

Exhibit 1004

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAINTEQ, LLC,
Petitioner,

v.

ORTHOCISION, INC.,
Patent Owner.

Patent No. 11,083,511
Issue Date: August 10, 2021
Title: METHOD AND IMPLANT SYSTEM FOR SACROILIAC
JOINT FIXATION AND FUSION

Inter Partes Review No. _____

DECLARATION OF DWAYNE POLZER

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I, Dwayne Polzer, hereby declare and state as follows:

I. INTRODUCTION

1. I am currently an employee of PainTEQ, LLC (“Petitioner”), the petitioner for the above captioned *inter partes* review (“IPR”) by the U.S. Patent & Trademark Office Patent Trial and Appeal Board.

2. I have been asked to provide my analysis and expert opinions with respect to certain prior art references cited in the IPR petition, which seeks invalidity of U.S. Patent No. 11,083,511 (“‘511 Patent”). Specifically, I have been asked to opine on whether an ordinary practitioner would have been motivated to modify the directional features of the instruments shown in U.S. Patent Nos. 8,162,981 (“Vestgaarden-981”) with the guidance slot shown in U.S. Patent Pub. No. 2015/0088200 (“Lins”).

3. In relation to this IPR, I am receiving no compensation outside the compensation that I receive in the normal scope of my employment with Petitioner. My employment compensation is not dependent on or related to the outcome of this matter.

4. Any citations I make in this declaration may refer to specific pages or patents and other technical documents, but these citations are exemplary and are not intended to convey the citations as the only source of evidence to support the propositions for which they are cited.



II. QUALIFICATIONS

5. My *curriculum vitae* is attached to this Declaration as Exhibit 1005 and describes my qualifications in detail.

6. My formal education includes a bachelor of science degree in mechanical engineering and a master of science degree in biomedical engineering.

7. I am currently Petitioner's Director of Quality and Research and Development, a position which I have held since 2019. In this role, I am directly involved in the design, development, manufacture, and quality control of Petitioner's sacroiliac joint ("SI joint") fusion instruments and implants. I am responsible for training and supervising Petitioner's employees who perform this work. I directly represent Petitioner's interest to partner manufacturers in all aspects of research, development, manufacturing, and post-production.

8. Prior to my current position, from 2010 until 2019, I was employed by VGI Medical, LLC, formerly known as VG Innovations, LLC ("VGI"), the patentee of Vestgaarden-981 and of U.S. Patent No. 8,882,818 ("Vestgaarden-818"). During my employment, I worked directly with Tov Inge Vestgaarden, the inventor named in Vestgaarden-981 and Vestgaarden-818.

9. From 2018 to 2019, I was a Quality Manager at VGI. In this role, I had extensive and direct involvement in the manufacturing process for VGI's surgical instruments and implants that are used for SI joint fusion, spinal facet fusion, and



for other spinal-related surgeries. My roles included, without limitation, the design and implementation of process for bringing all manufacturing in-house, including the training and supervising of manufacturing employees.

10. From 2016 to 2018, I was a Quality and Research and Development engineer at VGI. In this role I designed, developed, and oversaw prototyping for spinal implants and surgical instruments. I worked directly with machine shops on the manufacturing aspects of these instruments and implants.

11. From 2010 to 2011 and from 2014 to 2016, I was a research, development, and logistics engineer for VGI. My duties in this role included the performance of mock spinal surgeries for the purposes of design, development, and testing of surgical instruments and implants used in various spinal surgeries.

12. During my employment with VGI, I worked with the instrument set shown in Vestgaarden-981, and I have extensive knowledge of the manufacturing methods used to make these instruments.

III. RELEVANT LEGAL STANDARDS

13. In developing my opinions set forth below, I have discussed with Petitioner's attorneys various legal principles regarding the level of ordinary skill in the art and the motivation of an ordinary practitioner to combine certain prior art references. I understood those legal principles and have relied upon them in forming



my opinions stated in this declaration. I am not an attorney, and I am relying solely on explanations from Petitioner's attorneys for these legal standards.

A. Person of Ordinary Skill In the Art

14. I understand that a person of ordinary skill in the art is a hypothetical person who is presumed to have average knowledge and skill in the technical field of the invention at the time it was invented. I understand that a person of ordinary skill in the art understands related references in the technical field and reasonably understands the problem the claimed invention attempts to address.

