



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Acknowledgment Letter

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

09/16/2014

Sharyn Orton  
SENIOR CONSULTANT  
Renovis Surgical Technologies, Inc.  
200 HOMER AVE.  
ASHLAND, MA 01721  
United States

Dear Sharyn Orton:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Please refer prominently to this number in all future correspondence that relates to this submission. Failure to do so may result in processing delays. If the 'Applicant' identified below is incorrect, please notify the 510(k) Staff immediately at (301) 796-5640.

Submission Number: K142095/S002  
Received: 09/16/2014  
Applicant: Renovis Surgical Technologies, Inc.  
Device: RENOVIS S134 ANTERIOR LUMBAR INTERBODY FUSION (ALIF) SYSTEM

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.

If any additional information is required, we will notify you via an Acceptance Review communication, Additional Information (AI) request, and/or Interactive Review communication. For additional information on these types of communication and their effect on the FDA Review Clock (if any), please refer to the following guidance documents:

"FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals" at <http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm089735.htm>.

"Refuse to Accept Policy for 510(k)s" at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

"Types of Communication During the Review of Medical Device Submissions" at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm341918.htm>.

When responding to an information request that stops the FDA Review Clock (e.g., an AI request or refuse to accept (RTA) decision), you must submit your complete response with valid electronic copy (eCopy) to the Document Control Center (DCC) at the above address. An incomplete response or a response sent any other way (e.g., to another address or via email) will not be considered an official response and will not restart the FDA Review Clock. For more information about FDA's eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

To learn more about the overall 510(k) submission process, please refer to our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>.

If you have any procedural or policy questions, please refer to our website at <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm> or contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041, (301) 796-7100, or [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov).

Sincerely yours,

Marjorie Shulman  
Director, 510(k) Program  
Premarket Notification (510(k)) Staff  
Office of Device Evaluation  
Center for Devices and Radiological Health

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

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Silver Spring MD 20993-0002

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Questions? Contact FDA/CDRH/OCE/DTP at CDRH-FIS (703) 215-8999 or 301-792-8148 12645-17-39

20903 01058





K142095

FDA CDRH DMC

AUG 01 2014

Received

July 30, 2014

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

**Re:** Special 510(k) Premarket Notification for the Renovis S134 Anterior Lumbar Interbody Fusion (S134 ALIF) System

To Whom it May Concern:

This Special 510(k) Premarket Notification application is being submitted by MEDIcept, Inc. on behalf of our client Renovis Surgical Technologies, 1901 W. Lugonia Ave, Suite 340, Redlands, CA, 92374, registration number 3007932279. The contact person for this application is Sharyn Orton, Ph.D., Senior Consultant, MEDIcept, Inc.; phone number 401-330-8264; email [sorton@medicept.com](mailto:sorton@medicept.com).

The eCopy is an exact duplicate of the paper copy.

The folder MISC FILES contains:

- Word copies of the S134 ALIF System Instructions for Use (sterile and non-sterile)
- S134 ALIF System Surgical Technique
- Engineering Drawings

The files have been paginated per the FDA "Refuse to Accept Policy for 510(k)s Guidance for Industry and Food and Drug Administration Staff", December 31, 2012 with the exception of FDA Form 3514 which could not be paginated.

#### **Brief Description**

The Renovis S134 ALIF System is an additional offering to the Renovis lumbar interbody fusion system portfolio. Currently, the Renovis S128 ALIF System is 510(k) cleared under K131122 (original application) and K140106 (Special 510(k) for additional offering of gamma sterilization of implants). The S128 ALIF System is a standalone system, where the cages are to be used with

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Renovis S134 ALIF System

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Special 510(k) Premarket Notification

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A handwritten signature in blue ink, appearing to be "JL", located at the bottom right of the page.

MEDICAL  
Medical Device Compliance Consulting

July 30, 2014

2/2 Food and Drug Administration  
Center for Devices and Radiological Health  
3750 Reservoir Road - W 066-0609  
600 New Hampshire Avenue  
Silver Spring, MD 20903-0002

Special 510(k) Premarket Notification for the Renova 5104 ALIF System

Re: Renova 5104 ALIF System

This Special 510(k) Premarket Notification application is being submitted by W.L. Gore & Associates, Inc. (W.L. Gore) on behalf of our client Renova Surgical Technologies, Inc. (Renova). The registration number is 3007932239. The contact person for this application is Mr. [Name] at Renova, 401530-8204, and the phone number is 401-530-8204.

The enclosed is an exact duplicate of the paper copy of the folder 719211823 contains:

- Two copies of the 5104 ALIF System Instructions for Use (sterile and non-sterile)
- 5104 ALIF System Surgical Templates
- Engineering Drawings

The enclosed is being submitted per the FDA "Refuse to Issue" Policy for 510(k) applications. The enclosed is being submitted per the FDA "Refuse to Issue" Policy for 510(k) applications. The enclosed is being submitted per the FDA "Refuse to Issue" Policy for 510(k) applications.

Brief Description

The Renova 5104 ALIF System is an additional offer of a minimally invasive approach for the treatment of lumbar degenerative disc disease (LDD) and lumbar spinal stenosis (LSS). The 5104 ALIF System is a minimally invasive approach for the treatment of LDD and LSS. The 5104 ALIF System is a minimally invasive approach for the treatment of LDD and LSS.

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Special 510(k) Premarket Notification

the cover plate and screws provided with the system (but may be used with supplemental fixation).

This application is for the Renovis S134 ALIF System implants (cages) which *are not* standalone (no cover plate and screws) and *require* supplemental fixation. The S134 ALIF System cages are a modification of the S128 ALIF System cages cleared under K131122.

Device specific instrumentation was FDA cleared under K131122 and no new instrumentation is included in this application.

The entire system will now be called the Renovis Lumbar Interbody Fusion System, and will include the S128 ALIF System, the S134 ALIF System, and any future LIF offerings.

- Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar
- Common Name: Intervertebral body fusion device
- Proprietary Name: Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) System
- Device Class II – 21 CFR 888.3080, product codes MAX, MQP

#### **Administrative Information and Basis of Submission**

The additional offering of ALIF implants without screw holes and requiring supplemental fixation was assessed per the FDA guidance “Deciding When to Submit a 510(k) for a Change to an Existing Device”, January 1997. Per that guidance;

1. The footprint has the exact same physical ID and OD profile dimensions. The change is removal of the screw holes. This also results in a change to the patient/user interface.
2. The system in the Indications for Use has been modified to the Renovis Lumbar Interbody Fusion (LIF) System. Qualifiers have been added for the S128 ALIF System and the S134 ALIF System. The qualifier added to the Indications for Use for the S134 ALIF System states that it must be used with supplemental fixation.
3. There are associated changes in the labels.

The type of 510(k) Premarket Notification to submit was assessed per the FDA guidance “The New 510(k) Paradigm – Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications”, March 1998. Per that guidance:

1. The device represents modification to a FDA cleared Renovis device.
2. The modification is appropriate for reliance on results from design control process
3. Conformance is assured by assessment under Design Controls.

This application qualifies for a Special 510(k) Premarket Notification submission.

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### **Design and Use of the Device**

- The Renovis S134 ALIF System is for prescription use only.
- Renovis S134 ALIF System implants (cages) are offered as gamma sterilized and not sterilized (requiring steam sterilization by the end user).
- No Renovis S134 ALIF implants contain tissue or other biologic material.
- Renovis S134 ALIF implants (cages) are single use only.
- There is no software associated with this device.
- There is no clinical data included in this application.

### **Indications for Use**

**NOTE:** As Renovis intends to continue to add offerings to their Lumbar Interbody Fusion (LIF) System, the previously cleared indications for use (specific for the S128 ALIF System) has been modified, and the current Indications for Use is as follows:

The Renovis Lumbar Interbody Fusion (LIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis LIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

The Renovis S134 ALIF System must be used with supplemental fixation cleared by the FDA for use in the lumbar spine.

For this submission, there are no previous FDA document numbers associated with formal correspondence with FDA, e.g., IDE, pre-IDE, pre-Sub 510(k), PMA, request for designation (RFD), NSE letter, or AI letter with withdrawal for this device.

This Premarket Notification includes trade secret and commercial information that is privileged or confidential and, in accordance with 21 CFR 20.61, is not available for public disclosure. Therefore, we request continued confidentiality (21 CFR 807.95).

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Special 510(k) Premarket Notification

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In accordance with the Safe Medical Device Act of 1990, a 510(k) Summary is included in this notification. The 510(k) Summary, Indications for Use Statement, and Truthful and Accurate Statement are included along with other required contents of a Special 510(k) Premarket Notification.

This device will not be offered for sale until we first receive FDA clearance of the device as defined by the regulation. If there are any questions regarding this submission, please contact me at 401-330-8264 or by email at [sorton@medicept.com](mailto:sorton@medicept.com).

Sincerely yours,



Sharyn Orton, Ph.D.  
Senior Consultant  
MEDIcept, Inc.  
*for*  
Renovis Surgical Technologies

MEDIcept, Inc.  
Renovis S134 ALIF System

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Special 510(k) Premarket Notification

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July 30, 2014

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

**Re:** Special 510(k) Premarket Notification for the Renovis S134 Anterior Lumbar Interbody Fusion (S134 ALIF) System

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- Engineering Drawings

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Special 510(k) Premarket Notification

1-1

the cover plate and screws provided with the system (but may be used with supplemental fixation).

This application is for the Renovis S134 ALIF System implants (cages) which *are not* standalone (no cover plate and screws) and *require* supplemental fixation. The S134 ALIF System cages are a modification of the S128 ALIF System cages cleared under K131122.

Device specific instrumentation was FDA cleared under K131122 and no new instrumentation is included in this application.

The entire system will now be called the Renovis Lumbar Interbody Fusion System, and will include the S128 ALIF System, the S134 ALIF System, and any future LIF offerings.

- Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar
- Common Name: Intervertebral body fusion device
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2. The modification is appropriate for reliance on results from design control process
3. Conformance is assured by assessment under Design Controls.

This application qualifies for a Special 510(k) Premarket Notification submission.

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Special 510(k) Premarket Notification

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## **Design and Use of the Device**

- The Renovis S134 ALIF System is for prescription use only.
- Renovis S134 ALIF System implants (cages) are offered as gamma sterilized and not sterilized (requiring steam sterilization by the end user).
- No Renovis S134 ALIF implants contain tissue or other biologic material.
- Renovis S134 ALIF implants (cages) are single use only.
- There is no software associated with this device.
- There is no clinical data included in this application.

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The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

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For this submission, there are no previous FDA document numbers associated with formal correspondence with FDA, e.g., IDE, pre-IDE, pre-Sub 510(k), PMA, request for designation (RFD), NSE letter, or AI letter with withdrawal for this device.

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Renovis S134 ALIF System

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Special 510(k) Premarket Notification

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In accordance with the Safe Medical Device Act of 1990, a 510(k) Summary is included in this notification. The 510(k) Summary, Indications for Use Statement, and Truthful and Accurate Statement are included along with other required contents of a Special 510(k) Premarket Notification.

This device will not be offered for sale until we first receive FDA clearance of the device as defined by the regulation. If there are any questions regarding this submission, please contact me at 401-330-8264 or by email at [sorton@medicept.com](mailto:sorton@medicept.com).

Sincerely yours,



Sharyn Orton, Ph.D.  
Senior Consultant  
MEDIcept, Inc.

*for*

Renovis Surgical Technologies

MEDIcept, Inc.  
Renovis S134 ALIF System

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Special 510(k) Premarket Notification

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**Screening Checklist for Special 510(k) Premarket****Notification Submissions**

<b>Title</b>	<b>Related Information</b>	<b>Present</b>	<b>N/A</b>	
MDUFMA Cover Sheet		x		
FDA Form 3514	CDRH Premarket Review Submission Cover Sheet	x		
FDA Form 3674	Certification of Compliance under 42 U.S.C 282(j)(5)(B) with Requirements of ClinicalTrials.gov Data Bank (42. U.S.C.282(j))	x		
FDA Form 3654	Guidance for Industry and FDA Staff: Recognition and Use of Consensus Standards, September 17, 2007:	x		
510(k) Cover Letter	How to Prepare a Special 510(k): ucm134573 htm	x		
FDA Form 3881	Guidance for Industry and FDA Staff: Recognition and Use of Consensus Standards, September 17, 2007	x		
Indications for Use Statement				
510(k) Summary		x		
Truthful and Accurate Statement		x		
Class III Summary and Certification				x
Device Description, Description of the Change, and Compliance with Standards		x		
Substantial Equivalence Discussion		x		
Labels and Proposed Labeling		x		
Summary of Design Activities/Risk Analysis		x		
Declaration of Conformity to Design Controls		x		
Biocompatibility	Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, August 12, 2005:		x	
Software			x	
Electromagnetic Compatibility/Electrical Safety	Guidance Documents/ucm084365 htm		x	
Performance Testing – Bench			x	
Performance Testing – Animal			x	
Performance Testing – Clinical			x	
Kit Certification	Device Advice: Kit Certifications for 510(k)s		x	

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Renovis S134 ALIF System

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Ashland, MA 01721  
Special 510(k) Premarket Notification

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Ashland, MA 01721  
Special 510(k) Premarket Notification

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>	<b>PAYMENT IDENTIFICATION NUMBER:</b> (b)(4) 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: <a href="http://www.fda.gov/oc/mdufma/cover sheet.html">http://www.fda.gov/oc/mdufma/cover sheet.html</a>	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  RENOVIS SURGICAL TECHNOLOGIES INC 1901 W Lugonia Ave # 340  Redlands CA 923749703 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****2814	2. CONTACT NAME Jathan Merkel 2.1 E-MAIL ADDRESS jmerkel@renovis-surgical.com 2.2 TELEPHONE NUMBER (include Area code) 909-557-2360 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: <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm</a> ) Select an application type:	
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: (b)(4)	
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?  <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will	



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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Certification of Compliance

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

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

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter  Renovis Surgical Technologies, Inc.		2. Date of the Application/Submission Which This Certification Accompanies  07/30/2014	
3. Address		4. Telephone and Fax Numbers (Include country code if applicable and area code)	
Address 1 (Street address, P.O. box, company name c/o) 1901 W. Lugonia Ave		(Tel): 909-557-2360	
Address 2 (Apartment, suite, unit, building, floor, etc.) Suite 340		(Fax): 909-307-8571	
City Redland	State/Province/Region CA		
Country USA	ZIP or Postal Code 92374		

PRODUCT INFORMATION

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

Intervertebral body fusion device

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

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

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number (If number previously assigned)      If BLA was selected in item 6, provide Supplement Number

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

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

**CERTIFICATION STATEMENT / INFORMATION (Continued)**

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

NCT Number(s): \_\_\_\_\_

Continuation Page for #10

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

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

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

Name Sharyn Orton, Ph.D.	Title Senior Consultant
-----------------------------	----------------------------

12. Address

Address 1 (Street address, P.O. box, company name c/o) 200 Homer Ave	
Address 2 (Apartment, suite, unit, building, floor, etc.)	
City Ashland	State/Province/Region MA
Country USA	ZIP or Postal Code 01721

13. Telephone and Fax Numbers

(Include country code if applicable and area code)  
(Tel): 401-330-8264  
(Fax): 508-231-8861

14. Date of Certification

07/30/2014

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

Sign

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

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

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

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 <sup>1</sup>

• ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #8-377

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

Is a summary report <sup>4</sup> 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) <sup>5</sup>? .....    

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 <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> 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.

<sup>5</sup> 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>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE • ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)		
<b>CONFORMANCE WITH STANDARD SECTIONS*</b>		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *  		
DESCRIPTION Material, not testing, standard		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *  		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *  		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *  		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p><b>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</b></p> <p>The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRASStaff@fda.hhs.gov</p> </div> <div style="width: 35%; text-align: right;"> <p><i>"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."</i></p> </div> </div>		

Department of Health and Human Services  
Food and Drug Administration  
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

• ASTM F2026-12 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #8-340

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

Is a summary report <sup>4</sup> 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) <sup>5</sup>? .....    

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 <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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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.

<sup>5</sup> 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>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE • ASTM F2026-12 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications		
<b>CONFORMANCE WITH STANDARD SECTIONS*</b>		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION Material, not testing, standard		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
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Department of Health and Human Services  
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

• ASTM F560-08, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #8-372

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

Is a summary report <sup>4</sup> 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) <sup>5</sup>? .....    

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 <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE • ASTM F560-08, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION This is a material standard		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
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## TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

• ASTM F983-86 (Reapproved 2013) Standard Practice for Permanent Marking of Orthopaedic Implant Components

**Please answer the following questions**

Yes No

Is this standard recognized by FDA <sup>2</sup>? .....

FDA Recognition number<sup>3</sup> ..... #11-197

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

Is a summary report <sup>4</sup> 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) <sup>5</sup>? .....

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 <sup>6</sup> that is associated with this standard? .....    
If yes, was the guidance document followed in preparation of this 510k? .....

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE • ASTM F983-86 (Reapproved 2013) Standard Practice for Permanent Marking of Orthopaedic Implant Components		
<b>CONFORMANCE WITH STANDARD SECTIONS*</b>		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION This is a marking standard		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

• ASTM F565-04 (Reapproved 2013) Standard Practice for Care and Handling of Orthopedic Implants and Instruments

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number<sup>3</sup> ..... #11-199

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

Is a summary report <sup>4</sup> 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? .....       
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If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

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? .....       
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If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> 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.

<sup>5</sup> 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>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE • ASTM F565-04 (Reapproved 2013) Standard Practice for Care and Handling of Orthopedic Implants and Instruments		
<b>CONFORMANCE WITH STANDARD SECTIONS*</b>		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION This is a care and handling standard		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p><b>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</b></p> <p>The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff <a href="mailto:PRAStaff@fda.hhs.gov">PRAStaff@fda.hhs.gov</a></p> </div> <div style="width: 45%; text-align: right;"> <p><i>"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."</i></p> </div> </div>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug AdministrationForm Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.**Indications for Use**

510(k) Number (if known)

Device Name

Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) System

Indications for Use (Describe)

The Renovis Lumbar Interbody Fusion (LIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis LIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

The Renovis S134 ALIF System must be used with supplemental fixation cleared by the FDA for use in the lumbar spine.

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

 Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.****FOR FDA USE ONLY**

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

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Department of Health and Human Services  
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[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

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**Special 510(k) Summary  
as required by 21 CFR 807.92(a)**

A ) Submitted by: Renovis Surgical Technologies, Inc.  
1901 W. Lugonia Ave, Ste 340  
Redlands, CA 92374  
Phone: 909-557-2360  
Fax: 909-307-8571

Official Contact: Anthony DeBenedictis  
Vice President of Quality Assurance

Consultant: Sharyn Orton, Ph.D.  
MEDIcept, Inc.  
200 Homer Ave  
Ashland, MA 01721

Date: July 30, 2014

B) Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar  
Common Name: Intervertebral body fusion device  
Proprietary Name: S134 Anterior Lumbar Interbody Fusion (ALIF) System  
Device Class: Class II – 888.3080  
Regulation and 888.3080, MAX - Intervertebral body fusion device  
and product codes: 888.3060, MQP – Spinal intervertebral body fixation orthosis  
Classification panel: Orthopedic

C) Predicates:

- K131122; K140106 Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

D) Device Description:

The S134 Anterior Lumbar Interbody Fusion (ALIF) System includes implants (cages) that are available in a variety of sizes (widths, height, depths, and bone screw sizes) to suit the individual pathology and anatomical conditions of the patient. The implants are manufactured from PEEK or additively manufactured and machined Titanium. The PEEK markers are manufactured from Tantalum.

The Renovis S134 ALIF System cages are to be used with supplemental fixation, and are intended to be used with autogenous bone graft.

The Renovis S134 ALIF System is used with device specific instruments including trials.

The Renovis S134 ALIF System implants comply with the following material standards:

- ASTM F2026-08 Standard Specification for PEEK Polymers for Surgical Implant Applications
- ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F560-08, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications

The S134 ALIF implants are provided gamma sterilized, and non-sterile (requiring sterilization by the end user).

E) Indications For Use:

The Renovis Lumbar Interbody Fusion (LIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis LIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

The Renovis S134 ALIF System must be used with supplemental fixation cleared by the FDA for use in the lumbar spine.

F) Substantial Equivalence Comparison and Discussion

	Renovis S134 ALIF System	Renovis S128 ALIF System K131122; K140106
Product code	MAX, MQP	OVD
Indications for Use	The Renovis Lumbar Interbody Fusion (LIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc	The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc

	<p>disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis LIF System implants are to be used with autogenous bone graft.</p> <p>Patients should be skeletally mature and have at least six months of non-operative treatment.</p> <p>The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.</p> <p>The Renovis S134 ALIF System must be used with supplemental fixation cleared by the FDA for use in the lumbar spine.</p>	<p>disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S134 ALIF System implants are to be used with autogenous bone graft.</p> <p>Patients should be skeletally mature and have at least six months of non-operative treatment.</p> <p>The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.</p>
Implant (cage) material	PEEK or Titanium	
PEEK marker material	Tantalum	
Dimensions		
A/P	26, 28, 30	
M/L	30, 34, 38	
H	11-21	
Lordosis	7 <sup>0</sup> ; 12 <sup>0</sup>	
Screw and cover plate	No	Yes
Supplemental fixation	Yes	Not routinely Yes; if accompanying screws are not used
Sterilization	Gamma and non-sterile	

### *Conclusion*

The Renovis S134 ALIF System implants have the same footprint (ID and OD profile dimensions), materials, manufacturing methods, and sterilization offerings; and similar intended use, design and function as the Renovis S128 ALIF System implant. Therefore, the Renovis S134 ALIF System is substantially equivalent to the predicate device.

#### G) Compliance with Design Controls

The results of assessment under Design Controls support that the Renovis S134 ALIF System is substantially equivalent to the predicate device. The offering of implants that are not standalone and require supplemental fixation does not raise new issues of safety or effectiveness.

#### H) Compliance with Consensus Standards and FDA Guidance

The Renovis S134 ALIF System complies with:

- ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
- ASTM F2026-12 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications
- ASTM F560-08 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)
- ASTM F983-86 (Reapproved 2013) Standard Practice for Permanent Marking of Orthopaedic Implant Components
- ASTM F565-04 (Reapproved 2013) Standard Practice for Care and Handling of Orthopedic Implants and Instruments
- Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, October 2007



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**PREMARKET NOTIFICATION  
TRUTHFUL & ACCURATE STATEMENT  
(AS REQUIRED BY 21 CFR 807.87(k))**

I certify that, in my capacity as Vice President of Quality Assurance of Renovis Surgical Technologies, Inc., 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.

*Anthony DeBenedictis*

Signature

*Anthony DeBenedictis*

Anthony DeBenedictis

*7 / 30 / 14*

Date

---

\*(Premarket Notification [510(k)] Number)

\*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter]

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Renovis ALIF System

Special 510(k) Premarket Notification

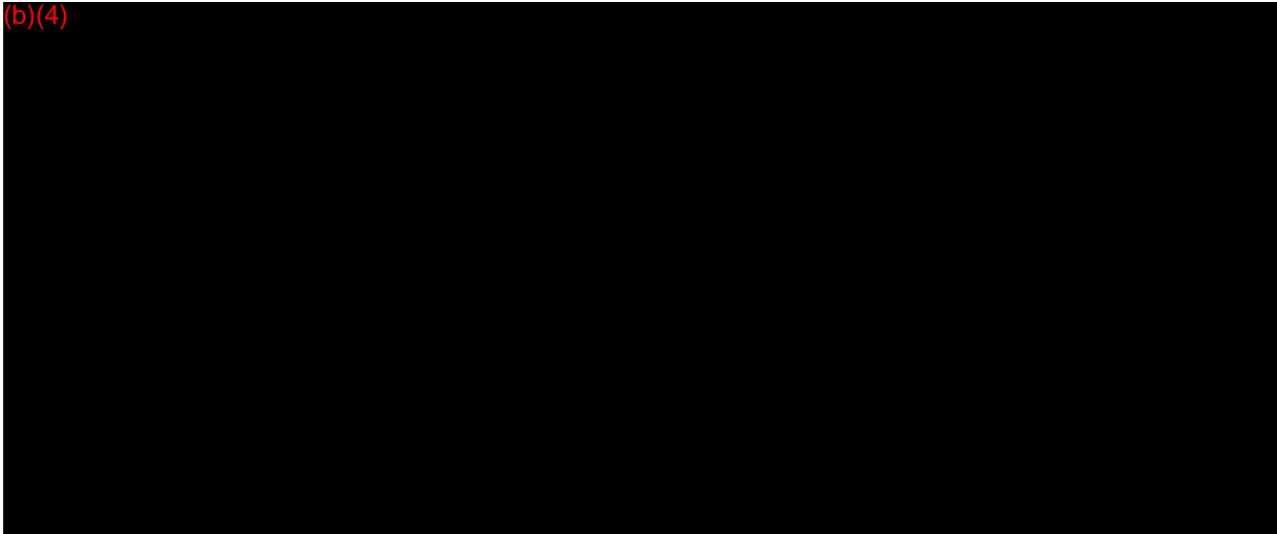
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## Device Description

The Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) System consists of implants (cages) and device specific instrumentation. The Renovis S134 ALIF System cages are developed for the anterior posterior stabilization of the lumbar spinal column, and are available in a variety of sizes (widths, height, depths, and bone screw sizes) to suit the individual pathology and anatomical conditions of the patient (Table 1). The cages are available in two lordotic configurations (7° and 12°) of various heights to restore lumbar lordosis and the associated sagittal balance. A large cavity is designed into the body of the cage allowing placement of bone graft material and facilitating fusion (see pictures below). The superior and inferior surfaces of the devices have a pattern of teeth to provide increased stability and inhibit movement of the cages. The Renovis S134 ALIF System cages are not stand alone and are to be used with FDA cleared supplementary fixation systems.

The S134 ALIF System cages (S134 cages) are a modification of the Renovis FDA cleared S128 ALIF System cages (S128 cages) in that the screw holes have been removed. The footprint of the S128 and S134 are exactly the same physical ID and OD profile dimensions. However, the S128 has screw holes which cut through a small portion of the ID profile, reducing endplate surface contact area. Therefore, the S134 not having screw holes has a slightly greater endplate surface contact area.

(b)(4)



Engineering drawings are included (b)(4).

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Renovis S134 ALIF System

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**Table 1 Summary**

<b>Cages</b>	<b>Description</b>
Materials	(b)(4) PEEK (b)(4) with Tantalum markers Titanium alloy Ti-6Al-4v
Manufacturing method	PEEK cages: traditional Ti-6Al-4v cages: additive manufacturing (EBM)
Dimensions	26, 28, 30
A/P	30, 34, 38
M/L	11 – 21
H	Δ1mm
Foot print	30 x 26D 34 x 28D 38 x 30D
Lordosis	7°, 12°
Bone graft volume	2270-7920 mm <sup>3</sup>
End plate coverage	(b)(4)
Sterilization	Gamma irradiation or non-sterile (requiring steam sterilization by end user)

*Materials*

The Renovis S134 ALIF System cages are manufactured from PEEK or titanium alloy (Ti-6Al-4V). The PEEK component is radiolucent with tantalum markers for visualization in the disc space.

The PEEK cages are manufactured from PolyEtherEtherKeytone (PEEK) per ASTM F2026-12 *Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications*. The PEEK is supplied by (b)(4) under the trade name (b)(4). Each cage has three X-Ray markers pressed into it for radiographic visualization. The three markers (pins) are manufactured from Tantalum per ASTM F560-08 *Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)*.

The titanium cages (also known as Tesera cages) are manufactured from Ti-6Al-4v per ASTM F136-13 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI*

(b)(4)

(b)

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further in this application. The titanium cages do not require radiographic markers. The Ti-6Al-4V cages are additively manufactured (ARCAM EBM) and machined titanium.

### *Sterilization*

The S134 ALIF System cages are offered either gamma irradiated or as non-sterile requiring steam sterilization by the end user.

### **Description of the Change – Removal of screw holes**

The Renovis S134 ALIF System cages are a modification to the S128 ALIF System cages, but are manufactured the same with the exception that the screw holes have been eliminated.

### **Parts Numbers**

The parts numbers and geometry are included in Tables 2 and 3. The Table 2 and 3 geometry is reproduced from K131122 (the bone graft volume and contact area/endplate are calculated estimates – rounded down to closest 10 mm<sup>3</sup>). The foot print of the S128 and S134 are exactly the same physical ID and OD profile dimensions. However, because the S134 does not have screw holes, the endplate surface contact area will be slightly greater than the figures presented here.

The part number for the non-sterilized is the same as the part number below, but will start with “11” rather than 10 (for example, 1034-302-611 and 1134-203-611).

**Table 2: PEEK Cage Geometry – Sterile**

Part Number	Width	Depth	Height	Lordosis	Bone Graft Volume	(b)(4)
1034-302-611	30mm	26mm	11mm	7°	2270mm <sup>3</sup>	
1034-302-612	30mm	26mm	12mm	7°	2520 mm <sup>3</sup>	
1034-302-613	30mm	26mm	13mm	7°	2770 mm <sup>3</sup>	
1034-302-614	30mm	26mm	14mm	7°	3020 mm <sup>3</sup>	
1034-302-615	30mm	26mm	15mm	7°	3270 mm <sup>3</sup>	
1034-302-616	30mm	26mm	16mm	7°	3530 mm <sup>3</sup>	
1034-302-617	30mm	26mm	17mm	7°	3780 mm <sup>3</sup>	
1034-302-618	30mm	26mm	18mm	7°	4030 mm <sup>3</sup>	
1034-302-619	30mm	26mm	19mm	7°	4280 mm <sup>3</sup>	
1034-302-620	30mm	26mm	20mm	7°	4540 mm <sup>3</sup>	
1034-302-621	30mm	26mm	21mm	7°	4790 mm <sup>3</sup>	
1034-342-811	34mm	28mm	11mm	7°	2940 mm <sup>3</sup>	
1034-342-812	34mm	28mm	12mm	7°	3270 mm <sup>3</sup>	
1034-342-813	34mm	28mm	13mm	7°	3600 mm <sup>3</sup>	
1034-342-814	34mm	28mm	14mm	7°	3920 mm <sup>3</sup>	
1034-342-815	34mm	28mm	15mm	7°	4250 mm <sup>3</sup>	

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1034-342-816	34mm	28mm	16mm	7°	4580 mm <sup>3</sup>
1034-342-817	34mm	28mm	17mm	7°	4910 mm <sup>3</sup>
1034-342-818	34mm	28mm	18mm	7°	5230 mm <sup>3</sup>
1034-342-819	34mm	28mm	19mm	7°	5560 mm <sup>3</sup>
1034-342-820	34mm	28mm	20mm	7°	5890 mm <sup>3</sup>
1034-342-821	34mm	28mm	21mm	7°	6210 mm <sup>3</sup>
1034-383-011	38mm	30mm	11mm	7°	3950 mm <sup>3</sup>
1034-383-012	38mm	30mm	12mm	7°	4400 mm <sup>3</sup>
1034-383-013	38mm	30mm	13mm	7°	4840 mm <sup>3</sup>
1034-383-014	38mm	30mm	14mm	7°	5290 mm <sup>3</sup>
1034-383-015	38mm	30mm	15mm	7°	5740 mm <sup>3</sup>
1034-383-016	38mm	30mm	16mm	7°	6190 mm <sup>3</sup>
1034-383-017	38mm	30mm	17mm	7°	6630 mm <sup>3</sup>
1034-383-018	38mm	30mm	18mm	7°	7080 mm <sup>3</sup>
1034-383-019	38mm	30mm	19mm	7°	7530 mm <sup>3</sup>
1034-383-020	38mm	30mm	20mm	7°	7970 mm <sup>3</sup>
1034-383-021	38mm	30mm	21mm	7°	8420 mm <sup>3</sup>
1035-302-611	30mm	26mm	11mm	12°	2060 mm <sup>3</sup>
1035-302-612	30mm	26mm	12mm	12°	2310 mm <sup>3</sup>
1035-302-613	30mm	26mm	13mm	12°	2560 mm <sup>3</sup>
1035-302-614	30mm	26mm	14mm	12°	2810 mm <sup>3</sup>
1035-302-615	30mm	26mm	15mm	12°	3060 mm <sup>3</sup>
1035-302-616	30mm	26mm	16mm	12°	3320 mm <sup>3</sup>
1035-302-617	30mm	26mm	17mm	12°	3570 mm <sup>3</sup>
1035-302-618	30mm	26mm	18mm	12°	3820 mm <sup>3</sup>
1035-302-619	30mm	26mm	19mm	12°	4070 mm <sup>3</sup>
1035-302-620	30mm	26mm	20mm	12°	4320 mm <sup>3</sup>
1035-302-621	30mm	26mm	21mm	12°	4570 mm <sup>3</sup>
1035-342-811	34mm	28mm	11mm	12°	2610 mm <sup>3</sup>
1035-342-812	34mm	28mm	12mm	12°	2940 mm <sup>3</sup>
1035-342-813	34mm	28mm	13mm	12°	3270 mm <sup>3</sup>
1035-342-814	34mm	28mm	14mm	12°	3590 mm <sup>3</sup>
1035-342-815	34mm	28mm	15mm	12°	3920 mm <sup>3</sup>
1035-342-816	34mm	28mm	16mm	12°	4250 mm <sup>3</sup>
1035-342-817	34mm	28mm	17mm	12°	4570 mm <sup>3</sup>
1035-342-818	34mm	28mm	18mm	12°	4900 mm <sup>3</sup>
1035-342-819	34mm	28mm	19mm	12°	5230 mm <sup>3</sup>
1035-342-820	34mm	28mm	20mm	12°	5560 mm <sup>3</sup>
1035-342-821	34mm	28mm	21mm	12°	5880 mm <sup>3</sup>

(b)(4)

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Renovis S134 ALIF System

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1035-383-011	38mm	30mm	11mm	12°	3450 mm <sup>3</sup>	(b)(4)
1035-383-012	38mm	30mm	12mm	12°	3900 mm <sup>3</sup>	
1035-383-013	38mm	30mm	13mm	12°	4340 mm <sup>3</sup>	
1035-383-014	38mm	30mm	14mm	12°	4790 mm <sup>3</sup>	
1035-383-015	38mm	30mm	15mm	12°	5240 mm <sup>3</sup>	
1035-383-016	38mm	30mm	16mm	12°	5680 mm <sup>3</sup>	
1035-383-017	38mm	30mm	17mm	12°	6130 mm <sup>3</sup>	
1035-383-018	38mm	30mm	18mm	12°	6580 mm <sup>3</sup>	
1035-383-019	38mm	30mm	19mm	12°	7030 mm <sup>3</sup>	
1035-383-020	38mm	30mm	20mm	12°	7470 mm <sup>3</sup>	
1035-383-021	38mm	30mm	21mm	12°	7920 mm <sup>3</sup>	

