A fastener apparatus for joining an associated first object having a first bore extending therethrough and a second object having a second bore extending therethrough which includes an elongated flexible member having a plurality of notches on a face thereof and first and second axial extremities; anchoring structure at the first axial extremity; and a first discrete locking member having a pawl and ratcheting mechanism dimensioned and configured for engagement with the plurality of notches, also disclosed is apparatus for supporting an associated ventilation apparatus which includes an engagement member for engaging and gripping a plurality of teeth of the user; an adjustment assembly for connecting the engagement member to associated ventilation apparatus. The adjustment assembly includes an elongated flexible member having a plurality of notches thereon. The apparatus may further including a first discrete locking member and the elongated flexible member may have a bulbous axial extremity.
CONNECTOR APPARATUS AND METHOD FOR JOINING OBJECTS

RELATED APPLICATIONS

[0001] This application is a division of U.S. application Ser. No. 10/861,752 filed Jun. 3, 2004 which matured into U.S. Pat. No. ________ on ________.

BACKGROUND OF THE INVENTION

[0002] The invention relates to apparatus and methods for joining or fastening objects. While the apparatus and method for joining will be described with respect to being utilized in a medical appliance for patient ventilation, the present invention also has application to a wide variety of joining applications.

[0003] Known fasteners include a wide variety of devices including screws and bolts. Many such fasteners are relatively expensive to manufacture, require a relatively long time to assemble with objects being held together, do not allow quick release and/or require special equipment such as welding equipment.

SUMMARY OF THE INVENTION

[0004] An object of the present invention is to provide a fastener apparatus is to provide a very simple and inexpensive fastener apparatus and method for fastening.

[0005] Another object of the invention is to provide embodiments of a fastener and method of joining that allows rapid release.

[0006] A further object of this invention is to provide a fastener and method that can be very rapidly secured.

[0007] Still another object of the invention is to provide a method of joining an apparatus that does not require welding or soldering or other expensive apparatus to utilize.

[0008] It has now been found that these other objects of invention may be attained in a fastener apparatus for joining an associated first object having a first bore extending therethrough and a second object having a second bore extending therethrough which includes an elongated flexible member having a plurality of notches on a face thereof and first and second axial extremities; anchoring structure at the first axial extremity; and a first discrete locking member having a pawl and ratcheting mechanism dimensioned and configured for engagement with the plurality of notches.

[0009] In some forms of the apparatus the anchoring structure is a bulbous part of the elongated flexible member and in others it is a second discrete locking member. The first locking member may be releasable.

[0010] The invention includes apparatus for supporting an associated ventilation apparatus which includes an engagement member for engaging and gripping a plurality of teeth of the user; an adjustment assembly for connecting the engagement member to associated ventilation apparatus. The adjustment assembly includes an elongated flexible member having a plurality of notches thereon. The apparatus may further including a first discrete locking member and the elongated flexible member may have a bulbous axial extremity. The apparatus may further including a second discrete locking member. Each locking member may be releasable.

[0011] In some cases the apparatus further includes a first discrete locking member and the apparatus may have an elongated flexible member that has a bulbous axial extremity. Some forms of the apparatus may include a second discrete locking member. The first locking member may be releasable. Some embodiments may include a ramp dimensioned and configured for mandible positioning. The engagement member may be a boil and bite formed product. In some cases the engagement member is at least partly formed of a polycarbonate resin material and lined with an ethylene vinyl acetate copolymer and terpolymer resin material.

[0012] The invention also includes the method for joining an associated first object having a first bore extending therethrough and a second object having a second bore extending therethrough which includes the steps of providing an elongated flexible member having a plurality of notches on a face thereof and first and second axial extremities; providing an anchoring structure at the first axial extremity; and providing a first discrete locking member having a pawl and ratcheting mechanism dimensioned and configured for engagement with the plurality of notches.

[0013] In some cases the method includes providing an anchoring structure that is a bulbous part of the elongated flexible member and the step of providing an anchoring structure includes providing a second discrete locking member and the step of providing a second locking member. In some cases the method includes the step of providing first locking member includes providing a locking member that is releasable.

[0014] In some cases the method further includes the step of providing a first discrete locking member, the step of providing an elongated flexible member includes providing an elongated flexible member having a bulbous axial extremity, the step of providing a second discrete locking member, and/or the step of providing a first locking member includes providing a first locking member that is releasable.

