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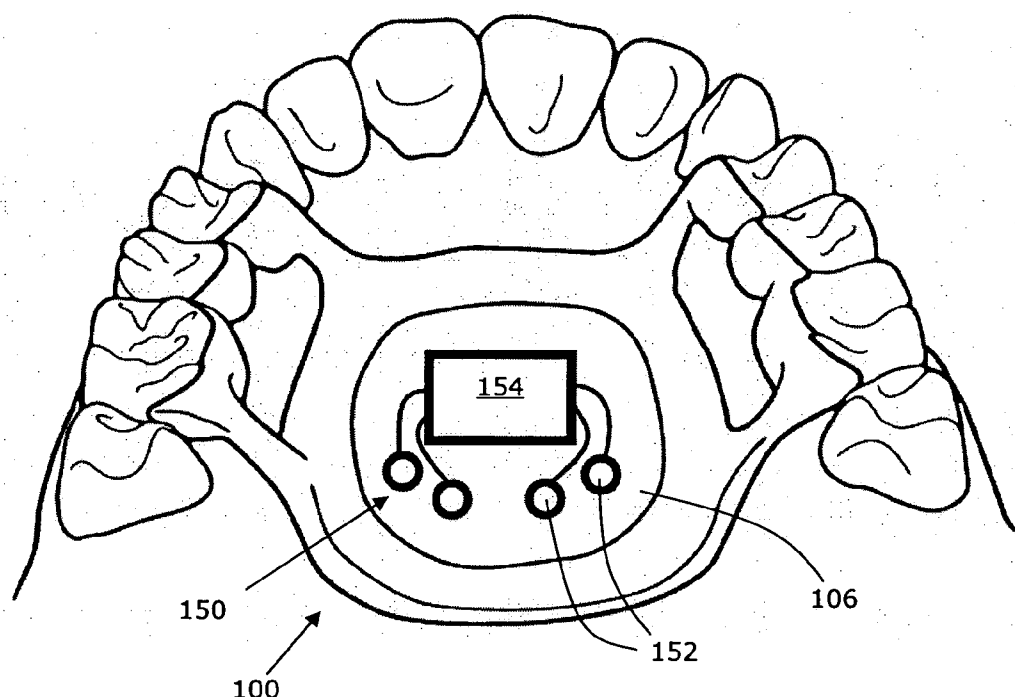
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(54) Title: AN ORAL DEVICE AND A METHOD FOR DISPENSING AN ACTIVE AGENT OR AN ELECTRICAL POTENTIAL TO AN ORAL CAVITY



(57) Abstract: An oral device and a method for dispensing an active agent and/or an electrical potential in an oral cavity of a living being and to allow the living being to chew when wearing the device, the device being adapted to be adhered to a non-masticating-surface of one or more teeth. Use of an oral device for dispensing an active agent.

WO 2007/140784 A2



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AN ORAL DEVICE AND A METHOD FOR DISPENSING AN ACTIVE AGENT OR AN ELECTRICAL POTENTIAL TO AN ORAL CAVITY

Field of the invention

The present invention relates to a device and a method for dispensing an active agent and/or an electrical potential in an oral cavity of a living being. In particular, the present invention relates to a device which is adapted to be adhered to a non-masticating surface of one or more teeth of a living being so as to allow normal chewing contact of masticating surfaces of teeth of a user. Additionally, the present invention relates to the use of such a device.

Background of the invention

Devices for dispensing an active agent in an oral cavity of a living being are known in the art. Examples are known from US 5,842,860 and JP 8117342. US 5,842,860 discloses a reservoir system for delivering an active agent into an oral cavity over a period of up to 12 hours. The system comprises at least one container for holding the active agent and a moulded plastic appliance for overlaying teeth of the patient.

It is an object of an embodiment of the present invention to provide an oral device, which allows a user to chew while wearing the device, so as to allow the device to be installed for a long period of time such as weeks, or months.

When wearing an oral device which the user cannot remove for cleaning, the risk of plaque and caries increases. Especially in areas which are not accessible to a toothbrush or dental floss as they are covered or partly covered by the oral device. Accordingly, it is an object of an embodiment of the present invention to provide an oral device for dispensing an active agent and/or an electrical potential which is designed to prevent formation of plaque and to prevent bacteria from causing caries in areas of the teeth close to the device.

Detailed description of the invention

In a FIRST aspect the present invention relates to an oral device adapted to dispense an active agent and/or an electrical potential in an oral cavity of a living being and to allow the living being to chew when wearing the device, the device comprising a dispensing portion adapted to dispense the active agent or the electrical potential to the living being, and a securing portion defining one or more attachment surfaces for adhering the oral device to a non-masticating-surface of one or more teeth, so as to allow normal chewing contact of masticating surfaces of teeth of the oral cavity when the living being is chewing.

The device according to the first aspect of the present invention allows a user to chew while wearing the device. Accordingly, one advantage of the device is that it may be installed during meals, thus, allowing the device to be installed for a long period of time such as weeks, or months.

- 5 Moreover by adhering the device to the teeth of a user, the user cannot reattach the device - if removed - as such reattachment requires use of dental tools and methods. Hence, a supervising medical person can easily determine if the device was removed during the period of treatment despite a patients claim to the contrary. Moreover, the patient will be reluctant to remove the device as such removal cannot be concealed.
- 10 Furthermore, by adhering the device to one or more teeth, plaque and caries in the area of attachment are eliminated as any cavity defined between the device and said one or more teeth is filled with the adhesive. Accordingly, formation of plaque is eliminated and bacteria are prevented from causing caries, as the critical areas of the teeth are covered - and, thus, protected - by the adhesive.
- 15 In the context of the present invention the term "dispense" shall cover dispensing/- administering an active agent such as a medicament and/or providing an electric potential e.g. by means on a galvanic element and/or by means of a battery.

- In the context of the present invention the term "active agent" shall be understood as a chemical or biological agent which interact with the living being when brought into contact
- 20 with the living being. Examples of such agents are, but are not limited to, vitamins, pharmaceuticals such as pharmaceuticals adapted to reduce addition to food, alcohol, tobacco or agents with a taste modifying effect.

- One embodiment of the device allows semi-permanent installation for a longer period of time such as weeks or months. In the context of the present invention the term "semi-permanent
- 25 installation" of a device shall be understood as installation which cannot be removed by hand and without tools.

In the context of the present invention the term "oral cavity" shall be understood as the cavity of the mouth as bounded by the lips and the area of the uvula.

- The securing portion may comprise at least one metal material, such as an intra orally
- 30 acceptable metal material(s) e.g. titanium and/or gold and/or platinum and/or silver and/or aluminium.

The device may comprise one or more contacting surfaces each of which in use contacts an oral mucosa such as the palate. In one embodiment at least one of said contacting surfaces comprises an intra orally acceptable metal material.

