E-mail: tiffani.rogers@stryker.com

Device Trade Name: XIA® 3 Spinal System

Manufacturer:

Stryker Spine
Zone Industrielle Demarticot
Cestas, France 33610
Phone: + 33 577 97 08 40
Manufacturer Establishment Number: 9617544

and

Stryker Spine
Le Cret Du Locle 10a
La Chaux De Fonds
Switzerland 2300
Establishment Registration Number: 3005525032

Date Prepared: August 22, 2012

Classification/	21 CFR§888.3070 (b) (1) & (b) (2) / Pedicle Screw Spinal System
Classification Name:	21 CFR§888.3050 / Spinal Interlaminal fixation orthosis
Classification:	III / II
Product Code:	OSH, MNH, MNI, KWP, NKB

Indication for Use:

The XIA® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fustion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

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- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion

The Ø5.5mm rods from the Stryker Spine Radius™ Spinal System and Ø6.0mm Vitallium Rods from the XIA® Spinal System are intended to be used with the other components of the XIA® 3 Spinal System.

When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA® 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis.
The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft.
Pediatric pedicle screw fixation is limited to a posterior approach.

Device Description:

The Stryker Spine XIA® 3 Spinal System is a noncervical pedicle screw system comprised of monoaxial and polyaxial bone screws, blocker (as a locking mechanism), rods, hooks, and connectors. The implants are manufactured from Ti6Al4V alloy, CP Ti, and CoCrMo alloy (Vitallium).
The expansion of indications for the XIA® 3 Spinal System is proposed for the inclusion of adolescent idiopathic scoliosis alone, and not other indications for a pediatric population. As pediatric patients are unlikely to exhibit symptoms of degenerative disc disease (DDD) or stenosis due to the wear and tear on the spine necessary to develop these diseases, expansion of these indications to a pediatric population is not warranted.

Predicate Devices:

- Synthes Spine USS Small Stature System, K994121
- Stryker Spine XIA® 3 Spinal System, K071373
- Paradigm Spine Orthobiom Spinal System, K071668
- Medtronic Sofamor Danek USA CD HORIZON Spinal System, K091445
- Medtronic Sofamor Danek TSRH Spinal System, K111492

Substantial Equivalence:

Testing performed on XIA® 3 Spinal System indicates that the system is substantially equivalent to predicate devices. Mechanical testing of the system included static and dynamic compression bending testing and static torsion testing per ASTM F1717-04 and interconnection strength testing per ASTM F1798-97, as well as, a clinical literature analysis.

The XIA® 3 Spinal System substantial equivalence determination to the predicate systems is based on dimensional comparisons and engineering analyses in addition to preclinical testing.

Conclusion:

The XIA® 3 Spinal System was shown to be substantially equivalent to previously cleared devices with respect to its indications for use, design, function, and materials.

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The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> "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."

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the

market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.
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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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.

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Sincerely yours,

Christy Foreman

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K113666

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(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christy Foreman

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113666

K113666

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

HOWMEDICA OSTEONICS CORP
2 PEARL COURT
ALLENDALE NJ 07401-1677
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****5390

2. CONTACT NAME
Soraya King
2.1 E-MAIL ADDRESS
Soraya.King@Stryker.com
2.2 TELEPHONE NUMBER (include Area code)
201-7608296
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[ ] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) [redacted]
21-Mar-2012

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Online Payment

Step 3: Confirm Payment 1 | 2 | **3**

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: FDA User Fees
Pay.gov Tracking ID: (b)(4)
Agency Tracking ID: (b)(4)
Transaction Date and Time: (b)(4)

Payment Summary

Address Information

Account Holder Name: HOWMEDICA OSTEONICS CORP
Billing Address: 2 Pearl Court
Billing Address 2:
City: Allendale
State / Province: NJ
Zip / Postal Code: 07401
Country: USA

Account Information

Card (b)(4)
Card (b)(4)

Payment Information

Payment Amount (b)(4)
Transaction Date and Time: (b)(4) EDT

King, Soraya

From: paygovadmin@mail.doc.twai.gov
Sent: Wednesday, March 21, 2012 9:47 AM
To: King, Soraya
Subject: Pay.gov Payment Confirmation: FDA User Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: FDA User Fees
Pay.gov Tracking ID: (b)(4)
Agency Tracking ID: (b)(4)
Transaction Type: (b)
Transaction Date: [redacted]

Account Holder Name: HOWMEDICA OSTEONICS CORP Transaction Amount: $4,049.00 Billing Address: 2 Pearl Court
City: Allendale
State/Province: NJ
Zip/Postal Code: 07401
Country: USA
Card Type: (b)(4)
Card Number: (b)(4)

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

K113666

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 09, 2012

STRYKER SPINE
C/O MUSCULOSKELETAL CLINICAL REGULATORY ADVISERS,
1331 H STREET NW
12TH FLOOR
WASHINGTON, DISTRICT OF COLUMBIA 20005
ATTN: G. STIEGMAN

510k Number: K113666
Product: XIA 3 SPINAL SYSTEM
On Hold As of 5/8/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

* * * COMMUNICATION RESULT REPORT (MAY. 9. 2012 3:21PM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : MAY. 9. 2012 3:17PM				
MODE	OPTION	ADDRESS	RESULT	PAGE
5079 MEMORY TX		912025525798	OK	2/2

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES — **Public Health Service**

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

May 09, 2012

STRYKER SPINE
C/O MUSCULOSKELETAL CLINICAL REGULATORY ADVISERS,
1331 H STREET NW
12TH FLOOR
WASHINGTON, DISTRICT OF COLUMBIA 20005
ATTN: G. STIEGMAN

510k Number: K113666
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We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 23, 2012

STRYKER SPINE
C/O MUSCULOSKELETAL CLINICAL REGULATORY ADVISERS,
1331 H STREET NW
12TH FLOOR
WASHINGTON, DISTRICT OF COLUMBIA 20005
ATTN: G. STIEGMAN

510k Number: K113666

Received: 3/22/2012

Product: XIA 3 SPINAL SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 14, 2011

USER FEE HOLD LETTER - HAVE NOT RECEIVED PAYMENT

STRYKER SPINE
C/O MUSCULOSKELETAL CLINICAL REGULATORY ADVISERS,
1331 H STREET NW
12TH FLOOR
WASHINGTON, DISTRICT OF COLUMBIA 20005
ATTN: G. STIEGMAN

510k Number: K113666
Received: 12/13/2011
User Fee ID Number: 6058234
Product: XIA 3 SPINAL SYSTEM

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to mail a check, please send a check to one of the addresses listed below:

By Regular Mail
Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

By Private Courier(e.g.,Fed Ex, UPS, etc.)
U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301)847-8120 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/cdrh/mdufma/fy09userfee.html. In addition, the 510k Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)796-7100 or its toll-fee number (800)638-2041, or contact them at their Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Edwena Jones at Edwena.Jones@fda.hhs.gov or directly at (301)796-7200. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Edwena Jones
Consumer Safety Technician
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Grayson, Giovanna *

From: Microsoft Exchange
To: 'gstiegman@mcra.com'
Sent: Wednesday, December 14, 2011 9:06 AM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'gstiegman@mcra.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

34

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Wednesday, December 14, 2011 9:06 AM
To: 'gstiegman@mcra.com'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
December 14, 2011
G.
STIEGMAN

USER FEE HOLD LETTER - HAVE NOT RECEIVED PAYMENT

STRYKER SPINE
C/O MUSCULOSKELETAL CLINICAL REGULATORY ADVISERS,
1331 H STREET NW
12TH FLOOR
WASHINGTON, DISTRICT OF COLUMBIA 20005
ATTN: G. STIEGMAN

510k Number: K113666

Received: 12/13/2011

Product: XIA 3 SPINAL SYSTEM

User Fee ID Number: 6058234

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

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The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301)847-8120 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/cdrh/mdufma/fy09userfee.html. In addition, the 510k Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm.

By Private Courier(e.g.,Fed Ex, UPS, etc.)
U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101

By Regular Mail
Food and Drug Administration
P.O. Box 956733

St. Louis, MO 63195-6733.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)796-7100 or its toll-fee number (800)638-2041, or contact them at their Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Edwena Jones at Edwena.Jones@fda.hhs.gov or directly at (301)796-7200. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Edwena Jones
Consumer Safety Technician
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

stryker®

Spine

K113666
OR | ISSORD

December 09, 2011

FDA CDRH DMC
DEC 13 2011
Received
KSI

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

RE: Traditional 510(k) Application
Stryker Spine XIA® 3 Spinal System

To Whom It May Concern:

In accordance with 21 CFR 807, Section E, Stryker Spine is submitting this Traditional Premarket Notification for the XIA® 3 Spinal System.

We are providing an electronic copy (eCopy) of this 510(k) per FDA's web instructions, and it is an exact duplicate of the paper copy.

Stryker Spine believes this device system is substantially equivalent to the following predicate devices:

510(k)	Company Name	Device Name
K111492	Medtronic Sofamor Danek	TSRH Spinal System
K091445	Medtronic Sofamor Danek USA	CD HORIZON Spinal System
K071668	Paradigm Spine	Orthobiom Spinal System
K071373	Stryker Spine	XIA 3 Spinal System
K994121	Synthes	USS Small Stature

With this letter, you may contact and discuss with Ms. Rogers any matters pertaining to this Stryker Spine Premarket Notification and associated FDA activities.

Stryker Spine considers all the material provided herein as Privileged and Confidential. We request that the FDA handle this information as such per the provisions detailed in 21 CFR §20.61.

Notice of the FDA decision to this Premarket Notification, should be faxed to the attention of Ms. Rogers at 201-760-8406 and forward an electronic copy of the letter to Tiffani.Rogers@stryker.com.

Kind regards,

Tiffani Rogers
Stryker Spine

ATTACHMENT A

(b)(4) Design Drawings

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ATTACHMENT B

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ATTACHMENT H

MAUDE Database Search for XIA Spinal System

A September 2011 search of the MAUDE Database identified a total of 625 MDRs related to the components and instrumentation of the Stryker XIA Spinal System. Reviewers independent of Stryker Spine knowledgeable in MDRs classified the events as related to the implant or instrumentation, and those occurring perioperatively (at time of surgery) and those occurring postoperatively (after wound closure). Postoperative device-related events are the most comparable to those reported in the literature as adverse events. Events leading to component or system revision surgery were also noted.

Instrumentation-related MDR's

A total of 125 MDR's were identified in the MAUDE database search for the Stryker XIA Spinal System that were instrument-related. Individual event listings are noted in **Appendix A.** The results are summarized by event type in Table 1.

Table 1: Breakdown of MAUDE database search results, Instrumentation-Related

Component	Event Type				
	Breakage	Malfunction	Migration/ Loosening	Unknown/ Other	Total
Instruments	94	24		7	**125**

Perioperative Implant-Related MDR's

A total of 194 MDR's were identified in the MAUDE database search for the Stryker XIA Spinal System that were implant-related and occurring perioperatively. Individual event listings are noted in **Appendix A.** The results are summarized by event type in Table 2.

Table 2: Breakdown of MAUDE database search results, Perioperative and Implant-Related

Component	Event Type				
	Breakage	Malfunction	Migration/ Loosening	Unknown/ Other	Total
Screw	68	42	3	5	**118**
Blocker	30	25	1		**56**
Connector	7	2		1	**10**
TOTAL	**105**	**79**	**4**	**6**	**194**

Postoperative Implant-Related MDR's

A total of 194 MDR's were identified in the MAUDE database search for the Stryker XIA Spinal System that were implant-related and occurring post-operatively. Individual event listings are

noted in **Appendix B**. The results are summarized by event type in Table 3. Table 4 summarizes the rates of occurrences for all events and revision/explant rates.

Table 3: Breakdown of MAUDE database search results, Post-operative and Implant-Related

Component	Event Type				
	Breakage	Malfunction	Migration/ Loosening	Unknown/ Other	Total
Screw	141	5	30	2	**178**
Rod	67		6	1	**74**
Blocker	9	3	40	2	**54**
Connector	6		3		**9**
Other*				1	**1**
TOTAL	**223**	**8**	**79**	**6**	**316**

*Including Allergy to Entire System

Table 4: Breakdown of Revision rates, Post-operative and Implant-Related

Component	Total Sales	Event Total	Event Rate	Revision/ Explant Total	Revision/ Explant Rate
Screw	262,613	178		110	
Rod		74		45	
Blocker		54		19	
Connector		9		8	
Other		1		0	
TOTAL	**52,222****	**316**	**0.605%**	**182**	**0.349%**

*Including Allergy to Entire System
**Total Sales Quantity is minimum total sales number based on an average of 5 screws per case

Device breakage was the most commonly reported event with 223 postoperative implant-related breakages. Of the total 316 reported events, 71% were a result of device breakage, 3% malfunction, 25% migration or loosening, and 2% for unknown or other reasons. Overall, the occurrence rates for Stryker XIA spinal system reported MAUDE events and revisions were extremely low at 0.605% and 0.349%, respectively.

All XIA Spinal System MDR's

A total of 625 MDR's were identified in the MAUDE database search for the Stryker XIA Spinal System. The results are summarized by event type in Table 5. Table 6 summarizes the rates of occurrences for all events.

Table 5: Breakdown of MAUDE database search results, XIA System

System	Event Type								
	Breakage		Malfunction		Migration/ Loosening		Unknown/ Other		Total
	PERI	POST	PERI	POST	PERI	POST	PERI	POST	
Screws	68	141	42	5	3	30	5	2	**296**

Rods		67				6		1	**74**
Blocker	30	9	25	3	1	40		2	**110**
Connector	7	6	2			3	1		**19**
Instruments	94		24				7		**125**
Other*								1	**1**
TOTAL	**199**	**223**	**93**	**8**	**4**	**79**	**13**	**6**	**625**

PERI = Perioperative event; POST = postoperative event
*Including Allergy to Entire System

Table 6: Breakdown of Revision rates, Post-operative and Implant-Related

Component	Total Sales	Event Total	Event Rate	Revision/ Explant Total	Revision/ Explant Rate
Screw	262,613	296		110	
Rod		74		45	
Blocker		110		19	
Connector		19		8	
Other		1		0	
TOTAL	**52,222****	**500**	**.957%**	**182**	**.349%**

*Including Allergy to Entire System
**Total Sales Quantity is minimum total sales number based on an average of 5 screws per case

Device breakage was the most commonly reported event with 199 perioperative breakages and 223 postoperative breakages. Of the total 625 reported events, 68% were a result of device breakage, 16% malfunction, 13% migration or loosening, and 3% for unknown reasons. Overall, the occurrence rates for Stryker XIA spinal system reported MAUDE events and revisions were extremely low at 0.957% and 0.349%, respectively.

Appendix A: Instrumentation-Related MDR Listings

Date Received	Product Code	Device	Description	Type of Event
06/05/2001	HXX	SCREWDRIVER POLYAXIAL	The tip of the screwdriver snapped off.	Breakage
06/13/2001	HXX	SCREWDRIVER POLYAXIAL	Screwdriver tip broke off during insertion of a polyaxial screw	Breakage
06/25/2001	HXX	SCREWDRIVER POLYAXIAL	screwdriver tip broke off during insertion of the screw	Breakage
07/02/2001	HXX	SCREWDRIVER POLYAXIAL	Tip of the screwdriver broke off in the screw while the surgeon was inserting the pedicale screw	Breakage
07/16/2001	HXX	SCREWDRIVER POLYAXIAL	The screwdriver tip broke off during pedicle screw insertion.	Breakage
08/03/2001	HXX	SCREWDRIVER POLYAXIAL	tip of the driver snapped off in the screw head	Breakage
08/13/2001	HXX	SCREWDRIVER POLYAXIAL	Tip of instrument broke off inside screw	Breakage
08/14/2001	HXX	SCREWDRIVER POLYAXIAL	Tip of the screwdriver broke off during use	Breakage
08/23/2001	HXX	SCREWDRIVER POLYAXIAL	Tip of the screwdriver broke during tightening of pedicle screw.	Breakage
08/30/2001	HXX	SCREWDRIVER POLYAXIAL	Tip of screwdriver broke during use.	Breakage
10/09/2001	HXX	SCREWDRIVER POLYAXIAL	During surgery, the hex tip of the driver broke	Breakage
10/15/2001	HXX	SCREWDRIVER POLYAXIAL	Screwdriver broke during surgery.	Breakage
11/13/2001	HXX	SCREWDRIVER POLYAXIAL	hex part at the tip of the screwdriver broke	Breakage
02/14/2002	HXX	SCREWDRIVER POLYAXIAL	polyaxial screwdriver tip broke off during screw insertion	Breakage
04/24/2002	HXX	SCREWDRIVER POLYAXIAL	While turning the screw the screw driver snapped	Breakage
04/29/2002	HXX	SCREWDRIVER POLYAXIAL	tip of the screwdriver had broken off and remains in the screw.	Breakage
08/19/2002	HXX	POLYAXIAL SCREWDRIVER	tip of the driver shaft was broken during the operation	Breakage
08/19/2002	HXX	POLYAXIAL SCREWDRIVER	"while inserting a xia polyaxial screw, the hex tip on the shaft broke.	Breakage
09/11/2002	HXX	POLYAXIAL SCREWDRIVER	"tip broke off screwdriver into patient upon screw insertion	Breakage
11/07/2002	HXX	POLYAXIAL SCREWDRIVER	The screwdriver broke while inserting the screw.	Breakage
01/28/2003	HXX	POLYAXIAL SCREWDRIVER	tip of the screwdriver broke off during surgery.	Breakage
02/28/2003	HXX	POLYAXIAL SCREWDRIVER	One of the four prongs broke off from the screwdriver while in use	Breakage
03/12/2003	HXX	POLYAXIAL SCREWDRIVER	"tip of screwdriver broke during use. No affect on pt".	Breakage
10/01/2003	HXX	POLYAXIAL SCREWDRIVER	During the operation, the instrument broke.	Breakage
05/05/2005	LHX	UNIVERSAL TIGHTENER 5MM	during the surgical operation (spondyolisys) the xia tightner broken	Breakage
02/23/2007	HXX	POLYAXIAL SCREWDRIVER	one of the 'prongs' on the end of the screw driver	Breakage

Date Received	Product Code	Device	Description	Type of Event
			sheered off.	
03/02/2007	LHX	STANDARD T HANDLE	quick release screwdriver handle had broken in the open wound	Breakage
02/15/2008	HXX	PA SCREWDRIVER SHAFT	During surgery, the tip of the screwdriver broke	Breakage
02/20/2008	LHX	XIA II HANDLE	It was reported that the surgeon was tapping the pedicle when the xia fixed handle trigger mechanism burst	Breakage
04/29/2008	HXC	CUSTOM XIA TORQUE WRENCH AS PER FILE IS0955	the final torque could not reach 12 nm since it could not be turned to the point where the two arrows match. After the surgery, it was found that the outer shaft was broken	Breakage
06/27/2008	LXH	UNIVERSAL TIGHTENER 5MM	The nurse found that the device was missing the very small ball-like part on the tip during cleaning prior to the surgery. It is unknown when this part was disassembled, whether it was during cleaning or during a previous surgery.	Other
07/07/2008	HXX	POLYAXIAL SCREWDRIVER	During surgery, it was found that these polyaxial screw drivers could not hold the screw securely thus it was wobbly even after locking	Malfunction
08/02/2008	LXH	XIA II CUTTING PLIERS	During surgery, the surgeon cut the rod and observed that some metal parts were flying in the air.	Malfunction
09/29/2008	LXH	UNIVERSAL TIGHTENER 5MM	It was reported that the instruments were used during surgery for the first time. The surgeon appeared to have problems since it was not possible to pick up or hold the screws with the instruments.	Malfunction
09/29/2008	LXH	XIA II HANDLE	scrub went to load modular tap onto handle when she let go of the hand piece of the handle when tap was in place, it (the handle) fell apart w/pieces falling on field table.	Breakage
10/14/2008	HXX	POLYAXIAL SCREWDRIVER	During surgery, the two drivers could not hold/assembled with the screw straight (slightly angled) also not stable (a little wobbly).	Malfunction
10/14/2008	LXH	UNIVERSAL TIGHTENER 5MM	The head nurse reported to our sales rep that she was observing a surgery procedure and the surgeon seemed to have problems with the tightener. The surgeon noticed that it was not possible to fix the screws.	Malfunction
12/11/2008	LXH	TITANIUM 4.5 ROD CUTTER DIAM 4.5	It was reported "first time to ever use set, the doctor tried to cut the rod. The pin flew out into patient. This	Malfunction

Date Received	Product Code	Device	Description	Type of Event
			is a brand new rod cutter never been used.	
12/22/2008	LXH	UNIVERSAL TIGHTENER 5MM	the surgeon attempted to insert blocker and blocker became disengaged from the driver prior to engaging to the screw.	Malfunction
01/02/2009	LXH	XIA II UNIVERSAL TIGHTENER 5MM	It was reported that "inserter would not hold blocker w/out putting wax on the end of the inserter.	Malfunction
01/02/2009	LXH	XIA II HOOK FORCEPS	the hook forceps fractured when placing the hook to the traverse process of the vertebrae with this forceps.	Breakage
01/02/2009	LXH	XIA REDUCTION 5MM BLOCKER INSERTER	It was reported that "tip snapped off during surgery while tighening.	Breakage
02/25/2009	LXH	XIA II HOOK FORCEPS	It was reported that "case was psf t4-11. The inner bar cracked off while being used in surgery. ".	Breakage
03/20/2009	LXH	TITANIUM 4.5 BENDING IRON RIGHT	The right in situ bender broke at the distal tip on the straight end. He then rotated the bender and used the curved end. Did not effect outcome.	Breakage
03/27/2009	LXH	XIA II PA ADUSTMENT DRIVER	It was reported as "2 prongs broke off instrument.	Breakage
03/27/2009	LXH	XIA II UNIVERSAL TIGHTENER 5MM	It was reported that "tightener did not hold the blocker. ".	Malfunction
04/28/2009	HXX	XIA II PA SCREW DRIVER SHAFT	The customer reported that the one of the tips on the device has snapped off.	Breakage
04/28/2009	HXX	XIA II POLYAXIAL SCREWDRIVER	Thus, the surgeon used the polyaxtial screw driver without the external shaft, however, it was still very hard and the tip of the driver fractured also the screwhead disassembled	Breakage
05/01/2009	LXH	XIA II LP MODULAR TAP 5.5 MM	dr was tapping the pedicle with a 5. 5mm tap and as he was backing it out, the tap broke	Breakage
05/14/2009	HXX	XIA II PA SCREWDRIVER SHAFT	the customer noticed shaft for polyaxial screwdriver was broken.	Breakage
06/30/2009	LXH	XIA II TORQUE WRENCH	It was reported that "tip of final tightener snapped off during final tightening.	Breakage
07/07/2009	LXH	PRECISION JAM SHIDI 10 GAUGE 5 INCH	Metal peeled off from the mantis instruments (3 pieces) during the spine surgery, metal pieces stuck inside l5 pedicle and finally flushed out;	Breakage
07/07/2009	HWX	XIA II LP MODULAR TAP 5.5 MM	It was reported during a posterior fixation, while tapping before inserting the xia screws, the taps 4. 5 and 5. 5 (modular) broke.	Breakage
07/07/2009	HWX	XIA II LP MODULAR TAP 4.5 MM	It was reported during a posterior fixation, while tapping before inserting the xia screws, the taps 4. 5	Breakage

Date Received	Product Code	Device	Description	Type of Event
			and 5. 5 (modular) broke.	
08/03/2009	NKB	XIA DUAL STAPLE (LARGE CAUDAL)	It was reported that "the product identifier etching on these implants have "rs" instead of "rl". Cat # is correct though.	Other
08/06/2009	LXH	XIA PRECISION T-HANDLE	Tip of the cannulated awl ((b) (4)) broke when surgeon used it to push into the pt's vertebral with hand.	Breakage
08/27/2009	LXH	XIA PRECISION JAM SHIDI 10 GAUGE 9 INCH	It was reported that "the jam shidi, expiration date was 12/2008. The surgery occurred on (b) (6) 2009. Expiration no realized until (b) (6) 2009 after surgery occurred. ".	Other
09/01/2009	LXH	XIA II UNIVERSAL TIGHTENER 5MM	During surgery, it was found that the xia universal tightener could not hold the blocker.	Malfunction
09/01/2009	LXH	XIA II UNIVERSAL TIGHTENER 5MM	During surgery, it was found that the xia universal tightener could not hold the blocker.	Malfunction
09/03/2009	LXH	XIA II UNIVERSAL TIGHTENER 5MM	The customer returned the instrument for credit for the reason it's locking mechanism is defective.	Malfunction
09/03/2009	LXH	XIA II HOOK FORCEPS	It was reported that "spring in the middle has broken off from the latch which connects it. ".	Malfunction
09/03/2009	LXH	XIA II HOOK FORCEPS	It was reported that "spring in the middle has broken off from the latch which connects it. ".	Malfunction
09/24/2009	HXX	POLYAXIAL SCREWDRIVER	On (b)(6) 2009, during the surgery, it was found that the driver could not hold the screw securely (wobbly). The surgeon stated that this driver had the same condition at the prior surgery and he asked the sales rep to evaluate the instrument. On (b)(6) 2009, the sales rep checked the driver and found that the tip (cross shaped part) is chipped.	Breakage
09/30/2009	LXH	XIA II UNIVERSAL TIGHTENER 5MM	It was reported that "instrument does not hold blocker. ".	Malfunction
10/22/2009	LXH	XIA II UNIVERSAL TIGHTENER 5MM	T-handle blocker inserter was noted to have bearing missing from the insertion tip.	Other
10/29/2009	HXX	XIA II PA SREWDRIVE SHAFT	It was reported that "during a hardware removal case. Dr was backing out a ti xia screw and one of the posts on the screwdriver broke.	Breakage
10/29/2009	LHX	XIA II LATERAL HOOK FORCEPS	It was reported that, "came back from a surgery with a broken spring. Rep says it was not used in the surgery.	Breakage
11/11/2009	HXX	XIA II PA SCREWDRIVER SHAFT	It was reported that, "doctor used the xia ii screwdriver assembly to back a screw out and 2 of the	Breakage

Date Received	Product Code	Device	Description	Type of Event
			4 teeth - on tip of driver - broke off.	
12/09/2009	LXH	UNIVERSAL TIGHTENER 5MM	Our sales rep, reported on behalf of the customer that the blocker does not fit on the tightener.	Malfunction
12/16/2009	LXH	XIA II UNIVERSAL TIGHTENER 5MM	During surgery, he noted that the selfholding-mechanism is out of function. The blocker is always fallen down.	Malfunction
12/16/2009	NKB	XIA System	It was reported "dr told the board of medicine that he would have abandoned the surgery had he known that the instrumentation he ordered was not present. He did not discover that, however, until it was too late.	Other
12/23/2009	LXH	XIA PRECISION JAM SHIDI 10 GAUGE 9 INCH	It was reported that "expired jam shidi's were used. (b)(4); (b)(6) 2009".	Other
12/23/2009	LXH	TITANIUM 4.5 ROD CUTTER DIAM 4.5	It was reported that, "return broken. ".	Breakage
12/23/2009	LXH	XIA PRECISION K-WIRE SHARP	During surgery, it was found that the surgeon tried to place a screw; however, the k-wire could not be removed from the screw, thus the screw together with the k-wire was removed and another k-wire was inserted and then another screw was placed.	Malfunction
12/23/2009	HXX	XIA 3 TITANIUM ILIAC SCREWDRIVER	It was reported that, "inner shaft broke while trying to implant a 7. 5 closed head iliac screw into an under tapped 6. 5 hole. ".	Breakage
01/21/2010	LXH	ANTERIOR CONNECTOR HOLDER	It was reported that "holder snapped".	Breakage
02/01/2010	LXH	ANTERIOR CONNECTOR HOLDER	It was reported that "instrument returned to loaners piece of spring broken off".	Breakage
02/05/2010	LXH	XIA II UNIVERSAL TIGHTENER 5MM	It was reported that, "tip broken. ".	Breakage
02/05/2010	LXH	XIA 3 TITANIUM TORQUE WRENCH	It was reported that "doctor went to tighten locking cap with anti torque and the torque wrench broke. Snapped in half by screw head. ".	Breakage
02/08/2010	LXH	XIA II TORQUE WRENCH	It was reported that, "the final tightener was not tightening all the way when the lines were lined up. I had another torque wrench what worked right.	Malfunction
02/08/2010	LXH	TITANIUM 4.5 CROSS CONNECTOR HOLDER	The distributor reported; when the surgeon tried to place the connector on the rod, it broke.	Breakage
02/08/2010	LXH	XIA II PA ADJUSTMENT DRIVER	It was reported that "(b)(6) was trying to implant a pedicle screw more deep w/ the poly adjustment driver. The prong broke as he was torquing the screw.	Breakage

Date Received	Product Code	Device	Description	Type of Event
02/08/2010	LXH	XIA II PERSUADER	It was stated that "rod bender snapped during bending of rod. Surgeon complained persuader wasn't fitting correctly, seem as though tips have expanded out. ".	Breakage
02/16/2010	HXX	TITANIUM POLYAXIAL SCREWDRIVER (EVERYTHING B	It was reported that "initially - ball housing broke so he used a different screw driver.	Breakage
02/16/2010	LXH	XIA II PERSUADER	It was reported that "dr was attaching the persuader to a tulip of a screw. She pressed the persuader over the tulip and in doing so part of the tip of the persuader broke off. ".	Breakage
02/16/2010	LXH	ANTERIOR CONNECTOR HOLDER	It was reported that "the instrument was returned from surgery with the spring broken. It was not used in surgery. ".	Breakage
02/16/2010	LXH	TITANIUM TORQUE WRENCH	It was reported that "when final tightening the blockers during a surgical case on (b)(6) 2010, the tip (hex head) of the final tightening torque wrench broke off when applying normal force to tighten the blockers.	Breakage
02/16/2010	HXX	TITANIUM ILIAC SCREWDRIVER	It was reported that "we were about half-way through screwing in the first 6. 5 x 40 screw into s1 when the shaft of the screwdriver broke.	Breakage
03/12/2010	LXH	TITANIUM 4.5 ROD ROTATION FORCEPS	It was reported by the kit loan service from stryker (b)(4) that the customer returned in a loan kit a xia forceps broken.	Breakage
04/05/2010	LXH	TITANIUM TORQUE WRENCH	It was reported that, "the tip of the xia 3 torque wrench snapped off when final tightening.	Breakage
04/05/2010	LRN	PRECISION K-WIRE SHARP	At the attempt to pull out the wire by using an accumulator drill, the tip of the k-wire got stuck into one vertebra.	Malfunction
04/05/2010	LRN	PRECISION K-WIRE SHARP	At the attempt to pull out the wire by using an accumulator drill, the tip of the k-wire got stuck into one vertebra.	Malfunction
04/08/2010	LXH	SURGICAL, TAP	4mm by 10mm tip of the tap (stryker xia 4. 0 mm) broke into center of vertebral body.	Breakage
04/27/2010	HXX	LOCKING POLYAXIAL SCREWDRIVER	It was reported that "screwdriver tip broke off after screw inserted. We had another screwdriver on hand, so no down time. ".	Breakage
05/07/2010	LXH	CANNULATED TAP 5.5MM	It was reported that "while using the 5. 5 cannulated tap, it was noted that the tap broke.	Breakage

Date Received	Product Code	Device	Description	Type of Event
05/07/2010	LXH	XIA TAP 4.0	"pt having posterior spinal fusion, 4mm by 10mm tip of the tap (stryker xia 4. 00 mm) broke into center of vertebral body.	Breakage
05/20/2010	HXX	PA SCREWDRIVER SHAFT	It was reported that "one prong from the tip of the screwdriver shaft broke during loading of screw. The screwdriver shaft was no longer used during procedure. ".	Breakage
06/16/2010	LXH	4.5 MM TAP	Patient undergoing a posterior spinal fusion. A 4. 5 tap broke off while being used by the surgeon.	Breakage
06/17/2010	NKB	TITANIUM COMPLEX SPINE INSTRUMENTS BOX	During inspection for our instruments when returned from customer, it was found that there was white powder on the tray inside the case	Other
06/17/2010	NKB	TITANIUM TORQUE WRENCH	It was reported that "while final tightening poly screw, tip of instrument broke off. ".	Breakage
06/17/2010	HXX	TITANIUM ILIAC SCREWDRIVER	It was stated that "dr was placing a 7. 5 x 80mm closed head screw into the ilium when the driver shaft for the 2 pc iliac screwdriver ((b)(4)) snapped in half.	Breakage
07/09/2010	LXH	XIA II TORQUE WRENCH	The distributor (b)(6) reported that the torque wrench broke when using it. It broke during the operation in the final tightening step.	Breakage
07/09/2010	HXX	XIA II UNIVERSAL TIGHTENER 5MM	It was reported that "screwdriver broke when backing out a polyaxial screw.	Breakage
07/09/2010	LXH	LP MODULAR TAP 5,5MM	It was reported that "the 5. 5 tap broke when inserting into pedicle.	Breakage
08/13/2010	LXH	TORQUE WRENCH	The item had been broken on the hexagon point by a surgeon while he did a spine case on l3.	Breakage
08/13/2010	LXH	TORQUE WRENCH	The item had been broken on the hexagon point by a surgeon while he did a spine case on l2.	Breakage
08/30/2010	LXH	TITANIUM TORQUE WRENCH	It was reported that "the end of the xia 3 torque wrench shaped off and broke into several pieces on the sterile field. ".	Breakage
09/07/2010	LXH	TORQUE WITH AUDIBLE CLICK	The torque is fairly new. It is a xia 3 torque that provides the audible click when torqued at 12mm. The problem with testing the torque is that they broke the tip off of it when using it in this case	Breakage
09/07/2010	LXH	SPECIALTY XIA II SHAFT	It was reported that, "2 prongs of xia 2 custom driver broke off during use in surgery. ".	Breakage
09/10/2010	HXX	PA SCREWDRIVER SHAFT	It was reported that "xia 2 polyaxial inner screwdriver shaft used for removal cases at tulsa spine and	Breakage

Date Received	Product Code	Device	Description	Type of Event
			specialty suffered broken teeth and was bent.	
09/10/2010	NKB	XIA II HANDLE	The surgeon had removed one screw and started to remove the 2nd one when the round handle broke and slid down the shaft of the screw driver into the patient	Malfunction
09/17/2010	LXH	TORQUE WRENCH	When final tightening, the blocker with the torque wrench, the doctor found the arrow had not arrived "12n", and heard the broken voice of the instrument. After checking with it, he found the head of torque wrench had been broken.	Breakage
09/17/2010	LXH	TITANIUM TORQUE WRENCH	Our sales rep, (b)(4) reports that the customer told him that the tip broke off during screwing in. The screw was fastened without using a torque key.	Breakage
09/17/2010	NKB	TITANIUM TORQUE WRENCH	It was reported that "the tip of the torque wrench broke off while trying to final tighten. ".	Breakage
10/11/2010	HXX	XIA II PA SCREWDRIVER SHAFT	It was reported that ?found driver broken in tray.	Breakage
10/22/2010	HXX	TITANIUM ILIAC SCREWDRIVER	was reported that "while implanting a 7. 5 x 80mm closed head poly axial iliac closed head iliac screwdriver broke along the shaft of the screwdriver at the junction where it tapers to a smaller diameter.	Breakage
10/22/2010	LXH	PROBE FEELER SET	During plif surgery, after the feeler was placed in the vertebra and x-ray image was taken, the surgeon moved the retractor and it came in contact with the feeler, then the feeler at right l3 broke.	Breakage
11/05/2010	LXH	TITANIUM ILIAC SCREWDRIVER	It was reported that, "during a case with dr. He was driving in a closed head iliac screw, when the 2 piece driver broke. The inner shaft broke about an inch under the handle.	Breakage
11/22/2010	LXH	XIA II PERSUADER	Nurse mrs (b)(6) reported via sales rep (b)(6), that while preparation prior to a surgery, the head was dressed to size. No further info were given, the head of the device is not available.	Malfunction
12/02/2010	LXH	XIA II TORQUE WRENCH	During surgery for spinal stenosis at l4/5, it was found that the tip of the torque wrench broke into 3 small pieces while final torquing.	Breakage
12/02/2010	LXH	PA SCREWDRIVER SHAFT	Nurse mrs. (b)(6) reported, via sales rep (b)(4), that during preparation prior to a surgery, a cleat of the shaft broke off.	Breakage
12/09/2010	LXH	TITANIUM TORQUE	Both the sales rep and surgeon do not believe that	Malfunction

Date Received	Product Code	Device	Description	Type of Event
		WRENCH	there is actually a specific issue with the torque wrench, but rather the surgeon did not torque enough in the initial surgery.	
12/17/2010	KWP	TITANIUM TORQUE WRENCH	It was reported that "the tip of the xia 3 torque wrench broke off into the blocker that was being placed in a side by side connector. ".	Breakage
12/17/2010	LXH	TITANIUM TORQUE WRENCH	It was reported that, "during final tightening, the hex tip of the xia3 torque wrench broke off. ".	Breakage

Appendix B: Perioperative Implant-Related MDR Listings

Date Received	Product Code	Device	Description	Type of Event
07/17/2001	KWQ	SCREW 5.5 X 40 IMPLANT	Fracture of screw head during insertion	Breakage
04/10/2002	KWQ	BLOCKER	Screw blocker damaged the screw during surgery	Breakage
01/12/2006	KWQ	SCREW	screw broke inside patient while doing lumbar spinal fusion. All pieces were intact and taken out of patient.	Breakage Revision
02/28/2006	HWC	LP POLYAXIAL SCREW 7.5 X 45MM	when using final tightening torque wrench and anti-torque, the head of the screw almost came off the screw. Head became locked in current position and contributed to cracking the pedicle. Screw had to be removed	Malfunction
03/21/2006	HWC	SCREW	screw broke inside pt. While doing lumbar spinal fusion. All pieces intact and taken out of pt.	Breakage Revision
11/15/2006	KWQ	PRECISION SCREW 6.5 X 50MM	Screw breakage during tightening during surgery	Breakage
10/15/2007	KWP	POLYAXIAL SCREW 8.5 X 50MM	During surgery second thread in the tulip head of the screw sheered off which caused the blocker to pop up. He did this a second time at l-l3 with a brand new screw.	Breakage
10/19/2007	KWQ	Blocker	blocker broke and could not be removed from the patient	Breakage
10/30/2007	KWP	Blocker	after the surgeon did the final tightening, he visualized that the blocker of the s1 screw was cracked. He attempted to remove the blocker with the inserter and was unable to do so. Surgeon then cut rod next to the screw and backed out construct with pliers. A new screw was inserted and new rod and blocker were used to complete surgery.	Break
12/05/2007	NKB	Blocker	When doing the final tightening with the antitorque instrument, the surgeon heard a sound, and discovered that the blocker was broken inside the screw head and it could not be removed.	Breakage
01/07/2008	KWQ	Blocker	During locking the monoaxial screw with torsional movement, it was observed that the xia blocker sheared off. Also a second device used presented the same problem.	Breakage
04/14/2008	KWQ	Blocker	blocker cracked/split during final tightening making it	Malfunction

Date Received	Product Code	Device	Description	Type of Event
			impossible to turn the blocker in either direction. Surgeon was able to remove the rod which allowed the screw to become polyaxial again.	
05/06/2008	KWP	Blocker	During surgery the blocker broke off.	Breakage
05/06/2008	NKB	LP POLYAXIAL SCREW 6.5 X 45MM	implant being subject to per fractured during surgery	Breakage
06/09/2008	NKB	POLYAXIAL SCREW 8.5 X 55MM	upon attempting to final tighten blocker, screw head splayed opened and blocker disengaged. Screw and blocker were both removed and replaced with new blocker and screw which seemed to have the same issue.	Breakage Revision
07/14/2008	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 35 MM	tulip head of a xia 3 screw had popped off at the s1 level of a 2-level construct.	Breakage
07/14/2008	KWP	LIP POLYAXIAL SCREW 6.5 X 40MM	During the surgery to remove the implants, one of the screws in s1 broke near the tip.	Breakage
07/18/2008	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 45 MM	When placing rods and blockers, the surgeon noticed a single popping noise when final tightening blockers on both sacral 7. 5mm diameter screws. The surgeon then noticed both of the tulips popped off the shaft of the screws. He then removed all screws and replaced them with xia ii screws.	Breakage
08/11/2008	KWQ	Blocker	Surgeon tightened the blocker with the universal tightener and fixed the blocker with a torque wrench and a torque key. During this, he noticed that the blocker was broken. It was not possible to screw it out.	Breakage
09/04/2008	KWP	Blocker	During a spine screw fixation the titanium blocker (closure mechanism) broke radially after at final tightening.	Breakage
09/08/2008	KWP	PRECISION SCREW 6.5 X 45 MM	It was reported that the surgeon placed the screw and rod and then final tightened. Then he decided to redirect the screw. The screw wouldn't slide over the k-wire because the cannulation was deformed.	Malfunction
10/06/2008	NKB	TITANIUM POLYAXIAL SCREW DIA 6.5 X 40 MM	screw heads locked (lost polyaxial capability) in the patient. Screwback couldn't be broken free in the patient. Screws were removed from patient and replaced. Upon trying to break the head free post operation, one screw head completely broke free. The other is still locked.	Malfunction

Date Received	Product Code	Device	Description	Type of Event
10/08/2008	KWQ	LP POLYAXIAL SCREW 7.5 X 60MM	During the revision surgery, the surgeon tried to move the screw head for a small adjustment using a driver. The screw disassembled thus the screw had to be removed and replaced with a new screw.	Breakage
11/03/2008	NKB	PRECISION SCREW 6.5 X 50MM	It was reported that: the screw tulip head came off when the rod was locked down. The screw was replaced and the surgery was completed without further incident.	Breakage
11/03/2008	KWQ	LP POLYAXIAL SCREW 6.5 X 45MM	During this extraction surgery, the blockers and rods were removed without problem; however, it was found that one of the screwhead was disassembled when the surgeon was about to extract it.	Breakage
11/12/2008	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 40MM	It was reported that the doctor did not like screw placement and decided to remove and replace screw. He had a hard time getting the tip of the xia 3 driver engaged inside the tulip head; most likely due to the fact that the tulip had become cold molded at too extreme an angle to make the connection. He was able to remove the screw, but the tulip is still rigid and at a sharp angle to the shaft.	Malfunction
12/11/2008	NKB	TITANIUM BLOCKER	The driver was slipping when the doctor attempted to remove the blocker so he cut the rod and used the torque tube to back out the screw. The poly-axial head came apart in the process and the adjustment driver was used to remove the screw.	Malfunction
12/11/2008	KWP	TITANIUM POLYAXIAL SCREW DIA 7.5 X 50 MM	Next, he attempted to torque the blocker on the left of l5 when it cracked 2 places. The driver was slipping when the doctor attempted to remove the blocker so he cut the rod and used the torque tube to back out the screw. The poly-axial head came apart in the process and the adjustment driver was used to remove the screw.	Malfunction
12/11/2008	KWP	LP POLYAXIAL SCREW 6.5 X 4.5MM	It was reported that the doctor had final tightened screws with the rod in place and decided to take the rod out and make some adjustments. When he took the rod out the screw heads were in a lock position he then used the mono driver head adjuster to loosen the heads and the tulip head came off the pedicle screw	Breakage
12/11/2008	NKB	TITANIUM REDUCTION	During placement of the blocker, we heard a pop and	Migration

Date Received	Product Code	Device	Description	Type of Event
		LONG ARM POLYAXIAL SCREW 7.	could not confirm what it was. Before closing, we took final x-rays and noticed the s2 screw head had popped off.	
12/11/2008	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 40 MM	It was reported that after provisional tightening, dr decided to revise the screw position at which point the screw head was locked at an angle. After trying to free the head position, the head popped off.	Breakage
12/11/2008	KWP	TITANIUM POLYAXIAL SCREW DIA 6.5 X 50 MM	It was reported that after provisional tightening, (b) (6) decided to revise the screw position at which point the screw head was locked at an angle. After trying to free the head position, the head popped off.	Breakage
01/21/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 5.5 X 50 MM	Whether it was the screw of concern in the attached picture or not, i cannot know. The head welding occurred during the tlif's and bone work in and around the pedicles and laminae of the spine.	Malfunction
01/21/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 30MM	When he locked the rod in the l5 screws, the s1 screw heads became loose and not locked down. The surgeon manipulated the heads and they came off in his hand with rod and blockers still in place.	Migration
02/06/2009	NKB	POLYAXIAL SCREW 8.5 X 50MM	screw was implanted and blocker inserted, but upon final torque, blocker kept turning and popping. Shards of metal also were coming off the screw. It was explanted	Malfunction
02/06/2009	KWP	TITANIUM BLOCKER	follow-up check-up the patient's rod seemed to have been moved. The surgeon has not decided to revise case was a revision. Patient had l3-5. Three levels	Migration
02/11/2009	NKB	POLYAXIAL SCREW 6.5 X 45MM	were added to construct. While placing blockers, head of l3 screw disengaged from screw body. Blockers and rod were removed	Malfunction
02/20/2009	NKB	Blocker	The nut cup broke during operation	Breakage
02/20/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 6.5 X 40 MM	"(b) (6) was doing a 3 level xia 3 removal. He was using the poly adjustment driver and 3 of the 8 heads popped off as he was trying to remove.	Breakage
02/20/2009	KWP	Blocker	It was reported that, "blockers shredded when being inserted. He was complaining about cross threading. Ultimately, the blockers were inserted and removed	Breakage
02/25/2009	NKB	TITANIUM 4.5 POLYAXIAL CROSS CONNECTOR 30-36 M	during a surgery on a (b) (6) pt, surgery for a duchene myopathy, an issue happened with the cross connector.	Unknown

Date Received	Product Code	Device	Description	Type of Event
02/25/2009	NKB	POLYAXIAL SCREW 8.5 X 50MM	screws were implanted and blockers inserted, but upon final torque, blocker kept turning and popping. Shards of metal also were coming off of the screws. It was explanted, and the blockers were stripped.	Malfunction
03/27/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 40 MM	The customer reported via the sales rep that 3 screws have broken during removal.	Revision
03/27/2009	NKB	Blocker	The surgeon then noticed that the blocker has split (was cracked). Removal was attempted using initial inserter.	Breakage
03/27/2009	KWP	Blocker	Two blockers got damaged during final tightening using the torque wrench and the anti torque key.	Breakage
03/27/2009	NKB	Blocker	during (b) (6) surgery on the (b) (6) 2009, the xia blocker fastening with final tightening device, he realizes a loosening in the device turning and doctor sees a split on the blocker top marker line.	Malfunction
04/03/2009	KWP	LP POLYAXIAL SCREW 6.5 X 45MM	It was reported that "dr. Was using the rod fork on the screw head, and the tulip just popped off. Next screw worked fine.	Malfunction
05/01/2009	NKB	Blocker	During surgery, he noted that the surgeon appeared to have problems with the blocker. It was not possible to turn it in.	Malfunction
05/01/2009	NKB	Blocker	It was reported that, "r side l5 doctor went to final tighten a snap occurred w/torque wrench on final blocker split unable to unscrew -	Malfunction
05/01/2009	NKB	Blocker	It was reported that, "doctor went to final tighter s1 screw blocker split had to leave screw in with broken blocker. ".	Malfunction
05/01/2009	HWC	TITANIUM POLYAXIAL SCREW DIA 7.5 X 45 MM	screw head looked wobbly, and he used a coker to just pull the head off the screw. We removed the screw and replaced it with another same size.	Malfunction
05/01/2009	KWP	TITANIUM BLOCKER	It was reported that, "surgeon noticed a crack in blocker after tightening.	Breakage
05/14/2009	NKB	Blocker	When tightening the closure screws with the torque wrench with the use of the anti torque key to line up the arrows of the instrument till 12n, two blockers were broken and they had to replace it.	Breakage
05/14/2009	NKB	Blocker	When tightening the closure screws with the torque wrench with the use of the anti torque key to line up the arrows of the instrument till 12n, two blockers	Breakage

Date Received	Product Code	Device	Description	Type of Event
			were broken and they had to replace it.	
06/09/2009	NKB	TITANIUM 4.5 POLYAXIAL CROSS CONNECTOR 30-36 M	The implant surgeon, (b)(6), reported the following event to the sales rep from stryker, (b)(4): during the tightening of the connector, the crossconnector broke.	Breakage
06/09/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 6.5 X 40 MM	Once he removed the blockers and the rod, he attempted to straighten the head to be able to load a poly drive in the screw. He was not able to manipulate the head, so he had to resort to twisting the screw out with a pair of pliers.	Malfunction
06/30/2009	NKB	Blocker	It was reported that "dr was final tightening the blocker into a 7. 5 mono screw. It was about 50% tightened and the blocker snapped. Dr then had to bur the blocker out of the screw. ".	Breakage
07/09/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 7.0 X 50 MM	It was reported that "doctor was distracting off of the screw heads and screw heads popped off.	Breakage
07/09/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 7.0 X 50 MM	It was reported that "doctor was distracting off of the screw heads and screw heads popped off.	Breakage
07/09/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 7.0 X 50 MM	It was reported that "doctor was distracting off of the screw heads and screw heads popped off.	Breakage
07/09/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 7.0 X 50 MM	It was reported that "doctor was distracting off of the screw heads and screw heads popped off.	Breakage
07/09/2009	KWP	LP POLYAXIAL SCREW 6.5 X 50MM	The head of the poly axial screw had come out of the shaft and was found to be dangling on the rod. The screw	Breakage
07/09/2009	KWP	LP MONOAXIAL SCREW 6.5X45MM	When the doctor locked the cup second time, the cup and screw were loosed and broken.	Breakage
07/09/2009	KWQ	Blocker	It was reported that "final tightened blocker and it split in half. One big crack on one side. Had good purchase - left in place. ".	Breakage
07/09/2009	NKB	Blocker	the surgeon did the final tightening using torque wrench and anti-torque key, but it seems to be it was not tightened thus the final tightening was redone, then a crack appeared on the blocker also the hex part got worn.	Malfunction
07/09/2009	NKB	Blocker	When the doctor locked the cup second time, the cup and screw were loosened and broken.	Breakage
07/31/2009	NKB	Blocker	When the doctor used the torque wrench to final tighten the last xia blocker, the torque wrench didn't indicated line up the two arrows to achieve the	Breakage

Date Received	Product Code	Device	Description	Type of Event
			optimum torque of 12nm, he heard the quite light sound that the material of blocker was broken, then the torque wrench was slippery.	
07/31/2009	NKB	Blocker	Two blockers got damaged during final tightening using the torque wrench and the anti torque key.	Breakage
08/06/2009	NKB	Blocker	When the doctor used the torque wrench to final tighten the last xia blocker, the torque wrench didn't indicated line up the two arrows to achieve the optimum torque of 12nm, he heard the quite light sound that the material of blocker was broken, then the torque wrench was slippery.	Breakage
08/12/2009	NKB	Blocker	It was reported that while tightening a xia titanium blocker, it cracked	Breakage
08/13/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 45 MM	It was reported that, "doctor was revising a case from may. He was adjusting the screw head with a xia ii head adjuster and the head popped off.	Breakage
08/13/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 6.5 X 50 MM	It was reported that, "doctor had all the screws in and locked down. He went back to reposition the screw, when he was readjusting the head to be able to get the screw driver in the head popped off.	Breakage
08/27/2009	NKB	TITANIUM BLOCKER	Doctor couldn't get the set screws in the right l4 screw started.	Malfunction
08/27/2009	NKB	TITANIUM BLOCKER	Doctor couldn't get the set screws in the right l4 screw started.	Malfunction
08/27/2009	NKB	TITANIUM BLOCKER	Three set screws were cross threaded and the doctor requested new set screw to make sure his construct was secure	Malfunction
09/01/2009	NKB	Blocker	When the doctor used the torque wrench to final tighten the last xia blocker, the torque wrench didn't indicate line up the two arrows to achieve the optimum torque of 12nm, he heard the quiet light sound that the material of blocker was broken, then the torque wrench was slippery.	Breakage
09/10/2009	NKB	TITANIUM POLYAXIAL SCREW 8.5 X 65MM	Screws were the wrong color (as stated "teal screws").	Other
09/10/2009	NKB	TITANIUM POLYAXIAL SCREW 8.5 X 65MM	It was reported that, "while investigating a field complaint - it was noticed that this item/lot was teal blue in color, while the remaining 8. 5 sizes were pink. The entire qty on hand was placed in the qa cage	Other

Date Received	Product Code	Device	Description	Type of Event
			in the d02 warehouse.	
09/10/2009	NKB	TITANIUM POLYAXIAL SCREW 8.5 X 65MM	It was reported that, "screws were manufactured the wrong color. ".	Other
09/11/2009	NKB	TITANIUM BLOCKER	It was reported that "3 blockers were stripped and or chipped or broken. ".	Breakage
09/17/2009	NKB	Blocker	When prof. Used the torque wrench to final tighten the last xia blocker, the torque wrench didn't indicated line up the two arrows to achieve the optimum torque of 12nm, he heard the quite light sound that the material of blocker was broken, then the torque wrench was slippery.	Malfunction
09/17/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 50 MM	The customer reported via the sales rep that during a revision procedure, the screw head became separated from the screw body.	Breakage
09/30/2009	NKB	TITANIUM MONOAXIAL SCREW DIA 6.5 X 45 MM	It was also reported that at the s1 level, when the surgeon tried to screw one last time, the screw head broke.	Breakage
10/01/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 35 MM	It was reported that "xia 3 screw originally implanted about 1 year earlier. Upon revising/removing s1 screw, the head popped off while removing, leaving the threaded part of the screw in the s1 pedicle	Breakage
10/05/2009	NKB	TITANIUM BLOCKER	that while the surgeon was removing an implant, when he tried to unscrew the blocker of the monoaxial screw, the internal part of the blocker broke.	Breakage
10/22/2009	NKB	LP POLYAXIAL SCREW 6.5 X 45MM	Upon observation the tulip head was completely separated.	Breakage
10/22/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 7.0 X 60MM	It was reported that "dr was trying to persuade the rod into the screw head. He used the anti torque wrench and a mallet to persuade rod into the screw head after numerous hits with the mallet the head disengaged from the screw shank.	Breakage
10/29/2009	NKB	TITANIUM BLOCKER	Surgeon removed the persuader and went to tighten the set screw a little more so he could compress and the set screw was cross thread. It actually made a popping sound as he was tightening it down.	Malfunction
11/06/2009	NKB	LP POLYAXIAL SCREW 6.5 X 40MM	It was reported that, "trying to reduce a grade 2 spondy from s1-l5 final tightened the xia screws at s1, then went to reduce l5 with persuader and tulip heads pulled of both s1 screws.	Breakage

Date Received	Product Code	Device	Description	Type of Event
11/06/2009	NKB	LP POLYAXIAL SCREW 6.5 X 40MM	It was reported that, "trying to reduce a grade 2 spondy from s1-l5 final tightened the xia screws at s1, then went to reduce l5 with persuader and tulip heads pulled of both s1 screws. ".	Breakage
11/11/2009	NKB	TITANIUM POLYAXIAL SCREW BIASED ANGEL 8.5 X	It was reported that "when surgeon was final tightening the 8. 5 x 70 biased angel screw the head splayed, this event was noted by the blocker, was removed and the screw was removed and replaced with a standard 10. 5 x 70 pa xia 3 screw. ".	Breakage
11/11/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 6.5 X 50 MM	It was reported that, "my rep brought to my attention that the screw has the wrong description on it. The screw has 6. 5x50 printed on it. But the actual screw is 6. 5x45. ".	Other
11/20/2009	NKB	TITANIUM BLOCKER	Screws and rods were placed and blockers were being inserted. Dr. Was initially inserting a blocker when it skipped. He backed the blocker out and asked for a new blocker. A new blocker was inserted and construct was finally tightened without further problems.	Malfunction
12/04/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 50 MM	Final tightened this s1 screw last and inner thread broke off. We pulled out screw and replaced.	Breakage
12/09/2009	KWQ	POLYAXIAL SCREW 7.5 X 45MM	It was reported that, "doctor was using screw head turner and tulip popped off of screw".	Breakage
12/09/2009	NKB	TITANIUM MULTIAXIAL CROSSLINK 53MM 73MM	It was reported that "while taking connector out of office to replish, a metal shard came off of the ctr nut. No instruments were used on this brand new implant shard is included in plastic container.	Breakage
12/09/2009	NKB	PRECISION SCREW 6.5 X 50MM	Dr reported via our sales rep, that he was conducting a revision surgery due to a wrong positioned screw. During removing the screw, it was not possible to move the head anymore	Malfunction
12/16/2009	NKB	TITANIUM POLYAXIAL SCREW BIASED ANGLE 7.5 X	It was reported that "xia 3 biased angle screw - tulip head splayed after final tight, (b)(4). Close extended connector was in attached to rod".	Migration
12/16/2009	NKB	TITANIUM POLYAXIAL SCREW 8.5 X 60MM	It was reported that "surgeon was doing a revision case. He removed a 7. 5 screw and put in a xia 3 8. 5 screw. He was final tightening and the blocker kept advancing in the tulip and we never hit 12mm	Malfunction
12/16/2009	NKB	TITANIUM MULTIAXIAL	It was reported that, "surgeon was backing out middle	Breakage

Date Received	Product Code	Device	Description	Type of Event
		CROSSLINK 53MM 73MM	nut and "leaves" of retaining ring broke off. He decided to use the implant. ".	
12/16/2009	NKB	TITANIUM REDUCTION LONG ARM POLYAXIAL SCREW 6	He then inserted blockers into the reduction screws. As he was inserting the blockers to reduce, both reduction screwhead splayed open and 1 tab broke off of each reduction screw. One tab broke off and tore the patient's dura.	Breakage
12/16/2009	NKB	BLOCKER	When prof. Used the torque wrench to final tighten the last xia blocker, the torque wrench did not indicate line up the two arrows to achieve the optimum of 12nm. He heard the quite light sound that the material of blocker was broken, then the torque wrench was slippery.	Malfunction
12/16/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 45 MM	It was reported that, "dr. Was removing xia 3 screws and a tulip head popped off the screw.	Breakage
12/16/2009	NKB	TITANIUM REDUCTION LONG ARM POLYAXIAL SCREW 6	He inserted the rod and locked down the blockers at s1. He then inserted blockers into the reduction screws. As he was inserting the blockers to reduce, both reduction screwhead splayed open and 1 tab broke off of each reduction screw. One tab broke off and tore the patient's dura.	Breakage
12/23/2009	NKB	TITANIUM R T R PARALLEL CONNECTOR ANGLED – S	It was reported that "implant broke while attempting to final tighten blocker".	Breakage
12/23/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 6.5 X 45 MM	Once seated, surgeon went to back screw out when the head of screw broke off.	Breakage
01/21/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 60 MM	Started final tightening at 11. Got to s1 and the blocker kept advancing. Never got to 12mm but heard an audible pop. Removed the screw from the pt and the head was off	Breakage
02/16/2010	KWQ	TITANIUM POLYAXIAL SCREW 10.5 X 100MM	On a different iliac screw he was placing a very high amt of torque on t-handle on after struggling to get the 10. 5 screw to advance, it sheared off underneath the tulip.	Breakage
02/16/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 45 MM	"dr was using torque wrench when the 7. 5x45 p. A screw head came off the shaft. This happened bi-laterally at s1 level.	Breakage
03/02/2010	NKB	PRECISION SCREW 6.5 X 45MM	It was reported that "screw was placed and when the screw was being removed, it came apart. Screw was removed and new screw placed. ".	Malfunction

Date Received	Product Code	Device	Description	Type of Event
03/02/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 35MM	It was reported that "head broke when final tightening - used 5. 5 ti rod".	Breakage
03/02/2010	KWQ	TITANIUM POLYAXIAL SCREW DIA 7.5 X 40 MM	It was reported that, "screw head popped off during explant. ".	Breakage
03/12/2010	KWP	TITANIUM POLYAXIAL SCREW 8.5 X 40MM	It was reported that "head splayed when final tightening - caused surgeon to have to revise screw. ".	Breakage
03/18/2010	NKB	TITANIUM POLYAXIAL SCREW 8.5 X 55 MM	It was reported that "at s1 the surgeon had not reached 12mm and the blocker kept spinning and the head popped off. Replaced with a 9. 5 x 60".	Malfunction
03/18/2010	NKB	TITANIUM BLOCKER	When he went to torque the blocker on the pt's left iliac screw, a pop was heard before he achieved 12m and the blocker spun freely in the head of the screw.	Malfunction
03/18/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 80 MM	When he went to torque the blocker on the pt's left iliac screw, a pop was heard before he achieved 12m and the blocker spun freely in the head of the screw. Surgeon indicated that it appeared that the iliac screw's head splayed.	Breakage
04/15/2010	NKB	DEFORMITY UNIPLANAR SCREW DIAM 6.5 X 40 MM	It was reported that "dr (b)(6) implanted the uniplanner screw and then before the rod and blocker was seated, dr (b)(6) felt as though the uniplanner screw had too much movement along the axial plane.	Malfunction
04/15/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 45 MM	during reduction using xia reduction screws, the s1 screw tulip disassociated from the screw. The surgeon removed the screw and replaced it with a new screw.	Malfunction
04/15/2010	NKB	TITANIUM BLOCKER	When dr was inserting the s1 cap screw (lot# 76m) he engaged the threads about 2 turns when the cap screw "skipped". The cap screw was not cross threaded upon initial insertion.	Malfunction
04/15/2010	NKB	TITANIUM BLOCKER	When dr was inserting the s1 cap screw (lot# 76m) he engaged the threads about 2 turns when the cap screw "skipped". The cap screw was not cross threaded upon initial insertion.	Malfunction
04/23/2010	KWP	TITANIUM POLYAXIAL SCREW DIA 6.5 X 40 MM	It was reported that "when explanting screw w/poly adjustment driver, the head popped off. Surgeon mentioned the set screws seemed "loose" upon removal.	Breakage
04/23/2010	NKB	LP POLYAXIAL SCREW 6.5 X 40MM	Head surgeon reported to our sales rep, that the tip of the screw broke off and was left in the patient in s1.	Breakage
04/27/2010	NKB	TITANIUM POLYAXIAL	It was reported that the "surgeon had the screw in and	Breakage

Date Received	Product Code	Device	Description	Type of Event
		SCREW DIA 7.0 X 50 MM	was using rod fork to persuade the rod into the screw when the screwhead popped off.	
04/27/2010	KWP	PRECISION SCREW 5.5 X 40MM	Dr. Reported via our sales rep, that he was performing a revision surgery due to a wrong position of a screw. When he tried to extract this screw, its head disengaged from the rest of the screw.	Breakage
05/20/2010	NKB	TITANIUM BLOCKER	While final tightening on his last screw (right l3) the blocker popped up crooked out of the tulip head. Doctor achieved the 12mm on the final tightener and decided that the blocker was tightened enough for the construct to hold.	Malfunction
05/20/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 5.5 X 40 MM	It was reported that "tulip head popped off xia 3 5. 5 x 40mm pedicle screw. Occurred during final tightening.	Breakage
05/28/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 45 MM	It was reported, "during the final tightening of a xia 3 screw during a 1-level tlif, the tulip head was splayed during an attempt to final tighten.	Breakage
06/17/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 6.5 X 55 MM	Then due to screw trajectory, dr (b)(6) had to remove the set screws and rod. When dr (b)(6) removed the rod, the left l4 screw head just fell off".	Breakage
09/07/2010	MNI	LP POLYAXIAL SCREW 7.5 X 35MM	The new screw can not run in the surgery, dealer requested to replace new.	Other
09/07/2010	MNI	TITANIUM POLYAXIAL SCREW DIA 7.5 X 45 MM	. Xrays were taken and on x-ray, it was noted that tulip of screw might be disengaged from screw. The rod was removed and was discovered that screwhead was disengaged. Screws were removed (both at l5 level). They were replaced and final tightened successfully.	Breakage
09/07/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 6.5 X 50 MM	It was reported that "the implant was inserted into the spine. At the end of the case, the dr attempted to insert the rod and the rod did not fit. We removed the screw and replaced it with another one. ".	Other
09/07/2010	NKB	LP POLYAXIAL SCREW 5.5 X 35MM	Medical report: during the surgery, it was verified that the screw ((b)(4) - xia ii screw poliaxia l 5,5 x 35mm - lot: 068587) were broken in the half of its extension. The same was removed.	Breakage
09/10/2010	KWQ	Blocker	The surgeon tried to remove the fracture blocker with a tightener, however, it could not be removed, then the surgeon left it.	Malfunction

Date Received	Product Code	Device	Description	Type of Event
09/10/2010	KWP	Blocker	The screw cap need to adjust in the surgery, doctor cannot insert. Now the screw was useless.	Malfunction
09/17/2010	KWP	TITANIUM BLOCKER	It was reported, "xia blocker cracked inside rod to rod connector.	Breakage
09/17/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 50 MM	Upon attempt to remove left-side l5 pedicle screw, tulip head portion disengaged from screw itself with a very small amount of force after threading screwdriver to tulip.	Malfunction
09/24/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 40 MM	It was reported that, "dr was final tightening xia 3 7. 5 x 40 screws to rod and set screws at l4-5 and the polyaxial heads popped off the screw shafts in left side of l4-5.	Breakage
09/24/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 40 MM	It was reported that "polyaxial tulip heads popped off of 2 xia 3 screws during final tightening. Screws were both 7. 5 x 40 mm.	Breakage
09/24/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 40 MM	It was reported that "polyaxial tulip heads popped off of 2 xia 3 screws during final tightening. Screws were both 7. 5 x 40 mm.	Breakage
10/01/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 45 MM	It was reported that, "splayed tulip head l5-s1 where tightening l5 set screw, after s1 already tightened, blocker popped out as result of tulip head splay.	Breakage
10/11/2010	NKB	Blocker	It was reported that ?threads on the blocker started to strip upon insertion of the blocker.	Breakage
10/28/2010	MNH	TITANIUM R T R PARALLEL CONNECTOR ANGLED – S	It was reported, "the implant broke while final tightening.	Breakage
11/11/2010	MNI	TITANIUM POLYAXIAL SCREW DIA 7.5 X 40 MM	It was reported that "the tulip head of a xia 3 screw (7. 5 x 40) popped off while the surgeon was using a cobb to move tissue away from the screw. ".	Breakage
12/02/2010	NKB	TITANIUM 4.5 EXTENDED CONNECTOR SMALL	It was reported, "small growth rod extenders were found to be broken bilaterally and removed and replaced. "	Breakage
12/02/2010	NKB	LP MONOAXIAL SCREW 6.5 X 50MM	Nurse (b)(6) reported, that the screw broke, while surgery.	Breakage
12/09/2010	NKB	Blocker	It was reported that "surgeon was inserting blocker into closed head iliac screw and the blocker started to come apart as he was threading it into the screw head.	Breakage
12/09/2010	KWP	Blocker	As reported to stryker, inners were broken during surgery.	Breakage
12/09/2010	MNI	TITANIUM POLYAXIAL	It was reported that, "as surgeon was final tightening,	Breakage

Date Received	Product Code	Device	Description	Type of Event
		SCREW DIA 7.5 X 50 MM	the tulip disengaged from the screw shank and popped off. When the surgeon pulled the tulip out, the blocker was cross threaded.	
12/17/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 35 MM	It was reported that "during a revision of hardware case, while using a monodriver to rotate the head on a 7. 5 x 35mm xia 3 polyaxial pedicle screw, the screw head came off of the screw.	Breakage
01/06/2011	NKB	XIA III TITANIUM POLYAXIAL SCREW DIA 7.5 X 40MM	It was reported that "we were doing a revision case and 3 tulip heads popped off of the XIA III screw heads. The surgeon was trying to remove them to put in larger screws".	Breakage
01/06/2011	MNI	XIA 3 TITANIUM POLYAXIAL SCREW DIA 7.5 X 45MM	It was reported that "we were doing a revision case and 3 tulip heads popped off of the XIA III screw heads. The surgeon was trying to remove them to put in larger screws".	Breakage
01/06/2011	MNI	XIA 3 TITANIUM POLYAXIAL SCREW DIA 7.5 X 35MM	It was reported that "we were doing a revision case and 3 tulip heads popped off of the XIA III screw heads. The surgeon was trying to remove them to put in larger screws".	Breakage
01/10/2011	NKB	XIA TITANIUM 4.5 POLYAXIAL SCREW DIAM 6.5 X 50	Doctor reports that during use of in situ bending, the head of the screw broke.	Malfunction
01/14/2011	MNI	XIA 3 TITANIUM POLYAXIAL SCREW DIA 6.5 X 55MM	One level extension fusion and tried to advance a screw that was previously implanted and the head disassembled when he tried to advance the screw.	Breakage
01/19/2011	NKB	XIA BLOCKER	Blocker broke into two pieces while final tightening. Surgeon could not remove broken blocker.	Breakage
01/19/2011	NKB	XIA S/S POLYAXIAL SCREW 6.5 X 45MM	The blocking head of the screw could not initially be inserted when the rod was in the screw and in a second try the head broke off.	Malfunction
01/28/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW DIA 6.5X50MM	During revision of rod and blockers, tulip disengaged from body of screw; parallel distractor was used.	Malfunction
02/03/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW DIA 7.5X45MM	Tulip head on xia 3 poly screw, size 7.5x45mm, popped off on final tightening of screw.	Malfunction
02/03/2011	MNI	XIA 3 TITANIUM POLYAXIAL SCREW DIA 6.5 X 45MM	Upon blocker insertion, the tulip head splayed and would not accept the blocker. Tried 2 separate blockers and same result.	Malfunction
02/11/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW DIA 7.5 X 40MM	The surgeon was trying to seat the rod for the second time, he had torqued down the construct once and	Malfunction

Date Received	Product Code	Device	Description	Type of Event
			then took it apart to reposition the L5 screw, when he noticed the head of the S1 screw had fallen off the shaft.	
02/15/2011	MNI	XIA LP POLYAXIAL SCREW 7.5 X 50MM	Mono driver was used to manipulate the poly axial screw head, screw head then popped off.	Malfunction
02/15/2011	NKB	XIA LP POLYAXIAL SCREW 6.5 X 40MM	The head of the screw jammed during the removal of the material.	Malfunction
02/23/2011	NKB	XIA 3 TITANIUM BLOCKER	Lower screw was being tightened and the blocker stripped; thread on the blocker had broken	Malfunction
03/02/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW DIA 7.5X55MM	Head loosened from screw	Malfunction
03/02/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW 8.5X50MM	In locking the sacral screws with the torque wrench, the surgeon noticed the blocker drove further into the head than it should have; polyaxial head had popped off screw entirely.	Malfunction
03/02/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW DIA 7.5 X 50MM	Screw head loosened from screw	Malfunction
03/03/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW DIA 7.5 X 40MM	L5-S1 lumbar fusion, during final tightening the lead pulled off the S1 screw.	Malfunction
03/11/2011	HWC	XIA 3 TITANIUM POLYAXIAL SCREW DIA 7.5 X 45MM	As we were final tightening a 7.5x45mm polyaxial screw, the tulip head separated from the shaft.	Malfunction
03/11/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW 8.5 X 50MM	During final tightening, the inner threads in the tulip head broke out of the screw.	Malfunction
03/11/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW 7.5 X 40MM	During final tightening, the inner threads in the tulip head broke out of the screw.	Malfunction
03/14/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW 7.5 X 45MM	The head of the screw loosened from the thread after inserting the locking cap	Malfunction
03/17/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW 7.5 X 50MM	The screw head broke off from the shaft of the screw during surgery. Surgeon noticed it was broken off when he was final tightening the blockers.	Malfunction
03/28/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW 8.5 X 60MM	Ring at the base of the polyaxial screw cracked and on insertion of the blocker, the head lifted off the threaded shaft of the screw.	Malfunction
04/05/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW 6.5 X 45MM	Tulip head popped of the shank of the screw and rode down the shaft of the screw; all screw were removed	Malfunction
04/05/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW 7.5 X 40MM	Tulip head popped of the shank of the screw and rode down the shaft of the screw; all screw were removed	Malfunction
04/07/2011	NKB	XIA 3 TITANIUM BLOCKER	Blocker split in half when torquing down last blocker at L4	Malfunction

Date Received	Product Code	Device	Description	Type of Event
04/12/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW 6.5 X 40MM	Heads of the screws popped off	Malfunction
04/14/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW 7.5 X 50MM	Threads from the inner part of the screw head sheared out.	Malfunction
04/14/2011	NKB	XIA BLOCKER	Blocker broke off the screw	Malfunction
04/20/2011	NKB	XIA LP MONOAXIAL SCREW 7.5 X 50MM	During removal of screw, screw broke inside pedicle.	Breakage
04/20/2011	NKB	XIA LP MONOAXIAL SCREW 6.5 X 40MM	During removal of screw, screw broke inside pedicle.	Breakage
05/04/2011	KWP	XIA 3 POLYAXIAL SCREW 8.5 X 40MM	Screw head was splayed out and the blocker just kept spinning in tulip head.	Malfunction
05/20/2011	NKB	XIA 3 TITANIUM BLOCKER	Blocker breaks	Breakage
06/02/2011	NKB	XIA 3 TITANIUM BLOCKER	Inner hex of the blocker was worn	Malfunction
06/23/2011	NKB	XIA TITANIUM 4.5 BLOCKER	Blocker popped off the screw head when the persuader was removed.	Malfunction
06/23/2011	NKB	XIA TITANIUM 4.5 EXTENDED CONNECTOR SMALL	Broken during routine lengthening procedure	Breakage
06/23/2011	NKB	XIA 3 TITANIUM MULTIAXIAL CROSSLINK 43MM 54MM	Upon tightening center nut of crosslink the set screw popped out into the wound	Malfunction
07/11/2011	KWQ	XIA ROD TO ROD CLAMP – PARALLEL	Rod was placed into slot, set screw tightened down. Physician needed to loosen screw in order to reposition screw, was unable to get screw loosened. Stripped out.	Malfunction

Appendix C: Post-Operative Implant-Related MDR Listings

Date Received	Product Code	Device	Description	Type of Event
07/05/2001	KWQ	XIA SPINAL SCREW MA 6.5 X 45	Fracture of screw was found in periodical examination. Remaining screw was extracted with bolt during revision surgery.	Breakage Revision
07/31/2001	KWQ	ROD 6 X 480	One of the rods broke after several months and eventually revision surgery became necessary because of a seroma.	Breakage Revision
08/13/2001	KWQ	ROD 6 MM X 480 MM	Revision surgery performed to replace broken rod	Breakage Revision
08/28/2001	KWQ	ROD 6 MM X 110 MM	rod was found to be fractured. Revision surgery performed.	Breakage Revision
09/06/2001	KWP	BONE SCREW 6.5 X 40	After about 1 year of implantation, the xia screw broke at the level of the thread's tip. Removal of the device was planned.	Breakage Revision
02/27/2002	KWQ	BLOCKER	Post-op x-rays showed blocker had backed out of the screw head. Patient was revised.	Migration Revision
06/25/2002	KWQ	ROD 6 MM X 480 MM	Patient required revision surgery to replace broken rod on a xia construct	Breakage Revision
07/10/2002	KWQ	**POLYAXIAL SCREW - 6.5X40MM**	Blocker came out of xia ii screw head as seen on postoperative x-ray	Migration
03/11/2003	KWQ	POLYAXIAL SCREW	rod/screw interface came apart at l5-s1. Patient fell post-op, which may have caused or contributed to the event. Rod disengaged from screw and revision surgery was required.	Migration Revision
05/21/2003	KWQ	Blocker	attempt was made to remove blockers and a construct at l4-l5 but the screwdriver would not fit in the blockers. The reason for removal was a suspected inflammation of the whole system.	Other Revision
05/21/2003	HWC	POLYAXIAL SCREW - 6.5 X 45 MM	screws had broken while in the pt. Surgery required to remove two broken screw	Breakage Revision
04/13/2004	KWQ	ROD 6MM X 150 MM	The pt underwent revision surgery to replace a fractured rod at l1.	Breakage Revision
04/29/2004	KWQ	Blocker	X-rays show that closing screws have dissociated. Revision surgery may be performed, but this has not yet been determined.	Migration

