



MAR 27 2014

**Special 510(k) Summary
as required by 21 CFR 807.92(a)
K140106**

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: February 28, 2014

B) Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar
Common Name: Intervertebral body fusion device
Proprietary Name: S128 Anterior Lumbar Interbody Fusion (ALIF) System
Device Class: Class II – 888.3080
Regulation and Product code: 888.3080, OVD - Intervertebral body fusion device
Classification panel: Orthopedic

C) Predicates:

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

D) Device Description:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is cleared under K131122. The S128 ALIF implants (cages) are to be used with the bone screws and anterior cover plate assembly and requires no additional supplementary fixation systems. The Renovis S128 ALIF System implants are available in a variety of sizes (widths, height, depths, and bone screw sizes; see below) to suit the individual pathology and anatomical conditions of the patient. The implants are manufactured from PEEK or additively manufactured and machined Titanium. The bone screws and cover plate

assembly are both manufactured from Titanium alloy. The PEEK markers are manufactured from Tantalum.

This Special 510(k) Premarket Notification is submitted for the additional offering of gamma sterilized S128 implants (PEEK cages; titanium cages, screws and cover plates).

E) Indications For Use:

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.

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.

F) Substantial Equivalence Comparison and Discussion

	Renovis S128 ALIF System	Renovis S128 ALIF System K131122
Product code	OVD	
Implant Material (cages, cover plate, and screws)	PEEK (ZA-500) per ASTM F2026 Titanium alloy Ti-6Al-4V per ASTM F136	
PEEK marker material	Tantalum per ASTM F 560-08	
Dimensions (mm)		
A/P	26, 28, 30	
M/L	30, 34, 38	
H	11 - 21	
Lordosis	7°, 12°	
Number of screws	4	
Screw Diameter (mm)	4.5, 5.	
Screw Length (mm)	20, 25, 30, 35	
Cover plate (mm)	8.3 x 22	
Provided sterile?	Yes - gamma	No

Conclusion

Based upon the same intended use, design, function, technology, and materials, the Renovis S128 ALIF System is substantially equivalent to the predicate devices and does not raise new issues of safety or effectiveness.

G) Performance Data

Implants are sterilized by ⁶⁰Co Gamma irradiation validated to a sterility assurance level (SAL) of 10⁻⁶ by selecting and substantiating a 25 kGy dose by the VDmax²⁵ method, according to ISO 11137-1. Titanium alloy components are not affected by gamma sterilization and/or aging. PEEK components were tested to an average dose of 200kGy and underwent accelerated aging to simulated 10 or more years. After aging the samples were tested, and the results did not show any significant difference between untreated PEEK and gamma treated and aged PEEK.

Packaging has been validated to maintain sterility for 3 years in compliance with ISO 11607-2 demonstrates compliance with accelerated aging simulation per ASTM F1980-7 and real time aging; and performance following distribution per ISTA 2A.

Conclusion

Gamma sterilization does not have a negative effect on Renovis S128 ALIF System implants.

H) Compliance with Design Controls

The results of design validation support that the Renovis S128 ALIF System is substantially equivalent to the predicate device and the offering of gamma irradiated implant components does not raise new issues of safety or effectiveness.

I) Compliance with Consensus Standards and FDA Guidance

Standards - Renovis complies with:

- ASTM F2026 Standard Specification for PEEK Polymers for Surgical Implant Applications
- ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, and
- ASTM F 560-08, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications
- ISO 11137-1: 2006: Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ANSI/AAMI/ISO 11137-2:2006 Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
- ISO11607-2: 2006 Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1980-07: 2007 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

- ASTM D4169:2009 Standard Practice for Performance Testing of Shipping Containers and Systems
- ISTA 2A, 2011 Partial-Simulation Performance Test Procedure: Packaged Products 150lb (68 kg) or Less

FDA guidance:

- Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA, August 2002
- Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, October 2007
- Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Review Guidance, April 1996
- Guidance for Industry and FDA Staff Spinal System 510(k)'s, May 2004 (for labeling language)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 27, 2014

Renovis Surgical Technologies, Incorporated
% Sharyn Orton, Ph.D.
MEDIcept, Incorporated
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K140106

Trade/Device Name: Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: March 5, 2014
Received: March 7, 2014

Dear Dr. Orton:

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

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

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

Page 2 – Sharyn Orton, Ph.D.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Ronald P. Jean -S for

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K140106

Device Name: Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

Indications for Use:

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Prescription Use X AND/OR Over-the-Counter Use _____
(21 CFR 801, Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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Renovis Surgical Technologies, Incorporated
% Sharyn Orton, Ph.D.
MEDIcept, Incorporated
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K140106

Trade/Device Name: Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System
Regulation Number: 21 CFR 888.3080
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Regulatory Class: Class II
Product Code: OVD
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Sharyn Orton, Ph.D.

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Sincerely yours,

Ronald P. Jean -S for

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K140106

Device Name: Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

Indications for Use:

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.

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.

Prescription Use X AND/OR Over-the-Counter Use _____
(21 CFR 801, Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

Collins, Virginia *

From: Collins, Virginia *
Sent: Friday, March 28, 2014 1:46 PM
To: 'sorton@medicept.com'
Cc: DCCLetters
Subject: K140106 SE Letter
Attachments: K140106.pdf

Tracking:	Recipient	Delivery
	'sorton@medicept.com'	
	DCCLetters	Delivered: 3/28/2014 1:46 PM

K140106



FDA CDRH DMC

JAN 15 2014

Received

January 14, 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 S128 Anterior Lumbar Intebody Fusion (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.

The eCopy is an exact duplicate of the paper copy with the exception of 003_FDA From 3514 which could not be paginated. The folder MISC FILES also contains a Word copy of the S128 Anterior Lumbar Intebody Fusion (IBF) System Instructions of Use. 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.

Brief Description

The Renovis S128 ALIF System is currently 510(k) cleared under K131122. Implants in K131122 are currently offered as clean but must be steam sterilized before use. This Special 510(k) Premarket Notification is being submitted as Renovis intends to additionally offer gamma sterilized S128 implants (PEEK and titanium cages; titanium alloy cover plate, and screws).

- Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar
- Common Name: Intervertebral body fusion device

CONFIDENTIAL
200 Homer Ave.

MEDIcept, Inc.
Renovis S128 ALIF System

Ashland, MA 01721
Special 510(k) Premarket Notification

Handwritten initials

- Proprietary Name: Renovis 128 Anterior Lumbar Interbody Fusion (ALIF) System
- Device Class II – 21 CFR 888.3080, product code OVD

Administrative Information and Basis of Submission

The additional offering of gamma sterilized implants 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. Change due to recall or corrective action? No
2. Labeling change? Yes, but only as it applies to item #3.
3. Technology or performance change? Yes
B1 – B8: No to changes
B9: Changes in packaging or expiration dating? Yes – sterilization method not described in the original 510(k) – requires a 510(k)
B10: Change in sterilization? Yes
B10.1: Lower SAL? No - Documentation
4. Materials change? No

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. Device represents modification to your own device? Yes
2. Modification appropriate for reliance on results from design control process? Yes
3. Design validation is performed? Yes
4. Conformance is assured? Yes – Special 510(k)

Design and Use of the Device

- The Renovis S128 ALIF System is for prescription use only.
- Renovis S128 ALIF System implants (cages, cover plate and screws) will also be offered as gamma sterilized.
- No Renovis S128 ALIF implants contain tissue or other biologic material.
- Renovis S128 ALIF implants (cages, cover plates and screws) are single use only.
- There is no software associated with this device.
- There is no clinical data included in this application.

Indications for Use

There is no change in the Indications for Use:

MEDIcept, Inc.
Renovis S128 ALIF System

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Special 510(k) Premarket Notification

1-2

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.

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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.

The Renovis S128 ALIF System components are currently cleared under K131122.

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).

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 an Traditional 510(k) Premarket Notification.

MEDIcept, Inc.
Renovis S128 ALIF System

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200 Homer Ave.

Ashland, MA 01721
Special 510(k) Premarket Notification

1-3

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.

Sincerely yours,



Sharyn Orton, Ph.D.

Senior Consultant

MEDIcept, Inc.

for

Renovis Surgical Technologies

MEDIcept, Inc.
Renovis S128 ALIF System

CONFIDENTIAL
200 Homer Ave.

Ashland, MA 01721
Special 510(k) Premarket Notification

1-4



January 14, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
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- Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar
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MEDIcept, Inc.
Renovis S128 ALIF System

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200 Homer Ave.

Ashland, MA 01721
Special 510(k) Premarket Notification

1-1

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Indications for Use

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MEDIcept, Inc.
Renovis S128 ALIF System

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Special 510(k) Premarket Notification

1-2

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Senior Consultant

MEDIcept, Inc.

for

Renovis Surgical Technologies

MEDIcept, Inc.
Renovis S128 ALIF System

CONFIDENTIAL
200 Homer Ave.

Ashland, MA 01721
Special 510(k) Premarket Notification

1-4

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

Title	Related Information	Present	N/A
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	
Indications for Use Statement		x	
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	
Compliance with Standards and Guidance	Guidance for Industry and FDA Staff: Recognition and Use of Consensus Standards, September 17, 2007	x	
Biocompatibility	Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, August 12, 2005: Guidance Documents/ucm084365.htm		x
Software			x
Electromagnetic Compatibility/Electrical Safety			x
Performance Testing – Bench			x
Performance Testing – Animal			x
Performance Testing – Clinical			x
Kit Certification	Device Advice: Kit Certifications for 510(k)s		x

CONFIDENTIAL
200 Homer Ave.

MEDIcept, Inc.
Renovis S128 ALIF System

Ashland, MA 01721
Special 510(k) Premarket Notification

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Renovis S128 ALIF System

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1-6

reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

07-Jan-2014

Form FDA 3601 (01/2007)

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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		2. Date of the Application/Submission Which This Certification Accompanies 1/14/2014	
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 Redlands	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
 S128 Anterior Lumbar Interbody Fusion (ALIF) System

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, MEDIcept, Inc.
-----------------------------	--

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

1/3/2014

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

Sharyn Orton

Sign

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

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 Paperwork Reduction Act (PRA) Staff
 PRAStaff@fda.hhs.gov

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

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

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

• ISO 11137-1: 2006: Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and rou

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # _____

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

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

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

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

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

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

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

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

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

Title of guidance: • Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA, August 2002

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

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

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

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 11137-1: 2006: Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and rou		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Summary included in section 013_Design Control activities and risk analysis		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement		
<p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:</p> <p style="margin-left: 40px;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> <p style="margin-left: 40px;"><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>		

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

Traditional Special Abbreviated

STANDARD TITLE ¹

• ANSI/AAMI/ISO 11137-2:2006 Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? Yes No

FDA Recognition number ³ # _____

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Yes No

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? Yes No
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? Yes No

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

Does this standard include more than one option or selection of tests? Yes No
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?..... Yes No
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? Yes No

Were deviations or adaptations made beyond what is specified in the FDA SIS?..... Yes No
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? Yes No
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?..... Yes No
If yes, was the guidance document followed in preparation of this 510k? Yes No

Title of guidance: • Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA, August 2002

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⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

• ANSI/AAMI/ISO 11137-2:2006 Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *
Summary included in section 013_Design Control activities and risk analysis

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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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

* 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.

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Paperwork Reduction Act Statement

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Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

•• ISO11607-2: 2006 Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # _____

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

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

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

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

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

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

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If yes, report these deviations or adaptations in the summary report table.

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

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

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

• ASTM F1980-07: 2007 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? Yes No

FDA Recognition number ³ # _____

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Yes No

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Food and Drug Administration
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM D4169:2009 Standard Practice for Performance Testing of Shipping Containers and Systems

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # _____

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

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
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Title of guidance: _____

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISTA 2A, 2011 Partial-Simulation Performance Test Procedure: Packaged Products 150lb (68 kg) or Less

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # _____

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

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

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⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Indications for Use Statement

510(k) Number (if known):

Device Name: Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

Indications for Use:

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.

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.

Prescription Use X AND/OR Over-the-Counter Use _____
(21 CFR 801, Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of *CDRH, Office of Device Evaluation (ODE)*



**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: January 7, 2014

B) Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar
Common Name: Intervertebral body fusion device
Proprietary Name: S128 Anterior Lumbar Interbody Fusion (ALIF) System
Device Class: Class II – 888.3080
Regulation and Product code: 888.3080, OVD - Intervertebral body fusion device
Classification panel: Orthopedic

C) Predicates:

- K0131122 Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

D) Device Description:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is cleared under K131122. The S128 ALIF implants (cages) are to be used with the bone screws and anterior cover plate assembly and requires no additional supplementary fixation systems. The Renovis S128 ALIF System implants 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 bone screws and cover plate assembly are both manufactured from Titanium alloy. The PEEK markers are manufactured from Tantalum.

This Special 510(k) Premarket Notification is submitted for the additional offering of gamma sterilized S128 implants (PEEK cages; titanium cages, screws and cover plates).