- 5 In one embodiment the securing portion is designed such that, for any position of the upper and lower teeth set, the teeth of the lower teeth set cannot contact the oral device. Thus, the device will not cause problems to users having a tendency to grind teeth during sleep.

In order to prevent fluid such as sputum from being trapped between the contacting surfaces and the oral mucosa, at least one of said contacting surfaces may define a protrusion
10 extending from said surface, along an edge of the dispensing portion. In use, the protrusion may contact the oral mucosa so as to define a barrier between the oral device and the oral mucosa, whereby bacteria contained in the sputum cannot be trapped between the device and the oral mucosa. Hence, the risk of inflammation or irritation of the mucosa is reduced or even eliminated.

- 15 In an embodiment of the device each attachment surface is shaped so as to fit the contour of the non-masticating surface of one or more teeth to which it is adhered during use. This provides a plurality of advantages. Firstly, the risk of plaque and caries is reduced as described in the aforementioned.

- 20 Secondly, the amount of adhesive which is required to adhere the device to the teeth may be reduced, as the space between the attachment surfaces and the non-masticating surfaces is reduced.

- Thirdly, as the amount of adhesive needed to secure the device to the teeth is reduced, it is
25 easier and faster to remove the layer of hardened used adhesive present on the teeth after removal of the device, as this layer is relatively thin.

- Fourthly, by shaping the attachment surfaces to the contour of the teeth, the device may be secured even better in the mouth, as such surfaces may define protrusions adapted to fit into
30 the spaces defined between the teeth. Such protrusions will prevent movement of the device in the rostral and caudal direction.

- It is well known that use of dental floss increases dental hygiene and reduces risk of plaque, caries and paradentosis. Thus, in one embodiment the securing portion is shaped such that
35 when the oral device is attached, dental floss may be inserted between any tooth to which the oral device is attached, and any tooth neighbouring said tooth.

In one embodiment the oral device is adapted to be adhered to a gum-facing surface of one or more teeth, and the dispensing portion is adapted to dispense the medication to the mucosa of the gum.

- 5 Alternatively, the oral device is adapted to be adhered to a palate-facing surface of one or more teeth, whereby the device may be adapted to dispense the active agent/electrical potential to the mucosa of the tongue and/or the palate of the user of the device.

10 The device may comprise at least three attachment surfaces, at least one of which is adapted to be adhered to a tooth in a left side to the oral cavity and at least one of which is adapted to be adhered to a tooth in a right side of the oral cavity. It will be appreciated that by increasing the number of attachment zones, the device is secured even better in the oral cavity.

- 15 In one embodiment the dispensing portion and the securing portion define a monolithic element, i.e. they are formed in one piece and without seams. Alternatively, the dispensing portion and the securing portion are attached to each other.

20 The dispensing portion may comprise one or more dispensing zones for dispensing the active agent said dispensing zone(s) being defined on an outer surface of the device, such as on a lower surface of the device whereby the tongue of a user may be brought into contact with said dispensing zone during a swallowing action of the user. Alternatively, or as a supplement, the dispensing zones may be provided so as to contact the mucosa of the palate of a user wearing the device.

- 25 The dispensing portion may comprise a reservoir for accommodation of an active agent, which reservoir may be fluidly connected to the dispensing zone(s). The reservoir may be designed to encapsulate the active agent contained in the reservoir such that the active agent exclusively is dispensed through the dispensing zones. Accordingly, the reservoir may contain concentrations of the active agent which in doses larger than the dispensing doses
30 are harmful to the patient or his mucosa, but which due to the encapsulation and low dosing rate does not harm to the patient during use.

In order to allow change or refilling of the active agent, the reservoir may be detachably attached to the oral device. In one embodiment the reservoir comprises a first fastening
35 means adapted to engage corresponding second fastening means of the oral device whereby the reservoir may be secured to the oral device.

Moreover, the oral device may comprise a pump for pumping the active agent from the reservoir to the dispensing zone(s). Said pump may be an electrical pump powered by a battery installed in the device.

5 Surprisingly it has been found, that application of an electrical potential to the oral cavity of the user such as to a mucosa of the oral cavity – especially when applied in connection with food intake – reduces the user's appetite. Accordingly, the dispensing portion may in one embodiment comprise a device for providing the electrical potential to a mucosa of the oral cavity of the living being, so as to control the behaviour of the user.

10 Especially it has been found, that application of the electrical potential to an area of the mouth comprising taste buds, reduces the users appetite and/or changes the gustatory pleasure during food intake. This can be used to reduce a users food intake, and thus to allow a user to loose weight. Accordingly in one embodiment, the device for providing the electrical
15 potential is arranged such that upon a users swallowing action, the electrical potential is applied to an area of the oral cavity comprising taste buds such as the tongue of the user.

In order to provide/dispense the electric potential to the user, the device for providing the electrical potential may comprise one or more galvanic elements. One advantage of providing
20 a galvanic element is that such a device may have a simple construction, whereby more complicated electrical components such as a battery or processor may be avoided. In one embodiment the galvanic element comprises two different metal materials electrically connected to each other so as to form a galvanic element and arranged such that electrolytes of the saliva present in the oral cavity interact with the two metal materials so as to provide
25 the electrical current/potential. The anode and/or the cathode may comprise an orally acceptably material such as gold, silver, titanium and/or aluminium. It will be appreciated, that the electrical potential provided by means of the anode and the cathode depends on which metals they comprise. Especially it will be appreciated, that two different metal materials located at different positions in the reactivity series will provide a galvanic element.

30 The means for providing the electrical potential may be provided so as to contact predetermined areas of the tongue which are sensitive to predetermined taste parameters such as sweet, sour, hot, etc. In one predetermined embodiment, the means for providing an electrical potential are provided at a position wherein they, upon a users swallowing action,
35 contacts a rim of the tongue.

In one embodiment the dispensing portion comprises a processor adapted to operate an electrically controllable dispensing device adapted to dispense the active agent and/or to dispense/provide the electrical potential to the oral cavity of the user.

In order to determine a predetermined condition in the oral cavity, such as a large amount of fat or sugar, the oral device may comprise a sensor adapted to determine at least one physio-chemical property in the oral cavity of the user. In one embodiment the sensor is adapted to determine a ph-value of a fluid present in the oral cavity. In another embodiment the sensor is adapted to determine the conductivity of a fluid present in the oral cavity. In yet another embodiment the sensor is adapted to determine the temperature of a fluid present in the oral cavity or of a mucosa of the oral cavity.

The sensor may be adapted to output a signal representing said property, and the processor may be adapted to operate the electrically controllable dispensing device on the basis of said signal so as to control the behaviour of the user. As an example the processor may be programmed to dispense the active agent or an electrical potential when the level of fat in the oral cavity exceeds a predetermined threshold. This may be used to prevent the user from eating food with a high level of fat.

