CLEAN CLAIM SET

1. A method of treating a sinus condition, comprising a) providing first and second implants, each comprising at least one coating containing about 7500 micrograms of mometasone furoate, and wherein the first implant is configured to fit inside a first middle meatus of a patient, and wherein the second implant is configured to fit inside a second middle meatus of said patient; b) implanting said first and second implants in a first and second middle meatus of a patient with symptoms of a sinus condition, and c) detecting a reduction in one or more symptoms, thereby treating said sinus condition.

2. The method of claim 1, wherein the mometasone furoate configured in each implant exhibits a zero-order release for 12 weeks or more of a planned implantation period.

3. The method of claim 1, wherein said reduction in one or more symptoms is reflected in a SNOT score.

4. The method of claim 1, wherein said sinus condition is a chronic sinus condition.

5. The method of claim 1, wherein said sinus condition is characterized by at least two symptoms selected from the group consisting of nasal obstruction, nasal congestion, difficulty breathing through nasal passages, nasal polyp, nasal discharge, loss of smell, and facial pain.

6. The method of claim 1, wherein said sinus condition is characterized by two or more symptoms lasting at least 12 weeks selected from the group consisting of nasal discharge, nasal obstruction or congestion, hyposmia, and facial pressure or pain.

7. The method of claim 1, wherein at least one of said first or second implants is a braided structure.

8. The method of claim 1, wherein at least one of said first or second implants is a tubular structure.

9. The method of claim 1, wherein at least one of said first or second implants is self-expanding.

10. The method of claim 1, wherein at least one of said first or second implants is configured as a sheet.

11. The method of claim 9, wherein at least one of said first or second implants is configured as a rolled sheet.

12. The method of claim 3, wherein said reduction comprises an improvement in a SNOT-22 scores by 50% at week 24 of the implantation period.

13. The method of claim 1, wherein said reduction comprises no symptoms at week 24 of the implantation period.

14. An implant configured to fit inside the middle meatus for preventing the need for surgery in a subject who is a candidate for sinus surgery, said implant comprising a coating comprising about 7500 micrograms of mometasone furoate, said implant configured to exhibit a zero-order release for at least 60% of said mometasone furoate, characterized in that the implant is delivered to the subject prior to surgery.

15. The implant of claim 14, wherein the subject is treated for at least 4 months.

16. The implant of claim 14, wherein said implant is configured to release 20 to 80% of said mometasone furoate during the first 12 weeks.

17. The implant of claim 14, wherein said zero-order release is exhibited in vitro in pH 7.4 PBS buffer containing 2% SDS at 37°C.

18. The implant of claim 14, wherein said implant is for use in a method of treating a chronic sinus condition.

19. The implant of claim 18, wherein said chronic sinus condition is characterized by at least two symptoms selected from the group consisting of nasal obstruction, nasal congestion, difficulty breathing through nasal passages, nasal polyp, nasal discharge, and facial pain.

20. The implant of claim 14, wherein said implant is a braided structure.

21. The implant of claim 14, wherein said implant is a tubular structure.

22. The implant of claim 14, wherein said implant is self-expanding.

23. The implant of claim 14, wherein said implant has a diameter of at least 13mm.

24. The implant of claim 14, wherein said implant has a length of at least 10mm.

25. A method of treating a sinus condition, a) implanting first and second implants in a first and second middle meatus of a patient with a sinus condition wherein said patient is a candidate for sinus surgery, each implant comprising at least one coating containing about 7500 micrograms of mometasone furoate, and b) detecting a reduction in one or more symptoms, wherein after 20 weeks said patient is no longer a candidate for sinus surgery, thereby treating said sinus condition.

26. The method of claim 25, wherein said patient is a candidate for sinus surgery based on a SNOT score of symptoms.

27. The method of claim 25, said patient is no longer a candidate for sinus surgery based on a SNOT score.

28. The method of claim 25, wherein said patient is no longer a candidate for sinus surgery based on the 3 cardinal symptom composite score (3CS), which includes nasal blockage, facial pain/pressure, and nasal discharge.

29. The method of claim 25, wherein said patient is no longer a candidate for sinus surgery where $3CS \leq 4$.

30. A combination of implants for preventing the need for surgery in a subject who is a candidate for sinus surgery, comprising first and second implants, each comprising at least one coating containing about 7500 micrograms of mometasone furoate, wherein the first implant is configured to fit inside a first middle meatus of the subject, the mometasone furoate configured to have a zero-order release for more than 12 weeks; and wherein the second implant is configured to fit inside a second middle meatus of said subject, the mometasone furoate configured to have a zero-order release for more than 12 weeks, characterized in that the combination is delivered to the subject prior to surgery, wherein the subject is treated for at least 4 months.

