



VAC Pack Introduction

*Class III Drug-Device Combination Product
Approved for Use in the Cervical Spine with
Published Level 1 Human IDE Study Data*

Created for Value Analysis Committee



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Enhancing the Science of Bone Repair

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KEY QUESTIONS

SAFETY

- Proven to be as safe as autograft in an FDA-designed IDE Study for single-level ACDF.
- Clinical usage in large international markets since 2008.

ECONOMICS

- Priced to be more cost-effective than rhBMP-2 or Cellular Bone Matrix (i.e. stem cell products).
- Average of +30% cost savings.¹

EVIDENCE

- Supported by a Level 1 human IDE trial published in SPINE (1-year) and NEUROSURGERY (2-year). This 319 patient FDA-IDE study proved that i-FACTOR was statistically superior to autograft in terms of overall success.²

INDICATIONS

- The only FDA approved bone graft substitute indicated for use in ACDF.

NOVEL SCIENCE

- A powerful cell attachment factor.
- First product to include P-15 Osteogenic Cell Binding Peptide.
- Full FDA-PMA approval based on large IDE trial.
- Only the second Class III Drug Device Combination Product, approved in Spine (Infuse being the first).
- All other spinal bone grafts are Class II, 510K cleared (synthetics/bioglass & DBMs) or unregulated HCTPs.

ADDED VALUE – ADDITIONAL COST SAVINGS

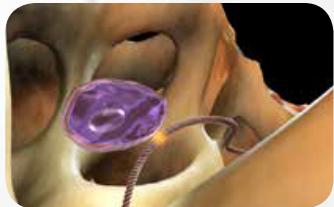
- No mixing, no reconstitution – comes in pre-sterilized syringe ready to use.
- No refrigeration – stored at room temperature with 3-year shelf life.
- No implant tracking – there is no human tissue component.
- Patient satisfaction – most important!

References

1. Internal Data Report
2. Arnold PM, Sasso RC, Janssen ME, Fehlings MG, Smucker JD, Vaccaro AR, Heary RF, Patel AI, Goulet B, Kalfas IH, and Kopjar BK. Efficacy of i-Factor Bone Graft versus Autograft in Anterior Cervical Discectomy and Fusion. (2016) Spine; 41(13):1075-1083

The Attachment Factor Quick Reference

i-FACTOR Peptide Enhanced Bone Graft creates a new category of bone graft.
It is the ONLY bone graft product FDA approved for ACDF.
It is the ONLY peptide-enhanced bone graft.



ATTRACT

The P-15 peptide facilitates and expedites the ingrowth of bone by promoting the immigration of mesenchymal stem (or bonepromoting) cells from the surrounding tissues.



ATTACH

The high, natural affinity between cells and P-15 supports the physiological mechanism in which cells bind to the P-15 and continue to organize the matrix by tractional forces.



ACTIVATE

P-15 has been shown to enhance bone formation by facilitating cellular attachment which activates natural signaling, creating a micro-environment conducive to new bone formation.

The novel i-FACTOR Bone Graft "**Attract, Attach, Activate**" mechanism of action enhances the body's natural bone healing process - resulting in bone formation that is predictably bound to the surface of the bone graft.

Indication for Use: i-FACTOR Peptide Enhanced Bone Graft is indicated for use in skeletally mature patients for reconstruction of a degenerated cervical disc at one level from C3-C4 to C6-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit), with or without neck pain, or myelopathy due to a single-level abnormality localized to the disc space, and corresponding to at least one of the following conditions confirmed by radiographic imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels, after failure of at least 6 weeks of conservative treatment. i-FACTOR Peptide Enhanced Bone Graft must be used inside an allograft bone ring and with supplemental anterior plate fixation.



