UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BEN-ZION KARMON, *Plaintiff*, v. MIAMBE LTD., MIAMBE USA. / MIAMBE LLC, EFRAIM KFIR *Defendants.*	Civil Action No. 16-cv-01643-DLC **FIRST AMENDED COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Dr. Ben-Zion Karmon ("Dr. Karmon" or "Plaintiff"), by and through his undersigned counsel, hereby brings this first amended complaint for patent infringement under the laws of the United States relating to patents, 35 U.S.C. §§1 et seq., against Defendants Miambe Ltd., Miambe USA/Miambe LLC. and Efraim Kfir hereby alleging as follows:

PARTIES

1. Dr. Karmon is an Israeli dentist, residing in Petach Tikva, Israel.

2. Dr. Karmon has been practicing dentistry for approximately 25 years, and is the inventor of 10 issued U.S patents in the field of dental implants and bone regeneration.

3. Upon information and belief, Defendant Miambe Ltd. is an Israeli company with an address of 40 Hanesiim Street, Petach-Tikva 4955042.

4. Upon information and belief, Defendant Miambe USA and/or Miambe LLC is a New Jersey Corporation, with an address of 18-00 Fair Lawn Avenue Fair Lawn, New Jersey

07410. Upon information and belief, Miambe USA/Miambe LLC. is owned and controlled by Miambe Ltd.

5. Upon information and belief, Defendant Dr. Efraim Kfir is an Israeli dentist, residing in Ganey-Tikva, Israel, and with an actual place of business at 40 Hanesiim Street, Petach-Tikva 4955042. Dr Efraim Kfir is the founder, medical developer, major equity holder, and chairman of the board of Miambe Ltd. Defendants Miambe Ltd, Miambe USA/Miambe LLC and Dr. Efraim Kfir are hereafter referred to as "Miambe."

JURISDICTION AND VENUE

6. This Court has exclusive subject matter jurisdiction pursuant to 28 U.S.C. §§1331 and 1338(a) because this action arises under the patent laws of the United States.

7. Miambe is subject to the personal jurisdiction of this Court at least by committing acts of infringement in the State of New York, thereby establishing its legal presence within the State, including, without limitation, directly and indirectly selling and offering for sale to New York residents products that, when used according to Miambe's instructions, infringe the patent-in-suit.

8. Upon information and belief, Miambe has also generally acted to place these infringing products into the stream of commerce with the intent, purpose, and reasonably foreseeable result of supplying the New York market therewith.

9. At least by virtue of its above-described actions, Miambe has transacted business (as that term is construed under N.Y. C.P.L.R. §§301 and 302(a)(1) and (2)), performed services, contracted to supply services, caused tortious injury, regularly done or solicited business,

engaged in a persistent course of conduct, and/or derived substantial revenues from infringing products used in New York.

10. In light of Miambe's aforementioned contacts with the State of New York and its purposeful availment of the rights and benefits of New York law, maintenance of this suit in this Court would not offend traditional notions of fair play and substantial justice.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c), and (d) and 1400(b) because, inter alia, a substantial part of the events or omissions giving rise to the claims occurred in this judicial district.

COUNT 1
INFRINGEMENT OF U.S. PATENT NO. 8,864,841

12. Dr. Karmon is the sole inventor of United States Patent No. 8,864,841 ("the '841 patent"), entitled "Method for Displacement of the Schneiderian Membrane", which was duly and legally issued by the United States Patent and Trademark Office on October 21, 2014. A true and correct copy of the '841 patent is attached hereto as Exhibit A.

13. Dr. Karmon is the owner of the '841 patent with all substantive rights in and to that patent, including the sole and exclusive right to prosecute this action and enforce the '841 patent against infringers, and to collect damages for all relevant times.

14. The application that issued as the '841 patent was published by the United States Patent and trademark Office on July 5, 2007 (the "Publication Date").

15. The claims of the '841 are directed to surgical methods for displacing the Schneiderian membrane from the maxillary bone with an expandable inflatable container, such as a balloon. Displacement of the Schneiderian membrane of the maxillary sinus is part of patient

dental treatment with dental implants in the posterior maxilla in cases with low alveolar ridge bone below the maxillary sinus. This procedure, enabling bone regeneration inside the maxillary sinus of the jaw, has several names such as: "sinus lift," "sinus augmentation," and "antral membrane elevation." There are several methods in the prior art for displacing the Schneiderian membrane, most of which use "curettes" to peel the Schneiderian membrane from the bone. These surgical methods involve relatively complicated surgeries and have a high incidence of tearing of the Schneiderian membrane – a significant patient hazard and drawback of the prior art. The methods claimed in the '841 patent avoid the disadvantages of the prior art. Embodiments of the '841 patent describe an initial stage of disconnecting of the Schneiderian membrane before inflation of an expandable inflatable container and subsequent main elevation of the Schneiderian membrane by the inflatable container.

16. Miambe sells and offers to sell sinus lift kits for use in sinus augmentation procedures, and instructs customers on the use of its sinus lift kits.

17. Miambe has been and is now indirectly infringing the '841 patent by way of inducement and/or contributory infringement, literally and/or under the doctrine of equivalents in violation of 35 U.S.C. §271, including by selling a product with no substantial non-infringing use, and by knowingly and actively inducing customers to infringe the '841 patent by performing a minimally invasive antral membrane balloon elevation sinus augmentation procedure covered by at least claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 14, 15, 16, 17, 18, 19, 20, 21, and 22 of the '841 patent.

Miambe's surgical method and kit

18. Miambe's surgical method is aimed at disconnecting the Schneiderian membrane from the maxillary bone with an inflatable balloon and displacing the Schneiderian membrane upwards with the balloon. In Miambe's website under the "Our Solution" tab, the first paragraph describes disconnecting the Schneiderian membrane with the balloon, and the second paragraph describes elevating the Schneiderian membrane with the balloon:[1]

> "Miambe
>
> The MIAMBE technology is based on the control technique **which uses the balloon to disconnect the Schneiderian membrane**, regardless of the sinus anatomy, membrane dehiscence, and countering many of the other problems associated with the conventional procedures.
>
> Minimal-invasive antral membrane balloon elevation (MIAMBE) is a modification of the closed method, **in which antral membrane elevation is executed via the osteotomy site** (of ≤ 3 mm) **using a dedicated balloon**." (emphasis added)

Below is a screenshot from Miambe's website:

[1] http://www.miambe.com/our-solution.html

In the surgical picture of the above screenshot, the lateral wall of the sinus was removed to show the amount of disconnection and elevation of the Schneiderian membrane by the inflatable balloon, which moves far above the small opening in the alveolar ridge. This picture demonstrates that the balloon is between the maxillary bone and the displaced Schneiderian membrane.

19. Miambe's website also includes instructions ("Miambe's Instructions") directing that the disconnection and elevation of the Schneiderian membrane be accomplished in two phases. Attached hereto as Exhibit B, are Miambe's Instructions as downloaded from Miambe's website.[2]

20. Miambe's Instructions start with guidelines for assembling its device. (*See* Exhibit B at 1 "Equipment and Materials.") In addition, attached hereto as exhibit C, is a

[2] http://www.miambe.com/media/files/Instructions-EN.pdf

collection of screenshots from Miambe's Facebook page, visually demonstrating how to assemble the device.[3]

21. Miambe's Instructions state that after assembling the device, a hole is drilled through the alveolar ridge bone towards the Schneiderian membrane:

> "With the MIAMBE 3mm drill (equipped with 4-6-8mm scale) drill gently with in – out movement, in the center of the alveolar crest until exposing the antral membrane."[4]

This step of Miambe's method corresponds to "*forming a path of insertion through the alveolar ridge of the maxillary bone towards the Schneiderian membrane*," as claimed in the '841 patent. Miambe's Instructions further teach inserting implant-depth-gauges (called "curettes" in Miambe's Instructions) into the 3 mm osteotomy "*for primary membrane elevation*" (emphasis added):

> "Then start disconnecting the antral membrane circumferentially 360° all around the osteotomy for primary membrane elevation."[5]

Miambe's Instructions clearly warn (in red color font) to always keep the "curette" in close contact with the bone, as follows:

> "(be in close contact with the bone during disconnection of the membrane, otherwise it can cause membrane perforation)."

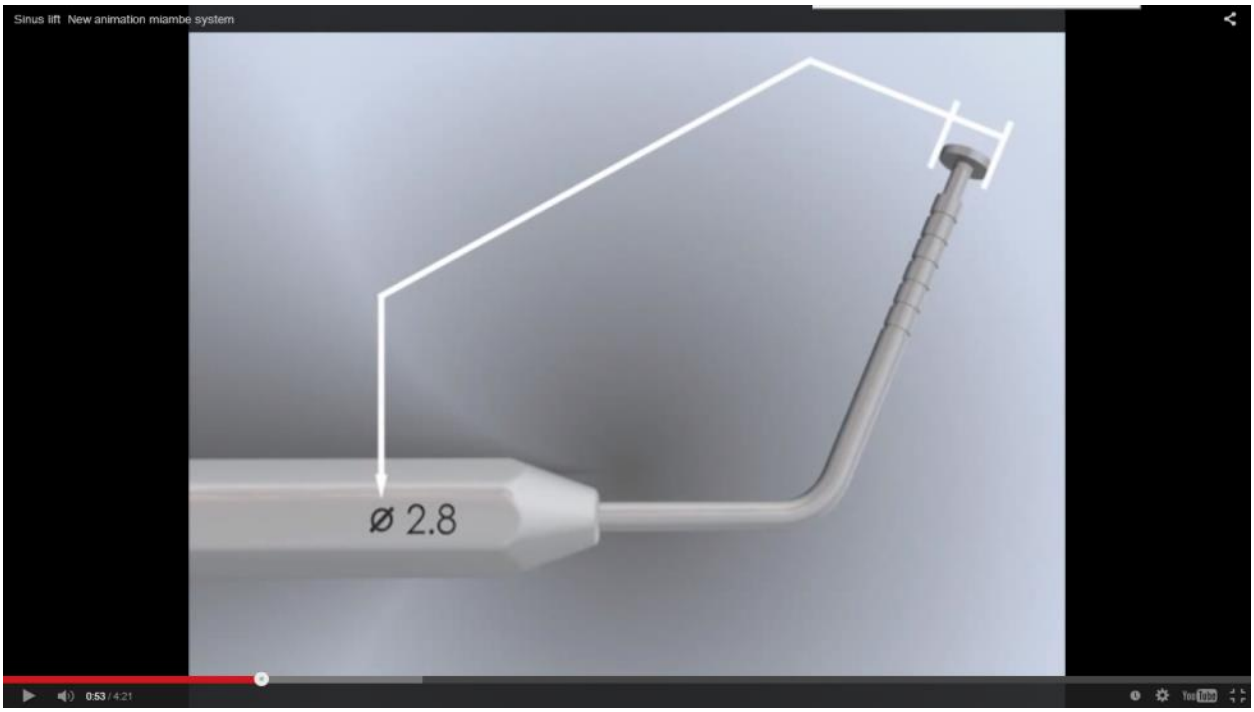
Two "curettes" are included in Miambe's kit, each having a circular tip on top of a narrow leg (mushroom- like). One "curette" has a 2.5 mm diameter circular tip; the second "curette" has a

[3] https://www.facebook.com/media/set/?set=a.190806641065108.66491.150094601802979&type=3

[4] Antral membrane is another name for the Schneiderian membrane.