Date Received	Product Code	Device	Description	Type of Event
06/08/2004	KWQ	POLYAXIAL SPINAL SCREW 6.5 X 40MM	It was reported that the screw had broken 3-6 months post operatively	Breakage
06/16/2004	KWQ	MA SCREW 5.5 X 50	X-rays showed broken screws. Pt was revised.	Breakage Revision
08/04/2004	KWQ	Blocker	x-ray showed the blocker had backed out of all 4 screws. Revision surgery was required.	Migration Revision
08/12/2004	HSB	ROD DIA. 6 X 100	After four years implantation, the surgeon found that the rods (both right and left) were broken. The pt needed revision surgery.	Breakage Revision
08/18/2004	KWQ	LP PA SCREW 5.5X35MM	both s1 screws (l5-s1 fusion) had fractured. Pt was revised about two months later and screws were removed.	Breakage Revision
10/23/2004	KWQ	MA SCREW 7.5X45MM	It has been reported by the surgeon that the pedicle screw had broken. The device has been in the pt for approx 4 yrs	Breakage
10/28/2004	HWC	PA SCREW 6.5 X 30MM	Patient called to report a broken xia ti pa screw left in his vertebra. Surgeon has told him that as he is asymptomatic and the screw material is inert to there is no reason to remove the broken screw.	Breakage
11/17/2004	KWQ	Blocker	After 1 yr from surgery, the surgeon found that the closing screw became loose and backed out from the pedicle screw.	Migration
12/07/2004	KWQ	Blocker	It was reported that 3 weeks after implantation, the patient fell. X-ray showed no abnormality. Later, it was discovered that one of the closing screws had backed out from the pedicle screw.	Migration
01/20/2005	HWC	LP POLYAXIAL SCREW 5.5 X 55MM	It was reported that the screw broke around 3 months after implantation. Revision surgery was required.	Breakage
02/02/2005	KWQ	Rod	The rod was broken after 1 year from implant and was subsequently removed.	Breakage Revision
02/02/2005	HWC	LP POLYAXIAL SCREW 6.5 X 55MM	noted broken screw on routine follow-up x-ray (5 months post-op).	Breakage
02/02/2005	JDN	ROD DIA. 6 X 200	found one rod was broken, and 3 months later, the rod was removed.	Breakage Revision
03/09/2005	KWQ	Blocker	"after one month from the surgery the blocker was sitting above screw. It was replaced with new blocker.	Migration Revision
03/12/2005	KWQ	SPINAL SCREWS	the implant had loosened and shifted anteriorly	Migration
04/07/2005	KWQ	ROD DIA. 6 X 480	Rod broke without outside influences	Breakage
04/19/2005	KWP	Blocker	It was reported that the patient had to be revised ('05) because 4 xia system blockers became loose.	Migration
04/28/2005	KWQ	Rod	rod has slipped out of the screw head while the blocker	Migration

Date Received	Product Code	Device	Description	Type of Event
			remains in place	
06/01/2005	HWC	POLYAXIAL SCREW 6.5 X 45MM	It was reported via legal that the patient had a surgery to revise broken sacral screws and repair psuedarthrosis. Broken screws were diagnosed several months earlier	Breakage Revision
06/27/2005	HWC	LP POLYAXIAL SCREW 5.5 X 45MM	screws which were implanted had snapped at the bottom in s1. He further reported that the screws were removed and he inserted an opposition product.	Breakage Revision
07/07/2005	KWQ	ROD DIA. 6 X 480	fracture of the rod on the right side just below the l4 screw. Pt presents to the hosp 2 months for surgery for the fractured rod	Breakage Revision
07/27/2005	HWC	MONOAXIAL SCREW 6.5 X 45MM	two screws in l3 were broken. In 2005, the surgeon extracted the implant and at the same time performed a second surgery.	Breakage Revision
07/27/2005	HWC	LP POLYAXIAL SCREW 6.5 X 50MM	Surgeon explanted unilaterally failed implant at l5-s1.	Breakage Revision
08/26/2005	KWP	MONOAXIAL SCREW 6.5 X 50MM	patient felt pain and the x-ray showed one screw broken. On 10th may 2005, the surgeon removed all the implants	Breakage Revision
09/12/2005	KWQ	Blocker	X-ray taken, surgeon noted blocker disengaged from screw.	Migration
10/11/2005	HWC	S/S POLYAXIAL SCREW 6.5 X 50MM	This pt fell and broke both rods. During the removal process dr noticed that the screw at l5 (6. 5x50) was loose. Upon further examination he realized that the head of the screw had popped off. He removed both pieces and finished his revision.	Breakage Revision
11/02/2005	KWQ	Blocker	closing screw on l5 right side is dislocated. " device was removed in a second surgery	Migration Removal
11/11/2005	KWQ	LP POLYAXIAL SCREW 6.5 X 45MM	Reported that the screw broke postoperatively. The screw remains in the pt.	Breakage
12/06/2005	HWC	LP MONOAXIAL SCREW 6.5 X 50MM	implantation at l4 to l5 that a revision became necessary due to the breakage of the screw.	Breakage Revision
12/08/2005	HWC	LP POLYAXIAL SCREW 6.5 X 50MM	during a revision case in a failed fusion, this screw was found broken.	Breakage Revision
12/13/2005	KWP	Blocker	It was found that the wound was infected for the mrsa. The surgeon will have another surgery for the pt to cleanse with saline containing antibiotics.	Other
12/19/2005	JDN	ROD DIA. 6 X 80	rod broke directly under the cross connector. Screws loosened during an inflammational process	Breakage Migration
01/17/2006	KWQ	POLYAXIAL SCREW 6.5 X 50MM	During a regular check-up in 2004 it was noted that one of the devices had broken. A second surgery was performed	Breakage Revision

Date Received	Product Code	Device	Description	Type of Event
			and the device was removed.	
01/23/2006	KWQ	LP POLYAXIAL SCREW 6.5 X 50MM	xia lp polyaxial screw is broken postoperatively. Screw remains implanted	Breakage
01/30/2006	KWQ	POLYAXIAL CROSS CONNECTOR MED	Post-op x-ray showed cross connector came loose and moved. Surgeon had to reopen and reposition cross connector.	Migration Revision
01/30/2006	KWQ	LP POLYAXIAL SCREW 6.5X50MM	During the second part of a level l fusion procedure it was noticed that the screws implanted during the first part of the procedure (over 2 yrs ago) had completely come away	Migration
02/08/2006	JDN	ROD DIA. 6 X 40	The surgeon found the xia rod to be broken	Breakage
02/15/2006	JDN	ROD DIA 6 X 100	Soon after the surgery, the rods at both sides were broken at around l1. The pt had a revision surgery in 2006, leaving all of the screws from the primary surgery and replacing the rods, blockers, and transverse connector	Breakage
02/15/2006	JDN	ROD DIA, 6 X 120	t12/l1 was having a thoracic kyphosis due to an adjacent-segment disease just above t12 which was resulting in the rod fracture.	Breakage
02/22/2006	KWQ	Blocker	on a follow up visit with x-ray it is evident that the blockers for the bottom screws have backed out	Migration
02/22/2006	KWQ	Blocker	follow up visit with x-ray it is evident that the blockers for the bottom screws have backed out. No revision is planned.	Migration
04/03/2006	HWC	LP POLYAXIAL SCREW 6.5 X 40MM	remove screws due to the s1 screw breaking in half	Breakage Revision
04/11/2006	KWQ	POLYAXIAL SCREW	during a revision the surgeon wanted to remove a polyaxial screw and noticed that the screw head was separated from the threaded part of the screw	Breakage Revision
06/01/2006	HWC	LP POLYAXIAL SCREW 5.5 X 40MM	tip of screw was broken. The surgeon does not have any plan for revision surgery at this point.	Breakage
06/20/2006	HWC	LP MONOAXIAL SCREW 6.5 X 50MM	Nurse reported to our salesrep that the implanted screw broke	Breakage
07/07/2006	HWC	LP MONOAXIAL SCREW 6.5 X 40MM	one of the screws broke inside the human body. In 2006, the product was explanted from the body.	Breakage Revision
07/17/2006	MCV	TRANSPEDICULAR SCREW (XIA)	The fixation screws broken, causing complication risk and pain, also disability	Breakage
07/17/2006	KWQ	Blocker	The patient needed to be re-operated because the blockers unscrewed	Migration Revision
07/17/2006	KWQ	Blocker	"blocker was separated from screw at l5 on an l4-l5 plif case	Migration

Date Received	Product Code	Device	Description	Type of Event
07/24/2006	HSB	ROD DIA. 6X480	It was reported by the surgeon that the implanted rod broke	Breakage
09/07/2006	JDN	ROD DIA. 6X200	The surgeon found that the rods were broken between l1 & l2. He revised the rods.	Breakage Revision
10/16/2006	HWC	MONOAXIAL SCREW 6.5 X 45MM	screw was broken on the l3 left side. Implants removed	Breakage Revision
10/24/2006	KWP	Blocker	backed out blocker and this one broke in two	Breakage
10/24/2006	KWQ	UNKNOWN PRODUCT XIA FUSION SYSTEM	patient underwent subsequent low back surgery to replace the fractured pedicle screw in 2006	Breakage Revision
10/24/2006	JDN	ROD DIA. 6 X 50	X-ray discovered broken rod. The surgeon revised the rod.	Breakage Revision
11/15/2006	KWQ	ROD DIA. 6 X 480	xia rod was damaged inside the patient after 6 months of implantation	Breakage
11/15/2006	KWQ	ROD DIA. 6 X 480	remove the rods implanted in 2003 because of the breakage of these ones with resulting pain for the patient affected	Breakage Revision
11/29/2006	HWC	LP POLYAXIAL SCREW 6.5 X 40 MM	removed xia in ls pedicle. Shaft of screw broken and remained in pt.	Breakage Revision
12/12/2006	HWC	POLYAXIAL SCREW 6.5 X 40MM	revision because of screw fracture on the right side of s1	Breakage Revision
12/12/2006	HWC	LP MONOAXIAL SCREW 5.5 X 45MM	Screw breakage on follow-up examination	Breakage
12/27/2006	HWC	LP POLYAXIAL SCREW 7.5 X 70MM	side connector connected to the iliac screw (03821770) head has popped off. In other words, the poly iliac screw on opposite side head popped off from the threaded portion	Migration Breakage
12/27/2006	KWQ	ROD DIA. 6 X 400	rod broke inside the body. Approx 6 months later, implants were explanted.	Breakage Revision
02/12/2007	MCV	TITANIUM 4.5 MONOAXIAL SCREW DIAM 6.5 X 40	l2 bone was fractured as well and the l2 screw was disassembled. The surgeon opened the pt again and extracted all of the screws in l2-l4	Breakage Revision
02/23/2007	KWQ	Blocker	x-rays showed a migrated rod on the right side. It migrated cephalad and was completely out of the inferior	Migration
03/16/2007	HWC	LP MONOAXIAL SCREW 6.5 X 50MM	Less than one year after surgery, the doctor had informed the distributor that 2 of the 4 monoaxial implants had broken. The following year, a revision surgery was performed on the patient to remove and replace the broken implants.	Breakage Revision
03/16/2007	HWC	LP POLYAXIAL SCREW	unanticipated revision surgery due to the crack that the	Breakage

Date Received	Product Code	Device	Description	Type of Event
		5.5 X 50MM	customer alleged to have while lifting weight. The surgeon further reported that the broken screw was extracted and that he implanted another 6. 5 diameter screw	Revision
03/26/2007	HWC	LP POLYAXIAL SCREW 6.5 X 45MM	Reporter reported via our product manager that the screw broke postoperatively	Breakage
04/17/2007	JDN	ROD DIA. 6 X 90	rods on both sides of the construct have snapped	Breakage
04/24/2007	HSB	ROD DIA. 6 X 130	Rod was broken for unknown reason	Breakage
04/24/2007	HSB	ROD DIA. 6 X 40	Rod was broken for unknown reason.	Breakage
04/24/2007	HWC	LP POLYAXIAL SCREW 7.5 X 40MM	top of the screw had sheared off. The customer reports that the patient underwent a revision procedure to remove the damaged screw	Breakage Revision
05/16/2007	KWP	LP POLYAXIAL SCREW 6.5X45MM	During the surgery to extract the implant, it was found that one of the screws (l6 on the left) was broken when it was extracted	Breakage Revision
05/30/2007	MNI	TITANIUM ROD	patient reported he underwent a third surgery in 2005 to remove all of the titanium rods along with the repair bridge and new rods were installed	Breakage Revision
08/13/2007	MNI	Blocker	set screw had popped off a screw on the right side at l5. Dr. Opened the patient up and found multiple set screws that were loose with set screws popping off the screws at the right l5 & left t3 & t4.	Migration
10/09/2007	KWQ	SCREW	screw popped out. The screw is splayed open. One screw and a rod came out. Patient had surgery to replace the screw	Migration Revision
10/19/2007	KWQ	LP POLYAXIAL SCREW 6.5 X 45MM	On approx four and a half months after surgery, the pt was revised since the left l3 screw was broken.	Breakage Revision
10/30/2007	KWQ	TITANIUM 4.5 BLOCKER	surgeon implanted a 4. 5 mm vitalium rod in a hook/screw construct over a 60 day period, the blocker caps came off the screw head.	Migration
11/12/2007	NKB	TITANIUM 4.5 POLYAXIAL SCREW DIAM 6.5 X 35	One month post op, it was found from the x-ray that one of the blockers was disassembled. During the revision surgery, the surgeon visually found the blocker l3 on the left loosened.	Migration Revision
11/12/2007	KWP	Blocker	bi-lateral blockers came off at l4 on a l4-s1 construct patient returned to have surgery to have a screw replaced.	Migration
11/15/2007	KWP	LP POLYAXIAL SCREW 6.5 X 45 MM	When he bent over in the shower the screw popped out. The screw is splayed open. One screw and a rod came out. He had surgery to replace screw	Migration Revision
12/05/2007	NKB	Blocker	blocker came loose at l5-31 and rod pulled out	Migration

Date Received	Product Code	Device	Description	Type of Event
12/05/2007	NKB	Blocker	blocker came off at s1 and rod pulled out	Migration
12/05/2007	KWP	Blocker	bi-lateral blockers came loose at s1 and rods pulled out	Migration
12/20/2007	NKB	LP POLYAXIAL SCREW 6.5 X 35MM	it was found at the 1 week post-op visit, that the blocker is loosened at th12.	Migration
01/07/2008	KWQ	LP MONOAXIAL SCREW 6.5 X 45MM	spacer had migrated posteriority into the cal sac. During the revision surgery the surgeons found both l5 screws had loosened	Migration Revision
01/25/2008	NKB	LP POLYAXIAL SCREW 6.5 X 35MM	It was reported that the patient was re-operated. Where broken screws were explanted, new screws were implanted, rod and blockers were replaced and patient was re-bonegrafted.	Breakage Revision
01/25/2008	NKB	LP MONOAXIAL SCREW 6.5 X 35MM	doctor performed an asf w/ ray cage and found a broken s1 screw. Approx two weeks later, the doctor removed the broken screw and replaced it with 7. 5x35 xia ii poly and re-bone grafted it	Breakage Revision
03/05/2008	NKB	LP MONOAXIAL SCREW 6.5 X 50MM	Unknown adverse event	Other
03/05/2008	HWC	LP MONOAXIAL SCREW 5.5 X 45MM	After x-ray examination a broken screw was detected.	Breakage
03/16/2008	KWP	ROD DIA. 6 X 480	When the patient returned for post-op xrays at about one month later, the surgeon noticed the rod at the top of the construct on the patient's left side had slipped out, resulting in loss of correction. The locking cap is still in place in the screw head, but the rod backed its way out.	Migration
03/16/2008	NKB	POLYAXIAL SCREW 6.5 X 40 MM	pt had a l3,4,s1 fusion from a previous surgery. The s1 screw was broken. The surgeon removed all screws and left the broken screw in the sacrum. The surgeon did a laminotomy on l2, checked whether the construct fused and determined that it did. No further instrumentation was done.	Breakage Revision
05/06/2008	HWC	LP POLYAXIAL SCREW 5.5 X 45MM	the claimant alleges xia screw failure, one of the sacral transpedicular screws was loose.	Migration
05/28/2008	JDN	4.5 TITANIUM ROD	5mm by 200 mm length. Ref # 48733200, lot # emf was cut in two pieces and implanted in pt. Both pieces of rod broke.	Breakage
06/18/2008	NKB	LP POLYAXIAL SCREW 5.5 X 40MM	On (b) (6) 2007, the patient underwent an x-ray for the follow-up check. At this time, the x-rays showed that the screws on th12 broke, however, the surgeon did not notice. The patient was not complaining of pain. On (b) (6), 2008,	Breakage Revision

Date Received	Product Code	Device	Description	Type of Event
			the patient underwent x-rays since the surgeon was planning to remove the implants because the bone fusion was obtained. Surgery was to remove hardware. Then, at that time, the surgeon found that the screws broke at th12.	
06/18/2008	KWP	TITANIUM MULTIAXIAL CROSSLINK 43MM 54MM	After surgery, the pt. Developed an infection, which required an irrigation and debridement. Upon i & d, surgeon removed hardware to reposition a screw. The crosslink seemed to become dismantled and non-functioning upon removal.	Migration
06/27/2008	KWQ	Blocker	During this he felt a "klick" and noticed that the blocker was broken.	Breakage
06/27/2008	NKB	LP POLYAXIAL SCREW 5.5 X 35MM	It is further reported that an x-ray was taken and this showed that a screw had fractured on l5 (left side.)	Breakage
07/07/2008	KWP	LP MONOAXIAL SCREW 5.5 X 40MM	The surgeon reported that the screws broke and the blockers came loose. According to the surgeon, it is not clear whether the screws broke because of no fusion, or no fusion occurred because the screws broke, or if the blockers finally were not tightened enough. The surgeon stated that during revision surgery, the screw threads had to be left in the pt, because it was not possible to remove them.	Breakage Revision
07/14/2008	KWP	LIP POLYAXIAL SCREW 6.5 X 40MM	The surgeon reported that one of his patient's had a broken xia screw at s1 level after nine months	Breakage
07/14/2008	KWP	LP POLYAXIAL SCREW 6.5 X 40	It was reported that when this screw was removed from the pt during a revision surgery, a part of it broke off and now remains in the pt.	Breakage Revision
07/14/2008	KWP	TITANIUM POLYAXIAL SCREW DIA 5.5 X 35 MM	There was in situ bending at the end of the case and the head of the last screw in the construct popped off. We had to take the screw out and put in a new one	Breakage Revision
08/02/2008	KWP	Blocker	The following month, the blockers at both sides of s1 appeared to be loosened on the post-op x-ray. Two days later, the patient was revised. During the revision surgery, it was confirmed that the blockers were loosened at both sides of s1 and the rod slide, thus the distance between l5 and s1 was increased.	Migration Revision
08/11/2008	NKB	Blocker	It was reported that, two months after the surgery date, the surgeon detected via x-ray that the ref. (b) (4) (xia blocker) had moved from the initial position.	Migration
08/18/2008	KWP	LP POLYAXIAL SCREW	Six months post-op, surgeon revised patient because the	Revision

Date Received	Product Code	Device	Description	Type of Event
		7.5 X 45MM	left s1 7. 5x45mm screw head detached. He reinstrumented with new 7. 35x45mm screws and blockers, re-used the 50mm crosslink rod and screws from l4.	Breakage
08/23/2008	NKB	LP POLYXIAL SCREW 7.5 X 50 MM	It was reported that "while doing revision, the screw head was found detached from the screw. This was found during inter-operation. This was not found pre-op through x-ray. This screw was located at union level. The surgeon was able to extract the screw with a poly adjustment screwdriver.	Breakage Revision
09/08/2008	KWQ	Blocker	It was reported that a post operative follow-up x-ray revealed a loose rod. A revision was scheduled and the surgeon found the blocker was almost completely out of the screw at l-2, and the blocker on the screw at l-3 was very loose.	Migration
09/08/2008	KWP	LP POLYAXIAL SCREW 4.5 X 40 MM	The patient subsequently complained of discomfort at the site and an x-ray taken four months later, revealed two fractured screws. The patient underwent a revision the following month, to remove all the implants.	Breakage Revision
09/16/2008	KWP	LP POLYAXIAL SCREW 6.5 X 40MM	"patient went into doctor's office for follow up visit and x-rays and it showed the head of the screw popped off the shaft. Doctor scheduled revision surgery immediately and replaced the old screw with a new mono axial style screw. Out come was very good.	Breakage Revision
09/16/2008	KWP	TITANIUM BLOCKER	the patient went to dr's office for a routine follow up. When films were taken of the patient, the physician determined that the instrumentation had failed. A revision surgery was then immediately scheduled.	Breakage Revision
09/29/2008	KWP	TITANIUM POLYAXIAL SCREW DIA 6.5 X 60 MM	that a patient underwent a revision surgery due to the fact that the head of the polyaxial screw became loose.	Migration Revision
10/06/2008	NKB	POLYAXIAL SCREW 9.5 X 100MM	surgeon implanted an iliac screw-9. 5x100, the head of the screw came off the shaft before rod insertion. The surgeon place another iliac screw in next to the shaft of 1st screw.	Breakage Revision
10/07/2008	NKB	LP POLYAXIAL SCREW 6.5 X 35MM	The doctor went in to check the placement of the screws and the unilift. After the surgeon removed the blockers and rods, he put light pressure to move the direction of the head. At that time, the head became detached from the screw portion. The screws were replaced, and the surgery ended with no complications.	Breakage

Date Received	Product Code	Device	Description	Type of Event
10/08/2008	KWQ	ROD DIA 6 X 480	On seven months later, the rods on both sides fractured. On twelve days later, the patient had revision surgery which the rods were replaced using a rod-to-rod clamp.	Breakage
10/28/2008	KWP	LP POLYAXIAL SCREW 6.5 X 45MM	screw at left l5 fractured near the tip. At approx 50 days later, the pt was revised.	Breakage Revision
10/28/2008	KWQ	LP POLYAXIAL SCREW 6.5X40MM	revision surgery to take out broken screw	Breakage Revision
10/28/2008	KWQ	LP MONOAXIAL SCREW 6.5X50MM	It was reported that a pt underwent a revision surgery due to the screw breaking 3 mos post op.	Breakage Revision
11/17/2008	NKB	LP POLYAXIAL SCREW 6.5 X 45MM	On (b) (6) 2008, during the extraction surgery, it was found that one of the screw head disassembled.	Breakage
11/17/2008	KWP	TITANIUM 4.5 POLYAXIAL SCREW DIAM 5.5 X 45	Was informed from the surgeon that the patient was complaining of pain and it was found that the two screws on s fractured.	Breakage
11/26/2008	NKB	LP POLYAXIAL SCREW 6.5 X 45MM	it was found that the screw on s fractured. In 2008, during the follow-up check, the surgeon found that the bone fusion was obtained. No revision surgery is planned at this moment.	Breakage
11/26/2008	KWQ	LP POLYAXIAL SCREW 6.5 X 45MM	In 2008 (exact date is unk), it was found that the screw on l5 fractured.	Breakage
11/26/2008	MNI	POLYAXIAL SCREW 6.5 X 45MM	At about 2 months post-op, it was found the screw on s fractured.	Breakage
11/26/2008	KWQ	4.5 PA SCREW	It was reported that during a follow up, the patient described a fall and x-rays were taken. Additionally, it was reported that xia pedicle screw was broken at distal 1/3 inside vertebral body.	Breakage
12/11/2008	NKB	TITANIUM POLYAXIAL SCREW DIA 5.5 X 40 MM	patient wanted hardware removed. During the removal, the tulip head came off the screw	Breakage
12/11/2008	NKB	TITANIUM REDUCTION LONG ARM MONOAXIAL SCREW 4	It was reported that, extended heads broke off (tabs) when the rod was being manipulated into place.	Breakage
12/11/2008	KWP	TITANIUM BLOCKER	It was reported that "resident working with dr crossthreaded a blocker, removed it and placed another one in the screw. After final tightening, dr cut open his thumb on a piece of metal protruding from the tulip head. He took off the blocker and noticed a sharp piece still attached to the underside of the blocker.	Breakage
12/11/2008	KWP	LP MONOAXIAL SCREW 6.5 X 55MM	It was reported that the pt underwent a trauma about 3 months post op. An x-ray was taken, and the doctor found	Breakage Revision

Date Received	Product Code	Device	Description	Type of Event
			the mono-axial screw was broken. A revision surgery was performed to replace the screw.	
01/09/2009	KWQ	LP POLYAXIAL SCREW 4.5 X 45MM	An x-ray showed a 4. 5 x 45 screw had broken. The screw was removed and repriced with a longer construct	Breakage Revision
01/09/2009	NKB	S/S DUAL CONNECTOR	Bent ss rods and broke crosslink. Revised in 2008. Cut rods and put domino's on. Had great difficulty getting them on. Tolerance too tight on implant. The following month, pt rolled over in bed and heard a "pop. " films showed that she pulled out of domino. Three days later, dr put another domino on failed side	Breakage Revision
01/21/2009	NKB	BLOCKER	revision surgery was performed because four xia blockers in the construct came loose.	Migration
02/06/2009	NKB	LP POLYAXIAL SCREW 6.5 X 50MM	patient fell off bike and screws broke. The hardware was removed and reinstrumentation completed.	Breakage Revision
02/06/2009	KWP	TITANIUM POLYAXIAL SCREW DIA 6.5 X 40 MM	The patient has fallen in a nursing home, and had fractured the (l+) l2 pedical, there for needed a revision.	Breakage Revision
02/25/2009	KWP	Blocker	The distributor in a foreign country claimed today, that patients had instrument failure because of blocker luxation.	Malfunction
03/20/2009	KWP	LP POLYAXIAL SCREW 6.5 X 45MM	both screws on s were fractured.	Breakage
03/20/2009	KWQ	TITANIUM POLYAXIAL SCREW DIA 7.5 X 45MM	upon taking post op x-rays, dr. Noticed that the tulip had become detached from the screw. He immediately notified me and scheduled the revision surgery for 2009	Breakage Revision
03/27/2009	NKB	LP POLYAXIAL SCREW 7.5 X 45MM	Revision surgery for xia screws at s1 due to the screw had loosened.	Migration Revision
03/27/2009	NKB	LP POLYAXIAL SCREW 6.5 X 40MM	Head of the polyaxial screw had come out of the shaft and was found dangling on the rod.	Breakage
03/27/2009	KWP	POLYAXIAL SCREW 8.5 X 45MM	Revision surgery for xia screws at s1 due to the screw had loosened.	Migration Revision
03/27/2009	KWQ	VITALIUM ROD 6.0 MM X 600 MM	Pt follow-up revealed vitallium rods broke bilaterally at l3. Pt also had some lordosis. Revision was required. Doctor removed rods distal to the break, replaced and connected new vitallium rods to the original construct.	Breakage
03/27/2009	KWQ	TITANIUM POLYAXIAL SCREW DIA 5.5X50 MM	It was reported that "pt reported hearing a noise coming from their back, flexion extension x-rays were taken and the s1 screw's tulip head had separated from the screw post. Revision surgery is scheduled for 2008.	Migration Revision
04/03/2009	NKB	LP MONOAXIAL SCREW	The pt felt pain in the fourth months after the operation of	Migration

Date Received	Product Code	Device	Description	Type of Event
		4.5 X 35MM	spine. The x-ray show two xia screws were disrupted.	
04/28/2009	NKB	LP POLYAXIAL SCREW 6.5 X 45MM	The x-ray and ct image taken 3 days before ((b) (6) 2009) the revision surgery ((b) (6) 2009), it was found the screw fractured.	Breakage Revision
05/01/2009	KWQ	ROD DIA. 6 X 480	it was found that the rod at right side at just above the offset connector. The revision surgery is not planned so far	Migration
05/01/2009	JDN	TITANIUM 4.5 VITALIUM ROD 4.5 X 600 MM	"both rods broke six months into post op. The surgeon is not clear as to what he plans on doing to fix patient.	Breakage
05/01/2009	JDN	TITANIUM 4.5 VITALIUM ROD 4.5 X 600 MM	"both rods broke six months into post op. The surgeon is not clear as to what he plans on doing to fix patient.	Breakage
05/01/2009	`MNI	TITANIUM 4.5 EXTENDED CONNECTOR SMALL	when the pt wound was opened that the extended connector and the rod as well as the soft tissue around there, were turned blackish. Also, it was found that the blockers of the extended connector were loose and the rod was extended about 3mm as the pt grew although no extension surgery had been performed.	Migration Revision
05/14/2009	KWQ	S/S POLYAXIAL SCREW 4.5 X 25MM	It was reported that, "patient pulled top (4) screws of construct did not fail, removed (4) top screws, cut rod. Closed".	Migration Revision
05/20/2009	KWP	LP MONOAXIAL SCREW 6.5 X 40 MM	the screw on l5 fractured (the date fractured or the date found is unknown). In 2009, the revision surgery was performed and l4-l5-s were fixated.	Breakage Revision
06/09/2009	MNH	ROD DIA 6 X 480	that a male pt underwent a revision surgery, due to the rod fracturing one yr post op.	Breakage Revision
06/09/2009	KWQ	Blocker	It was reported that, "pt pulled top (2) screws out of rods. Did not fail, blockers were still in screw heads. Removed screws, cut top portions of rods, closed".	Migration Revision
06/09/2009	MNH	Blocker	It was reported that, "pt pulled out multiple screws, blockers failed (see x-ray), replaced screws, offset connector used opi, used larger bolts, add'l cross connector, closed.	Breakage
06/30/2009	MNI	3 7.5MM SCREW	screw head popped off the screw.	Breakage
06/30/2009	KWP	LP POLYAXIAL SCREW 6.5 X 45MM	Approximately 6 months after the surgery, it was found that the left screw on s fractured into two pieces near the screw tip (about 1 cm from the tip). There was no complaint of pain from the patient. In 2009 another surgery was performed in order to give additional reduction. (this surgery was not done due to the fracture of the screw.) and, at this surgery, the fractured screw was	Breakage Revision

Date Received	Product Code	Device	Description	Type of Event
			retrieved and another new screw was placed.	
06/30/2009	KWP	LP MONOAXIAL SCREW 5.5 X 40MM	It was reported that, "l3-l4 screw case no interbody. Post-op she did great until the screw broke. She is not revised yet.	Breakage
06/30/2009	KWP	LP MONOAXIAL SCREW 6.5 X 45MM	reported that two pieces of broken xia lp mono axial screw has been pull out from the patient body (both items have been twice sterilized).	Breakage Revision
06/30/2009	KWP	LP MONOAXIAL SCREW 6.5 X 45 MM	reported that two pieces of broken xia lp mono axial screw has been pull out from the patient body (both items have been twice sterilized).	Breakage Revision
07/09/2009	NKB	LP POLYAXIAL SCREW 6.5X40MM	It was reported that "l3-l5 plif. L4 screw head pulled off from top of threads.	Breakage
07/09/2009	KWP	LP POLYAXIAL SCREW 6.5 X 40MM	At a six week post op visit, the x-ray indicated that the s1 screw was still in place with locking nut in place and the rod was out of the screw overlapping the top. See drawing on per. The rod had slipped out with the locking nut still in place.	Migration
08/03/2009	KWP	LP MONOAXIAL SCREW 6.5 X 45MM	Dr. Reported via our sales rep, that a female underwent a revision surgery, due to the screw breaking 15 months post op.	Breakage Revision
08/03/2009	KWP	LP POLYAXIAL SCREW 6.5 X 50MM	It was reported that "patient had screw at s1 break through the thread.	Breakage
08/06/2009	KWP	LP POLYAXIAL SCREW 6.5 X 50MM	When the rods were taken out, doctor noticed that the tulip head was loose and pulled the tulip directed up off of the screw post.	Breakage Revision
08/12/2009	KWQ	LP MONOAXIAL SCREW 6.5 X 50MM	Dr. Reported that a male patient underwent a revision surgery, due to the screw breaking 9 months post op.	Breakage Revision
08/12/2009	KWP	LP POLYAXIAL SCREW 6.5 X 50MM	At approx 3 month later, it was found that the both screws (6. 5x50 mm) on s1 which was bicortically placed were fractured at point approx 35mm from the tip. In 2009, the pt was revised.	Breakage Revision
08/12/2009	KWP	LP POLYAXIAL SCREW 6.5 X 50MM	At approx 3 months later, it was found that the both screws (6. 5x50 mm) on s1 which was bicortically placed were fractured at point approx 35mm from the tip. In 2008, the pt was revised.	Breakage Revision
08/13/2009	NKB	ROD DIA.	We received a letter from (b) (6) stating that a rod broke after a scoliosis stabilization.	Breakage
08/13/2009	MNI	LP POLYAXIAL SCREW 5.5 X 40MM	It was reported that "fractured pedicle screws at s-1 - bilateral fracture	Breakage

Date Received	Product Code	Device	Description	Type of Event
08/13/2009	MNI	LP POLYAXIAL SCREW 5.5 X 35MM	It was reported that "fractured pedicle screws at s-1 - bilateral fracture".	Breakage
08/21/2009	KWP	LP POLYAXIAL SCREW 6.5 X 30MM	Six months post op, the patient started complaining about pain. Dr thomas requested a ct and discovered that the s1 screws were broken. In 2009, we removed the 6. 5 x 30 xia ii screws, and put in 8. 5 x 45 screws back in the same holes in the s1 space.	Breakage Revision
08/27/2009	NKB	TITANIUM BLOCKER	It was reported that, "3 blockers were stripped and or chipped or broken. ".	Breakage
08/27/2009	NKB	TITANIUM BLOCKER	It was reported that, "3 blockers were stripped and or chipped or broken. ".	Breakage
08/27/2009	NKB	Blocker	It was reported that, "surgeon was final tightening xia ii blocker with a breakaway torque wrench, the wrench would not click and as a result, the blocker was over tightened and shredded. ".	Malfunction
09/03/2009	NKB	TITANIUM 4.5 BLOCKER	It was found through the x-rays that the one of the blocker was disassembled, thus one end of the rod was disassembled as well. Nine days later, the revision surgery is scheduled in order to replace the blocker.	Migration Revision
09/11/2009	KWP	TITANIUM POLYAXIAL SCREW 8.5 X 80MM	It was reported that," pt had a two-level procedure, l4-s1, conducted using depuy in 2006, dr. Operated on her again, and this is her third procedure. " dr. Would like a report of the findings to see if the screw tulip actually was splayed.	Migration
09/11/2009	KWP	TITANIUM BLOCKER	Dr believes the blocker cross threaded on the screw interface. " dr was unaware of the cross threading at the time of implanting.	Migration
09/24/2009	MNI	PRECISION SCREW 5.5 X 35MM	Dr reported via our sales rep, that a pt underwent a revision surgery, due to the screws fracturing 3 months post op.	Breakage Revision
09/24/2009	KWP	PRECISION SCREW 5.5 X 40MM	Dr reported via our sales rep, that a pt underwent a revision surgery, due to the screws fracturing 3 months post op.	Breakage Revision
10/15/2009	KWP	LP POLYAXIAL SCREW 6.5 X 40MM	In 2008, after the bone fusion was obtained, it was found that the screw at s1 fractured at the middle of threads however, the surgeon had not informed the sale rep	Breakage
10/29/2009	NKB	LP POLYAXIAL SCREW 6.5 X 50MM	X-rays revealed that a screw at l5 had broken about halfway down the shaft.	Breakage
11/06/2009	NKB	LP MONOAXIAL SCREW 6.5 X 45MM	The xia lp monoaxial screw 6. 5 x 45mm inserted into the body for nine months after the fracture.	Breakage

Date Received	Product Code	Device	Description	Type of Event
12/02/2009	NKB	ROD DIA. 6 X 480	After scoliosis redressment (th11-s2) in 2006 and screw removal in 2009, the pt underwent a revision surgery due to the rod breaking. The rod broke on high of the screw l4 left.	Breakage Revision
12/09/2009	NKB	TITANIUM POLYAXIAL SCREW BIASED ANGLE 8.5 X	It was reported that, "notified today (b) (6) 2009 via dr of patient with apparent multiaxial head dislodgement of an iliac screw - 8. 5 mm biased angle 100 mm ilios screw, no screw revision surgery planned at this time.	Migration
12/09/2009	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 65 MM	It was reported that "1 day post op while the pt was still in the hospital he thought he heard a pop. They did a cat scan and xray and saw screw failure. They went in to remove the 8. 5 screw that the head had popped off of.	Breakage Revision
12/09/2009	NKB	Blocker	the surgeon sees bilateral loosen blockers and displaced rods. The distributor reported that during the revision surgery, two upper screws were loosened as well.	Migration Revision
12/16/2009	NKB	TITANIUM POLYAXIAL SCREW 8.5 X 60MM	It was reported that "1 day post op, while the patient was still in the hospital, they did a cat scan & x-ray and saw screw failure. They went in to remove the 8. 5 screw that the head had popped off of.	Breakage
12/16/2009	NKB	TITANIUM POLYAXIAL SCREW 8.5 X 60MM	It was reported that "1 day post op, while the patient was still in the hospital, they did a cat scan & x-ray and saw screw failure. They went in to remove the 8. 5 screw that the head had popped off of.	Breakage
12/23/2009	KWQ	TITANIUM BLOCKER	It was reported that "patient came back into office for post-op appt. The surgery was a l2-5 fusion with instrumentation at every level. The blockers have popped off on the bottom left screw and top right screw	Migration
12/23/2009	KWP	TITANIUM BLOCKER	It was reported that "patient came back into office for post-op appt. The surgery was a l2-5 fusion with instrumentation at every level. The blockers have popped off on the bottom left screw and top right screw	Migration
12/23/2009	NKB	LP POLYAXIAL SCREW 6.5 X 45MM	Eight months later, the patient underwent a revision surgery, extension of the arthrodesis up to l4 (l4/s1 to the left and l4/l5/s1 to the right) was performed. The head of the broken screw was removed but not thread,	Breakage Revision
12/23/2009	NKB	ROD DIA. 6 X 110	Distributor has informed that they have received this product broken some time after to be implanted	Breakage
12/23/2009	NKB	ROD DIA. 6 X 480	It was reported via the sales rep that a revision surgery has been planned to extract 2 broken screw xia and a broken	Breakage Revision

Date Received	Product Code	Device	Description	Type of Event
			stem.	
12/23/2009	NKB	LP MONOAXIAL SCREW 5.5 X 40MM	It was reported via the sales rep that a revision surgery had been planned to extract 2 broken screw xia and a broken stem.	Breakage Revision
01/11/2010	NKB	LP POLYAXIAL SCREW 6.5 X 40MM	One week later, it was found from the x-ray that the left cage was backed out also the screws at right l5 and right s were not placed correctly. Two days later, the revision surgery was performed	Migration Revision
01/11/2010	KWP	LP POLYAXIAL SCREW 6.5 X 40MM	Six days later, it was found from the x-ray that the left cage was backed out also the screws at right l5 and right s were not placed correctly. Two days later, the revision surgery was performed.	Migration Revision
01/21/2010	NKB	LP POLYAXIAL SCREW 6.5 X 30MM	At the end of last year (2009), it was found through the f/u x-ray check that the screw at left l5 fractured. In 2010, the pt had another surgery just to remove all the implants except for the tip of the fractured screw remained in left l5	Breakage Revision
01/21/2010	KWP	LP POLYAXIAL SCREW 5.5 X 40 MM	At the end of last year (2009), it was found through the f/u x-ray check that the screw at left l5 fractured. In 2010, the pt had another surgery just to remove all the implants except for the tip of the fractured screw remained in left l5	Breakage Revision
01/21/2010	NKB	LP MONOAXIAL SCREW 6.5 X 40MM	At the end of last year (2009), it was found through the f/u x-ray check that the screw at left l5 fractured. In 2010, the pt had another surgery just to remove all the implants except for the tip of the fractured screw remained in left l5	Breakage Revision
02/01/2010	NKB	LP POLYAXIAL SCREW 6.5 X 40MM	It was reported that "revision, fixed l2-l5 multi level pseudoarthrosis 2 7. 5 x 40 screws and 2 8. 5 x 40 screws put in. ".	Unknown
02/05/2010	NKB	ROD DIA. 6 X 200	During the surgery which was in order to extract the implants (not revision) after 7 years from the primary surgery, it was found that the rod was fractured at just above l4 when the wound was opened.	Breakage
02/16/2010	NKB	LP POLYAXIAL SCREW 7.5 X 50MM	The customer, the hospital (b) (6) reported via ages pharmmed/basg on a rod breakage and a screw breakage approximately 4 years post scoliosis raising surgery with the stabilizing system xia for spine surgeries	Breakage
02/16/2010	NKB	ROD DIA. 6 X 480	The customer, the hospital (b) (6) reported via ages pharmmed/basg on a rod breakage and a screw breakage approximately 4 years post scoliosis raising surgery with the stabilizing system xia for spine surgeries	Breakage

Date Received	Product Code	Device	Description	Type of Event
02/16/2010	NKB	VITALIUM ROD 6.0 MM X 600 MM	On (b) (4) 2010, patient underwent revision psf with removal of hardware and reinstrumentation. Exploration of fusion noted a solid posterior lateral fusion mass. No pseudarthrosis was noted. The rods were broken bilaterally at l4-l5.	Breakage Revision
02/18/2010	NKB	TITANIUM 4.5 TA6V LONG ROD DIAM 4.5 X 480	it was found that the both sides of the rods fractured. On (b) (6) 2010, the pt is scheduled to be revised which the titanium alloy rods will be replaced with the vitalium rods and also two transverse connectors will be added	Breakage Revision
02/18/2010	KWP	TITANIUM POLYAXIAL SCREW DIA 7.5 X 50 MM	It was reported that, "doctor delivered separation of screw head from screw shaft during xray review. ".	Breakage
02/18/2010	NKB	ROD DIA. 6 X 480	It was further reported that on (b) (6) 2010 a revision surgery had to take place as the implant xia ii had broken	Breakage Revision
03/02/2010	NKB	LP POLYAXIAL SCREW 6.5 X 45MM	The surgeon mentioned that he stated during the revision surgery that the screw head of the xia polyaxial screw has come loose from the screw shaft.	Breakage Revision
03/02/2010	KWP	LP POLYAXIAL SCREW 6.5 X 45MM	"after fusion th12-s1 from the dorsal on (b) (6) 2009 between l5/s1 right a loosing of the screws at sacrum was detected because of a new lumbol ischialgia. During revision surgery, a spiral fracture l5 left was shown as a fortune result.	Migration Revision
03/08/2010	NKB	TITANIUM 4.5 TA6V LONG ROD DIAM 4.5 X 200	On (b) (6) 2009 (exact date unk), the pt heard some cracking sound in his back while riding a roller coaster and visited hospital, then it was found that both rods fractured, however, the bone fusion was obtained. On (b) (6) 2010, the pt was revised which all the small xia implants were removed and another company's implant was used.	Breakage Revision
03/08/2010	KWQ	TITANIUM 4.5 TA6V LONG ROD DIAM 4.5 X 200	On (b) (6) 2009 (exact date unk), the pt heard some cracking sound in his back while riding a roller coaster and visited hospital, then it was found that both rods fractured, however, the bone fusion was obtained. On (b) (6) 2010, the pt was revised which all the small xia implants were removed and another company's implant was used.	Breakage Revision
03/12/2010	NKB	TITANIUM BLOCKER	Post op a cap screw on the left l1 screw dislodged. Had to revise, going down to l2,4 new rod to rod connectors and a crosslink	Migration Revision
04/05/2010	NKB	LP POLYAXIAL SCREW	male pt underwent a revision surgery due to a broken xia	Breakage

Date Received	Product Code	Device	Description	Type of Event
		5.5 X 55M	polyaxial screw approximately 10 1/2 months after implantation.	Revision
04/15/2010	NKB	ROD DIA. 6 X 480	It was reported that "on f/u visit, x-ray confirmed that rod was broken at l3/4 uni laterally. Tlif was performed at l3-4. Rod was placed in a revision surgery l3-s1.	Breakage Revision
04/15/2010	NKB	VITALIUM ROD 6.0 MM X 600 MM	It was reported that "pt was getting into a car and heard a popping noise. Xrays confirmed vitallium rod to be broken bi-laterally at multiple levels.	Breakage
04/23/2010	KWP	PRECISION SCREW 5.5 X 50MM	It was reported that "xia 3 screw head disassociated from threaded shank of xia 3 screw.	Migration
04/23/2010	KWP	PRECISION SCREW 5.5 X 50MM	It was reported that "xia 3 screw head disassociated from threaded shank of xia 3 screw.	Migration
04/23/2010	KWQ	PRECIESION SCREW 5.5 X 40MM	Both l5 screws broke approx half way down the screw, approx. Where the pedicle meets the vertebral body.	Breakage
04/23/2010	NKB	ROD DIA. 6 X 480	Head surgeon reported to our sales rep, that both rods are broken. April 6, 2010 further information from the surgeon, received: implantation in (b) (6) 2008 in thoracic vertebra 11 - lumbar vertebra 2.	Breakage
04/27/2010	NKB	Blocker	It was reported that "dr tried final tightening & blocker stripped".	Breakage
04/27/2010	KWP	LP MONOAXIAL SCREW 6.5 X 45MM	The distributor (b) (6) reported that in x-ray images, the surgeon finds broken screw. The distributor (b) (6) reported that the surgeon decides to do revision surgery.	Breakage Revision
04/27/2010	NKB	LP MONOAXIAL SCREW 6.5 X 40MM	The patient implanted 2 screws on (b) (6), 2007, and found screws broken on (b) (6), 2009.	Breakage
04/27/2010	NKB	TITANIUM 4.5 VITALIUM ROD 4.5 X 600 MM	It was reported that, "on april 7, 2010 when i was visiting dr in his clinic, he reported to me that a xia 4. 5 vitallium rod had come out of the screw head in one of his patient's, initials (b) (6). He said it popped out, so he removed it and then the other side popped out and now he is not sure if he'll remove all the patient's hardware or not.	Migration Revision
05/07/2010	NKB	TITANIUM 4.5 EXTENDED CONNECTOR LARGE	It was reported that "case was scheduled to distract bilateral xia 4. 5 extended connector large (48135104). As an x-ray was taken when patient entered the room. At that time, it was noted that the left construct had broken at the cepholant end of the extended connector just below the blocker, the right side connector had fractured, but not completely broken. The bilateral connectors were removed and replaced and the construct was lengthened.	Breakage Revision

Date Received	Product Code	Device	Description	Type of Event
05/07/2010	NKB	LP POLYAXIAL SCREW 6.5 X 35MM	It was reported that "patient's sacral screws broke at 12 months post-op. Dr (b) (6) revised this patient on (b) (6) 2010 and put new sacral screws in. ".	Breakage Revision
05/20/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 6.5 X 45 MM	It was reported that "dr (b)(6) informed me that a xia 3 pedicle screw (6. 5 x 45mm) has broken. The case (trauma) was performed on (b)(6)-2009. The broken screw in right l3 was noticed on x-ray taken on (b)(6) 2010. There are no plans currently to remove the broken screw.	Breakage
05/20/2010	NKB	MONOAXIAL SCREW 5.5 X 40MM	As stated "received a voicemail from patient stating that she has a broken xia screw in l5. " initial surgery was on (b)(6), 2008, l4-5 fusion surgery. Patient stated "3 months post-op there was no healing "and" 7 months post-op x-rays showed broken screw in l5".	Breakage
05/28/2010	NKB	Blocker	It was reported that "patient initial surgery on (b) (6) 2010. On follow-up, visit doctor noticed blocker had come off of a screw on x-ray. Pt reported on (b) (6) 2010, a screw and rod replaced.	Migration Revision
05/28/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 45 MM	Post op x-ray showed that one of the screws has moved into spine canal. On (b) (6) approx, the patient was operated. During the surgery, the head of the screw was next to the bar, separated of the screw body.	Breakage Revision
05/28/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 7.0 X 45 MM	It was reported that, "patient was 6 weeks post op l3-s1 fusion with left l5 radiculopathy. Upon review of the ct scan of the lumbar spine, the left l5 pedicle screw was placed laterally. Doctor removed the left l5 screw but when he placed and seated the screwdriver, the tulip head of the screw popped off. We then removed the screw from the pedicle and placed a new xia screw under navigation.	Breakage Revision
05/28/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 45 MM	Two months later approximately, the patient went to hospital because, she has pain and infection. On (b) (6) 2010 approximately, the patient was operated. During this surgery, the surgeon detected that one of the screws has the thread in the pedicle and the head came loose, close to the bar.	Migration Revision
06/03/2010	KWP	TITANIUM POLYAXIAL SCREW DIA 7.5 X 45 MM	The customer reported via our distributer (b) (4) that the screw head popped off post operation. The customer reported that there is an adverse consequence as the patient was in pain and the case had to be revised on Friday	Migration Revision

Date Received	Product Code	Device	Description	Type of Event
07/09/2010	NKB	TITANIUM 4.5 TA6V LONG ROD DIAM 4.5 X 480	On (b)(6), 2010, the pt visited the surgeon and it was found that the rod fractured. The surgeon was planning to perform the revision surgery to replace the fractured rod and elongate the growing rods, but it was found that the anesthesia would not be working well, thus the revision surgery was postponed.	Breakage Revision
07/09/2010	NKB	LP POLYAXIAL SCREW 7.5 X 50MM	It was reported that "patient had adjacent level disease so (b)(6) extended the fusion up to 11. Upon removal of the rod, it was discovered the head was popped off the 7. 5 screw. The screw was located at the sacrum. Screw had to be replaced. ".	Breakage Revision
07/09/2010	NKB	Unknown Screw size	It was reported by our (b)(6) that the customer, (b)(6), claimed that a revision surgery took place after a screw xia had broken.	Breakage Revision
08/13/2010	NKB	TITANIUM 4.5 TA6V LONG ROD DIAM 4.5 X 480	Date unk: it was found that the rods (both sides) fractured at right above th10 screw. On (b)(6), 2010, the revision surgery was performed to replace the rods and added a transverse connector.	Breakage Revision
08/30/2010	NKB	PRECISION SCREW 5.5 X 50MM	During removal, surgeon noted one of the xia 3 tulips had completely popped off screw shaft. The shaft is still intact and he was able to remove with poly-adjustment driver.	Breakage Revision
08/30/2010	KWQ	LP POLYAXIAL SCREW 6.5 X 50MM	the surgeon reported via the sales rep that pt had to have revision surgery to remove 4 xia ii screws due to unk leg and back pain. The surgeon further reported that the revision surgery took place on (b)(6) 2010 for removal of the units. The surgeon further reported that the l4 right polyaxial screws lot a83062 the shaft was broken with approximately 35mm left buried in the pedicle.	Breakage Revision
08/30/2010	NKB	LP POLYAXIAL SCREW 6.5 X 50MM	the surgeon reported via the sales rep that pt had to have revision surgery to remove 4 xia ii screws due to unk leg and back pain. The surgeon further reported that the revision surgery took place on (b)(6) 2010 for removal of the units. The surgeon further reported that the l4 right polyaxial screws lot a83062 the shaft was broken with approximately 35mm left buried in the pedicle.	Breakage Revision
08/30/2010	KWQ	LP POLYAXIAL SCREW 5.5 X 35MM	medical report: in a surgery was verified that the screw ((b)(4) - xia ii screw poliaxia l 5. 5 x 35 mm - lot: 068587) were broken in the half of its extension. The unit was replaced.	Breakage Revision

Date Received	Product Code	Device	Description	Type of Event
08/30/2010	NKB	LP POLYAXIAL SCREW 6.5 X 45MM	medical report: poliaxial screw xia ii - 6. 5x45mm, ref. (b)(4), lot: 068051, was broken in the half of its extension.	Breakage
08/30/2010	KWP	Unspecified Rod	X-rays revealed the stryker rods had broken in her lumbar spine at approximately the level of lumbar-2 and lumbar-3 vertebrae. Patient was scheduled for explantation and had new hardware placed.	Breakage Revision
09/07/2010	NKB	TITANIUM 4.5 TA6V LONG ROD DIAM 4.5 X 480	The surgeon was planning to perform another surgery to replace the rods soon since the extended connector was fully extended but before that surgery, it was found (when found is unk) that one side of the rod fractured (when fractured is unk) underneath the extended connector. On (b)(6), 2010, the pt will be revised to replace the rods.	Breakage Revision
09/07/2010	KWQ	LP MONOAXIAL SCREW 6.5 X 55MM	(b)(6) reports via our sales rep, (b)(4), that the screw broke around 6 month after implantation for monosegmental stabilization of a lumber vertebra v fracture.	Breakage
09/07/2010	KWQ	LP POLYAXIAL SCREW 6.5 X 45MM	It is further reported that the original implantation occurred approx (b)(6) 2008 and 2 screws were inserted at s1 on both the left and right. It is further reported that the revision procedure occurred approximately 6 months later ((b)(6) 2008).	Breakage Revision
09/10/2010	KWP	TITANIUM ROD DIAM 6MM CP TI L 480MM	(b)(6) brought the pt back because both of the rods were broken. He exchanged the rods and crosslinks and blockers but left all the screws in.	Breakage Revision
09/10/2010	NKB	Blocker	It was reported that "l4-s1 revision surgery for pseudo orthrosis - blocker loose - left side. ".	Migration Revision
09/10/2010	NKB	TITANIUM RAD ROD DIAM 6MM L 45MM	The rod at s1 connector (sometime after orig surgery (b)(6)) was loose (came loose). It disengaged from connector and caused pt pain. Surgeon had to re-operate to re-attach rod to screw via connector.	Migration Revision
09/17/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 6.5 X 40 MM	It was reported that "revision due to fractured rod - set screws were removed along entire construct. Rod was then lifted for removal and as rod pulled up, tulip screw head came with it. Shank remained in pt.	Breakage Revision
09/17/2010	NKB	TITANIUM ROD DIAM 6MM CP TI L 30MM	Moreover she informs stryker (b)(4) of the failure of a not well specified stryker device as she called "rod" (i suppose that the device in subject is a plate or a rod) and that she will undergo a new surgical procedure in (b)(6) 2010.	Breakage Revision
09/17/2010	NKB	LP POLYAXIAL SCREW 7.5 X 45MM	The distributor (b)(4) in (b)(4) reported that after 90 days of a posterior lumbar fusion due to spine fracture, the	Breakage Revision

Date Received	Product Code	Device	Description	Type of Event
			doctor wanted to remove the jacket. The distributor reported that when the doctor saw the control x-ray, he found out that the head of the polyaxial screws became detached.	
10/01/2010	NKB	TITANIUM 4.5 TA6V LONG ROD DIAM 4.5 X 200	(date unknown), it was found that both sides of the rods fractured at l1/l2. On (b)(6) 2010, the patient was revised	Breakage Revision
10/01/2010	NKB	LP POLYAXIAL SCREW 6.5 X 40MM	It was reported that "post surgery evaluation x-ray, noticed both s1 screws were broken.	Breakage
10/01/2010	NKB	LP POLYAXIAL SCREW 6.5 X 35MM	It was reported that "post surgery evaluation x-ray, noticed both s1 screws were broken.	Breakage
10/01/2010	NKB	LP POLYAXIAL SCREW 6.5 X 45MM	Head surgeon dr. (b)(6) reports via our sales rep, (b)(4), that the head loosened from the screw. He further reports that the screw was implanted end of 2008.	Migration
10/11/2010	KWP	ROD DIA. 6 X 480	The distributor (b)(4) reported that a broken rod was reported by the doctor in a previous surgery done on (b)(6) 2010. Distributor reported that five months later, the pt complained from back pain and the rod was found broken.	Breakage
10/22/2010	KWQ	TITANIUM 4.5 POLYAXIAL SCREW DIAM 4.5 X 35	the surgeon confirmed that the screws at l3 were backed out. (it appears the screws at l4 as well backed out but difficult to confirm by x-ray.) the surgeon called the sales rep. And informed him that the patient who had the primary surgery on (b)(6) using xia for l2 fracture will have revision surgery due to the screw's back-out.	Migration Revision
10/22/2010	KWP	TITANIUM RAD ROD DIAM 6MM L 40MM	It was reported that, "the patient was discharged from the hospital on (b)(6) and sometime between then and (b)(6)2010 the patient reported a "pop" and was in severe pain. X-rays were taken on (b)(6)2010 and the rod appears to be displaced from the tulip head of the screw.	Migration
10/28/2010	NKB	TITANIUM POLYAXIAL SCREW DIA 7.5 X 60 MM	It was reported that "patient went in for post op films surgeon noticed that the head was popped off the screw months post op. Patient was brought back in for surgery today and the screw, blockers, & amp; rod was removed.	Breakage Revision
10/28/2010	NKB	ROD DIA 6 X 400	He found one side rod was broken in (b)(6), 2010 and two sides rods were broken in (b)(6), 2010. Now the doctor wants to do the revision operation.	Breakage Revision
11/05/2010	NKB	LP POLYAXIAL SCREW 6.5 X 45MM	It was reported that "pt had adjacent level disease, not related to broken screw, and was brought back to fuse the level above prior fusion. Upper portion of broken screw	Breakage Revision

Date Received	Product Code	Device	Description	Type of Event
			was removed and lower portion was left in (l4). "	
11/05/2010	NKB	LP POLYAXIAL SCREW 5.5. X 40 MM	During this surgery, it was found that the tip of the screws at l5 (both sides) were broken about 5-10 mm.	Breakage Revision
12/02/2010	KWQ	Blocker	On (b)(6) 2010, the x-ray was taken for follow up showed that the blocker at left l4 was loosened together with the rod.	Migration
12/02/2010	NKB	Blocker	Upon cleaning out the wound, the resident and surgeon noticed 4 xia 3 blocker missing from right side of construct. The blockers were later retrieved from muscles of patient.	Migration
12/02/2010	NKB	ROD DIA. 6 X 400	The patient got the operation because of scoliosis in (b)(6) 2008. He found one side rod was broken in (b)(6) 2010. The doctor has done the revision operation and removed the broken rod.	Breakage Revision
12/09/2010	NKB	Titanium Blocker	It was reported "dr. Wanted an audible torque wrench ordered. He performed the primary surgery in (b)(6) 2010 and used a non-stryker torque wrench to implant the xia 3 system. One month later, the blocker was found to be floating and a revision surgery was performed.	Migration Revision
12/17/2010	NKB	TITANIUM 4.5 EXTENDED CONNECTOR SMALL	Date unknown: the extended connector fractured. On (b)(6) 2010, the surgeon confirmed through the x-rays that the extended connector fractured. The revision surgery is planned;	Breakage Revision
12/17/2010	NKB	MONOAXIAL SCREW 6.5 X 50MM	Nail Broken	Breakage
01/10/2011	NKB	XIA 3 TITANIUM BLOCKER	It was reported that "bilateral distal blockers loosened post op and 6.0 vitallium rod was sliding through xia 3 pedicle screws".	Loosening
01/10/2011	NKB	XIA LP MONOAXIAL SCREW 6.5 X 45MM	After the first surgery, the blockers were loose and then after one of the screws broke; due to this incident the pt went for a second surgery for changing the loose blockers and third surgery for changing the broken screw.	Breakage Revision
01/10/2011	NKB	XIA 3 TITANIUM BLOCKER	Bilateral distal blockers loosened post op and 6.0 vitallium rod was sliding through xia 3 pedicle screws.	Loosening
01/10/2011	NKB	XIA BLOCKER	Blocker at right L5 loosened then disassembled; blocker at T9 disassembled and found at posterior L1 within.	Loosening
01/14/2011	NKB	XIA	Rod broke; revision performed	Breakage Revision
01/14/2011	NKB	XIA 3 TIGE D OST	Radidium arthrodesis osteosynthesis stem broke; stem	Breakage

Date Received	Product Code	Device	Description	Type of Event
		OSYNTHESE	means rod	Revision
01/14/2011	NKB	XIA 3 (NOT CONFIRMED)	Patient complaining of allergic reaction to implants	Injury
01/19/2011	NKB	XIA LP POLYAXIAL SCREW 6.5 X 45MM	Bilateral pedicle screw fracture at S1 using xia 2 6.5x45mm polyaxial screws; 11 ½ months post surgery	Breakage
01/19/2011	NKB	XIA 3 TITANIUM BLOCKER	Locking cap came off construct; patient returned to operating room and screw was replaced along with a new locking cap.	Malfunction Revision
01/19/2011	NKB	XIA LP POLYAXIAL SCREW 6.5 X 45MM	Bilateral pedicle screw fracture at S1 using xia 2 6.5x45mm polyaxial screws; 11 ½ months from surgery	Breakage
01/28/2011	NKB	XIA II VITALLIUM ROD 6.0MM X 600MM	Rod breakage at L3 and advancing spondylolisthesis.	Breakage Revision
01/28/2011	NKB	XIA LP MONAXIAL SCREW 6.5X40MM	After about 5 months, the patient felt achy, and back to hospital, x-ray shows screw broken.	Breakage
01/28/2011	NKB	XIA LP MONAXIAL SCREW 6.5X40MM	After about 5 months, the patient felt achy, and back to hospital, x-ray shows screw broken.	Breakage
02/03/2011	NKB	XIA ROD DIA 6 X 400	Breakage of the connection rod between the left peduncolar screw L5-S1.	Breakage Revision
02/11/2011	NKB	XIA ROD DIA 6 X 400	Traumatic fracture of L1; post surgery patient showed post-traumatic kyphosis with loosening of the implants	Loosening Revision
02/11/2011	NKB	XIA ROD DIA 6 X 400	When the doctor took the screw out, he found nearly parenchyma became black and smell metal and odorous.	Injury Revision
02/15/2011	NKB	XIA TITANIUM 4.5 EXTENDED CONNECTOR SMALL	Connector was broken at site which was not inserted with rod	Breakage Revision
03/03/2011	NKB	XIA 3 TITANIUM BLOCKER	When removing blocker, the surgeon noticed a crack in the blocker.	Breakage Revision
03/03/2011	NKB	XIA TITANIUM 4.5 TA6V ROD DIAM 4.5 X 30	Breakage of rod	Breakage Revision
03/11/2011	NKB	XIA LP POLYAXIAL SCREW 5.5 X 40MM	L2 screw broke at site of intermediate position of the shaft of the screw	Breakage
03/17/2011	NKB	XIA TITANIUM 4.5 TA6V LONG ROD DIAM 4.5X480	Rod broke; rod frequently practiced horse jumping	Breakage
03/31/2011	NKB	XIA TITANIUM 4.5 EXTENDED CONNECTOR SMALL	Xia 4.5 extended connector broken on post-op xray	Breakage Revision
04/05/2011	NKB	XIA II VITALLIUM ROD 6.0 X 600MM	Breakage of implant	Breakage Revision
04/20/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW 6.5 X	L4 screw was misplaced out of the pedicle and S1 polyaxial screw head was detached	Migration Revision

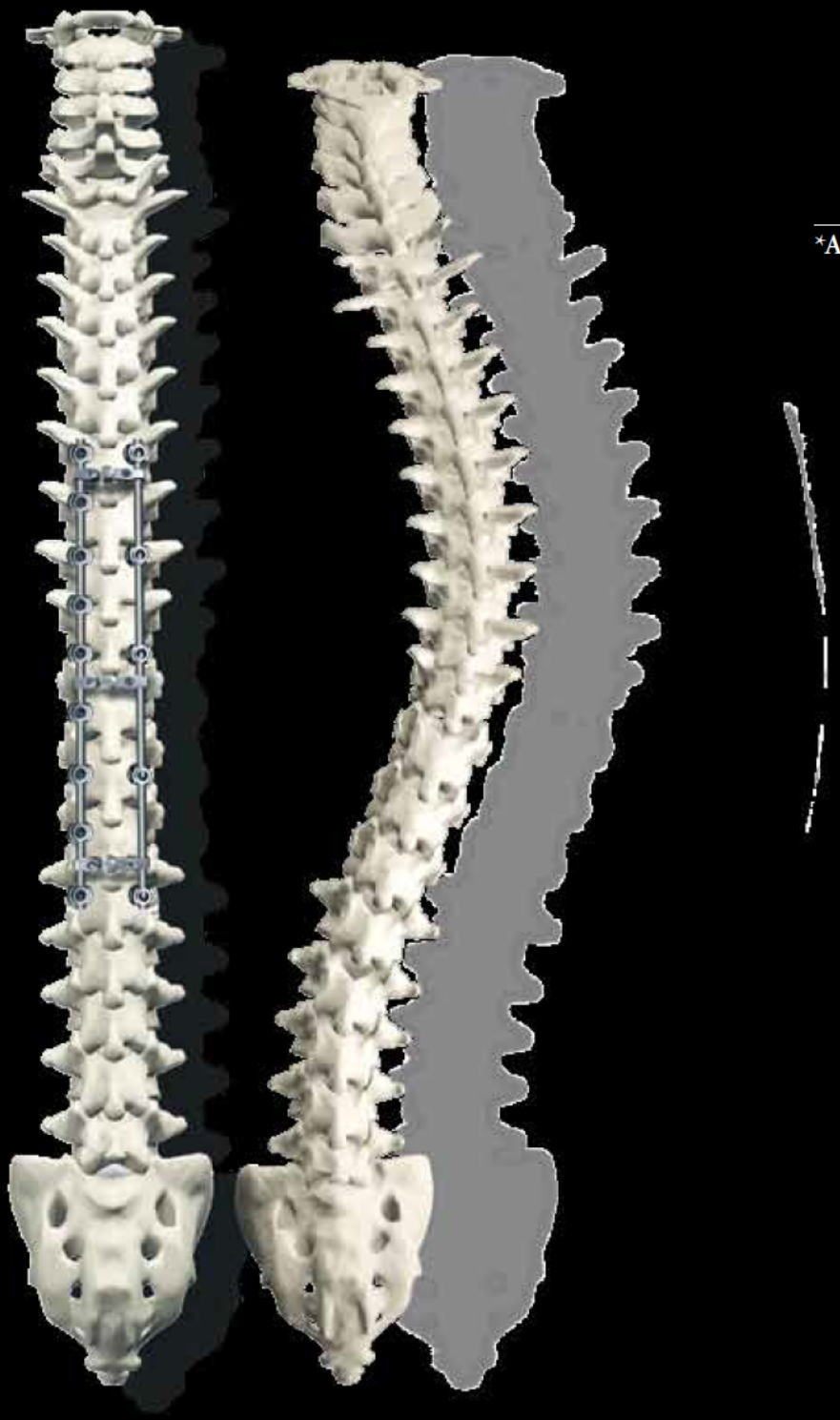
Date Received	Product Code	Device	Description	Type of Event
		50MM		
04/20/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW 8.5 X 90MM	Right iliac screw head was popped off	Malfunction Revision
04/20/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW 7.5 X 45MM	L4 screw was misplaced out of the pedicle and S1 polyaxial screw head was detached	Malfunction Revision
04/22/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW 7.5 X 50MM	Heads loosened from the screws	Malfunction Revision
04/22/2011	MNH	XIA TITANIUM 4.5 POLYAXIAL SCREW	Screw head loosened and rod loosened from another screw	Malfunction Revision
04/29/2011	NKB	XIA 3 TITANIUM POLYAXIAL SCREW 7.5 X 55MM	Heads loosened from the screws	Malfunction Revision
04/29/2011	NKB	XIA 3 TITANIUM ROD DIAM 6MM ALLOY L 480MM	Broken rods and screw one year post-op	Breakage Revision
05/04/2011	NKB	XIA 3 TITANIUM RAD ROD DIAM 6MM L 45MM	Rad rod was slided from the head of L4 left monoaxial screw head.	Migration
05/11/2011	KWP	XIA BLOCKER	Loosening of the system	Loosening Revision
05/18/2011	NKB	XIA LP POLYAXIAL SCREW 6.5 X 50MM	Screws broken	Breakage
05/18/2011	NKB	XIA LP POLYAXIAL SCREW 6.5 X 50MM	Screws broken	Breakage
06/02/2011	KWQ	XIA ROD DIA 6 X 480	Cage sank and xia rod was broken	Breakage Revision
06/14/2011	NKB	XIA 3	Rod fractured	Breakage Revision
06/23/2011	NKB	XIA TITANIUM 4.5 VITALLIUM ROD 4.5 X 600MM	Broken rod	Breakage
06/23/2011	NKB	XIA TITANIUM 4.5 BLOCKER	Blockers of right side of L4 and L5 were loosened so rod came off	Loosening Revision
07/05/2011	NKB	XIA II VITALLIUM ROD 6.0 X 600MM	Rod broke	Breakage Revision
08/03/2011	KWQ	XIA ROD DIA 6 X 480	Rods were broken	Breakage Revision

Date Received	Product Code	Device	Description	Type of Event
08/04/2011	MNI	XIA LP POLYAXIAL SCREW 6.5 X 45MM	S1 screws broken	Breakage Revision
08/04/2011	MNI	XIA TITANIUM 4.5 EXTENDED CONNECTOR SMALL IMPLANT	Connector broke	Breakage Revision

stryker®

Spine

Xia® 3 Spinal System
AIS* Technique



*Adolescent Idiopathic Scoliosis

Introduction

Introduction

Built on the successful foundation of Xia®'s history, Stryker® Spine is proud to introduce Xia® 3; a pedicle screw system designed to deliver **"Simplicity with Options."**

Xia® 3 is a comprehensive system that is designed to treat modern deformity, degenerative, and trauma applications. Xia® 3 is based upon the same design rationale and philosophy that has made Xia® one of the leading spinal systems in the market.

- Ease of Use
- Comprehensive System
- Proven Core Technology
- Successful Clinical History

Acknowledgements

Stryker® Spine would like to extend their thanks to the following surgeons for their dedication and contributions:

- Tushar Patel, MD
- Alex Vaccaro, MD

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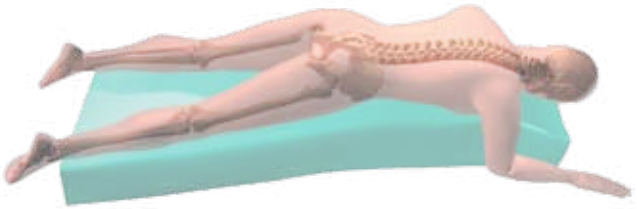
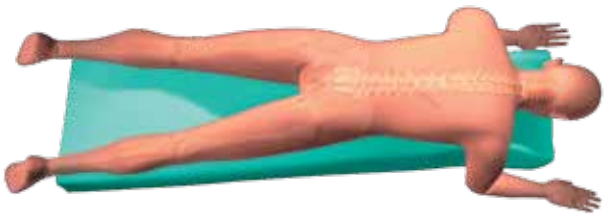
Operative Technique

A.Patient Positioning





Patient Positioning

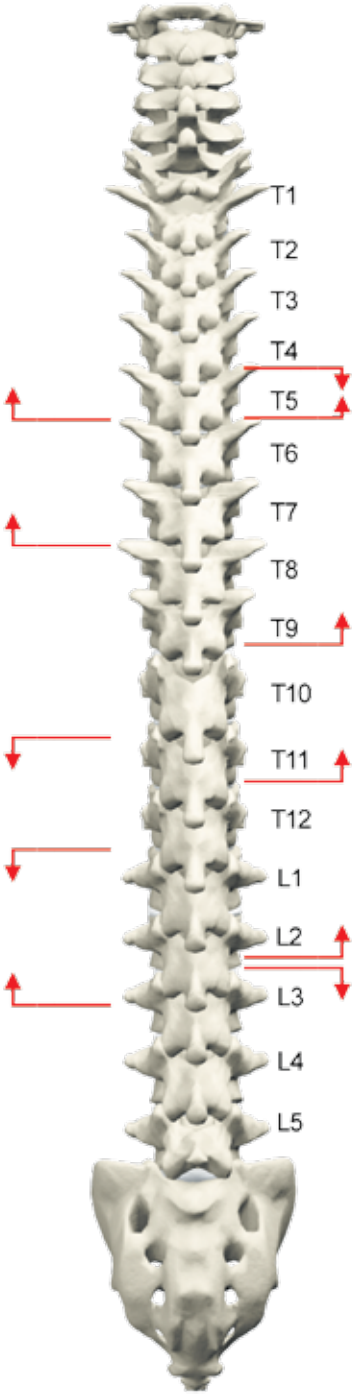
Diagnosis of deformity is based upon patient history, physical findings and preoperative radiographic assessment.

The patient is usually positioned prone on an appropriate spinal table. Care is taken to pad all bony prominences. The abdomen should not be compressed to facilitate venous drainage.

Surgical levels may be verified clinically or radiographically. To ensure adequate exposure the incision is made to extend just beyond the length of the intended fusion.

Presurgical planning defines the most appropriate implants as well the optimal location of the implants to be inserted.

A.Hook Design

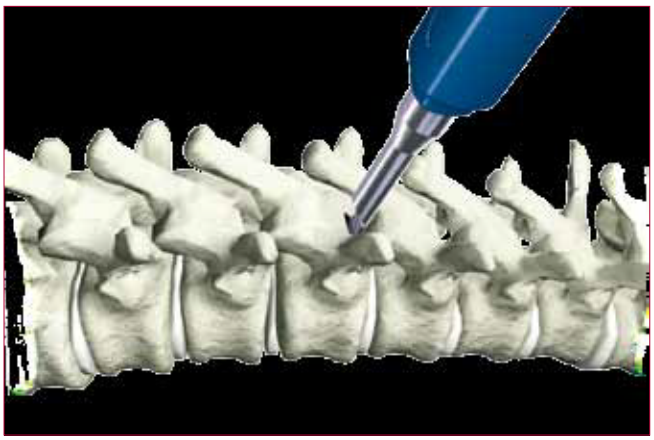


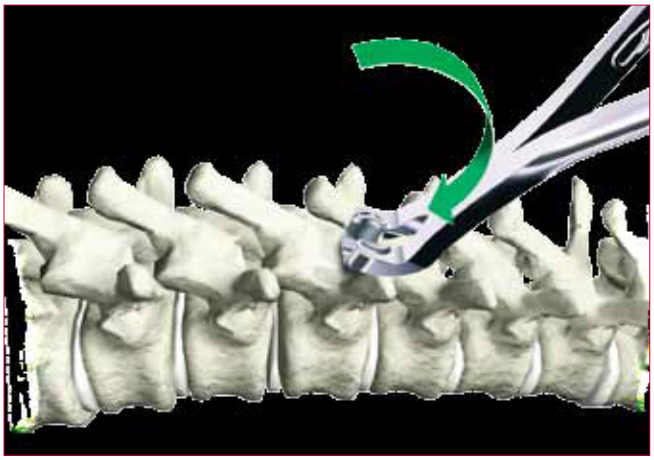
Screw Preparation and Insertion

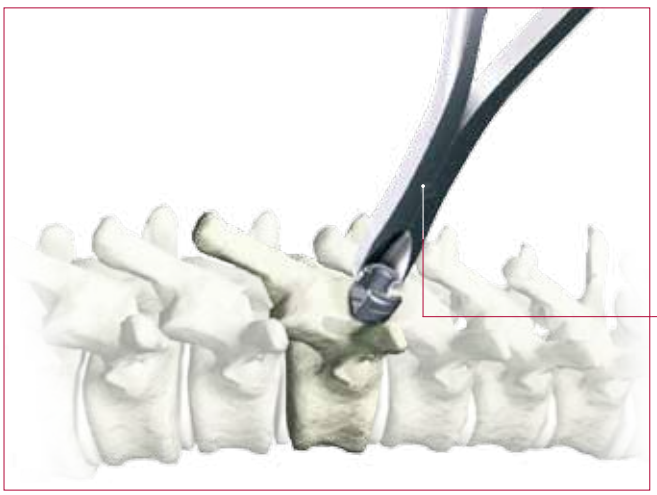
Once appropriate dissection has been achieved and anatomic levels are confirmed by X-Ray and anatomic landmarks, the hook sites are identified and prepared. The appropriate hook is chosen according to a number of factors:
Patient anatomy, bone quality, correction technique and the forces applied. The surgeon has several options in choosing a hook pertaining to the blade width, throat length, body extension and hook shape. Hooks consist of three blade types. They are wide blade, narrow blade and bifid pedicle blade. The surgeon should choose the hooks that will allow the most successful outcome of the procedure.

Offset hooks are available in both wide and narrow blade widths. They may be inserted in thoracic or lumbar segments. Offset connectors can be helpful in lining up hook connections.

B.Hook Insertion







Supralaminar Hooks

Supralaminar hooks are directed caudally. The blade of the hook sits within the epidural space. A narrow blade hook with a throat size that does not allow pistoning on the lamina is recommended. The ligamentum flavum is dissected from the lamina and a small laminatomy is made. The Lamina Preparer may be used to estimate the appropriate hook size. Care must be utilized in introducing hooks and instruments into the open spinal canal. The Lamina Preparer comes in two blade widths to accurately match the patient's anatomy.

The appropriate hook is determined by the patient's anatomy. Once the site is confirmed to be well prepared, the selected lamina hook is loaded onto a Hook Forceps.

Two options are possible for preparing the site and to insert the hook:
Option 1: A horizontal window is created by excising the ligamentum flavum combined with a limited osteotomy of the edge of the lamina. The window is prepared large enough to accommodate the blade of the hook to be inserted. The blade is then turned down 90° and seated on the lamina.
This technique will assist in stabilization of the hook, which can help facilitate rod introduction.

Option 2: A more squared window is managed by opening the ligamentum flavum in conjunction with a limited laminotomy.
A Laminar Preparer may be used with great care to dissect the ligamentum flavum.
Once the site is confirmed to be well prepared, the selected lamina hook is loaded on either the straight or Lateral Hook Forceps. The hook is inserted in a downward rotational movement so that the tip of the blade hugs the anterior surface of the lamina at all times. A gentle burring of the lamina is sometimes necessary to ease the access to the canal.