E) Indications For Use:

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.

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.

F) Substantial Equivalence Comparison and Discussion

	Renovis S128 ALIF System	Renovis S128 ALIF System K131122
Product code	OVD	
Implant Material	PEEK Titanium	
PEEK marker material	Tantalum	
Dimensions A/P M/L H	Multiple; no change	
Lordosis	No change	
Screw and cover plate material	Titanium	
Number of screws	4	
Screw dimensions	Multiple; no change	
Provided sterile?	Yes - gamma	No

Conclusion

Based upon the same intended use, design, function, technology, and materials, the Renovis S128 ALIF System is substantially equivalent to the predicate devices and does not raise new issues of safety or effectiveness.

G) Compliance with Design Controls

The results of design validation support that the Renovis S128 ALIF System is substantially equivalent to the predicate device and the offering of gamma irradiated implant components does not raise new issues of safety or effectiveness.

H) Compliance with Consensus Standards and FDA Guidance

Standards - Relevant to this submission, Renovis complies with:

- ISO 11137-1: 2006: Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ANSI/AAMI/ISO 11137-2:2006 Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
- ISO11607-2: 2006 Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1980-07: 2007 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D4169:2009 Standard Practice for Performance Testing of Shipping Containers and Systems
- ISTA 2A, 2011 Partial-Simulation Performance Test Procedure: Packaged Products 150lb (68 kg) or Less

FDA guidance:

- Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA, August 2002
- Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, October 2007



**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

1 / 14 / 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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Device Description

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is cleared under K131122. The S128 ALIF implants consist of cages, bone screws and cover plates. Cages are to be used with the bone screws and anterior cover plate assembly and require no additional supplementary fixation systems. The Renovis S128 ALIF System 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 cages are manufactured from PEEK or additively manufactured and machined Titanium. The bone screws and cover plate assembly are both manufactured from Titanium alloy. The PEEK markers are manufactured from Tantalum. The implants are currently offered as non-sterile and require steam sterilization before use.

Renovis intends to also offer gamma sterilized S128 implants (PEEK cages; titanium cages, screws and cover plates). There are no other changes to the S128 implants as described in K131122 in Table 1; details in Tables 2, 3, 4 and 5), and the characteristics are the same as those described in K131122. Engineering drawings were included in K131122 and are not included in this 510(k).

Table 1 Summary

Cages	Description
Materials	(b)(4) PEEK (ZA-500) Titanium alloy Ti-6Al-4V
PEEK cage Marker material	Tantalum
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 ³
End plate coverage	340-360 mm ³
Screws and cover plates	
Material	Titanium alloy Ti-6Al-4V
Number of screws	4
Screw Diameter (mm)	4.5, 5.0
Screw Length (mm)	20, 25, 30, 35
Sterilization	Gamma irradiation

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Description of the Change – Gamma IrradiationDescription of Gamma Sterilization and Validation

Gamma sterilization will be conducted at a minimum of 25 kGy and will demonstrate achievement of a sterility assurance level (SAL) of 10^{-6} according to ANSI/AAMI/ISO 11137-2:2006.

Implant components will be sterilized by ^{60}Co Gamma irradiation validated to a sterility assurance level (SAL) of 10^{-6} by selecting and substantiating a 25 kGy dose by the VDmax²⁵ method, according to ISO 11137-1 *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* and ISO 11137-2 *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose*.

Parts Numbers

The parts numbers are the same as noted in K131122 except an “S” has been added.

Table 2: PEEK Cage Geometry

Part Number	Width	Depth	Height	Lordosis	Bone Graft Volume*	(b)(4)
1128-302-611S	30mm	26mm	11mm	7°	2270mm ³	
1128-302-612S	30mm	26mm	12mm	7°	2520 mm ³	
1128-302-613S	30mm	26mm	13mm	7°	2770 mm ³	
1128-302-614S	30mm	26mm	14mm	7°	3020 mm ³	
1128-302-615S	30mm	26mm	15mm	7°	3270 mm ³	
1128-302-616S	30mm	26mm	16mm	7°	3530 mm ³	
1128-302-617S	30mm	26mm	17mm	7°	3780 mm ³	
1128-302-618S	30mm	26mm	18mm	7°	4030 mm ³	
1128-302-619S	30mm	26mm	19mm	7°	4280 mm ³	
1128-302-620S	30mm	26mm	20mm	7°	4540 mm ³	
1128-302-621S	30mm	26mm	21mm	7°	4790 mm ³	
1128-342-811S	34mm	26mm	11mm	7°	2940 mm ³	
1128-342-812S	34mm	26mm	12mm	7°	3270 mm ³	
1128-342-813S	34mm	26mm	13mm	7°	3600 mm ³	
1128-342-814S	34mm	26mm	14mm	7°	3920 mm ³	
1128-342-815S	34mm	26mm	15mm	7°	4250 mm ³	
1128-342-816S	34mm	26mm	16mm	7°	4580 mm ³	
1128-342-817S	34mm	26mm	17mm	7°	4910 mm ³	
1128-342-818S	34mm	26mm	18mm	7°	5230 mm ³	
1128-342-819S	34mm	26mm	19mm	7°	5560 mm ³	

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1128-342-820S	34mm	26mm	20mm	7°	5890 mm ³
1128-342-821S	34mm	26mm	21mm	7°	6210 mm ³
1128-383-011S	38mm	26mm	11mm	7°	3950 mm ³
1128-383-012S	38mm	26mm	12mm	7°	4400 mm ³
1128-383-013S	38mm	26mm	13mm	7°	4840 mm ³
1128-383-014S	38mm	26mm	14mm	7°	5290 mm ³
1128-383-015S	38mm	26mm	15mm	7°	5740 mm ³
1128-383-016S	38mm	26mm	16mm	7°	6190 mm ³
1128-383-017S	38mm	26mm	17mm	7°	6630 mm ³
1128-383-018S	38mm	26mm	18mm	7°	7080 mm ³
1128-383-019S	38mm	26mm	19mm	7°	7530 mm ³
1128-383-020S	38mm	26mm	20mm	7°	7970 mm ³
1128-383-021S	38mm	26mm	21mm	7°	8420 mm ³
1129-302-611S	30mm	26mm	11mm	12°	2060 mm ³
1129-302-612S	30mm	26mm	12mm	12°	2310 mm ³
1129-302-613S	30mm	26mm	13mm	12°	2560 mm ³
1129-302-614S	30mm	26mm	14mm	12°	2810 mm ³
1129-302-615S	30mm	26mm	15mm	12°	3060 mm ³
1129-302-616S	30mm	26mm	16mm	12°	3320 mm ³
1129-302-617S	30mm	26mm	17mm	12°	3570 mm ³
1129-302-618S	30mm	26mm	18mm	12°	3820 mm ³
1129-302-619S	30mm	26mm	19mm	12°	4070 mm ³
1129-302-620S	30mm	26mm	20mm	12°	4320 mm ³
1129-302-621S	30mm	26mm	21mm	12°	4570 mm ³
1129-342-811S	34mm	26mm	11mm	12°	2610 mm ³
1129-342-812S	34mm	26mm	12mm	12°	2940 mm ³
1129-342-813S	34mm	26mm	13mm	12°	3270 mm ³
1129-342-814S	34mm	26mm	14mm	12°	3590 mm ³
1129-342-815S	34mm	26mm	15mm	12°	3920 mm ³
1129-342-816S	34mm	26mm	16mm	12°	4250 mm ³
1129-342-817S	34mm	26mm	17mm	12°	4570 mm ³
1129-342-818S	34mm	26mm	18mm	12°	4900 mm ³
1129-342-819S	34mm	26mm	19mm	12°	5230 mm ³
1129-342-820S	34mm	26mm	20mm	12°	5560 mm ³
1129-342-821S	34mm	26mm	21mm	12°	5880 mm ³
1129-383-011S	38mm	26mm	11mm	12°	3450 mm ³
1129-383-012S	38mm	26mm	12mm	12°	3900 mm ³
1129-383-013S	38mm	26mm	13mm	12°	4340 mm ³
1129-383-014S	38mm	26mm	14mm	12°	4790 mm ³
1129-383-015S	38mm	26mm	15mm	12°	5240 mm ³
1129-383-016S	38mm	26mm	16mm	12°	5680 mm ³
1129-383-017S	38mm	26mm	17mm	12°	6130 mm ³
1129-383-018S	38mm	26mm	18mm	12°	6580 mm ³
1129-383-019S	38mm	26mm	19mm	12°	7030 mm ³

(b)(4)

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

1129-383-020S	38mm	26mm	20mm	12°	7470 mm ³	(b)(4)
1129-383-021S	38mm	26mm	21mm	12°	7920 mm ³	(b)(4)

Table 3: Titanium Cage Geometry

Part Number	Width	Depth	Height	Lordosis	Bone Graft Volume*	(b)(4)
1131-302-611S	30mm	26mm	11.25mm	7°	2270mm ³	(b)(4)
1131-302-612S	30mm	26mm	12.25mm	7°	2520 mm ³	(b)(4)
1131-302-613S	30mm	26mm	13.25mm	7°	2770 mm ³	(b)(4)
1131-302-614S	30mm	26mm	14.25mm	7°	3020 mm ³	(b)(4)
1131-302-615S	30mm	26mm	15.25mm	7°	3270 mm ³	(b)(4)
1131-302-616S	30mm	26mm	16.25mm	7°	3530 mm ³	(b)(4)
1131-302-617S	30mm	26mm	17.25mm	7°	3780 mm ³	(b)(4)
1131-302-618S	30mm	26mm	18.25mm	7°	4030 mm ³	(b)(4)
1131-302-619S	30mm	26mm	19.25mm	7°	4280 mm ³	(b)(4)
1131-302-620S	30mm	26mm	20.25mm	7°	4540 mm ³	(b)(4)
1131-302-621S	30mm	26mm	21.25mm	7°	4790 mm ³	(b)(4)
1131-342-811S	34mm	28mm	11.25mm	7°	2940 mm ³	(b)(4)
1131-342-812S	34mm	28mm	12.25mm	7°	3270 mm ³	(b)(4)
1131-342-813S	34mm	28mm	13.25mm	7°	3600 mm ³	(b)(4)
1131-342-814S	34mm	28mm	14.25mm	7°	3920 mm ³	(b)(4)
1131-342-815S	34mm	28mm	15.25mm	7°	4250 mm ³	(b)(4)
1131-342-816S	34mm	28mm	16.25mm	7°	4580 mm ³	(b)(4)
1131-342-817S	34mm	28mm	17.25mm	7°	4910 mm ³	(b)(4)
1131-342-818S	34mm	28mm	18.25mm	7°	5230 mm ³	(b)(4)
1131-342-819S	34mm	28mm	19.25mm	7°	5560 mm ³	(b)(4)
1131-342-820S	34mm	28mm	20.25mm	7°	5890 mm ³	(b)(4)
1131-342-821S	34mm	28mm	21.25mm	7°	6210 mm ³	(b)(4)
1131-383-011S	38mm	30mm	11.25mm	7°	3950 mm ³	(b)(4)
1131-383-012S	38mm	30mm	12.25mm	7°	4400 mm ³	(b)(4)
1131-383-013S	38mm	30mm	13.25mm	7°	4840 mm ³	(b)(4)
1131-383-014S	38mm	30mm	14.25mm	7°	5290 mm ³	(b)(4)
1131-383-015S	38mm	30mm	15.25mm	7°	5740 mm ³	(b)(4)
1131-383-016S	38mm	30mm	16.25mm	7°	6190 mm ³	(b)(4)
1131-383-017S	38mm	30mm	17.25mm	7°	6630 mm ³	(b)(4)
1131-383-018S	38mm	30mm	18.25mm	7°	7080 mm ³	(b)(4)
1131-383-019S	38mm	30mm	19.25mm	7°	7530 mm ³	(b)(4)
1131-383-020S	38mm	30mm	20.25mm	7°	7970 mm ³	(b)(4)
1131-383-021S	38mm	30mm	21.25mm	7°	8420 mm ³	(b)(4)
1133-302-611S	30mm	26mm	11.25mm	12°	2060 mm ³	(b)(4)
1133-302-612S	30mm	26mm	12.25mm	12°	2310 mm ³	(b)(4)
1133-302-613S	30mm	26mm	13.25mm	12°	2560 mm ³	(b)(4)

