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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF ALABAMA

SOUTHERN DIVISION

Vertos Medical, Inc., Plaintiff, vs. Folsom Metal Products, Inc., Greg Martin, Jeff Wright, Natalie Blasco, John Reed and Deanna Miller Defendants.	Civil Action No. JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Vertos Medical, Inc. ("Plaintiff" or "Vertos") brings this Complaint against Folsom Metal Products, Inc., aka Frontier Devices ("Folsom" or "Frontier"), Greg Martin, Jeff Wright, Natalie Blasco, John Reed and Deanna Miller as follows:

NATURE OF THE ACTION

1. Vertos is a medical device company that has developed an innovative, minimally invasive treatment known as ***mild***® for lumbar spinal stenosis (LSS), a sometimes debilitating condition in which the lower spinal canal narrows and compresses the spinal nerves in the lower back. Vertos' proprietary ***mild***® technology, is a safe and minimally invasive outpatient procedure designed to

restore space in the spinal canal through a small incision. Vertos received FDA 510(k) clearance for its *mild*® instrument kit in 2006 and 2010. The *mild*® procedure is also approved for Medicare reimbursement under Current Procedural Terminology ("CPT") code 0275T, but only for physicians performing percutaneous image-guided lumbar decompression (PILD) procedures on patients enrolled in Vertos' CMS-approved study. *See* Centers for Medicare & Medicaid Serv's, *Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis, available at* https://www.cms.gov/medicare/coverage/evidence/lumbar-spinal-stenosis (last accessed Nov. 13, 2023). Vertos has been granted several patents on aspects of the *mild*® procedure and on certain instruments included in the *mild*® instrument kit.

2. As part of a fraudulent enterprise, Folsom has manufactured an unlawful knock-off *mild*®-like device kit called Disposable Kerrison System (DKS) that endangers patient safety. The DKS kit has not been cleared by the FDA and lacks several safety components contained in the *mild*® kit. Folsom's knock-off DKS kit is covertly sold through a network of distributors including Defendants Greg Martin, Jeff Wright, Natalie Blasco, John Reed and Deanna Miller (the "Distributors").

3. Upon information and belief, Folsom and the Distributors are marketing the DKS kit as a cheaper alternative to *mild*®, by among other things,

falsely representing that the DKS kit has received FDA clearance and claiming that DKS kits are "just like ***mild***®," despite the DKS kits lacking important safety features of the FDA cleared ***mild***® kits. Folsom and the Distributors are also fraudulently informing medical providers that PILD procedures with DKS kits are eligible for Medicare reimbursement using improper CPT codes.

4. Folsom and the Distributors' fraudulent enterprise to sell knock-off devices not only damages Vertos, it does so by misleading physicians and endangering patients. Folsom and the Distributors' scheme and blatant disregard for regulatory requirements allows them to offer DKS to medical providers at a lower price than ***mild***®, which induces unknowing physicians and facilities to purchase DKS to increase their margins on PILD procedures. Providers are thus being induced under fraudulent pretenses to use a device that has not been cleared by the FDA and to submit false claims to Medicare.

5. Defendants' are attempting to conceal their unlawful activities and are conducting their misleading promotion of DKS "off the grid," through direct communications with physicians. Unlike other medical devices sold by Folsom, the non-approved DKS device kit is not listed on its website. *See* Frontier Devices, *Our Products*, *available at* http://www.frontierdevices.com/products.php (last accessed Nov. 13, 2023). Vertos has only been able to uncover much of the unlawful conduct by Folsom and the Distributors through an intensive

investigation. The full extent of Defendants' scheme to distribute its knock-off product by misleading medical providers is unknown.

6. These representations and conduct by Folsom and the Distributors violates Section 43(A) of the Lanham Act, 15 U.S.C. § 1125(a), by misrepresenting the nature, characteristics and qualities of Folsom's goods and commercial activities.

7. In addition, through their conduct summarized above and detailed below, Defendants have engaged in an unlawful pattern of racketeering activity through a RICO enterprise ("Defendants' Enterprise"). *See* Racketeer Influenced & Corrupt Organizations Act ("RICO"), including 18 U.S.C. §§ 1961 – 1962. Among other things, "having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises, and for the purpose of executing such scheme or artifice or attempting so to do," Defendants are causing unregistered and misbranded medical devices to be delivered by private or commercial interstate carrier, in violation of 18 U.S.C. § 1341.

8. Folsom is also infringing on Vertos' design and method patents. Specifically, the DKS includes instruments that infringe on Vertos' design patents and Folsom is inducing physicians to perform PILD procedures using the DKS that infringe on Vertos' method patents.

9. Plaintiff Vertos brings this action for false advertising, RICO violations and patent infringement to redress Defendants' illegal scheme that is misleading physicians and compromising their patients' safety.

THE PARTIES

10. Plaintiff Vertos Medical, Inc. is a Delaware corporation with its principal place of business in Aliso Viejo, California.

11. Upon information and belief, Defendant Folsom is an Alabama corporation, which does business through "Frontier Devices, A division of Folsom Metal Products," at

1449 Court Place, Pelham, Alabama 35124. *See* Frontier Devices, http://www.frontierdevices.com/index.php (last accessed Nov. 13, 2023).

12. Upon information and belief, Defendant Jeff Wright is an individual residing in Ellicottville, New York. Jeff Wright is affiliated with Wright Health Solutions.

13. Upon information and belief, Defendant Greg Martin is an individual residing in or near White Lake, Michigan. Greg Martin is affiliated with Milford Medical.

14. Upon information and belief, Defendant Natalie Blasco is an individual residing in or near Philadelphia, Pennsylvania.

15. Upon information and belief, Defendant John Reed is an individual residing in or near Houston, Texas. John Reed is affiliated with Momentum Medical and the IVP Group.

16. Upon information and belief, Defendant Deanna Miller is an individual residing in or near New Roads, Louisiana. Deanna Miller is affiliated with Niche Medical Products.

JURISDICTION AND VENUE

17. This Court has subject matter jurisdiction over this action pursuant to 15 U.S. Code § 1121; 35 U.S.C. § 1, *et seq.*; 28 U.S.C. §§ 1331, 1338(a)–(b); and 18 U.S.C. § 1964(c).

18. This Court has personal jurisdiction over Folsom because it is an Alabama corporation doing business in Alabama. This Court has personal jurisdiction over each of the Distributors because they purposefully availed themselves of the privilege of conducting business in the State of Alabama and established minimum contacts sufficient to confer jurisdiction over the Distributors by transacting business with Folsom in Alabama and arranging with Folsom in Alabama for the shipment of DKS devices kits from the state of Alabama, through a private or commercial interstate carrier, in furtherance of the RICO enterprise alleged herein. As such, the exercise of jurisdiction over the Distributors will not

offend traditional notions of fair play and substantial justice and is consistent with the constitutional requirements of due process.

19. The Court further has personal jurisdiction over the Defendants pursuant to 18 U.S.C. § 1965(b), which provides: "In any action under section 1964 of this chapter in any district court of the United States in which it is shown that the ends of justice require that other parties residing in any other district be brought before the court, the court may cause such parties to be summoned, and process for that purpose may be served in any judicial district of the United States by the marshal thereof." The ends of justice require the exercise of personal jurisdiction over the Distributors because the Defendants are engaged in a RICO enterprise as described herein and, on information and belief, there is no single jurisdiction where all participants in Defendants' Enterprise are otherwise subject to personal jurisdiction.

20. The Court further has personal jurisdiction over the Defendants pursuant to 18 U.S.C. § 1965(d), which provides: "All other process in any action or proceeding under this chapter may be served on any person in any judicial district in which such person resides, is found, has an agent, or transacts his affairs." *See Repub. of Panama v. BCCI Holdings (Luxembourg)*, 119 F.3d 935, 942 (11th Cir. 1997) ("When a federal statute [18 U.S.C. § 1965(d)] provides for nationwide service of process, it becomes the statutory basis for personal

jurisdiction."). Each of the Defendants resides and transacts its/his/her affairs in the United States, and is thus subject to jurisdiction pursuant to 18 U.S.C. § 1965 (d).

21. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1400(b) because a substantial part of the events or omissions giving rise to the claims occurred in this District, because Defendant Folsom is located and incorporated in this District, does business in this district, and, on information and belief, makes, offers to sell and sells accused products in this District. Venue is also proper in this District under 18 U.S.C. § 1965(b). Upon information and belief, and in furtherance of the scheme, Distributors purchase or otherwise obtain DKS device kits directly from Defendant Folsom in this District as part of Defendants' Enterprise.

FACTS

The mild® Kit and Vertos' Development and Regulatory Clearance for the Technology.

22. Founded in 2005, Vertos is a medical device company focused on the treatment of debilitating spinal conditions. Traditional spinal surgeries for the treatment of lumbar spinal stenosis are invasive as they require significant incisions in order to operate on a specific vertebra. Such procedures often require implants and the use of general anesthetic. Traditional invasive procedures also

require the cutting and removal of a substantial amount of tissue, including spinal tissue.

23. In conjunction with several well-respected physicians, Vertos pioneered a novel procedure for the treatment of Lumbar Spinal Stenosis (LSS), a condition that affects 1.5 million patients annually in the United States alone. LSS is a condition where either the spinal canal (central canal stenosis) or the vertebral foramen (foraminal stenosis) narrows, often with age. If the narrowing is substantial it causes nerve compression and the painful symptoms of LSS. Vertos' procedure for treating LSS allows percutaneous, image-guided treatment by accessing the interlaminar space, concurrently removing tissue and bone to decompress the spine, ideally alleviating the symptoms associated with LSS.

24. Using Vertos' process, a surgeon locates visual landmarks through fluoroscopy, then inserts a guide through the skin (percutaneously) along a desired trajectory toward the affected area. Once the portal is secured to the skin surface, the physician can then advance either a bone sculpter or a tissue sculpter through the access portal to perform the procedure. This minimally invasive procedure allows practitioners to remove targeted portions of the bone, and protects against the destabilization of the spine during the procedure. The procedure requires only local anesthesia and thus avoids the potential for complications associated with general anesthesia. The minimally invasive nature of the procedure also enables

shorter in-patient therapy and recovery, in contrast to open surgical treatment options such as Laminotomy, Laminectomy and Spinal Fusion for LSS. Patients undergoing this procedure are typically discharged the day of the procedure.

25. To identify and promote its procedure, Vertos coined the phrase "Minimally Invasive Lumbar Decompression" procedure and registered the trademark *mild*® to identify the procedure to customers. Vertos has been developing, promoting, and marketing the *mild*® procedure since approximately 2006.

26. Vertos obtained 510k FDA clearance for the sale of its *mild*® devices for the *mild*® procedure in the United States in 2006 and 2010, and physicians have performed the procedure on more than 85,000 patients.

27. Vertos sells the instruments to perform its *mild*® procedure as a kit. The *mild*® kit contains the following items: a trocar, a cannula, a depth guide, a bone rongeur, a tissue sculptor, a surgical clamp and a cannula stabilizer. A photograph of the *mild*® kit appears below:

The Unlawful DKS Device

28. In late 2019, Vertos learned that a former *mild*® clinical investigator named Dr. Louis Bojrab had approached Defendant Martin, who is involved with a medical device distributor called Milford Medical, about manufacturing a kit that duplicates the components of a *mild*® kit, but that could be sold as a cheaper means to perform a PILD procedure. Vertos learned that instruments from a *mild*® kit, which are disposable, were saved after a procedure and cleaned/sterilized for the purpose of using them to design a knock-off kit. During that investigation, Vertos discovered that Defendant Martin planned to work with Folsom to manufacture the knock-off device.

29. An officer of Vertos contacted Defendant Martin by telephone, told him that he was aware of their efforts to create a knock-office device and informed Defendant Martin that the *mild*® procedure and certain *mild*® instruments were

protected by Vertos' patents, and that doctors who performed the procedure would be infringing these patents.

30. Specifically, in mid-December 2019, Vertos officer David Lalor informed Defendant Martin as follows: On separate occasions, two Vertos field personnel had discussions with a person they understood to be a former employee of Milford Medical (affiliated with Defendant Martin). The former Milford Medical employee told them that Defendant Martin and Milford Medical, with the assistance of Dr. Louis Bojrab, planned to work with Folsom/Frontier to duplicate *mild*® instruments and sell them. Defendant Martin acknowledged the plan and informed Mr. Lalor that he could duplicate the *mild*® tools if he wanted to do so.

31. Mr. Lalor warned Defendant Martin about Vertos' patents, stating that use or sale of duplicate tools/kit would constitute patent infringement, including method patents that covered the procedure. Mr. Lalor also read Defendant Martin Claim 1 of Vertos' U.S. Patent No. 8,734,477, which covers a method of accessing the interlaminar space to remove tissue to relieve stenosis. Mr. Lalor directed Defendant Martin to the list of Vertos patents on Vertos' website (https://www.vertosmed.com/patents/) to obtain the patent numbers and review them with an attorney.

32. Vertos continued to monitor through its sales representatives any indication that Defendants Martin or Folsom were attempting to market or sell knock-off device kits, and did not learn of any such activity until 2023.

Defendants Violated the Lanham Act and Engaged in a Pattern of Racketeering Activity through a RICO Enterprise By Commercializing DKS and Fraudulently Inducing Providers to Buy It.

33. Despite Vertos providing notice that Defendants' manufacture and use of knock-off device kits would infringe Vertos' patents, Defendants' fraudulent, concealed scheme to make and sell a knock-off device kit apparently continued, culminating in the recent commercialization of the unregistered and misbranded DKS kit. Starting in the summer of 2023, Vertos received information that the certain distributors were attempting to market and sell a knock-off device kit called DKS. Vertos learned over the ensuing months that the Distributors were making various false representations about the DKS kit to induce healthcare providers to purchase it, such as asserting that it is FDA approved and that providers can submit claims for Medicare reimbursement for PILD procedures—under improper CPT codes—using the knock-off kit. Through its investigation, Vertos learned of Defendants' Enterprise and the Lanham Act and RICO violations alleged herein.

34. A photograph of the DKS device it is reproduced below.

35. Upon information and belief, the Distributors are providing this or similar photos of the DKS kit when attempting to sell it to providers.

36. The DKS tools and the package design are remarkably similar in appearance to the *mild*® kit.

37. Upon information and belief, Folsom specifically designed DKS to be an inexpensive *mild*® substitute, but has apparently sought to evade regulatory requirements requiring 510(k) clearance for devices to be used for PILD procedures by enclosing a single page Instructions for Use that is misleading and improper for such procedures.

- ***The DKS is an Unregistered, Misbranded Class II Device.***

38. DKS is not cleared by the FDA. Upon information and belief, the knock-off device kit, called "Disposable Kerrison System" or "DKS" is manufactured by Defendant Folsom and packaged with a purported "Instructions for Use" ("DKS IFU") that is materially deficient for inclusion with a Class II medical device like DKS. Moreover, upon information and belief, the DKS IFU are part of Folsom and the Distributors' scheme to conceal their true purpose, as single-page instructions for use would only be appropriate for standard surgical instruments and not for "*mild*®-like" or PILD procedures for which DKS is marketed. Indeed, the instructions for use for the *mild*® kit, a Class II device, are 16

pages long. A reproduction of a photograph of the single-page DKS IFU is attached hereto as Exhibit 1. For comparison, the 16-page *mild*® Instructions for Use are attached hereto as Exhibit 2.