**Table 3: Titanium Cage Geometry – Sterile**

Part Number	Width	Depth	Height	Lordosis	Bone Graft Volume	(b)(4)
1036-302-611	30mm	26mm	11mm	7°	2270mm <sup>3</sup>	
1036-302-612	30mm	26mm	12mm	7°	2520 mm <sup>3</sup>	
1036-302-613	30mm	26mm	13mm	7°	2770 mm <sup>3</sup>	
1036-302-614	30mm	26mm	14mm	7°	3020 mm <sup>3</sup>	
1036-302-615	30mm	26mm	15mm	7°	3270 mm <sup>3</sup>	
1036-302-616	30mm	26mm	16mm	7°	3530 mm <sup>3</sup>	
1036-302-617	30mm	26mm	17mm	7°	3780 mm <sup>3</sup>	
1036-302-618	30mm	26mm	18mm	7°	4030 mm <sup>3</sup>	
1036-302-619	30mm	26mm	19mm	7°	4280 mm <sup>3</sup>	
1036-302-620	30mm	26mm	20mm	7°	4540 mm <sup>3</sup>	
1036-302-621	30mm	26mm	21mm	7°	4790 mm <sup>3</sup>	
1036-342-811	34mm	28mm	11mm	7°	2940 mm <sup>3</sup>	
1036-342-812	34mm	28mm	12mm	7°	3270 mm <sup>3</sup>	
1036-342-813	34mm	28mm	13mm	7°	3600 mm <sup>3</sup>	
1036-342-814	34mm	28mm	14mm	7°	3920 mm <sup>3</sup>	
1036-342-815	34mm	28mm	15mm	7°	4250 mm <sup>3</sup>	
1036-342-816	34mm	28mm	16mm	7°	4580 mm <sup>3</sup>	
1036-342-817	34mm	28mm	17mm	7°	4910 mm <sup>3</sup>	
1036-342-818	34mm	28mm	18mm	7°	5230 mm <sup>3</sup>	
1036-342-819	34mm	28mm	19mm	7°	5560 mm <sup>3</sup>	
1036-342-820	34mm	28mm	20mm	7°	5890 mm <sup>3</sup>	
1036-342-821	34mm	28mm	21mm	7°	6210 mm <sup>3</sup>	
1036-383-011	38mm	30mm	11mm	7°	3950 mm <sup>3</sup>	

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1036-383-012	38mm	30mm	12mm	7°	4400 mm <sup>3</sup>	(b)(4)
1036-383-013	38mm	30mm	13mm	7°	4840 mm <sup>3</sup>	(b)(4)
1036-383-014	38mm	30mm	14mm	7°	5290 mm <sup>3</sup>	(b)(4)
1036-383-015	38mm	30mm	15mm	7°	5740 mm <sup>3</sup>	(b)(4)
1036-383-016	38mm	30mm	16mm	7°	6190 mm <sup>3</sup>	(b)(4)
1036-383-017	38mm	30mm	17mm	7°	6630 mm <sup>3</sup>	(b)(4)
1036-383-018	38mm	30mm	18mm	7°	7080 mm <sup>3</sup>	(b)(4)
1036-383-019	38mm	30mm	19mm	7°	7530 mm <sup>3</sup>	(b)(4)
1036-383-020	38mm	30mm	20mm	7°	7970 mm <sup>3</sup>	(b)(4)
1036-383-021	38mm	30mm	21mm	7°	8420 mm <sup>3</sup>	(b)(4)
1037-302-611	30mm	26mm	11mm	12°	2060 mm <sup>3</sup>	(b)(4)
1037-302-612	30mm	26mm	12mm	12°	2310 mm <sup>3</sup>	(b)(4)
1037-302-613	30mm	26mm	13mm	12°	2560 mm <sup>3</sup>	(b)(4)
1037-302-614	30mm	26mm	14mm	12°	2810 mm <sup>3</sup>	(b)(4)
1037-302-615	30mm	26mm	15mm	12°	3060 mm <sup>3</sup>	(b)(4)
1037-302-616	30mm	26mm	16mm	12°	3320 mm <sup>3</sup>	(b)(4)
1037-302-617	30mm	26mm	17mm	12°	3570 mm <sup>3</sup>	(b)(4)
1037-302-618	30mm	26mm	18mm	12°	3820 mm <sup>3</sup>	(b)(4)
1037-302-619	30mm	26mm	19mm	12°	4070 mm <sup>3</sup>	(b)(4)
1037-302-620	30mm	26mm	20mm	12°	4320 mm <sup>3</sup>	(b)(4)
1037-302-621	30mm	26mm	21mm	12°	4570 mm <sup>3</sup>	(b)(4)
1037-342-811	34mm	28mm	11mm	12°	2610 mm <sup>3</sup>	(b)(4)
1037-342-812	34mm	28mm	12mm	12°	2940 mm <sup>3</sup>	(b)(4)
1037-342-813	34mm	28mm	13mm	12°	3270 mm <sup>3</sup>	(b)(4)
1037-342-814	34mm	28mm	14mm	12°	3590 mm <sup>3</sup>	(b)(4)
1037-342-815	34mm	28mm	15mm	12°	3920 mm <sup>3</sup>	(b)(4)
1037-342-816	34mm	28mm	16mm	12°	4250 mm <sup>3</sup>	(b)(4)
1037-342-817	34mm	28mm	17mm	12°	4570 mm <sup>3</sup>	(b)(4)
1037-342-818	34mm	28mm	18mm	12°	4900 mm <sup>3</sup>	(b)(4)
1037-342-819	34mm	28mm	19mm	12°	5230 mm <sup>3</sup>	(b)(4)
1037-342-820	34mm	28mm	20mm	12°	5560 mm <sup>3</sup>	(b)(4)
1037-342-821	34mm	28mm	21mm	12°	5880 mm <sup>3</sup>	(b)(4)
1037-383-011	38mm	30mm	11mm	12°	3450 mm <sup>3</sup>	(b)(4)
1037-383-012	38mm	30mm	12mm	12°	3900 mm <sup>3</sup>	(b)(4)
1037-383-013	38mm	30mm	13mm	12°	4340 mm <sup>3</sup>	(b)(4)
1037-383-014	38mm	30mm	14mm	12°	4790 mm <sup>3</sup>	(b)(4)
1037-383-015	38mm	30mm	15mm	12°	5240 mm <sup>3</sup>	(b)(4)
1037-383-016	38mm	30mm	16mm	12°	5680 mm <sup>3</sup>	(b)(4)
1037-383-017	38mm	30mm	17mm	12°	6130 mm <sup>3</sup>	(b)(4)

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1037-383-018	38mm	30mm	18mm	12°	6580 mm <sup>3</sup>	(b)(4)
1037-383-019	38mm	30mm	19mm	12°	7030 mm <sup>3</sup>	
1037-383-020	38mm	30mm	20mm	12°	7470 mm <sup>3</sup>	
1037-383-021	38mm	30mm	21mm	12°	7920 mm <sup>3</sup>	

### *Device Specific Instruments*

Instruments are provided that allow performance of a discectomy, preparation of the disc space, trialing to determine optimal implant width and height, endplate preparation, and implant insertion. The device specific instruments used with the S134 ALIF System cages are the same as those included in K131122 for the S128 ALIF System cages (listed in K131122, 011\_Device Description) and include trials, sizers, and implant/cage inserters. There are no new device specific instruments. The device specific instruments from K131122 are listed in Table 4. General use (Class I), non-device specific instruments are also provided, but are not included here.

**Table 4: Instruments provided (from K131122)**

Part Number	Description	Functionality
2128-001-001	Implant Inserter	Insert Cage
2128-001-032	Angled Implant Inserter	Insert Cage
2128-003-026	Small Paddle Sizer	Implant determination
2128-003-428	Medium Paddle Sizer	Implant determination
2128-003-830	Large Paddle Sizer	Implant determination
2128-302-611	11mm Trial, 30x26 7°	Trialing
2128-302-612	12mm Trial, 30x26 7°	Trialing
2128-302-613	13mm Trial, 30x26 7°	Trialing
2128-302-614	14mm Trial, 30x26 7°	Trialing
2128-302-615	15mm Trial, 30x26 7°	Trialing
2128-302-616	16mm Trial, 30x26 7°	Trialing
2128-302-617	17mm Trial, 30x26 7°	Trialing
2128-302-618	18mm Trial, 30x26 7°	Trialing
2128-302-619	19mm Trial, 30x26 7°	Trialing
2128-302-620	20mm Trial, 30x26 7°	Trialing
2128-302-621	21mm Trial, 30x26 7°	Trialing
2128-342-811	11mm Trial, 34x28 7°	Trialing
2128-342-812	12mm Trial, 34x28 7°	Trialing
2128-342-813	13mm Trial, 34x28 7°	Trialing
2128-342-814	14mm Trial, 34x28 7°	Trialing
2128-342-815	15mm Trial, 34x28 7°	Trialing
2128-342-816	16mm Trial, 34x28 7°	Trialing
2128-342-817	17mm Trial, 34x28 7°	Trialing
2128-342-818	18mm Trial, 34x28 7°	Trialing

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2128-342-819	19mm Trial, 34x28 7°	Trialing
2128-342-820	20mm Trial, 34x28 7°	Trialing
2128-342-821	21mm Trial, 34x28 7°	Trialing
2128-383-011	11mm Trial, 38x28 7°	Trialing
2128-383-012	12mm Trial, 38x30 7°	Trialing
2128-383-013	13mm Trial, 38x30 7°	Trialing
2128-383-014	14mm Trial, 38x30 7°	Trialing
2128-383-015	15mm Trial, 38x30 7°	Trialing
2128-383-016	16mm Trial, 38x30 7°	Trialing
2128-383-017	17mm Trial, 38x30 7°	Trialing
2128-383-018	18mm Trial, 38x30 7°	Trialing
2128-383-019	19mm Trial, 38x30 7°	Trialing
2128-383-020	20mm Trial, 38x30 7°	Trialing
2128-383-021	21mm Trial, 38x30 7°	Trialing
2129-302-611	11mm Trial, 30x26 12°	Trialing
2129-302-612	12mm Trial, 30x26 12°	Trialing
2129-302-613	13mm Trial, 30x26 12°	Trialing
2129-302-614	14mm Trial, 30x26 12°	Trialing
2129-302-615	15mm Trial, 30x26 12°	Trialing
2129-302-616	16mm Trial, 30x26 12°	Trialing
2129-302-617	17mm Trial, 30x26 12°	Trialing
2129-302-618	18mm Trial, 30x26 12°	Trialing
2129-302-619	19mm Trial, 30x26 12°	Trialing
2129-302-620	20mm Trial, 30x26 12°	Trialing
2129-302-621	21mm Trial, 30x26 12°	Trialing
2129-342-811	11mm Trial, 34x28 12°	Trialing
2129-342-812	12mm Trial, 34x28 12°	Trialing
2129-342-813	13mm Trial, 34x28 12°	Trialing
2129-342-814	14mm Trial, 34x28 12°	Trialing
2129-342-815	15mm Trial, 34x28 12°	Trialing
2129-342-816	16mm Trial, 34x28 12°	Trialing
2129-342-817	17mm Trial, 34x28 12°	Trialing
2129-342-818	18mm Trial, 34x28 12°	Trialing
2129-342-819	19mm Trial, 34x28 12°	Trialing
2129-342-820	20mm Trial, 34x28 12°	Trialing
2129-342-821	21mm Trial, 34x28 12°	Trialing
2129-383-011	11mm Trial, 38x28 12°	Trialing
2129-383-012	12mm Trial, 38x30 12°	Trialing
2129-383-013	13mm Trial, 38x30 12°	Trialing
2129-383-014	14mm Trial, 38x30 12°	Trialing
2129-383-015	15mm Trial, 38x30 12°	Trialing
2129-383-016	16mm Trial, 38x30 12°	Trialing
2129-383-017	17mm Trial, 38x30 12°	Trialing
2129-383-018	18mm Trial, 38x30 12°	Trialing

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2129-383-019	19mm Trial, 38x30 12°	Trialing
2129-383-020	20mm Trial, 38x30 12°	Trialing
2129-383-021	21mm Trial, 38x30 12°	Trialing

## Summary of Design Control Activities

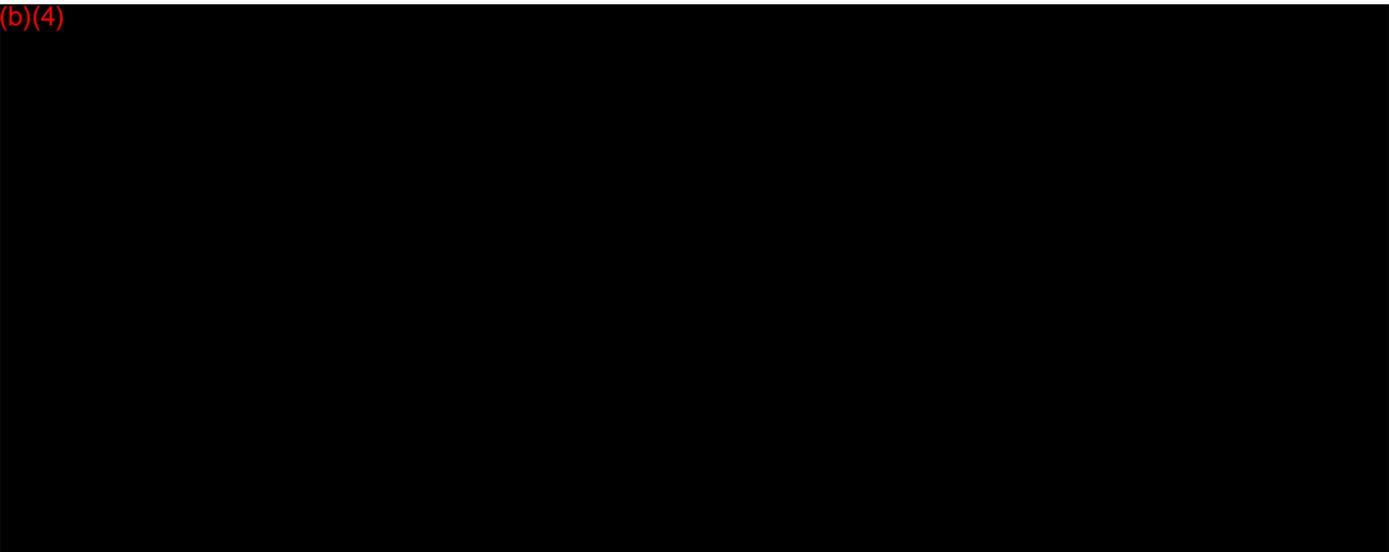
### *Description*

(b)(4)



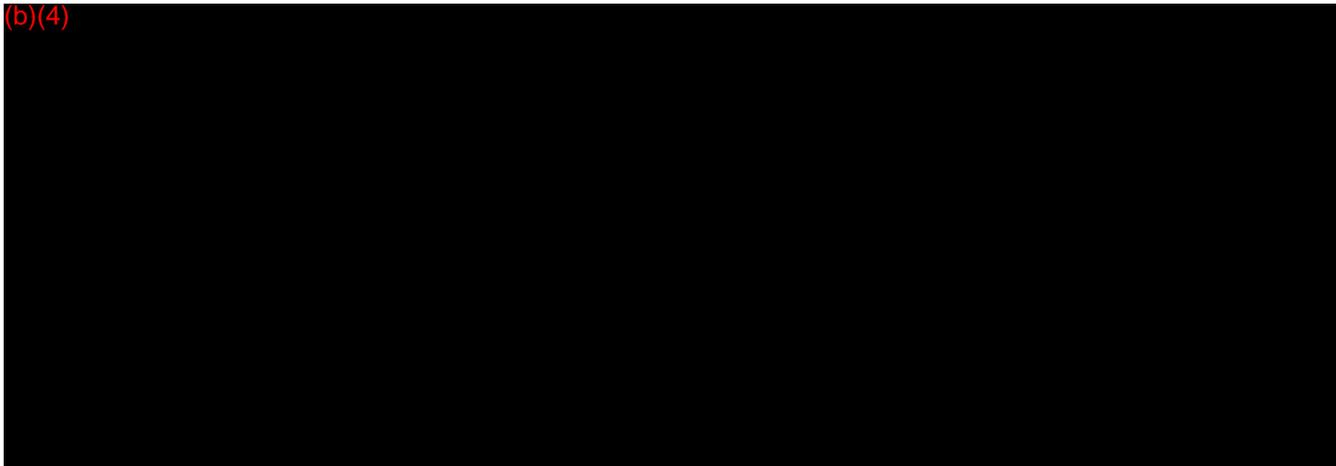
### *Discussion of Risk*

(b)(4)



### Biocompatibility

(b)(4)



### Sterilization

There is no new sterility risk associated with this change. Renovis S134 ALIF System implants will be provided gamma sterilized, or non-sterile (requiring steam sterilization by the end user). This is the same as the S128 ALIF cages.

Renovis S134 ALIF System

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Special 510(k) Premarket Notification

(b)(4)



Packaging

There is no new packaging risk associated with this change. The S134 ALIF System implants will be packaged the same as the S128 ALIF cages.

Shelf Life

There is no new shelf life risk for gamma sterilized implants associated with this change. The shelf life of the S134 ALIF System cages will be the same as the S128 ALIF System cages as described in K140106.

Non-sterile implants are not provided sterile and storage conditions should not affect should not affect device safety or effectiveness. The shelf life of a facility sterilized component should be determined by that facility per their internal SOPs. This is the same as the S128 ALIF System implants as described in K131122.

The Declaration of Conformance with Design Controls is included (016).

Renovis S134 ALIF System

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Special 510(k) Premarket Notification









































































## Appendix B: Part Listing

Part Number	Description
1034-302-611	PEEK ALIF Implant 30 X 26 11mm height 7° lordosis
1034-302-613	PEEK ALIF Implant 30 X 26 13mm height 7° lordosis
1034-302-615	PEEK ALIF Implant 30 X 26 15mm height 7° lordosis
1034-302-617	PEEK ALIF Implant 30 X 26 17mm height 7° lordosis
1034-302-619	PEEK ALIF Implant 30 X 26 19mm height 7° lordosis
1034-342-811	PEEK ALIF Implant 34 X 28 11mm height 7° lordosis
1034-342-813	PEEK ALIF Implant 34 X 28 13mm height 7° lordosis
1034-342-815	PEEK ALIF Implant 34 X 28 15mm height 7° lordosis
1034-342-817	PEEK ALIF Implant 34 X 28 17mm height 7° lordosis
1034-342-819	PEEK ALIF Implant 34 X 28 19mm height 7° lordosis
1034-383-011	PEEK ALIF Implant 38 X 30 11mm height 7° lordosis
1034-383-013	PEEK ALIF Implant 38 X 30 13mm height 7° lordosis
1034-383-015	PEEK ALIF Implant 38 X 30 15mm height 7° lordosis
1034-383-017	PEEK ALIF Implant 38 X 30 17mm height 7° lordosis
1034-383-019	PEEK ALIF Implant 38 X 30 19mm height 7° lordosis
1035-302-611	PEEK ALIF Implant 30 X 26 11mm height 12° lordosis
1035-302-613	PEEK ALIF Implant 30 X 26 13mm height 12° lordosis
1035-302-615	PEEK ALIF Implant 30 X 26 15mm height 12° lordosis
1035-302-617	PEEK ALIF Implant 30 X 26 17mm height 12° lordosis
1035-302-619	PEEK ALIF Implant 30 X 26 19mm height 12° lordosis
1035-342-811	PEEK ALIF Implant 34 X 28 11mm height 12° lordosis
1035-342-813	PEEK ALIF Implant 34 X 28 13mm height 12° lordosis
1035-342-815	PEEK ALIF Implant 34 X 28 15mm height 12° lordosis
1035-342-817	PEEK ALIF Implant 34 X 28 17mm height 12° lordosis
1035-342-819	PEEK ALIF Implant 34 X 28 19mm height 12° lordosis
1035-383-011	PEEK ALIF Implant 38 X 30 11mm height 12° lordosis
1035-383-013	PEEK ALIF Implant 38 X 30 13mm height 12° lordosis
1035-383-015	PEEK ALIF Implant 38 X 30 15mm height 12° lordosis
1035-383-017	PEEK ALIF Implant 38 X 30 17mm height 12° lordosis
1035-383-019	PEEK ALIF Implant 38 X 30 19mm height 12° lordosis
1036-302-611	T3 ALIF Implant 30 X 26 11mm height 7° lordosis
1036-302-613	T3 ALIF Implant 30 X 26 13mm height 7° lordosis
1036-302-615	T3 ALIF Implant 30 X 26 15mm height 7° lordosis
1036-302-617	T3 ALIF Implant 30 X 26 17mm height 7° lordosis
1036-302-619	T3 ALIF Implant 30 X 26 19mm height 7° lordosis
1036-342-811	T3 ALIF Implant 34 X 28 11mm height 7° lordosis

1036-342-813	T3 ALIF Implant 34 X 28 13mm height 7° lordosis
1036-342-815	T3 ALIF Implant 34 X 28 15mm height 7° lordosis
1036-342-817	T3 ALIF Implant 34 X 28 17mm height 7° lordosis
1036-342-819	T3 ALIF Implant 34 X 28 19mm height 7° lordosis
1036-383-011	T3 ALIF Implant 38 X 30 11mm height 7° lordosis
1036-383-013	T3 ALIF Implant 38 X 30 13mm height 7° lordosis
1036-383-015	T3 ALIF Implant 38 X 30 15mm height 7° lordosis
1036-383-017	T3 ALIF Implant 38 X 30 17mm height 7° lordosis
1036-383-019	T3 ALIF Implant 38 X 30 19mm height 7° lordosis
1037-302-611	T3 ALIF Implant 30 X 26 11mm height 12° lordosis
1037-302-613	T3 ALIF Implant 30 X 26 13mm height 12° lordosis
1037-302-615	T3 ALIF Implant 30 X 26 15mm height 12° lordosis
1037-302-617	T3 ALIF Implant 30 X 26 17mm height 12° lordosis
1037-302-619	T3 ALIF Implant 30 X 26 19mm height 12° lordosis
1037-342-811	T3 ALIF Implant 34 X 28 11mm height 12° lordosis
1037-342-813	T3 ALIF Implant 34 X 28 13mm height 12° lordosis
1037-342-815	T3 ALIF Implant 34 X 28 15mm height 12° lordosis
1037-342-817	T3 ALIF Implant 34 X 28 17mm height 12° lordosis
1037-342-819	T3 ALIF Implant 34 X 28 19mm height 12° lordosis
1037-383-011	T3 ALIF Implant 38 X 30 11mm height 12° lordosis
1037-383-013	T3 ALIF Implant 38 X 30 13mm height 12° lordosis
1037-383-015	T3 ALIF Implant 38 X 30 15mm height 12° lordosis
1037-383-017	T3 ALIF Implant 38 X 30 17mm height 12° lordosis
1037-383-019	T3 ALIF Implant 38 X 30 19mm height 12° lordosis

**Substantial Equivalence Discussion**

The Renovis S134 ALIF System implants (cages) are a modification of the S128 ALIF System standalone implants (PEEK and titanium cages) cleared under K131122. The S134 ALIF System cages are not stand alone and require supplemental fixation. Therefore, the change is removal of the screw holes. The Indications for Use are described in Table 1. The implants technical comparison is described in Table 2.

**Table 1 Indications for Use**

	Renovis S134 ALIF System	Renovis S128 ALIF System K131122 (cages)
Product code	MAX, MQP	OVD
Indications for Use	<p>The Renovis Lumbar Interbody Fusion (LIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis LIF System implants are to be used with autogenous bone graft.</p> <p>Patients should be skeletally mature and have at least six months of non-operative treatment.</p> <p>The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.</p> <p>The Renovis S134 ALIF System must be used with supplemental fixation cleared by the FDA for use in the lumbar spine.</p>	<p>The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft.</p> <p>Patients should be skeletally mature and have at least six months of non-operative treatment.</p> <p>The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.</p>

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**Table 2 Technical comparison**

	Renovis S134 ALIF System	Renovis S128 ALIF System K131122 (cages)
Product code	MAX, MQP	OVD
Implant Material	(b)(4) PEEK (b)(4) Titanium alloy Ti-6Al-4V	
Marker material	Tantalum	
Manufacturing	PEEK cages: traditional manufacturing Ti-6Al-4v cages: additive manufacturing (EBM)	
Dimensions		
A/P	26, 28, 30	
M/L	30, 34, 38	
H	11 – 21 Δ1mm	
Foot print	30 x 26D 34 x 28D 38 x 30D	
Lordosis	7°, 12°	
Bone graft	2270-7920 mm <sup>3</sup>	
End plate	(b)(4)	
Provided sterile?	Yes - gamma	(b)(4) Yes- gamma
Cover plate and screws	No	Yes
Supplemental Fixation	Required. Supplemental fixation cleared by the FDA for use in the lumbar spine must be used.	Not required, but should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

*Discussion*Similarities

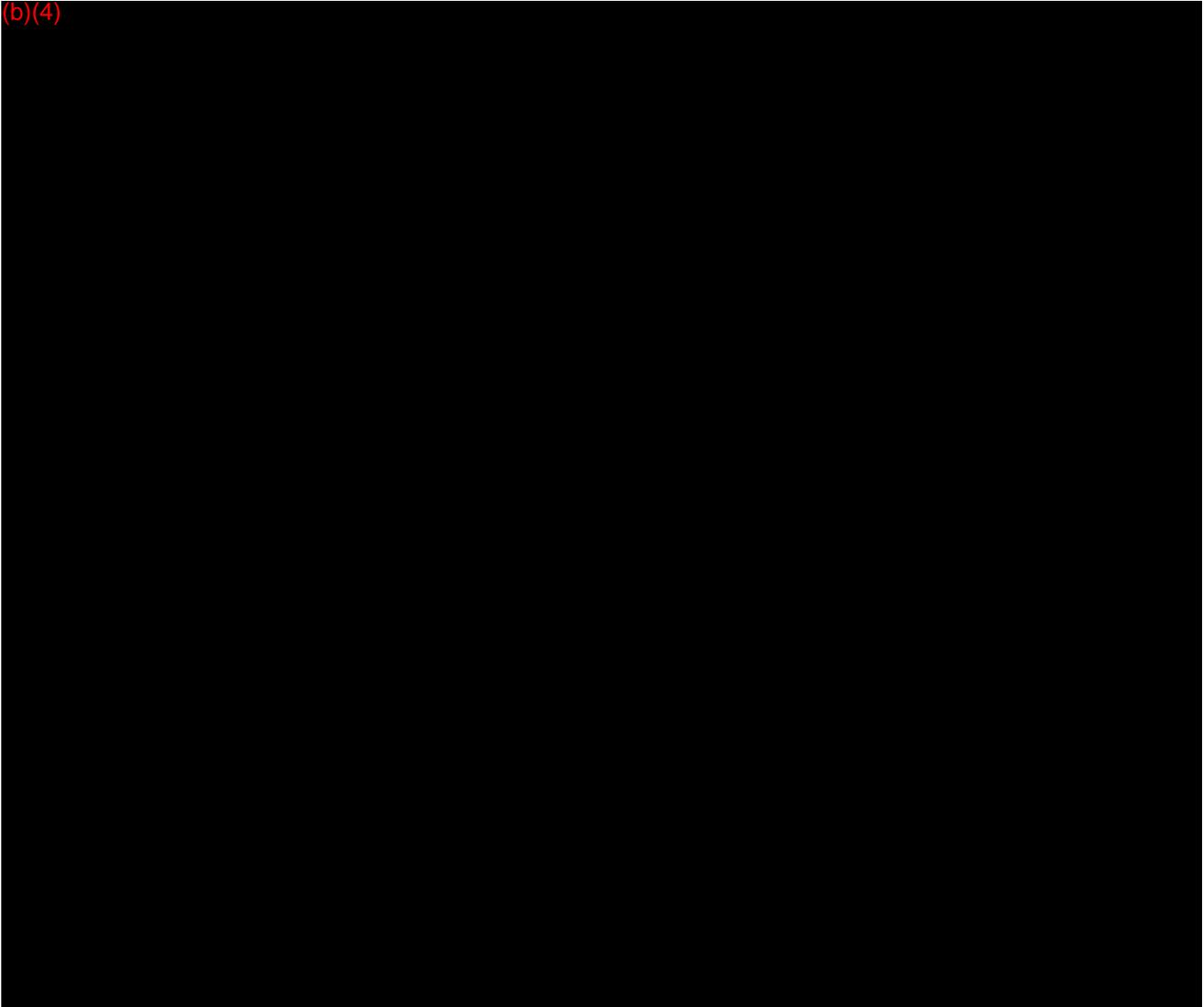
The foot print of the Renovis S128 ALIF System cages and S134 ALIF System cages are exactly the same physical ID and OD profile dimensions. The Renovis S134 cages also have the same materials and manufacturing methods; and similar intended use, design, and function (as addressed under design control activities) as the Renovis S128 cages.

The specific dimensions and explanation of the S134 ALIF System cages are included in 009\_Device Description Description of Changes. These are the same as the dimensions of the

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S128 ALIF System cages described in K140416 (009\_Device Description Description of Change and Standards). Footprint and isometric views may be compared in the drawings included below.

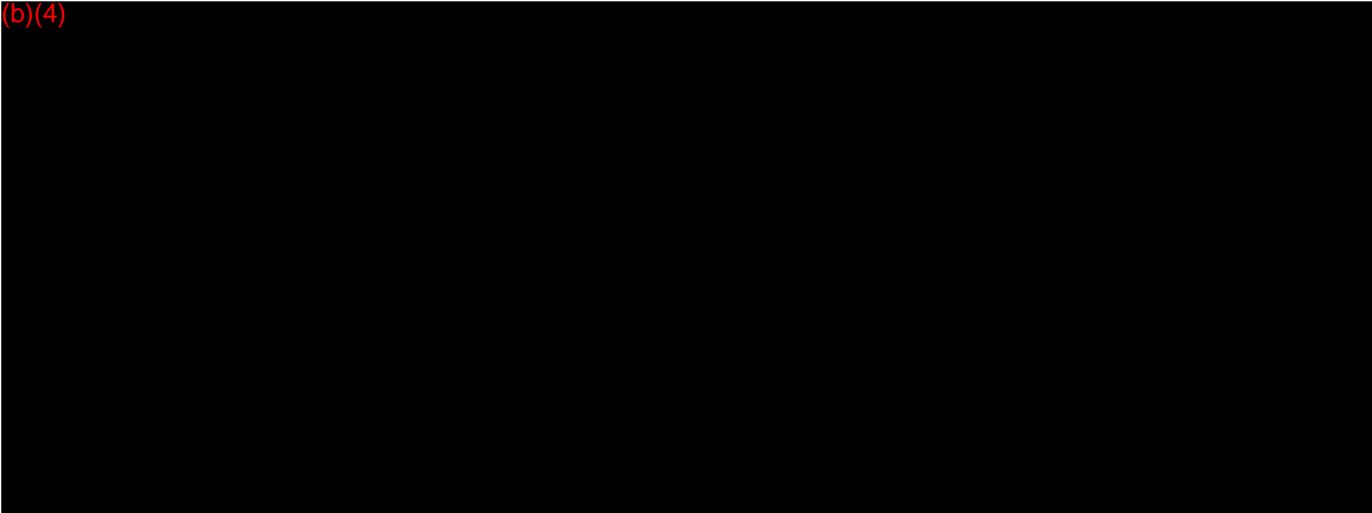
(b)(4)



As noted in the Indications for Use, the Renovis S128 cage is intended to be used with the cover plate and screws provided, but should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

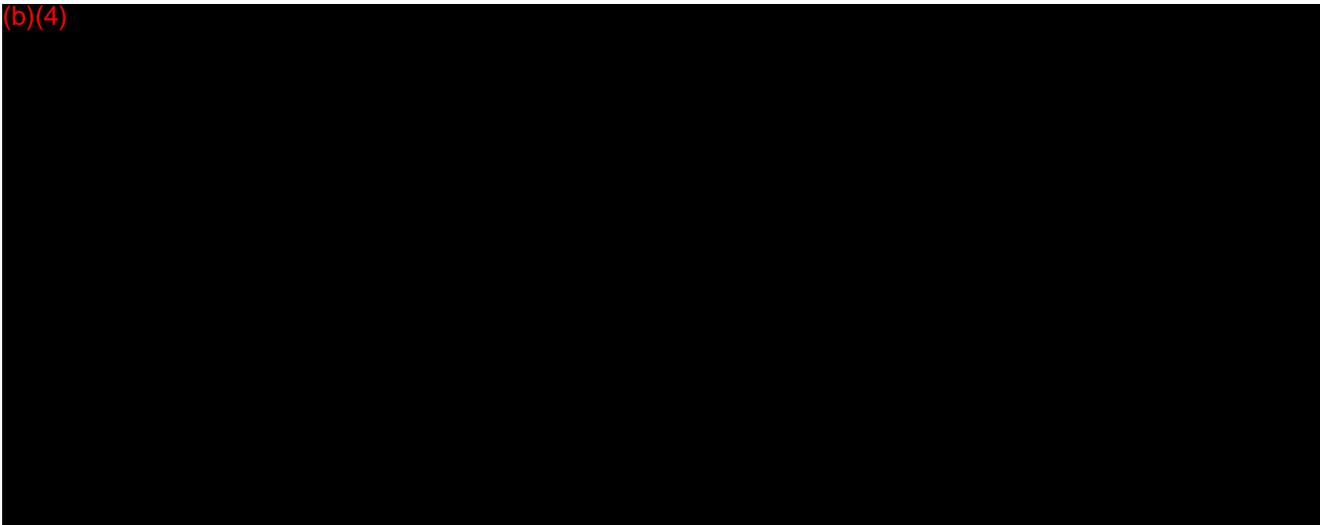
Differences

(b)(4)



*Testing per Design Controls*

(b)(4)



## **Labeling**

The labels for the Renovis S134 ALIF System are included below.