[5] "Primary" in this context would be understood by one of ordinary skill in the art to mean initial.

2.8 mm diameter circular tip. Below is a screenshot from a Youtube-linked animation on the Home page of Miambe's website (at 0:53) that demonstrates the 2.8 mm "curette":



The narrow leg of the "curette" has a diameter of about 1 mm so that the circular tip extends laterally from the narrow leg up to 1 mm all around. Therefore, primary (initial) disconnection of the Schneiderian membrane by the "curettes" as taught by Miambe is at most of a segment of the membrane measuring approximately 1 mm around the drilled opening in the sinus floor. Miambe's website also includes instructional videos of actual surgeries performed according to Miambe's method. The video titled "MIAMBE curette," shows that after use of the "curette", the Schneiderian membrane is only slightly disconnected from the bone.[6]

[6] http://www.miambe.com/video-5/ at 1:27-2:09 minutes.

22. Miambe's Instructions and videos show that "curettes" are used in the Miambe method to enable a safe path of insertion for the cannula (harboring the inflatable balloon), without tearing the Schneiderian membrane during the insertion. Use of the "curettes" enables insertion of the cannula to a depth of 1 mm above the floor of the maxillary sinus, which creates a small space above the floor of the sinus (for the cannula).

23. In the Miambe method, the small segment of the Schneiderian membrane around the osteotomy that was separated from the maxillary bone by the "curettes", tends to recoil back towards the maxillary bone. Indeed, Miambe's Instructions state:

> "The balloon should be left inflated for 5 minutes in the sinus to reduce the *membrane elastic recoil*"[7] (emphasis added).

Therefore, in Miambe's method even the small portion of the Schneiderian membrane that is separated by the "curette" at the site of the osteotomy likely touches the maxillary bone before being mainly displaced by the balloon.

24. After primary disconnection and elevation of the Schneiderian membrane, Miambe's Instructions state that a cannula harboring an inflatable balloon for the main disconnection and elevation of the Schneiderian membrane is inserted through the path of insertion. In the Miambe kit, the cannula is called a "metal sleeve." The metal sleeve is connected to an extension tube called a "plastic tube" which is connected to an injecting mechanism called an "indeflator".[8]

[7] *See* Exhibit C

[8] *See* Exhibits C and D.

25. According to Miambe's Instructions, after the balloon emerges from the cannula, elevation of the Schneiderian membrane by the balloon commences:

> "In this phase the antral membrane balloon elevation is taking place. At this point the balloon is to be slowly inflated to the desired elevation…."[9]

26. Miambe's Instructions direct expanding the balloon with 1-1.5 ml of a saline solution such that the balloon achieves a height of 11-13 mm and width of 11.5-13 mm. Therefore, the main or majority of the disconnection and elevation of the Schneiderian membrane from the maxillary bone is performed with the inflatable balloon.

Miambe's website animation

27. The Home page of Miambe's website (http://www.miambe.com/) includes a Youtube-linked animation ("Miambe's Animation"), which visually animates the Miambe surgical method and kit in somewhat exaggerated fashion for teaching purposes.[10]

28. The description of Miambe's Animation states:

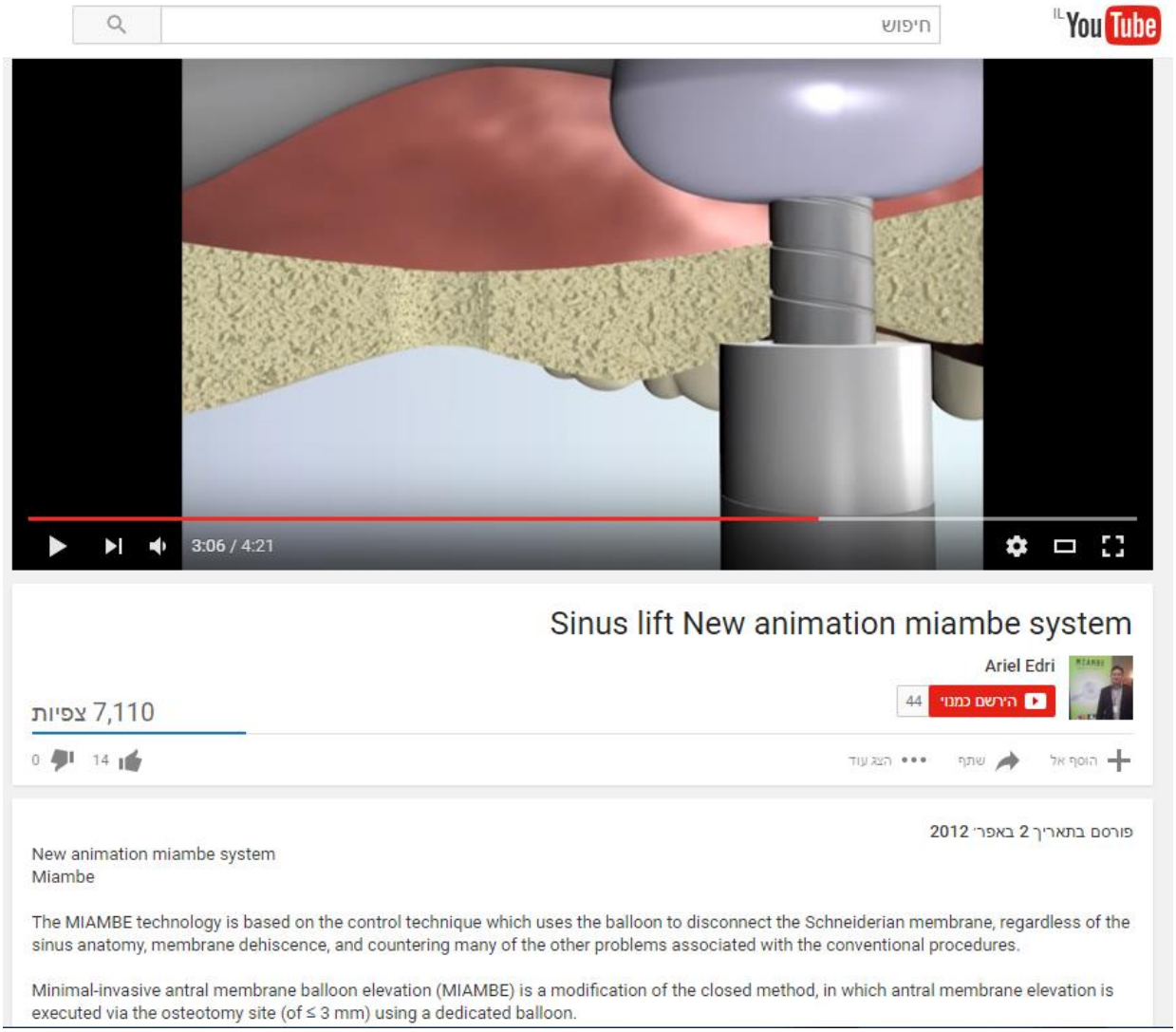
> "The MIAMBE technology is based on the control technique which uses the balloon to disconnect the Schneiderian membrane, regardless of the sinus anatomy, membrane dehiscence, and countering many of the other problems associated with the conventional procedures."
>
> "Minimal-invasive antral membrane balloon elevation (MIAMBE) is a modification of the closed method, in which antral membrane elevation is executed via the osteotomy site (of ≤ 3 mm) using a dedicated balloon."[11]

[9] *See* Exhibit C.

[10] https://www.youtube.com/watch?v=XfW65Fw3aK4

[11] The same description appears in Miambe's website under the "Our Solution" tab.

Below is a screenshot from the Miambe's Animation (3:06):

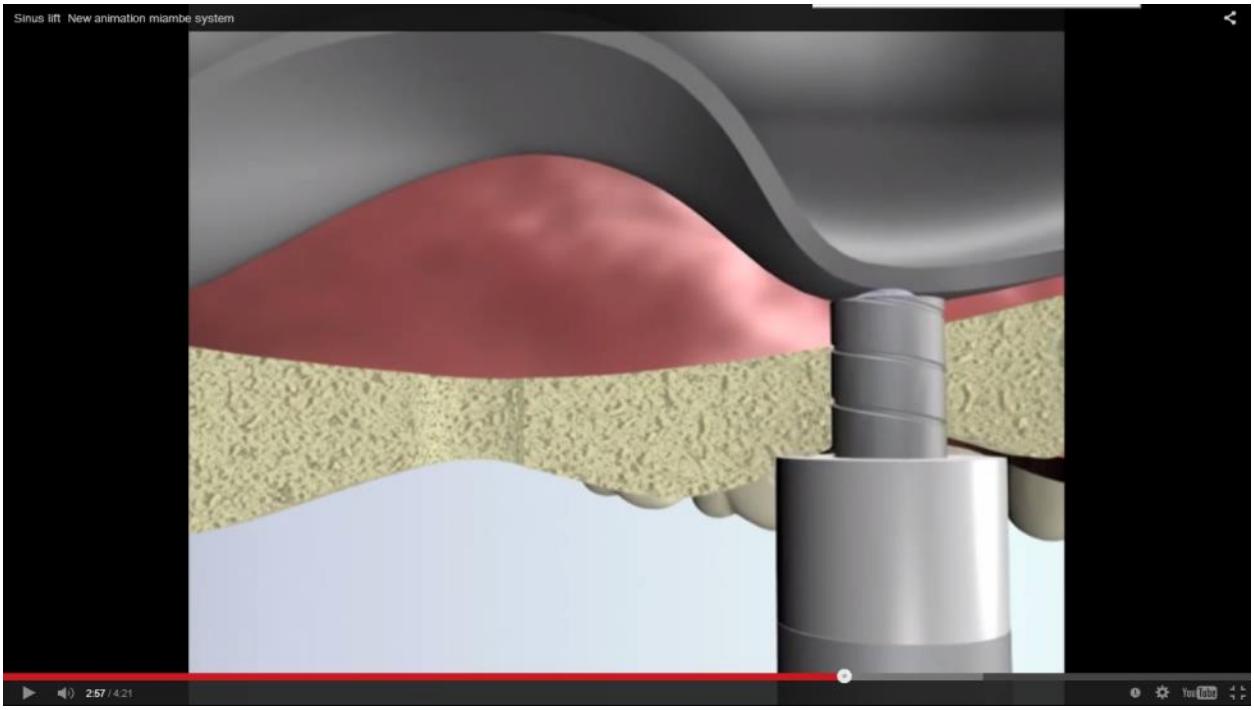


29. Miambe's Animation shows the inflation of the balloon below the Schneiderian membrane and elevation of the Membrane.[12] Miambe Animation's shows a special use of

