IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

DR. FORD ALBRITTON IV	
Plaintiff,	**Civil Action No.**
v.	
ACCLARENT, INC.	**JURY TRIAL**
Defendant.	

ORIGINAL COMPLAINT

Plaintiff Dr. Ford Albritton IV ("Dr. Albritton" or "Plaintiff") files this Original Complaint against Defendant Acclarent, Inc. ("Acclarent" or "Defendant") and hereby alleges as follows:

PARTIES

1. Dr. Albritton is a prominent, pioneering ENT surgeon who resides in Dallas, Texas and has been practicing medicine for more than 15 years.

2. Upon information and belief, Acclarent is a medical device corporation organized under the laws of Delaware that conducts business throughout the United States, including within this District. Acclarent has a principal place of business at 33 Technology Drive, Irvine, California 92618. Acclarent's registered agent in Texas is CT Corporation System, 1999 Bryan St., Suite 900, Dallas, Texas 75201.

JURISDICTION AND VENUE

3. This is an action containing claims for patent infringement arising under the patent laws of the United States, Title 35, U.S.C. § 271. This Court has exclusive subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1367, and/or 1338.

4. In addition to jurisdiction based upon a federal question, there is jurisdiction under 28 U.S.C. § 1332(a) due to diversity of citizenship. Dr. Albritton is a citizen of the State of Texas and Acclarent is a citizen of another state, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

5. The Court has supplemental jurisdiction over Dr. Albritton's claims for breach of contract, fraud, and fraudulent inducement, pursuant to 28 U.S.C. § 1367, as these claims arise from a common nucleus of operative facts and are so related to the patent infringement claims in this action that they form part of the same case or controversy under Article III of the United States Constitution.

6. This Court has personal jurisdiction over Acclarent. Acclarent does extensive business in Texas and has committed acts of infringement within the State, as herein alleged. Acclarent, by or through subsidiaries or intermediaries (including distributors, retailers, and others), ships, distributes, offers for sale, sells, and advertises (including the provision of an interactive web page) its products (including infringing products) in the United States, the State of Texas, and the Northern District of Texas. Acclarent, directly and through subsidiaries or intermediaries, has purposefully and voluntarily placed one or more of its infringing products, as described below, into the stream of commerce with the expectation that they will be purchased and used by consumers in the Northern District of Texas. These infringing products have been and continue to be purchased and used by consumers in the Northern District of Texas. Acclarent has committed acts of patent infringement within the State of Texas and, more particularly, within the Northern District of Texas. As set forth in Paragraph 2, Acclarent maintains a registered agent for service of process in Texas. By virtue of these contacts, this Court has personal jurisdiction over Acclarent.

7. This Court has personal jurisdiction over Acclarent because Acclarent is subject to an enforceable forum selection clause requiring that claims arising out of the parties' Mutual Non-Disclosure Agreement ("NDA") be litigated in Dallas, Texas.

8. This Court has personal jurisdiction over Acclarent because Dr. Albritton's claims for breach of contract, fraud, and patent infringement arise directly out of the contacts between Acclarent and the State of Texas (and more particularly, the Northern District of Texas). In particular, Acclarent's agents and/or employees visited Dr. Albritton in Texas; communicated with Dr. Albritton in Texas to negotiate the terms of the NDA and a subsequent consulting agreement ("Consulting Agreement"); and Acclarent entered into the NDA and Consulting Agreement with Dr. Albritton in Texas. Moreover, Acclarent communicated with Dr. Albritton in Texas multiple times regarding his invention of a novel surgical catheter—even sending agents to Dallas, Texas to observe surgeries performed by Dr. Albritton—before taking Dr. Albritton's confidential information and intellectual property, and using it to design (and apply for patent protection for) Acclarent's Relieva Spin® and SpinPlus® devices (the "Relieva Devices").

9. Venue is proper under 28 U.S.C. §§ 1391 and 1400 because Acclarent has committed, and continues to commit, acts of infringement in this District and is subject to personal jurisdiction within this state.

FACTUAL ALLEGATIONS

10. Plaintiff refers to and incorporates herein the allegations of Paragraphs 1-9 above.

11. Dr. Albritton is a prominent ENT surgeon in Dallas, Texas. Dr. Albritton was the first surgeon to perform a balloon dilation procedure in Dallas, and the second surgeon to perform that procedure in Texas. Dr. Albritton has been an innovator in the field of nasal and

sinus surgery for over a decade. Beginning in 2006, Dr. Albritton worked to develop a surgical catheter device that could, among other things, be operated with a single hand.

12. Acclarent is a medical device company that sells balloon sinuplasty devices. When Acclarent learned of Dr. Albritton's innovative techniques and methods for use in a surgical catheter device, Acclarent contacted Dr. Albritton to learn more.

13. Recognizing the importance of protecting his innovation and before discussing any technical details, Dr. Albritton requested that Acclarent enter into the NDA. The NDA was executed on June 12, 2007. Ex. A.

14. Among other provisions, the NDA prohibits Acclarent and Dr. Albritton from using "any confidential information of the other party for its own use . . ." and provides that "[t]o the extent that either party breaches this agreement by using the other party's confidential information . . . any inventions, improvements, or other intellectual property resulting from such impermissible use will be the property of the non-breaching party." Ex. A at 1.

15. Throughout 2007, Dr. Albritton continued to improve his inventive device design. In January 2008, Dr. Albritton used the first working prototype of his single-handed suction device in surgery in Dallas.

16. Acclarent continued its pursuit of Dr. Albritton, purportedly under the protection of the NDA, requesting additional information about his new device. Acclarent employees frequently visited Dr. Albritton at his workplace in Dallas, Texas, observed his work, and studied his single-handed device prototypes and drawings.

17. Dr. Albritton disclosed confidential information during this period that included (without limitation) the working prototypes of the single-handed guide and catheter device

developed by Dr. Albritton, and later, a prototype containing Dr. Albritton's novel mechanism for providing improved tactile feedback to the surgeon through contact with the guidewire.

18. On May 9, 2008, Acclarent employee Dan Harfe sent an email to Acclarent employee Ryan Clark acknowledging that Dr. Albritton had previously invented a device combining suction in a guide catheter, and stating that Acclarent would like to incorporate those features in its "next generation Guide Catheter" and that it would "be great to chat with [Dr. Albritton] about his experience." Ex. B.

19. On May 11, 2008 Clark forwarded the email about Dr. Albritton's developments from Harfe to Dr. Albritton, commenting that "[t]his is pretty exciting and I have to say it is about time" and asking Dr. Albritton to consult with Acclarent's lead design engineer. *Id.*

20. On May 16, 2008, Dr. Albritton filed a provisional patent application for his inventions in order to protect his novel ideas. Ex. C. This application disclosed a single-handed surgical catheter device, and later became U.S. Patent No. 9,011,412 ("the '412 Patent"). Ex. D.

21. On May 19, 2008, after filing his provisional patent application, Dr. Albritton spoke to Serena Swei, the lead design engineer at Acclarent who was working to improve Acclarent's inferior guide catheter device. On that call, Swei assured Dr. Albritton that he would be named as a co-inventor on any patent applications filed by Acclarent covering devices he helped develop. Based in part on this representation, and under the protection of the NDA, Dr. Albritton continued working with Acclarent and advising Acclarent's engineers on how to improve their devices.

22. On May 28, 2008, Acclarent sent Dr. Albritton a draft consulting services agreement regarding Dr. Albritton's services and consultation on several specified Acclarent products. Ex. E. The original draft agreement would have given Acclarent a royalty-free license

to Dr. Albritton's pre-existing inventions. *Id*. at 2-3. Dr. Albritton refused to agree to that provision, in part because of the provisional patent application he had already filed.

23. Instead, Dr. Albritton insisted that he would own his pre-existing inventions, including the invention described in the provisional patent application he had provided to Acclarent. The royalty-free license provision was then removed and Dr. Albritton signed the Consulting Agreement on December 18, 2008, with an effective date of June 8, 2008. Ex. F.

24. Relying on the protections of the 2007 NDA and 2008 Consulting Agreement, Dr. Albritton continued to work with Acclarent employees, providing advice and guidance on the devices identified in Exhibit A to the Consulting Agreement, as well as insurance codes to achieve coverage for sinuplasty procedures.

25. On June 11, 2008, Dr. Albritton had his first meeting with Acclarent's then-CEO Bill Facteau and Acclarent's engineering team. He also provided a copy of his then-pending provisional application that became the '412 Patent to Acclarent employees Greg Garfield and Scott Smith (the Director of Intellectual Property at Acclarent).

26. On September 18, 2008, after meeting with Dr. Albritton, Acclarent filed provisional Patent Application No. 61/098,157, which does not list Dr. Albritton as an inventor. Ex. G. Acclarent's provisional application misappropriates and incorporates the ideas Dr. Albritton shared with Acclarent under the protections of the NDA and the Consulting Agreement. The provisional Patent Application No. 61/098,157 eventually issued as U.S. Patent No. 8,414,473 ("the '473 patent").

27. Dr. Albritton's contributions to the invention claimed in the '473 patent include (among other things) the development of a surgical catheter device that:

a. allows for single handed control of the device, including control of wire introduction and balloon catheter introduction with the same (single) hand;

b. incorporates a thumb-port suction hole;

c. adds various stabilization points for the fingers, thumb and hand to provide for improved single-hand use; and

d. incorporates Albritton's tactile feedback improvements that allow the surgeon to gain full tactile feel during the insertion, advancement, and steering of the surgical guide wire.

28. Acclarent's misappropriation of Dr. Albritton's innovations is demonstrated at least by comparing Acclarent's provisional Patent Application No. 61/098,157 (the "Acclarent Provisional Application")—which Acclarent filed after meeting with Dr. Albritton—with Dr. Albritton's previously-filed provisional application No. 61/127,848 (the "Albritton Provisional Application"). Ex. C.

29. For example, the Albritton Provisional Application provides for the single handed control of a surgical catheter, including control of wire introduction and balloon catheter introduction with the same (single) hand.

30. The Albritton Provisional Application also provides for the incorporation of suction into the surgical catheter handle, and manipulation of suction using a finger or thumb.

31. Moreover, the Albritton Provisional Application provides for the manipulation of suction and/or a working device using a free finger or thumb of the same hand operating the surgical catheter.

32. These innovations, among others, were invented by Dr. Albritton before he entered into the NDA or Consulting Agreement with Acclarent—as recognized by Acclarent

employees and officers. Dr. Albritton only shared these innovations with Acclarent under the protection of the NDA and/or Consulting Agreement.

33. However, despite agreeing to the terms of the NDA and Consulting Agreement, Acclarent misappropriated Dr. Albritton's innovations, incorporating them into the Acclarent Provisional Application and other applications leading to the issuance of the '473 patent. The following chart lists examples of Acclarent's incorporation of Dr. Albritton's confidential information into its own patent filings:

Representative Description in Albritton Provisional	**Duplication in Acclarent Provisional**
"A surgeon or other user holds the handle 350 in a hand by some or all of the small finger, the ring finger and the middle finger . . ." Ex. C at 4.	"Generally, each of the various embodiments combines two or more surgical instruments or instrument features into a device (or system) that can be held in one hand . . . in one embodiment a guide and a balloon catheter may be coupled together via a handle." Ex. G at 3. "The surgical hand tool 510 shown in FIGS. 8A and 8B allows the user to hold the device in the palm of the hand, balance the device with preferably the fourth and fifth fingers, and advance the guidewire 520 with the index finger and thumb. In this manner, the surgical hand tool 510 is held in the same hand that is used to control the guidewire 520." *Id.* at 25.
"Suction may be applied to the catheter 200 via the branch section 212A . . . an operator of the catheter 200 may vary the [a]mount of blockage of the opening 216 with a finger or valve, in order to control the amount of suction . . . " *Id.* at 1. "The fore finger and thumb are left free to manipulate a working device inserted into the opening 318 or to cover the opening 318 to redirect suction to the distal end of guide 302" *Id.* at 5.	"The hub 338 is also in communication with a suction line 344 that when activated can suction fluid out of a target area through the guide catheter 304." *Id*. at 18. "In cases where a balloon catheter or other dilator device having a through lumen is used to accomplish the dilation step, the irrigation and/or suction step may be carried out by passing fluid or negative pressure through the through lumen of the dilation catheter . . ." *Id*. at 37.
"The fore finger and thumb are left free to	"allowing a user to control the guidewire behind

Representative Description in Albritton Provisional	Duplication in Acclarent Provisional
manipulate a working device . . .” Ex. C at 5.	the guide catheter using a thumb and index finger.” Ex. G at 24.

34. In addition to the features described in the Albritton Provisional Application, Dr. Albritton also disclosed to Acclarent his invention of a concept to provide better tactile feedback to a surgeon during insertion and advancement of the guidewire and/or balloon catheter. Dr. Albritton suggested improvements to the Acclarent equipment that would reduce points of friction and overcome shortcomings in their products at the time.

35. Information regarding Dr. Albritton’s tactile feedback improvements was, at the time, a trade secret that had not been disclosed to the public or the U.S. Patent and Trademark Office. Dr. Albritton shared this innovation with Acclarent in reliance on the NDA and/or Consulting Agreement with the intent to keep it secret.

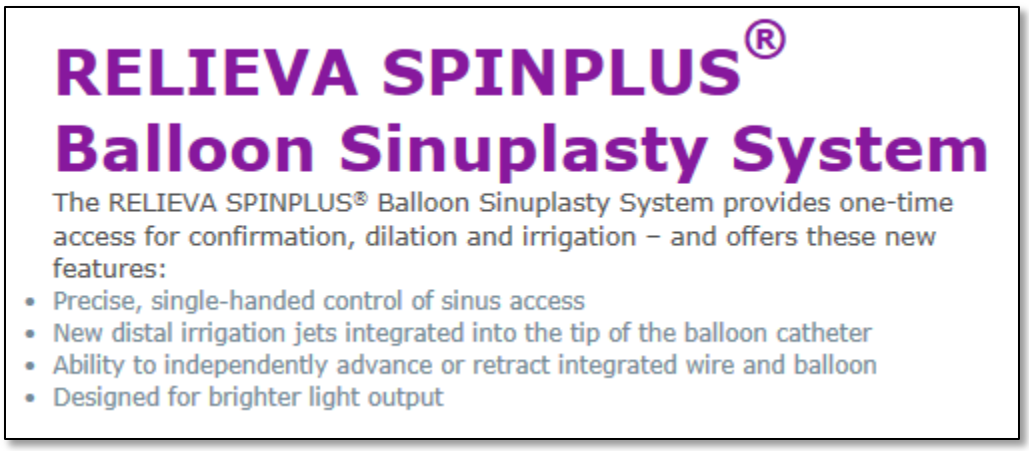
36. Nevertheless, Acclarent misappropriated Dr. Albritton’s confidential information and incorporated Dr. Albritton’s tactile feedback improvements into its patent filings and products, later calling it the “Albritton-hole.” *See* Ex. G at 25 (“Further, the user has direct access to the guidewire giving full tactile feel during advance and steering of the guidewire.”).

37. Acclarent’s misappropriation of Dr. Albritton’s confidential information is further confirmed in Acclarent’s promotional materials for the Relieva Devices.