- Representative label – PEEK cage sterile (12-2)
- Representative label – Titanium cage sterile (12-4)
- Representative label – PEEK cage non-sterile (12-6)
- Representative label – Titanium cage non-sterile (12-7)

Symbols are defined on the box labels used (page 12-8).

As noted in the Cover Letter, Renovis intends to continue to add offerings to their Lumbar Interbody Fusion (LIF) System. Therefore, the IFU will apply to all LIF offerings and will not be specific to the individual systems (i.e. S128 or S134).

The Renovis LIF System Instructions for Use include:

- LIF IFU - sterile (013)
- LIF IFU non-sterile (014)

The S134 ALIF System Surgical Manual is included (015).

As there are no new instruments associated with the S134 ALIF System, the Renovis Instrument IFU has not been included.

**RENOVIS SURGICAL TECHNOLOGIES**

Label	S 134 ALIF PEEK Implant Label	July 2014
L 061	Revision A	Page 1 of 2

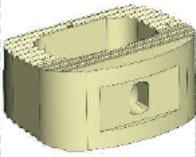
1. The label illustrated in this specification should serve as a template for the creation of the external, internal and chart labels.
2. The labels shall be printed in color with a minimum resolution of 300 dpi.
3. Fields 1 through 9 are variable.
  - Consult 4001-003, *Sterile Implant Packaging Specification*, for the proper label content of fields 1 through 4 (product description). Do not include, in the final label, the field identifiers (i.e. Field 1) or the dotted boxes drawn around them.
  - Fields 5 and 6 are based on the work order.
  - Field 7 is based in the validated expiration date. Consult 4001-003, *Sterile Implant Packaging Specification*, for the number of validated sterile years. The expiration date shall be in the YYYY-MM format.
  - Fields 8 and 9 are the barcodes for the numbers in fields 5 and 6.
  - The QTY number and corresponding barcode is 1.
  - The barcodes are created using Code 39 and shall contain the information pertaining to the respective field. i.e. REF, LOT, QTY. The barcodes in this label are for illustration purposes only.

Rev #	Date	Reason for Revision	Change Order #
A	July 2014	Initial Release	TBD

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**RENOVIS SURGICAL TECHNOLOGIES**

Label	S 134 ALIF PEEK Implant Label	July 2014
L 061	Revision A	Page 2 of 2



**RENOVIS™**

Field 1	<b>S 134 ALIF System Cage</b>
Field 2	<b>PEEK</b>
Field 3	<b>30 X 26 - 11 mm Height</b>
Field 4	<b>7° Lordosis</b>

<b>REF</b> 1034-302-611	<b>LOT</b> 1234-123	<b>QTY</b> 1	<b>YYYY-MM</b>
-------------------------	---------------------	--------------	----------------

Material: PEEK per ASTM F2026 and Tantalum per ASTM F560

Field 8

**REF** 





Field 9

**LOT** 



**R<sub>x</sub>**

ONLY

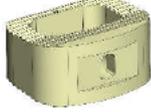
See outer package label for key to Symbols  
See Instructions for Use (IFU) for labeling limitations  
For Instructions for Use (IFU) go to [www.renovis-surgical.com](http://www.renovis-surgical.com)  
Paper copy of IFU available upon request at [info@renovis-surgical.com](mailto:info@renovis-surgical.com)

**Renovis Surgical Technologies, Inc. Redlands, CA 92374** **L 061 Rev. A**

**RENOVIS™**

Field 1	<b>S 134 ALIF System Cage</b>
Field 2	<b>PEEK</b>
Field 3	<b>30 X 26 - 11 mm Height</b>
Field 4	<b>7° Lordosis</b>

<b>REF</b> 1034-302-611	<b>LOT</b> 1234-123	<b>QTY</b> 1	<b>YYYY-MM</b>
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Material: PEEK per ASTM F2026 and Tantalum per ASTM F560

**STERILE** **R**

L 061 Rev. A

VOID

 <p style="font-size: 8px; margin-top: 5px;"><b>REF</b> 1034-302-611</p> <p style="font-size: 8px; margin-top: 5px;"><b>LOT</b> 1234-123</p> <p style="font-size: 8px; margin-top: 5px;"><b>YYYY-MM</b></p> <p style="font-size: 8px; margin-top: 5px;">S 134 ALIF System Cage PEEK 30 X 26 - 11 mm Height 7° Lordosis</p> <p style="font-size: 8px; margin-top: 5px;">L 061 Rev. A</p>	COPY	COPY	COPY	COPY	COPY	COPY
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**RENOVIS SURGICAL TECHNOLOGIES**

Label	S 134 ALIF Ti-6Al-4V Implant Label	July 2014
L 062	Revision A	Page 1 of 2

1. The label illustrated in this specification should serve as a template for the creation of the external, internal and chart labels.
2. The labels shall be printed in color with a minimum resolution of 300 dpi.
3. Fields 1 through 9 are variable.
  - Consult 4001-003, *Sterile Implant Packaging Specification*, for the proper label content of fields 1 through 4 (product description). Do not include, in the final label, the field identifiers (i.e. Field 1) or the dotted boxes drawn around them.
  - Fields 5 and 6 are based on the work order.
  - Field 7 is based in the validated expiration date. Consult 4001-003, *Sterile Implant Packaging Specification*, for the number of validated sterile years. The expiration date shall be in the YYYY-MM format.
  - Fields 8 and 9 are the barcodes for the numbers in fields 5 and 6.
  - The QTY number and corresponding barcode is 1.
  - The barcodes are created using Code 39 and shall contain the information pertaining to the respective field. i.e. REF, LOT, QTY. The barcodes in this label are for illustration purposes only.

Rev #	Date	Reason for Revision	Change Order #
A	July 2014	Initial Release	TBD

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**RENOVIS SURGICAL TECHNOLOGIES**

Label	S 134 ALIF Ti-6Al-4V Implant Label	July 2014
L 062	Revision A	Page 2 of 2



**RENOVIS™**

Field 1	<b>S 134 ALIF System Cage</b>
Field 2	<b>Titanium</b>
Field 3	<b>30 X 26 - 11 mm Height</b>
Field 4	<b>7° Lordosis</b>

REF <b>1036-302-611</b>	LOT <b>1234-123</b>	QTY <b>1</b>	YYYY-MM
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Material: Ti-6Al-4V per ASTM F136

REF	Field 8 			
LOT	Field 9 		<b>Rx</b> ONLY	
QTY		See outer package label for key to Symbols See Instructions for Use (IFU) for labeling limitations For Instructions for Use (IFU) go to <a href="http://www.renovis-surgical.com">www.renovis-surgical.com</a> Paper copy of IFU available upon request at <a href="mailto:info@renovis-surgical.com">info@renovis-surgical.com</a>		

**Renovis Surgical Technologies, Inc. Redlands, CA 92374** L 062 Rev. A

**RENOVIS™**

Field 1	<b>S 134 ALIF System Cage</b>
Field 2	<b>Titanium</b>
Field 3	<b>30 X 26 - 11 mm Height</b>
Field 4	<b>7° Lordosis</b>

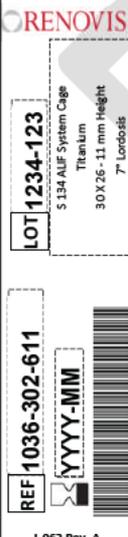
REF <b>1036-302-611</b>	Field 5	Field 6	Field 7
LOT <b>1234-123</b>		QTY <b>1</b>	YYYY-MM

Material: Ti-6Al-4V per ASTM F136

	<b>STERILE</b> <b>R</b>
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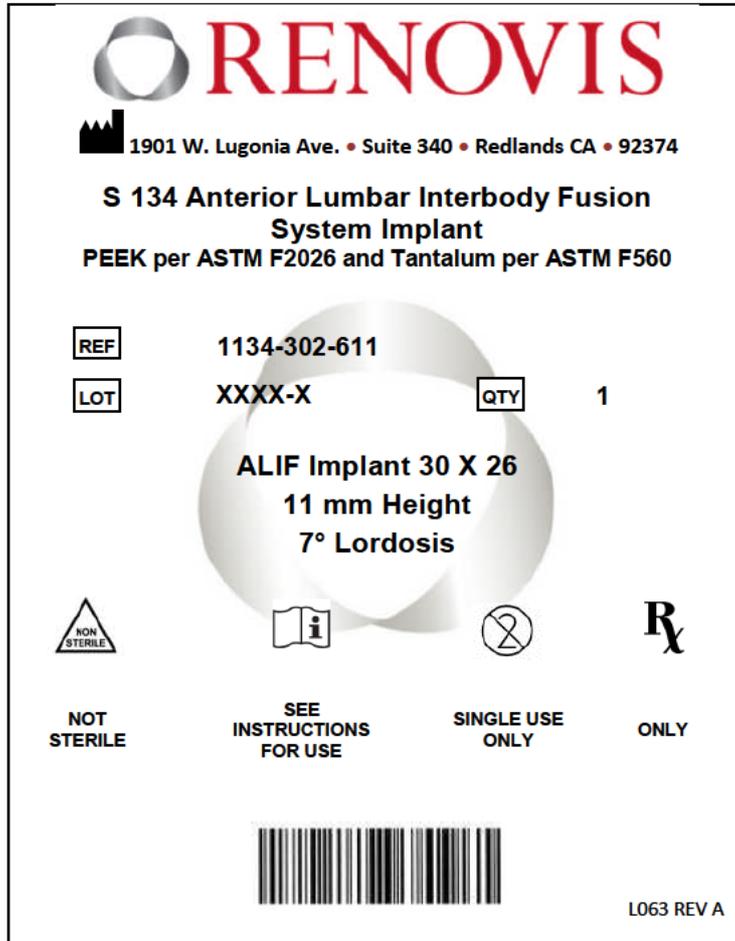
L 062 Rev. A

VOID

	COPY	COPY	COPY	COPY	COPY	COPY
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**RENOVIS SURGICAL TECHNOLOGIES**

Label	S 134 Anterior Lumbar Interbody Fusion System Implant	July 2014
L 063	Revision A	Page 1 of 1



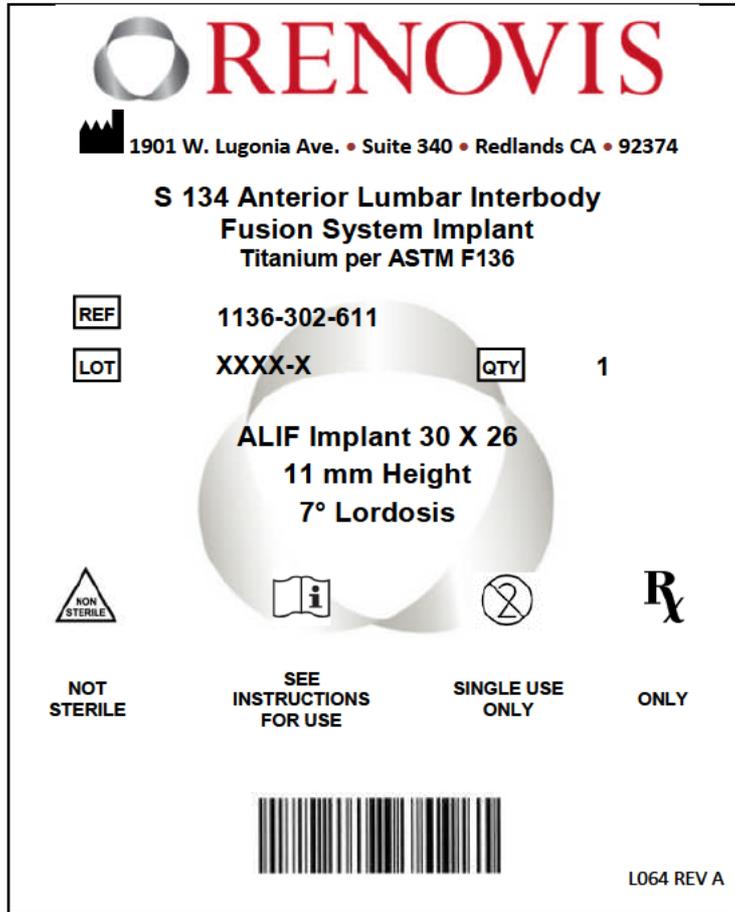
Notes:

1. The label illustrated above should serve as an example. The material, LOT number, REF number, barcode containing lot number, quantity, and description may vary based on the actual part.

Rev #	Date	Reason for Revision	Change Order #
A	July 2014	Initial Release	TBD

**RENOVIS SURGICAL TECHNOLOGIES**

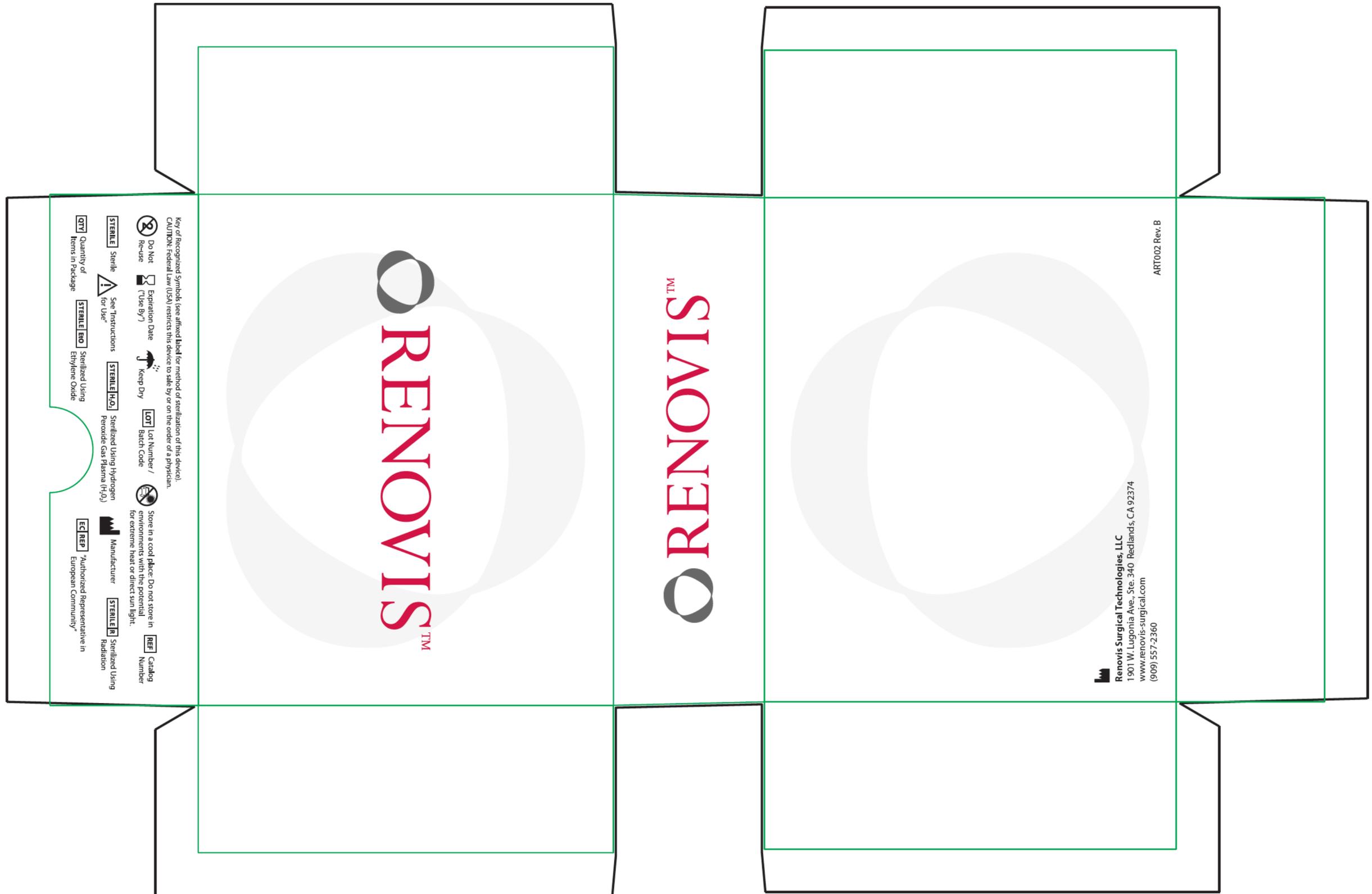
Label	S 134 Anterior Lumbar Interbody Fusion System Implant - Titanium	July 2014
L 064	Revision A	Page 1 of 1



Notes:

1. The label illustrated above should serve as an example. The material, LOT number, REF number, barcode containing lot number, quantity, and description may vary based on the actual part.

Rev #	Date	Reason for Revision	Change Order #
A	July 2014	Initial Release	TBD



**UTAH PAPER BOX - ELECTRONIC DIE PATTERN**

**Please Do Not Modify Design**

Customer: Pro-Tech Design & Mfg.  
 Box Name: Box 2, Renovis Clamshell, Q21040  
 Box Sizes: 6+5/8 x 5+3/8 x 1+15/16  
 CAD File: pt /pt2rcw

Design Side: printed  
 Date: 07/28/2011  
 Stock: Kivar .010  
 Part Number: ART002 Rev. B

**Renovis Lumbar Interbody Fusion (LIF) System, Sterile Packaging**



Rev. Draft



Instructions For Use

**DESCRIPTION:**

The Renovis Lumbar Interbody Fusion (LIF) System is an internal spinal fixation system comprised of PEEK or Titanium Interbody cages. The system also includes several instruments that assist in proper implantation; these instruments include: Trials, Sizers, Cage Inserters, and Cover Plate Inserters. The LIF System includes the S128 Anterior Lumbar Interbody Fusion (ALIF) System and the S134 Anterior Lumbar Interbody Fusion (ALIF) System.

LIF System Implants – Summary Description		
	Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System	Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) System
Dimensions (mm)		
A/P	26, 28, 30	
M/L	30, 34, 38	
H	11 - 21	
Lordosis	7°, 12°	
Number of screws	4	Not applicable
Screw diameter (mm)	4.5, 5	
Screw length (mm)	20, 25, 30, 35	
Cover plate (mm)	8.3 H; 22W	Not applicable

For implant and instrument parts numbers, as well as implant dimensions, refer to the Renovis S128 Surgical Technique Manual or the Renovis S134 System Surgical Technique manual.

**IMPORTANT NOTE:**

This product is marked for the specific indications described in its labeling. The use of this product for other than its intended purpose(s) is either contraindicated (see CONTRAINDICATIONS) or is without evidence to support the safety and effectiveness of such use. For the information of individuals and institutions contemplating use of this product for other than labeled indications (i.e., off-labeled use), such use may be experimental and may be the subject of restrictions under applicable laws and regulations.

**MATERIAL:**

All implant components of the Lumbar Interbody Fusion (LIF) System are made of the following materials:

1. Titanium Alloy: Ti6Al4V according to ASTM F-136
2. Polyetheretherketone (ZA-500): according to ASTM F-2026

**INDICATIONS FOR USE:**

The Renovis Lumbar Interbody Fusion (LIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis LIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

The Renovis S134 ALIF System must be used with supplemental fixation cleared by the FDA for use in the lumbar spine.

**GENERAL CONDITIONS OF USE:**

The safe implantation of Lumbar Interbody Fusion (LIF) Systems requires an in-depth knowledge of human vertebral anatomy as well as the specific patient's anatomical variations. The implantation of the LIF System should be performed only by experienced spinal surgeons with specific training in the use of interbody fusion. In addition, the surgeon must be knowledgeable of the mechanical and metallurgical limitations of this implant. The LIF System should not be used in conjunction with components from a different source, a different manufacturer, or made of a different material.

Under no circumstances should any component of the LIF System be reused after implantation or any other circumstance that has subjected an individual component to mechanical stress.

The S128 ALIF System has been tested as a standalone construct.  
The S134 ALIF System has not been tested as a standalone construct.

**CONTRAINDICATIONS:**

Contraindications to using the Lumbar Interbody Fusion (LIF) System are similar to those of other Lumbar Interbody Fusion (LIF) Systems and consist of the following:

1. Prior fusion at the level(s) to be treated
2. Any condition not describe in the Indications for Use
3. Patients that are overweight, obese, or are occupationally or recreationally subject to heavy lifting, twisting, repetitive bending, or stooping, to a degree that would produce loads on the spinal system leading to failure of fixation or implant failure.
4. Any patient not needing a bone graft and fusion, or where fracture healing is not required.
5. Patients with bony abnormalities that grossly distort anatomy and/or prevent placement of the implant without risk of impairment to anatomical structures or physiologic performance.
6. Patients with a suspected or documented metal allergy or intolerance.
7. Inadequate tissue coverage over the operative site.

8. Recent or active infection, particularly if in or adjacent to the spine or spinal structures.
9. Relative contraindications include open wounds as well as fever, leukocytosis, or other signs of systemic infection. Diminished bone quality is a relative contraindication. This may limit the surgeon's ability to achieve adequate implant fixation, structural support, or anatomic correction. These conditions include certain degenerative diseases, postoperative irradiation, smoking, and a history of previous spinal fixation failure. Diminished ability to comprehend and adhere to post-operative care instructions is a relative contraindication. These conditions include diminished mental capacity, mental illness, alcohol or drug abuse and Pregnancy.

#### **POTENTIAL RISKS:**

Potential risks identified with the use of this device, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, vertebral fracture, neurological injury, and vascular or visceral injury.

1. Correct implant selection is vital. Selecting the proper implant size, shape, and design increases the potential for satisfactory fixation. While proper selection can help minimize risks, the size and shape of human bones present implant size, shape, and strength limitations. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
2. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels among other conditions will dictate implant longevity. Notches, scratches or implant bending during the surgery may also contribute to early failure. Fully inform patients of the implant failure risks.
3. Mixing metals can cause corrosion. There are many forms of corrosion damage, and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel, and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., that come into contact with other metal objects, must be made from like or compatible materials.

#### **PATIENT SELECTION:**

The following factors can be extremely important to the eventual success of the procedure:

1. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.
2. Senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the device use, leading to implant failure or other complications.
3. Certain degenerative diseases. In some cases, degenerative disease progression may be so advanced at implantation that it may substantially decrease the device's expected useful life. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
4. Foreign body sensitivity. No pre-operative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

5. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

#### **WARNINGS AND CAUTIONS:**

Only experienced spinal surgeons with specific training in the use of interbody fusion systems should implant interbody fusion devices, because this is a technically demanding procedure presenting a risk of serious injury to the patient.

These warnings do not include all possible adverse surgical effects, but are particular to metallic internal fixation devices. Explain general surgical risks to the patient before surgery.

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, share, and design of the implant. The size and shape of the human bones present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. Single use only. Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns, which may lead to early breakage.
3. Correct implant handling is vital. These devices may not be contoured. Avoid any notching, scratching or reverse bending of the devices when handling. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage. Do not use the implant if damage is suspected. Do not use implants that exhibit surface or configuration damage.
4. The LIF System **implants** are provided sterile. For Sterile-packaged implants, do not resterilize any implant. Do not use any implant from an opened or damaged package. Do not use implants after expiration date.
5. The LIF System **instruments** are provided non-sterile, and therefore, must be thoroughly cleaned and sterilized before each use.
6. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
7. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. Inform the patient about the implant limitations, and to limit physical activities, especially lifting and twisting motions and participating in any type of sports. Tell the patient that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. Active, debilitated, or demented patients who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
8. Renovis Implants and Instruments have not been tested for adverse effect in a Magnetic Resonance Imaging (MRI) environment. The implants in the Lumbar Interbody Fusion System are manufactured from non-ferromagnetic materials as listed in the materials section of this IFU. Potential risks of placing implants in or near the magnetic field include:
  - a. Movement of ferromagnetic components through magnetically induced force and torque.
  - b. Localized heating of components caused by radio frequency induction heating.
  - c. Image artifacts created by interaction between metallic components and the magnetic field.

#### **ADVERSE AFFECTS:**

In addition to the obvious risk that any orthopedic implant may fail, loosen, or fracture, the following risks of adverse tissue responses and possible complications must be explained to and discussed with the patient:

1. There have been reports in literature that a variety of metals, polymers, chemicals, and other materials used in the manufacturing of orthopedic implants may cause cancer and other adverse reactions. Because of the long latency period required to induce tumors in humans, there is no conclusive evidence of

the relationship between orthopedic implants and malignant tumors. Even though no clear association has been established, any risks and uncertainties regarding the long term effects of artificial joints and fixation devices should be discussed with the patient prior to surgery. The patient should also know that any condition that causes chronic damage to tissues may be oncogenic. Cancer found in the vicinity of an implant may be due to factors unrelated to the implant materials such as: metastasis from soft tissue sites (lung, breast, digestive system, and others) to bone or seeded to those locations during operative and diagnostic procedures such as biopsies, and from progression of Paget's disease. Patients suffering from Paget's disease who are candidates for implantation procedures in the affected areas should be warned accordingly.

2. Implantation of foreign materials in tissues can elicit an inflammatory reaction. Recent literature suggests that wear debris (including metal, polyethylene, ceramic, and cemented particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening. While the formation of wear debris may be an inevitable consequence of motion at bone-to-implant surfaces, optimal technique for fixation of the device should be employed in order to minimize motion that can generate such particles at the bone/prosthesis or prosthesis/prosthesis interface.
3. Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitizers (nickel, cobalt, and chromium) are present in orthopedic grade stainless steel and cobalt-chrome alloys. Titanium and its alloys (such as Ti-6AL-4V Alloy) are markedly less antigenic and are recommended for use in persons with a history of allergies or metal sensitivity.

#### **HANDLING OF IMPLANTS**

1. Receipt – Carefully unwrap and handle non-sterilized instruments upon receipt to avoid scratching, marking, or abrasion by other implants, instruments, unpacking tools, or by dropping or otherwise endangering the surface finish or configuration. Implants are provided sterile. Wrappings should not be removed by receiving personnel.
2. Transport - Transport in a manner to preclude any damage or alteration to the received condition of the implant or instrument.
3. Storage - Store implants or instruments prior to use in such a manner as to maintain the device's surface finish or configuration, or both. Stock Rotation— The principle of first in, first out, is recommended. Store implants in the operating room in such a manner as to isolate and protect the implant's surface, sterility, and configuration. Keep implants made of different metals separated. Store the implants and instruments in the operating room in such a manner as to isolate the instruments from the implants.
4. Traceability - Implants are identified by a catalog number or lot number, or both, on the package label and surface of the device. Record these control numbers and retain for transfer to patient records, to facilitate inventory, stock rotation, medical device reporting, and/or possible traceability to the manufacturer.

#### **INSTRUMENTS –CLEANING, DECONTAMINATION AND STERILIZATION:**

All instruments must be thoroughly cleaned before each sterilization (including first use) and introduction into a sterile field. All devices should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device. More information is provided in Renovis Surgical Instruments IFU (p/n 4001-001).

Instruments that are specifically designed for use with the LIF System include trials, sizers, and implant/cage inserters. Other instruments are also provided for use with the LIF ALIF System. For a list of all instruments, refer to the Renovis S128 ALIF Surgical Technique Manual or the S134 ALIF Surgical Technique manual.

1. **Decontamination:** Saturate the surface completely with full strength disinfectant/cleaner\* (e.g. ENZOL<sup>®</sup> Enzymatic Detergent). Fully immerse the devices and allow them to soak for a minimum of 5 minutes.
2. **Pre-Cleaning:** The Large Modular Handle (2128-001-030) must be disassembled before cleaning. No other LIF System instruments require disassembly. Prepare a room temperature neutral pH enzymatic cleaner\* (e.g. ENZOL<sup>®</sup> Enzymatic Detergent) and remove gross contaminants by thoroughly brushing devices with a soft bristled brush ensuring all hard to reach areas are accessed.
3. **Washing:** Immerse devices in the ultrasonic washer/cleaner with room temperature neutral pH enzymatic cleaner\* (e.g. ENZOL<sup>®</sup> Enzymatic Detergent) and sonicate for a minimum of 10 minutes. For ultrasonic cleaning, follow the manufacturer's specifications for suggested water level and concentration. When using mechanical washers, make sure the instruments are secured in place and do not touch or overlap.
4. **Rinsing:** Thoroughly rinse the devices with deionized or distilled water for a minimum of 2 minutes. Repeat rinsing a total of three (3) times.
5. **Drying:** Allow devices to air dry for a minimum of 20 minutes prior to inspection for moisture and sterilization preparation. Instruments must be thoroughly dried to remove residual moisture before they are stored.
6. **Inspection:** After cleaning/disinfection, instruments should be visually inspected for contamination. If contamination is still visible, repeat steps 3, 4 and 5. If instruments continue to have visual contamination, they should not be used and should be disposed of.
7. **Preparation:** After cleaning/disinfection and inspection, the Large Modular Handle (2128-001-030) should be reassembled and visually inspected for damage. Visually inspect all instruments for misalignment, burrs, bent, or fractured tips. Do not use if any of this damage is observed. Place instruments into appropriate configuration within instrument case and wrap with protective sterilization wrap according to AAMI / AORN guidelines. FDA cleared sterilization wrap must be used.

\* Do not use high acidic (pH <4) or high alkaline (pH >10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures. Renovis has qualified the above cleaning method with the provided solution examples, for a 3 Spore Log Reduction (SLR). Other cleaning/disinfection methods may also be suitable; however, individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques.

## STERILIZATION

### Implants:

All implants are sterilized by exposure to a minimum dose of 25kGy of gamma radiation.

Do not resterilize any implant. Do not use any implant from an opened or damaged package. Do not use implants after the expiration date.

### Instruments:

Renovis Instruments are provided non-sterile. Sterilization is recommended as follows:

<b>Cycle</b>	Dynamic-air-removal Steam
<b>Minimum Temperature</b>	132° C (270° F)

<b>Exposure</b>	4 Minutes
<b>Drying Time</b>	30 minutes minimum; 40 minutes maximum

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

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

The packaging in which non-sterile instruments are supplied should not be used for sterilization methods in the hospital. Repackaged and resterilized items must be properly labeled and marked with the expiration date mandated by hospital policy.

**References:** References to relevant literature including the Surgical Technique manuals may be obtained by calling Renovis Surgical Technologies, INC. at +1.800-RENOVIS

**Caution:** Federal Law USA restricts this device to sale by or on the order of a physician.



**Renovis Lumbar Interbody Fusion (LIF) System, Non-Sterile Packaging**

Rev. DRAFT

Instructions For Use

**DESCRIPTION:**

The Renovis Lumbar Interbody Fusion (LIF) System is an internal spinal fixation system comprised of PEEK or Titanium Interbody cages. The system also includes several instruments that assist in proper implantation; these instruments include: Trials, Sizers, and Cage Inserters. The LIF System includes the S128 Anterior Lumbar Interbody Fusion (ALIF) System and the S134 Anterior Lumbar Interbody Fusion (ALIF) System.

LIF System Implants – Summary Description		
	Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System	Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) System
Dimensions (mm)		
A/P	26, 28, 30	
M/L	30, 34, 38	
H	11 - 21	
Lordosis	7°, 12°	
Number of screws	4	Not applicable
Screw diameter (mm)	4.5, 5	
Screw length (mm)	20, 25, 30, 35	
Cover plate (mm)	8.3 H; 22W	Not applicable

For implant and instrument parts numbers, as well as implant dimensions, refer to the Renovis S128 Surgical Technique Manual or the Renovis S134 System Surgical Technique manual.

**IMPORTANT NOTE:**

This product is marked for the specific indications described in its labeling. The use of this product for other than its intended purpose(s) is either contraindicated (see CONTRAINDICATIONS) or is without evidence to support the safety and effectiveness of such use. For the information of individuals and institutions contemplating use of this product for other than labeled indications (i.e., off-labeled use), such use may be experimental and may be the subject of restrictions under applicable laws and regulations.

**MATERIAL:**

All implant components of the Lumbar Interbody Fusion (LIF) System are made of the following materials:

1. Titanium Alloy: Ti6Al4V
2. Polyetheretherketone (PEEK): according to ASTM F-2026

3. Tantalum: according to ISO 13782-1996 and ASTM F-560

### **INDICATIONS FOR USE:**

The Renovis Lumbar Interbody Fusion (LIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis LIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

The Renovis S134 ALIF System must be used with supplemental fixation cleared by the FDA for use in the lumbar spine.

### **GENERAL CONDITIONS OF USE:**

The safe implantation of Lumbar Interbody Fusion (LIF) Systems requires an in-depth knowledge of human vertebral anatomy as well as a specific patient's anatomical variations. The implantation of the Lumbar Interbody Fusion (LIF) System should be performed only by experienced spinal surgeons with specific training in the use of interbody fusion. In addition, the surgeon must be knowledgeable of the mechanical and metallurgical limitations of this implant. The Lumbar Interbody Fusion (LIF) System should not be used in conjunction with components from a different source, a different manufacturer, or made of a different material.

Under no circumstances should any component of the Lumbar Interbody Fusion (ALIF) System be reused after implantation or any other circumstance that has subjected an individual component to mechanical stress.

The S128 ALIF System has been tested as a standalone construct.

The S134 ALIF System has not been tested as a standalone construct.

### **CONTRAINDICATIONS:**

Contraindications to using the Lumbar Interbody Fusion (LIF) System are similar to those of other Lumbar Interbody Fusion (LIF) Systems and consist of the following:

1. Patients that are overweight, obese, or are occupationally or recreationally subject to heavy lifting, twisting, repetitive bending, or stooping, to a degree that would produce loads on the spinal system leading to failure of fixation or implant failure.
2. Any patient not needing a bone graft and fusion, or where fracture healing is not required.
3. Patients with bony abnormalities that grossly distort anatomy and/or prevent placement of the implant without risk of impairment to anatomical structures or physiologic performance.
4. Patients with a suspected or documented metal allergy or intolerance.
5. Inadequate tissue coverage over the operative site.
6. Recent or active infection, particularly if in or adjacent to the spine or spinal structures.
7. Relative contraindications include open wounds as well as fever, leukocytosis, or other signs of systemic infection. Diminished bone quality is a relative contraindication. This may limit the surgeon's ability to achieve adequate implant fixation, structural support, or anatomic correction. These conditions include certain degenerative diseases, postoperative irradiation, smoking, and a history of previous spinal fixation failure. Diminished ability to comprehend and

adhere to post-operative care instructions is a relative contraindication. These conditions include diminished mental capacity, mental illness, alcohol or drug abuse and Pregnancy.

### **POTENTIAL RISKS:**

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, vertebral fracture, neurological injury, and vascular or visceral injury.