39. A Class II medical device requires 510(k) clearance from the FDA or a De Novo approval if the device is considered novel. The DKS IFU indicates that there is a "patent pending" for "unique" instruments with delineated uses consistent with Class II Claims. (*See* Exhibit 1.) For example, the DKS IFU lists the intended uses as: "surgical procedures of bones, joints, and ligamentous/soft tissue structures that exist around the nervous system." In addition, the DKS IFU states the delineated specific surgical uses, including the removal of "soft tissues," as well as the functions of "open[ing] a window in bone, often in the spine or skull," to "cut traumatic amputated bone in hand surgery" or the "remov[al of] anterior chest wall." All such uses would require DKS to be registered as a Class II device. However, DKS is not registered with the FDA and has not received 510(k) clearance.

40. Moreover, on information and belief, even the individual instruments within the DKS kit require 510(k) clearance prior to commercialization. For example, on June 29, 2023, the FDA granted 510(k) clearance for a "Manual Rongeur" as a Class II Device. (*See* Exhibit 3.) The Intended Use/Indications for Use in the application states: "The SQ.line KERRISONS (bone punches) are

manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column." Relatedly, according to the FDA's "Product Classification" tool, a Manual Rongeur used in Neurology (HAE) is listed as a Class II device. *See* U.S. Food & Drug Admin., *Product Classification*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=3913 (last accessed Nov. 13, 2023). Although the DKS kit contains two Kerrisons (Bone Rongeurs) indicated "to open a window in bone, often the spine or skull," Folsom has commercialized DKS without receiving the 510(k) clearance required for a Class II device, in violation of the Food Drug & Cosmetic ("FDC") Act. Accordingly, the DKS is an unregistered device, and the single-page DKS IFU is insufficient for a Class II device, such that DKS is misbranded.

41. On information and belief, DKS Distributors are fraudulently informing physicians and nurses that DKS is cleared or approved by the FDA. Moreover, Folsom cannot credibly argue that the DKS device or its individual instruments do not require 510(k) clearance from the FDA. The inclusion of a single-page IFU that could only be appropriate for general surgical instruments renders DKS (a Class II device) misbranded. The single-page IFU also reveals the true purpose and nature of Folsom's commercialization of DKS, which is the direct solicitation of doctors as a cheaper version of ***mild***®.

b. ***DKS Distributors are Inducing Providers to Purchase DKS by Providing Improper Coding Information and Causing Providers To Submit False Claims to Medicare.***

42. Upon information and belief, DKS distributors are fraudulently inducing providers to bill for DKS procedures under CPT codes 0275T, 63030 and 63047 and causing the submission of false Medicare claims. Upon information and belief, the Distributors are expressly citing these codes when marketing DKS to providers and when recruiting other distributors to sell DKS kits, although none of these codes are proper under Medicare guidelines or the AMA's determinations for PILD procedures.

- ***Improper Use of CPT Code 0275T***

43. DKS distributors are targeting providers and fraudulently inducing these physicians and facilities to submit for Medicare reimbursement using CPT Code 0275T. For example, the document entitled "DKS Product Common Uses" is being utilized for this purpose by DKS distributors, including Deanna Miller and Jeff Wright. (*See* Exhibits 3 and 5.) The metadata for this document reveals that it was authored by Dr. Louis Bojrab, the very same physician who was identified as providing a *mild*® kit to Defendant Martin in 2019 for copying by Folsom. Dr. Bojrab's creation of the DKS Product Common Uses is important evidence of Defendants' RICO Enterprise, directly connecting at least Defendants Martin,

Miller, Wright and Folsom in the scheme to knock off *mild*® kits and sell them by misleading providers regarding Medicare reimbursement for use of DKS kits to perform PILD procedures. Upon information and belief, Defendants Blasco and Reed also have been promoting DKS pursuant to Defendants' Enterprise. For example, Defendant Blasco has falsely represented that the DKS devices were FDA approved and that procedures with DKS would be covered under CPT codes 0275T or 63030.

44. "DKS Product Common Uses" describes a number of procedures, including "Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis" on page 2. At the conclusion of this section, the document provides: "CPT code 0275T is common to use." In addition, "DKS Product Common Uses" provides a link to Vertos' billing guide for *mild*®. (*See* Exhibit 5 (citing Vertos Med. Inc., 2023 Billing Guidance for the *mild*® Procedure (NCT03072927), *available at* https://www.vertosmed.com/wp-content/uploads/2023/01/2023-BillingGuide_Rev-8.pdf (last accessed Nov. 13, 2023)).) A note under "References" in the same document states: "Medicare only CPT Category III: 0275T – Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image

guidance (*e.g.*, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar."[1]

45. Contrary to the false or misleading representations in "DKS Product Common Uses" and the representations by at least Defendants Miller, Wright, Martin and Blasco, PILD procedures with DKS are not covered under CPT Code 0275T, because DKS has not been cleared by the FDA, nor has Folsom completed the required clinical trial and regulatory processes for DKS to be eligible for Medicare reimbursement for CPT code 0275T.

46. Medicare has a longstanding national coverage determination ("NCD") on the PILD procedure, attached hereto as Exhibit 6. That NCD provides for affirmative coverage of procedures using an FDA approved/cleared device that are furnished under the auspices of a CMS approved study. And, in a section of the NCD on nationally non-covered indications, CMS states that the PILD procedure for lumbar spinal stenosis "may only be covered under the context of a clinical trial" approved by CMS pursuant to the NCD.

47. A PILD procedure using DKS does not fall within the affirmative coverage provided by the NCD for two reasons. First, as explained earlier, Folsom has not secured approval or clearance from the FDA for DKS. The lack of FDA

[1] "DKS Common Product Uses" does not provide an accurate descriptor for CPT code 0275T. The code was revised in 2017 and no longer includes "with or without endoscope."

approval or clearance means a PILD procedure performed with DKS cannot be covered by Medicare because the NCD requires use of an FDA approved or cleared device to be covered. Second, even if DKS were FDA approved or cleared, in order to be covered under the NCD, the procedure using DKS must be furnished pursuant to a CMS approved study. If Folsom desired for DKS to be covered by Medicare when used in a PILD procedure, it was required to secure CMS approval for a study involving its device. Absent doing so, a PILD procedure using DKS cannot fall within the affirmative coverage elements on the PILD NCD.

48. Given that Medicare cannot cover a PILD procedure using DKS submitted under CPT code 0275T, the submission of a claim for Medicare payment for such a procedure is necessarily false, and representations by Folsom to healthcare providers that payment is available are inaccurate.

49. Currently, CPT code 0275T is covered by Medicare exclusively for the ***mild***® procedure "in conjunction with a CMS-approved study." This is due to Vertos' successful completion of a multi-site randomized control trial (RCT) for ***mild***® that occurred from 2014–2016. Thereafter, CMS granted expanded coverage for ***mild***® under Coverage with Evidence Development ("CED"), which requires a "prospective longitudinal study using an FDA-approved/cleared device that successfully completed a CMS-approved RCT with certain conditions." *See* Centers for Medicare & Medicaid Serv's, *Percutaneous Image-guided Lumbar*

Decompression for Lumbar Spinal Stenosis, available at https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/PILD (last accessed Nov. 13, 2023).

50. In contrast, DKS is not cleared by the FDA, Folsom has not completed a multi-site RCT, and patients undergoing a PILD procedure with DKS are not allowed to be enrolled in a "prospective, longitudinal study using an FDA-approved/cleared device." As a result, CPT code 0275T is unavailable to healthcare providers using DKS for PILD procedures when billing to Medicare. However, as part of their scheme, DKS distributors are marketing directly to physicians familiar with ***mild***®, who may be susceptible to false representations that CPT code 0275T can be reported to seek Medicare reimbursement for procedures with the copycat DKS device.