B. Obviousness and Motivation to Combine

15. I understand that an obviousness analysis is based on the understanding of a person of ordinary skill in the art at the time of the claimed invention and involves a consideration of the scope and content of the prior art, the differences between the prior art and the challenged claims, the knowledge of a person of ordinary skill in the pertinent art, and objective factors indicative of non-obviousness, when such factors are present.

16. I understand that in determining whether a patent claim would have been obvious over a combination of prior art references, a person of ordinary skill in the art must have had a reason for combining teachings from these references in the fashion proposed and would have reasonably expected success in such combination.



17. I have been informed of the following examples of rationales for combining teachings from multiple prior art references: (A) combining prior art elements according to known methods to yield predictable results; (B) simple substitution of one known element for another to obtain predictable results; (C) use of known technique to improve similar devices (methods, or products) in the same way; (D) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) “obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; and (G) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

IV. OVERVIEW OF THE PRIOR ART DIRECTIONAL FEATURES

A. U.S. Patent No. 8,162,981 (“Vestgaarden-981”) (Ex. 1009)

18. Vestgaarden-981 describes various fusion implants for fusing a facet joint. Ex. 1009 at Abstract; FIGS. 29-74. Vestgaarden-981 further describes a set of surgical instruments for implanting the implant into a facet joint. *Id.* at Abstract.



1. Surgical instruments

19. With respect to surgical devices for implantation of the fusion implant, Vestgaarden-981 describes a set of nesting instruments. *Id.* 6:10-15. This instrument set includes a directional cannula (working channel) having blunt tangs on its distal end. *Id.* at 8:36-39; FIG. 8.

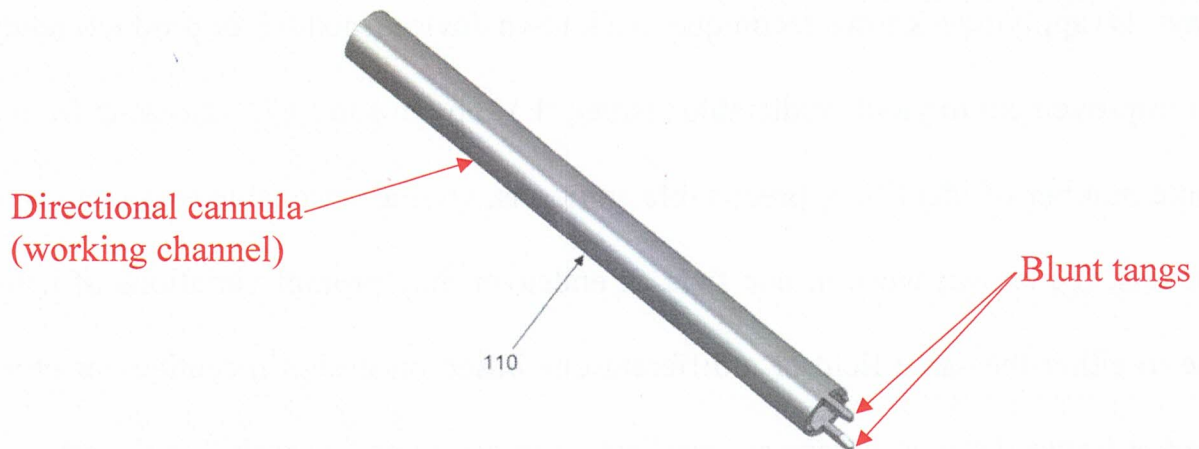


FIG. 8

20. The described surgical tools include a cavity cutter that is used to “make an opening having the perfect shape for fusion implant.” *Id.* at 6:57-58; FIG. 9A. Another surgical tool is an implant holder (inserter) used to insert the fusion implant into the void within the joint. *Id.* at 59-64; FIG. 11. FIG. 11 shows that the implant holder has a pair of implant-engaging arms for holding the implant as the implant

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holder advances the implant through the working channel and inserts the implant into the void within the joint. *Id.* at 6:59-64.