38. For example, Acclarent advertises the Relieva Spin as able to “singlehandedly” change patient treatment, and prominently displays the “Albritton-hole” aperture used to provide tactile feedback to a surgeon:

"Relieva Spin Marketing Brochure," Ex. H at 1 ("Albritton-hole" notation added).

39. In a second example, Acclarent touts the one-handed operation of its Relieva SpinPlus® products on its website:



Ex. I (available at https://www.acclarent.com/solutions/products/balloon-sinuplasty-system/relieva-spinplus-balloon-sinuplasty-system).

40. Before it misappropriated Dr. Albritton's confidential information, Acclarent had not developed a single-handed surgical catheter or other similar device. To the contrary, Acclarent had designed a two-handed device.

41. At all relevant times in 2008 and 2009, Dr. Albritton was unaware of Acclarent's misappropriation of his confidential information. Accordingly, Dr. Albritton continued to work with Acclarent under the NDA and Consulting Agreement.

42. On March 28, 2009, Dr. Albritton again reached out to Acclarent regarding a license to his pending '412 Patent. Ex. J at 3.

43. On March 31, 2009 Acclarent Employee Greg Garfield responded to Dr. Albritton. He claimed that Acclarent's Director of Intell1_ectual Property, Scott Smith, looked at Acclarent's "filed patent applications" as well as a more recent, "new and unique guide with suction, for which we recently filed an additional patent application." *Id*. at 2-3. Garfield failed to acknowledge that Acclarent's "new and unique guide with suction" was based on the confidential information taken from Dr. Albritton without his knowledge and in violation of the NDA and Consulting Agreement.

44. On April 1, 2009, Acclarent declined to take a license, and instead instructed Dr. Albritton to pursue the IP process and explore its uses with other partners. *Id*. at 1.

45. In 2010, Ethicon, a subsidiary of Johnson & Johnson, acquired Acclarent for $785 million. On information and belief, Acclarent shared Dr. Albritton's confidential information with Ethicon, which encouraged Ethicon to purchase Acclarent for its position in the balloon-dilation device market and the new and innovative devices it was currently developing through the improper use of Dr. Albritton's confidential information.

46. On information and belief, Acclarent was unjustly enriched by its unauthorized use of Dr. Albritton's confidential information, including at least by the advantage of entering the market sooner than it would have without Dr. Albritton's confidential information and by

obtaining a higher acquisition price than it would have without Dr. Albritton's confidential information.

47. On April 21, 2015, the United States Patent and Trademark Office issued the '412 Patent. Shortly thereafter, Dr. Albritton again contacted Acclarent to gauge their interest in a license to the '412 Patent for the Relieva Devices Acclarent was selling and planned to sell in the future.

48. On January 14, 2016, Dr. Albritton and Acclarent entered into a Tolling and Standstill Agreement (the "Tolling Agreement"). The Tolling agreement provides, in pertinent part, that Dr. Albritton and Acclarent desired to engage in discussions relating to the '412 Patent and related claims, and that both Dr. Albritton and Acclarent desired to engage in such discussions free from the threat of litigation.

49. Pursuant to the terms of the Tolling Agreement, Dr. Albritton refrained from filing this action until December 1, 2016.

COUNT ONE: BREACH OF CONTRACT – THE NDA

50. Plaintiff refers to and incorporates herein the allegations of Paragraphs 1-49 above.

51. The 2007 NDA is a valid contract.

52. Dr. Albritton has performed in accordance with all material obligations, terms, and conditions of the NDA.

53. Section two of the NDA prohibits the disclosure of confidential information or the use of confidential information for any purpose other than the business relationship contemplated in the NDA.

54. Acclarent breached section two of the NDA by using the confidential information Dr. Albritton provided to Acclarent—including without limitation Dr. Albritton's tactile feedback improvement discussed above—to develop its Relieva Devices.

55. Dr. Albritton has sustained damages as a result of Acclarent's breach.

56. Conditions precedent to the filing of this action have been performed or have occurred.

57. In addition to declaratory relief, Dr. Albritton seeks recovery from Acclarent of all damages proximately caused by such breaches of the NDA, including his reasonable attorneys' fees.

58. Further, Dr. Albritton seeks specific performance of NDA Section 2, and an order from the Court assigning any and all rights, title and interest in the '473 patent and any patent family members to Dr. Albritton.

COUNT TWO: BREACH OF CONTRACT – THE CONSULTING AGREEMENT

59. Plaintiff refers to and incorporates herein the allegations of Paragraphs 1-58 above.

60. The 2008 Consulting Agreement is a valid contract.

61. Dr. Albritton has performed in accordance with all material obligations, terms, and conditions of the Consulting Agreement.

62. In section 2(B) of the Consulting Agreement, Acclarent represented (among other things) that Acclarent would not:

a. use confidential information provided to Acclarent by Dr. Albritton for any purpose other than the provision of services under the agreement; or

b. disclose confidential information provided to Acclarent by Dr. Albritton to any third party.

63. Acclarent further agreed that all confidential information provided by Dr. Albritton would remain the sole property of Dr. Albritton.

64. Acclarent breached the Consulting Agreement by using Dr. Albritton's confidential information to develop its Relieva Devices, using Dr. Albritton's confidential information to apply for patent protection, and (in the process of applying for patent protection) disclosing confidential information provided to Acclarent by Dr. Albritton to third parties.

65. Dr. Albritton has sustained damages as a result of Acclarent's breach.

66. Conditions precedent to the filing of this action have been performed or have occurred.

67. In addition to declaratory relief, Dr. Albritton seeks recovery from Acclarent of all damages proximately caused by such breaches of the Consulting Agreement, including his reasonable attorneys' fees.

COUNT THREE: FRAUDULENT INDUCEMENT

68. Plaintiff refers to and incorporates herein the allegations of Paragraphs 1-67 above.

69. Acclarent made numerous material misrepresentations to Dr. Albritton throughout the course of the parties' dealings in order to induce Dr. Albritton to sign the NDA and later, the Consulting Agreement. The material misrepresentations include at least the following:

70. In 2007, Acclarent induced Dr. Albritton to sign the NDA by representing to Dr. Albritton that:

a. Acclarent would not use Dr. Albritton's confidential information for its own use;

b. Acclarent would not disclose Dr. Albritton's confidential information to any other third party; and

c. Acclarent would not reverse engineer any of the prototypes Dr. Albritton provided to Acclarent under the NDA or Consulting Agreement.

71. Acclarent omitted from and failed to disclose to Dr. Albritton that it had had no intent to operate in the manner called for in the NDA, and instead intended to use the NDA to gain access to Dr. Albritton's inventions, so that Acclarent could incorporate the innovative features created by Dr. Albritton in its "next generation Guide Catheter." *See* Ex. G.

72. Further, when negotiating the Consulting Agreement in late 2008, Acclarent:

a. accepted Dr. Albritton's amendment to the original draft agreement deleting provisions that would have given Acclarent a royalty-free license to Dr. Albritton's pre-existing inventions;

b. represented that Dr. Albritton would own his own pre-existing inventions; and

c. represented that Acclarent would not disclose Dr. Albritton's inventions or other confidential information to third parties.

73. Again, Acclarent omitted from and failed to disclose to Dr. Albritton that it had no intent to operate in the manner called for in the Consulting Agreement, and instead intended to use the Consulting Agreement to misappropriate Dr. Albritton's inventions, and incorporate the innovative features created by Dr. Albritton in its "next generation Guide Catheter," and file a patent application covering Dr. Albritton's confidential information.

74. At the time of its misrepresentations, Acclarent was aware that it was pursuing its own patent applications based on Dr. Albritton's confidential information and was working to incorporate Dr. Albritton's confidential information into the new Relieva Devices. However,

Acclarent failed to disclose to Dr. Albritton that it was pursuing a patent application based on Dr. Albritton's misappropriated confidential information.

75. Additionally, Acclarent misrepresented to Dr. Albritton that it had already developed a single-handed handle concept and that Dr. Albritton's novel intellectual property was worthless, when in fact Acclarent had not conceived of this design before Dr. Albritton.

76. As described above, Acclarent in fact misappropriated Dr. Albritton's confidential information and incorporated that information into the Acclarent Provisional Application, which led to the issuance of the '473 patent.

77. Acclarent made the above material misrepresentations and omissions with the intent to induce Dr. Albritton to sign the NDA, sign the Consulting Agreement, and to continue sharing his confidential and innovative information with Acclarent.

78. Dr. Albritton was induced to sign the NDA and Consulting Agreement based on Acclarent's misrepresentations that Acclarent would not make improper use of Dr. Albritton's confidential information, and that Dr. Albritton would retain exclusive ownership of his pre-existing inventions.

79. Acclarent intended for Dr. Albritton to rely on each of these representations, and Dr. Albritton justifiably relied on them.

80. Dr. Albritton relied on Acclarent's material misrepresentations and omissions to his detriment, and was injured as a result of acting without knowledge of Acclarent's true intent. Had Dr. Albritton known Acclarent's true intent, he would not have disclosed his confidential information, including the details of his innovations, to Acclarent, and Acclarent would not have been able to incorporate his inventions and other confidential information into its products without Dr. Albritton's consent, knowledge, or credit. Had Dr. Albritton known Acclarent would

use his confidential information without his consent, he could have withheld that information and/or refused to sign the NDA and/or Consulting Agreement, and/or not performed the consulting services thereunder.

COUNT FOUR: FRAUD

81. Plaintiff refers to and incorporates herein the allegations of Paragraphs 1-80 above.

82. At all times following the execution of the NDA, the execution of the Consulting Agreement, and the promise by Acclarent to list Dr. Albritton as a co-inventor on any patent application based on technology Dr. Albritton helped to design, Acclarent was under a duty to disclose any and all use of the confidential information provided by Dr. Albritton, including in particular the use of such information to apply for patent protection.

83. At no time prior to the filing of the Acclarent Provisional Application did Acclarent inform Dr. Albritton that it was using Dr. Albritton's confidential information and inventions for Acclarent's own purposes, namely filing for patent protection. Nor did Acclarent honor its commitment to list Dr. Albritton as a co-inventor on the Acclarent Provisional Application or the '473 patent.

84. The March 31 and April 1, 2009 communications from Acclarent employee Greg Garfield to Dr. Albritton were crafted to conceal the fact that Acclarent was using Dr. Albritton's confidential information. At the time Acclarent made its deceptive statements and omissions, it intentionally omitted the details regarding Acclarent's unpublished patent applications. By doing so, Acclarent demonstrated that it knew Dr. Albritton was unaware of Acclarent's use of Dr. Albritton's confidential information and did not have an equal opportunity to discover the truth.

85. Further, Acclarent made affirmative misrepresentations to Dr. Albritton regarding the status of Acclarent's efforts to use Dr. Albritton's confidential information. In particular, Acclarent claimed that "we [Acclarent] have also developed another new and unique guide with suction, for which we recently filed an additional patent application." Ex. J.

86. Acclarent's claims regarding the development of "another new and unique guide with suction" were false, because that "new and unique" guide was in fact developed by Dr. Albritton.

87. Acclarent knew its misrepresentations to be false when made, as the Acclarent employees making the misrepresentations (Garfield and Smith) were among the employees that received Dr. Albritton's confidential information, including, among other things, the Albritton Provisional Application, working prototypes of the single-handed catheter device developed by Dr. Albritton, and Dr. Albritton's tactile feedback improvements.

88. Dr. Albritton acted in reliance on the misrepresentations and omissions by Acclarent, including by providing Acclarent with valuable intellectual property as well as his confidential information.

89. Dr. Albritton suffered injury as a result of Acclarent's misrepresentations, including the misappropriation of Dr. Albritton's intellectual property and confidential information, which was taken by Acclarent and incorporated into Acclarent's Relieva Devices and/or Acclarent's patent applications.

COUNT FIVE: DIRECT INFRINGEMENT OF U.S. PATENT NO. 9,011,412

90. Plaintiff refers to and incorporates herein the allegations of Paragraphs 1-89 above.

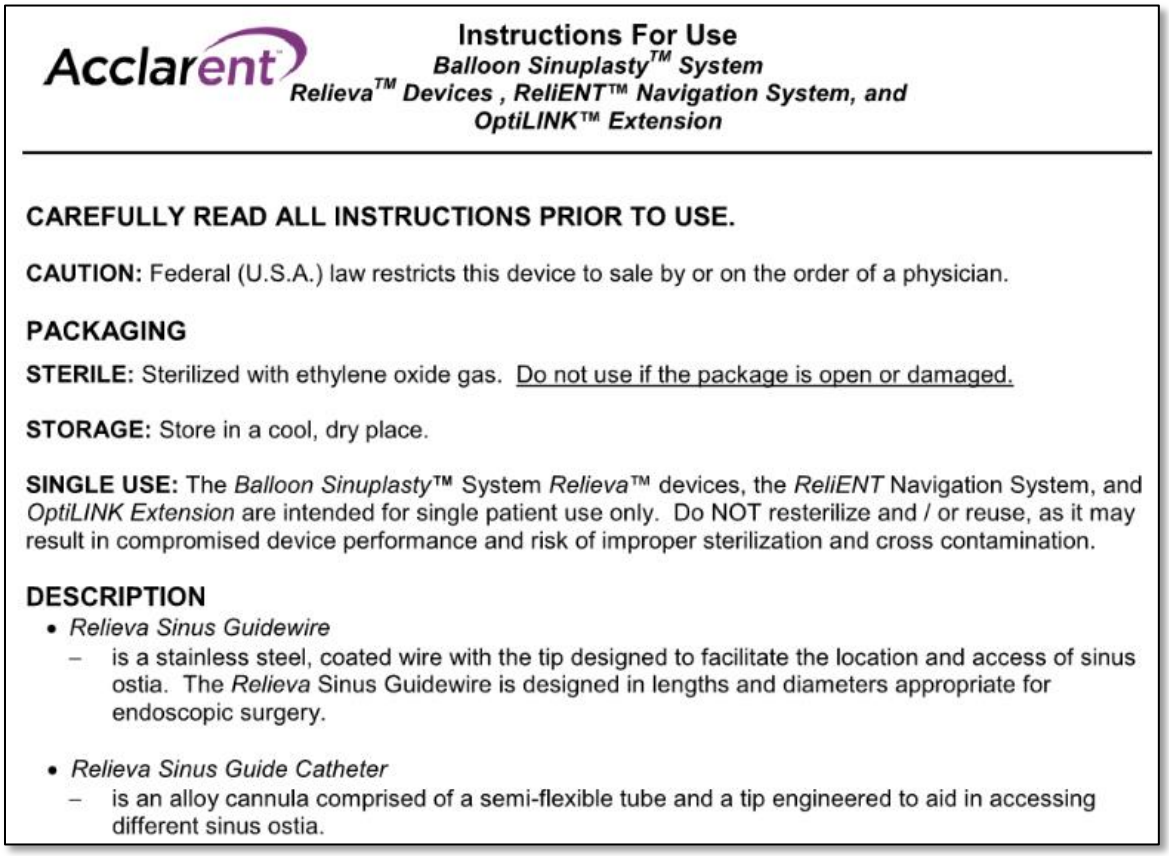
91. On April 21, 2015, after a full and fair examination, the United States Patent and Trademark Office duly and legally issued the ’412 Patent, entitled “Apparatus, System and Method for Manipulating a Surgical Catheter and Working Device with a Single Hand,” naming Dr. Albritton and Bryan Lunsford as the inventors. Lunsford assigned all right, title, and interest in and to the ’412 Patent to Dr. Albritton, who possesses all rights of recovery under the ’412 Patent. A copy of the ’412 Patent is attached as Ex. D.