- ***Improper Use of CPT Code 63030 and 63047***

51. DKS distributors are also inappropriately misleading healthcare providers to use CPT codes 63030 and 63047 when utilizing DKS for a PILD procedure. The DKS IFU from Defendant Folsom references DKS as "Catalog Number DKS-63030" and the "DKS Product Common Uses" document references "DKS product number 63030," apparently to reinforce Defendants' attempts to mislead physicians regarding Medicare coverage for procedures with DKS. (*See* Exhibits 1 and 5.) At least one DKS distributor, Defendant Miller, is providing an

Excel file that includes information on CPT codes for DKS procedures that lists 63030, among others, attached hereto as Exhibit 7. For the Court's convenience, Vertos recreated the Excel in a more legible format, attached hereto as Exhibit 8. Along with the coding suggestions, this Excel document purports to denote the Medicare national average for ASC reimbursement rates, as well as the Medicare national average for professional fees, retail prices and profit for the ASC. CPT code 63030 is listed for "DKS decompression (hemi lami)" (*Id.*) A reproduction of this portion of the Excel document as distributed by Defendant Miller is provided below:

Procedure	CPt Code	ASC Payment Year	ASC Reimbursement*	Physician Payment Year	Professional Fee*	Retail Price	Profit ASC
DKS decompression (hemi lami)	63030	2022	$3,000.00	2022	$1,003.00	$2,000.00	$1,000.00

52. As alleged below, Defendant Miller sent an email to a physician falsely representing that, for PILD procedures with DKS, "you can bill as a T-Code Medicare MILD or a 63030 – 63047 etc other insurances. … I will forward a billing sheet to you." (*See* Exhibit 4.) Defendant Miller then emailed "DKS Product Common Uses" to the physician. This document, also distributed by Defendant Wright and authored by Dr. Bojrab, indicates that "CPT Code 63030 is common to use" for "Laminectomy and Decompression via Direct Visualization." (*See* Exhibit 5 at 1.) Later, under "References," the "DKS Product Common Uses"

informs physicians that "CPT 63047 is for the decompression of spinal stenosis. Percutaneous Decompression Laminotomy PDL Removal of small portion of lamina · Removal of excess ligamentum flavum". (*Id.* at 4.)

53. By promoting DKS in conjunction with these materials as part of their fraudulent enterprise, DKS distributors are inducing healthcare providers to buy DKS for PILD procedures and to utilize CPT codes 63030 and 63047, thereby causing the submission of false claims to Medicare for decompression or PILD procedures. Notably, CPT codes 63030 and 63047 command a higher reimbursement rate than 0275T because they require an open surgical incision with *direct, continuous visualization*, which is far more invasive than a PILD procedure like *mild*®.

54. A detailed explanation of the relevant CPT codes, including an explanation of why CPT codes 63030 and 63047 are not appropriate for a PILD procedure like *mild*®, can be seen in *Coding Brief: Minimally Invasive Lumbar Spinal Decompression (MILD) Procedure* from AMA, CPT® Assistant November 2010/Volume 20 Issue 11, attached hereto as Exhibit 9. The code descriptor for CPT code 63030 is Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated vertebral disc; 1 interspace, lumbar. The code descriptor for CPT code 63047 is Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with

decompression of spinal cord, cauda equina, and/or nerve root(s), [e.g., spinal or lateral recess stenosis]), single vertebral segment; lumbar. Both of these are "open" surgical procedures and are not performed percutaneously, as is the case with PILD procedures.

55. Attached hereto as Exhibit 9 is a document entitled *Coding Brief: Minimally Invasive Lumbar Spinal Decompression (MILD) Procedure* from AMA, CPT® Assistant November 2010/Volume 20 Issue 11. CPT Assistant is an authoritative monthly publication by the AMA on the proper use of CPT codes. This CPT Assistant concludes that CPT codes 63030 and 63047 may not be reported for a "Minimally Invasive Lumbar Decompression (MILD)" procedure.

56. Based on Defendants' misleading representations and the complexity of CPT codes for various spinal procedures, it is highly misleading to physicians to suggest that procedures to be performed with DKS kits—promoted as an alternative to *mild*®—can be reported using CPT codes 0275T, 63030 or 63047, without making it very clear that: (a) PILD procedures may not be reported under 0275T unless performed with an FDA approved or cleared device pursuant to a CMS approved study; (b) PILD procedures may not be reported under CPT code 63030 or 63047; and (c) CPT codes 63030 or 63047 are only appropriate for open surgical procedures.

57. Notably, *mild*® procedures are commonly performed by interventional pain physicians, whereas laminectomies and laminotomies are performed by neurologists. Interventional pain physicians are not typically trained to perform laminectomies or laminotomies.

58. Defendants' false representations to induce healthcare providers to submit false claims to Medicare is part of their overall fraudulent enterprise to entice providers to purchase their unregistered, misbranded and unsafe knock-off medical device. By fraudulently inducing providers to buy DKS instead of *mild*® with the promise of greater financial margins, Defendants are collectively engaged in a scheme to profit by means of false pretenses and representations.

c. *The Role of Distributors in the Racketeering Enterprise.*

59. Upon information and belief and as described below, the Distributors are covertly marketing DKS directly to physicians that are already familiar with *mild*® to avoid more general promotional avenues that might draw attention to the fact that DKS is misbranded and not cleared with the FDA. The DKS Distributors are engaging in a number of fraudulent tactics to convince physicians to purchase the knock-off kit.

60. **Distributor Defendant Deanna Miller.** Upon information and belief, on or about October 2, 2023, Defendant Miller sent an email to a physician

and Vertos *mild*® customer promoting DKS. Among other things, Defendant Miller made the following representations:

- With respect to the sale of DKS kits, "We are typically beating or agreeing to beat Vertos pricing." *This shows that Defendant Miller was actively promoting DKS as a competitor to mild®.*
- "Yes you can bill PILD procedures using the DKS kit as T-Code Medicare MILD or a 63030 - 63047 etc other insurances." As discussed further below, Defendant Miller attached the "DKS Product Common Uses" document for the physician's reference. *This demonstrates Defendant Miller's intention to induce physicians to submit false claims to Medicare using inappropriate coding.*
- Defendant Miller confirmed that the DKS kit is for "ligament resection and bone removal." *Defendant Miller's statement evidences that she was promoting DKS for a PILD procedure likely protected by Vertos' patents, and that DKS is being promoted as a device that requires FDA clearance as a Class II device.*
- Defendant Miller stated: "No training needed if they have used competitive product. We have been doing demos with synthetic

> trainers with kits. I have an actual kit we are using for those demos." *"Competitive product" likely refers to mild®. By stating that training is not needed, Miller is further obscuring the need for FDA clearance, safety features and robust training.*

The Vertos *mild®* customer provided the substance of Defendant Miller's email communication via a text message received by Vertos on October 17, 2023. (*See* Exhibit 4.)

61. The "DKS Product Common Uses" document provided to the Vertos *mild®* customer by Defendant Miller contains supplemental instructions for DKS and directly discusses PILD Procedures, inappropriate reimbursement coding options (including a link to Vertos' billing guide) and (incomplete) safety warnings in the document entitled "DKS Product Common Uses." (*See* Exhibit 5.)

62. Defendant Miller also provided the "DKS Product Common Uses" document in attempting to recruit another DKS distributor, as well as the photos of DKS, the single page DKS IFU and the Excel file containing inappropriate CPT codes for DKS and purportedly citing the national average reimbursement rates and expected "profits" for ambulatory surgery centers. (*See* Exhibits 1, 4–5, 7–8, 10–15.)

63. Upon information and belief, Defendant Miller attended the ASPN Conference in Miami in July 2023 and directly approached physicians attending the conference about DKS, and attempted to sell the DKS kit.

64. **Distributor Defendant Jeff Wright.** Upon information and belief, in the summer of 2023, Defendant Wright approached numerous physicians in the State of New York to promote DKS for use in PILD procedures with a model DKS kit (Exhibit 16). Upon information and belief, Defendant Wright is also disseminating the "DKS Common Product Uses" document that provides improper supplemental instructions for DKS and directly discusses PILD Procedures, and misleads physicians regarding improper reimbursement coding options (including a link to Vertos' billing guide) and (incomplete) safety warnings. (Exhibit 4.)