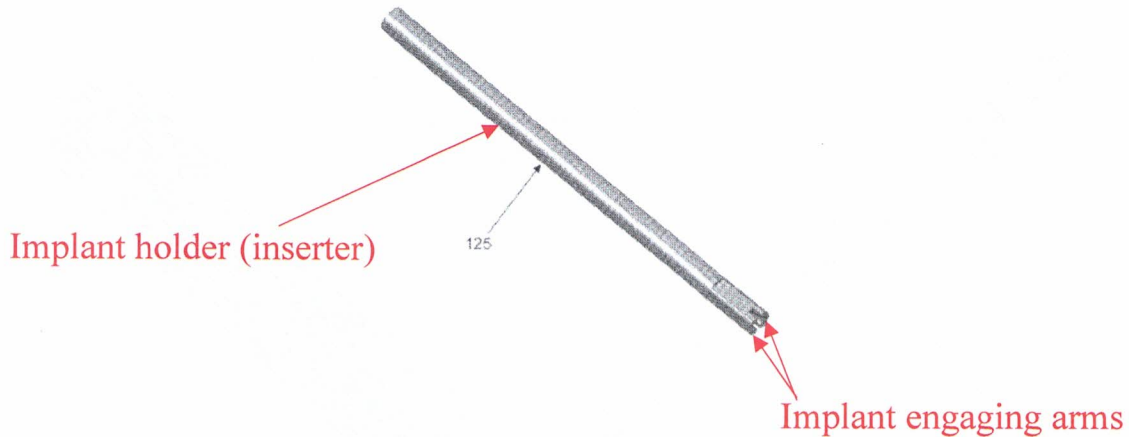


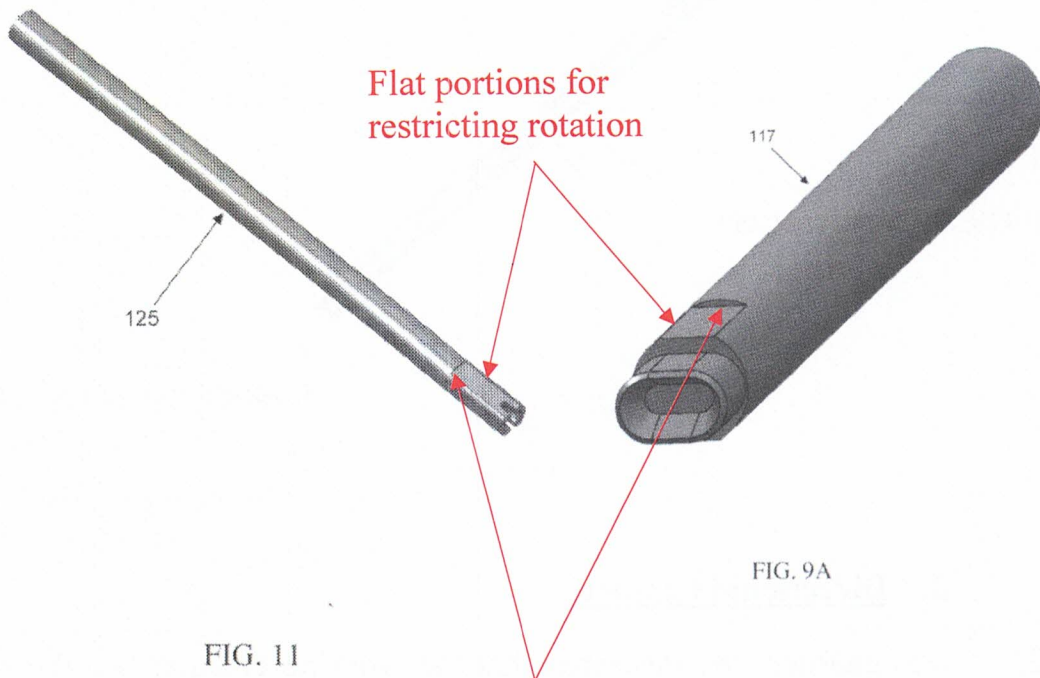
FIG. 11

2. Directional Features

21. Vestgaarden-981 describes that the working channel and the surgical tools have “directional feature[s] which [are] used to maintain the alignment of the instrumentation with ... the joint.” *Id.* at 5:1-4. Vestgaarden-981 describes an example of directional features, in which the directional features are implemented as complementary flat surfaces placed within the interior surface of the working channel and also positioned on the external surfaces of the distal ends of the surgical tools, respectively. *Id.* at 5:4-9. Figures 9A and 11 show the cavity cutter and the implant holder with the exemplary “flat portions,” or “flats,” which serve the role of the “directional features” for maintaining radial alignment between the surgical tools and the working channel. Figures 9A and 11 also show that the flat portions have

