A hand-held vacuum pump apparatus for use in attaching one or more saliva control devices over one or more selected salivary ducts. The apparatus can be operated using a single hand. The apparatus includes a body having a grippable handle and a support member, a hollow suction tube supported by the support member of the body, a plunger slidably disposed within the hollow suction tube, and means for proximally moving the plunger within the hollow suction tube in response to squeezing a practitioner’s hand and/or at least one finger.
VACUUM PUMP APPARATUS FOR USE WITH SALIVA CONTROL DEVICES

BACKGROUND OF THE INVENTION

1. Related Applications

The present application is a continuation-in-part of copending U.S. patent application Ser. No. 11/208,897, filed Aug. 22, 2005 and entitled “VACUUM SEALED SALIVA CONTROL DEVICE,” the disclosure of which is incorporated by reference in its entirety.

2. The Field of the Invention

The present invention relates to saliva control devices and an integral hand-held vacuum pump apparatus for use in attaching one or more of the saliva control devices over a salivary duct so as to reduce or eliminate the flow and production of saliva. The saliva control devices and associated vacuum pump apparatus are particularly useful for a dental practitioner or oral surgeon (hereinafter practitioner) when performing a procedure within the oral cavity.

3. The Relevant Technology

When performing various procedures within the oral cavity, it is often desirable or necessary for the practitioner to slow or at least divert the flow of saliva produced by the salivary ducts. There are four principal salivary ducts within the oral cavity. The two parotid salivary ducts are located inside the mouth and near each ear. There are also two submandibular salivary ducts located on the floor of the mouth, near the base of the tongue. The vast majority of saliva produced enters a patient’s mouth through these principal salivary ducts. A minor amount also enters through other auxiliary salivary ducts. Several devices and techniques have been employed in order to prevent saliva from interfering with a practitioner’s work inside the oral cavity.

Rolls of cotton have been used in an attempt to prevent saliva produced by the principal salivary ducts from interfering with the work of a practitioner within the oral cavity. Cotton rolls are placed below the parotid salivary ducts and/or over the submandibular salivary ducts. As saliva is produced, it drains downward, and is absorbed by the cotton. One disadvantage of using cotton rolls is that they are rather large and can restrict the ability of the practitioner to work within the oral cavity because they take up considerable space. In addition, they can quickly become saturated, necessitating removal and replacement of the cotton during the procedure. It is often difficult to maintain the cotton roll in the position placed. Finally, cotton rolls can be uncomfortable for the patient.

Rubber dams have also been used for isolating an area of the mouth from saliva. Rubber dams are difficult to use as they must be assembled, which can take a significant amount of time. In addition, when using a rubber dam, the patient cannot completely close his or her mouth. This makes it difficult for the practitioner to check the patient’s occlusion, and is generally uncomfortable for the patient.

Dental suction tubes have also been used to remove excess saliva produced by the salivary ducts. Generally, the suction tube is inserted periodically to remove excess saliva as it pools in the patient’s mouth. This either requires an assistant to periodically insert the suction tube, or it requires interrupting the practitioner’s work.

Systemic medications (e.g., scopolamine and atropine) have been used to control the production of saliva. While useful in arresting saliva production, side effects include disorientation, amnesia, and lingering dry mouth. Furthermore, such medications typically require several minutes time after administration to begin working.

Improved saliva control devices have been developed by one of the present inventors which can be easily employed by a practitioner with a minimum of discomfort to the patient. Such devices are disclosed in copending U.S. application Ser. No. 11/208,897, filed Aug. 22, 2005, previously incorporated by reference. Generally, these saliva control devices are attached over the salivary duct and act to minimize or prevent the production and/or flow of saliva. The saliva control devices remain in place during the course of the practitioner’s work within the oral cavity and are easily removed once work is completed.

During attachment of some of the saliva control devices over a salivary duct, a vacuum is needed in order to facilitate attachment of the device over the salivary duct. As such, it would be an improvement in the art to provide a specially designed hand-held vacuum pump apparatus for use in attaching saliva control devices over a salivary duct.

BRIEF SUMMARY OF THE INVENTION

The present invention is directed to an integral hand-held vacuum pump apparatus for use in attaching one or more saliva control devices over one or more selected salivary ducts. The vacuum pump apparatus can be operated by a single hand of a practitioner in order to adhere a saliva control device, e.g., by drawing a portion of a salivary duct into an orifice of a saliva control device by suction.

The pump apparatus includes a body having a grippable handle and a support member, a hollow suction tube that is supported by the support member of the body, a plunger slidably disposed within the hollow suction tube, and means for moving the plunger proximally within the hollow suction tube in response to squeezing a practitioner’s hand and/or at least one finger. An example of such means includes a finger grippable lever which when squeezed causes the plunger to slide proximally within the hollow suction tube so as to create a vacuum within the hollow suction tube. Release of the plunger releases the vacuum.