65. **DKS Distributor Greg Martin.** Upon information and belief, Defendant Martin distributes DKS. As set forth in paragraphs 28 through 32 above, Defendant Martin has participated in a scheme to create a knock-off *mild*® device since 2019.

66. Upon information and belief, Defendant Martin is now promoting DKS jointly with Defendant Wright. Upon information and belief, Distributor Defendants Martin and Wright participated in a phone call with a physician during which Defendant Martin falsely represented that a PILD procedure with the DKS

device kit could be billed under CPT code 0275T or 63030 (a billing code for a related spinal procedure called laminotomy).

67. **DKS Distributor Natalie Blasco.** Upon information and belief, while in New Jersey, Defendant Blasco took the instruments from the DKS kit into an operating room during a procedure to market the DKS devices to a physician. When confronted about the devices Defendant Blasco falsely represented that the DKS devices were FDA approved.

68. Upon information and belief, shortly thereafter, Defendant Blasco falsely stated to a Vertos employee that procedures with DKS would be covered under CPT code 63030 or the CPT code 0275T.

69. **DKS Distributor Jeff Reed.** Upon information and belief, Defendant Reed is also marketing and selling DKS to physicians as part of Defendants' Enterprise.

d. ***The DKS Kits Lack Key Safety Components For PILD Procedures and Threaten Patient Safety.***

70. DKS kits lack key safety components necessary for successful PILD outcomes. For example, a Kerrison is not designed to extract multiple bits of tissue from the interlaminar space, and using a Kerrison for this purpose may cause significant trauma and leave behind tissue that will become scar tissue, potentially resulting in recurrence of stenosis. In some instances, this will require an additional

surgery to correct the issue(s). For this reason, the *mild*® kit includes a Tissue Sculpter, which is specifically designed to gently remove multiple bits of tissue from the interlaminar space. (*See* Exhibit 2.)

71. Also, DKS kits lack instruments designed to measure the depth of instrument insertion during a PILD procedure. For comparison, Vertos has labeled images of the DKS device and the *mild*® kit, attached hereto as Exhibits 17 and 18, respectively. This increases the risk of a physician penetrating too deeply and causing a thecal sac tear (which could cause paralysis and/or subsequent invasive surgical procedure to repair). The *mild*® kit contains a Depth Guide and depth markings to mitigate these risks, which enhances patient safety and successful outcomes.

72. Of the *mild*® kit's seven instruments, four constitute safety components for a PILD procedure. While the DKS contains various sizes of Kerrisons, trocars and cannulas, the DKS does not include any of the four safety components found in the *mild*® kit. This makes the marketing of DKS as merely a cheaper alternative to *mild*® particularly egregious for patient safety.

VERTOS' PATENTS

73. In order to protect its valuable rights in the *mild*® devices and procedure, Vertos has obtained a number of United States patents on the content of the *mild*® kit and the *mild*® procedure itself.

74. On March 1, 2011, U.S. Patent No. 7,896,879 (the "'879 Patent"), entitled "Spinal Ligament Modification," was granted by the United States Patent and Trademark Office. The '879 Patent lists Vertos as the assignee. The priority date of the '879 Patent is July 29, 2004. A true and correct copy of the '879 Patent is attached as Exhibit 19 hereto.

75. The '879 Patent is in full force and effect as of the date of this Complaint and all times relevant to the allegations herein.

76. The '879 Patent covers aspects of the *mild*® surgical procedure. For example, claim 1 covers:

> 1. A method for treating stenosis in a spine, the spine including a thecal sac, a canal, an epidural space between the thecal sac and the canal, and a ligamentum flavum, the stenosis determining a region of interest in the spine, comprising the steps of:
>
> a) compressing the thecal sac in the region of interest by injecting a fluid into the epidural space to form a modified epidural space and a safety zone and establish a working zone, the safety zone lying generally within the modified epidural space, and the working zone lying generally outside the modified epidural space and generally posterior to the thecal sac, wherein the working zone is outside the safety zone;

b) inserting a tool into tissue in the working zone without breaching an anterior surface of the ligamentum flavum;

c) using the tool to percutaneously reduce the stenosis by excising a portion of tissue in the working zone; and

d) utilizing imaging to visualize the position of the tool during at least a part of step c).

77. On May 17, 2011, U.S. Patent No. 7,942,830 (the "'830 Patent"), entitled "Ipsilateral Approach To Minimally Invasive Ligament Decompression Procedure," was granted by the United States Patent and Trademark Office. The '830 Patent lists Vertos as the assignee. The priority date of the '830 Patent is May 9, 2006. A true and correct copy of the '830 Patent is attached as Exhibit 20 hereto.

78. The '830 Patent is in full force and effect as of the date of this Complaint and all times relevant to the allegations herein.

79. The '830 Patent covers aspects of the *mild*® surgical procedure. For example, claim 1 covers:

1. A method for treating stenosis in a spine of a patient having a median plane, the spine including a spinal canal having a posterior surface, a dural sac and an epidural space between the posterior surface and dural sac, the location of the stenosis determining a region of interest in the spine, comprising the steps of:

a) generating at least one view of a portion of the spinal canal in the region of interest;

b) compressing the dural sac in the region of interest by injecting a fluid to form a safety zone and establish a working zone in the region of interest, the safety zone lying generally between the working zone and the dural sac;

c) percutaneously accessing the region of interest on a first lateral side of the median plane via a tool trajectory that passes generally between a lamina of a superior first vertebra and a lamina of an inferior second vertebra and generally between the two superior articular processes of the inferior second vertebra, wherein the first and second vertebra are adjacent;

d) inserting a tissue removal tool into tissue in the working zone on the first lateral side of the median plane via the tool trajectory;

e) using the tissue removal tool to percutaneously reduce the stenosis on the first lateral side of the median plane; and

f) utilizing the at least one view to position the tissue removal tool during at least a part of step d) and at least part of step e).

80. On December 17, 2013, U.S. Patent No. 8,608,762 (the "'762 Patent"), entitled "Translaminar Approach To Minimally Invasive Ligament

Decompression Procedure," was granted by the United States Patent and Trademark Office. The '762 Patent lists Vertos as the assignee. The priority date of the '762 Patent is May 9, 2006. A true and correct copy of the '762 Patent is attached as Exhibit 21 hereto.

81. The '762 Patent is in full force and effect as of the date of this Complaint and all times relevant to the allegations herein.

82. The '762 Patent covers aspects of the *mild*® surgical procedure. For example, claim 1 covers:

> 1. A method for treating stenosis of a patient comprising:
>
> percutaneously accessing tissue with a tool from a first side of the medial plane of the spine, wherein the tool is inserted into a back surface of the patient on the first side and at an initial angle relative to the longitudinal axis of the spine;
>
> advancing the tool generally between adjacent vertebrae and substantially parallel to a long axis of the interlaminar space; and
>
> reducing stenosis.

83. On May 27, 2014, U.S. Patent No. 8,734,477 (the "'477 Patent"), entitled "Translaminar Approach To Minimally Invasive Ligament Decompression Procedure," was granted by the United States Patent and Trademark Office. The

’477 Patent lists Vertos as the assignee. The priority date of the ’477 Patent is May 9, 2006. A true and correct copy of the ’477 Patent is attached as Exhibit 22 hereto.

84. The ’477 Patent is in full force and effect as of the date of this Complaint and all times relevant to the allegations herein.

85. The ’ 477 Patent covers aspects of the *mild*® surgical procedure. For example, claim 1 covers:

> 1. A method for treating a spinal stenosis of a patient, comprising:
>
> inserting a tool into an incision in a skin surface of the patient;
>
> advancing the tool along a trajectory generally parallel to a long axis of the interlaminar space into an interlaminar region located between adjacent vertebrae to access a tissue; and
>
> removing the tissue to reduce the spinal stenosis.