B.Hook Insertion

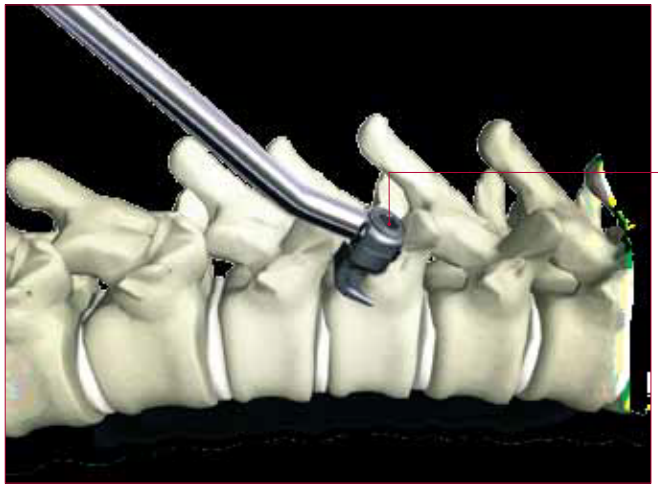
Infralaminar Hooks

Infralaminar hooks are directed cephalad. The Lamina Preparer is used to dissect the ligamentum flavum from the inferior lamina and prepare a path for the hook. The blade will seat between the anterior surface of the lamina and the ligamentum flavum and not interdural.

A wide blade hook may be selected if the patient's anatomy permits. This hook loaded onto a Hook Forceps and inserted into the path created by the Lamina Preparer.

The Hook Pusher may be used in conjunction with the Hook Forceps to facilitate hook seating against the inferior lamina.

B.Hook Insertion



Pedicle Hooks

The pedicle hook is always directed cephalad and is recommended for T10 and above. A limited osteotomy (facetectomy) at the base of the facet opens the facet joint and exposes the underlying articular cartilage of the superior facet of the caudal vertebra. The Pedicle Hook Preparer is inserted into the facet joint with great care, aiming slightly lateral of the midline to identify the pedicle. Once the pedicle is localized, the bifid on the Pedicle Preparer can be utilized to insure that the fork is well applied onto the pedicle. The preparer, properly engaged on the pedicle, can be used to confirm a reliable fit on the vertebra by mobilizing the vertebra laterally. A prominent element indicates the appropriate location of the final osteotomy so that the hook will evenly seat onto the pedicle and on the facet.

Once the pedicle hook site is clearly identified, the pedicle hook is inserted.

The hook is firmly gripped by the Hook Forceps. The Hook Impactor is inserted into the hook. The hook is slid into the desired position, and then gently tamped against the pedicle. The hook is then moved side to side to ensure the hook is around the pedicle.

This combination provides an optimal level of force and guidance to safely insert the hook.

Alternate method: The hook is temporarily secured to the Hook Impactor by tightening a Closure Screw. The screw may be removed once the hook has been placed

Note: To facilitate the introduction of the pedicle hook it may be necessary to remove the prominence of the caudal lamina below the hook.

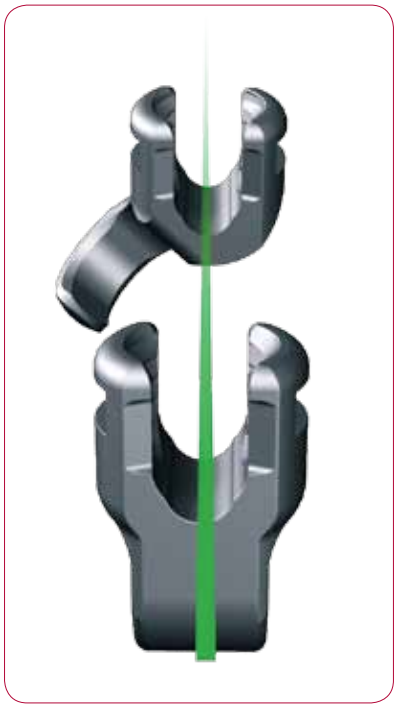
B.Hook Insertion

Based on the patient's anatomy, a Xia® 3 Transverse Process Hook or a standard lamina hook may be selected. The hook is loaded onto a Hook Forceps. The hook is then inserted into the space created with the Lamina Preparer.

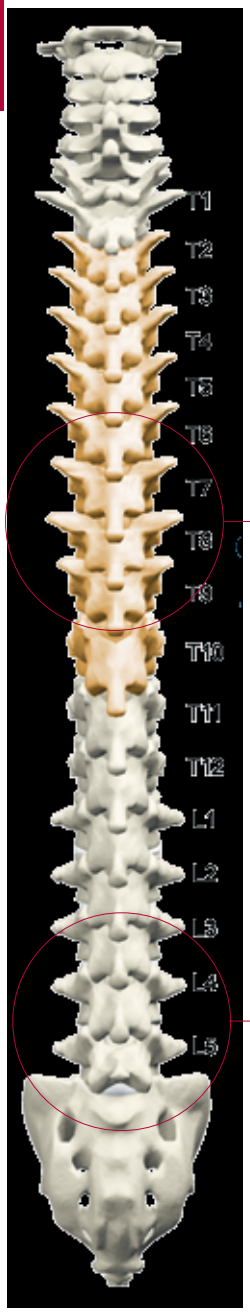
The transverse process hook may be directed cephalad or caudal.

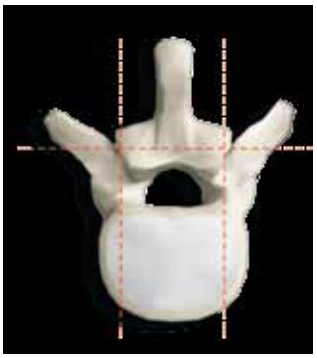
Caudally directed transverse process hooks are often the top portion of the transverse pedicle claw configuration. The Xia® 3 Transverse Process Hook is designed to closely line up with the inferior pedicle hook to help avial angulation and allow easy introduction of the Closure Screw.

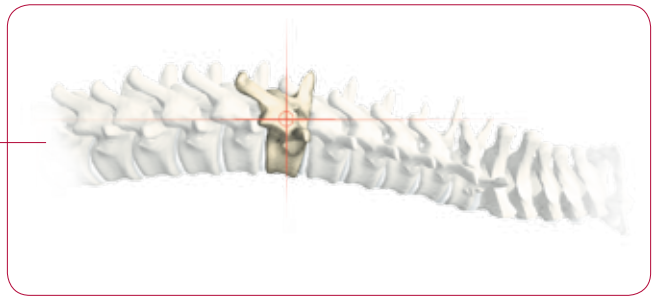
Again, the Lamina Hook Preparer can be used to dissect around the superior and anterior surface of the transverse process to create room between the anterior aspect of the transverse process and the rib head.

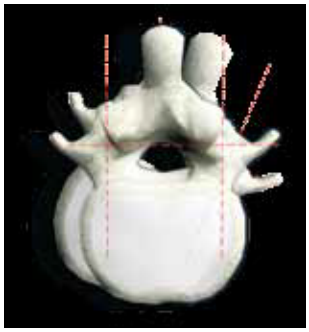


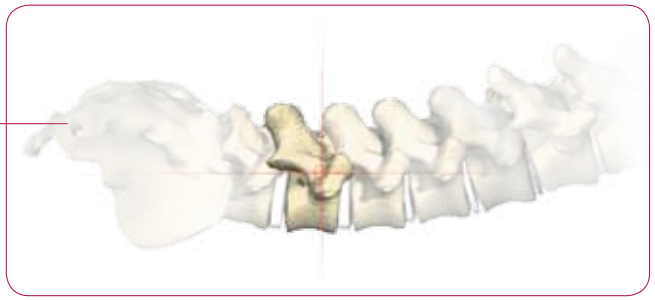
C.Screw Insertion











Thoracic Pedicle Entry:

Landmarks usually lie at the intersection of a vertical line through the middle of the convex part of each articular process and a horizontal line drawn across the middle to upper third of the base of the transverse process. This intersection is usually 2mm below the edge of the articular cartilage and just level with the small horizontal crest of bone. The use of CT scans may be used to verify any anatomic variations.

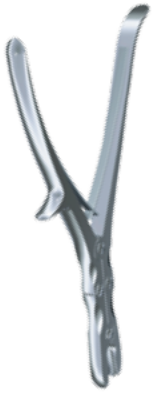
Note:
A pedicle, and the drilling direction, is usually globally perpendicular to the posterior plane of the vertebra (plane of the transverse process).

This is an important point to consider, especially when instrumenting the apical vertebrae, which are usually the most rotated ones.

Lumbar Pedicle Entry:

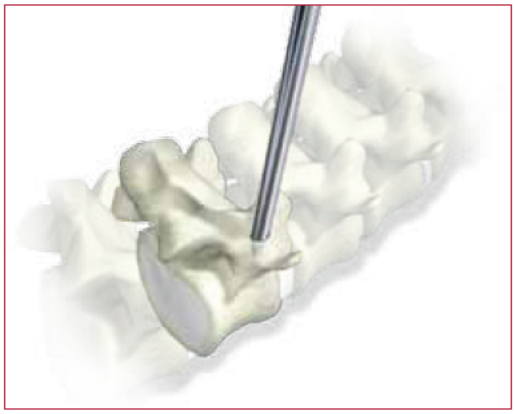
Landmarks are at the intersection of a vertical line through the facet joint space and a horizontal line through the middle of the base of the transverse process.
These two lines intersect at a small sharp crest of cortical bone which can be a reliable landmark since it is extra-articular and not affected by osteoarthritic deformities.

C.Screw Insertion



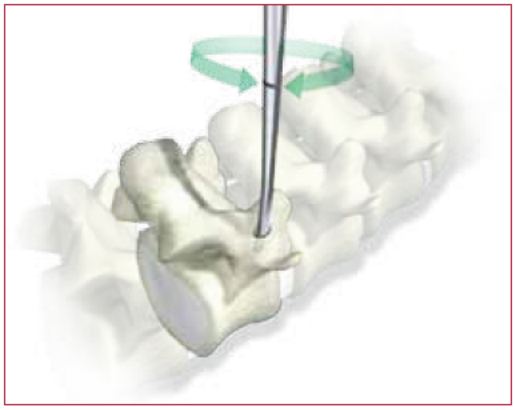
Screw Preparation and Insertion

The small cortical crest is removed with a rongeur or power burr to expose the underlying cancellous bone.

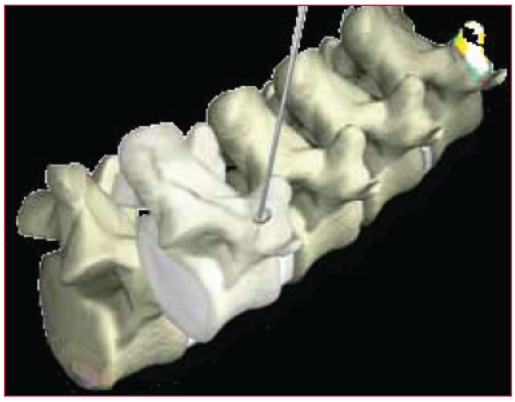


Pedicle entry identification

The entry point is prepared with the Square Awl, which should be driven in no more than 10mm.



A pathway is then opened up with the Blunt Probe. The probe should contact bone at all times. The correct rotational insertion of the instrument will allow the probe to follow a path of least resistance without violating the pedicle walls. In the event that resistance is felt, the entry point and trajectory should be re-evaluated. The Pedicle Probe is calibrated and laser etched with 5mm intervals to help indicate the depth in which the probe has been inserted as well as to help determine proper screw length.



The prepared pathway is checked with the Probe Feeler or the Tapered Ball Probe to verify that all walls of the pedicle have not been violated and that cancellous bone is felt at the distal end of the path. The Probe Feeler is calibrated in the same manner as the Pedicle Probe.

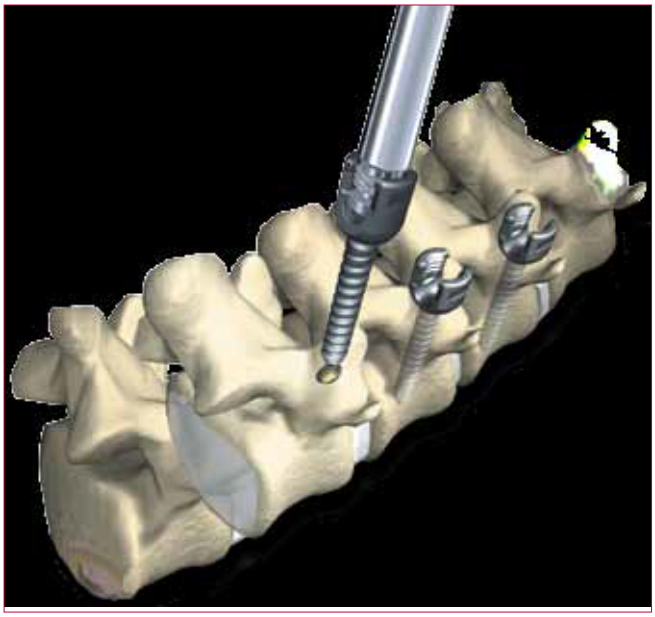
C.Screw Insertion

Screw Preparation and Insertion

If the bone is too hard, the appropriate tap may be used to prepare the pedicle screw canal. The tap sizes are 4.5mm/5.5mm and 6.5mm/7.5mm. Modular 4.0, 4.5, 5.0, 5.5, 6.5, and 7.5 taps and cannulated 5.5 and 6.5mm taps are available.

The taps are calibrated in the same manner as the probe and feeler.

Both Polyaxial and Monoaxial Screwdrivers provide a very rigid connection between the polyaxial and monoaxial screws and the screwdriver.



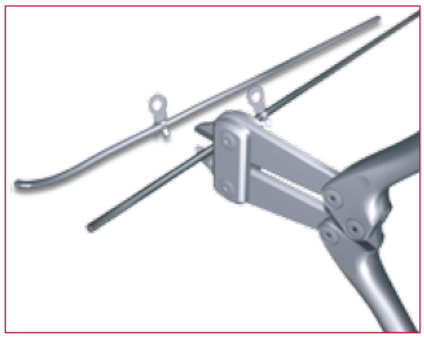
With the pedicle pathways prepared and proper screw length and diameter determined, the screw is prepared for insertion.

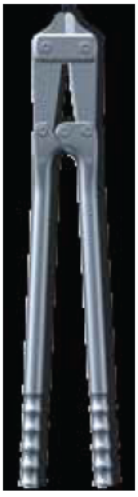
Note: The polyaxial screws may lock upon insertion. Use the Inserter to unlock the heads before introducing the rod.

D.Rod Contouring

Once all screws are inserted, the appropriate length rod is cut according to the required construction. The Xia® 3 Spinal System Template is utilized to accurately determine the appropriate rod length.

Use the appropriate pre-cut rods or cut a longer rod with the Cutting Pliers. A Table top rod cutter is also available. Pre-bent rods are also offered with the Xia® 3 System.



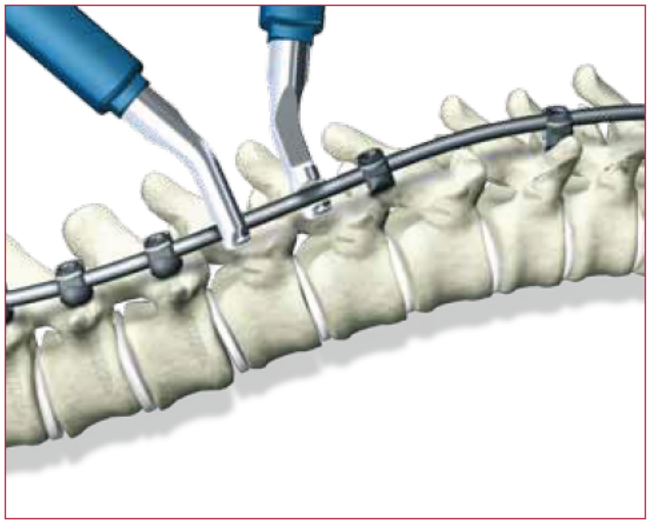


Note:
The Vitallium Rods and Stainless Steel implants should not be mixed in patients, otherwise corrosion may occur resulting in decreased mechanical resistance.

Note:
It is recommended that the Xia® 3 Table Top Rod Cutter is used to cut the Vitallium Rod.

Note:
The 600mm Vitallium Rod is for sale in the USA only.

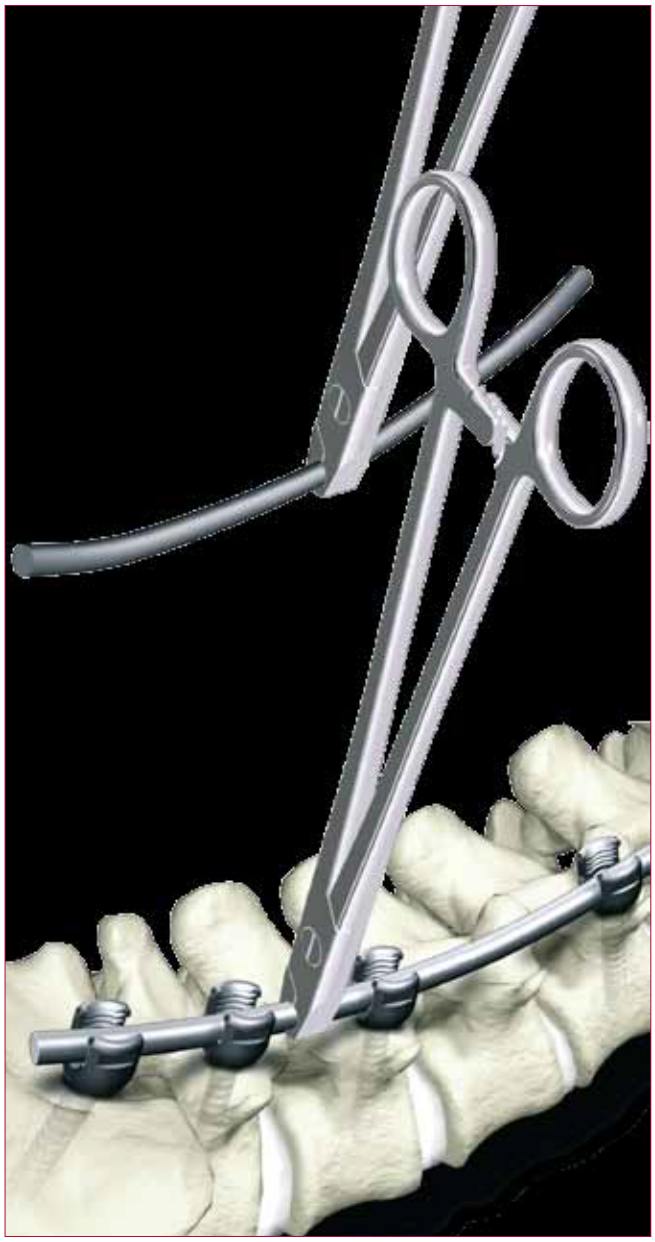
The rod bending is performed to fit the desired spinal contours.



Bending can be performed with the Xia® 3 French Benders. To contour the rod, a series of small incremental adjustments will bend the rod gradually and ensure even stress distribution on the rod.

The Bending Irons can be used for *in-situ* bending to achieve final incremental correction maneuvers. Care should be taken to not make extreme bends, so as to avoid stress concentration and notching of the rod.

D.Rod Contouring



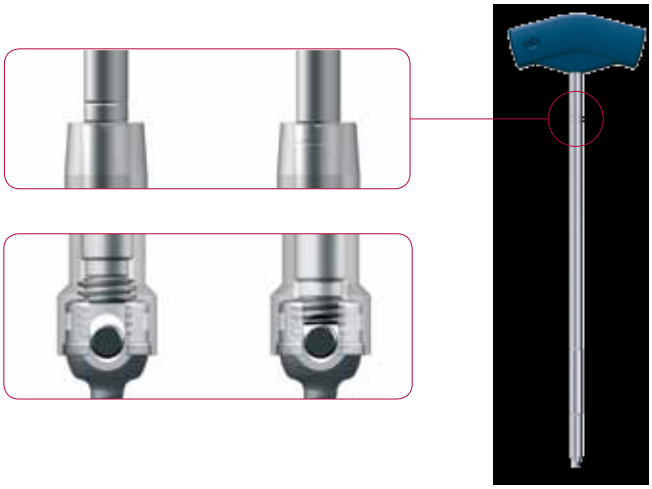
Rod Insertion

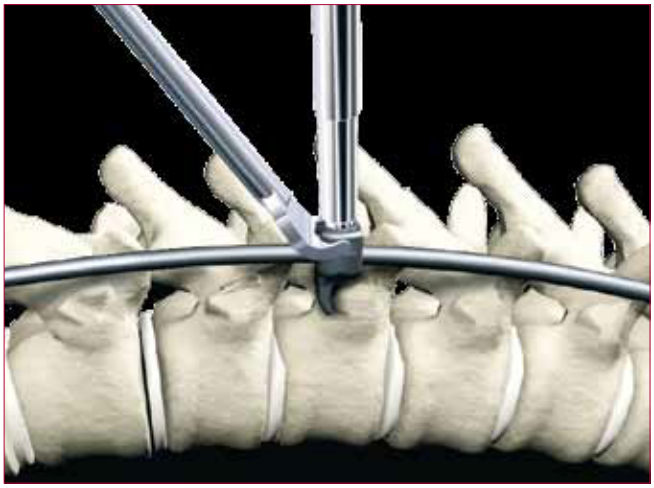
Once the rod is bent to the desired contour, the Rod Insertion Forceps can be used to facilitate the rod into the grooves of the implant. This can be done in any sequence at the discretion of the surgeon. It can be helpful to begin the closure at the easiest place. This may help facilitate the seating of the rod in adjacent hooks.

Titanium Stainless Steel

Note:
The Titanium Closure Screw is laser etched to clearly differentiate it from the Stainless Steel Closure Screw. It is important not to mix Stainless Steel and Titanium metals

E.Rod Linkage





Inserter and Universal Tightener

The Xia® 3 System offers three options for linking the rod to the spine:

Option 1:

The Inserter can help align the Universal Tightener, 5mm and the Closure Screw with the implant.

The two engraved lines on the Universal Tightener denote the following:

- When the lower line is aligned with the top of the Inserter, the Closure Screw is at the top of the implant.

- When the upper line is aligned with the top of the Inserter, the Closure Screw is fully introduced into the implant.

Note:
Do not perform final tightening of the Closure Screw with the Inserter in place, or it will not be possible to remove the Inserter.

Option 2:

Rod Fork and Universal Tightener

The Rod Fork is used when the rod is slightly proud with respect to the seat of the implant.

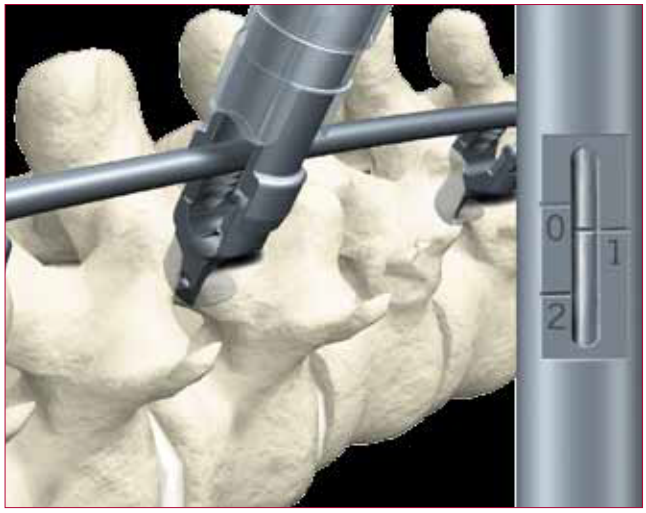
The Rod fork easily slides into the lateral grooves on the implant head and is rotated backwards. This levers the rod into the head of the implant. The Closure Screw is inserted with the Universal Tightener when the rod is fully seated into the head of the implant.

E.Rod Linkage

Using the Persuader

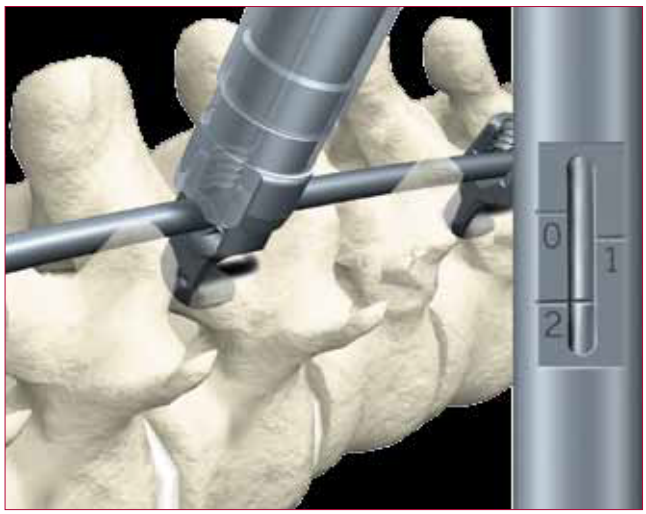
Option 3:

The Persuader is used when additional force is needed to bring the rod to the implant.



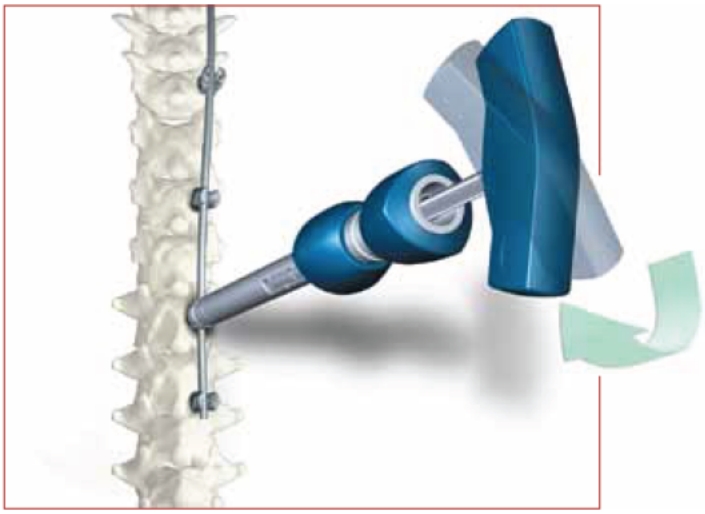
In the position “0”, connect the Persuader to the head of the implant.

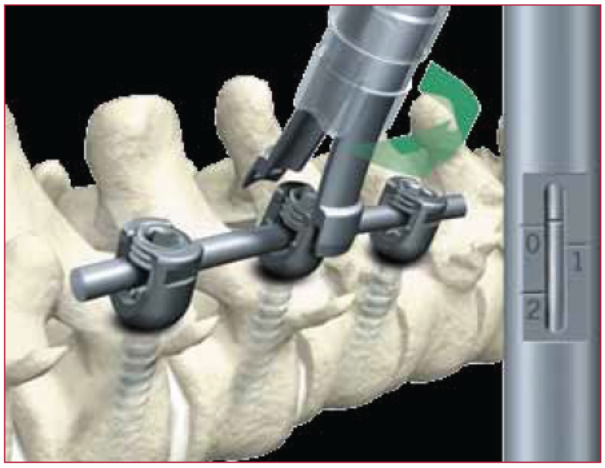
Turn the head of the Persuader until the indication line moves to the position “1”. The Persuader is now locked to the implant. From this position the rod can be pushed into the screw.



Turn the head of the Persuader until the indication line moves into position “2“. The rod is now fully seated allowing insertion of the Closure Screw.

E.Rod Linkage





Persuader and Universal Tightener

Introduce the Closure Screw with the Universal Tightener through the Persuader.

To remove the Persuader, turn the head of the instrument back to the position "0" and rotate the complete instrument.

Tip 1: The rod cannot be linked to the screws or the hooks if the rod has a sharp, acute bend at the point of linkage.

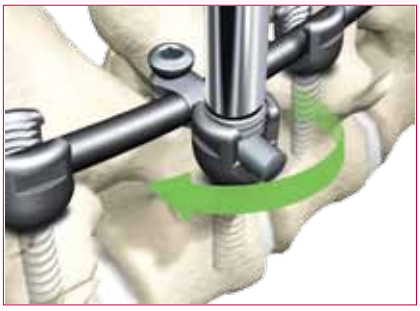
Tip 2: If the position "2" cannot be achieved by turning the Persuader, it may not be positioned properly on the implant. Remove the instrument and start the application process from the beginning.

Tip 3: The Persuader is not designed to bend the rod.

In the event the rod is forced down while tightening the Closure Screw, be sure that the Closure Screw is fully engaged into the screw head. This will help resist the high reactive forces generated by the final-tightening maneuvers.

Extra caution is advised when:
1) The rod is not horizontally placed into the screw head
2) The rod is high in the screw head
3) An acute convex or concave bend is contoured into the rod.

F.Lateral Offset Connector



Operative Technique

Lateral Offset Connector

The Offset Connector allows medial or lateral variability in connecting screws to the rod. They can be helpful in lining up the screws with hook connections.

The head of the screw is rotated 90° clockwise.

The Offset Connector is preloaded onto the rod in the appropriate orientation. To obtain some stability between the rod and Offset Connector, the connector can be tightened lightly at this stage.

The Offset Connector is inserted into the head of the screw. Care must be taken to insure that at least 1mm of the connector is protruding out of the spinal screw.

The Closure Screw is now applied using the Universal Tightener. The final tightening sequence utilized with a pedicle screw is applied to the Closure Screw when used in conjunction with the Offset Connector.

Note:
The Offset Connector is most easily applied in conjunction with the Polyaxial Screw.

Note:
The Offset connector in use with the Monoaxial Screw requires accurate alignment in the sagittal plane of the screw head and rod.

G.Final Tightening

Using Torque Wrench

Once the correction procedures have been carried out and the spine is fixed in a satisfactory position, the final tightening of the Closure Screw is done by utilizing the Anti-Torque Key and the Torque Wrench.

The Torque Wrench indicates the optimum force which has to be applied to the implant for final tightening. Line up the two arrows to achieve this optimum torque of 12Nm.

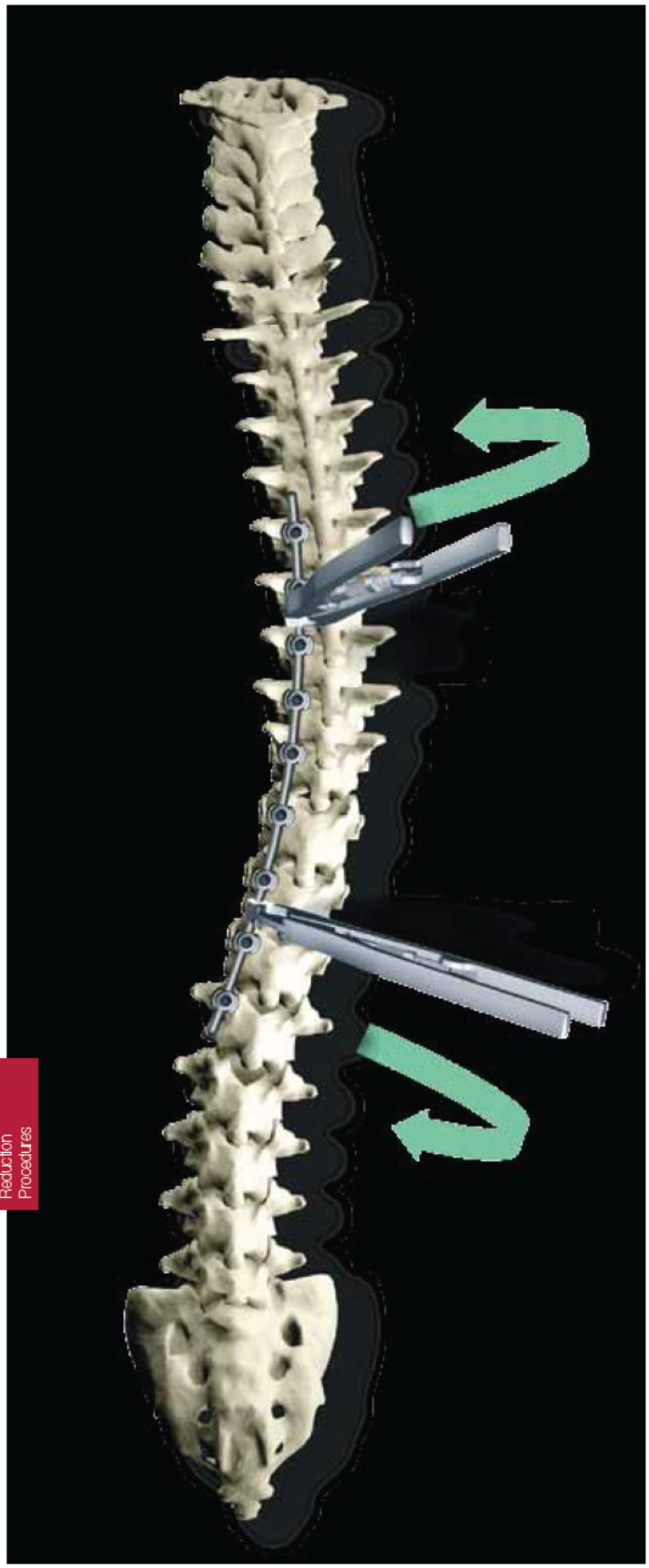
Note:
It is not recommended to exceed 12Nm during final tightening.

Note:
The Anti-Torque Key must be used for final tightening. The Anti-Torque performs two important functions:

1) It allows the Torque Wrench to align with the axis of the tightening axis.
2) It allows one to maximize the torque needed to lock the implant assembly.

Note: If the Anti-Torque Key cannot be easily removed from the implant head, the rod may not be fully seated.

H.Reduction Procedures



Deformity Correction

In working with our global panel of scoliosis specialists, the Xia® 3 System was designed to offer solutions that accommodate various surgical philosophies. The Xia® 3 System advantage is that the surgeon does not have to deviate from their surgical philosophy.

Deformity correction may be obtained using one of four different reduction procedures:

1. Rod Derotation
2. Translation
3. Distraction/Compression
4. In Situ Bending

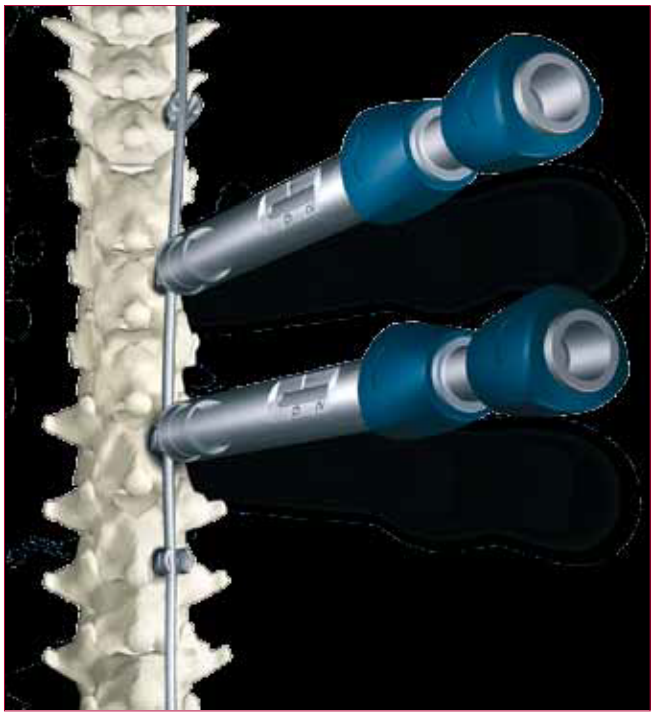
These maneuvers may be utilized independently or in any combination to facilitate optimal spinal deformity correction.

Rod Derotation

Option 1: Traditional rod derotation:

With the rod inserted into all of the implants and the Closure Screws inserted but not tightened, the rotational correction maneuver can be applied.
The rod may be rotated using the two Rod Rotation Forceps. Insure that the Closure Screws are only provisionally tightened to allow free movement of the rod.
The C-Ring instrumentation can be utilized to maintain hook position while the rod rotation maneuver is performed. Typically, the rod is then rotated to an arch of 90 degrees converting a scoliotic deformity in the thoracic spine into a sagittal kyphosis and translating a lumbar scoliotic deformity into lumbar lordosis. Once the rod has been fully rotated, the Closure Screws are provisionally tightened.
Additional deformity correction may be obtained by further distraction/compression maneuvers.

H.Reduction Procedures



Option 2: Rod Rotation for implant approximation:

The rotation technique for approximation is to contour the rod in the sagittal plane to the desired shape. The rod can then be inserted in the implants up to 90 degrees out of phase to minimize the implant approximation necessary. The rod is then rotated, not to derotate the spine, but to place the implants in the proper alignment. Final correction is then performed using distraction and compression techniques.

Translation

Translation can be achieved by utilizing a sublaminar wiring technique or utilizing the persuader instruments. If using the persuader instruments to perform translation, utilize the two persuaders contained in the set. These persuaders are typically placed at the distal and proximal ends of the curve apex. As the spine is carefully translated at these points the Closure Screws are inserted and the implants secured. The persuaders are then moved toward the apex of the curve until translation is complete.

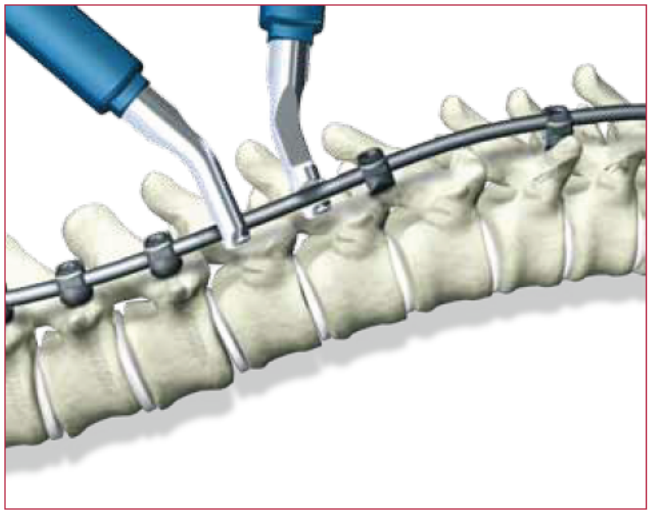
Distraction/Compression

Spinal deformities can be further effected by creating a distraction in the concavity of the deformity and compression on the convexity of the deformity.

Note: Posterior distraction creates a kyphosis in the sagittal plane, compression creates a lordosis in the sagittal plane. Compression is achieved with the Compressor and distraction can be achieved with the Spreader. Once the construct is in the desired position, lock the Closure Screws with the Universal Tightener.

***In Situ* Bending**
Great care must be taken during *in situ* bending not to overload the bone implant interface. Also care must be used not to acutely notch the rod, which may weaken the implant. Ensure that the Closure Screws are not completely tightened during rotation maneuvers or the compression/ distraction process.

H.Reduction Procedures

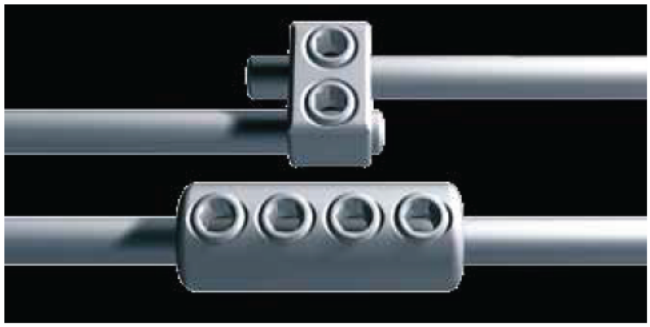


Deformity Correction

Rod to Rod Connection
Rod to Rod connection is occasionally necessary. There are two options available:

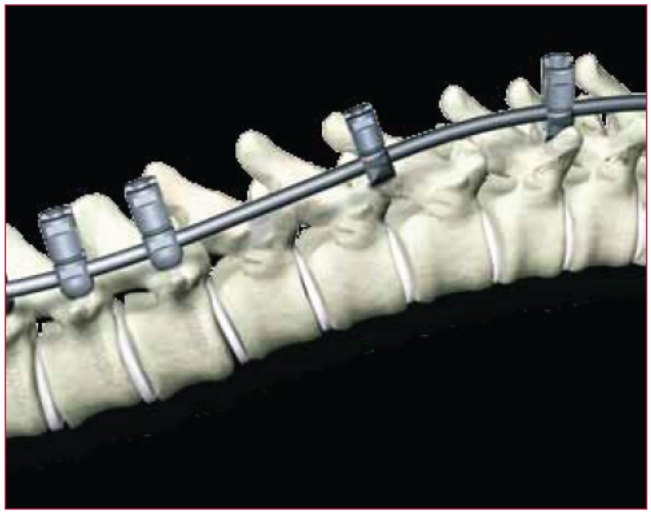
1. Dual Connector
2. Axial Connector

For tightening the Dual Connector and the Axial Connector use the 3.5mm Hexagonal driver.



1) Dual Rod to Rod Clamp
2) Axial Rod to Rod Clamp

H.Reduction Procedures



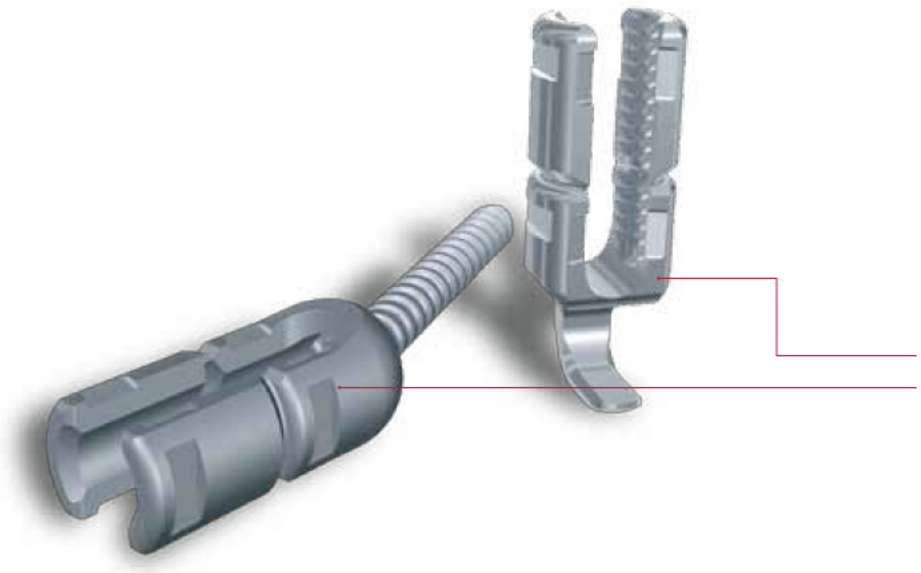
Deformity Correction

Xia® 3 Long Arm Screws and Hooks can be used during a reduction procedure.
The Xia® 3 Reduction monoaxial and polyaxial screwdrivers are used to insert the Xia Long Arm Screws into the pedicles.
The Xia® 3 Long Arm Hooks are manipulated using Xia® 3 Hooks Forceps.

Final tightening will take place once the closure mechanism is inserted and the arms are broken off.

When the Xia® 3 Long Arm Screws and Hooks are used, the arms are broken off when the reduction is complete. A snap line allows a clean and easy break. The first arm is broken away using the rod rotation forceps to grip the arm and bend it in a back and forth motion.

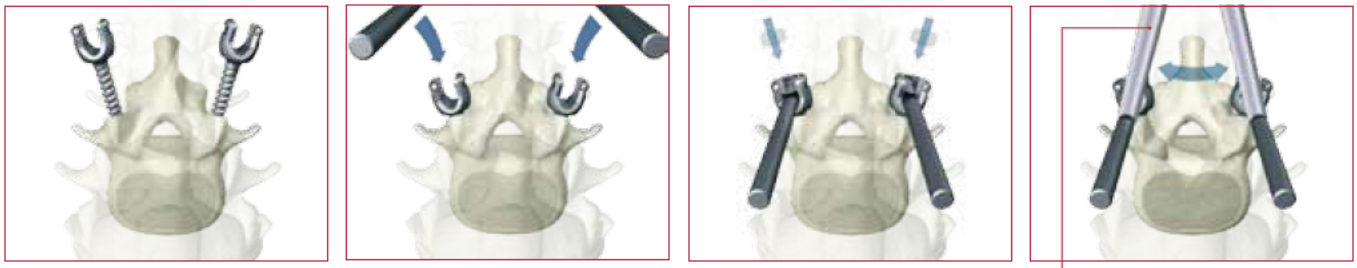
The second arm is broken off in the same manner as the first.



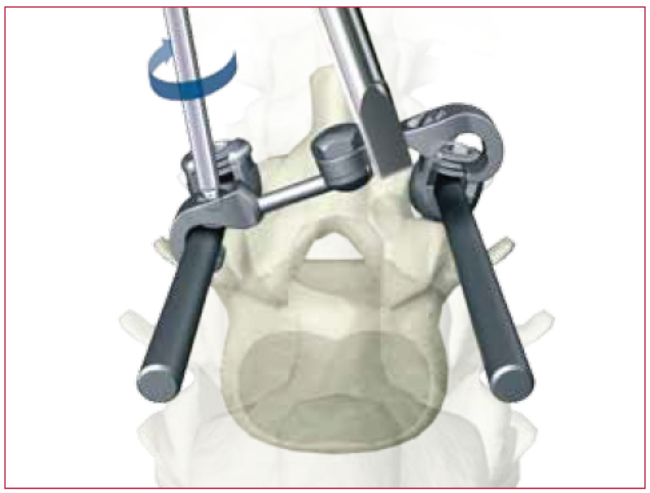
1) Long Arm Hook
2) Long Arm Screw

I.Multi-Axial Connector (M.A.C.)

Standard M.A.C.

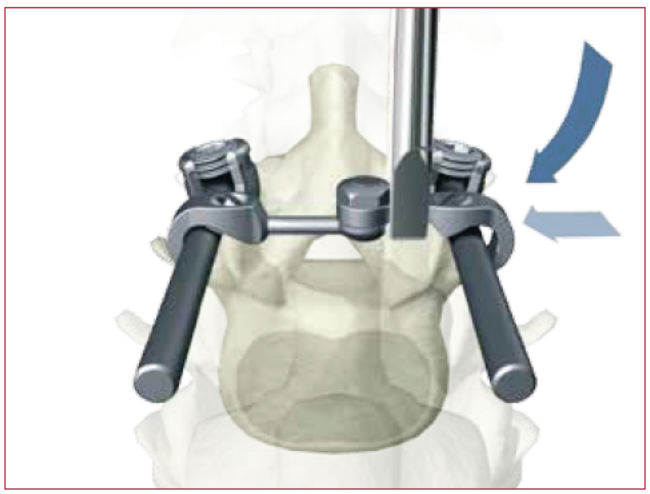


Once the final tightening of the construct has been achieved, the appropriate M.A.C. size can be determined by utilizing the MAC Caliper.



To allow for smooth and rapid insertion of the M.A.C. over the rods, insure that the center bolt is loose to achieve full range of motion and that the tightening screws are adequately backed out.

With the M.A.C. Forceps fixed on the longer J-Hook, place the appropriate length connector on the rod inserting the shortest J-Hook on first. Using the MAC Screwdriver (3.5mm) or MAC Round Tip Screwdriver (3.5mm), proceed to gently tighten the tightening screw onto the rod.



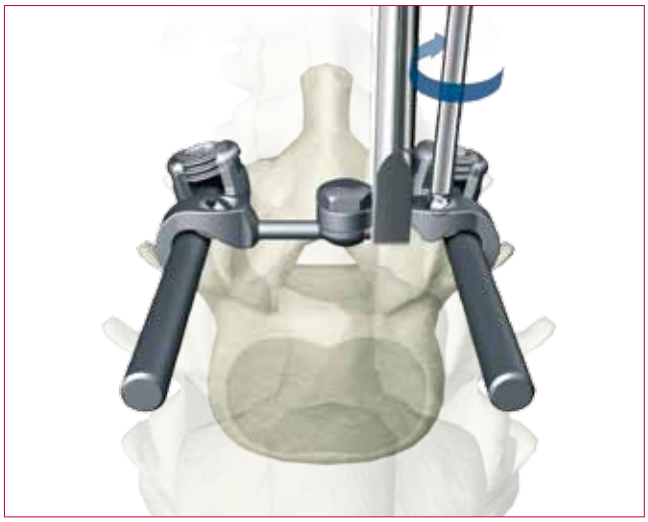
Continue with the insertion of the second J-Hook and tighten fully. Return to the first tightening screw for further tightening.

Check that the M.A.C. is correctly connected to the rods (firmly press the J-Hook if necessary).

Important!
Do not use any other instrumentation other than dedicated M.A.C. instrumentation.

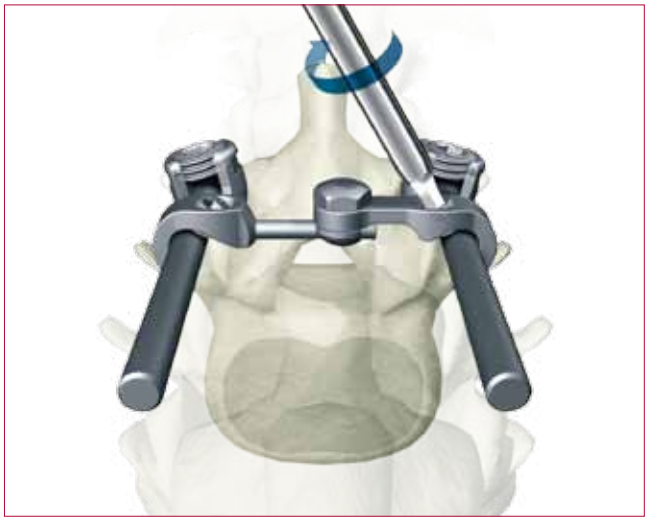
Note:
When using the Monobloc M.A.C. the rods must be parallel.

I.Multi-Axial Connector (M.A.C.)

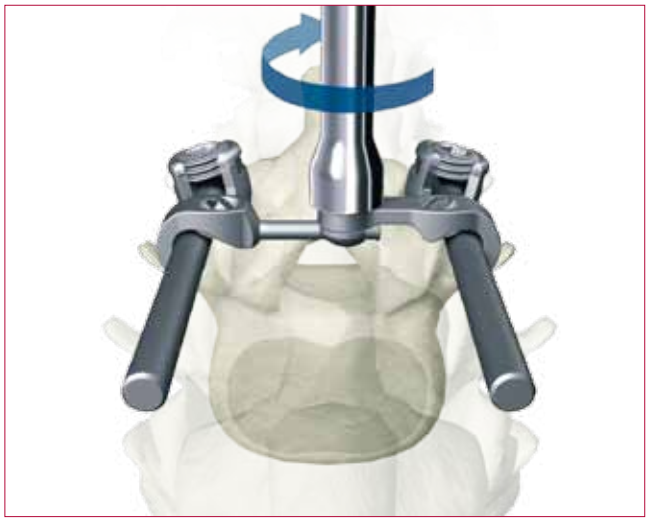


Standard M.A.C.

Note: The Round-Tip Screwdriver allows a 35° angulation around an axis of 360° of the tightening screw.



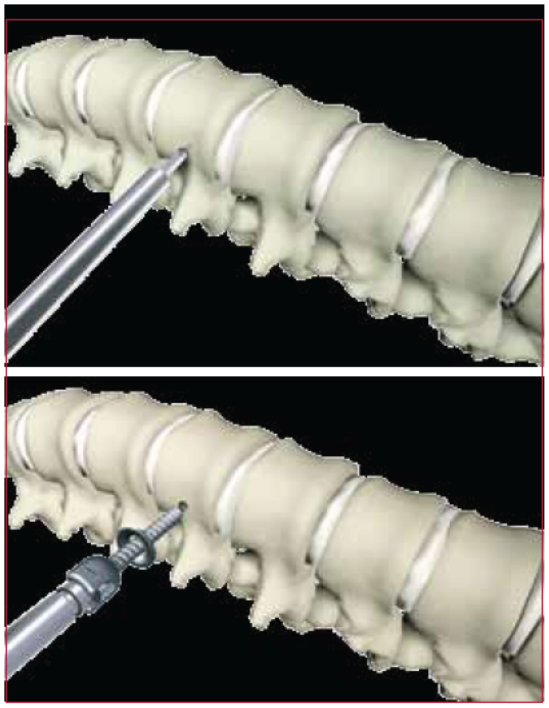
The 3.5mm standard Screwdriver must be used for the final tightening of the tightening screws in order to optimize the contact surface and to avoid damaging the hex of the screws and the tip of the Round-Tip Screwdriver.



The central bolt is finally fully tightened with the 8mm MAC Screwdriver.

Revisit the outside set screws to insure proper tightening.

J.Anterior Approach

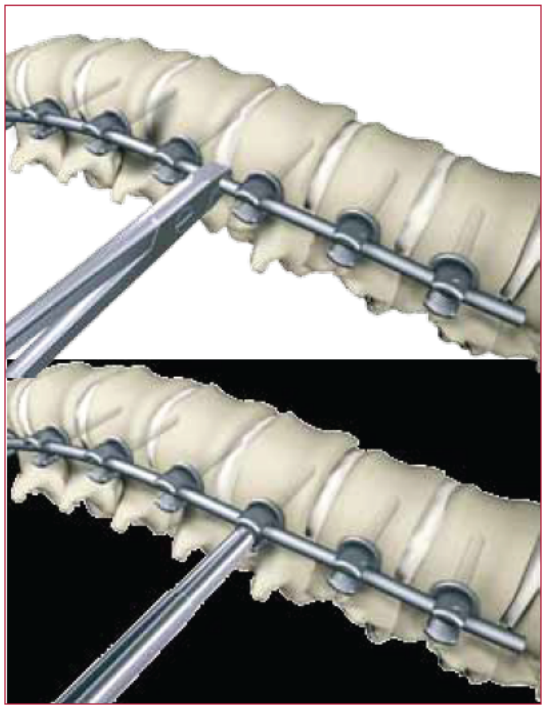


Screw Insertion

The patient is usually approached via a transcostal approach in the thoracic spine or retoperitoneal approach in the lumbar area. A combined incision can be used to access both.

The patient is usually positioned in lateral decubitus position with the convex side up. The highest intended instrumented vertebra is selected and typically defines the rib to be excised (e.g. 6th rib to access 6th thoracic vertebra). The rib can be morcellized for bone graft.

Exposure of the vertebral bodies is completed allowing discectomies and release of the anterior longitudinal ligament and concave soft tissue. Removal of the vertebral end plates at this stage could likely result in additional blood loss and should be delayed until screw insertion is completed.



Once the entry point and screw direction is defined (directed away from the spinal canal) the cortex can be perforated using the Xia® 3 Awl.

The length of the screws is selected according to Computed Tomographic (CT) scans or the use of a standard depth gauge. The head of the screw should be inserted to contact the first cortex or a washer can be added for additional surface contact. The screws are inserted through the washers. Screw purchase should be bicortical for optimal fixation.

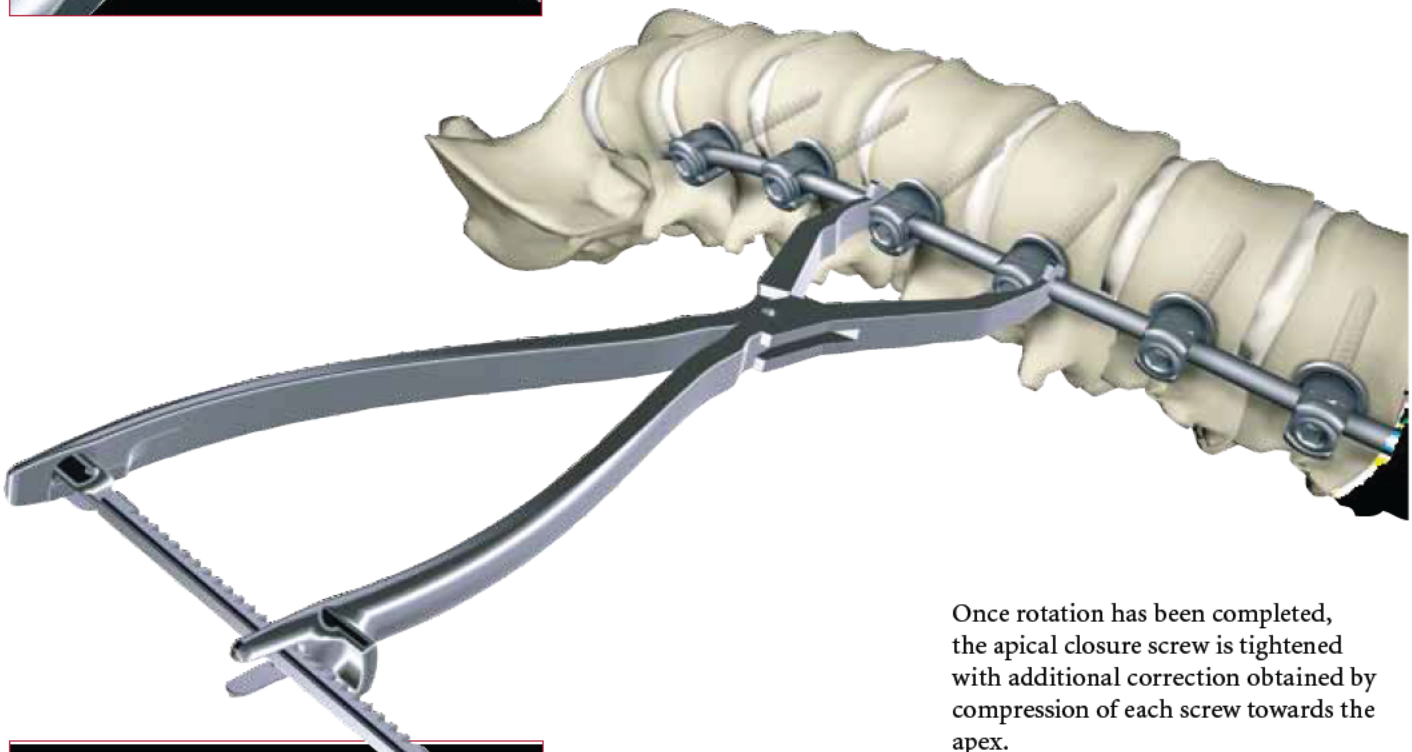
J.Anterior Approach

Deformity Correction

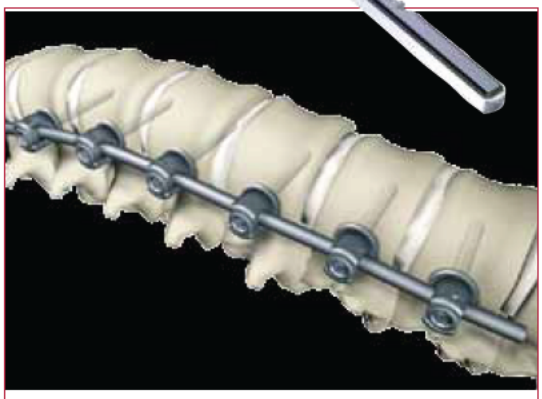
The rod is cut to proper length and bent to fit the contours of the spine.

End plates are removed and bone graft inserted especially into the concavity of the deformity.
The rod is inserted into the head of the implants.

The Closure Screws are partially introduced to allow rotation of the construct.



Once rotation has been completed, the apical closure screw is tightened with additional correction obtained by compression of each screw towards the apex.



Perform final tightening according to standard tightening sequence (Page 20).

Indications and Contraindications

The XIA® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative disc disease (DDD) (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, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

The Ø5.5mm rods from the Stryker Spine Radius™ Spinal System and Ø6.0mm Vitallium rods from the XIA® Spinal System are intended to be used with the other components of XIA® 3 Spinal System. When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA® 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Contraindications

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Insufficient quality or quantity of bone which would inhibit rigid device fixation.
- Previous history of infection.
- Excessive local inflammation.
- Open wounds.
- Any neuromuscular deficit which places an unsafe load level on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself. Obesity is defined according to the W.H.O. standards.
- Patients having inadequate tissue coverage of the operative site.
- Pregnancy.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.

These contraindications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive.

General Conditions Of Use

General Conditions of Use

The implantation of pedicle screw spinal systems must be performed only by experienced spinal surgeons having undergone the necessary specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

The information contained in the Package Insert is necessary but not sufficient for the use of this device. This information is in no sense intended as a substitute for the professional judgment, skill and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient's cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

Information for Patients

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up.

The surgeon must warn the patient of the surgical risks and made aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advice the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise patients of this fact and warn of the potential consequences. For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief.

Infection

Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have been associated with transient bacteremia. To help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

Implant Selection and Use

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice which depends on each patient.

General Conditions Of Use

Patients who are overweight may be responsible for additional stresses and strains on the device which can speed up metal fatigue and/or lead to deformation or failure of the implants.

The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants should be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause metal fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

Improper selection, placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant. Contouring or bending of rods or plates is recommended only if necessary according to the surgical technique of each system. Rods or plates should only be contoured with the proper contouring instruments. Incorrectly contoured rods/plates, or rods/plates which have been repeatedly or excessively contoured must not be implanted. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Refer to the Stryker® Spine surgical protocols for additional procedural information. Periodic follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

Post-Operative Care

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician should closely monitor the patient if a change at the site has been detected

Adverse Effects

- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Bending, disassembly or fracture of any or all implant components.
- Fatigue fracture of spinal fixation devices, including screws and rods, has occurred.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin.
- Dural leak requiring surgical repair.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) should be revised or removed immediately before serious injury occurs.
- Loosening of spinal fixation implants can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, migration and/or pain.
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Serious complications may be associated with any spinal surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Decrease in bone density due to stress shielding.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft, the intervertebral body, pedicle, and/or sacrum above and/or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision. The surgeon must warn the patient of these adverse effects as deemed necessary.

Removal of Implants

These implants are temporary internal fixation devices designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and can be removed. Removal may also be recommended in other cases, such as:

- corrosion with a painful reaction,
- migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions,
- pain or abnormal sensations due to the presence of the implants,
- infection or inflammatory reactions,
- reduction in bone density due to the different distribution of mechanical and physiological stresses and strains,
- failure or mobilization of the implant.

Standard ancillaries provided by Stryker® Spine can be used to remove the implants. Any decision by a physician to remove the internal fixation device must take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically. Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture. Removal of the implant after fracture healing is recommended. Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain or stress shield bone.

General Conditions Of Use

Pre-Operative Precautions

Anyone using Stryker® Spine products can obtain a Surgical Technique brochure by requesting one from a distributor or from Stryker® Spine directly. Those using brochures published more than two years before the surgical intervention are advised to get an updated version.

Stryker® Spine devices can only be used by doctors who are fully familiar with the surgical technique required and who have been trained to this end. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by Stryker® Spine. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to causes injury to the patient.

To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable Stryker® Spine Surgical Technique.

Extreme care must be taken when the instruments are used near vital organs, nerves or vessels.

Unless otherwise specified on the label, the instruments can be reused after decontamination, cleaning and sterilization.

Caution

Federal law (U.S.A) restricts this device to sale by or on the order of a licensed physician.

Warning

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 spondylolisthesis (grades 3 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurological 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.

Xia® 3 implant components have not been tested for heating or migration in MR environment.

Precautions

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

Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

Adolescent Idiopathic Scoliosis Application

Xia® 3 Implants

	Part Number	Description
	48230000	Blocker
	4823040(20)-(45)	Xia® 3 Monoaxial Screw, Ø4.0mm
	4823045(20)-(45)	Xia® 3 Monoaxial Screw, Ø4.5mm
	4823050(20)-(50)	Xia® 3 Monoaxial Screw, Ø5.0mm
	4823055(25)-(55)	Xia® 3 Monoaxial Screw, Ø5.5mm
	4823060(25)-(90)	Xia® 3 Monoaxial Screw, Ø6.0mm
	4823065(25)-(90)	Xia® 3 Monoaxial Screw, Ø6.5mm
	4823070(25)-(90)	Xia® 3 Monoaxial Screw, Ø7.0mm
	4823075(25)-(90)	Xia® 3 Monoaxial Screw, Ø7.5mm
	4823140(20)-(45)	Xia® 3 Polyaxial Screw, Ø4.0mm
	4823145(20)-(45)	Xia® 3 Polyaxial Screw, Ø4.5mm
	4823150(20)-(50)	Xia® 3 Polyaxial Screw, Ø5.0mm
	4823155(25)-(55)	Xia® 3 Polyaxial Screw, Ø5.5mm
	4823160(25)-(90)	Xia® 3 Polyaxial Screw, Ø6.0mm
	4823165(25)-(90)	Xia® 3 Polyaxial Screw, Ø6.5mm
	4823170(25)-(90)	Xia® 3 Polyaxial Screw, Ø7.0mm
	4823175(25)-(90)	Xia® 3 Polyaxial Screw, Ø7.5mm
	482334(20)-(45)	Xia® 3 Uniplanar Screw, Ø4.5mm
	4823350(20)-(45)	Xia® 3 Uniplanar Screw, Ø5.0mm
	482335(20)-(55)	Xia® 3 Uniplanar Screw, Ø5.5mm
	4823360(25)-(60)	Xia® 3 Uniplanar Screw, Ø6.0mm
	482336(25)-(60)	Xia® 3 Uniplanar Screw, Ø6.5mm
	4823370(30)-(60)	Xia® 3 Uniplanar Screw, Ø7.0mm
	482337(30)-(60)	Xia® 3 Uniplanar Screw, Ø7.5mm

	Part Number	Description
	4823645(20)-(45)	Xia® 3 Reduction Uniplanar Screw, Ø4.5mm
	4823650(20)-(45)	Xia® 3 Reduction Uniplanar Screw, Ø5.0mm
	4823655(20)-(55)	Xia® 3 Reduction Uniplanar Screw, Ø5.5mm
	4823660(25)-(60)	Xia® 3 Reduction Uniplanar Screw, Ø6.0mm
	4823665(25)-(60)	Xia® 3 Reduction Uniplanar Screw, Ø6.5mm
	4823670(30)-(60)	Xia® 3 Reduction Uniplanar Screw, Ø7.0mm
	4823675(30)-(60)	Xia® 3 Reduction Uniplanar Screw, Ø7.5mm
	4823965(60)-(00)	Xia® 3 Angled Monoaxial Screw, Ø6.5mm
	4823975(60)-(00)	Xia® 3 Angled Monoaxial Screw, Ø7.5mm
	4823985(60)-(00)	Xia® 3 Angled Monoaxial Screw, Ø8.5mm
	4823840(20)-(45)	Xia® 3 Angled Polyaxial Screw, Ø4.0mm
	4823845(20)-(45)	Xia® 3 Angled Polyaxial Screw, Ø4.5mm
	4823850(20)-(45)	Xia® 3 Angled Polyaxial Screw, Ø5.0mm
	4823855(25)-(55)	Xia® 3 Angled Polyaxial Screw, Ø5.5mm
	4823865(25)-(90)	Xia® 3 Angled Polyaxial Screw, Ø6.5mm
	4823875(25)-(90)	Xia® 3 Angled Polyaxial Screw, Ø7.5mm
	4823885(60)-(00)	Xia® 3 Angled Polyaxial Screw, Ø8.5mm
	4823895(60)-(00)	Xia® 3 Angled Polyaxial Screw, Ø9.5mm

Adolescent Idiopathic Scoliosis Application
Xia® 3 Implants

	Part Number	Description
	48237140(20)-(45)	Xia® 3 Angled Medial, Screw, Ø4.0mm
	48237145(20)-(45)	Xia® 3 Angled Medial, Screw, Ø4.5mm
	48237150(20)-(45)	Xia® 3 Angled Medial, Screw, Ø5.0mm
	48237155(25)-(55)	Xia® 3 Angled Medial, Screw, Ø5.5 mm
	48237165(25)-(90)	Xia® 3 Angled Medial Screw, Ø6.5mm
	48237175(25)-(90)	Xia® 3 Angled Medial Screw, Ø7.5mm
	48237185(60)-(00)	Xia® 3 Angled Medial Screw, Ø8.5mm
	48237195(60)-(00)	Xia® 3 Angled Medial Screw, Ø9.5mm
	4823265(30)-(00)	Xia® 3 Closed Head Monoaxial Screw, Ø6.5mm
	4823275(30)-(00)	Xia® 3 Closed Head Monoaxial Screw, Ø7.5mm
	4823285(30)-(00)	Xia® 3 Closed Head Monoaxial Screw, Ø8.5mm
	4823295(30)-(00)	Xia® 3 Closed Head Monoaxial Screw, Ø9.5mm
	4823765(30)-(00)	Xia® 3 Closed Head Polyaxial Screw, Ø6.5mm
	4823775(30)-(00)	Xia® 3 Closed Head Polyaxial Screw, Ø7.5mm
	4823785(30)-(00)	Xia® 3 Closed Head Polyaxial Screw, Ø8.5mm
	4823795(30)-(00)	Xia® 3 Closed Head Polyaxial Screw, Ø9.5mm
	4823265(30)-(00)	Xia® 3 Closed Head Revision Screw, Ø6.5mm
	4823275(30)-(00)	Xia® 3 Closed Head Revision Screw, Ø7.5mm
	4823285(30)-(00)	Xia® 3 Closed Head Revision Screw, Ø8.5mm
	4823295(30)-(00)	Xia® 3 Closed Head Revision Screw, Ø9.5mm
	48230250	Xia® 3 Laminar Hook Medium, Standard Blade
	48230201	Xia® 3 Laminar Hook Medium, Narrow Blade
	48230202	Xia® 3 Laminar Hook Large, Standard Blade
	48230203	Xia® 3 Laminar Hook Large, Narrow Blade

	Part Number	Description
	48230204	Xia® 3 Laminar Hook Extended Body
	48230205	Xia® 3 Laminar Hook Small, Extended Body
	48230206	Xia® 3 Laminar Hook Offset, Right
	48230207	Xia® 3 Laminar Hook Offset, Left
	48230208	Xia® 3 Laminar Hook Large, Angled Blade
	48230209	Xia® 3 Laminar Hook Small, Angled Blade
	48230210	Xia® 3 Thoracic Laminar Hook, Standard Blade
	48230211	Xia® 3 Thoracic Laminar Hook, Narrow Blade
	48230212	Xia® 3 Thoracic Laminar Hook Small Offset, Right
	48230213	Xia® 3 Thoracic Laminar Hook Small Offset, Left
	48230214	Xia® 3 Thoracic Laminar Hook Large Offset, Right
	48230215	Xia® 3 Thoracic Laminar Hook Large Offset, Left
	48230216	Xia® 3 Thoracic Laminar Hook Small, Narrow Blade
	48230217	Xia® 3 Offset Hook Large, Right
	48230218	Xia® 3 Offset Hook Large, Left
	48230220	Xia® 3 Pedicle Hook, Medium
	48230221	Xia® 3 Pedicle Hook, Small
	48230222	Xia® 3 Pedicle Hook, Large
	48230232	Xia® 3 Transverse Process Hook, Right
	48230233	Xia® 3 Transverse Process Hook, Left
	48230240	Xia® 3 Laminar Hook Small, Narrow Blade
	48230241	Xia® 3 Laminar Hook Small, Standard Blade

Adolescent Idiopathic Scoliosis Application

Xia® 3 Implants

	Part Number	Description
	03820200	Xia® Laminar Hook Medium, Standard Blade
	03820201	Xia® Laminar Hook Medium, Narrow Blade
	03820202	Xia® Laminar Hook Large, Standard Blade
	03820210	Xia® Thoracic Laminar Hook, Standard Blade
	03820220	Xia® Pedicle Hook, Medium
	48232(030)-(150), 480, 600	Ø6.0mm CP Titanium Rod, with Hex
	48233(030)-(150), 480, 600	Ø6.0mm Titanium Alloy Rod, with Hex
	03822601	Ø6.0mm Vitallium® Rod, 600mm
	48232601	Ø6.0mm Vitallium®, with Hex 600mm
	48238(030)-(120)	Ø6.0mm Titanium Alloy Rad Rod
	48239(050)-(120)	Ø6.0mm Titanium Alloy Max Rad Rod

	Part Number	Description
	4866130(03)-(20)	Ø5.5mm Titanium Alloy Rod, without Hex
	486613(110)-(600)	Ø5.5mm Titanium Alloy Rod, with Hex
	4866150(30)-(20)	Ø5.5mm Titanium Alloy Rad Rod
	4866155(50)-(20)	Ø5.5mm Titanium Alloy Max Rad Rod
	482360(14)-(26)	Xia® 3 Monoblock Cross Connector
	48236028	Xia® 3 Multi-Axial Cross Connector, 28mm-31mm
	48236030	Xia® 3 Multi-Axial Cross Connector, 30mm-35mm
	48236035	Xia® 3 Multi-Axial Cross Connector, 35mm-44mm
	48236043	Xia® 3 Multi-Axial Cross Connector, 43mm-54mm
	48236053	Xia® 3 Multi-Axial Cross Connector, 53mm-73mm
	48236070	Xia® 3 Multi-Axial Cross Connector, 70mm-99mm

Adolescent Idiopathic Scoliosis Application
Xia® 3 Instruments

	Part Number	Description
	48237111	Awl
	482397002	Sacral Awl
	48237024	Curved Blunt Probe
	48237055	Thoracic Pedicle Probe
	482397001	Adjustable Curette Probe
	48237060	Malleable Pedicle Feeler
	48237059	Medium Pedicle Feeler
	48237003	Stiff Pedicle Feeler
	48237061	Double-Ended Ball Tip Probe
	48230(030)-(105)	Modular Tap, Ø3.0mm-Ø10.5mm
	48231201	T-Handle
	48231202	T-Handle, Ratchet
	48231301	Round Handle
	48231302	Round Handle, Ratchet
	482397006	Small Round Handle
	482397005	Small Round Handle, Ratchet
	48231330	Xia® 3 Polyaxial Screwdriver
	48231320	Xia® 3 Monoaxial Screwdriver
	48231311	Xia® 3 Polyaxial Screwdriver Shaft
	48231321	Xia® 3 Monoaxial Screwdriver Shaft
	48231330S	Screwdriver Sleeve
	482391330S	Xia® 3 Short Polyaxial Screwdriver
	482391330L	Xia® 3 Long Polyaxial Screwdriver
	482391320S	Xia® 3 Short Monoaxial Screwdriver

	Part Number	Description
	482391320L	Xia® 3 Long Monoaxial Screwdriver
	482397004	Xia® 3 Low Profile Polyaxial Screwdriver
	482391311S	Xia® 3 Short Polyaxial Screwdriver Shaft
	482391311L	Xia® 3 Long Polyaxial Screwdriver Shaft
	482391321S	Xia® 3 Short Monoaxial Screwdriver Shaft
	482391321L	Xia® 3 Long Monoaxial Screwdriver Shaft
	482391312S	Xia® 3 Short Xia® II Polyaxial Screwdriver Shaft
	482397009	Xia® 3 Low Profile Polyaxial Screwdriver Shaft
	482397010	Xia® 3 Low Profile Polyaxial Screwdriver Shaft Adapter
	03710620	Rod Template
	48238400S	Table-Top Rod Cutter Stand
	48238400	Table-Top Rod Cutter
	48237010	French Bender
	48230191L	Tube Bender, Left
	48230191R	Tube Bender, Right
	48230140	Rod Insertion Forceps
	48231140	Rod Gripper
	48237011L	*In-Situ* Rod Bender, Left
	48237011R	*In-Situ* Rod Bender, Right
	48230180	Coronal Rod Bender, Left
	48230190	Coronal Rod Bender, Right
	48230180S	Ball-Joint
	48237008	Universal Tightener
	482397008	Short Universal Tightener

Adolescent Idiopathic Scoliosis Application

Xia® 3 Instruments

	Part Number	Description
	48237065	Double-Ended Universal Tightener
	48237109	Inserter Tube
	482397109	Short Inserter Tube
	48237018	Rod Fork
	48237016	Persuader
	482397016	Short Persuader
	48237015	One-Handed Persuader
	48236100	Small Compressor
	48236101	Large Compressor
	48236000	Small Distractor
	48236001	Large Distractor
	48237026	Anti-Torque Key
	482397026	Small Anti-Torque Key
	48237028	Torque Wrench
	482397028	Small Torque Wrench
	48230123	Cross Connector Measuring Device
	675024	MAC Caliper
	48230120	Cross Connector Inserter
	48230121	3.5mm Hex Driver
	48237092	Double-Ended 3.5mm Set Screw Inserter
	48230122	8mm Hex Driver
	48237087	SUK™ One-Piece Tube
	48237077	SUK™ Two-Piece Tube
	48237097	SUK™ T-Handle

	Part Number	Description
	48237067	SUK™ Derotator Clip
	48237078	SUK™ DVR Reduction Tube
	48237068	Short SUK™ DVR Clamp
	48237069	Long SUK™ DVR Clamp
	482331330	Xia® 3 Reduction Uniplanar Screwdriver
	482339110	Reduction Screw Tab Remover
	48237021	Lamina Preparer
	48230110	Lamina Preparer, Narrow
	48231020	Standard Hook Holder
	48231040	Lateral Hook Holder
	48231170	Straight Hook Holder
	48237029	Hook Impactor
	48237025	Pedicle Hook Preparer
	48230100	Vise Grip
	48237019	Rod Pusher
	48237032	Monodriver
	482397032	Short Monodriver
	48237091	Modular Monodriver Shaft
	48237033	Modular Polyadjustment Driver
	48231313	Xia® 3 Self-Holding Polyaxial Screwdriver Shaft
	48237056	Rod Rotation Key (Ø6.0mm)
	48235001	Lateral Persuader
	48237079	Reduction Clip
	486619160	4.5mm Combination Wrench (Ø5.5mm)

Xia® 3 Instruments

	Part Number	Description
	48237080	Pedicle Marker Inserter
	48237081	Pedicle Markers (Set of 6)
	48237093	Soft Tissue Retractor
	482397007	Jacobs Chuck Handle
	48230001	Degenerative Implant Tray
	48230002	Degenerative Instrument Tray
	48230003	Complex Spine Implant Tray
	48230004	Complex Spine Instrument Tray
	48230005	Complex Spine Hooks and Instrument Tray
	48230006	Complex Spine Rod and Cross Connector Tray
	48230011	Degenerative Implant Tray Version B (SS)
	48230012	Degenerative Instrument Tray Version B (SS)
	48230013	Uniplanar Tray
	48230015	SUK™ Tray
	48230020	Outlier Implant Tray
	48230010	Outlier Instrument Tray

Notes

Notes

Notes

stryker®

Joint Replacements

Trauma, Extremities & Deformities

Craniomaxillofacial

Spine

Biologics

Surgical Products

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Interventional Spine

Navigation

Endoscopy

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Imaging

Patient Care & Handling Equipment

EMS Equipment

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Literature Number: TLXLPST11121
SC/GS 12/11

CE 0459

G MED ISO9001-ISO13485

ATTACHMENT J

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Spine
% Ms. Simona Voic
Regulatory Affairs Project Manager
2 Pearl Court
Allendale, New Jersey 07401

AUG 2 7 2007

Re: K071373
Trade/Device Name: Xia® III Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWP
Dated: August 1, 2007
Received: August 2, 2007

Dear Ms. Voic:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071373

Device Name: Stryker Spine Xia® III Spinal System

Indications For Use:

The Stryker Spine XIA® III Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA®III Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative disc disease (DDD) (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, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

The Ø5.5mm rods from the Stryker Spine Radius™ Spinal System and Ø6.0 mm Vitallium rods from XIA® Spinal System are intended to be used with the other components of Xia® III Spinal System.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K071373

K071663
Page 1 of 1

510(k) Summary according to 807.92(c)

JUL - 2 2008

Contact: Justin Eggleton
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
(202) 552 – 5800

Trade Name: Orthobiom™ Spinal System

Common Name: Pedicle Screw System

Device Regulatory Class: Pedicle Screw System (21 CFR 888.3070)
Class II

Product Code: 87MNI

Indications For Use:
The Orthobiom™ Spinal System is a posterior, non-cervical pedicle screw system indicated to treat pediatric scoliosis by (1) correction, (2) stabilization, (3) adjustment and (4) fixation of the scoliotic spine.