92. Acclarent has directly and indirectly infringed and continues to directly and indirectly infringe the ’412 Patent by engaging in acts constituting infringement under 35 U.S.C. § 271(a), (b), (c), and/or (f), including but not limited to one or more of making, using, selling, and/or offering to sell, in this District and elsewhere in the United States, and/or importing into this District and elsewhere in the United States, the Relieva Devices marketed under the trade names Relieva Spin® and Relieva SpinPlus®.

93. Acclarent does business in the United States and, more particularly, in the Northern District of Texas by making, using, selling, importing, and/or offering for sale the Relieva Devices that infringe the ’412 Patent in this District.

94. The Relieva Devices infringe at least claims 1, 4, 5, 6, 7, 8, 11, 12, 13, 14, 17, 18, 19, and 20 of the ’412 Patent. Acclarent makes, uses, sells, offers for sale, imports, exports, supplies, and/or distributes within the United States these products and thus directly infringes at least claims 1, 4, 5, 6, 7, 14, 17, 18, 19, and 20 of the ’412 Patent.

95. In a first example, the Relieva Devices practice each limitation of claim 1 of the '412 Patent. The Relieva Devices include a guide catheter insertable through a patient's external body passage. In the case of the Relieva Devices, the body passage is the nostril, as confirmed in Acclarent's promotional material, Instructions for Use, and website, available at: https://www.acclarent.com/solutions/products/balloon-sinuplasty-system/relieva-spin-balloon-sinuplasty-system. As shown below, the Instructions for Use state that the Relieva Spin system includes a "Relieva Sinus Guide Catheter." Ex. K ("Relieva Spin IFU"). The Instructions for Use also state that the Relieva Spin is intended to provide access to the "sinus space for diagnostic and therapeutic procedures." The Instructions for Use of the Relieva SpinPlus have similar statements, noting that the SpinPlus is intended for sinus therapeutic and diagnostic procedures, as shown below. Ex. L ("Relieva SpinPlus IFU").



Acclarent

Instructions For Use
Balloon Sinuplasty™ System
Relieva™ Devices , ReliENT™ Navigation System, and OptiLINK™ Extension

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

PACKAGING

STERILE: Sterilized with ethylene oxide gas. Do not use if the package is open or damaged.

STORAGE: Store in a cool, dry place.

SINGLE USE: The *Balloon Sinuplasty*™ System *Relieva*™ devices, the *ReliENT* Navigation System, and *OptiLINK Extension* are intended for single patient use only. Do NOT resterilize and / or reuse, as it may result in compromised device performance and risk of improper sterilization and cross contamination.

DESCRIPTION

- *Relieva Sinus Guidewire*
  - is a stainless steel, coated wire with the tip designed to facilitate the location and access of sinus ostia. The *Relieva* Sinus Guidewire is designed in lengths and diameters appropriate for endoscopic surgery.
- *Relieva Sinus Guide Catheter*
  - is an alloy cannula comprised of a semi-flexible tube and a tip engineered to aid in accessing different sinus ostia.

Relieva Spin IFU

- *Relieva Sinus Guide Catheter*
  - is intended to provide a means to access the sinus space for diagnostic and therapeutic procedures.

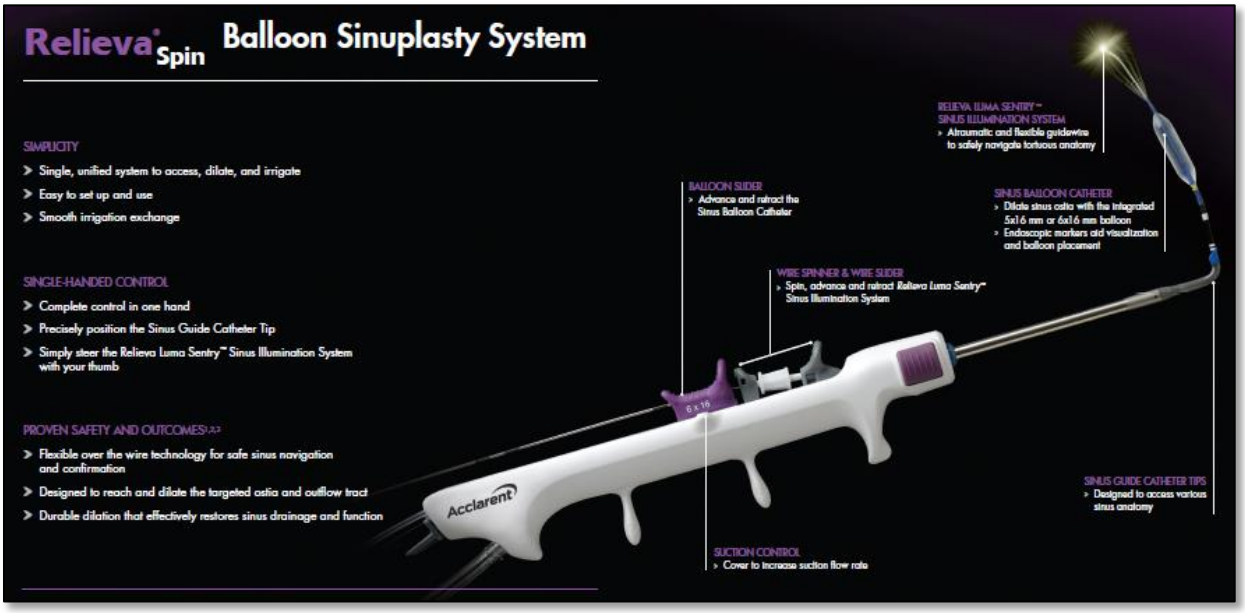
Relieva Spin IFU

INDICATIONS FOR USE

The RELIEVA SPINPLUS™ Balloon Sinuplasty System is intended to: provide a means to access the sinus space and illuminate within and transilluminate across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; and irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures.

Relieva SpinPlus IFU

96. The Relieva Devices' guide catheters have a substantially rigid shaft, a proximal opening, a distal opening, and a lumen extending between the proximal and distal openings. For example, as shown below, the Relieva Spin and SpinPlus include a "Sinus Balloon Catheter" that has a rigid shaft with openings at both ends and a lumen between the two openings. The Relieva Spin Instructions for Use also note that the balloon catheters include either a "shaft [that] is dual lumen tubing" or a "single lumen shaft," as shown below. Similarly, the Relieva SpinPlus includes a balloon catheter with a shaft containing a lumen between the openings at each end as shown in Figures 3 and 4 of the Instructions for Use (excerpted below).



Relieva Spin Marketing Brochure

- *Relieva Sinus Balloon Catheter*

Relieva Sinus Balloon Catheter – Over-the-wire Configuration

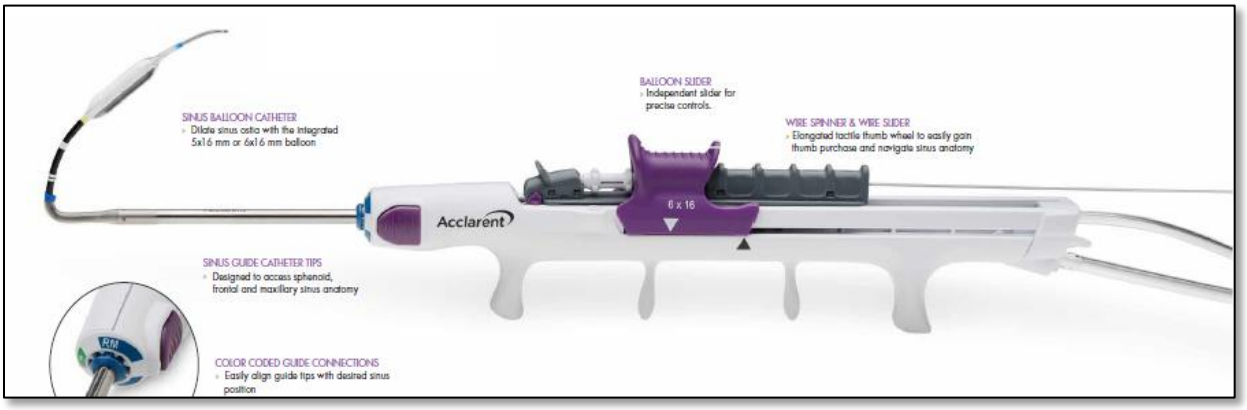
– is a sinus remodeling catheter with an integrated shaft system and a high pressure sinus balloon near the distal tip. The shaft is dual lumen tubing. One lumen is used for inflation of the sinus balloon with liquid medium. The second lumen permits the use of a *Relieva* Sinus Guidewire to facilitate advancement of the *Relieva* Sinus Balloon Catheter to the target sinus. The sinus balloon is covered with a coating which enhances the durability of the sinus balloon required for sinus remodeling.

– is a device with several markers. The balloon has radiopaque marker(s) to aid in positioning the sinus balloon in the target sinus. The *Relieva* Sinus Balloon Catheter's proximal shaft has markers which aid in determining the *Relieva* Sinus Balloon Catheter position relative to the entry and exit from the *Relieva* Sinus Guide Catheter.

Relieva Acella™ Sinus Balloon Catheter-- Integrated Guidewire Configuration

– is a sinus remodeling catheter with an integrated guidewire, a single lumen shaft, and a high pressure sinus balloon near the distal tip. The guidewire is designed to facilitate the location and access of sinus ostia. The lumen is used for inflation of the sinus balloon with liquid medium. The sinus balloon is covered with a coating which enhances the durability of the sinus balloon required for sinus remodeling.

Relieva Spin IFU



Relieva SpinPlus Marketing Brochure (Ex. M)

Figure 3: RELIEVA SPINPLUS™ Balloon Sinuplasty System Proximal Connections

Each system contains four separate connection points (shown in Figure 3). Three of the connectors are associated with separate tubing, and the fourth connector is for the wire. Each of the four lines are attached to the proximal end of the Handle: The grey inflation line with grey Inflation Luer, the white irrigation line with white Irrigation Connector, the clear suction tubing with clear Suction Connector, and the Sinus Illumination System wire with purple Sinus Illumination System Connector.

The RELIEVA SPINPLUS™ Balloon Sinuplasty System is packaged with one or more RELIEVA® Spin Sinus Guide Catheter Tips.

Figure 4: M-110C Sinus Guide Catheter Tip

Each Sinus Guide Catheter Tip incorporates a specially designed distal end that enables placement near the targeted sinus. There are four Sinus Guide Catheter Tip options: S-0 (yellow hub), F-70 (green hub), M-110 (blue hub) and M-110C (blue hub). In addition, the Sinus Guide Catheter Tip includes a translucent balloon window for visualization of devices that pass in and out of its distal end and an orientation marker that helps with Sinus Guide Catheter Tip and Handle System alignment. The proximal hub of the Sinus Guide Catheter Tip enables connection to the distal end of the Handle System, which is color-coded to match alignment with the guide tip hubs.

Relieva SpinPlus IFU

97. The Relieva Devices include a handle coupled to the guide catheter, the handle having a handle opening, a handle coupling and a structure. The Relieva Devices' structure is configured to allow a position of the guide catheter to be controlled by some or all of three fingers of one hand of an operator of the handle. The Relieva Devices' handle coupling is configured to couple a source of suction to the lumen. For example, the Relieva SpinPlus includes a handle that couples to the guide catheter as shown in the Instructions for Use below. The handle includes a handle opening, a handle coupling, and a structure. The Relieva Spin uses

a similar handle that couples to the guide catheter, and has a handle opening, handle coupling, and structure, as shown in the marketing materials below.

DESCRIPTION

The RELIEVA SPINPLUS™ Balloon Sinuplasty System (shown in Figure 1) is packaged with:

- A Handle with integrated flexible balloon catheter and flexible Sinus Illumination System
- One or more RELIEVA® Spin Sinus Guide Catheter Tips

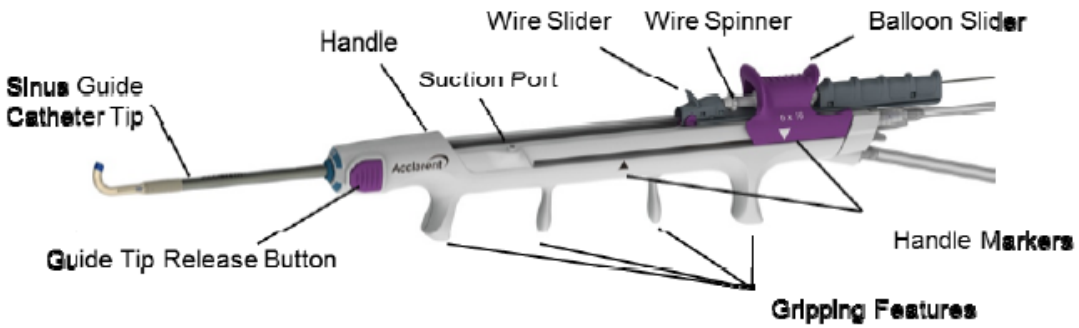
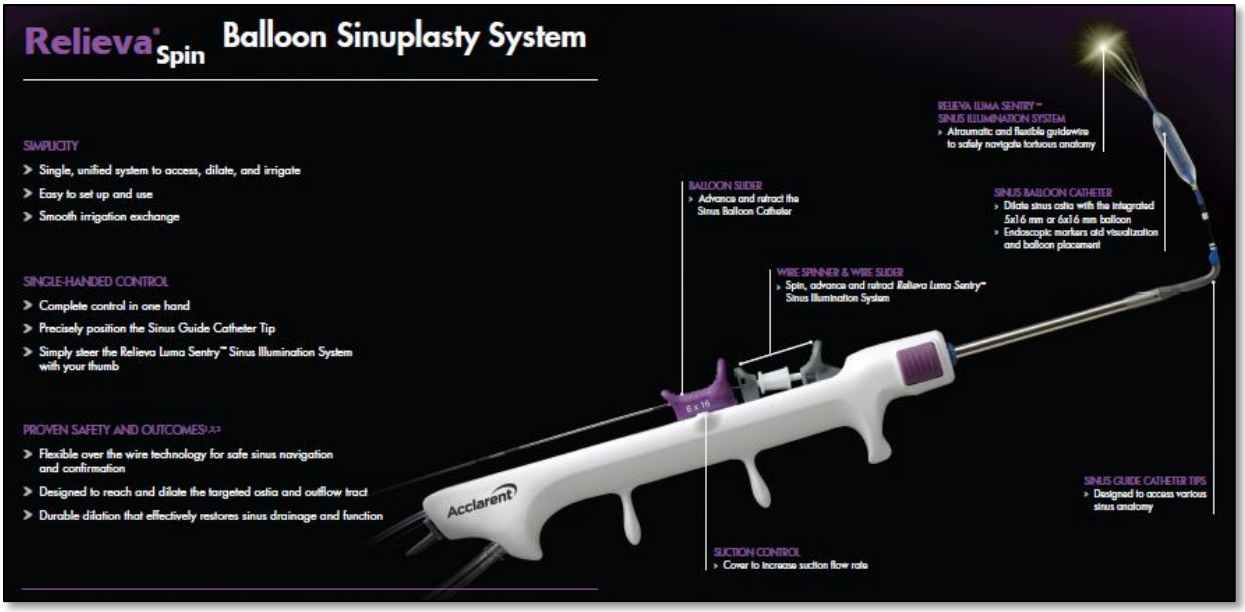


Figure 1: RELIEVA SPINPLUS™ Balloon Sinuplasty System Handle with a RELIEVA® Spin Sinus Guide Catheter Tip

The system features a Handle with an integrated flexible balloon catheter. Features of the Handle include a Guide Tip Release Button, a suction system, a Balloon Guard, and several Gripping Features to grip the device. The Guide Tip Release Button must be depressed to separate the Sinus Guide Catheter Tip from the Handle System. The suction system consists of a suction line and a Suction Port. Suction may be used to clear the field of fluids and/or blood. The suction line is attached to the proximal end of the Handle System and may be removed if desired. The Suction Port may be covered by the user's finger to increase the suction flow rate. A clear Balloon Guard is connected to the distal end of the Handle System and protects the Sinus Balloon during Sinus Guide Catheter Tip exchanges.