At least a portion of the finger grippable lever is spaced apart from the grippable handle of the body, and the lever is also movably mounted to the grippable handle such that the lever may be selectively squeezed or otherwise moved relative to the handle. The lever is operatively coupled to the plunger so as to cause the plunger to slide proximally within the hollow suction tube when the lever is squeezed, resulting in the creation of a vacuum suction force within the hollow suction tube. Depending on the configuration of the saliva control device to be attached, the vacuum can advantageously be used to vacuum adhere the device over a salivary duct, or in another embodiment, the vacuum can advantageously be used to suction up the mub of tissue surrounding the salivary duct, after which the saliva control device can be positioned so as to constrict around the salivary duct, effectively cutting off saliva flow. The vacuum is released (e.g., by releasing force on the lever), after which the pump apparatus is detached from the saliva control device and removed from the patient’s mouth.
The integral hand-held vacuum pump apparatus advantageously requires no connection to an external vacuum source. In other words, no cords or tubes run from the apparatus at one end to an external vacuum source at another end as in, e.g., a cored dental suction tool. The elimination of cords or tubes greatly improves the maneuverability of such an apparatus relative to devices that require connection to an external vacuum source. This maximizes the ability of the practitioner to manipulate the device into a desired one of many possible positions so as to ensure proper placement of the saliva control device. Because the apparatus is self-contained, no external connection is needed, and the necessary vacuum is generated within the hand-held apparatus itself (e.g., by squeezing the lever).

The hollow suction tube may be detachable from the rest of the apparatus to facilitate changing of the tube between patients (e.g., the hollow suction tube may be disposable) so as to prevent or minimize the possibility of cross-contamination between patients. The remainder of the apparatus advantageously may be easily washed or disinfected by autoclaving, as needed.

These and other benefits, advantages and features of the present invention will become more full apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

**BRIEF DESCRIPTION OF THE DRAWINGS**

In order that the manner in which the above recited and other benefits, advantages and features of the invention are obtained, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. Understanding that these drawings depict only typical embodiments of the invention and are not therefore to be considered limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

**FIG. 1** is a perspective view of an exemplary saliva control device;

**FIGS. 2A and 2B** are top and bottom views, respectively, of an alternative saliva control device;

**FIG. 2C** is a perspective view of the device of FIGS. 2A-2B with the device in an open position so as to allow viewing into the interior of the saliva control device;

**FIG. 3** is a perspective view of a hand-held vacuum pump apparatus for use in attaching a saliva control device over a salivary duct;

**FIG. 4** is an exploded view of the vacuum pump apparatus of FIG. 3;

**FIG. 5A** is a perspective view of an alternative hand-held vacuum pump apparatus for use in attaching a saliva control device over a salivary duct;

**FIG. 5B** is an exploded view of the vacuum pump apparatus of FIG. 5A;

**FIG. 6** is a perspective view of another alternative vacuum pump apparatus;

**FIG. 7** illustrates the inside of a patient's mouth including the two submandibular salivary ducts on the floor of the mouth;

**FIG. 8A** illustrates placement of a saliva control device with the hand-held vacuum pump apparatus of FIG. 3; and

**FIG. 8B** illustrates a saliva control device in place over the salivary duct so as to prevent production and flow of saliva out of the salivary duct to which it is attached.

**DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

I. Introduction

The present invention is directed to an integral (i.e., self-contained) hand-held vacuum pump apparatus for use in attaching one or more saliva control devices over one or more selected salivary ducts. The inventive hand-held vacuum pump apparatus allows a practitioner to easily install one or more saliva control devices over one or more salivary ducts so as to control production and flow of saliva into the oral cavity during dental surgery or another procedure where elimination of saliva would be advantageous. The apparatus can be operated using a single hand.

II. Exemplary Saliva Control Devices

**FIG. 1** illustrates one exemplary saliva control device 100 including an elastic body 102 and a constriction hole 104 formed near the center of elastic body 102. Elastic body 102 is illustrated as comprising a substantially flat circular disc, although other configurations are possible (e.g., oval, rectangular, etc.). Illustrated saliva control device 100 advantageously includes an optional rim 106 extending around an outer perimeter of elastic body 102. As illustrated, rim 106 has a cross sectional thickness T that is greater than the cross sectional thickness of the elastic body 102 adjacent to constriction hole 104. Optional rim 106 advantageously adds an additional degree of rigidity to device 100, which is helpful during handling and placement of the device, particularly when inserting a tissue stub surrounding a selected salivary duct through constriction hole 104. In addition, the interior surface 107 of rim 106 advantageously provides a surface against which the hollow suction tube of the hand-held vacuum pump apparatus can friction fit (i.e., the tube can friction within the interior space defined by interior surface 107 of outer rim 106. This mating configuration will be described in further detail below.