In one embodiment the sensor is provided in the dispensing portion e.g. by being detachably attachable to the dispensing portion. In an alternative embodiment, the sensor is provided as a separate unit which may be positioned at a position of the oral cavity which is different from the position of the dispensing portion. In the latter embodiment the sensor may be adapted to be attached to a gum facing surface of a tooth while the dispensing portion via the securing portion is attached to a palate facing surface of one or more teeth. In order to allow the sensor to communicate with the dispensing portion, the sensor may comprise a transmitter for transmitting signals to the dispensing portion. In order to receive the transmitted signals, the processor may be electrically coupled to a transceiver or a receiver.

Accordingly, the processor may be electrically connected to a transceiver for transmitting and receiving an electromagnetical signal. Moreover, the processor may be adapted to operate the transceiver to transmit a signal upon determination of a predetermined condition of the dispenser and/or the sensor.

Moreover, the device may comprise a palate lowering portion for positioning against the palate of a user, the palate lowering portion defining a central thickened portion which in use extends from the palate towards the lower part of the mouth of the user so as to define an artificial palate and to reduce the volume of the mouth. By reducing the volume of the mouth, food intake per time unit is reduced as smaller amount of food may be accommodated in the oral cavity per bite. As satiety occurs 10-20 minutes after food has reached the stomach, the risk of eating more food than necessary is reduced, as a palate lowering portion prolongs meals. It will be appreciated that by combining a palate lowering

portion with an appetite reducing active agent weight loss and control may be improved even more.

In a SECOND aspect, the present invention relates to a method of dispensing an active agent to a living being by application of an oral device according to the first aspect of the invention, the method comprising the steps of:

- providing the oral device, and
- adhering at least one attachment surface to the non-masticating-surface of at least one tooth.

Moreover, the step of adhering may comprise the steps of:

- cleaning the non-masticating-surface of the tooth/teeth to which the device is to be adhered,
- providing an adhesive to the cleaned surface and/or the attachment surface of the oral device, and
- placing the oral device in the mouth of the user so as to bring the non-masticating-surface in contact with the attachment surface of oral device.

In a THIRD aspect, the present invention relates to the use of an oral device according to the first aspect of the invention, for dispensing an active agent such as a medicament.

Any feature or element of the first aspect of the invention may be combined with the invention according to the second and/or third aspect of the invention.

DETAILED DESCRIPTION OF THE INVENTION

In the following the present invention is described in further detail with reference to the drawings in which:

Figs. 1 and 2 disclose an uninstalled oral devices according to the present invention,

Figs. 3 and 4 disclose an oral device installed in the upper part of an oral cavity,

Fig. 5 discloses an embodiment of the dispensing portion,

Figs. 6a-7 disclose an embodiment of fastening means for fastening the dispensing portion to the securing portion,

Figs. 8-10 disclose electronics such as sensors provided in the dispensing portion, and

Figs. 11-12 disclose dispensing portions comprising galvanic elements.

Fig. 1 discloses an oral device 100 which is adapted to be installed in the upper part 102 of an oral cavity 104 (see Figs. 3 and 4) of a user. The device 100 comprises a dispensing portion 106 (visible in Fig. 3) and a securing portion 108. The securing portion 108 comprises a plurality of attachment surfaces 110 for adhering the oral device to a non-masticating surfaces 112 of one or more teeth 114 (see Fig. 3), so as to allow normal chewing contact of masticating surfaces 116 of the teeth. The securing portion 108 is designed such that, for any position of the upper and lower teeth set, the teeth of the lower teeth set cannot be brought into contact with the oral device. Thus, the device will not cause problems to users having a tendency to grind teeth during sleep.

10 The securing portion 108 comprises a plurality of attachment surfaces 110 which in the embodiment of Fig. 1 are directly interconnected. Moreover, the interconnected attachment surfaces 110 are connected to the dispensing portion 108 by means of two connecting arms 118. The attachment surfaces 110 are shaped so as to fit the contour of non-masticating surfaces.

15 The device comprises a contacting surface 120, which during use contacts the oral mucosa. In order to prevent fluid such as sputum from being trapped between the contacting surface and the oral mucosa, the oral device may comprise a protrusion 122 extending along an edge 124, such that during use a confined space is defined by the oral mucosa, the protrusion and the contacting surface. By preventing septum from being trapped, the risk of inflammation or
20 irritation of the mucosa is reduced or even eliminated.

In the embodiment of Fig. 2 the contacting surfaces are not directly interconnected. This enables a user to use dental floss while wearing the device, as the floss may be inserted into the spaces 126, and, thus, pass between the attachment surfaces by means of which the device is attached to the teeth. Each of the attachment surfaces are connected to the
25 dispensing portion by means of a contacting arm 118.

In Fig. 3 and 4 the oral device of Fig. 1 is attached to the teeth 114 of a user. Fig. 3 discloses the upper part of the oral cavity of the user, which oral cavity comprises a oral mucosa 128, incisors 130, premolars 132 and molars 134. The device of Fig. 3 is adapted to be attached to the six molars 134 – three in each side of the upper part of the mouth. In order to minimise
30 the contact between the oral device and the oral mucosa, the oral device defines an opening 136. The attachment surfaces are shaped so as to fit the contour of the palate facing non-masticating surface of the teeth, whereby the risk of plaque is reduced as any space defined between the contacting surface and the non-masticating surface is reduced, and any such space is filled out with an adhesive when the device is attached to the teeth.

The attachment surfaces define protrusions 135 adapted to fit into the spaces defined between the teeth. Such protrusions will prevent movement of the device in the rostral and caudal direction

A dispensing area 138 is defined centrally in the device and such that a tongue (not shown) of the user contacts the dispensing area during a swallowing action.

Fig. 5 discloses a simplified embodiment of the oral device 100 which has a dispensing portion 106 to which a container or means for providing an electrical potential may be detachably attached by means of the grooves 140 illustrated in Figs. 6a-7. Fig. 6a-6c show grooves 140 having different cross-sectional shape(s). It will be appreciated, that in some embodiments the detachable device may be detachably attached to the dispensing portion solely by means of engagement between the grooves 140 a corresponding engagement means (not shown) of the container or the device for providing an electrical potential. In other embodiments, glue may be provided in the grooves 140 in order to strengthen the fastening of the two elements to each other. Fig. 6d discloses an embodiment comprising one or more single spot attachment means 142, 142'. Fig. 7 discloses one embodiment wherein a container 144 comprising an active agent provided in a reservoir 146 is attached to the oral device 100 by means of two grooves 140 into which correspondingly shaped protrusions 148 of the container are inserted. In one embodiment glue is provided in the grooves 140 in order to strengthen the attachment.

Figs. 8-10 disclose different embodiments of the oral device 100 into which electronics 150 have been embedded. The electronics 150 comprise sensors 152 for determining physio-chemical properties in the oral cavity. As shown in Fig. 9 the sensors 152 may be electrically connected to a processor/controller 154 which is adapted to operate an injector 156 such as an acoustic and/or piezoelectric ejector which when operated ejects an active agent provided in the reservoir. The processor 154 may be electrically connected to a transceiver 158 for communicating data such as status data to an external device or for receiving data such as instructions/operational data from an external device (not shown). In one embodiment the external device which may be a personal computer, is used to change a dispensing regime/pattern which the processor 154 is programmed to use during dispensing of the active agent.