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1133-302-614S	30mm	26mm	14.25mm	12°	2810 mm ³	(b)(4)
1133-302-615S	30mm	26mm	15.25mm	12°	3060 mm ³	
1133-302-616S	30mm	26mm	16.25mm	12°	3320 mm ³	
1133-302-617S	30mm	26mm	17.25mm	12°	3570 mm ³	
1133-302-618S	30mm	26mm	18.25mm	12°	3820 mm ³	
1133-302-619S	30mm	26mm	19.25mm	12°	4070 mm ³	
1133-302-620S	30mm	26mm	20.25mm	12°	4320 mm ³	
1133-302-621S	30mm	26mm	21.25mm	12°	4570 mm ³	
1133-342-811S	34mm	28mm	11.25mm	12°	2610 mm ³	
1133-342-812S	34mm	28mm	12.25mm	12°	2940 mm ³	
1133-342-813S	34mm	28mm	13.25mm	12°	3270 mm ³	
1133-342-814S	34mm	28mm	14.25mm	12°	3590 mm ³	
1133-342-815S	34mm	28mm	15.25mm	12°	3920 mm ³	
1133-342-816S	34mm	28mm	16.25mm	12°	4250 mm ³	
1133-342-817S	34mm	28mm	17.25mm	12°	4570 mm ³	
1133-342-818S	34mm	28mm	18.25mm	12°	4900 mm ³	
1133-342-819S	34mm	28mm	19.25mm	12°	5230 mm ³	
1133-342-820S	34mm	28mm	20.25mm	12°	5560 mm ³	
1133-342-821S	34mm	28mm	21.25mm	12°	5880 mm ³	
1133-383-011S	38mm	30mm	11.25mm	12°	3450 mm ³	
1133-383-012S	38mm	30mm	12.25mm	12°	3900 mm ³	
1133-383-013S	38mm	30mm	13.25mm	12°	4340 mm ³	
1133-383-014S	38mm	30mm	14.25mm	12°	4790 mm ³	
1133-383-015S	38mm	30mm	15.25mm	12°	5240 mm ³	
1133-383-016S	38mm	30mm	16.25mm	12°	5680 mm ³	
1133-383-017S	38mm	30mm	17.25mm	12°	6130 mm ³	
1133-383-018S	38mm	30mm	18.25mm	12°	6580 mm ³	
1133-383-019S	38mm	30mm	19.25mm	12°	7030 mm ³	
1133-383-020S	38mm	30mm	20.25mm	12°	7470 mm ³	
1133-383-021S	38mm	30mm	21.25mm	12°	7920 mm ³	

Table 4: Screw Geometry

Part Number	Description	Shaft Length	(b)(4)	Thread OD	(b)(4)
1128-453-020S	4.5mm Variable Screw	20mm	(b)(4)	4.5mm	(b)(4)
1128-453-025S	4.5mm Variable Screw	25mm	(b)(4)	4.5mm	(b)(4)
1128-453-030S	4.5mm Variable Screw	30mm	(b)(4)	4.5mm	(b)(4)
1128-453-035S	4.5mm Variable Screw	35mm	(b)(4)	4.5mm	(b)(4)
1129-453-020S	4.5mm Constrained Screw	20mm	(b)(4)	4.5mm	(b)(4)

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1129-453-025S	4.5mm Constrained Screw	25mm	(b)(4)	4.5mm	(b)(4)
1129-453-030S	4.5mm Constrained Screw	30mm	(b)(4)	4.5mm	(b)(4)
1129-453-035S	4.5mm Constrained Screw	35mm	(b)(4)	4.5mm	(b)(4)
1129-503-020S	5.0mm Constrained Screw	20mm	(b)(4)	5.0mm	(b)(4)
1129-503-025S	5.0mm Constrained Screw	25mm	(b)(4)	5.0mm	(b)(4)
1129-503-030S	5.0mm Constrained Screw	30mm	(b)(4)	5.0mm	(b)(4)
1129-503-035S	5.0mm Constrained Screw	35mm	(b)(4)	5.0mm	(b)(4)
1130-503-020S	5.0mm Rescue Screw	20mm	(b)(4)	5.0mm	(b)(4)
1130-503-025S	5.0mm Rescue Screw	25mm	(b)(4)	5.0mm	(b)(4)
1130-503-030S	5.0mm Rescue Screw	30mm	(b)(4)	5.0mm	(b)(4)
1130-503-035S	5.0mm Rescue Screw	35mm	(b)(4)	5.0mm	(b)(4)

Table 5: Cover Plate Assembly Geometry

Part Number	Height	Width	(b)(4)
1128-003-001S	8.3mm	22mm	(b)(4)

Compliance with Standards and Guidance

Standards - Relevant to this submission, Renovis complies with:

- ISO 11137-1: 2006: Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ANSI/AAMI/ISO 11137-2:2006 Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
- ISO11607-2: 2006 Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes, Operational Qualification Section 5.3 and Performance Qualification Section 5.4 (Peel and Burst Testing)
- ASTM F1980-07: 2007 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D4169:2009 Standard Practice for Performance Testing of Shipping Containers and Systems

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- ISTA 2A, 2011 Partial-Simulation Performance Test Procedure: Packaged Products 150lb (68 kg) or Less

FDA guidance:

- Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA, August 2002
- Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, October 2007 – Section 11. Sterility

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Substantial Equivalence Discussion

Renovis S128 ALIF System implants (PEEK cages; titanium cages, screws and cover plates) are cleared under K131122. There are no changes to these implants with the exception of the additional offering of gamma sterilized implants. The implant characteristics in the Table below are the same as were described in K131122.

	Renovis S128 ALIF System	Renovis S128 ALIF System K131122
Product code	OVD	
Implant Material	(b)(4) PEEK (ZA-500) Titanium alloy Ti-6Al-4V	
Marker material	Tantalum	
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 volume	2270-7920 mm ³	
End plate coverage	(b)(4)	
Screw and cover plate material	Titanium alloy Ti-6Al-4V	
Number of screws	4	
Screw Diameter (mm)	4.5, 5.0	
Screw Length (mm)	20, 25, 30, 35	
Provided sterile?	Yes - gamma	No

Indications for Use are the same:

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

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spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF 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.

Conclusion

The Renovis S128 ALIF implants have the same intended use, design, function, technology, and materials as the implants cleared under K131122. The additional offering of gamma irradiated implants is managed in conformance with Design Control requirements. The addition of gamma irradiated implants does not raise new issues of safety or effectiveness. Therefore, the Renovis S128 ALIF System is substantially equivalent to the predicate device.

Labeling

The labels for the gamma irradiated implants (cages, cover plate and screws) are included below (page 11-2).

- Representative label – PEEK cage (11-2)
- Representative label – Titanium cage (11-4)
- Label – Cover plate (11-6)
- Representative label – Screws (11-8)

Symbols are defined on the box labels used (page 11-10 and 11-11).

In addition, gamma sterilized Renovis S128 implants will have separate Instructions for Use (012). The IFU is highlighted to clarify the differences between this additional IFU and the IFU previously submitted for use with the non-sterilized implants.

The only change to the FDA cleared Surgical Manual will be the addition of the new parts numbers. There are no other changes; therefore the Surgical Manual is not included here.

RENOVIS SURGICAL TECHNOLOGIES

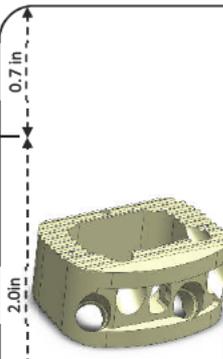
Label	ALIF PEEK Implant Label	June 2013
L 042	Revision A	Page 1 of 2

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	June 2013	Initial Release	TBD

RENOVIS SURGICAL TECHNOLOGIES

Label	ALIF PEEK Implant Label	June 2013
L 042	Revision A	Page 2 of 2



RENOVIS™

Field 1	ALIF Cage
Field 2	PEEK
Field 3	30 X 26 - 11 mm Height
Field 4	7° Lordosis

REF 1128-302-611S LOT 1234-123 QTY 1 YYYY-MM

Material: PEEK and Tantalum **STERILE** **R**

Field 8: REF 

Field 9: LOT 

QTY 

For Instructions For Use (IFU) go to www.renovis-surgical.com
Paper copy of IFU available upon request at info@renovis-surgical.com

Label 042 Rev. A

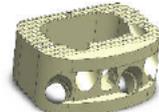
RENOVIS™

Field 1	ALIF Cage
Field 2	PEEK
Field 3	30 X 26 - 11 mm Height
Field 4	7° Lordosis

Field 5: REF 1128-302-611S

Field 6: LOT 1234-123

Field 7: QTY 1 YYYY-MM



Material: PEEK and Tantalum **STERILE** **R**
Label 042 Rev. A

VOID

 <p style="font-size: 8px;">REF 1128-302-611S LOT 1234-123 YYYY-MM</p> <p style="font-size: 8px;">Field 1: ALIF Cage Field 2: PEEK Field 3: 30 X 26 - 11 mm Height Field 4: 7° Lordosis</p> <p style="font-size: 8px;">Label 042 Rev. A</p>	COPY						
--	------	------	------	------	------	------	------

RENOVIS SURGICAL TECHNOLOGIES

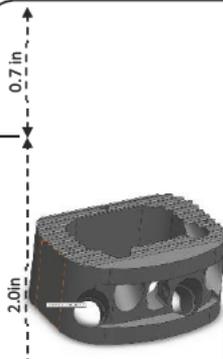
Label	ALIF Ti-6Al-4V Implant Label	June 2013
L 043	Revision A	Page 1 of 2

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	June 2013	Initial Release	TBD

RENOVIS SURGICAL TECHNOLOGIES

Label	ALIF Ti-6Al-4V Implant Label	June 2013
L 043	Revision A	Page 2 of 2



RENOVIS™

Field 1: **ALIF Cage**

Field 2: **Titanium**

Field 3: **30 X 26 - 11 mm Height**

Field 4: **7° Lordosis**

Field 5: REF: **1131-302-611S** Field 6: LOT: **1234-123** QTY: **1** Field 7: **YYYY-MM**

Material: **Ti-6Al-4V**

Field 8: REF: 

Field 9: LOT: 

QTY: 








For Instructions For Use (IFU) go to www.renovis-surgical.com
Paper copy of IFU available upon request at info@renovis-surgical.com

Label 043 Rev. A

RENOVIS™

Field 1: **ALIF Cage**

Field 2: **Titanium**

Field 3: **30 X 26 - 11 mm Height**

Field 4: **7° Lordosis**

Field 5: REF: **1131-302-611S**

Field 6: LOT: **1234-123**

Field 7: QTY: **1** **YYYY-MM**



Material: **Ti-6Al-4V**

STERILE

R

Label 043 Rev. A

VOID



Field 1: **ALIF Cage**

Field 2: **Titanium**

Field 3: **30 X 26 - 11 mm Height**

Field 4: **7° Lordosis**

Field 5: REF: **1131-302-611S**

Field 6: LOT: **1234-123**

Field 7: **YYYY-MM**

Label 043 Rev. A

COPY

COPY

COPY

COPY

COPY

COPY

COPY

RENOVIS SURGICAL TECHNOLOGIES

Label	ALIF Locking Cover Plate	June 2013
L 044	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 and 2 (product description). Do not include, in the final label, the field identifiers (i.e. Field 1) or the dotted boxes drawn around them. No text for fields 2, 3 and 4 is needed.
 - 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	June 2013	Initial Release	TBD

Field 7

RENOVIS SURGICAL TECHNOLOGIES

Label	ALIF Locking Cover Plate	June 2013
L 044	Revision A	Page 2 of 2

The diagram illustrates the layout of the ALIF Locking Cover Plate label. It features a large main label area, a 'STERILE R' label, and seven vertical bars labeled 'COPY'. The main label area includes the RENOVIS logo, a 'Rx' symbol, and various safety icons. It contains the following fields and information:

- Field 1:** Locking Cover Plate
- Field 2:** Material: Ti-6Al-4V
- Field 3:** REF 1128-003-001S
- Field 4:** LOT 1234-123
- Field 5:** QTY 1
- Field 6:** YYY-YY-MM (Date)
- Field 7:** For instructions for use (IFU) go to www.renovis-surgical.com. Paper copy of IFU available upon request at info@renovis-surgical.com.
- Field 8:** REF (Barcode)
- Field 9:** LOT (Barcode)
- Field 10:** QTY (Barcode)

Dimensions are indicated as 0.65 in and 0.8 in for specific label components.