[0015] In some cases this method includes the step of providing an adjustment assembly further includes providing a first discrete locking member, the step of providing an adjustment assembly includes providing an elongated flexible member that has a bulbous axial extremity, the step of providing an adjustment assembly further includes providing a second discrete locking member, the step of providing an engagement member includes providing a first locking member that is releasable, the step of providing an engagement member includes providing an engagement member that includes a ramp dimensioned and configured for mandible positioning, the step of providing an engagement member includes providing an engagement member that is a boil and bite formed product, the step of providing an engagement member includes providing an engagement member that is at least partly formed of a polycarbonate resin material, and/or the step of providing an engagement member includes providing an engagement member that is lined with an ethylene vinyl acetate copolymer and terpolymer resin material.

BRIEF DESCRIPTION OF THE DRAWING

[0016] The invention will be better understood by reference to the accompanying drawing in which:

[0017] FIG. 1 shows a schematic view of ventilation apparatus with a quick release nylon tie in accordance with one form of the present invention.

[0018] FIG. 2 shows a schematic view of the ventilation apparatus being fitted to a patient with the mask loose.

[0019] FIG. 3 shows a schematic view of the ventilation apparatus as it is tightened against the patient's face.

[0020] FIG. 4 shows a prior art ventilator mask with patient. Lower jaw is not moved forward.
The view of FIG. 10 show the pawl engagement with and enlarged view of axial section of cable tie.

[0029] The upper portion of one form of the oral device in accordance with the present invention defines a trough for receiving some of the upper teeth. Once inserted into the mouth the device snugly engages the upper teeth, particularly the front teeth, and remains positioned independent of natural motions of the lower jaw. This trough forms a practical anchor point for attachment of a face mask for receiving ventilation of breathing air by means of a ventilator machine and tube.

[0030] Some embodiments of the invention include a lower portion that defines a ramp structure whereby natural jaw motion results in the engagement of the lower teeth with the ramp, which will cam the lower jaw into a more forward position. This action acts to help keep the airway open, thereby, allowing the attached ventilator mask to operate more effectively.

[0031] An adjustable fastener system similar to that described above connects the mask to the oral device. The adjustment feature allows the mask to be moved closer or further from the face until the mask seal is in the ideal position as desired. This feature allows the mask portion to be fitted to the patient without the need for straps or other uncomfortable headgear.

[0032] Most embodiments of the present invention utilize a mouthpiece of the general type that is referred to in the dental industry as a “boil and bite” oral appliance. Such devices include, but are not limited to, anti-snoring medical oral appliances as described in U.S. Pat. Nos. 5,092,346 and 5,277,202. The disclosures therein are incorporated by reference.

[0033] Such oral or anti-snoring appliances are also referred to as mandible repositioning devices and act to keep the airway open during sleep. The appliance is heated and custom molded directly to the patient's teeth. The upper trough of the appliance forms a very stable anchor point that holds it securely in place. This stable anchor feature not only holds the mouthpiece in place but becomes the central anchor point for holding the mask against the patients nose and mouth. With the flip of the tongue, or pulling down on the mouthpiece it can be instantly released by the patient or hospital staff.

[0034] The substantial improvements include an adjustable connection method between the mask and mouthpiece. The adjustable connection allows for external adjustment of the tightness of the mask against the patient’s mouth and face by using the mouthpiece as an anchor point. In other words, the adjustment feature allows the mask to be moved closer or further from the face until the ideal position is desired. This not only helps keep the airway open but also eliminates the need for bulky and uncomfortable headgear.

[0035] This invention consists of three primary parts that are connected to a ventilation machine by others. The ventilation machine provides the proper amount of breathing air supply and control. It contains necessary alarms and tubing.

[0036] The invention components include the mouthpiece, adjustment assembly and face mask. These may be factory provided in one single assembled unit or provided as a kit so it can be simply connected to most of the conventional face masks available on the market. In this latter case, the straps and headgear would be removed. Existing masks come in numerous sizes, shapes, and a variety of types. Most have straps and headgear in common. Thus, it is clear that other masks can be utilized with the present invention.
Mouthpiece: The mouthpiece is sometimes referred to as a "boil and bite" oral appliance in the dental industry. Adjustment assembly: The adjustment assembly includes all components necessary for connecting the mouthpiece to the full face mask. The preferred adjustment components may include an extension from the mouthpiece, in the form of a releasable type, nylon cable tie fastener. Representative prior art includes fasteners manufactured by 3M Company, 3M Center, St. Paul, Minn. 55144-1000.

