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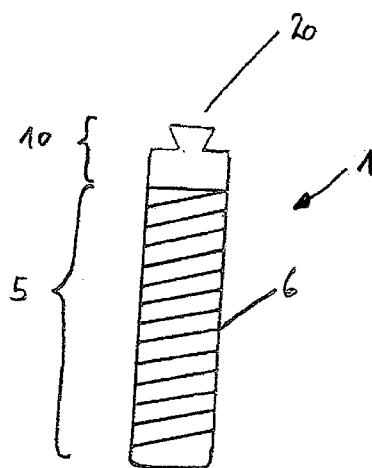


Fig. 1

(57) Abstract: The present invention relates to an inva-
sive fastening device that is intended to be inserted into
bone. Said reference device is preferably made of a ra-
diopaque, biocompatible material and comprises fixing
means which allow the fastening of dental restoration de-
vices such as drill templates and prostheses to the palatal
or retromolar region of a patient's mouth.

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Invasive fastening device

The present invention relates to an invasive fastening device for use in dental surgery and/or prosthetics.

Dental implants are becoming more and more widely used in dental surgery. Said implants are devices that are surgically inserted into the jaw bone of a patient, where they replace the root of a tooth and serve as a support for prosthetic caps, bridges and crowns.

Implants must be positioned and fastened in a specific position and in alignment to the prospective teeth that they will eventually support. Therefore, the positioning of these dental implants must be precise to enable teeth to be made that will function properly and be aesthetic in appearance.

Aiding means used to achieve a precise placement of a dental implant are for instance drill templates. Such drill templates assist the surgeon in angling and positioning of the dental instruments during implantation. In a first step, a wax model of a dental prosthesis is made using an impression that has been taken of the patient's jaw. A scan template is then prepared in synthetic resin which fits over the patient's gums and teeth and which contains defined reference points, for example x-ray opaque spheres. A computer tomography scan (CT-scan) is then made of this template when it has been placed on the jaw of the patient, in order to determine the individual anatomical bone structure and the precise location of nerve bundles and blood vessels. In this way it is checked whether the placing of an implant is

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possible, taking into account the anatomical structure of the jaw, such as, inter alia, the position of nerve bundles or blood vessels present there.

In a subsequent step, a drill template is then produced on the basis of the above-mentioned scan template, and the implants are placed in position. The drill template contains openings corresponding to the desired position of the implants for the purpose of drilling holes in the jaw. During this procedure it is vital that the template is firmly fixed in relation to the patient's jaw in order to ensure that the implants are correctly placed.

When these implants have been placed and the gums and the bone have healed after this surgical procedure, a number of impressions of the jaw together with the implants are taken, in order to produce a provisional model, i.e., a wax model, of the superstructure. This provisional model then has to be customized for the patient. If the provisional model is satisfactory, the final superstructure is produced on the basis of this provisional model. Until the final superstructure is provided the patient maybe provided with a temporary superstructure for aesthetic purposes and also to protect the implant from damage. This temporary structure must again be firmly fixed within the patient's mouth so as to withstand the forces exerted during eating etc. Once the final superstructure is ready for insertion the temporary prosthesis is removed and the final superstructure fixedly secured.

In a variant of the above method, the first step is to make a CT-scan of the jaw on which the superstructure is to be fixed, and a template is produced directly, on the

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basis of the electronic information from this CT scan. The superstructure is then further produced according to the technique described above.

Another variant to the above described method involves the use of different imaging technology. As well as CT scanning, other methods are known. For example, single X-ray images of a patient's mouth provide a cheaper alternative to CT scanning, although this method does not enable a 3-D model to be created. On the other hand, cone beam technology achieves the same results as CT scanning, i.e. an accurate 3-D model, but with a greatly reduced radiation exposure. These and other methods are used by dentists to gain an insight into the anatomical structure of a patient's mouth in order to plan the most suitable implant type and position. This practice is generally referred to as preoperative planning.

WO 03/003933 describes a method for producing a superstructure for a toothless jaw. At least one reference element in the form of a mini implant is fixed into the jaw, and the location of anatomical structures of the jaw relative to this reference element is then determined. A template is then created, with means being provided on the template for detachably fixing this to the reference element. Taking into account the determined location of the anatomical structures, the position of the aperture in the template is determined in such a way that the critical anatomical structures, such as nerve bundles or blood vessels, are not injured during the drilling of the above mentioned hole when the template has been fixed on the jaw by attachment to the reference means.