Figs. 11 and 12 disclose two different embodiments of galvanic elements 160 each of which comprise an anode 162 and a cathode 164 which are electrically connected. In the embodiment of Fig. 11 the dispensing portion comprises a first metal such as titanium, and a second metal is provided on the surface of the dispensing portion in order to define the galvanic element. The layer of the second metal may be attached/fastened to the dispensing

portion 106 by means of any suitable process such as spraying the metal on the dispensing portion or such as by means of welding.

5 In the embodiment of Fig. 12 the dispensing portion 106 comprises a non-conductive material, and the anode and the cathode are provided in said non-conductive material in such a way that the anode and the cathode are electrically connected, and in such a way that upon a swallowing action by the user, the tongue of said user contacts the galvanic element.

CLAIMS

1. An oral device adapted to dispense an active agent and/or an electrical potential in an oral cavity of a living being and to allow the living being to chew when wearing the device, the device comprising a dispensing portion adapted to dispense the active agent or the electrical potential to the living being, and a securing portion defining one or more attachment surfaces for adhering the oral device to a non-masticating-surface of one or more teeth, so as to allow normal chewing contact of masticating surfaces of teeth of the oral cavity when the living being is chewing.
2. An oral device according to claim 1, wherein the securing portion is made of an intra orally acceptable the metal material.
3. An oral device according to claim 1 or 2, wherein the device comprises one or more contacting surfaces each of which in use contacts an oral mucosa.
4. An oral device according to claim 3, wherein any of said contacting surfaces comprises an intra orally acceptable metal material.
5. An oral device according to claim 3 or 4, wherein at least one of said contacting surfaces defines a protrusion extending from said surface and which in use contacts an oral surface so as to define a barrier between the oral device and the oral surface.
6. An oral device according to any of the preceding claims, wherein each attachment surface is shaped so as to fit the contour of the non-masticating surface of one or more teeth to which it is adhered during use.
7. An oral device according to any of the preceding claims, wherein the securing portion is shaped such that when the oral device is attached, dental floss may be inserted between any tooth to which the oral device is attached, and any neighbouring tooth.
8. An oral device according to any of the preceding claims, wherein the oral device is adapted to be adhered to a gum-facing surface of one or more teeth.
9. An oral device according to any of claims 1-8, wherein the oral device is adapted to be adhered to a palate-facing surface of one or more teeth.
10. An oral device according to any of the preceding claims, comprising at least three attachment surfaces, at least one of which is adapted to be adhered to a tooth in a left side

of the oral cavity and at least one of which is adapted to be adhered to a tooth in a right side of the oral cavity.

5 11. An oral device according to any of the preceding claims, wherein the metallic material comprises one or more of: titanium, gold, platinum, silver and aluminium.

12. An oral device according to any of the preceding claims, wherein the dispensing portion is attached to securing portion.

10 13. An oral device according to any of the preceding claims, wherein the dispensing portion and the securing portion define a monolithic element.

14. An oral device according to any of the preceding claims, wherein the dispensing portion comprises one or more dispensing zones for dispensing the active agent said dispensing zones being defined on an outer surface of the device.

15 15. An oral device according to claim 14, wherein at least one dispensing zone is arranged such that upon a users swallowing action, the tongue of the user is brought into contact with said dispensing zone.

20 16. An oral device according to any of claims 14-15, wherein the dispensing portion comprises a reservoir for accommodation of an active agent and wherein the reservoir is fluidly interconnected with the dispensing zone(s)

17. An oral device according to claim 16, wherein the reservoir is detachably attached to the oral device.

25 18. An oral device according to any of the preceding claims, wherein the dispensing portion comprises a device for providing the electrical potential to a mucosa of the oral cavity of the living being so as to control the behaviour of the user.

30 19. An oral device according to claim 18, wherein the device for providing the electrical potential is arranged such that upon a users swallowing action, the electrical potential is applied to the tongue of the user.

35 20. An oral device according to claim 18 or 19, wherein the device for providing the electrical potential comprises one or more galvanic elements.

21. An oral device according to any of the preceding claims, wherein the dispensing portion comprises a processor adapted to operate a dispensing device adapted to dispense the active agent or the electrical potential to the oral cavity of the user.

22. An oral device according to claim 21, wherein the oral device comprises a sensor adapted to determine at least one physio-chemical property in the oral cavity of the user and to output a signal representing said property, and wherein the processor is adapted to operate the dispensing device on the basis of said signal so as to control the behaviour of the user.

23. An oral device according to claim 22, wherein the dispensing portion comprises the sensor.

24. An oral device according to any of claims 21-23, wherein the processor is electrically connected to a transceiver for transmitting and receiving an electro-magnetic signal, and wherein the processor is adapted to operate the transceiver to transmit a signal upon determination of a predetermined condition of the dispenser and/or the sensor.

25. An oral device according to any of the preceding claims, further comprising a palate lowering portion for positioning against the palate of a user, the palate lowering portion defining a central thickened portion which in use extends from the palate towards the lower part of the mouth of the user so as to define an artificial palate and to reduce the volume of the mouth.

26. A method of dispensing an active agent to a living being by application of an oral device according to any of claims 1-25, the method comprising the steps of:

- providing the oral device, and
- adhering at least one attachment surface to the non-masticating-surface of at least one tooth.