**FIG. 3** illustrates the inside of a patient's mouth including the two submandibular salivary ducts on the floor of the mouth.

**FIG. 8A** illustrates placement of a saliva control device with the hand-held vacuum pump apparatus of FIG. 3; and

**FIG. 8B** illustrates a saliva control device in place over the salivary duct so as to prevent production and flow of saliva out of the salivary duct to which it is attached.

**FIG. 1** illustrates one exemplary saliva control device 100 including an elastic body 102 and a constriction hole 104 formed near the center of elastic body 102. Elastic body 102 is illustrated as comprising a substantially flat circular disc, although other configurations are possible (e.g., oval, rectangular, etc.). Illustrated saliva control device 100 advantageously includes an optional rim 106 extending around an outer perimeter of elastic body 102. As illustrated, rim 106 has a cross sectional thickness T that is greater than the cross sectional thickness of the elastic body 102 adjacent to constriction hole 104. Optional rim 106 advantageously adds an additional degree of rigidity to device 100, which is helpful during handling and placement of the device, particularly when inserting a tissue stub surrounding a selected salivary duct through constriction hole 104. In addition, the interior surface 107 of rim 106 advantageously provides a surface against which the hollow suction tube of the hand-held vacuum pump apparatus can friction fit (i.e., the tube can friction within the interior space defined by interior surface 107 of outer rim 106. This mating configuration will be described in further detail below.

**FIG. 3** illustrates the inside of a patient's mouth including the two submandibular salivary ducts on the floor of the mouth.

**FIG. 8A** illustrates placement of a saliva control device with the hand-held vacuum pump apparatus of FIG. 3; and

**FIG. 8B** illustrates a saliva control device in place over the salivary duct so as to prevent production and flow of saliva out of the salivary duct to which it is attached.

**FIG. 1** illustrates one exemplary saliva control device 100 including an elastic body 102 and a constriction hole 104 formed near the center of elastic body 102. Elastic body 102 is illustrated as comprising a substantially flat circular disc, although other configurations are possible (e.g., oval, rectangular, etc.). Illustrated saliva control device 100 advantageously includes an optional rim 106 extending around an outer perimeter of elastic body 102. As illustrated, rim 106 has a cross sectional thickness T that is greater than the cross sectional thickness of the elastic body 102 adjacent to constriction hole 104. Optional rim 106 advantageously adds an additional degree of rigidity to device 100, which is helpful during handling and placement of the device, particularly when inserting a tissue stub surrounding a selected salivary duct through constriction hole 104. In addition, the interior surface 107 of rim 106 advantageously provides a surface against which the hollow suction tube of the hand-held vacuum pump apparatus can friction fit (i.e., the tube can friction within the interior space defined by interior surface 107 of outer rim 106. This mating configuration will be described in further detail below.

**FIG. 3** illustrates the inside of a patient's mouth including the two submandibular salivary ducts on the floor of the mouth.

**FIG. 8A** illustrates placement of a saliva control device with the hand-held vacuum pump apparatus of FIG. 3; and

**FIG. 8B** illustrates a saliva control device in place over the salivary duct so as to prevent production and flow of saliva out of the salivary duct to which it is attached.
substantially cutting off blood flow within the tissue nub surrounding the salivary duct when the tissue nub is inserted through the constriction hole (i.e., when the elastic body springs closed or otherwise constricts around the tissue nub surrounding the salivary duct). Constriction hole diameters between about 0.1 mm and about 2 mm, more preferably between about 0.5 mm and about 1.75 mm, and most preferably between about 0.8 mm and about 1.5 mm have been found to be satisfactory. The selected diameter depends on the stiffness versus the stretchability of the material, among other physical properties. Relatively larger diameters may be used with materials having lower stretchability values. In other words, if the elastic body is formed of a material having relatively low stretchability (i.e., high stiffness), the constriction hole diameter may be relatively large (e.g., slightly smaller than a diameter of the tissue nub of a salivary duct). Conversely, if the elastic body is formed of a material having relatively high stretchability (e.g., at least about 500 percent), the constriction hole diameter may be relatively small (e.g., less than about 0.8 mm).

FIGS. 2A-2C illustrate an exemplary saliva control device 200. FIGS. 2A and 2B illustrate top and bottom perspective views, respectively, while FIG. 2C illustrates a perspective view with the device 200 in an open position so as to better see the interior of the device. Device 200 includes a body 202, a cavity (i.e., a hole) 204, a vacuum chamber 206, and an air evacuation passage (e.g., a one way valve) 208. A lifeline (or leash) 211 may advantageously be included to prevent the device 200 from inadvertently falling down the patient's throat or being inhaled. One end of the lifeline 211 is attached to device 200, such as through a depression or protrusion (e.g., through eyelet 213), and the other end is attached to any suitable anchor (e.g., a dental device external to the patient's mouth) so as to prevent device 200 from being swallowed, choked on, inhaled, or otherwise lost in the event it becomes detached from the inside of the patient's mouth. Examples of suitable lifeline materials include ordinary string, dental floss, and monofilament. Although illustrated as being substantially circular in FIGS. 2A-2C, the body 202 and cavity 204 may be of any desired shape.