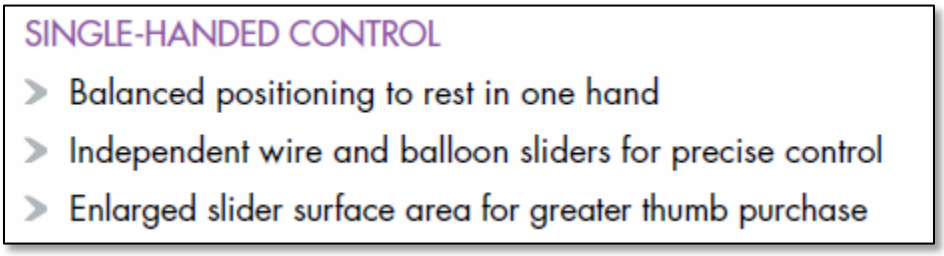
The Handle features a Wire Slider, a Wire Spinner, a Balloon Slider, a Sinus Balloon, Handle Markers, and proximal connections. The Wire Slider allows the user to advance, retract and spin the Sinus Illumination System with a single hand while simultaneously supporting the Handle. The Balloon Slider allows the user to advance and retract the Sinus Balloon Catheter (shown in Figure 2).

Relieva SpinPlus IFU



Relieva Spin Marketing Brochure

98. The Relieva Devices allow a position of the guide catheter to be controlled by some or all of three fingers of one hand of the user. As shown above, the Relieva Spin marketing material states that the device offers "single-handed control" and "complete control in one hand." The Relieva SpinPlus marketing literature notes also describes "single-handed control" and "balanced positioning to rest in one hand" as shown below.



Relieva Spin Marketing Brochure

99. The Relieva Devices' handle coupling is configured to couple a source of suction to the lumen. For example, the Relieva SpinPlus Instructions for Use state that the Relieva SpinPlus includes "clear suction tubing with Clear Suction Connector," and a suction port on the handle as shown in the marketing material below. The SpinPlus Instructions for Use also state

that if the physician elects to use suction, he or she should "connect the Clear Suction Connector to a vacuum source," and that if the physician desires to increase suction strength, he or she can "cover the suction port with a finger." The Relieva Spin operates in a similar manner, having suction tubing, a connector, and suction port as shown in the marketing materials below.

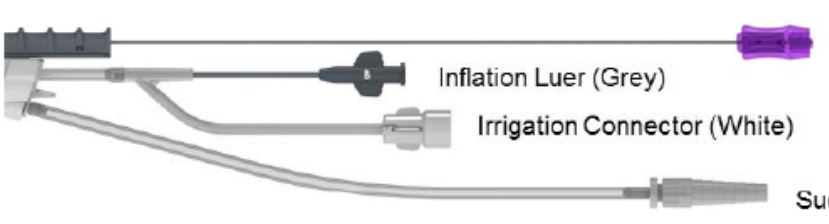
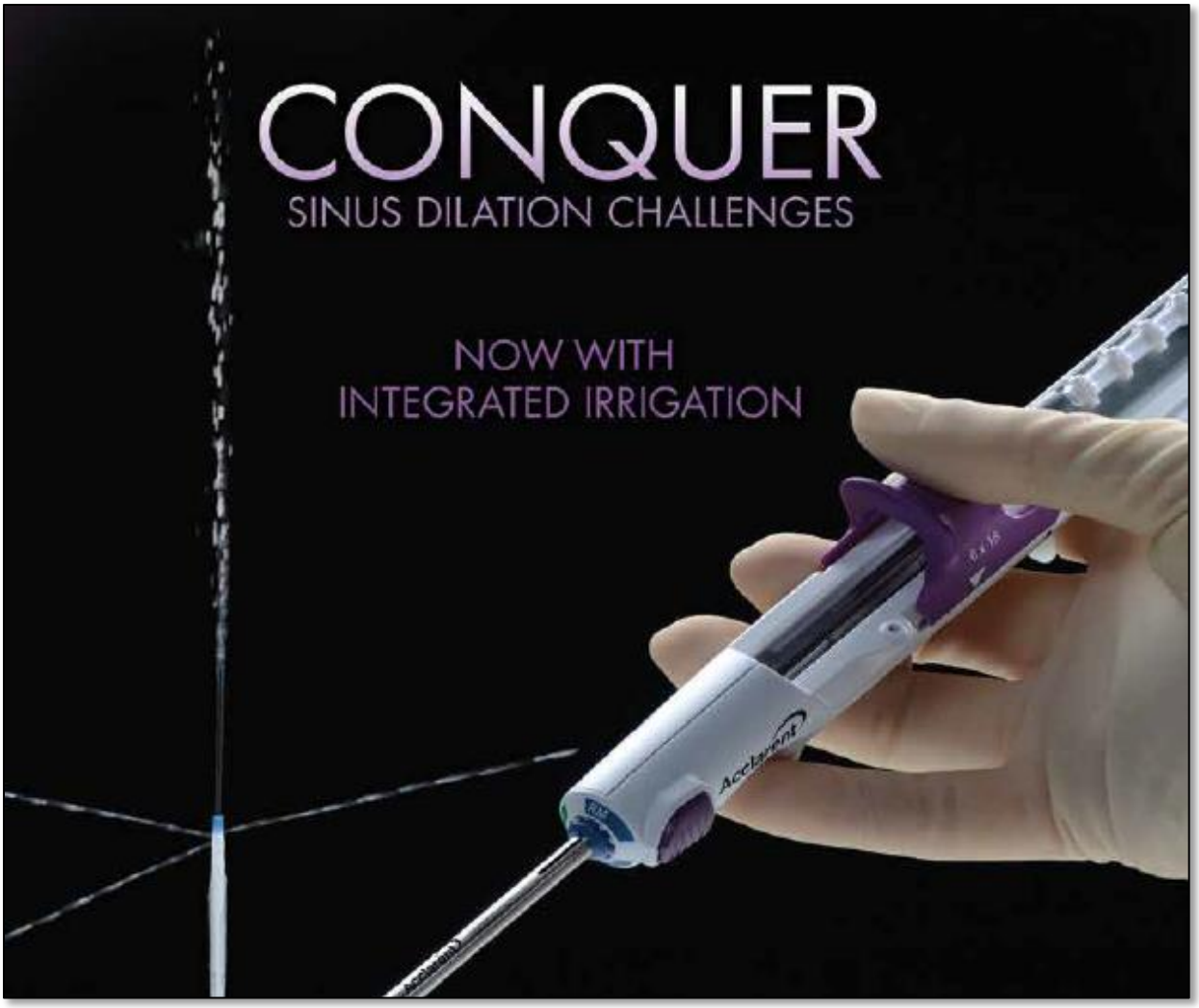


Figure 3: RELIEVA SPINPLUS™ Balloon Sinuplasty System Proximal Connections

Each system contains four separate connection points (shown in Figure 3). Three of the connectors are associated with separate tubing, and the fourth connector is for the wire. Each of the four lines are attached to the proximal end of the Handle: The grey inflation line with grey Inflation Luer, the white irrigation line with white Irrigation Connector, the clear suction tubing with clear Suction Connector, and the Sinus Illumination System wire with purple Sinus Illumination System Connector.

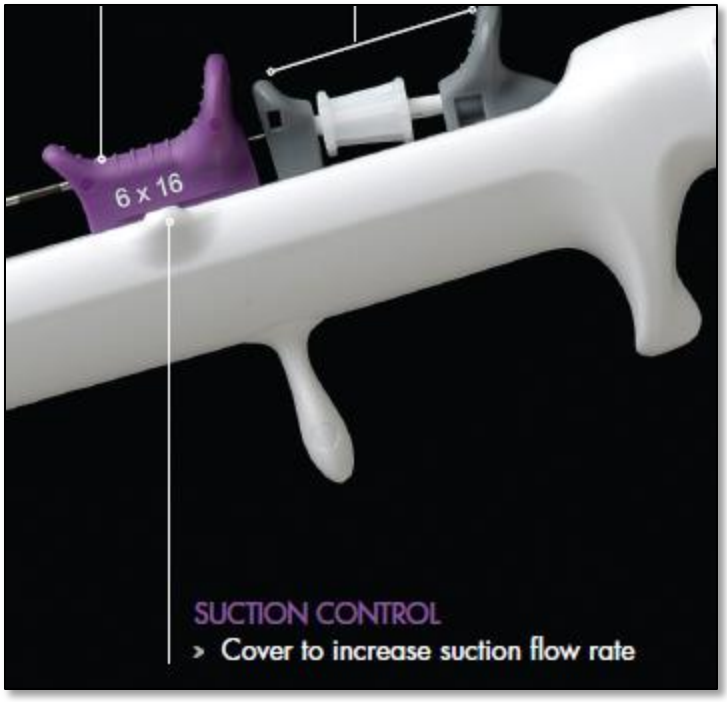
Relieva SpinPlus IFU



6. Should the physician elect to use suction with the RELIEVA SPINPLUS™ Balloon Sinuplasty System, connect the clear Suction Connector to a vacuum source and adjust to the appropriate level.

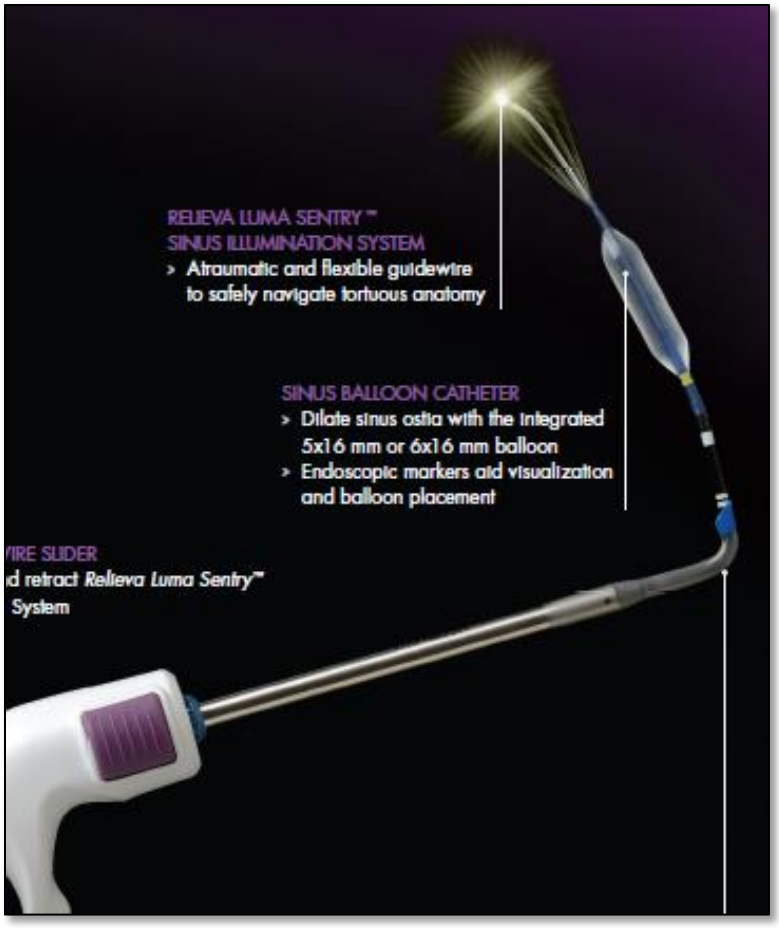
2. Suction may be used to clear the field of fluids and/or blood. To increase the suction strength, cover the suction port with a finger.

Relieva SpinPlus Marketing Brochure

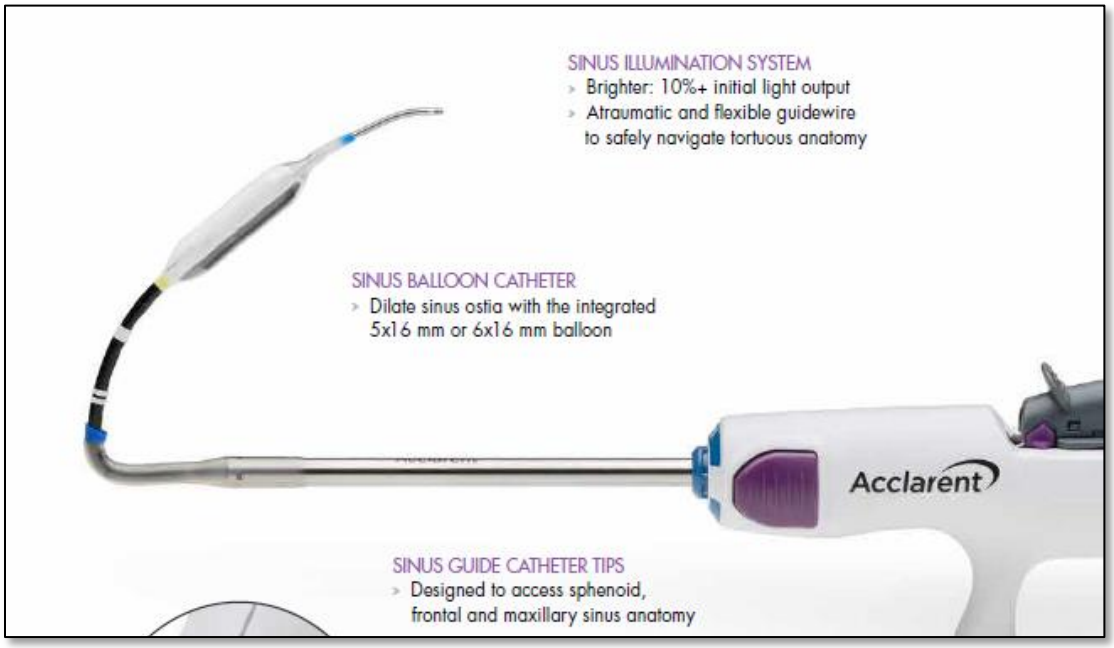


Relieva Spin Marketing Brochure

100. The Relieva Devices contain a working device adapted to be insertable through the handle opening into the lumen of the guide catheter. For example, the Relieva Spin marketing literature describes the "Relieva Luma Sentry Sinus Illumination System" and integrated "Sinus Balloon Cather." The Relieva SpinPlus marketing materials similarly describe a "Sinus Balloon Catheter" and "Sinus Illumination System" as shown below.