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The placement of these mini-implants is critical and it very much depends on the experience of the surgeon to avoid any injury of blood vessels or nerve bundles. Moreover, the mini-implants are often placed in regions of
5 the jaw where the mucosa is quite thick rendering the necessary surgery to place said mini-implants intricate. Further, in many patients that are partially or completely toothless, the alveolar ridge has undergone atrophy leaving only a minimal bone mass. It is disadvantageous if
10 this minimal bone mass is also taken up for mini-implants that are removed after some time leaving an additional bone defect in the alveolar ridge. It would be highly desirable to find alternative possibilities to fasten aiding means for dental surgery or even superstructures.

15 Therefore, there is an ongoing need for fastening devices which allow simple and reliable fastening of aiding means and/or superstructures. The urge for such a device is particularly evident in the case of patients that are completely toothless and where non-invasive alternatives
20 cannot be used.

The problem of the present invention is to provide a device allowing simple and reliable fastening of surgical aiding means or superstructures.

The problem is solved by an invasive fastening device
25 according to claim 1. Preferred embodiments are subject to dependent claims.

An invasive fastening device according to one aspect of the present invention comprises an anchoring part for anchoring within the bone. The invasive fastening device
30 is arranged for temporary or permanent placement in the palatal or retromolar region. The device is made of a

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biocompatible material. Further, the invasive fastening device comprises fixing means for connection to a dental restoration device.

By "dental restoration device" it is meant a device used
5 in the process, or forming the result, of replacing or restoring teeth or parts of teeth. This includes scan and drill templates, which are used during pre-operative planning and surgery respectively. It also covers
10 prosthetic superstructures, such as crowns and bridges, which form the final or temporary dental prosthesis. However this term does not extend to corrective devices, such as braces, which merely alter the orientation or alignment of pre-existing teeth.

The invasive fastening device of the present invention
15 allows the reliable and simple fastening of dental restoration devices. The fastening provided for by the invasive fastening device may either be of a temporary or permanent nature.

The invasive fastening device according to the present
20 invention is designed for implantation in the palatal region or in the retromolar region of a human patient. While the alveolar ridge may be quite different between patients, in the palatal region the anatomical structures show a greater similarity. The median palatal region is
25 an anatomical structure which shows some uniformity between individuals and is thus suitable for the placement of an invasive device. There is sufficient bone mass for an invasive fastening device to be inserted and there are few other anatomical structures, such as blood vessels or
30 nerves, nearby that are very susceptible to irritation or injury caused by the inserted fastening device. Thus, an

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area of approximately 2 cm² in the median palatal region provides great flexibility for insertion of fastening devices according to the present invention. Preferably therefore the invasive fastening device is arranged for
5 placement in the median palatal region.

A device arranged for insertion in the palatal or retromolar region differs considerably from one, such as the mini implant of WO03/003933, which is intended for insertion in the alveolar ridge. These differences stem
10 from physical variations between these two areas and the other demands on these areas.

A mini implant or other fastening device designed for insertion in the alveolar ridge must be of sufficient length to be both securely held within the bone and to
15 extend through the relatively thick mucosa layer. In addition, as discussed above, when a tooth or teeth are missing from the jaw, bone loss occurs in this area. Drilling a bore for a fastening device removes further bone mass from this already depleted region. It is also
20 necessary for the fastening device to be inserted at a position remote from the eventual dental implant site. It can be very problematic if a fastening device is inserted in an area later determined as a useful implant site.

A suitable fastening device for use in the alveolar ridge
25 therefore has a small diameter, so that this can fit between teeth and reduce the bone mass lost during insertion. Thus, "thin, long" fastening devices are used in the alveolar region.

In contrast to the alveolar ridge, the palatal region does
30 not require mechanical forces to maintain bone volume. Therefore this area is unaffected by tooth loss. In

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addition, as the dental implants themselves are not located in this area, the space available for the fastening device is not limited. However, this bone is much thinner than the alveolar ridge. Consequently, a fastening device designed for use in this area would tend to be shorter than an alveolar ridge device. The device is shorter as, firstly, there is less bone depth for this to be inserted into and, secondly, to reduce the effect the protruding part will have on the comfort of the patient, e.g. during talking, eating etc.