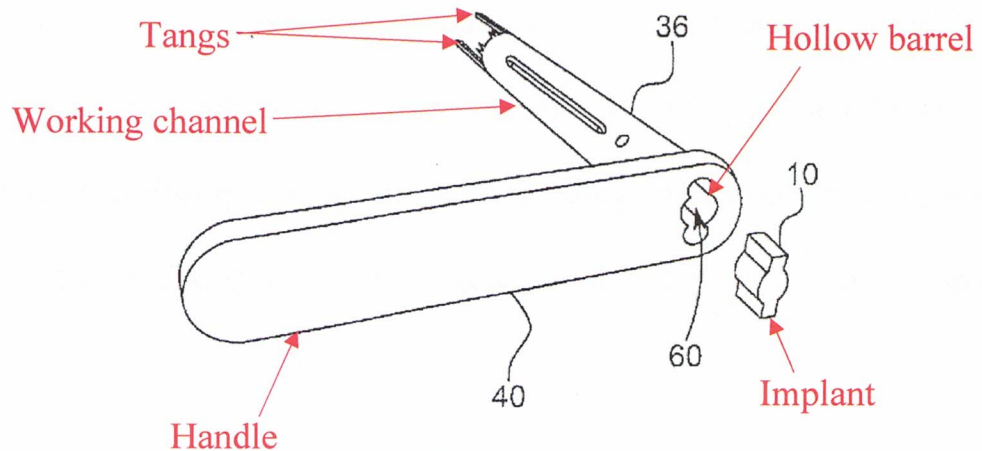


mechanical depth stops that control the depth to which the surgical tools can be inserted into the working channel and the joint.

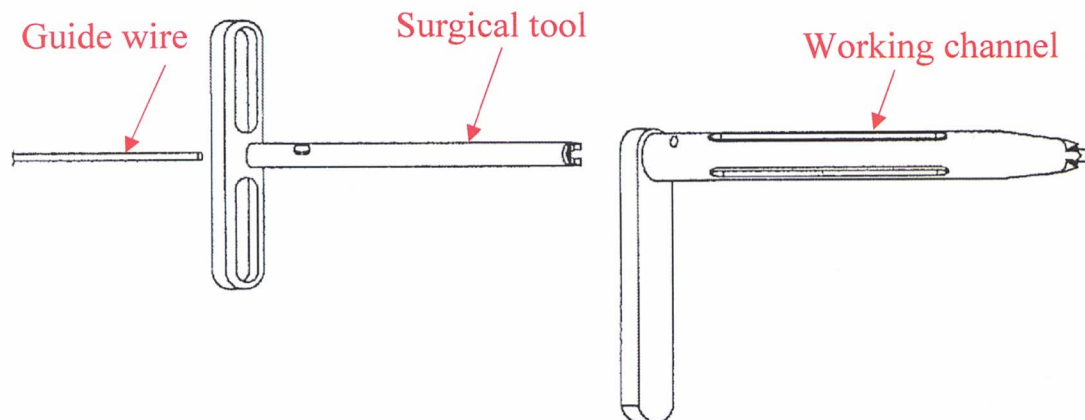


B. U.S. Patent Pub. No. 2015/0088200 (“Lins”) (Ex. 1011)

22. Like Vestgaarden-981, Lins teaches a nesting surgical tool set for implanting a fusion implant into a joint. Ex. 1011 at Abstract; [0034]; FIG. 6. The surgical tool set includes a working channel, to which Lins refers to as a “cannulated retention portion 36.” *Id.* at [0034]; FIG. 4; FIG. 16. The working channel has a hollow barrel and tangs. *Id.*



23. Lins further teaches a surgical tool called “translation portion 34” that is configured to access the joint via the working channel. *Id.* at [0034]; FIG. 6.



24. Lins teaches that the hollow barrel of the working channel has interior guidance slots, to which Lins refers to as “recesses.” *Id.* [0034]. Lins explains that the surgical tools have “guide protrusions” that are configured to engage the interior guidance slots of the working channel to “control and guide the depth of penetration

and degree of rotation” of the surgical instruments relative to the working channel and relative to the joint. *Id.* FIG. 11 of Lins shows the entrance of the guidance slot and the complementary guide protrusion, or pin, positioned on the shaft of the surgical tool. *Id.* at FIG. 11. Annotated FIG. 11 is provided below.