1. Correct implant selection is vital. Selecting the proper implant size, shape, and design increases the potential for satisfactory fixation. While proper selection can help minimize risks, the size and shape of human bones present implant size, shape, and strength limitations. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
2. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels among other conditions will dictate implant longevity. Notches, scratches or implant bending during the surgery may also contribute to early failure. Fully inform patients of the implant failure risks.
3. Mixing metals can cause corrosion. There are many forms of corrosion damage, and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel, and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., that come into contact with other metal objects, must be made from like or compatible materials.

### **PATIENT SELECTION:**

The following factors can be extremely important to the eventual success of the procedure:

1. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.
2. Senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the device use, leading to implant failure or other complications.
3. Certain degenerative diseases. In some cases, degenerative disease progression may be so advanced at implantation that it may substantially decrease the device's expected useful life. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
4. Foreign body sensitivity. No pre-operative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.
5. Smoking. Patients who smoke have been observed to experience higher rates of pseudoarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

### **WARNINGS AND CAUTIONS:**

Only experienced spinal surgeons with specific training in the use of interbody fusion system should implant interbody fusion devices, because this is a technically demanding procedure presenting a risk of serious injury to the patient

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, share, and design of the implant. The size and shape of the human bones present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. Single use only. Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
3. Correct implant handling is vital. These devices may not be contoured. Avoid any notching, scratching or reverse bending of the devices when handling. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage. Do not use the implant if damage is suspected.
4. The LIF System implants and instruments are provided non-sterile, and therefore, must be sterilized before each use.
5. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
6. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. Inform the patient about the implant limitations, and to limit physical activities, especially lifting and twisting motions and participating in any type of sports. Tell the patient that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. Active, debilitated, or demented patients who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
7. Renovis Implants and Instruments have not been tested for adverse effect in a Magnetic Resonance Imaging (MRI) environment. The implants in the Lumbar Interbody Fusion System are manufactured from non-ferromagnetic materials as listed in the materials section of this IFU. Potential risks of placing implants in or near the magnetic field include:
  - a. Movement of ferromagnetic components through magnetically induced force and torque.
  - b. Localized heating of components caused by radio frequency induction heating.
  - c. Image artifacts created by interaction between metallic components and the magnetic field.

#### **ADVERSE AFFECTS:**

In addition to the obvious risk that any orthopedic implant may fail, loosen, or fracture, the following risks of adverse tissue responses and possible complications must be explained to and discussed with the patient:

1. There have been reports in literature that a variety of metals, polymers, chemicals, and other materials used in the manufacturing of orthopedic implants may cause cancer and other adverse reactions. Because of the long latency period required to induce tumors in humans, there is no conclusive evidence of the relationship between orthopedic implants and malignant tumors. Even though no clear association has been established, any risks and uncertainties regarding the long term effects of artificial joints and fixation devices should be discussed with the patient prior to surgery. The patient should also know that any condition that causes chronic damage to tissues may be oncogenic. Cancer found in the vicinity of an implant may be due to factors unrelated to the implant materials such as: metastasis from soft tissue sites (lung, breast, digestive system, and others) to bone or seeded to those locations during operative and diagnostic procedures such as biopsies, and from progression of Paget's disease. Patients suffering from Paget's disease who are candidates for implantation procedures in the affected areas should be warned accordingly.
2. Implantation of foreign materials in tissues can elicit an inflammatory reaction. Recent literature suggests that wear debris (including metal, polyethylene, ceramic, and cemented particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening. While the formation of wear debris may be an inevitable consequence of motion at bone-to-implant surfaces, optimal technique for fixation of the device should be employed in order to minimize motion that can generate such particles at the bone/prosthesis or prosthesis/prosthesis interface.
3. Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitizers (nickel, cobalt, and chromium) are present in orthopedic grade stainless steel and cobalt-chrome alloys. Titanium and its alloys (such as Titanium Ti-6AL-4V Alloy) are markedly less antigenic and are recommended for use in persons with a history of allergies or metal sensitivity.

**HANDLING**

1. Receipt – Carefully unwrap and handle non-sterilized implants and instruments upon receipt to avoid scratching, marking, or abrasion by other implants, instruments, unpacking tools, or by dropping or otherwise endangering the surface finish or configuration.
2. Transport - Transport in a manner to preclude any damage or alteration to the received condition of the implant or instrument.
3. Storage - Store implants or instruments prior to use in such a manner as to maintain the device’s surface finish or configuration, or both. Stock Rotation—The principle of first in, first out, is recommended. Store implants in the operating room in such a manner as to isolate and protect the implant’s surface, sterility, and configuration. Keep implants made of different metals separated. Store the implants and instruments in the operating room in such a manner as to isolate the instruments from the implants.
4. Traceability - Implants are identified by a catalog number or lot number, or both, on the package label and surface of the device. Record these control numbers and retain for transfer to patient records, to facilitate inventory, stock rotation, medical device reporting, and/or possible traceability to the manufacturer.

**CLEANING:**

All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning can include the use of neutral cleaners followed by a deionized water rinse. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device. Renovis Instrument IFU 4001-001 provides more detailed information about proper cleaning of the instruments in the LIF System.

**STERILITY:**

Renovis LIF System implants and instruments are provided non-sterile, and must be sterilized before use. Sterilization is recommended as follows:

<b>Cycle</b>	Dynamic-air-removal Steam
<b>Minimum Temperature</b>	132° C (270° F)
<b>Exposure</b>	4 Minutes
<b>Drying Time</b>	30 minutes minimum; 40 minutes maximum

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

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

The packaging in which non-sterile implants are supplied should not be used for sterilization methods in the hospital. The implants should be sterilized in the provided caddies. Repackaged and re-sterilized items must be properly labeled and marked with the expiration date mandated by hospital policy.

**References:** References to relevant literature including the Surgical Technique manuals may be obtained by calling Renovis Surgical Technologies, Inc. at 1-800-RENOVIS.

**Caution:** Federal Law USA restricts this device to sale by or on the order of a physician.



 **RENOVIS**

Renovis Surgical Technologies, Inc.  
1901 W. Lagonia Ave. Suite 340  
Redlands CA 92374 USA  
1-800-RENOVIS

# Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) Surgical Technique

## Indications for Use

The Renovis Lumbar Interbody Fusion (LIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis LIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

The Renovis S134 ALIF System must be used with supplemental fixation cleared by the FDA for use in the lumbar spine.

## Description

The S134 Anterior Lumbar Interbody Fusion (ALIF) System is an internal spinal fixation system comprised of PEEK or Titanium Interbody (Tesera) cages. The system also includes instruments that assist in proper implantation; these instruments include: Trials, Sizers, and Cage Inserters.

## Contraindications

Contraindications to using the Lumbar Interbody Fusion (LIF) Systems are similar to those of other Lumbar Interbody Fusion (LIF) Systems and consist of the following:

1. Prior fusion at the level(s) to be treated
2. Any condition not describe in the Indications for Use
3. Patients that are overweight, obese, or are occupationally or recreationally subject to heavy lifting, twisting, repetitive bending, or stooping, to a

- degree that would produce loads on the spinal system leading to failure of fixation or implant failure.
4. Any patient not needing a bone graft and fusion, or where fracture healing is not required.
  5. Patients with bony abnormalities that grossly distort anatomy and/or prevent placement of the implant without risk of impairment to anatomical structures or physiologic performance.
  6. Patients with a suspected or documented metal allergy or intolerance.
  7. Inadequate tissue coverage over the operative site.
  8. Recent or active infection, particularly if in or adjacent to the spine or spinal structures.
  9. Relative contraindications include open wounds as well as fever, leukocytosis, or other signs of systemic infection. Diminished bone quality is a relative contraindication. This may limit the surgeon's ability to achieve adequate implant fixation, structural support, or anatomic correction. These conditions include certain degenerative diseases, postoperative irradiation, smoking, and a history of previous spinal fixation failure. Diminished ability to comprehend and adhere to post-operative care instructions is a relative contraindication. These conditions include diminished mental capacity, mental illness, alcohol or drug abuse and Pregnancy.

## **Warnings and Cautions**

Only experienced spinal surgeons with specific training in the use of interbody fusion systems should implant interbody fusion devices, because this is a technically demanding procedure presenting a risk of serious injury to the patient.

These warnings do not include all possible adverse surgical effects, but are particular to metallic internal fixation devices. Explain general surgical risks to the patient before surgery.

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape, and design of the implant. The size and shape of the human bones present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. Single use only. Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns, which may lead to early breakage.
3. Correct implant handling is vital. These devices may not be contoured. Avoid any notching, scratching or reverse bending of the devices when handling.

Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage. Do not use the implant if damage is suspected. Do not use implants that exhibit surface or configuration damage.

4. The LIF System implants are provided sterile and non-sterile. For Sterile-packaged implants, do not resterilize any implant. Do not use implants after expiration date. Non-sterile implants must be thoroughly cleaned and sterilized before each use. Do not use any implant from an opened or damaged package.

5. The LIF System instruments are provided non-sterile, and therefore, must be thoroughly cleaned and sterilized before each use.

6. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

7. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. Inform the patient about the implant limitations, and to limit physical activities, especially lifting and twisting motions and participating in any type of sports. Tell the patient that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. Active, debilitated, or demented patients who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

8. Renovis Implants and Instruments have not been tested for adverse effect in a Magnetic Resonance Imaging (MRI) environment. The implants in the Lumbar Interbody Fusion System are manufactured from non-ferromagnetic materials as listed in the materials section of this IFU. Potential risks of placing implants in or near the magnetic field include:

- a. Movement of ferromagnetic components through magnetically induced force and torque.
- b. Localized heating of components caused by radio frequency induction heating.
- c. Image artifacts created by interaction between metallic components and the magnetic field.

## Preparation

### Anterior access and Approach

Locate the correct operative disc level and incision location by taking a lateral fluoroscopic view while holding a straight metal instrument at the side of the patient. This ensures that the incision and exposure will allow direct visualization into the disc space. Expose the operative disc level through a standard retroperitoneal approach.

### Exposure

The S134 ALIF system must be inserted from a direct anterior approach. Expose the segment to produce sufficient space on either side of the vertebral midline, equal to half the width of the implant. This allows insertion of the implant, without interference from adjacent soft tissue structures.

*Note: Give proper consideration to the exposure so instrumentation can be used as described in the following sections.*

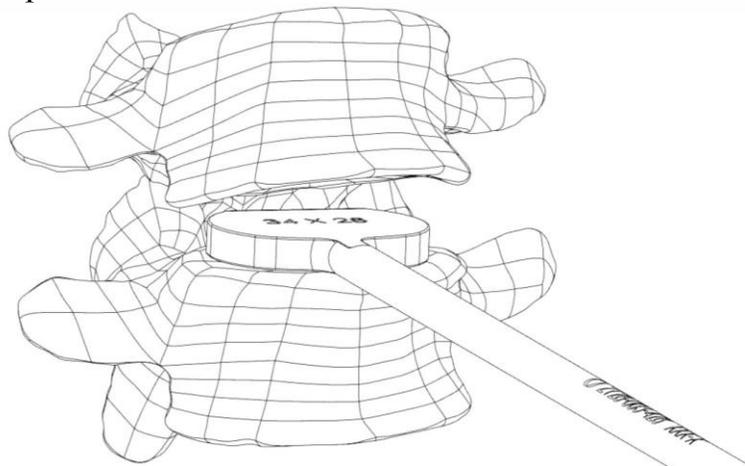
## Discectomy and Endplate Preparation

### Discectomy

Create an annulotomy centered on the midline and wide enough to accommodate the S134 implant. A Paddle Sizer (2128-003-026\_830) may be used as a template to indicate the width of the annular window required.

Perform a thorough discectomy, ensuring the posterolateral corners are freed of disc material.

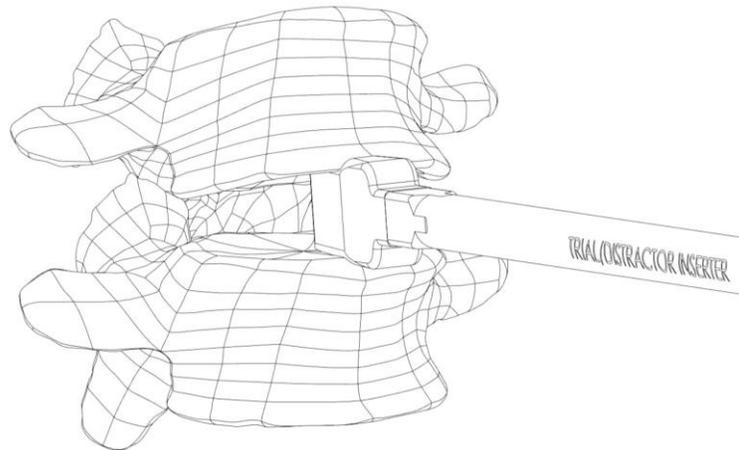
Remove non-ossified fibrocartilage, taking care to not compromise the integrity of the bony endplates.



## Endplate Preparation

If additional disc space distraction or remobilization is necessary, the Bullet Nose Distractors (2128-002-009\_021) are available in the S134 Instrument Set.

Firmly attach the Bullet Nose Distractors to the Trial Implant/ Bullet Nose Distractor Inserter (2128-001-005). Insert a Distractor into the disc space and rotate to distract the disc space to facilitate disc plate preparation.



*Note: Excessive removal of subchondral bone may weaken the vertebral endplate. If the entire endplate is removed, subsidence and a loss of segmental stability may result.*

For a safe placement, verify Bullet Nose Distractor position with the help of intraoperative lateral imaging.

## Trialing

Select the Trial Implant with the appropriate footprint and lordotic angle. Firmly attach it to the Trial Implant/Bullet Nose Distractor Inserter (2128-001-005).

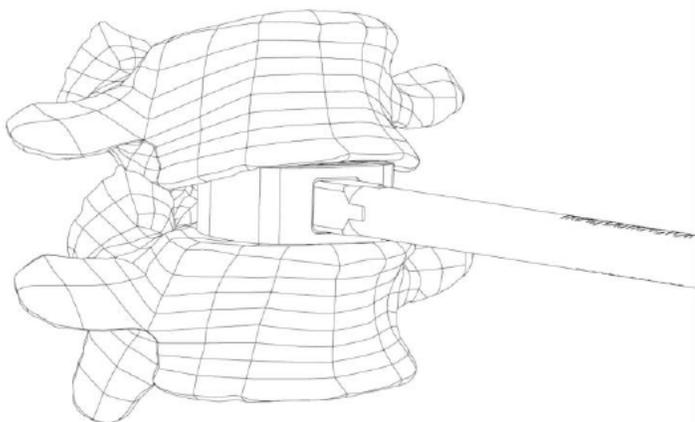
Controlled, light impaction of the trial spacer handle may be required to advance the trial spacer into the disc space.

If a tight fit is not achieved, repeat the process using incrementally larger trial spacers. Conversely, if the trial spacer cannot be inserted, repeat using incrementally smaller trial spacers.

Select the maximum size, to optimize the stability of the segment.

When rocking the trial spacer handle in a cranial to caudal direction, no toggling of the trial spacer should be evident.

X-ray may be used to check the position of the trial implant, restoration of disc and foraminal height, and overall alignment before selecting the final S134 implant size.

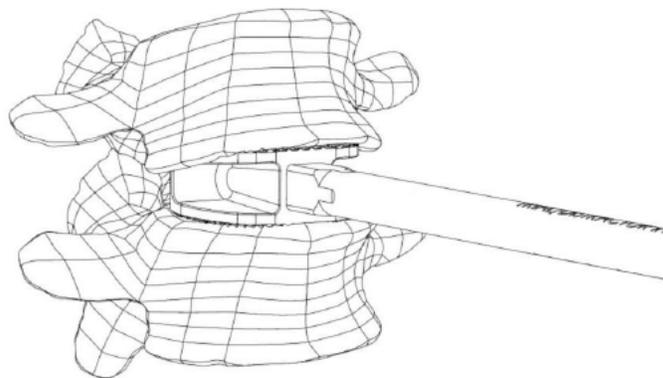
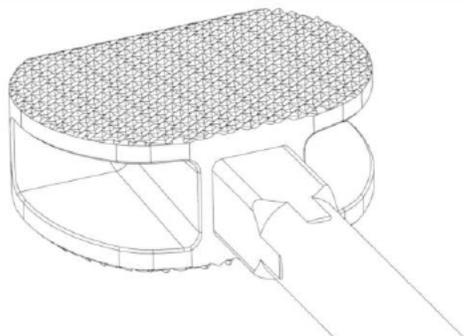


## Broaching

If using the Tesera ALIF Cage, broaching is necessary to ensure that the vertebral endplates are properly prepared for the implant. For this step, attach the appropriate Broach to the Trial Implant/Bullet Nose Distractor Inserter (2128-001-005) based upon the size indicated during the Trialing step. Insert the assembly into the disc space and gently tap on the proximal end with a mallet.

Note: take caution not to over-insert the Broach into the disc space. Do not countersink the broach head beyond the rim of the vertebral endplate. Broaches are 1mm wider per side than the implant, and 2mm deeper than the implant.

Remove the assembly and repeat this step several times to ensure the endplates are roughened and ready to receive the Tesera implant.



## Implant Selection and Graft Packing

Select the appropriate S134 Implant, and insert into the Packing Block (2128-001-035). To facilitate selection of the implant, trial implants are laser etched with the height, lordotic angle and footprint of the implant. Select the S134 implant corresponding to the final trial spacer size.

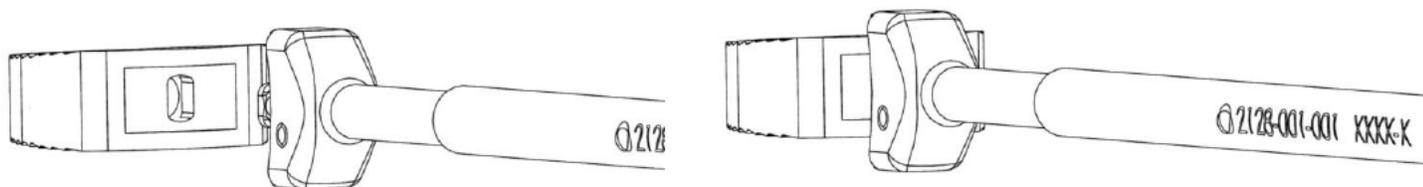
After placing the implant into the Packing Block, fill the implant with autograft material using the Implant Impactor (2128-001-003) to ensure the implant cavities are densely packed.

## Implant Insertion

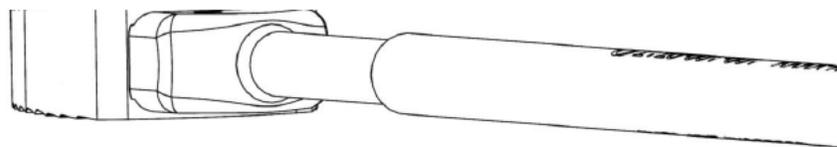
The implant is now ready to be inserted, using the method described below:

### Using the Implant Inserter

Attach the S134 cage to the inserter by inserting distal end of the Implant Inserter (2128-001-001) into the open end of the implant with the attachment slot present. The rectangular post that extends from the inserter must align and fit into the corresponding rectangular slot in the center of the face of the cage.

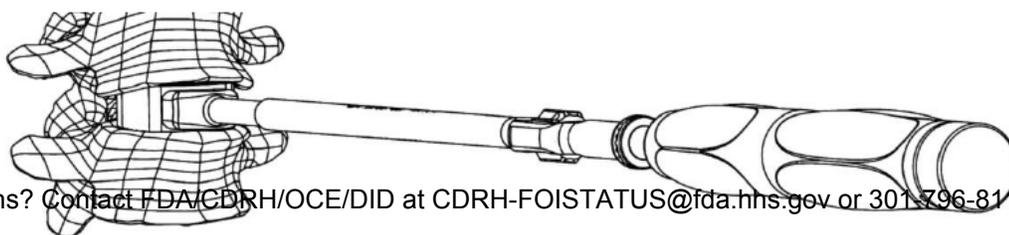


Once the rectangular post of the inserter has penetrated into the interior of the implant, rotate the instrument 90° to align the impaction face with the flat face of the implant and seat the implant up against the inserter face.



When the implant is fully seated, rotate the knob at the proximal end of the implant inserter clockwise to lock the implant to the inserter.

Controlled, light impaction of the Implant Inserter handle may be required to advance the implant into the disc space.



Remove the Implant Inserter by rotating the proximal knob counterclockwise until the inserter can be rotate 90° and removed.

Verify final implant position with the help of an intraoperative lateral imaging.

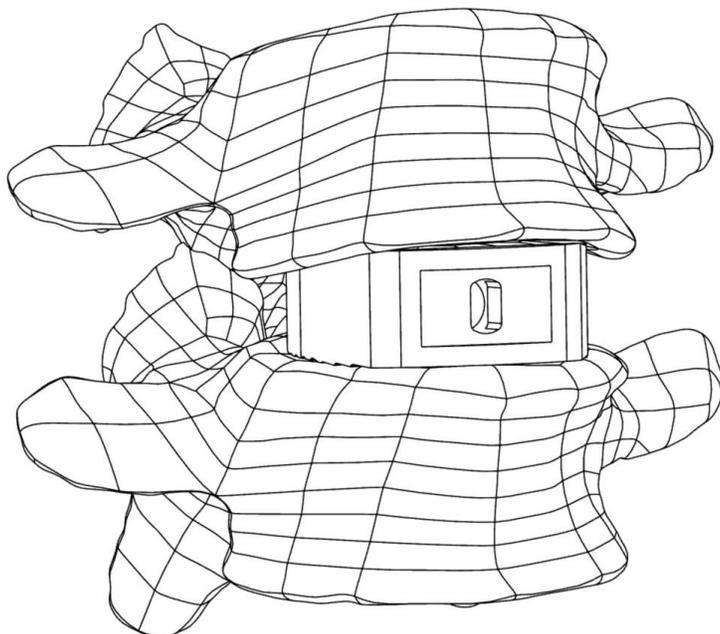
*Note: The posterior x-ray marker incorporated into the implant allows accurate intraoperative radiographic assessment of the position of the implant. The posterior x-ray marker is located approximately 3 mm from the posterior wall of the cage.*

Depending on the size of the vertebrae, the anterior edge of the implant will usually be flush to three-millimeters- recessed relative to the anterior aspect of the adjacent vertebrae.

*Note: All instruments must be removed carefully to avoid possible injury to adjacent structures.*

## **Final Construct Inspection**

Visually inspect the implant, and confirm placement of the construct via lateral and A/P fluoroscopy.



## **Removal or Revisions**

Use extreme caution when exposing the implant upon revision. The approach may be more difficult than at the time of the original surgery due to adhesion between and around the great vessels. It is vitally important to gain full exposure of the Renovis S134 Implant to prevent injury to the great vessels.

Once exposure is gained, simply reverse the surgical technique:

1. Ensure the implant is not hindered by any bone or soft tissue.
2. Attach the Implant Inserter to the exposed front of the implant and gently remove.

## **Patient care following surgery**

A routine wound closure should be performed after x-ray confirmation of proper implant placement. Following surgery, observe standard patient care protocols and monitoring, including, but not limited to:

- Routine monitoring of the vital signs, and of the hemodynamic and neurologic status of the patient.
- Pain medication.
- NG tubes and/or Foley catheters are generally discontinued.
- Diet is restricted per surgeon recommendation to small amounts of liquids until return of bowel function is completed.
- The patient is encouraged to ambulate as soon as possible.
- Braces and activity are to be used at each surgeon's discretion.

## Parts Numbers

### Renovis PEEK Implants -Sterile

Part Number	Width	Depth	Height	Lordosis
1034-302-611	30mm	26mm	11mm	7°
1034-302-612	30mm	26mm	12mm	7°
1034-302-613	30mm	26mm	13mm	7°
1034-302-614	30mm	26mm	14mm	7°
1034-302-615	30mm	26mm	15mm	7°
1034-302-616	30mm	26mm	16mm	7°
1034-302-617	30mm	26mm	17mm	7°
1034-302-618	30mm	26mm	18mm	7°
1034-302-619	30mm	26mm	19mm	7°
1034-302-620	30mm	26mm	20mm	7°
1034-302-621	30mm	26mm	21mm	7°
1034-342-811	34mm	28mm	11mm	7°
1034-342-812	34mm	28mm	12mm	7°
1034-342-813	34mm	28mm	13mm	7°
1034-342-814	34mm	28mm	14mm	7°
1034-342-815	34mm	28mm	15mm	7°
1034-342-816	34mm	28mm	16mm	7°
1034-342-817	34mm	28mm	17mm	7°
1034-342-818	34mm	28mm	18mm	7°
1034-342-819	34mm	28mm	19mm	7°
1034-342-820	34mm	28mm	20mm	7°
1034-342-821	34mm	28mm	21mm	7°
1034-383-011	38mm	30mm	11mm	7°
1034-383-012	38mm	30mm	12mm	7°
1034-383-013	38mm	30mm	13mm	7°
1034-383-014	38mm	30mm	14mm	7°
1034-383-015	38mm	30mm	15mm	7°
1034-383-016	38mm	30mm	16mm	7°
1034-383-017	38mm	30mm	17mm	7°
1034-383-018	38mm	30mm	18mm	7°
1034-383-019	38mm	30mm	19mm	7°
1034-383-020	38mm	30mm	20mm	7°
1034-383-021	38mm	30mm	21mm	7°
1035-302-611	30mm	26mm	11mm	12°
1035-302-612	30mm	26mm	12mm	12°
1035-302-613	30mm	26mm	13mm	12°
1035-302-614	30mm	26mm	14mm	12°
1035-302-615	30mm	26mm	15mm	12°

1035-302-616	30mm	26mm	16mm	12°
1035-302-617	30mm	26mm	17mm	12°
1035-302-618	30mm	26mm	18mm	12°
1035-302-619	30mm	26mm	19mm	12°
1035-302-620	30mm	26mm	20mm	12°
1035-302-621	30mm	26mm	21mm	12°
1035-342-811	34mm	28mm	11mm	12°
1035-342-812	34mm	28mm	12mm	12°
1035-342-813	34mm	28mm	13mm	12°
1035-342-814	34mm	28mm	14mm	12°
1035-342-815	34mm	28mm	15mm	12°
1035-342-816	34mm	28mm	16mm	12°
1035-342-817	34mm	28mm	17mm	12°
1035-342-818	34mm	28mm	18mm	12°
1035-342-819	34mm	28mm	19mm	12°
1035-342-820	34mm	28mm	20mm	12°
1035-342-821	34mm	28mm	21mm	12°
1035-383-011	38mm	30mm	11mm	12°
1035-383-012	38mm	30mm	12mm	12°
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1035-383-016	38mm	30mm	16mm	12°
1035-383-017	38mm	30mm	17mm	12°
1035-383-018	38mm	30mm	18mm	12°
1035-383-019	38mm	30mm	19mm	12°
1035-383-020	38mm	30mm	20mm	12°
1035-383-021	38mm	30mm	21mm	12°

### Renovis PEEK Implants - Non-Sterile

Part Number	Width	Depth	Height	Lordosis
1134-302-611	30mm	26mm	11mm	7°
1134-302-612	30mm	26mm	12mm	7°
1134-302-613	30mm	26mm	13mm	7°
1134-302-614	30mm	26mm	14mm	7°
1134-302-615	30mm	26mm	15mm	7°
1134-302-616	30mm	26mm	16mm	7°
1134-302-617	30mm	26mm	17mm	7°
1134-302-618	30mm	26mm	18mm	7°
1134-302-619	30mm	26mm	19mm	7°
1134-302-620	30mm	26mm	20mm	7°
1134-302-621	30mm	26mm	21mm	7°
1134-342-811	34mm	28mm	11mm	7°

1134-342-812	34mm	28mm	12mm	7°
1134-342-813	34mm	28mm	13mm	7°
1134-342-814	34mm	28mm	14mm	7°
1134-342-815	34mm	28mm	15mm	7°
1134-342-816	34mm	28mm	16mm	7°
1134-342-817	34mm	28mm	17mm	7°
1134-342-818	34mm	28mm	18mm	7°
1134-342-819	34mm	28mm	19mm	7°
1134-342-820	34mm	28mm	20mm	7°
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1134-383-014	38mm	30mm	14mm	7°
1134-383-015	38mm	30mm	15mm	7°
1134-383-016	38mm	30mm	16mm	7°
1134-383-017	38mm	30mm	17mm	7°
1134-383-018	38mm	30mm	18mm	7°
1134-383-019	38mm	30mm	19mm	7°
1134-383-020	38mm	30mm	20mm	7°
1134-383-021	38mm	30mm	21mm	7°
1135-302-611	30mm	26mm	11mm	12°
1135-302-612	30mm	26mm	12mm	12°
1135-302-613	30mm	26mm	13mm	12°
1135-302-614	30mm	26mm	14mm	12°
1135-302-615	30mm	26mm	15mm	12°
1135-302-616	30mm	26mm	16mm	12°
1135-302-617	30mm	26mm	17mm	12°
1135-302-618	30mm	26mm	18mm	12°
1135-302-619	30mm	26mm	19mm	12°
1135-302-620	30mm	26mm	20mm	12°
1135-302-621	30mm	26mm	21mm	12°
1135-342-811	34mm	28mm	11mm	12°
1135-342-812	34mm	28mm	12mm	12°
1135-342-813	34mm	28mm	13mm	12°
1135-342-814	34mm	28mm	14mm	12°
1135-342-815	34mm	28mm	15mm	12°
1135-342-816	34mm	28mm	16mm	12°
1135-342-817	34mm	28mm	17mm	12°
1135-342-818	34mm	28mm	18mm	12°
1135-342-819	34mm	28mm	19mm	12°
1135-342-820	34mm	28mm	20mm	12°
1135-342-821	34mm	28mm	21mm	12°
1135-383-011	38mm	30mm	11mm	12°

1135-383-012	38mm	30mm	12mm	12°
1135-383-013	38mm	30mm	13mm	12°
1135-383-014	38mm	30mm	14mm	12°
1135-383-015	38mm	30mm	15mm	12°
1135-383-016	38mm	30mm	16mm	12°
1135-383-017	38mm	30mm	17mm	12°
1135-383-018	38mm	30mm	18mm	12°
1135-383-019	38mm	30mm	19mm	12°
1135-383-020	38mm	30mm	20mm	12°
1135-383-021	38mm	30mm	21mm	12°

### Renovis Titanium Implants - Sterile

Part Number	Width	Depth	Height	Lordosis
1036-302-611	30mm	26mm	11mm	7°
1036-302-612	30mm	26mm	12mm	7°
1036-302-613	30mm	26mm	13mm	7°
1036-302-614	30mm	26mm	14mm	7°
1036-302-615	30mm	26mm	15mm	7°
1036-302-616	30mm	26mm	16mm	7°
1036-302-617	30mm	26mm	17mm	7°
1036-302-618	30mm	26mm	18mm	7°
1036-302-619	30mm	26mm	19mm	7°
1036-302-620	30mm	26mm	20mm	7°
1036-302-621	30mm	26mm	21mm	7°
1036-342-811	34mm	28mm	11mm	7°
1036-342-812	34mm	28mm	12mm	7°
1036-342-813	34mm	28mm	13mm	7°
1036-342-814	34mm	28mm	14mm	7°
1036-342-815	34mm	28mm	15mm	7°
1036-342-816	34mm	28mm	16mm	7°
1036-342-817	34mm	28mm	17mm	7°
1036-342-818	34mm	28mm	18mm	7°
1036-342-819	34mm	28mm	19mm	7°
1036-342-820	34mm	28mm	20mm	7°
1036-342-821	34mm	28mm	21mm	7°
1036-383-011	38mm	30mm	11mm	7°
1036-383-012	38mm	30mm	12mm	7°
1036-383-013	38mm	30mm	13mm	7°
1036-383-014	38mm	30mm	14mm	7°
1036-383-015	38mm	30mm	15mm	7°
1036-383-016	38mm	30mm	16mm	7°
1036-383-017	38mm	30mm	17mm	7°

1036-383-018	38mm	30mm	18mm	7°
1036-383-019	38mm	30mm	19mm	7°
1036-383-020	38mm	30mm	20mm	7°
1036-383-021	38mm	30mm	21mm	7°
1037-302-611	30mm	26mm	11mm	12°
1037-302-612	30mm	26mm	12mm	12°
1037-302-613	30mm	26mm	13mm	12°
1037-302-614	30mm	26mm	14mm	12°
1037-302-615	30mm	26mm	15mm	12°
1037-302-616	30mm	26mm	16mm	12°
1037-302-617	30mm	26mm	17mm	12°
1037-302-618	30mm	26mm	18mm	12°
1037-302-619	30mm	26mm	19mm	12°
1037-302-620	30mm	26mm	20mm	12°
1037-302-621	30mm	26mm	21mm	12°
1037-342-811	34mm	28mm	11mm	12°
1037-342-812	34mm	28mm	12mm	12°
1037-342-813	34mm	28mm	13mm	12°
1037-342-814	34mm	28mm	14mm	12°
1037-342-815	34mm	28mm	15mm	12°
1037-342-816	34mm	28mm	16mm	12°
1037-342-817	34mm	28mm	17mm	12°
1037-342-818	34mm	28mm	18mm	12°
1037-342-819	34mm	28mm	19mm	12°
1037-342-820	34mm	28mm	20mm	12°
1037-342-821	34mm	28mm	21mm	12°
1037-383-011	38mm	30mm	11mm	12°
1037-383-012	38mm	30mm	12mm	12°
1037-383-013	38mm	30mm	13mm	12°
1037-383-014	38mm	30mm	14mm	12°
1037-383-015	38mm	30mm	15mm	12°
1037-383-016	38mm	30mm	16mm	12°
1037-383-017	38mm	30mm	17mm	12°
1037-383-018	38mm	30mm	18mm	12°
1037-383-019	38mm	30mm	19mm	12°
1037-383-020	38mm	30mm	20mm	12°
1037-383-021	38mm	30mm	21mm	12°

### Renovis Titanium Implants -Non-Sterile

Part Number	Width	Depth	Height	Lordosis
1136-302-611	30mm	26mm	11mm	7°
1136-302-612	30mm	26mm	12mm	7°