The fastener in accordance with the present invention includes an elongated member, a ratchet releasable lock and a quick release lever of the type known in the art. This fastener is secured to the mask whereby the tie is tightened by simply pulling on the end of the tie. To release, it is only necessary to depress the quick release lever. The tie is flexible and allows for off-sets to occur between the mask and mouthpiece while it keeps the seal of the mask snugly fitted to the patient's face. In other variations a screw, bushing and adjustment knob may be used to accomplish the adjustment feature.

The masks used may be of a number of sizes and shapes but the preferred type is considered the full face mask. This is usually a clear plastic mask that covers the nose and mouth and has a tube for connection to a ventilator. The mask usually contains a soft sealing portion that fits snugly against the patient's face. Some masks have an air filled chamber seal that easily deforms to the patient's face to obtain a tight fit. The prior art apparatus requires the nurse or respiratory therapist to hold the mask in place with several straps along with other complicated headgear as shown in FIG. 4. These cumbersome straps and headgear are not used with this invention.

Referring now to FIGS. 1, 2, and 3 there is shown a mouthpiece mask 10 that includes a mouthpiece 20. The mouthpiece 20 in the preferred embodiment is made with a polycarbonate shell such as that sold by General Electric and identified by the trademark Lexan. The ventilation apparatus is fitted directly to the patient 60 without the need for any laboratory work or molds for teeth impressions. The mouthpiece 20 may, in one form of the invention, have an integral connection port or fastening method for receiving the adjustment assembly that includes a cable tie 57 with locking ridges and a free end and a Quick release lever lock 38. The end of the tie 57 remote from the free end has a smooth shaped head or bulbous end 58a that is larger than the opening 25 in the mouthpiece to prevent it from being pulled through the mouthpiece. The entire cable tie is made of nylon. The quick release lever lock 38 includes a release lever that allows the free end of the cable tie to be moved when release lever is depressed. The quick release lever lock 38 has a short tab that allows it to be riveted or fastened to the mask. The quick release lever lock 38 is positioned in line with a hole 44 in the mask to allow the cable tie 37 end to pass through the mask and through the quick release lever lock 38. The quick release lever lock 38 allows the free end of the cable tie 37 to pass through and thus allow for exterior adjustment to be made for tightening or loosening the mask with respect to the mouthpiece. The fastener also includes a slip on lock 39 for securing the cable tie to mouthpiece. This lock 39 is made of nylon and has an opening to allow the tie to slip through but prevents the tie from moving back in the opposite direction. This lock 39 may include a release lever for removal.

The mouthpiece 20 is designed to be custom fit one patient 60 and is durable and long lasting. Once custom fit for one patient 60 it cannot be used for any other patient. It may be discarded when the patient 60 no longer uses the ventilator 52 and mask 40. Once the patient 60 is custom fitted with the mouthpiece 20 it only takes a few seconds for the patient 60 or medical staff to place it in the patient's mouth 61 for use.

The geometric relationships between the patient and the apparatus are best seen in FIG. 3 which illustrates the head and face of a patient 60, palate 66, tongue 65, oral anti snoring device 20, mouth of patient 61, mask assembly, clear plastic mask assembly 40, quick lock release lever lock 38, cable tie with locking ridges and a free end 37, upper teeth 62, lower teeth 63, lower jaw 64, tongue 65, palate 66, uvula 67, trachea 68 and esophagus 69.

The mouthpiece mask includes an adjustment assembly 37. The adjustment assembly 37 is preferably made of Nylon or another FDA approved material for medical use. The adjustable fastener may include a releasable nylon cable tie 37 secured by an attachment 39 to the mouthpiece 20 as best seen in FIG. 1. Releasable cable ties are manufactured and sold by a number of business entities. The opposite end of the tie 37 extends through a quick release lever 38 that is bonded to the mask 40. This type adjustment is simple to use, easy to manufacture, inexpensive, easy to clean and can be rapidly adjusted and released.

The attachment 39 may be achieved by bonding, welding, snap-on connection, a clamp, a screw, or other means secured to the mouthpiece 20. Likewise the quick connect lever 38 portion may be bonded, screwed or otherwise secured to the mask 40.

Referring now to FIG. 5 there are shown an alternate embodiment of the adjustment assembly in which a screw 30 portion may have a slotted head 31 for secure attachment to the mouthpiece 20 as best shown in FIG. 5. The mouthpiece 20 may have a threaded opening located between the upper trough 22 and the lower ramp 23. The threaded screw 30 is secured to the mouthpiece 20. The shoulder 35 of threaded bushing 33 protrudes though an opening in the mask 40. A knob 36 outside the mask 40 is securely fastened to the bushing 33. By turning the knob 36 close-wise, the screw 33 travels inside the bushing threads 34 and causes the mask 40 and mouthpiece 20 to come closer together. The knob 36 is tightened until a comfortable mask 40 fit and seal 41 is realized. When the knob 36 is turned counter-clock-wise the mask 40 and mouthpiece 20 move further apart.