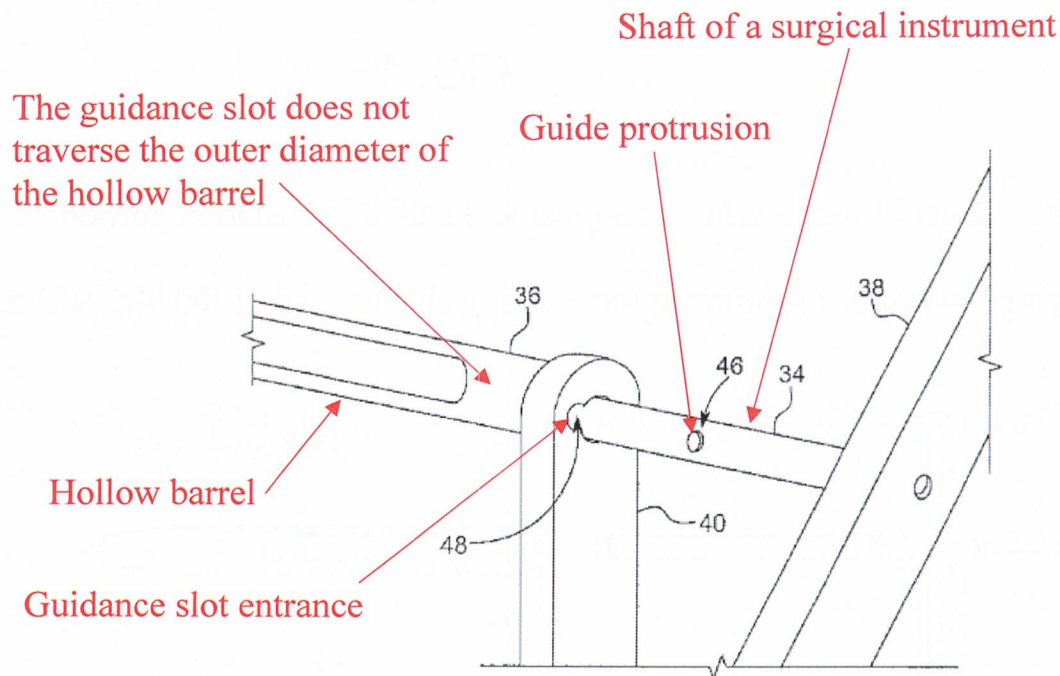


FIG. 11

C. Combination of Vestgaarden-981 and Lins

1. Motivation to combine

25. Controlling depth and orientation of the surgical tools are important and well-known considerations when performing posterior SI joint fusion. When using a posterior approach, the surgeon should take care to maintain all instruments and

implants within the joint to avoid damage to sensitive blood vessels and nerves on the anterior side of the SI joint. Further, Vestgaarden-818 requires that “implant 5 is preferably countersunk 1-2 mm into sacroiliac joint.” Ex. 1010 at 6:35-36. To consistently achieve this countersink without over penetration, it is important that the surgical tools be equipped with a mechanism for precisely controlling the depth at which the void is created and at which the implant holder positions the implant into the void. In addition, because Vestgaarden-981’s cavity cutter and implant have oblong cross-sections, it is important to restrict their ability to rotate within the working channel to ensure that they are properly oriented with respect to the joint, enabling a surgeon to consistently create a correctly oriented void and to precisely orient the implant within an SI joint, as depicted in Figures 3 and 3A of Vestgaarden-818.

26. Vestgaarden-981 recognizes these considerations and explains that the surgical tools and the working channel have “directional features” that control the advancement of the surgical tools within the working channel. Ex. 1009 at 5:1-9. Vestgaarden-981 provides a non-limiting example of directional features that involves complementary “flat portions.” *Id.* at 5:1-9. Figures 9, 9A, and 11 of Vestgaarden-981 depict that the flat portions are positioned on the distal ends of the surgical tools and have shoulders that would function as depth-stops when they engage the corresponding shelves of the flat portions within the working channel.