RENOVIS SURGICAL TECHNOLOGIES

Label	ALIF Screw Label	June 2013
L 045	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 and 2 (product description). Do not include, in the final label, the field identifiers (i.e. Field 1) or the dotted boxes drawn around them. No text for fields 3 and 4 is needed.
 - 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	June 2013	Initial Release	TBD

RENOVIS SURGICAL TECHNOLOGIES

Label	ALIF Screw Label	June 2013
L 045	Revision A	Page 2 of 2

0.65 in
0.8 in

STERILE

R

Rx ONLY



RENOVIS™

Field 5: 1128-453-020S

Field 6: 1234-123

Field 7: YYY-YY-MM

Field 8: REF 1128-453-020S

Field 9: LOT 1234-123

Field 10: QTY 1

Field 1: Variable Angle Screw

Field 2: 4.5mm X 20mm

Material: Ti-6Al-4V

Field 3: For Instructions For Use (IFU) go to www.renovis-surgical.com

Paper copy of IFU available upon request at info@renovis-surgical.com

Label 045 Rev. A

REF

Field 8



LOT

Field 9



QTY

Field 10



Label 045 Rev. A

RENOVIS

Field 3: 1128-453-020S

Field 6: 1234-123

Field 1: Variable Angle Screw

Field 2: 4.5 mm x 20mm

Field 7: YYY-YY-MM

Field 8: REF 1128-453-020S

Field 9: LOT 1234-123

Field 10: QTY 1

Label 045 Rev. A

COPY

COPY

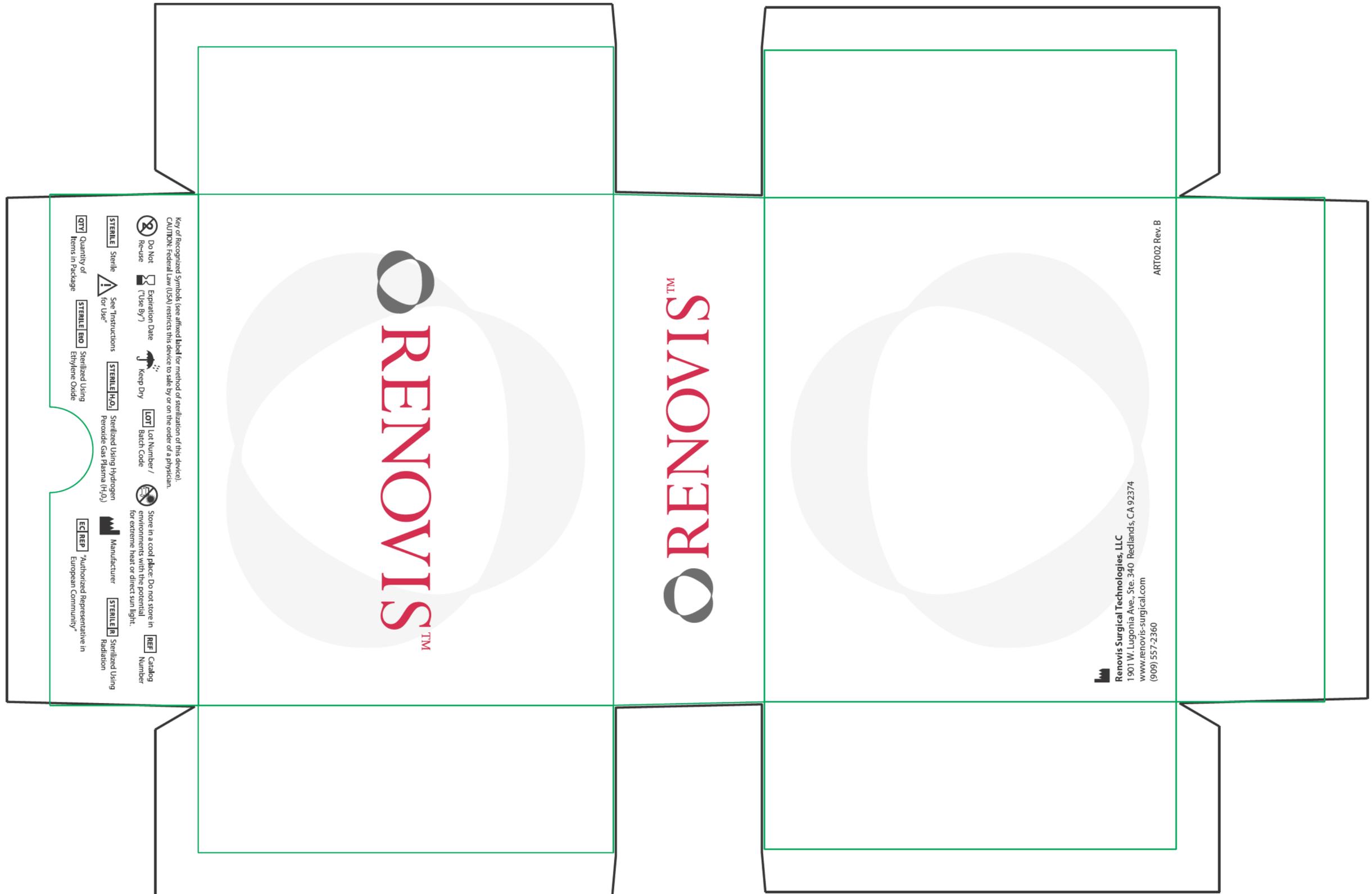
COPY

COPY

COPY

COPY

COPY



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



UTAH PAPER BOX - ELECTRONIC DIE PATTERN

Please Do Not Modify Design

Customer: Pro-Tech Design & Mfg.
 Box Name: Renovis Folding Carton-02
 Box Sizes: 3+1/2 x 3/4 x 9
 CAD File: jf /PTRFC-02

Design Side: printed
 Date: 08/10/2011
 Stock: SBS .020
 Part Number: ART004 Rev. A



*S 128 Anterior Lumbar Interbody Fusion
(ALIF) System, Sterile Packaging*



4128-005

Rev. A (Draft)
Instructions For Use

DESCRIPTION:

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

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 S128 Anterior Lumbar Interbody Fusion (ALIF) System are made of the following materials:

1. Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136
2. Polyetheretherketone (PEEK): according to ASTM F-2026
3. Tantalum: according to ISO 13782-1996 and ASTM F-560

INDICATIONS FOR USE:

The S128 ALIF System is a standalone system for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) in the lumbar spine (L2 to S1).

When used as a lumbar intervertebral body fusion device, the S128 implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. S128 implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin

with degeneration of the disc confirmed by history and radiographic studies. The S128 implants are intended to be used in patients who have had six months of non-operative treatment

The S128 ALIF System may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device the S128 implants are intended to be used with the bone screws and cover plate provided. When using a 4-screw implant, four (4) screws must be used. The accompanying Cover Plate must be used anytime the device is used with any number of screws. If the physician chooses to use less than the recommended number, or none of the provided screws, then additional supplemental fixation for use in the lumbar spine must be used to augment stability.

GENERAL CONDITIONS OF USE:

The safe implantation of Anterior Lumbar Interbody Fusion (ALIF) Systems requires an in-depth knowledge of human vertebral anatomy as well as a specific patient's anatomical variations. The implantation of the S128 Anterior Lumbar Interbody Fusion (ALIF) 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 S128 Anterior Lumbar Interbody Fusion (ALIF) 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 S128 Anterior Lumbar Interbody Fusion (ALIF) System be reused after implantation or any other circumstance that has subjected an individual component to mechanical stress. After spinal fusion occurs, these devices serve no functional purpose and may be removed. The decision to explant the surgical devices is made between the surgeon and the patient with due regard to the risks associated with a second surgery compared to the benefits of such. The S128 ALIF System has been tested as a standalone construct.

CONTRAINDICATIONS:

Contraindications to using the S128 Anterior Lumbar Interbody Fusion (ALIF) System are similar to those of other Anterior Lumbar Interbody Fusion (ALIF) 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, 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.
4. The S128 Anterior Interbody Fusion System **implants** are provided sterile. 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 S128 Anterior Lumbar Interbody Fusion System **instruments** are provided non-sterile, and therefore, must be 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 S128 ALIF 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 formation 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 TitaniumTM 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 AND STERILIZATION:

All instruments must be cleaned following instructions provided in Renovis Instrument IFU 4001-001 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.

IMPLANT - STERILITY:

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.

References: References to relevant literature including the Surgical Technique Manual may be obtained by calling Renovis Surgical Technologies, INC. at +1.909.557.2360.

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



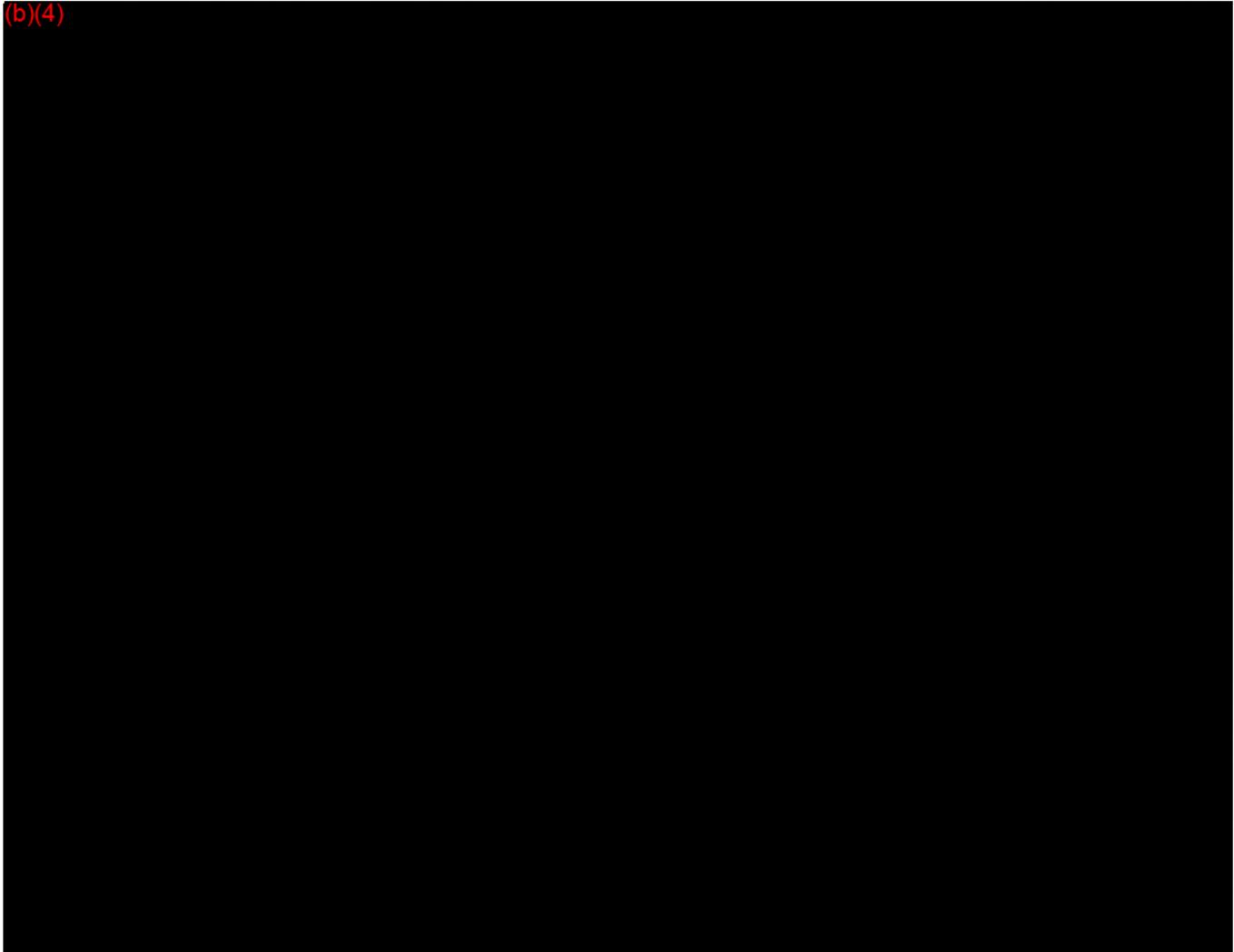
 **RENOVIS**

Renovis Surgical Technologies,
Inc.
1901 W. Lagonia Ave. Suite 340
Redlands CA 92374 USA
909.557.2360

Summary of Design Control Activities

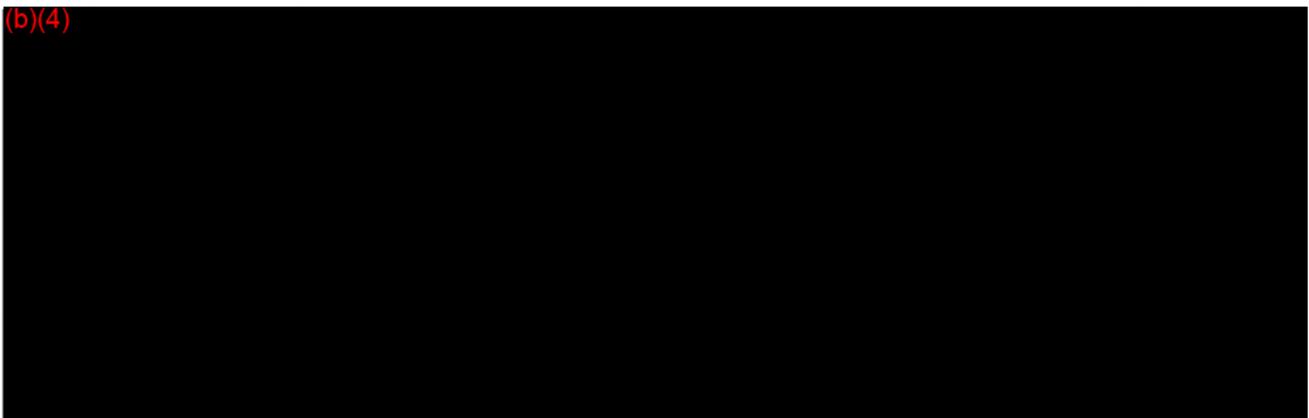
Description of Gamma Sterilization

(b)(4)