The stability of the device can be ensured by having a wide diameter. Unlike in the alveolar ridge the width of the device is not limited due to concerns over bone loss or the need to fit this among existing teeth. Alternatively or in addition, stability can be ensured by providing the fastening device with a thread having a small pitch, e.g. between 0.5 and 1.2mm.

A fastening device intended for use in the palatal or retromolar region has an anchoring part having a length of preferably between 3 and 6 mm, most preferably 4-5mm. The diameter of the anchoring part is preferably between 1 and 5 mm, more preferably between 3 and 5mm, and most preferably 4 and 5 mm. In order not to cause discomfort to the patient, the upper part, which protrudes into the mouth after insertion, is preferably less than 5 mm, most preferably less than 4mm. The total length of the fastening device is preferably between 5 and 11mm, most preferably between 6 and 9mm.

The anchoring part of the invasive fastening device preferably comprises a thread. The thread may be a self-tapping thread. This enables the fastening device to be

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anchored within the palatal or retro-molar region quickly and simply. In order to provide good stability despite the short length of the anchoring part the thread preferably has a small pitch, e.g. between 0.5 and 1.2mm.

5 A preferred thread pitch is 0.8mm.

The mechanical stability of an invasive fastening device made of one single piece is higher compared to fastening devices comprising a separate anchoring part and fixing means that are attached to each other. Therefore
10 preferably the anchoring part and fixing means are integrally formed. However in certain embodiments the fixing means may comprise a separable part, such as a snap cap.

In a preferred embodiment the biocompatible material is
15 selected from the group consisting of titanium, titanium alloys, ceramics and plastics. Titanium and its alloys are preferred as titanium shows an excellent biocompatibility. Ceramics and plastics are even more preferred. An advantage of ceramics and plastics is the possibility to
20 match their appearance, in particular their colour, to the surrounding environment (e.g. flesh). They may also be colourless.

The invasive fastening device comprises fixing means for connection to a dental restoration device, e.g. a scan
25 template or a drill template, or a superstructure, e.g. a bridge or crown. It is thus possible to accommodate a provisional (temporary) bridge or crown. Additionally or alternatively it may allow the (repeated) fixing, for instance, of a scan template.

30 The fixing means of the fastening device and its respective counterpart comprised in the dental restoration

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device provide a stable and, in some cases, detachable connection between them. Thus, a template can be fixed on the fastening device as many times as needed. Most advantageously, the spatial orientation of the template is always precisely the same as the invasive fastening device remains in its position.

The fastening device can be removed from the patient's jaw by the dentist only. This means that the information can not get lost between two consultations.

10 Additionally, if the template has to be fixed several times, it is guaranteed that each time the template has the same position in the patient's mouth.

Preferred fixing means are means for providing a clicking, clamping and/or sliding connection to the dental restoration device. For example, the fixing means may comprise a slide rail or a slide member. In such embodiments the attachment means of the dental restoration device would comprise a complementary slide rail or member, in order to form a sliding assembly.

20 The slide rail or slide member may comprise a stop to limit relative movement of the sliding assembly. In a further embodiment the slide rail or slide member has a locking element. Such a locking element can be a pin, a screw or a detachable snap cap.

25 The slide rail and slide member preferably have a dovetail configuration. This means essentially that the slide rail has a dovetail slot cross-section, whereas the slide member has a dovetail projection cross-section. This construction allows simple assembly of the slide rail or the slide member. In addition the dovetail slot cross-

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section of the slide rail allows very good guiding of the slide member. The sliding assembly can additionally be secured by clamping the slide member to the slide rail using a locking element as discussed above.

5

In preferred embodiments however, the fixing means comprises means for providing a clicking, or snap fit, connection. This provides the dentist with an aural and physical indication that a connection has been achieved.