86. On November 11, 2014, U.S. Patent No. 8,882,772 (the “’772 Patent”), entitled “Percutaneous Tissue Excision Devices and Methods,” was granted by the United States Patent and Trademark Office. The ’772 Patent lists Vertos as the assignee. The priority date of the ’772 Patent is July 29, 2005. A true and correct copy of the ’772 Patent is attached as Exhibit 23 hereto.

87. The ’772 Patent is in full force and effect as of the date of this Complaint and all times relevant to the allegations herein.

88. The ’772 Patent covers aspects of the *mild*® surgical procedure. For example, claim 1 covers:

> 1. A method for reducing a spinal stenosis of a patient, comprising:
>
> positioning a distal end of a first instrument in an interlaminar space and external to an epidural space by passing the distal end of the first instrument in a generally anterior direction between adjacent vertebrae of the patient, wherein the first instrument has a lumen with a distal aperture;
>
> advancing a distal portion of a second instrument into the lumen of the first instrument to extend at least part of the distal portion beyond the distal aperture and external to the epidural space; and
>
> moving the distal portion relative to the patient to separate a tissue from the surrounding tissue.

89. On July 6, 2011, U.S. Patent No. D619,253 (the “’253 Patent”), entitled “Tissue Modification Device,” was granted by the United States Patent and Trademark Office. The ’253 Patent lists Vertos as the assignee. The priority date of the ’253 Patent is October 23, 2008. A true and correct copy of the ’253 Patent is attached as Exhibit 24 hereto.

90. The ’253 Patent is in full force and effect as of the date of this Complaint and all times relevant to the allegations herein.

91. The ’253 Patent covers the ornamental design for the *mild*® Bone Rongeur. For example, claim 1 covers, *inter alia*:

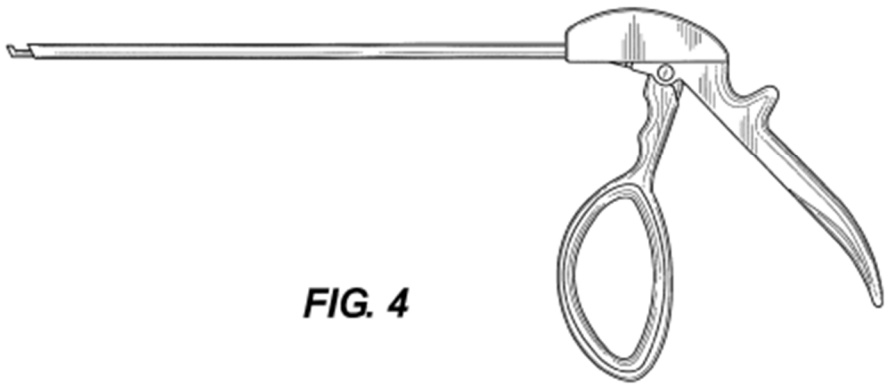


FIG. 4

92. On February 26, 2013, U.S. Patent No. D676,964 (the “’964 Patent”), entitled “Tissue Modification Device,” was granted by the United States Patent and Trademark Office. The ’964 Patent lists Vertos as the assignee. The priority date of the ’964 Patent is October 23, 2008. A true and correct copy of the ’964 Patent is attached as Exhibit 25 hereto.

93. The ’964 Patent is in full force and effect as of the date of this Complaint and all times relevant to the allegations herein.

94. The ’964 Patent covers the ornamental design for the *mild*® Bone Rongeur. For example, claim 1 covers, *inter alia*:

FIG. 1

95. On February 16, 2010, U.S. Patent No. D610,259 (the "'259 Patent"), entitled "Tissue Modification Device," was granted by the United States Patent and Trademark Office. The '259 Patent lists Vertos as the assignee. The priority date of the '259 Patent is October 23, 2008. A true and correct copy of the '259 Patent is attached as Exhibit 26 hereto.

96. The '259 Patent is in full force and effect as of the date of this Complaint and all times relevant to the allegations herein.

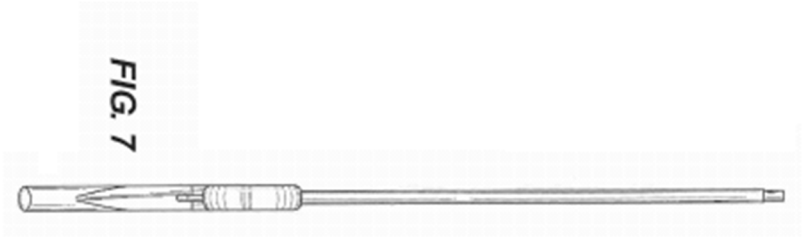
97. The '259 Patent covers the ornamental design for the *mild*® Bone Rongeur. For example, claim 1 covers, *inter alia*:

FIG. 8

98. On July 6, 2010, U.S. Patent No. D619,252 (the "'252 Patent"), entitled "Tissue Modification Device," was granted by the United States Patent and Trademark Office. The '252 Patent lists Vertos as the assignee. The priority date of the '252 Patent is October 23, 2008. A true and correct copy of the '252 Patent is attached as Exhibit 27 hereto.

99. The '252 Patent is in full force and effect as of the date of this Complaint and all times relevant to the allegations herein.

100. The '252 Patent covers the ornamental design for the *mild*® Bone Rongeur. For example, claim 1 covers, *inter alia*:



101. On March 2, 2010, U.S. Patent No. D611,146 (the "'146 Patent"), entitled "Tissue Modification Device," was granted by the United States Patent and Trademark Office. The '146 Patent lists Vertos as the assignee. The priority date of the '146 Patent is October 23, 2008. A true and correct copy of the '146 Patent is attached as Exhibit 28 hereto.

102. The '146 Patent is in full force and effect as of the date of this Complaint and all times relevant to the allegations herein.

103. The '146 Patent covers the ornamental design for the *mild*® Bone Rongeur. For example, claim 1 covers, *inter alia*:

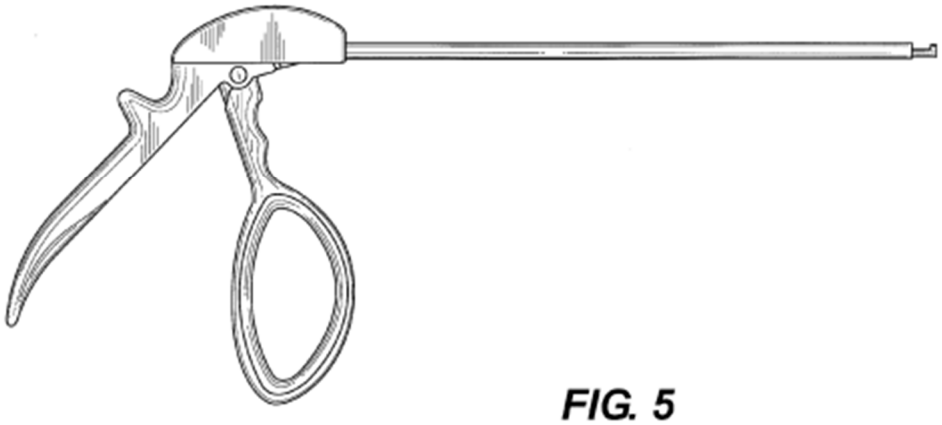


FIG. 5

104. On March 2, 2010, U.S. Patent No. D621,939 (the "'939 Patent"), entitled "Tissue Modification Device," was granted by the United States Patent and Trademark Office. The '939 Patent lists Vertos as the assignee. The priority date

of the ’939 Patent is October 23, 2008. A true and correct copy of the ’939 Patent is attached as Exhibit 29 hereto.

105. The ’939 Patent is in full force and effect as of the date of this Complaint and all times relevant to the allegations herein.