1136-302-613	30mm	26mm	13mm	7°
1136-302-614	30mm	26mm	14mm	7°
1136-302-615	30mm	26mm	15mm	7°
1136-302-616	30mm	26mm	16mm	7°
1136-302-617	30mm	26mm	17mm	7°
1136-302-618	30mm	26mm	18mm	7°
1136-302-619	30mm	26mm	19mm	7°
1136-302-620	30mm	26mm	20mm	7°
1136-302-621	30mm	26mm	21mm	7°
1136-342-811	34mm	28mm	11mm	7°
1136-342-812	34mm	28mm	12mm	7°
1136-342-813	34mm	28mm	13mm	7°
1136-342-814	34mm	28mm	14mm	7°
1136-342-815	34mm	28mm	15mm	7°
1136-342-816	34mm	28mm	16mm	7°
1136-342-817	34mm	28mm	17mm	7°
1136-342-818	34mm	28mm	18mm	7°
1136-342-819	34mm	28mm	19mm	7°
1136-342-820	34mm	28mm	20mm	7°
1136-342-821	34mm	28mm	21mm	7°
1136-383-011	38mm	30mm	11mm	7°
1136-383-012	38mm	30mm	12mm	7°
1136-383-013	38mm	30mm	13mm	7°
1136-383-014	38mm	30mm	14mm	7°
1136-383-015	38mm	30mm	15mm	7°
1136-383-016	38mm	30mm	16mm	7°
1136-383-017	38mm	30mm	17mm	7°
1136-383-018	38mm	30mm	18mm	7°
1136-383-019	38mm	30mm	19mm	7°
1136-383-020	38mm	30mm	20mm	7°
1136-383-021	38mm	30mm	21mm	7°
1137-302-611	30mm	26mm	11mm	12°
1137-302-612	30mm	26mm	12mm	12°
1137-302-613	30mm	26mm	13mm	12°
1137-302-614	30mm	26mm	14mm	12°
1137-302-615	30mm	26mm	15mm	12°
1137-302-616	30mm	26mm	16mm	12°
1137-302-617	30mm	26mm	17mm	12°
1137-302-618	30mm	26mm	18mm	12°
1137-302-619	30mm	26mm	19mm	12°
1137-302-620	30mm	26mm	20mm	12°
1137-302-621	30mm	26mm	21mm	12°
1137-342-811	34mm	28mm	11mm	12°
1137-342-812	34mm	28mm	12mm	12°

1137-342-813	34mm	28mm	13mm	12°
1137-342-814	34mm	28mm	14mm	12°
1137-342-815	34mm	28mm	15mm	12°
1137-342-816	34mm	28mm	16mm	12°
1137-342-817	34mm	28mm	17mm	12°
1137-342-818	34mm	28mm	18mm	12°
1137-342-819	34mm	28mm	19mm	12°
1137-342-820	34mm	28mm	20mm	12°
1137-342-821	34mm	28mm	21mm	12°
1137-383-011	38mm	30mm	11mm	12°
1137-383-012	38mm	30mm	12mm	12°
1137-383-013	38mm	30mm	13mm	12°
1137-383-014	38mm	30mm	14mm	12°
1137-383-015	38mm	30mm	15mm	12°
1137-383-016	38mm	30mm	16mm	12°
1137-383-017	38mm	30mm	17mm	12°
1137-383-018	38mm	30mm	18mm	12°
1137-383-019	38mm	30mm	19mm	12°
1137-383-020	38mm	30mm	20mm	12°
1137-383-021	38mm	30mm	21mm	12°

### Renovis Instrumentation

Part Number	Description
2128-001-001	Implant Inserter
2128-001-003	Implant Impactor
2128-001-005	Trial Implant/Bullet Distractor Inserter
2128-001-006	Rasp
2128-001-015	Small Cup Curette
2128-001-016	Large Cup Curette
2128-001-017	Small Up Angled Cup Curette
2128-001-018	Ringed Curette
2128-001-019	Chisel
2128-001-020	23mm Sharp Cobb
2128-001-021	17mm Sharp Cobb
2128-001-023	Small Syper Rongeur
2128-001-024	Large Syper Rongeur
2128-001-025	3mm Pituitary Rongeur
2128-001-026	5mm Pituitary Rongeur
2128-001-027	Small Kerrison Rongeur
2128-001-028	Large Kerrison Rongeur
2128-001-029	Small Modular Handle
2128-001-030	Large Modular Handle
2128-001-031	Large Threaded Handle

2128-001-032	Angled Implant Inserter
2128-001-035	Packing Block
2128-001-036	Long Scalpel Handle
2128-003-026	Small Paddle Sizer
2128-003-428	Medium Paddle Sizer
2128-003-830	Large Paddle Sizer
2128-002-009	9mm Bullet Nose Distractor
2128-002-011	11mm Bullet Nose Distractor
2128-002-013	13mm Bullet Nose Distractor
2128-002-015	15mm Bullet Nose Distractor
2128-002-017	17mm Bullet Nose Distractor
2128-002-019	19mm Bullet Nose Distractor
2128-002-021	21mm Bullet Nose Distractor
2128-302-611	11mm Trial, 30x26 7°
2128-302-612	12mm Trial, 30x26 7°
2128-302-613	13mm Trial, 30x26 7°
2128-302-614	14mm Trial, 30x26 7°
2128-302-615	15mm Trial, 30x26 7°
2128-302-616	16mm Trial, 30x26 7°
2128-302-617	17mm Trial, 30x26 7°
2128-302-618	18mm Trial, 30x26 7°
2128-302-619	19mm Trial, 30x26 7°
2128-302-620	20mm Trial, 30x26 7°
2128-302-621	21mm Trial, 30x26 7°
2128-342-811	11mm Trial, 34x28 7°
2128-342-812	12mm Trial, 34x28 7°
2128-342-813	13mm Trial, 34x28 7°
2128-342-814	14mm Trial, 34x28 7°
2128-342-815	15mm Trial, 34x28 7°
2128-342-816	16mm Trial, 34x28 7°
2128-342-817	17mm Trial, 34x28 7°
2128-342-818	18mm Trial, 34x28 7°
2128-342-819	19mm Trial, 34x28 7°
2128-342-820	20mm Trial, 34x28 7°
2128-342-821	21mm Trial, 34x28 7°
2128-383-011	11mm Trial, 38x28 7°
2128-383-012	12mm Trial, 38x30 7°
2128-383-013	13mm Trial, 38x30 7°
2128-383-014	14mm Trial, 38x30 7°
2128-383-015	15mm Trial, 38x30 7°
2128-383-016	16mm Trial, 38x30 7°
2128-383-017	17mm Trial, 38x30 7°
2128-383-018	18mm Trial, 38x30 7°
2128-383-019	19mm Trial, 38x30 7°
2128-383-020	20mm Trial, 38x30 7°

2128-383-021	21mm Trial, 38x30 7°
2129-302-611	11mm Trial, 30x26 12°
2129-302-612	12mm Trial, 30x26 12°
2129-302-613	13mm Trial, 30x26 12°
2129-302-614	14mm Trial, 30x26 12°
2129-302-615	15mm Trial, 30x26 12°
2129-302-616	16mm Trial, 30x26 12°
2129-302-617	17mm Trial, 30x26 12°
2129-302-618	18mm Trial, 30x26 12°
2129-302-619	19mm Trial, 30x26 12°
2129-302-620	20mm Trial, 30x26 12°
2129-302-621	21mm Trial, 30x26 12°
2129-342-811	11mm Trial, 34x28 12°
2129-342-812	12mm Trial, 34x28 12°
2129-342-813	13mm Trial, 34x28 12°
2129-342-814	14mm Trial, 34x28 12°
2129-342-815	15mm Trial, 34x28 12°
2129-342-816	16mm Trial, 34x28 12°
2129-342-817	17mm Trial, 34x28 12°
2129-342-818	18mm Trial, 34x28 12°
2129-342-819	19mm Trial, 34x28 12°
2129-342-820	20mm Trial, 34x28 12°
2129-342-821	21mm Trial, 34x28 12°
2129-383-011	11mm Trial, 38x28 12°
2129-383-012	12mm Trial, 38x30 12°
2129-383-013	13mm Trial, 38x30 12°
2129-383-014	14mm Trial, 38x30 12°
2129-383-015	15mm Trial, 38x30 12°
2129-383-016	16mm Trial, 38x30 12°
2129-383-017	17mm Trial, 38x30 12°
2129-383-018	18mm Trial, 38x30 12°
2129-383-019	19mm Trial, 38x30 12°
2129-383-020	20mm Trial, 38x30 12°
2129-383-021	21mm Trial, 38x30 12°

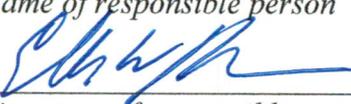


### Declaration of Conformity with Design Controls

1. As required by risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met; and
2. Renovis Surgical Technologies is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Charles Mumme

\_\_\_\_\_  
*Name of responsible person*

  
\_\_\_\_\_  
*Signature of responsible person*

7/24/2014  
\_\_\_\_\_  
*Date*

CONFIDENTIAL

**MEDICEPT**  
Medical Device Compliance Consulting

K142095/S001

FDA CDRH DMC

AUG 13 2014

Received

August 12, 2014

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

**Re:** RTA response 510(k) Number K142095 – Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) System

To Whom It May Concern:

Enclosed please find responses to the Refuse To Accept notification received by email on 8/6/2014.

The eCopy is an exact duplicate of the paper copy. The files have been paginated per the FDA "Refuse to Accept Policy for 510(k)s Guidance for Industry and Food and Drug Administration Staff", December 31, 2012.

Revised and updated engineering drawings are included in the folder MISC FILES.

If there are any questions regarding this submission, please contact me at 401-330-8264 or by email at [sorton@medicept.com](mailto:sorton@medicept.com).

Sincerely yours,

*Sharyn Orton*

Sharyn Orton, Ph.D.  
Senior Consultant  
MEDIcept, Inc.  
for  
Renovis Surgical Technologies

CONFIDENTIAL  
200 Homer Ave.

MEDIcept, Inc.  
Renovis S134 ALIF System

Ashland, MA 01721  
RTA Response K142095  
1-1

59  
led



August 12, 2014

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

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Sincerely yours,

Sharyn Orton, Ph.D.  
Senior Consultant  
MEDIcept, Inc.  
*for*  
Renovis Surgical Technologies

CONFIDENTIAL  
200 Homer Ave.

MEDIcept, Inc.  
Renovis S134 ALIF System

Ashland, MA 01721  
RTA Response K142095

1-1

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RTA K142095 revised Device Description Description of Change	003

MEDIcept, Inc.  
Renovis S134 ALIF System

CONFIDENTIAL  
200 Homer Ave.

Ashland, MA 01721  
RTA Response K142095  
1-2



From: [Hall, Melissa A \(CDRH\)  
\[Melissa.A.Hall@fda.hhs.gov\]](mailto:Melissa.A.Hall@fda.hhs.gov) Sent: Thu 8/7/2014 10:21 AM  
To: [Sharyn Orton](mailto:Sharyn.orton@medicept.com)  
Cc:  
Subject: RE: K142095 was Refused

Attachments:

Dear Ms. Orton,

Please provide **(b)(4) Deficiencies** for your subject device.

Thank you,

Melissa

Melissa Hall, M.S.  
Biomedical Engineer  
Anterior Spine Devices Branch  
FDA/CDRH/ODE/DOD  
10903 New Hampshire Avenue  
WO66 Room 1545  
Silver Spring, MD 20993-0002  
301-796-6920  
301-796-6947 (direct)  
301-847-8119 (fax)  
[Melissa.A.Hall@fda.hhs.gov](mailto:Melissa.A.Hall@fda.hhs.gov)

Excellent customer service is important to us. Please take a moment to provide [feedback](#) regarding the customer service you have received.

**From:** Sharyn Orton [mailto:sorton@medicept.com]  
**Sent:** Thursday, August 07, 2014 10:02 AM  
**To:** Hall, Melissa A (CDRH)  
**Subject:** RE: K142095 was Refused

Ms. Hall

**(b)(4) Deficiencies**

(b)(4) Deficiencies



Thank you in advance for your assistance.

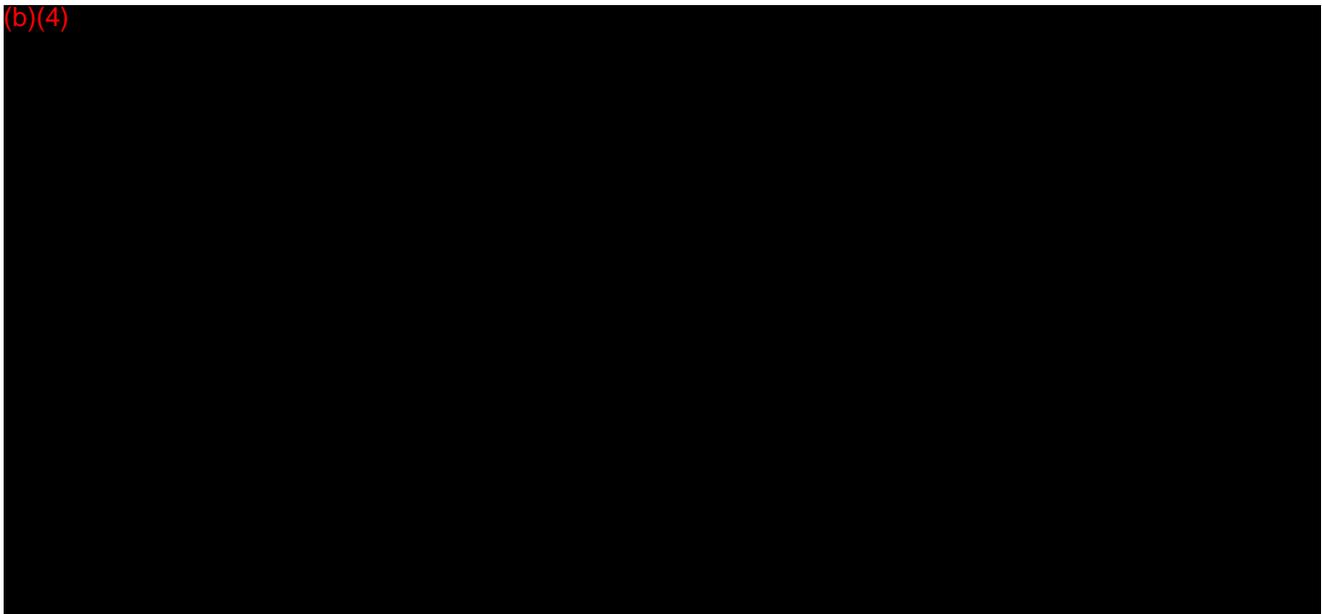
Sharyn Orton, PhD  
Senior Consultant  
MEDicept, Inc.  
401-330-8264

## Device Description

The Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) System consists of implants (cages) and device specific instrumentation. The Renovis S134 ALIF System cages are developed for the anterior posterior stabilization of the lumbar spinal column, and are available in a variety of sizes (widths, height, depths, and bone screw sizes) to suit the individual pathology and anatomical conditions of the patient (Table 1). The cages are available in two lordotic configurations (7° and 12°) of various heights to restore lumbar lordosis and the associated sagittal balance. A large cavity is designed into the body of the cage allowing placement of bone graft material and facilitating fusion (see pictures below). The superior and inferior surfaces of the devices have a pattern of teeth to provide increased stability and inhibit movement of the cages. The Renovis S134 ALIF System cages are not stand alone and are to be used with FDA cleared supplementary fixation systems.

The S134 ALIF System cages (S134 cages) are a modification of the Renovis FDA cleared S128 ALIF System cages (S128 cages) in that the screw holes have been removed. This modification is being made for the purpose of expanding the Renovis ALIF System offerings, per customer request. The footprint of the S128 and S134 are exactly the same physical ID and OD profile dimensions. However, the S128 has screw holes which cut through a small portion of the ID profile, reducing endplate surface contact area. Therefore, the S134 not having screw holes has a slightly greater endplate surface contact area.

(b)(4)



Engineering drawings are included in (b)(4)

Renovis S134 ALIF System

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RTA response K142095

**Table 1 Summary**

<b>Cages</b>	<b>Description</b>
Materials	(b)(4) PEEK (b)(4) with Tantalum markers Titanium alloy Ti-6Al-4v
Manufacturing method	PEEK cages: traditional Ti-6Al-4v cages: additive manufacturing (EBM)
Dimensions	26, 28, 30
A/P	30, 34, 38
M/L	11 – 21
H	Δ1mm
Foot print	30 x 26D 34 x 28D 38 x 30D
Lordosis	7°, 12°
Bone graft volume	2270-7920 mm <sup>3</sup>
End plate coverage	(b)(4)
Sterilization	Gamma irradiation or non-sterile (requiring steam sterilization by end user)

*Materials*

The Renovis S134 ALIF System cages are manufactured from PEEK or titanium alloy (Ti-6Al-4V). The PEEK component is radiolucent with tantalum markers for visualization in the disc space.

The PEEK cages are manufactured from PolyEtherEtherKetone (PEEK) per ASTM F2026-12 *Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications*. The PEEK is supplied by (b)(4) letter included on page 3-10). Each cage has three X-Ray markers pressed into it for radiographic visualization. The three markers (pins) are manufactured from Tantalum per ASTM F560-08 *Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)*.

The titanium cages (also known as Tesera cages) are manufactured from Ti-6Al-4v per ASTM F136-13 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*.

(b)(4)

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Renovis S134 ALIF System

RTA response K142095

further in this application. The titanium cages do not require radiographic markers. The Ti-6Al-4V cages are additively manufactured (ARCAM EBM) and machined titanium.

*Sterilization*

The S134 ALIF System cages are offered either gamma irradiated or as non-sterile requiring steam sterilization by the end user.

**Description of the Change – Removal of screw holes**

The Renovis S134 ALIF System cages are a modification to the S128 ALIF System cages, but are manufactured the same with the exception that the screw holes have been eliminated.

**Parts Numbers**

The parts numbers and geometry are included in Tables 2 and 3. The Table 2 and 3 geometry is reproduced from K131122 (the bone graft volume and contact area/endplate are calculated estimates – rounded down to closest 10 mm<sup>3</sup>). The foot print of the S128 and S134 are exactly the same physical ID and OD profile dimensions. However, because the S134 does not have screw holes, the endplate surface contact area will be slightly greater than the figures presented here.

The part number for the non-sterilized is the same as the part number below, but will start with “11” rather than 10 (for example, 1034-302-611 and 1134-203-611).

**Table 2: PEEK Cage Geometry – Sterile**

Part Number	Width	Depth	Height	Lordosis	Bone Graft Volume
1034-302-611	30mm	26mm	11mm	7°	2270mm <sup>3</sup>
1034-302-612	30mm	26mm	12mm	7°	2520 mm <sup>3</sup>
1034-302-613	30mm	26mm	13mm	7°	2770 mm <sup>3</sup>
1034-302-614	30mm	26mm	14mm	7°	3020 mm <sup>3</sup>
1034-302-615	30mm	26mm	15mm	7°	3270 mm <sup>3</sup>
1034-302-616	30mm	26mm	16mm	7°	3530 mm <sup>3</sup>
1034-302-617	30mm	26mm	17mm	7°	3780 mm <sup>3</sup>
1034-302-618	30mm	26mm	18mm	7°	4030 mm <sup>3</sup>
1034-302-619	30mm	26mm	19mm	7°	4280 mm <sup>3</sup>
1034-302-620	30mm	26mm	20mm	7°	4540 mm <sup>3</sup>
1034-302-621	30mm	26mm	21mm	7°	4790 mm <sup>3</sup>
1034-342-811	34mm	28mm	11mm	7°	2940 mm <sup>3</sup>
1034-342-812	34mm	28mm	12mm	7°	3270 mm <sup>3</sup>
1034-342-813	34mm	28mm	13mm	7°	3600 mm <sup>3</sup>
1034-342-814	34mm	28mm	14mm	7°	3920 mm <sup>3</sup>
1034-342-815	34mm	28mm	15mm	7°	4250 mm <sup>3</sup>

(b)(4)

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1034-342-816	34mm	28mm	16mm	7°	4580 mm <sup>3</sup>	(b)(4)
1034-342-817	34mm	28mm	17mm	7°	4910 mm <sup>3</sup>	
1034-342-818	34mm	28mm	18mm	7°	5230 mm <sup>3</sup>	
1034-342-819	34mm	28mm	19mm	7°	5560 mm <sup>3</sup>	
1034-342-820	34mm	28mm	20mm	7°	5890 mm <sup>3</sup>	
1034-342-821	34mm	28mm	21mm	7°	6210 mm <sup>3</sup>	
1034-383-011	38mm	30mm	11mm	7°	3950 mm <sup>3</sup>	
1034-383-012	38mm	30mm	12mm	7°	4400 mm <sup>3</sup>	
1034-383-013	38mm	30mm	13mm	7°	4840 mm <sup>3</sup>	
1034-383-014	38mm	30mm	14mm	7°	5290 mm <sup>3</sup>	
1034-383-015	38mm	30mm	15mm	7°	5740 mm <sup>3</sup>	
1034-383-016	38mm	30mm	16mm	7°	6190 mm <sup>3</sup>	
1034-383-017	38mm	30mm	17mm	7°	6630 mm <sup>3</sup>	
1034-383-018	38mm	30mm	18mm	7°	7080 mm <sup>3</sup>	
1034-383-019	38mm	30mm	19mm	7°	7530 mm <sup>3</sup>	
1034-383-020	38mm	30mm	20mm	7°	7970 mm <sup>3</sup>	
1034-383-021	38mm	30mm	21mm	7°	8420 mm <sup>3</sup>	
1035-302-611	30mm	26mm	11mm	12°	2060 mm <sup>3</sup>	
1035-302-612	30mm	26mm	12mm	12°	2310 mm <sup>3</sup>	
1035-302-613	30mm	26mm	13mm	12°	2560 mm <sup>3</sup>	
1035-302-614	30mm	26mm	14mm	12°	2810 mm <sup>3</sup>	
1035-302-615	30mm	26mm	15mm	12°	3060 mm <sup>3</sup>	
1035-302-616	30mm	26mm	16mm	12°	3320 mm <sup>3</sup>	
1035-302-617	30mm	26mm	17mm	12°	3570 mm <sup>3</sup>	
1035-302-618	30mm	26mm	18mm	12°	3820 mm <sup>3</sup>	
1035-302-619	30mm	26mm	19mm	12°	4070 mm <sup>3</sup>	
1035-302-620	30mm	26mm	20mm	12°	4320 mm <sup>3</sup>	
1035-302-621	30mm	26mm	21mm	12°	4570 mm <sup>3</sup>	
1035-342-811	34mm	28mm	11mm	12°	2610 mm <sup>3</sup>	
1035-342-812	34mm	28mm	12mm	12°	2940 mm <sup>3</sup>	
1035-342-813	34mm	28mm	13mm	12°	3270 mm <sup>3</sup>	
1035-342-814	34mm	28mm	14mm	12°	3590 mm <sup>3</sup>	
1035-342-815	34mm	28mm	15mm	12°	3920 mm <sup>3</sup>	
1035-342-816	34mm	28mm	16mm	12°	4250 mm <sup>3</sup>	
1035-342-817	34mm	28mm	17mm	12°	4570 mm <sup>3</sup>	
1035-342-818	34mm	28mm	18mm	12°	4900 mm <sup>3</sup>	
1035-342-819	34mm	28mm	19mm	12°	5230 mm <sup>3</sup>	
1035-342-820	34mm	28mm	20mm	12°	5560 mm <sup>3</sup>	
1035-342-821	34mm	28mm	21mm	12°	5880 mm <sup>3</sup>	

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1035-383-011	38mm	30mm	11mm	12°	3450 mm <sup>3</sup>	(b)(4)
1035-383-012	38mm	30mm	12mm	12°	3900 mm <sup>3</sup>	
1035-383-013	38mm	30mm	13mm	12°	4340 mm <sup>3</sup>	
1035-383-014	38mm	30mm	14mm	12°	4790 mm <sup>3</sup>	
1035-383-015	38mm	30mm	15mm	12°	5240 mm <sup>3</sup>	
1035-383-016	38mm	30mm	16mm	12°	5680 mm <sup>3</sup>	
1035-383-017	38mm	30mm	17mm	12°	6130 mm <sup>3</sup>	
1035-383-018	38mm	30mm	18mm	12°	6580 mm <sup>3</sup>	
1035-383-019	38mm	30mm	19mm	12°	7030 mm <sup>3</sup>	
1035-383-020	38mm	30mm	20mm	12°	7470 mm <sup>3</sup>	
1035-383-021	38mm	30mm	21mm	12°	7920 mm <sup>3</sup>	

**Table 3: Titanium Cage Geometry – Sterile**

Part Number	Width	Depth	Height	Lordosis	Bone Graft Volume	(b)(4)
1036-302-611	30mm	26mm	11mm	7°	2270mm <sup>3</sup>	
1036-302-612	30mm	26mm	12mm	7°	2520 mm <sup>3</sup>	
1036-302-613	30mm	26mm	13mm	7°	2770 mm <sup>3</sup>	
1036-302-614	30mm	26mm	14mm	7°	3020 mm <sup>3</sup>	
1036-302-615	30mm	26mm	15mm	7°	3270 mm <sup>3</sup>	
1036-302-616	30mm	26mm	16mm	7°	3530 mm <sup>3</sup>	
1036-302-617	30mm	26mm	17mm	7°	3780 mm <sup>3</sup>	
1036-302-618	30mm	26mm	18mm	7°	4030 mm <sup>3</sup>	
1036-302-619	30mm	26mm	19mm	7°	4280 mm <sup>3</sup>	
1036-302-620	30mm	26mm	20mm	7°	4540 mm <sup>3</sup>	
1036-302-621	30mm	26mm	21mm	7°	4790 mm <sup>3</sup>	
1036-342-811	34mm	28mm	11mm	7°	2940 mm <sup>3</sup>	
1036-342-812	34mm	28mm	12mm	7°	3270 mm <sup>3</sup>	
1036-342-813	34mm	28mm	13mm	7°	3600 mm <sup>3</sup>	
1036-342-814	34mm	28mm	14mm	7°	3920 mm <sup>3</sup>	
1036-342-815	34mm	28mm	15mm	7°	4250 mm <sup>3</sup>	
1036-342-816	34mm	28mm	16mm	7°	4580 mm <sup>3</sup>	
1036-342-817	34mm	28mm	17mm	7°	4910 mm <sup>3</sup>	
1036-342-818	34mm	28mm	18mm	7°	5230 mm <sup>3</sup>	
1036-342-819	34mm	28mm	19mm	7°	5560 mm <sup>3</sup>	
1036-342-820	34mm	28mm	20mm	7°	5890 mm <sup>3</sup>	
1036-342-821	34mm	28mm	21mm	7°	6210 mm <sup>3</sup>	
1036-383-011	38mm	30mm	11mm	7°	3950 mm <sup>3</sup>	

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Renovis S134 ALIF System

RTA response K142095

1036-383-012	38mm	30mm	12mm	7°	4400 mm <sup>3</sup>
1036-383-013	38mm	30mm	13mm	7°	4840 mm <sup>3</sup>
1036-383-014	38mm	30mm	14mm	7°	5290 mm <sup>3</sup>
1036-383-015	38mm	30mm	15mm	7°	5740 mm <sup>3</sup>
1036-383-016	38mm	30mm	16mm	7°	6190 mm <sup>3</sup>
1036-383-017	38mm	30mm	17mm	7°	6630 mm <sup>3</sup>
1036-383-018	38mm	30mm	18mm	7°	7080 mm <sup>3</sup>
1036-383-019	38mm	30mm	19mm	7°	7530 mm <sup>3</sup>
1036-383-020	38mm	30mm	20mm	7°	7970 mm <sup>3</sup>
1036-383-021	38mm	30mm	21mm	7°	8420 mm <sup>3</sup>
1037-302-611	30mm	26mm	11mm	12°	2060 mm <sup>3</sup>
1037-302-612	30mm	26mm	12mm	12°	2310 mm <sup>3</sup>
1037-302-613	30mm	26mm	13mm	12°	2560 mm <sup>3</sup>
1037-302-614	30mm	26mm	14mm	12°	2810 mm <sup>3</sup>
1037-302-615	30mm	26mm	15mm	12°	3060 mm <sup>3</sup>
1037-302-616	30mm	26mm	16mm	12°	3320 mm <sup>3</sup>
1037-302-617	30mm	26mm	17mm	12°	3570 mm <sup>3</sup>
1037-302-618	30mm	26mm	18mm	12°	3820 mm <sup>3</sup>
1037-302-619	30mm	26mm	19mm	12°	4070 mm <sup>3</sup>
1037-302-620	30mm	26mm	20mm	12°	4320 mm <sup>3</sup>
1037-302-621	30mm	26mm	21mm	12°	4570 mm <sup>3</sup>
1037-342-811	34mm	28mm	11mm	12°	2610 mm <sup>3</sup>
1037-342-812	34mm	28mm	12mm	12°	2940 mm <sup>3</sup>
1037-342-813	34mm	28mm	13mm	12°	3270 mm <sup>3</sup>
1037-342-814	34mm	28mm	14mm	12°	3590 mm <sup>3</sup>
1037-342-815	34mm	28mm	15mm	12°	3920 mm <sup>3</sup>
1037-342-816	34mm	28mm	16mm	12°	4250 mm <sup>3</sup>
1037-342-817	34mm	28mm	17mm	12°	4570 mm <sup>3</sup>
1037-342-818	34mm	28mm	18mm	12°	4900 mm <sup>3</sup>
1037-342-819	34mm	28mm	19mm	12°	5230 mm <sup>3</sup>
1037-342-820	34mm	28mm	20mm	12°	5560 mm <sup>3</sup>
1037-342-821	34mm	28mm	21mm	12°	5880 mm <sup>3</sup>
1037-383-011	38mm	30mm	11mm	12°	3450 mm <sup>3</sup>
1037-383-012	38mm	30mm	12mm	12°	3900 mm <sup>3</sup>
1037-383-013	38mm	30mm	13mm	12°	4340 mm <sup>3</sup>
1037-383-014	38mm	30mm	14mm	12°	4790 mm <sup>3</sup>
1037-383-015	38mm	30mm	15mm	12°	5240 mm <sup>3</sup>
1037-383-016	38mm	30mm	16mm	12°	5680 mm <sup>3</sup>
1037-383-017	38mm	30mm	17mm	12°	6130 mm <sup>3</sup>

(b)(4)

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1037-383-018	38mm	30mm	18mm	12°	6580 mm <sup>3</sup>	(b)(4)	(b)(4)
1037-383-019	38mm	30mm	19mm	12°	7030 mm <sup>3</sup>		
1037-383-020	38mm	30mm	20mm	12°	7470 mm <sup>3</sup>		
1037-383-021	38mm	30mm	21mm	12°	7920 mm <sup>3</sup>		

### *Device Specific Instruments*

Instruments are provided that allow performance of a discectomy, preparation of the disc space, trialing to determine optimal implant width and height, endplate preparation, and implant insertion. The device specific instruments used with the S134 ALIF System cages are the same as those included in K131122 for the S128 ALIF System cages (listed in K131122, 011\_Device Description) and include trials, sizers, and implant/cage inserters. There are no new device specific instruments. The device specific instruments from K131122 are listed in Table 4. General use (Class I), non-device specific instruments are also provided, but are not included here.

**Table 4: Instruments provided (from K131122)**

Part Number	Description	Functionality
2128-001-001	Implant Inserter	Insert Cage
2128-001-032	Angled Implant Inserter	Insert Cage
2128-003-026	Small Paddle Sizer	Implant determination
2128-003-428	Medium Paddle Sizer	Implant determination
2128-003-830	Large Paddle Sizer	Implant determination
2128-302-611	11mm Trial, 30x26 7°	Trialing
2128-302-612	12mm Trial, 30x26 7°	Trialing
2128-302-613	13mm Trial, 30x26 7°	Trialing
2128-302-614	14mm Trial, 30x26 7°	Trialing
2128-302-615	15mm Trial, 30x26 7°	Trialing
2128-302-616	16mm Trial, 30x26 7°	Trialing
2128-302-617	17mm Trial, 30x26 7°	Trialing
2128-302-618	18mm Trial, 30x26 7°	Trialing
2128-302-619	19mm Trial, 30x26 7°	Trialing
2128-302-620	20mm Trial, 30x26 7°	Trialing
2128-302-621	21mm Trial, 30x26 7°	Trialing
2128-342-811	11mm Trial, 34x28 7°	Trialing
2128-342-812	12mm Trial, 34x28 7°	Trialing
2128-342-813	13mm Trial, 34x28 7°	Trialing
2128-342-814	14mm Trial, 34x28 7°	Trialing
2128-342-815	15mm Trial, 34x28 7°	Trialing
2128-342-816	16mm Trial, 34x28 7°	Trialing
2128-342-817	17mm Trial, 34x28 7°	Trialing
2128-342-818	18mm Trial, 34x28 7°	Trialing

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2128-342-819	19mm Trial, 34x28 7°	Trialing
2128-342-820	20mm Trial, 34x28 7°	Trialing
2128-342-821	21mm Trial, 34x28 7°	Trialing
2128-383-011	11mm Trial, 38x28 7°	Trialing
2128-383-012	12mm Trial, 38x30 7°	Trialing
2128-383-013	13mm Trial, 38x30 7°	Trialing
2128-383-014	14mm Trial, 38x30 7°	Trialing
2128-383-015	15mm Trial, 38x30 7°	Trialing
2128-383-016	16mm Trial, 38x30 7°	Trialing
2128-383-017	17mm Trial, 38x30 7°	Trialing
2128-383-018	18mm Trial, 38x30 7°	Trialing
2128-383-019	19mm Trial, 38x30 7°	Trialing
2128-383-020	20mm Trial, 38x30 7°	Trialing
2128-383-021	21mm Trial, 38x30 7°	Trialing
2129-302-611	11mm Trial, 30x26 12°	Trialing
2129-302-612	12mm Trial, 30x26 12°	Trialing
2129-302-613	13mm Trial, 30x26 12°	Trialing
2129-302-614	14mm Trial, 30x26 12°	Trialing
2129-302-615	15mm Trial, 30x26 12°	Trialing
2129-302-616	16mm Trial, 30x26 12°	Trialing
2129-302-617	17mm Trial, 30x26 12°	Trialing
2129-302-618	18mm Trial, 30x26 12°	Trialing
2129-302-619	19mm Trial, 30x26 12°	Trialing
2129-302-620	20mm Trial, 30x26 12°	Trialing
2129-302-621	21mm Trial, 30x26 12°	Trialing
2129-342-811	11mm Trial, 34x28 12°	Trialing
2129-342-812	12mm Trial, 34x28 12°	Trialing
2129-342-813	13mm Trial, 34x28 12°	Trialing
2129-342-814	14mm Trial, 34x28 12°	Trialing
2129-342-815	15mm Trial, 34x28 12°	Trialing
2129-342-816	16mm Trial, 34x28 12°	Trialing
2129-342-817	17mm Trial, 34x28 12°	Trialing
2129-342-818	18mm Trial, 34x28 12°	Trialing
2129-342-819	19mm Trial, 34x28 12°	Trialing
2129-342-820	20mm Trial, 34x28 12°	Trialing
2129-342-821	21mm Trial, 34x28 12°	Trialing
2129-383-011	11mm Trial, 38x28 12°	Trialing
2129-383-012	12mm Trial, 38x30 12°	Trialing
2129-383-013	13mm Trial, 38x30 12°	Trialing
2129-383-014	14mm Trial, 38x30 12°	Trialing
2129-383-015	15mm Trial, 38x30 12°	Trialing
2129-383-016	16mm Trial, 38x30 12°	Trialing
2129-383-017	17mm Trial, 38x30 12°	Trialing
2129-383-018	18mm Trial, 38x30 12°	Trialing

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2129-383-019	19mm Trial, 38x30 12°	Trialing
2129-383-020	20mm Trial, 38x30 12°	Trialing
2129-383-021	21mm Trial, 38x30 12°	Trialing

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K142095/S002



FDA/CDRH/DCC

September 15, 2014

SEP 16 2014

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

RECEIVED

**Re:** K142095 Response to Additional Information Request – Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) System

Dear Dr. Hwang,

Enclosed please find the response to the additional information request received by email on September 11, 2014.