31. The combination of claim 30, wherein said subject is a candidate for Functional Endoscopic Sinus surgery (FESS).

32. The combination of claim 30, wherein said first and second implants are configured to release 20 to 80% of said mometasone furoate during the first 12 weeks.

33. The combination of claim 30, wherein said each of said first and second implants is configured to exhibit a zero-order release after week 1.

34. The combination of claim 30, wherein said zero-order release is exhibited in vitro in pH 7.4 PBS buffer containing 2% SDS at 37°C.

35. The combination of claim 30, wherein said combination is for use in a method of treating a chronic sinus condition.

36. The combination of claim 35, wherein said chronic sinus condition is characterized by at least two symptoms selected from the group consisting of nasal obstruction, nasal congestion, difficulty breathing through nasal passages, nasal polyp, nasal discharge, and facial pain.

37. The combination of claim 30, wherein at least one of said first or second implants is a braided structure.

38. The combination of claim 30, wherein at least one of said first or second implants is a tubular structure.

39. The combination of claim 30, wherein at least one of said first or second implants comprises helical strands.

40. The combination of claim 30, wherein at least one of said first or second implants is self-expanding.

41. A method of treating a sinus condition, comprising:

a) providing first and second implants, each comprising about 7500 micrograms of mometasone furoate;

b) implanting said first implant inside a first middle meatus of a first patient having a sinus condition;

c) implanting said second implant inside a second middle meatus of said first patient; and

d) monitoring the first patient's sinus condition for a period of at least 12 weeks, wherein the first patient implanted with first and second implants each comprising about 7500 micrograms of mometasone furoate exhibits a reduction in the need for rescue treatment when compared to a second patient having a sinus condition implanted with first and second implants each comprising about 2500 micrograms of mometasone furoate.

42. The method of claim 41, wherein said first and second implants are configured to release 20 to 80% of said mometasone furoate during the first 12 weeks.

43. The method of claim 41, wherein the sinus condition of said first patient improves more quickly than a second patient implanted with first and second implants comprising 2500 micrograms of mometasone furoate.

44. The method of claim 41, wherein said sinus condition is a chronic sinus condition.

45. The method of claim 41, wherein said sinus condition is characterized by at least two symptoms selected from the group consisting of nasal obstruction, nasal congestion, difficulty breathing through nasal passages, nasal polyp, nasal discharge, loss of smell, and facial pain.

46. The method of claim 41, wherein at least one of said first or second implants is a braided structure.

47. The method of claim 41, wherein at least one of said first or second implants is a tubular structure.

48. The method of claim 41, wherein at least one of said first or second implants is self-expanding.

49. The method of claim 41, wherein said implant comprises helical strands.

50. The method of claim 41, wherein said monitoring of the first patient's sinus condition is done for a period of at least 16 weeks.

51. The method of claim 41, wherein said monitoring of the first patient's sinus condition is done for a period of at least 20 weeks.

52. The method of claim 41, wherein said first and second implants each comprise at least one coating, said coating containing about 7500 micrograms of mometasone furoate.

53. A method of treating a sinus condition, comprising:

a) providing first and second implants, each comprising about 7500 micrograms of mometasone furoate;

b) implanting said first implant inside a first middle meatus of a first patient having a sinus condition;

c) implanting said second implant inside a second middle meatus of said first patient; and

d) monitoring the first patient's sinus condition for a period of at least 12 weeks, wherein the first patient implanted with first and second implants each comprising about 7500 micrograms of mometasone furoate exhibits a reduction in the need for rescue treatment when compared to a second patient having a sinus condition given only saline irrigation treatment and no mometasone furoate.

54. The method of claim 53, wherein said first and second implants are configured to release 20 to 80% of said mometasone furoate during the first 12 weeks.

55. The method of claim 53, wherein the sinus condition of said first patient improves when compared to said second patient.

56. The method of claim 53, wherein said sinus condition is a chronic sinus condition.

57. The method of claim 53, wherein said sinus condition is characterized by at least two symptoms selected from the group consisting of nasal obstruction, nasal congestion, difficulty breathing through nasal passages, nasal polyp, nasal discharge, loss of smell and facial pain.

58. The method of claim 53, wherein at least one of said first or second implants is a braided structure.

59. The method of claim 53, wherein at least one of said first or second implants is a tubular structure.

60. The method of claim 53, wherein at least one of said first or second implants is self-expanding.

61. The method of claim 53, wherein said implant comprises helical strands.

62. The method of claim 53, wherein said monitoring of the first patient's sinus condition is done for a period of at least 16 weeks.