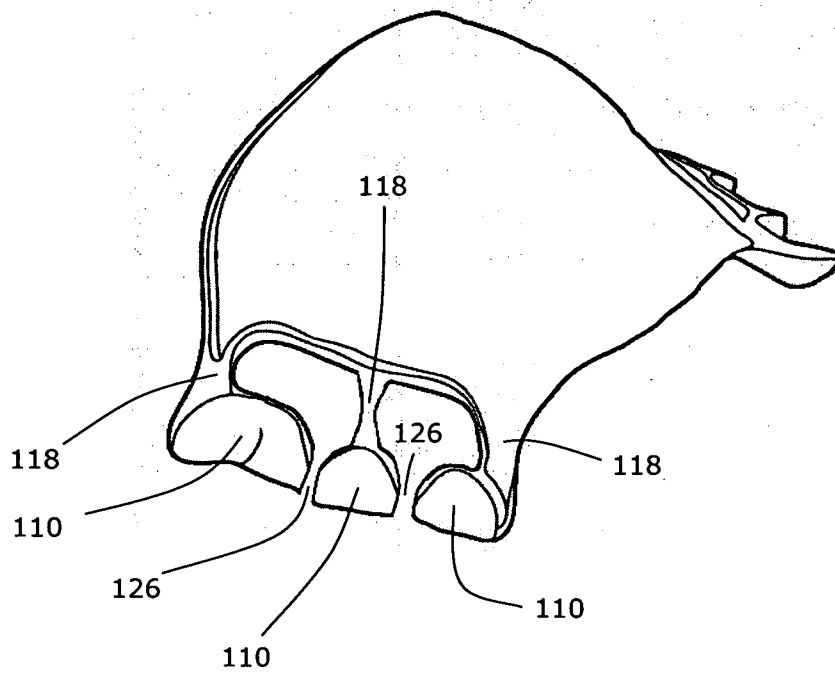
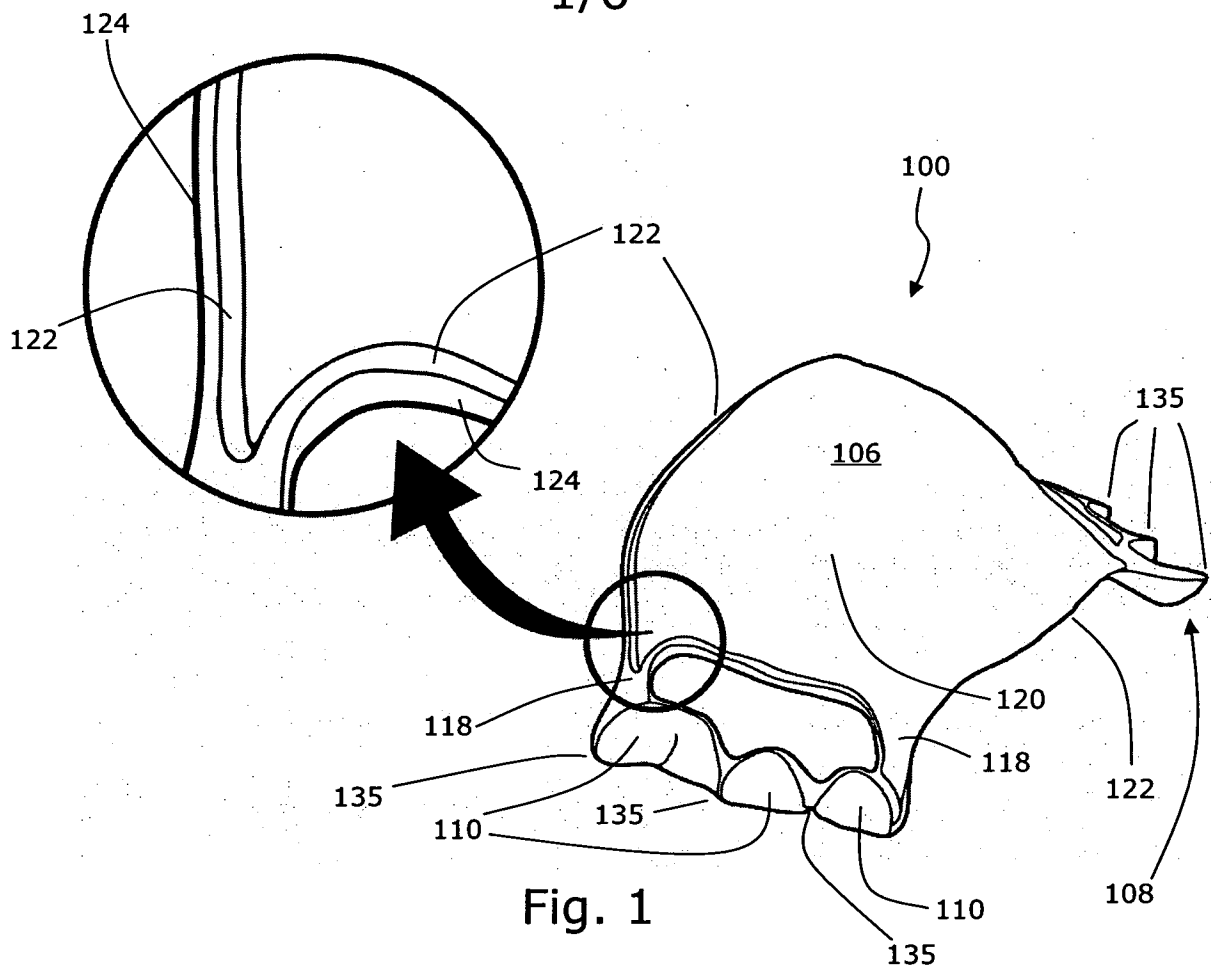
27. A method according to claim 26, wherein the step of adhering comprises the steps of:

- cleaning the non-masticating-surface of the tooth/teeth to which the device is to be adhered,
- providing an adhesive to the cleaned surface and/or the attachment surface of the oral device, and
- placing the oral device in the mouth of the user so as to bring the non-masticating-surface in contact with the attachment surface of the oral device.

28. Use of an oral device according to any of claims 1-25, for dispensing an active agent.

29. Use of an oral device according to claim 26, wherein the active agent is a medicament.

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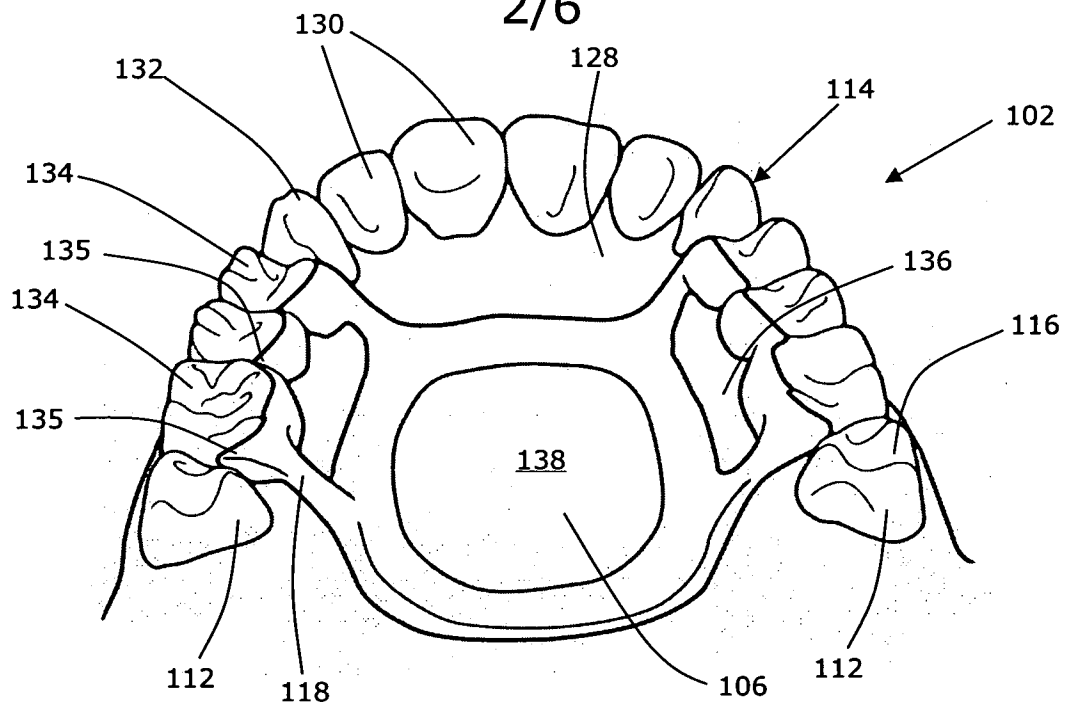