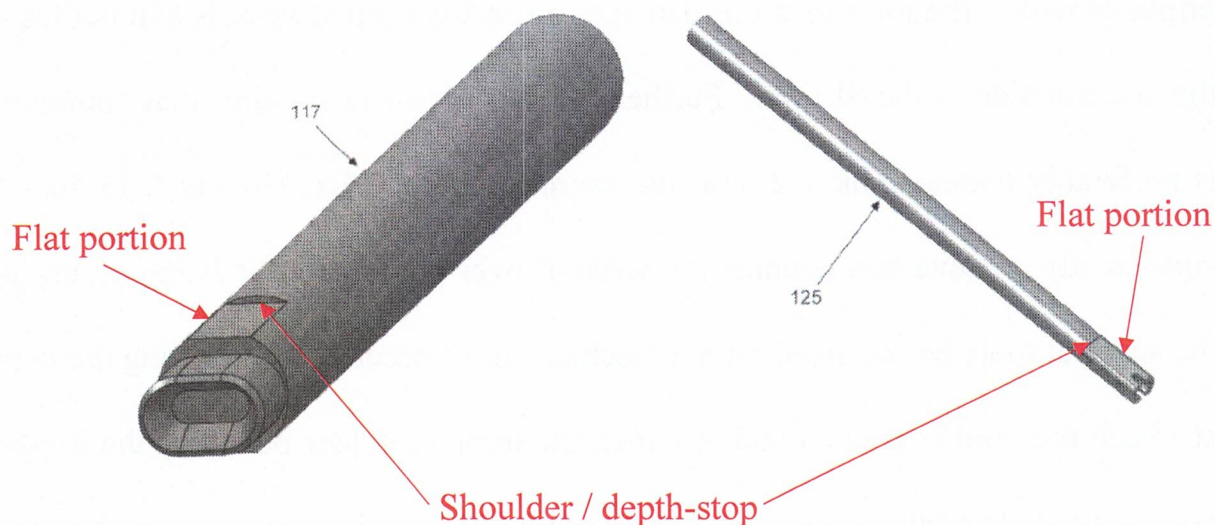
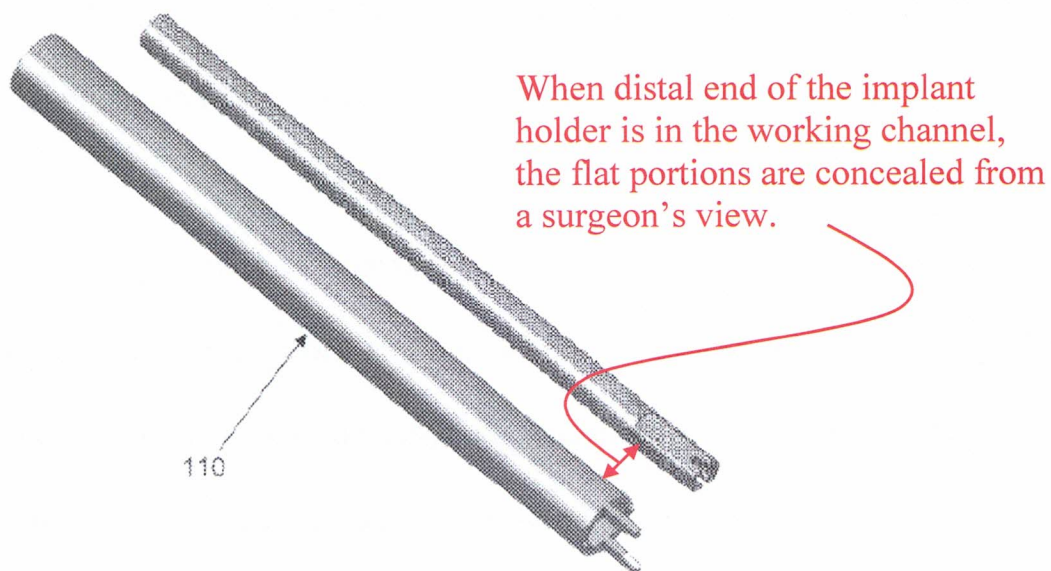


FIG. 9A

FIG. 11

27. Vestgaarden-981's exemplary directional features—i.e., flat portions—do not provide a surgeon with a visual reference for aligning the implant holder with the working channel. After the distal end of the implant holder is inserted into the working channel, the hollow barrel conceals the flat portions on the distal end of the implant holder, such that the surgeon cannot see these “directional features.” After the implant holder is inserted into the working channel and until the distal end of the implant holder reaches the flat surfaces at the distal end of the working channel, the orientation of the implant holder (and the implant coupled thereto) is only controlled by the surgeon's hand. Even slight rotation of the surgeon's hand as they advance the implant holder into the working channel can misalign the flat portions of the implant holder and the flat portions within the working channel.

28. When this happens, the rounded edge of the distal end of the implant holder will hit the straight edge of the flat portion within the working channel, which will stop the advancement of the implant holder. At that point, the surgeon must blindly realign the flat portions of the implant holder with the flat portions within the working channel to continue advancing the implant holder. To do so, the surgeon will gradually rotate the implant holder while pushing it forward to “feel” for the flat portions of the implant holder and the working channel to come into alignment. After the alignment is achieved, the distal end of the implant holder can continue its advancement into the working channel. Only during these final few centimeters of advancement, Vestgaarden-981’s flat portions control the alignment between the surgical tool and the working channel.