Product Information:

- i-FACTOR Bone Graft is the only biologic bone graft that utilizes a small peptide (P-15) bound to an anorganic bone mineral (ABM). This unique P-15/ABM combination acts as an attachment factor for osteogenic cells.
- Unlike many synthetic growth factors, P-15 will only stimulate a healing response in the presence of bone forming cells. This anchorage-dependent mechanism of action leads to safe, natural, and predictable bone formation.
- i-FACTOR Bone Graft was evaluated in a prospective, randomized, controlled, multi-center IDE clinical trial assessing its safety and efficacy compared to standard-of-care (autograft). Patients underwent anterior cervical discectomy and fusion (ACDF) and received either i-FACTOR Bone Graft or local autograft in a cortical allograft ring implanted into the target vertebral interbody space prior to placement of the screw/implant fixation construct.
 - » Primary Endpoints: i-FACTOR Bone Graft met all four pre-specified primary endpoints investigated in this study by demonstrating: non-inferiority to autograft relative to fusion rate, improvement in neck disability index, and neurological success; and no statistical difference in adverse event rates relative to autograft.
 - » Overall Success: An assessment of "overall success", as judged by success in all primary endpoints, was applied to the data analysis in this investigation. At 24 months, the investigational group demonstrated 69.83% overall success. The control group demonstrated 56.35% overall success. i-FACTOR demonstrated a fusion rate of 97.3% at 24 months. i-FACTOR was demonstrated to be statistically superior to autograft in overall clinical success at one year and two years.

Supporting Literature:

- Qian JJ Bhatnagar RS, "Enhanced cell attachment to anorganic bone mineral in the presence of a synthetic peptide related to collagen", *J Biomed Mater Res*, 1996; 31(4):545-54.
- Hennessy KM, Pollot BE, Clem WC, Sawyer AA, Culpepper BK, Bellis SL, "The effect of collagen I mimetic peptides on mesenchymal stem cell adhesion and differentiation, and on bone formation at hydroxyapatite surfaces", *Biomaterials*, 2009; 30(10):1898-909.
- Nguyen H, Qian JJ, Bhatnagar RS, Li S. Enhanced cell attachment and osteoblastic activity by P-15 peptide-coated matrix in hydrogels. *Biochem Biophys Res Commun*. 2003 Nov 7;311(1):179-86.
- Yang XB, Bhatnagar RS, Li S, Oreffo RO. Biomimetic collagen scaffolds for human bone cell growth and differentiation. *Tissue Eng*. 2004 Jul-Aug;10(7-8):1148-59.
- Arnold PM, et. al., "Efficacy of i-FACTOR Bone Graft versus Autograft in Anterior Cervical Discectomy and Fusion: Results of the Prospective Randomized Single-blinded Food and Drug Administration Investigational Device Exemption Study", *SPINE*, Forthcoming 2016.
- Arnold PM, Sasso RC, Janssen ME, Fehlings MG, Heary RF, Vaccaro AR, Kopjar B. i-FACTOR Bone Graft vs Autograft in Anterior Cervical Discectomy and Fusion: 2-Year Follow-up of the Randomized Single-Blinded Food and Drug Administration Investigational Device Exemption Study. (2018) *Neurosurgery*; Vol-83(3): pages 377-384.

i-FACTOR Peptide Enhanced Bone Graft		
700-010	i-FACTOR Putty	1.0cc
700-025	i-FACTOR Putty	2.5cc
700-050	i-FACTOR Putty	5.0cc