Cavity 204 is configured for forming a seal over a salivary duct. In other words, device 200 is configured for vacuum adhering over a selected salivary duct. The cavity 204 formed in the body 202 forms a seal over the salivary duct, while vacuum chamber 206 and air evacuation passage 208 assist the cavity in forming a seal. Air evacuation passage 208 is in fluid communication with vacuum chamber 206, which is in communication with cavity 204. A vacuum is applied to air evacuation passage 208, which creates and maintains a vacuum within the vacuum chamber 206 and cavity 204. The device is positioned over a selected salivary duct, a reduced pressure is applied through passage 208 to chamber 206 and cavity 204, and the salivary duct is pulled into cavity 204. In this way the device reduces production of saliva and/or prevents saliva produced by the salivary duct from flowing beyond the confines of the device. According to one embodiment, the body 202 surrounding cavity 204 may be formed of a soft, adaptable material. In addition to forming a tight seal, a soft flexible material may provide a higher degree of comfort for the patient.

Air evacuation passage 208 is configured so as to allow selective evacuation of air from vacuum chamber 206 and cavity 204, allowing the practitioner to vacuum adhere device 200 over a person's salivary duct. The saliva control device may be formed as a single integral piece. As illustrated in FIG. 2C, body 202 may comprise two integral portions connected together by a flexible hinge 210. In the illustrated embodiment air evacuation passage 208 comprises a one way slit valve although other configurations may be used.

Additional embodiments and more details regarding device 200 are disclosed in U.S. patent application Ser. No. 11/208,897 filed Aug. 22, 2005 and entitled “VACUUM SEALED SALIVARY DEVICE,” already incorporated by reference. Additional embodiments and more details of the saliva control device illustrated in FIG. 1 are disclosed in an application filed on the same day as the present application entitled “SALIVARY DUCT CONSTRUCTION DEVICES SYSTEMS AND METHODS” and bearing Attorney Docket No. 7678.987. Still additional saliva control devices which may be used with the pump apparatus of the present invention are disclosed in PCT Patent Application Publication No. WO 2004069984 entitled “VACUUM SEALED SALIVARY CONTROL DEVICE.” Each of the above mentioned applications is hereby incorporated by reference.

III. Exemplary Integral Hand-Held Vacuum Pump Apparatuses

FIGS. 3 and 4 illustrate an exemplary integral hand-held vacuum pump apparatus 150. FIG. 3 shows a perspective view, while FIG. 4 is an exploded view of apparatus 150. As illustrated, vacuum pump apparatus 150 includes a body 152 having a grippable handle 154 and a support member, e.g., cradle 156. A finger grippable lever 158 is spaced apart from and substantially parallel to grippable handle 154. Lever 158 is an example of means for moving the plunger proximally within the hollow suction tube in response to squeezing a practitioner's hand and/or at least one finger. Grippable lever 158 is movably mounted to grippable handle 154 such that the finger grippable lever 158 may be selectively moved relative to grippable handle 154. Positioning lever 158 so as to be substantially parallel to handle 154 facilitates easy gripping of both the handle and lever with a single hand, and provides for efficient, simple, and comfortable operation with a single hand. In the illustrated embodiment, handle 154 includes a pivot pin 155 (FIG. 4) configured to be received within a hole 157 formed near an end of lever 158. Pivot pin 155 may be secured within hole 157 by a snap fit. For example, the end of pin 155 opposite its base where it is attached to handle 154 may include an enlarged ridge 155a and a slit 155b so as to allow the pin 155 and enlarged ridge 155a to flex together. When flexed together, the effective diameter of pin 155 is reduced, and pin 155 including enlarged ridge 155a can be inserted through hole 157. Once fully inserted, ridge 155a and slit 155b spring back to their original unflexed configuration, locking pin 155 within hole 157.

A hollow suction tube 160 is supported by cradle support member 156 (e.g., having a U-shaped cross section so as to support and cradle tube 160). Hollow suction tube 160 includes a proximal end 162 and a distal end 164. A plunger 166 is slidably disposed within hollow suction tube
160. Plunger 166 includes a stem 168 and a sealing plug 170 (FIG. 4). The sealing plug 170 and at least a portion of stem 168 are slidably disposed within hollow suction tube 160. Tube 160 may advantageously be soft and flexible, making it comfortable and easily maneuverable within the mouth of a patient, while cradle 156 provides any necessary support and/or rigidity.