29. In addition to these difficulties in using the flat portions on these instruments, the flat portions are relatively difficult to manufacture in commercial quantities. Because of wide material availability and cost-effectiveness, it is common to use round stainless steel stock as a starting point for cylindrical or tubular instruments. Machining flats into or onto round stock can interfere with wall thickness requirement for strength, or it can require a wall thickness that makes the instruments heavy and bulky, in order allow room for a flat to be machined into the round. Machining a flat into the interior of a tubular instrument, such as a cannula, would either not take advantage of common stainless steel stock, or require major modification of the stock as machining methods only *remove* material. In other words, in Vestgaarden-981, the flats cannot be *added* to the internal surface of the cannula, and therefore all material around them and before them must be removed in costly and time-consuming machining, likely with high-end equipment. This is impractical and not cost effective at commercial volumes.

30. By contrast, Lins describes a different and better mechanism for controlling the depth and orientation of the surgical tools relative to the joint. Ex. 1011 at [0038]. In Lins, guide protrusions are affixed to shaft of a surgical tool while complementary guidance slots are positioned on the interior surface of the hollow bore of the working channel. *Id.* The engagement between guide protrusion and the



guidance slot controls the depth of insertion and orientation of the surgical tools relative to the working channel and the joint.

31. A major improvement of Lins over Vestgaarden-981 is that Lins enables a surgeon to **visually** align the guide protrusions on a shaft of a surgical tool with the guidance slots of the working channel, as depicted in Figure 11. After the guide protrusion enters the guidance slot, the guidance slot controls the orientation of the surgical tool during the entire advancement process, thereby giving the surgeon a feeling of control and eliminating the need for blind adjustment.

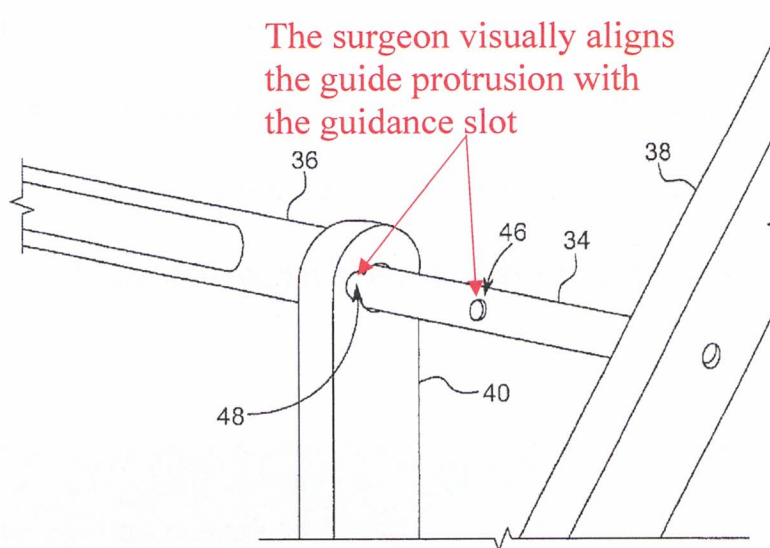


FIG. 11

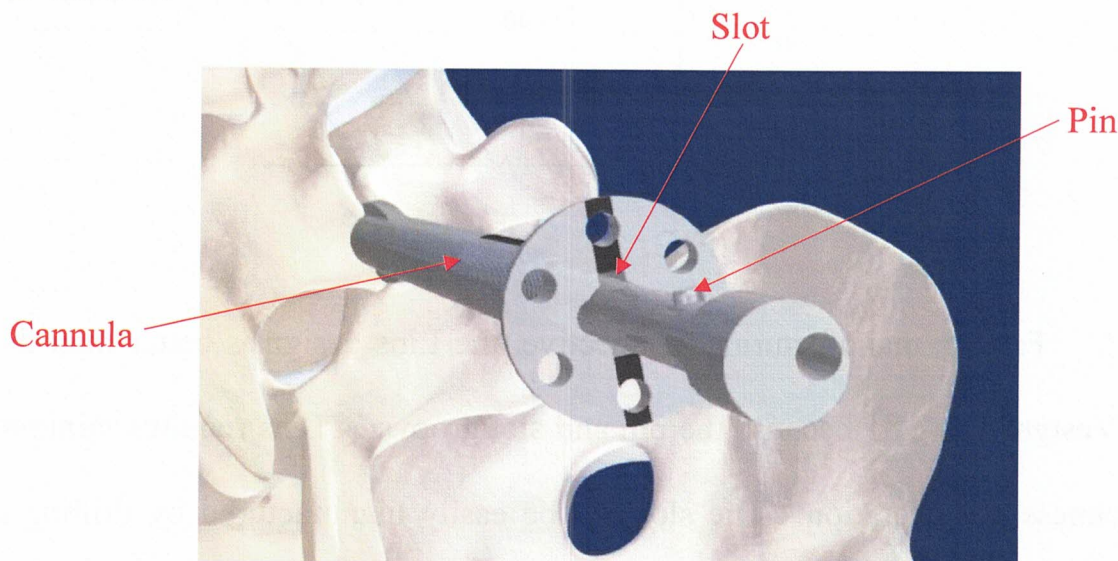
32. From a manufacturing perspective, the Lins design is better than the flats of Vestgaarden-981 because the pin and slot/groove in Lins requires minimal wall-thickness consideration. The slot can be easily manufactured by drilling a smaller, depth-gauged hole for the slot prior to drilling the remaining interior