(b)(4)

The eCopy is an exact duplicate of the paper copy.  
The files have been paginated per the FDA "Refuse to Accept Policy for 510(k)s Guidance for Industry and Food and Drug Administration Staff", December 31, 2012.

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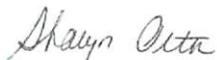
Renovis S134 ALIF System

K142095 AI response  
1-1

ICD 54

If there are any questions regarding this submission, please contact me at 401-330-8264 or by email at [sorton@medicept.com](mailto:sorton@medicept.com).

Sincerely yours,



Sharyn Orton, Ph.D.  
Senior Consultant  
MEDicept, Inc.  
*for*  
Renovis Surgical Technologies Inc.

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Renovis S134 ALIF System

K142095 AI response  
1-2



September 15, 2014

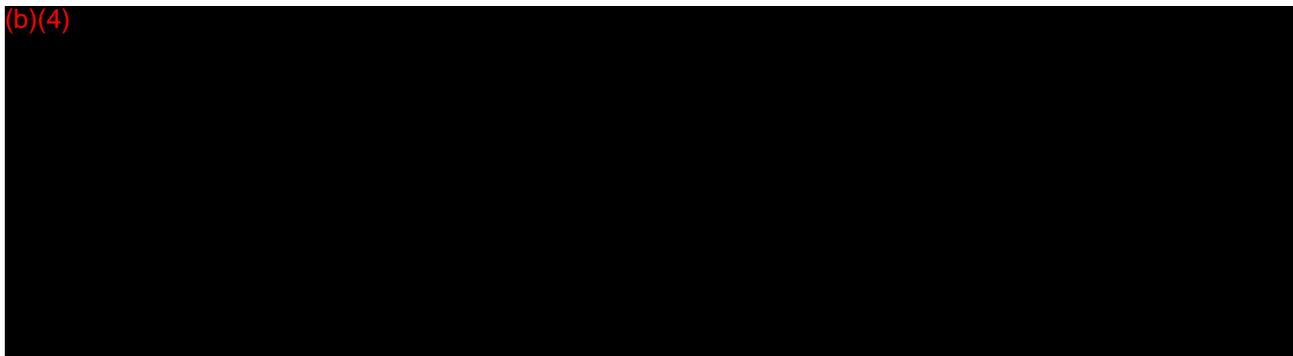
David Hwang, Ph.D.  
U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

**Re:** K142095 Response to Additional Information Request – Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) System

Dear Dr. Hwang,

Enclosed please find the response to the additional information request received by email on September 11, 2014.

(b)(4)

A large black rectangular redaction box covers the majority of the page content below the opening paragraph.

The eCopy is an exact duplicate of the paper copy.  
The files have been paginated per the FDA “Refuse to Accept Policy for 510(k)s Guidance for Industry and Food and Drug Administration Staff”, December 31, 2012.

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Renovis S134 ALIF System

K142095 AI response

1-1

If there are any questions regarding this submission, please contact me at 401-330-8264 or by email at [sorton@medicept.com](mailto:sorton@medicept.com).

Sincerely yours,

A handwritten signature in cursive script that reads "Sharyn Orton".

Sharyn Orton, Ph.D.  
Senior Consultant  
MEDIcept, Inc.  
*for*  
Renovis Surgical Technologies Inc.

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Renovis S134 ALIF System

K142095 AI response

1-2

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Cover Letter K142095 AI response	001
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K142095 revised 510k Summary highlighted	003
K142095 revised 510k Summary	004
K142095 revised non-sterile LIF IFU highlighted	005
K142095 revised non-sterile LIF IFU	006
K142095 revised Surgical Technique highlighted	007
K142095 revised Surgical Technique	008

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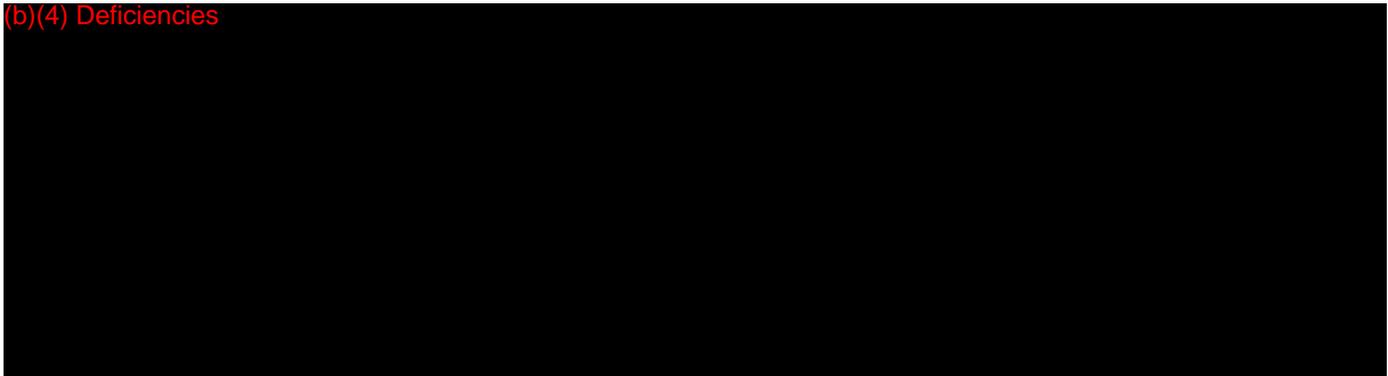
Renovis S134 ALIF System

K142095 AI response

1-3



(b)(4) Deficiencies



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Renovis S134 ALIF System

K142095 AI response

2-2



**Special 510(k) Summary  
as required by 21 CFR 807.92(a)  
K142095**

A ) Submitted by: Renovis Surgical Technologies, Inc.  
1901 W. Lugonia Ave, Ste 340  
Redlands, CA 92374  
Phone: 909-557-2360  
Fax: 909-307-8571

Official Contact: Anthony DeBenedictis  
Vice President of Quality Assurance

Consultant: Sharyn Orton, Ph.D.  
MEDIcept, Inc.  
200 Homer Ave  
Ashland, MA 01721

Date: September 5, 2014

B) Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar  
Common Name: Intervertebral body fusion device  
Proprietary Name: S134 Anterior Lumbar Interbody Fusion (ALIF) System  
Device Class: Class II – 888.3080  
Regulation and  
and product codes: 21 CFR 888.3080  
OVD – Intervertebral Body Fusion Device with Integrated  
Fixation, Lumbar  
MAX - Intervertebral Body Fusion Device with Bone Graft,  
Lumbar  
Classification panel: Orthopedic

C) Predicates:

- K131122; K140106 Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

#### D) Device Description:

The purpose of this submission is an additional offering to the Renovis lumbar interbody fusion system portfolio. The S134 Anterior Lumbar Interbody Fusion (ALIF) System implants (cages) are intervertebral body fusion devices with a screw-less design that requires supplemental fixation. The S134 ALIF cages are available in a variety of sizes (widths, height, depths, and bone screw sizes) to suit the individual pathology and anatomical conditions of the patient. The implants are manufactured from PEEK or additively manufactured and machined Titanium. The PEEK markers are manufactured from Tantalum.

The Renovis S134 ALIF System cages are to be used with supplemental fixation, and are intended to be used with autogenous bone graft.

The Renovis S134 ALIF System is used with device specific instruments including trials.

The Renovis S134 ALIF System implants comply with the following material standards:

- ASTM F2026-08 Standard Specification for PEEK Polymers for Surgical Implant Applications
- ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F560-08, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications

The S134 ALIF implants are provided gamma sterilized, and non-sterile (PEEK cages only; requiring sterilization by the end user).

#### E) Indications For Use:

The Renovis Lumbar Interbody Fusion (LIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis LIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

The Renovis S134 ALIF System must be used with supplemental fixation cleared by the FDA for use in the lumbar spine.

#### F) Substantial Equivalence Comparison and Discussion

Comparison of technological characteristics, engineering rationale and FEA were used to determine that this design change does not introduce a new worst case.

##### *Conclusion*

The Renovis S134 ALIF System implants have the same footprint (ID and OD profile dimensions), materials, manufacturing methods, ~~and sterilization offerings~~; and similar ~~sterilization offerings~~, intended use, design and function as the Renovis S128 ALIF System implant. Therefore, the Renovis S134 ALIF System is substantially equivalent to the predicate device.

#### G) Compliance with Design Controls

The results of assessment under Design Controls support that the Renovis S134 ALIF System is substantially equivalent to the predicate device. The offering of implants that are not standalone and require supplemental fixation does not raise new issues of safety or effectiveness.

#### H) Compliance with Consensus Standards and FDA Guidance

The Renovis S134 ALIF System complies with:

- ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
- ASTM F2026-12 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications
- ASTM F560-08 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)
- ASTM F983-86 (Reapproved 2013) Standard Practice for Permanent Marking of Orthopaedic Implant Components
- ASTM F565-04 (Reapproved 2013) Standard Practice for Care and Handling of Orthopedic Implants and Instruments
- Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, October 2007



**Special 510(k) Summary  
as required by 21 CFR 807.92(a)  
K142095**

A ) Submitted by: Renovis Surgical Technologies, Inc.  
1901 W. Lugonia Ave, Ste 340  
Redlands, CA 92374  
Phone: 909-557-2360  
Fax: 909-307-8571

Official Contact: Anthony DeBenedictis  
Vice President of Quality Assurance

Consultant: Sharyn Orton, Ph.D.  
MEDIcept, Inc.  
200 Homer Ave  
Ashland, MA 01721

Date: September 5, 2014

B) Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar  
Common Name: Intervertebral body fusion device  
Proprietary Name: S134 Anterior Lumbar Interbody Fusion (ALIF) System  
Device Class: Class II – 888.3080  
Regulation and  
and product codes: 21 CFR 888.3080  
OVD – Intervertebral Body Fusion Device with Integrated  
Fixation, Lumbar  
MAX - Intervertebral Body Fusion Device with Bone Graft,  
Lumbar  
Classification panel: Orthopedic

C) Predicates:

- K131122; K140106 Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

#### D) Device Description:

The purpose of this submission is an additional offering to the Renovis lumbar interbody fusion system portfolio. The S134 Anterior Lumbar Interbody Fusion (ALIF) System implants (cages) are intervertebral body fusion devices with a screw-less design that requires supplemental fixation. The S134 ALIF cages are available in a variety of sizes (widths, height, depths, and bone screw sizes) to suit the individual pathology and anatomical conditions of the patient. The implants are manufactured from PEEK or additively manufactured and machined Titanium. The PEEK markers are manufactured from Tantalum.

The Renovis S134 ALIF System cages are to be used with supplemental fixation, and are intended to be used with autogenous bone graft.

The Renovis S134 ALIF System is used with device specific instruments including trials.

The Renovis S134 ALIF System implants comply with the following material standards:

- ASTM F2026-08 Standard Specification for PEEK Polymers for Surgical Implant Applications
- ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F560-08, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications

The S134 ALIF implants are provided gamma sterilized, and non-sterile (PEEK cages only; requiring sterilization by the end user).

#### E) Indications For Use:

The Renovis Lumbar Interbody Fusion (LIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis LIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

The Renovis S134 ALIF System must be used with supplemental fixation cleared by the FDA for use in the lumbar spine.

#### F) Substantial Equivalence Comparison and Discussion

Comparison of technological characteristics, engineering rationale and FEA were used to determine that this design change does not introduce a new worst case.

#### *Conclusion*

The Renovis S134 ALIF System implants have the same footprint (ID and OD profile dimensions), materials, manufacturing methods; and similar sterilization offerings, intended use, design and function as the Renovis S128 ALIF System implant. Therefore, the Renovis S134 ALIF System is substantially equivalent to the predicate device.

#### G) Compliance with Design Controls

The results of assessment under Design Controls support that the Renovis S134 ALIF System is substantially equivalent to the predicate device. The offering of implants that are not standalone and require supplemental fixation does not raise new issues of safety or effectiveness.

#### H) Compliance with Consensus Standards and FDA Guidance

The Renovis S134 ALIF System complies with:

- ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
- ASTM F2026-12 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications
- ASTM F560-08 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)
- ASTM F983-86 (Reapproved 2013) Standard Practice for Permanent Marking of Orthopaedic Implant Components
- ASTM F565-04 (Reapproved 2013) Standard Practice for Care and Handling of Orthopedic Implants and Instruments
- Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, October 2007


**Renovis Lumbar Interbody Fusion (LIF) System, Non-Sterile Packaging**


Rev. DRAFT

Instructions For Use

**DESCRIPTION:**

The Renovis Lumbar Interbody Fusion (LIF) System is an internal spinal fixation system comprised of PEEK or Titanium Interbody cages. The system also includes several instruments that assist in proper implantation; these instruments include: Trials, Sizers, and Cage Inserters.

The LIF System includes the S128 Anterior Lumbar Interbody Fusion (ALIF) System and the S134 Anterior Lumbar Interbody Fusion (ALIF) System (PEEK only cages).

LIF System Implants – Summary Description		
	Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System	Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) System
Dimensions (mm)		
A/P	26, 28, 30	
M/L	30, 34, 38	
H	11 - 21	
Lordosis	7°, 12°	
Number of screws	4	Not applicable
Screw diameter (mm)	4.5, 5	
Screw length (mm)	20, 25, 30, 35	
Cover plate (mm)	8.3 H; 22W	Not applicable

For implant and instrument parts numbers, as well as implant dimensions, refer to the Renovis S128 Surgical Technique Manual or the Renovis S134 System Surgical Technique manual.

**IMPORTANT NOTE:**

This product is marked for the specific indications described in its labeling. The use of this product for other than its intended purpose(s) is either contraindicated (see CONTRAINDICATIONS) or is without evidence to support the safety and effectiveness of such use. For the information of individuals and institutions contemplating use of this product for other than labeled indications (i.e., off-labeled use), such use may be experimental and may be the subject of restrictions under applicable laws and regulations.

**MATERIAL:**

All implant components of the Lumbar Interbody Fusion (LIF) System are made of the following materials:

1. Titanium Alloy: Ti6Al4V
2. Polyetheretherketone (PEEK): according to ASTM F-2026
3. Tantalum: according to ISO 13782-1996 and ASTM F-560

**INDICATIONS FOR USE:**

The Renovis Lumbar Interbody Fusion (LIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis LIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

The Renovis S134 ALIF System must be used with supplemental fixation cleared by the FDA for use in the lumbar spine.

**GENERAL CONDITIONS OF USE:**

The safe implantation of Lumbar Interbody Fusion (LIF) Systems requires an in-depth knowledge of human vertebral anatomy as well as a specific patient's anatomical variations. The implantation of the Lumbar Interbody Fusion (LIF) System should be performed only by experienced spinal surgeons with specific training in the use of interbody fusion. In addition, the surgeon must be knowledgeable of the mechanical and metallurgical limitations of this implant. The Lumbar Interbody Fusion (LIF) System should not be used in conjunction with components from a different source, a different manufacturer, or made of a different material.

Under no circumstances should any component of the Lumbar Interbody Fusion (ALIF) System be reused after implantation or any other circumstance that has subjected an individual component to mechanical stress.

The S128 ALIF System has been tested as a standalone construct.

The S134 ALIF System has not been tested as a standalone construct.

**CONTRAINDICATIONS:**

Contraindications to using the Lumbar Interbody Fusion (LIF) System are similar to those of other Lumbar Interbody Fusion (LIF) Systems and consist of the following:

1. Patients that are overweight, obese, or are occupationally or recreationally subject to heavy lifting, twisting, repetitive bending, or stooping, to a degree that would produce loads on the spinal system leading to failure of fixation or implant failure.
2. Any patient not needing a bone graft and fusion, or where fracture healing is not required.
3. Patients with bony abnormalities that grossly distort anatomy and/or prevent placement of the implant without risk of impairment to anatomical structures or physiologic performance.
4. Patients with a suspected or documented metal allergy or intolerance.
5. Inadequate tissue coverage over the operative site.
6. Recent or active infection, particularly if in or adjacent to the spine or spinal structures.

7. Relative contraindications include open wounds as well as fever, leukocytosis, or other signs of systemic infection. Diminished bone quality is a relative contraindication. This may limit the surgeon's ability to achieve adequate implant fixation, structural support, or anatomic correction. These conditions include certain degenerative diseases, postoperative irradiation, smoking, and a history of previous spinal fixation failure. Diminished ability to comprehend and adhere to post-operative care instructions is a relative contraindication. These conditions include diminished mental capacity, mental illness, alcohol or drug abuse and Pregnancy.

#### **POTENTIAL RISKS:**

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, vertebral fracture, neurological injury, and vascular or visceral injury.

1. Correct implant selection is vital. Selecting the proper implant size, shape, and design increases the potential for satisfactory fixation. While proper selection can help minimize risks, the size and shape of human bones present implant size, shape, and strength limitations. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
2. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels among other conditions will dictate implant longevity. Notches, scratches or implant bending during the surgery may also contribute to early failure. Fully inform patients of the implant failure risks.
3. Mixing metals can cause corrosion. There are many forms of corrosion damage, and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel, and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., that come into contact with other metal objects, must be made from like or compatible materials.

#### **PATIENT SELECTION:**

The following factors can be extremely important to the eventual success of the procedure:

1. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.
2. Senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the device use, leading to implant failure or other complications.
3. Certain degenerative diseases. In some cases, degenerative disease progression may be so advanced at implantation that it may substantially decrease the device's expected useful life. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
4. Foreign body sensitivity. No pre-operative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.
5. Smoking. Patients who smoke have been observed to experience higher rates of pseudoarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

## **WARNINGS AND CAUTIONS:**

Only experienced spinal surgeons with specific training in the use of interbody fusion system should implant interbody fusion devices, because this is a technically demanding procedure presenting a risk of serious injury to the patient

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, share, and design of the implant. The size and shape of the human bones present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. Single use only. Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
3. Correct implant handling is vital. These devices may not be contoured. Avoid any notching, scratching or reverse bending of the devices when handling. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage. Do not use the implant if damage is suspected.
4. The LIF System implants and instruments are provided non-sterile, and therefore, must be sterilized before each use.
5. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
6. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. Inform the patient about the implant limitations, and to limit physical activities, especially lifting and twisting motions and participating in any type of sports. Tell the patient that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. Active, debilitated, or demented patients who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
7. Renovis Implants and Instruments have not been tested for adverse effect in a Magnetic Resonance Imaging (MRI) environment. The implants in the Lumbar Interbody Fusion System are manufactured from non-ferromagnetic materials as listed in the materials section of this IFU. Potential risks of placing implants in or near the magnetic field include:
  - a. Movement of ferromagnetic components through magnetically induced force and torque.
  - b. Localized heating of components caused by radio frequency induction heating.
  - c. Image artifacts created by interaction between metallic components and the magnetic field.

## **ADVERSE AFFECTS:**

In addition to the obvious risk that any orthopedic implant may fail, loosen, or fracture, the following risks of adverse tissue responses and possible complications must be explained to and discussed with the patient:

1. There have been reports in literature that a variety of metals, polymers, chemicals, and other materials used in the manufacturing of orthopedic implants may cause cancer and other adverse reactions. Because of the long latency period required to induce tumors in humans, there is no conclusive evidence of the relationship between orthopedic implants and malignant tumors. Even though no clear association has been established, any risks and uncertainties regarding the long term effects of artificial joints and fixation devices should be discussed with the patient prior to surgery. The patient should also know that any condition that causes chronic damage to tissues may be oncogenic. Cancer found in the vicinity of an implant may be due to factors unrelated to the implant materials such as: metastasis from soft tissue sites (lung, breast, digestive system, and others) to bone or seeded to those locations during operative and diagnostic procedures such as biopsies, and from progression of Paget's disease. Patients suffering from Paget's disease who are candidates for implantation procedures in the affected areas should be warned accordingly.
2. Implantation of foreign materials in tissues can elicit an inflammatory reaction. Recent literature suggests that wear debris (including metal, polyethylene, ceramic, and cemented particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening. While the formation of wear debris may be an inevitable consequence of motion at bone-to-implant surfaces, optimal technique for fixation of the device should be employed in order to minimize motion that can generate such particles at the bone/prosthesis or prosthesis/prosthesis interface.

3. Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitizers (nickel, cobalt, and chromium) are present in orthopedic grade stainless steel and cobalt-chrome alloys. Titanium and its alloys (such as Titanium Ti-6AL-4V Alloy) are markedly less antigenic and are recommended for use in persons with a history of allergies or metal sensitivity.

**HANDLING**

1. Receipt – Carefully unwrap and handle non-sterilized implants and instruments upon receipt to avoid scratching, marking, or abrasion by other implants, instruments, unpacking tools, or by dropping or otherwise endangering the surface finish or configuration.
2. Transport - Transport in a manner to preclude any damage or alteration to the received condition of the implant or instrument.
3. Storage - Store implants or instruments prior to use in such a manner as to maintain the device’s surface finish or configuration, or both. Stock Rotation—The principle of first in, first out, is recommended. Store implants in the operating room in such a manner as to isolate and protect the implant’s surface, sterility, and configuration. Keep implants made of different metals separated. Store the implants and instruments in the operating room in such a manner as to isolate the instruments from the implants.
4. Traceability - Implants are identified by a catalog number or lot number, or both, on the package label and surface of the device. Record these control numbers and retain for transfer to patient records, to facilitate inventory, stock rotation, medical device reporting, and/or possible traceability to the manufacturer.

**CLEANING:**

All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning can include the use of neutral cleaners followed by a deionized water rinse. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device. Renovis Instrument IFU 4001-001 provides more detailed information about proper cleaning of the instruments in the LIF System.

**STERILITY:**

Renovis LIF System implants and instruments are provided non-sterile, and must be sterilized before use. Sterilization is recommended as follows:

<b>Cycle</b>	Dynamic-air-removal Steam
<b>Minimum Temperature</b>	132° C (270° F)
<b>Exposure</b>	4 Minutes
<b>Drying Time</b>	30 minutes minimum; 40 minutes maximum

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

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

The packaging in which non-sterile implants are supplied should not be used for sterilization methods in the hospital. The implants should be sterilized in the provided caddies. Repackaged and re-sterilized items must be properly labeled and marked with the expiration date mandated by hospital policy.

**References:** References to relevant literature including the Surgical Technique manuals may be obtained by calling Renovis Surgical Technologies, Inc. at 1-800-RENOVIS.

**Caution:** Federal Law USA restricts this device to sale by or on the order of a physician.



 **RENOVIS**

Renovis Surgical Technologies, Inc.  
1901 W. Lagonia Ave. Suite 340  
Redlands CA 92374 USA  
1-800-RENOVIS


**Renovis Lumbar Interbody Fusion (LIF) System, Non-Sterile Packaging**


Rev. DRAFT

Instructions For Use

**DESCRIPTION:**

The Renovis Lumbar Interbody Fusion (LIF) System is an internal spinal fixation system comprised of PEEK or Titanium Interbody cages. The system also includes several instruments that assist in proper implantation; these instruments include: Trials, Sizers, and Cage Inserters.

The LIF System includes the S128 Anterior Lumbar Interbody Fusion (ALIF) System and the S134 Anterior Lumbar Interbody Fusion (ALIF) System (PEEK only cages).

LIF System Implants – Summary Description		
	Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System	Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) System
Dimensions (mm)		
A/P	26, 28, 30	
M/L	30, 34, 38	
H	11 - 21	
Lordosis	7°, 12°	
Number of screws	4	Not applicable
Screw diameter (mm)	4.5, 5	
Screw length (mm)	20, 25, 30, 35	
Cover plate (mm)	8.3 H; 22W	Not applicable

For implant and instrument parts numbers, as well as implant dimensions, refer to the Renovis S128 Surgical Technique Manual or the Renovis S134 System Surgical Technique manual.

**IMPORTANT NOTE:**

This product is marked for the specific indications described in its labeling. The use of this product for other than its intended purpose(s) is either contraindicated (see CONTRAINDICATIONS) or is without evidence to support the safety and effectiveness of such use. For the information of individuals and institutions contemplating use of this product for other than labeled indications (i.e., off-labeled use), such use may be experimental and may be the subject of restrictions under applicable laws and regulations.

**MATERIAL:**

All implant components of the Lumbar Interbody Fusion (LIF) System are made of the following materials:

1. Titanium Alloy: Ti6Al4V
2. Polyetheretherketone (PEEK): according to ASTM F-2026
3. Tantalum: according to ISO 13782-1996 and ASTM F-560

**INDICATIONS FOR USE:**

The Renovis Lumbar Interbody Fusion (LIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis LIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

The Renovis S134 ALIF System must be used with supplemental fixation cleared by the FDA for use in the lumbar spine.

**GENERAL CONDITIONS OF USE:**

The safe implantation of Lumbar Interbody Fusion (LIF) Systems requires an in-depth knowledge of human vertebral anatomy as well as a specific patient's anatomical variations. The implantation of the Lumbar Interbody Fusion (LIF) System should be performed only by experienced spinal surgeons with specific training in the use of interbody fusion. In addition, the surgeon must be knowledgeable of the mechanical and metallurgical limitations of this implant. The Lumbar Interbody Fusion (LIF) System should not be used in conjunction with components from a different source, a different manufacturer, or made of a different material.

Under no circumstances should any component of the Lumbar Interbody Fusion (ALIF) System be reused after implantation or any other circumstance that has subjected an individual component to mechanical stress.

The S128 ALIF System has been tested as a standalone construct.

The S134 ALIF System has not been tested as a standalone construct.

**CONTRAINDICATIONS:**

Contraindications to using the Lumbar Interbody Fusion (LIF) System are similar to those of other Lumbar Interbody Fusion (LIF) Systems and consist of the following:

1. Patients that are overweight, obese, or are occupationally or recreationally subject to heavy lifting, twisting, repetitive bending, or stooping, to a degree that would produce loads on the spinal system leading to failure of fixation or implant failure.
2. Any patient not needing a bone graft and fusion, or where fracture healing is not required.
3. Patients with bony abnormalities that grossly distort anatomy and/or prevent placement of the implant without risk of impairment to anatomical structures or physiologic performance.
4. Patients with a suspected or documented metal allergy or intolerance.
5. Inadequate tissue coverage over the operative site.
6. Recent or active infection, particularly if in or adjacent to the spine or spinal structures.

7. Relative contraindications include open wounds as well as fever, leukocytosis, or other signs of systemic infection. Diminished bone quality is a relative contraindication. This may limit the surgeon's ability to achieve adequate implant fixation, structural support, or anatomic correction. These conditions include certain degenerative diseases, postoperative irradiation, smoking, and a history of previous spinal fixation failure. Diminished ability to comprehend and adhere to post-operative care instructions is a relative contraindication. These conditions include diminished mental capacity, mental illness, alcohol or drug abuse and Pregnancy.

#### **POTENTIAL RISKS:**

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, vertebral fracture, neurological injury, and vascular or visceral injury.

1. Correct implant selection is vital. Selecting the proper implant size, shape, and design increases the potential for satisfactory fixation. While proper selection can help minimize risks, the size and shape of human bones present implant size, shape, and strength limitations. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
2. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels among other conditions will dictate implant longevity. Notches, scratches or implant bending during the surgery may also contribute to early failure. Fully inform patients of the implant failure risks.
3. Mixing metals can cause corrosion. There are many forms of corrosion damage, and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel, and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., that come into contact with other metal objects, must be made from like or compatible materials.

#### **PATIENT SELECTION:**

The following factors can be extremely important to the eventual success of the procedure:

1. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.
2. Senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the device use, leading to implant failure or other complications.
3. Certain degenerative diseases. In some cases, degenerative disease progression may be so advanced at implantation that it may substantially decrease the device's expected useful life. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
4. Foreign body sensitivity. No pre-operative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.
5. Smoking. Patients who smoke have been observed to experience higher rates of pseudoarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

## **WARNINGS AND CAUTIONS:**

Only experienced spinal surgeons with specific training in the use of interbody fusion system should implant interbody fusion devices, because this is a technically demanding procedure presenting a risk of serious injury to the patient

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, share, and design of the implant. The size and shape of the human bones present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. Single use only. Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
3. Correct implant handling is vital. These devices may not be contoured. Avoid any notching, scratching or reverse bending of the devices when handling. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage. Do not use the implant if damage is suspected.
4. The LIF System implants and instruments are provided non-sterile, and therefore, must be sterilized before each use.
5. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
6. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. Inform the patient about the implant limitations, and to limit physical activities, especially lifting and twisting motions and participating in any type of sports. Tell the patient that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. Active, debilitated, or demented patients who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
7. Renovis Implants and Instruments have not been tested for adverse effect in a Magnetic Resonance Imaging (MRI) environment. The implants in the Lumbar Interbody Fusion System are manufactured from non-ferromagnetic materials as listed in the materials section of this IFU. Potential risks of placing implants in or near the magnetic field include:
  - a. Movement of ferromagnetic components through magnetically induced force and torque.
  - b. Localized heating of components caused by radio frequency induction heating.
  - c. Image artifacts created by interaction between metallic components and the magnetic field.

## **ADVERSE AFFECTS:**

In addition to the obvious risk that any orthopedic implant may fail, loosen, or fracture, the following risks of adverse tissue responses and possible complications must be explained to and discussed with the patient:

1. There have been reports in literature that a variety of metals, polymers, chemicals, and other materials used in the manufacturing of orthopedic implants may cause cancer and other adverse reactions. Because of the long latency period required to induce tumors in humans, there is no conclusive evidence of the relationship between orthopedic implants and malignant tumors. Even though no clear association has been established, any risks and uncertainties regarding the long term effects of artificial joints and fixation devices should be discussed with the patient prior to surgery. The patient should also know that any condition that causes chronic damage to tissues may be oncogenic. Cancer found in the vicinity of an implant may be due to factors unrelated to the implant materials such as: metastasis from soft tissue sites (lung, breast, digestive system, and others) to bone or seeded to those locations during operative and diagnostic procedures such as biopsies, and from progression of Paget's disease. Patients suffering from Paget's disease who are candidates for implantation procedures in the affected areas should be warned accordingly.
2. Implantation of foreign materials in tissues can elicit an inflammatory reaction. Recent literature suggests that wear debris (including metal, polyethylene, ceramic, and cemented particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening. While the formation of wear debris may be an inevitable consequence of motion at bone-to-implant surfaces, optimal technique for fixation of the device should be employed in order to minimize motion that can generate such particles at the bone/prosthesis or prosthesis/prosthesis interface.

3. Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitizers (nickel, cobalt, and chromium) are present in orthopedic grade stainless steel and cobalt-chrome alloys. Titanium and its alloys (such as Titanium Ti-6AL-4V Alloy) are markedly less antigenic and are recommended for use in persons with a history of allergies or metal sensitivity.

**HANDLING**

1. Receipt – Carefully unwrap and handle non-sterilized implants and instruments upon receipt to avoid scratching, marking, or abrasion by other implants, instruments, unpacking tools, or by dropping or otherwise endangering the surface finish or configuration.
2. Transport - Transport in a manner to preclude any damage or alteration to the received condition of the implant or instrument.
3. Storage - Store implants or instruments prior to use in such a manner as to maintain the device’s surface finish or configuration, or both. Stock Rotation—The principle of first in, first out, is recommended. Store implants in the operating room in such a manner as to isolate and protect the implant’s surface, sterility, and configuration. Keep implants made of different metals separated. Store the implants and instruments in the operating room in such a manner as to isolate the instruments from the implants.
4. Traceability - Implants are identified by a catalog number or lot number, or both, on the package label and surface of the device. Record these control numbers and retain for transfer to patient records, to facilitate inventory, stock rotation, medical device reporting, and/or possible traceability to the manufacturer.

**CLEANING:**

All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning can include the use of neutral cleaners followed by a deionized water rinse. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device. Renovis Instrument IFU 4001-001 provides more detailed information about proper cleaning of the instruments in the LIF System.

**STERILITY:**

Renovis LIF System implants and instruments are provided non-sterile, and must be sterilized before use. Sterilization is recommended as follows:

<b>Cycle</b>	Dynamic-air-removal Steam
<b>Minimum Temperature</b>	132° C (270° F)
<b>Exposure</b>	4 Minutes
<b>Drying Time</b>	30 minutes minimum; 40 minutes maximum

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

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

The packaging in which non-sterile implants are supplied should not be used for sterilization methods in the hospital. The implants should be sterilized in the provided caddies. Repackaged and re-sterilized items must be properly labeled and marked with the expiration date mandated by hospital policy.

**References:** References to relevant literature including the Surgical Technique manuals may be obtained by calling Renovis Surgical Technologies, Inc. at 1-800-RENOVIS.