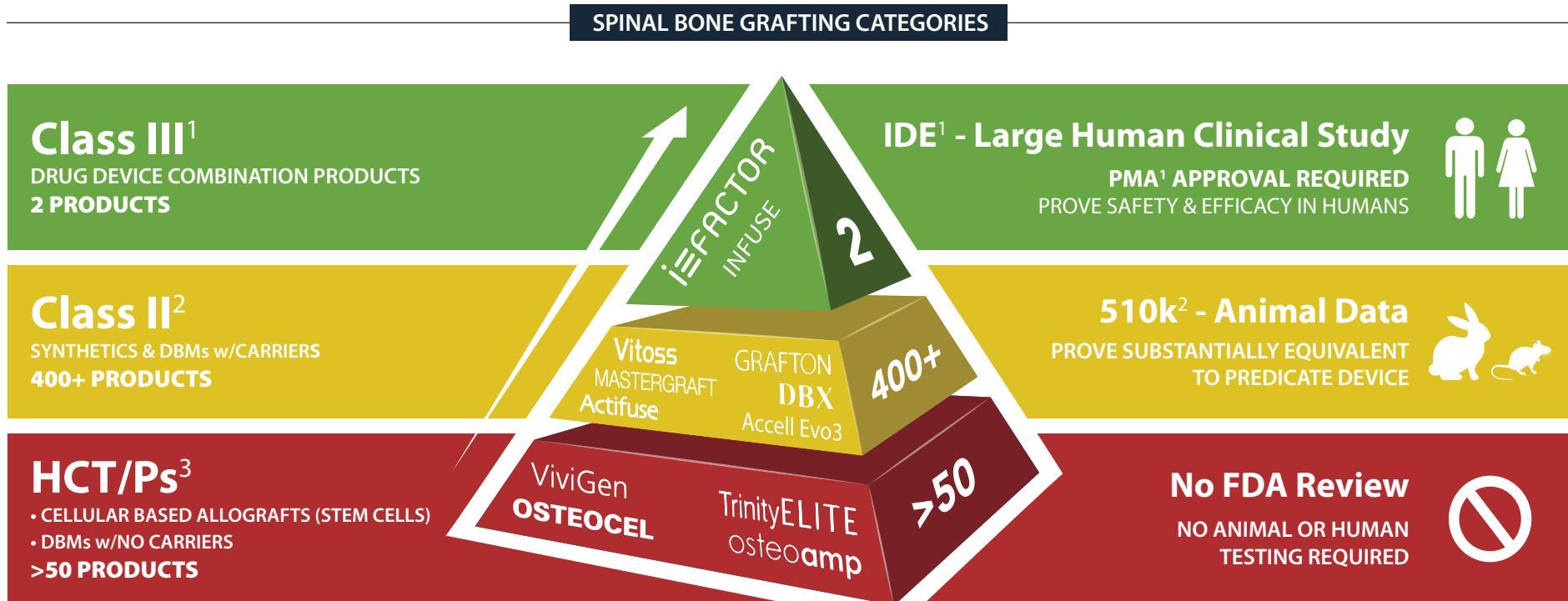


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ML-0049 12/15

FDA Regulatory Pathways & Evidence Requirements



FDA REGULATORY PATHWAY DEFINITIONS

¹ Drug-Device Combination bone grafts are Class III devices and have the most rigorous FDA regulatory pathway. These devices require a Premarket Approval (PMA) on a Level 1 Investigational Device Exemption (IDE) clinical trial that reviews safety and efficacy on humans in order for these products to be brought to market.

² Synthetic bone grafts and Demineralized Bone Matrices (DBMs) with carriers are categorized as Class II devices which require a 510k for market clearance, generally based on an animal study that demonstrates the product is substantially equivalent to a predicate device already on the market. Human testing is not required to bring these products to market.

³ Nonstructural Allografts, Cellular Based Allografts (CBAs aka stem cells) and DBMs without carriers are categorized as Human Cells or Tissue Products (HCT/Ps) which are defined as products that do not rely on the metabolic activity of living cells. These products do not require any FDA review for safety and efficacy on animals or humans to be brought to market.

ISASS, the Largest International Spine Society, Recommends Only 2 Drug-Device Combination Spinal Bone Grafts Backed by Level 1 Human Clinical Data: i-FACTOR and Infuse¹

*"There are only two drug-device combination products approved via the PMA process for spinal use by the FDA based on Level 1 clinical trials showing them to be safe and effective as autograft replacements. These two spine products are **Infuse** and **i-FACTOR**."*

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ISASS Recommendations and Coverage Criteria for Bone Graft Substitutes used in Spinal Surgery

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ABSTRACT
Autograft bone graft remains the gold standard by which bone graft substitutes are compared in spine fusion surgery. The utilization of bone graft substitutes, either as (1) an extender for spinal fusion (extender) or (2) as alternative to autograft, has increased over the last 20 years. The U.S. Food and Drug Administration (FDA) approved i-FACTOR in 2009 (became effective in 2010) defining bone marrow aspirate for bone grafting, spine surgery only. Changes in the regulatory pathway for bone graft substitutes have occurred in the last 20 years. This article reviews the history of bone graft substitutes, the regulatory pathways, mechanisms of action, and supportive clinical evidence for these bone graft substitutes.