In another form of the invention a semi-flexible section is placed in line with the adjustment fastener. This would allow for an offset to occur thereby, allowing the mouthpiece to fit securely without undue stress of strain that could act to dislocate the upper trough of the mouthpiece from the upper teeth.

The mask 40 as shown in FIG. 1 is of a full face type that covers the nose and mouth. This type allows for breathing to occur through the nose and/or mouth. The mouth 61 may also be "open" or "closed". The mask 40 has a 15 to 22 mm connection port for attachment to an air tube 50, for breathing air 51, and a ventilator machine 52. Various attachment may be provided with the mask 40 and include ports or connections for supplemental oxygen, other gasses, mixtures or vapors. In certain variations or for certain patients 60 a safety strap or straps may be necessary to hold the mask and attachments in place.

In accordance with present invention the apparatus is fitted to a patient in the following manner:

1. The patient's normal bite is inspected by the doctor. The doctor then asks the patient to swallow as that tends
to align the lower jaw. The doctor then asks the patient to move the lower jaw or mandible slightly forward of the normal bite. This may be 2 to 6 millimeters and is determined by the doctor. The patient is then asked to practice biting down several times with the jaw advanced in this forward position. When the mandible is moved slightly forward the tongue reflex is to move forward. This in turn helps keep the airway in a more open position.

[0051] 2. A cup of water is brought to a boil in a microwave or water heater and then removed from heat. The oral mouthpiece portion of the device is placed in the cup of hot water for 3 minutes. The oral device is then removed from the hot water and allowed to air cool for 25 seconds. This prevents burning the patient.

[0052] 3. The oral device is then fitted to the upper teeth. The patient is then asked to bite down on the ramp with the jaw in a slightly forward position as practiced. The device is removed after approximately 30 seconds and placed in cool water. Any excess material from the impression is cut away and polished with an acrylic burr.

[0053] 4. When the patient is ready to receive ventilated air the mouthpiece is re-inserted into the patient’s mouth as shown in FIG. 2. The tie end is inserted through the quick release lever on the mask.

[0054] 5. The tie end is pulled snugly to ensure a tight mask seal as shown in FIG. 3.

[0055] 6. In another variation of the invention where a screw type adjustment is used as shown in FIG. 5, the screw end with bushing is facing away from the patient mouth.

[0056] 7. The threaded portion of the bushing passes through a hole in the mask portion and the knob is screwed onto the bushing. This allows the knob and bushing to be turned from outside the mask. When the bushing is turned it moves along the anchored screw. This causes the mask to move away from the patient’s face. The bushing is inserted through the mask opening and the adjustment knob is locked in place.

[0057] 8. The adjustment knob is tightened until the mask is snugly fitted to the patient.

[0058] 9. The air tubing from the ventilator is then connected to the mask tube connector fitting.

[0059] 10. The ventilator unit is energized and airflow calibrated and set per manufacturers instructions. That completes the basic fitting process of the device.

[0060] Once fitted with this invention the patient then has a preferred system that helps insure that the airway remains open. This reduces the unnecessary alarms that are activated when too little air reaches the patients lungs. This help free up the medical staff for other duties.

[0061] Each day the device can be removed and washed in warm soap and water and or placed in a denture cleaning solution such as Polident for maintaining it clean and fresh. When not in use it should be cleaned, dried and stored for later use.

[0062] Other forms of the present invention utilize an engagement member, trough or tray for engaging either the upper teeth or the lower teeth of the user. Ordinarily, the upper teeth are preferred because there is less movement. The entire trough for the upper (or lower) teeth is made with a heat formable plastic or polymer. This type tray is, manufactured in a preformed shape so that one size can be used to fit most patients. It is made from a clear polymer and is molded by heating it in warm water and then placing it in the mouth to form a snug mold directly to the upper teeth. The heated plastic will stretch and or shrink during the molding process to provide a snug fit.