106. The ’939 Patent covers the ornamental design for the *mild*® Bone Rongeur. For example, claim 1 covers, *inter alia*:

FIG. 3

107. On April 5, 2011, U.S. Patent No. D635,671 (the “’671 Patent”), entitled “Tissue Modification Device,” was granted by the United States Patent and Trademark Office. The ’671 Patent lists Vertos as the assignee. The priority date

of the ’671 Patent is February 19, 2010. A true and correct copy of the ’671 Patent is attached as Exhibit 30 hereto.

108. The ’671 Patent is in full force and effect as of the date of this Complaint and all times relevant to the allegations herein.

109. The ’671 Patent covers the ornamental design for the *mild*® Bone Rongeur. For example, claim 1 covers, *inter alia*:

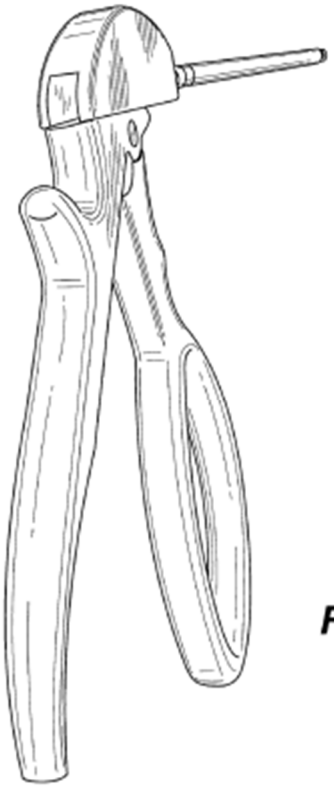


FIG. 9

110. As a result of Folsom’s intentional and illegal behavior, surgeons performing the mild® procedure using the DKS kit infringe Vertos’ patents.

FIRST CAUSE OF ACTION

(False Advertising Under The Lanham Act, 15 U.S.C. § 1125(a), Against All Defendants)

111. Plaintiff realleges and incorporates by reference the full text of all of the foregoing numbered paragraphs, including Exhibits as though each such paragraph has been fully set forth herein.

112. This claim arises under the Lanham Act, 15 U.S.C. § 1125(a).

113. On the basis of the foregoing paragraphs and allegations, Defendants, in connection with goods or services in interstate commerce, have used false and misleading descriptions and representations of fact in commercial advertising or promotion regarding the nature, characteristics, and qualities of the goods sold and marketed by them and at their specific direction.

114. Moreover, Defendants' intentional and deliberate withholding of material facts in connection with the sale and marketing of the DKS device kit also constitute misrepresentation of the nature, characteristics, and qualities of their products and services.

115. Among other things and as alleged herein, Defendants have misrepresented that DKS device kits are FDA approved and/or have misled physicians regarding their lack of approval by promoting the DKS kits for use in

PILD procedures, for which devices require FDA clearance as a Class II medical device.

116. Among other things, and as alleged herein, Defendants have misrepresented that PILD procedures performed with DKS device kits are eligible for Medicare reimbursement and/or have misled physician regarding eligibility for Medicare reimbursement by the statements and conduct alleged herein. These representations include, but, as detailed elsewhere herein, are not limited to, the following:

- The "DKS Product Common Uses" document falsely represents that PILD procedures performed with DKS are eligible for Medicare reimbursement using CPT code 0275T because it refers physicians to Veros' billing guide for *mild*®, which, in turn, directs physicians to the CPT billing codes for the *mild*® procedure. *See ante*, ¶¶ 43–45.
- Defendant Miller has affirmatively represented that use of the DKS device for PILD can be billed to "Medicare MILD" (CPT code 0275T). *See ante*, ¶ 60.
- Defendant Miller has affirmatively represented that use of the DKS device for PILD can be billed to CPT code 0275T. *See ante*, ¶ 66.

117. Defendants' statements and omissions have the tendency to deceive and have actually deceived customers purchasing or contemplating the purchase

DKS device kits. That is because Defendants' misrepresentations that the DKS device is eligible for Medicare reimbursement are material misrepresentations that are likely to induce a physician to use the DKS device.

118. Defendants' deception was material and did influence the purchasing decisions of customers who would otherwise have purchased Vertos' ***mild***® device kits. On information and belief, Defendants' representations regarding the DKS device's suitability for Medicare reimbursement have induced an unknown number to purchase, and use, the DKS device.

119. Defendants' improper activities, as described above and including the material misrepresentation and omissions as described above, were willful and deliberate and part of an intentional business plan to avoid discovery of their deception.

120. On information and belief, as a result of Defendants' improper misleading representations and conduct, Vertos has suffered and continues to suffer injury and damages, including, but not limited to, reputational harm, loss of market share and/or price erosion, and other harm that is irreparable and/or cannot be quantified.

121. On information and belief, as a result of Defendants' improper misleading representations and conduct, Vertos has also suffered and continues to

suffer loss of sales and profits that it would have made but for the false and deceptive advertising and marketing made by Defendants.

122. This injuries alleged herein will continue, unless Defendants are preliminarily and permanently enjoined by this Court.

SECOND CAUSE OF ACTION

(RICO Violations Under 18 U.S.C. §§ 1962 and 1964(c), Against All Defendants)

123. Plaintiff realleges and incorporates by reference the full text of all of the foregoing numbered paragraphs, including Exhibits, as though each such paragraph has been fully set forth herein.

124. 18 U.S.C. section 1964 creates a private cause of action for persons and entities injured by violations of 18 U.S.C. section 1962 (the federal Racketeer Influenced & Corrupt Organizations Act ("RICO")).

125. Plaintiff is a "person" within the meaning of 18 U.S.C. sections 1961(3) and 1964(c).

126. Defendants are "persons" within the meaning of 18 U.S.C. sections 1961(3) and 1962.

127. As alleged herein, Defendants devised a scheme or artifice to defraud and/or to obtain money or property by means of false or fraudulent pretenses, representations, or promises, and/or to sell, DKS device kits for unlawful use.

Defendants thereafter acted in concert to implement, conduct, and conceal the fraudulent scheme to sell the DKS device kits, thus constituting an "enterprise" within the meaning of 18 U.S.C. sections 1961(4) and 1962 (the "Enterprise").

128. On information and belief, for the purpose of furthering their Enterprise and to obtain money and Vertos' customers' business by false or fraudulent pretenses, on multiple, separate occasions Defendants engaged in racketeering activity by depositing or causing to be deposited DKS device kits and the DKS IFU in Alabama to be delivered to locations outside the State of Alabama by private or commercial interstate carriers, in violation of 18 U.S.C. section 1341. The Defendants' multiple uses of private or commercial interstate carriers to further Defendants' Enterprise are substantially similar such that they constitute a pattern of racketeering activity under 18 U.S.C. section 1961

129. Upon information and belief, all the Defendants agreed to the overall goal of the RICO conspiracy—to profit by marketing and selling DKS kits through the false and misleading representation alleged herein—and worked together to achieve that results.

130. Healthcare providers utilizing the DKS device kits to perform PILD procedures and/or requesting Medicare reimbursement for PILD procedures for using DKS kits relied on Defendants' fraudulent conduct to their detriment.

131. Through their pattern of racketeering activities, Defendants acquired or maintained, directly or indirectly, an interest in or control of the Enterprise, which was engaged in, or the activities of which, affect interstate commerce within the meaning of 18 U.S.C. sections 1961(5) and 1962(b).

132. Defendants were an owner of, employed by, or associated with the Enterprise, which is engaged in, or the activities of which affect, interstate commerce, and Defendants conducted or participated, directly or indirectly, in the conduct of the Enterprise's affairs, and conspired to do so, through a pattern of racketeering activity within the meaning of 18 U.S.C. sections 1961(5) and 1962 (c).

133. In violation of 18 U.S.C. section 1962(d), Defendants conspired and/or endeavored to violate the provisions of 18 U.S.C. sections 1962 (a), (b) and (c).