Fig. 3

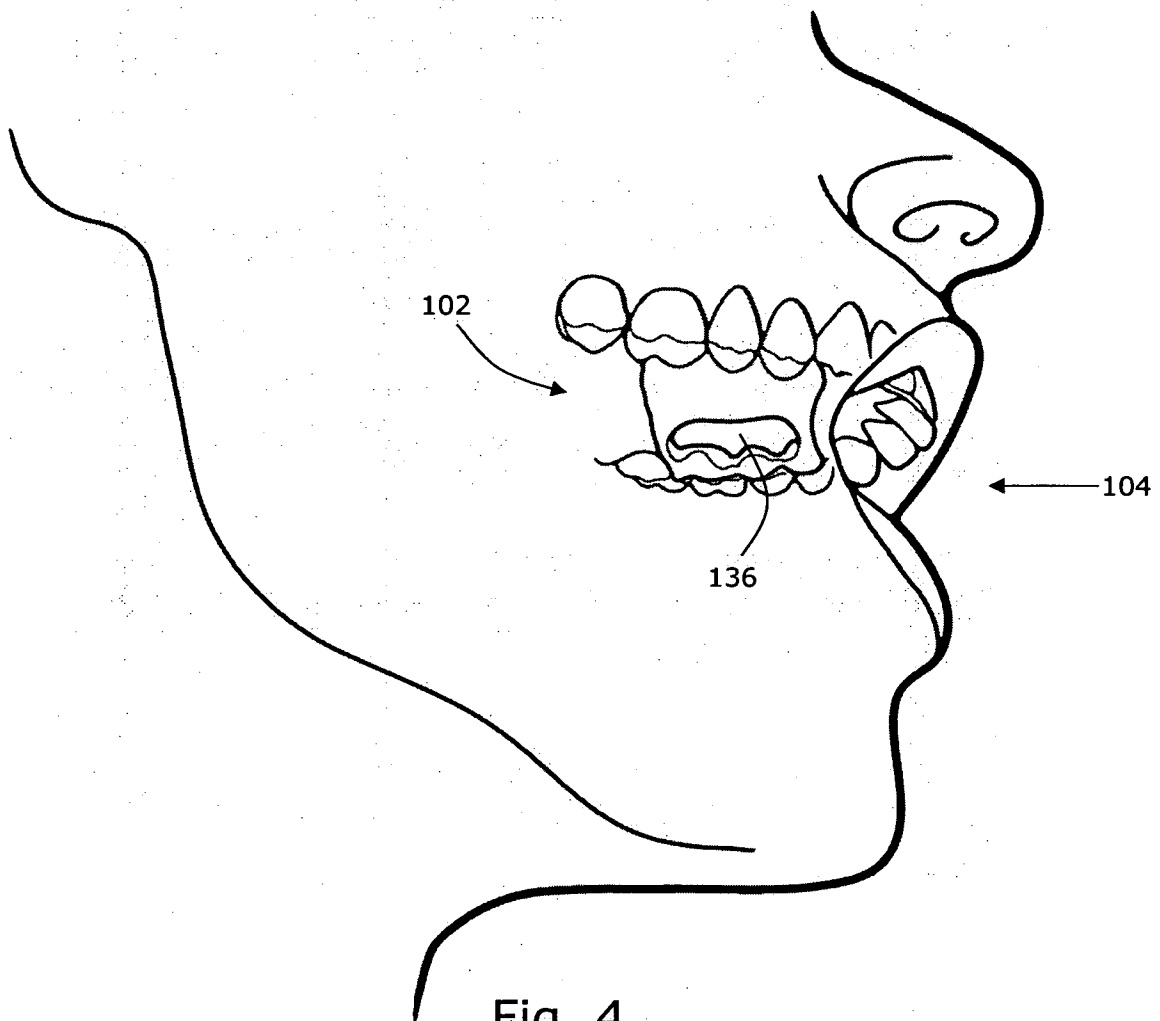
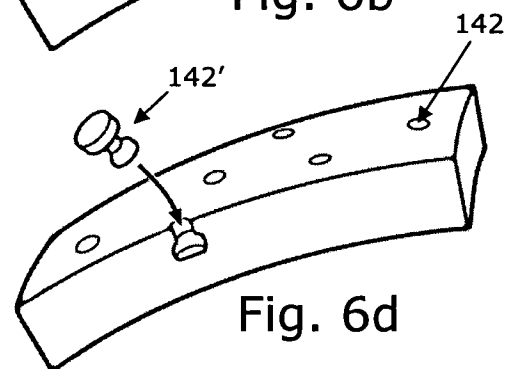
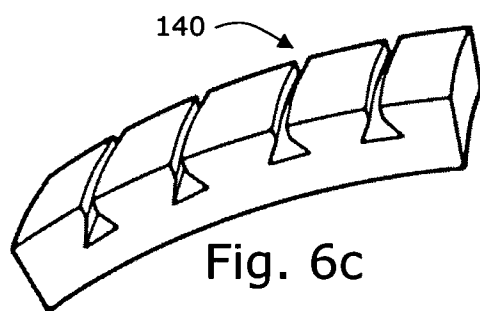
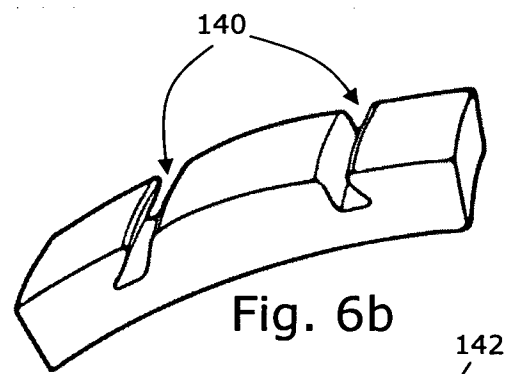