[0063] Although the description above contains many specifics, these should not be construed as limiting the scope of the invention, but as merely providing illustrations of some of the presently preferred embodiments of this invention. Thus, the scope of this invention should be determined by the appended claims and their legal equivalents. Therefore, it will be appreciated that the scope of the present invention fully encompasses other embodiments which may become obvious to those skilled in the art, and that the scope of the present invention is accordingly to be limited by the appended claims, in which reference to an element in the singular is not intended to mean “one and only one” unless explicitly so stated, but rather “one or more.” All structural, chemical, and functional equivalents to the elements of the above-described preferred embodiment that are known to those of ordinary skill in the art are expressly incorporated herein by reference and are intended to be encompassed by the present claims. Moreover, it is not necessary for a device or method to address each and every problem sought to be solved by the present invention, for it to be encompassed by the present claims. Furthermore, no element, component, or method step in the present disclosure is intended to be dedicated to the public regardless of whether the element, component, or method step is explicitly recited in the claims. No claim element herein is to be construed under the provisions of 35 U.S.C. 112, sixth paragraph, unless the element is expressly recited using the phrase “means for.”

REFERENCE NUMBERS USED IN THE DRAWING

[0064] 10 mouthpiece mask assembly
[0065] 20 oral anti snoring device
[0066] 21 trough, a hard plastic shell (Polycarbonate such as Lexan brand)
[0067] 22 soft moldable plastic fill for upper teeth (ethylene vinyl acetate copolymer and terpolymer resin material such as Elvax brand, softens at 160°F).
[0068] 23 soft moldable plastic ramp for engaging lower teeth (ethylene vinyl acetate copolymer and terpolymer resin material such as Elvax brand)
[0069] 24 hard plastic posts between trough and ramp
[0070] 25 slot or opening between trough and ramp
[0071] 26 threaded portion at opening
[0072] 27 screw, threaded. (Part of adjustable assembly)
[0073] 31 head of screw, slotted
[0074] 32 bushing, threaded
[0075] 33 outside threads of bushing for knob
[0076] 34 inside threads of bushing for screw travel
[0077] 35 shoulder or collar of bushing to stop knob
[0078] 36 knob with textured surface
[0079] 37 cable tie with locking ridges and a free end
[0080] 37a shaped head end of cable tie
[0081] 37 cable tie with locking ridges and a free end
[0082] 38 quick lock release lever lock
[0083] 39 slip on lock for securing cable tie to mouthpiece
[0084] 40 mask assembly, clear plastic
[0085] 41 cushion surface, soft plastic for a snug fit
[0086] 42 hole in mask for exterior threads of bushing to pass through
43 connection fitting for tubing from ventilator includes a swivel elbow fitting, a check valve and a vent opening for exhaled air.

44 hole in mask for cable tie to pass through

50 tubing from ventilator machine

51 air flow in tube from ventilator machine

52 ventilator machine

53 exhaust or exhaled air

60 patient, head and face

61 mouth of patient

62 upper teeth

63 lower teeth

64 lower jaw

65 tongue

66 palate

67 uvula

68 trachea

69 esophagus

70 existing mask

71 straps

80 oral anti-bruxism device

81 trough, a hard plastic shell, Lexan material

82 soft moldable plastic fill at upper teeth. Elvax material

83 connection tab and fastener for cable tie

90 oral tray for upper teeth

91 trough, a moldable plastic or polymer

92 connection tab and fastener for cable tie

100, 102 blocks of wood

104, 106 bores

108 elongated body

109 head

110 locking channel or slip lock

111 pawl

113 enlarged view of axial section of cable tie

1. A fastener apparatus for joining an associated first object having a first bore extending therethrough and a second object having a second bore extending therethrough which comprises:

- an elongated flexible member having a plurality of notches on a face thereof and first and second axial extremities;
- anchoring structure at the first axial extremity; and
- a first discrete locking member having a pawl and ratcheting mechanism dimensioned and configured for engagement with said plurality of notches.

2. The apparatus as described in claim 1 wherein said anchoring structure is a bulbous part of said elongated flexible member.

3. The apparatus as described in claim 1 wherein said anchoring structure is a second discrete locking member.

4. The apparatus as described in claim 2 further including a second locking member.

5. The apparatus as described in claim 1 wherein said first locking member is releasable.

6. A method for joining an associated first object having a first bore extending therethrough and a second object having a second bore extending therethrough which comprises:

- providing an elongated flexible member having a plurality of notches on a face thereof and first and second axial extremities;
- providing an anchoring structure at the first axial extremity; and
- providing a first discrete locking member having a pawl and ratcheting mechanism dimensioned and configured for engagement with said plurality of notches.

7. The method as described in claim 6 wherein said providing steps includes providing an anchoring structure is a bulbous part of the elongated flexible member.

8. The method as described in claim 7 wherein said step of providing an anchoring structure includes providing a second discrete locking member.

9. The method as described in claim 7 further including the step of providing a second locking member.

10. The method as described in claim 6 wherein said step of providing first locking member includes providing a locking member that is releasable.

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