10 Examples of snap fit connections include a resilient barb element which flexes to allow passage of a dental restoration device in one direction (i.e. towards the anchoring part) but which resists movement of the device in the opposite direction. This barb element may, for

15 example, take the form of an arrowhead or crescent located at the distal end of the fastening means. Alternatively barb elements may be positioned within a hollow or bore of the fastening means. In another embodiment the fixing means may comprise outwardly biased spring elements

20 arranged to engage with a complementary groove or indent in the dental restoration device. It is equally possible that the barb or biasing elements are formed on the dental restoration device, with complementary features forming the fixing means of the fastening device. Both the barb

25 and biasing elements form clicking, or snap, connections due to the fact that connection is achieved through the displacement and subsequent release of resilient element(s) in response to relative movement between the fixing means and restoration device. It is this release

30 of the resilient element(s) which creates the "snap" or "click".

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In contrast in a clamping connection the dental restorative device is pressed between two parts of the fixing means.

Using the fastening device of the present invention, the template is no longer fixed on the tooth itself but on the fixing means of the fastening device. Therefore, the template can not slip away, which is dangerous during drilling.

According to another aspect, the present invention provides a dental restoration device comprising attachment means suitable for connecting said device to an invasive fastening device located in the palatal or retromolar region.

Preferably the device is arranged for connection to an invasive fastening device in accordance with the present invention.

The dental restoration device may comprise a scan template, drill template, permanent or temporary prosthesis such as a bridge or crown or any other superstructure. A restoration device according to the present invention has attachment means located in a position or positions which enable a functional connection to a fastening device or devices located in the palatal or retromolar region. By "functional connection" is it meant that, when the restoration device is connected to the fastening device by way of the attachment means, the restoration device is fixedly positioned such that it can fulfil its function, e.g. as a scan template or prosthesis. This differs from traditional restoration devices in which the attachment means are located in positions which enable functional connection to fastening

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means provided in the alveolar ridge.

In a preferred embodiment the attachment means comprises either a slide rail or slide member, preferably having a dovetail configuration.

- 5 In an alternative preferred embodiment the attachment means comprises means for providing a snap fit or clicking connection to the fastening device.

Preferably the attachment means are arranged for connection to an invasive fastening device located in the
10 median palatal region.

Viewed from another aspect the present invention provides a dental restoration kit comprising; at least one invasive fastening device comprising an anchoring part for anchoring within the bone, whereby said fastening device
15 is arranged for temporary or permanent placement in the palatal or retromolar region, the device being made of a biocompatible material and comprising fixing means, and a dental restoration device comprising attachment means, wherein said fixing means and attachment means comprise
20 complementary features which enable the dental restoration device to be functionally connected to the fastening means when the fastening means is located in the palatal or retromolar region.

The complementary features are preferably features which
25 can be clicked or snapped together to securely fix the devices together. Complementary features which can be clamped together are also possible.

The complementary features could alternatively form a sliding assembly, preferably having a dovetail

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configuration. In such embodiments the fastening or attachment means may comprise a locking element. Alternatively the features of the sliding assembly may form an interference, or friction, fit. In either case
5 the sliding assembly may also comprise a stop to limit relative movement between the fixing and attachment means.

In preferred embodiments the fastening device of the present invention has not only the function to serve as a fixation point for templates or superstructures, the
10 fastening device also provides a reference point for the determination of the relative locations of other structures in the jaw.

As discussed previously, X-rays are used during pre-surgical planning to assess the anatomy of a patient. It
15 is necessary for the model or image obtained to be scaled to the actual dimensions of the patient's mouth, in order to account for image distortion. In order to achieve this, a reference object must be included in the images whose precise size and location is known. As the
20 fastening means is fixedly secured within the patient's mouth and can be connected in a defined manner to a scan template, this provides a suitable reference object.

The use of the fastening means as a reference object reduces the number of components used and simplifies the
25 planning procedure.

Therefore, in a preferred embodiment the biocompatible material is also radiopaque. Fastening devices made of biocompatible and radiopaque material can be precisely located in images resulting from X-ray scans or CT-scans,
30 thereby serving as reference point for the surrounding anatomical structures. Titanium is a preferred material as

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this is radiopaque and - importantly - does not scatter radiation such as X-rays. Alternatively ceramic and plastics can also be used. Ceramics and plastics may comprise a marker material, such as barium sulphate.