63. The method of claim 53, wherein said monitoring of the first patient's sinus condition is done for a period of at least 20 weeks.

64. The method of claim 53, wherein said first and second implants each comprise at least one coating, said coating containing about 7500 micrograms of mometasone furoate.

65. A method of treating a sinus condition, comprising:

a) providing first and second implants, each comprising about 7500 micrograms of mometasone furoate;
b) implanting said first implant inside a first middle meatus of a first patient having a sinus condition;
c) implanting said second implant inside a second middle meatus of said first patient; and
d) monitoring the first patient's sinus condition for a period of at least 8 weeks, wherein the first patient implanted with first and second implants each comprising about 7500 micrograms of mometasone furoate improves more quickly than a second patient with a sinus condition implanted with first and second implants each comprising about 2500 micrograms of mometasone furoate.

66. The method of claim 65, wherein said improvement in the first patient implanted with first and second implants each comprising about 7500 micrograms of mometasone furoate, as compared to the second patient implanted with first and second implants each comprising about 2500 micrograms of mometasone furoate, is observed at least as early as 8 weeks after implantation of said implants.

67. The method of claim 65, wherein said first and second implants are configured to release 20 to 80% of said mometasone furoate during the first 12 weeks.

68. The method of claim 65, wherein said sinus condition is a chronic sinus condition.

69. The method of claim 65, wherein said sinus condition is characterized by at least two symptoms selected from the group consisting of nasal obstruction, nasal congestion, difficulty breathing through nasal passages, nasal polyp, nasal discharge, loss of smell and facial pain.

70. The method of claim 65, wherein at least one of said first or second implants is a braided structure.

71. The method of claim 65, wherein at least one of said first or second implants is a tubular structure.

72. The therapy of claim 65, wherein at least one of said first or second implants is self-expanding.

73. The method of claim 65, wherein said monitoring of the first patient's sinus condition is done for a period of at least 16 weeks.

74. The method of claim 65, wherein said monitoring of the first patient's sinus condition is done for a period of at least 20 weeks.

75. The method of claim 65, wherein said first and second implants each comprise at least one coating, said coating containing about 7500 micrograms of mometasone furoate.

76. The method of claim 65, wherein said implant comprises helical strands.

77. The method of claim 65, wherein said first patient is a patient with nasal polyps.

78. The method of claim 65, wherein said 7500μg implants reduced rescue treatment use for said first patient.

79. The method of claim 65, wherein said 7500μg implants reduced radiographic ethmoid opacification at week 24 in said first patient.

80. The method of claim 65, further comprising e) measuring plasma concentrations of mometasone furoate in said first patient.

81. The method of claim 80, wherein said patient displayed dose-dependent plasma concentrations.

82. The method of claim 81, wherein said patient displayed said dose-dependent plasma concentrations for 56-days.

83. A self-expanding implantable device comprising about 7500 micrograms of mometasone furoate.

84. The device of claim 83, wherein the device is a braided structure.

85. The device of claim 83, wherein the device is a tubular structure.

86. The device of claim 83, wherein the device comprises helical strands.

87. The device of claim 83, wherein the device comprises at least one coating, said coating containing about 7500 micrograms of mometasone furoate.

88. The device of claim 83, wherein the device is configured to conform to the middle meatus space.

89. A method of treating a sinus condition, comprising:

a) providing first and second implants, each comprising mometasone furoate;

b) implanting said first implant inside a first middle meatus of a patient having a sinus condition;

c) implanting said second implant inside a second middle meatus of said patient;

d) removing said first and second implants from said patient; and

e) detecting improvement in said patient's sinus condition after said implants are removed for a period of at least 4 weeks.

90. The method of Claim 89, wherein the patient is implanted with first and second implants each comprising about 7500 micrograms of mometasone furoate.

91. The method of Claim 89, wherein the patient is implanted with first and second implants each comprising about 2500 micrograms of mometasone furoate.

92. The method of Claim 89, wherein said improvement detected in said patient's sinus condition is reduced nasal blockage, facial pain, nasal discharge (anterior/posterior), and/or loss of smell.

93. The method of Claim 89, wherein said patient's condition continues to improve for a period of at least 8 weeks after the implants are removed.

94. The method of Claim 89, wherein said patient's condition continues to improve for a period of at least 12 weeks after the implants are removed.

95. The method of Claim 89, wherein said patient's condition continues to improve for a period of at least 16 weeks after the implants are removed.

96. The method of Claim 89, wherein said implants are removed after 24 weeks.

97. A combination of implants for use in the treatment of a sinus conditions, comprising first and second implants, each comprising i) at least one drug-containing coating containing over 7500 micrograms of mometasone furoate and ii) a topcoat layer,
wherein the first implant is configured to fit inside a first middle meatus of a patient,
wherein the second implant is configured to fit inside a second middle meatus of a patient,
wherein said first and second implants are configured to remain implanted for at least 24 weeks.