Discussion of Risk Analysis

(b)(4)



Confidential

Renovis S128 ALIF System

Special 510(k) Premarket Notification

13-1

(b)(4)

Sterility and Packaging

(b)(4)

Shelf Life

The packaging has been validated to maintain sterility for 3 years on test (b)(4)
(b)(4) Test Report (b)(4)

(b)(4)
(b)(4) shows compliance with ISO11607-2
Operational Qualification Section 5.3 and Performance Qualification (b)(4)
(b)(4) and shows compliance with accelerated aging simulation per ASTM F1980-07
and real time aging (b)(4)

Additionally, (b)(4)
(b)(4)
(b)(4) per ISTA 2A, 2011, *Partial-Simulation Performance Test Procedure: Packaged Products 150lb (68 kg) or Less* and ASTM D4169:2009, *Standard Practice for Performance Testing of Shipping Containers and Systems* (b)(4)

Therefore, a shelf life of 3 years will be placed on the PEEK cages; and the titanium cover plate, screws and cages. (b)(4)

(b)(4)

Demonstration of Performance over Shelf-Life

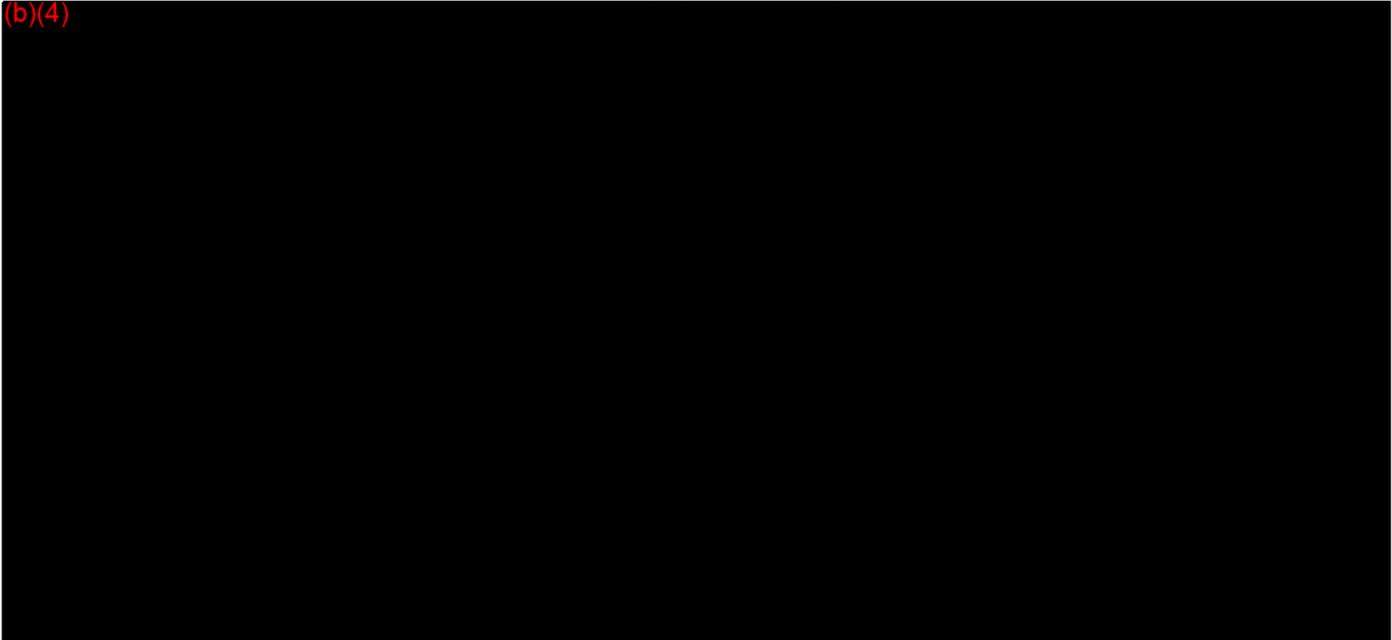
(b)(4)

Confidential

Packaging and Demonstration of Maintenance of Sterility over Shelf-Life

As noted above, implants will be sterilized by ^{60}Co Gamma irradiation. Sterilization by gamma irradiation will be validated to a sterility assurance level (SAL) of 10^{-6} by selecting and substantiating a 25 kGy dose by the VDmax²⁵ method, according to ISO 11137-1.

(b)(4)



As previously stated, the packaging has been qualified for a three year shelf life. Validation of sterility of the starting packaging and demonstration of packaging integrity at the end of aging supports that sterility of the implants is maintained over the shelf life.

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Renovis S128 ALIF System

Special 510(k) Premarket Notification

13-3

Declaration of Conformity with Design Controls

1. As required by the risk analysis, 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 is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Thomas Ross, VP of Product Development

Name of responsible person



1-7-14

Signature of responsible person

Date

Confidential



COVER SHEET MEMORANDUM

NOTE: This form is REQUIRED for holds and for final decisions.

Reviewer Name John Bowsher

510(k) Number K140106/S002

Please list CTS decision code: SE - Substantially Equivalent

Hold (Additional Information or Telephone Hold) Hold Date

Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Incomplete Response - Convert Supplement to Amendment (attach email sent to firm)

Add to File

(review staff should follow the instructions and complete the memo/routing sheet at:
http://eroom.fda.gov/eRoom/CDRH3/CDRHPreMarketNotification510kProgram/0_3bba7. DCC should refer to that documentation for the close-out code and mail any provided letter.)

The remainder of this form must be filled out for close-outs only

Class:	II
Regulation Number:	21 CFR 888.3080
Product Code:	OVD
Additional Product Codes:	

Please complete the following for a final clearance decision (i.e. SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page (<i>Attach IFU</i>)	X	
510(k) Summary or 510(k) Statement (<i>Attach Summary</i>)	X	
Truthful and Accurate Statement (<i>Must be present for a Final Decision</i>)	X	
Is the device Class III?		X
Is this a combination product?		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X

Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X
Is this device subject to the Tracking Regulation? (<u>Medical Device Tracking Guidance</u>)		X

Digital Signature Concurrence Table

(Not all signatures may be required)

Branch Chief Sign-Off

Anton E. Dmitriev -S
 2014.03.27 14:19:58 -04'00'

Division Sign-Off

Ronald P. Jean -S
 2014.03.27 16:25:41 -04'00'

K140106/S1



FDA CDRH DMC
JAN 31 2014
Received

January 30, 2014

John Bowsher
U.S. Food and Drug Administration
CDRH/ODE/DOD/ASDB
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: RTA response 510(k) Number K140106 – Renovis S128 ALIF

Dear Mr. Bowsher:

Enclosed please find responses to the Refuse To Accept notification received by email on 1/28/2014.

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.

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

Sincerely yours,

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

MEDICEPT, Inc.
Renovis S128 ALIF

CONFIDENTIAL
200 Homer Ave.

Ashland, MA 01721
RTA Response K140106

1-1

21



January 30, 2014

John Bowsher
U.S. Food and Drug Administration
CDRH/ODE/DOD/ASDB
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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Sincerely yours,

A handwritten signature in cursive, appearing to read "Sharyn Orton".

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

CONFIDENTIAL
200 Homer Ave.

MEDICEPT, Inc.
Renovis S128 ALIF

Ashland, MA 01721
RTA Response K140106

1-1

Table of Contents

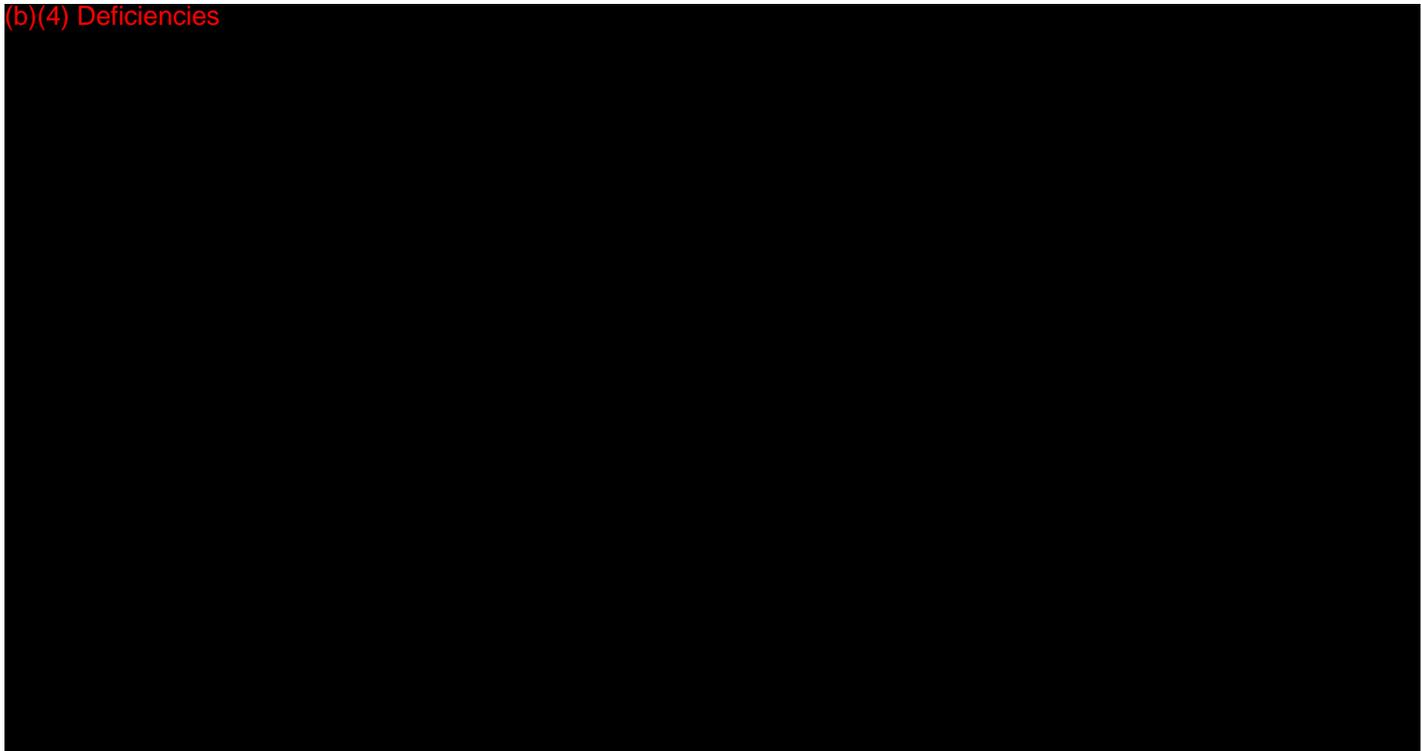
<u>Document</u>	<u>File Number</u>
Cover letter RTA response K140106	001
RTA responses	002

MEDIcept, Inc.
Renovis S128 ALIF

CONFIDENTIAL
200 Homer Ave.

Ashland, MA 01721
RTA Response K140106
1-2

(b)(4) Deficiencies



MEDIcept, Inc.
Renovis S128 ALIF

CONFIDENTIAL
200 Homer Ave.

Ashland, MA 01721
RTA Response K140106
2-1

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MEDIcept, Inc.
Renovis S128 ALIF

CONFIDENTIAL
200 Homer Ave.

Ashland, MA 01721
RTA Response K140106

2-2

Part Number	System Specific - Description	Functionality
2128-001-001	Implant Inserter	Insert Cage
2128-001-004	Cover Plate Inserter Assembly	Insert and lock Coverplate
2128-001-032	Angled Implant Inserter	Insert Cage
2128-001-033	Angled Cover Plate Inserter	Insert Cover plate
2128-003-026	Small Paddle Sizer	Implant determination
2128-003-428	Medium Paddle Sizer	Implant determination
2128-003-830	Large Paddle Sizer	Implant determination

MEDIcept, Inc.
Renovis S128 ALIF

CONFIDENTIAL
200 Homer Ave.

Ashland, MA 01721
RTA Response K140106

2-3

K140106/S002

MEDICEPT

Medical Device Compliance Consulting

March 5, 2014

John Bowsher, Ph.D.
U.S. Food and Drug Administration
CDRH/ODE/DOD/ASDB
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
MAR 07 2014
Received

Re: K140106 S001 AI response – Renovis S128 ALIF System

Dear Dr. Bowsher:

Enclosed please find responses to the Telephone Hold deficiencies received by email on Friday February 28, 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.