5 Materials showing a high proportion of scattered radiation in an X-ray scan (e.g. steel) are less suitable for an invasive fastening device intended for use also as a reference device.

When it is intended to use the fastening device as a

10 reference object, it can be preferred to shape the upper part of the device in a particular way to aid its function as a reference object. However, the preferred shape is dependent on the type of scanning undertaken.

In some cases a complete three dimensional model is not

15 created and instead only one or two 2-D X-ray images are obtained.

In such instances the shape of the reference object is particularly important. Therefore, in order to enable the fastening device of the present invention to be used as a

20 reference point in both CT and X-ray based pre-operative planning it is preferred for the upper part of the fastening device to comprise a spherical portion. This is desirable as the spherical portion of the fastening device will have the same shape regardless of the direction from

25 which it is viewed. This quality is very important when only a single or handful of x-rays are taken, as the diameter of the reference object remains constant.

By "spherical portion" it is meant that the fastening device need not comprise a complete sphere, but may

30 instead comprise a hemisphere or other partial sphere. The important requirement is that the diameter of the

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spherical portion remains the same regardless of the viewing angle.

This is considered to be inventive in its own right and therefore, viewed from another aspect the present invention provides an invasive reference device comprising
5 an anchoring part for anchoring within the bone of the palatal or retromolar region and an upper part, whereby said device is made of a biocompatible radiopaque material and said upper part comprises a spherical portion.

10 In contrast to traditional X-ray images, during a CT or cone beam scan numerous images are taken which are later combined to form a 3-D image. Therefore, any object can act as a reference point so long as its precise dimensions and location relative to the patient's mouth and the
15 template are known. Therefore it is possible for an invasive fastening device to be used as reference means without any necessary additional design requirements.

However, certain shapes are preferred. Shapes such as protruding features, and in particular protruding edges or
20 peaks, provide "landmarks" which are easily detectable in CT-scans. These "landmarks" can be used to determine the relative location of anatomical structures in the jaw. An edge is suitable as reference point ("landmark") for a 3D-scan (3-dimensional scan), since it is detectable with
25 accuracy.

Therefore, in a preferred embodiment the distal end of the invasive fastening device comprises an edge. By "edge" it is meant a sharp, well defined boundary between two planar surfaces. Preferably the distal end comprises a
30 protruding feature, said protruding feature comprising said edge. By providing an edge capable of acting as a

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"landmark" detectable during CT scans, the fastening device is particularly suited to use as a reference device.

This is considered to be inventive in its own right and therefore, viewed from another aspect the present invention provides an invasive reference device comprising an anchoring part for anchoring within the bone of the palatal or retromolar region and an upper part, whereby said device is made of a biocompatible radiopaque material and said upper part comprises an edge.

In a preferred embodiment the distal end comprises at least two subareas which form the protruding feature. This feature can be, for example, a raised surface. In this example two flat subareas would be formed on either side of a third subarea, located in a plane distally remote from the other subareas. Alternatively an outer, planar subarea could surround a second, central raised subarea, or vice versa. In such embodiments the edge is formed by at least a part of the perimeter of the raised surface.

Preferably the protruding feature is linear as this provides a clear "landmark".

In preferred embodiments the at least two subareas slope upwards in the distal direction to meet and form an edge. In this way the edge forms the most distal part of the device.

Most preferably the protruding feature takes the form of a point, or peak.

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Although one edge is sufficient to provide a "landmark" relative to which the location of any other (anatomical) structure in the jaw can be determined, more than one edge is preferred since a plurality of edges and/or peaks
5 further improves the precision of determining the location of other structures. This advantage also applies if different X-ray scans are superimposed.

Ideally therefore, in a preferred embodiment the fastening means preferably comprises a protruding feature consisting
10 of a plurality of edges, corners and peaks. These can be linear, curved or a combination of both. One particularly preferred shape is a Lego® block. This type of complex shape helps with the orientation of the 3-D model. In this sense, the preferred features of a reference object
15 for use in 3-D modelling is the opposite from one used in single X-rays, as in 2-D X-rays it is desirable for the shape to remain relatively unchanged regardless of viewing angle whereas in 3-D modelling it is preferable for the viewing angle to be immediately apparent through changes
20 in the appearance of the reference object.

