

# **EXHIBIT 16**

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(71) Applicant (for all designated States except US): **NUVASIVE, INC.** [US/US]; 4545 Towne Centre Court, San Diego, CA 92121 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **MARTINELLI, Scot** [US/US]; 15973 Crown Valley Rd, San Diego, CA 92064 (US). **ARAMBULA, Jared** [US/US]; 1803 Burton Street, San Diego, CA 92111 (US). **FINLEY, Eric** [US/US]; 5663 West I-6 Ave, Lancaster, CA 93536 (US). **MILES, Patrick** [US/US]; 5227 Greenwillow Lane, San Diego, CA 92130 (US).

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(74) Agent: **SPANGLER, Jonathan, D.**; 4545 Towne Centre Court, San Diego, CA 92121 (US).



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(54) Title: SURGICAL ACCESS SYSTEM AND RELATED METHODS

(57) Abstract: A surgical access system including a tissue distraction assembly 40 and a tissue retraction assembly 10, both of which may be equipped with one or more electrodes 23 for use in detecting the existence of (and optionally the distance and/or direction to) neural structures before, during, and after the establishment of an operative corridor 15 to a surgical target site. The tissue retraction assembly 10 has a plurality of blades 12, 16, 18 which may be introduced while in a closed configuration, after which point they may be opened to create an operation corridor 15 to the surgical target site, including pivoting at least one blade 12, 16, 18 to expand the operative corridor 15 adjacent to the operative site.

## SURGICAL ACCESS SYSTEM AND RELATED METHODS

### CROSS-REFERENCES TO RELATED APPLICATIONS

The present international patent application claims the benefit of priority from commonly owned and co-pending U.S. Provisional Patent Application Serial No. 60/617,498, entitled "Surgical Access System and Related Methods," filed on October 8, 2004 and U.S. Provisional Patent Application Serial No. 60/720,710, entitled "Surgical Access System and Related Methods," filed on September 26, 2005, the entire contents of which are hereby expressly incorporated by reference into this disclosure as if set forth fully herein. The present application also incorporates by reference the following co-pending and co-assigned patent applications in their entireties: PCT App. Ser. No. PCT/US02/22247, entitled "System and Methods for Determining Nerve Proximity, Direction, and Pathology During Surgery," filed on July 11, 2002; PCT App. Ser. No. PCT/US02/30617, entitled "System and Methods for Performing Surgical Procedures and Assessments," filed on Sept. 25, 2002; PCT App. Ser. No. PCT/US02/35047, entitled "System and Methods for Performing Percutaneous Pedicle Integrity Assessments," filed on October 30, 2002; and PCT App. Ser. No. PCT/US03/02056, entitled "System and Methods for Determining Nerve Direction to a Surgical Instrument," filed January 15, 2003 (collectively "NeuroVision PCT Applications").

### BACKGROUND OF THE INVENTION

#### I. Field of the Invention

The present invention relates generally to systems and methods for performing surgical procedures and, more particularly, for accessing a surgical target site in order to perform surgical procedures.

#### II. Discussion of the Prior Art

A noteworthy trend in the medical community is the move away from performing surgery via traditional "open" techniques in favor of minimally invasive or minimal access techniques.

Open surgical techniques are generally undesirable in that they typically require large incisions

and high amounts of tissue displacement to gain access to the surgical target site, which produces concomitantly high amounts of pain, lengthened hospitalization (increasing health care costs), and high morbidity in the patient population. Less-invasive surgical techniques (including so-called “minimal access” and “minimally invasive” techniques) are gaining favor due to the fact that they involve accessing the surgical target site via incisions of substantially smaller size with greatly reduced tissue displacement requirements. This, in turn, reduces the pain, morbidity and cost associated with such procedures. The access systems developed to date, however, fail in various respects to meet all the needs of the surgeon population.

One drawback associated with prior art surgical access systems relates to the ease with which the operative corridor can be created, as well as maintained over time, depending upon the particular surgical target site. For example, when accessing surgical target sites located beneath or behind musculature or other relatively strong tissue (such as, by way of example only, the psoas muscle adjacent to the spine), it has been found that advancing an operative corridor-establishing instrument directly through such tissues can be challenging and/or lead to unwanted or undesirable effects (such as stressing or tearing the tissues). While certain efforts have been undertaken to reduce the trauma to tissue while creating an operative corridor, such as (by way of example only) the sequential dilation system of US Pat No. 5,792,044 to Foley et al., these attempts are nonetheless limited in their applicability based on the relatively narrow operative corridor. More specifically, based on the generally cylindrical nature of the so-called “working cannula,” the degree to which instruments can be manipulated and/or angled within the cannula can be generally limited or restrictive, particularly if the surgical target site is a relatively deep within the patient.

This highlights yet another drawback with the prior art surgical access systems, namely, the challenges in establishing an operative corridor through or near tissue having major neural structures which, if contacted or impinged, may result in neural impairment for the patient. Due to the threat of contacting such neural structures, efforts thus far have largely restricted to establishing operative corridors through tissue having little or substantially reduced neural structures, which effectively limits the number of ways a given surgical target site can be

accessed. This can be seen, by way of example only, in the spinal arts, where the exiting nerve roots and neural plexus structures in the psoas muscle have rendered a lateral or far lateral access path (so-called trans-psoas approach) to the lumbar spine virtually impossible. Instead, spine surgeons are largely restricted to accessing the spine from the posterior (to perform, among other  
5 procedures, posterior lumbar interbody fusion (PLIF)) or from the anterior (to perform, among other procedures, anterior lumbar interbody fusion (ALIF)).

Posterior-access procedures involve traversing a shorter distance within the patient to establish the operative corridor, albeit at the price of oftentimes having to reduce or cut away part  
10 of the posterior bony structures (e.g. lamina, facets, spinous process) in order to reach the target site (which typically comprises the disc space). Anterior-access procedures are relatively simple for surgeons in that they do not involve reducing or cutting away bony structures to reach the surgical target site. However, they are nonetheless disadvantageous in that they require traversing through a much greater distance within the patient to establish the operative corridor,  
15 oftentimes requiring an additional surgeon to assist with moving the various internal organs out of the way to create the operative corridor.

The present invention is directed at eliminating, or at least minimizing the effects of, the above-identified drawbacks in the prior art.

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**SUMMARY OF THE INVENTION**

The present invention accomplishes this goal by providing a novel access system and related methods which involve detecting the existence of (and optionally the distance and/or direction to) neural structures before, during, and after the establishment of an operative corridor  
25 through (or near) any of a variety of tissues having such neural structures which, if contacted or impinged, may otherwise result in neural impairment for the patient. It is expressly noted that, although described herein largely in terms of use in spinal surgery, the access system of the present invention is suitable for use in any number of additional surgical procedures wherein tissue having significant neural structures must be passed through (or near) in order to establish  
30 an operative corridor. It is also expressly noted that, although shown and described herein

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