[0041] Cradle 156 is an example of a support member for supporting tube 160. The support member may be of any configuration capable of supporting tube 160. Cradle 156 partially surrounds and supports nearly the full length of tube 160, although alternative support members may surround the more or less of the circumference of tube 160 along any desired length and be of any configuration, so long as the support member is able to provide support to tube 160. Tube 160 may advantageously extend distally past the distal end of cradle 156 (e.g., about 1 cm or less), which is advantageous when using tube 160 to position a saliva control device 100 over a salivary duct, as it prevents the support member from interfering with maneuvering and/or positioning. Furthermore, it may be advantageous to form tube 160 of a transparent material so that the practitioner can more easily see when placing the tube and a saliva control device (e.g., device 100) over a salivary duct. In other words, a transparent tube allows a practitioner to more easily determine whether the tube and saliva control device are oriented correctly with respect to the salivary duct. For these same reasons, it may be advantageous in some embodiments for the saliva control device to also be transparent. Hollow suction tube may be formed of a suitable flexible, soft, adoptable thermoplastic material. Examples of suitable materials include various polyolefins, for example polypropylene.

[0042] Plunger 166 is operatively coupled at its proximal end to lever 158. In the illustrated embodiment, the coupling means comprises a slot 172 into which an end of lever 158 is inserted. This configuration provides that selective movement of lever 158 (i.e., pulling it towards handle 154) causes plug 170 to slide proximally within hollow suction tube 160 so as to create a vacuum within tube 160. The vacuum can be released by releasing lever 158, permitting distal movement of plug 170 within tube 160. The sliding movement of lever 158 is guided by a second slot 163 formed within body 152 through which lever 158 is also inserted so as to result in a smooth and guided feel for the practitioner during use. Such a smooth and guided feel is advantageous as it allows the practitioner to concentrate on positioning and placement of the saliva control device rather than the operation of the vacuum pump apparatus. In addition, the apparatus can advantageously be operated with a single hand, leaving the other hand free for other needs.

[0043] The body 152, finger grippable lever 158, and plunger stem 168 of apparatus 150 may be formed by injection molding a suitable plastic material. Exemplary materials include, but are not limited to acrylonitrile butadiene styrene and/or polyphenylsulphone. Polyanlylarsulphone is particularly preferred, as it can be autoclaved many times while still retaining structural integrity (e.g., 100 or more cycles). Handle 154, the support member (e.g., cradle 156), lever 158, and plunger stem 168 may advantageously be formed of a material that is easily cleaned, so as to minimize the risk of cross-contamination between patients. Cleaning may be accomplished by wiping down or otherwise washing the handle, cradle, plunger stem, and lever, or by autoclaving these portions. Hollow suction tube 160 is advantageously separable from the remainder of the apparatus so as to be disposable, which also acts to minimize risk of cross-contamination between patients, particularly as tube 160 is the part of the apparatus most likely to touch bodily fluids of patient. As plunger 166 is also detachable from the remainder of apparatus 150, it is also possible for the plunger to be disposed of (rather than cleaned) after a single use also, if desired.

[0044] FIGS. 5A-5J illustrate an alternative apparatus 150 including a body 152 having a grippable handle 154 and a support member 156. A finger grippable lever 158 is substantially parallel to and spaced distally apart from grippable handle 154. In use, the practitioner is able to pull lever 158 towards handle 154 (e.g., by squeezing the hand and/or at least one finger). The substantially parallel configuration of lever 158 relative to handle 154 facilitates easy gripping of both the handle and lever with a single hand, and provides for efficient, simple, and comfortable single hand operation. A hollow suction tube 160 is supported by support member 156, and a plunger 166 is slidably disposed within hollow suction tube 160. In the illustrated embodiment, tube 160 extends far beyond the distal end of support member 156, and as such, tube 160 may be formed of a more rigid material as compared to tube 160, which is almost completely supported by cradle support member 156.

[0045] In the illustrated embodiment, lever 158 is connected to handle 154 by first and second support members 159 and 161, respectively. Each of support members 159 and 161 is pivotally connected at each end, i.e., one end of each support member is pivotally connected to lever 158, while the other end of each support member is pivotally connected to handle 154, such that lever 158 and handle 154 are substantially parallel. Support member 159 is pivotally connected at one end to lever 158 by a pin 157, while the opposite end of support member 159 is pivotally connected to handle 154 by another pin 165. Pin 157 passes through a pair of holes 157a formed near an end of support member 159, and end sections of pin 157 may be retained within a pair of holes 157b formed within lever 158. Pin 165 passes through a pair of holes 165a formed near an opposite end of support member 159, and end sections of pin 165 may be retained within a pair of holes 165b formed within handle 154. Support member 161 is pivotally connected to lever 158 and handle 154 in a similar manner. Pin 167 passes through a pair of holes 167a formed near an end of support member 161, and end sections of pin 167 may be retained within a pair of holes 167b formed within lever 158. Another pin 171 passes through a pair of holes 173a formed near an opposite end of support member 161, and end sections of pin 171 may be retained within a pair of holes 173b formed within handle 154. Other attachment configurations will be apparent to one skilled in the art.