In a particularly preferred embodiment, the protruding feature or spherical portion is formed by the fixing means. This simplifies the design of the device while still enabling it to perform two discrete functions. For
25 example, when the fixing means comprises a dovetail slot or a dovetail projection, the upper surface of the dovetail projection or the planar surfaces on either side of the dovetail slot may act as the protruding feature. Alternatively these surfaces may be shaped so as to form a
30 distally protruding edge. In such embodiments the corresponding attachment means would need to comprise a

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complementary shape, e.g. with a V-shaped groove to accommodate the protruding edge.

In another embodiment, the fixing means may comprise a sphere or partial sphere. The corresponding attachment
5 means can comprise a resilient matrix shaped so as to snap over this (partial) sphere.

The invasive fastening device of the present invention allows the reliable and simple fastening of dental restoration devices. In addition, with the fastening
10 device according to the present invention it is advantageously possible to obtain very precise relative locations of the anatomical structures in the jaw. The protruding features, e.g. of the fixing means can serve as a point of reference for all other structures. Since the
15 invasive fastening device is stably anchored in the bone its position is maintained and thus scans performed at different times can be easily compared or superimposed.

By using the fastening device according to the present invention a drill template may be produced. In a preferred
20 method, a wax model is first made using an impression that is taken from the patient's jaw. Then a scan template is prepared based on said wax model comprising attachment means which are complementary to the fixing means of the fastening device. The fixing means of the fastening device
25 are engaged with the attachment means of the template. The template and the fastening device together are then brought into the correct position in the patient's mouth. After fixation of the fastening device in the palatal or retromolar region the template may be removed as often as
30 it is required (for comfort of the patient etc.). A CT or cone beam scan is then made when the scan template has

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been placed in the correct position, in order to determine the anatomical bone structure and the precise location of nerve bundles and blood vessels. Thereafter, the scan template is removed and converted into a drill template by
5 creating openings in the template in the positions which correspond to the insertion point of the implants. Said openings are provided with a guiding cylinder in order to allow an optimal guiding of a drill. The conversion of the scan template into the drill template has the advantage
10 that no information is lost which could be the case if a template is produced based on a replica.

In a preferred embodiment the invasive fastening device comprising fixing means intended to be connected to a prosthesis or (drill) template is used as a temporary
15 anchor for the prosthesis or (drill) template. This allows fixing a (drill) template several times during pre-operative planning or surgery or at other times without losing any positional information. Further, the fastening device can also be used as anchor for a temporary
20 prosthesis. The temporary prosthesis can be fixed and removed as necessary either by the surgeon or even by the patient themselves.

Since the invasive fastening device is stably integrated in the bone it may also be used as permanent anchor for a
25 prosthesis. This is particularly useful in cases where the alveolar ridge has undergone atrophy. In these cases the bone mass available for anchoring known implants is very often insufficient. However, regenerating alveolar bone is difficult to achieve and - if at all possible - a very
30 lengthy procedure. The invasive fastening device anchored in the median palatal region or in the retromolar region can be conveniently used as an alternative permanent

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anchor for prostheses. In this respect it is a further advantage that the removal of the invasive fastening device is not necessary, thereby avoiding a further surgery.

5 The invasive fastening device may also be used as reference to determine the anatomical structures in a jaw. In this aspect the invasive fastening device according to the present invention serves as an invasive reference device. In such circumstances the fastening device
10 preferably comprises a spherical or partially spherical region or a protruding feature forming a complex shape.

According to another aspect, the present invention provides the use of a fastening device located in the palatal or retromolar region as a permanent or temporary
15 anchor for a dental restoration device.

According to a further aspect the present invention provides a method of fitting a template or prosthesis (dental restoration device) within the mouth, comprising the step of attaching a template or prosthesis to an
20 invasive fastening device located in the palatal or retromolar region.

Preferably the method further comprises the step of anchoring said fastening device into the palatal or retromolar region.