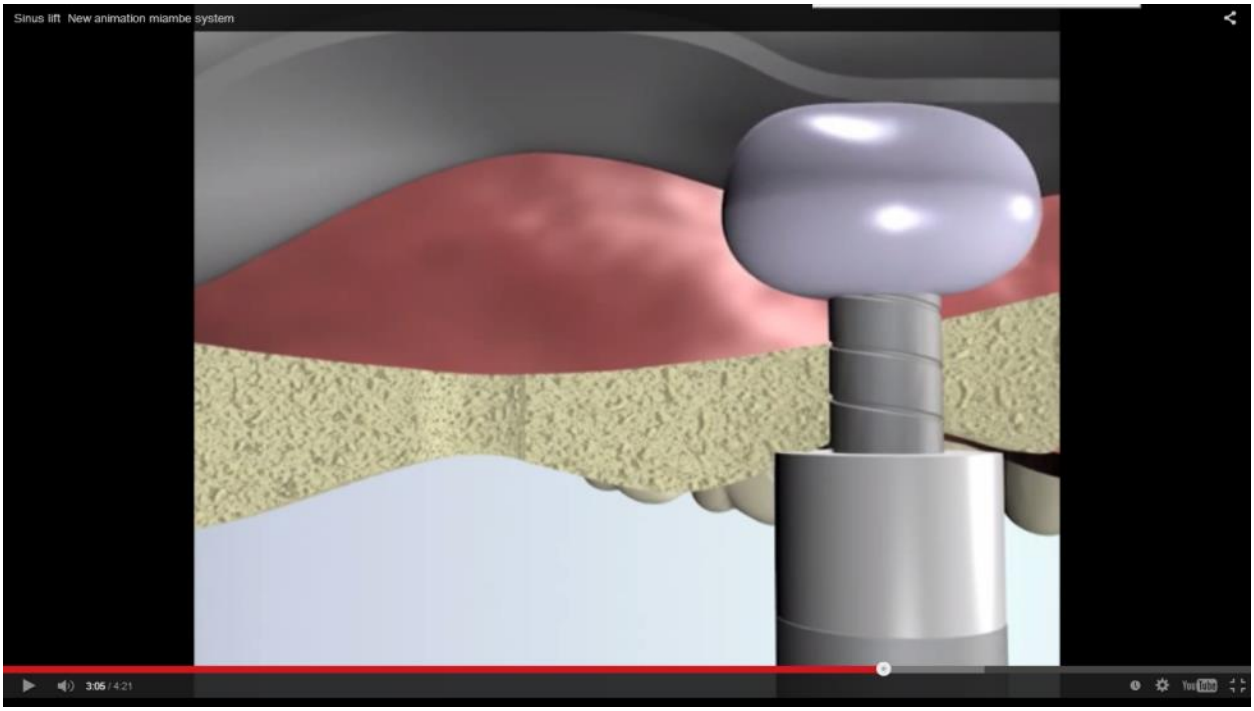
[12] Although Miambe's Animation doesn't show the entire expanded balloon and the entire separated and elevated Schneiderian membrane, the separation and elevation of the Schneiderian membrane by the balloon is clear to any person of ordinary skill in the art, especially towards the right side of Miambe's Animation.

Miambe's method in two adjacent sites. There are two drillings, two sites of using the "curettes" and two inflations of the balloon with influences from one site on the other.

30. Below are two screenshots from Miambe's Animation showing the condition of the Schneiderian membrane before and during the second expansion of the balloon in the second site (on the right side). Before the second expansion of the balloon in Miambe's Animation (2:57):

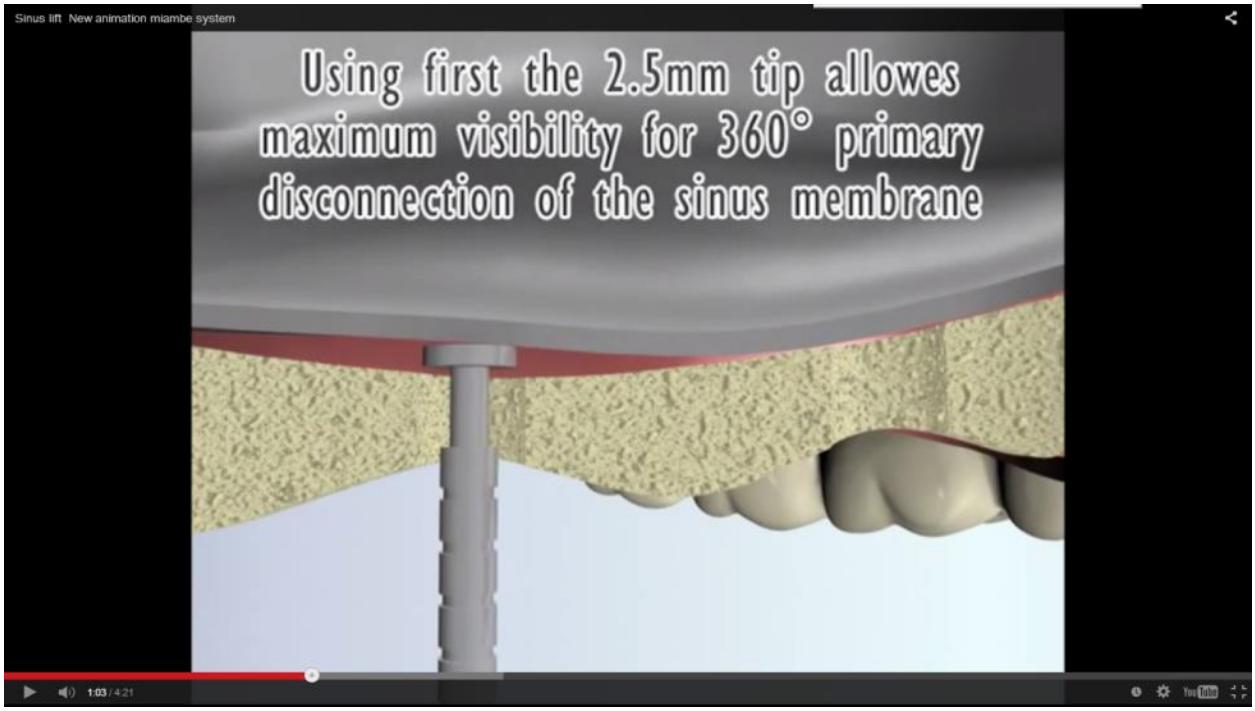


And, during the second expansion of the balloon in Miambe's Animation (3:05):



31. Miambe's Instructions and Miambe's Animation demonstrate that the inflatable balloon displaces the small segment of the Schneiderian membrane that was previously slightly separated by the "curettes", and that the balloon mainly separates and displaces additional segments of the Schneiderian membrane from the maxillary bone. Specifically, in Miambe's surgical method the "curette" separates the Schneiderian membrane from the maxillary bone only in a very small segment (essentially the circumference of the "curette's edge" which is about 1 mm). The "curette" is used to create a safe path of insertion for the cannula (metal sleeve) with the harbored balloon. The balloon that is subsequently inflated from the narrow (3 mm diameter) osteotomy location of the primary membrane separation, mainly displaces a much wider segment of the Schneiderian membrane from touching the bone.

32. Miambe's Animation confirms that the "curettes" perform only ***"primary disconnection"*** of the Schneiderian membrane. Below is screenshot from Miambe's Animation (1:03):



33. Consistent with Miambe's Instructions, Miambe's Animation cautions that the "*curette edge*" must be "*always in tight contact with the bone*." Below is screenshot from Miambe's Animation (1:12):

Miambe's patent

34. Miambe's balloon harboring device has been marked with a patent-pending notice label. The internal assembly of the Miambe device, including the inflatable balloon, the connector, and the cannula as well as their use inside the sinus are described and illustrated in United States Patent No. 8,333,589 titled "Assembly for Lifting the Sinus Membrane for Use in Dental Implant Surgery" ("the '589 patent"). Dr. Efraim Kfir is the sole listed inventor of the '589 patent. A copy of the '589 patent is attached hereto as Exhibit D.

35. The section of the '589 patent titled "Background of the Invention" states:

> "In the journal of Oral Implantology, Vol. XXXII No. 1 (2006) of February 2006, there has been published an article titled "Minimally by Invasive Antral Membrane Balloon Elevation Followed by Maxillary Bone Augmentation and Implant Fixation" (Dr. Efraim Kfir et al.) In the article there has been described implementation *of a technique using a balloon for separating and lifting the Shneiderian membrane* in order to gain more bone substrate for placement of maxillary dental implants…
>
> *The general object of the present invention* is to provide an apparatus for *practicing this method* in a safe and reliable manner."[13](emphasis added)

36. The Miambe method as described in the '589 patent corresponds identically to the methods claimed in the '841 patent. According to the '589 patent, a path of insertion is formed in the alveolar bone towards the Schneiderian membrane, the assembly of the cannula with the balloon is inserted through the osteotomy, and the injecting mechanism (pump) is activated to inflate the balloon which displaces the Schneiderian membrane:

[13] *See* Exhibit D.