[0046] When a practitioner pulls lever 158 towards handle 154, lever 158 slides proximally towards handle 154. In addition to support members 159 and 161, the sliding movement of lever 158 is guided by a channel 163 formed within body 152 so as to result in a smooth and guided feel for the practitioner during use. Such a smooth and guided feel is advantageous as it allows the practitioner to concen-
trate on positioning and placement of the saliva control device rather than the operation of the vacuum pump apparatus.

[0047] Plunger 166" includes a stem 168" and a sealing plug 170". A proximal end of stem 168" is attached to a coupler 174" that is attached to lever 158" (e.g., at a distal end of element 174" by pin 177"). In use, when the practitioner holds handle 154" and squeezes lever 158", lever 158" is pulled towards handle 154". Coupler 174" moves proximally, pulling plunger 166" proximally within hollow suction tube 160", which results in the creation of a vacuum within hollow suction tube 160". Release of lever 158" allows distal movement of sealing plug 170", which releases the vacuum. Coupler 174" is another example of coupling means for operatively coupling the plunger 166" to lever 158".

[0048] Distal end 164" of tube 160" may advantageously be configured to couple with or otherwise mate with a saliva control device to be installed. For example, the distal end 164" of hollow suction tube 160" may be configured to friction fit over a hub or protrusion formed on the top of saliva control device 200, as illustrated (FIG. 5A). Of course, distal end 164" may be configured to mate with saliva control device 100 of FIG. 1, or with any other saliva control device. Other configurations of distal end 164" for coupling or attaching to a saliva control device will be apparent to those skilled in the art.

[0049] In one embodiment, tube 160" may advantageously include an outer tube 185" which is slidably disposed over hollow suction tube 160" for forcing device 200 off distal end 164" once the saliva control device is in the desired position. Tweezers, the practitioner's fingers, or another dental tool may alternatively be used to slide and/or push device 200 distally off distal end 164". Although illustrated in conjunction with apparatus 150", it will be understood that a slidable outer tube (e.g., tube 185") may be included with any of the illustrated hand-held vacuum pump apparatuses. For example, such a slidable outer tube may be included with device 150 of FIGS. 3-4. After positioning the saliva control device as needed over a salivary duct, the outer tube may be used to force a saliva control device (e.g., device 100) over and/or off distal end 164" (e.g., constriction hole 104 of device 100 may be stretched so as to initially position device 100 over tube 160, and an outer tube may be used to push device 100 over distal end 164"). Once device 100 is slid off distal end 164, elastic body 102 springs closed because of the elasticity of elastic body 102 surrounding constriction hole 104. The result is that the base of the tissue tube surrounding the salivary duct becomes inserted through constriction hole 104. The vacuum within hollow suction tube 160" may then be released.

[0050] FIG. 6 illustrates another alternative hand-held vacuum pump apparatus 150" including a body 152" having a grippable handle 154" and a support member 156". A finger grippable lever 158" is substantially parallel to and spaced distally apart from grippable handle 154". In use, the practitioner is able to pull lever 158" towards handle 154" (e.g., by squeezing the hand and/or at least one finger). A hollow suction tube 160" is supported by support member 156", and a plunger 166" is slidably disposed within hollow suction tube 160".

[0051] Apparatus 150" is similar to apparatus 150 of FIGS. 3-4, with a principal difference being the means for coupling plunger 166" to lever 158". Plunger 166" is operatively coupled at its proximal end to lever 158". In the illustrated embodiment, plunger 166" is not smooth, but rather includes a series of indented locking positions 176" for engagement with a fork 172" disposed at an end of lever 158". The practitioner is advantageously able to adjust the force of the vacuum generated by selecting which locking position fork 172" is engaged in, which adjusts the length of displacement of plunger 166" for any given locking position. Adjustability of the force of the produced vacuum is advantageous as it allows the practitioner to select and deliver a sufficient vacuum force to enable adhering the saliva control device over a salivary duct, while also minimizing any discomfort of the patient as a result of application of a very strong vacuum force, which may be uncomfortable.

[0052] This coupling configuration of lever 158" and plunger 166" provides that selective movement of lever 158" (i.e., pulling it towards handle 154") causes plug 170" of plunger 166" to slide proximally within hollow suction tube 160" so as to create a vacuum within tube 160". The vacuum can be released by releasing lever 158", permitting distal movement of plug 170" of plunger 166" within tube 160".