Keywords & Registry Affiliations

INTRODUCTION
Over the past 3 decades, there has been increased interest in bone graft substitutes as these materials have become a vital part of most spinal procedures. Unlike other areas of orthopedics, spinal surgery has been slow to embrace bone graft substitutes to induce de novo bone in an area stabilized by metal devices. When considering potential graft materials, it is important to understand that it is important to note that a successful graft needs to have three basic characteristics: (1) osteoconduction, (2) osteoinduction, and (3) osteogenesis. *Cells* refers to the processes of osteogenesis that is defined as cellular formation of new bone. These cells can be endogenous (existing in the body such as osteoblasts or stem cells, that enter the osteoclast lineage and ultimately form new bone) or exogenous (implanted cells). *Matrix* refers to the basic molecules, primarily low-molecular-weight molecules, that are secreted by the cells that form the matrix that actively recruit mesenchymal stem cells, and stimulate them to differentiate into bone-forming cells (osteoblasts). *Signaling* refers to the process that permits cell infiltration and ingrowth of new bone into the graft material. The combination of these properties can either come from materials produced on the site or those received from the host.

When evaluating the complex landscape of grafting materials, it is difficult to compare the options as is the regulatory pathway, mechanism of action, and supportive clinical evidence for these materials may vary. In 1998, demineralized bone matrix (DBM) and synthetic bone grafts became widely available. DBM was a combination of a bone tissue product and not a medical device, synthetic bone grafts were a medical device and followed the 510(k) pathway. In 2006, the regulatory pathway significantly changed in the United States regarding bone graft substitutes when the FDA issued a guidance (FDA) reclassifying versions of DBMs with a non-tissue carrier to require 510(k) clearance, while synthetic DBMs were reclassified as medical devices. Although autologous bone grafting (ABG), most commonly from the iliac crest or local bone, is the

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Table 1. Safety and efficacy of bone graft substitutes.

Category	Regulatory Pathway	Mechanism of Action	Available Data
Nonstructural allografts	HCT/P	Osteoconduction: matrix	No premarket data review by FDA. Long-standing clinical experience, reasonable body of literature
Demineralized bone grafts 510(k) as autograft extender in PLF		Osteoconduction, theoretical osteoinduction: matrix, signals?	Animal study for 510(k) clearance, limited clinical studies
Cellular-based allografts	HCT/P*	Osteoconduction, theoretical osteoinduction: matrix, signals?	No premarket data review by FDA, very limited preclinical and clinical studies
Synthetic bone grafts	510(k) as autograft extender in PLF	Osteoconduction: matrix	Animal study for 510(k) clearance, limited clinical studies
Autologous cellular grafts 510(k) for the concentration devices		Osteogenesis: cells	In vitro data for 510(k), limited clinical studies
Class III, drug-device combination products	IDE/PMA as stand-alone autograft replacements	BMP-2 osteoinductivity P-15 cellular attachment and activation	Level I IDE human clinical study required for PMA approval.

Abbreviations: HCT/P, human cell or tissue product; FDA, Food and Drug Administration; PLF, posterolateral fusion; IDE, investigational device exemption; PMA, premarket approval; BMP, bone morphogenic protein.

*HCT/P status requires that the market product's mechanism of action not "be dependent on the metabolic activity of living cells."

i-FACTOR PARALLELS to Infuse

Drug and Carrier

Both are Class III Drug-Device Combination products

Advanced Biologics

Both enhance cell migration, proliferation and differentiation to bone forming cells^{2,3,4,5}