Relieva Spin Marketing Brochure



Relieva SpinPlus Marketing Brochure

101. The structure of the Relieva Devices' handle is adapted to permit the operator to position a thumb and index finger of the hand to manipulate the working device via a portion of the working device immediately adjacent to the handle opening. For example, the Relieva Spin marketing literature describes the a "Balloon Slider" and "Wire Spinner and Wire Slider," as depicted below. Similarly, the Relieva SpinPlus marketing literature describes an independent "Balloon Slider" that allows for precise control of the balloon catheter, and "Wire Spinner and Wire Slider," described as "[an] [e]longated tactile thumb wheel to easily gain thumb purchase and navigate sinus anatomy."

Relieva Spin Marketing Brochure

Relieva SpinPlus Marketing Brochure

102. The structure of the Relieva Devices' handle is also adapted to control, by one of the thumb or index finger, an amount of suction coupled to the distal opening of the lumen. For example, The Relieva Spin marketing literature identifies a "Suction Control" opening that a surgeon can "cover to increase suction flow rate." The Relieva SpinPlus Instructions for Use state that the Relieva SpinPlus system includes a "Suction Port" that "may be covered by the user's finger to increase the suction flow rate."

Relieva Spin Marketing Brochure

DESCRIPTION

The RELIEVA SPINPLUS™ Balloon Sinuplasty System (shown in Figure 1) is packaged with:

- A Handle with integrated flexible balloon catheter and flexible Sinus Illumination System
- One or more RELIEVA® Spin Sinus Guide Catheter Tips

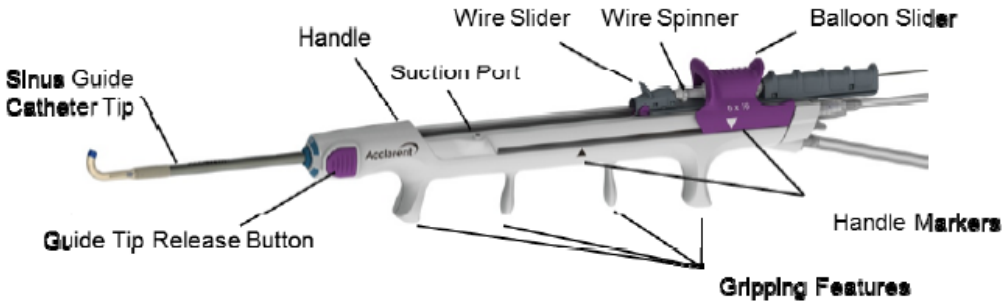


Figure 1: RELIEVA SPINPLUS™ Balloon Sinuplasty System Handle with a RELIEVA® Spin Sinus Guide Catheter Tip

The system features a Handle with an integrated flexible balloon catheter. Features of the Handle include a Guide Tip Release Button, a suction system, a Balloon Guard, and several Gripping Features to grip the device. The Guide Tip Release Button must be depressed to separate the Sinus Guide Catheter Tip from the Handle System. The suction system consists of a suction line and a Suction Port. Suction may be used to clear the field of fluids and/or blood. The suction line is attached to the proximal end of the Handle System and may be removed if desired. The Suction Port may be covered by the user's finger to increase the suction flow rate. A clear Balloon Guard is connected to the distal end of the Handle System and protects the Sinus Balloon during Sinus Guide Catheter Tip exchanges.

The Handle features a Wire Slider, a Wire Spinner, a Balloon Slider, a Sinus Balloon, Handle Markers, and proximal connections. The Wire Slider allows the user to advance, retract and spin the Sinus Illumination System with a single hand while simultaneously supporting the Handle. The Balloon Slider allows the user to advance and retract the Sinus Balloon Catheter (shown in Figure 2).

Relieva SpinPlus IFU

103. In a second example, the Relieva Devices are configured to (and when used do) practice each limitation of claim 8 of the '412 Patent. The Relieva Devices have been offered for sale in a configuration in which they would allow an operator to insert the guide catheter through an external body passage of a subject. In the case of the Relieva Devices, the body passage is the nostril, as confirmed in Acclarent's promotional material, Instructions for Use, and website, available at: https://www.acclarent.com/solutions/products/balloon-sinuplasty-system/relieva-spin-balloon-sinuplasty-system. As shown below, the Instructions for Use state that the Relieva Spin system includes a "Relieva Sinus Guide Catheter" that is "intended to provide a means to access the sinus space for diagnostic and therapeutic procedures." The Instructions for the

Relieva SpinPlus have similar statements, noting that the SpinPlus is intended for sinus therapeutic and diagnostic procedures.

Acclarent

Instructions For Use
Balloon Sinuplasty™ System
Relieva™ Devices , ReliENT™ Navigation System, and OptiLINK™ Extension

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

PACKAGING

STERILE: Sterilized with ethylene oxide gas. Do not use if the package is open or damaged.

STORAGE: Store in a cool, dry place.

SINGLE USE: The *Balloon Sinuplasty*™ System *Relieva*™ devices, the *ReliENT* Navigation System, and *OptiLINK Extension* are intended for single patient use only. Do NOT resterilize and / or reuse, as it may result in compromised device performance and risk of improper sterilization and cross contamination.

DESCRIPTION

- *Relieva Sinus Guidewire*
  - is a stainless steel, coated wire with the tip designed to facilitate the location and access of sinus ostia. The *Relieva* Sinus Guidewire is designed in lengths and diameters appropriate for endoscopic surgery.
- *Relieva Sinus Guide Catheter*
  - is an alloy cannula comprised of a semi-flexible tube and a tip engineered to aid in accessing different sinus ostia.

- *Relieva Sinus Guide Catheter*
  - is intended to provide a means to access the sinus space for diagnostic and therapeutic procedures.

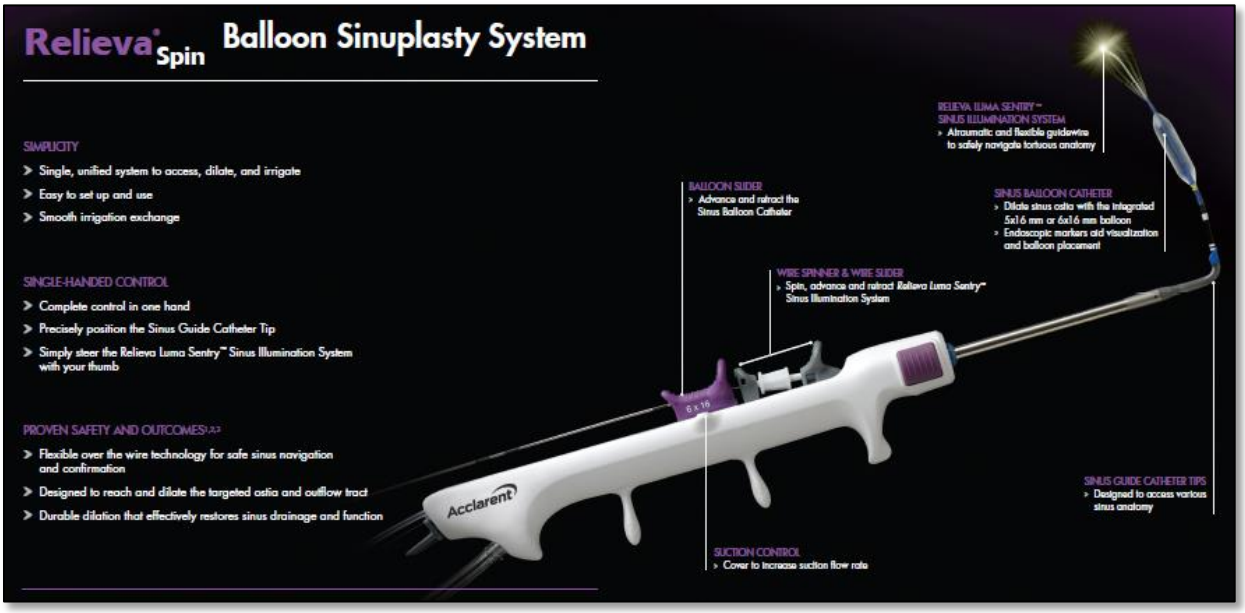
INDICATIONS FOR USE

The RELIEVA SPINPLUS™ Balloon Sinuplasty System is intended to: provide a means to access the sinus space and illuminate within and transilluminate across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; and irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures.

Relieva Spin IFU

104. The Relieva Devices' guide catheters have a substantially rigid shaft, a proximal opening, a distal opening, and a lumen extending between the proximal and distal openings. For example, as shown below, the Relieva Spin and SpinPlus include a "Sinus Balloon Catheter" that has a rigid shaft with openings at both ends and a lumen between the two openings. The Relieva

Spin Instructions for Use also note that the balloon catheters include either a "shaft [that] is dual lumen tubing" or a "single lumen shaft," as shown below. Similarly, the Relieva SpinPlus includes a balloon catheter with a shaft containing a lumen between the openings at each end as shown in Figures 3 and 4 of the Instructions for Use (excerpted below).



Relieva Spin Marketing Brochure

- *Relieva Sinus Balloon Catheter*

Relieva Sinus Balloon Catheter – Over-the-wire Configuration

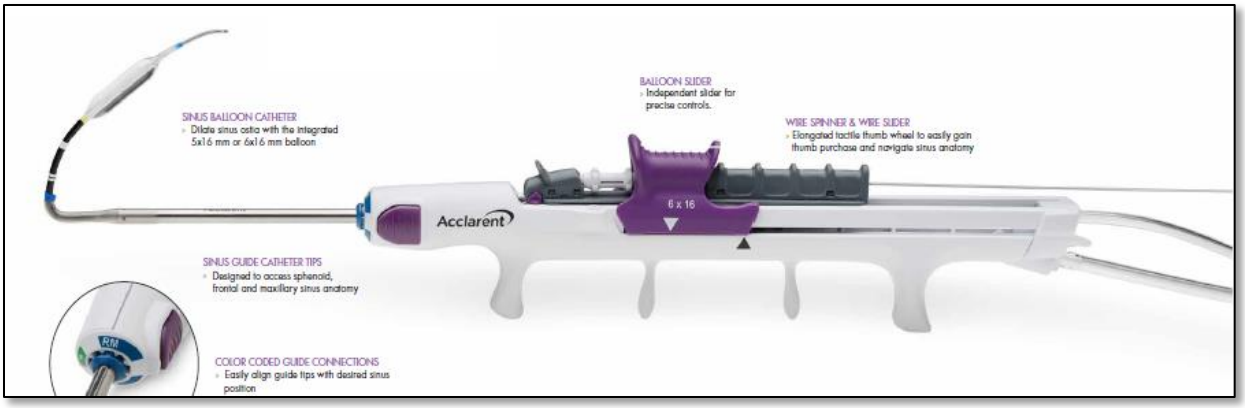
– is a sinus remodeling catheter with an integrated shaft system and a high pressure sinus balloon near the distal tip. The shaft is dual lumen tubing. One lumen is used for inflation of the sinus balloon with liquid medium. The second lumen permits the use of a *Relieva* Sinus Guidewire to facilitate advancement of the *Relieva* Sinus Balloon Catheter to the target sinus. The sinus balloon is covered with a coating which enhances the durability of the sinus balloon required for sinus remodeling.

– is a device with several markers. The balloon has radiopaque marker(s) to aid in positioning the sinus balloon in the target sinus. The *Relieva* Sinus Balloon Catheter's proximal shaft has markers which aid in determining the *Relieva* Sinus Balloon Catheter position relative to the entry and exit from the *Relieva* Sinus Guide Catheter.

Relieva Acella™ Sinus Balloon Catheter-- Integrated Guidewire Configuration

– is a sinus remodeling catheter with an integrated guidewire, a single lumen shaft, and a high pressure sinus balloon near the distal tip. The guidewire is designed to facilitate the location and access of sinus ostia. The lumen is used for inflation of the sinus balloon with liquid medium. The sinus balloon is covered with a coating which enhances the durability of the sinus balloon required for sinus remodeling.

Relieva Spin IFU



Relieva SpinPlus Marketing Brochure

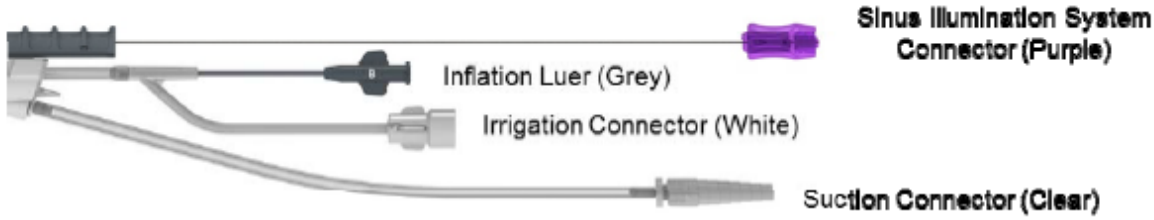


Figure 3: RELIEVA SPINPLUS™ Balloon Sinuplasty System Proximal Connections

Each system contains four separate connection points (shown in Figure 3). Three of the connectors are associated with separate tubing, and the fourth connector is for the wire. Each of the four lines are attached to the proximal end of the Handle: The grey inflation line with grey Inflation Luer, the white irrigation line with white Irrigation Connector, the clear suction tubing with clear Suction Connector, and the Sinus Illumination System wire with purple Sinus Illumination System Connector.

The RELIEVA SPINPLUS™ Balloon Sinuplasty System is packaged with one or more RELIEVA® Spin Sinus Guide Catheter Tips.

Figure 4: M-110C Sinus Guide Catheter Tip

Each Sinus Guide Catheter Tip incorporates a specially designed distal end that enables placement near the targeted sinus. There are four Sinus Guide Catheter Tip options: S-0 (yellow hub), F-70 (green hub), M-110 (blue hub) and M-110C (blue hub). In addition, the Sinus Guide Catheter Tip includes a translucent balloon window for visualization of devices that pass in and out of its distal end and an orientation marker that helps with Sinus Guide Catheter Tip and Handle System alignment. The proximal hub of the Sinus Guide Catheter Tip enables connection to the distal end of the Handle System, which is color-coded to match alignment with the guide tip hubs.

Relieva SpinPlus IFU

105. The Relieva Devices are configured to couple a source of suction to the lumen through the handle. For example, the Relieva SpinPlus Instructions for use identify "four connection points" including the "clear suction tubing with clear Suction Connector" that is "attached to the proximal end of the Handle[.]" The Relieva Spin promotional materials likewise features a clear suction connection and suction port, as depicted below (red indicator box added to emphasize suction connection).