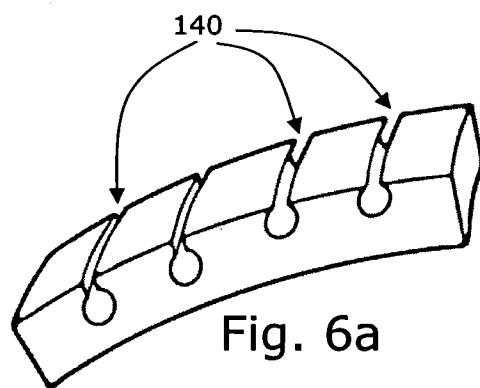
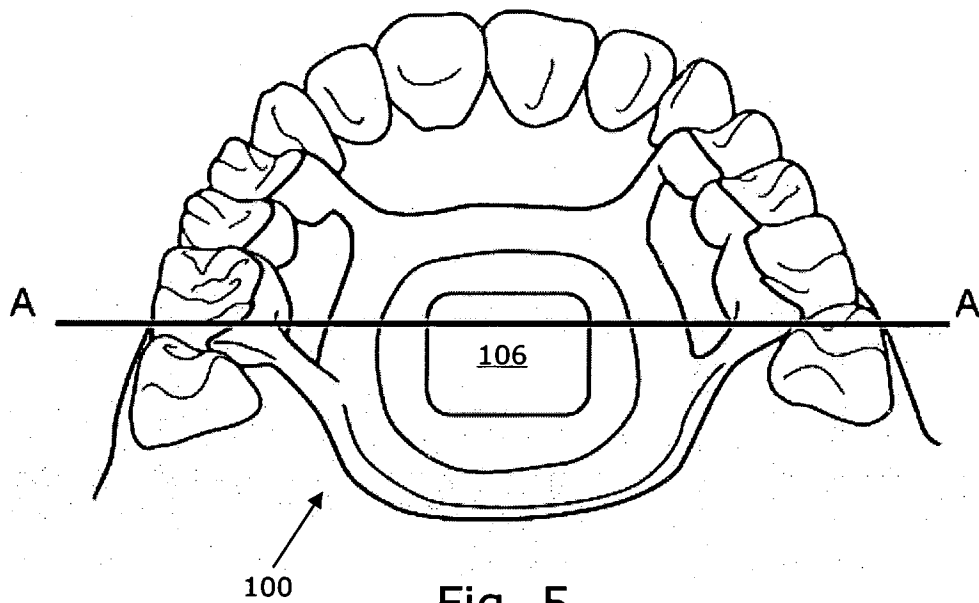
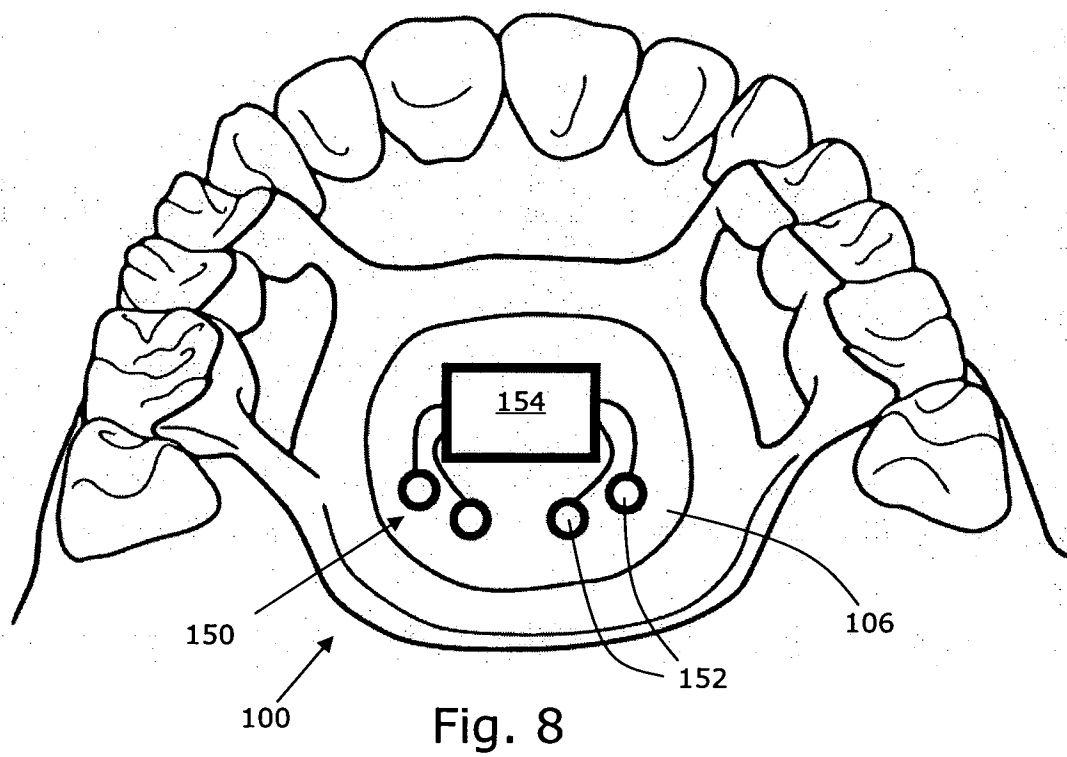
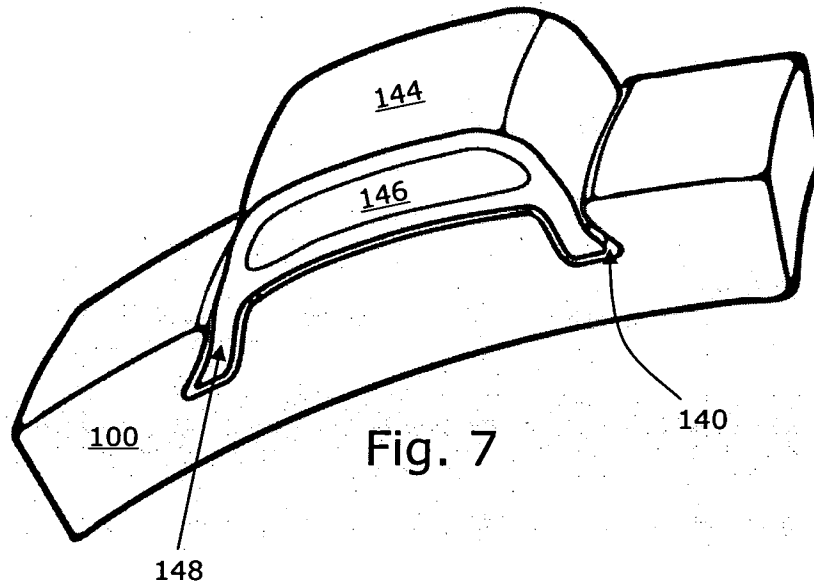