> "For preparation of the sinus membrane lifting there must first be drilled an osteotomy through the alveolar crest…The assembly components 20-30 (see FIG. 4)… after insertion (see below) the top thereof will extend flush with or slightly higher (say by 1mm) than the sinus floor… The sub-assembly 20-30 is connected to the pump 12, the valve 20 opened and the pressurized fluid is pumped into the balloon 30 – see FIG. 5… the membrane lifting has reached the desired amount, say by balloon inflation of 10mm – 20mm in diameter…."[14]

37. The use of "curettes" is not mentioned in the '589 patent.

Infringement of claim 1 of the '841 patent

38. Independent claim 1 of the '841 patent recites: A method for displacing the Schneiderian membrane from the maxillary bone comprising: forming a path of insertion through the alveolar ridge of said maxillary bone towards said Schneiderian membrane; inserting through said path of insertion a hollow cannula, said cannula has a distal portion and a proximal portion, at least part of said distal portion of said cannula being inside said alveolar ridge, said proximal portion of said cannula being proximally to said alveolar ridge, said cannula being part of a device, said device further includes an expandable inflatable container, an extension tube and injecting element, said container has a proximal portion and a distal portion, said proximal portion of said container being located adjacent said distal portion of said cannula, said extension tube has a proximal portion and a distal portion, said proximal portion of said extension tube being located proximally to said cannula, said proximal portion of said extension tube being connected to said injecting element; activating said injecting element to inflate through said

[14] *See* Exhibit D at Col. 3 lines 6-47.

extension tube said distal portion of said container so said distal portion of said container is expanded and advanced distally to the distal end of said cannula inside said maxillary bone to displace a segment of said Schneiderian membrane from a surface of said maxillary bone, said segment of said Schneiderian membrane was touching said surface before being displaced, at least part of said expanded distal portion of said container being between said displaced segment of said Schneiderian membrane and said surface, said surface is selected from the group consisting of the floor of the maxillary sinus and the floor of the nasal cavity.

39. Miambe's promotional materials, including Miambe's Instructions, Miambe's Animation, pictures, and clinical demonstrations available on its websites, www.miambe.com, www.miambeusa.com, https://www.facebook.com/Miambeusa/ (the "Miambe Instructional Material") instructs customers to use the Miambe device for displacing the Schneiderian membrane from the maxillary bone as recited in claim 1. For example, the page "Our Solution" in Miambe's website, discussed *supra*, describes this basic principle of Miambe's surgical method and the use of Miambe's kit.

40. The Miambe Instructional Material shows drilling through the alveolar crest (also called the alveolar ridge) until exposure of the antral membrane (called also the Schneiderian membrane), and inserting a metal sleeve cannula of a balloon-harboring device into the osteotomy. These steps are taught in Miambe's Instructions (Exhibit B):

> "Multi-use kit: …osteotomy with stoppers, screw-tap... drills (2.25:2.9:3.1)… With the MIAMBE 3mm drill (equipped with 4-6-8mm scale) drill gently with in - out movement, in the center of the alveolar crest until exposing the antral membrane. (The drilling depth is predetermined according to measurements obtained from the CT scan)."

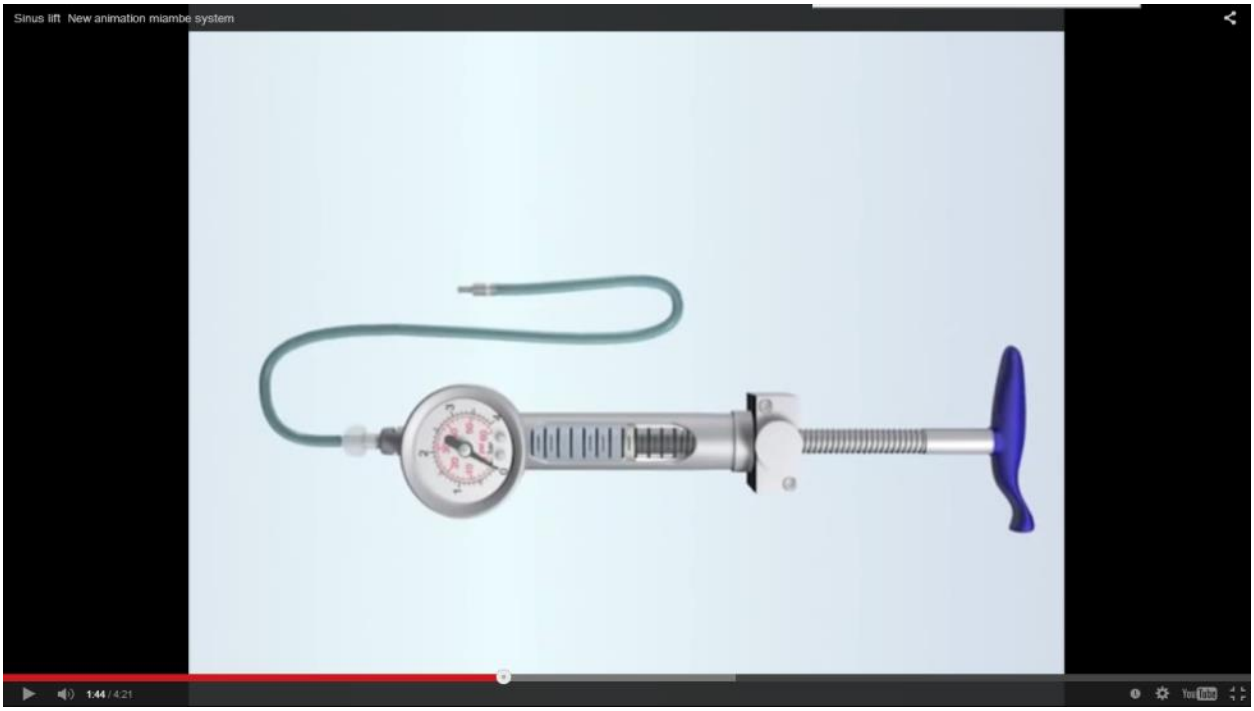
> ”Then insert the metal sleeve of the balloon-harboring device into the osteotomy 1mm beyond the sinus floor {use the balloon's stoppers to control depth of penetration}.”

These steps of forming the path of insertion and inserting the cannula with the harbored balloon can be also seen in Miambe’s Animation (0:14 – 2:30). These steps are also demonstrated for example in Miambe’s videos of actual surgeries performed according to Miambe’s method. The video titled “Miambe primary drilling” on the Miambe website[15] demonstrates forming the path of insertion. The video “MIAMBE Sinus Lift controlled with Balloon”[16] (0:00-0:10) demonstrates insertion of the cannula.

41. The Miambe Instructional Material shows that the Miambe device includes an injecting element, cannula, balloon (expandable inflatable container), connector, and extension tube, and further instructs that the device is prepared by cutting the distal edge of the plastic tube (extension tube), connecting the plastic tube to an indeflator (injecting element), injecting saline with the indeflator until the saline emerges from the distal end of the plastic tube and connecting the balloon-harboring device to the distal edge of the plastic tube. These elements and steps are disclosed and taught, for example, at the beginning of Miambe’s Instructions (Exhibit B). This can also be seen in the screenshots in Exhibit C. The assembled Miambe device can also be seen in Miambe’s Animation (1:44):

[15] http://www.miambe.com/video-3/

[16] http://www.miambe.com/video-2/

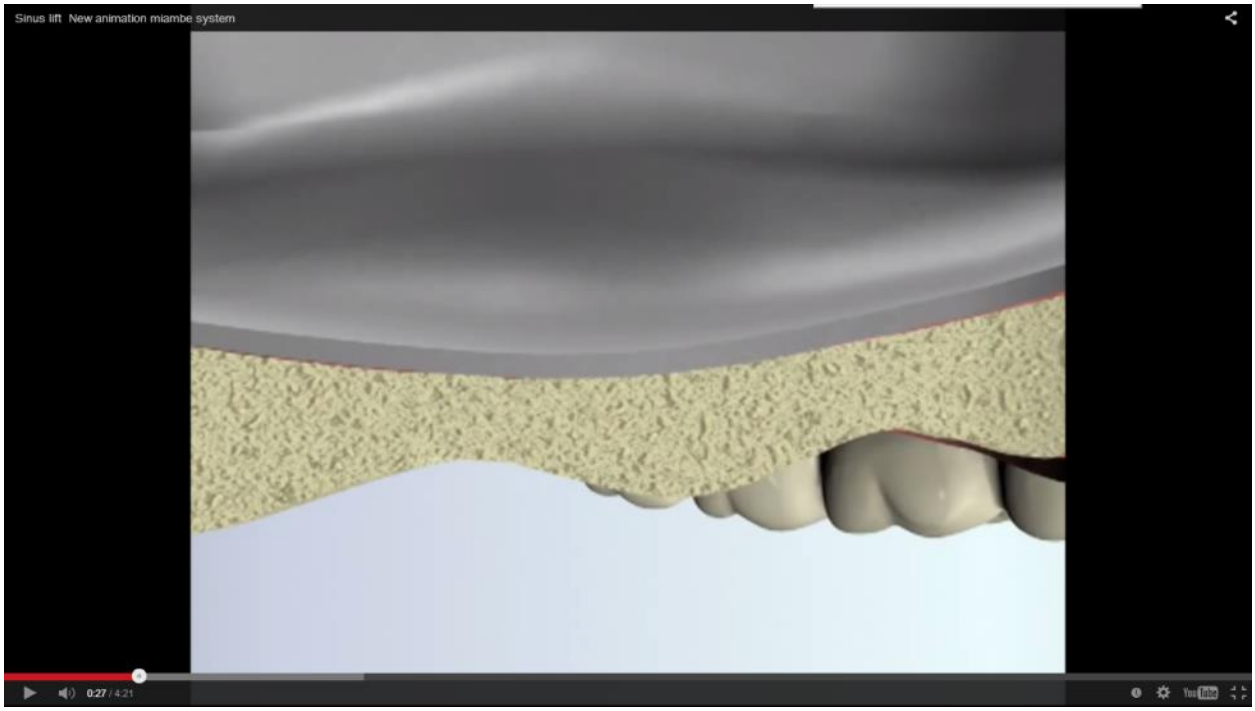


42. The Miambe Instructional Material further shows that the Schneiderian membrane elevation is controlled with the balloon by rotation of the indeflator until the desired elevation. This step is taught, for example, in Miambe's Instructions under the section titled "Balloon inflation" (Exhibit B). It can also be seen in Miambe's Animation (2:00-3:08), and in the surgical video titled "MIAMBE Sinus Lift controlled with Balloon"[17] (0:11-1:48).