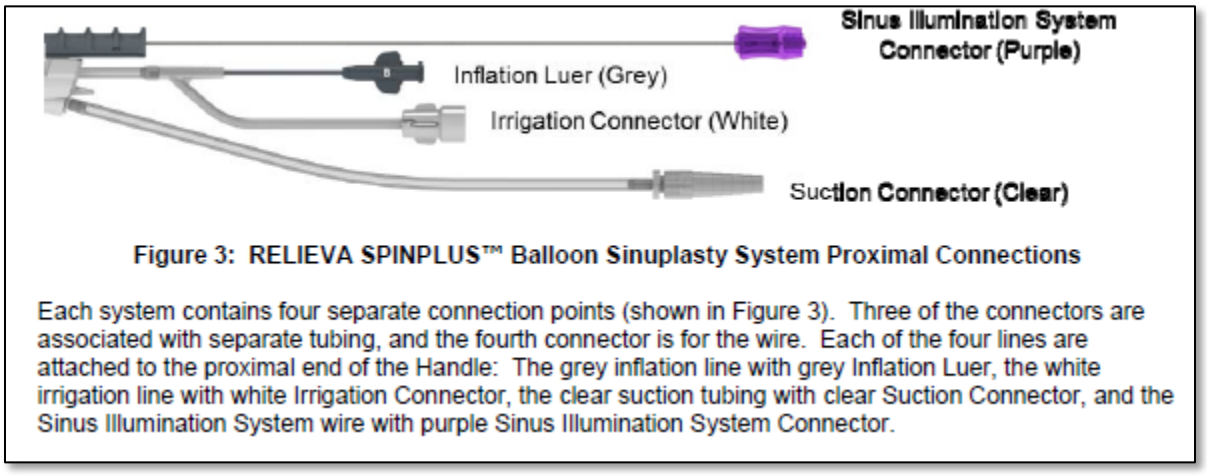


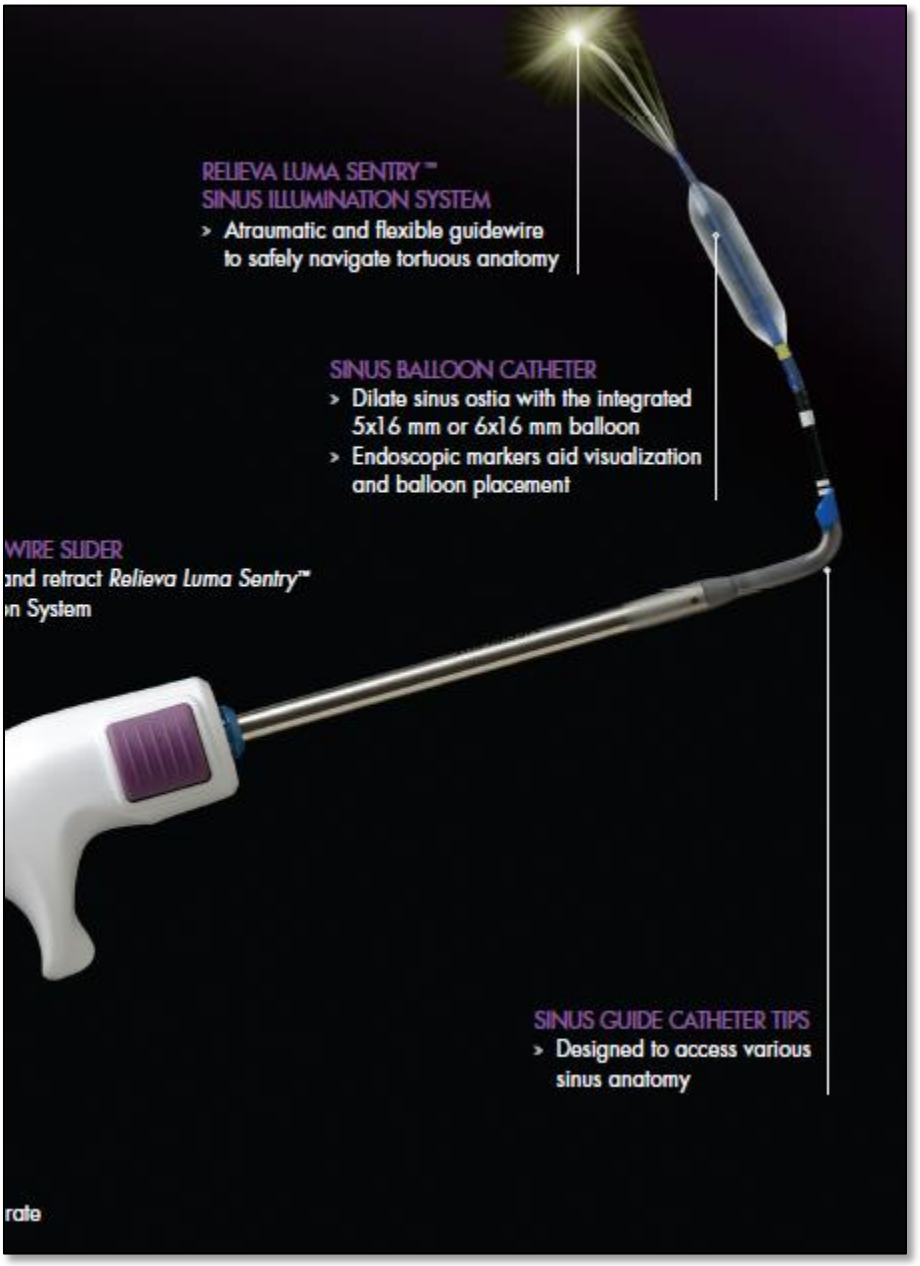
Figure 3: RELIEVA SPINPLUS™ Balloon Sinuplasty System Proximal Connections

Each system contains four separate connection points (shown in Figure 3). Three of the connectors are associated with separate tubing, and the fourth connector is for the wire. Each of the four lines are attached to the proximal end of the Handle: The grey inflation line with grey Inflation Luer, the white irrigation line with white Irrigation Connector, the clear suction tubing with clear Suction Connector, and the Sinus Illumination System wire with purple Sinus Illumination System Connector.

Relieva SpinPlus IFU

Relieva Spin Marketing Brochure

106. The Relieva Devices are configured to allow a user to insert a working device through the handle opening in the handle coupled to the guide catheter and into the lumen of the guide catheter. For example, the promotional material for both the Relieva Spin and Relieva SpinPlus illustrate a system where a working device, such as an "Integrated Dilation and Irrigation Catheter" or "Sinus Illumination System," have been inserted through the handle opening in the handle coupled to the guide catheter and into the lumen of the guide catheter.

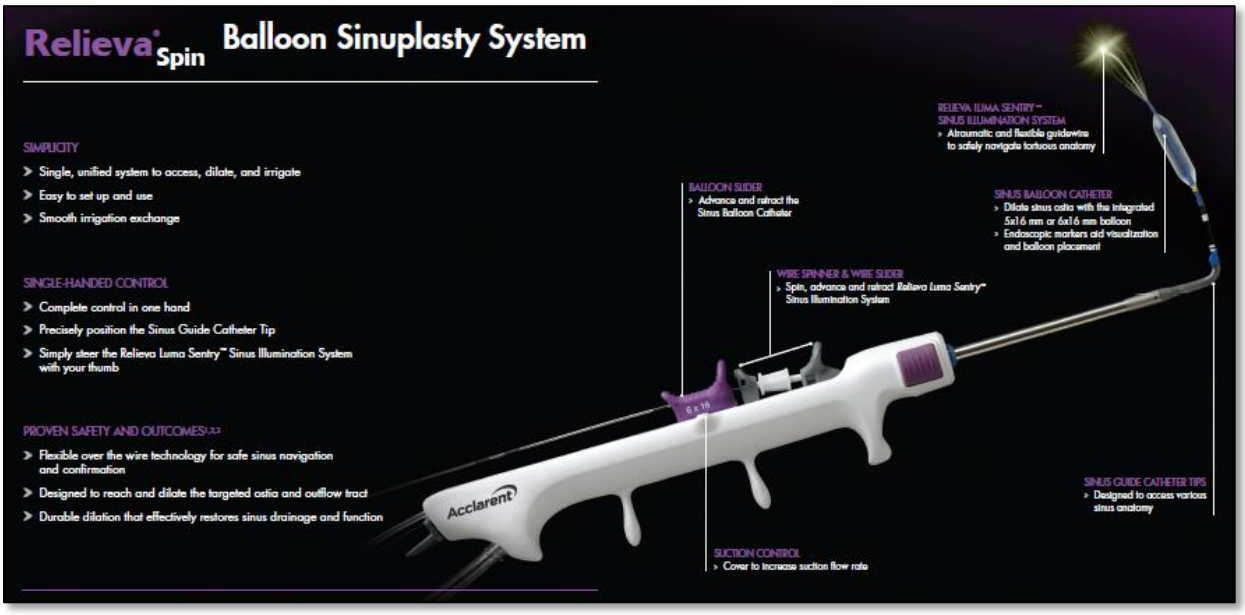


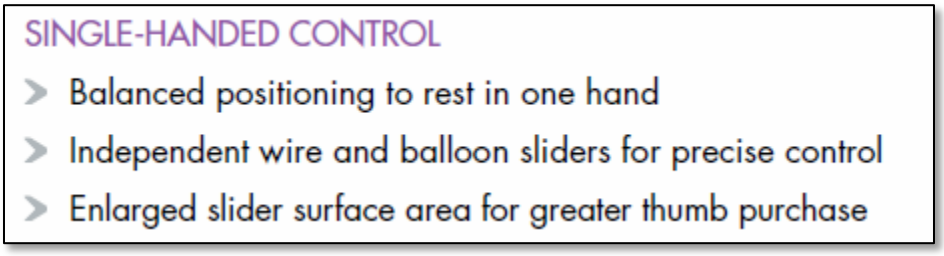
Relieva Spin Marketing Brochure

Relieva SpinPlus Marketing Brochure

107. The Relieva Devices are configured to allow a user to control a position of the guide catheter using the handle that is formed to allow the position of the guide catheter to be controlled by some or all of three fingers of a hand, while substantially simultaneously manipulating the working device with a thumb and index finger of the hand via a portion of the working device immediately adjacent to the handle opening. For example, the Relieva Spin marketing material states that the device offers "single-handed control" and "complete control in

one hand," as shown below. The Relieva SpinPlus marketing literature also describes "single-handed control" and "balanced positioning to rest in one hand" as shown below.





Relieva SpinPlus Marketing Brochure

108. The Relieva Devices also allow the user to substantially simultaneously manipulate the working device with a thumb and index finger of the hand via a portion of the working device immediately adjacent to the handle opening. For example, the Relieva Spin marketing literature describes a handle featuring a "Balloon Slider" and "Wire Spinner and Wire Slider" as depicted below. Similarly, the Relieva SpinPlus marketing literature describes an independent "Balloon Slider" that allows for precise control of the balloon catheter, and "Wire Spinner and Wire Slider," described as "[an] [e]longated tactile thumb wheel to easily gain thumb purchase and navigate sinus anatomy."

Relieva Spin Marketing Brochure

Relieva SpinPlus Marketing Brochure

109. The Relieva Devices are configured to allow the user to control the position of the guide catheter using the handle, while substantially simultaneously controlling, by one of the thumb or index finger, an amount of suction coupled to the distal opening of the lumen. For

example, The Relieva Spin marketing literature identifies a handle featuring a "Suction Control" opening which a surgeon can "cover to increase suction flow rate." The Relieva SpinPlus Instructions for Use state that the Relieva SpinPlus system includes a "Suction Port" that "may be covered by the user's finger to increase the suction flow rate," as shown below.

Relieva Spin Marketing Brochure

DESCRIPTION

The RELIEVA SPINPLUS™ Balloon Sinuplasty System (shown in Figure 1) is packaged with:

- A Handle with integrated flexible balloon catheter and flexible Sinus Illumination System
- One or more RELIEVA® Spin Sinus Guide Catheter Tips

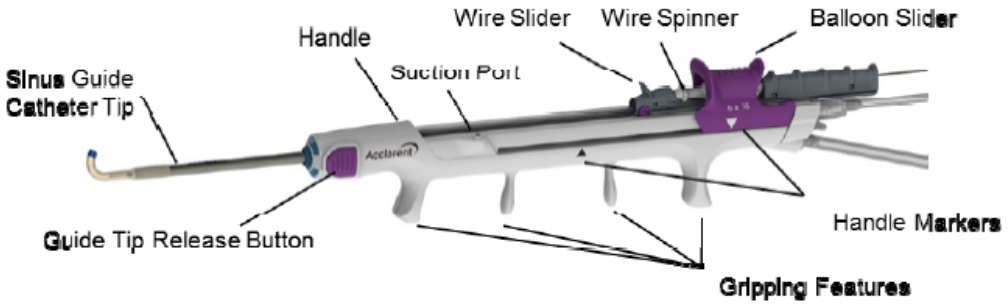


Figure 1: RELIEVA SPINPLUS™ Balloon Sinuplasty System Handle with a RELIEVA® Spin Sinus Guide Catheter Tip

The system features a Handle with an integrated flexible balloon catheter. Features of the Handle include a Guide Tip Release Button, a suction system, a Balloon Guard, and several Gripping Features to grip the device. The Guide Tip Release Button must be depressed to separate the Sinus Guide Catheter Tip from the Handle System. The suction system consists of a suction line and a Suction Port. Suction may be used to clear the field of fluids and/or blood. The suction line is attached to the proximal end of the Handle System and may be removed if desired. The Suction Port may be covered by the user's finger to increase the suction flow rate. A clear Balloon Guard is connected to the distal end of the Handle System and protects the Sinus Balloon during Sinus Guide Catheter Tip exchanges.

The Handle features a Wire Slider, a Wire Spinner, a Balloon Slider, a Sinus Balloon, Handle Markers, and proximal connections. The Wire Slider allows the user to advance, retract and spin the Sinus Illumination System with a single hand while simultaneously supporting the Handle. The Balloon Slider allows the user to advance and retract the Sinus Balloon Catheter (shown in Figure 2).

Relieva SpinPlus IFU

110. In a third example, the Relieva Devices practice each limitation of claim 14 of the '412 Patent. The Relieva Devices include a guide catheter apparatus insertable through a patient's external body passage. In the case of the Relieva Devices, the body passage is the nostril, as confirmed in Acclarent's promotional material, Instructions for Use, and website available at: https://www.acclarent.com/solutions/products/balloon-sinuplasty-system/relieva-spin-balloon-sinuplasty-system. As shown below, the Instructions for Use state that the Relieva Spin system includes a "Relieva Sinus Guide Catheter." The Instructions for Use also state that the Relieva Spin is intended to provide access to the "sinus space for diagnostic and therapeutic

procedures." The Instructions for Use of the Relieva SpinPlus have similar statements, noting that the SpinPlus is intended for sinus therapeutic and diagnostic procedures.

Acclarent

Instructions For Use
Balloon Sinuplasty™ System
Relieva™ Devices , ReliENT™ Navigation System, and OptiLINK™ Extension

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

PACKAGING

STERILE: Sterilized with ethylene oxide gas. Do not use if the package is open or damaged.

STORAGE: Store in a cool, dry place.

SINGLE USE: The *Balloon Sinuplasty*™ System *Relieva*™ devices, the *ReliENT* Navigation System, and *OptiLINK Extension* are intended for single patient use only. Do NOT resterilize and / or reuse, as it may result in compromised device performance and risk of improper sterilization and cross contamination.

DESCRIPTION

- *Relieva Sinus Guidewire*
  - is a stainless steel, coated wire with the tip designed to facilitate the location and access of sinus ostia. The *Relieva* Sinus Guidewire is designed in lengths and diameters appropriate for endoscopic surgery.