The Orthobiom™ Spinal System is intended to be used with bone graft.

Device Description:
The Orthobiom™ Spinal System is designed as a pedicle screw based system. The system consists of rods, pedicle screws, fixed connectors, and one cross connector. The Orthobiom™ Spinal System uses rods, screws, and/or hooks to achieve correction and subsequent maintenance of the corrected scoliotic spine and use fusion to maintain the corrected spine.

Predicate Device(s):
The Orthobiom Spinal System™ was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. These predicates include Harrington Rods (K781443), Synthes Small Stature USS (K994121), DePuy Spine Kaneda Spinal System (K974757), Acromed Pediatric ISOLA (K962984), and DePuy Spine Frontier Anterior Deformity System (K012916).

Performance Standards:
Testing performed indicate that the Orthobiom™ Spinal System is as mechanically sound as predicate devices.

510(k) Summary of Safety and Effectiveness
Stryker Spine Xia® III Spinal System

AUG 27 2007

Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	**Ms. SIMONA VOIC** **REGULATORY AFFAIRS PROJETC MANAGER** **TELEPHONE: 201-760-8145** **FAX: 201-760-8345** **EMAIL:** simona.voic@stryker.com
Date Prepared	May 14, 2007
Trade Name	Stryker Spine Xia® III Spinal System
Proposed Class	Class III and II
Classification Name and Number	Pedicle Screw Spinal System 21 CFR 888.3070 Spinal Interlaminal Fixation Orthosis 21 CFR 888.3050
Product Code	NKB, MNH, MNI, and KWP
Predicate Devices	Stryker Spine Xia® Spinal Systems: 510(k) #K060361, K060979, and #K013823, Stryker Spine Radius™ Spinal System: 510(k) # K062270, DePuy's Moss Miami Spinal System: 510(k) #K950697.

Device Description	The Stryker Spine Xia® III Spinal System is comprised of monoaxial & polyaxial bone screws, blocker (as a locking mechanism), rods , hooks, and connectors. The implants are manufactured from Ti6Al4V alloy, and CPTi. The subject system also offers MoCoCr alloy (Vitallium) rods.
Intended Use	The Stryker Spine XIA® III Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA®III Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: • Degenerative disc disease (DDD) (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, and/or lordosis); • Tumor; • Pseudoarthrosis; and • Failed previous fusion. The Ø5.5mm rods from the Stryker Spine Radius™ Spinal System and Ø6.0 mm Vitallium rods from XIA® Spinal System are intended to be used with the other components of Xia® III Spinal System.

Summary of the Technological Characteristics	Testing in compliance with FDA's Guidance for Spinal System 510(k)'s May 3, 2004 was performed for the Xia® III Spinal System, and demonstrated substantial equivalent performance characteristics to the predicate device systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Spine
% Mr. Curtis Truesdale
Regulatory Affairs Project Manager
2 Pearl Court
Allendale, New Jersey 07401

APR 23 2009

Re: K083393
Trade/Device Name: Stryker Spine XIA 3 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Names: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWQ, KWP
Dated: January 14, 2009
Received: January 16, 2009

Dear Mr. Truesdale:

This letter corrects the substantially equivalent letter dated April 1, 2009.

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083393
Device Name: Stryker Spine XIA 3 Spinal System – Line Extension

Indications for Use:

The Stryker Spine XIA 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative disc disease (DDD) (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, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

The Ø5.5 mm rods from the Stryker Spine Radius Spinal System and Ø6.0 mm Vitallium rods from XIA Spinal System are intended to be used with the other components of XIA 3 Spinal System.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083393

K083393
Page 1 of 2

Special 510(k) Summary of Safety and Effectiveness:
Xia® 3 Spinal System - Line Extension

Proprietary Name:	Xia® 3 Spinal System – Line Extension
Common Name:	Spinal Fixation Appliances
Classification Name and Reference:	1) Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 2) Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060 3) Pedicle Screw Spinal System, 21 CFR §888.3070 (b) (1) & (b) (2)
Device Product Code:	NKB, KWP, KWQ, MNH, MNI
Proposed Regulatory Class:	Class III
For Information contact:	Curtis Truesdale Regulatory Affairs Project Manager 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8296 Fax: (201) 760-8496 Email: Curtis.Truesdale@Stryker.com
Date Summary Prepared:	November 14, 2008
Predicate Devices	▪ Stryker Spine Xia® 3 Spinal System, K071373; ▪ Stryker Spine Radius® Spinal System, K062270; ▪ Stryker Spine Xia® II, K013823; ▪ Moss Miami System, K950697;
Description of Device Modification	This 510(k) is intended to introduce an extension to the existing Xia® 3 Spinal System. The proposed line extension includes the addition of various screws, connectors and a hook.

Intended Use	The Xia® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation, the Xia® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (DDD) (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, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The Ø5.5mm rods from the Stryker Spine Radius® Spinal System and Ø6.0mm Vitallium rods from Xia® Spinal System are intended to be used with the other components of Xia® 3 Spinal System.
Summary of the Technological Characteristics	Documentation is provided which demonstrates the new components of the Stryker Spine Xia® 3 Spinal System to be substantially equivalent to the predicate devices in terms of material, design, and indications for use. Engineering analysis and testing to demonstrate compliance with FDA's Guidance for Spinal System 510(k)'s May 3, 2004 were completed for the Stryker Spine Xia® 3 Spinal System, including the subject components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2009

Stryker Spine
% Mr. Curtis D. Truesdale
Regulatory Affairs Project Manager
2 Pearl Court
Allendale, New Jersey 07401

Re: K091291
Trade/Device Name: Stryker Spine XIA® 3 Spinal System-Line Extension
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: III
Product Code: NKB, MNH, MNI, KWP, KWQ
Dated: June 2, 3009
Received: June 3, 2009

Dear Mr. Truesdale:

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.

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K091291
Device Name: Stryker Spine XIA® 3 Spinal System – Line Extension

Indications for Use:

The Stryker Spine XIA® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative disc disease (DDD) (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, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

The Ø5.5 mm titanium and Vitallium® rods from the Stryker Spine Radius® Spinal System and Ø6.0 mm Vitallium® rods from XIA Spinal System are intended to be used with the other components of XIA® 3 Spinal System.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(EXT for MXM)
(Division Sign-Off)
Division of Surgical Orthopedic,
and Restorative Devices

510(k) Number K 091291

Pg 1 of 1

K091291

Special 510(k) Summary of Safety and Effectiveness:
Xia® 3 Spinal System - Line Extension

JUN 24 2009

Proprietary Name:	Xia® 3 Spinal System – Line Extension
Common Name:	Spinal Fixation Appliances
Classification Name and Reference:	1) Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 2) Spinal Intervertebral Body Fixation Orthosis, 21 CFR §888.3060 3) Pedicle Screw Spinal System, 21 CFR §888.3070 (b) (1) & (b) (2)
Device Product Code:	NKB, KWP, KWQ, MNH, MNI
Proposed Regulatory Class:	Class III
For Information contact:	Curtis Truesdale Regulatory Affairs Project Manager 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8296 Fax: (201) 760-8496 Email: Curtis.Truesdale@Stryker.com
Date Summary Prepared:	April 30, 2009
Predicate Devices	▪ Stryker Spine Xia® 3 Spinal System, K071373; ▪ Stryker Spine Xia® Spinal System, K080928; ▪ Stryker Spine Xia® Spinal System, K063428; ▪ Stryker Spine Radius® Spinal System, K062270, K082608; ▪ Stryker Spine Xia II Spinal System, K013823; and ▪ DePuy Spine Moss Miami Spinal System, K950697

Pg 1 of 2

K091291

Description of Device Modification	This 510(k) is intended to introduce an extension to the existing Xia® 3 Spinal System. The proposed line extension includes the addition of titanium Uniplanar Screws, titanium Uniplanar Reduction Screws, and use of the Stryker Spine Radius Ø5.5 mm Vitallium® rod with the Xia® 3 Spinal System.
Intended Use	The Xia® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation, the Xia® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (DDD) (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, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The Ø5.5mm titanium and Vitallium® rods from the Stryker Spine Radius® Spinal System and Ø6.0mm Vitallium® rods from Xia® Spinal System are intended to be used with the other components of Xia® 3 Spinal System.
Summary of the Technological Characteristics	The Stryker Spine Xia® 3 Spinal System, with the incorporation of the subject components, is substantially equivalent to the predicate devices in terms of material, design, and indications for use. Engineering analysis and testing to demonstrate compliance with FDA's Guidance for Spinal System 510(k)'s May 3, 2004 were completed for the Stryker Spine Xia® 3 Spinal System.

Pg 2 of 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Medtronic Sofamor Danek
% Mr. Lee Grant
Principal, Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

SEP 27 2010

Re: K091445
Trade/Device Name: CD HORIZON® Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP, KWQ
Dated: September 01, 2010
Received: September 02, 2010

Dear Mr. Grant:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

"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."

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Christy Foreman

Christy Foreman
Acting Director
Office of Device Evaluation
Center for Devices and
Radiological Health
Food and Drug Administration

510(k) Number (if known): K091445

K091445

Device Name: CD HORIZON® Spinal System

SEP 27 2010

Indications for Use:

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 and/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 adolescent idiopathic scoliosis. The CD HORIZON® Pediatric Spinal System is intended 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, 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.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091445

CD HORIZON® Spinal System
510(k) Summary – K091445

SEP 27 2010

September 2010

I. Company:

Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: Lee Grant
Principal, Regulatory Affairs Specialist

II. **Proposed Proprietary Trade Name: CD HORIZON® Spinal System**

III. **Classification Name(s):** Spinal Interlaminal Fixation and Spinal Intervertebral Fixation Orthosis and/or Pedicle Screw Spinal System (per 21CFR Section 888.3050, 888.3060 and/or 888.3070); Product Code(s): OSH, KWP, KWQ, MNH, MNI and NKB

IV. **Description:** 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.

A subset of CD HORIZON® Spinal System components may be used for posterior pedicle screw fixation in pediatric cases. These constructs may be comprised of a variety of shapes and sizes of rods (ranging in diameter from 3.5mm to 6.35mm), hooks, screws, CROSSLINK® Plates, and connecting components. Similarly to the CD HORIZON® implants used in adult cases, these components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Certain components within the CD HORIZON® Spinal System are specifically excluded for use in pediatric patients. These include PEEK rods, CD HORIZON® SPIRE spinous process plate devices, Shape Memory Alloy Staples, DYNALOK® bolts, TSRH® screws and washers. All screws used in pediatric cases are only cleared for use via a posterior approach. All of the components used in pediatric cases are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy and medical grade cobalt-chromium-molybdenum alloy.

Certain implant components from other Medtronic spinal systems can be used with the CD HORIZON® Spinal System in non-pediatric cases. These components include TSRH® rods, hooks, screws, plates, CROSSLINK® plates, connectors, staples and washers, GDLH® rods, hooks, connectors and CROSSLINK® bar and connectors; LIBERTY® rods and screws; DYNALOK® PLUS and DYNALOK CLASSIC® bolts along with rod/bolt connectors; and Medtronic Multi-Axial rods and screws. Please note that certain components are specifically designed to connect to ϕ3.5mm, ϕ4.5mm, ϕ5.5mm rods or ϕ6.35mm rods, while other components can connect to both ϕ5.5mm rods and ϕ6.35mm rods. Care should be taken so that the correct components are used in the spinal construct.

CD HORIZON® hooks are intended for posterior use only. CD HORIZON® staples and CD HORIZON® ECLIPSE® rods and associated screws are intended for anterior use only. However, for patients of smaller stature and pediatric patients, CD HORIZON® 4.5mm rods and associated components may be used posteriorly.

The CD HORIZON® Spinal System implant components are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, medical grade cobalt-chromium-molybdenum alloy, or medical grade PEEK OPTIMA-LT1. Certain CD HORIZON® Spinal System components may be coated with hydroxyapatite. No warranties express, or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MDT Catalog for further information about warranties and limitations of liability.

Never use stainless steel and titanium implant components in the same construct. Medical grade titanium, titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy may be used together. Never use titanium, titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy with stainless steel in the same construct.

The CD HORIZON® Spinal System also includes anterior staples made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium, titanium alloy and cobalt-chromium-molybdenum alloy. Do not use with stainless steel. These staples are not to be used in pediatric patients.

PEEK OPTIMA-LT1 implants may be used with stainless steel, titanium or cobalt-chromium-molybdenum alloy implants. CD HORIZON® PEEK Rods are not to be used with CROSSLINK® Plates or in pediatric patients.

To achieve best results, do not use any of the CD HORIZON® Spinal System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another Medtronic document. As with all orthopaedic and neurosurgical implants, none of the CD HORIZON® Spinal System components should ever be reused under any circumstances.

The purpose of this 510(k) submission is to expand the indications of use to allow for use of pedicle screw based constructs to treat pediatric patients.

V. **Indications for Use**: 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 and/or lordosis); tumor; pseudarthosis; 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 adolescent idiopathic scoliosis. The CD HORIZON® Pediatric Spinal System is intended 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, 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.

V1. **Clinical Assessment**: Published clinical data of pediatric patients diagnosed with adolescent idiopathic scoliosis and treated specifically with CD HORIZON® Spinal System pedicle screw instrumentation was provided in support of this application. This data included results of more than 600 pediatric patients treated with pedicle screw constructs alone, along with more than 900 patients treated with a hybrid construct consisting of both pedicle screws and hooks.

VII. **Substantial Equivalence**: The design features, material and indications for use of the CD HORIZON® Spinal System are substantially equivalent to the Orthobiom Spinal System (Paradigm Spine) previously cleared in K071668 (SE 07/02/2008) and to the Synthes Small Stature USS Spinal System applications K082572 (SE 11/24/08) and in K994121 (SE 10/17/00). No new implants were included in this application as this submission sought only to expand the indication for posterior pedicle screw constructs previously cleared by the FDA, including those in K091974, SE 09/02/09 for use in pediatric patients diagnosed with adolescent idiopathic scoliosis. The safety and effectiveness of the CD HORIZON® Spinal System for this expanded indication has been adequately supported by reported clinical results of this and similar devices which is contained within this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 30 2011

Medtronic Sofamor Danek USA, Inc.
% Ms. Lila Joe
Sr. Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K111942
Trade/Device Name: TSRH Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP, KWQ
Dated: August 04, 2011
Received: August 05, 2011

Dear Ms. Joe:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions/Warnings/Contraindications section of the device's labeling:

"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."

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (301) 796-6926. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Christy Foreman

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K111942

Device Name: TSRH® Spinal System

Indications for Use:
When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients using allograft and/or autograft, the TSRH® Spinal System is indicated as an adjunct to fusion for one or more of the following: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, (5) scoliosis, (6) kyphosis, (7) spinal tumor, and/or (8) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the TSRH® Spinal System is indicated as an adjunct to fusion for skeletally mature patients using allograft and/or autograft: (1) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint: (2) who are receiving fusions using autogenous bone graft only: (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the TSRH® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spondylolisthesis, (3) fracture, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) spinal stenosis, (6) pseudarthrosis, (7) tumor resection, and/or (8) unsuccessful previous attempts at spinal fusion.

When used as a unilateral supplemental fixation device in the antero-lateral thoracic/lumbar region, the TSRH® L-Plate and VANTAGE™ screws are intended for the following indications: spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

For anterior use only the TSRH® Spinal System has the additional indication of: spondylolysis.

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

Prescription Use __X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (21CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

Pg 1 of 1

K111942

TSRH® Spinal System
510(k) Summary

August 4, 2011

AUG 30 2011

I. Company:

Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: Lila Joe
Prin. Regulatory Affairs Specialist

II. **Proposed Proprietary Trade Name:** TSRH® Spinal System

III. **Classification Name(s):** Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis, and Pedicle Screw Spinal System (per 21CFR Section 888.3050, 888.3060, and/or 888.3070, respectively);
Product Code(s): KWQ, KWP, MNI, MNH, NKB, OSH

IV. **Description:**

The TSRH® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors, staples, plates, 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.

A subset of TSRH® Spinal System components may be used for posterior pedicle screw fixation in pediatric cases. These constructs may be comprised of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK® Plates, plates, and connecting components as well as CD HORIZON® Spinal System components cleared for pediatric use such as Low Profile MULTI-SPAN® CROSSLINK® Plates, and CD HORIZON® rods, screws, set screws and locking screws. Similarly to the TSRH® implants used in adult case, these components can be rigidly locked into a variety of configurations, with each construct being tailored-made for the individual case. All screws used in pediatric cases are only cleared for use via a posterior approach. All of the components used in pediatric cases are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy and medical grade cobalt –chromium-molybdenum alloy.

K111942

TSRH® Spinal System staples, unit rods, s-rods and 7.0 mm diameter rods are specifically excluded for use in pediatric patients.

Certain implant components from other Medtronic spinal systems can be used with the TSRH® Spinal System in non-pediatric components. These components include GDLH® rods, rod/bolt connectors, Variable Angle T-bolts, set screws and locking screws; DYNALOK® PLUS bolts, and VANTAGE™ Anterior Fixation System screws.

The hooks are intended for posterior use only. The staples are for anterior use only. The TSRH-3D® and TSRH® 3Dx™ connectors, and TSRH-3D® and TSRH® 3Dx™ screws are intended for posterior use only. Within the TSRH® family, the cobalt chromium rods should only be used with TSRH® 3Dx™ Spinal System. All CROSSLINK® Plates are for posterior use and the CROSSLINK® Axial and Offset Plates may be used anteriorly as well.

The TSRH® Spinal System implant components are fabricated from medical grade stainless steel, medical grade titanium or titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy. Medical grade titanium, titanium alloy, and/or cobalt-chromium-molybdenum alloy may be used together. Certain TSRH® Spinal System components may be coated with hydroxyapatite. Never use titanium, titanium alloy, and/or cobalt-chromium-molybdenum alloy with stainless steel in the same construct.

No warranties, express, or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MDT Catalog for further information about warranties and limitations of liability.

To achieve best results, do not use any of the TSRH® Spinal System implant components with components from any other system, except those components listed above, or any other manufacturer. As with all orthopaedic and neurosurgical implants, none of the TSRH® Spinal System components should ever be reused under any circumstances.

V. Indications for Use:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients using allograft and/or autograft, the TSRH® Spinal System is indicated as an adjunct to fusion for one or more of the following: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, (5) scoliosis, (6) kyphosis, (7) spinal tumor, and/or (8) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the TSRH® Spinal System is indicated as an adjunct to fusion for skeletally mature patients using allograft and/or autograft: (1) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint: (2) who are receiving fusions using autogenous bone graft only: (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the TSRH® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spondylolisthesis, (3) fracture, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) spinal stenosis, (6) pseudarthrosis, (7) tumor resection, and/or (8) unsuccessful previous attempts at spinal fusion.

When used as a unilateral supplemental fixation device in the antero-lateral thoracic/lumbar region, the TSRH® L-Plate and VANTAGE™ screws are intended for the following indications: spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

For anterior use only the TSRH® Spinal System has the additional indication of: spondylolysis.

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

VI. Summary of the Technological Characteristics

The purpose of this Special 510(k) submission is to include a 5.5mm diameter rod that is 500mm long and manufactured from ASTM F1537 Wrought Cobalt-28Chromium-6Molybdenum Alloy that is single annealed.

The legally marketed predicate is the CD HORIZON® Chromaloy 5.5mm diameter x 500mm long rod cleared to be used with the TSRH® Spinal System by the Agency in the K093058 (S.E. 10/28/2009) and the TSRH® Chromaloy+ Precut Contoured 5.5mm Diameter Rods in lengths from 30mm - 120mm cleared in K103049 (S.E. 12/23/2010).

K111942

The table below lists the differences between the predicate devices and the subject device.

Predicate CD HORIZON Spinal System (K093058)	Predicate TSRH® Spinal System (K103049)	Subject TSRH® Spinal System Rod
Material Wrought Cobalt – 28Chromium – 6Molybdenum, Double Annealed (ASTM F1537)	Wrought Cobalt – 28Chromium – 6Molybdenum, Single Annealed (ASTM F1537)	Wrought Cobalt – 28Chromium – 6Molybdenum, Single Annealed (ASTM F1537)
Length 500mm	30mm ≅ 120mm	500mm
Diameter 5.5mm	Identical	Identical
Shape Straight	Contoured	Straight
Fundamental Scientific Technology (Rod and Screw System)	Identical	Identical

VII. Identification of Legally Marketed Devices

Documentation was provided demonstrating that the TSRH® Spinal System is substantially equivalent to other commercially available fixation systems including the TSRH® Spinal System in K093058 (S.E. 10/28/2009), K103049 (S.E. 12/23/2010), and K110070 (S.E. 6/8/2011).

VIII. Discussion of the Non-Clinical Testing

Subject Device: TSRH® 3Dx Chromaloy Plus Straight 5.5mm Diameter Rod

The test performed per ASTM F1798-97 (2008). "Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants." (approved 2003) was axial grip around the rod.

The test performed per ASTM F2193 (2002). "Standard Specifications and Test Methods fro Components Used in the Surgical Fixation of the Spinal Skeletal System." (approved June 2002) was four point fatigue testing.

Medtronic believes that the results of the testing performed above and supporting documentation provided in this Special 510(k) submission demonstrate that the subject TSRH® 3Dx Chromaloy Plus 5.5mm diameter x 500mm long rod does not introduce new issues of safety, effectiveness, or performance.

K111942

IX. Conclusion

The TSRH® 3Dx CHROMALOY™ + Straight 5.5mm Diameter Rod is identical to its predicate devices in the indications, material, diameter, sterilization, surgical technique, and fundamental scientific technology. Additionally, a risk analysis was completed and non-clinical mechanical testing was performed in accordance to ASTM F1798-97 and ASTM F2193 that demonstrates the subject device does not introduce new issues of safety, effectiveness, or performance. Therefore, the subject device is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2000

Mr. Jonathan M. Gilbert
Senior Regulatory Affairs Associate
SYNTHES (USA)
1690 Russell Road
Post Office Box 1766
Paoli, Pennsylvania 19301

Re: K994121
Trade Name: Small Statue USS
Regulatory Class: II
Product Code: MNI, MNH and KWP
Dated: July 19, 2000
Received: July 20, 2000

Dear Mr. Gilbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

Page 1 of 1

510(k) Number (if known): NA K994121

Device Name: Synthes Small Stature USS

Indications for Use:

When used as a posterior pedicle screw fixation system, the Synthes Small Stature USS is intended to provide immobilization and stabilization of spinal segments in skeletally mature **patients (including small stature)** 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 spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

In addition, the Synthes Small Stature USS is intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature **patients (including small stature) and pediatric patients** receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of the implants after the attainment of a solid fusion. The levels of pedicle screw fixation for these patients are L3-S2.

When used as a posterior non-pedicle screw fixation **system in skeletally mature patients (including small stature) and pediatric patients**, the Synthes Small Stature USS is intended for scoliotic, lordotic, or kyphotic deformities (such as scoliosis, Schuermann's disease), degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), and fractures of the posterior thoracolumbar spine.

The anterior components of the Synthes Small Stature USS **when used in skeletally mature patients (including small stature) and pediatric patients** are intended for anterolateral screw and/or staple fixation for the correction of anterolateral lordotic deformities for the spine, lumbar scoliosis, pseudoarthrosis, and fracture or dislocation of the thoracolumbar spine (levels T8-L5).

In addition, when used with 3.5/5.0mm parallel connectors, the Synthes Small Stature USS can be linked to the CerviFix System. When used with 5.0/6.0mm parallel connectors, the Synthes Small Stature USS can be linked to the Universal Spinal System

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994121

K994121

OCT 17 2000

Synthes Small Stature USS
Summary of Safety and Effectiveness
12/2/99

SYNTHES (U.S.A.)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Device
Synthes Small Stature USS

Product Description
The Synthes Small Stature USS consists of a variety of rods, hooks, screws, staples and other connecting components used to build a spinal construct. Instrumentation is also available to facilitate implantation of the device components.

Certain implant components from the Synthes Small Stature USS can be used to connect the rods of the Synthes Small Stature USS to rods of other Synthes posterior spinal systems (USS or CerviFix).

Indications
When used as a posterior pedicle screw fixation system, the Synthes Small Stature USS is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients (including small stature) 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 spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

In addition, the Synthes Small Stature USS is intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients (including small stature) and pediatric patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of the implants after the attainment of a solid fusion. The levels of pedicle screw fixation for these patients are L3-S2.

When used as a posterior non-pedicle screw fixation system in skeletally mature patients (including small stature) and pediatric patients, the Synthes Small Stature USS is intended for scoliotic, lordotic, or kyphotic deformities (such as scoliosis, Schuermann's disease), degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), and fractures of the posterior thoracolumbar spine.

The anterior components of the Synthes Small Stature USS when used in skeletally mature patients (including small stature) and pediatric patients are intended for anterolateral screw and/or staple fixation for the correction of anterolateral lordotic deformities for the spine, lumbar scoliosis, pseudoarthrosis, and fracture or dislocation of the thoracolumbar spine (levels T8-L5).

In addition, when used with 3.5/5.0mm parallel connectors, the Synthes Small Stature USS can be linked to the CerviFix System. When used with 5.0/6.0mm parallel connectors, the Synthes Small Stature USS can be linked to the Universal Spinal System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Musculoskeletal Clinical Regulatory Adviser, LLC
% Mr. Justin Eggleton
1131 H Street NW
12th Floor
Washington, DC 20005

JUL - 2 2008

Re: K071668
Trade/Device Name: Orthobiom™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI
Dated: April 2, 2008
Received: April 3, 2008

Dear Mr. Eggleton:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071668

Device Name: Orthobiom™ Spinal System

Indications for Use:

The Orthobiom™ Spinal System is a posterior, non-cervical pedicle screw system indicated to treat pediatric scoliosis by (1) correction, (2) stabilization, (3) adjustment and (4) fixation of the scoliotic spine.

The Orthobiom™ Spinal System is intended to be used with bone graft.

Prescription Use __√__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071668

ATTACHMENT K

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

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 F1717 - 04 (2004)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 181	
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: Spinal System 510(k) - Guidance for Industry and FDA Staff, issued on May 3, 2004

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[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 www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F1717 - 04 (2004)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Applicable		☑ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

* 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.

* 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.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☑ Special ☐ Abbreviated

STANDARD TITLE[1]

ASTM F1798-97 (2003)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3]	# 172	
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: Spinal System 510(k) - Guidance for Industry and FDA Staff, issued on May 3, 2004

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[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 www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F1798-97 (2003)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Applicable		☑ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

* 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.

* 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.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☑ Special ☐ Abbreviated

STANDARD TITLE[1]

ISO 5832-3 (1996)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3] # 017		
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: Spinal System 510(k) - Guidance for Industry and FDA Staff, issued on May 3, 2004

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[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 www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 5832-3 (1996)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Applicable		☐ Yes ☐ No ☑ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◊		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◊		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◊		
DESCRIPTION		
JUSTIFICATION		

* 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.

◊ 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.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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.

stryker®

Spine

December 09, 2011

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

RE: Traditional 510(k) Application
Stryker Spine XIA® 3 Spinal System

To Whom It May Concern:

In accordance with 21 CFR 807, Section E, Stryker Spine is submitting this Traditional Premarket Notification for the XIA® 3 Spinal System.

We are providing an electronic copy (eCopy) of this 510(k) per FDA's web instructions, and it is an exact duplicate of the paper copy.

Stryker Spine believes this device system is substantially equivalent to the following predicate devices:

510(k)	Company Name	Device Name
K111492	Medtronic Sofamor Danek	TSRH Spinal System
K091445	Medtronic Sofamor Danek USA	CD HORIZON Spinal System
K071668	Paradigm Spine	Orthobiom Spinal System
K071373	Stryker Spine	XIA 3 Spinal System
K994121	Synthes	USS Small Stature

With this letter, you may contact and discuss with Ms. Rogers any matters pertaining to this Stryker Spine Premarket Notification and associated FDA activities.

Stryker Spine considers all the material provided herein as Privileged and Confidential. We request that the FDA handle this information as such per the provisions detailed in 21 CFR §20.61.

Notice of the FDA decision to this Premarket Notification, should be faxed to the attention of Ms. Rogers at 201-760-8406 and forward an electronic copy of the letter to Tiffani.Rogers@stryker.com.

Kind regards,

Tiffani Rogers
Stryker Spine

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
December 9, 2011	(b) (4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (120 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class 3 Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Stryker Spine	3004024955		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	201-760-8206		
Street Address	**FAX Number *(including area code)***		
2 Pearl Court	201-760-8406		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Allendale	New Jersey	07401	USA
Contact Name			
Tiffani Rogers			
Contact Title	**Contact E-mail Address**		
Manager, Regulatory Affairs	Tiffani.Rogers@stryker.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Musculoskeletal Clinical Regulatory Advisers, LLC			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Regulatory Affairs	(202) 552-5800		
Street Address	**FAX Number *(including area code)***		
1331 H Street NW, 12th Floor	(202) 552-5798		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Washington	DC	20005	USA
Contact Name			
Glenn Stiegman			
Contact Title	**Contact E-mail Address**		

Vice President, Regulatory and Clinical Affairs	gstiegman@mcra.com

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☒ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	OSH	2	NKB	3	MNH	4	MNI
5	KWP	6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K091445	1	CD HORIZON Spinal System	1	Medtronic Sofamor Danek USA
2	K071668	2	Orthobiom Spinal System	2	Paradigm Spine
3	K071373	3	XIA 3 Spinal System	3	Stryker Spine
4	K994121	4	USS Small Stature System	4	Synthes Spine
5	K111942	5	TSRH Spinal System	5	Medtronic Sofamor Danek
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Pedicle Screw Spinal System

	Trade or Proprietary or Model Name for This Device		Model Number
1	XIA 3 Spinal System	1	See Device Description Section
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Codes	C.F.R. Section *(if applicable)*	Device Class
OSH	21 CFR 888.3070	☐ Class I ☒ Class II ☒ Class III ☐ Unclassified

Classification Panel

Orthopedic

Indications *(from labeling)*

The XIA 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative disc disease (DDD) (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, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

The Ø5.5mm rods from the Stryker Spine Radius Spinal System and Ø6.0mm Vitallium rods from the XIA Spinal System are intended to be used with the other components of XIA 3 Spinal System

When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The XIA 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H	MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number 3003112432	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☒ Repackager / Relabeler	
Company / Institution Name Stryker Spine		Establishment Registration Number 9617544		
Division Name *(if applicable)* 		Phone Number *(including area code)* 33 557 970 840		
Street Address Zone Industrielle Demarticot		FAX Number *(including area code)* 33 557970827		
City Cestas		State / Province Aquitaine	ZIP/Postal Code 33610	Country France
Contact Name Philippe Faucher	Contact Title Sr. Director Quality Assurance		Contact E-mail Address Philippe faucher@stryker.com	

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number 3005525032	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name Stryker Spine		Establishment Registration Number 3005525032		
Division Name *(if applicable)* 		Phone Number *(including area code)* 33 577 97 08 40		
Street Address Le Cret Du Locle 10a		FAX Number *(including area code)* 		
City La Chaux De Fonds, Switzerland		State / Province 	ZIP/Postal Code 	Country
Contact Name Philippe Faucher	Contact Title Sr. Director Quality Assurance		Contact E-mail Address Philippe faucher@stryker.com	

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number 3004024955	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☒ Repackager / Relabeler	
Company / Institution Name Stryker Spine		Establishment Registration Number 		
Division Name *(if applicable)* 		Phone Number *(including area code)* 		
Street Address 		FAX Number *(including area code)* 		
City 		State / Province 	ZIP/Postal Code 	Country
Contact Name Tiffani Rogers	Contact Title Manager, Regulatory Affairs		Contact E-mail Address Tiffani.rogers@stryker.com	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No.	Standards Organization	Standards Title See Forms 3654 provided in Attachment K.	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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

Medical Device User Fee Cover Sheet

1. Table of Contents

2. Administrative Information

2.1 510(k) Sponsor

Stryker Spine
2 Pearl Court
Allendale, NJ 07401
Establishment Registration Number: 3004024955

2.2 Manufacturer

Stryker Spine
ZI Marticot 33610
Cestas, France
Establishment Registration Number: 9617544

And

Stryker Spine
Le Cret Du Locle 10a
La Chaux De Fonds
Switzerland 2300
Establishment Registration Number: 3005525032

2.3 Submission Correspondent

Tiffani Rogers
Stryker Spine
Office: 201-760-8206
Fax: 201-760-8406
Tiffani.Rogers@stryker.com

2.3 Device Information

Trade Name: XIA® 3 Spinal System

Device Type: Pedicle Screw Spinal System

2.4 New Device Classification

Class: II

Classification: 21 CFR 888.3070

Classification Name: Pedicle Screw Spinal System

Product Code: OSH

2.5 Additional Device Classifications (K071373, K083393, K091291)

Class: II / III

Classification: 21 CFR 888.3070; 21 CFR 888.3050

Classification Name: Pedicle Screw Spinal System; Spinal Interlaminal Fixation Orthosis

Product Code: KWP, MNH, MNI, NKB

3. Introduction

Overview
The expansion of indications for the XIA 3 Spinal System is proposed for the inclusion of adolescent idiopathic scoliosis alone, and not other indications for a pediatric population. As pediatric patients are unlikely to exhibit symptoms of degenerative disc disease (DDD) or stenosis due to the wear and tear on the spine necessary to develop these diseases, expansion of these indications to a pediatric population is not warranted.

Pediatric Scoliosis
Alterations in normal spinal alignment that occur in the frontal plane are termed scoliosis. The majority of scoliotic deformities are idiopathic; however, others can be congenital, associated with a neuromuscular disorder or syndrome, compensatory from a leg-length discrepancy, or caused by an intraspinal abnormality.

Idiopathic scoliosis is the most common cause of spinal deformity in children and adolescents and can be divided into five groups on the basis of age at onset: infantile (birth–3 yr), juvenile (4–10 yr), adolescent (11- 18 yr or puberty to maturity), adult (18+ or individuals who have reached maturity), and *de novo* (seen in older individuals, its cause may be due to osteoporosis or arthritis.) Adolescent idiopathic scoliosis (AIS) is the most common cause accounting for approximately 80% of cases while infantile idiopathic scoliosis is extremely rare. However, for those children who develop deformities before the age of 5, the prognosis is poor with the potential to exceed 100 degrees in magnitude of scoliosis and subsequent cardiopulmonary complications.[1]

The prevalence of AIS, or deformity in the coronal plane measuring greater than 10 degrees, is 2–3% and about 0.2% require treatment.[2,3] The prevalence of curves in excess of 20 degrees is 0.3 to 0.5% whereas that of curves in excess of 40 degrees is 0.1%.[4] Depending on the criteria used, some studies estimate between 2% to 14% of the North American population is afflicted with scoliosis.[5,6,7,8,9,10,11]

---

[1] Dickson RA: Early-onset idiopathic scoliosis, in Weinstein SL (ed): The Pediatric Spine: Practice and Principles. New York: Raven Press, 1994, pp 421-430.
[2] Rogala EJ, Drummond DS, Gurr J. Scoliosis: incidence and natural history. A prospective epidemiological study. J Bone Joint Surg Am. 1978 Mar;60(2):173-6.
[3] Lowe TG et al. Etiology of Idiopathic Scoliosis: Current Trends in Research. J Bone Joint Surg Am. 2000;82:1157.
[4] Wiggins GC, Shaffrey CI, Abel MF, Menezes AH. Pediatric spinal deformities. Neurosurg Focus. 2003 Jan 15;14(1):e3.
[5] Rogala EJ, Drummond DS, Gurr J. Scoliosis: incidence and natural history. A prospective epidemiological study. JBJS-A 1978; 60 (2): 173-6.
[6] Stirling AJ, Howel D, Millner PA, Sadiq S, Sharples D, Dickson RA. Late-onset idiopathic scoliosis in children six to fourteen years old. A cross-sectional prevalence study. JBJS-A 1996; 78 (9): 1330-6.
[7] Brooks HL, Azen SP, Gerberg E, Brooks R, Chan L. Scoliosis: A prospective epidemiological study. JBJS-A 1975; 57 (7): 968-72.
[8] Morais T, Bernier M, Turcotte F. Age- and sex-specific prevalence of scoliosis and the value of school screening programs. Am J Public Health 1985; 75 (12):1377-80.
[9] Kane WJ. Scoliosis prevalence: a call for a statement of terms. Clinical Orthopaedics 1977; 126: 43-6.

Idiopathic scoliosis occurs in healthy, neurologically normal children and its cause is unknown. The incidence in boys is approximately one tenth that in girls.[12] There appears to be a genetic component, but the disorder is not transmitted in a pure Mendelian fashion. An additional point to note is that idiopathic scoliosis is found all over the world and that incidence is equal among various ethnic groups.[13] Melatonin deficiency was considered a possible cause of human AIS due to that fact that pinealectomy caused scoliosis in chickens but this link has not been demonstrated in humans.[14]

Curve progression in untreated AIS is primarily related to curve size, curve type, gender, and physiologic age.[15,16] Thoracic curves >50° and lumbar curves >40° tend to progress slowly (1 degree per year) after skeletal maturity.[17] Curves of less magnitude at maturity tend to remain stable. In rapidly growing pubertal patients, untreated curves >25° may progress 1° per month. These numbers reflect the rationale for brace treatment in curves >25° in young children and the recommendation for surgical treatment in curves >50° after maturity. In late adulthood, large curves do have increased incidence of back pain and disability in addition to poor cosmesis, but IAS does not appear to increase mortality rate.[18]

Manifestations

Symptoms of AIS may include: difference in shoulder height, the head is not centered with the rest of the body, difference in hip height or position, difference in shoulder blade height or position when standing straight, difference in the way the arms hang beside the body when bending forward, the sides of the back appear different in height. Back pain, leg pain, and changes in bowel and bladder habits are not commonly associated with idiopathic scoliosis. An adolescent experiencing these types of symptoms requires further medical evaluation by a physician.

Pulmonary and cardiac function that are not impeded by lumbar curves and significant changes of pulmonary function are not seen in patients with thoracic curves until the curve reaches a level greater than 70°.[19] According to Nilsonne and Lundergren,[20] the

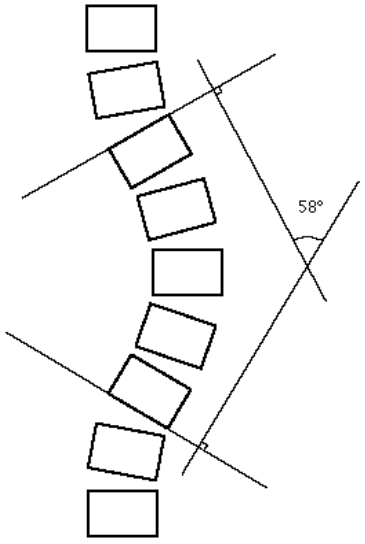
[10]Robitaille Y, Villavicencio-Pereda C, Gurr J. Adolescent idiopathic scoliosis: epidemiology and treatment outcome in a large cohort of children six years after screening. Int J Epidemiol 1984; 13 (3): 319-23.
[11]Payne WK 3rd, Ogilvie JW, Resnick MD, Kane RL, Transfeldt EE, Blum RW. Does scoliosis have a psychological impact and does gender make a difference? Spine 1997; 22 (12): 1380-4.
[12] Dickson RA. The aetiology of spinal deformities. Lancet. 1988 May 21;1(8595):1151-5.
[13] http://www.hss.edu/Conditions/Braces/Idiopathic-Scoliosis
[14]Brodner W et al. Melatonin and adolescent idiopathic scoliosis J Bone Joint Surg Br 2000 82-B: 399-403.
[15] Lonstein JE, Carlson JM. The prediction of curve progression in untreated idiopathic scoliosis during growth. J Bone Joint Surg Am. 1984 Sep;66(7):1061-71.
[16] Peterson LE, Nachemson AL. Prediction of progression of the curve in girls who have adolescent idiopathic scoliosis of moderate severity. Logistic regression analysis based on data from The Brace Study of the Scoliosis Research Society. J Bone Joint Surg Am. 1995 Jun;77(6):823-7.
[17] Weinstein SL, Ponseti IV. Curve progression in idiopathic scoliosis. J Bone Joint Surg Am. 1983 Apr;65(4):447-55.
[18] Pehrsson K, Larsson S, Oden A, Nachemson A. Long-term follow-up of patients with untreated scoliosis. A study of mortality, causes of death, and symptoms. Spine. 1992 Sep;17(9):1091-6.
[19] Aaro S, Ohlund C. Scoliosis and pulmonary function. Spine. 1984 Mar;9(2):220-2.

severe curves (>100°) resulted in death due to cardiac or pulmonary causes in 60% of their cases.

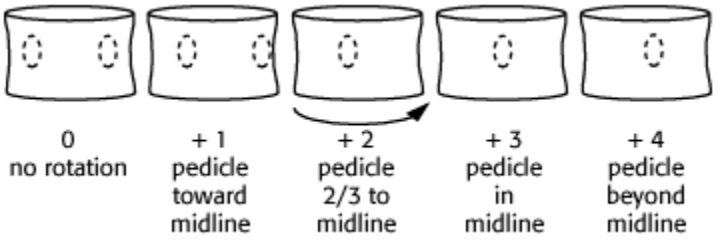
Evaluation

Radiographic examination is the reference standard for evaluation of patients with scoliosis. Standing posteroanterior (PA) and lateral standing radiographs of the entire spine should be obtained for these patients. The degree of curvature is determined by measuring the angular relationships between the most tilted vertebrae at either end of the apparent curve (the Cobb method). A line is drawn across the proximal end-plate of the superior end vertebra and the distal end-plate of the inferior end vertebra, and perpendicular lines are erected. The angle at the intersection of the perpendicular lines determines the degree of curvature.

It should be noted that a certain amount of lateral curvature in the spine is normal. Scoliosis is not diagnosed unless the curve exceeds 10 degrees. Additionally, many mild cases of scoliosis may go undetected because minimal curvature oftentimes does not cause troublesome symptoms.



Once the Cobb angle has been measured, the degree of rotation of the vertebra should be addressed by looking at the relation of the pedicles to midline.



[20]Nilsonne U, Lundgren KD. Long-term prognosis in idiopathic scoliosis. Acta Orthop Scand. 1968;39(4):456-65.

Treatment Options

The course of treatment for patients in different scoliosis age groups varies considerably and depends on a variety of factors including the extent of the curve at the time of diagnosis and during follow-up, the patient's stage of bone growth, the amount of pain and deformity associated with the condition, and the patient's willingness and ability to withstand surgery should it be deemed necessary. For all patients with scoliosis the goal of treatment is the same: to alleviate symptoms and to stop the curve from progressing.

Non-operative / Brace

The easiest way to understand non-surgical treatment options for idiopathic scoliosis is to break down options by age group.

About 80% of all infantile idiopathic scoliosis cases resolve on their own.[21] For all young children with a curve that is less than 30 degrees, the surgeon will observe the patient and examine them at regular intervals. If the curve continues to progress, the infant will be fitted with a brace which is designed to slow or arrest the progression of the curve. Unfortunately, they do not correct the underlying problem and due to the patient's small size it is harder for the surgeon to achieve the correct alignment with the brace. The discomfort and restriction of wearing a brace also presents a challenge for the patient and parent. The goal of non-surgical treatment for these patients is to control the curve so that surgical treatment does not become necessary until the child has achieved most, if not all, of their growth.

For juveniles with idiopathic scoliosis, observation, followed by the use of a brace if the curve progresses, are the only available non-surgical treatment options. Braces work to arrest the curve permanently in about 60% of juvenile patients, and no further treatment is needed.[22] In the remaining group, as with cases of infantile idiopathic scoliosis, the goal is to control the curve well enough so that surgery can be delayed until after the adolescent growth spurt has been reached. Unfortunately, complications of scoliosis can occur requiring the need for surgery prior to that time such as pulmonary compromise and heart disease secondary to pulmonary complications.

Adolescent idiopathic scoliosis patients whose curves remain stable undergo regular physical examinations. A brace is used in the case of curve progression and is approximately 80% effective in preventing curve progression of more than 5 degrees. In addition, braces have been shown in prospective studies to significantly reduce the risk of progression when compared to untreated controls.[23,24,25] If the curve can be controlled at

[21] http://www.hss.edu/Conditions/Braces/Idiopathic-Scoliosis
[22] http://www.hss.edu/Conditions/Braces/Idiopathic-Scoliosis
[23] Nachemson AL, Peterson LE. Effectiveness of treatment with a brace in girls who have adolescent idiopathic scoliosis. A prospective, controlled study based on data from the Brace Study of the Scoliosis Research Society. J Bone Joint Surg Am. 1995 Jun;77(6):815-22.
[24] Lonstein JE, Winter RB. The Milwaukee brace for the treatment of adolescent idiopathic scoliosis. A review of one thousand and twenty patients. J Bone Joint Surg Am. 1994 Aug;76(8):1207-21.

less than 40 degrees, the patient may never require additional treatment. However, if the curve surpasses 45 to 50 degrees, it can be expected to worsen, even after full growth is achieved, and to eventually require surgical treatment.[26] General guidelines include re-evaluation every 4-6 months for patients who are skeletally immature (but still not fully skeletally mature) and have curves less than 25°.[27] Brace management of adolescent idiopathic scoliosis is used in children with spinal deformity and curve magnitudes of 25-40° who are skeletally immature and with significant growth remaining.[28]

Adult idiopathic scoliosis patients receive treatment based on symptoms. For patients experiencing pain and restrictions on mobility, pain medication and physical therapy are prescribed. The use of braces offers little benefit, and is reserved for short term pain relief in a minority of patients. As with younger patients, the decision to proceed to surgical treatment is guided by progression of the curve and related symptoms. Since the spine is a mobile structure, it does not spontaneously fuse until beyond 70 to 80 years of age. So these patients experience a prolonged period of pain. It should be noted that adults with progressive deformities should forgo non-surgical treatment for surgical treatment ideally when they are in the 40s and/or 50s because at later points they become inoperable on the basis of age and associated risk factors, including poor bone density.

Studies of brace compliance show that patients actually wear braces about 65% of the time recommended and that braces must be used at least 16 hours per day to be effective.[29]

Surgical Alternatives

Historically, the primary surgical treatment for scoliosis was to fuse those areas of the spine in which the curve was developing. While this process prevented progression of the curve it also prohibited additional growth of the spine. In addition, this surgery was followed by a long recovery period in a cast.

However, Dr. Paul Harrington invented a device that could provide stability and correction of the scoliotic spine, while possibly allowing spine growth. Depending on the patient and the scoliosis progression, fusion was also a possibility. However, it was one of the "internal braces" used to correct and maintain the scoliotic spine. Other similar devices were the Dwyer device, Luque device, and Zielke device. All of these devices were the innovative scoliosis devices that led to the current standard of care of AIS.

The current standard of care is to provide some instrumentation and fuse the apical level (i.e., fusing only the level at which the curve is progressing) or the entire spine. Some

[25]Fernandez-Feliberti R, Flynn J, Ramirez N, Trautmann M, Alegria M. Effectiveness of TLSO bracing in the conservative treatment of idiopathic scoliosis. J Pediatr Orthop. 1995 Mar-Apr;15(2):176-81.

[26] Ascani E et al. Natural history of untreated idiopathic scoliosis after skeletal maturity. Spine. 1986 Oct;11(8):784-9.

[27] http://www.srs.org/patients/review/default.asp?page=7

[28] Lonstein JE, Winter RB. The Milwaukee brace for the treatment of adolescent idiopathic scoliosis. A review of one thousand and twenty patients. J Bone Joint Surg Am. 1994 Aug;76(8):1207-21.

[29] DiRaimondo CV, Green NE. Brace-wear compliance in patients with adolescent idiopathic scoliosis. J Pediatr Orthop. 1988 Mar-Apr;8(2):143-6.

methods of correction include hemiepiphysiodesis or removing a piece of the vertebral body to straighten the spine, fusing that level, and maintaining correction with instrumentation. For today, surgery for scoliosis is more sophisticated and combines the fusing procedure with instrumentation. This procedure may require more than one operation as the surgeon may need to approach the site from different angles. For younger patients alternatives are available that help preserve growth. With the use of instrumentation, recovery is also significantly shortened.

If the early–onset curve fails to be halted by several attempts with brace therapy, surgery should be considered for infants or juveniles once the curve exceeds 55 to 60 degrees. The placement of spinal instrumentation without fusion is the preferred procedure in patients younger than 9 years of age.[30] This technique involves placing an internal brace to hold the spine in proper alignment, and then adjusting these instruments periodically to correct the curve and to accommodate the growing spine. This is often considered preferable to pursuing definitive treatment (i.e., fusion) since it offers the patient the best chance to achieve normal growth and height. The drawback to this technique is that it requires multiple operations, the first to implant the devices, and subsequent ones to adjust the rods. These surgeries are needed about every six months-whenever the curve is seen to progress-and continue until the patient has reached puberty or enters a period of growth spurt, or patient and physician decide to go on to a final, definitive surgical treatment ideally once adolescence is reached. Complications can occur such as an instrument breaking or pulling out of the bone. Although these complications are not life-threatening they require surgical correction. Furthermore, in addition to the physical pain and discomfort associated with surgery, the psychological prospect of repeated operations can be quite discouraging. Finally, the amount of additional growth that is achieved using this technique is somewhat limited and may amount to no more than a few inches in height.

By fusing the entire spine, this will arrest the growth of the spine. The primary drawback to proceeding to a definitive surgery is that although the spine is elongated by straightening the curve, the patient's natural growth is arrested. The choice of surgical treatment is therefore often based on the age of the infant or child and how close they are to puberty and skeletal maturity.

In adolescents with progressive curves who have achieved full bone growth, definitive surgery is recommended. Performed successfully, no further treatment is needed. The standard of care for these patients is the use of rigid rods and screws to correct their curve surgically. Recently, these rigid rod and screw systems are gaining marketing clearance and are able to safely and effectively treat these patients. In many cases, rigid rod and screws must be used due to the severity of curve.

A limited amount of clinical outcome data is present in the literature for patients treated for adolescent idiopathic scoliosis. This is understandable, as pediatric patients with scoliotic deformity generally do not experience the level of pain and functional

[30] Dickson RA: Early-onset idiopathic scoliosis, in Weinstein SL (ed): The Pediatric Spine: Practice and Principles. New York: Raven Press, 1994, pp 421-430.

impairment as older patients with DDD, stenosis, or spondylolisthesis. However, those studies that did include clinical outcome measurements, specifically those created by the Scoliosis Research Society (SRS), demonstrated significant clinical benefit in patients who receive posterior pedicle screw systems following surgery. The curve correction obtained utilizing posterior instrumentation with pedicle screws is hypothesized to achieve better clinical results by achieving proper alignment of the spine, allowing for greater pulmonary function and patient mobility. The long-term stabilization of these curvatures allows for continued clinical success throughout long term follow up of these pediatric patients into early adulthood.

In the United States, the CD HORIZON and TSRH systems, manufactured by Medtronic Sofamor Danek, are both cleared for use with an AIS indication. Other systems with literature data for AIS are the MOSS MIAMI System manufactured by DePuy Spine, and the Universal Spinal System (USS), manufactured by Synthes. In the majority of clinical studies for AIS, the results from patients receiving different spinal systems were pooled due to similar effectiveness of these systems, as specifically noted in a study by Wright et al (2007). In this study, patient outcomes with 2 different systems (USS and MOSS MIAMI) demonstrated no statistically significant differences in clinical or radiographic outcomes between treatments, showing the interchangeability of clinical results from cleared spinal systems.

This pooled data on the use of posterior instrumentation for the treatment of adolescent idiopathic scoliosis has shown a favorable safety profile, with complication rates similar to the use of posterior instrumentation for other indications. A review of complications from multiple studies by Hicks et al. (2010)[31] demonstrated a low level (<5%) of complications when reviewing the literature on various pedicle screw systems for the treatment of adolescent idiopathic scoliosis, including Medtronic CD HORIZON system currently cleared for the treatment of AIS in the US. Screw malpositioning (4%) and infection (1%) were the largest single adverse events present in the studies reviewed, with all other complications occurring in less than 1% of the reviewed patient population.

In contrast, Thomsen et al. (1997)[32] noted 4.8% of patients having misplaced pedicle screws and 1.6% deep wound infections in a study of posterior instrumentation with pedicle screws utilized for the treatment of Grade I or II spondylolisthesis. In addition, the overall low rates of pedicle breakage and screw loosening noted in the literature review specifically address concerns specific to a pediatric population for the treatment of scoliosis, as bone size is smaller in these patients and bone has not completely developed to an adult stage of durability. The rates of adverse events were similar for other indications and skeletally mature patients. There are no event rates or risks for this population that has not been characterized for skeletally mature patients.

[31] Hicks JM, Singla A, Shen FH, Arlet V. Complications of pedicle screw fixation in scoliosis surgery: a systematic review. Spine (Phila Pa 1976). 2010 May 15;35(11):E465-70.
[32] Thomsen K, Christensen F, Eiskjaer S, Hansen E, Fruensgaard S, Bunger C, and Mardjetko S. The Effect of Pedicle Screw Instrumentation on Functional Outcome and Fusion Rates in Posterolateral Lumbar Spinal Fusion: A prospective, Randomized Clinical Study. Spine, 22(24): 2813 – 2822, 1997.

As demonstrated in the literature, data from pedicle screw systems present significant evidence for the overall safety of posterior instrumentation for the treatment of adolescent idiopathic scoliosis, as well as the interchangeability of clinical results between rod and pedicle screw based systems from different manufacturers.

4. Device Description

4.1 Design

The XIA 3 Spinal System is designed as a pedicle screw system for non-cervical use in support of spinal fusion. It includes monoaxial, polyaxial, uniplanar, and closed bone screws, blockers (as a locking mechanism), rods (straight and pre-bent), hooks, cross connectors (monoaxial and polyaxial), offset connectors, and rod to rod connectors.

The purpose of this 510(k) is to expand the Indications for Use to include Adolescent Idiopathic Scoliosis (AIS).

> The XIA 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:
>
> - Degenerative disc disease (DDD) (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, and/or lordosis);
> - Tumor;
> - Pseudoarthrosis; and
> - Failed previous fusion.
>
> The Ø5.5mm rods from the Stryker Spine Radius Spinal System and Ø6.0mm Vitallium rods from the XIA Spinal System are intended to be used with the other components of XIA 3 Spinal System
>
> **When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The XIA 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.**

An illustration of the XIA 3 Spinal System is provided in **Figure 4-1**.

Figure 4-1: XIA 3 Spinal System

All components described below are identical to those described in K071373, K083393, and K091291. The Uniplanar and Uniplanar Reduction screws were added to the Xia 3 System via K091291, while the angled, closed head, offset connectors, and rod to rod connectors were added under K083393.

XIA 3 Polyaxial Screws

Polyaxial Screw

The polyaxial screw is composed of a bone screw and a screw head; see Figure 4-2 below. The bone screw is pressed into the screw head from the top of the screw head, after which the head can rotate freely with respect to the bone screw. The polyaxial screws are offered in diameters ranging from 4.0mm to 7.5mm and in lengths ranging from 20mm to 90mm. The subject polyaxial screws are colored by diameter.

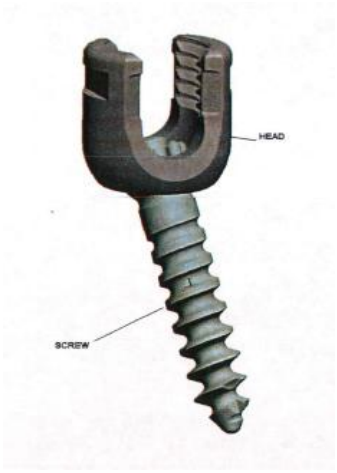


Figure 4-2: Polyaxial Screw

Screw Head
The screw head couples the rod to the bone screw. The screw head is the same for the entire subject polyaxial screws. The screw head features the previously cleared 10mm XIA buttress thread (K013823) and grooves and recesses which serve as instrument interfaces. It is 14mm in diameter and 15.3mm in height.

Figure 4-3: Screw Head

Bone Screw
The bone screw has a spherical head and features six point drive geometry that are used to drive the screw into the bone. The threaded portion of the screw conforms to the previously cleared XIA thread design (K013823): a tapering minor diameter and a

constant outer diameter. The tip of the screw is tapered to facilitate screw introduction and advancing the screw in hard bone.

Figure 4-4: Bone Screw

XIA 3 Monoaxial Screws

Monaxial Screw
The monoaxial screw has a fixed head and is offered in diameters ranging from 4.0mm to 7.5mm and in lengths ranging from 20mm to 90mm. The screws are colored by diameter. The monoaxial screw has a head and a threaded portion. The head is 14mm in diameter and has a 10mm run on the rod. The monoaxial screw utilizes the same XIA buttress thread, the XIA bone thread and the grooves and recesses which serve as instrument interfaces (K013823). The tip of the screw is tapered like that of the subject polyaxial bone screw.

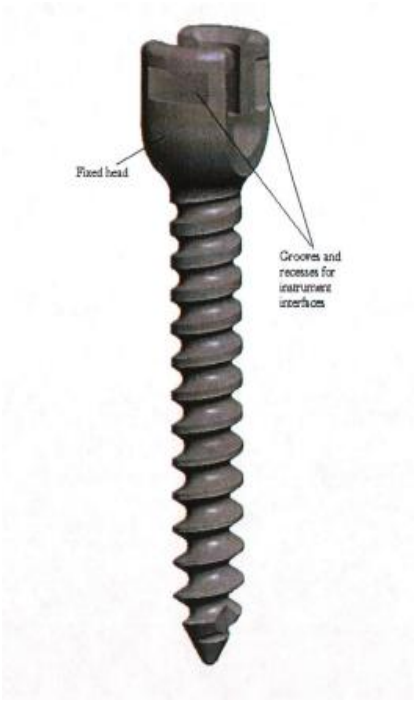


Figure 4-5: Monoaxial Screw

Xia 3 Uniplanar Screw

The Uniplanar and Reduction Uniplanar screws are bone screws that allow polyaxiality in one plane, the Cephalic – Caudal plane. The screws are fixed in the medial – lateral plane. The Uniplanar and Reduction Uniplanar screws range from 4.5mm to 7.5mm diameters and in lengths of 20mm to 60mm in 5mm increments. Illustrations of both the Uniplanar and Reduction Uniplanar Screws are provided below as **Figure 4-6**.

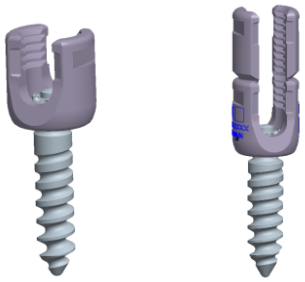


Figure 4-6: Uniplanar and Reduction Uniplanar Screws

XIA 3 Closed Head Screw

The monoaxial and polyaxial closed head screws are available in 6.5mm to 9.5mm diameters and in lengths ranging from 30mm to 100mm. The Closed Head Polyaxial screws feature a small closed head to allow low profile. The rod locks to the screw with an M6x1setscrew.

Figure 4-7: Closed Head Monoaxial and Polyaxial Screws

XIA 3 Angled Screws

The XIA 3 Angled screws are available in a Biased Angle Polyaxial design ranging from Ø4.0mm to Ø9.5mm in diameter and from 20mm to 100mm in length are designed to allow the screw head to rotate freely with respect to the bone screw with a biased angle to give additional angulation in the Cephalic Caudal direction to facilitate easier rod insertion into tulip.

A Medial Biased Angle Polyaxial Screw ranging from Ø4.0mm to Ø9.5mm in diameter and from 20mm to 100mm in length is also available and is designed to allow the screw head to rotate freely with respect to the bone screw with a biased angle. This provides more angulation in the Medial Lateral direction, facilitating easier rod insertion into tulip. Biased Angle Polyaxial screws designed with buttress thread to reduce spreading forces during final tightening.

Finally, Angled Monoaxial Screws ranging from Ø6.5mm to Ø9.5mm in diameter and from 60mm to 100mm in length are designed with a fixed 15˚angle screw head are also included in the XIA 3 System.

Figure 4-8

Biased Angle Polyaxial Screw

Medial Biased Angle Polyaxial Screw

Angled Monoaxial Screw

XIA 3 Blocker

The blocker locks either a 5.5mm diameter or 6.0mm diameter rod to the screw (polyaxial and monoaxial) and the hook. This is a 10mm buttress set screw. The design of the subject blocker is identical to the design of the XIA blocker cleared via K071373.

Figure 4-9: Blocker

XIA 3 Hooks

Hooks have a head and a blade (see picture below). The head design is the same for all hooks and is identical to the head of the monoaxial screw: the outer diameter is 14mm. The head is vertically split by a U-shape slot to accommodate the 6mm and 5.5mm rods. The head is threaded with a 10mm buttress thread to accommodate the closure screw. The head presents two lateral slots for mating with various instruments. The blade design is specific to each hook. Hooks are available for laminar, thoracic, pedicle, and transverse process attachment, and come in different sizes (small, medium, large), offsets, and blade designs (standard, angled, narrow).

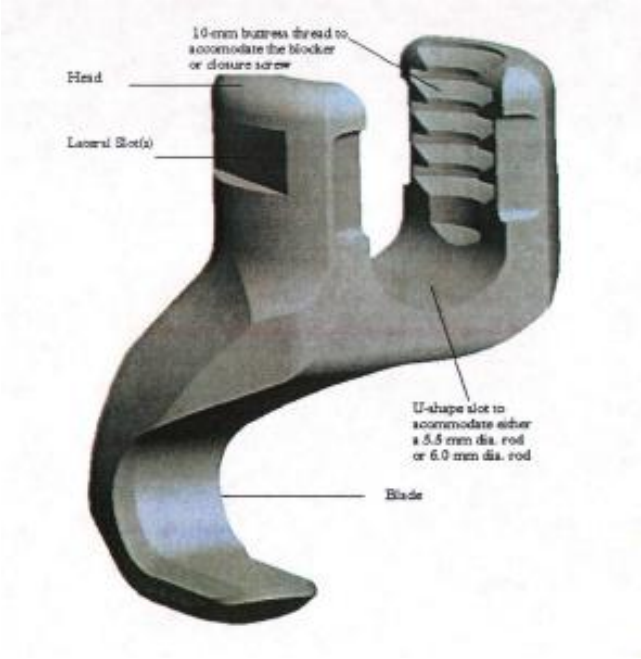


Figure 4-10: Hook

XIA 3 Straight 6mm diameter Rods

The subject rods have a 6mm diameter and are offered in lengths ranging from 30mm to 150mm in 10mm increments, in addition to a 480mm and 600mm. There are laser marked dots going down the axis of the rod to provide a reference to surgeons for bending. For rods longer than 90mm there is a hex on one end of the rod for rod rotation. The rods come in both CP Ti and Ti6Al4V.

The straight XIA Vitallium rod in 6mm and 600mm length is also intended to be used with the other components of the subject system. This rod will keep the name and catalog number referenced in K060979.

The straight and pre-bent 5.5mm diameter Ti6Al4V alloy rods from Stryker Spine Radius Spinal System are also intended to be used with the XIA 3 system. These rods will keep the name and catalog number reference in K062270. The straight 5.5mm diameter Vitallium rods from the Radius Spinal System are also intended to be used with Xia 3 as specified in K091291.

XIA 3 Rad Rods (Pre-bent)

The subject rad rods have a 6mm diameter and are offered pre-bent in lengths ranging from 30mm to 50mm in 5mm increments and 10mm increments from 60mm to 120mm. These rods have a single curve with a radius of 32mm to 127mm. The rad rods are designed to accommodate one, two, or three level fusion. The lengths of 30mm and 35mm are well suited for single level fusion from S1 to L5.

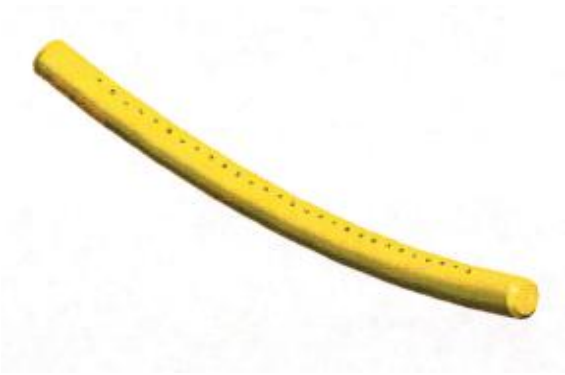


Figure 4-11: Rad (Pre-Bent) Rod

XIA 3 Max Rad Rods (Pre-bent)

The max rad rods have a 6mm diameter and are offered pre-bent in lengths ranging from 50mm to 120mm in 10mm increments. These rods have two curves blended together and resemble a hockey stick or a J shape. The max rad rods are useful for 2 or 3 level fusions that extend from the lumbar to the sacrum.

Figure 4-12: Max Rad (Pre-Bent) Rod

XIA 3 Poly Cross Connector

As shown in Figure 4-12below, the subject poly cross connector is composed of several elements:

- Two J hooks
- Two closure set screws
- Center bolt
- Rivet bolt
- Bellville washer
- Lock nut

These elements are delivered pre-assembled. The poly cross connector is designed to connect the bilateral 6mm or 5.5mm rods of a spinal fusion construct. Each J hook is attached to one rod.

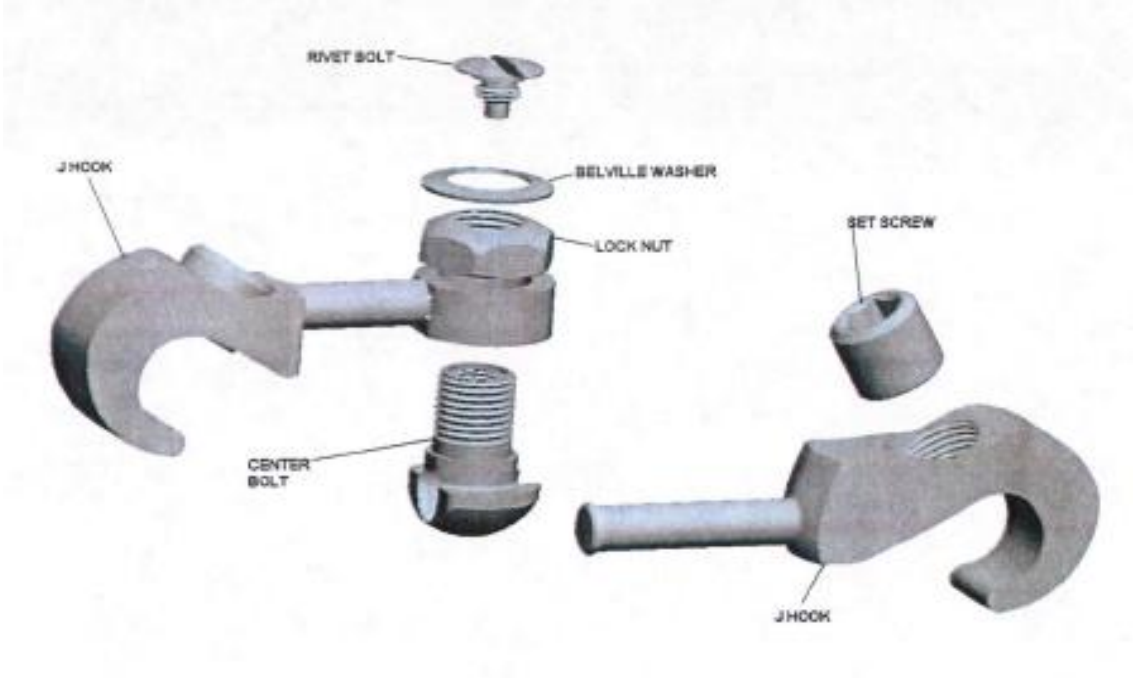


Figure 4-13: Poly Cross Connector

XIA 3 Mono Cross Connector

The mono cross connectors are monolithic cross connectors which have two hooks at fixed lengths and set screws (see figure below). The mono cross connector is composed of two components:

- A monoblock body with two closure J hooks extremity
- Two closure set screws

These elements are delivered assembled and the cross connector is proposed on 10 sizes for cross linking. The sizes are 14, 15, 16, 17, 18, 19, 20, 22, 24, 26mm rod-to-rod axis. The cross connector is designed to connect (top loading, top screwing, two step locking) the parallel bilateral 6mm and 5.5mm rods of a spinal fusion construct. Each J hook is attached to one rod.

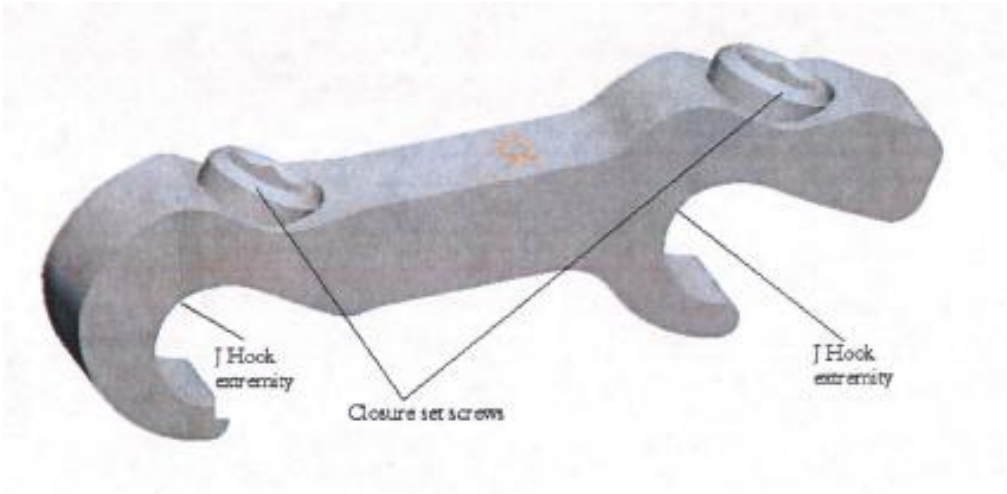
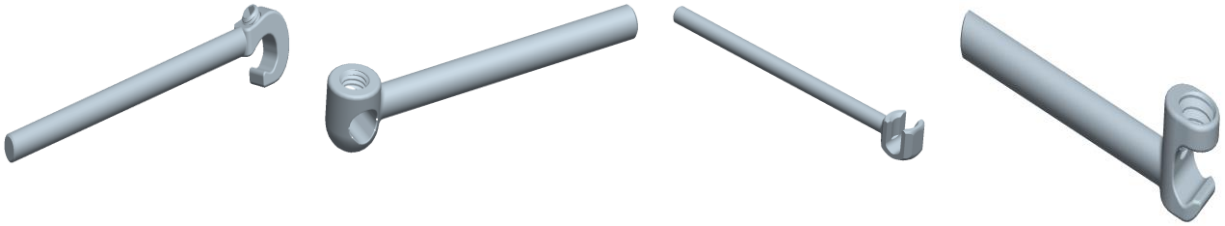


Figure 4-14: Mono Cross Connector

Xia 3 Offset Connectors and Rod to Rod Connectors

The Xia 3 Offset Connectors are available in four designs, the J-Hook Offset Connector, the Closed Head Offset Connector, the Long Open Offset Connector, and the Open Side Loading Offset Connector. Each offset connector is for use from T1 to S1 and in the ilium. J-Hook Offset Connector is 100mm long and is designed to allow offset rod connection from main construct rod to Ilium or other fixation point. The offset connectors are designed to allow offset rod connection from the main construct rod to the Ilium or other fixation point. The J-Hook and Long Open Offset Connectors are each 100mm in length, while the Closed Head and Open Side Loaded Offset Connectors are 65mm and 60mm in length respectively.

Figure 4-15: Xia 3 Offset Connectors

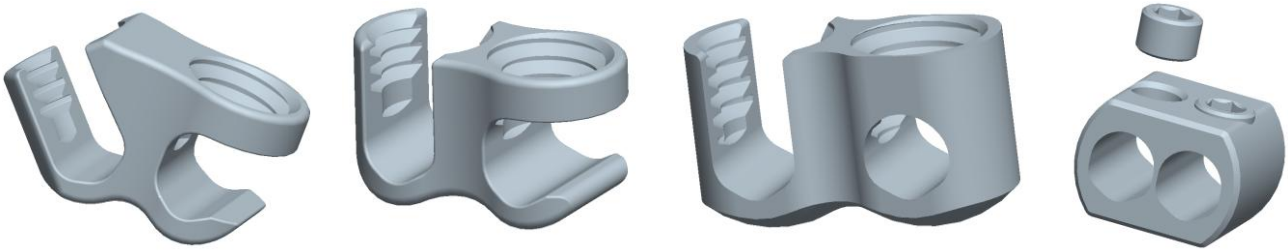


J-Hook **Closed Head** **Long Open** **Open Side Loading**

The Xia 3 Rod to Rod Connectors are available in various designs. The Angled Loading/Side Loading Rod to Rod Connector, Top Loading/Side Loading Rod to Rod Connector, Revision Rod to Rod Connector, and Parallel Rod to Rod Connectors feature combinations of angled, side, and top loading designs and are used from T1 to S1 to

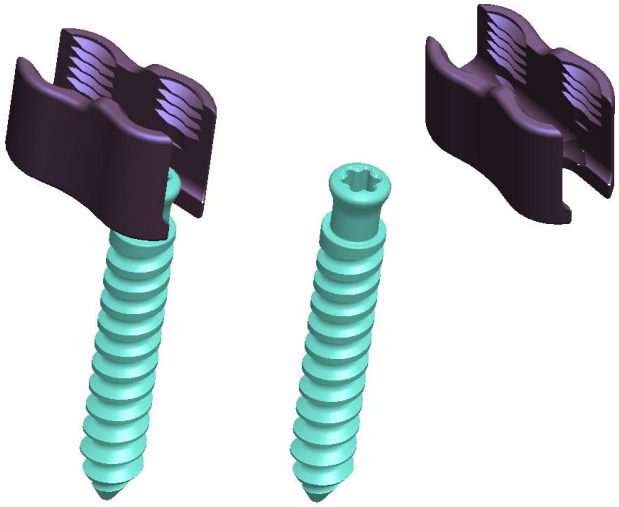
extend an existing spinal construct. The Revision Rod to Rod Connector is designed with an open side and closed side, while the Parallel Closed Rod to Rod Connector is designed in two sizes and uses M6x1 setscrew for locking. The Revision Axial Rod to Rod Connector is designed to have three points of fixation, two rods and a screw anchor point to avoid skipping a level when connecting between rods in revision cases. A bone screw anchors the connector to the pedicle. The connecting rods are dropped in to the connector and then the screw/rod subassembly is locked utilizing a buttress blocker. Figure 4-15 below depicts the Angled Loading/Side Loading, Top Loading/Side Loading, Revision, and Parallel Rod to Rod Connectors. Figure 4-16 depicts the Revision Axial Rod to Rod Connector.