25 The invasive fastening device according to the present invention and also exemplary embodiments of the invasive fastening device will be explained in more detail in the following text with reference to specific, exemplary embodiments, which are illustrated in the drawings and in
30 which, purely schematically:

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- Fig. 1 shows an invasive fastening device in accordance with the present invention in a side view;
- Fig. 2 shows an upper jaw seen from below with the invasive fastening device of Figure 1;
- 5 Fig. 3 shows an upper jaw seen from below with two of the invasive fastening devices of Figure 1;
- Fig. 4 shows fixing and attachment means of the invasive fastening device and dental restorative device in an exploded view;
- 10 Fig. 5 shows the fixing and attachment means of Fig. 4 when said means are engaged;
- Fig. 6 shows an alternative invasive fastening device in accordance with the present invention in a side view;
- 15 Fig. 7A-C show alternative fastening devices according to the present invention;
- Fig. 8 shows a fastening device of the present invention which can also function as an invasive reference device;
- 20 Fig. 9A shows the an end surface of the fastening device of Figure 8 from above;
- Fig. 9B shows an alternative embodiment of an end surface of an upper part from above;

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Fig. 9C shows a further embodiment of an end surface of an upper part from above;

Fig. 10 shows a cross section of a further embodiment of an upper part of the fastening device in accordance with the present invention; and

Fig. 11 shows a cross section of a further embodiment of an upper part of the fastening device in accordance with the present invention.

Fig. 1 shows an invasive fastening device 1 comprising an anchoring part 5 with a thread 6 and an upper part 10, which in use protrudes into the patient's mouth. Upper part 10 comprises fixing means 20, which in this instance take the form of a sliding member having a dovetail configuration. The anchoring part 5 and the upper part 10 are made of one single piece.

Invasive fastening device 1 is designed for anchoring within the palatal or retromolar region. Fig. 2 shows an upper jaw seen from below with one invasive fastening device 1. More precisely the invasive fastening device has been implanted in the median palatal region. As can be seen, in use upper part 10 extends into the patient's mouth such that fixing means 20 are accessible.

The length, diameter and thread pitch of anchoring part 5 are chosen to enable secure anchoring within the bone with minimal discomfort to the patient. For example the anchoring part may have a length of 4.2mm and a diameter of between 4.1 and 4.8 mm. In addition the length of

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upper part 10 is kept to a minimum to increase the comfort to the patient, for example between 2 and 4mm.

Once secured within the patient's mouth, fastening device 1 provides a fixed connection point for dental restoration devices such as drill templates and prostheses.

Fig. 3 shows an upper jaw seen from below with two invasive fastening devices 1. The two fixing means 20 serve as connection points for a single or multiple dental restoration devices. In the example shown in Figure 3, where the fixing means 20 are sliding members, the different orientation of these members means that separate restoration devices will be attached to each fastening device 1. However, when the orientation of the fixing means 20 are aligned or a clicking connection is used, a single restoration device can be attached to both fastening devices 1.

In order to connect to fastening device 1, the dental restoration device must comprise complementary attachment means. Together the fixing means 20 of the fastening device 1 and the attachments means of the dental restorative device form a fixing system.

One such fixing system 40 is shown in Figures 4 and 5. This system 40 comprises a part 50 together with a counterpart 55. The part 50 has a dovetailed projection 45 and the counterpart 55 has a dovetailed slot 60. The arrow in Figure 4 indicates how the part 50 and the counterpart 55 are slid together for engagement, as seen in Figure 5. Either part 50 or counterpart 55 could form the fixing means 20 of the fastening device 1. The dental

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restoration device, such as a scan template or prosthesis, would then comprise attachment means conforming to the complementary part 55. For example, as shown in Figure 1 the fixing means 20 of the fastening device 1 could
5 comprise part 50, namely a dovetail projection 45. In this case the template or prosthesis would comprise counterpart 55 at a position suitable for connection to the fastening device 1 once this is anchored in the palatal or retromolar region. In this way the dovetail
10 projection 45 and the dovetail slot 60 provide a secure and detachable connection between the fastening device and the template/prosthesis.

In order to increase the security of this system part 50 or counterpart 55 could comprise a stop (not shown) such
15 as a flange, to limit movement of counterpart 55 in the direction of the arrow shown in Figure 4. Alternatively or in addition a snap cap can be placed over the connected part 50 and counterpart 55. However, in some systems the dimensions of the dovetailed slot 60 and projection 45
20 allow for an interference or friction fit such that no additional locking means are required.