Fig. 4

3/6



4/6



5/6

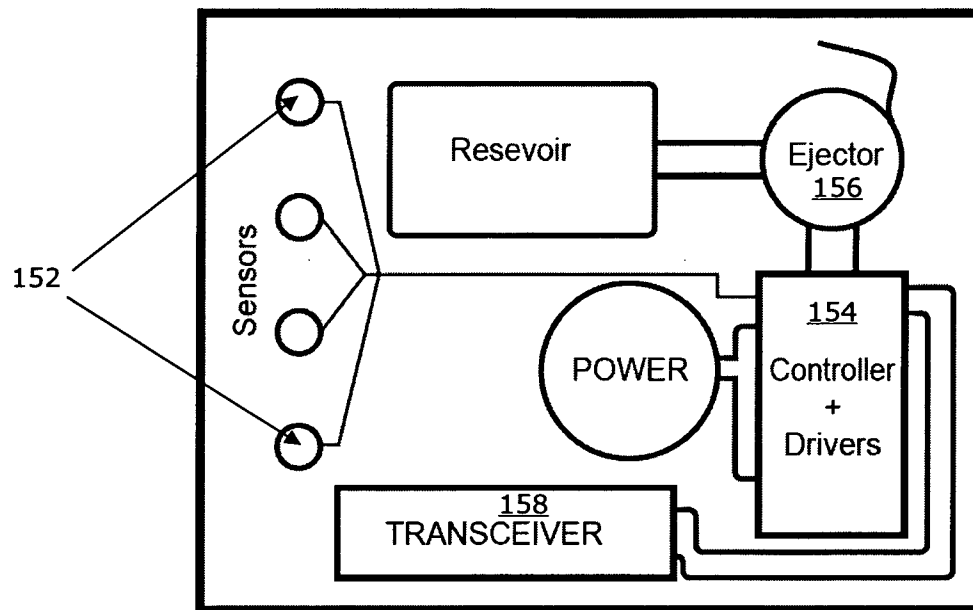


Fig. 9

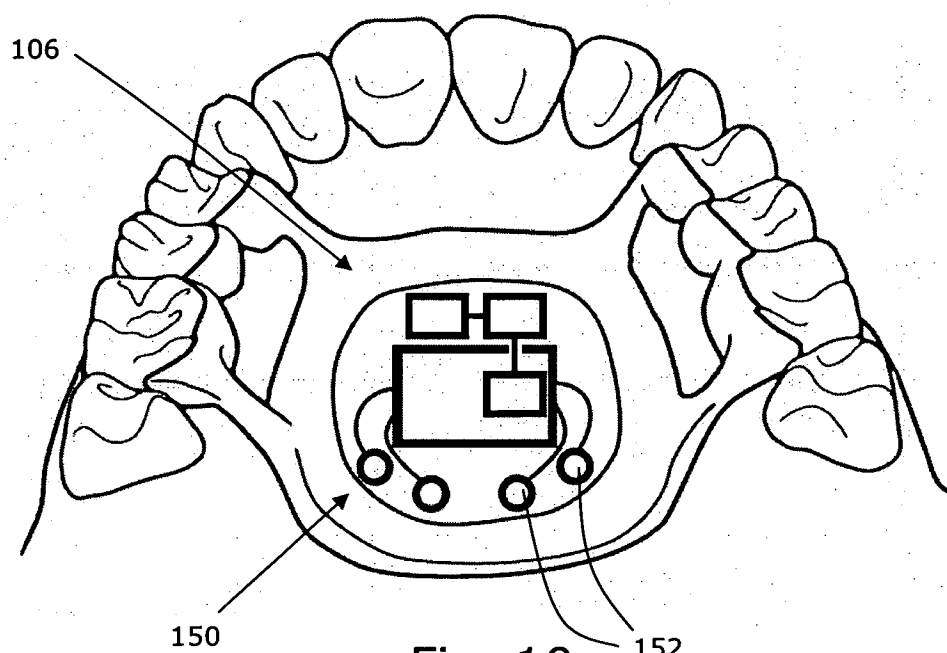


Fig. 10

6/6

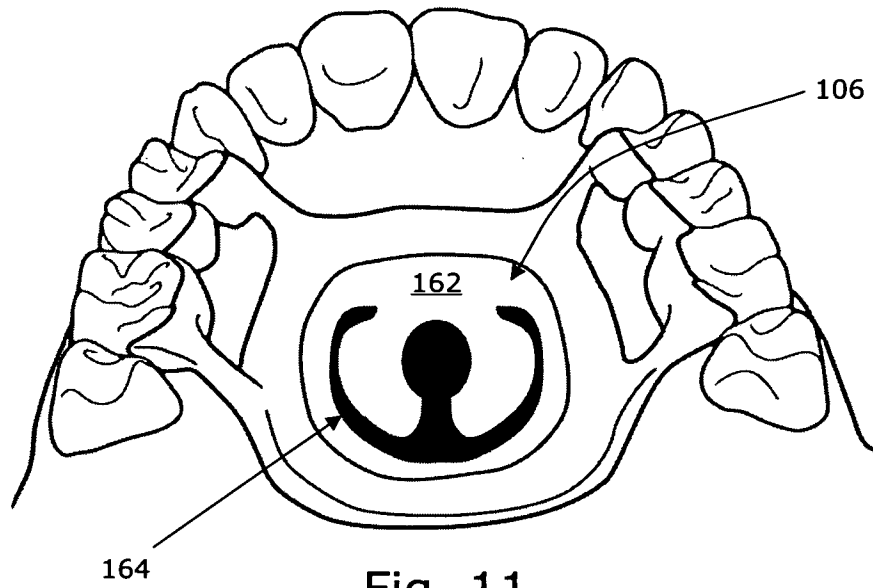


Fig. 11

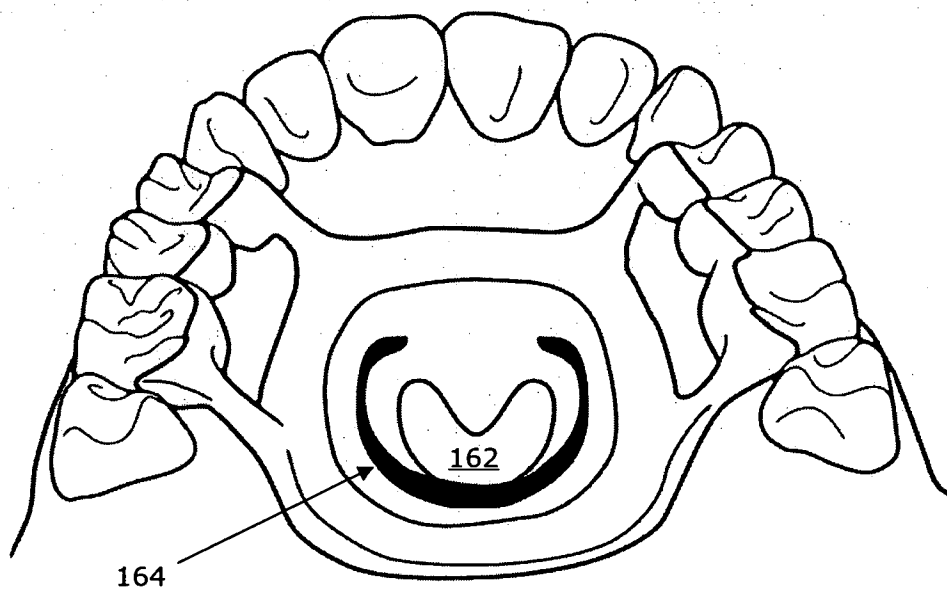


Fig. 12