Figure 4-15: Xia 3 Rod to Rod Connectors



Angled Loading Side Loading | **Top Loading Side Loading** | **Revision** | **Parallel Closed**

Figure 4-16: Xia 3 Revision Axial Rod to Rod Connector



Testing has been performed to determine the ability of the spinal system to function in a pediatric population (see *Section 7, 'Pre-Clinical Testing*). Engineering drawings for the XIA 3 Spinal System are provided in **Attachment A** of this submission.

AIS Sizes
Comparing to predicates and pedicle sizes in an adolescent spine, all diameter screws could be used. Having the ability to fix and stabilize the spine with the most clinically appropriate screw size provides the surgeon to treat the patient most successfully. It may be appropriate on some levels to use hooks to correct the curvature. The size range and components described above are applicable in providing the necessary tools to provide the stability and correction needed for these patients.

4.2 Instruments

The instruments associated with implantation are standard manual surgical instruments, such as hook holders, awls, probes, taps, screwdrivers, wrenches, rod benders/cutters and others, that are Class I and exempt from 510(k) requirements.

4.3 Materials

The components of Stryker Spine's XIA 3 Spinal System are available in Ti6Al4V alloy in accordance with ISO 5832-3 and ASTM F136 and commercially pure titanium in accordance with CP Ti grade 4 according to ISO 5832-2 and ASTM F67. The system also includes XIA rods manufactured from CoCrMo alloy (Vitallium) in accordance with Cobalt-Chromium-Molybdenum alloy #1 according to ISO 5832-12 and ASTM F1537.

4.4 Device Component Listing

The following tables list the components of the XIA 3 Spinal System. All components listed were provided in K071373, K083393, and K091291.

Table 4-1: XIA 3 Spinal System Component Listing - Screws

Part Number	Component	Size	
		Diameter	Lengths
4823140xx	XIA 3 Polyaxial Screw	4.0mm	20, 25, 30, 35, 40, 45mm
4823145xx	XIA 3 Polyaxial Screw	4.5mm	20, 25, 30, 35, 40, 45mm
4823150xx	XIA 3 Polyaxial Screw	5.0mm	20, 25, 30, 35, 40, 45, 50mm
4823155xx	XIA 3 Polyaxial Screw	5.5mm	25, 30, 35, 40, 45, 50, 55mm
4823160xx	XIA 3 Polyaxial Screw	6.0mm	25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90mm
4823165xx	XIA 3 Polyaxial Screw	6.5mm	25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90mm
4823170xx	XIA 3 Polyaxial Screw	7.0mm	25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90mm
4823175xx	XIA 3 Polyaxial Screw	7.5mm	25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90mm
4823040xx	XIA 3 Monoaxial Screw	4.0mm	20, 25, 30, 35, 40, 45mm
4823045xx	XIA 3 Monoaxial Screw	4.5mm	20, 25, 30, 35, 40, 45mm
4823050xx	XIA 3 Monoaxial Screw	5.0mm	20, 25, 30, 35, 40, 45, 50mm
4823055xx	XIA 3 Monoaxial Screw	5.5mm	25, 30, 35, 40, 45, 50, 55mm
4823060xx	XIA 3 Monoaxial Screw	6.0mm	25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90mm
4823065xx	XIA 3 Monoaxial Screw	6.5mm	25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90mm
4823070xx	XIA 3 Monoaxial Screw	7.0mm	25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90mm
4823075xx	Xia 3 Monoaxial Screw	7.5mm	25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90mm
482334xx	XIA 3 Uniplanar Screw	4.5mm	20, 25, 30, 35, 40, 45mm
4823350xx	XIA 3 Uniplanar Screw	5.0mm	20, 25, 30, 35, 40, 45mm
482335xx	XIA 3 Uniplanar Screw	5.5mm	25, 30, 35, 40, 45, 50, 55mm
4823360xx	XIA 3 Uniplanar Screw	6.0mm	25, 30, 35, 40, 45, 50, 55, 60mm
482336xx	XIA 3 Uniplanar Screw	6.5mm	25, 30, 35, 40, 45, 50, 55, 60mm
4823370xx	XIA 3 Uniplanar Screw	7.0mm	30, 35, 40, 45, 50, 55, 60mm
482337xx	XIA 3 Uniplanar Screw	7.5mm	30, 35, 40, 45, 50, 55, 60mm
4823645xx	XIA 3 Uniplanar Reduction Screw	4.5mm	20, 25, 30, 35, 40, 45mm
4823650xx	XIA 3 Uniplanar Reduction Screw	5.0mm	20, 25, 30, 35, 40, 45mm
4823655xx	XIA 3 Uniplanar Reduction Screw	5.5mm	20, 25, 30, 35, 40, 45, 50, 55mm
4823660xx	XIA 3 Uniplanar Reduction Screw	6.0mm	25, 30, 35, 40, 45, 50, 55, 60mm
4823665xx	XIA 3 Uniplanar Reduction Screw	6.5mm	25, 30, 35, 40, 45, 50, 55, 60mm
4823670xx	XIA 3 Uniplanar Reduction Screw	7.0mm	30, 35, 40, 45, 50, 55, 60mm
4823675xx	XIA 3 Uniplanar Reduction Screw	7.5mm	30, 35, 40, 45, 50, 55, 60mm
4823965xx	XIA 3 Angled Monoaxial Screw	6.5mm	60, 70, 80, 90, 100mm

4823975xx	XIA 3 Angled Monoaxial Screw	7.5mm	60, 70, 80, 90, 100mm
4823985xx	XIA 3 Angled Monoaxial Screw	8.5mm	60, 70, 80, 90, 100mm
4823995xx	XIA 3 Angled Monoaxial Screw	9.5mm	60, 70, 80, 90, 100mm
4823840xx	XIA 3 Angled Polyaxial Screw	4.0mm	20, 25, 30, 35, 40, 45mm
4823845xx	XIA 3 Angled Polyaxial Screw	4.5mm	20, 25, 30, 35, 40, 45mm
4823850xx	XIA 3 Angled Polyaxial Screw	5.0mm	20, 25, 30, 35, 40, 45mm
4823855xx	XIA 3 Angled Polyaxial Screw	5.5mm	25, 30, 35, 40, 45, 50, 55mm
4823865xx	XIA 3 Angled Polyaxial Screw	6.5mm	25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90mm
4823875xx	XIA 3 Angled Polyaxial Screw	7.5mm	25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90mm
4823885xx	XIA 3 Angled Polyaxial Screw	8.5mm	60, 70, 80, 90, 100mm
4823895xx	XIA 3 Angled Polyaxial Screw	9.5mm	60, 70, 80, 90, 100mm
48237140xx	XIA 3 Angled Medial Screw	4.0mm	20, 25, 30, 35, 40, 45mm
48237145xx	XIA 3 Angled Medial Screw	4.5mm	20, 25, 30, 35, 40, 45mm
48237150xx	XIA 3 Angled Medial Screw	5.0mm	20, 25, 30, 35, 40, 45mm
48237155xx	XIA 3 Angled Medial Screw	5.5mm	25, 30, 35, 40, 45, 50, 55mm
48237165xx	XIA 3 Angled Medial Screw	6.5mm	25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90mm
48237175xx	XIA 3 Angled Medial Screw	7.5mm	25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90mm
48237185xx	XIA 3 Angled Medial Screw	8.5mm	60, 70, 80, 90, 100mmmm
48237195xx	XIA 3 Angled Medial Screw	9.5mm	60, 70, 80, 90, 100mm
4823265xx	XIA 3 Closed Head Monoaxial Screw	6.5mm	30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90, 100mm
4823275xx	XIA 3 Closed Head Monoaxial Screw	7.5mm	30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90, 100mm
4823285xx	XIA 3 Closed Head Monoaxial Screw	8.5mm	30, 35, 40, 45, 60, 65, 70, 80, 90, 100mm
4823295xx	XIA 3 Closed Head Monoaxial Screw	9.5mm	30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90, 100mm
4823765xx	XIA 3 Closed Head Polyaxial Screw	6.5mm	30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90, 100mm
4823775xx	XIA 3 Closed Head Polyaxial Screw	7.5mm	30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90, 100mm
4823785xx	XIA 3 Closed Head Polyaxial Screw	8.5mm	30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90, 100mm
4823795xx	XIA 3 Closed Head Polyaxial Screw	9.5mm	30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90, 100mm

Table 4-2: XIA 3 Spinal System Component Listing - Rods

Part Number	Component	Size	
		Diameter	Lengths
482330xx	Ti6Al4V XIA 3 Rod	6.0mm	30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 480, 600mm
482320xx	CP Ti XIA 3 Rod	6.0mm	30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 480, 600mm
482380xx	XIA 3 Rad Rod	6.0mm	30, 35, 40, 45, 50, 60, 70, 80, 90, 100, 110, 120mm
482390xx	XIA 3 Max Rad Rod	6.0mm	50, 60, 70, 80, 100, 110, 120mm
03822601	XIA Vitallium Rod	6.0mm	600mm
486613xxx	Radius Rod w/out Hex	5.5mm	30, 35, 40, 45, 50, 60, 70, 80, 90, 100, 110, 120mm
486613xxx	Radius Rod w/ Hex	5.5mm	50, 60, 70, 80, 90, 100, 110, 120, 140, 160, 180, 200, 220, 240, 260, 280, 300, 320, 340, 360, 380, 400, 600mm
486615xxx	Radius Rad Rod	5.5mm	30, 35, 40, 45, 50, 60, 70, 80, 90, 100, 110, 120mm
486615xxx	Radius Max Rod	5.5mm	50, 60, 70, 80, 90, 100, 110, 120mm
486613601	Radius Vitallium	5.5mm	600mm

Table 4-3: XIA 3 Spinal System Component Listing - Hooks

Part Number	Component
48230200	Medium Laminar Hook, Standard-Blade
48230201	Medium Laminar Hook, Narrow-Blade
48230202	Large Laminar Hook, Standard-Blade
48230203	Large Laminar Hook, Narrow-Blade
48230204	Extended-Body Laminar Hook
48230205	Extended-Body Laminar Hook Small
48230206	Offset Laminar Hook, Right
48230207	Offset Laminar Hook, Left
48230208	Angled-Blade Laminar Hook, Large
48230209	Angled-Blade Laminar Hook, Small
48230210	Thoracic Laminar Hook, Standard-Blade
48230211	Thoracic Laminar Hook, Narrow-Blade
48230212	Small-Offset Thoracic Laminar Hook, Right
48230213	Small-Offset Thoracic Laminar Hook, Left
48230214	Large-Offset Thoracic Laminar Hook, Right
48230215	Large-Offset Thoracic Laminar Hook, Left
48230216	Thoracic Laminar Hook, Small Narrow Blade
48230217	Large Offset Hook Right
48230218	Large Offset Hook Left
48230220	Medium Pedicle Hook
48230221	Small Pedicle Hook
48230222	Large Pedicle Hook
48230232	Transverse Process Hook, Right
48230233	Transverse Process Hook, Left
48230240	Small Laminar Hook, Narrow Blade
48230241	Small Laminar Hook, Standard Blade

Table 4-4: XIA 3 Spinal System Component Listing – Cross Connectors

Part Number	Component	Size
48236028	XIA 3 Multi Axial Cross Connector	28mm – 31mm
48236030	XIA 3 Multi Axial Cross Connector	30mm – 35mm
48236035	XIA 3 Multi Axial Cross Connector	35mm – 44mm
48236043	XIA 3 Multi Axial Cross Connector	43mm – 54mm
48236053	XIA 3 Multi Axial Cross Connector	53mm – 73mm
48236070	XIA 3 Multi Axial Cross Connector	70mm – 99mm
48236014	XIA 3 Mono Block Cross Connector	14mm
48236015	XIA 3 Mono Block Cross Connector	15mm
48236016	XIA3 Mono Block Cross Connector	16mm
48236017	XIA 3 Mono Block Cross Connector	17mm
48236018	XIA 3 Mono Block Cross Connector	18mm
48236019	XIA 3 Mono Block Cross Connector	19mm
48236020	XIA 3 Mono Block Cross Connector	20mm
48236022	XIA 3 Mono Block Cross Connector	22mm
48236024	XIA 3 Mono Block Cross Connector	24mm
48236026	XIA 3 Mono Block Cross Connector	26mm

Table 4-5: XIA 3 Spinal System Component Listing – Offset and Rod to Rod Connectors

Part Number	Component	Size
48230133	XIA 3 Long Offset Connector	100mm
48230143	XIA 3 J-Hook Offset Connector	100mm
48230138	XIA 3 Closed Head Offset	65mm
48230139	XIA 3 Long Offset Connector Open	100mm
48230144	XIA 3 Open Side Loading Offset Connector	60mm
48235010	XIA 3 Angled Loading Side Loading Rod to Rod Connector	14mm
48235011	XIA 3 Top Loading Side Loading Rod to Rod Connector	15mm
48235007	XIA3 Revision Rod to Rod Connector	16mm
48235008	XIA 3 Revision Rod to Rod Connector	17mm
48230141	XIA 3 Parallel Closed Rod to Rod Connector	18mm
48235009	XIA 3 Parallel Closed Rod to Rod Connector	19mm
48235012	XIA 3 Revision Axial Rod to Rod Connector and Bone Screw	
48236540	XIA 3 Revision Axial Rod to Rod Connector and Bone Screw	6.5mm x 40mm
48236550	XIA 3 Revision Axial Rod to Rod Connector and Bone Screw	6.5mm x 50mm
48236560	XIA 3 Revision Axial Rod to Rod Connector and Bone Screw	6.5mm x 60mm
48237540	XIA 3 Revision Axial Rod to Rod Connector and Bone Screw	7.5mm x 40mm
48237550	XIA 3 Revision Axial Rod to Rod Connector and Bone Screw	7.5mm x 50mm
48237560	XIA 3 Revision Axial Rod to Rod Connector and Bone Screw	7.5mm x 60mm
48238540	XIA 3 Revision Axial Rod to Rod Connector and Bone Screw	8.5mm x 40mm

48238550	XIA 3 REVISION AXIAL ROD TO ROD CONNECTOR AND BONE SCREW	8.5mm x 50mm
48238560	XIA 3 REVISION AXIAL ROD TO ROD CONNECTOR AND BONE SCREW	8.5mm x 60mm
48239540	XIA 3 REVISION AXIAL ROD TO ROD CONNECTOR AND BONE SCREW	9.5mm x 40mm
48239550	XIA 3 REVISION AXIAL ROD TO ROD CONNECTOR AND BONE SCREW	9.5mm x 50mm
48239560	XIA 3 REVISION AXIAL ROD TO ROD CONNECTOR AND BONE SCREW	9.5mm x 60mm

Table 4-6: XIA 3 Spinal System Component Listing – Blocker

Part Number	Component	Description
48230000	XIA 3 Blocker	Used to capture rod in tulip of polyaxial screws, monoaxial screws, and hooks

5. Indications for Use

510(k) Number (if known):

Device Name: XIA® 3 Spinal System

The XIA® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative disc disease (DDD) (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, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

The Ø5.5mm rods from the Stryker Spine Radius™ Spinal System and Ø6.0mm Vitallium rods from the XIA® Spinal System are intended to be used with the other components of XIA® 3 Spinal System.

When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA® 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Prescription Use ___√____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

6. 510(k) Summary

Device Trade Name: XIA® 3 Spinal System

Manufacturer:
Stryker Spine
ZI Marticot 33610
Cestas, France
Establishment Registration Number: 9617544

And

Stryker Spine
Le Cret Du Locle 10a
La Chaux De Fonds
Switzerland 2300
Establishment Registration Number: 3005525032

Contact:
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Tiffani.Rogers@stryker.com

Date Prepared: December 11, 2011

Common Name: Pedicle Screw Spinal System

Classification: 21 CFR 888.3070; 21 CFR 888.3050

Class: III / II

Product Code: OSH, MNH, MNI, KWP, NKB

Indications For Use:
The XIA® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative disc disease (DDD) (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, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

The Ø5.5mm rods from the Stryker Spine Radius™ Spinal System and Ø6.0mm Vitallium rods from the XIA® Spinal System are intended to be used with the other components of XIA® 3 Spinal System.

When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA® 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Device Description:
The Stryker Spine XIA 3 Spinal System is a noncervical pedicle screw system comprised of monoaxial and polyaxial bone screws, blocker (as a locking mechanism), rods, hooks, and connectors. The implants are manufactured from Ti6Al4V alloy, CP Ti, and CoCrMo alloy (Vitallium).

Predicate Devices:
The XIA 3 Spinal System was shown to be substantially equivalent to previously cleared devices (K994121, K071373, K071668, K091445, and K111492).

Substantial Equivalence:
Testing performed on this device indicates that the XIA 3 Spinal System is substantially equivalent to predicate devices. Mechanical testing of the system included static and dynamic compression bending testing and static torsion testing per ASTM F1717-04 and interconnection strength testing per ASTM F1798-97, as well as, a clinical literature analysis.

Conclusion
The XIA 3 Spinal System was shown to be substantially equivalent to previously cleared devices with respect to its indications for use, design, function, and materials.

7. Class III Summary and Certification

CLASS III CERTIFICATION

Certification of Adverse Safety and Effectiveness Information
Pursuant to 513(f) of the Federal Food, Drug and Cosmetic Act

I certify that, in my capacity as Manager of Regulatory Affairs of Stryker Spine I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety and effectiveness problems that have been reported for pedicle screws. I further certify that I am aware of the types of problems to which pedicle screws are susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety and/or effectiveness problems about pedicle screws are complete and accurate.

Following the summary is a bibliography of the materials upon which the summary is based.

Tiffani D. Rogers
Manager Regulatory Affairs

CLASS III SUMMARY

THE USE OF PEDICLE SCREWS FOR THE TREATMENT OF DEGENERATIVE DISC DISEASE AND SPONDYLOLISTHESIS

A Class III Summary has been submitted in predicate 510(k) # K071373 for the XIA® 3 Spinal System.

The Class III summary, incorporated into the current Traditional 510(k) by reference, reviewed information relevant to the types of safety and effectiveness problems reported for pedicle screw/rod systems when used for the Class III indications of degenerative disc disease and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment).

The conclusion of the Class III Summary was that current literature and MAUDE experience reports suggest that the types of safety and effectiveness problems associated with pedicle screw and rod systems are well known and include: device-related events such as screw breakage, component disassembly, pedicle fracture, component migration/loosening/fracture, and infection; and procedure-related events such as intraoperative assembly difficulty, and events associated with any major surgical procedure (such as myocardial infarction, deep vein thrombosis, and urinary tract infection). Complications can lead to revision surgery, and are sometimes associated with neural injury. Further, surgery does not always achieve its goals of stability and pain relief, and patients can develop instability or pain at adjacent spinal segments. The information presented in this summary does not suggest that the Class III use of pedicle screw/rod systems as described in 21 CFR 888.3070 is associated with any different types of safety and effectiveness problems than are seen with the Class II uses of the same pedicle screw/rod systems.

8. Pre-Clinical Testing

Mechanical testing has been performed on the XIA 3 Spinal System to demonstrate substantial equivalence. The following test battery was performed by Stryker Spine and presented previously in K071373:

1. Static Compression Bending
2. Dynamic Compression Bending
3. Static Torsion
4. Interconnection Strength (in support of worst case rationale)

In addition to the battery of test presented in K071373, Stryker Spine completed Dynamic Fatigue Torsion testing on the worst-case Xia 3 construct. All testing was performed in accordance with ASTM 1717-04, "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model" and ASTM F1798-97, "Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants."

Please see *Section 8, 'Substantial Equivalence Summary,'* for a detailed comparison of the XIA 3 Spinal System and the predicates.

8.1 Worst Case Construct Rationale

An engineering analysis was performed to determine and provide a rationale for the worst case construct. The analysis is summarized below, and the full report is provided in **Attachment B**.

Screw/Hook Components
Testing was performed on the XIA 3 sub-assemblies in accordance with ASTM F1798-97. Testing included cantilever, axial rod gripping, and rod rotation testing on the system screws and hooks. It was determined that the smallest diameter 4.0mm polyaxial screws represent the worst case size. Therefore, 4.0mm diameter polyaxial screws were used for subsequent construct testing. The full ASTM F1798-97 test report is provided in **Attachment C**.

Rods
As explained in the engineering analysis (**Attachment B**), calculations examining the torque on the screw head/rod interface showed that the torque was lower with the pre-bend rods construct than with the straight rod construct. In addition, the manufacturing process used to pre-bend the rods is a "cold-working" process, which increases the load required to further plastically deform the rod. For these reasons, the straight rod was determined to be worst case.

Static compression bending testing was performed in accordance with ASTM F1717-04 to determine which 6.0mm diameter XIA 3 rod represents the worst case for dynamic compression bending testing. Specifically, static compression bending testing was performed on constructs using:

1. XIA 3 6.0mm CP Ti rods
2. XIA 3 6.0mm Ti6Al4V rods
3. XIA 6.0mm CoCrMo alloy (Vitallium) rods

The test results are provided in the following table.

Table 8-1: Static Compression Bending Test Results

Rod System	Stiffness (SD)	Yield (SD)
6.0mm CoCrMo alloy rods (Vitallium)	52 (4) N/mm	253 (11) N
6.0mm Ti6Al4V rods	40 (2) N/mm	279 (13) N
6.0mm CP Ti rods	40 (9) N/mm	272 (14) N

Based on these results, the 6.0mm CoCrMo alloy (Vitallium) rod was selected as worst case for dynamic compression bending testing for the following two reasons:

1. The stiffness of the Vitallium rod construct was the greatest compared to the two titanium rods which would allow more energy to be transmitted to the screws.
2. The yield load of the Vitallium rod construct was lowest compared to the two titanium rods.

The full ASTM F1717-04 test report for the XIA 3 Spinal System is provided in **Attachment D**.

In addition, static and dynamic axial compression bending and static torsion testing were also performed on XIA 3 constructs using 5.5mm rods from Stryker Spine Radius Spinal System. The 5.5mm diameter rods that can be used with the XIA 3 Spinal System are from Stryker Spine's Radius Spinal System (K062270), which are made from Ti6Al4V alloy. The full test report is provided in **Attachment E**.

Note: For the purpose of ASTM F1717-04 testing, the hexagonal vs. non-hexagonal feature is not relevant to an assessment of worst case. This area of the rod is not under constraint during testing.

Cross Connectors
The poly cross connectors are considered worst case compared to the mono cross connectors for the following two reasons:

1. The mono cross connector is fabricated as monolithic design as compared to the poly cross connector screw which is fabricated from several parts.

2. The mono cross connector has a greater cross-sectional area compared to the poly cross connector at the minimum cross sectional area (see calculation in engineering analysis in **Attachment B**). The hook forms are the same between mono cross connectors and poly cross connectors so the fixation to the rod is the same.

Furthermore, the poly cross connectors were bent for the ASTM F1717 testing. Bent connectors are considered worst case because the metal in the cross beam is plastically deformed during the bending process which incurs stresses in the cross member which do not exist in straight connectors.

Worst Case Construct Conclusion

Static and Dynamic Compression Bending:
The following two XIA 3 worst case constructs were used for static and dynamic compression bending tests:

Worst Case Construct #1:

- XIA 3 Ø4.0 x 20mm polyaxial screws
- XIA Ø6.0 x 600mm Vitallium rods
- XIA 3 blockers
- XIA 3 poly cross connectors – bent

Worst Case Construct #2:

- XIA 3 Ø4.0 x 20mm polyaxial screws
- Radius Ø5.5 x 100mm rods – without hex
- XIA 3 blockers
- XIA 3 poly cross connectors – bent

Static Torsion:
The following two XIA 3 worst case constructs were used for the static torsion tests:

Worst Case Construct #1:

- XIA 3 Ø4.0 x 20mm polyaxial screws
- XIA Ø6.0 x 600mm Vitallium rods
- XIA 3 blockers

Worst Case Construct #2:

- XIA 3 Ø4.0 x 20mm polyaxial screws
- Radius Ø5.5 x 100mm rods – without hex
- XIA 3 blockers

8.2 Static Compression Bending

Static compression bending testing was performed on all three XIA 3 rod types (Ti6Al4V, CP Ti, Vitallium) as part of the worst case construct engineering analysis. Additionally, static compression bending testing was performed using 5.5mm diameter Radius rods with the XIA 3 assembly. The results are summarized in **Table 8-2**.

Table 8-2: Static Compression Bending Test Results

Construct	Sample ID	Stiffness (N/mm)	Yield Load (N)	Comments/ Failure Mode
6.0mm diameter Ti6Al4V XIA 3 rods (**Attachment D**)	S1a	41	301	Slippage at screw/rod interface
	S1b	44	272	
	S1c	37	278	
	S1d	39	267	
	S1e	40	286	
	S1f	39	270	
	Mean (SD)	**40 (2)**	**279 (13)**	
6.0mm diameter CP Ti XIA 3 rods (**Attachment D**)	S2a	39	278	Slippage at screw/rod interface
	S2b	58	253	
	S2c	40	270	
	S2d	37	260	
	S2e	33	288	
	S2f	35	284	
	Mean (SD)	**40 (9)**	**272 (14)**	
6.0mm diameter Vitallium XIA rods (**Attachment D**)	S3a	56	242	Slippage at screw/rod interface
	S3b	53	245	
	S3c	54	249	
	S3d	52	249	
	S3e	47	267	
	S3f	47	267	
	Mean (SD)	**52 (4)**	**253 (11)**	
5.5mm diameter Ti6Al4V Radius rods (**Attachment E**)	S1a	29.6	289	Slippage at screw/rod interface
	S1b	27.9	289	
	S1c	28.7	283	
	S1d	28.6	283	
	S1e	28.9	279	
	S1f	28.3	287	
	Mean (SD)	**28.7 (0.6)**	**285 (4)**	

The constructs using the Vitallium rods and Radius rods were determined to be worst case. The mean stiffness for the Vitallium and Radius rod constructs was 52 N/mm and

28.7 N/mm, respectively. The mean yield load for the Vitallium and Radius rod constructs was 253 N and 285 N, respectively.

8.3 Dynamic Compression Bending

Dynamic compression bending testing was performed on the worst case constructs determined in the engineering analysis in **Attachment B**. The results are summarized in **Table 8-3.**

Table 8-3: Dynamic Compression Bending Test Results

Construct	Sample ID	Min-Max Load (N)	# of Cycles	Comments/ Failure Mode
6.0mm diameter Vitallium XIA rods (**Attachment D**)	061112 F1a	20.5 – 205	5,000,000	No failure
	061112 F2a	**22 – 220**	**5,000,000**	**No failure**
	061112 F2b		**5,000,000**	**No failure**
	061112 F3a	24 – 240	5,000,000	Crack on screw head
	061112 F4a	26 - 260	5,000,000	Crack on screw head
	061112 F4b		5,000,000	No failure
5.5mm diameter Ti6Al4V Radius rods (**Attachment E**)	061113 F1a	24 - 240	356,000	Rod failure
	061113 F1b		451,000	Rod failure
	061113 F2a	22 – 220	1,070,000	Rod failure
	061113 F3a	20.5 - 205	5,000,000	No failure
	061113 F3b		5,000,000	Crack on screw head
	061113 F4a	19 - 190	1,900,000	Rod failure
	061113 F4b		1,035,000	Rod failure
	061113 F5a	**17.5 -175**	**5,000,000**	**No failure**
	061113 F5b		**5,000,000**	**No failure**

The run-out load of XIA 3 construct with Vitallium rods was determined to be 220 N. Screw head cracks initiating rod contact was observed at 240 N and 260 N loads, without generating loss of functionality of the construct while reaching 5 million cycles. An image of the typical crack observed during dynamic compression bending testing of the XIA Vitallium rods is shown in **Figure8-1**.

The run-out load of the XIA 3 construct with Radius rods was determined to be 175 N. Observed failure modes were rod failure and crack on screw head without loss of functionality of the construct up to 5 million cycles. An image of the typical failure modes observed during dynamic compression bending testing of the Radius rod constructs is shown in **Figure 8-2**.

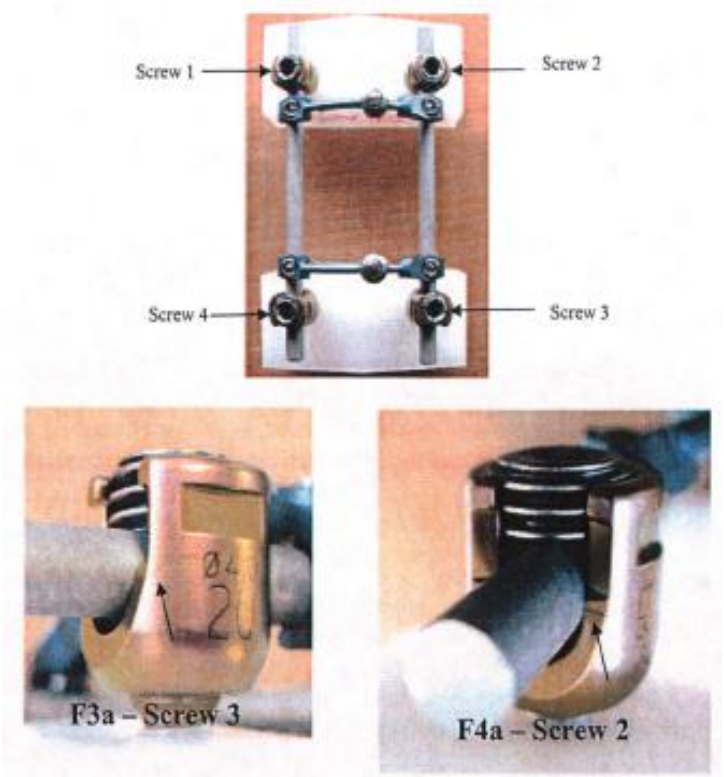


Figure8-1: Typical Failure Mode Identified Under Fatigue Compression Test on XIA 3 Constructs Assembled with Radius Rod

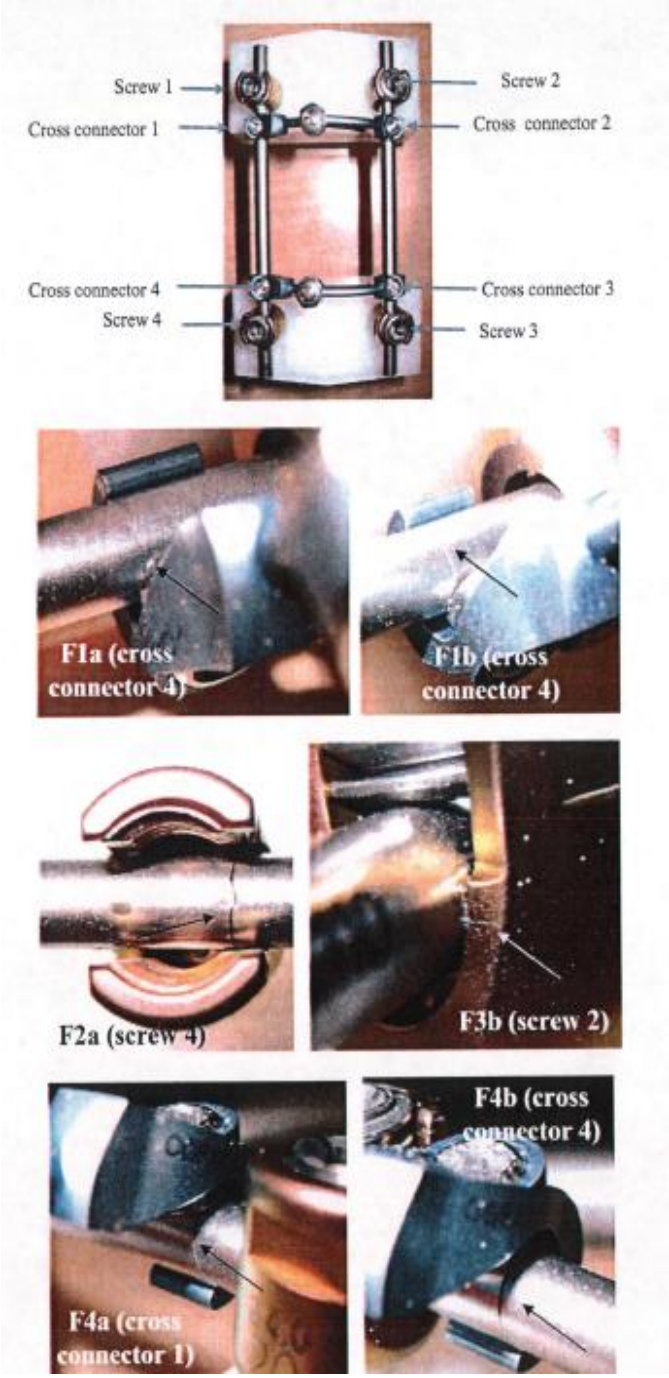


Figure 8-2: Failure Modes Identified Under Fatigue Compression Test on XIA 3 Constructs Assembled with Radius Rod

8.4 Static Torsion

Static torsion testing was performed on all three XIA 3 rod types (Ti6Al4V, CP Ti, and Vitallium). Additionally, static torsion testing was performed using 5.5mm diameter Radius rods with the XIA 3 assembly. The results are summarized in **Table 8-4**.

Table 8-4: Static Torsion Test Results

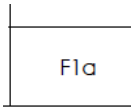
Construct	Sample ID	Stiffness (Nm/°)	Yield Torque (Nm)	Comments/ Failure Mode
6.0mm diameter Ti6Al4V XIA 3 rods (**Attachment D**)	S4a	2.8	9.1	Slippage at screw/rod interface
	S4b	2.8	8.7	
	S4c	3.1	8.3	
	S4d	2.9	8.6	
	S4e	2.8	7.9	
	S4f	2.8	9.0	
	Mean (SD)	**2.9 (0.1)**	**8.6 (0.5)**	
6.0mm diameter CP Ti XIA 3 rods (**Attachment D**)	S5a	3.0	8.2	Slippage at screw/rod interface
	S5b	2.8	8.8	
	S5c	2.8	9.0	
	S5d	2.8	8.5	
	S5e	2.8	9.3	
	S5f	2.9	8.4	
	Mean (SD)	**2.9 (0.1)**	**8.7 (0.4)**	
6.0mm diameter Vitallium XIA rods (**Attachment D**)	S6a	3.1	9.9	Slippage at screw/rod interface
	S6b	3.2	9.6	
	S6c	3.1	10.0	
	S6d	3.1	10.4	
	S6e	2.8	10.1	
	S6f	3.1	10.2	
	Mean (SD)	**3.0 (0.1)**	**10.0 (0.3)**	
5.5mm diameter Ti6Al4V Radius rods (**Attachment E**)	S2a	2.6	8.2	Slippage at screw/rod interface
	S3b	2.7	8.8	
	S4c	2.7	8.2	
	S5d	2.7	8.8	
	S6e	2.7	8.5	
	S7f	2.6	8.2	
	Mean (SD)	**2.7 (0.0)**	**8.4 (0.3)**	

The constructs using the Vitallium rods and Radius rods were determined to be worst case. The mean stiffness for the Vitallium and Radius rod constructs was 3.0 Nm/° and 2.7 Nm/°, respectively. The mean yield torque for the Vitallium and Radius rod constructs was 10.0 Nm and 8.4 Nm, respectively.

8.5 Dynamic Fatigue Torsion

Dynamic fatigue torsion testing was performed on utilizing the Xia 3 pedicle screws, blocker, and 6mm Ti6Al4V rods. The run out load was 5 x10^6 cycles at 9Nm with no failure. Test results are provided in Table 7-5 below. The detailed test report and engineering analysis which includes identification of the worst-case construct are provided in Attachment F.

Table 8-5: Fatigue Torsion Test Results



8.6 Conclusion

The test results confirm that the XIA 3 Spinal System is equivalent to the predicate pediatric pedicle screw systems, and that the system can withstand the physiologic loading for this patient population. The static and axial compression testing results for the XIA 3 Spinal System are expected to out-perform both the Orthobiom Spinal System (K071668) and the USS Small Stature (K994121) worst case rods. In addition, the static torsional yield loads for the XIA 3 Spinal System are equal to or greater than the predicate 5.5mm or smaller rods. The test results above have been FDA reviewed and determined to be substantially equivalent for use in skeletally mature patients and scoliotic patients (K071373), which have higher loads than the pediatric patient population. The test results have been shown to be equivalent to previously cleared pediatric pedicle screw systems, and the XIA 3 Spinal System is equivalent to these systems in device sizes, indications, and surgical technique.

A review of safety and efficacy in the literature for predicate pediatric pedicle screw systems that are comparable to the XIA 3 Spinal System has also been performed (**Attachment G**). The use of posterior instrumentation for the treatment of adolescent idiopathic scoliosis was demonstrated to be effective in correction of spinal deformity, as evidenced by overall Cobb Angle correction. The systems were also shown to have a favorable safety profile, with complication rates similar to the use of posterior instrumentation for other indications. While the XIA 3 Spinal System was not utilized in any of the clinical data obtained, studies comparing similar pedicle screw-based systems showed substantially equivalent clinical data, even when comparing different cleared pedicle screw-based systems. The XIA 3 Spinal System performs as well as, if not better, than the cited predicates in static and dynamic testing, and the predicate devices have been 510(k) cleared and have been shown to be safe and effective in the clinical literature. From the mechanical testing results, the clinical literature review, and the comparability of the XIA 3 Spinal System to the predicates, it can be concluded that the XIA 3 Spinal System is substantially equivalent. A more detailed comparison of the XIA 3 constructs and the predicate devices can be found in *Section 8, Substantial Equivalence*. Therefore, it is believed that these tests adequately characterize the loads seen by an adolescent scoliotic spine and that the results demonstrate safety, effectiveness, and ultimately substantial equivalence to the cited predicates.

9. Substantial Equivalence Summary

The XIA 3 Spinal System is substantially equivalent to the following predicate devices. Substantial equivalence is based on a comparison of the technological characteristics, intended use and indications for use, materials, mechanism of action, surgical technique, and performance characteristics of the subject device with these cleared devices.

Table 9-1: Predicate Devices

510(k)	Company Name	Device Name
K111492	Medtronic Sofamor Danek	TSRH Spinal System
K091445	Medtronic Sofamor Danek USA	CD HORIZON Spinal System
K071668	Paradigm Spine	Orthobiom Spinal System
K071373	Stryker Spine	XIA 3 Spinal System
K994121	Synthes	USS Small Stature

Like the subject XIA 3 Spinal System, each of the predicate systems has similar geometries, available sizes, performance characteristics, and intended use.

The XIA 3 Spinal System is similar in geometry, size, and indications to the Medtronic TSRH Spinal System (K111492) and CD HORIZON Spinal System (K091445), the Paradigm Spine Orthobiom Spinal System (K071668), and the Synthes USS Small Stature (K994121). All systems are intended for posterior noncervical pedicle screw fixation in pediatric patients as an adjunct to fusion to treat adolescent idiopathic scoliosis.

In addition to the legally marketed predicate devices, the Pediatric ISOLA Spinal System from DePuy Spine is another example of a system intended to be used for pediatric scoliosis but cleared for skeletally mature patients. This can be seen in various literature articles and on the company's websites.

Stryker Spine has conducted several analyses included in the following pages demonstrating the substantial equivalence of the XIA 3 Spinal System to the predicate devices. A risk analysis (Section 8.1) was performed along with a detailed device comparison summary (Section 8.2) including a literature review of the clinical outcomes of pediatric pedicle screw systems.

9.1 Risk Analysis and Safety Discussion

For a system like the XIA 3 Spinal System to be cleared a large body of evidence that establishes substantial equivalence, describes technological characteristics, and characterizes any potential safety issues must be provided to the FDA. Under most circumstances, the information needed to clear a pedicle screw system such as the USS Small Stature System, Orthobiom Spinal System, or CD HORIZON Spinal System are indication comparison, adequate mechanical testing (i.e., ASTM F1717), and, if needed, material characterization. These criteria are the same for all pedicle screw systems and are outlined in the Guidance for the Preparation of Spinal System 510(k). However, because the intended patient population that the XIA 3 Spinal System is indicated to treat are adolescent, great care was taken to ensure thoroughness of characterization of the system and its components driven by a detailed risk analysis and safety evaluation before clearance of any device with similar technological characteristics. Provided in this submission is extensive evidence demonstrating how the device is substantially equivalent to other devices used for treating this patient population.

A risk analysis and MAUDE database search for events related to Stryker Spine's XIA Spinal System have been performed. The results are present below.

9.2 Risk Analysis

In general, criteria for clearing pedicle screw systems are providing a valid predicate device and determining whether the technological characteristics can affect the safety and effectiveness of the device. The most efficient method of determining the risks or failure modes of the XIA 3 Spinal System is to conduct a Risk Analysis and evaluate all the possible risks that may affect safety and characterize the methods of mitigation. This was done for the XIA 3 Spinal System to ensure that all potential safety concerns, design features, mechanism of action, and performance characteristics had been fully addressed. This table is provided below.

Table 9-2: Risk Analysis for XIA 3 Spinal System

Potential Failure Mode/Risk	Potential Failure Effect	Potential Cause/Mechanism of Failure	Verification Activity	Acceptance Criteria	Verification Test Results/Acceptance Criteria Met (Yes/No)
Biocompatibility/Material					
Ti6Al4V, CP Ti and Vitallium components	Inflammation response	Material particulates	Ensure medical grade materials per ISO/ASTM standards	Materials meet criteria established in ISO/ASTM standards	Yes
Hardware Failure					
• Screw Breakage • Rod Breakage • Cross Connector	Loss of stability, inability to maintain correction	Loading/displacement conditions outside those expected	Construct Testing: • Static axial compression bending • Dynamic axial compression bending	Construct Testing: • Static axial comp. bending: ≥ 217N yield load[33] [34] • Dynamic axial comp. bending: ≥ 100N @ 5Mc	Construct Testing: • Static axial comp. bending: 285N • Dynamic axial comp. bending: 175N @ 5Mc (n=6) Additionally, the predicate rod sizes are smaller than the XIA 3 rods indicating that the XIA 3 will have higher performance values compared to the predicates.

[33] Puttlitz CM, Masaru F, Barkley A, Diab M, Acaroglu E. A biomechanical assessment of thoracic spine stapling. Spine. 2007 Apr 1;32(7):766-71.
[34] Stanford, Ralph Edward FRACS, PhD; Loefler, Andreas Herman FRACS; Stanford, Philip Mark; Walsh, William R. PhD. Multiaxial Pedicle Screw Designs: Static and Dynamic Mechanical Testing. Spine. 29(4):367-375, February 15, 2004.

9.3 MAUDE Database Search

A September 2011 search of the MAUDE Database identified a total of 625 MDRs related to the components and instrumentation of the Stryker XIA Spinal System. It is important to note the MAUDE Database search included all Stryker Xia components and was not limited to the Xia 3 components that are presented in this 510k submission. Reviewers from Musculoskeletal Clinical Regulatory Advisers, LLC, independent of Stryker Spine knowledgeable in MDRs, classified the events as related to the implant or instrumentation, and those occurring perioperatively (at time of surgery) and those occurring postoperatively (after wound closure). Postoperative device-related events are the most comparable to those reported in the literature as adverse events. Events leading to component or system revision surgery were also noted.

Instrumentation-related MDR's

A total of 125 MDR's were identified in the MAUDE database search for the Stryker XIA Spinal System that were instrument-related. Individual event listings are noted in **Attachment H**. The results are summarized by event type in **Table 9-3**.

Table 9-3: Breakdown of MAUDE database search results, Instrumentation-Related

Component	Event Type				
	Breakage	Malfunction	Migration/ Loosening	Unknown/ Other	Total
Instruments	94	24		7	**125**

Perioperative Implant-Related MDR's

A total of 194 MDR's were identified in the MAUDE database search for the Stryker XIA Spinal System that were implant-related and occurring perioperatively. Individual event listings are noted in **Attachment H**. The results are summarized by event type in **Table 9-4**.

Table 9-4: Breakdown of MAUDE database search results, Perioperative and Implant-Related

Component	Event Type				
	Breakage	Malfunction	Migration/ Loosening	Unknown/ Other	Total
Screw	68	42	3	5	**118**
Blocker	30	25	1		**56**
Connector	7	2		1	**10**
TOTAL	**105**	**79**	**4**	**6**	**194**

Postoperative Implant-Related MDR's

A total of 316 MDR's were identified in the MAUDE database search for the Stryker XIA Spinal System that were implant-related and occurring post-operatively. Individual event listings are noted in **Attachment H**. The results are summarized by event type in **Table 9-5**. **Table 9-6** summarizes the rates of occurrences for all events and revision/explant rates.

Table 9-5: Breakdown of MAUDE database search results, Post-operative and Implant-Related

Component	Event Type				
	Breakage	**Malfunction**	**Migration/ Loosening**	**Unknown/ Other**	**Total**
Screw	141	5	30	2	**178**
Rod	67		6	1	**74**
Blocker	9	3	40	2	**54**
Connector	6		3		**9**
Other*				1	**1**
TOTAL	**223**	**8**	**79**	**6**	**316**

*Including Allergy to Entire System

Table 9-6: Breakdown of Revision rates, Post-operative and Implant-Related

Component	Total Sales	Event Total	Event Rate	Revision/ Explant Total	Revision/ Explant Rate
Screw	262,613	178		110	
Rod		74		45	
Blocker		54		19	
Connector		9		8	
Other		1		0	
TOTAL	**52,222****	**316**	**.957%**	**182**	**.349%**

*Including Allergy to Entire System
**Total Sales Quantity is minimum total sales number based on an average of 5 screws per case

Device breakage was the most commonly reported event with 223 postoperative implant-related breakages. Of the total 316 reported events, 71% were a result of device breakage, 3% malfunction, 25% migration or loosening, and 2% for unknown or other reasons. Overall, the occurrence rates for Stryker XIA 3 spinal system reported MAUDE events and revisions were extremely low at 0.957% and 0.349%, respectively.

All XIA Spinal System MDR's

A total of 625 MDR's were identified in the MAUDE database search for the Stryker XIA Spinal System. The results are summarized by event type in **Table 9-7**. **Table 9-8** summarizes the rates of occurrences for all events.

Table 9-7: Breakdown of MAUDE database search results, XIA System

System	Event Type								
	Breakage		Malfunction		Migration/ Loosening		Unknown/ Other		Total
	PERI	POST	PERI	POST	PERI	POST	PERI	POST	
Screws	68	141	42	5	3	30	5	2	**296**
Rods		67				6		1	**74**
Blocker	30	9	25	3	1	40		2	**110**
Connector	7	6	2			3	1		**19**
Instruments	94		24				7		**125**
Other*								1	**1**
TOTAL	**199**	**223**	**93**	**8**	**4**	**79**	**13**	**6**	**625**

PERI = Perioperative event; POST = postoperative event
*Including Allergy to Entire System

Table 9-8: Breakdown of Revision rates, Post-operative and Implant-Related

Component	Total Sales	Event Total	Event Rate	Revision/ Explant Total	Revision/ Explant Rate
Screw	262,613	296		110	
Rod		74		45	
Blocker		110		19	
Connector		19		8	
Instruments		125		0	
Other		1		0	
TOTAL	**52,222****	**625**		**182**	**.349%**

*Including Allergy to Entire System

Device breakage was the most commonly reported event with 199 perioperative breakages and 223 postoperative breakages. Of the total 625 reported events, 68% were a result of device breakage, 16% malfunction, 13% migration or loosening, and 3% for unknown reasons. Overall, the occurrence rates for Stryker XIA Spinal System reported MAUDE events and revisions were extremely low at 0.957% and 0.349%, respectively.

The complete listing of reported MAUDE database events is provided in **Attachment H**.

9.4 Predicate Device Comparison

9.4.1 Intended Use / Indications For Use

The Intended Use and Indications for Use for the XIA 3 Spinal System are the same as the predicate Medtronic TSRH Spinal System (K111942) and CD HORIZON Spinal System (K091445) and similar to the Paradigm Spine Orthobiom Spinal System (K071668) and Synthes USS Small Stature (K994121). All systems are intended for posterior noncervical pedicle screw fixation in pediatric patients.

9.4.2 Mechanism of Action

Each scoliosis system is intended to do the same thing, that is, correct, stabilize and fix the scoliotic spine to facilitate fusion. The XIA 3 Spinal System is not different. It has rods and screws which allow the surgeon to correct and stabilize the spine and maintain that correction over time. The only way to show equivalence of a system that is intended to do this is to show mechanically that it is as strong and stiff as other similar systems and clinical justifications with valid references.

9.4.3 Geometry / Device Sizes

Based on a literature review of pediatric pedicle screw systems and the cited predicate data, the following table describes device rod sizing for comparison to the XIA 3 Spinal System rods.

Table 9-9: Predicate Comparison – Device Sizes

Device	510(k) Number	Indicated for AIS (Y/N)	Available Rod Sizes (diameter)
CD HORIZON Spinal System	K091445	Y	3.5, 4.5, 5.5, 6.35mm
Orthobiom Spinal System	K071668	Y	5.0mm
USS Small Stature System	K994121	Y	5.0, 6.0mm
XIA 3 Spinal System	**Subject**	**Y**	**5.5, 6.0mm**
Universal Clamp Spinal Fixation System	K110348	Y	5.5, 6.0, 6.35mm
TSRH Spinal System	K111942	Y	5.5, 6.35mm
ISOLA Spinal System	K962984	Y	6.5mm

The rod sizes for the XIA 3 Spinal System are comparable to the predicate rod sizes, and in many cases, the predicate systems include rods with smaller diameters. It can therefore be expected that the XIA 3 Spinal System will be mechanically equivalent, if not better, than the predicate systems (see Section 8.2.4 below).

In addition to having larger rods than several of the predicate systems, the 5.5mm and 6.0mm XIA 3 rods are smaller than several of the 510(k) cleared systems. The CD

HORIZON Spinal System, Orthobiom Spinal System, and USS Small Stature System include rods less than 5.5mm at 3.5mm, 5.0mm, and 5.0mm, respectively. On the other hand, the Universal Clamp, the TSRH Spinal System, and ISOLA Spinal System include rods with diameters larger than 6.0mm: 6.35mm, 6.35mm, and 6.5mm, respectively. The XIA 3 rods fall within the size range of predicate systems rods that have been cleared by FDA for AIS indications or pediatric use. The literature review also includes evidence that the above systems are being used clinically with successful outcomes in safety and effectiveness (see Section 8.2.5).

9.4.4 Mechanical Equivalence

Mechanical testing was conducted in conformance with ASTM F1717-04 and ASTM F1798-97 (in determining worst case). The FDA is very familiar with the ASTM F1717 testing. This testing demonstrates that the XIA 3 Spinal System has the same or higher mechanical strength as most pedicle screw systems on the market including those indicated for both skeletally mature and those indicated for AIS, including Synthes' USS Small Stature System and Paradigm Spine's Orthobiom System (**Table 9-10** and **Table 9-11**). A summary of the testing and results is provided below and in Section 7.

Table 9-10: Summary of XIA 3 Spinal System Static Mechanical Testing

Test	Construct	Stiffness (SD)	Yield
Static Compression Bending	6.0mm XIA Vitallium rods	52 (4) N/mm	253 (11) N
	5.5mm Radius rods	28.7 (0.6) N/mm	285 (4) N
Static Torsion	6.0mm XIA Vitallium rods	3.0 (0.1) Nm/°	10.0 (0.03) Nm
	5.5mm Radius rods	2.7 (0) Nm/°	8.4 (0.3) Nm

Table 9-11: Summary of XIA 3 Spinal System Dynamic Mechanical Testing

Test	Construct	Load	Run out
Dynamic Compression Bending	6.0mm XIA Vitallium rods	220 N	5,000,000 cycles
	5.5mm Radius rods	175 N	5,000,000 cycles

The testing presented above demonstrates that the XIA 3 Spinal System can be considered substantially equivalent to the predicates.

Due to predicate devices being unavailable testing, an exact side-by-side comparison cannot be made. However, several comparisons to the literature are available regarding device sizes, physiologic loading and clinical outcomes. One of the newer technologies being used in scoliosis correction are the Medtronic Sofamor Danek CD HORIZON nitinol and titanium alloy staples. Literature reports document their use for anterior scoliosis curve correction.[35] In comparing the CD HORIZON staple to the XIA 3 Spinal System its clear the XIA 3 construct has higher cross-sectional area and more rigidity to correct a scoliotic curve. While no side-by-side fatigue data is available to support this,

[35] Betz RR, Kim J, D'Andrea LP, Mulcahey MJ, Balsara RK, Clements DH. An innovative technique of vertebral body stapling for the treatment of patients with adolescent idiopathic scoliosis: a feasibility, safety, and utility study. Spine. 2003 Oct 15;28(20):S255-65.

these design principles support the notion that the XIA 3 Spinal System has greater fatigue resistance than CD HORIZON staples. Despite the fusion indications, much of the literature describes "fusionless" treatments with no reports of fatigue related failures. This worst-case condition for the staples further supports the safety of the XIA 3 Spinal System.

In a paper by Périé et al[36], pressure measurements and finite element analysis was performed on 12 idiopathic scoliosis patients to analyze Boston brace effectiveness. The results demonstrate the largest forces required to sufficiently correct the scoliosis curve was 113N, which the subject fatigue test surpasses. There are obvious limitations in this comparison since the XIA 3 Spinal System is an internal fixation system designed to correct and stabilize to facilitate fusion, whereas the Boston brace is an external brace designed to apply pressure to curves in hopes of correction without fusion. However, both systems are subjected to forces from the scoliotic curves and must counter them with their respective correction method.

A study by Daniels et al[37] attached strain gages to Harrington Rods and measured the forces imparted on the device intra-operatively. In this article, the authors fixed strain gages to the hook/rod interconnect and measured the forces during scoliosis correction and 30 minutes afterwards to characterize the change in loading (i.e., decrease in loading) over time after correction. They measured an approximate load of 245N during correction and this reduced to approximately 64N after correction. The author does report some potential variability with the position of the strain gage. The author states that the "outrigger" (the device that corrects the spine) is accurate within ±1%, while the distractor is less accurate, within ±10%. However, it is important to note, that the highest loads during correction of the curve were being measured by the Harrington outrigger, therefore, the 245N is a relatively certain value. This article demonstrates that the correction forces observed by the Harrington Rods (i.e., device) are much lower than reported in the literature.

Unfortunately, the most important value is the load on the Harrington after correction. Even under worst case conditions and the reported results are 10% higher, 70N is much lower than the 175N the XIA 3 Spinal System run out. It is also only expected that this load will continue to decrease over time as the muscles adjust to the corrected curve. In summary, this article demonstrates that the mechanical integrity of the XIA 3 Spinal System is high enough to maintain the scoliotic curve.

The mechanical performance of the XIA 3 Spinal System is equivalent to other pedicle screw systems indicated for skeletally mature and pediatric patient populations. Stryker Spine believes that the XIA 3 Spinal System is mechanically equivalent to the predicate

[36] Périé D, Aubin CE, Petit Y, Beauséjour M, Dansereau J, Labelle H. Boston brace correction in idiopathic scoliosis: a biomechanical study. Spine 2003 Aug 1;28(15):1672-7.

[37] Daniels, A.U., Gemperline, Patrick, Grahn, Allen R., Dunn, Harold K., A New Method of Continuous Intraoperative Measurement of Harrington Rods Loading Patterns. Annals of Biomedical Engineering, Vol 12. 1984. pp.233-246.

CD HORIZON Spinal System, Orthobiom Spinal System, and USS Small Stature based on the following reasons:

1. XIA 3 ASTM F1717-04 test results are comparable to other pedicle screw systems;
2. The predicate CD HORIZON and Orthobiom rods are available in smaller, worst case sizes; and
3. The loads in the adolescent spine are less than those observed in skeletally mature spines.

The literature also shows that the XIA 3 Spinal System can withstand physiological loading in the scoliotic spine, and that other predicates in the literature are inferior in their mechanical strength.

9.4.5 Clinical Safety and Effectiveness

A comprehensive literature review was performed comparing the clinical outcomes of pedicle screw systems indicated for pediatric use and compared the results to the XIA 3 Spinal System and its comparable sizes. The clinical results were consistently successful, and the results of this literature review provide a justification for mechanical equivalence of the XIA 3 Spinal System compared to predicates based on implant sizing. The full literature review report is provided in **Attachment G**.

A total of 32 articles were identified relating to the use of posterior instrumentation in the thoracolumbar spine. **Table 9-12** below provides a summary of the study types that comprise this clinical evaluation. This analysis does not include literature that neglected to divulge the study type (retrospective vs. prospective).

Table 9-12: Summary of Publications

Study Design	All Studies Reviewed
Prospective, Randomized	1
Prospective, Multiple Cohorts	3
Prospective, Single Cohort	6
Retrospective, Multiple Cohorts	14
Retrospective, Single Cohort	6
Other/Review	2
Total	**32**

The articles identified were checked to determine which devices were used by the authors in each study. **Table 9-13** details the devices, materials, and sizes which were used in the identified literature, where available. The majority of articles which are included utilized devices whose size and materials are more “worst case” when compared to the parameters of the testing which was performed on the XIA 3 Spinal System. Literature

rod diameters are the same as or smaller than the tested XIA 3 construct, which again makes them more "worst case." When device material or size data was not available in the articles, a check of the commercially available sizes of each device shows that each is within the parameters of the tested XIA 3 construct, and may therefore be compared for purposes of this literature review. Thus the literature sample may be used as a basis to compare existing clinical data on AIS devices to the possible clinical outcomes for the XIA 3 Spinal System. The clinical results are provided below.

Table 9-13: Literature Results – Device Sizing and Materials

Reference	Sample Size	Device(s) Utilized	Device Material(s)	Device Size(s)
Asher 2004	185	Isola	Stainless Steel or Titanium	6.5 mm rod
Dobbs 2006	34	CD-Horizon	--	5.5 mm rod
Kim 2004	26	CD Horizon	--	5.5 mm rod
		Moss-Miami		5.0 mm rod
Kuklo 2007	1428	--	Stainless Steel or Titanium	--
Lehman 2008	112	CD Horizon	Stainless Steel	5.5 mm rod
Mazda 2009	75	Universal Clamp	Stainless Steel or Titanium, Polyester	
Ruf 2002	16	Summit (Depuy)	--	--
		Biederman Motech		3.5 mm screws
		Baby Moss-Miami		3 mm rod
Wright 2007	129	USS (Synthes)	Stainless Steel	6.0 mm
		Moss-Miami	Titanium	5.5 mm

Literature Safety Summary

The use of posterior instrumentation for the treatment of adolescent idiopathic scoliosis has been demonstrated to have a favorable safety profile, with complication rates similar to the use of posterior instrumentation for other indications. A review of complications by Hicks et al. (2010)[38] demonstrated a low level (<5%) of complications when utilizing various pedicle screw systems for the treatment of adolescent idiopathic scoliosis. Screw malpositioning (4%) and infection (1%) were the largest single adverse events present in the studies reviewed, with all other complications occurring in less than 1% of the reviewed patient population. In contrast, Thomsen et al. (1997)[39] noted 4.8% of patients having misplaced pedicle screws and 1.6% deep wound infections in a study of posterior instrumentation with pedicle screws utilized for the treatment of Grade I or II spondylolisthesis. In addition, the overall low rates of pedicle breakage and screw loosening noted in the literature review specifically address concerns specific to a pediatric population for the treatment of scoliosis, as bone size is smaller in these patients and bone has not completely developed to an adult stage of durability. The rates of adverse events were similar for other indications and skeletally mature patients. The overall low rate of adverse events demonstrated in the reviewed studies, shown in **Table 9-14** below, presents significant evidence for the overall safety of posterior instrumentation for the treatment of adolescent idiopathic scoliosis. There are no event rates or risks for this population that has not been characterized for skeletally mature

[38]Hicks JM, Singla A, Shen FH, Arlet V. Complications of pedicle screw fixation in scoliosis surgery: a systematic review. Spine (Phila Pa 1976). 2010 May 15;35(11):E465-70.

[39] Thomsen K, Christensen F, Eiskjaer S, Hansen E, Fruensgaard S, Bunger C, and Mardjetko S. The Effect of Pedicle Screw Instrumentation on Functional Outcome and Fusion Rates in Posterolateral Lumbar Spinal Fusion: A prospective, Randomized Clinical Study. Spine, 22(24): 2813 – 2822, 1997.

patients. Therefore, pedicle screw systems with similar sizes and materials to the XIA 3 Spinal System are safe.

Table 9-14: Adverse Event Rates – Thomsen et al.

Reference	Sample Size	Total Complications
Asher 2004	185	21
Brown 1998	223	5
Cochran 1983	95	35
Diab 2007	1301	9
Dobbs 2006	34	0
Frennered 1991	66	34
Kim 2004	26	0
Kim 2006	29	0
Kuklo 2007	1428	64
Lamberg 2005	107	29
Lehman 2008	112	5
Li 2009	30	0
Luhmann 2005	84	0
Marks 2007	547	84
Mazda 2009	75	14
Muschik 1997	59	5
Patel 2008	176	0
Poussa 1993	22	4
Ruf 2002	16	5
Storer 2005	25	0
Suk 2008	87	11
Wong 2004	31	2
Wright 2007	129	23
Total	**4887**	**350 (7.2%)**

Efficacy Summary

The use of posterior instrumentation for the treatment of adolescent idiopathic scoliosis has been demonstrated to be effective in correction of spinal deformity, as evidenced by overall Cobb Angle correction as demonstrated in the clinical literature. A summary of the clinical evidence of spinal curve correction for patients with adolescent idiopathic scoliosis as treated with posterior pedicle screw systems is located in **Table 9-15**.

Table 9-15: Summary of Clinical Evidence

Article	Patient Number	Immediate Post-Operative Curve Correction (%)	Last Follow-up Time Point	Curve Correction at Last Follow-up (%)
Arlet 2009	20	--	1.7 Years	71%
Asher 2004	176	--	5 Years	63%
Dobbs 2006	34	56%	2 Years	53%
Geck 2009	31	87.6%	2 Years	84.2%
Kim 2004	26	75.6%	2 Years	70.2%
Kim 2006	29	70%	2 Years	65%
Lehman 2008	114	72%	3 Years	68%
Li 2009	30	--	1.5 Years	74%
Luhman 2005	11	61%	2.7 Years	59%
Storer 2005	10	70.3%	--	--
Suk 2003	42	--	2 Years	75.2%
Wang 2009	94	66.3%	3.4 Years	68.8%
TOTAL	**617**	**70.3%**	**3.25 Years**	**67.3%**

In contrast to studies for patients receiving posterior instrumentation for other indications, a limited amount of clinical outcome data is present for patients treated for adolescent idiopathic scoliosis. This is understandable, as pediatric patients with scoliotic deformity generally do not experience the level of pain and functional impairment as older patients with DDD, stenosis, or spondylolisthesis. However, those studies that did include clinical outcome measurements, specifically those created by the Scoliosis Research Society (SRS), demonstrated significant clinical benefit in patients who receive posterior pedicle screw systems following surgery. The curve correction obtained utilizing posterior instrumentation with pedicle screws is hypothesized to achieve better clinical results by achieving proper alignment of the spine, allowing for greater pulmonary function and patient mobility. The long-term stabilization of these curvatures allows for continued clinical success throughout long term follow up of these pediatric patients into early adulthood.

While the XIA 3 Spinal System was not utilized in any of the clinical data obtained, studies comparing similar pedicle screw-based systems showed substantially equivalent clinical data, even when comparing different cleared pedicle screw-based systems. In particular, the CD HORIZON system, manufactured by Medtronic Sofamor Danek, has similar indications and is comprised of similar materials (Ti Alloy, Stainless Steel), and has comparable sizing to the XIA 3 Spinal System. The MOSS MIAMI System is a pedicle screw-based system, manufactured by DePuy Spine for similar indications and comprised of the same materials (Ti Alloy, Stainless Steel, CoCr), and has comparable sizing to the XIA 3 Spinal System. The Universal Spinal System, manufactured by Synthes, has similar indications and is comprised of similar materials (Ti Alloy, Stainless Steel), and has comparable sizing to the Xia 3 Spinal System. In the majority of these studies, the patients receiving different spinal systems were pooled due to similar effectiveness of these systems. In a study by Wright et al (2007), patient outcomes with 2 different systems (Universal Spinal System and MOSS MIAMI) were compared with no statistically significant differences in clinical or radiographic outcomes between

treatments. Overall, this demonstrates the interchangeability of clinical results from cleared spinal systems considered substantially equivalent.

From the above data (risk analysis, predicate comparison, and literature review of clinical data), it can be concluded that the XIA 3 Spinal System is substantially equivalent to the predicate devices, and that systems with similar and smaller rod sizes are successfully used in clinical applications. The XIA 3 Spinal System has similar mechanical strength, geometry, size, and indications as other AIS pedicle screw systems. A predicate device comparison table is provided below.

Table 9-16: Predicate Comparison Table

	Subject Device	Predicate Devices			
Manufacturer	Stryker Spine	Medtronic Sofamor Danek USA	Paradigm Spine	Synthes	Stryker Spine
Trade Name	XIA 3 Spinal System	CD HORIZON Spinal System	Orthobiom Spinal System	USS Small Stature	XIA 3 Spinal System
510(k) Number	n/a	K091445	K071668	K994121	K071373
Components	Rods, screws, hooks, cross connectors	Rods, hooks, screws, plates, connecting components	Rods, screws, fixed, mobile and cross connectors	Rods, hooks, screws, staples, connecting components	Rods, screws, hooks, cross connectors
Screw diameters	4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5mm		4.0, 5.0, 6.0mm	3.2, 4.2, 5.0, 6.0, 7.0mm	4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5mm
Rod diameters	5.5, 6.0mm	3.5, 4.5, 5.5, 6.35mm	5.0mm	5.0mm	5.5, 6.0mm
Materials	Titanium alloy CPTi CoCrMo alloy (Vitallium)	Titanium alloy Medical grade titanium CoCrMo alloy Stainless steel	Stainless steel	Titanium alloy Stainless steel	Titanium alloy CPTi CoCrMo alloy (Vitallium)
Approach	Posterior	Posterior	Posterior	Posterior; Anterior	Posterior
Indications for Use	The XIA® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: • Degenerative disc disease (DDD) (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, and/or lordosis); • Tumor; • Pseudoarthrosis; and • Failed previous fusion. The Ø5.5mm rods from the Stryker	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 and/or lordosis); tumor; pseudoarthrosis; 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	The Orthobiom Spinal System is a posterior, non-cervical pedicle screw system indicated to treat pediatric scoliosis by (1) correction, (2) stabilization, (3) adjustment and (4) fixation of the scoliotic spine. The Orthobiom Spinal System is intended to be used with bone graft.	The Synthes USS (including the Click'X, USS VAS variable axis components, and Pangea), Click'X Monoaxial, Pangea Monoaxial, Dual-Opening and the Small Stature USS (which includes small stature and pediatric patients) are noncervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2), a posterior hook fixation system (T1-L5), or as an anterolateral fixation system (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS. These devices are indicated for all the following indications regardless of intended use: 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, pseudoarthrosis, and failed	The XIA® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: • Degenerative disc disease (DDD) (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, and/or lordosis); • Tumor; • Pseudoarthrosis; and • Failed previous fusion.

	Spine Radius™ Spinal System and Ø6.0mm Vitallium rods from the XIA® Spinal System are intended to be used with the other components of XIA® 3 Spinal System. When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA® 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach. 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.	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 adolescent idiopathic scoliosis. The CD HORIZON Pediatric Spinal System is intended 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, non-pedicle supplemental fixation device intended for use in the non-cervical spine (TI-SI1) 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.		previous fusion. When treating patients with degenerative disc disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle screw construct. When used with the 3.5mm/ 6.0mm parallel connectors, the Synthes USS (including the Click'X, USS VAS variable axis components, and Pangea), Click'X Monaxial, Pangea Monoaxial, and Dual-Opening USS can be linked to the CerviFix system. In addition, when used with the 3.5mm/ 5.0mm parallel connectors, the Synthes Small Stature USS, can be linked to the CerviFix system. When used with the 5.0mm/ 6.0mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS (including the Click'X, USS VAS variable axis components, and Pangea), the Click'X Monoaxial, Pangea Monoaxial, and Dual-Opening USS Systems. In addition, Synthes USS (including Click'X, USS VAS variable axis components, and Pangea), Click'X Monoaxial, Pangea Monoaxial and the Dual-Opening USS can be interchanged with all USS 6.0mm rods and transconnectors.	The Ø5.5mm rods from the Stryker Spine Radius™ Spinal System and Ø6.0mm Vitallium rods from the XIA® Spinal System are intended to be used with the other components of XIA® 3 Spinal System.

10. Sterilization

There have been no changes to the sterilization method compared to the previously cleared XIA 3 Spinal System method cleared in K071373.

The XIA 3 Spinal System components will be provided non-sterile.

Method: Water vapor, autoclave

Sterility Validation Method: AAMI TIR 12, ASTM ST-79.

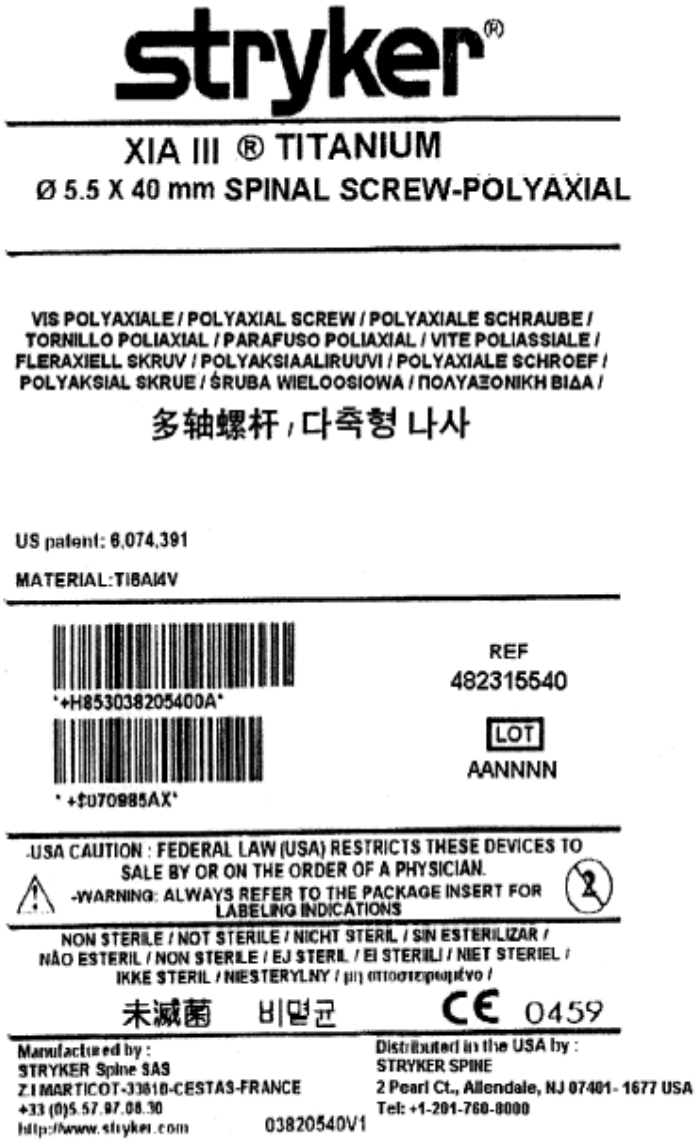
Sterility Assurance Level (SAL): 10^{-6}.

Packaging: Clear plastic tubes and polyethylene bags

No claims will be made that the device is "pyrogen-free."

11. Labeling and Package Insert

A sample label for the XIA 3 Spinal System is provided below. The sample IFU for the XIA 3 Spinal System is provided on the following page. The surgical technique is provided in **Attachment I**.



STRYKER SPINE Spinal Fixation Systems
XIA® - XIA®3

NON STERILE PRODUCT

The STRYKER Spine XIA® and XIA®3 Spinal Systems are comprised of devices intended for the fixation of the non cervical spine. It includes smooth rods, bone screws (monoaxial and polyaxial), hooks, blocker, connectors, washers, and staples. The components are manufactured from either titanium material (Titanium alloy and CP Titanium), Stainless Steel or Cobalt-Chromium-Molybdenum Alloy.

MATERIALS

XIA® Spinal System and XIA®3 Spinal System

Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136: Screws, hooks, closure screws, rods, staples, washers, fasteners and connectors.
Pure Titanium: CP Ti grade 4 according to ISO 5832-2 and ASTM F-67: Rods
Stainless Steel: X2CrNiMo18.14.3 according to ISO 5832-1: Rods, connectors, staples, washers and screws.
Stainless Steel: X4CrNiMnMo21.9.4 according to ISO 5832-9 and ASTM F 1586: Screws, hooks, closure screws, connectors and rods
Cobalt-Chromium-Molybdenum Alloy #1 according to ISO 5832-12 and ASTM F-1537: Rods.

Titanium and Stainless steel implants should not be mixed in patient otherwise corrosion may occur resulting in decreased mechanical resistance.
Cobalt-Chromium-Molybdenum Alloy and Stainless steel implants should not be mixed in patient otherwise corrosion may occur resulting in decreased mechanical resistance.

MATERIALS IDENTIFICATION

Titanium: symbol T
Stainless Steel: symbol S
Cobalt-Chromium-Molybdenum: symbol C

INDICATIONS

XIA® Spinal System

The Xia® Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation 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, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.
The 6 mm diameter rods from the DIAPASON™ Spinal System and OPUS™ Spinal System are intended to be used with the other components of the XIA® Titanium Spinal System. The Titanium Multi-Axis Cross-Connectors are intended to be used with the other components of the XIA® Titanium Spinal System.

XIA®3 Spinal System

The XIA®3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA®3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (DDD) (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, and/or lordosis); tumor; pseudoarthrosis and failed previous fusion.

The Ø5.5mm rods from the STRYKER Spine Radius™ Spinal System and Ø6.0 mm Vitallium rods from XIA® Spinal System are intended to be used with the other components of Xia®3 Spinal System.

When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA® 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

CONTRAINDICATIONS

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Insufficient quality or quantity of bone which would inhibit rigid device fixation.
- Previous history of infection.
- Excessive local inflammation.
- Open wounds.
- Any neuromuscular deficit which places an unsafe load level on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself. Obesity is defined according to the W.H.O. standards.
- Patients having inadequate tissue coverage of the operative site.
- Pregnancy.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.

These contraindications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive.

GENERAL CONDITIONS OF USE

The implantation of pedicle screw spinal systems must be performed only by experienced spinal surgeons having undergone the necessary specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

The information contained in the Package Insert is necessary but not sufficient for the use of this device. This information is in no sense intended as a substitute for the professional judgment, skill and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient's cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

INFORMATION FOR PATIENTS

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up.

The surgeon must warn the patient of the surgical risks and made aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advice the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise patients of this fact and warn of the potential consequences. For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief.

INFECTION

Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have been associated with transient bacteremia. To help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

INSTRUMENTS

Specialized instruments are provided by STRYKER Spine and must be used to assure accurate implantation of the device. While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or extensive force are more susceptible to fracture depending on the operative precaution, number of procedures, disposal attention. Instruments should be examined for wear or damage prior to surgery.

REUSE
An implant should never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity which would reduce its service life.
Surgeons must verify that the instruments are in good condition and operating order prior to use during surgery.

HANDLING
Correct handling of the implant is extremely important. The operating surgeon should avoid notching or scratching the device.

ALLERGY AND HYPERSENSITIVITY TO FOREIGN BODIES
When hypersensitivity is suspected or proven, it is recommended that the tolerance of the skin to the materials that make up the implants be checked before they are implanted

IMPLANT SELECTION AND USE
The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice which depends on each patient.
Patients who are overweight may be responsible for additional stresses and strains on the device which can speed up metal fatigue and/or lead to deformation or failure of the implants.
The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants should be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause metal fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.
Improper selection, placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant. Contouring or bending of rods or plates is recommended only if necessary according to the surgical technique of each system. Rods or plates should only be contoured with the proper contouring instruments. Incorrectly contoured rods/plates, or rods/plates which have been repeatedly or excessively contoured must not be implanted. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Refer to the STRYKER Spine surgical protocols for additional procedural information. Periodic follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

METAL COMPONENTS
Some of the alloys utilized to produce orthopaedic implants contain metallic elements that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomena.

SYSTEM COMPATIBILITY

While some degree of corrosion occurs on all implanted metal and alloys, contact of dissimilar metals may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system may also increase. Internal fixation devices, such as rods, hooks, screws, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of the system should not be used in conjunction with components from any other manufacturer's spinal system. Any such use will negate the responsibility of STRYKER Spine for the performance of the resulting mixed component implant.

POSTOPERATIVE CARE

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician should closely monitor the patient if a change at the site has been detected.