134. Defendants intentionally injured Plaintiff in its business and its property by engaging in the Enterprise detailed herein, including through Plaintiff's loss of sales of its FDA approved ***mild***® device kits.

135. As a direct and proximate result of Defendants' fraudulent acts and the Enterprise alleged herein, Plaintiff was damaged in an amount to be determined.

THIRD CAUSE OF ACTION

(Patent Infringement Under 35 U.S.C. § 271(a), Against Folsom)

136. Plaintiff realleges and incorporates by reference the full text of all of the foregoing numbered paragraphs, including Exhibits, as though each such paragraph has been fully set forth herein.

137. Vertos is the assignee and owner of all rights, title, and interest to the ’671, ’939, ’146, ’252, ’259, ’964 and ’253 Patents (the “Bone Rongeur Design Patents”), which were duly and legally issued by the United States Patent and Trademark Office and which have been duly and legally assigned to Vertos. The Bone Rongeur Design Patents are valid and enforceable.

138. On information and belief, Defendant infringed the Bone Rongeur Design Patents by making offering to sell, selling and making its knock-off bone rongeur as shown in Exhibits 10–14. Defendant’s actions violate claim 1 of each of the Bone Rongeur Design Patents under 35 U.S.C. § 271(a). An ordinary observer would find the knock-off bone rongeur substantially the same as Vertos’ bone rongeur as claimed in the Bone Rongeur Design Patents and the resemblance is such as to deceive such an observer.

139. Defendant does not have a license or permission to use the Bone Rongeur Design Patents.

140. On information and belief, before their first acts of infringement, Defendant knew of Vertos' Bone Rongeur Design Patents, knew their infringing bone rongeur product was substantially similar to the inventions disclosed in the Bone Rongeur Design Patents in such manner as would infringe on the Bone Rongeur Design Patents, and knew that their use of those designs was unauthorized. Defendant nevertheless deliberately and willfully carried out the acts of infringement described herein.

141. As a result of Defendant's infringement of the Bone Rongeur Design Patents, Vertos has been irreparably injured. Unless such infringing acts are enjoined by this Court, Vertos will continue to suffer irreparable injury.

142. On information and belief, Defendant's conduct as alleged above has damaged and will continue to damage Plaintiff, or is likely to damage Plaintiff.

143. On information and belief, as a result of their conduct as alleged above, Defendant has been unjustly enriched and has wrongfully profited.

144. On information and belief, despite knowledge of the Bone Rongeur Design Patents, Defendant will continue to infringe these patents with reckless disregard, by continuing to infringe the patents when it knows or should have known that its actions constituted infringement of the claimed designs of the Bone Rongeur Design Patents. Upon information and belief, Defendant has acted and/or

is continuing to act despite an objectively high likelihood that its actions constitute direct infringement of Vertos' valid patents.

FOURTH CAUSE OF ACTION

(Induced Patent Infringement Under 35 U.S.C. § 271(b), Against Folsom)

145. Plaintiff realleges and incorporates by reference the full text of all of the foregoing numbered paragraphs, including Exhibits as though each such paragraph has been fully set forth herein.

146. Vertos is the assignee and owner of all rights, title, and interest to the '879, '772, '830, '762 and '477 Patents (the "*mild*® Procedure Patents"), which were duly and legally issued by the United States Patent and Trademark Office and which has been duly and legally assigned to Vertos. The *mild*® Procedure Patents are valid and enforceable.

147. On information and belief, Folsom, with knowledge that use of DKS to perform PILD procedures infringes the *mild*® Procedure Patents has intentionally induced and continues to intentionally induce physicians to infringe of at least claim 1 of each *mild*® Procedure Patent, in violation of 35 U.S.C. § 271(b), including by making the DKS kits and promoting their use for PILD procedures in the United States through the DKS IFU and the DKS Product Common Uses document. Among other thing, the DKS Product Common Uses instructs patients of the following procedure for DKS:

Procedure

- Perform an epidural gram. (Optional)
- Target the level below the impingement.
- Place the device from lateral to medial to the central part of the laminar window. Perform your bone and ligament resection under a contralateral view.
- Work from central medial to lateral and then work to the lateral edges.
- Resect the Superior and inferior lamina.
- Changes noted in Epidurogram (improved /easier flow, thicker / straighter line) Epidurogram reveals space estoration in debulked / previously stenosed area

148. Defendant Folsom thus indirectly infringes the *mild*® Procedure Patents by instructing, directing and/or requiring others, including physicians, to perform the steps of the method claims, either literally or under the doctrine of equivalents, of the *mild*® Procedure Patents.

149. Defendant does not have a license or permission to use the claimed subject matter of the *mild*® Procedure Patents.

150. As a direct and proximate result of the Defendant's induced infringement of the *mild*® Procedure Patents, Vertos has been injured and has been caused significant financial damages.

151. Vertos alleges upon information and belief that Defendant has, knowingly or with willful blindness, willfully induced infringement of one or more claims of the *mild*® Procedure Patents. Upon information and belief, Defendant acted with knowledge of the *mild*® Procedure Patents, and, despite that knowledge or despite that it should have known of an objectively high likelihood that its actions constituted inducement of infringement of Vertos' valid patent rights, continue to so infringe.

DEMAND FOR RELIEF

WHEREFORE, Plaintiff Vertos Medical, Inc. respectfully requests that this Court enter judgment in favor of Plaintiff and against Defendants as follows:

A. Awarding Plaintiff compensatory and consequential damages, in an amount to be proven at trial, trebled, in the Court's discretion, and which may include Defendants profits, in an amount to be proven at trial, and the costs of the action;

B. Preliminarily and permanently enjoining Defendants from making any false or misleading representations regarding the DKS device kits, including without limitation that DKS device kits are FDA approved, that PILD procedures performed with DKS device kits are eligible for Medicare reimbursement, or that DKS kits are an appropriate substitute for *mild*® kits.

C. Preliminarily and permanently enjoining Folsom from infringing Vertos' Patents;

D. For pre- and post-judgment interest;

E. For a finding that this case is exceptional pursuant to 35 U.S.C. § 285;

F. Awarding reasonable attorneys' fees and costs; and

G. Ordering such other and further relief as the Court deems just and equitable.

Respectfully submitted this 14th Day of November, 2023.

By: *s / Marcus R. Chatterton*
Marcus R. Chatterton

One of the Attorneys for Vertos Medical, Inc.

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Appendix A

Exhibit No.	Description
1	DKS Instructions for Use
2	The *mild*® Instructions for Use
3	FDA 510(k) clearance for a "Manual Rongeur"
4	Text message between Dr. Aaron Calodney and a Vertos sales representative
5	DKS Product Common Uses
6	National coverage determination ("NCD") on the PILD procedure
7	Excel file containing coding and reimbursement information
8	Vertos recreation of Excel file containing coding and reimbursement information
9	*Coding Brief: Minimally Invasive Lumbar Spinal Decompression (MILD) Procedure* from AMA, CPT® Assistant November 2010/Volume 20 Issue 11
10	Image of DKS in packaging showing DKS-63030 and enclosed IFU
11	Image of DKS in case (blue)
12-14	Images of DKS instruments outside of case
15	Rendering of DKS
16	Image of DKS in case (tan)
17	Image of DKS in case (labeled by Vertos)
18	Image of *mild*® in case (labeled by Vertos)
19	U.S. Patent No. 7,896,879
20	U.S. Patent No. 7,942,830
21	U.S. Patent No. 8,608,762
22	U.S. Patent No. 8,734,477
23	U.S. Patent No. 8,882,772
24	U.S. Patent No. D619,253
25	U.S. Patent No. D676,964
26	U.S. Patent No. D610,259
27	U.S. Patent No. D619,252
28	U.S. Patent No. D611,146
29	U.S. Patent No. D621,939
30	U.S. Patent No. D635,671