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

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

MEDIcept, Inc.
Renovis S128 ALIF System

CONFIDENTIAL
200 Homer Ave.

Ashland, MA 01721
K140106 S001 AI response
1-1

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March 5, 2014

John Bowsher, Ph.D.
U.S. Food and Drug Administration
CDRH/ODE/DOD/ASDB
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K140106 S001 AI response – Renovis S128 ALIF System

Dear Dr. Bowsher:

Enclosed please find responses to the Telephone Hold deficiencies received by email on Friday February 28, 2014.

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

MEDICEPT, Inc.
Renovis S128 ALIF System

CONFIDENTIAL
200 Homer Ave.

Ashland, MA 01721
K140106 S001 AI response

1-1

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K140106 S001 revised (b)(4) Deficiencies	007

MEDIcept, Inc.
Renovis S128 ALIF System

CONFIDENTIAL
200 Homer Ave.

Ashland, MA 01721
K140106 S001 AI response
1-2



**Special 510(k) Summary
as required by 21 CFR 807.92(a)
K140106**

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: February 28, 2014

B) Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar
Common Name: Intervertebral body fusion device
Proprietary Name: S128 Anterior Lumbar Interbody Fusion (ALIF) System
Device Class: Class II – 888.3080
Regulation and Product code: 888.3080, OVD - Intervertebral body fusion device
Classification panel: Orthopedic

C) Predicates:

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

D) Device Description:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is cleared under K131122. The S128 ALIF implants (cages) are to be used with the bone screws and anterior cover plate assembly and requires no additional supplementary fixation systems. The Renovis S128 ALIF System implants are available in a variety of sizes (widths, height, depths, and bone screw sizes; see below) to suit the individual pathology and anatomical conditions of the patient. The implants are manufactured from PEEK or additively manufactured and machined Titanium. The bone screws and cover plate

assembly are both manufactured from Titanium alloy. The PEEK markers are manufactured from Tantalum.

This Special 510(k) Premarket Notification is submitted for the additional offering of gamma sterilized S128 implants (PEEK cages; titanium cages, screws and cover plates).

E) Indications For Use:

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.

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.

F) Substantial Equivalence Comparison and Discussion

	Renovis S128 ALIF System	Renovis S128 ALIF System K131122
Product code	OVD	
Implant Material (cages, cover plate, and screws)	PEEK (ZA-500) per ASTM F2026 Titanium alloy Ti-6Al-4V per ASTM F136	
PEEK marker material	Tantalum per ASTM F 560-08	
Dimensions (mm)		
A/P	26, 28, 30	
M/L	30, 34, 38	
H	11 - 21	
Lordosis	7°, 12°	
Number of screws	4	
Screw Diameter (mm)	4.5, 5.	
Screw Length (mm)	20, 25, 30, 35	
Cover plate (mm)	8.3 x 22	
Provided sterile?	Yes - gamma	No

Conclusion

Based upon the same intended use, design, function, technology, and materials, the Renovis S128 ALIF System is substantially equivalent to the predicate devices and does not raise new issues of safety or effectiveness.

G) Performance Data

Implants are sterilized by ^{60}Co Gamma irradiation validated to a sterility assurance level (SAL) of 10^{-6} by selecting and substantiating a 25 kGy dose by the VDmax²⁵ method, according to ISO 11137-1. Titanium alloy components are not affected by gamma sterilization and/or aging. PEEK components were tested to an average dose of 200kGy and underwent accelerated aging to simulated 10 or more years. After aging the samples were tested, and the results did not show any significant difference between untreated PEEK and gamma treated and aged PEEK.

Packaging has been validated to maintain sterility for 3 years in compliance with ISO 11607-2 demonstrates compliance with accelerated aging simulation per ASTM F1980-7 and real time aging; and performance following distribution per ISTA 2A.

Conclusion

Gamma sterilization does not have a negative effect on Renovis S128 ALIF System implants.

H) Compliance with Design Controls

The results of design validation support that the Renovis S128 ALIF System is substantially equivalent to the predicate device and the offering of gamma irradiated implant components does not raise new issues of safety or effectiveness.

I) Compliance with Consensus Standards and FDA Guidance

Standards - Renovis complies with:

- ASTM F2026 Standard Specification for PEEK Polymers for Surgical Implant Applications
- ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, and
- ASTM F 560-08, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications
- ISO 11137-1: 2006: Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ANSI/AAMI/ISO 11137-2:2006 Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
- ISO11607-2: 2006 Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1980-07: 2007 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

- ASTM D4169:2009 Standard Practice for Performance Testing of Shipping Containers and Systems
- ISTA 2A, 2011 Partial-Simulation Performance Test Procedure: Packaged Products 150lb (68 kg) or Less

FDA guidance:

- Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA, August 2002
- Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, October 2007
- Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Review Guidance, April 1996
- Guidance for Industry and FDA Staff Spinal System 510(k)'s, May 2004 (for labeling language)

RENOVIS SURGICAL TECHNOLOGIES

Label	ALIF PEEK Implant Label	March 2014
L 042	Revision A	Page 1 of 2

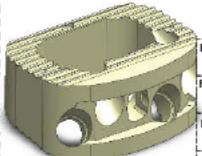
1. The label illustrated in this specification should serve as a template for the creation of the external, internal and chart labels.
2. The labels shall be printed in color with a minimum resolution of 300 dpi.
3. Fields 1 through 9 are variable.
 - Consult 4001-003, *Sterile Implant Packaging Specification*, 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	March 2014	Initial Release	TBD

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RENOVIS SURGICAL TECHNOLOGIES

Label	ALIF PEEK Implant Label	March 2014
L 042	Revision A	Page 2 of 2



RENOVIS™

Field 1	S 128 ALIF System Cage
Field 2	PEEK
Field 3	30 X 26 - 11 mm Height
Field 4	7° Lordosis

REF 1128-302-611S	LOT 1234-123	QTY 1	YYYY-MM
--------------------------	---------------------	--------------	----------------

Material: PEEK per ASTM F2026 and Tantalum per ASTM F560-08

Field 8

REF







Field 9

LOT





Rx

ONLY

Field 5

REF 1128-302-611S
 LOT 1234-123 | **QTY** 1 | **YYYY-MM** |

Material: PEEK per ASTM F2026 and Tantalum per ASTM F560-08

Field 8

REF







Field 9

LOT





Rx

ONLY

Field 5

REF 1128-302-611S
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Field 9

LOT





Rx

ONLY

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Field 9

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Field 9

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Rx

ONLY

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Field 9

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Rx

ONLY

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Field 9

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Rx

ONLY

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ONLY

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Field 9

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Rx

ONLY

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Field 9

LOT





Rx

ONLY

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Rx

ONLY

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Field 9

LOT





Rx

ONLY

Field 5

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 LOT 1234-123 | **QTY** 1 | **YYYY-MM** |

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RENOVIS SURGICAL TECHNOLOGIES

Label	ALIF Ti-6Al-4V Implant Label	March 2014
L 043	Revision A	Page 1 of 2

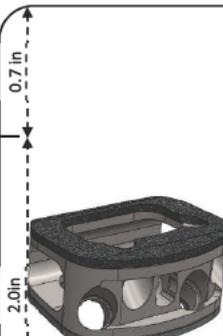
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Rev #	Date	Reason for Revision	Change Order #
A	March 2014	Initial Release	TBD

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RENOVIS SURGICAL TECHNOLOGIES

Label	ALIF Ti-6Al-4V Implant Label	March 2014
L 043	Revision A	Page 2 of 2



RENOVIS™

Field 1	S 128 ALIF System Cage
Field 2	Titanium
Field 3	30 X 26 - 11 mm Height
Field 4	7° Lordosis

REF 1131-302-611S LOT 1234-123 QTY 1 YYYY-MM

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

REF    

LOT   **Rx**

QTY  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
Paper copy of IFU available upon request at info@renovis-surgical.com

Renovis Surgical Technologies, Inc. Redlands, CA 92374 L 043 Rev. A

RENOVIS™

Field 1	S 128 ALIF System Cage
Field 2	Titanium
Field 3	30 X 26 - 11 mm Height
Field 4	7° Lordosis

Field 5: REF 1131-302-611S

Field 6: LOT 1234-123

Field 7: QTY 1 YYYY-MM



Field 7: YYYY-MM

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

STERILE R

L 043 Rev. A

VOID



REF 1131-302-611S LOT 1234-123 YYYY-MM

L 043 Rev. A

COPY

COPY

COPY

COPY

COPY

COPY

COPY

RENOVIS SURGICAL TECHNOLOGIES

Label	ALIF Locking Cover Plate	March 2014
L 044	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	March 2014	Initial Release	TBD

RENOVIS SURGICAL TECHNOLOGIES

Label	ALIF Screw Plate	March 2014
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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.
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Rev #	Date	Reason for Revision	Change Order #
A	March 2014	Initial Release	TBD

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**S 128 Anterior Lumbar Interbody Fusion
(ALIF) System, Sterile Packaging**



4128-005

Rev. A (Draft)
Instructions For Use

DESCRIPTION:

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

S128 ALIF System Implants – Summary Description	
Dimensions (mm)	
A/P	26, 28, 30
M/L	30, 34, 38
H	11 - 21
Lordosis	7°, 12°
Number of screws	4
Screw Diameter (mm)	4.5, 5
Screw Length (mm)	20, 25, 30, 35
Cover plate (mm)	8.3 H; 22 W

For implant and instrument parts numbers, as well as implant dimensions, refer to the Renovis S128 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 S128 Anterior Lumbar Interbody Fusion (ALIF) 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
3. Tantalum: according to ISO 13782-1996 and ASTM F-560

INDICATIONS FOR USE:

The S128 ALIF System is a standalone system for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) in the lumbar spine (L2 to S1).

When used as a lumbar intervertebral body fusion device, the S128 implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. S128 implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The S128 implants are intended to be used in patients who have had six months of non-operative treatment

The S128 ALIF System may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device the S128 implants are intended to be used with the bone screws and cover plate provided. When using a 4-screw implant, four (4) screws must be used. The accompanying Cover Plate must be used anytime the device is used with any number of screws. If the physician chooses to use less than the recommended number, or none of the provided screws, then additional supplemental fixation for use in the lumbar spine must be used to augment stability.

GENERAL CONDITIONS OF USE:

The safe implantation of Anterior Lumbar Interbody Fusion (ALIF) Systems requires an in-depth knowledge of human vertebral anatomy as well as a specific patient's anatomical variations. The implantation of the S128 Anterior Lumbar Interbody Fusion (ALIF) 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 S128 Anterior Lumbar Interbody Fusion (ALIF) 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 S128 Anterior Lumbar Interbody Fusion (ALIF) System be reused after implantation or any other circumstance that has subjected an individual component to mechanical stress. After spinal fusion occurs, these devices serve no functional purpose and may be removed. The

decision to explant the surgical devices is made between the surgeon and the patient with due regard to the risks associated with a second surgery compared to the benefits of such. The S128 ALIF System has been tested as a standalone construct.

CONTRAINDICATIONS:

Contraindications to using the S128 Anterior Lumbar Interbody Fusion (ALIF) System are similar to those of other Anterior Lumbar Interbody Fusion (ALIF) 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 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, 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.
4. The S128 Anterior Interbody Fusion System **implants** are provided sterile. 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 S128 Anterior Lumbar Interbody Fusion 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 S128 ALIF 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 formation 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 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.

IMPLANT - STERILITY:

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 –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 S128 ALIF System include trials, sizers, implant/cage inserters and the cover plate inserter. Other instruments are also provided for use with the S128 ALIF System. For a list of all instruments, refer to the Renovis S128 ALIF Surgical Technique manual.

All instruments must be thoroughly cleaned, decontaminated and sterilized as follows (and as per Renovis Surgical Instrument IFU, p/n 4001-001):

1. **Decontamination:** Saturate the surface completely with full strength disinfectant/cleaner* (e.g. ENZOL[®] Enzymatic Detergent). Fully immerse the devices and allow them to soak for a minimum of 5 minutes.
2. **Pre-Cleaning:** The Large Modular Handle must be disassembled before cleaning. No other S128 ALIF System instruments require disassembly. Prepare a room temperature neutral pH enzymatic cleaner* (e.g. ENZOL[®] 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[®] 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 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

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

Cycle	Dynamic-air-removal Steam
Preconditioning Pulses	4
Minimum Temperature	132° C (270° F)
Exposure	4 Minutes
Drying Time	40 Minutes

This sterilization cycle (drying time) is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and

sterilization cassettes) that have been cleared by 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.

References: References to relevant literature including the Surgical Technique Manual may be obtained by calling Renovis Surgical Technologies, INC. at +1.909.557.2360.