Level 1 Human Clinical Trials

Both have PMA Approvals based on IDE Studies

Autograft Replacements

Both are autograft replacements, not extenders like most Synthetics & DBMs

i-FACTOR DIFFERENCES to Infuse

Safety Profile

i-FACTOR has no evidence of ectopic bone formation⁶

Cost

On average, i-FACTOR is 30% less expensive than Infuse⁶

Active Ingredients

i-FACTOR has P-15 Osteogenic Cell Binding Peptide

Indications

i-FACTOR's ACDF indication is based on FDA IDE Study Design protocols

1. Abjorson, C. et al. ISASS Recommendations and Coverage Criteria for Bone Graft Substitutes used in Spinal Surgery. International Journal of Spine Surgery 2018, 12(6): 757-771.
2. Hennessy KM, Pollot BE, Cimic WC, Culpepper BK, Bellis SL. The effect of collagen 1 mimetic peptides on mesenchymal stem cells adhesion and differentiation, and on bone formation at hydroxyapatite surfaces. Biomaterials 2009 Apr; 30(10): 1898-909.
3. Nguyen H, Qian JJ, Bhatnagar RS, Li S. Enhanced cell attachment and osteoblastic activity by P-15 peptide-coated matrix in hydrogels. Biochem Biophys Res Commun 2003 Nov 7;311(1):179-86
4. Yang XB, Bhatnagar RS, Li S, Orefeo RO. Biomimetic collagen scaffolds for human bone cell growth and differentiation. Tissue Eng 2004 Jul-Aug;10(7-8):1148-54.
5. Qian JJ, Bhatnagar RS. Enhanced cell attachment to anorganic bone mineral in the presence of a synthetic peptide related to collagen. J Biomed Mater Res 1996 Aug;31(4):545-54.
6. Internal Data Report.

i-FACTOR – THE SAFE, BIOLOGICAL WAY TO STIMULATE NATURAL BONE GROWTH



PEPTIDE POWER

The only bone graft to harness the intense biological activity of P-15 osteogenic cell binding peptide.

SAFETY BY DESIGN

i-FACTOR's unique P-15 action is surface-bound and unlike growth factors only grows bone where you need it.

FILL AND FORGET

Don't assume your bone graft will perform: with i-FACTOR you know it will.

READY TO USE

Store at room temperature. Ready to use without mixing.

CLINICAL SUPERIORITY

Level 1 data supports your evidence-based clinical decision-making and challenges cell-based allografts that are unsupported by objective data.

TRIED AND TRUSTED

i-FACTOR is an FDA PMA approved (2015) Class III drug-device combination product and has been CE Marked since 2008.



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i-FACTOR: THE SAFE, BIOLOGICAL WAY TO STIMULATE NATURAL BONE GROWTH

i-FACTOR – Peptide Enhanced Bone Graft

i-FACTOR is the only biologic bone graft that is based upon the activity of a 15-amino-acid peptide sequence naturally found in type 1 human collagen.

This protein segment, P-15, is an osteogenic cell binding peptide. Osteogenic cells produce new bone.

i-FACTOR uses a biomimetic version of the P-15 Peptide bound to an anorganic bone mineral (ABM) to provide a unique mechanism of action that enhances the body's natural bone healing process, resulting in safe, predictable bone formation.

Mechanism of Action – Attract, Attach, Activate

P-15 is a powerful Cell Attachment Factor. i-FACTOR's unique ABM/P-15 combination increases the opportunity for cell binding in the fusion site by making an abundance of P-15 attachment sites available for osteogenic cells.

This creates a surface-bound 'Attract, Attach, Activate' mechanism of action in which all cellular activity resulting from P-15 attachment is restricted to the implant surface.

Therefore, you can be confident that bone will only form where you want it to. In other words, safety by design.

Published Human Studies Available Upon Request for Committee Review

- Published, peer-reviewed, human clinical studies available by emailing: MedicalAffairs@cerapedics.com
- Includes Level-1 human spine data

“BONE GRAFTING OPTIONS & EVIDENCE”

VIDEO PRESENTATION BY JEFF MARX, PHD

cerapedics.com/value-analysis

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Watch how i-FACTOR is manufactured in this 2-minute video:

www.cerapedics.com/tour



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Cerapedics Certification of NON-PHYSICIAN OWNERSHIP & COMPENSATION

The person, company, business named and signed for Cerapedics hereby certifies that information provided by Vendor in connection with this Certification is true and accurate.

Cerapedics is NOT owned directly or indirectly by a physician or immediate family member of a physician, and NO physician or immediate family member of a physician is known to have a direct or indirect ownership interest in a business that is an Affiliate of Vendor.