DP

diameter, or by a one-step machining operation that can be accomplished with common equipment. The pin is easily be added with a drill and press, again requiring minimal time, cost, and effort when compared to machining the flats in Vestgaarden-981.

33. In fact, having personally worked with Tov Vestgaarden and VG Innovations, I can attest to the fact that the design utilizing flats for alignment of the VerteLoc instruments (shown in Vestgaarden-981) saw limited application in commercial production. The eventual large-scale commercial production implemented a pin and slot design, as can be seen in the technique video guide available at <http://vgimedical.com/verteloc/>, last accessed on January 6, 2023. Selected frames from this video are shown below for discussion.

34. The frame below shows the pin aligned with the slot for insertion into the cannula:



35. The VGI instructions for this step instruct the surgeon to “[a]lign the pins of the Drill Guide into the Directional Cannula slot”



36. As can be seen from this technique guide, VGI changed the flats in the Vestgaarden-981 reference to the pin and groove mechanism depicted in Lins. This change was made for manufacturing ease and for ease of use. This pin and slot mechanism was in commercial use by VGI at least as early as 2010.

37. In sum, Lins’s guide protrusions and guidance slots offer advantages over Vestgaarden-981’s “flats” in terms of manufacturing and ease of use. To achieve these advantages, a person of ordinary skill in the art would have been motivated to combine Vestgaarden-981 and Lins, as VGI in fact did commercially implement at least as early as 2010. A person of ordinary skill in the art would have implemented Lins’s guide protrusions and guidance slots as the “directional



features” of Vestgaarden-981’s surgical tools and working channel, as VGI Medical in fact did commercially implement at least as early as 2010.

2. Predictable Result

38. Implementing Lins’s guidance slot and guide protrusions as the directional features of Vestgaarden’s working channel and surgical tools would have been straightforward, and a person of ordinary skill in the art would have had a reasonable expectation of success in making this improvement. Indeed, the flats in Vestgaarden-981 never became widely adopted commercially, and it is the pin and groove design that was incorporated into the commercial embodiment.

39. VGI Medical’s adoption of the pin and groove design over the flats design demonstrates that a person of ordinary skill in the art would have had a reasonable expectation of success when implementing Lins’s guidance slots and guide protrusions as the directional features of Vestgaarden-981’s working channel and surgical tools.

3. Summary

40. Lins’s guidance slot and guide protrusions offer manufacturing advantages over VGI’s flat portions. Machining interior slots into a uniform tubular barrel is a simpler manufacturing process than creating a working channel with a non-uniform lumen, whose proximal portion has a circular cross-section while the distal end has flat sides. Likewise, attaching guide protrusions to the exterior surface



of the tubular shaft of the implant holder is a simpler manufacturing process than creating a tubular shaft with flat faces having precise dimensions. Thus, an instrument designer would be motivated to implement Lins's guidance slots and guide protrusions as VGI's "directional features" to achieve the associated manufacturing advantages.

V. RIGHT TO SUPPLEMENT

41. The opinions in this declaration are based upon my work to date. I reserve the right to supplement this declaration should additional information come to light that bears on my opinions contain herein. I reserve the right to consider and comment on additional evidence, if presented by experts for the Patent Owner. I reserve the right to add to, alter, or delete my opinions and my declaration upon discovery of any additional information and I reserve the right to make such changes as may be deemed necessary.



Inter Partes Review of U.S. Patent No. 11,083,511
Declaration of Dwayne Polzer

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: January 6, 2023

Respectfully submitted,



Dwayne Polzer