ADVERSE EFFECTS

- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Bending, disassembly or fracture of any or all implant components.
- Fatigue fracture of spinal fixation devices, including screws and rods, has occurred.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin.
- Dural leak requiring surgical repair.
- Cessation of growth of the fused portion of the spine.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) should be revised or removed immediately before serious injury occurs.
- Loosening of spinal fixation implants can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or

trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, migration and/or pain.
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Serious complications may be associated with any spinal surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Decrease in bone density due to stress shielding.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft, the intervertebral body, pedicle, and/or sacrum above and/or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision.
The surgeon must warn the patient of these adverse effects as deemed necessary.

ADDITIONAL ADVERSE EFFECTS FOR PEDIATRIC PATIENTS
- Inability to use pedicle screw fixation due to limitations (pedicle dimensions, distorted anatomy).
- Pedicle screw malpositioning, with or without neurological or vascular injury.
- Proximal or distal junctional kyphosis.
- Pancreatitis.

REMOVAL OF IMPLANTS
These implants are temporary internal fixation devices designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and can be removed. Removal may also be recommended in other cases, such as:
- corrosion with a painful reaction,
- migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions,
- pain or abnormal sensations due to the presence of the implants,
- infection or inflammatory reactions,
- reduction in bone density due to the different distribution of mechanical and physiological stresses and strains,
- failure or mobilization of the implant.

Standard ancillaries provided by STRYKER Spine can be used to remove the implants. Any decision by a physician to remove the internal fixation device must take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This

technique may require practice in the laboratory before being attempted clinically. Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture. Removal of the implant after fracture healing is recommended. Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain or stress shield bone.

PACKAGING AND STORAGE

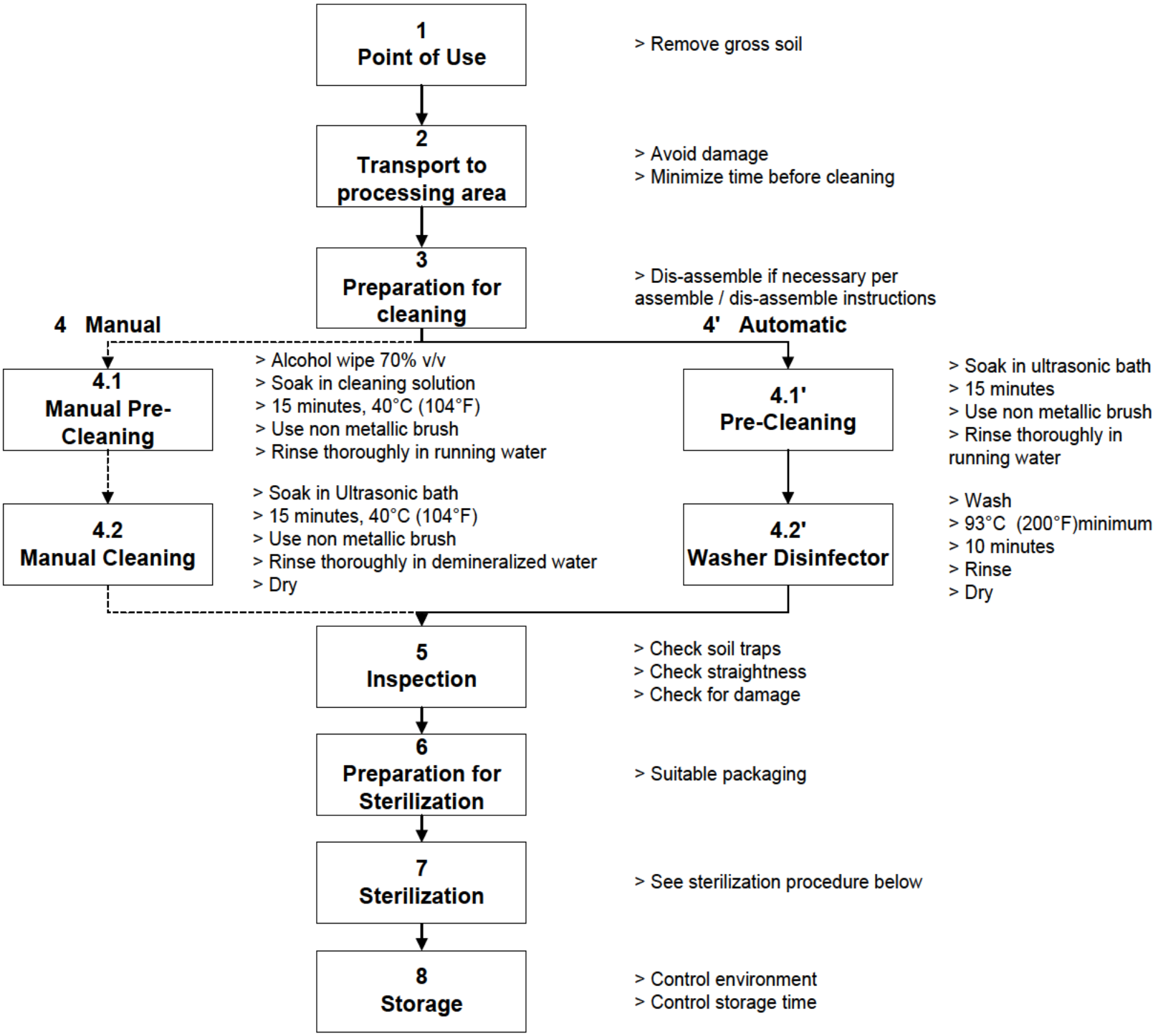
The implants are delivered in packages; these must be intact at the time of receipt.
The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.
They must be stored in a clean, dry and temperate place.

FURTHER INFORMATION

A surgical technique brochure is available on request through your STRYKER agent or directly from STRYKER Spine. Users with brochures that are over two years old at the time of surgery are advised to ask for an updated version.

PRE-CLEANING / CLEANING AND STERILISATION PROCEDURE RECOMMENDED FOR NON STERILE MEDICAL DEVICE

For safety reasons, non-sterile devices must be pre-cleaned, cleaned and sterilized prior to use. Moreover, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps described in the following chart.



Sterilization procedure recommended for non-sterile medical devices including implants

Medical Devices should be sterilized in their container with water vapor in an autoclave in accordance with standard hospital procedure. The sterilization method suggested has been validated according to the AAMI ST 79 in order to obtain a Sterility Assurance Level (SAL) of 10^{-6}.

STERILIZATION CONDITIONS: 2 sets of low parameters have been validated on wrapped items:

- Prevacuum steam sterilization (Porous load autoclave): TEMPERATURE: 132°C (270°F), EXPOSURE TIME: 4 minutes, DRY TIME: 45min.
- Gravity-displacement steam sterilization: TEMPERATURE: 132°C (270°F), EXPOSURE TIME: 10 minutes, DRY TIME: 45min.

Caution: Stryker Spine has not validated and does not recommend Flash Sterilization. For Product being used in the US, a sterilization wrap that is FDA cleared for the cycle parameters noted should be used.

The autoclave must be validated by the hospital and regularly checked to guarantee the recommended sterilization temperature is reached for the entire exposure time.
If sterilization containers with paper filters are used, it is advisable to use a new filter for each sterilization.
If after having followed this sterilization method there is still water in the sterilization containers or on/inside the device, the device must be dried and sterilization repeated.

PRE-OPERATIVE PRECAUTIONS
Anyone using STRYKER Spine products can obtain a Surgical Technique brochure by requesting one from a distributor or from STRYKER Spine directly. Those using brochures published more than two years before the surgical intervention are advised to get an updated version.

STRYKER Spine devices can only be used by doctors who are fully familiar with the surgical technique required and who have been trained to this end. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by STRYKER Spine. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to causes injury to the patient.

To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable STRYKER Spine Surgical Technique.

Extreme care must be taken when the instruments are used near vital organs, nerves or vessels.

Unless otherwise specified on the label, the instruments can be reused after decontamination, cleaning and sterilization.

CAUTION
Federal law (U.S.A) restricts this device to sale by or on the order of a licensed physician.

WARNING (U.S.A.)
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 spondylolisthesis (grades 3 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurological 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.

ADDITIONAL WARNINGS FOR PEDIATRIC PATIENTS
Warning: 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.

The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature or skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter and 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 reduce longitudinal spinal growth, or may be at risk for rotational spinal deformities (the “crankshaft phenomenon”) due to continued differential growth of the anterior spine.

Other adverse effects related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients. Pediatric patients may be at increased risk for device-related injury because of their small stature.

PRECAUTIONS (U.S.A.)
The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

ADDITIONAL PRECAUTIONS FOR PEDIATRIC PATIENTS
The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients.

The selection of the proper size, shape, and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

COMPLAINTS

Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, safety, effectiveness and / or its performance, should notify STRYKER Spine or its representative. Moreover, if a device has malfunctioned, or is suspected of having malfunctioned, STRYKER Spine or its representative must be advised immediately.

If a STRYKER Spine product has ever worked improperly and could have caused or contributed to the death of or serious injury to a patient, the distributor or STRYKER Spine must be informed as soon as possible by telephone, fax or in writing.

For all complaints, please give the name and reference along with the batch number of the component(s), your name and address and an exhaustive description of the event to help STRYKER Spine understand the causes of the complaint.

For further information regarding services, please contact:
STRYKER SPINE SA
Le Crêt-du-Locle 10a - 2300 La Chaux-de-Fonds - Switzerland
Tel. +41.32.924.6000
Fax. +41.32.926.2410 (Customer Service)

For further information regarding complaints, please contact:
STRYKER SPINE SAS
ZI de Marticot, 33610 CESTAS – France
Tel. (33) (0)5.57.97.06.30
Fax. (33) (0)5.57.97.06.31 (Quality Assurance)
http://www.stryker.com

STRYKER SPINE
2 Pearl Court, Allendale, NJ 07401- 1677 USA
Tel: +1-201-760-8000

12. Biocompatibility

The components of Stryker Spine's XIA 3 Spinal System are available in Ti6Al4V alloy in accordance with ISO 5832-3 and ASTM F136 and commercially pure titanium in accordance with CP Ti grade 4 according to ISO 5832-2 and ASTM F67. The system also includes previously cleared XIA rods manufactured from CoCrMo alloy (Vitallium) in accordance with Cobalt-Chromium-Molybdenum alloy #1 according to ISO 5832-12 and ASTM F1537.

Compliance with the referenced materials standards ensures the suitability, with regard to biocompatibility, for the device system's intended purpose. The above mentioned titanium alloy and CoCrMo alloy materials have a long history in orthopedic clinical use, and the use of these materials for the specific new indications for use raise no new issues with regard to substantial equivalence or safety and effectiveness.

12. Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Regulatory Affairs Manager of Stryker Spine, I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____

Tiffani D. Rogers

_____

Date

13. Declaration of Conformity

No declarations of conformity are provided because this is not an Abbreviated 510(k) submission.

Summaries of performance testing are presented in Section 8.

14. Attachments

A. Engineering Drawings
B. Engineering Analysis Xia 3 Spinal System
C. ASTM 1798-07 Test Report
D. ASTM 1717-04 Test Report Xia 3 Spinal System
E. ASTM 1717-04 Test Report Xia 3 Spinal System w/ Radius Rods
F. ASTM 1717-04 Engineering Analysis and Test Report Dynamic Torsion
G. Literature Analysis of Pediatric Pedicle Screw Systems
H. MAUDE Database Event Listing
I. Xia 3 AIS DRAFT Surgical Technique
J. Predicate Clearance Letters and 510(k) Summaries
K. FDA Forms 3654

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Amy Graf

Subject: 510(k) Number K113666

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold)

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NM	NSE requires PMA
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):	YES	NO
Indications for Use Page — *Attach IFU*		
510(k) Summary /510(k) Statement — *Attach Summary*		
Truthful and Accurate Statement — *Must be present for a Final Decision*		
Is the device Class III?		
If yes, does firm include Class III Summary? — *Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC		
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		
Is this device intended for pediatric use only?		
Is this a prescription device? (If both prescription & OTC, check both boxes.)		
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		
Is clinical data necessary to support the review of this 510(k)?		
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)		
Does this device include an Animal Tissue Source?		
All Pediatric Patients age<=21		

Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

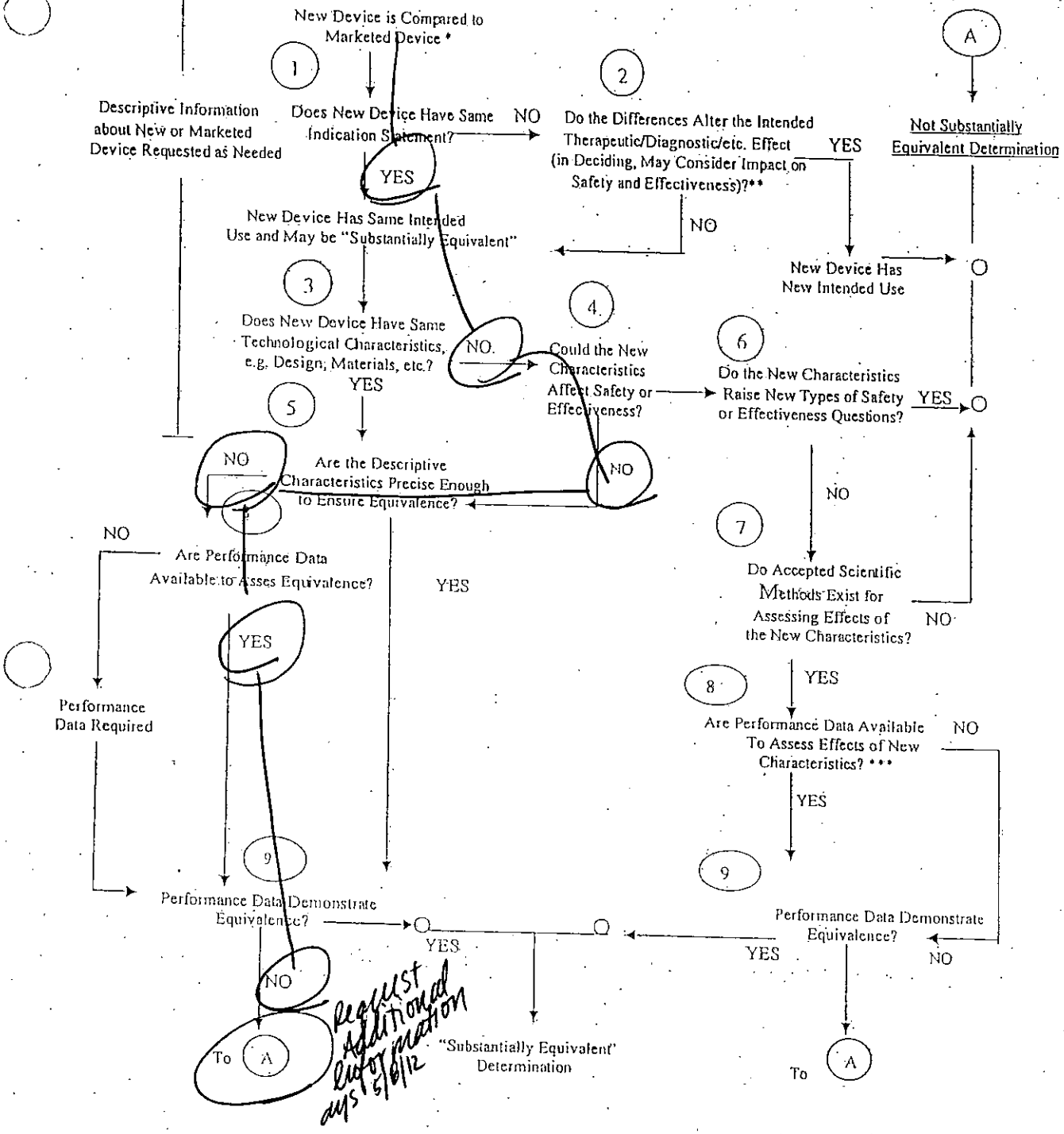
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: _____ OSDB 05/08/2012
(Branch Chief) (Branch Code) (Date)

Final Review: _____ for 05/08/2012
(Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated
K113666

Date: May 8, 2012
To: The Record
From: Amy Graf, Biomedical Engineer

Office: ODE
Division: DSORD

510(k) Holder: Stryker Spine
2 Pearl Court
Allendale, New Jersey 07401

Device Name: XIA 3 Spinal System

Decision Contact: % Musculoskeletal Clinical Regulatory Advisers, LLC
Mr. Glenn Stiegman
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005

Phone: (202) 552-5800
Fax: (202) 552-5798
Email: gstiegman@mcra.com

Review Contact: Tiffani Rogers
Phone: (201) 760-8406
Email: tiffani.rogers@stryker.com

RECOMMENDATION: REQUEST ADDITIONAL INFORMATION (TELEPHONE HOLD, TH)

I. Purpose and Submission Summary

The 510(k) holder would like to introduce XIA 3 Spinal System into interstate commerce.

This submission seeks to add adolescent idiopathic scoliosis (AIS) to the XIA 3 Spinal System. The sponsor is not adding any new components to the system. All components have previously been cleared through 510(k) for typical pedicle screw system indications for use.

(b) (4)

[redacted]

Therefore, I recommend the file be placed on telephone hold until the above comparison may be provided for review.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: **Prescription** or OTC)	Section 5		
Truthful and Accuracy Statement	Page 86		
510(k) Summary or 510(k) Statement	Section 6		
Standards Form	Attachment K		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? (Reusable instruments)	X		
Are "cleaning" instructions included for the end user?	X		

The XIA 3 Spinal System is a noncervical pedicle screw system that includes a variety of monoaxial, polyaxial, uniplanar, and closed bone screws, blockers (as a locking mechanism), rods (straight and pre-bent), hooks, cross connectors (monoaxial and polyaxial), offset connectors, and rod to rod connectors.

Polyaxial Screws - ∅4.0 – 7.5mm X 20 – 90mm
Monoaxial Screws - ∅4.0 – 7.5mm X 20 – 90mm
Uniplanar / Reduction Uniplanar Screws - ∅4.0 – 7.5mm X 20 – 60mm
Closed Head Monoaxial/Polyaxial Screw - ∅6.5 – 9.5mm X 30 – 100mm
Biased/Medial Biased Angled Polyaxial Screw - ∅4.0 – 9.5mm X 20 – 100mm
Angled Monoaxial Screw - ∅6.5 – 9.5mm X 60 – 100mm

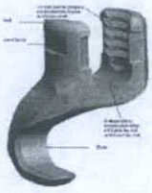
Figure 4-2: Polyaxial Screw Figure 4-5: Monoaxial Screw Uniplanar and Reduction Uniplanar Closed Head Monoaxial and Polyaxial

Angle Polyaxial **Angled Monoaxial**

Blocker (set screw) - ∅10mm

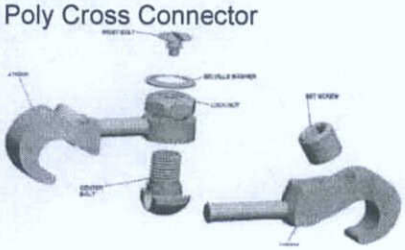
Figure 4-9: Blocker

Hooks – Laminar, thoracic, pedicle, transverse process; Small, medium, large

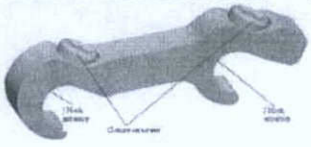


Straight Rods (CP Ti, Ti6Al4V) - ∅6 mm X 30 – 150mm and 480 – 600mm
Straight Rods (Ti6Al4V, Radius Spinal System, K062270) - ∅5.5 mm
Bent Rods (Ti6Al4V, Radius Spinal System, K062270) - ∅5.5 mm
Straight Vitallium rod (CoCrMo alloy, K060979, K091291) - ∅5.5 and 6 mm X 600mm
Rad Rods/Pre-bent - ∅6 mm X 30 – 50mm and 60 – 120mm
Max Rad Rods/Pre-bent - ∅6 mm X 50 – 120mm

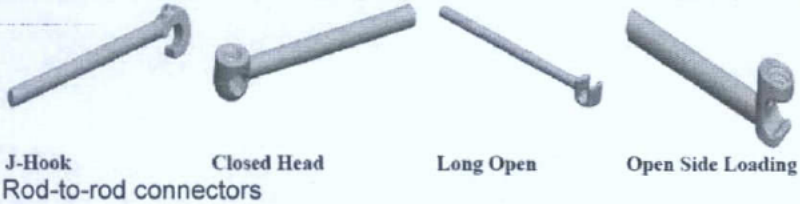
Poly Cross Connector



Mono Cross Connector – 14 – 26mm

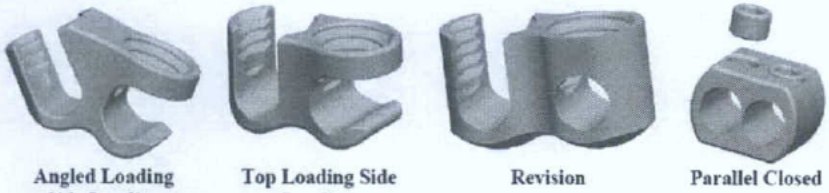


Offset Connectors:J-hook and Long Open – 100mm, Closed head – 65mm, Open Side – 60mm



J-Hook Closed Head Long Open Open Side Loading

Rod-to-rod connectors



Angled Loading Side Loading | Top Loading Side Loading | Revision | Parallel Closed

(b) (4)

[redacted]

The Class III certification and summary are provided in Section 7 for the NKB pedicle screw product code indications.

The instruments provided with the device are described in Section 4.2 and are described as Class I, 510(k) instruments including hook holdesr, awls, probes, taps, screwdrivers, wrenches, rod benders, and rod cutters.

IV. Indications for Use

The XIA® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- *Degenerative disc disease (DDD) (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, and/or lordosis);*
- *Tumor;*
- *Pseudoarthrosis; and*
- *Failed previous fusion.*

The Ø5.5mm rods from the Stryker Spine Radius™ Spinal System and Ø6.0mm Vitallium rods from the XIA® Spinal System are intended to be used with the other components of XIA® 3 Spinal System.

When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA® 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Reviewer Comment

(b)(4)

[redacted]

V. Predicate Device Comparison

K091445 – Medtronic Sofamor Danek CD Horizon Spinal System
K071668 – Paradigm Spine Orthobiom Spinal System
K071373 – Stryker Spine XIA 3 Spinal System
K994121 – Synthes Spine USS Small Stature System
K111942 – Medtronic Sofamor Danek TSRH Spinal System

Table 9-16: Predicate Comparison Table

	Subject Device	Predicate Devices			
facturer	Stryker Spine	Medtronic Sofamor Danek USA	Paradigm Spine	Synthes	Stryker Spine
Name	XIA 3 Spinal System	CD HORIZON Spinal System	Orthobiom Spinal System	USS Small Stature	XIA 3 Spinal System
510(k) Number	n/a	K091445	K071668	K994121	K071373
Components	Rods, screws, hooks, cross connectors	Rods, hooks, screws, plates, connecting components	Rods, screws, fixed, mobile and cross connectors	Rods, hooks, screws, staples, connecting components	Rods, screws, hooks, cross connectors
Screw diameters	4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5mm		4.0, 5.0, 6.0mm	3.2, 4.2, 5.0, 6.0, 7.0mm	4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5mm
Rod diameters	5.5, 6.0mm	3.5, 4.5, 5.5, 6.35mm	5.0mm	5.0mm	5.5, 6.0mm
Materials	Titanium alloy CPTi CoCrMo alloy (Vitallium)	Titanium alloy Medical grade titanium CoCrMo alloy Stainless steel	Stainless steel	Titanium alloy Stainless steel	Titanium alloy CPTi CoCrMo alloy (Vitallium)
Approach	Posterior	Posterior	Posterior	Posterior; Anterior	Posterior
Indications for Use	The XIA® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: • Degenerative disc disease (DDD) (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, and/or lordosis); • Tumor; • Pseudoarthrosis; and • Failed previous fusion. The Ø5.5mm rods from the Stryker	The CD HORIZON Spinal System with or without SEXTANT reimplantation 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 and/or lordosis); tumor; pseudoarthrosis; 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	The Orthobiom Spinal System is a posterior, non-cervical pedicle screw system indicated to treat pediatric scoliosis by (1) correction, (2) stabilization, (3) adjustment and (4) fixation of the scoliotic spine. The Orthobiom Spinal System is intended to be used with bone graft.	The Synthes USS (including the Click'X, USS VAS variable axis components, and Pengas). Click'X Monoaxial, Pengas Monoaxial, Dual-Opening and the Small Stature USS (which includes small stature and pediatric patients) are noncervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2), a posterior hook fixation system (T1-L5), or as an anterolateral fixation system (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS. These devices are indicated for all the following indications regardless of intended use: 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, pseudoarthrosis, and failed	The XIA® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: • Degenerative disc disease (DDD) (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, and/or lordosis); • Tumor; • Pseudoarthrosis; and • Failed previous fusion.

	Subject Device	Predicate Devices			
facturer	Stryker Spine	Medtronic Sofamor Danek USA	Paradigm Spine	Synthes	Stryker Spine
	Spine Radius™ Spinal System and Ø6.0mm Vitallium rods from the XIA® Spinal System are intended to be used with the other components of XIA® 3 Spinal System. When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA® 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach. 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.	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 adolescent idiopathic scoliosis. The CD HORIZON Pediatric Spinal System is intended 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, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-SI) 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.		previous fusion. When treating patients with degenerative disc disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle screw construct. When used with the 3.5mm/ 6.0mm parallel connectors, the Synthes USS (including the Click'X USS VAS variable axis components, and Pangea), Click'X Monoaxial, Pangea Monoaxial, and Dual-Opening USS can be linked to the CerviFix system. In addition, when used with the 3.5mm/ 5.0mm parallel connectors, the Synthes Small Stature USS, can be linked to the CerviFix system. When used with the 5.0mm/ 6.0mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS (including the Click'X USS VAS variable axis components, and Pangea), the Click'X Monoaxial, Pangea Monoaxial, and Dual-Opening USS Systems. In addition, Synthes USS (including Click'X USS VAS variable axis components, and Pangea), Click'X Monoaxial, Pangea Monoaxial and the Dual-Opening USS can be interchanged with all USS 6.0mm rods and transconnectors.	The Ø5.5mm rods from the Stryker Spine Radius™ Spinal System and Ø6.0mm Vitallium rods from the XIA® Spinal System are intended to be used with the other components of XIA® 3 Spinal System.

Reviewer Comment

(b)(4)

[redacted]

VI. Labeling

LABEL (Section 11)

- ☒ Component & system name
- ☒ Material
- ☒ Part number/Lot number
- ☐ Single use statement – Has symbol only, need to add text

INSERT (Section 11)

- ☒ System name
- ☒ Material
- ☒ Indications for use, including levels of fixation
- ☒ Single use statement*

☐ Sterile notation	☐ Sterile notation
☒ Non-sterile notation	☒ Non-sterile notation
☐ Shelf life (if applicable)	☒ Sterilization parameters
☒ Statement referring to package insert for labeling limitations	☒ Contraindications, warnings and precautions – specific to pediatric
☒ Cautionary symbol restricting sale to a physician	☒ Appropriate warnings for product codes (KWQ, KWP, MNI, MNH, NKB)
☒ Company name and address	☒ Company name, address & telephone number
SURGICAL TECHNIQUE MANUAL *(Attachment I)*	☒ Cautionary statement restricting sale to a physician
☒ Device description	☒ Precaution statement addressing relationship between fatigue testing, device performance, and patient selection
☐ Contraindications, precautions and warnings – specific to pediatric – Need to provide this	☒ Statement warning against using titanium and stainless steel components together
☒ Magnified sketches of important steps	☒ Statement indicating components of this system should not be used with components of any other system or manufacturer
☐ Identification of supplemental fixation system (for VBRs only)	☐ Identification of supplemental fixation system (for VBRs only)
☐ Indications and intended use – Need to provide this	☒ Statement indicating how to obtain surgical technique manual
☒ Removal/revision procedures	☐ MR Compatibility – Need to provide this

Reviewer Comments

(b)(4) [redacted]

VII. Sterilization/Shelf Life/Reuse

(b)(4) [redacted]

1. Sterilant:	YES	NO
a. **Sterilization method** description (e.g., Steam (moist heat), EO, Radiation):	Steam	
b. **Dose**, for radiation (e.g., 25 – 50 kGy):	N/A	

c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the standards that have been, or currently are recognized, "ANSI/AAMI/ISO 10993-7:1995 and 2008 *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals*," do not include measurement of ethylene glycol residuals);	N/A
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended including date (e.g., ANSI/AAMI/ISO 11135:2007)),	AAMI TIR 12
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}
4. Is it labeled "Pyrogen Free"?	No
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))	
5. A description of the packaging (not including package integrity test data):	Clear plastic tubes and polyethylene bags.

Method	Cycle	Temperature	Time	Drying Time
Steam	Prevacuum	132°C	4 min.	45 min.
Steam	Gravity	132°C	10 min.**	45 min.

An FDA-cleared wrap is recommended.

Reviewer Comment

(b)(4) [redacted]

VIII. Biocompatibility

The system is manufactured from the following materials:

Titanium alloy (Ti6Al4V) per ASTM F136
Commercially Pure Titanium (CP Ti) per ASTM F67
Cobalt Chrome Alloy (CoCrMo) per ASTM F1537

Reviewer Comment

(b)(4) [redacted]

IX. Software

There is no software for the subject device.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Please see Section VI, the sponsor should add a statement to the package insert with respect to MR

compatibility.

XI. Performance Testing – Bench

(b)(4)

[redacted]

Reviewer Comments
(b)(4) [redacted]

XII. Performance Testing – Animal

Not provided in this submission.

XIII. Performance Testing – Clinical

There is no clinical data provided in the subject submission.

The sponsor has provided references to several peer-reviewed journal articles and textbooks in Section 3 of the submission.

Reviewer Comment
(b)(4) [redacted]

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?		X	Final Decision: Request additional information.

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. **Describe the new technological characteristics:**

(b)(4) [redacted]

4. **Explain how new characteristics could or could not affect safety or effectiveness:**
(b)(4)

5. Explain how descriptive characteristics are not precise enough:

6. **Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:**
(b)(4)

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. **Explain how the performance data demonstrates that the device is or is not substantially equivalent:**
(b)(4)

XV. Deficiencies

(b)(4)

(b)(4)

XVI. Contact History

5/4/2012	Glenn Stiegman and Tiffani Rogers confirmed via email that the subject system does not contain any new components since the last clearance, K071373.
5/4/2012	G. Stiegman (MCRA) stated via email that both he and T. Rogers (Stryker) may be contacted for interactive review.
5/7/2012	T. Rogers confirmed via email that the neither the cleaning instructions nor sterilization parameters have changed since the last clearance, K071373.
5/8/2012	Emailed deficiencies for telephone hold.

XVII. Recommendation

~~Regulation Number: 21 CFR 888.3070~~
~~Regulation Name: Pedicle screw spinal system~~
~~Regulatory Class: Class III~~
~~Product Code: NKB, OSH, KWP, KWQ, MNH, MNI~~

Reviewer — Date: 5/8/2012

Branch Chief — Date: 05/08/2012

Graf, Amy S.

From: Graf, Amy S.
Sent: Tuesday, May 08, 2012 12:16 PM
To: 'Rogers, Tiffani (Spine)'
Cc: 'Glenn Stiegman'
Subject: K113666 - Telephone hold

Dear Tiffani,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following information:

(b)(4)

[redacted]

(b)(4)

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).
If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. .

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

Please feel free to call or email with respect to the above deficiencies. Especially with regard to Deficiency #1, I think it would be good to discuss expectations for the requested comparison table. I have also been assigned the XIA 4.5

pediatric indications submission. I have not looked through the submission yet, but a similar table to the one requested for K113666 will be necessary if you did not provide clinical data in your submission.

Thanks,

Amy

Amy Graf amy.graf@fda.hhs.gov
Biomedical Engineer
FDA/CDRH/ODE/DSORD/OSDB
WO 66, Room G408
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Tel: 301-796-5613

Graf, Amy S.

From: Rogers, Tiffani (Spine) [Tiffani.Rogers@stryker.com]
Sent: Monday, May 07, 2012 3:13 PM
To: Graf, Amy S.
Subject: RE: Cleaning instructions K113666

Hi Amy,

(b)(4) [redacted]

Thanks.
-Tiffani

Tiffani Rogers
Manager, Regulatory Affairs
Stryker Spine
T: 201-760-8206
F: 201-760-8406

From: Graf, Amy S. [mailto:Amy.Graf@fda.hhs.gov]
Sent: Monday, May 07, 2012 2:42 PM
To: Rogers, Tiffani (Spine)
Subject: Cleaning instructions K113666

Hi Tiffani,

(b)(4) [redacted]

Thanks,

Amy

Graf, Amy S.

From: Glenn Stiegman [gstiegman@mcra.com]
Sent: Friday, May 04, 2012 2:02 PM
To: Graf, Amy S.
Subject: RE: K113666 Xia 3 AIS

Hi Amy,

(b)(4)

[redacted]

Glenn

Glenn Stiegman, MS
VP, Regulatory and Clinical Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA)
1331 H Street, NW
12th Floor
Washington DC, 20005
Office: 202-552-5800
Direct: 202-552-5803
gstiegman@mcra.com

From: Graf, Amy S. [mailto:Amy.Graf@fda.hhs.gov]
Sent: Friday, May 04, 2012 11:24 AM
To: Glenn Stiegman
Cc: 'tiffani.rogers@stryker.com'
Subject: RE: K113666 Xia 3 AIS

Should Tiffani be the contact for this file?

From: Glenn Stiegman [mailto:gstiegman@mcra.com]
Sent: Friday, May 04, 2012 11:21 AM
To: Graf, Amy S.
Cc: 'tiffani.rogers@stryker.com'
Subject: RE: K113666 Xia 3 AIS

Hi Amy,

(b)(4) [redacted]

Glenn

Glenn Stiegman, MS
VP, Regulatory and Clinical Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA)
1331 H Street, NW
12th Floor
Washington DC, 20005
Office: 202-552-5800
Direct: 202-552-5803
gstiegman@mcra.com

From: Graf, Amy S. [mailto:Amy.Graf@fda.hhs.gov]
Sent: Friday, May 04, 2012 11:19 AM
To: Glenn Stiegman
Cc: 'tiffani.rogers@stryker.com'
Subject: K113666 Xia 3 AIS

Dear Mr. Stiegman

(b)(4) [redacted]

Amy

Amy Graf amy.graf@fda.hhs.gov
Biomedical Engineer
FDA/CDRH/ODE/DSORD/OSDB
WO 66, Room G408
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Tel: 301-796-5613

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Graf, Amy S.

From: Rogers, Tiffani (Spine) [Tiffani.Rogers@stryker.com]
Sent: Friday, May 04, 2012 12:56 PM
To: Graf, Amy S.; 'gstiegman@mcra.com'
Subject: RE: K113666 Xia 3 AIS

Hello Amy,
(b)(4) [redacted]

Best regards,
-Tiffani

Tiffani Rogers
Manager, Regulatory Affairs
Stryker Spine
T: 201-760-8206
F: 201-760-8406

From: Graf, Amy S. [mailto:Amy.Graf@fda.hhs.gov]
Sent: Friday, May 04, 2012 11:19 AM
To: 'gstiegman@mcra.com'
Cc: Rogers, Tiffani (Spine)
Subject: K113666 Xia 3 AIS

Dear Mr. Stiegman,

(b)(4) [redacted]

Amy

Amy Graf amy.graf@fda.hhs.gov
Biomedical Engineer
FDA/CDRH/ODE/DSORD/OSDB
WO 66, Room G408
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Tel: 301-796-5613

Graf, Amy S.

From: Glenn Stiegman [gstiegman@mcra.com]
Sent: Friday, May 04, 2012 11:21 AM
To: Graf, Amy S.
Cc: 'tiffani.rogers@stryker.com'
Subject: RE: K113666 Xia 3 AIS

Hi Amy,

(b)(4) [redacted]

Glenn

Glenn Stiegman, MS
VP, Regulatory and Clinical Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA)
1331 H Street, NW
12th Floor
Washington DC, 20005
Office: 202-552-5800
Direct: 202-552-5803
gstiegman@mcra.com

From: Graf, Amy S. [mailto:Amy.Graf@fda.hhs.gov]
Sent: Friday, May 04, 2012 11:19 AM
To: Glenn Stiegman
Cc: 'tiffani.rogers@stryker.com'
Subject: K113666 Xia 3 AIS

Dear Mr. Stiegman,

(b)(4) [redacted]

Amy

Amy Graf amy.graf@fda.hhs.gov
Biomedical Engineer
FDA/CDRH/ODE/DSORD/OSDB
WO 66, Room G408
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Tel: 301-796-5613

K113666/S1 V1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Stryker Spine
% Musculoskeletal Clinical Regulatory Advisers, LLC
Mr. Glenn Stiegman
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005

AUG 28 2012

Re: K113666
Trade/Device Name: Xia® 3 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, OSH, KWP, MNH, MNI
Dated: July 25, 2012
Received: August 1, 2012

Dear Mr. Stiegman:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> "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."

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the

market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.
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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Christy Foreman

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K113666

Device Name: XIA® 3 Spinal System

Indications for Use:

The XIA® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fustion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative disc disease (DDD) (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, and/or lordosis)
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion

The Ø5.5mm rods from the Stryker Spine Radius™ Spinal System and Ø6.0mm Vitallium Rods from the XIA® Spinal System are intended to be used with the other components of the XIA® 3 Spinal System.

When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA® 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis.

The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christy Foreman

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113666

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –W066-G609
Silver Spring, MD 20993-0002

Stryker Spine
% Musculoskeletal Clinical Regulatory Advisers, LLC
Mr. Glenn Stiegman
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005

Re: K113666
Trade/Device Name: Xia® 3 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, OSH, KWP, MNH, MNI
Dated: July 25, 2012
Received: August 1, 2012

Dear Mr. Stiegman:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> "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."

8/24/12

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the

Date: August 28, 2012

To: Mr. Glenn Stiegman

From: Edwena Jones

Re: K113666

As was discussed earlier on the phone, please send back a written affirmation to the limitations language in the device's warning section of your 510(k). You may sign off on the letter and fax back if that is the easiest course of action for you. Please call me at (301) 796-6308 or email me at Edwena.Jones@fda.hhs.gov if you have any questions or would like to discuss further. Please fax your response to (301) 847-8120 to my attention. Thank you.

Edwena Jones
Premarket Notification Staff
Program Operations Staff
Office of Device Evaluation
Center for Devices and Radiological Health

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Amy Graf

Subject: 510(k) Number K113666/S1

To: The Record

Please list CTS decision code SU

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?		✓	
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*	✓	
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			✓

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)	
Does this device include an Animal Tissue Source?	✓
All Pediatric Patients age<=21	✓
Neonate/Newborn (Birth to 28 days)	✓
Infant (29 days -< 2 years old)	✓
Child (2 years -< 12 years old)	✓
Adolescent (12 years -< 18 years old)	✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21. (different device design or testing, different protocol procedures, etc.)	✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	✓
Nanotechnology	✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*	✓

Regulation Number	**Class***	**Product Code**
21 CFR 888.3070	III	NKB

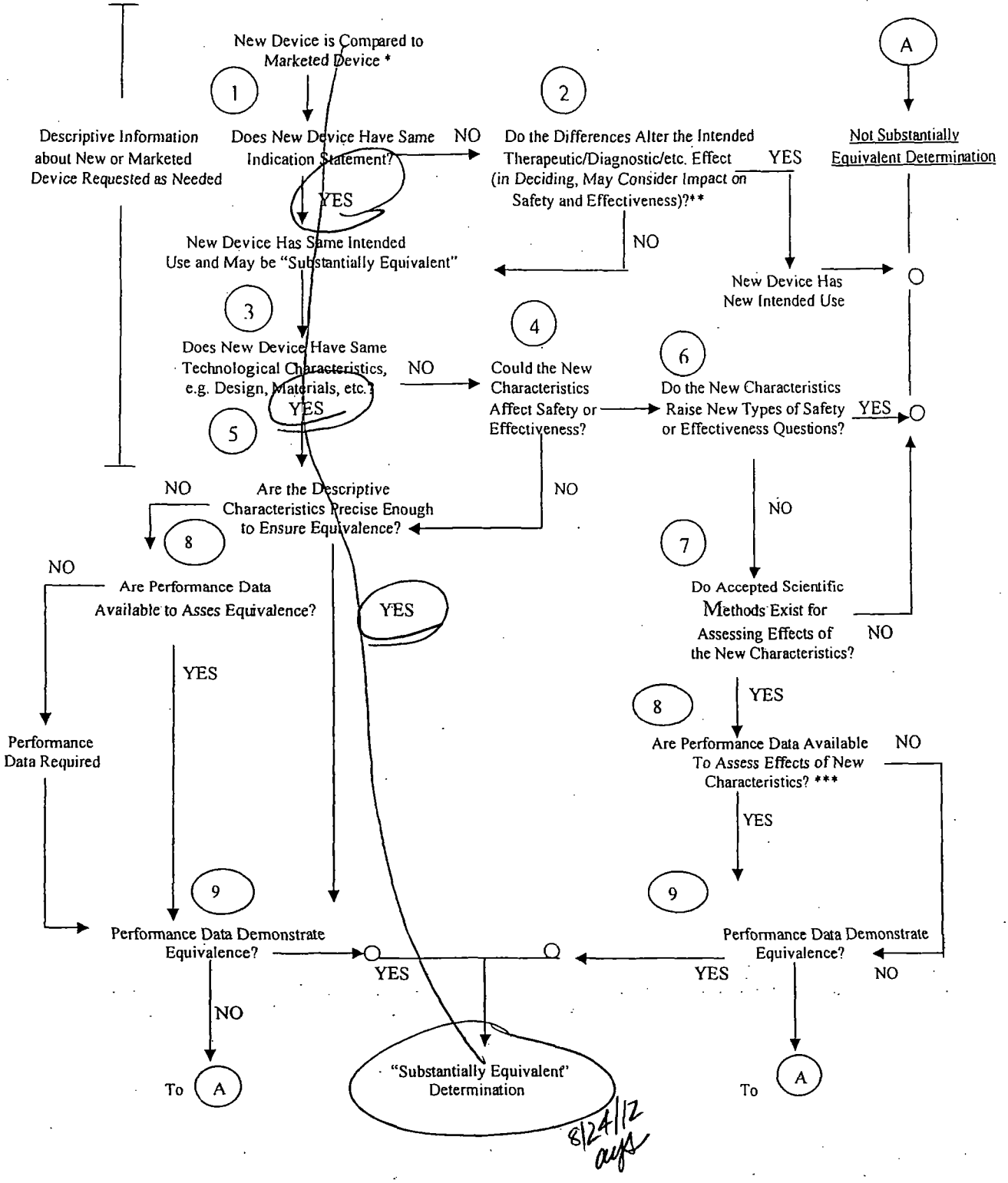
(*If unclassified, see 510(k) Staff)

Additional Product Codes: OSH, KWP, MNH, MNI

Review: Carl O'Neill for RPJ — (Branch Chief) — OSDB (Branch Code) — 8/27/12 (Date)

Final Review: [signature] — (Division Director) — 8/27/12 (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated
K113666

Date: August 22, 2012
To: The Record
From: Amy Graf, Biomedical Engineer
Office: ODE
Division: DSORD

510(k) Holder: Stryker Spine
2 Pearl Court
Allendale, New Jersey 07401
Device Name: XIA 3 Spinal System
Decision Contact: % Musculoskeletal Clinical Regulatory Advisers, LLC
Mr. Glenn Stiegman
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005
Phone: (202) 552-5800
Fax: (202) 552-5798
Email: gstiegman@mcra.com
Review Contact: Tiffani Rogers
Phone: (201) 760-8406
Email: tiffani.rogers@stryker.com

RECOMMENDATION: SUBSTANTIALLY EQUIVALENT with LIMITATIONS (SU)

I. Purpose and Submission Summary

The 510(k) holder would like to introduce XIA 3 Spinal System into interstate commerce.

This submission seeks to add adolescent idiopathic scoliosis (AIS) to the XIA 3 Spinal System. The sponsor is not adding any new components to the system. All components have previously been cleared through 510(k) for typical pedicle screw system indications for use.

(b)(4)

(b)(4) [redacted]

Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, KWP, MNH, MNI

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: **Prescription** or OTC)	Section 5		
Truthful and Accuracy Statement	Page 86		
510(k) Summary or 510(k) Statement	Section 6		
Standards Form	Attachment K		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? (Reusable instruments)	X		
Are "cleaning" instructions included for the end user?	X		

The XIA 3 Spinal System is a noncervical pedicle screw system that includes a variety of monoaxial, polyaxial, uniplanar, and closed bone screws, blockers (as a locking mechanism), rods (straight and pre-bent), hooks, cross connectors (monoaxial and polyaxial), offset connectors, and rod to rod connectors.

Polyaxial Screws - Ø4.0 – 7.5mm X 20 – 90mm
Monoaxial Screws - Ø4.0 – 7.5mm X 20 – 90mm
Uniplanar / Reduction Uniplanar Screws - Ø4.0 – 7.5mm X 20 – 60mm
Closed Head Monoaxial/Polyaxial Screw - Ø6.5 – 9.5mm X 30 – 100mm
Biased/Medial Biased Angled Polyaxial Screw - Ø4.0 – 9.5mm X 20 – 100mm
Angled Monoaxial Screw - Ø6.5 – 9.5mm X 60 – 100mm

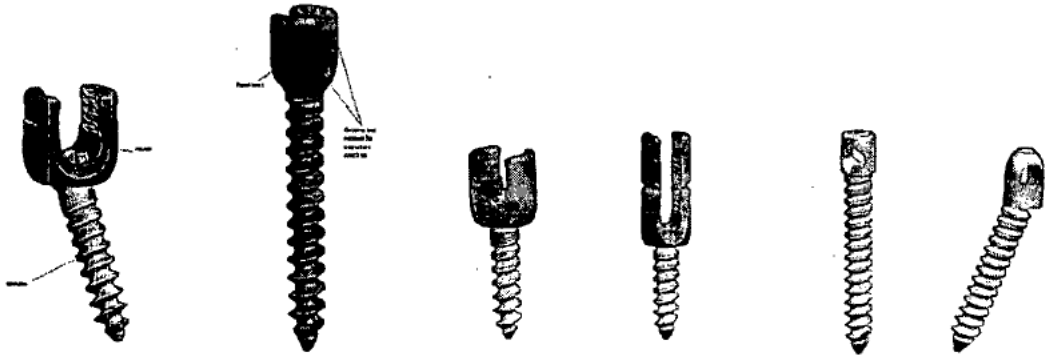
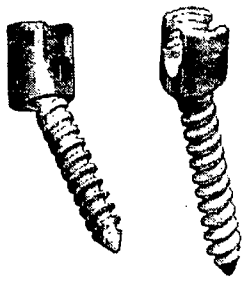


Figure 4-2: Polyaxial Screw Figure 4-5: Monoaxial Screw Uniplanar and Reduction Uniplanar Closed Head Monoaxial and Polyaxial

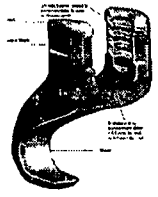


Angle Polyaxial Angled Monoaxial

Blocker (set screw) - Ø10mm

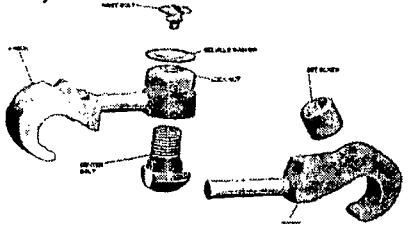
Figure 4-9: Blocker

Hooks – Laminar, thoracic, pedicle, transverse process; Small, medium, large

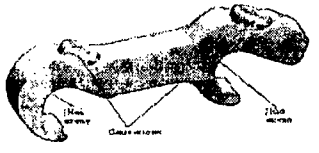


Straight Rods (CP Ti, Ti6Al4V) - Ø6 mm X 30 – 150mm and 480 – 600mm
Straight Rods (Ti6Al4V, Radius Spinal System, K062270) - Ø5.5 mm
Bent Rods (Ti6Al4V, Radius Spinal System, K062270) - Ø5.5 mm
Straight Vitallium rod (CoCrMo alloy, K060979, K091291) - Ø5.5 and 6 mm X 600mm
Rad Rods/Pre-bent - Ø6 mm X 30 – 50mm and 60 – 120mm
Max Rad Rods/Pre-bent - Ø6 mm X 50 – 120mm

Poly Cross Connector



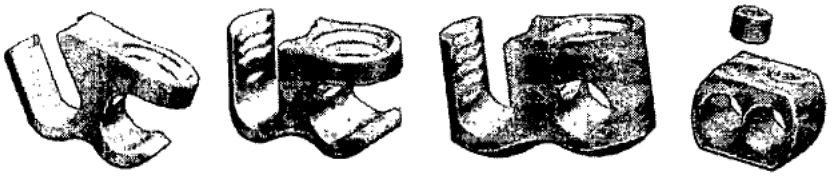
Mono Cross Connector – 14 – 26mm



Offset Connectors:J-hook and Long Open – 100mm, Closed head – 65mm, Open Side – 60mm

J-Hook Closed Head Long Open Open Side Loading

Rod-to-rod connectors



Angled Loading Side Loading | Top Loading Side Loading | Revision | Parallel Closed

(b) (4)

The Class III certification and summary are provided in Section 7 for the NKB pedicle screw product code indications.

The instruments provided with the device are described in Section 4.2 and are described as Class I, 510(k) instruments including hook holders, awls, probes, taps, screwdrivers, wrenches, rod benders, and rod cutters.

IV. Indications for Use

The XIA® 3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- *Degenerative disc disease (DDD) (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, and/or lordosis);*
- *Tumor;*
- *Pseudoarthrosis; and*
- *Failed previous fusion.*

The Ø5.5mm rods from the Stryker Spine Radius™ Spinal System and Ø6.0mm Vitallium rods from the XIA® Spinal System are intended to be used with the other components of XIA® 3 Spinal System.

When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA® 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

(b) (4)

V. Predicate Device Comparison

K091445 – Medtronic Sofamor Danek CD Horizon Spinal System
K071668 – Paradigm Spine Orthobiom Spinal System
K071373 – Stryker Spine XIA 3 Spinal System
K994121 – Synthes Spine USS Small Stature System
K111942 – Medtronic Sofamor Danek TSRH Spinal System

Table 9-16: Predicate Comparison Table

	Subject Device	Predicate Devices			
Manufacturer	Stryker Spine	Medtronic Sofamor Danek USA	Paradigm Spine	Synthes	Stryker Spine
[redacted] Name	XIA 3 Spinal System	CD HORIZON Spinal System	Orthobiom Spinal System	USS Small Stature	XIA 3 Spinal System
510(k) Number	n/a	K091445	K071668	K994121	K071373
Components	Rods, screws, hooks, cross connectors	Rods, hooks, screws, plates, connecting components	Rods, screws, fixed, mobile and cross connectors	Rods, hooks, screws, staples, connecting components	Rods, screws, hooks, cross connectors
Screw diameters	4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5mm		4.0, 5.0, 6.0mm	3.2, 4.2, 5.0, 6.0, 7.0mm	4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5mm
Rod diameters	5.5, 6.0mm	3.5, 4.5, 5.5, 6.35mm	5.0mm	5.0mm	5.5, 6.0mm
Materials	Titanium alloy CPTi CoCrMo alloy (Vitallium)	Titanium alloy Medical grade titanium CoCrMo alloy Stainless steel	Stainless steel	Titanium alloy Stainless steel	Titanium alloy CPTi CoCrMo alloy (Vitallium)
Approach	Posterior	Posterior	Posterior	Posterior, Anterior	Posterior
Indications for Use	The XIA® 3 Spinal System is intended for use in the nonocervical spine. When used as an anterior/anterolateral and posterior, nonocervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: • Degenerative disc disease (DDD) (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, and/or lordosis); • Tumor; • Pseudoarthrosis; and • Failed previous fusion. The Ø5.5mm rods from the Stryker	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 and/or lordosis); tumor; pseudoarthrosis; 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	The Orthobiom Spinal System is a posterior, non-cervical pedicle screw system indicated to treat pediatric scoliosis by (1) correction, (2) stabilization, (3) adjustment and (4) fixation of the scoliotic spine. The Orthobiom Spinal System is intended to be used with bone graft.	The Synthes USS (including the Click'X, USS VAS variable axis components, and Pangea), Click'X Monoaxial, Pangea Monoaxial, Dual-Opening and the Small Stature USS (which includes small stature and pediatric patients) are nonocervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2), a posterior hook fixation system (T1-L5), or as an anterolateral fixation system (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS. These devices are indicated for all the following indications regardless of intended use: 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, pseudoarthrosis, and failed	The XIA® 3 Spinal System is intended for use in the nonocervical spine. When used as an anterior/anterolateral and posterior, nonocervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: • Degenerative disc disease (DDD) (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, and/or lordosis); • Tumor; • Pseudoarthrosis; and • Failed previous fusion.

	Subject Device	Predicate Devices			
[redacted]ufacturer	Stryker Spine	Medtronic Sofamor Danek USA	Paradigm Spine	Synthes	Stryker Spine
	Spine Radius™ Spinal System and Ø6.0mm Vitallium rods from the XIA® Spinal System are intended to be used with the other components of XIA® 3 Spinal System. When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA® 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach. 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.	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 adolescent idiopathic scoliosis. The CD HORIZON Pediatric Spinal System is intended 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, 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.		previous fusion. When treating patients with degenerative disc disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle screw construct. When used with the 3.5mm/ 6.0mm parallel connectors, the Synthes USS (including the Click'X, USS VAS variable axis components, and Pangea), Click'X Monoaxial, Pangea Monoaxial, and Dual-Opening USS can be linked to the CerviFix system. In addition, when used with the 3.5mm/ 5.0mm parallel connectors, the Synthes Small Stature USS, can be linked to the CerviFix system. When used with the 5.0mm/ 6.0mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS (including the Click'X, USS VAS variable axis components, and Pangea), the Click'X Monoaxial, Pangea Monoaxial, and Dual-Opening USS Systems. In addition, Synthes USS (including Click'X, USS VAS variable axis components, and Pangea), Click'X Monoaxial, Pangea Monoaxial, and the Dual-Opening USS can be interchanged with all USS 6.0mm rods and transconnectors.	The Ø5.5mm rods from the Stryker Spine Radius™ Spinal System and Ø6.0mm Vitallium rods from the XIA® Spinal System are intended to be used with the other components of XIA® 3 Spinal System.

Reviewer Comment

(b) (4)

[redacted]

S001 Deficiency #1

(b) (4)

[redacted]

(b)(4) Testing

[redacted]

Response/Reviewer Comment

(b)(4) Testing

[redacted]

S001 Deficiency #2

(b)(4) Testing

[redacted]

Response/Reviewer Comment

(b)(4) Testing

[redacted]

VI. Labeling

LABEL (Section 11)	*INSERT (Section 11)*
☒ Component & system name	☒ System name
☒ Material	☒ Material
☒ Part number/Lot number	☒ Indications for use, including levels of fixation
☒ Single use statement – ~~Has symbol only, need to add text~~ (S001)	☒ Single use statement*
☐ Sterile notation	☐ Sterile notation
☒ Non-sterile notation	☒ Non-sterile notation
☐ Shelf life (if applicable)	☒ Sterilization parameters
☒ Statement referring to package insert for labeling limitations	☒ Contraindications, warnings and precautions – specific to pediatric
☒ Cautionary symbol restricting sale to a physician	☒ Appropriate warnings for product codes (KWQ, KWP, MNI, MNH, NKB)
☒ Company name and address	☒ Company name, address & telephone number
SURGICAL TECHNIQUE MANUAL *(Attachment I)*	☒ Cautionary statement restricting sale to a physician

- ☒ Device description
- ☒ Contraindications, precautions and warnings – specific to pediatric – ~~Need to provide this~~ (S001)
- ☒ Magnified sketches of important steps
- ☐ Identification of supplemental fixation system (for VBRs only)
- ☒ Indications and intended use – ~~Need to provide this~~ (S001)
- ☒ Removal/revision procedures
- ☒ Precaution statement addressing relationship between fatigue testing, device performance, and patient selection
- ☒ Statement warning against using titanium and stainless steel components together
- ☒ Statement indicating components of this system should not be used with components of any other system or manufacturer
- ☐ Identification of supplemental fixation system (for VBRs only)
- ☒ Statement indicating how to obtain surgical technique manual
- ☒ MR Compatibility – ~~Need to provide this~~ (S001)

Reviewer Comments

(b) (4)

[redacted]

S001 Deficiency #3

(b) (4)

[redacted]

Response/Reviewer Comment

(b) (4)

[redacted]

(b) (4)

[redacted]

VII. Sterilization/Shelf Life/Reuse

The sponsor indicates the sterilization method has not changed since the K071373 clearance.

1. Sterilant:	YES	NO
a. **Sterilization method** description (e.g., Steam (moist heat), EO, Radiation):	Steam	
b. **Dose**, for radiation (e.g., 25 – 50 kGy):	N/A	
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the standards that have been, or currently are recognized, "ANSI/AAMI/ISO 10993-7:1995 and 2008 *Biological Evaluation of Medical*	N/A	

Devices – Part 7: Ethylene Oxide sterilization residuals," do not include measurement of ethylene glycol residuals);	
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended including date (e.g., ANSI/AAMI/ISO 11135:2007)),	AAMI TIR 12
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}
4. Is it labeled "Pyrogen Free"?	No
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))	
5. A description of the packaging (not including package integrity test data):	Clear plastic tubes and polyethylene bags.

Method	Cycle	Temperature	Time	Drying Time
Steam	Prevacuum	132°C	4 min.	45 min.
Steam	Gravity	132°C	10 min.**	45 min.

An FDA-cleared wrap is recommended.

Reviewer Comment

(b) (4)

[redacted]

S001 Deficiency #4

(b) (4)

[redacted]

(b)(4) Testing

[redacted]

Response/Reviewer Comment
(b) (4) [redacted]

VIII. Biocompatibility

The system is manufactured from the following materials:

Titanium alloy (Ti6Al4V) per ASTM F136
Commercially Pure Titanium (CP Ti) per ASTM F67
Cobalt Chrome Alloy (CoCrMo) per ASTM F1537

Reviewer Comment
(b) (4) [redacted]

IX. Software

There is no software for the subject device.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Please see Section VI, the sponsor should add a statement to the package insert with respect to MR compatibility.

XI. Performance Testing – Bench

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

Reviewer Comments

(b) (4)

[redacted]

XII. Performance Testing – Animal

Not provided in this submission.

XIII. Performance Testing – Clinical

There is no clinical data provided in the subject submission.

The sponsor has provided references to several peer-reviewed journal articles and textbooks in Section 3 of the submission.

(b) (4)

[redacted]

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

XV. Deficiencies

N/A

XVI. Contact History

5/4/2012	Glenn Stiegman and Tiffani Rogers confirmed via email that the subject system does not contain any new components since the last clearance, K071373.
5/4/2012	G. Stiegman (MCRA) stated via email that both he and T. Rogers (Stryker) may be contacted for interactive review.
5/7/2012	T. Rogers confirmed via email that the neither the cleaning instructions nor sterilization parameters have changed since the last clearance, K071373.
5/8/2012	Emailed deficiencies for telephone hold.
8/21/2012	Requested revised 510(k) Summary and labeling clarification via email. The clarifying information was provided via email on 8/22/2012.

XVII. Recommendation

I recommend the submission be found Substantially Equivalent with Limitations.

Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, KWP, MNH, MNI

Reviewer Amy Gleaf — Date 8/24/12

Branch Chief Celi O'Neill for RPJ — Date 8/27/12

Graf, Amy S.

From: Foreman, Christy
Sent: Monday, August 27, 2012 3:13 PM
To: Graf, Amy S.; Shulman, Marjorie G.; de del Castillo, Sergio; Jones, Edwena
Cc: Jean, Ronald P; Melkerson, Mark N.; O'Neill, Colin
Subject: RE: K113666 - SE with Limitations

Ok with me.
Christy

From: Graf, Amy S.
Sent: Monday, August 27, 2012 2:18 PM
To: Foreman, Christy; Shulman, Marjorie G.; de del Castillo, Sergio; Jones, Edwena
Cc: Jean, Ronald P; Melkerson, Mark N.; O'Neill, Colin
Subject: K113666 - SE with Limitations

Hello Everyone,

I have an SE with Limitations recommendation for a pedicle screw system that is adding pediatric indications for use. The SU decision has division concurrence. Please see the attached email that gives the limitation language our branch has been using for these systems.

Stryker Spine
K113666
Xia 3 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, KWP, MNH, MNI

<< Message: FW: SE with Limitations for pediatric pedicle screw spinal systems (21 CFR 888.3070 - OSH) >>
Once we have office concurrence I will add the concurrence email to the file and bring it to Edwena.

Thanks,

Amy

Amy Graf amy.graf@fda.hhs.gov
Biomedical Engineer
FDA/CDRH/ODE/DSORD/OSDB
WO 66, Room 1215B
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Tel: 301-796-5613

Graf, Amy S.

From: Voic, Simona [simona.voic@stryker.com]
Sent: Wednesday, August 22, 2012 5:58 PM
To: Graf, Amy S.
Cc: Rogers, Tiffani (Spine)
Subject: RE: K113666 Xia 3
Importance: High
Sensitivity: Confidential
Attachments: Xia 3 AIS Revised IFU_082212.pdf; Xia 3 AIS Revised IFU redline_082212.pdf; 510(k) Summary_08222012.pdf; Indications for Use Statement_Xia3 AIS.docx

Hi Amy:
Please see below Stryker Spine reply to your inquiry (in red font). Also, attached are the revised documents requested.
Please let us know if additional information is needed, and ***please confirm the receipt of this email***. Thank you.

Regards,
Simona

Simona Voic, RAC
Sr. RA Project Manager
Stryker Spine
59 Pearl Court
Allendale, NJ, 07401
t: 201-760-8033
f: 201-962-4033
c: 201-707-6112
simona.voic@stryker.com

From: King, Soraya
Sent: Wednesday, August 22, 2012 8:52 AM
To: Voic, Simona
Cc: Rogers, Tiffani (Spine)
Subject: FW: K113666 Xia 3

Tiffani,

Simona agreed to follow-up with the items below.

Thanks,
Soraya

From: Rogers, Tiffani (Spine)
Sent: Tuesday, August 21, 2012 7:19 PM
To: Graf, Amy S.; King, Soraya
Subject: Re: K113666 Xia 3

Hi Amy
We will work on getting this information to you as soon as possible. I am copying Soraya King who will

probably send over the information. I am on vacation this week and of course a hurricane is expected to pass over the island, so I may not have email access for a couple of days.

Thank you for getting back to us.
-Tiffani

Sent from my iPad

On Aug 21, 2012, at 12:28 PM, "Graf, Amy S." <Amy.Graf@fda.hhs.gov> wrote:

> Hi Tiffany,
>
> I have completed my review of this submission. There are a few outstanding issues.
>
> (b) (4)
> 
>
> Please let me know if you have any questions.
>
> Thanks,
>
> Amy

Amy Graf amy.graf@fda.hhs.gov
Biomedical Engineer
FDA/CDRH/ODE/DSORD/OSDB
WO 66, Room 1215B
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Tel: 301-796-5613

STRYKER SPINE Spinal Fixation Systems
XIA® - XIA®3

NON STERILE PRODUCT

The STRYKER Spine XIA® and XIA®3 Spinal Systems are comprised of devices intended for the fixation of the non cervical spine. It includes smooth rods, bone screws (monoaxial and polyaxial), hooks, blocker, and connectors. Washers and staples are also provided as part of the Xia® Spinal System. The components are manufactured from either titanium material (Titanium alloy and CP Titanium), Stainless Steel or Cobalt-Chromium-Molybdenum Alloy.

MATERIALS
XIA® Spinal System
Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136: Screws, hooks, blocker, rods, staples, washers, fasteners and connectors.
Stainless Steel: X2CrNiMo18.14.3 according to ISO 5832-1: Rods, connectors, staples, washers and screws.
Stainless Steel: X4CrNiMnMo21.9.4 according to ISO 5832-9 and ASTM F 1586: Screws, hooks, blocker, connectors and rods

XIA®3 Spinal System
Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136: Screws, hooks, blocker, rods, and connectors.
Pure Titanium: CP Ti grade 4 according to ISO 5832-2 and ASTM F-67: Rods
Cobalt-Chromium-Molybdenum Alloy #1 according to ISO 5832-12 and ASTM F-1537: Rods.

Titanium and Stainless steel implants should not be mixed in patient otherwise corrosion may occur resulting in decreased mechanical resistance.
Cobalt-Chromium-Molybdenum Alloy and Stainless steel implants should not be mixed in patient otherwise corrosion may occur resulting in decreased mechanical resistance.

MATERIALS IDENTIFICATION
Titanium: symbol T
Stainless Steel: symbol S
Cobalt-Chromium-Molybdenum: symbol C

INDICATIONS
XIA® Spinal System
The Xia® Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation 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, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.
The 6 mm diameter rods from the DIAPASON™ Spinal System and OPUS™ Spinal System are intended to be used with the other components of the XIA® Titanium Spinal System. The Titanium Multi-Axis Cross-Connectors are intended to be used with the other components of the XIA® Titanium Spinal System.

XIA®3 Spinal System
The XIA®3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the *XIA®3 Spinal System is intended to provide additional support during fusion using autograft or* allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (DDD) (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, and/or lordosis); tumor; pseudoarthrosis and failed previous fusion.

The Ø5.5mm rods from the STRYKER Spine Radius™ Spinal System and Ø6.0 mm Vitallium rods from XIA® Spinal System are intended to be used with the other components of Xia®3 Spinal System.

When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA® 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

CONTRAINDICATIONS
Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Any abnormality present which affects the normal process of bone remodeling including, but *not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary* or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Insufficient quality or quantity of bone which would inhibit rigid device fixation.
- Previous history of infection.
- Excessive local inflammation.
- Open wounds.
- Any neuromuscular deficit which places an unsafe load level on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself. Obesity is defined according to the W.H.O. standards.
- Patients having inadequate tissue coverage of the operative site.
- Pregnancy.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.

These contraindications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive.

GENERAL CONDITIONS OF USE
The implantation of pedicle screw spinal systems must be performed only by experienced spinal surgeons having undergone the necessary specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.
The information contained in the Package Insert is necessary but not sufficient for the use of this device. This information is in no sense intended as a substitute for the professional judgment, skill and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient's cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

INFORMATION FOR PATIENTS
The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up.
The surgeon must warn the patient of the surgical risks and made aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advice the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise patients of this fact and warn of the potential consequences. For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief.

INFECTION
Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have been associated with transient bacteremia. To help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

INSTRUMENTS
Specialized instruments are provided by STRYKER Spine and must be used to assure accurate implantation of the device. While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or extensive force are more susceptible to fracture depending on the operative precaution, number of procedures, disposal attention. Instruments should be examined for wear or damage prior to surgery.

REUSE
An implant should never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity which would reduce its service life.
Surgeons must verify that the instruments are in good condition and operating order prior to use during surgery.

HANDLING
Correct handling of the implant is extremely important. The operating surgeon should avoid notching or scratching the device.

ALLERGY AND HYPERSENSITIVITY TO FOREIGN BODIES
When hypersensitivity is suspected or proven, it is recommended that the tolerance of the skin to the materials that make up the implants be checked before they are implanted

IMPLANT SELECTION AND USE
The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice which depends on each patient.
Patients who are overweight may be responsible for additional stresses and strains on the device which can speed up metal fatigue and/or lead to deformation or failure of the implants.
The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants should be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause metal fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.
Improper selection, placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant. Contouring or bending of rods or plates is recommended only if necessary according to the surgical technique of each system. Rods or plates should only be contoured with the proper contouring instruments. Incorrectly contoured rods/plates, or rods/plates which have been repeatedly or excessively contoured must not be implanted. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Refer to the STRYKER Spine surgical protocols for additional procedural information. Periodic follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

METAL COMPONENTS
Some of the alloys utilized to produce orthopaedic implants contain metallic elements that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomena.

SYSTEM COMPATIBILITY
While some degree of corrosion occurs on all implanted metal and alloys, contact of dissimilar metals may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system may also increase. Internal fixation devices, such as rods, hooks, screws, wires, etc., which

come into contact with other metal objects, must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of the system should not be used in conjunction with components from any other manufacturer's spinal system. Any such use will negate the responsibility of STRYKER Spine for the performance of the resulting mixed component implant.

POSTOPERATIVE CARE

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need *additional help to accommodate full load bearing. External support may be recommended by the* physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician should closely monitor the patient if a change at the site has been detected.

ADVERSE EFFECTS

- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Bending, disassembly or fracture of any or all implant components.
- Fatigue fracture of spinal fixation devices, including screws and rods, has occurred.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin.
- Dural leak requiring surgical repair.
- Cessation of growth of the fused portion of the spine.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) should be revised or removed immediately before serious injury occurs.
- Loosening of spinal fixation implants can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening *may result from trauma, infection, biological complications or mechanical problems,* with the subsequent possibility of bone erosion, migration and/or pain.
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Serious complications may be associated with any spinal surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli: bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Decrease in bone density due to stress shielding.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft, the intervertebral body, pedicle, and/or sacrum above and/or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision.
The surgeon must warn the patient of these adverse effects as deemed necessary.

ADDITIONAL ADVERSE EFFECTS FOR PEDIATRIC PATIENTS

- Inability to use pedicle screw fixation due to limitations (pedicle dimensions, distorted anatomy).
- Pedicle screw malpositioning, with or without neurological or vascular injury.
- Proximal or distal junctional kyphosis.
- Pancreatitis.

REMOVAL OF IMPLANTS

These implants are temporary internal fixation devices designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and can be removed. Removal may also be recommended in other cases, such as:

- corrosion with a painful reaction,
- migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions,
- pain or abnormal sensations due to the presence of the implants,
- infection or inflammatory reactions,
- reduction in bone density due to the different distribution of mechanical and physiological stresses and strains,
- failure or mobilization of the implant.

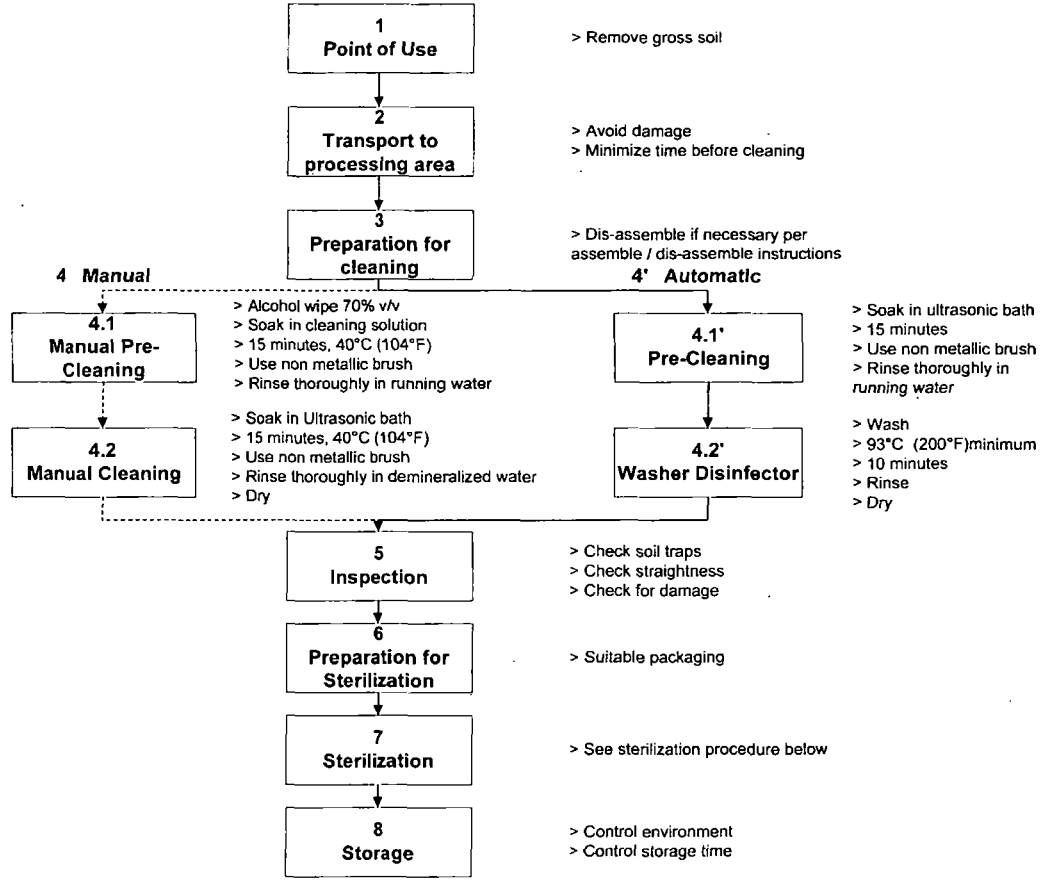
Standard ancillaries provided by STRYKER Spine can be used to remove the implants. Any decision by a physician to remove the internal fixation device must take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically. Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture. Removal of the implant after fracture healing is recommended. Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain or stress shield bone.

PACKAGING AND STORAGE

The implants are delivered in packages; these must be intact at the time of receipt.
The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.
They must be stored in a clean, dry and temperate place.

FURTHER INFORMATION
A surgical technique brochure is available on request through your STRYKER agent or directly from STRYKER Spine. Users with brochures that are over two years old at the time of surgery are advised to ask for an updated version.

PRE-CLEANING / CLEANING AND STERILISATION PROCEDURE RECOMMENDED FOR NON STERILE MEDICAL DEVICE
For safety reasons, non-sterile devices must be pre-cleaned, cleaned and sterilized prior to use. Moreover, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps described in the following chart.



Sterilization procedure recommended for non-sterile medical devices including implants
Medical Devices should be sterilized in their container with water vapor in an autoclave in accordance with standard hospital procedure. The sterilization method suggested has been

validated according to the AAMI ST 79 in order to obtain a Sterility Assurance Level (SAL) of 10^{-6}.

STERILIZATION CONDITIONS: 2 sets of low parameters have been validated on wrapped items:

- Prevacuum steam sterilization (Porous load autoclave): TEMPERATURE: 132°C (270°F), EXPOSURE TIME: 4 minutes, DRY TIME: 45min.
- Gravity-displacement steam sterilization: TEMPERATURE: 132°C (270°F), EXPOSURE TIME: 10 minutes, DRY TIME: 45min.

U.S.A - The gravity-displacement steam sterilization cycle above is not considered by the FDA to be a standard sterilization cycle. 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 FDA for the selected sterilization cycle specifications (time and temperature).

Caution: Stryker Spine has not validated and does not recommend Flash Sterilization. For Product being used in the US, a sterilization wrap that is FDA cleared for the cycle parameters noted should be used.

The autoclave must be validated by the hospital and regularly checked to guarantee the recommended sterilization temperature is reached for the entire exposure time.
If sterilization containers with paper filters are used, it is advisable to use a new filter for each sterilization.
If after having followed this sterilization method there is still water in the sterilization containers or on/inside the device, the device must be dried and sterilization repeated.

PRE-OPERATIVE PRECAUTIONS
Anyone using STRYKER Spine products can obtain a Surgical Technique brochure by requesting one from a distributor or from STRYKER Spine directly. Those using brochures published more than two years before the surgical intervention are advised to get an updated version.

STRYKER Spine devices can only be used by doctors who are fully familiar with the surgical technique required and who have been trained to this end. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by STRYKER Spine. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to causes injury to the patient.

To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable STRYKER Spine Surgical Technique.

Extreme care must be taken when the instruments are used near vital organs, nerves or vessels.

Unless otherwise specified on the label, the instruments can be reused after decontamination, cleaning and sterilization.

CAUTION
Federal law (U.S.A) restricts this device to sale by or on the order of a licensed physician.

WARNING (U.S.A.)
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 spondylolisthesis (grades 3 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurological 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.

The Xia® 3 Spinal System has not been tested for heating or migration in the MR environment.

ADDITIONAL WARNINGS FOR PEDIATRIC PATIENTS
Warning: 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.

The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature or skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter and 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 reduce longitudinal spinal growth, or may be at risk for rotational spinal deformities (the "crankshaft phenomenon") due to continued differential growth of the anterior spine.

Other adverse effects related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients. Pediatric patients may be at increased risk for device-related injury because of their small stature.

PRECAUTIONS (U.S.A.)
The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

ADDITIONAL PRECAUTIONS FOR PEDIATRIC PATIENTS
The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients.

The selection of the proper size, shape, and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

COMPLAINTS

Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, safety, effectiveness and / or its performance, should notify STRYKER Spine or its representative. Moreover, if a device has malfunctioned, or is suspected of having malfunctioned, STRYKER Spine or its representative must be advised immediately.

If a STRYKER Spine product has ever worked improperly and could have caused or contributed to the death of or serious injury to a patient, the distributor or STRYKER Spine must be informed as soon as possible by telephone, fax or in writing.

For all complaints, please give the name and reference along with the batch number of the component(s), your name and address and an exhaustive description of the event to help STRYKER Spine understand the causes of the complaint.