- *Relieva Sinus Guide Catheter*
  - is an alloy cannula comprised of a semi-flexible tube and a tip engineered to aid in accessing different sinus ostia.

- *Relieva Sinus Guide Catheter*
  - is intended to provide a means to access the sinus space for diagnostic and therapeutic procedures.

Relieva Spin IFU

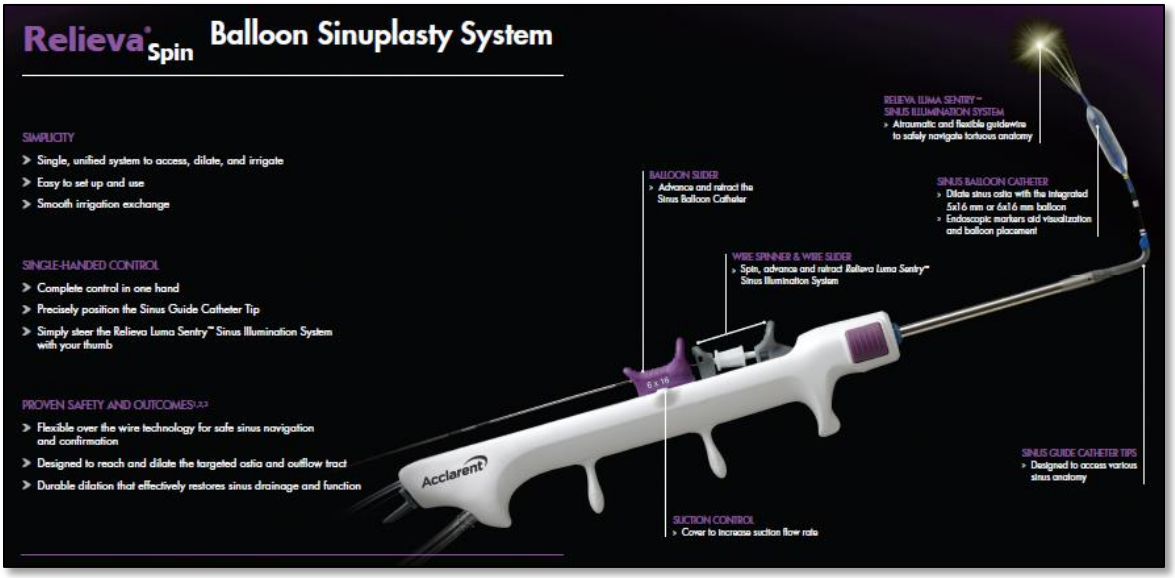
INDICATIONS FOR USE

The RELIEVA SPINPLUS™ Balloon Sinuplasty System is intended to: provide a means to access the sinus space and illuminate within and transilluminate across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; and irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures.

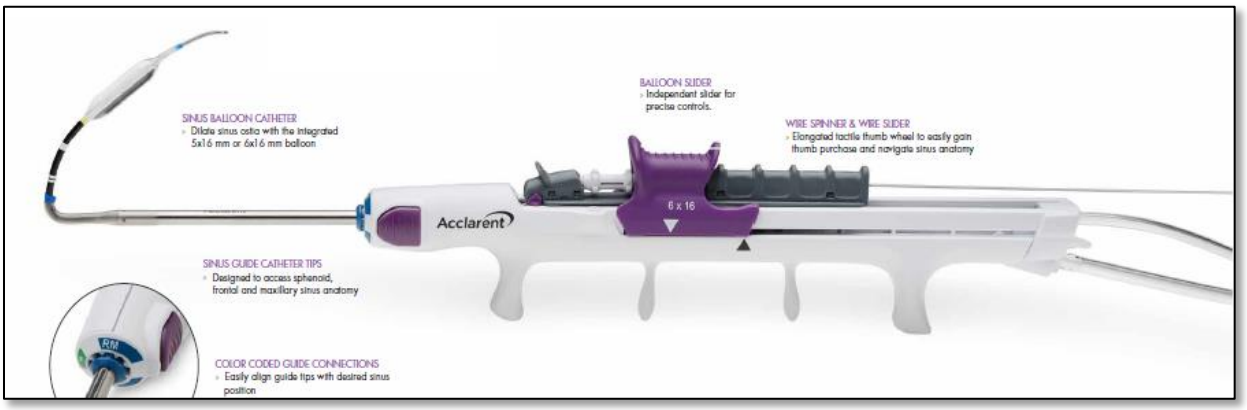
Relieva SpinPlus IFU

111. The Relieva Devices' have a substantially rigid shaft, a proximal opening, a distal opening, and a lumen extending between the proximal and distal openings. For example, as shown below, the Relieva Spin and SpinPlus include a rigid shaft with openings at both ends and

a lumen between the two openings as shown in the marketing literature below. The Relieva Spin Instructions for Use also note that the balloon catheters include either a "shaft [that] is dual lumen tubing" or a "single lumen shaft," as shown below. Similarly, the Relieva SpinPlus includes a balloon catheter with a shaft containing a lumen between the openings at each end as shown in Figures 3 and 4 of the Instructions for Use (excerpted below).



Relieva Spin Marketing Brochure



Relieva SpinPlus Marketing Brochure

112. The Relieva Devices include a handle coupled to the shaft, the handle having a handle opening, a handle coupling and a structure. For example, the Relieva SpinPlus includes a handle that couples to the shaft as shown in the Instructions for Use below. The handle includes a

handle opening, a handle coupling, and a structure. The Relieva Spin uses a similar handle that couples to the shaft, and has a handle opening, handle coupling, and structure, as shown in the marketing materials below.

DESCRIPTION

The RELIEVA SPINPLUS™ Balloon Sinuplasty System (shown in Figure 1) is packaged with:

- A Handle with integrated flexible balloon catheter and flexible Sinus Illumination System
- One or more RELIEVA® Spin Sinus Guide Catheter Tips

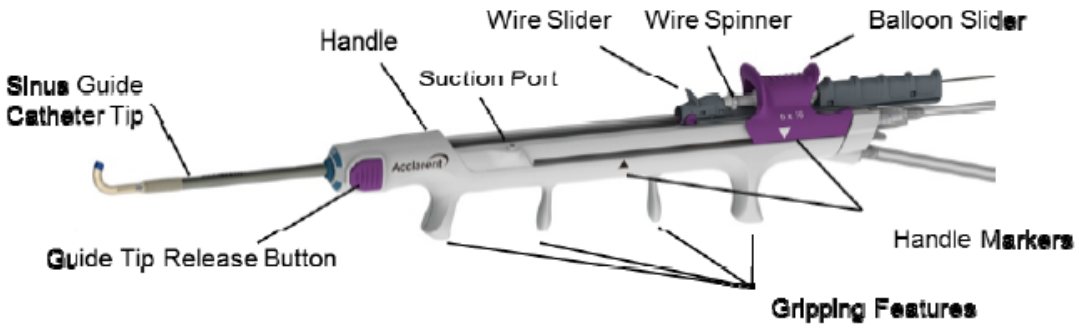
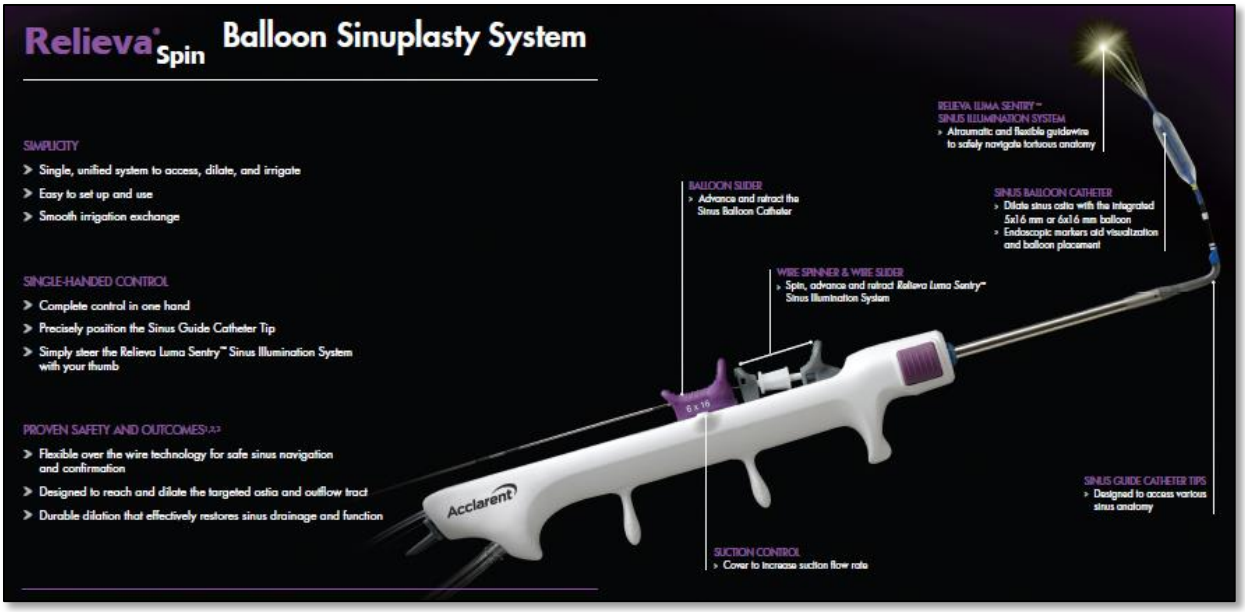


Figure 1: RELIEVA SPINPLUS™ Balloon Sinuplasty System Handle with a RELIEVA® Spin Sinus Guide Catheter Tip

The system features a Handle with an integrated flexible balloon catheter. Features of the Handle include a Guide Tip Release Button, a suction system, a Balloon Guard, and several Gripping Features to grip the device. The Guide Tip Release Button must be depressed to separate the Sinus Guide Catheter Tip from the Handle System. The suction system consists of a suction line and a Suction Port. Suction may be used to clear the field of fluids and/or blood. The suction line is attached to the proximal end of the Handle System and may be removed if desired. The Suction Port may be covered by the user's finger to increase the suction flow rate. A clear Balloon Guard is connected to the distal end of the Handle System and protects the Sinus Balloon during Sinus Guide Catheter Tip exchanges.

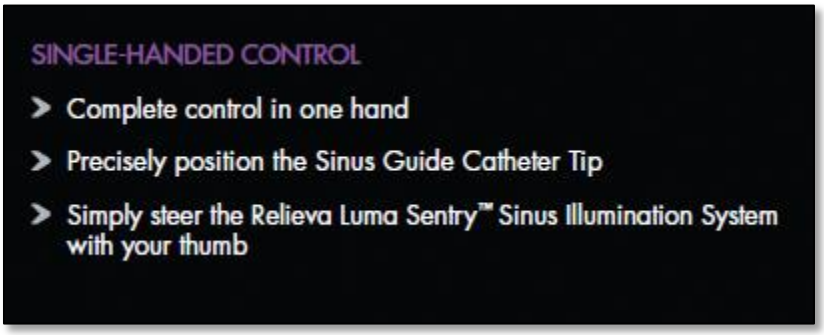
The Handle features a Wire Slider, a Wire Spinner, a Balloon Slider, a Sinus Balloon, Handle Markers, and proximal connections. The Wire Slider allows the user to advance, retract and spin the Sinus Illumination System with a single hand while simultaneously supporting the Handle. The Balloon Slider allows the user to advance and retract the Sinus Balloon Catheter (shown in Figure 2).

Relieva SpinPlus IFU

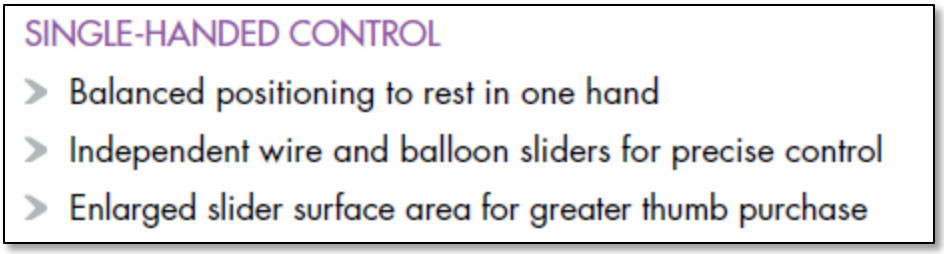


Relieva Spin Marketing Brochure

113. The Relieva Devices allow a position of the guide catheter to be controlled by some or all of three fingers of one hand of the user. As shown above, the Relieva Spin marketing material further states that the device offers "single-handed control" and "complete control in one hand." The Relieva SpinPlus marketing literature notes also describes "single-handed control" and "balanced positioning to rest in one hand" as shown below.



Relieva Spin Marketing Brochure



Relieva SpinPlus Marketing Brochure

114. The Relieva Devices' handle coupling is configured to couple a source of suction to the lumen. For example, the Relieva SpinPlus Instructions for Use state that the Relieva SpinPlus includes "clear suction tubing with Clear Suction Connector," and a suction port on the handle as shown in the marketing material below. The SpinPlus Instructions for Use also state that if the physician elects to use suction, he or she should "connect the Clear Suction Connector to a vacuum source," and that if the physician desires to increase suction strength, he or she can "cover the suction port with a finger." The Relieva Spin operates in a similar manner, having suction tubing, a connector, and suction port as shown in the marketing materials below.