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



 **RENOVIS**

Renovis Surgical
Technologies, Inc.
1901 W. Lugonia Ave.
Suite 340

Surgical Instruments

Instructions For Use



Rev. E

**Recommendations for the Care and Handling for Renovis Surgical Technologies
Surgical Instruments and Instrument Cases****DESCRIPTION**

Renovis instrumentation consists of devices and their accessories used in surgical procedures. Before using Renovis instrumentation for any surgical procedure, familiarity with, and attention to the appropriate, recommended surgical technique is imperative. Renovis instrumentation should only be used in combination with other Renovis products.

Renovis instruments and instrument cases are generally composed of titanium, stainless steel, aluminum, and/or polymeric materials. The cases may be multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The inserts may consist of trays, holders, and silicone mats. The instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing the cleaning, sterilization, and drying cycle that has been validated and listed below. Instrument cases do not provide a sterile barrier and must be used in conjunction with sterilization wrap to maintain sterility. Instruments are provided nonsterile and should be stored in their original packaging until cleaned and sterilized according to the recommended guidelines listed below.

DISCLAIMER

Renovis instrument cases are intended to protect instrumentation and facilitate the sterilization process by allowing steam penetration and drying. Renovis has verified through laboratory testing that our instrument cases are suitable for the specific sterilization cycles for which they have been tested. Health care personnel are ultimately responsible for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in their particular health care facility. Testing should be conducted in health care facility to assure that conditions essential to sterilization can be achieved. Renovis and its distributors do not accept responsibility or liability arising from a lack of cleanliness or sterility of any medical device supplied by Renovis that should have been cleaned and sterilized by the end user. All instruments are to be examined for wear and damage prior to surgery.

CLEANING AND DECONTAMINATION

Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. The decontamination process should begin immediately after completion of the surgical procedure.

Renovis rigid instrument cases may be washed and/or disinfected by using an automated washer-disinfection unit utilizing thermal disinfection. Temperatures, cycles, and disinfectant type used as instructed by manufacturer of washer-disinfection unit.

All instruments must be thoroughly cleaned before use.

1. **Decontamination:** Saturate the surface completely with full strength disinfectant/cleaner* (e.g. ENZOL[®] Enzymatic Detergent). Fully immerse the devices and allow them to soak for a minimum of 5 minutes.
2. **Pre-Cleaning:** Disassemble devices where applicable. The majority of the surgical instruments and trial devices are simply constructed and will not require disassembly. However, some of the more complex instruments are made of several components and these should be disassembled into their individual parts. Prepare a room temperature neutral pH enzymatic cleaner* (e.g. ENZOL[®] 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[®] 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 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 and Assembly:** After cleaning/disinfection and inspection, the disassembled instruments should be reassembled and visually inspected. Check for misalignment, burrs, bent, or fractured tips. Do not use if any of this damage is observed. Mechanically test the working parts to verify that each instrument functions correctly. Place instruments into appropriate configuration within instrument case and wrap with protective sterilization wrap according to AAMI / AORN guidelines.

* 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.

CARE AND HANDLING OF INSTRUMENTS

1. **General** – Surgical instruments and instrument cases are susceptible to damage from prolonged use, and through misuse or rough handling. Care must be taken to avoid compromising their performance. To minimize damage, conduct the following:
 - Inspect instrument cases and instruments for damage when received and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned, and those that need repair returned for servicing.

- Only use an instrument for its intended purpose.
 - When handling sharp instruments use extreme caution to avoid injury. Consult with an infection control practitioner to develop safety procedures appropriate for all levels of direct instrument contact.
 - Instruments designated as “Single Use Only” are to be disposed of immediately after use. Reuse can cause small defects and internal stress patterns which may result in premature breakage.
2. **General Cleaning** – Clean instruments as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate enzymatic detergent to delay drying. Wash all instruments whether or not they were used or were inadvertently contacted with blood. Loosen and/or disassemble instruments with removable parts.
 3. **Ultrasonic Cleaners** – can be used with hot water per the manufacturers’ recommended temperature, however, room temperature was qualified. Be aware that loading patterns, water temperature, and other external factors may change the effectiveness of the equipment.

RESPONSIBILITIES OF THE USER

General – Health care personnel are ultimately responsible for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in their particular health care facility.

Sterility – Users should conduct testing in health care facility to assure that conditions essential to sterilization can be achieved.

STORAGE AND SHELF LIFE

Instrument cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be taken in handling wrapped cases to prevent damage to the barrier. The health care facility should establish a shelf life for wrapped instruments cases, based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time and with handling.

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

Cycle	Dynamic-air-removal Steam
Preconditioning Pulses	4
Minimum Temperature	132° C (270° F)
Exposure	4 Minutes
Drying Time	40 Minutes

This sterilization cycle (drying time) is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by 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 may be obtained by calling Renovis Surgical Technologies, LLC. at +1-909-557-2360.

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



The CE marks above are valid only if they are also printed on the product label.



**Emergo Europe
Molenstraat 15
2513 BH The Hague
Netherlands**



S128 ALIF System Surgical Technique (DRAFT)

1. Indications for Use

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.

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.

2. Description

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

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.



S128 ALIF System Surgical Technique (DRAFT)

3. Material

1. Titanium Alloy: Ti6Al4V: according to ASTM F-136
2. Polyetheretherketone (PEEK, ZA-500): according to ASTM F-2026
3. Tantalum: according to ISO 13782-1996 and ASTM F-560

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4. Contraindications

Contraindications to using the S128 Anterior Lumbar Interbody Fusion (ALIF) System are similar to those of other Anterior Lumbar Interbody Fusion (ALIF) 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.



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5. Warnings and Cautions

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.

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1. The safety and effectiveness of intervertebral body fusion systems has been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
2. Based on fatigue testing results, when using the S128 Anterior Lumbar Interbody Fusion (ALIF) System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.
3. Do not use if any component package is opened or damaged or if expiration date has passed.
4. Do not use implants that exhibit surface or configuration damage.

6. Precautions

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. 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.
2. 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.



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3. Implant removal after healing. If the device is not removed after the completion of its intended use, any of the following complications may occur:
 - a. Corrosion , with localized tissue reaction or pain;
 - b. Implant migration resulting in injury;
 - c. Risk of additional injury from postoperative trauma;
 - d. Bending, loosening, and/or breakage , which could make removal impractical or difficult;
 - e. Pain, discomfort , or abnormal sensations due to device presence;
 - f. Possible increased risk of infection;
 - g. Bone loss due to stress shielding. Carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture or deformity. If the patient is older and has a low activity level, the surgeon may choose not to remove implant thus eliminating the risks involved in a second surgery.
4. 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.

Renovis Implants and Instruments have not been tested for adverse effect in a Magnetic Resonance Imaging (MRI) environment. The Implants in the S128 ALIF 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:

1. Movement of ferromagnetic components through magnetically induced force and torque.
2. Localized heating of components caused by radio frequency induction heating.



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3. Image artifacts created by interaction between metallic components and the magnetic field.

7. Preparation

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7.1. 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.

7.2. Exposure

The locking screws of the S128 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: When the spacer has been inserted, visualization of the entire anterior plate is necessary for insertion of the locking screws. Give proper consideration to the exposure so instrumentation can be used as described in the following sections.

8. Discectomy and Endplate Preparation

Create an annulotomy centered on the midline and wide enough to accommodate the S128 implant. A Paddle Sizer (2128-003-026_830) may be used as a template to indicate the width of the annular window required.



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

Remove the cartilaginous endplates to bleeding bone, taking care to not compromise the integrity of the bony endplates. If additional disc space distraction or remobilization is necessary, the Bullet Nose Distractors (2128-002-009_021) are available in the S128 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 an intraoperative lateral x-ray.

9. 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 hammering on the trial spacer handle may be required to advance the trial spacer into the disc space.

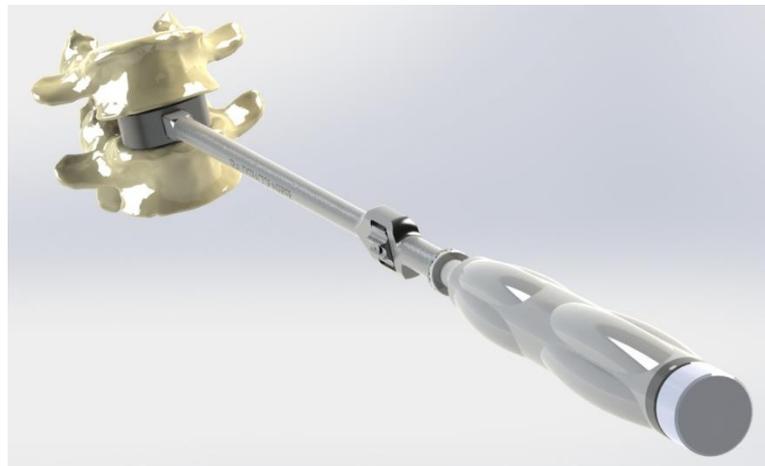


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If a tight fit is not achieved, repeat the process using incrementally larger trial spacers. Conversely, if the trial spacer cannot be inserted, repeat using incrementally smaller trial spacers.

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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 S128 implant size.

10. Implant Selection and Graft Packing

Select the appropriate S128 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 S128 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.

The implant is now ready to be inserted, using one of the two methods described below:

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11. Implant Insertion

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11.1. Option A: using the Implant Inserter/Distractor Assembly

Remove the Implant Inserter/Distractor Assembly (2128-001-002) from the tray and rotate the T-handle counter clockwise to fully retract the implant carrier into the ramps. Slide the cage in-between the ramps and place the open end of the implant with screw holes present against the carrier. Push and rotate the knob at the proximal end of the inserter to set the inserter in the loading position. The rectangular post that extends from the carrier must align and fit into the corresponding rectangular slot in the center of the face of the cage, between the medial screw holes. Release the knob at proximal end of the instrument to allow it to move to the locked position.

Note: The tips of the inserter will be inserted into the disc space up to the depth stops on the ramps; to allow full insertion, the tips must not be spread apart.

Place the tips of the instrument into the disc space so the depth stops on the ramps touch the anterior rim of the vertebral body. The tips of the instrument are 20 mm deep and 21.8 mm wide.

Turn the T-handle on the inserter to advance the implant down the ramps and into the disc space. The force required to turn the T-handle will increase as the implant advances down the ramps and the instrument distracts the disc space. Once the implant is fully seated, continue turning the T-handle until the ramps are removed from the disc space. At this point, the implant is in its final position, and can be released. Rotate the push and rotate the knob at the proximal end of the inserter counter-clockwise to unlock the implant from the inserter.

Verify final implant position with the help of an intraoperative lateral x-ray.

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.

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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.

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

11.2. Option B: Using the Implant Inserter

Attach the S128 cage to the inserter by inserting distal end of the Implant Inserter (2128-001-001) into the open end of the implant with screw holes 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, between the medial screw holes. 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 hammering on 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 x-ray.



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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.

12. Screw Preparation and Placement

12.1. Using the Drill Guide

The Adjustable Drill Guide (2128-001-007) ensures appropriate alignment of the screws into the cage.

Insert the Adjustable Drill Guide into the exposure, and dock into the first screw hole. When seated, it should fit snugly against the cage. The angle of the Drill Guide can be adjusted by pulling back on the collar at the proximal end of the Drill Guide. While holding the collar back, adjust the drill guide to the desired angle. Each notch equals a 20° adjustment in angle. Release the collar when the appropriate angle is reached.

Warning: Do not use the awl or screwdriver without the Drill Guide.

12.2. Opening the Cortex with the Awl and/or Drill

Insert the Awl with Universal Joint (2128-001-012) into the Adjustable Drill Guide. Prepare the vertebral body for screw insertion by applying pressure on the handle of the awl with rotational motions.

It is not necessary to impact or completely rotate the awl to break the cortex. Rotational motions clockwise and counterclockwise are sufficient.

For harder bone, the Drill Bit (2128-001-013) can be used in conjunction with the Modular Flexible Shaft (2128-001-014). Insert the Drill Bit into the end of the Flexible shaft, and attach a Small or Large Modular Handle (2128-



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001-029_030). This assembly can now be placed through the Drill Guide and forward, clockwise rotational pressure applied to drill through the bone, creating a clear path for the screw.

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Note: The awl and drill bit will create 2.8mm diameter hole in the bone. This will create a .2mm per side press fit with the internal diameter of the Variable and Constrained screws and a .4mm per side press fit with the Rescue Screw. The awl and drill bit penetration is approximately 15 mm, equivalent to the purchase length of a 15 mm screw.

When the screw hole is prepared, the Adjustable Drill Guide can be removed.

12.3. Inserting a screw

Select the appropriate screw. Variable screw can be inserted at a slight angle and have some clearance with the screw holes in the implant. Constrained screws closely fit the minor diameter of the screw holes in the implant and can not vary in insertion angle. Rescue screws function similar to the constrained screw but have a larger outer diameter and inner diameter of the screw shank. Screw length should be selected to penetrate completely through the cortical bone. For a two-level procedure, proper consideration should be given to the length of screw in the common vertebral body to prevent screw interference. The same consideration should be given if posterior supplemental fixation is intended.