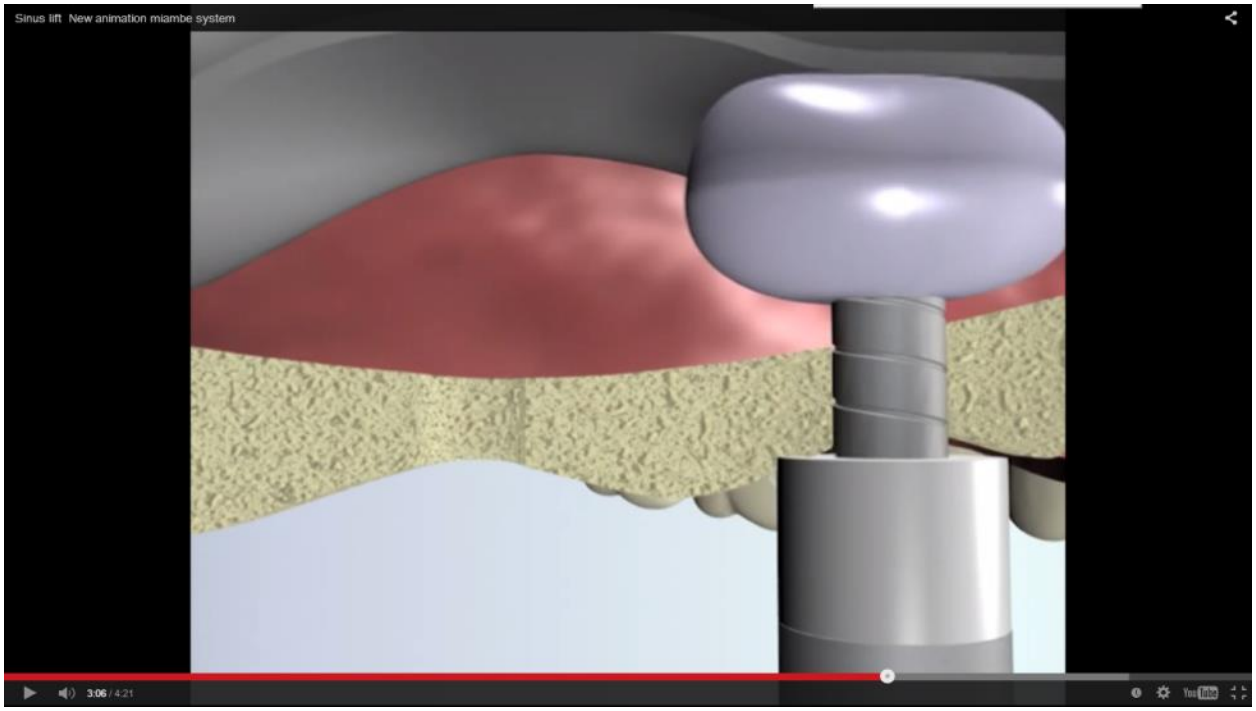
43. The Miambe Instructional Material shows a segment of the Schneiderian membrane displaced from a surface of the maxillary bone (*i.e.*, floor of the maxillary sinus or floor of the nasal cavity). This can be seen for example in Miambe's Animation (2:30-3:09). This feature can also be seen in the clinical picture from Miambe's website under the "Our Solution," discusses *supra*, demonstrating the presence of the balloon and the elevated Schneiderian membrane.

[17] http://www.miambeusa.com/sinusliftvideopg.html

44. The Miambe Instructional Materials further shows that the Schneiderian membrane was touching the surface of the maxillary bone before being displaced. Before surgery, the Schneiderian membrane is always touching the floor of the maxillary sinus in normal conditions. This can be seen for example in any anatomical textbook and also for example in Miambe's Animation. Below is a screenshot from Miambe's Animation (0:27) demonstrating the Schneiderian membrane touching the floor of the maxillary sinus before being elevated:



Below is a screenshot from Miambe's Animation (3:06) demonstrating that the Schneiderian membrane that was previously touching the maxillary bone is now elevated by the expanded balloon:



45. The Miambe Instructional Materials further shows that at least part of the expanded distal portion of the balloon is between the displaced segment of the Schneiderian membrane and the surface of the maxillary bone. This claim element can be seen for example in the Miambe's Instructions:

> "The balloon should be left inflated for 5 minutes in the sinus to reduce the membrane elastic recoil."[18]

Miambe's Instructions direct maintain the expanded balloon between the elevated Schneiderian membrane and the maxillary bone to prevent the membrane from recoiling towards the bone. This element can also be seen for example in Miambe's Animation (3:06), *supra*, demonstrating that the expanded distal portion of the balloon is between the displaced segment of the Schneiderian membrane and the surface of the maxillary bone.

[18] *See* Exhibit B

Infringement of claim 2 of the '841 patent

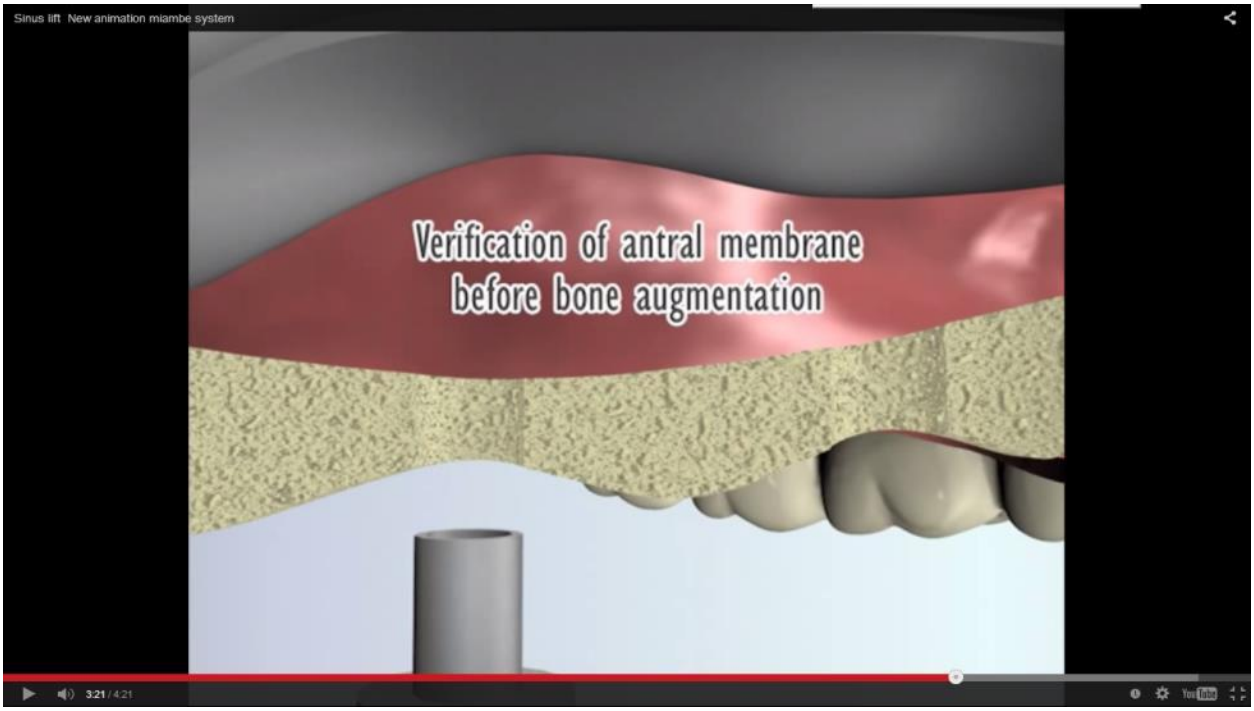
46. Dependent claim 2 recites: The method of claim 1, wherein the entire displaced Schneiderian membrane being free of perforations along the entire procedure.

47. The Miambe Instructional Material instructs verifying that the sinus membrane is free of perforation after forming the path of insertion, verifying that the membrane is free of perforation after inserting the cannula and expanding the container (balloon), evaluating membrane integrity after drilling by direct membrane visualization using a suction syringe, and evaluating membrane integrity after balloon removal, as recited in claim 2. This element can be seen for example in Miambe's Instructions:

> "3. After drilling, the membrane integrity is evaluated by direct membrane visualization using the suction syringe.
> 4. In case of Schneiderian membrane perforation abort the procedure….
> 5. …In case of Schneiderian membrane perforation abort the procedure….
> 10. After balloon removal evaluate membrane integrity…."[19]

This element can also be seen for example in Miambe's Animation and in the surgical videos on Miambe's website. Below is a screenshot from Miambe's Animation (3:21) instructing to verify the integrity of the Schneiderian membrane after elevation of the membrane:

[19] *See* Exhibit B



Infringement of claim 3 of the '841 patent

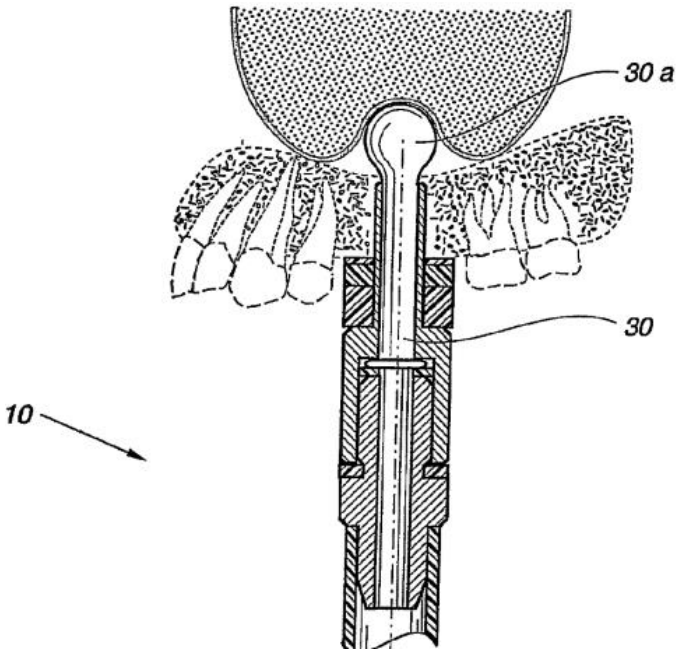
48. Dependent claim 3 recites: The method of claim 2, wherein at least part of said proximal portion of said container being inside said distal portion of said cannula while said distal portion of said container being expanded distally to said distal end of said cannula.