For further information regarding services, please contact:
STRYKER SPINE SA
Le Crêt-du-Locle 10a - 2300 La Chaux-de-Fonds - Switzerland
Tel. +41.32.924.6000
Fax. +41.32.926.2410 (Customer Service)

For further information regarding complaints, please contact:
STRYKER SPINE SAS
ZI de Marticot, 33610 CESTAS – France
Tel. (33) (0)5.57.97.06.30
Fax. (33) (0)5.57.97.06.31 (Quality Assurance)
http://www.stryker.com

STRYKER SPINE
2 Pearl Court, Allendale, NJ 07401- 1677 USA
Tel: +1-201-760-8000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 01, 2012

STRYKER SPINE
C/O MUSCULOSKELETAL CLINICAL REGULATORY ADVISERS,
1331 H STREET NW
12TH FLOOR
WASHINGTON, DISTRICT OF COLUMBIA 20005
ATTN: G. STIEGMAN

510k Number: K113666

Product: XIA 3 SPINAL SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Mcdonald, Lisa *

From: Microsoft Outlook
To: gstiegman@mcra.com
Sent: Wednesday, August 01, 2012 12:57 PM
Subject: Relayed: K113666 AI Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

gstiegman@mcra.com

Subject: K113666 AI Letter

Sent by Microsoft Exchange Server 2007

K113666/S1

2 Pearl Court
Allendale, NJ 07401
t: 866 45 SPINE
www.stryker.com

stryker

Spine

July 25, 2012

FDA CDRH DMC

AUG 01 2012

Received

FDA CDRH DMC

AUG 0 . 2012

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room, WO66-G609
Silver Spring, MD 20993-0002

Re: K113666/S1, Stryker Spine Xia® 3 Spinal System

Dear Ms. Graf,

Stryker Spine hereby provides the information requested by FDA on May 18, 2012. We trust the responses are satisfactory and allow FDA to continue its review of the Stryker Spine Xia® 3 AIS submission to determine substantial equivalence.

The information is organized such that each FDA item is stated and then followed by Stryker Spine's response. Supporting documents are provided in specified attachments.

A paper version and two electronic versions of the response are being provided. One of the electronic copies is the file copy. The other electronic copy is intended as a courtesy copy for the lead reviewer of our 510(k) document to facilitate ease of review. Please note that Stryker Spine's contact regarding this specific 510k is the undersigned.

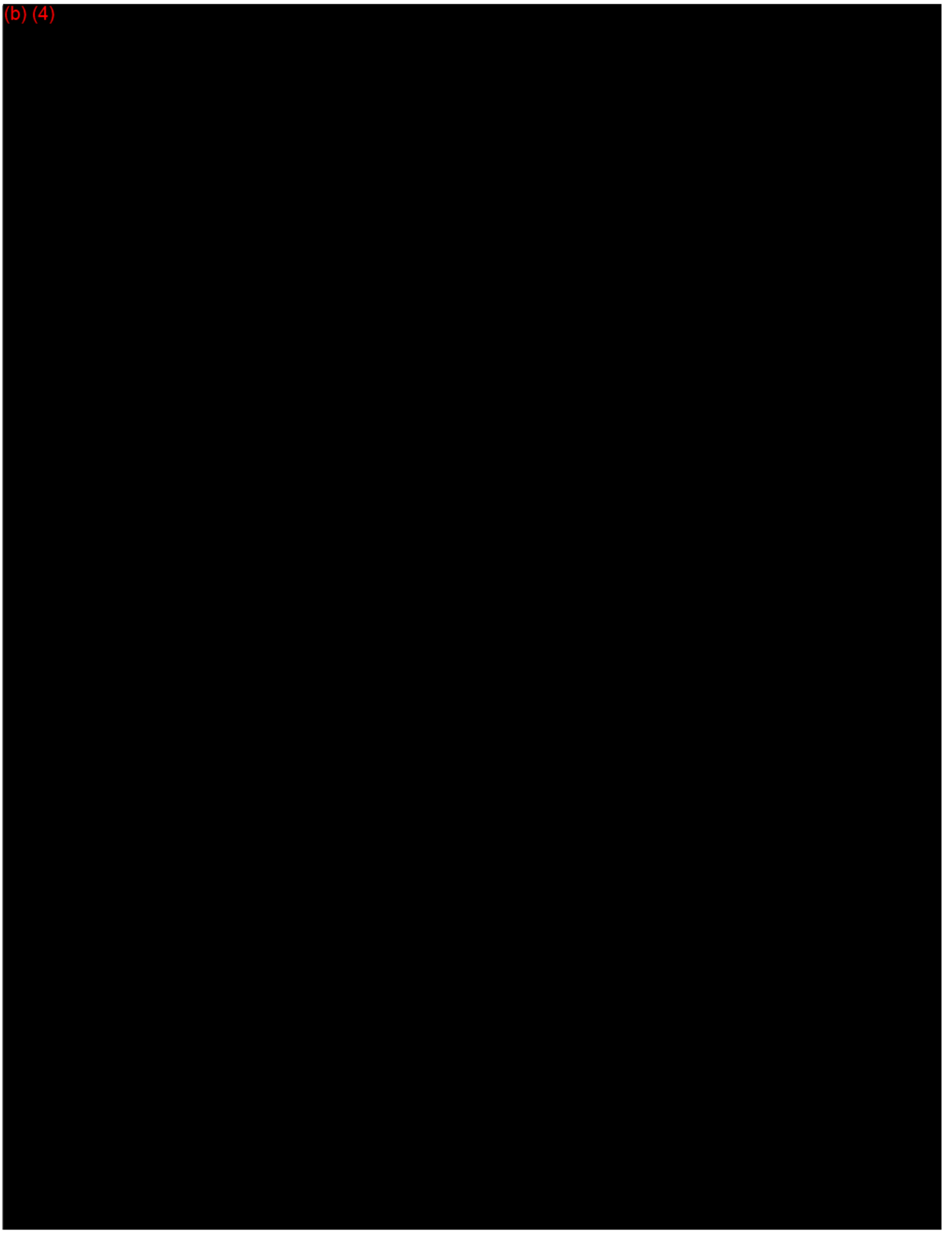
Thank you again for the review of our 510(k). We look forward to hearing from the Agency regarding the 510(k) clearance decision.

Sincerely,

Tiffani D. Rogers
Regulatory Affairs Manager
Stryker Spine
t: 201-760-8206
f: 201-962-4206
email: tiffani.rogers@stryker.com

K-34

(b) (4)



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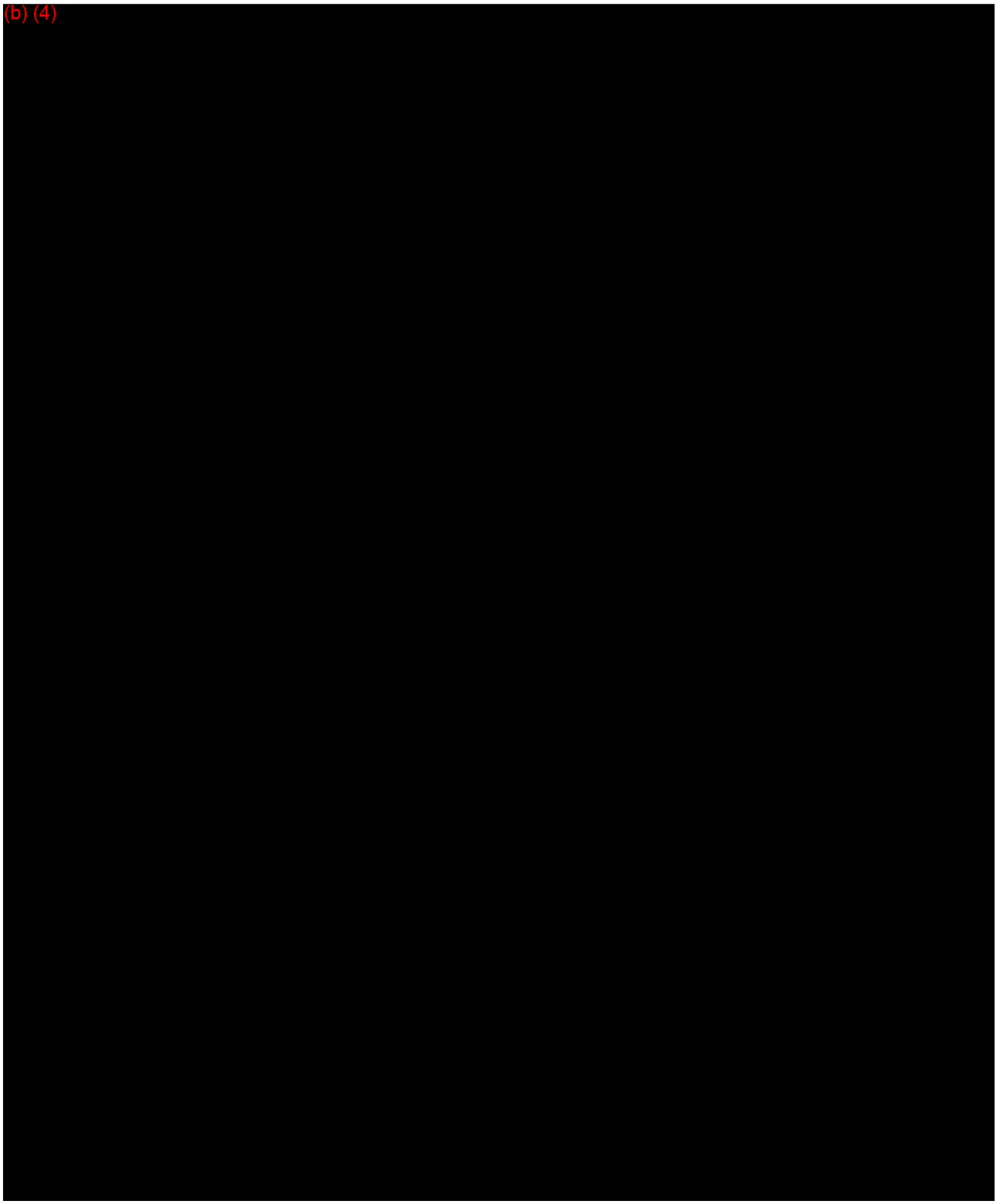
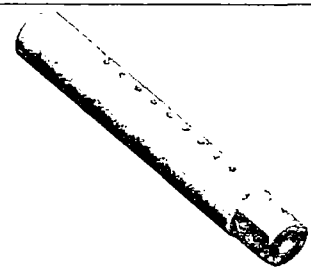
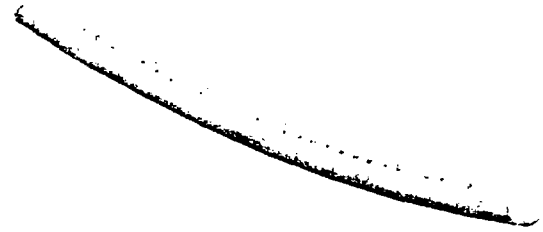
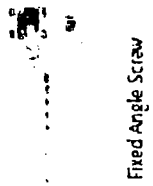
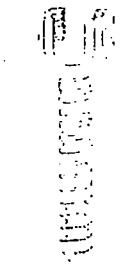
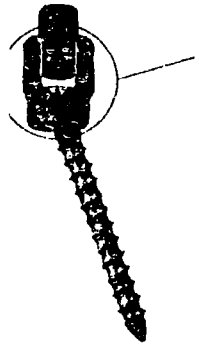
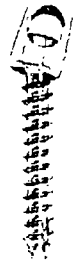
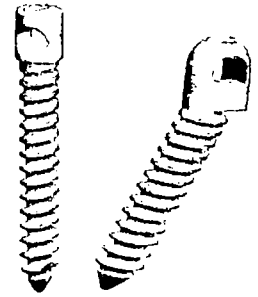


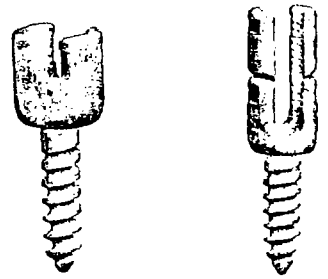
ATTACHMENT 1

XIA III and CD Horizon Spinal Systems Side by Side Comparison for Equivalence			
	CD Horizon	**XIA III**	**Substantially Equivalent**
Manufacturer	**Medtronic Sofamor Danek USA**	**Stryker Spine**	
Trade Name	CD HORIZON Spinal System	XIA III Spinal System	
510(k) Number	K091445	K113666	
Components	Rods, hooks, screws, plates, connecting components and cross connectors	Rods, screws, hooks, connecting components and cross connectors	**Similar**
Material	Titanium alloy (Ti6Al4V), CoCrMo alloy, Stainless steel	Titanium alloy (Ti6Al4V) CP Ti CoCrMo alloy (Vitallium)	**Similar**
Rods			
Dimensional Characteristics	3.5, 4.5, 5.5, 6.35mm diameters 30, 40, 50, 60, 70, 80, 90, 100, 110, 120mm lengths	5.5, 6.0mm diameters 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 140, 160, 180, 200, 220, 240, 260, 280, 300, 320, 340, 360, 380, 400, 600mm lengths	**Similar**
Material	Medical grade titanium, Stainless steel	Titanium alloy (Ti6Al4V) CP Ti CoCrMo alloy (Vitallium)	**Similar**
Comments	The Xia® 3 rods are available in the same titanium alloy as the CD Horizon rods. The Xia® 3 rods are also provided in CP Ti and Vitallium. There is long term use of CP Ti and Vitallium in medical devices and the use of such materials is not impacted by patient age or anatomy. The Xia® 3 rods do not introduce a worst-case size rod compared to the CD Horizon rod diameters and the additional lengths accommodate different patient anatomy. The 140mm to 600mm length rods have the same design as the CD Horizon rods. Both systems offer straight rods and pre-bent, pre-contoured rods. The literature also shows that the Xia® 3 Spinal System can withstand physiological loading in the scoliotic spine, and that other predicates in the literature are inferior in their mechanical strength.		

	 5.5mm Rod	 **TITANIUM ROD**	**Same**
	 5.5mm Rod	 **VITALLIUM ROD**	**Similar**
	 CD HORIZON Precut Contoured Rod *NOTE: Available in titanium only.*	 **Rad Pre-Bent Rod**	**Same**

	CD HORIZON Precut Contoured Rod *NOTE: Available in titanium only.*	 **Max Rad Pre-Bent Rod**	**Similar**
Screws			
Material	Medical grade titanium (Ti6Al4V), Stainless steel	Titanium Ti6Al4V alloy	**Similar**
Dimensional Characteristics	4.0, 4.5, 5.0, 6.0, 6.5, 7.5, 8.5mm diameters 25mm to 60 mm lengths	4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.5, 9.5, 10.5mm diameters 20mm to 100mm lengths	**Similar**
Comments	The Xia® 3 pedicle screws are available in the same titanium alloy (Ti6Al4V) as the CD Horizon screws. The Xia® 3 screw diameters are within the range of the CD Horizon diameters and do not introduce a worst-case size. The additional lengths and diameters accommodate different patient anatomy and allow for iliac and sacral fixation in deformity cases. Testing provided demonstrates longer screw lengths are not worst-case. The Xia® 3 system offers Uni-Planar standard and Uni-Planar Reduction screws. The CD Horizon systems both offer monoaxial (fixed angle), polyaxial, and Standard Uni-Planar & reduction Uni-Planar screws. The Xia® 3 system offers closed head monoaxial and closed head polyaxial screws. The Xia® 3 Polyaxial and Uni-Planar screws feature up to 50 degrees of angulation. The mechanical testing performed demonstrates the closed head screws are able to withstand the same loads as open screws. Once implanted, the Xia® 3 monoaxial reduction screw has the same design as the standard Xia®3 monoxial screw and a similar design to the CD Horizon fixed angle screw. After removal of the reduction tabs the monoaxial reduction screw option is considered to be the same as the fixed angle option in the CD Horizon system.		**Similar**

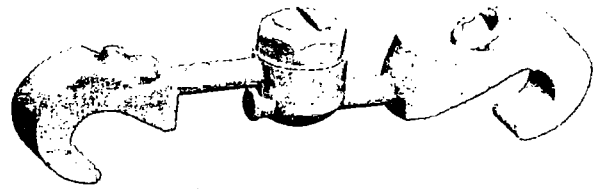
	 **Monoaxial Screw available only in Titanium**	 **Titanium Monoaxial Screw**	**Same**
	 **Polyaxial Screws**	 **Polyaxial Screws**	**Same**
	 MEDTRONIC CD HORIZON LEGACY CLOSED HEAD POLY SCREW REF 70469511	 **Closed Head Monoaxial and Polyaxial Screws**	**Same**

	Uniplanar and Uniplanar Reduction Screws are available. Images are not available.	 **Uniplanar and Reduction Uniplanar Screws**	**Same**
Hooks			
Material	Medical grade titanium, Stainless steel	Titanium Ti6Al4V alloy	**Similar**
Dimensional Characteristics	Head Design accommodates 3.5, 4.5, 5.5, 6.35mm rods	Head Design accommodates 5.5, 6.0mm rods	**Similar**
Comments	Head design similar to screws, head vertically split by a U-shape slot to accommodate the 3.5, 4.5, 5.5, 6.35mmrods, head is threaded set screw, Hooks are available for laminar, thoracic, pedicle, and transverse process attachment, and come in different sizes (small, medium, large), offsets, and blade designs (standard, angled, narrow) and pediatric sizes.	Head design similar to screws, head vertically split by a U-shape slot to accommodate the 6mm and 5.5mm rods, head is threaded with a 10mm buttress thread to accommodate the closure screw, Hooks are available for laminar, thoracic, pedicle, and transverse process attachment, and come in different sizes (small, medium, large), offsets, and blade designs (standard, angled, narrow).	
	 **Pedicle Hook**	 **Pedicle Hook Small**	**Same**

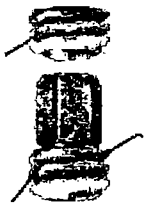
	 Laminar Wide Blade Hook - Laminar Narrow Blade Hook	 Laminar Hook Angled Blade	Same
	 Extended Body Hook	 Extended Lamina Hook	Same
	 Offset Hook	 Offset Thoracic Laminar Hook Left	Same

Xia 3 Ref #	Description	Blade width	Throat diameter	Blade angle	Blade length	Comments
	Laminar Hooks					
48230200	Xia Laminar Hook Medium, Standard Blade	7	7.5		14	
48230201	Xia Laminar Hook Medium, Narrow Blade	5	7.5		14	
48230202	Xia Laminar Hook Large, Standard Blade	7	9.5		14	
48230203	Xia Laminar Hook Large, Narrow Blade	5	9.5		14	
48230240	Xia Laminar Hook Small, Narrow Blade	4.5	6		12	
48230241	Xia Laminar Hook Small, Standard Blade	6	7.4		13.5	
48230206	Xia Laminar Hook Offset, Right	6	9.5		13	11.5mm offset
48230207	Xia Laminar Hook Offset, Left	6	9.5		13	11.5mm offset
48230208	Xia Laminar Hook Angled Blade, Large	5	9	19°	15.5	
48230209	Xia Laminar Hook Angled Blade, Small	4.5	7.4	20°	13	
	Thoracic Laminar Hooks					
48230210	Xia Thoracic Laminar Hook, Standard Blade	6	6		14	
48230211	Xia Thoracic Laminar Hook, Narrow Blade	4.5	6		14	
48230216	Xia Thoracic Laminar Hook, Small Narrow Blade	4.5	5		12	
48230212	Xia Thoracic Laminar Hook, Small Offset, Right	4.5	6		14	4.75mm offset
48230213	Xia Thoracic Laminar Hook, Small Offset, Left	4.5	6		14	4.75mm offset
48230214	Xia Thoracic Laminar Hook, Large Offset, Right	4.5	6		14	9mm offset
48230215	Xia Thoracic Laminar Hook, Large Offset, Left	4.5	6		14	9mm offset
	Extended Body Hooks					
48230204	Xia Laminar Hook Extended Body	7	9.5		14	total height 29.5mm
48230205	Xia Laminar Hook Extended Body Small	7	9.5			total height 26mm

Xia 3 Ref #	Description	Blade	Throat	Blade	Blade length	Comments
	Pedicle Hooks					
48230220	Xia Pedicle Hook, Medium	9	6	12°	15.5	
48230221	Xia Pedicle Hook, Small	7.5	4.5	12°	13.5	
	TP Hooks					
48230232	Xia Transverse Process Hook, Right	6	9.5	45° lateral	13.4	
48230233	Xia Transverse Process Hook, Left	6	9.5	45° lateral	13.4	
48230218	LARGE OFFSET HOOK Left					13.5 Offset
48230217	LARGE OFFSET HOOK Right	5	8	20	13	15° Angle

Cross Connectors			
Material	Medical grade titanium, Stainless steel 5.5mm available in stainless steel only	Titanium Ti6Al4V alloy	**Similar**
Dimensional Characteristics	The multi span plate is designed to connect the bilateral 5.5, 6.35mm rods of a spinal fusion construct	poly cross connector is designed to connect the bilateral 6mm or 5.5mm rods of a spinal fusion construct	**Similar**
Comments	The X10 Crosslink Multi-span Plate is composed of several elements: • Two J hooks • Two closure set screws • Center bolt • Rivet bolt • Washer • Lock nut	The poly cross connector is composed of several elements: • Two J hooks • Two closure set screws • Center bolt • Rivet bolt • Bellville washer • Lock nut	**Same**
	 X10 CROSSLINK Multi-Span™ Plate	 **Poly Cross Connector**	**Same**
Mono Cross Connector			
Material	Medical grade titanium, Stainless steel	Titanium Ti6Al4V alloy	**Similar**
Dimensional Characteristics		10 sizes for cross linking - 14, 15, 16, 17, 18, 19, 20, 22, 24, 26mm rod-to-rod axis.	
Comments	The multi span plate is designed to connect (top loading, top screwing, two step locking) the parallel bilateral 5.5mm and 6.35mm rods of a	The cross connector is designed to connect (top loading, top screwing, two step locking) the parallel bilateral 6mm	**Similar**

	spinal fusion construct	and 5.5mm rods of a spinal fusion construct.	
	 X10 CROSSLINK Fixed Plate	 **Mono Cross Connector**	**Similar**

Blocker			
Material	Medical grade titanium, Stainless steel	Titanium Ti6Al4V alloy	**Similar**
Dimensional Characteristics		10mm buttress set screw	
Comments	The screw set locks either a 5.5 or 6.35mm diameter rod to the screw (polyaxial and fixed angle) and the hook	The blocker locks either a 5.5mm diameter or 6.0mm diameter rod to the screw (polyaxial and monoaxial) and the hook. The Xia® 3 blocker is the similar to the standard CD Horizon set screw.	**Similar**
	 Set Screws   Break Off Set Screw Reduction Break Off Set Screw	 Blocker	**Same**

Connectors (Rod to Rod Connectors and Offset Connectors)			
Material	Medical grade titanium, Stainless steel	Titanium Ti6Al4V alloy	**Similar**
Dimensional Characteristics	Rod Connection side and rod side.	Rod Connection side and rod side.	**Similar**
Comments	Offset connectors allow attachment of main rod construct to be attached to offset screw. Example: Attach Iliac bolt to the main rod construct	Offset connectors allow attachment of main rod construct to be attached to offset screw. The Xia 3 offset connectors are available in 35mm, 65mm, 69mm, 80mm and 100mm lengths. Example Iliac bolt.	Similar
		 Example of offset connector	Similar
	Rod to Rod Connectors allow rod construct to be extended to add additional levels	Rod to Rod Connectors allow rod construct to be extended to add additional levels	Similar
	 CROSSLINK Offset Plate	 Example of one RRC	Similar

ATTACHMENT 2

stryker®

XIA® 3

Ø 5.5 X 40mm SPINAL SCREW POLYAXIAL

SPINAL SCREW-POLYAXIAL / VIS VERTEBRALE - POLYAXIALE / TORNILLO ESPINAL - POLIAXIAL / WIRBELSCHRAUBE - POLYAXIAL / VITE VERTEBRALE - POLIASSIALE / WERVELSCHROEF-POLYAXIAAL / PARAFUSO VERTEBRAL-POLIAXIAL / ΠΑΛΜΟΝΙΚΗ ΣΠΟΝΔΥΛΙΚΗ ΒΙΔΑ / VERTEBRALESKRUE-POLYAKSIAL / SELKÄRANKARUUVI-POLYAKSIAALINEN / RYGGRADSSKRUV-FLERAXLIG / SSTIFTAL SKRUE-POLYAKSIAL / ŚRUBA KRĘGOWA WIELOOSIOWA / SURUB SPINAL-POLIAXIAL / ГРЪБНАЧЕН ВИНТ - ПОЛИАКСИАЛЕН / SPINAL VİDA-POLİAKSİYEL /

多軸脊骨螺釘 / 척추용 나사 다축형

Ti6Al4V

US patent: 6,074,391; 6,261,287; 6,537,276 ; 6,488,681

+H8534823155400K

+$AANNNNK/

REF

482315540

LOT

AANNNN

2009-02

Manufacturing Date

CE 0459

-USA CAUTION : FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

-WARNING: ALWAYS REFER TO THE PACKAGE INSERT FOR LABELING INDICATIONS

Single Use

NOT STERILE - NON STERILE - SIN ESTERILIZAR - NICHT STERIL - NON STERILE - NIET STERIEL - NÃO ESTERIL - ΜΗ ΑΠΟΣΤΕΙΡΩΜΕΝΟ - IKKE STERIL - EI STERIILI - EJ STERIL - IKKE STERIL - NIESTERYLNY - NESTERIL - НЕ СТЕРИЛЕН - STERIL DEGİL -

未消毒 / 비멸균

Manufactured by :
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Z.I MARTICOT-33610-CESTAS-FRANCE
+33 (0)5.57.97.06.30
http://www.stryker.com

482315540V1

Distributed in the USA by :
Stryker Spine
2 Pearl Ct. Allendale,
N.J 07401-1677 USA
+1-201-760-8000

ATTACHMENT 3

STRYKER SPINE Spinal Fixation Systems
XIA® - XIA®3

NON STERILE PRODUCT

The STRYKER Spine XIA® and XIA®3 Spinal Systems are comprised of devices intended for the fixation of the non cervical spine. It includes smooth rods, bone screws (monoaxial and polyaxial), hooks, blocker, connectors, washers, and staples. The components are manufactured from either titanium material (Titanium alloy and CP Titanium), Stainless Steel or Cobalt-Chromium-Molybdenum Alloy.

MATERIALS
XIA® Spinal System and XIA®3 Spinal System

Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136: Screws, hooks, closure screws, rods, staples, washers, fasteners and connectors.
Pure Titanium: CP Ti grade 4 according to ISO 5832-2 and ASTM F-67: Rods
Stainless Steel: X2CrNiMo18.14.3 according to ISO 5832-1: Rods, connectors, staples, washers and screws.
Stainless Steel: X4CrNiMnMo21.9.4 according to ISO 5832-9 and ASTM F 1586: Screws, hooks, closure screws, connectors and rods
Cobalt-Chromium-Molybdenum Alloy #1 according to ISO 5832-12 and ASTM F-1537: Rods.

Titanium and Stainless steel implants should not be mixed in patient otherwise corrosion may occur resulting in decreased mechanical resistance.
Cobalt-Chromium-Molybdenum Alloy and Stainless steel implants should not be mixed in patient otherwise corrosion may occur resulting in decreased mechanical resistance.

MATERIALS IDENTIFICATION
Titanium: symbol T
Stainless Steel: symbol S
Cobalt-Chromium-Molybdenum: symbol C

INDICATIONS
XIA® Spinal System

The Xia® Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation 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, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.
The 6 mm diameter rods from the DIAPASON™ Spinal System and OPUS™ Spinal System are intended to be used with the other components of the XIA® Titanium Spinal System. The Titanium Multi-Axis Cross-Connectors are intended to be used with the other components of the XIA® Titanium Spinal System.

XIA®3 Spinal System

The XIA®3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA®3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (DDD) (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, and/or lordosis); tumor; pseudoarthrosis and failed previous fusion.

The Ø5.5mm rods from the STRYKER Spine Radius™ Spinal System and Ø6.0 mm Vitallium rods from XIA® Spinal System are intended to be used with the other components of Xia®3 Spinal System.

When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA® 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

CONTRAINDICATIONS

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Insufficient quality or quantity of bone which would inhibit rigid device fixation.
- Previous history of infection.
- Excessive local inflammation.
- Open wounds.
- Any neuromuscular deficit which places an unsafe load level on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself. Obesity is defined according to the W.H.O. standards.
- Patients having inadequate tissue coverage of the operative site.
- Pregnancy.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.

These contraindications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive.

GENERAL CONDITIONS OF USE

The implantation of pedicle screw spinal systems must be performed only by experienced spinal surgeons having undergone the necessary specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.
The information contained in the Package Insert is necessary but not sufficient for the use of this device. This information is in no sense intended as a substitute for the professional judgment, skill and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient's cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

INFORMATION FOR PATIENTS

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up.
The surgeon must warn the patient of the surgical risks and made aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advice the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise patients of this fact and warn of the potential consequences. For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief.

INFECTION

Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have been associated with transient bacteremia. To help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

INSTRUMENTS

Specialized instruments are provided by STRYKER Spine and must be used to assure accurate implantation of the device. While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or extensive force are more susceptible to fracture depending on the operative precaution, number of procedures, disposal attention. Instruments should be examined for wear or damage prior to surgery.

REUSE

An implant should never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity which would reduce its service life.
Surgeons must verify that the instruments are in good condition and operating order prior to use during surgery.

HANDLING

Correct handling of the implant is extremely important. The operating surgeon should avoid notching or scratching the device.

ALLERGY AND HYPERSENSITIVITY TO FOREIGN BODIES

When hypersensitivity is suspected or proven, it is recommended that the tolerance of the skin to the materials that make up the implants be checked before they are implanted

IMPLANT SELECTION AND USE

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice which depends on each patient.

Patients who are overweight may be responsible for additional stresses and strains on the device which can speed up metal fatigue and/or lead to deformation or failure of the implants.

The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants should be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause metal fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

Improper selection, placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant. Contouring or bending of rods or plates is recommended only if necessary according to the surgical technique of each system. Rods or plates should only be contoured with the proper contouring instruments. Incorrectly contoured rods/plates, or rods/plates which have been repeatedly or excessively contoured must not be implanted. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Refer to the STRYKER Spine surgical protocols for additional procedural information. Periodic follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

METAL COMPONENTS

Some of the alloys utilized to produce orthopaedic implants contain metallic elements that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomena.

SYSTEM COMPATIBILITY

While some degree of corrosion occurs on all implanted metal and alloys, contact of dissimilar metals may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system may also increase. Internal fixation devices, such as rods, hooks, screws, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of the system should not be used in conjunction with components from any other manufacturer's spinal system. Any such use will negate the responsibility of STRYKER Spine for the performance of the resulting mixed component implant.

POSTOPERATIVE CARE

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician should closely monitor the patient if a change at the site has been detected.

ADVERSE EFFECTS

- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Bending, disassembly or fracture of any or all implant components.
- Fatigue fracture of spinal fixation devices, including screws and rods, has occurred.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin.
- Dural leak requiring surgical repair.
- Cessation of growth of the fused portion of the spine.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) should be revised or removed immediately before serious injury occurs.
- Loosening of spinal fixation implants can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, migration and/or pain.
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Serious complications may be associated with any spinal surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.

- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Decrease in bone density due to stress shielding.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft, the intervertebral body, pedicle, and/or sacrum above and/or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision.
The surgeon must warn the patient of these adverse effects as deemed necessary.

ADDITIONAL ADVERSE EFFECTS FOR PEDIATRIC PATIENTS

- Inability to use pedicle screw fixation due to limitations (pedicle dimensions, distorted anatomy).
- Pedicle screw malpositioning, with or without neurological or vascular injury.
- Proximal or distal junctional kyphosis.
- Pancreatitis.

REMOVAL OF IMPLANTS

These implants are temporary internal fixation devices designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and can be removed. Removal may also be recommended in other cases, such as:

- corrosion with a painful reaction,
- migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions,
- pain or abnormal sensations due to the presence of the implants,
- infection or inflammatory reactions,
- reduction in bone density due to the different distribution of mechanical and physiological stresses and strains,
- failure or mobilization of the implant.

Standard ancillaries provided by STRYKER Spine can be used to remove the implants. Any decision by a physician to remove the internal fixation device must take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically. Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture. Removal of the implant after fracture healing is recommended. Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain or stress shield bone.

PACKAGING AND STORAGE

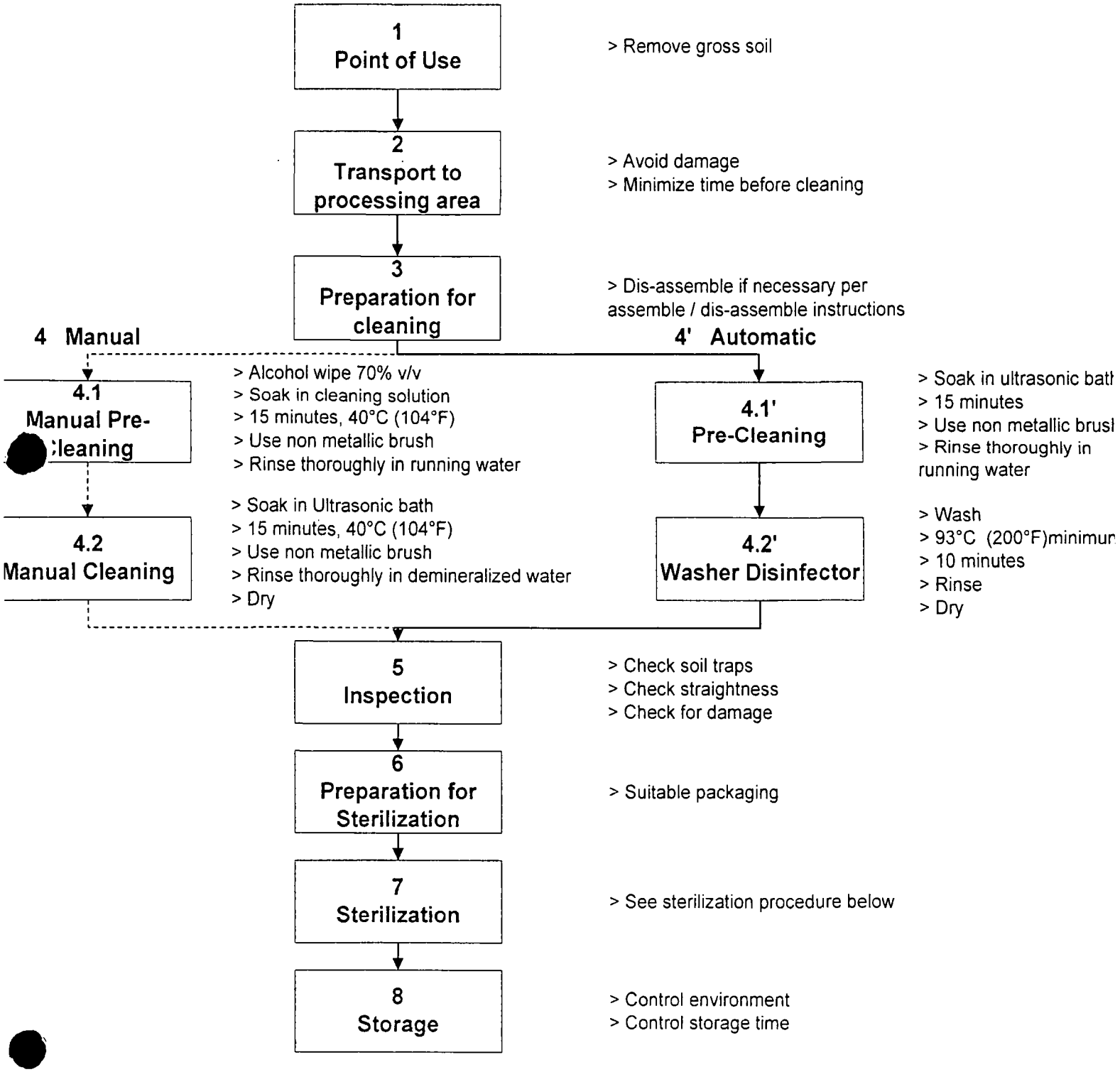
The implants are delivered in packages; these must be intact at the time of receipt.
The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.
They must be stored in a clean, dry and temperate place.

FURTHER INFORMATION

A surgical technique brochure is available on request through your STRYKER agent or directly from STRYKER Spine. Users with brochures that are over two years old at the time of surgery are advised to ask for an updated version.

PRE-CLEANING / CLEANING AND STERILISATION PROCEDURE RECOMMENDED FOR NON STERILE MEDICAL DEVICE

For safety reasons, non-sterile devices must be pre-cleaned, cleaned and sterilized prior to use. Moreover, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps described in the following chart.



Sterilization procedure recommended for non-sterile medical devices including implants

Medical Devices should be sterilized in their container with water vapor in an autoclave in accordance with standard hospital procedure. The sterilization method suggested has been validated according to the AAMI ST 79 in order to obtain a Sterility Assurance Level (SAL) of 10^{-6}.

STERILIZATION CONDITIONS: 2 sets of low parameters have been validated on wrapped items:

- Prevacuum steam sterilization (Porous load autoclave): TEMPERATURE: 132°C (270°F), EXPOSURE TIME: 4 minutes, DRY TIME: 45min.
- Gravity-displacement steam sterilization: TEMPERATURE: 132°C (270°F), EXPOSURE TIME: 10 minutes, DRY TIME: 45min.

U.S.A - The gravity-displacement steam sterilization cycle above is not considered by the FDA to be a standard sterilization cycle. 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 FDA for the selected sterilization cycle specifications (time and temperature).

Caution: Stryker Spine has not validated and does not recommend Flash Sterilization. For Product being used in the US, a sterilization wrap that is FDA cleared for the cycle parameters noted should be used.

The autoclave must be validated by the hospital and regularly checked to guarantee the recommended sterilization temperature is reached for the entire exposure time.
If sterilization containers with paper filters are used, it is advisable to use a new filter for each sterilization.
If after having followed this sterilization method there is still water in the sterilization containers or on/inside the device, the device must be dried and sterilization repeated.

PRE-OPERATIVE PRECAUTIONS

Anyone using STRYKER Spine products can obtain a Surgical Technique brochure by requesting one from a distributor or from STRYKER Spine directly. Those using brochures published more than two years before the surgical intervention are advised to get an updated version.

STRYKER Spine devices can only be used by doctors who are fully familiar with the surgical technique required and who have been trained to this end. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by STRYKER Spine. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to causes injury to the patient.

To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable STRYKER Spine Surgical Technique.

Extreme care must be taken when the instruments are used near vital organs, nerves or vessels.

Unless otherwise specified on the label, the instruments can be reused after decontamination, cleaning and sterilization.

CAUTION
Federal law (U.S.A) restricts this device to sale by or on the order of a licensed physician.

WARNING (U.S.A.)
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 spondylolisthesis (grades 3 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurological 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.

The Xia® 3 Spinal System has not been tested for heating or migration in the MR environment.

ADDITIONAL WARNINGS FOR PEDIATRIC PATIENTS
Warning: 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.

The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature or skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter and 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 reduce longitudinal spinal growth, or may be at risk for rotational spinal deformities (the "crankshaft phenomenon") due to continued differential growth of the anterior spine.

Other adverse effects related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients. Pediatric patients may be at increased risk for device-related injury because of their small stature.

PRECAUTIONS (U.S.A.)
The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

ADDITIONAL PRECAUTIONS FOR PEDIATRIC PATIENTS
The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients.

The selection of the proper size, shape, and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

COMPLAINTS

Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, safety, effectiveness and / or its performance, should notify STRYKER Spine or its representative. Moreover, if a device has malfunctioned, or is suspected of having malfunctioned, STRYKER Spine or its representative must be advised immediately.

If a STRYKER Spine product has ever worked improperly and could have caused or contributed to the death of or serious injury to a patient, the distributor or STRYKER Spine must be informed as soon as possible by telephone, fax or in writing.

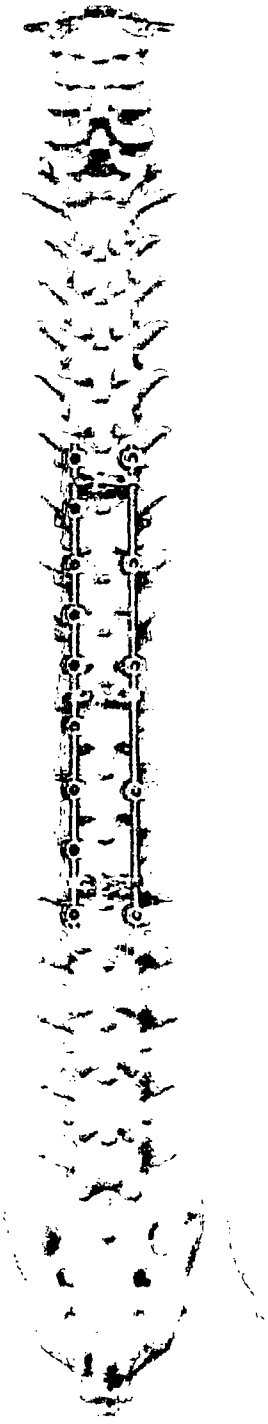
For all complaints, please give the name and reference along with the batch number of the component(s), your name and address and an exhaustive description of the event to help STRYKER Spine understand the causes of the complaint.

For further information regarding services, please contact:
STRYKER SPINE SA
Le Crêt-du-Locle 10a - 2300 La Chaux-de-Fonds - Switzerland
Tel. +41.32.924.6000
Fax. +41.32.926.2410 (Customer Service)

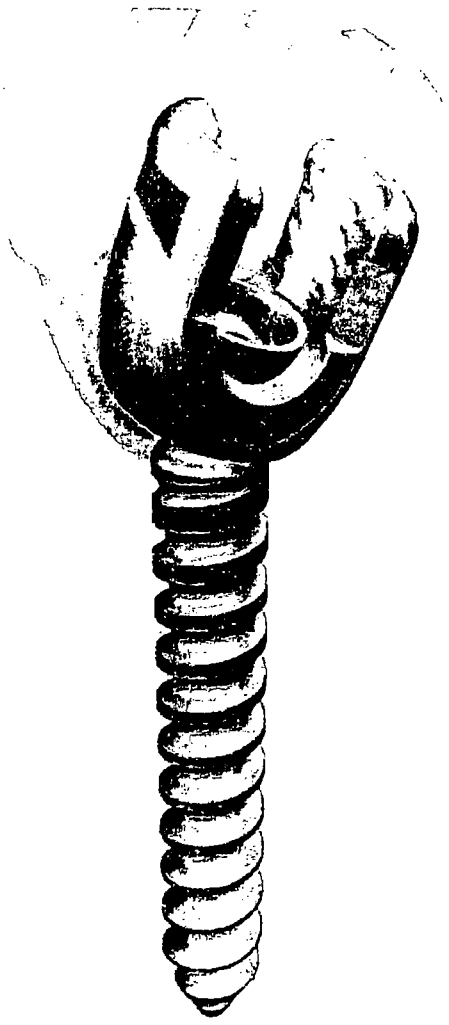
For further information regarding complaints, please contact:
STRYKER SPINE SAS
ZI de Marticot, 33610 CESTAS – France
Tel. (33) (0)5.57.97.06.30
Fax. (33) (0)5.57.97.06.31 (Quality Assurance)
http://www.stryker.com

STRYKER SPINE
2 Pearl Court, Allendale, NJ 07401- 1677 USA
Tel: +1-201-760-8000

ATTACHMENT 4



Introduction



Introduction

Built on the successful foundation of Xia®'s history, Stryker® Spine is proud to introduce Xia® 3; a pedicle screw system designed to deliver **"Simplicity with Options."**

Xia® 3 is a comprehensive system that is designed to treat modern deformity, degenerative, and trauma applications. Xia® 3 is based upon the same design rationale and philosophy that has made Xia® one of the leading spinal systems in the market.

- Ease of Use
- Comprehensive System
- Proven Core Technology
- Successful Clinical History

Acknowledgements

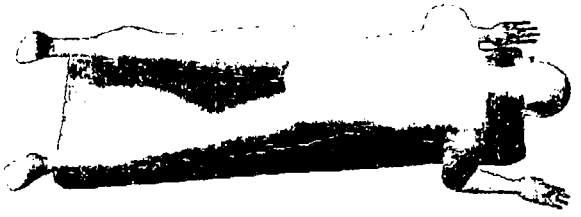
Stryker® Spine would like to extend their thanks to the following surgeons for their dedication and contributions:

- Tushar Patel, MD
- Alex Vaccaro, MD

Table of Contents

Operative Technique

A.Patient Positioning



Patient Positioning

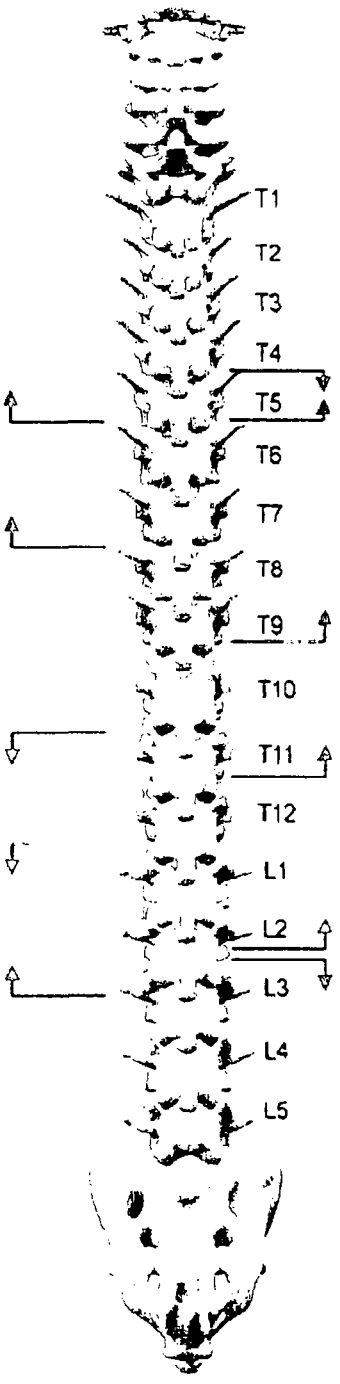
Diagnosis of deformity is based upon patient history, physical findings and preoperative radiographic assessment.

The patient is usually positioned prone on an appropriate spinal table. Care is taken to pad all bony prominences. The abdomen should not be compressed to facilitate venous drainage.

Surgical levels may be verified clinically or radiographically. To ensure adequate exposure the incision is made to extend just beyond the length of the intended fusion.

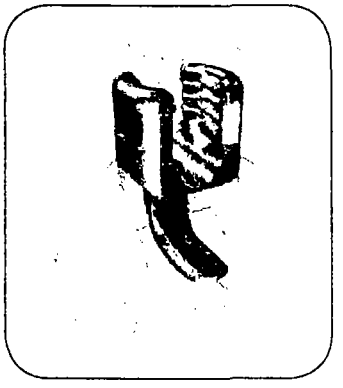
Presurgical planning defines the most appropriate implants as well the optimal location of the implants to be inserted.

A.Hook Design



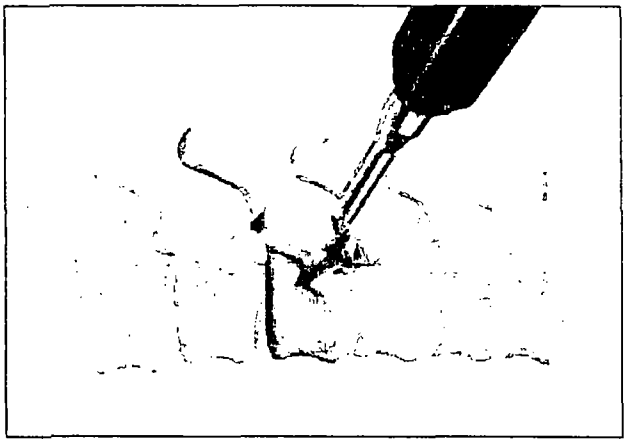
Screw Preparation and Insertion

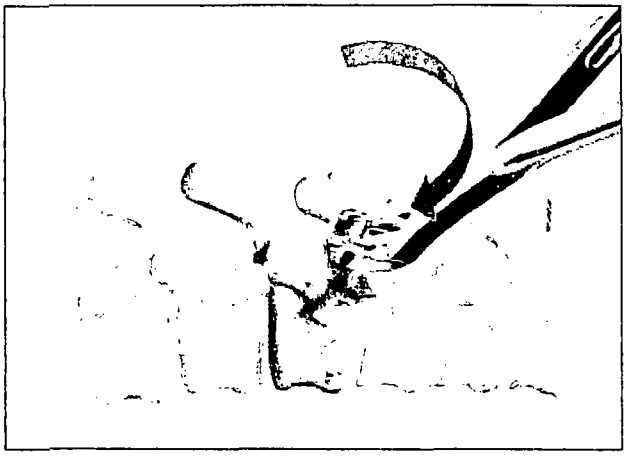
Once appropriate dissection has been achieved and anatomic levels are confirmed by X-Ray and anatomic landmarks, the hook sites are identified and prepared. The appropriate hook is chosen according to a number of factors:
Patient anatomy, bone quality, correction technique and the forces applied. The surgeon has several options in choosing a hook pertaining to the blade width, throat length, body extension and hook shape. Hooks consist of three blade types. They are wide blade, narrow blade and bifid pedicle blade. The surgeon should choose the hooks that will allow the most successful outcome of the procedure.

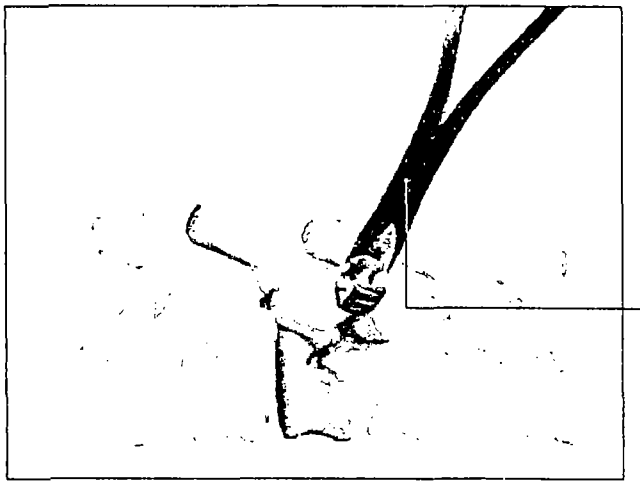


Offset hooks are available in both wide and narrow blade widths. They may be inserted in thoracic or lumbar segments. Offset connectors can be helpful in lining up hook connections.

B.Hook Insertion







Supralaminar Hooks

Supralaminar hooks are directed caudally. The blade of the hook sits within the epidural space. A narrow blade hook with a throat size that does not allow pistoning on the lamina is recommended. The ligamentum flavum is dissected from the lamina and a small laminatomy is made. The Lamina Preparer may be used to estimate the appropriate hook size. Care must be utilized in introducing hooks and instruments into the open spinal canal. The Lamina Preparer comes in two blade widths to accurately match the patient's anatomy.

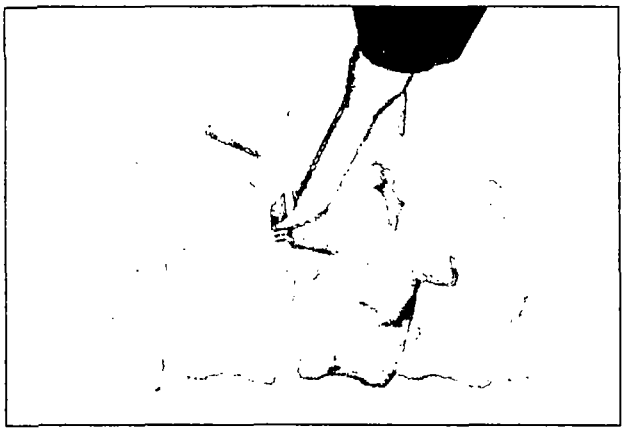
The appropriate hook is determined by the patient's anatomy. Once the site is confirmed to be well prepared, the selected lamina hook is loaded onto a Hook Forceps.

Two options are possible for preparing the site and to insert the hook:
Option 1: A horizontal window is created by excising the ligamentum flavum combined with a limited osteotomy of the edge of the lamina. The window is prepared large enough to accommodate the blade of the hook to be inserted. The blade is then turned down 90° and seated on the lamina.
This technique will assist in stabilization of the hook, which can help facilitate rod introduction.

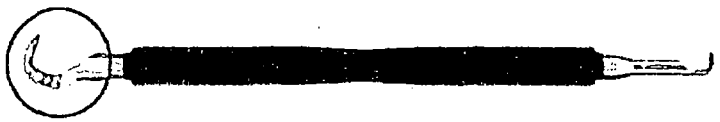
Option 2: A more squared window is managed by opening the ligamentum flavum in conjunction with a limited laminotomy.
A Laminar Preparer may be used with great care to dissect the ligamentum flavum.
Once the site is confirmed to be well prepared, the selected lamina hook is loaded on either the straight or Lateral Hook Forceps. The hook is inserted in a downward rotational movement so that the tip of the blade hugs the anterior surface of the lamina at all times. A gentle burring of the lamina is sometimes necessary to ease the access to the canal.

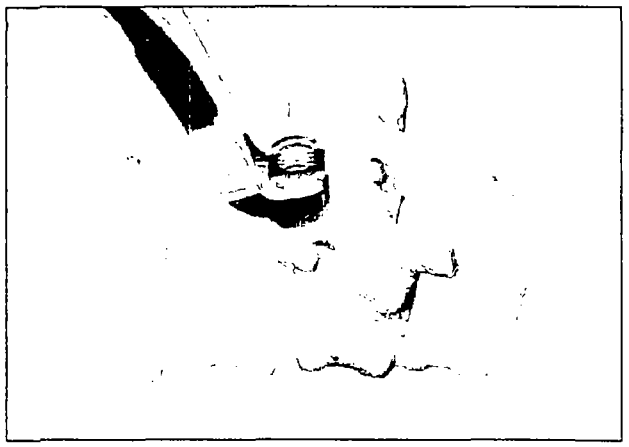
B.Hook Insertion

Infralaminar Hooks

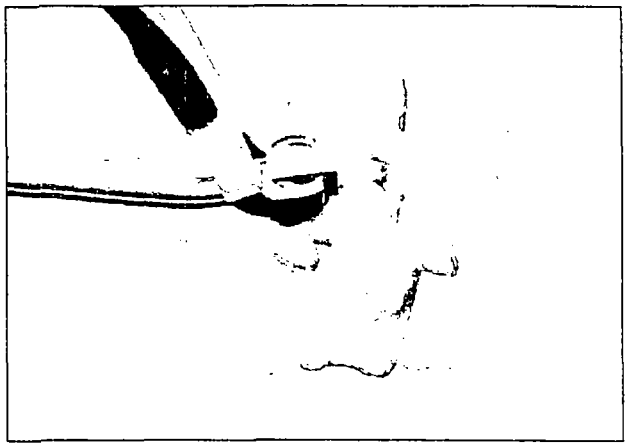


Infralaminar hooks are directed cephalad. The Lamina Preparer is used to dissect the ligamentum flavum from the inferior lamina and prepare a path for the hook. The blade will seat between the anterior surface of the lamina and the ligamentum flavum and not interdural.





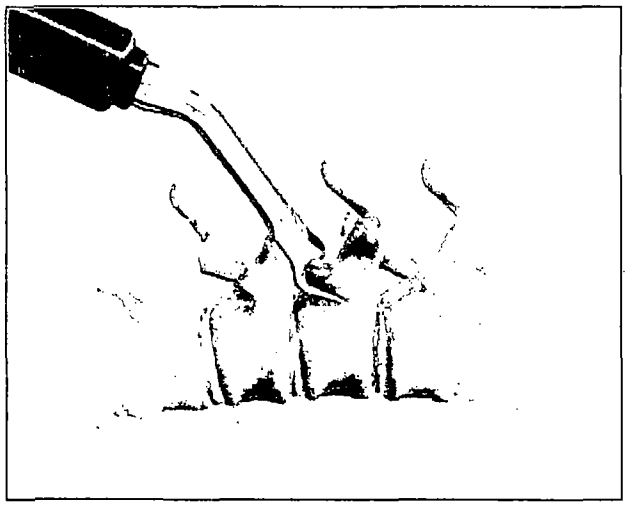
A wide blade hook may be selected if the patient's anatomy permits. This hook loaded onto a Hook Forceps and inserted into the path created by the Lamina Preparer.

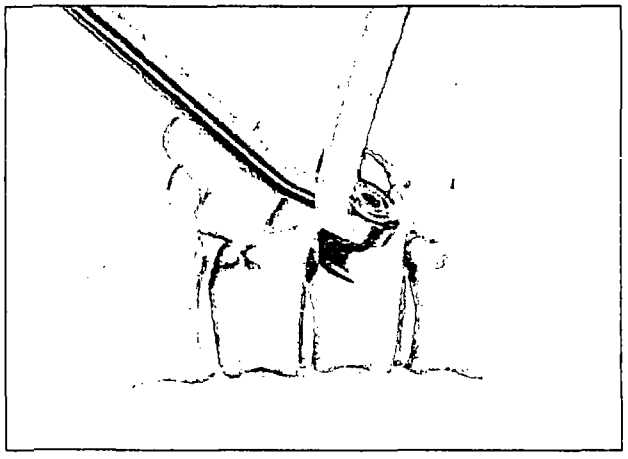


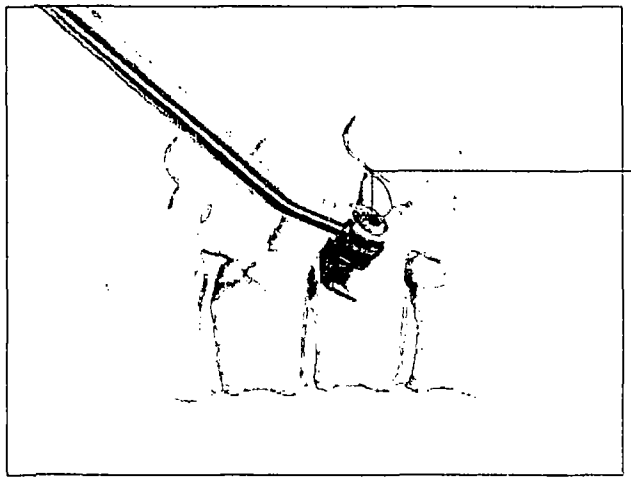
The Hook Pusher may be used in conjunction with the Hook Forceps to facilitate hook seating against the inferior lamina.

B.Hook Insertion

Hook Insertion







Pedicle Hooks

The pedicle hook is always directed cephalad and is recommended for T10 and above. A limited osteotomy (facetectomy) at the base of the facet opens the facet joint and exposes the underlying articular cartilage of the superior facet of the caudal vertebra. The Pedicle Hook Preparer is inserted into the facet joint with great care, aiming slightly lateral of the midline to identify the pedicle. Once the pedicle is localized, the bifid on the Pedicle Preparer can be utilized to insure that the fork is well applied onto the pedicle. The preparer, properly engaged on the pedicle, can be used to confirm a reliable fit on the vertebra by mobilizing the vertebra laterally. A prominent element indicates the appropriate location of the final osteotomy so that the hook will evenly seat onto the pedicle and on the facet.

Once the pedicle hook site is clearly identified, the pedicle hook is inserted.

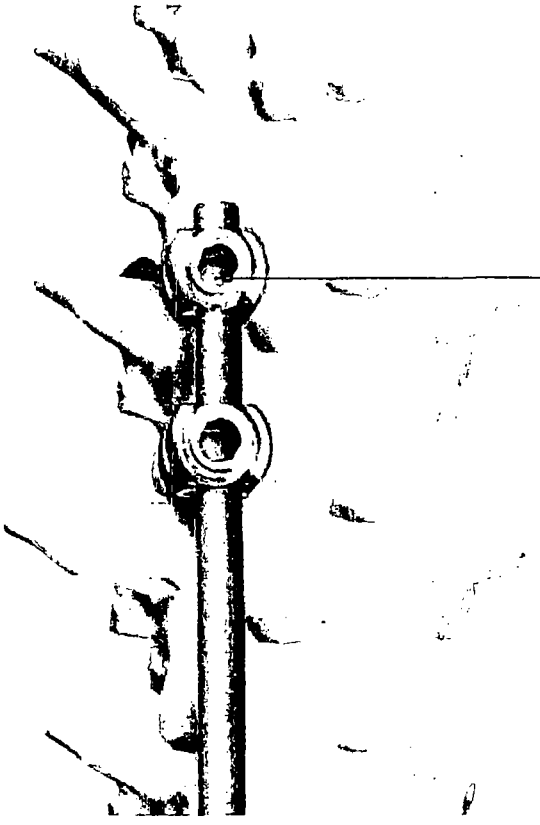
The hook is firmly gripped by the Hook Forceps. The Hook Impactor is inserted into the hook. The hook is slid into the desired position, and then gently tamped against the pedicle. The hook is then moved side to side to ensure the hook is around the pedicle.

This combination provides an optimal level of force and guidance to safely insert the hook.

Alternate method: The hook is temporarily secured to the Hook Impactor by tightening a Closure Screw. The screw may be removed once the hook has been placed

Note: To facilitate the introduction of the pedicle hook it may be necessary to remove the prominence of the caudal lamina below the hook.

B.Hook Insertion

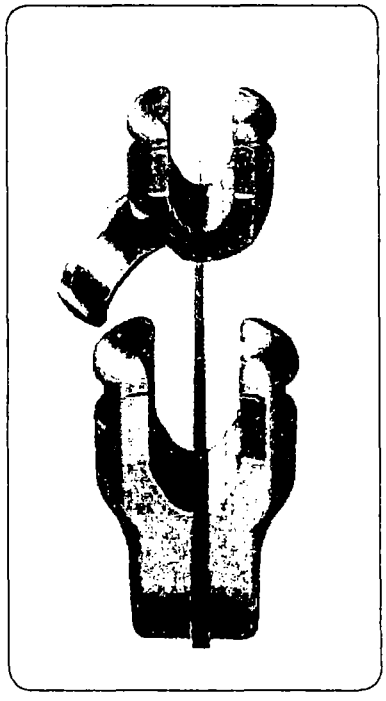


Based on the patient's anatomy, a Xia® 3 Transverse Process Hook or a standard lamina hook may be selected. The hook is loaded onto a Hook Forceps. The hook is then inserted into the space created with the Lamina Preparer.

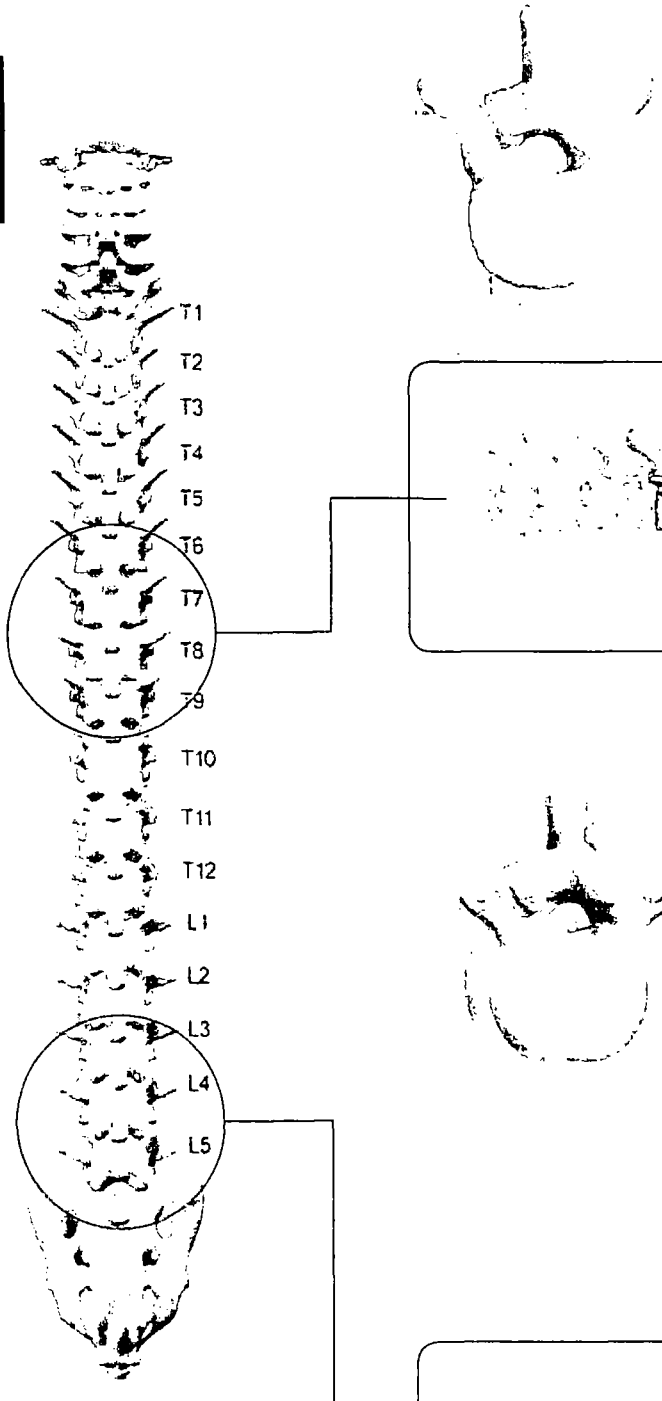
The transverse process hook may be directed cephalad or caudal.

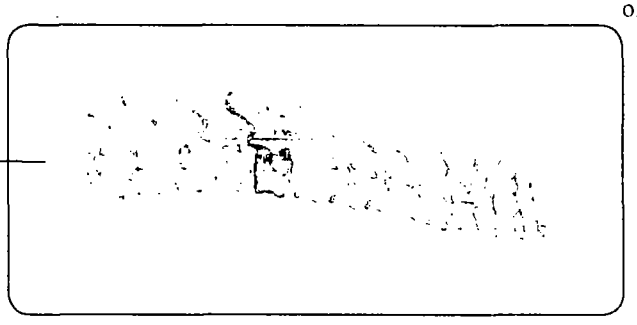
Caudally directed transverse process hooks are often the top portion of the transverse pedicle claw configuration. The Xia® 3 Transverse Process Hook is designed to closely line up with the inferior pedicle hook to help avial angulation and allow easy introduction of the Closure Screw.

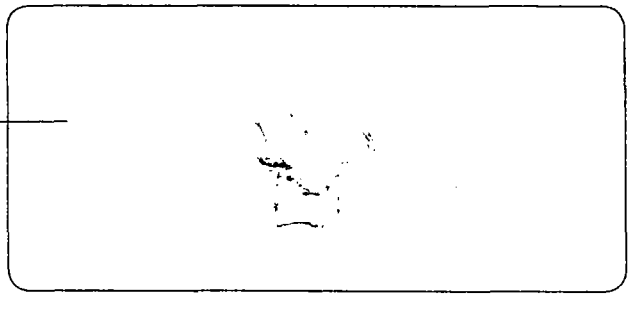
Again, the Lamina Hook Preparer can be used to dissect around the superior and anterior surface of the transverse process to create room between the anterior aspect of the transverse process and the rib head.



C.Screw Insertion







Thoracic Pedicle Entry:

Landmarks usually lie at the intersection of a vertical line through the middle of the convex part of each articular process and a horizontal line drawn across the middle to upper third of the base of the transverse process. This intersection is usually 2mm below the edge of the articular cartilage and just level with the small horizontal crest of bone. The use of CT scans may be used to verify any anatomic variations.

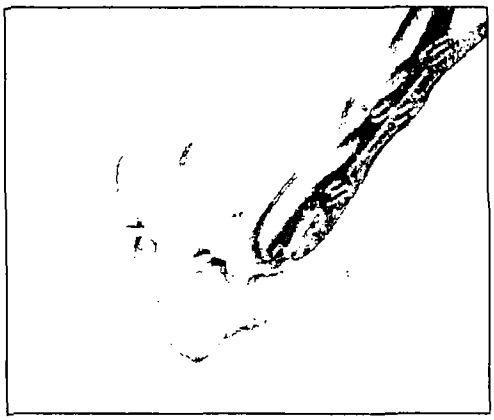
Note:
A pedicle, and the drilling direction, is usually globally perpendicular to the posterior plane of the vertebra (plane of the transverse process).

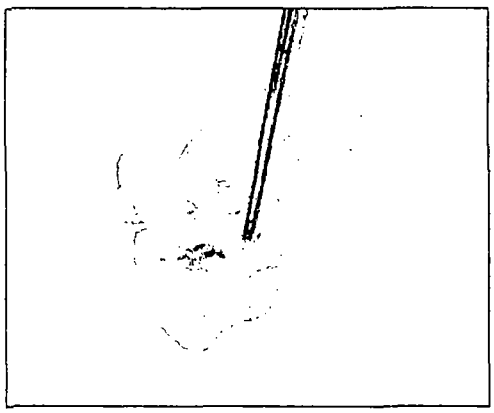
This is an important point to consider, especially when instrumenting the apical vertebrae, which are usually the most rotated ones.

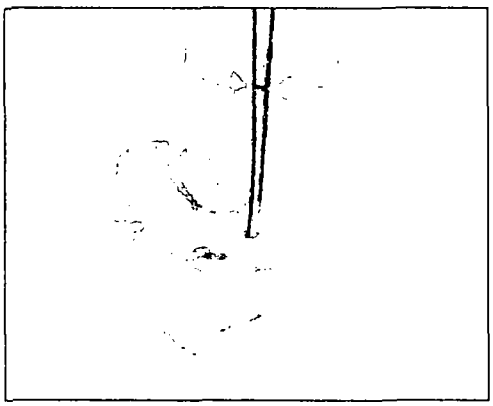
Lumbar Pedicle Entry:

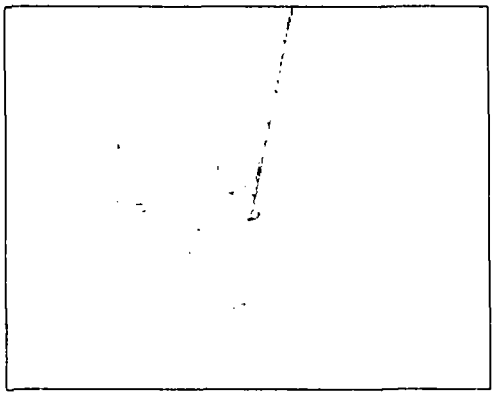
Landmarks are at the intersection of a vertical line through the facet joint space and a horizontal line through the middle of the base of the transverse process.
These two lines intersect at a small sharp crest of cortical bone which can be a reliable landmark since it is extra-articular and not affected by osteoarthritic deformities.

C.Screw Insertion









Screw Preparation and Insertion

The small cortical crest is removed with a rongeur or power burr to expose the underlying cancellous bone.

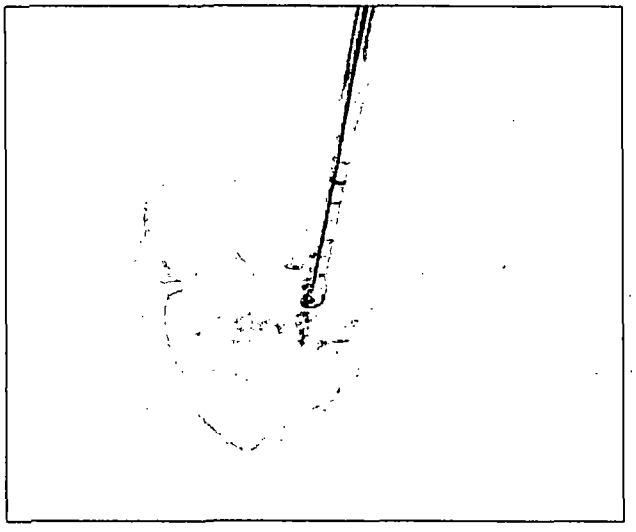
Pedicle entry identification

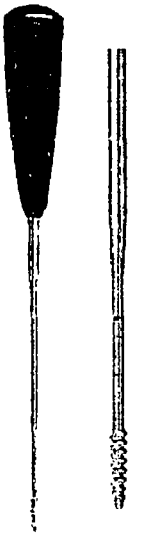
The entry point is prepared with the Square Awl, which should be driven in no more than 10mm.

A pathway is then opened up with the Blunt Probe. The probe should contact bone at all times. The correct rotational insertion of the instrument will allow the probe to follow a path of least resistance without violating the pedicle walls. In the event that resistance is felt, the entry point and trajectory should be re-evaluated. The Pedicle Probe is calibrated and laser etched with 5mm intervals to help indicate the depth in which the probe has been inserted as well as to help determine proper screw length.

The prepared pathway is checked with the Probe Feeler or the Tapered Ball Probe to verify that all walls of the pedicle have not been violated and that cancellous bone is felt at the distal end of the path. The Probe Feeler is calibrated in the same manner as the Pedicle Probe.

C.Screw Insertion

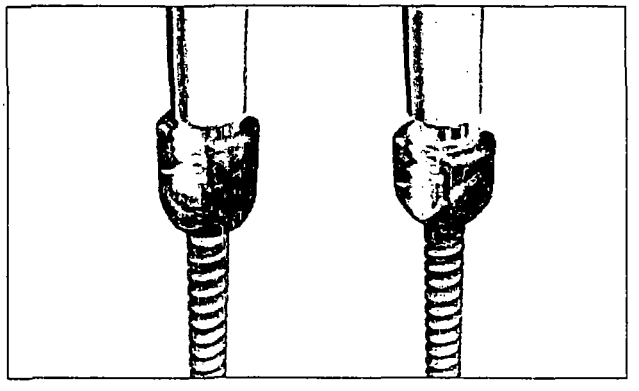




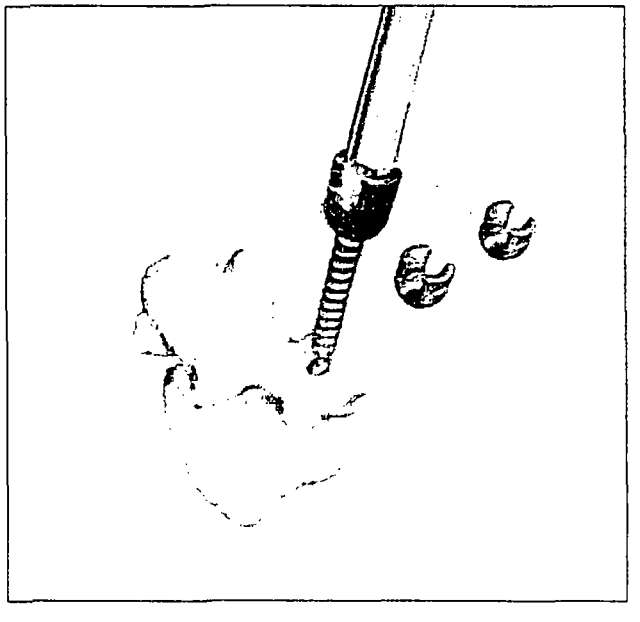
Screw Preparation and Insertion

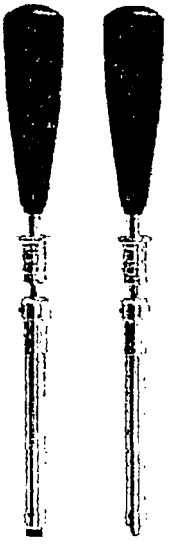
If the bone is too hard, the appropriate tap may be used to prepare the pedicle screw canal. The tap sizes are 4.5mm/5.5mm and 6.5mm/7.5mm. Modular 4.0, 4.5, 5.0, 5.5, 6.5, and 7.5 taps and cannulated 5.5 and 6.5mm taps are available.

The taps are calibrated in the same manner as the probe and feeler.



Both Polyaxial and Monoaxial Screwdrivers provide a very rigid connection between the polyaxial and monoaxial screws and the screwdriver.

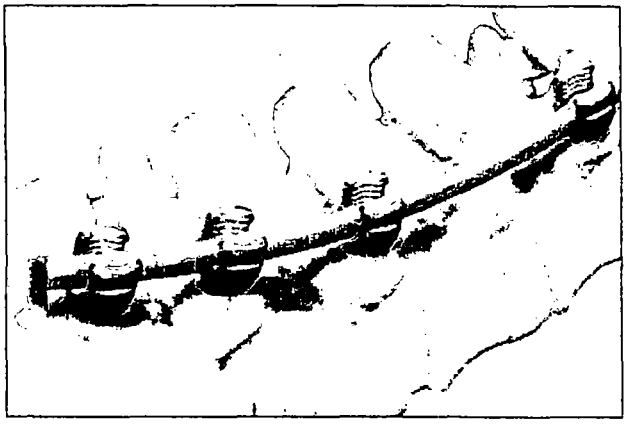


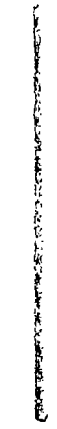


With the pedicle pathways prepared and proper screw length and diameter determined, the screw is prepared for insertion.