**Caution:** Federal Law USA restricts this device to sale by or on the order of a physician.



 **RENOVIS**

Renovis Surgical Technologies, Inc.  
1901 W. Lagonia Ave. Suite 340  
Redlands CA 92374 USA  
1-800-RENOVIS

# Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) Surgical Technique

## Indications for Use

The Renovis Lumbar Interbody Fusion (LIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis LIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

The Renovis S134 ALIF System must be used with supplemental fixation cleared by the FDA for use in the lumbar spine.

## Description

The S134 Anterior Lumbar Interbody Fusion (ALIF) System is an internal spinal fixation system comprised of PEEK or Titanium Interbody (Tesera) cages. The system also includes instruments that assist in proper implantation; these instruments include: Trials, Sizers, and Cage Inserters.

## Contraindications

Contraindications to using the Lumbar Interbody Fusion (LIF) Systems are similar to those of other Lumbar Interbody Fusion (LIF) Systems and consist of the following:

1. Prior fusion at the level(s) to be treated
2. Any condition not describe in the Indications for Use
3. Patients that are overweight, obese, or are occupationally or recreationally subject to heavy lifting, twisting, repetitive bending, or stooping, to a

- degree that would produce loads on the spinal system leading to failure of fixation or implant failure.
4. Any patient not needing a bone graft and fusion, or where fracture healing is not required.
  5. Patients with bony abnormalities that grossly distort anatomy and/or prevent placement of the implant without risk of impairment to anatomical structures or physiologic performance.
  6. Patients with a suspected or documented metal allergy or intolerance.
  7. Inadequate tissue coverage over the operative site.
  8. Recent or active infection, particularly if in or adjacent to the spine or spinal structures.
  9. Relative contraindications include open wounds as well as fever, leukocytosis, or other signs of systemic infection. Diminished bone quality is a relative contraindication. This may limit the surgeon's ability to achieve adequate implant fixation, structural support, or anatomic correction. These conditions include certain degenerative diseases, postoperative irradiation, smoking, and a history of previous spinal fixation failure. Diminished ability to comprehend and adhere to post-operative care instructions is a relative contraindication. These conditions include diminished mental capacity, mental illness, alcohol or drug abuse and Pregnancy.

## **Warnings and Cautions**

Only experienced spinal surgeons with specific training in the use of interbody fusion systems should implant interbody fusion devices, because this is a technically demanding procedure presenting a risk of serious injury to the patient.

These warnings do not include all possible adverse surgical effects, but are particular to metallic internal fixation devices. Explain general surgical risks to the patient before surgery.

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape, and design of the implant. The size and shape of the human bones present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. Single use only. Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns, which may lead to early breakage.
3. Correct implant handling is vital. These devices may not be contoured. Avoid any notching, scratching or reverse bending of the devices when handling.

Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage. Do not use the implant if damage is suspected. Do not use implants that exhibit surface or configuration damage.

4. The LIF System implants are provided sterile (PEEK and Titanium) and non-sterile (PEEK only). For Sterile-packaged implants, do not resterilize any implant. Do not use implants after expiration date. Non-sterile implants must be thoroughly cleaned and sterilized before each use. Do not use any implant from an opened or damaged package.

5. The LIF System instruments are provided non-sterile, and therefore, must be thoroughly cleaned and sterilized before each use.

6. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

7. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. Inform the patient about the implant limitations, and to limit physical activities, especially lifting and twisting motions and participating in any type of sports. Tell the patient that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. Active, debilitated, or demented patients who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

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- a. Movement of ferromagnetic components through magnetically induced force and torque.
- b. Localized heating of components caused by radio frequency induction heating.
- c. Image artifacts created by interaction between metallic components and the magnetic field.

## Preparation

### Anterior access and Approach

Locate the correct operative disc level and incision location by taking a lateral fluoroscopic view while holding a straight metal instrument at the side of the patient. This ensures that the incision and exposure will allow direct visualization into the disc space. Expose the operative disc level through a standard retroperitoneal approach.

### Exposure

The S134 ALIF system must be inserted from a direct anterior approach. Expose the segment to produce sufficient space on either side of the vertebral midline, equal to half the width of the implant. This allows insertion of the implant, without interference from adjacent soft tissue structures.

*Note: Give proper consideration to the exposure so instrumentation can be used as described in the following sections.*

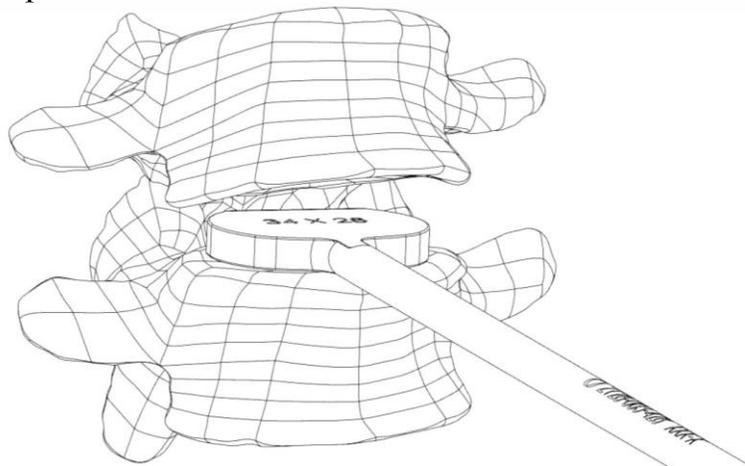
## Discectomy and Endplate Preparation

### Discectomy

Create an annulotomy centered on the midline and wide enough to accommodate the S134 implant. A Paddle Sizer (2128-003-026\_830) may be used as a template to indicate the width of the annular window required.

Perform a thorough discectomy, ensuring the posterolateral corners are freed of disc material.

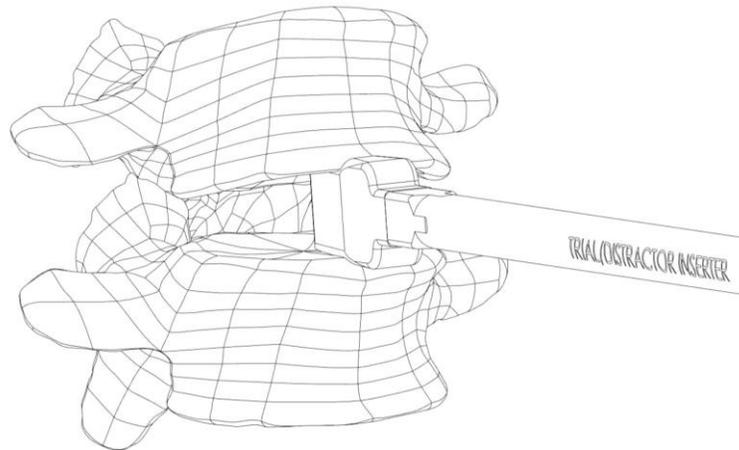
Remove non-ossified fibrocartilage, taking care to not compromise the integrity of the bony endplates.



## Endplate Preparation

If additional disc space distraction or remobilization is necessary, the Bullet Nose Distractors (2128-002-009\_021) are available in the S134 Instrument Set.

Firmly attach the Bullet Nose Distractors to the Trial Implant/ Bullet Nose Distractor Inserter (2128-001-005). Insert a Distractor into the disc space and rotate to distract the disc space to facilitate disc plate preparation.



*Note: Excessive removal of subchondral bone may weaken the vertebral endplate. If the entire endplate is removed, subsidence and a loss of segmental stability may result.*

For a safe placement, verify Bullet Nose Distractor position with the help of intraoperative lateral imaging.

## Trialing

Select the Trial Implant with the appropriate footprint and lordotic angle. Firmly attach it to the Trial Implant/Bullet Nose Distractor Inserter (2128-001-005).

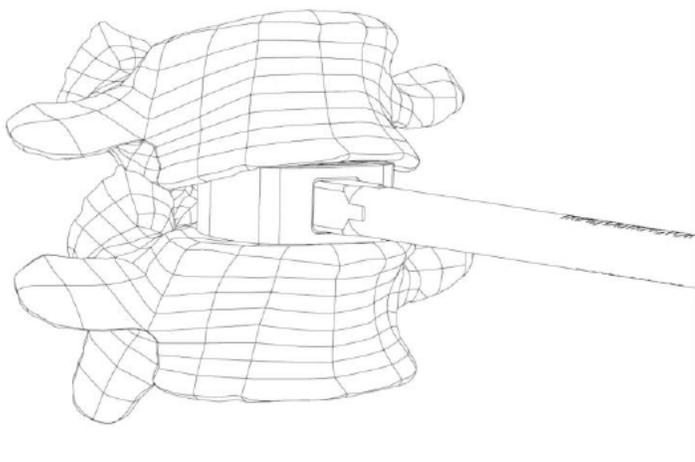
Controlled, light impaction of the trial spacer handle may be required to advance the trial spacer into the disc space.

If a tight fit is not achieved, repeat the process using incrementally larger trial spacers. Conversely, if the trial spacer cannot be inserted, repeat using incrementally smaller trial spacers.

Select the maximum size, to optimize the stability of the segment.

When rocking the trial spacer handle in a cranial to caudal direction, no toggling of the trial spacer should be evident.

X-ray may be used to check the position of the trial implant, restoration of disc and foraminal height, and overall alignment before selecting the final S134 implant size.

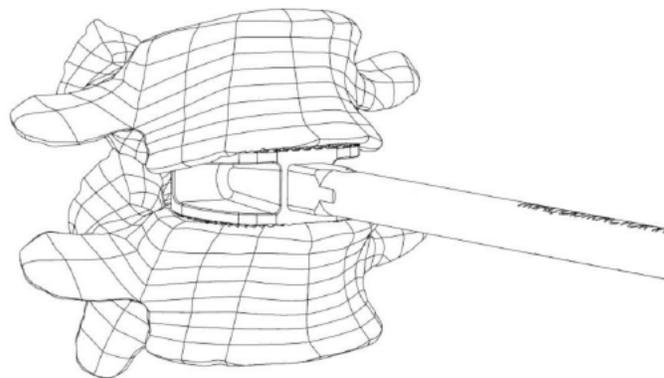
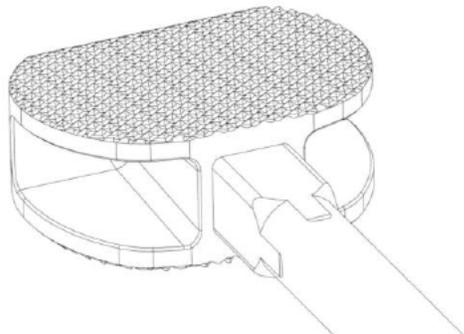


## Broaching

If using the Tesera ALIF Cage, broaching is necessary to ensure that the vertebral endplates are properly prepared for the implant. For this step, attach the appropriate Broach to the Trial Implant/Bullet Nose Distractor Inserter (2128-001-005) based upon the size indicated during the Trialing step. Insert the assembly into the disc space and gently tap on the proximal end with a mallet.

Note: take caution not to over-insert the Broach into the disc space. Do not countersink the broach head beyond the rim of the vertebral endplate. Broaches are 1mm wider per side than the implant, and 2mm deeper than the implant.

Remove the assembly and repeat this step several times to ensure the endplates are roughened and ready to receive the Tesera implant.



## Implant Selection and Graft Packing

Select the appropriate S134 Implant, and insert into the Packing Block (2128-001-035). To facilitate selection of the implant, trial implants are laser etched with the height, lordotic angle and footprint of the implant. Select the S134 implant corresponding to the final trial spacer size.

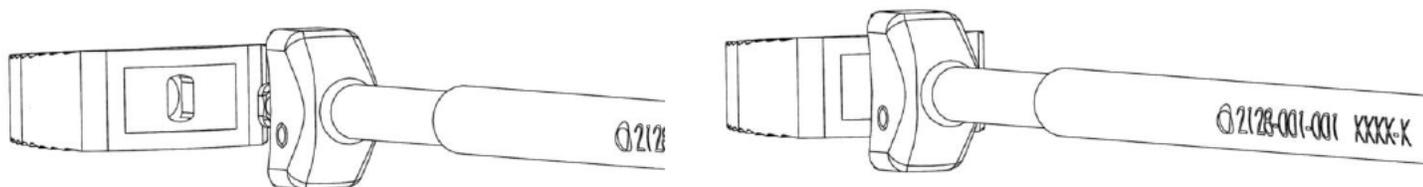
After placing the implant into the Packing Block, fill the implant with autograft material using the Implant Impactor (2128-001-003) to ensure the implant cavities are densely packed.

## Implant Insertion

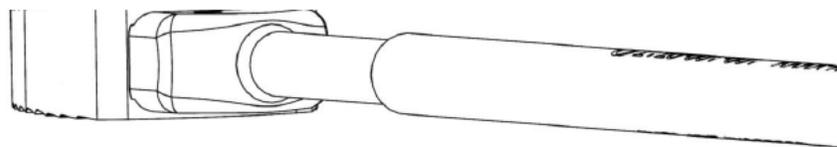
The implant is now ready to be inserted, using the method described below:

### Using the Implant Inserter

Attach the S134 cage to the inserter by inserting distal end of the Implant Inserter (2128-001-001) into the open end of the implant with the attachment slot present. The rectangular post that extends from the inserter must align and fit into the corresponding rectangular slot in the center of the face of the cage.

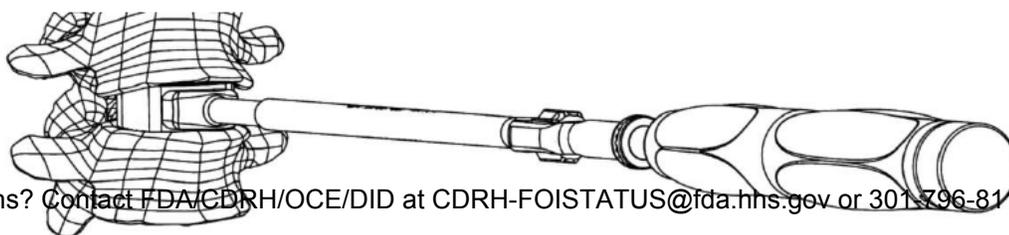


Once the rectangular post of the inserter has penetrated into the interior of the implant, rotate the instrument 90° to align the impaction face with the flat face of the implant and seat the implant up against the inserter face.



When the implant is fully seated, rotate the knob at the proximal end of the implant inserter clockwise to lock the implant to the inserter.

Controlled, light impaction of the Implant Inserter handle may be required to advance the implant into the disc space.



Remove the Implant Inserter by rotating the proximal knob counterclockwise until the inserter can be rotate 90° and removed.

Verify final implant position with the help of an intraoperative lateral imaging.

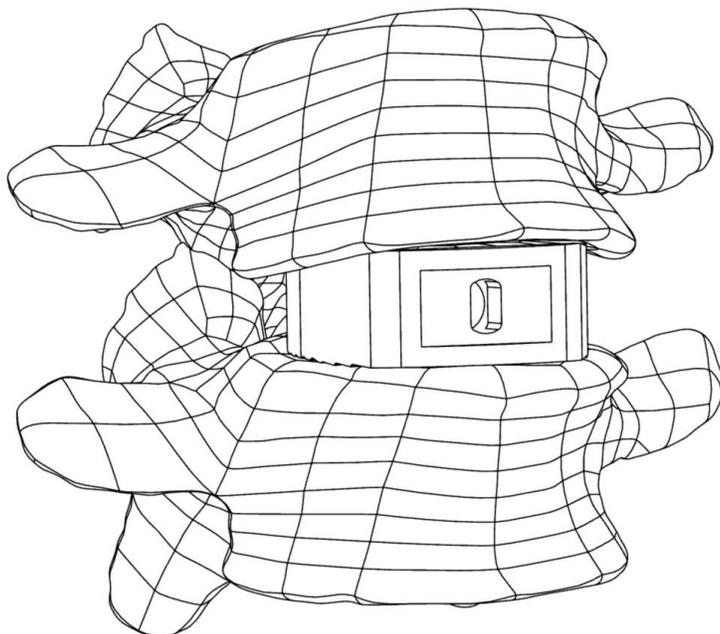
*Note: The posterior x-ray marker incorporated into the implant allows accurate intraoperative radiographic assessment of the position of the implant. The posterior x-ray marker is located approximately 3 mm from the posterior wall of the cage.*

Depending on the size of the vertebrae, the anterior edge of the implant will usually be flush to three-millimeters- recessed relative to the anterior aspect of the adjacent vertebrae.

*Note: All instruments must be removed carefully to avoid possible injury to adjacent structures.*

## **Final Construct Inspection**

Visually inspect the implant, and confirm placement of the construct via lateral and A/P fluoroscopy.



## **Removal or Revisions**

Use extreme caution when exposing the implant upon revision. The approach may be more difficult than at the time of the original surgery due to adhesion between and around the great vessels. It is vitally important to gain full exposure of the Renovis S134 Implant to prevent injury to the great vessels.

Once exposure is gained, simply reverse the surgical technique:

1. Ensure the implant is not hindered by any bone or soft tissue.
2. Attach the Implant Inserter to the exposed front of the implant and gently remove.

## **Patient care following surgery**

A routine wound closure should be performed after x-ray confirmation of proper implant placement. Following surgery, observe standard patient care protocols and monitoring, including, but not limited to:

- Routine monitoring of the vital signs, and of the hemodynamic and neurologic status of the patient.
- Pain medication.
- NG tubes and/or Foley catheters are generally discontinued.
- Diet is restricted per surgeon recommendation to small amounts of liquids until return of bowel function is completed.
- The patient is encouraged to ambulate as soon as possible.
- Braces and activity are to be used at each surgeon's discretion.

## Parts Numbers

### Renovis PEEK Implants -Sterile

Part Number	Width	Depth	Height	Lordosis
1034-302-611	30mm	26mm	11mm	7°
1034-302-612	30mm	26mm	12mm	7°
1034-302-613	30mm	26mm	13mm	7°
1034-302-614	30mm	26mm	14mm	7°
1034-302-615	30mm	26mm	15mm	7°
1034-302-616	30mm	26mm	16mm	7°
1034-302-617	30mm	26mm	17mm	7°
1034-302-618	30mm	26mm	18mm	7°
1034-302-619	30mm	26mm	19mm	7°
1034-302-620	30mm	26mm	20mm	7°
1034-302-621	30mm	26mm	21mm	7°
1034-342-811	34mm	28mm	11mm	7°
1034-342-812	34mm	28mm	12mm	7°
1034-342-813	34mm	28mm	13mm	7°
1034-342-814	34mm	28mm	14mm	7°
1034-342-815	34mm	28mm	15mm	7°
1034-342-816	34mm	28mm	16mm	7°
1034-342-817	34mm	28mm	17mm	7°
1034-342-818	34mm	28mm	18mm	7°
1034-342-819	34mm	28mm	19mm	7°
1034-342-820	34mm	28mm	20mm	7°
1034-342-821	34mm	28mm	21mm	7°
1034-383-011	38mm	30mm	11mm	7°
1034-383-012	38mm	30mm	12mm	7°
1034-383-013	38mm	30mm	13mm	7°
1034-383-014	38mm	30mm	14mm	7°
1034-383-015	38mm	30mm	15mm	7°
1034-383-016	38mm	30mm	16mm	7°
1034-383-017	38mm	30mm	17mm	7°
1034-383-018	38mm	30mm	18mm	7°
1034-383-019	38mm	30mm	19mm	7°
1034-383-020	38mm	30mm	20mm	7°
1034-383-021	38mm	30mm	21mm	7°
1035-302-611	30mm	26mm	11mm	12°
1035-302-612	30mm	26mm	12mm	12°
1035-302-613	30mm	26mm	13mm	12°
1035-302-614	30mm	26mm	14mm	12°
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1035-302-620	30mm	26mm	20mm	12°
1035-302-621	30mm	26mm	21mm	12°
1035-342-811	34mm	28mm	11mm	12°
1035-342-812	34mm	28mm	12mm	12°
1035-342-813	34mm	28mm	13mm	12°
1035-342-814	34mm	28mm	14mm	12°
1035-342-815	34mm	28mm	15mm	12°
1035-342-816	34mm	28mm	16mm	12°
1035-342-817	34mm	28mm	17mm	12°
1035-342-818	34mm	28mm	18mm	12°
1035-342-819	34mm	28mm	19mm	12°
1035-342-820	34mm	28mm	20mm	12°
1035-342-821	34mm	28mm	21mm	12°
1035-383-011	38mm	30mm	11mm	12°
1035-383-012	38mm	30mm	12mm	12°
1035-383-013	38mm	30mm	13mm	12°
1035-383-014	38mm	30mm	14mm	12°
1035-383-015	38mm	30mm	15mm	12°
1035-383-016	38mm	30mm	16mm	12°
1035-383-017	38mm	30mm	17mm	12°
1035-383-018	38mm	30mm	18mm	12°
1035-383-019	38mm	30mm	19mm	12°
1035-383-020	38mm	30mm	20mm	12°
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### Renovis PEEK Implants - Non-Sterile

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1134-302-611	30mm	26mm	11mm	7°
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1135-383-014	38mm	30mm	14mm	12°
1135-383-015	38mm	30mm	15mm	12°
1135-383-016	38mm	30mm	16mm	12°
1135-383-017	38mm	30mm	17mm	12°
1135-383-018	38mm	30mm	18mm	12°
1135-383-019	38mm	30mm	19mm	12°
1135-383-020	38mm	30mm	20mm	12°
1135-383-021	38mm	30mm	21mm	12°

### Renovis Titanium Implants - Sterile

Part Number	Width	Depth	Height	Lordosis
1036-302-611	30mm	26mm	11mm	7°
1036-302-612	30mm	26mm	12mm	7°
1036-302-613	30mm	26mm	13mm	7°
1036-302-614	30mm	26mm	14mm	7°
1036-302-615	30mm	26mm	15mm	7°
1036-302-616	30mm	26mm	16mm	7°
1036-302-617	30mm	26mm	17mm	7°
1036-302-618	30mm	26mm	18mm	7°
1036-302-619	30mm	26mm	19mm	7°
1036-302-620	30mm	26mm	20mm	7°
1036-302-621	30mm	26mm	21mm	7°
1036-342-811	34mm	28mm	11mm	7°
1036-342-812	34mm	28mm	12mm	7°
1036-342-813	34mm	28mm	13mm	7°
1036-342-814	34mm	28mm	14mm	7°
1036-342-815	34mm	28mm	15mm	7°
1036-342-816	34mm	28mm	16mm	7°
1036-342-817	34mm	28mm	17mm	7°
1036-342-818	34mm	28mm	18mm	7°
1036-342-819	34mm	28mm	19mm	7°
1036-342-820	34mm	28mm	20mm	7°
1036-342-821	34mm	28mm	21mm	7°
1036-383-011	38mm	30mm	11mm	7°
1036-383-012	38mm	30mm	12mm	7°
1036-383-013	38mm	30mm	13mm	7°
1036-383-014	38mm	30mm	14mm	7°
1036-383-015	38mm	30mm	15mm	7°
1036-383-016	38mm	30mm	16mm	7°
1036-383-017	38mm	30mm	17mm	7°

1036-383-018	38mm	30mm	18mm	7°
1036-383-019	38mm	30mm	19mm	7°
1036-383-020	38mm	30mm	20mm	7°
1036-383-021	38mm	30mm	21mm	7°
1037-302-611	30mm	26mm	11mm	12°
1037-302-612	30mm	26mm	12mm	12°
1037-302-613	30mm	26mm	13mm	12°
1037-302-614	30mm	26mm	14mm	12°
1037-302-615	30mm	26mm	15mm	12°
1037-302-616	30mm	26mm	16mm	12°
1037-302-617	30mm	26mm	17mm	12°
1037-302-618	30mm	26mm	18mm	12°
1037-302-619	30mm	26mm	19mm	12°
1037-302-620	30mm	26mm	20mm	12°
1037-302-621	30mm	26mm	21mm	12°
1037-342-811	34mm	28mm	11mm	12°
1037-342-812	34mm	28mm	12mm	12°
1037-342-813	34mm	28mm	13mm	12°
1037-342-814	34mm	28mm	14mm	12°
1037-342-815	34mm	28mm	15mm	12°
1037-342-816	34mm	28mm	16mm	12°
1037-342-817	34mm	28mm	17mm	12°
1037-342-818	34mm	28mm	18mm	12°
1037-342-819	34mm	28mm	19mm	12°
1037-342-820	34mm	28mm	20mm	12°
1037-342-821	34mm	28mm	21mm	12°
1037-383-011	38mm	30mm	11mm	12°
1037-383-012	38mm	30mm	12mm	12°
1037-383-013	38mm	30mm	13mm	12°
1037-383-014	38mm	30mm	14mm	12°
1037-383-015	38mm	30mm	15mm	12°
1037-383-016	38mm	30mm	16mm	12°
1037-383-017	38mm	30mm	17mm	12°
1037-383-018	38mm	30mm	18mm	12°
1037-383-019	38mm	30mm	19mm	12°
1037-383-020	38mm	30mm	20mm	12°
1037-383-021	38mm	30mm	21mm	12°

### **~~Renovis Titanium Implants – Non-Sterile~~**

<b><del>Part Number</del></b>	<b><del>Width</del></b>	<b><del>Depth</del></b>	<b><del>Height</del></b>	<b><del>Lordosis</del></b>
<b><del>1136-302-611</del></b>	<b><del>30mm</del></b>	<b><del>26mm</del></b>	<b><del>11mm</del></b>	<b><del>7°</del></b>
<b><del>1136-302-612</del></b>	<b><del>30mm</del></b>	<b><del>26mm</del></b>	<b><del>12mm</del></b>	<b><del>7°</del></b>

1136-302-613	30mm	26mm	13mm	7°
1136-302-614	30mm	26mm	14mm	7°
1136-302-615	30mm	26mm	15mm	7°
1136-302-616	30mm	26mm	16mm	7°
1136-302-617	30mm	26mm	17mm	7°
1136-302-618	30mm	26mm	18mm	7°
1136-302-619	30mm	26mm	19mm	7°
1136-302-620	30mm	26mm	20mm	7°
1136-302-621	30mm	26mm	21mm	7°
1136-342-811	34mm	28mm	11mm	7°
1136-342-812	34mm	28mm	12mm	7°
1136-342-813	34mm	28mm	13mm	7°
1136-342-814	34mm	28mm	14mm	7°
1136-342-815	34mm	28mm	15mm	7°
1136-342-816	34mm	28mm	16mm	7°
1136-342-817	34mm	28mm	17mm	7°
1136-342-818	34mm	28mm	18mm	7°
1136-342-819	34mm	28mm	19mm	7°
1136-342-820	34mm	28mm	20mm	7°
1136-342-821	34mm	28mm	21mm	7°
1136-383-011	38mm	30mm	11mm	7°
1136-383-012	38mm	30mm	12mm	7°
1136-383-013	38mm	30mm	13mm	7°
1136-383-014	38mm	30mm	14mm	7°
1136-383-015	38mm	30mm	15mm	7°
1136-383-016	38mm	30mm	16mm	7°
1136-383-017	38mm	30mm	17mm	7°
1136-383-018	38mm	30mm	18mm	7°
1136-383-019	38mm	30mm	19mm	7°
1136-383-020	38mm	30mm	20mm	7°
1136-383-021	38mm	30mm	21mm	7°
1137-302-611	30mm	26mm	11mm	12°
1137-302-612	30mm	26mm	12mm	12°
1137-302-613	30mm	26mm	13mm	12°
1137-302-614	30mm	26mm	14mm	12°
1137-302-615	30mm	26mm	15mm	12°
1137-302-616	30mm	26mm	16mm	12°
1137-302-617	30mm	26mm	17mm	12°
1137-302-618	30mm	26mm	18mm	12°
1137-302-619	30mm	26mm	19mm	12°
1137-302-620	30mm	26mm	20mm	12°
1137-302-621	30mm	26mm	21mm	12°
1137-342-811	34mm	28mm	11mm	12°
1137-342-812	34mm	28mm	12mm	12°

<del>1137-342-813</del>	<del>34mm</del>	<del>28mm</del>	<del>13mm</del>	<del>12°</del>
<del>1137-342-814</del>	<del>34mm</del>	<del>28mm</del>	<del>14mm</del>	<del>12°</del>
<del>1137-342-815</del>	<del>34mm</del>	<del>28mm</del>	<del>15mm</del>	<del>12°</del>
<del>1137-342-816</del>	<del>34mm</del>	<del>28mm</del>	<del>16mm</del>	<del>12°</del>
<del>1137-342-817</del>	<del>34mm</del>	<del>28mm</del>	<del>17mm</del>	<del>12°</del>
<del>1137-342-818</del>	<del>34mm</del>	<del>28mm</del>	<del>18mm</del>	<del>12°</del>
<del>1137-342-819</del>	<del>34mm</del>	<del>28mm</del>	<del>19mm</del>	<del>12°</del>
<del>1137-342-820</del>	<del>34mm</del>	<del>28mm</del>	<del>20mm</del>	<del>12°</del>
<del>1137-342-821</del>	<del>34mm</del>	<del>28mm</del>	<del>21mm</del>	<del>12°</del>
<del>1137-383-011</del>	<del>38mm</del>	<del>30mm</del>	<del>11mm</del>	<del>12°</del>
<del>1137-383-012</del>	<del>38mm</del>	<del>30mm</del>	<del>12mm</del>	<del>12°</del>
<del>1137-383-013</del>	<del>38mm</del>	<del>30mm</del>	<del>13mm</del>	<del>12°</del>
<del>1137-383-014</del>	<del>38mm</del>	<del>30mm</del>	<del>14mm</del>	<del>12°</del>
<del>1137-383-015</del>	<del>38mm</del>	<del>30mm</del>	<del>15mm</del>	<del>12°</del>
<del>1137-383-016</del>	<del>38mm</del>	<del>30mm</del>	<del>16mm</del>	<del>12°</del>
<del>1137-383-017</del>	<del>38mm</del>	<del>30mm</del>	<del>17mm</del>	<del>12°</del>
<del>1137-383-018</del>	<del>38mm</del>	<del>30mm</del>	<del>18mm</del>	<del>12°</del>
<del>1137-383-019</del>	<del>38mm</del>	<del>30mm</del>	<del>19mm</del>	<del>12°</del>
<del>1137-383-020</del>	<del>38mm</del>	<del>30mm</del>	<del>20mm</del>	<del>12°</del>
<del>1137-383-021</del>	<del>38mm</del>	<del>30mm</del>	<del>21mm</del>	<del>12°</del>

### Renovis Instrumentation

Part Number	Description
2128-001-001	Implant Inserter
2128-001-003	Implant Impactor
2128-001-005	Trial Implant/Bullet Distractor Inserter
2128-001-006	Rasp
2128-001-015	Small Cup Curette
2128-001-016	Large Cup Curette
2128-001-017	Small Up Angled Cup Curette
2128-001-018	Ringed Curette
2128-001-019	Chisel
2128-001-020	23mm Sharp Cobb
2128-001-021	17mm Sharp Cobb
2128-001-023	Small Syper Rongeur
2128-001-024	Large Syper Rongeur
2128-001-025	3mm Pituitary Rongeur
2128-001-026	5mm Pituitary Rongeur
2128-001-027	Small Kerrison Rongeur
2128-001-028	Large Kerrison Rongeur
2128-001-029	Small Modular Handle
2128-001-030	Large Modular Handle
2128-001-031	Large Threaded Handle

2128-001-032	Angled Implant Inserter
2128-001-035	Packing Block
2128-001-036	Long Scalpel Handle
2128-003-026	Small Paddle Sizer
2128-003-428	Medium Paddle Sizer
2128-003-830	Large Paddle Sizer
2128-002-009	9mm Bullet Nose Distractor
2128-002-011	11mm Bullet Nose Distractor
2128-002-013	13mm Bullet Nose Distractor
2128-002-015	15mm Bullet Nose Distractor
2128-002-017	17mm Bullet Nose Distractor
2128-002-019	19mm Bullet Nose Distractor
2128-002-021	21mm Bullet Nose Distractor
2128-302-611	11mm Trial, 30x26 7°
2128-302-612	12mm Trial, 30x26 7°
2128-302-613	13mm Trial, 30x26 7°
2128-302-614	14mm Trial, 30x26 7°
2128-302-615	15mm Trial, 30x26 7°
2128-302-616	16mm Trial, 30x26 7°
2128-302-617	17mm Trial, 30x26 7°
2128-302-618	18mm Trial, 30x26 7°
2128-302-619	19mm Trial, 30x26 7°
2128-302-620	20mm Trial, 30x26 7°
2128-302-621	21mm Trial, 30x26 7°
2128-342-811	11mm Trial, 34x28 7°
2128-342-812	12mm Trial, 34x28 7°
2128-342-813	13mm Trial, 34x28 7°
2128-342-814	14mm Trial, 34x28 7°
2128-342-815	15mm Trial, 34x28 7°
2128-342-816	16mm Trial, 34x28 7°
2128-342-817	17mm Trial, 34x28 7°
2128-342-818	18mm Trial, 34x28 7°
2128-342-819	19mm Trial, 34x28 7°
2128-342-820	20mm Trial, 34x28 7°
2128-342-821	21mm Trial, 34x28 7°
2128-383-011	11mm Trial, 38x28 7°
2128-383-012	12mm Trial, 38x30 7°
2128-383-013	13mm Trial, 38x30 7°
2128-383-014	14mm Trial, 38x30 7°
2128-383-015	15mm Trial, 38x30 7°
2128-383-016	16mm Trial, 38x30 7°
2128-383-017	17mm Trial, 38x30 7°
2128-383-018	18mm Trial, 38x30 7°
2128-383-019	19mm Trial, 38x30 7°
2128-383-020	20mm Trial, 38x30 7°

2128-383-021	21mm Trial, 38x30 7°
2129-302-611	11mm Trial, 30x26 12°
2129-302-612	12mm Trial, 30x26 12°
2129-302-613	13mm Trial, 30x26 12°
2129-302-614	14mm Trial, 30x26 12°
2129-302-615	15mm Trial, 30x26 12°
2129-302-616	16mm Trial, 30x26 12°
2129-302-617	17mm Trial, 30x26 12°
2129-302-618	18mm Trial, 30x26 12°
2129-302-619	19mm Trial, 30x26 12°
2129-302-620	20mm Trial, 30x26 12°
2129-302-621	21mm Trial, 30x26 12°
2129-342-811	11mm Trial, 34x28 12°
2129-342-812	12mm Trial, 34x28 12°
2129-342-813	13mm Trial, 34x28 12°
2129-342-814	14mm Trial, 34x28 12°
2129-342-815	15mm Trial, 34x28 12°
2129-342-816	16mm Trial, 34x28 12°
2129-342-817	17mm Trial, 34x28 12°
2129-342-818	18mm Trial, 34x28 12°
2129-342-819	19mm Trial, 34x28 12°
2129-342-820	20mm Trial, 34x28 12°
2129-342-821	21mm Trial, 34x28 12°
2129-383-011	11mm Trial, 38x28 12°
2129-383-012	12mm Trial, 38x30 12°
2129-383-013	13mm Trial, 38x30 12°
2129-383-014	14mm Trial, 38x30 12°
2129-383-015	15mm Trial, 38x30 12°
2129-383-016	16mm Trial, 38x30 12°
2129-383-017	17mm Trial, 38x30 12°
2129-383-018	18mm Trial, 38x30 12°
2129-383-019	19mm Trial, 38x30 12°
2129-383-020	20mm Trial, 38x30 12°
2129-383-021	21mm Trial, 38x30 12°

# Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) Surgical Technique

## Indications for Use

The Renovis Lumbar Interbody Fusion (LIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis LIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

The Renovis S134 ALIF System must be used with supplemental fixation cleared by the FDA for use in the lumbar spine.