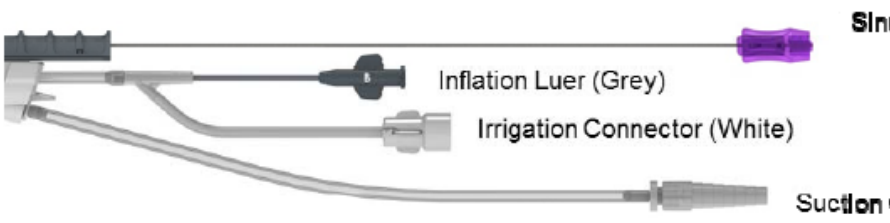
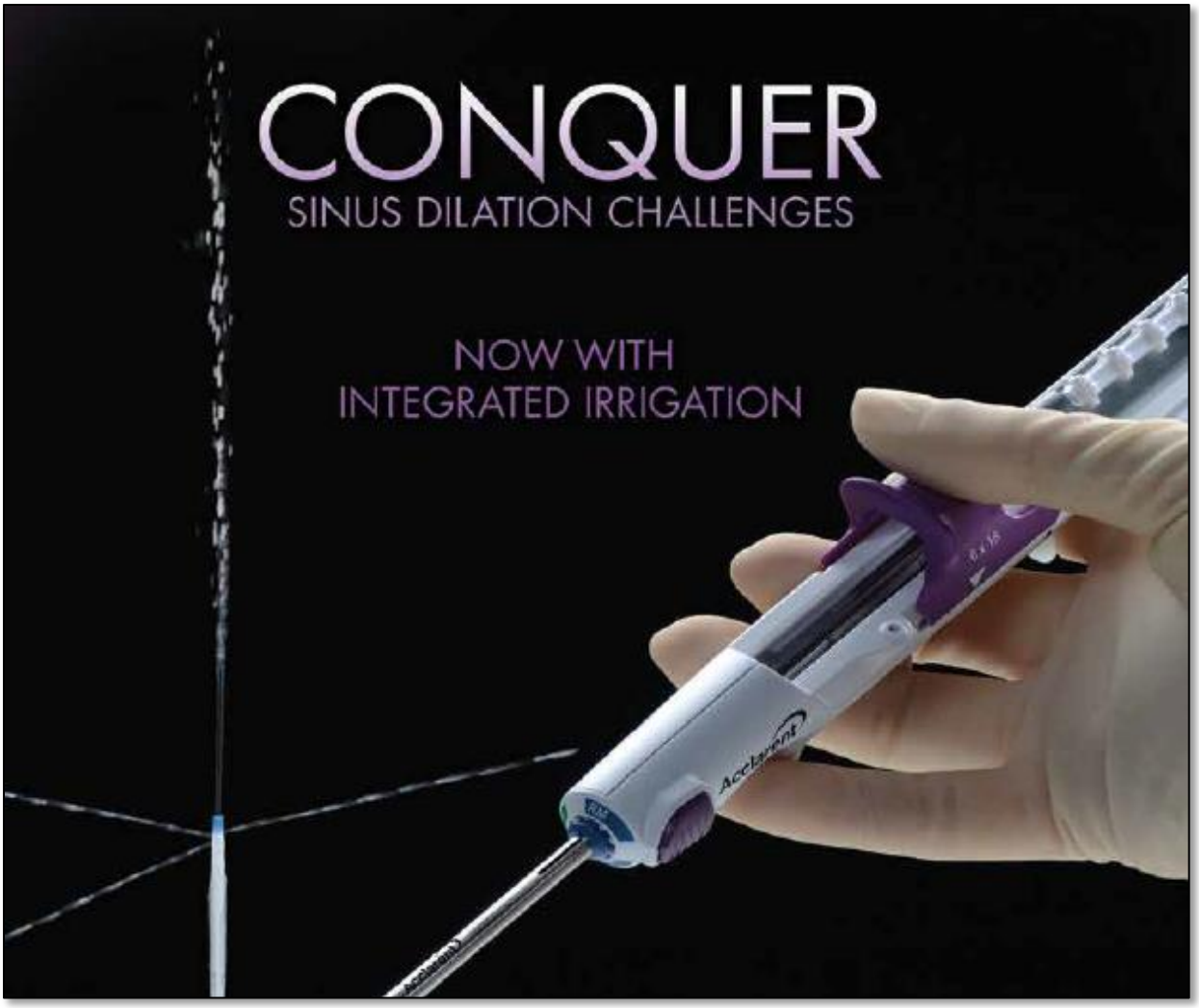


Figure 3: RELIEVA SPINPLUS™ Balloon Sinuplasty System Proximal Connections

Each system contains four separate connection points (shown in Figure 3). Three of the connectors are associated with separate tubing, and the fourth connector is for the wire. Each of the four lines are attached to the proximal end of the Handle: The grey inflation line with grey Inflation Luer, the white irrigation line with white Irrigation Connector, the clear suction tubing with clear Suction Connector, and the Sinus Illumination System wire with purple Sinus Illumination System Connector.

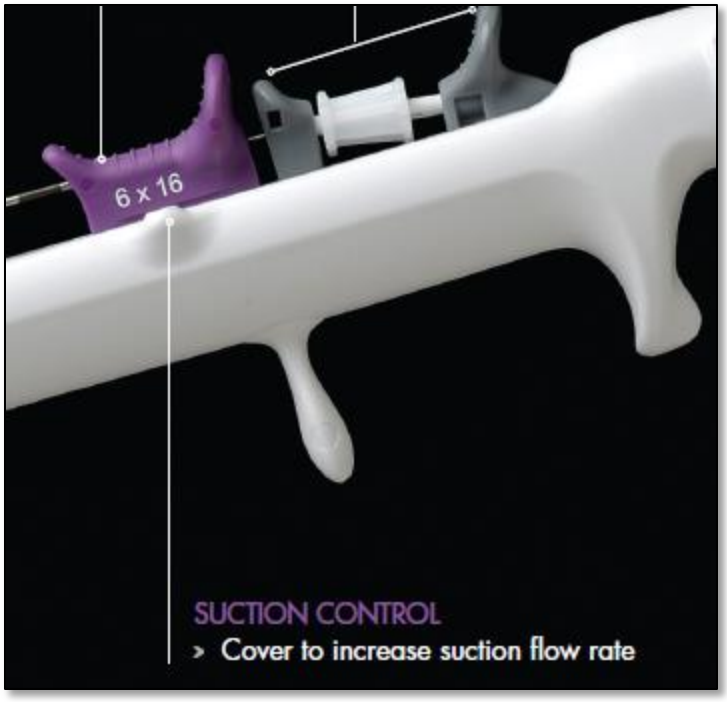
Relieva SpinPlus IFU



6. Should the physician elect to use suction with the RELIEVA SPINPLUS™ Balloon Sinuplasty System, connect the clear Suction Connector to a vacuum source and adjust to the appropriate level.

2. Suction may be used to clear the field of fluids and/or blood. To increase the suction strength, cover the suction port with a finger.

Relieva SpinPlus Marketing Brochure



Relieva Spin Marketing Brochure

115. The Relieva Devices include a handle structure that is adapted to permit the operator to position a thumb and index finger of the hand to manipulate a working device via a portion of the working device immediately adjacent to the handle opening when the working device is inserted through the handle opening into the lumen of the shaft. For example, the Relieva Spin marketing literature describes a "Balloon Slider" and "Wire Spinner and Wire Slider," as depicted below. Similarly, the Relieva SpinPlus marketing literature describes an independent "Balloon Slider" that allows for precise control of the balloon catheter, and "Wire Spinner and Wire Slider," described as "[an] [e]longated tactile thumb wheel to easily gain thumb purchase and navigate sinus anatomy," as shown below.

Relieva Spin Marketing Brochure

Relieva SpinPlus Marketing Brochure

116. The Relieva Devices include a structure of the handle that is configured to permit the operator to control, by one of the thumb or index finger, an amount of suction coupled to the distal opening of the lumen. For example, the Relieva Spin marketing literature identifies a

handle featuring a "Suction Control" opening which a surgeon can "cover to increase suction flow rate." The Relieva SpinPlus Instructions for Use state that the Relieva SpinPlus system includes a "Suction Port" that "may be covered by the user's finger to increase the suction flow rate."

Relieva Spin Marketing Brochure

DESCRIPTION

The RELIEVA SPINPLUS™ Balloon Sinuplasty System (shown in Figure 1) is packaged with:

- A Handle with integrated flexible balloon catheter and flexible Sinus Illumination System
- One or more RELIEVA® Spin Sinus Guide Catheter Tips

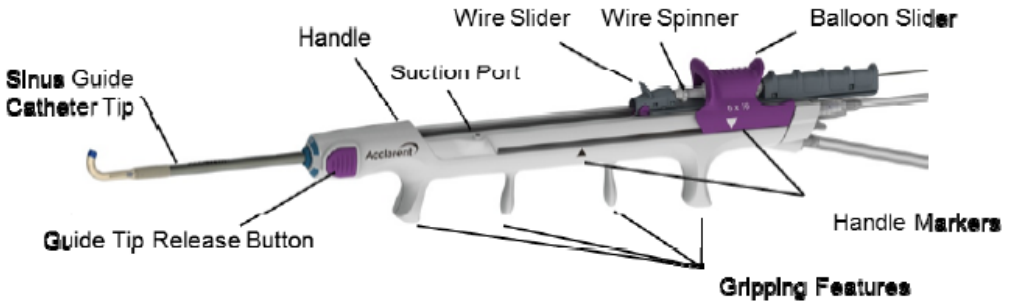


Figure 1: RELIEVA SPINPLUS™ Balloon Sinuplasty System Handle with a RELIEVA® Spin Sinus Guide Catheter Tip

The system features a Handle with an integrated flexible balloon catheter. Features of the Handle include a Guide Tip Release Button, a suction system, a Balloon Guard, and several Gripping Features to grip the device. The Guide Tip Release Button must be depressed to separate the Sinus Guide Catheter Tip from the Handle System. The suction system consists of a suction line and a Suction Port. Suction may be used to clear the field of fluids and/or blood. The suction line is attached to the proximal end of the Handle System and may be removed if desired. The Suction Port may be covered by the user's finger to increase the suction flow rate. A clear Balloon Guard is connected to the distal end of the Handle System and protects the Sinus Balloon during Sinus Guide Catheter Tip exchanges.

The Handle features a Wire Slider, a Wire Spinner, a Balloon Slider, a Sinus Balloon, Handle Markers, and proximal connections. The Wire Slider allows the user to advance, retract and spin the Sinus Illumination System with a single hand while simultaneously supporting the Handle. The Balloon Slider allows the user to advance and retract the Sinus Balloon Catheter (shown in Figure 2).

Relieva SpinPlus IFU

117. Acclarent's acts of direct infringement have caused damage to Dr. Albritton. Dr. Albritton is entitled to recover from Acclarent the damages sustained by him as a result of Acclarent's wrongful acts in an amount subject to proof at trial. In addition, the infringing acts and practices of Acclarent have caused, are causing, and unless such acts and practices are enjoined by the Court, will continue to cause immediate and irreparable harm to Dr. Albritton for which there is no adequate remedy at law, and for which Dr. Albritton is entitled to injunctive relief under 35 U.S.C. § 283.

118. As early as March 2009, Acclarent was notified that Dr. Albritton would be filing the non-provisional patent application that led to the '412 Patent.

119. When the ’412 Patent issued in April 2015, Dr. Albritton notified Acclarent that his patent covered his surgical catheter device that could, among other things, be operated with a single hand.

120. Prior to this lawsuit, Dr. Albritton specifically indicated to Acclarent that the Relieva Devices would infringe the claims of the ’412 Patent.

121. Despite this notice, Acclarent refused to license the ’412 Patent, and continued to infringe the claims of the ’412 Patent as explained above.

122. Given Acclarent’s extensive pre-suit knowledge of the ’412 Patent, in addition to Acclarent’s fraud and misappropriation of Dr. Albritton’s intellectual property, Acclarent’s direct infringement of the ’412 Patent is therefore intentional and willful, and represents egregious misconduct beyond typical infringement.

COUNT SIX: INDIRECT INFRINGEMENT OF U.S. PATENT NO. 9,011,412

123. Plaintiff refers to and incorporates herein the allegations of Paragraphs 1-122 above.

124. Acclarent indirectly infringes the ’412 Patent by inducing infringement by others, such as end users, of at least claims 1, 4, 5, 6, 7, 8, 11, 12, 13, 14, 17, 18, 19, and 20 in accordance with 35 U.S.C. § 271(b) in this District and elsewhere in the United States. Direct infringement is the result of activities performed by the end users of the Relieva Devices as detailed in paragraphs 88 to 121 above.

125. Acclarent’s affirmative acts of selling the Relieva Devices, causing the Relieva Devices to be manufactured and distributed, and providing marketing materials, labeling, package inserts, a website, and other promotional materials encourage, aid, instruct, and cause the public, including doctors and other health care professionals, to use the Relieva Devices in a

manner that infringes the claims of the ’412 Patent. Acclarent performed the acts that constitute induced infringement, and would induce actual infringement, with the knowledge of the ’412 Patent and with the knowledge or willful blindness that the induced acts would constitute infringement.

126. Acclarent’s acts constitute active inducement of infringement of the ’412 Patent, and it is liable as an infringer.

127. Acclarent further indirectly infringes the ’412 Patent by contributing to the infringement by others, such as end users, and Acclarent has contributed to and/or continues to contribute to infringement of at least claims 1, 4, 5, 6, 7, 8, 11, 12, 13, 14, 17, 18, 19, and 20 of the ’412 Patent, pursuant to 35 U.S.C. § 271(c), by virtue of its offer to sell and/or sale within the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, which are not staple articles or commodities of commerce and which have no substantial non-infringing use.

128. In particular, Acclarent has offered to sell and/or sold the Relieva Devices, which constitute a material part of the invention of the ’412 Patent, knowing the same to be especially made or especially adapted for use in an infringement of the ’412 Patent, and knowing that the same are not staple articles or commodities of commerce suitable for substantial noninfringing use.

129. Acclarent had actual notice of the provisional and non-provisional applications that became the ’412 Patent, by June 6, 2008, at the latest, when Acclarent entered the Consulting Agreement with Dr. Albritton. Ex. E.

130. Acclarent had actual notice of the ’412 Patent, as issued, by April, 2015 at the latest, when Dr. Albritton notified Acclarent that his patent covered his surgical catheter device that can, among other things, be operated with a single hand.

131. Acclarent’s acts of indirect infringement have caused damage to Dr. Albritton. Dr. Albritton is entitled to recover from Acclarent the damages sustained by him as a result of Acclarent’s wrongful acts in an amount subject to proof at trial. In addition, the infringing acts and practices of Acclarent have caused, are causing, and unless such acts and practices are enjoined by the Court, will continue to cause immediate and irreparable harm to Dr. Albritton for which there is no adequate remedy at law, and for which Dr. Albritton is entitled to injunctive relief under 35 U.S.C. § 283.

132. For the reasons stated in paragraphs 124-130, above, Acclarent’s indirect infringement of the ’412 Patent is intentional and willful, and represents egregious misconduct beyond typical infringement.

JURY DEMAND

133. Plaintiff hereby demands a trial by jury as to all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Dr. Albritton respectfully requests that this Court enter judgment in his favor and grant the following relief:

1. A judgment and order requiring Acclarent to pay Dr. Albritton’s monetary damages that were caused by Acclarent’s breaches of contract, fraud, and fraudulent inducement;
2. A judgment and order requiring Acclarent to assign all rights to the ’473 Patent to Dr. Albritton.
3. A judgment that Acclarent has infringed and continues to infringe the ’412 Patent;

4. A judgment and order requiring Acclarent to pay Dr. Albritton's monetary damages sufficient to compensate Dr. Albritton for Acclarent's infringement of the '412 Patent, but in no event less than a reasonable royalty under 35 U.S.C. § 284;
5. An award of enhanced damages pursuant to 35 U.S.C. §284;
6. An award of treble damages for willful infringement;
7. A judgment and order requiring Acclarent to pay Dr. Albritton's pre-judgment and post-judgment interest on the damages awarded, to the full extent allowed under the law, as well as its costs;
8. A judgment and order finding this to be an exceptional case under 35 U.S.C. § 285 and requiring Acclarent to pay costs of this action and attorneys' fees;
9. A permanent injunction against all Acclarent's products found to infringe the '412 Patent;
10. In lieu of an injunction, an award of a compulsory forward royalty;
11. An order for an accounting of damages; and
12. An award of such further relief as the Court may deem appropriate and just under the circumstances.

Dated: December 1, 2016.

MCKOOL SMITH, P.C.

s/ Ashley N. Moore

Ashley N. Moore
Texas State Bar No. 24074748
amoore@McKoolSmith.com
Travis E. DeArman
Texas State Bar No. 24074117
tdearman@McKoolSmith.com
Meredith Elkins
Texas State Bar No. 24084584
melkins@McKoolSmith.com
MCKOOL SMITH, P.C.
300 Crescent Court Suite 1500
Dallas, TX 75201
Telephone: (214) 978-4000
Telecopier: (214) 978-4044

ATTORNEYS FOR Plaintiff
DR. FORD ALBRITTON