98. The therapy combination of implants of claim 97, wherein at least one of said first or second implants is a braided structure.

99. The therapy combination of implants of claim 97, wherein at least one of said first or second implants is a tubular structure.

100. The therapy combination of implants of claim 97, wherein at least one of said first or second implants comprises helical strands.

101. The therapy combination of implants of claim 97, wherein at least one of said first or second implants is self-expanding.

102. The therapy combination of implants of claim 97, wherein at least one of said first or second implants is a rolled sheet.

CLAIMS

1. An implant configured to fit inside the middle meatus for preventing the need for surgery in a subject who is a candidate for sinus surgery, the implant comprising a coating comprising about 7500 micrograms of mometasone furoate, the implant configured to exhibit a zero-order release for at least 60% of the mometasone furoate, characterized in that the implant is adapted to be delivered to the subject prior to surgery.

2. An implant according to Claim 1, in which the subject is to be treated for at least 4 months.

3. An implant according to Claim 1, in which the implant is configured to release 20 to 80% of the mometasone furoate during the first 12 weeks.

4. An implant according to Claim 1, in which the zero-order release is exhibited in vitro in pH 7.4 PBS buffer containing 2% SDS at 37ºC.

5. An implant according to Claim 1, in which the implant is for use in a method of treating a chronic sinus condition.

6. An implant according to Claim 5, in which the chronic sinus condition is characterized by at least two symptoms selected from the group consisting of nasal obstruction, nasal congestion, difficulty breathing through nasal passages, nasal polyp, nasal discharge, and facial pain.

7. An implant according to Claim 1, in which the implant:

(a) is a braided structure;

(b) is a tubular structure;

(c) is self-expanding;

(d) has a diameter of at least 13mm; and/or

(e) has a length of at least 10mm.

8. A combination of implants for preventing the need for surgery in a subject who is a candidate for sinus surgery, comprising first and second implants, each comprising at least one coating containing about 7500 micrograms of mometasone furoate, in which the first implant is configured to fit inside a first middle meatus of the subject, the mometasone furoate

configured to have a zero-order release for more than 12 weeks; and in which the second implant is configured to fit inside a second middle meatus of the subject, the mometasone furoate configured to have a zero-order release for more than 12 weeks, characterized in that the combination is to be delivered to the subject prior to surgery, in which the subject is to be treated for at least 4 months.

9. A combination according to Claim 8, in which the subject is a candidate for Functional Endoscopic Sinus surgery (FESS).

10. A combination according to Claim 8, in which the first and second implants are configured to release 20 to 80% of the mometasone furoate during the first 12 weeks.

11. A combination according to Claim 8, in which the each of the first and second implants is configured to exhibit a zero-order release after week 1.

12. A combination according to Claim 8, in which the zero-order release is exhibited in vitro in pH 7.4 PBS buffer containing 2% SDS at 37^{o}C.

13. A combination according to Claim 8, in which the combination is for use in a method of treating a chronic sinus condition.

14. A combination according to Claim 13, in which the chronic sinus condition is characterized by at least two symptoms selected from the group consisting of nasal obstruction, nasal congestion, difficulty breathing through nasal passages, nasal polyp, nasal discharge, and facial pain.

15. A combination according to Claim 12, in which at least one of the first or second implants:

(a) is a braided structure;

(b) is a tubular structure;

(c) comprises helical strands; and/or

(d) is self-expanding.

16. A self-expanding implantable device comprising about 7500 micrograms of mometasone furoate.

17. A device according to Claim 16, in which the device:

(a) is a braided structure;

(b) is a tubular structure; and/or

(c) comprises helical strands.

18. A device according to Claim 16, in which the device comprises at least one coating, the coating containing about 7500 micrograms of mometasone furoate.

19. A device according to Claim 16, in which the device is configured to conform to the middle meatus space.

20. A combination of implants for use in the treatment of a sinus conditions, comprising first and second implants, each comprising (i) at least one drug-containing coating containing over 7500 micrograms of mometasone furoate and (ii) a topcoat layer,

in which the first implant is configured to fit inside a first middle meatus of a patient,

in which the second implant is configured to fit inside a second middle meatus of a patient,

in which the first and second implants are configured to remain implanted for at least 24 weeks.

21. A combination of implants according to Claim 20, in which at least one of the first or second implants:

(a) is a braided structure;

(b) is a tubular structure;

(c) comprises helical strands;

(d) is self-expanding; and/or

(e) is a rolled sheet.