## Description

The S134 Anterior Lumbar Interbody Fusion (ALIF) System is an internal spinal fixation system comprised of PEEK or Titanium Interbody (Tesera) cages. The system also includes instruments that assist in proper implantation; these instruments include: Trials, Sizers, and Cage Inserters.

## Contraindications

Contraindications to using the Lumbar Interbody Fusion (LIF) Systems are similar to those of other Lumbar Interbody Fusion (LIF) Systems and consist of the following:

1. Prior fusion at the level(s) to be treated
2. Any condition not describe in the Indications for Use
3. Patients that are overweight, obese, or are occupationally or recreationally subject to heavy lifting, twisting, repetitive bending, or stooping, to a

- degree that would produce loads on the spinal system leading to failure of fixation or implant failure.
4. Any patient not needing a bone graft and fusion, or where fracture healing is not required.
  5. Patients with bony abnormalities that grossly distort anatomy and/or prevent placement of the implant without risk of impairment to anatomical structures or physiologic performance.
  6. Patients with a suspected or documented metal allergy or intolerance.
  7. Inadequate tissue coverage over the operative site.
  8. Recent or active infection, particularly if in or adjacent to the spine or spinal structures.
  9. Relative contraindications include open wounds as well as fever, leukocytosis, or other signs of systemic infection. Diminished bone quality is a relative contraindication. This may limit the surgeon's ability to achieve adequate implant fixation, structural support, or anatomic correction. These conditions include certain degenerative diseases, postoperative irradiation, smoking, and a history of previous spinal fixation failure. Diminished ability to comprehend and adhere to post-operative care instructions is a relative contraindication. These conditions include diminished mental capacity, mental illness, alcohol or drug abuse and Pregnancy.

## **Warnings and Cautions**

Only experienced spinal surgeons with specific training in the use of interbody fusion systems should implant interbody fusion devices, because this is a technically demanding procedure presenting a risk of serious injury to the patient.

These warnings do not include all possible adverse surgical effects, but are particular to metallic internal fixation devices. Explain general surgical risks to the patient before surgery.

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape, and design of the implant. The size and shape of the human bones present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. Single use only. Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns, which may lead to early breakage.
3. Correct implant handling is vital. These devices may not be contoured. Avoid any notching, scratching or reverse bending of the devices when handling.

Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage. Do not use the implant if damage is suspected. Do not use implants that exhibit surface or configuration damage.

4. The LIF System implants are provided sterile (PEEK and Titanium) and non-sterile (PEEK only). For Sterile-packaged implants, do not resterilize any implant. Do not use implants after expiration date. Non-sterile implants must be thoroughly cleaned and sterilized before each use. Do not use any implant from an opened or damaged package.

5. The LIF System instruments are provided non-sterile, and therefore, must be thoroughly cleaned and sterilized before each use.

6. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

7. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. Inform the patient about the implant limitations, and to limit physical activities, especially lifting and twisting motions and participating in any type of sports. Tell the patient that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. Active, debilitated, or demented patients who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

8. Renovis Implants and Instruments have not been tested for adverse effect in a Magnetic Resonance Imaging (MRI) environment. The implants in the Lumbar Interbody Fusion System are manufactured from non-ferromagnetic materials as listed in the materials section of this IFU. Potential risks of placing implants in or near the magnetic field include:

- a. Movement of ferromagnetic components through magnetically induced force and torque.
- b. Localized heating of components caused by radio frequency induction heating.
- c. Image artifacts created by interaction between metallic components and the magnetic field.

## Preparation

### Anterior access and Approach

Locate the correct operative disc level and incision location by taking a lateral fluoroscopic view while holding a straight metal instrument at the side of the patient. This ensures that the incision and exposure will allow direct visualization into the disc space. Expose the operative disc level through a standard retroperitoneal approach.

### Exposure

The S134 ALIF system must be inserted from a direct anterior approach. Expose the segment to produce sufficient space on either side of the vertebral midline, equal to half the width of the implant. This allows insertion of the implant, without interference from adjacent soft tissue structures.

*Note: Give proper consideration to the exposure so instrumentation can be used as described in the following sections.*

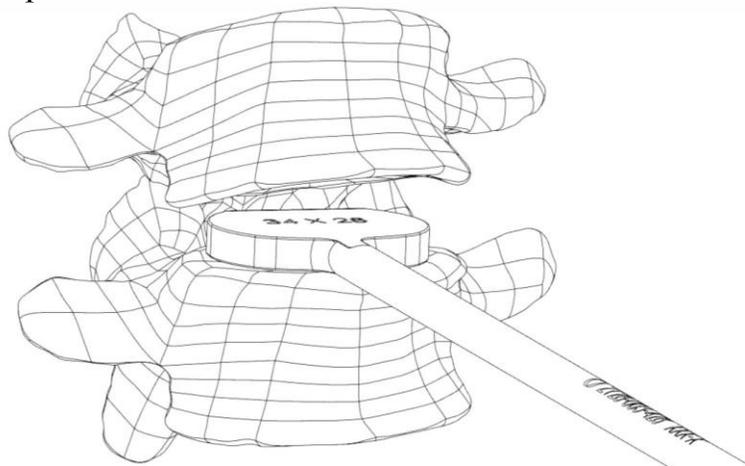
## Discectomy and Endplate Preparation

### Discectomy

Create an annulotomy centered on the midline and wide enough to accommodate the S134 implant. A Paddle Sizer (2128-003-026\_830) may be used as a template to indicate the width of the annular window required.

Perform a thorough discectomy, ensuring the posterolateral corners are freed of disc material.

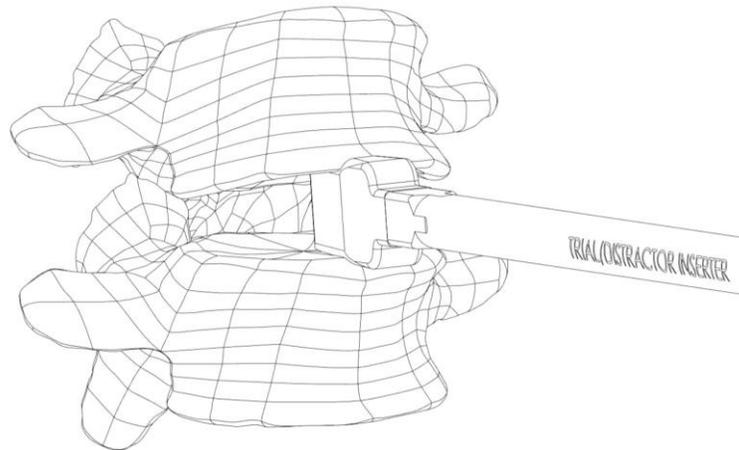
Remove non-ossified fibrocartilage, taking care to not compromise the integrity of the bony endplates.



## Endplate Preparation

If additional disc space distraction or remobilization is necessary, the Bullet Nose Distractors (2128-002-009\_021) are available in the S134 Instrument Set.

Firmly attach the Bullet Nose Distractors to the Trial Implant/ Bullet Nose Distractor Inserter (2128-001-005). Insert a Distractor into the disc space and rotate to distract the disc space to facilitate disc plate preparation.



*Note: Excessive removal of subchondral bone may weaken the vertebral endplate. If the entire endplate is removed, subsidence and a loss of segmental stability may result.*

For a safe placement, verify Bullet Nose Distractor position with the help of intraoperative lateral imaging.

## Trialing

Select the Trial Implant with the appropriate footprint and lordotic angle. Firmly attach it to the Trial Implant/Bullet Nose Distractor Inserter (2128-001-005).

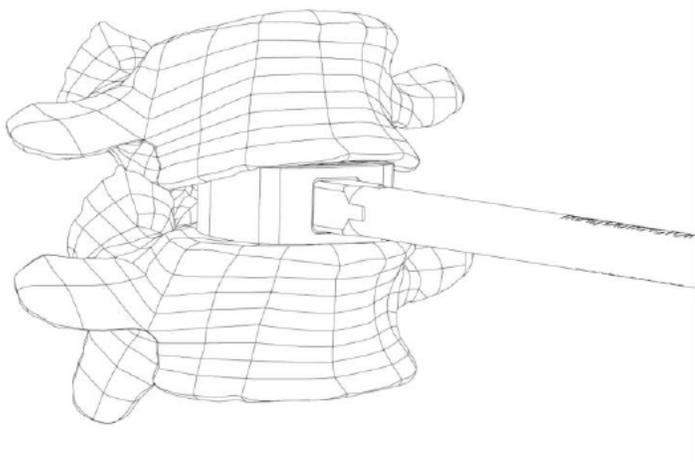
Controlled, light impaction of the trial spacer handle may be required to advance the trial spacer into the disc space.

If a tight fit is not achieved, repeat the process using incrementally larger trial spacers. Conversely, if the trial spacer cannot be inserted, repeat using incrementally smaller trial spacers.

Select the maximum size, to optimize the stability of the segment.

When rocking the trial spacer handle in a cranial to caudal direction, no toggling of the trial spacer should be evident.

X-ray may be used to check the position of the trial implant, restoration of disc and foraminal height, and overall alignment before selecting the final S134 implant size.

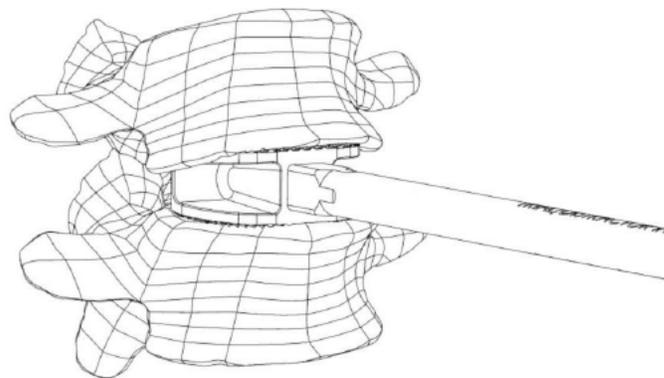
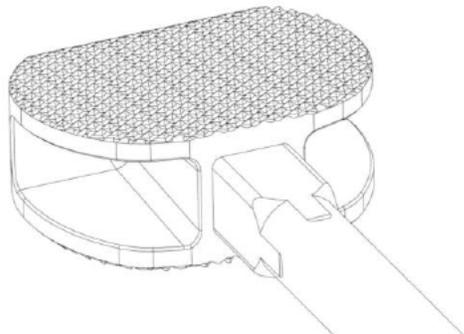


## Broaching

If using the Tesera ALIF Cage, broaching is necessary to ensure that the vertebral endplates are properly prepared for the implant. For this step, attach the appropriate Broach to the Trial Implant/Bullet Nose Distractor Inserter (2128-001-005) based upon the size indicated during the Trialing step. Insert the assembly into the disc space and gently tap on the proximal end with a mallet.

Note: take caution not to over-insert the Broach into the disc space. Do not countersink the broach head beyond the rim of the vertebral endplate. Broaches are 1mm wider per side than the implant, and 2mm deeper than the implant.

Remove the assembly and repeat this step several times to ensure the endplates are roughened and ready to receive the Tesera implant.



## Implant Selection and Graft Packing

Select the appropriate S134 Implant, and insert into the Packing Block (2128-001-035). To facilitate selection of the implant, trial implants are laser etched with the height, lordotic angle and footprint of the implant. Select the S134 implant corresponding to the final trial spacer size.

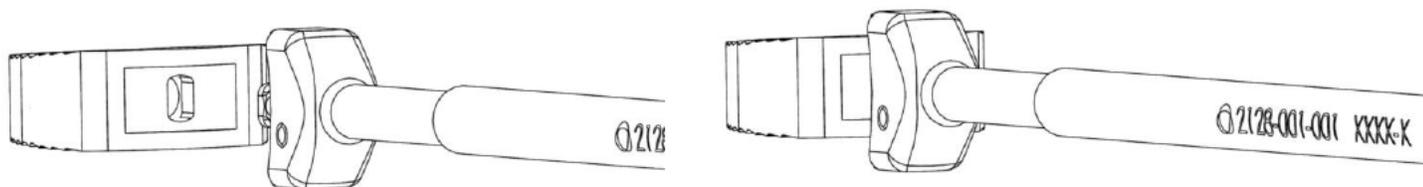
After placing the implant into the Packing Block, fill the implant with autograft material using the Implant Impactor (2128-001-003) to ensure the implant cavities are densely packed.

## Implant Insertion

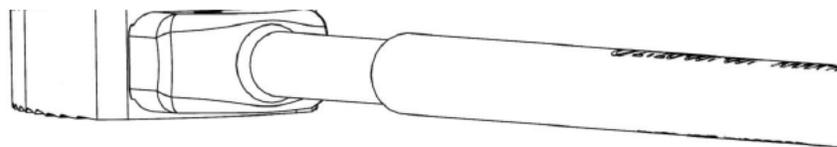
The implant is now ready to be inserted, using the method described below:

### Using the Implant Inserter

Attach the S134 cage to the inserter by inserting distal end of the Implant Inserter (2128-001-001) into the open end of the implant with the attachment slot present. The rectangular post that extends from the inserter must align and fit into the corresponding rectangular slot in the center of the face of the cage.

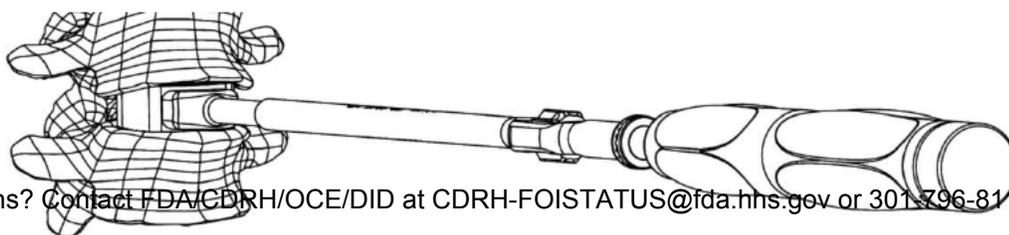


Once the rectangular post of the inserter has penetrated into the interior of the implant, rotate the instrument 90° to align the impaction face with the flat face of the implant and seat the implant up against the inserter face.



When the implant is fully seated, rotate the knob at the proximal end of the implant inserter clockwise to lock the implant to the inserter.

Controlled, light impaction of the Implant Inserter handle may be required to advance the implant into the disc space.



Remove the Implant Inserter by rotating the proximal knob counterclockwise until the inserter can be rotate 90° and removed.

Verify final implant position with the help of an intraoperative lateral imaging.

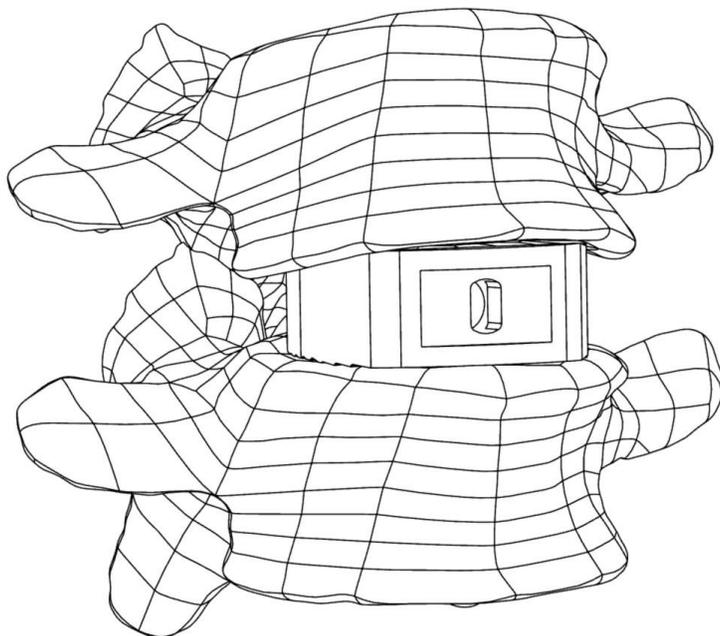
*Note: The posterior x-ray marker incorporated into the implant allows accurate intraoperative radiographic assessment of the position of the implant. The posterior x-ray marker is located approximately 3 mm from the posterior wall of the cage.*

Depending on the size of the vertebrae, the anterior edge of the implant will usually be flush to three-millimeters- recessed relative to the anterior aspect of the adjacent vertebrae.

*Note: All instruments must be removed carefully to avoid possible injury to adjacent structures.*

## **Final Construct Inspection**

Visually inspect the implant, and confirm placement of the construct via lateral and A/P fluoroscopy.



## **Removal or Revisions**

Use extreme caution when exposing the implant upon revision. The approach may be more difficult than at the time of the original surgery due to adhesion between and around the great vessels. It is vitally important to gain full exposure of the Renovis S134 Implant to prevent injury to the great vessels.

Once exposure is gained, simply reverse the surgical technique:

1. Ensure the implant is not hindered by any bone or soft tissue.
2. Attach the Implant Inserter to the exposed front of the implant and gently remove.

## **Patient care following surgery**

A routine wound closure should be performed after x-ray confirmation of proper implant placement. Following surgery, observe standard patient care protocols and monitoring, including, but not limited to:

- Routine monitoring of the vital signs, and of the hemodynamic and neurologic status of the patient.
- Pain medication.
- NG tubes and/or Foley catheters are generally discontinued.
- Diet is restricted per surgeon recommendation to small amounts of liquids until return of bowel function is completed.
- The patient is encouraged to ambulate as soon as possible.
- Braces and activity are to be used at each surgeon's discretion.

## Parts Numbers

### Renovis PEEK Implants -Sterile

Part Number	Width	Depth	Height	Lordosis
1034-302-611	30mm	26mm	11mm	7°
1034-302-612	30mm	26mm	12mm	7°
1034-302-613	30mm	26mm	13mm	7°
1034-302-614	30mm	26mm	14mm	7°
1034-302-615	30mm	26mm	15mm	7°
1034-302-616	30mm	26mm	16mm	7°
1034-302-617	30mm	26mm	17mm	7°
1034-302-618	30mm	26mm	18mm	7°
1034-302-619	30mm	26mm	19mm	7°
1034-302-620	30mm	26mm	20mm	7°
1034-302-621	30mm	26mm	21mm	7°
1034-342-811	34mm	28mm	11mm	7°
1034-342-812	34mm	28mm	12mm	7°
1034-342-813	34mm	28mm	13mm	7°
1034-342-814	34mm	28mm	14mm	7°
1034-342-815	34mm	28mm	15mm	7°
1034-342-816	34mm	28mm	16mm	7°
1034-342-817	34mm	28mm	17mm	7°
1034-342-818	34mm	28mm	18mm	7°
1034-342-819	34mm	28mm	19mm	7°
1034-342-820	34mm	28mm	20mm	7°
1034-342-821	34mm	28mm	21mm	7°
1034-383-011	38mm	30mm	11mm	7°
1034-383-012	38mm	30mm	12mm	7°
1034-383-013	38mm	30mm	13mm	7°
1034-383-014	38mm	30mm	14mm	7°
1034-383-015	38mm	30mm	15mm	7°
1034-383-016	38mm	30mm	16mm	7°
1034-383-017	38mm	30mm	17mm	7°
1034-383-018	38mm	30mm	18mm	7°
1034-383-019	38mm	30mm	19mm	7°
1034-383-020	38mm	30mm	20mm	7°
1034-383-021	38mm	30mm	21mm	7°
1035-302-611	30mm	26mm	11mm	12°
1035-302-612	30mm	26mm	12mm	12°
1035-302-613	30mm	26mm	13mm	12°
1035-302-614	30mm	26mm	14mm	12°
1035-302-615	30mm	26mm	15mm	12°

1035-302-616	30mm	26mm	16mm	12°
1035-302-617	30mm	26mm	17mm	12°
1035-302-618	30mm	26mm	18mm	12°
1035-302-619	30mm	26mm	19mm	12°
1035-302-620	30mm	26mm	20mm	12°
1035-302-621	30mm	26mm	21mm	12°
1035-342-811	34mm	28mm	11mm	12°
1035-342-812	34mm	28mm	12mm	12°
1035-342-813	34mm	28mm	13mm	12°
1035-342-814	34mm	28mm	14mm	12°
1035-342-815	34mm	28mm	15mm	12°
1035-342-816	34mm	28mm	16mm	12°
1035-342-817	34mm	28mm	17mm	12°
1035-342-818	34mm	28mm	18mm	12°
1035-342-819	34mm	28mm	19mm	12°
1035-342-820	34mm	28mm	20mm	12°
1035-342-821	34mm	28mm	21mm	12°
1035-383-011	38mm	30mm	11mm	12°
1035-383-012	38mm	30mm	12mm	12°
1035-383-013	38mm	30mm	13mm	12°
1035-383-014	38mm	30mm	14mm	12°
1035-383-015	38mm	30mm	15mm	12°
1035-383-016	38mm	30mm	16mm	12°
1035-383-017	38mm	30mm	17mm	12°
1035-383-018	38mm	30mm	18mm	12°
1035-383-019	38mm	30mm	19mm	12°
1035-383-020	38mm	30mm	20mm	12°
1035-383-021	38mm	30mm	21mm	12°

### Renovis PEEK Implants - Non-Sterile

Part Number	Width	Depth	Height	Lordosis
1134-302-611	30mm	26mm	11mm	7°
1134-302-612	30mm	26mm	12mm	7°
1134-302-613	30mm	26mm	13mm	7°
1134-302-614	30mm	26mm	14mm	7°
1134-302-615	30mm	26mm	15mm	7°
1134-302-616	30mm	26mm	16mm	7°
1134-302-617	30mm	26mm	17mm	7°
1134-302-618	30mm	26mm	18mm	7°
1134-302-619	30mm	26mm	19mm	7°
1134-302-620	30mm	26mm	20mm	7°
1134-302-621	30mm	26mm	21mm	7°
1134-342-811	34mm	28mm	11mm	7°

1134-342-812	34mm	28mm	12mm	7°
1134-342-813	34mm	28mm	13mm	7°
1134-342-814	34mm	28mm	14mm	7°
1134-342-815	34mm	28mm	15mm	7°
1134-342-816	34mm	28mm	16mm	7°
1134-342-817	34mm	28mm	17mm	7°
1134-342-818	34mm	28mm	18mm	7°
1134-342-819	34mm	28mm	19mm	7°
1134-342-820	34mm	28mm	20mm	7°
1134-342-821	34mm	28mm	21mm	7°
1134-383-011	38mm	30mm	11mm	7°
1134-383-012	38mm	30mm	12mm	7°
1134-383-013	38mm	30mm	13mm	7°
1134-383-014	38mm	30mm	14mm	7°
1134-383-015	38mm	30mm	15mm	7°
1134-383-016	38mm	30mm	16mm	7°
1134-383-017	38mm	30mm	17mm	7°
1134-383-018	38mm	30mm	18mm	7°
1134-383-019	38mm	30mm	19mm	7°
1134-383-020	38mm	30mm	20mm	7°
1134-383-021	38mm	30mm	21mm	7°
1135-302-611	30mm	26mm	11mm	12°
1135-302-612	30mm	26mm	12mm	12°
1135-302-613	30mm	26mm	13mm	12°
1135-302-614	30mm	26mm	14mm	12°
1135-302-615	30mm	26mm	15mm	12°
1135-302-616	30mm	26mm	16mm	12°
1135-302-617	30mm	26mm	17mm	12°
1135-302-618	30mm	26mm	18mm	12°
1135-302-619	30mm	26mm	19mm	12°
1135-302-620	30mm	26mm	20mm	12°
1135-302-621	30mm	26mm	21mm	12°
1135-342-811	34mm	28mm	11mm	12°
1135-342-812	34mm	28mm	12mm	12°
1135-342-813	34mm	28mm	13mm	12°
1135-342-814	34mm	28mm	14mm	12°
1135-342-815	34mm	28mm	15mm	12°
1135-342-816	34mm	28mm	16mm	12°
1135-342-817	34mm	28mm	17mm	12°
1135-342-818	34mm	28mm	18mm	12°
1135-342-819	34mm	28mm	19mm	12°
1135-342-820	34mm	28mm	20mm	12°
1135-342-821	34mm	28mm	21mm	12°
1135-383-011	38mm	30mm	11mm	12°

1135-383-012	38mm	30mm	12mm	12°
1135-383-013	38mm	30mm	13mm	12°
1135-383-014	38mm	30mm	14mm	12°
1135-383-015	38mm	30mm	15mm	12°
1135-383-016	38mm	30mm	16mm	12°
1135-383-017	38mm	30mm	17mm	12°
1135-383-018	38mm	30mm	18mm	12°
1135-383-019	38mm	30mm	19mm	12°
1135-383-020	38mm	30mm	20mm	12°
1135-383-021	38mm	30mm	21mm	12°

### Renovis Titanium Implants - Sterile

Part Number	Width	Depth	Height	Lordosis
1036-302-611	30mm	26mm	11mm	7°
1036-302-612	30mm	26mm	12mm	7°
1036-302-613	30mm	26mm	13mm	7°
1036-302-614	30mm	26mm	14mm	7°
1036-302-615	30mm	26mm	15mm	7°
1036-302-616	30mm	26mm	16mm	7°
1036-302-617	30mm	26mm	17mm	7°
1036-302-618	30mm	26mm	18mm	7°
1036-302-619	30mm	26mm	19mm	7°
1036-302-620	30mm	26mm	20mm	7°
1036-302-621	30mm	26mm	21mm	7°
1036-342-811	34mm	28mm	11mm	7°
1036-342-812	34mm	28mm	12mm	7°
1036-342-813	34mm	28mm	13mm	7°
1036-342-814	34mm	28mm	14mm	7°
1036-342-815	34mm	28mm	15mm	7°
1036-342-816	34mm	28mm	16mm	7°
1036-342-817	34mm	28mm	17mm	7°
1036-342-818	34mm	28mm	18mm	7°
1036-342-819	34mm	28mm	19mm	7°
1036-342-820	34mm	28mm	20mm	7°
1036-342-821	34mm	28mm	21mm	7°
1036-383-011	38mm	30mm	11mm	7°
1036-383-012	38mm	30mm	12mm	7°
1036-383-013	38mm	30mm	13mm	7°
1036-383-014	38mm	30mm	14mm	7°
1036-383-015	38mm	30mm	15mm	7°
1036-383-016	38mm	30mm	16mm	7°
1036-383-017	38mm	30mm	17mm	7°

1036-383-018	38mm	30mm	18mm	7°
1036-383-019	38mm	30mm	19mm	7°
1036-383-020	38mm	30mm	20mm	7°
1036-383-021	38mm	30mm	21mm	7°
1037-302-611	30mm	26mm	11mm	12°
1037-302-612	30mm	26mm	12mm	12°
1037-302-613	30mm	26mm	13mm	12°
1037-302-614	30mm	26mm	14mm	12°
1037-302-615	30mm	26mm	15mm	12°
1037-302-616	30mm	26mm	16mm	12°
1037-302-617	30mm	26mm	17mm	12°
1037-302-618	30mm	26mm	18mm	12°
1037-302-619	30mm	26mm	19mm	12°
1037-302-620	30mm	26mm	20mm	12°
1037-302-621	30mm	26mm	21mm	12°
1037-342-811	34mm	28mm	11mm	12°
1037-342-812	34mm	28mm	12mm	12°
1037-342-813	34mm	28mm	13mm	12°
1037-342-814	34mm	28mm	14mm	12°
1037-342-815	34mm	28mm	15mm	12°
1037-342-816	34mm	28mm	16mm	12°
1037-342-817	34mm	28mm	17mm	12°
1037-342-818	34mm	28mm	18mm	12°
1037-342-819	34mm	28mm	19mm	12°
1037-342-820	34mm	28mm	20mm	12°
1037-342-821	34mm	28mm	21mm	12°
1037-383-011	38mm	30mm	11mm	12°
1037-383-012	38mm	30mm	12mm	12°
1037-383-013	38mm	30mm	13mm	12°
1037-383-014	38mm	30mm	14mm	12°
1037-383-015	38mm	30mm	15mm	12°
1037-383-016	38mm	30mm	16mm	12°
1037-383-017	38mm	30mm	17mm	12°
1037-383-018	38mm	30mm	18mm	12°
1037-383-019	38mm	30mm	19mm	12°
1037-383-020	38mm	30mm	20mm	12°
1037-383-021	38mm	30mm	21mm	12°

### Renovis Instrumentation

Part Number	Description
2128-001-001	Implant Inserter

2128-001-003	Implant Impactor
2128-001-005	Trial Implant/Bullet Distractor Inserter
2128-001-006	Rasp
2128-001-015	Small Cup Curette
2128-001-016	Large Cup Curette
2128-001-017	Small Up Angled Cup Curette
2128-001-018	Ringed Curette
2128-001-019	Chisel
2128-001-020	23mm Sharp Cobb
2128-001-021	17mm Sharp Cobb
2128-001-023	Small Syptert Rongeur
2128-001-024	Large Syptert Rongeur
2128-001-025	3mm Pituitary Rongeur
2128-001-026	5mm Pituitary Rongeur
2128-001-027	Small Kerrison Rongeur
2128-001-028	Large Kerrison Rongeur
2128-001-029	Small Modular Handle
2128-001-030	Large Modular Handle
2128-001-031	Large Threaded Handle
2128-001-032	Angled Implant Inserter
2128-001-035	Packing Block
2128-001-036	Long Scalpel Handle
2128-003-026	Small Paddle Sizer
2128-003-428	Medium Paddle Sizer
2128-003-830	Large Paddle Sizer
2128-002-009	9mm Bullet Nose Distractor
2128-002-011	11mm Bullet Nose Distractor
2128-002-013	13mm Bullet Nose Distractor
2128-002-015	15mm Bullet Nose Distractor
2128-002-017	17mm Bullet Nose Distractor
2128-002-019	19mm Bullet Nose Distractor
2128-002-021	21mm Bullet Nose Distractor
2128-302-611	11mm Trial, 30x26 7°
2128-302-612	12mm Trial, 30x26 7°
2128-302-613	13mm Trial, 30x26 7°
2128-302-614	14mm Trial, 30x26 7°
2128-302-615	15mm Trial, 30x26 7°
2128-302-616	16mm Trial, 30x26 7°
2128-302-617	17mm Trial, 30x26 7°
2128-302-618	18mm Trial, 30x26 7°
2128-302-619	19mm Trial, 30x26 7°
2128-302-620	20mm Trial, 30x26 7°
2128-302-621	21mm Trial, 30x26 7°
2128-342-811	11mm Trial, 34x28 7°
2128-342-812	12mm Trial, 34x28 7°

2128-342-813	13mm Trial, 34x28 7°
2128-342-814	14mm Trial, 34x28 7°
2128-342-815	15mm Trial, 34x28 7°
2128-342-816	16mm Trial, 34x28 7°
2128-342-817	17mm Trial, 34x28 7°
2128-342-818	18mm Trial, 34x28 7°
2128-342-819	19mm Trial, 34x28 7°
2128-342-820	20mm Trial, 34x28 7°
2128-342-821	21mm Trial, 34x28 7°
2128-383-011	11mm Trial, 38x28 7°
2128-383-012	12mm Trial, 38x30 7°
2128-383-013	13mm Trial, 38x30 7°
2128-383-014	14mm Trial, 38x30 7°
2128-383-015	15mm Trial, 38x30 7°
2128-383-016	16mm Trial, 38x30 7°
2128-383-017	17mm Trial, 38x30 7°
2128-383-018	18mm Trial, 38x30 7°
2128-383-019	19mm Trial, 38x30 7°
2128-383-020	20mm Trial, 38x30 7°
2128-383-021	21mm Trial, 38x30 7°
2129-302-611	11mm Trial, 30x26 12°
2129-302-612	12mm Trial, 30x26 12°
2129-302-613	13mm Trial, 30x26 12°
2129-302-614	14mm Trial, 30x26 12°
2129-302-615	15mm Trial, 30x26 12°
2129-302-616	16mm Trial, 30x26 12°
2129-302-617	17mm Trial, 30x26 12°
2129-302-618	18mm Trial, 30x26 12°
2129-302-619	19mm Trial, 30x26 12°
2129-302-620	20mm Trial, 30x26 12°
2129-302-621	21mm Trial, 30x26 12°
2129-342-811	11mm Trial, 34x28 12°
2129-342-812	12mm Trial, 34x28 12°
2129-342-813	13mm Trial, 34x28 12°
2129-342-814	14mm Trial, 34x28 12°
2129-342-815	15mm Trial, 34x28 12°
2129-342-816	16mm Trial, 34x28 12°
2129-342-817	17mm Trial, 34x28 12°
2129-342-818	18mm Trial, 34x28 12°
2129-342-819	19mm Trial, 34x28 12°
2129-342-820	20mm Trial, 34x28 12°
2129-342-821	21mm Trial, 34x28 12°
2129-383-011	11mm Trial, 38x28 12°
2129-383-012	12mm Trial, 38x30 12°
2129-383-013	13mm Trial, 38x30 12°

2129-383-014	14mm Trial, 38x30 12°
2129-383-015	15mm Trial, 38x30 12°
2129-383-016	16mm Trial, 38x30 12°
2129-383-017	17mm Trial, 38x30 12°
2129-383-018	18mm Trial, 38x30 12°
2129-383-019	19mm Trial, 38x30 12°
2129-383-020	20mm Trial, 38x30 12°
2129-383-021	21mm Trial, 38x30 12°