[0053] FIGS. 7 and 8A-8B illustrate a method of using the apparatus 150 of FIG. 3 to install a saliva control device over one or more of a patient's salivary ducts. Referring to FIG. 7, the two submandibular salivary ducts 180a and 180b, which are normally covered by the tongue 182, are seen on the floor of the mouth of patient 175. Each duct 180a and 180b is surrounded by a raised nub of tissue 181a and 181b, respectively. The two parotid salivary ducts 190a and 190b and their associated tissue nubs 191a and 191b are also visible on the inside of the patient's cheeks. As illustrated in FIG. 8A, saliva control device 100 is fitted over the distal end of hollow suction tube 160 of suction apparatus 150. Saliva control device 100 is then positioned over a selected salivary duct and raised tissue nub (e.g., nub 181a). A vacuum is applied to hollow suction tube 160 so as to cause tissue nub 181a surrounding salivary duct 180a to be pulled up into hollow suction tube 160. Where device 100 is friction fitted with a distal end of hollow suction tube 160 as described above, the vacuum is also applied through constriction hole 104, and tissue nub 181a becomes inserted through constriction hole 104 and into suction tube 160. Once tissue nub 181a is inserted through constriction hole 104, the vacuum of suction apparatus 150 can be released and apparatus 150 can be removed.

[0054] An adhesive, anesthetic, and/or lubricant may be applied (e.g., either pre-applied during manufacture of the saliva control device or applied just prior to use) to an underside of device 100 prior to positioning of the device over the salivary duct. An adhesive may be helpful in keeping the device in place, particularly for relatively long time periods (e.g., greater than 90 minutes). Examples of suitable oral adhesives that can adhere to moist oral tissue include polyvinylpyrrolidone, carboxymethylcellulose, carbopol, or a light curable adhesive (e.g., a hydrophilic polycrylamide, a hydrophilic acrylic, or a hydrophilic polyurethane-acrylate). An anesthetic (e.g., benzocaine) or a lubricant may advantageously be applied to an underside of device 100 to reduce any discomfort felt by the patient as a result of the constriction around the salivary ducts to which control devices are applied.
As seen in FIG. 8B, elastic body 102 surrounding constriction hole 104 constricts around tissue nub 181a surrounding salivary duct 180a. Tissue nub 181a may protrude out the top of constriction hole 104. Constriction hole 104 is of a sufficiently small diameter and the stiffness and stretchability of the material from which elastic body 102 is formed is such so as to constrict around salivary duct 180a such that production and flow of saliva from salivary duct 180a is prevented. Preferably, the diameter of constriction hole 104 and the stiffness and stretchability of the material of elastic body 102 is formed is such so as to prevent the flow of blood through tissue nub 181a surrounding salivary duct 180a. In other words, tissue nub 181a may advantageously remain red and vital throughout the procedure while device 100 is in place so as to not permanently damage the patient's tissue. Although the method is illustrated with respect to one particular saliva control device 100 and salivary duct 180a, it is to be understood that any one or more of the four principal salivary ducts may be selected for attachment of a saliva control device. Furthermore, it is to be understood that the various other saliva control devices (e.g., device 200) may be installed in lieu of device 100. Tube 160 may be used with a single patient to install as many devices as desired, after which it may be discarded. The plunger may also be discarded, or cleaned, along with with the body and lever of the apparatus prior to use with another patient.

The saliva control device may remain in place as long as necessary, typically between about 10 minutes and about 3 hours, more typically between about 20 minutes and about 2.5 hours, and most typically between about 30 minutes and about 2 hours, after which the saliva control device or devices are removed (e.g., by prying them off with pliers, a dental tool or even a fingernail). The raised rim 106 (FIG. 1) assists in gripping of the device for removal.

It will be appreciated that the present claimed invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative, not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A hand-held vacuum pump apparatus for attaching a saliva control device to a salivary duct comprising:
   a body including a grippable handle and a support member;
   a hollow suction tube having a proximal end and a distal end, the hollow suction tube being supported by the support member of the body;
   a plunger having a stem and a plug at a distal end of the stem, the plug being slidably disposable within the hollow suction tube; and
   means for moving the plunger proximally within the hollow suction tube in response to squeezing a practitioner's hand and/or at least one finger.

2. A hand-held vacuum pump apparatus as recited in claim 1, wherein means for proximally moving the plunger within the hollow suction tube comprises a finger grippable lever spaced apart from the grippable lever, the finger grippable lever being movably mounted to the grippable handle such that the finger grippable lever may be selectively moved relative to the grippable handle, the lever being operatively coupled to the stem of the plunger such that selectively moving the lever causes the plug to slide proximally within the hollow suction tube so as to create a vacuum within the hollow suction tube.

3. A hand-held vacuum pump apparatus as recited in claim 2, wherein the finger grippable lever and the grippable handle are substantially parallel.

4. A hand-held vacuum pump apparatus as recited in claim 2, wherein the grippable handle further comprises a pivot pin adapted to be received within a hole formed in the finger grippable lever such that the finger grippable lever may be selectively pivoted relative to the grippable handle.

5. A hand-held vacuum pump apparatus as recited in claim 2, wherein the body and finger grippable lever are made from an autoclavable material.