Note: The polyaxial screws may lock upon insertion. Use the Inserter to unlock the heads before introducing the rod.

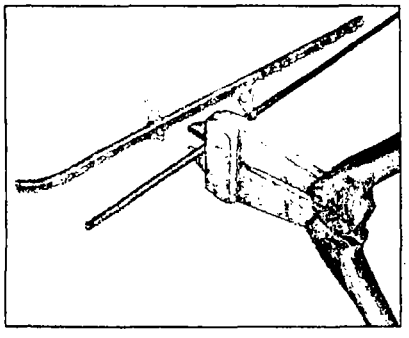
D.Rod Contouring



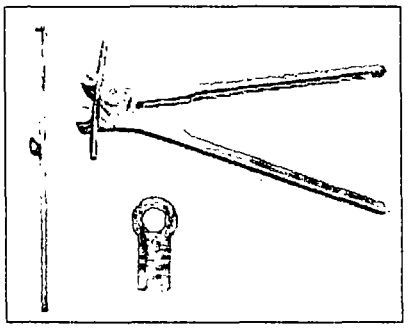


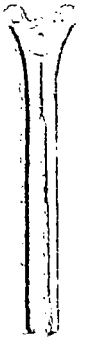
Once all screws are inserted, the appropriate length rod is cut according to the required construction. The Xia® 3 Spinal System Template is utilized to accurately determine the appropriate rod length.

Use the appropriate pre-cut rods or cut a longer rod with the Cutting Pliers. A Table top rod cutter is also available. Pre-bent rods are also offered with the Xia® 3 System.



Note:
The Vitallium Rods and Stainless Steel implants should not be mixed in patients, otherwise corrosion may occur resulting in decreased mechanical resistance.

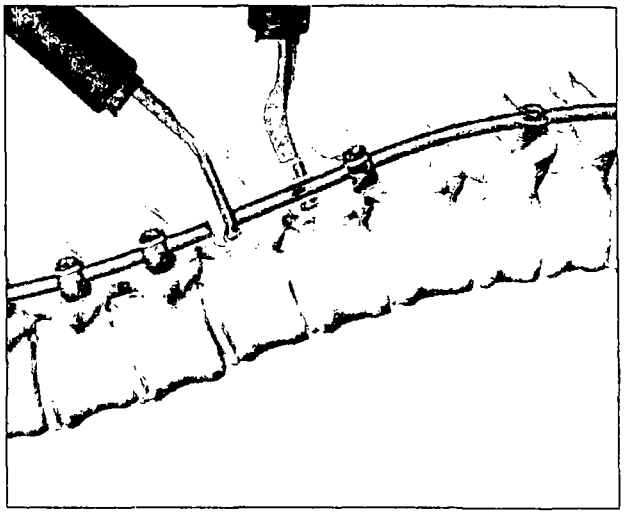




Note:
It is recommended that the Xia® 3 Table Top Rod Cutter is used to cut the Vitallium Rod.

Note:
The 600mm Vitallium Rod is for sale in the USA only.

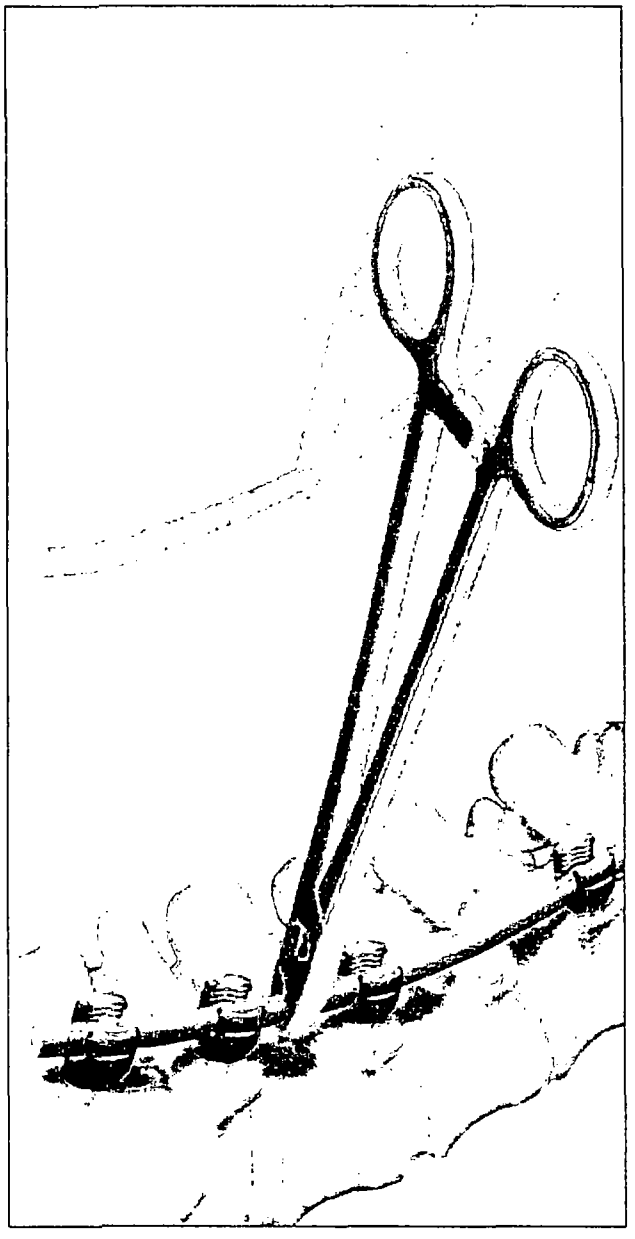
The rod bending is performed to fit the desired spinal contours.

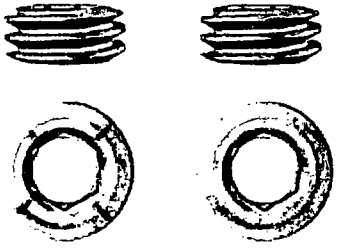


Bending can be performed with the Xia® 3 French Benders. To contour the rod, a series of small incremental adjustments will bend the rod gradually and ensure even stress distribution on the rod.

The Bending Irons can be used for *in-situ* bending to achieve final incremental correction maneuvers. Care should be taken to not make extreme bends, so as to avoid stress concentration and notching of the rod.

D.Rod Contouring





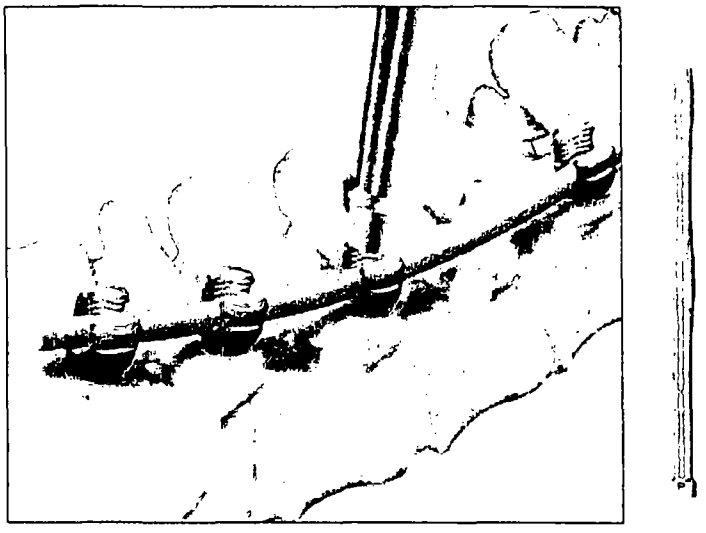
Titanium Stainless Steel

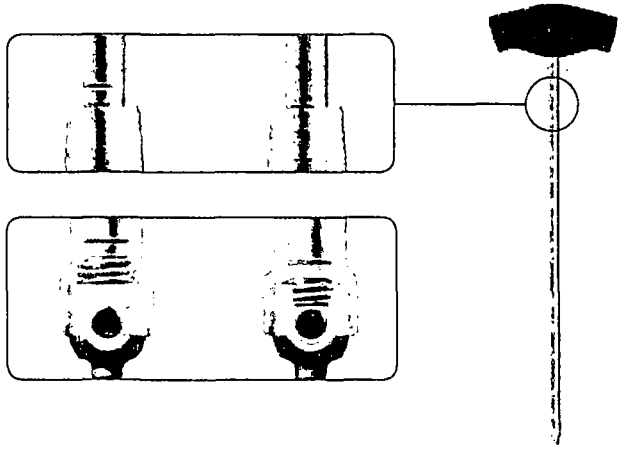
Rod Insertion

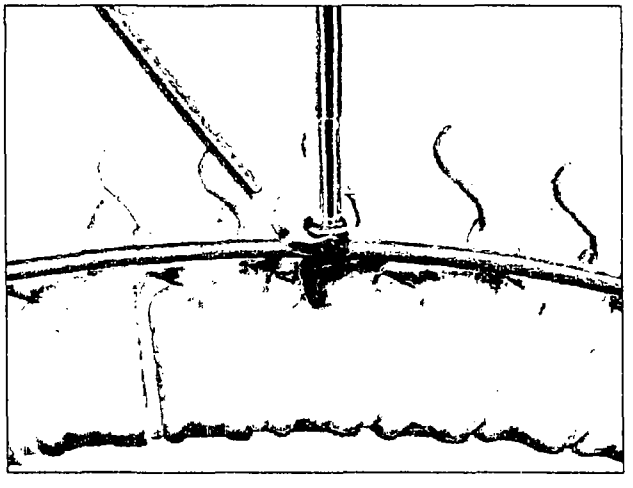
Once the rod is bent to the desired contour, the Rod Insertion Forceps can be used to facilitate the rod into the grooves of the implant. This can be done in any sequence at the discretion of the surgeon. It can be helpful to begin the closure at the easiest place. This may help facilitate the seating of the rod in adjacent hooks.

Note:
The Titanium Closure Screw is laser etched to clearly differentiate it from the Stainless Steel Closure Screw. It is important not to mix Stainless Steel and Titanium metals

E.Rod Linkage







Inserter and Universal Tightener

The Xia® 3 System offers three options for linking the rod to the spine:

Option 1:

The Inserter can help align the Universal Tightener, 5mm and the Closure Screw with the implant.

The two engraved lines on the Universal Tightener denote the following:

- When the lower line is aligned with the top of the Inserter, the Closure Screw is at the top of the implant.

- When the upper line is aligned with the top of the Inserter, the Closure Screw is fully introduced into the implant.

Note:
Do not perform final tightening of the Closure Screw with the Inserter in place, or it will not be possible to remove the Inserter.

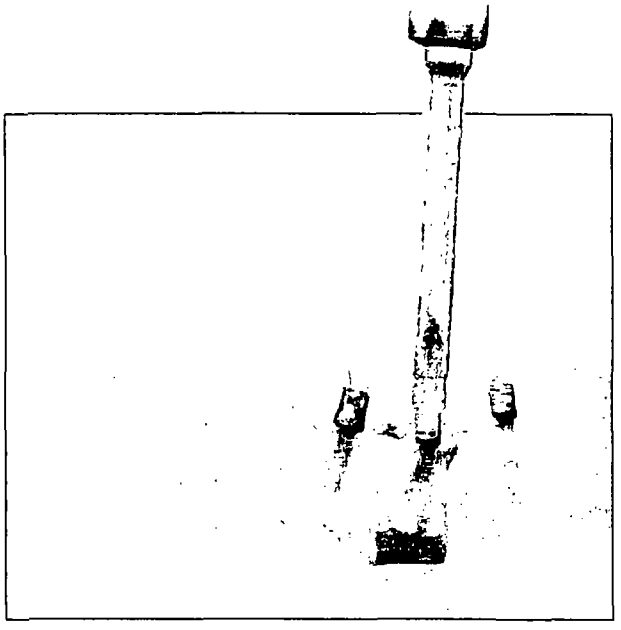
Option 2:

Rod Fork and Universal Tightener

The Rod Fork is used when the rod is slightly proud with respect to the seat of the implant.

The Rod fork easily slides into the lateral grooves on the implant head and is rotated backwards. This levers the rod into the head of the implant. The Closure Screw is inserted with the Universal Tightener when the rod is fully seated into the head of the implant.

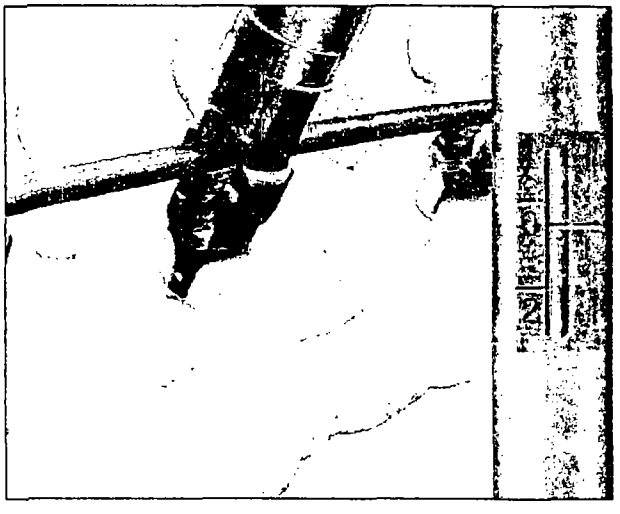
E.Rod Linkage



Using the Persuader

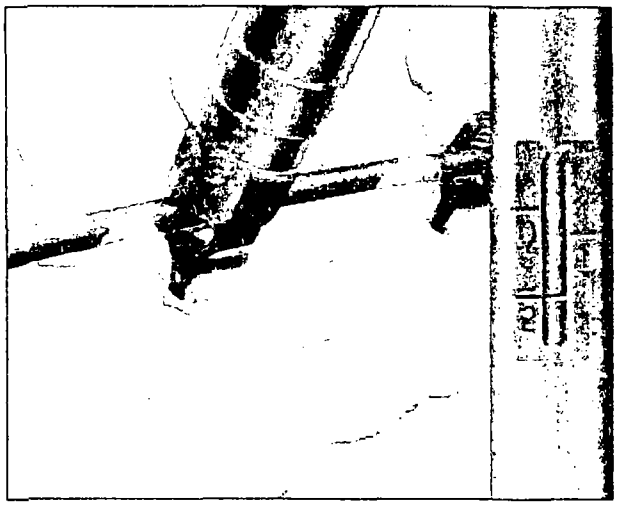
Option 3:

The Persuader is used when additional force is needed to bring the rod to the implant.



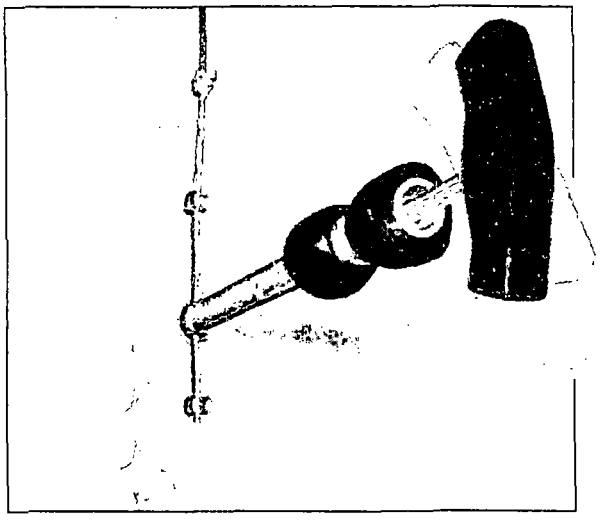
In the position "0", connect the Persuader to the head of the implant.

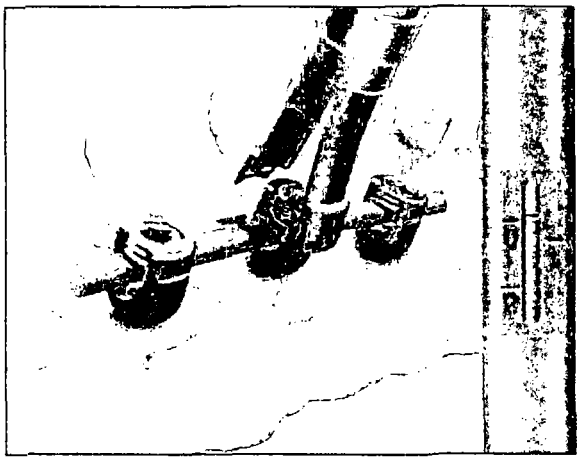
Turn the head of the Persuader until the indication line moves to the position "1". The Persuader is now locked to the implant. From this position the rod can be pushed into the screw.

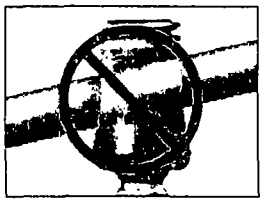


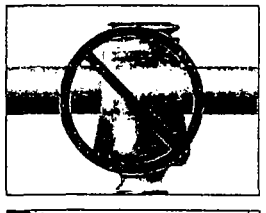
Turn the head of the Persuader until the indication line moves into position "2". The rod is now fully seated allowing insertion of the Closure Screw.

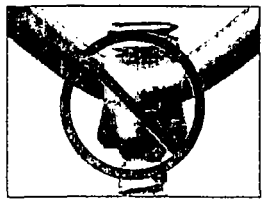
E.Rod Linkage











Persuader and Universal Tightener

Introduce the Closure Screw with the Universal Tightener through the Persuader.

To remove the Persuader, turn the head of the instrument back to the position "0" and rotate the complete instrument.

Tip 1: The rod cannot be linked to the screws or the hooks if the rod has a sharp, acute bend at the point of linkage.

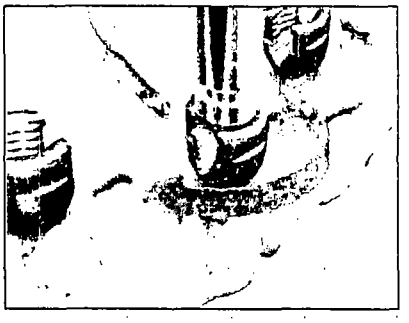
Tip 2: If the position "2" cannot be achieved by turning the Persuader, it may not be positioned properly on the implant. Remove the instrument and start the application process from the beginning.

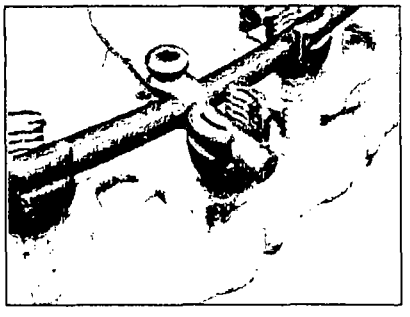
Tip 3: The Persuader is not designed to bend the rod.

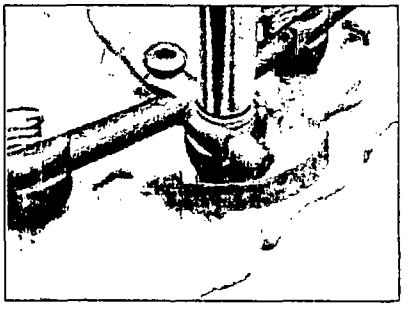
In the event the rod is forced down while tightening the Closure Screw, be sure that the Closure Screw is fully engaged into the screw head. This will help resist the high reactive forces generated by the final-tightening maneuvers.

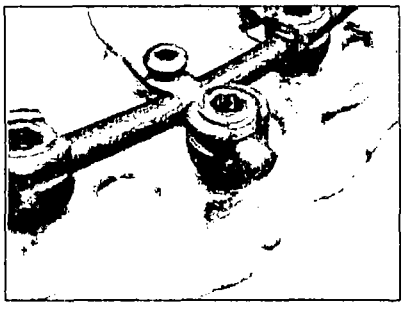
Extra caution is advised when:
1) The rod is not horizontally placed into the screw head
2) The rod is high in the screw head
3) An acute convex or concave bend is contoured into the rod.

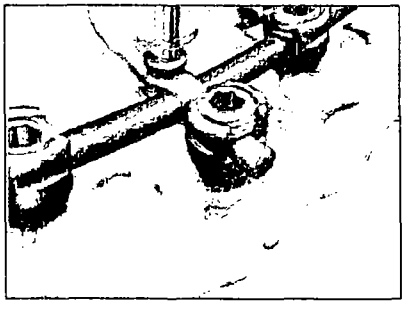
F.Lateral Offset Connector











Operative Technique

Lateral Offset Connector

The Offset Connector allows medial or lateral variability in connecting screws to the rod. They can be helpful in lining up the screws with hook connections.

The head of the screw is rotated 90° clockwise.

The Offset Connector is preloaded onto the rod in the appropriate orientation. To obtain some stability between the rod and Offset Connector, the connector can be tightened lightly at this stage.

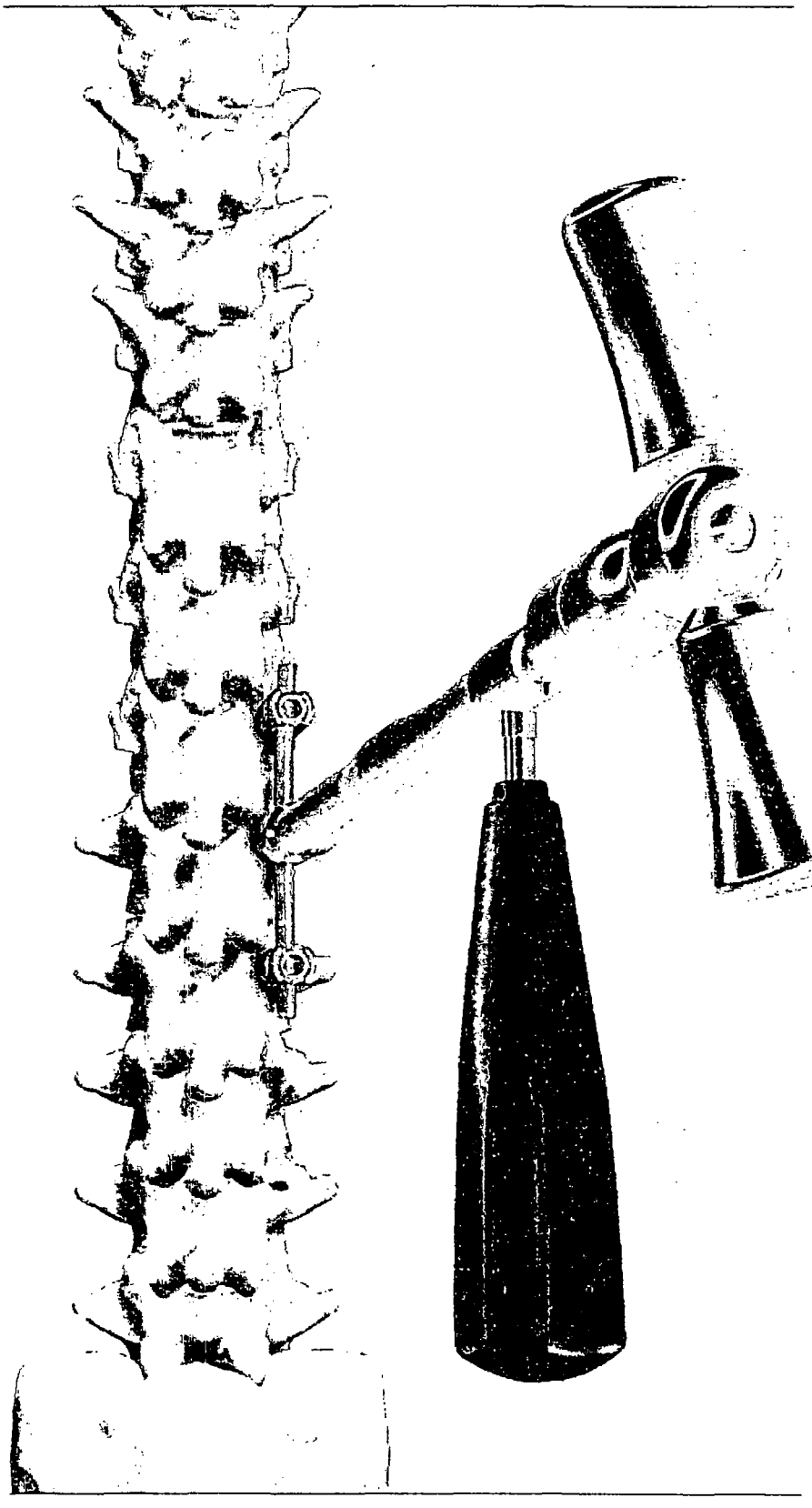
The Offset Connector is inserted into the head of the screw. Care must be taken to insure that at least 1mm of the connector is protruding out of the spinal screw.

The Closure Screw is now applied using the Universal Tightener. The final tightening sequence utilized with a pedicle screw is applied to the Closure Screw when used in conjunction with the Offset Connector.

Note:
The Offset Connector is most easily applied in conjunction with the Polyaxial Screw.

Note:
The Offset connector in use with the Monoaxial Screw requires accurate alignment in the sagittal plane of the screw head and rod.

G.Final Tightening

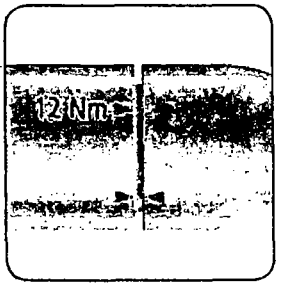


Using Torque Wrench

Once the correction procedures have been carried out and the spine is fixed in a satisfactory position, the final tightening of the Closure Screw is done by utilizing the Anti-Torque Key and the Torque Wrench.

The Torque Wrench indicates the optimum force which has to be applied to the implant for final tightening. Line up the two arrows to achieve this optimum torque of 12Nm.

Note:
It is not recommended to exceed 12Nm during final tightening.

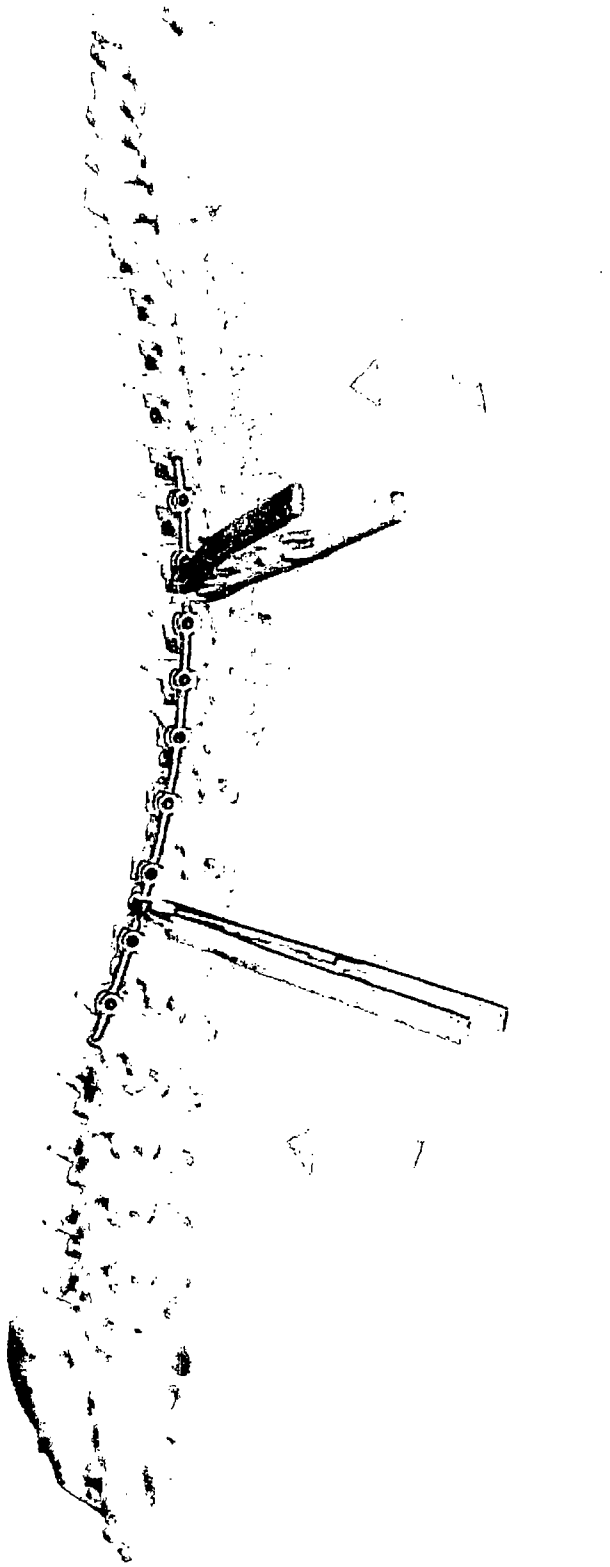


Note:
The Anti-Torque Key must be used for final tightening. The Anti-Torque performs two important functions:

1) It allows the Torque Wrench to align with the axis of the tightening axis.
2) It allows one to maximize the torque needed to lock the implant assembly.

Note: If the Anti-Torque Key cannot be easily removed from the implant head, the rod may not be fully seated.

H.Reduction Procedures



Deformity Correction

In working with our global panel of scoliosis specialists, the Xia® 3 System was designed to offer solutions that accommodate various surgical philosophies. The Xia® 3 System advantage is that the surgeon does not have to deviate from their surgical philosophy.

Deformity correction may be obtained using one of four different reduction procedures:

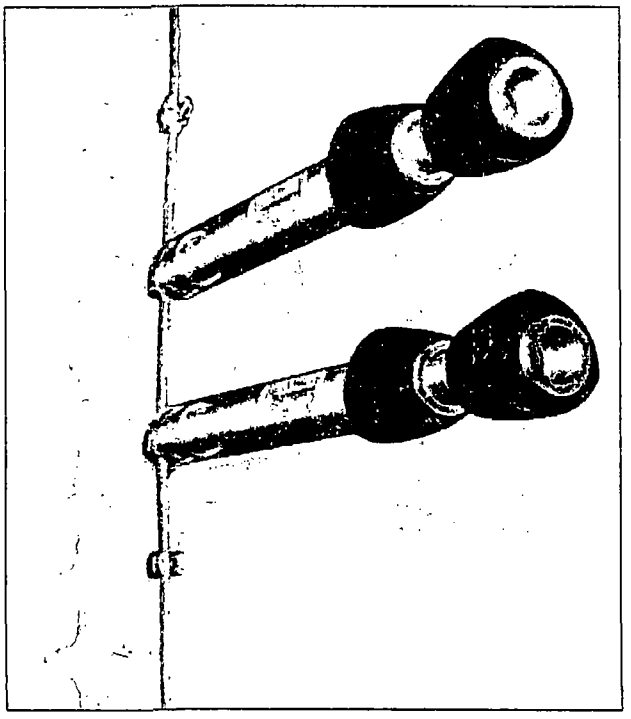
1. Rod Derotation
2. Translation
3. Distraction/Compression
4. In Situ Bending

These maneuvers may be utilized independently or in any combination to facilitate optimal spinal deformity correction.

Rod Derotation
Option 1: Traditional rod derotation:

With the rod inserted into all of the implants and the Closure Screws inserted but not tightened, the rotational correction maneuver can be applied.
The rod may be rotated using the two Rod Rotation Forceps. Insure that the Closure Screws are only provisionally tightened to allow free movement of the rod.
The C-Ring instrumentation can be utilized to maintain hook position while the rod rotation maneuver is performed. Typically, the rod is then rotated to an arch of 90 degrees converting a scoliotic deformity in the thoracic spine into a sagittal kyphosis and translating a lumbar scoliotic deformity into lumbar lordosis. Once the rod has been fully rotated, the Closure Screws are provisionally tightened.
Additional deformity correction may be obtained by further distraction/ compression maneuvers.

H.Reduction Procedures

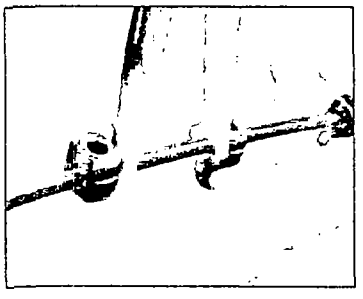


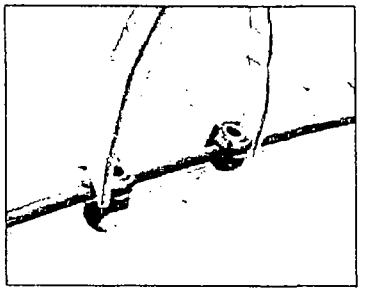
Option 2: Rod Rotation for implant approximation:

The rotation technique for approximation is to contour the rod in the sagittal plane to the desired shape. The rod can then be inserted in the implants up to 90 degrees out of phase to minimize the implant approximation necessary. The rod is then rotated, not to derotate the spine, but to place the implants in the proper alignment. Final correction is then performed using distraction and compression techniques.

Translation

Translation can be achieved by utilizing a sublaminar wiring technique or utilizing the persuader instruments. If using the persuader instruments to perform translation, utilize the two persuaders contained in the set. These persuaders are typically placed at the distal and proximal ends of the curve apex. As the spine is carefully translated at these points the Closure Screws are inserted and the implants secured. The persuaders are then moved toward the apex of the curve until translation is complete.





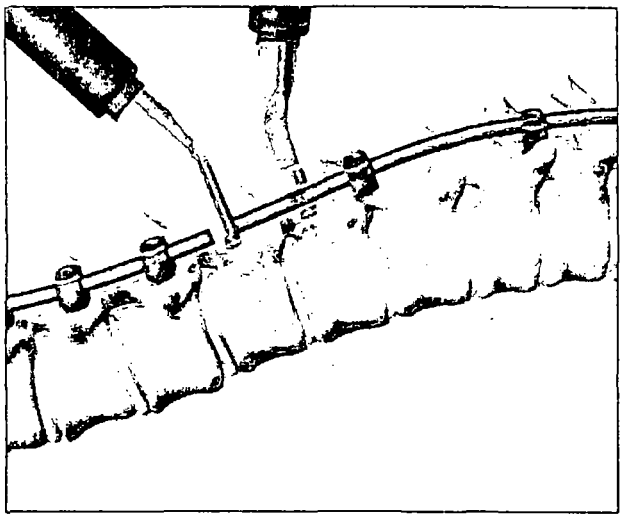
Distraction/Compression

Spinal deformities can be further effected by creating a distraction in the concavity of the deformity and compression on the convexity of the deformity.

Note: Posterior distraction creates a kyphosis in the sagittal plane, compression creates a lordosis in the sagittal plane. Compression is achieved with the Compressor and distraction can be achieved with the Spreader. Once the construct is in the desired position, lock the Closure Screws with the Universal Tightener.

In Situ Bending
Great care must be taken during *in situ* bending not to overload the bone implant interface. Also care must be used not to acutely notch the rod, which may weaken the implant. Ensure that the Closure Screws are not completely tightened during rotation maneuvers or the compression/ distraction process.

H.Reduction Procedures

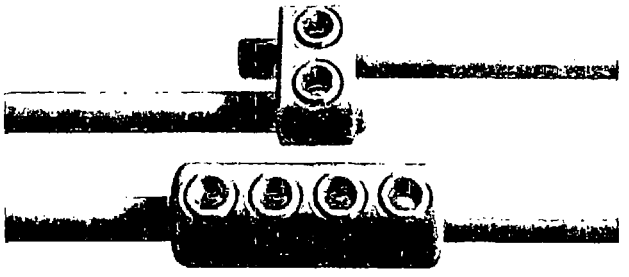


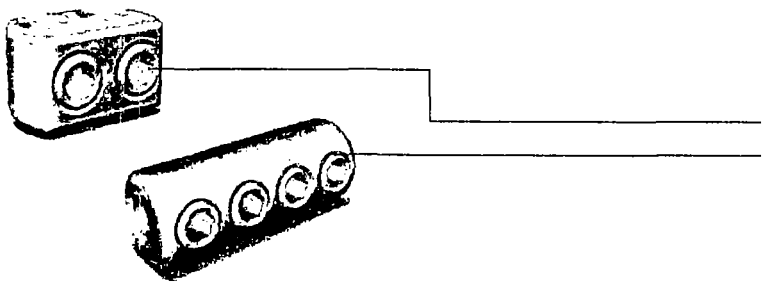
Deformity Correction

Rod to Rod Connection
Rod to Rod connection is occasionally necessary. There are two options available:

1. Dual Connector
2. Axial Connector

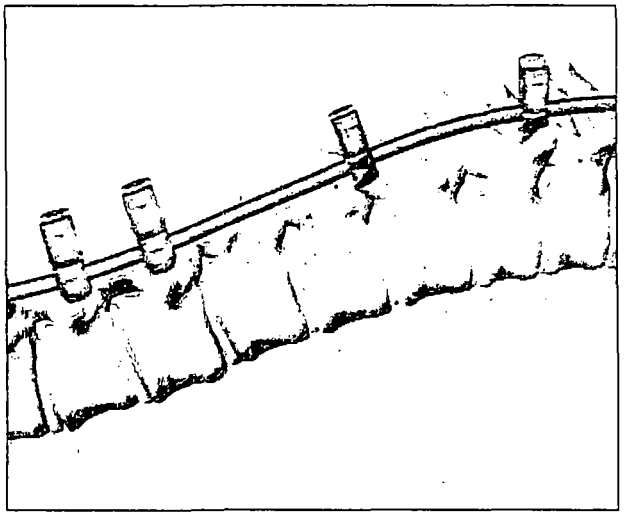
For tightening the Dual Connector and the Axial Connector use the 3.5mm Hexagonal driver.





1) Dual Rod to Rod Clamp
2) Axial Rod to Rod Clamp

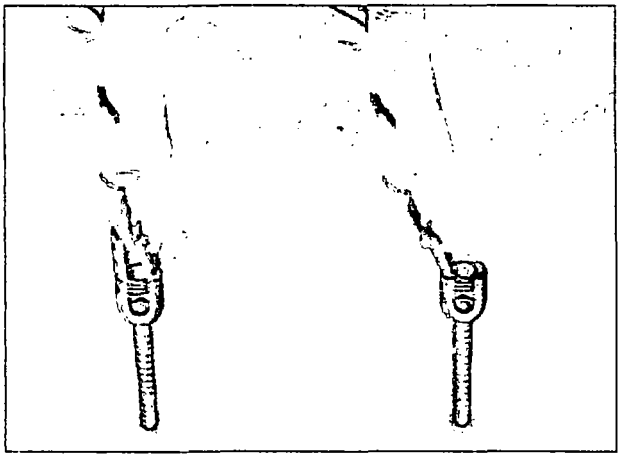
H.Reduction Procedures



Deformity Correction

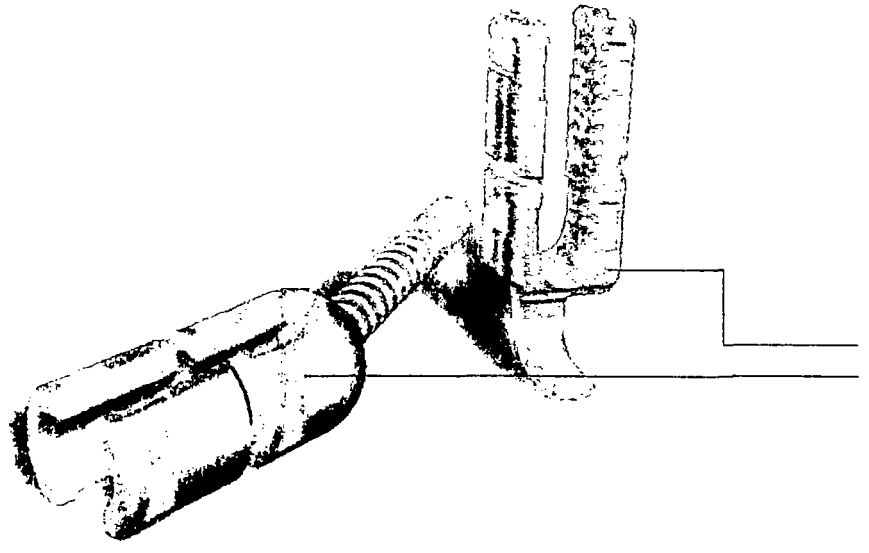
Xia® 3 Long Arm Screws and Hooks can be used during a reduction procedure.
The Xia® 3 Reduction monoaxial and polyaxial screwdrivers are used to insert the Xia Long Arm Screws into the pedicles.
The Xia® 3 Long Arm Hooks are manipulated using Xia® 3 Hooks Forceps.

Final tightening will take place once the closure mechanism is inserted and the arms are broken off.



When the Xia® 3 Long Arm Screws and Hooks are used, the arms are broken off when the reduction is complete. A snap line allows a clean and easy break. The first arm is broken away using the rod rotation forceps to grip the arm and bend it in a back and forth motion.

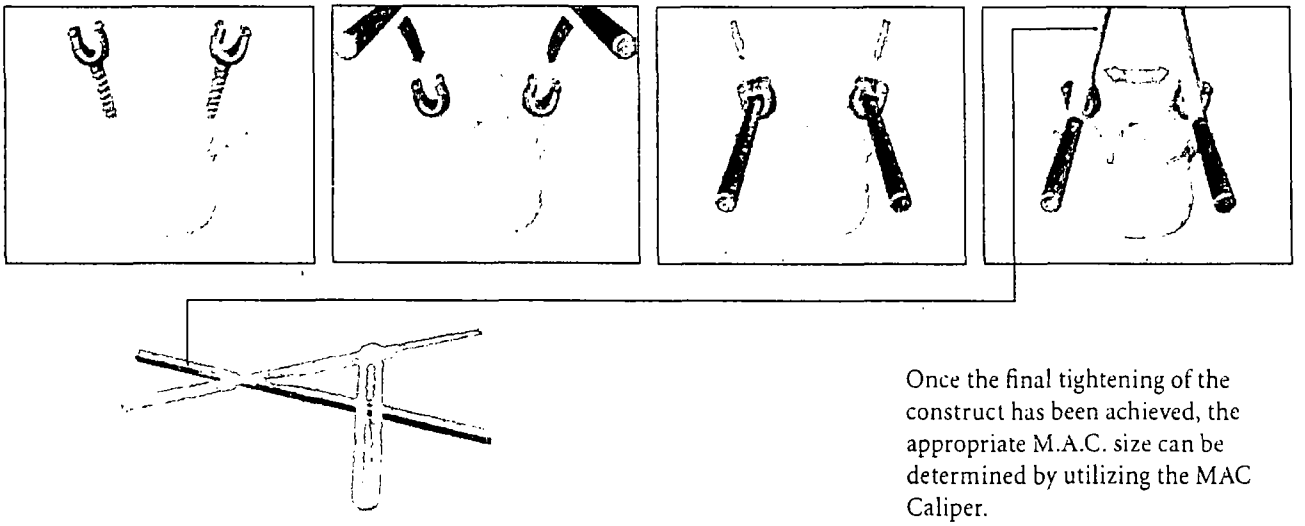
The second arm is broken off in the same manner as the first.



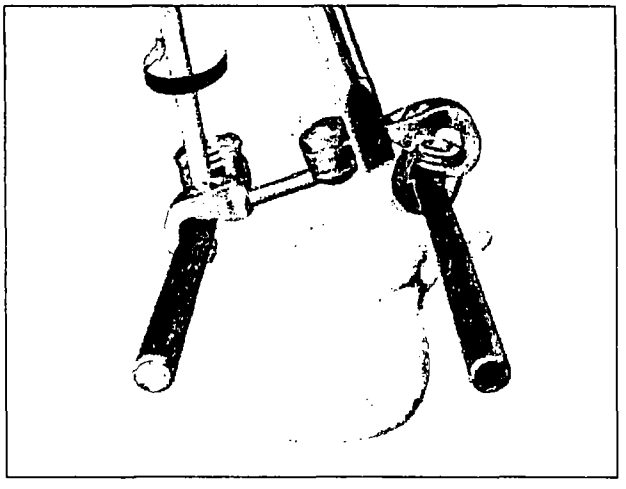
1) Long Arm Hook
2) Long Arm Screw

I.Multi-Axial Connector (M.A.C.)

Standard M.A.C.

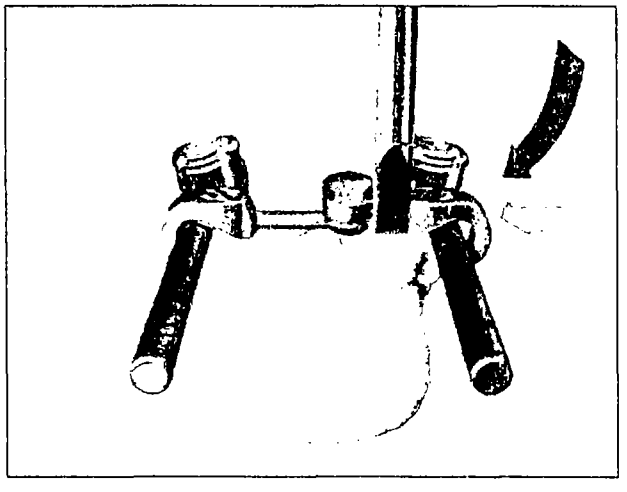


Once the final tightening of the construct has been achieved, the appropriate M.A.C. size can be determined by utilizing the MAC Caliper.



To allow for smooth and rapid insertion of the M.A.C. over the rods, insure that the center bolt is loose to achieve full range of motion and that the tightening screws are adequately backed out.

With the M.A.C. Forceps fixed on the longer J-Hook, place the appropriate length connector on the rod inserting the shortest J-Hook on first. Using the MAC Screwdriver (3.5mm) or MAC Round Tip Screwdriver (3.5mm), proceed to gently tighten the tightening screw onto the rod.



Continue with the insertion of the second J-Hook and tighten fully. Return to the first tightening screw for further tightening.

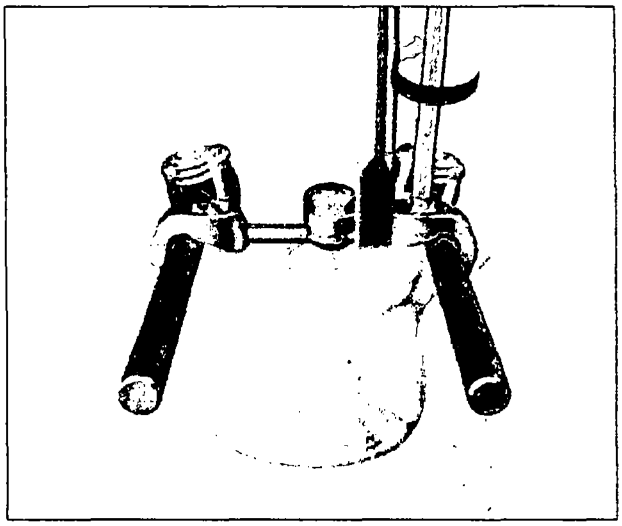
Check that the M.A.C. is correctly connected to the rods (firmly press the J-Hook if necessary).

Important!
Do not use any other instrumentation other than dedicated M.A.C. instrumentation.

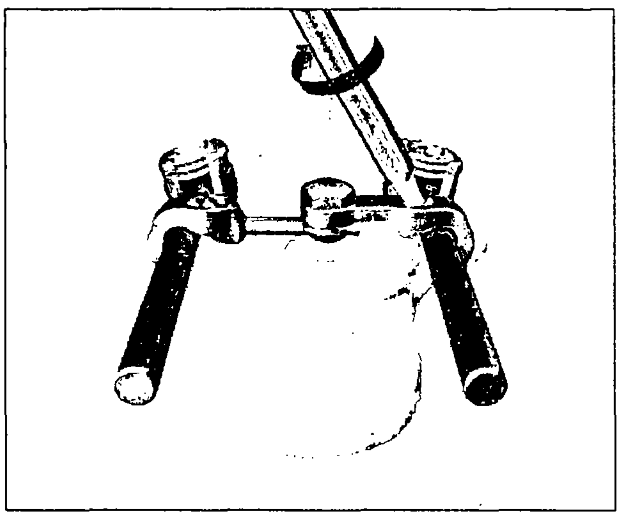
Note:
When using the Monobloc M.A.C. the rods must be parallel.

I.Multi-Axial Connector (M.A.C.)

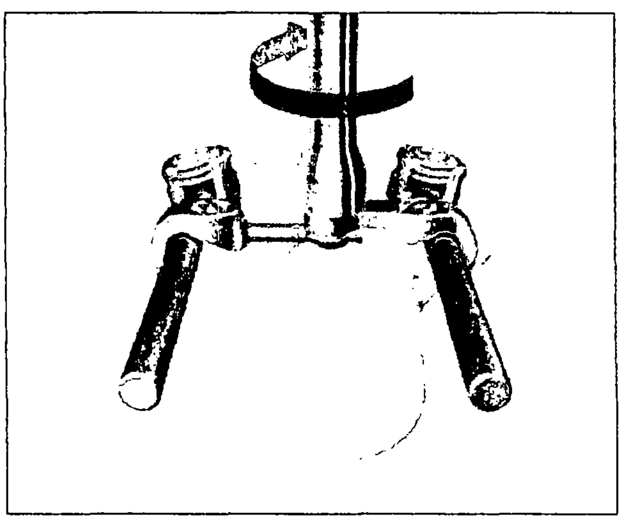
Standard M.A.C.



Note: The Round-Tip Screwdriver allows a 35° angulation around an axis of 360° of the tightening screw.



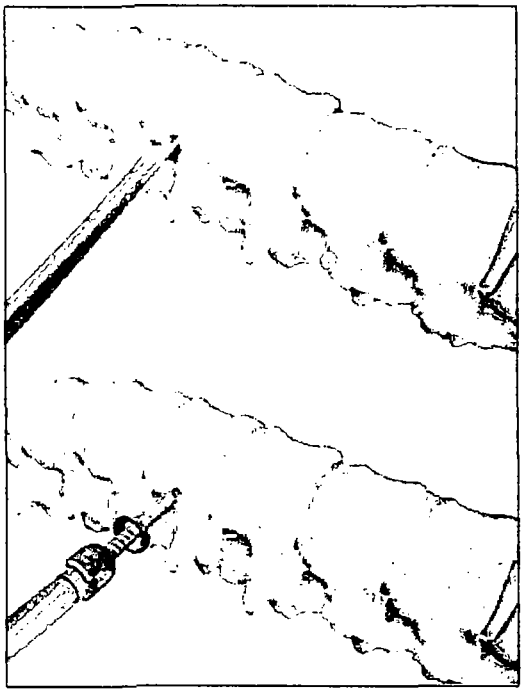
The 3.5mm standard Screwdriver must be used for the final tightening of the tightening screws in order to optimize the contact surface and to avoid damaging the hex of the screws and the tip of the Round-Tip Screwdriver.

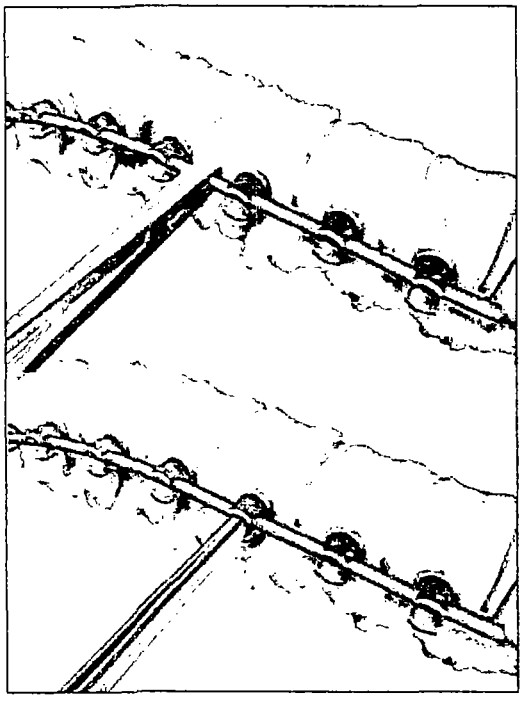


The central bolt is finally fully tightened with the 8mm MAC Screwdriver.

Revisit the outside set screws to insure proper tightening.

J.Anterior Approach





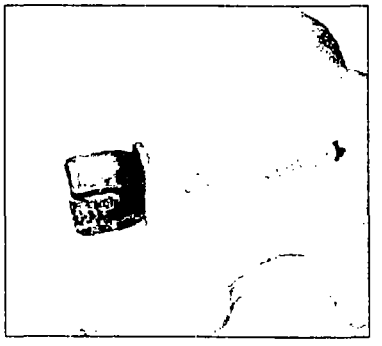
Screw Insertion

The patient is usually approached via a transcostal approach in the thoracic spine or retoperitoneal approach in the lumbar area. A combined incision can be used to access both.

The patient is usually positioned in lateral decubitus position with the convex side up. The highest intended instrumented vertebra is selected and typically defines the rib to be excised (e.g. 6th rib to access 6th thoracic vertebra). The rib can be morcellized for bone graft.

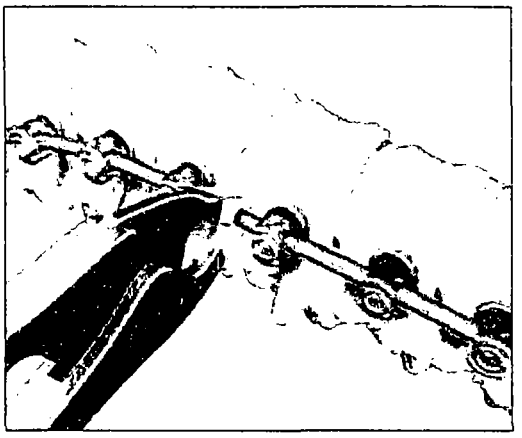
Exposure of the vertebral bodies is completed allowing discectomies and release of the anterior longitudinal ligament and concave soft tissue. Removal of the vertebral end plates at this stage could likely result in additional blood loss and should be delayed until screw insertion is completed.

Once the entry point and screw direction is defined (directed away from the spinal canal) the cortex can be perforated using the Xia® 3 Awl.



The length of the screws is selected according to Computed Tomographic (CT) scans or the use of a standard depth gauge. The head of the screw should be inserted to contact the first cortex or a washer can be added for additional surface contact. The screws are inserted through the washers. Screw purchase should be bicortical for optimal fixation.

J.Anterior Approach

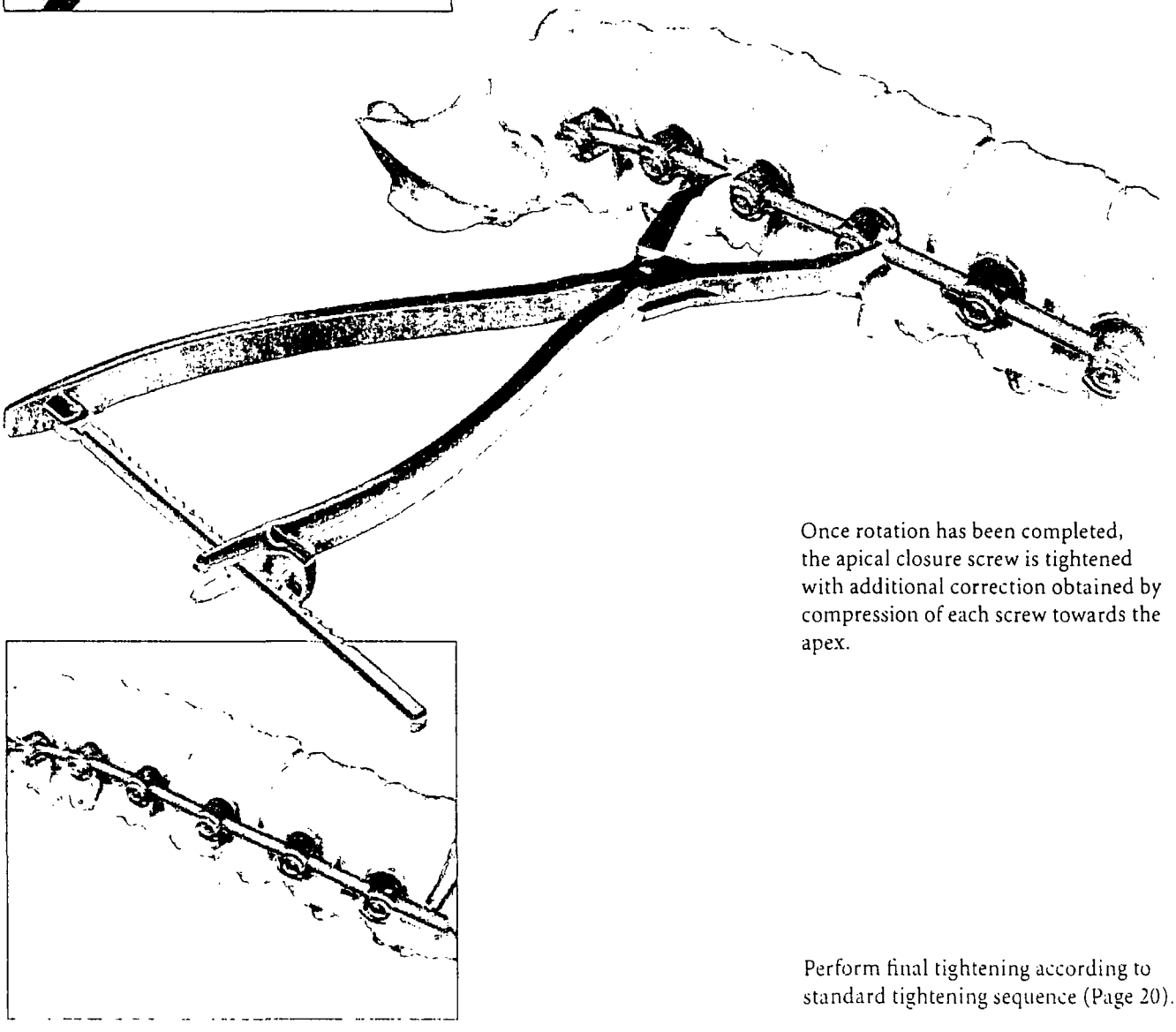


Deformity Correction

The rod is cut to proper length and bent to fit the contours of the spine.

End plates are removed and bone graft inserted especially into the concavity of the deformity.
The rod is inserted into the head of the implants.

The Closure Screws are partially introduced to allow rotation of the construct.



Once rotation has been completed, the apical closure screw is tightened with additional correction obtained by compression of each screw towards the apex.

Perform final tightening according to standard tightening sequence (Page 20).

XIA®3 Spinal System

The XIA®3 Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA®3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (DDD) (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, and/or lordosis); tumor; pseudoarthrosis and failed previous fusion.

The Ø5.5mm rods from the STRYKER Spine Radius™ Spinal System and Ø6.0 mm Vitallium rods from XIA® Spinal System are intended to be used with the other components of Xia®3 Spinal System.

When used for posterior noncervical pedicle screw fixation in pediatric patients, the XIA® 3 Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The XIA® 3 Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

CONTRAINDICATIONS

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Insufficient quality or quantity of bone which would inhibit rigid device fixation.
- Previous history of infection.
- Excessive local inflammation.
- Open wounds.
- Any neuromuscular deficit which places an unsafe load level on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself. Obesity is defined according to the W.H.O. standards.
- Patients having inadequate tissue coverage of the operative site.
- Pregnancy.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.

These contraindications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive.

ADVERSE EFFECTS

- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Bending, disassembly or fracture of any or all implant components.

- Fatigue fracture of spinal fixation devices, including screws and rods, has occurred.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin.
- Dural leak requiring surgical repair.
- Cessation of growth of the fused portion of the spine.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) should be revised or removed immediately before serious injury occurs.
- Loosening of spinal fixation implants can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, migration and/or pain.
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Serious complications may be associated with any spinal surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Decrease in bone density due to stress shielding.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft, the intervertebral body, pedicle, and/or sacrum above and/or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision.
The surgeon must warn the patient of these adverse effects as deemed necessary.

ADDITIONAL ADVERSE EFFECTS FOR PEDIATRIC PATIENTS

- Inability to use pedicle screw fixation due to limitations (pedicle dimensions, distorted anatomy).
- Pedicle screw malpositioning, with or without neurological or vascular injury.
- Proximal or distal junctional kyphosis.
- Pancreatitis.

WARNING (U.S.A.)

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 spondylolisthesis (grades 3 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurological 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.

The Xia® 3 Spinal System has not been tested for heating or migration in the MR environment.

ADDITIONAL WARNINGS FOR PEDIATRIC PATIENTS

Warning: 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.

The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature or skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter and 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 reduce longitudinal spinal growth, or may be at risk for rotational spinal deformities (the "crankshaft phenomenon") due to continued differential growth of the anterior spine.

Other adverse effects related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients. Pediatric patients may be at increased risk for device-related injury because of their small stature.

PRECAUTIONS (U.S.A.)

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

Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

ADDITIONAL PRECAUTIONS FOR PEDIATRIC PATIENTS

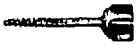
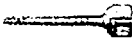
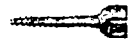
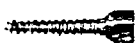
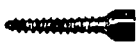
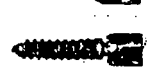
The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury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

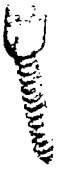
Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients.

The selection of the proper size, shape, and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

Adolescent Idiopathic Scoliosis Application

Xia® 3 Implants

	Part Number	Description
	48230000	Blocker
	4823040(20)-(45)	Xia® 3 Monoaxial Screw, Ø4.0mm
	4823045(20)-(45)	Xia® 3 Monoaxial Screw, Ø4.5mm
	4823050(20)-(50)	Xia® 3 Monoaxial Screw, Ø5.0mm
	4823055(25)-(55)	Xia® 3 Monoaxial Screw, Ø5.5mm
	4823060(25)-(90)	Xia® 3 Monoaxial Screw, Ø6.0mm
	4823065(25)-(90)	Xia® 3 Monoaxial Screw, Ø6.5mm
	4823070(25)-(90)	Xia® 3 Monoaxial Screw, Ø7.0mm
	4823075(25)-(90)	Xia® 3 Monoaxial Screw, Ø7.5mm
	4823140(20)-(45)	Xia® 3 Polyaxial Screw, Ø4.0mm
	4823145(20)-(45)	Xia® 3 Polyaxial Screw, Ø4.5mm
	4823150(20)-(50)	Xia® 3 Polyaxial Screw, Ø5.0mm
	4823155(25)-(55)	Xia® 3 Polyaxial Screw, Ø5.5mm
	4823160(25)-(90)	Xia® 3 Polyaxial Screw, Ø6.0mm
	4823165(25)-(90)	Xia® 3 Polyaxial Screw, Ø6.5mm
	4823170(25)-(90)	Xia® 3 Polyaxial Screw, Ø7.0mm
	4823175(25)-(90)	Xia® 3 Polyaxial Screw, Ø7.5mm
	482334(20)-(45)	Xia® 3 Uniplanar Screw, Ø4.5mm
	4823350(20)-(45)	Xia® 3 Uniplanar Screw, Ø5.0mm
	482335(20)-(55)	Xia® 3 Uniplanar Screw, Ø5.5mm
	4823360(25)-(60)	Xia® 3 Uniplanar Screw, Ø6.0mm
	482336(25)-(60)	Xia® 3 Uniplanar Screw, Ø6.5mm
	4823370(30)-(60)	Xia® 3 Uniplanar Screw, Ø7.0mm
	482337(30)-(60)	Xia® 3 Uniplanar Screw, Ø7.5mm

	Part Number	Description
	4823645(20)-(45)	Xia® 3 Reduction Uniplanar Screw, Ø4.5mm
	4823650(20)-(45)	Xia® 3 Reduction Uniplanar Screw, Ø5.0mm
	4823655(20)-(55)	Xia® 3 Reduction Uniplanar Screw, Ø5.5mm
	4823660(25)-(60)	Xia® 3 Reduction Uniplanar Screw, Ø6.0mm
	4823665(25)-(60)	Xia® 3 Reduction Uniplanar Screw, Ø6.5mm
	4823670(30)-(60)	Xia® 3 Reduction Uniplanar Screw, Ø7.0mm
	4823675(30)-(60)	Xia® 3 Reduction Uniplanar Screw, Ø7.5mm
	4823965(60)-(00)	Xia® 3 Angled Monoaxial Screw, Ø6.5mm
	4823975(60)-(00)	Xia® 3 Angled Monoaxial Screw, Ø7.5mm
	4823985(60)-(00)	Xia® 3 Angled Monoaxial Screw, Ø8.5mm
	4823840(20)-(45)	Xia® 3 Angled Polyaxial Screw, Ø4.0mm
	4823845(20)-(45)	Xia® 3 Angled Polyaxial Screw, Ø4.5mm
	4823850(20)-(45)	Xia® 3 Angled Polyaxial Screw, Ø5.0mm
	4823855(25)-(55)	Xia® 3 Angled Polyaxial Screw, Ø5.5mm
	4823865(25)-(90)	Xia® 3 Angled Polyaxial Screw, Ø6.5mm
	4823875(25)-(90)	Xia® 3 Angled Polyaxial Screw, Ø7.5mm
	4823885(60)-(00)	Xia® 3 Angled Polyaxial Screw, Ø8.5mm
	4823895(60)-(00)	Xia® 3 Angled Polyaxial Screw, Ø9.5mm

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Part Number	Description
48237140(20)-(45)	Xia® 3 Angled Medial, Screw, Ø4.0mm
48237145(20)-(45)	Xia® 3 Angled Medial, Screw, Ø4.5mm
48237150(20)-(45)	Xia® 3 Angled Medial, Screw, Ø5.0mm
48237155(25)-(55)	Xia® 3 Angled Medial, Screw, Ø5.5 mm
48237165(25)-(90)	Xia® 3 Angled Medial Screw, Ø6.5mm
48237175(25)-(90)	Xia® 3 Angled Medial Screw, Ø7.5mm
48237185(60)-(00)	Xia® 3 Angled Medial Screw, Ø8.5mm
48237195(60)-(00)	Xia® 3 Angled Medial Screw, Ø9.5mm

4823265(30)-(00)	Xia® 3 Closed Head Monoaxial Screw, Ø6.5mm
4823275(30)-(00)	Xia® 3 Closed Head Monoaxial Screw, Ø7.5mm
4823285(30)-(00)	Xia® 3 Closed Head Monoaxial Screw, Ø8.5mm
4823295(30)-(00)	Xia® 3 Closed Head Monoaxial Screw, Ø9.5mm

4823765(30)-(00)	Xia® 3 Closed Head Polyaxial Screw, Ø6.5mm
4823775(30)-(00)	Xia® 3 Closed Head Polyaxial Screw, Ø7.5mm
4823785(30)-(00)	Xia® 3 Closed Head Polyaxial Screw, Ø8.5mm
4823795(30)-(00)	Xia® 3 Closed Head Polyaxial Screw, Ø9.5mm

4823265(30)-(00)	Xia® 3 Closed Head Revision Screw, Ø6.5mm
4823275(30)-(00)	Xia® 3 Closed Head Revision Screw, Ø7.5mm
4823285(30)-(00)	Xia® 3 Closed Head Revision Screw, Ø8.5mm
4823295(30)-(00)	Xia® 3 Closed Head Revision Screw, Ø9.5mm

48230250	Xia® 3 Laminar Hook Medium, Standard Blade
48230201	Xia® 3 Laminar Hook Medium, Narrow Blade
48230202	Xia® 3 Laminar Hook Large, Standard Blade
48230203	Xia® 3 Laminar Hook Large, Narrow Blade

Part Number	Description
48230204	Xia® 3 Laminar Hook Extended Body
48230205	Xia® 3 Laminar Hook Small, Extended Body
48230206	Xia® 3 Laminar Hook Offset, Right
48230207	Xia® 3 Laminar Hook Offset, Left
48230208	Xia® 3 Laminar Hook Large, Angled Blade
48230209	Xia® 3 Laminar Hook Small, Angled Blade
48230210	Xia® 3 Thoracic Laminar Hook, Standard Blade
48230211	Xia® 3 Thoracic Laminar Hook, Narrow Blade
48230212	Xia® 3 Thoracic Laminar Hook Small Offset, Right
48230213	Xia® 3 Thoracic Laminar Hook Small Offset, Left
48230214	Xia® 3 Thoracic Laminar Hook Large Offset, Right
48230215	Xia® 3 Thoracic Laminar Hook Large Offset, Left
48230216	Xia® 3 Thoracic Laminar Hook Small, Narrow Blade
48230217	Xia® 3 Offset Hook Large, Right
48230218	Xia® 3 Offset Hook Large, Left
48230220	Xia® 3 Pedicle Hook, Medium
48230221	Xia® 3 Pedicle Hook, Small
48230222	Xia® 3 Pedicle Hook, Large
48230232	Xia® 3 Transverse Process Hook, Right
48230233	Xia® 3 Transverse Process Hook, Left
48230240	Xia® 3 Laminar Hook Small, Narrow Blade
48230241	Xia® 3 Laminar Hook Small, Standard Blade

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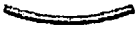
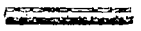
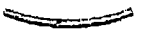
Xia® 3 Implants

	Part Number	Description
	03820200	Xia® Laminar Hook Medium, Standard Blade
	03820201	Xia® Laminar Hook Medium, Narrow Blade
	03820202	Xia® Laminar Hook Large, Standard Blade
	03820210	Xia® Thoracic Laminar Hook, Standard Blade
	03820220	Xia® Pedicle Hook, Medium
	48232(030)-(150), 480, 600	Ø6.0mm CP Titanium Rod, with Hex
	48233(030)-(150), 480, 600	Ø6.0mm Titanium Alloy Rod, with Hex
	03822601	Ø6.0mm Vitallium® Rod, 600mm
	48232601	Ø6.0mm Vitallium®, with Hex 600mm
	48238(030)-(120)	Ø6.0mm Titanium Alloy Rad Rod
	48239(050)-(120)	Ø6.0mm Titanium Alloy Max Rad Rod

	Part Number	Description
	4866130(03)-(20)	Ø5.5mm Titanium Alloy Rod, without Hex
	486613(110)-(600)	Ø5.5mm Titanium Alloy Rod, with Hex
	4866150(30)-(20)	Ø5.5mm Titanium Alloy Rad Rod
	4866155(50)-(20)	Ø5.5mm Titanium Alloy Max Rad Rod
	482360(14)-(26)	Xia® 3 Monoblock Cross Connector
	48236028	Xia® 3 Multi-Axial Cross Connector, 28mm-31mm
	48236030	Xia® 3 Multi-Axial Cross Connector, 30mm-35mm
	48236035	Xia® 3 Multi-Axial Cross Connector, 35mm-44mm
	48236043	Xia® 3 Multi-Axial Cross Connector, 43mm-54mm
	48236053	Xia® 3 Multi-Axial Cross Connector, 53mm-73mm
	48236070	Xia® 3 Multi-Axial Cross Connector, 70mm-99mm

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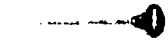
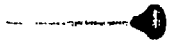
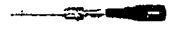
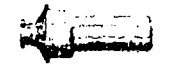
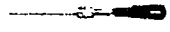
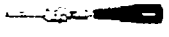
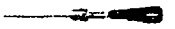
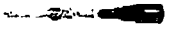
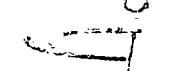
Xia® 3 Instruments

	Part Number	Description
	48237111	Awl
	482397002	Sacral Awl
	48237024	Curved Blunt Probe
	48237055	Thoracic Pedicle Probe
	482397001	Adjustable Curette Probe
	48237060	Malleable Pedicle Feeler
	48237059	Medium Pedicle Feeler
	48237003	Stiff Pedicle Feeler
	48237061	Double-Ended Ball Tip Probe
	48230(030)-(105)	Modular Tap, Ø3.0mm-Ø10.5mm
	48231201	T-Handle
	48231202	T-Handle, Ratchet
	48231301	Round Handle
	48231302	Round Handle, Ratchet
	482397006	Small Round Handle
	482397005	Small Round Handle, Ratchet
	48231330	Xia® 3 Polyaxial Screwdriver
	48231320	Xia® 3 Monoaxial Screwdriver
	48231311	Xia® 3 Polyaxial Screwdriver Shaft
	48231321	Xia® 3 Monoaxial Screwdriver Shaft
	48231330S	Screwdriver Sleeve
	482391330S	Xia® 3 Short Polyaxial Screwdriver
	482391330L	Xia® 3 Long Polyaxial Screwdriver
	482391320S	Xia® 3 Short Monoaxial Screwdriver

	Part Number	Description
	482391320L	Xia® 3 Long Monoaxial Screwdriver
	482397004	Xia® 3 Low Profile Polyaxial Screwdriver
	482391311S	Xia® 3 Short Polyaxial Screwdriver Shaft
	482391311L	Xia® 3 Long Polyaxial Screwdriver Shaft
	482391321S	Xia® 3 Short Monoaxial Screwdriver Shaft
	482391321L	Xia® 3 Long Monoaxial Screwdriver Shaft
	482391312S	Xia® 3 Short Xia® II Polyaxial Screwdriver Shaft
	482397009	Xia® 3 Low Profile Polyaxial Screwdriver Shaft
	482397010	Xia® 3 Low Profile Polyaxial Screwdriver Shaft Adapter
	03710620	Rod Template
	48238400S	Table-Top Rod Cutter Stand
	48238400	Table-Top Rod Cutter
	48237010	French Bender
	48230191L	Tube Bender, Left
	48230191R	Tube Bender, Right
	48230140	Rod Insertion Forceps
	48231140	Rod Gripper
	48237011L	*In-Situ* Rod Bender, Left
	48237011R	*In-Situ* Rod Bender, Right
	48230180	Coronal Rod Bender, Left
	48230190	Coronal Rod Bender, Right
	48230180S	Ball-Joint
	48237008	Universal Tightener
	482397008	Short Universal Tightener

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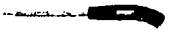
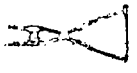
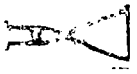
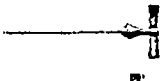
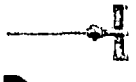
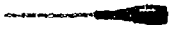
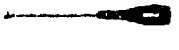
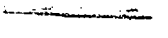
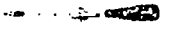
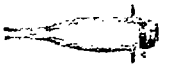
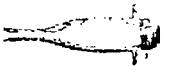
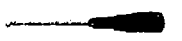
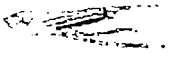
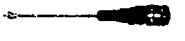
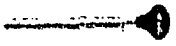
Xia® 3 Instruments

	Part Number	Description
	48237065	Double-Ended Universal Tightener
	48237109	Inserter Tube
	482397109	Short Inserter Tube
	48237018	Rod Fork
	48237016	Persuader
	482397016	Short Persuader
	48237015	One-Handed Persuader
	48236100	Small Compressor
	48236101	Large Compressor
	48236000	Small Distractor
	48236001	Large Distractor
	48237026	Anti-Torque Key
	482397026	Small Anti-Torque Key
	48237028	Torque Wrench
	482397028	Small Torque Wrench
	48230123	Cross Connector Measuring Device
	675024	MAC Caliper
	48230120	Cross Connector Inserter
	48230121	3.5mm Hex Driver
	48237092	Double-Ended 3.5mm Set Screw Inserter
	48230122	8mm Hex Driver
	48237087	SUK™ One-Piece Tube
	48237077	SUK™ Two-Piece Tube
	48237097	SUK™ T-Handle

	Part Number	Description
	48237067	SUK™ Derotator Clip
	48237078	SUK™ DVR Reduction Tube
	48237068	Short SUK™ DVR Clamp
	48237069	Long SUK™ DVR Clamp
	482331330	Xia® 3 Reduction Uniplanar Screwdriver
	482339110	Reduction Screw Tab Remover
	48237021	Lamina Preparer
	48230110	Lamina Preparer, Narrow
	48231020	Standard Hook Holder
	48231040	Lateral Hook Holder
	48231170	Straight Hook Holder
	48237029	Hook Impactor
	48237025	Pedicle Hook Preparer
	48230100	Vise Grip
	48237019	Rod Pusher
	48237032	Monodriver
	482397032	Short Monodriver
	48237091	Modular Monodriver Shaft
	48237033	Modular Polyadjustment Driver
	48231313	Xia® 3 Self-Holding Polyaxial Screwdriver Shaft
	48237056	Rod Rotation Key (Ø6.0mm)
	48235001	Lateral Persuader
	48237079	Reduction Clip
	486619160	4.5mm Combination Wrench (Ø5.5mm)

Xia® 3 Instruments

	Part Number	Description
	48237080	Pedicle Marker Inserter
	48237081	Pedicle Markers (Set of 6)
	48237093	Soft Tissue Retractor
	482397007	Jacobs Chuck Handle
	48230001	Degenerative Implant Tray
	48230002	Degenerative Instrument Tray
	48230003	Complex Spine Implant Tray
	48230004	Complex Spine Instrument Tray
	48230005	Complex Spine Hooks and Instrument Tray
	48230006	Complex Spine Rod and Cross Connector Tray
	48230011	Degenerative Implant Tray Version B (SS)
	48230012	Degenerative Instrument Tray Version B (SS)
	48230013	Uniplanar Tray
	48230015	SUK™ Tray
	48230020	Outlier Implant Tray
	48230010	Outlier Instrument Tray

Notes

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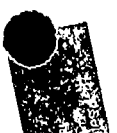

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