Attach the selected screw onto the Screw Driver (2128-001-010) by pushing the hexalobe end into the open hexalobe of the screw and pressing firmly to ensure a snug fit.

Insert the screw into the pilot hole created by the awl/drill. When the screw is fully seated into the cage, tighten firmly.

Warning: Excessive torque can damage or break the instruments or implant. Use four fingers for final tightening.

Important: Four (4) screws should always be used for every S128 construct.

Repeat steps 6.1 through 6.3 until all four (4) screws are in place and confirmed by lateral fluoroscopy. The four screws should be inserted sequentially.



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13. Locking the Screws with the Cover Plate

The Cover Plate locks into the cage to cover the heads of the screws and prevent screw migration.

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Warning: The Cover Plate should ALWAYS be used with the S128 implant if a screw is also implanted, whether a single screw is used, or up to the maximum four (4).

The indicator sleeve on the shaft of the Cover Plate Inserter should be rotated to indicate “Unlocked” prior to loading

Attach the Cover Plate (1128-003-001) to the Cover Plate Inserter Assembly (2128-001-004) by pushing hexalobe end of the inserter into the open hexalobe head of the cover plate locking post. The Cover Plate should be prevented from rotating by the flat extensions on the upper and lower surfaces of the inserter.

Insert the Cover Plate Inserter into the exposure, and into the exposed face of the cage, being sure to align the post, which protrudes from the Cover Plate, into the slot in the middle of the cage, located between the medial screws.



When the Cover Plate is fully seated push forward and rotate the handle of the inserter until the indicator line is in the “Locked” position. A tactile “click” should be felt.

The Cover Plate Inserter can now be removed.

14. Final construct inspection



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Visually inspect the implant to be sure the cage and the cover plate are engaged properly, and confirm placement of the construct via lateral and a/p fluoroscopy.

Page | 13 **15. Removal or revisions**

If, during implantation, the surgeon determines the interaction between a screw and bone is loose or has stripped, the loose screw should be removed and replaced with a 5.0mm Rescue screw.

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 S128 Implant to prevent injury to the great vessels.

Once exposure is gained, simply reverse the surgical technique:

1. Remove the Cover Plate Assembly with either the Cover Plate Inserter Assembly or Cover Plate Driver.
2. Remove the Screws with the Screw Driver with Universal Joint, Screw Driver with Straight Shaft, or Modular Driver bit on the Flexible Shaft.
3. Ensure the implant is not hindered by any bone or soft tissue then, attach the Implant Inserter to the exposed front of the implant and gently remove.

16. 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 discontinued within 24 - 48 hours
- Diet is restricted to small amounts of liquids until return of bowel function is completed
- The patient is encouraged to ambulate as soon as possible. The individual surgeon determines activity level



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- Braces are to be used at each surgeon's discretion

Renovis ALIF Implants and Instrumentation

Renovis Implants

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PEEK ALIF Cages				
Part Number	Width	Depth	Height	Lordosis
1128-302-611S	30mm	26mm	11mm	7°
1128-302-612S	30mm	26mm	12mm	7°
1128-302-613S	30mm	26mm	13mm	7°
1128-302-614S	30mm	26mm	14mm	7°
1128-302-615S	30mm	26mm	15mm	7°
1128-302-616S	30mm	26mm	16mm	7°
1128-302-617S	30mm	26mm	17mm	7°
1128-302-618S	30mm	26mm	18mm	7°
1128-302-619S	30mm	26mm	19mm	7°
1128-302-620S	30mm	26mm	20mm	7°
1128-302-621S	30mm	26mm	21mm	7°
1128-342-811S	34mm	26mm	11mm	7°
1128-342-812S	34mm	26mm	12mm	7°
1128-342-813S	34mm	26mm	13mm	7°
1128-342-814S	34mm	26mm	14mm	7°
1128-342-815S	34mm	26mm	15mm	7°
1128-342-816S	34mm	26mm	16mm	7°
1128-342-817S	34mm	26mm	17mm	7°
1128-342-818S	34mm	26mm	18mm	7°
1128-342-819S	34mm	26mm	19mm	7°
1128-342-820S	34mm	26mm	20mm	7°
1128-342-821S	34mm	26mm	21mm	7°
1128-383-011S	38mm	26mm	11mm	7°
1128-383-012S	38mm	26mm	12mm	7°
1128-383-013S	38mm	26mm	13mm	7°
1128-383-014S	38mm	26mm	14mm	7°
1128-383-015S	38mm	26mm	15mm	7°
1128-383-016S	38mm	26mm	16mm	7°
1128-383-017S	38mm	26mm	17mm	7°
1128-383-018S	38mm	26mm	18mm	7°
1128-383-019S	38mm	26mm	19mm	7°
1128-383-020S	38mm	26mm	20mm	7°
1128-383-021S	38mm	26mm	21mm	7°

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1129-302-611S	30mm	26mm	11mm	12°
1129-302-612S	30mm	26mm	12mm	12°
1129-302-613S	30mm	26mm	13mm	12°
1129-302-614S	30mm	26mm	14mm	12°
1129-302-615S	30mm	26mm	15mm	12°
1129-302-616S	30mm	26mm	16mm	12°
1129-302-617S	30mm	26mm	17mm	12°
1129-302-618S	30mm	26mm	18mm	12°
1129-302-619S	30mm	26mm	19mm	12°
1129-302-620S	30mm	26mm	20mm	12°
1129-302-621S	30mm	26mm	21mm	12°
1129-342-811S	34mm	26mm	11mm	12°
1129-342-812S	34mm	26mm	12mm	12°
1129-342-813S	34mm	26mm	13mm	12°
1129-342-814S	34mm	26mm	14mm	12°
1129-342-815S	34mm	26mm	15mm	12°
1129-342-816S	34mm	26mm	16mm	12°
1129-342-817S	34mm	26mm	17mm	12°
1129-342-818S	34mm	26mm	18mm	12°
1129-342-819S	34mm	26mm	19mm	12°
1129-342-820S	34mm	26mm	20mm	12°
1129-342-821S	34mm	26mm	21mm	12°
1129-383-011S	38mm	26mm	11mm	12°
1129-383-012S	38mm	26mm	12mm	12°
1129-383-013S	38mm	26mm	13mm	12°
1129-383-014S	38mm	26mm	14mm	12°
1129-383-015S	38mm	26mm	15mm	12°
1129-383-016S	38mm	26mm	16mm	12°
1129-383-017S	38mm	26mm	17mm	12°
1129-383-018S	38mm	26mm	18mm	12°
1129-383-019S	38mm	26mm	19mm	12°
1129-383-020S	38mm	26mm	20mm	12°
1129-383-021S	38mm	26mm	21mm	12°

Titanium ALIF Cages				
Part Number	Width	Depth	Height	Lordosis
1131-302-611S	30mm	26mm	11.25mm	7°
1131-302-612S	30mm	26mm	12.25mm	7°
1131-302-613S	30mm	26mm	13.25mm	7°
1131-302-614S	30mm	26mm	14.25mm	7°

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1131-302-615S	30mm	26mm	15.25mm	7°
1131-302-616S	30mm	26mm	16.25mm	7°
1131-302-617S	30mm	26mm	17.25mm	7°
1131-302-618S	30mm	26mm	18.25mm	7°
1131-302-619S	30mm	26mm	19.25mm	7°
1131-302-620S	30mm	26mm	20.25mm	7°
1131-302-621S	30mm	26mm	21.25mm	7°
1131-342-811S	34mm	28mm	11.25mm	7°
1131-342-812S	34mm	28mm	12.25mm	7°
1131-342-813S	34mm	28mm	13.25mm	7°
1131-342-814S	34mm	28mm	14.25mm	7°
1131-342-815S	34mm	28mm	15.25mm	7°
1131-342-816S	34mm	28mm	16.25mm	7°
1131-342-817S	34mm	28mm	17.25mm	7°
1131-342-818S	34mm	28mm	18.25mm	7°
1131-342-819S	34mm	28mm	19.25mm	7°
1131-342-820S	34mm	28mm	20.25mm	7°
1131-342-821S	34mm	28mm	21.25mm	7°
1131-383-011S	38mm	30mm	11.25mm	7°
1131-383-012S	38mm	30mm	12.25mm	7°
1131-383-013S	38mm	30mm	13.25mm	7°
1131-383-014S	38mm	30mm	14.25mm	7°
1131-383-015S	38mm	30mm	15.25mm	7°
1131-383-016S	38mm	30mm	16.25mm	7°
1131-383-017S	38mm	30mm	17.25mm	7°
1131-383-018S	38mm	30mm	18.25mm	7°
1131-383-019S	38mm	30mm	19.25mm	7°
1131-383-020S	38mm	30mm	20.25mm	7°
1131-383-021S	38mm	30mm	21.25mm	7°
1133-302-611S	30mm	26mm	11.25mm	12°
1133-302-612S	30mm	26mm	12.25mm	12°
1133-302-613S	30mm	26mm	13.25mm	12°
1133-302-614S	30mm	26mm	14.25mm	12°
1133-302-615S	30mm	26mm	15.25mm	12°
1133-302-616S	30mm	26mm	16.25mm	12°
1133-302-617S	30mm	26mm	17.25mm	12°
1133-302-618S	30mm	26mm	18.25mm	12°
1133-302-619S	30mm	26mm	19.25mm	12°
1133-302-620S	30mm	26mm	20.25mm	12°
1133-302-621S	30mm	26mm	21.25mm	12°



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1133-342-811S	34mm	28mm	11.25mm	12°
1133-342-812S	34mm	28mm	12.25mm	12°
1133-342-813S	34mm	28mm	13.25mm	12°
1133-342-814S	34mm	28mm	14.25mm	12°
1133-342-815S	34mm	28mm	15.25mm	12°
1133-342-816S	34mm	28mm	16.25mm	12°
1133-342-817S	34mm	28mm	17.25mm	12°
1133-342-818S	34mm	28mm	18.25mm	12°
1133-342-819S	34mm	28mm	19.25mm	12°
1133-342-820S	34mm	28mm	20.25mm	12°
1133-342-821S	34mm	28mm	21.25mm	12°
1133-383-011S	38mm	30mm	11.25mm	12°
1133-383-012S	38mm	30mm	12.25mm	12°
1133-383-013S	38mm	30mm	13.25mm	12°
1133-383-014S	38mm	30mm	14.25mm	12°
1133-383-015S	38mm	30mm	15.25mm	12°
1133-383-016S	38mm	30mm	16.25mm	12°
1133-383-017S	38mm	30mm	17.25mm	12°
1133-383-018S	38mm	30mm	18.25mm	12°
1133-383-019S	38mm	30mm	19.25mm	12°
1133-383-020S	38mm	30mm	20.25mm	12°
1133-383-021S	38mm	30mm	21.25mm	12°

Titanium Screws and Locking Cover Plate		
Part Number	Description	Shaft Length
1128-453-020S	4.5mm Variable Angle Screw	20mm
1128-453-025S	4.5mm Variable Angle Screw	25mm
1128-453-030S	4.5mm Variable Angle Screw	30mm
1128-453-035S	4.5mm Variable Angle Screw	35mm
1129-453-020S	4.5mm Constrained Screw	20mm
1129-453-025S	4.5mm Constrained Screw	25mm
1129-453-030S	4.5mm Constrained Screw	30mm
1129-453-035S	4.5mm Constrained Screw	35mm
1129-503-020S	5.0mm Constrained Screw	20mm
1129-503-025S	5.0mm Constrained Screw	25mm
1129-503-030S	5.0mm Constrained Screw	30mm
1129-503-035S	5.0mm Constrained Screw	35mm
1130-503-020S	5.0mm Rescue Screw	20mm
1130-503-025S	5.0mm Rescue Screw	25mm

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1130-503-030S	5.0mm Rescue Screw	30mm
1130-503-035S	5.0mm Rescue Screw	35mm
1128-003-001S	Locking Cover Plate	NA

Renovis Instrumentation

Part Number	Description
2128-001-001	Implant Inserter
2128-001-003	Implant Impactor
2128-001-004	Cover Plate Inserter Assembly
2128-001-005	Trial Implant/Bullet Distractor Inserter
2128-001-006	Rasp
2128-001-007	Adjustable Drill Guide
2128-001-008	Captured Spring Loaded Awl
2128-001-009	Cover Plate Driver
2128-001-010	Screw Driver with Universal Joint
2128-001-011	Screw Driver with Solid Shaft
2128-001-012	Awl with Universal Joint
2128-001-013	Modular Drill Bit 3.0mm Diameter
2128-001-014	Modular Flexible Drill Shaft
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
2128-001-033	Angled Cover Plate Inserter
2128-001-034	Modular Screw Driver Bit



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

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



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Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding this device can be directed to:

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