6. A hand-held vacuum pump apparatus as recited in claim 2, wherein the body and finger grippable lever are formed from at least one of acrylonitrile butadiene styrene or polyphenylsulphone.

7. A hand-held vacuum pump apparatus as recited in claim 2, further comprising a slot formed in the stem of the plunger into which an end of the lever is receivable such that selectively pulling the lever towards the handle causes the plunger to slide proximally within the hollow suction tube so as to create a vacuum within the hollow suction tube.

8. A hand-held vacuum pump apparatus as recited in claim 2, further comprising a series of indented locking positions formed in the stem of the plunger and a fork disposed at an end of the lever, the fork being configured to engage within the indented locking positions such that selectively pulling the lever towards the handle causes the plunger to slide proximally within the hollow suction tube so as to create a vacuum within the hollow suction tube.

9. A hand-held vacuum pump apparatus as recited in claim 1, wherein the hollow suction tube is releasably attached to the support member so as to be disposable.

10. A hand-held vacuum pump apparatus as recited in claim 1, wherein the support member of the body comprises a cradle.

11. A hand-held vacuum pump apparatus as recited in claim 10, wherein the distal end of the hollow suction tube extends beyond the distal end of the cradle.

12. A hand-held vacuum pump apparatus as recited in claim 1, wherein the body is integrally molded as a single piece of injection molded plastic.

13. A hand-held vacuum pump apparatus as recited in claim 1, wherein the hollow suction tube is flexible.

14. A hand-held vacuum pump apparatus as recited in claim 1, wherein the hollow suction tube is transparent.

15. A hand-held vacuum pump apparatus as recited in claim 1, wherein the hollow suction tube is formed from polypropylene.
16. A hand-held vacuum pump apparatus as recited in claim 1, wherein the plunger is removably attached to the body so as to be disposable.

17. A hand-held vacuum pump apparatus as recited in claim 1, wherein the hand-held vacuum pump apparatus is a self-contained unit such that no connection to an external vacuum source is required for the apparatus to produce a vacuum.

18. A hand-held vacuum pump apparatus for attaching a saliva control device to a salivary duct comprising:

- a body including a grippable handle and a support member;
- a finger grippable lever spaced apart from the grippable handle, the finger grippable lever being movably mounted to the grippable handle such that the finger grippable lever may be selectively moved relative to the grippable handle;
- a hollow suction tube having a proximal end and a distal end, the hollow suction tube being supported by the support member of the body;
- a plunger having a stem and a plug at a distal end of the stem, the plug being slidably disposable within the hollow suction tube; and
- a slot formed in the stem of the plunger into which an end of the lever is receivable such that selectively pulling the lever towards the handle causes the plunger to slide proximally within the hollow suction tube so as to create a vacuum within the hollow suction tube.

19. A kit for use in attaching a saliva control device over a salivary duct comprising:

- at least one saliva control device; and
- a hand-held vacuum pump apparatus comprising:
  - a body including a grippable handle and a support member;
  - a hollow suction tube having a proximal end and a distal end, the hollow suction tube being supported by the support member of the body;
  - a plunger having a stem and a plug at a distal end of the stem, the plug being slidably disposable within the hollow suction tube; and
  - means for moving the plunger proximally within the hollow suction tube in response to squeezing a practitioner’s hand and/or at least one finger.

20. A kit as recited in claim 19, wherein the at least one saliva control device comprises:

- an elastic body comprising at least one elastomer; and
- a constriction hole formed through the elastic body for constricting around a salivary duct;

- wherein a stiffness of the elastic body and/or a diameter of the constriction hole are configured so as to provide a degree of constriction to a salivary duct sufficient to prevent a flow of saliva without substantially cutting off blood flow to a salivary duct so as to not damage tissue surrounding a salivary duct.

21. A kit as recited in claim 19, wherein the at least one saliva control device further comprises a rim extending around an outer perimeter of the elastic body, the rim having a cross-sectional thickness that is greater than a cross-sectional thickness of the elastic body adjacent to the constriction hole.

22. A kit as recited in claim 21, wherein an outside diameter of the hollow suction tube is configured to friction fit within an inside diameter of the rim extending around the outer perimeter of the elastic body of the at least one saliva control device.

23. A kit as recited in claim 19, wherein the kit comprises at least four saliva control devices.

24. A kit as recited in claim 19, wherein the at least one saliva control device comprises:

- a body;
- a cavity in the body for forming a seal over a salivary duct;
- a vacuum chamber in the body that assists the cavity in forming a seal over a salivary duct upon placing the saliva control device over a salivary duct and applying a vacuum to the vacuum chamber; and
- an air evacuation passage for selectively applying and maintaining a vacuum to the vacuum chamber.

25. A kit as recited in claim 24, wherein the air evacuation passage comprises a one way slit valve.

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