49. The Miambe Instructional Material instructs that the balloon is inflated with the indeflator and verifying the balloon enters into the metal sleeve cannula such that at least part of the proximal portion of the balloon is inside the distal portion of the cannula while the distal portion of the balloon is expanded distally to the distal end of the cannula, as recited in claim 3. This element can be seen for example in Miambe's Instructions:

> "Inflate the balloon with the indeflator (1-1.5 ml maximum) to verify its integrity and to reduce the pressure on the balloon when it emerges from the metal sleeve under the antral membrane (A-11). Then, aspirate the saline or the contrast fluid into the indeflator and verify that the balloon

> entered into the metal sleeve (emphasis in original).... In this phase the balloon emerges from the metal sleeve."[20]

50. The specification and figures of the '589 patent (Exhibit D) likewise illustrate that part of the balloon is inside the cannula while the balloon is inflated outside the cannula. Below is the upper part of Figure 5 from the '589 patent illustrating in cross section that the proximal part of the balloon (30) is inside the cannula while the distal part (30 a) of the balloon is inflated distally to the distal end of the cannula:



51. This element of claim 3 can be also seen in Miambe's Animation (2:07-3:09) and in the video "MIAMBE set up" from Miambe's website.[21]

[20] *See* Exhibit B

[21] http://www.miambe.com/video-1/ (1:45-2:30)

Infringement of claim 4 of the '841 patent

52. Dependent claim 4 recites: The method of claim 2, wherein said method includes the insertion of a dental implant through said path of insertion.

53. The Miambe Instructional Material instructs that the insertion of a dental implant through the path of insertion is recommended, as recited in claim 4. This element can be seen for example in Miambe's Instructions:

> "11…In case the original bone height is >4mm, it is possible to place an implant, provided that adequate primary stabilization can be obtained."[22]

This element can also be seen towards the end of Miambe's Animation (3:34-3:43).

Infringement of claim 5 of the '841 patent

54. Dependent claim 5 recites: The method of claim 3, wherein at least part of said distal portion of said container being inside said distal portion of said cannula before being expanded, said at least part of said distal portion of said container being advanced outside said distal portion of said cannula.

55. The Miambe Instructional Material instructs that at least part of the distal portion of the balloon is inside the distal portion of the metal sleeve cannula before being expanded, and that at least part of the distal portion of the balloon is advanced outside the distal portion of the metal sleeve cannula, as recited in claim 5. This element step is practiced in Miambe's method, as disclosed for example in the Miambe Instructional Material discussed *supra* regarding dependent claim 3.

[22] *See* Exhibit B

Infringement of claim 6 of the '841 patent

56. Dependent claim 6 recites: The method of claim 5, wherein said at least part of said distal portion of said container being advanced outside said distal portion of said cannula solely by the inflation of said container.

57. The Miambe Instructional Material instructs that at least part of the distal portion of the balloon is advanced outside the distal portion of the metal sleeve cannula by inflating of the balloon using the indeflator, as recited in claim 6. This element step is practiced in Miambe's method, as disclosed for example in the Miambe Instructional Material discussed *supra* regarding dependent claim 3.

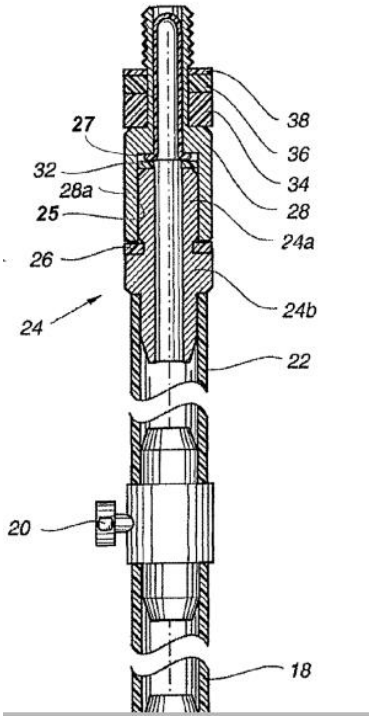
Infringement of claim 7 of the '841 patent

58. Dependent claim 7 recites: The method of claim 5, wherein the device further includes a connector, the connector has a proximal portion and a distal portion, said proximal portion of said connector being connected to said distal portion of said extension tube, said distal portion of said connector being connected to said proximal portion of said cannula.

59. The Miambe Instructional Material shows that the Miambe device includes a tube connector element, that the connector has a proximal portion and a distal portion, that the proximal portion of the connector is connected to the distal portion of the extension tube, and that the distal portion of the connector is connected to the proximal portion of the metal sleeve cannula, as recited in claim 7. This element can be seen for example in Miambe's Instructions:

> "Connect the balloon harboring device to the distal edge of the tubing."[23]

60. The specification and figures of the '589 patent (Exhibit D) likewise illustrate the internal connection between the cannula and the connector and the connection between the connector and the extension tube. Below is the upper part of Figure 2a from the '589 patent illustrating the connection of the connector, the cannula and the extension tube:



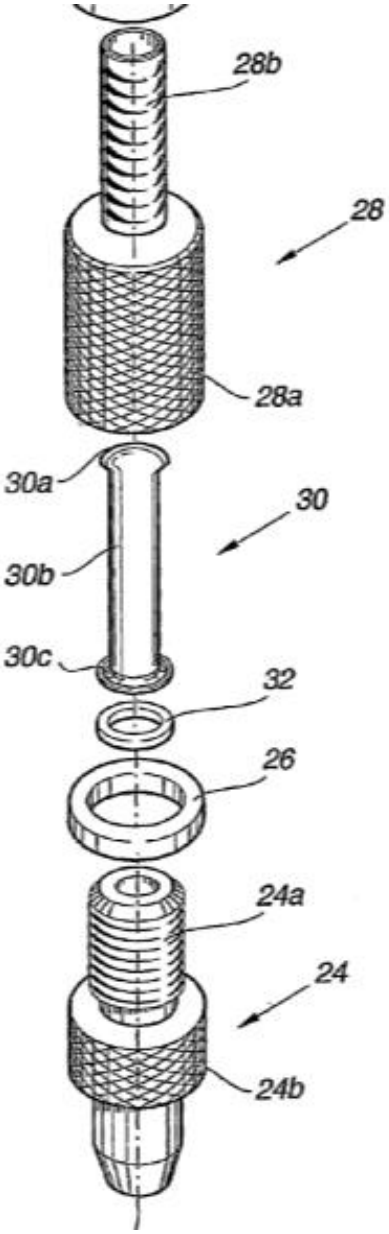
61. This element of dependent claim 7 can also be seen in Miambe's Animation (1:45-2:14) and in the video "MIAMBE set up" on Miambe's website.

[23] *See* Exhibit B

Infringement of claim 8 of the '841 patent

62. Dependent claim 8 recites: The method of claim 7, wherein said proximal portion of said cannula has an internal thread, said distal portion of said connector has an external thread, said distal portion of said connector being screwed inside said proximal portion of said cannula.

63. The specification and figures of the '589 patent (Exhibit D) show that in the Miambe device the proximal portion of the metal sleeve cannula has an internal thread, the distal portion of the tube connector element has an external thread, and the distal portion of the connector element is screwed inside the proximal portion of the metal sleeve cannula, as recited in claim 8. Below is the part of Figure 1 from the '589 patent illustrating the threads of the connector:



64. This element of dependent claim 8 can also be seen upon disassembling the balloon-harboring device, which is sold pre-assembled.

Infringement of claim 9 of the '841 patent

65. Dependent claim 9 recites: The method of claim 8, wherein the distal end of said connector being located proximally to the proximal end of said container.

66. The specification and figures of the ’589 patent (Exhibit D) show that the distal end of the tube connector element of the Miambe device is located proximally to the proximal end of the balloon, as recited in claim 9. This can be seen for example in Figure 2 of the ’589 patent shown *supra*. This element can also be seen upon disassembling the balloon-harboring device, which is sold pre-assembled.

Infringement of claim 10 of the ’841 patent

67. Dependent claim 10 recites: The method of claim 3, wherein said activating of said injecting element is advancing a flowable material inside said container, said flowable material is passing through and touching said proximal portion of said container proximally to said distal end of said cannula.

68. The Miambe Instructional Material shows that inflation of the balloon in the Miambe device is performed using the indeflator (injecting element) and advancing a flowable material such as saline or contrast fluid inside the balloon, the flowable material passing through and touching the proximal portion of the balloon proximally to the distal end of the metal sleeve cannula, as recited in claim 10. This step can be seen for example in Miambe’s Instructions:

> “Inflate the balloon with the indeflator.…
>
> In this phase the balloon emerges from the metal sleeve. The inflation is performed by slow rotation of the Indeflator's handle (0.2 bars every rotation)….
>
> At this point the balloon is to be slowly inflated to the desired elevation by gentle clockwise rotation of the Indeflator handle (0.10.2 ml each rotation)…”

69. The specification and figures of the '589 patent (Exhibit D) likewise illustrate the advancement of the flowable material from the indeflator through the plastic tubing and inside Miambe's balloon. Below is Figure 5 from the '589 patent illustrating this feature:

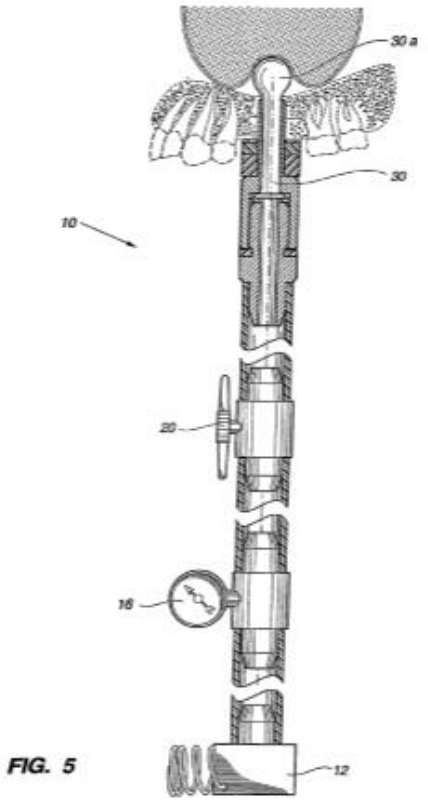


FIG. 5

70. This step of dependent claim 10 can also be seen in Miambe's Animation (1:51-2:05) and in the surgical videos on Miambe's website, for example, the video titled "MIAMBE set up."

Infringement of claim 11 of the '841 patent

71. Dependent claim 11 recites: The method of claim 3, wherein said at least part of said proximal portion of said container being fixated inside said cannula during the entire surgical procedure.

72. The Miambe Instructional Material instructs that the balloon is inflated using the indeflator to verify integrity of the balloon when it emerges from the metal sleeve cannula, and further shows that at least part of the proximal portion of the balloon is fixated inside the metal sleeve cannula during the entire surgical procedure, as recited in claim 11. This element can also be seen in Miambe's Animation (2:20-3:09) and in the video titled "MIAMBE set up" on Miambe's website.

73. The specification and figures of the '589 patent (Exhibit D) likewise illustrate the fixation of the balloon inside the cannula by the connector. Figure 5 of the '589 patent shown *supra* illustrates this element. This element can be also seen after disassembling the balloon-harboring device, which is sold pre-assembled.