Vendor has read and is familiar with the Federal Anti-Kickback Statute and the U.S. Department of Health and Human Services Office of Inspector General ("OIG") Special Fraud Alert: Physician Owned Entities, dated March 26, 2013, addressing the specific attributes and practices of Physician-Owned Entities that the OIG believes produce substantial fraud and abuse risk and pose dangers to patient safety. The OIG's Special Fraud Alert is available at: https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf

VENDOR CERTIFICATION

The Vendor hereby certifies that is not currently excluded or ineligible to participate in any Federal or State health care programs, that the information provided and contained herein is true and accurate, that Vendor will promptly notify the Company and update this Certification form in writing within thirty (30) days of any change in the information provided.

Cerapedics Inc.

11025 Dover Street, Suite 1600

Westminster, CO 80021

303-974-6275

Certified by: _____

Printed Name: _____

Title: _____

Date: _____



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Tax ID #: 20-8302692
DUNS #: 800339702
Website: www.cerapedics.com

Contact Customer Service for Payment Options and ACH Payments



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W-9

Form (Rev. October 2018)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

► Go to www.irs.gov/FormW9 for instructions and the latest information.

Give Form to the requester. Do not send to the IRS.

Print or type.
See Specific Instructions on page 3.

1 Name (as shown on your income tax return). Name is required on this line; do not leave this line blank.	
Cerapedics, Inc.	
2 Business name/disregarded entity name, if different from above	
3 Check appropriate box for federal tax classification of the person whose name is entered on line 1. Check only one of the following seven boxes.	
<input type="checkbox"/> Individual/sole proprietor or <input type="checkbox"/> C Corporation <input type="checkbox"/> S Corporation <input type="checkbox"/> Partnership <input type="checkbox"/> Trust/estate <input type="checkbox"/> Limited liability company. Enter the tax classification (C=C corporation, S=S corporation, P=Partnership) ► Note: Check the appropriate box in the line above for the tax classification of the single-member owner. Do not check LLC if the LLC is classified as a single-member LLC that is disregarded from the owner unless the owner of the LLC is another LLC that is not disregarded from the owner for U.S. federal tax purposes. Otherwise, a single-member LLC that is disregarded from the owner should check the appropriate box for the tax classification of its owner. <input type="checkbox"/> Other (see instructions) ►	
4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):	
Exempt payee code (if any) _____ Exemption from FATCA reporting code (if any) _____ <small>(Applies to accounts maintained outside the U.S.)</small>	
5 Address (number, street, and apt. or suite no.) See instructions.	
11025 Dover Street, Suite 1600	
6 City, state, and ZIP code	
Westminster, CO 80021	
7 List account number(s) here (optional)	

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. Also see *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number

or

Employer identification number

2	0	-	8	3	0	2	6	9	2
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Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here

Signature of U.S. person ►

Andrew Barnes

Digitally signed by Andrew Barnes
DN: cn=Andrew Barnes, o=Cerapedics, Inc., ou=cert, email=abarnes.cerapedics@gmail.com, c=US
Date: 2022-01-10 12:15:59 -06'00'

Date ► **01-10-22**

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to www.irs.gov/FormW9.

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS must obtain your correct taxpayer identification number (TIN) which may be your social security number (SSN), individual taxpayer identification number (ITIN), adoption taxpayer identification number (ATIN), or employer identification number (EIN), to report on an information return the amount paid to you, or other amount reportable on an information return. Examples of information returns include, but are not limited to, the following.

- Form 1099-INT (interest earned or paid)

- Form 1099-DIV (dividends, including those from stocks or mutual funds)
- Form 1099-MISC (various types of income, prizes, awards, or gross proceeds)
- Form 1099-B (stock or mutual fund sales and certain other transactions by brokers)
- Form 1099-S (proceeds from real estate transactions)
- Form 1099-K (merchant card and third party network transactions)
- Form 1098 (home mortgage interest), 1098-E (student loan interest), 1098-T (tuition)
- Form 1099-C (canceled debt)
- Form 1099-A (acquisition or abandonment of secured property)

Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN.

If you do not return Form W-9 to the requester with a TIN, you might be subject to backup withholding. See What is backup withholding, later.



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