Infringement of claim 14 of the '841 patent

74. Independent claim 14 recites: A method for displacing the Schneiderian membrane from the maxillary bone comprising: Forming a path of insertion through the alveolar ridge of said maxillary bone towards said Schneiderian membrane; inserting through said path of insertion a hollow cannula, said cannula being part of a device, said device further includes an expandable inflatable container, an extension tube and injecting element, at least part of said container being inside said cannula, said extension tube has a proximal portion and a distal

portion, said proximal portion of said extension tube being located proximally to said cannula, said proximal portion of said extension tube being connected to said injecting element; activating said injecting element to inflate through said extension tube said container so said at least part of said container is expanded and advanced from inside said cannula to be distally to the distal end of said cannula inside said maxillary bone to displace a segment of said Schneiderian membrane from a surface of said maxillary bone, said segment of said Schneiderian membrane was touching said surface before being displaced, said surface is selected from the group consisting of the floor of the maxillary sinus and the floor of the nasal cavity.

75. The Miambe Instructional Material demonstrates that the Miambe device and method are intended for displacing the Schneiderian membrane from the maxillary bone as recited in claim 14. *See supra* independent claim 1.

76. The Miambe Instructional Material shows drilling through the alveolar crest until exposure of the antral membrane (called also Schneiderian membrane), and inserting a metal sleeve cannula of a balloon-harboring device into the osteotomy. *See supra* independent claim 1.

77. The Miambe Instructional Material shows that the Miambe device includes an injecting element (indeflator), cannula, balloon (expandable inflatable container), connector, and extension tube, and further instructs that the Miambe device is prepared by cutting the distal edge of the plastic tube (extension tube), connecting the plastic tube to an indeflator (injecting element), injecting saline with the indeflator until the saline emerges from the distal end of the plastic tube and connecting the balloon harboring device to the distal edge of the plastic tube. *See supra* independent claim 1.

78. The Miambe Instructional Material further shows that the Schneiderian membrane elevation is controlled with the balloon by rotation of the indeflator until the desired elevation, as recited in claim 14. *See supra* independent claim 1.

79. The Miambe Instructional Materials further shows that the Schneiderian membrane was touching the surface of the maxillary bone before being displaced. *See supra* independent claim 1.

Infringement of claim 15 of the '841 patent

80. Dependent claim 15 recites: The method of claim 14, wherein the entire displaced Schneiderian membrane being free of perforations along the entire procedure.

81. The Miambe Instructional Material instructs verifying that the membrane is free of perforation after forming the path of insertion, verifying that the membrane is free of perforation after inserting the cannula and expanding the balloon (expandable inflatable container), evaluating membrane integrity after drilling by direct membrane visualization using a suction syringe, and evaluating membrane integrity after balloon removal, as recited in claim 15. *See supra* dependent claim 2.

Infringement of claim 16 of the '841 patent

82. Dependent claim 16 recites: The method of claim 15, wherein said container has a proximal portion and a distal portion, said proximal portion of said container being inside said distal portion of said cannula while said distal portion of said container being expanded distally to said distal end of said cannula.

83. The Miambe Instructional Material instructs that the balloon is inflated with the indeflator and verifying the balloon enters into the metal sleeve cannula such that at least part of the proximal portion of the balloon is inside the distal portion of the cannula while the distal portion of the balloon is expanded distally to the distal end of the cannula, as recited in claim 16. *See supra* dependent claim 3.

Infringement of claim 17 of the '841 patent

84. Dependent claim 17 recites: The method of claim 15, wherein said at least part of said container being advanced outside said cannula solely by the inflation of said container.

85. The Miambe Instructional Material instructs that at least part of the balloon is advanced outside the metal sleeve cannula by inflating of the balloon using the indeflator, as recited in claim 17. *See supra* dependent claim 3.

Infringement of claim 18 of the '841 patent

86. Dependent claim 18 recites: The method of claim 15, wherein said device further includes a connector, said connector has a proximal portion and a distal portion, said cannula has a proximal portion and a distal portion, said proximal portion of said connector being connected to said distal portion of said extension tube, said distal portion of said connector being connected to said proximal portion of said cannula.

87. The Miambe Instructional Material shows that the Miambe device includes a tube connector element, that the connector has a proximal portion and a distal portion, that the metal sleeve cannula has a proximal portion and a distal portion, that the proximal portion of the connector is connected to the distal portion of the extension tube, and that the distal portion of

the connector is connected to the proximal portion of the metal sleeve cannula, as recited in claim 18. *See supra* dependent claim 7.

Infringement of claim 19 of the '841 patent

88. Dependent claim 19 recites: The method of claim 18, wherein said proximal portion of said cannula has an internal thread, said distal portion of said connector has an external thread, said distal portion of said connector being screwed inside said proximal portion of said cannula.

89. The Miambe Instructional Material shows that in the Miambe device the proximal portion of the metal sleeve cannula has an internal thread, the distal portion of the tube connector element has an external thread, and the distal portion of the connector element is screwed inside the proximal portion of the metal sleeve cannula, as recited in claim 19. *See supra* dependent claim 8.

Infringement of claim 20 of the '841 patent

90. Dependent claim 20 recites: The method of claim 19, wherein the distal end of said connector being located proximally to the proximal end of said container, said proximal portion of said cannula being proximally to said alveolar ridge.

91. The Miambe Instructional Material shows that the distal end of the tube connector element of the Miambe device is located proximally to the proximal end of the balloon, and that the proximal portion of the metal sleeve cannula is proximal to the alveolar ridge, as recited in claim 20. *See supra* dependent claim 9. This element can also be seen for example in Miambe's

Animation (2:07-2:51) and in the surgical video titled "MIAMBE Sinus Lift controlled with Balloon" (0:04-0:58).

92. The specification and figures of the '589 patent (Exhibit D) likewise illustrate that the distal end of the connector is located proximally to the proximal end of the container and the proximal portion of the cannula is located proximally to the alveolar ridge. This element can also be seen for example in Figure 5 from the '589 patent *supra*.

Infringement of claim 21 of the '841 patent

93. Dependent claim 21 recites: The method of claim 14, wherein said activating of said injecting element is advancing a flowable material inside said container, said flowable material is touching said container proximally to said distal end of said cannula.

94. The Miambe Instructional Material shows that inflation of the balloon in the Miambe device is performed using the indeflator and advancing a flowable material such as saline or contrast fluid inside the balloon, the flowable material touching the balloon proximally to the distal end of the metal sleeve cannula, as recited in claim 21. *See supra* dependent claim 10.

Infringement of claim 22 of the '841 patent

95. Independent claim 22 recites: A method for displacing the Schneiderian membrane from the maxillary bone comprising: Forming a path of insertion through the alveolar ridge of said maxillary bone towards said Schneiderian membrane; inserting through said path of insertion a hollow cannula, said cannula being part of a device, said device further includes an expandable inflatable container, an extension tube and injecting element, said container has a

proximal portion and a distal portion, said proximal portion of said container being inside said cannula, said extension tube has a proximal portion and a distal portion, said proximal portion of said extension tube being located proximally to said cannula, said proximal portion of said extension tube being connected to said injecting element; activating said injecting element to advance a flowable material through said extension tube into said container so said flowable material is touching said proximal portion of said container inside said cannula, said distal portion of said container being expanded distally to the distal end of said cannula inside said maxillary bone to displace a segment of said Schneiderian membrane from a surface of said maxillary bone, said segment of said Schneiderian membrane was touching said surface before being displaced, said surface is selected from the group consisting of the floor of the maxillary sinus and the floor of the nasal cavity.

96. The Miambe Instructional Material demonstrate that the Miambe device and method are intended for displacing the Schneiderian membrane from the maxillary bone as recited in claim 22. *See supra* independent claim 1.

97. The Miambe Instructional Material shows drilling through the alveolar crest until exposure of the antral membrane (The Schneiderian membrane), and inserting a metal sleeve cannula of a balloon-harboring device into the osteotomy. *See supra* independent claim 1.

98. The Miambe Instructional Material shows that the Miambe device includes an injecting element (indeflator), cannula, balloon (expandable inflatable container), connector, and extension tube, and further instructs that the Miambe device is prepared by cutting the distal edge of the plastic tube, connecting the plastic tube to an indeflator, injecting saline with the indeflator

until the saline emerges from the distal end of the plastic tube and connecting the balloon-harboring device to the distal edge of the plastic tube. *See supra* independent claim 1.

99. The Miambe Instructional Material shows activating the injecting element to advance the flowable material through the plastic tubing into the balloon so the flowable material is touching the proximal portion of the balloon inside the cannula. *See supra* dependent claim 10.

100. The Miambe Instructional Material further shows that the elevation of the sinus membrane (Schneiderian membrane) is controlled with the balloon by rotation of the indeflator until the desired elevation, as recited in claim 22. *See supra* independent claim 1.

101. The Miambe Instructional Materials further shows that the Schneiderian membrane was touching the surface of the maxillary bone before being displaced. *See supra* independent claim 1.

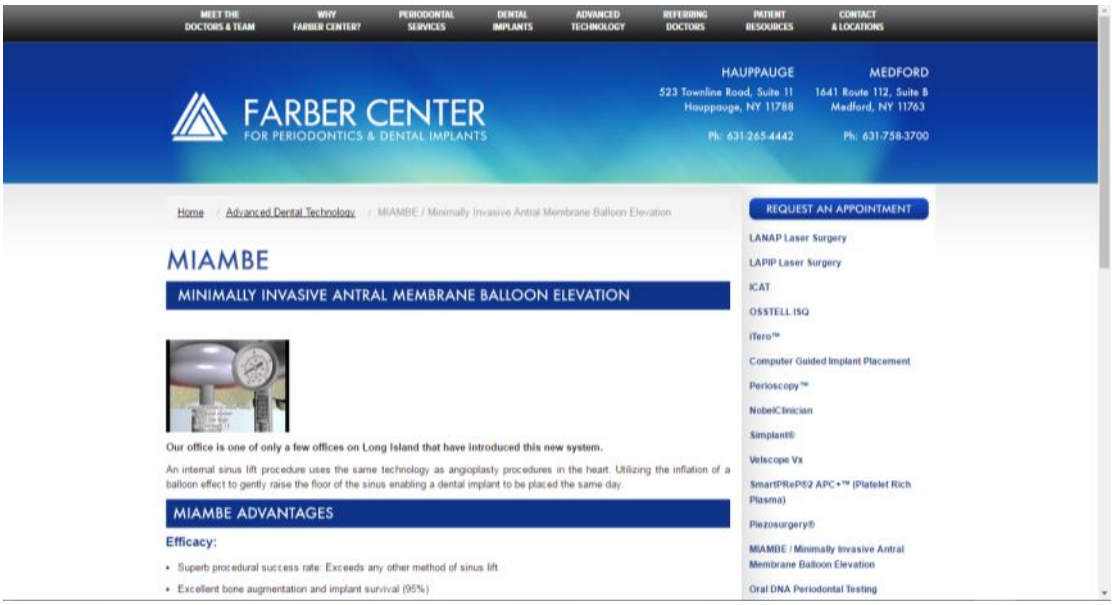
Active inducement

102. Miambe actively induces dentists and other health-care professionals to infringe the '841 patent, by among other things, (a) selling, distributing, and/or offering to sell and distribute its sinus lift kits for use in sinus augmentation procedures according to its minimally invasive antral membrane balloon elevation procedure and system; (b) providing instructions for using such kits in practicing its minimally invasive antral membrane balloon elevation procedure; and (c) marketing, performing promotional activities and providing advertising for using such kits in practicing its minimally invasive antral membrane balloon elevation procedure. Miambe has had knowledge of the claims as issued in the '841 patent since no later than 2011 in connection with a litigation between Dr. Karmon and Miambe in Israel. Miambe

engages in the foregoing activities because it specifically intends that dentists and other health-care professionals use its sinus lift kits to perform its minimally invasive antral membrane balloon elevation procedure, which is covered by the '841 patent. Miambe has acted with knowledge or with willful blindness that the induced acts constitute infringement of the '841 patent. Miambe thereby specifically intends dentists and other health-care professionals to infringe the '841 patent.

103. Below is a screenshot from the website of a New York dental clinic advertising and promoting use of Miambe method and device and incorporating pictures and text from the Miambe website.[24] According to the website:

> "Utilizing the inflation of a balloon effect to gently raise the floor of the sinus…"



104. Miambe has also conducted courses and hands-on training using the Miambe method and device. Attached hereto as Exhibit E are screenshots from Miambe's Facebook page

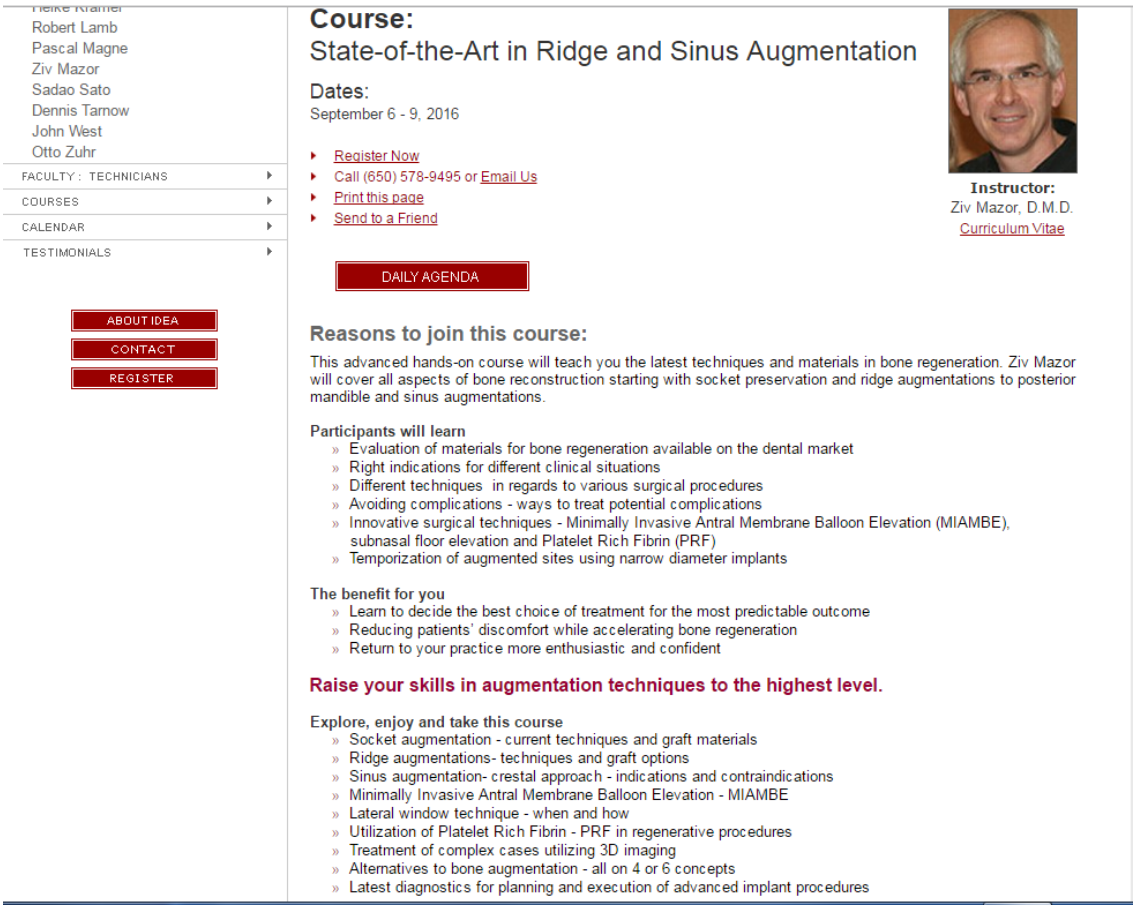
[24] http://www.longislandperio.com/technology/miambe-minimally-invasive-antral-membrane-balloon-elevation/

reporting on its participation in professional conferences and lectures in the United States. The Facebook page states:

> "MIAMBE attended The Midwest Society of Periodontology! Dr. Ziv Mazor, world renowned periodontics, lectured the State of the Art in Sinus Augmentation and the advantages of using the MIAMBE technique."
>
> "Come and join MIAMBE and the xperts at the 2013 Dentalxp Global Symposium with hands on courses all day Thursday February 7th, 2013."

105. Dr. Ziv Mazor, a Miambe Ltd. shareholder, is also expected to conduct a hands-on course on ridge and sinus augmentation in San Francisco on September 6-9, 2016, which will include a lecture on the Miambe method. Below is a screenshot from the U.S. website of the Interdisciplinary Dental Education Academy (IDEA):[25]

[25] http://www.ideausa.net/lecturers_courses_details.asp?guid=%7B0B002FCC-9EEE-4F79-8ACF-137D69713793%7D



106. Miambe also advertises its surgical method in professional magazines in the United States. Attached hereto as Exhibit F is a Miambe advertisement in The Journal of Implant & Advanced Clinical Dentistry.

107. Miambe's website includes videos of actual surgeries instructing dentists how to perform the Miambe method, and Defendant Dr. Efraim Kfir's name appears on these videos. Below is a screenshot from one of these videos:[26]

[26] http://www.miambe.com/video-2/

The screenshot is from Miambe's video titled "MIAMBE sinus lift controlled with balloon." The screenshot shows the cannula, harboring the balloon, before being inserted through the osteotomies in the alveolar ridge (timeframe 0:06).

Thus, Defendant Dr. Kfir is personally active in specifically inducing dentists and other health-care professionals to infringe the '841 patent. Attached hereto as Exhibit G, is a screenshot from Miambe's website describing Dr. Kfir.

Contributory infringement

108. Miambe also contributorily infringes the '841 patent because there is no substantial non-infringing use for its sinus lift kits.

109. Miambe has derived and received and will continue to derive and receive gains, profits, advantages and revenue from the aforesaid acts of infringement and sale of its sinus lift kits and the third-party infringers' infringing activities in an amount that is not presently known to Dr. Karmon.

110. Miambe's infringing activities are without the consent of, authority of or license from Dr. Karmon.

111. Miambe's infringement will continue unless enjoined by this court.

112. Dr. Karmon has been damaged as a result of the infringing conduct by Miambe alleged above and, thus, Miambe is liable to Dr. Karmon in an amount that adequately compensates Dr. Karmon for such infringements, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

Willful infringement

113. Miambe has had notice of the '841 patent, or the underlying patent application with the claims as issued in the '841 patent, since no later than 2011. Accordingly, Miambe is also liable to Dr. Karmon for a reasonable royalty that adequately compensates Dr. Karmon for Miambe's infringement during the period between the Publication Date and the issuance of the '841 patent under 35 U.S.C. §154(d).

114. Miambe's infringements occurred and continue to occur with knowledge of and/or objective recklessness and thus has been and continues to be willful and deliberate. Miambe's willful and deliberate infringement entitles Dr. Karmon to enhanced damages under 35 U.S.C. §285.

115. This case is "exceptional" within the meaning of 35 U.S.C. §285, and Dr. Karmon is entitled to an award of attorneys' fees.

JURY DEMAND

Dr. Karmon hereby requests a trial by jury on all issues so triable by right.

DEMAND FOR RELIEF

Dr. Karmon requests that the Court find in its favor and against Miambe, and that the Court grant Dr. Karmon the following relief:

a. Judgment that one or more claims of the '841 patent have been infringed, either literally and/or under the doctrine of equivalents, by Miambe and/or by others to whose infringement defendants have contributed and/or by others whose infringement have been actively induced by Miambe;

b. Judgment that Miambe's infringement has been willful;

c. A permanent injunction enjoining Miambe and its respective officers, directors, agents, servants, affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting in active concert therewith from infringement, inducing infringement of, or contributing to infringement of the '841 patent;

d. Judgment that Miambe account for and pay to Dr. Karmon all damages to and costs incurred by Dr. Karmon because of Miambe's infringing activities including treble damages for willful infringement and other conduct complained of herein;

e. That Dr. Karmon be granted pre-judgment and post-judgment interest on the damages caused by Miambe's infringing activities and other conduct complained of herein;

f. That the Court declare this to be an exceptional case and award Dr. Karmon his reasonable attorney's fees and costs in accordance with 35 U.S.C. § 285; and

g. That Dr. Karmon be granted such other and further relief as the Court may deem just and proper under the circumstances.

RESPECTFULLY SUBMITTED,

June 10, 2016

/s/ Daniel J. Melman
Daniel J. Melman (DM-8239)
Guy Yonay (GY-3028)
PEARL COHENZEDEK LATZER BARATZ LLP
1500 Broadway, 12th Floor
New York, NY 10036
(646) 878-0800
DMelman@PearlCohen.com
GYonay@PearlCohen.com

Attorneys for Plaintiff Ben-Zion Karmon