Figure 6 shows alternative invasive fastening device 31 in a side view. The invasive fastening device comprises an anchoring part 5 with a thread 6 and an upper part 11.
25 Upper part 11 comprises the counterpart 55 of fastening system 40 shown in figures 4 and 5. The counterpart 55 provides dovetailed slot 60. Therefore in this instance the dental restoration device would comprise part 50 (comprising a dovetail projection) of the fastening system
30 40.

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Figures 7A-C show alternative forms of the fastening device. Each fastening device 70a, 70b, 70c comprises an identical anchoring part 5 to that shown in Figure 1. However, each device 70a, 70b, 70c comprises a different
5 form of fixing means 72, 74, 78.

Figure 7A has a fixing means 72 which can act as a slide member for sliding connection within a complementary slide groove or rail. Alternatively the attachment means of the dental restoration device could comprise resilient arms or
10 a collar for snap connection with fixing means 72. In other words the resilient arms or collar would be shaped to fit into the gap 73 located under the distal end of fixing means 72.

Figure 7B shows a fastening device 70b having a crescent shaped resilient fixing means 74. The arms of this
15 crescent flex downwards to allow easy passage of a complementary attachment means into gap 75, however subsequent movement in the opposite direction, towards the distal end of the fastening device 70b, is resisted.

Figure 7C shows a fastening device 70c in which the fixing means 78 comprises a blind bore 76, which extends into the upper part 51 and may also extend into anchoring part 5. Bore 76 comprises spring or pivot elements 77 which are biased to project into the bore 76. These can engage with
20 a groove or indents provided on a projection on the dental restoration device.
25

Figures 7A-C therefore show various examples of a snap or click fit connection. Such connections provide the

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dentist with a clear aural and physical confirmation that fastening of the restoration device has been achieved.

It is possible for all of the above embodiments to act as a reference object during CT scanning or other forms of 3-D modeling.

Figure 8 shows a further fastening device 100 which also functions as a reference device. Distal end 15 comprises two subareas 15a and 15b, which slope upwards in the distal direction to form a protruding edge 200. The thread 6 extends along the whole anchoring part 5. The anchoring part 5 and the upper part 10 are made of one single piece. Both the anchoring part 5 and the upper part 10 have a shape of a substantially circular cylinder. Fixing means 20 is formed by distal end 15 and radial groove 25. Complementary attachment means in the dental restoration device can be snapped or slid over this fixing means 20.

Fig. 9a shows the distal end 15 of the invasive reference device 100 shown in Fig. 8. The distal end 15 is seen from above and rotated by 90°. The distal end 15 made up by the two subareas 15a and 15b. These two subareas 15a, 15b form protruding edge 200. As can be seen from Fig. 9a the protruding edge 200 is a linear edge.

Fig. 9b shows a further embodiment whereby the distal end 15 comprises three subareas 15a, 15b and 15c. In this embodiment the distal end 15 has three protruding edges 200. Said edges 200 are formed by the three subareas 15a, 15b and 15c, more precisely between subarea 15a and 15b, between the subarea 15b and 15c and between the subarea

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15c and 15a. The edges 200 themselves slope upwards to form a peak 250.

Fig. 9c shows another embodiment of a distal end of an upper part seen from above. This embodiment shows a distal
5 end 15 having four subareas 15a, 15b, 15c and 15d. Again, pairs of subareas (e.g. 15d and 15a) form protruding edges 200. The four protruding edges 200 form peak 250 and the edges 200 are linear edges.

Fig. 10 shows a cross section of a further embodiment of
10 an upper part 10. The anchoring part 5 is not shown. The distal end comprises three subareas 15a, 15b, 15c. Two of these subareas 15a, 15c form level flat surfaces, while third subarea 15b forms a raised surface distally remote from the other subareas 15a, 15c. This subarea 15b forms
15 a protruding dovetail feature 650. In this way, subarea 15b can form both a fixing means and provide a landmark for 3D scanning.

Fig. 11 shows a cross section of a further embodiment of an upper part 10. The anchoring part 5 is not shown.
20 Upper part 10 comprises, at its distal end, spherical portion 2. In this example spherical portion 2 is located at the distal end of protrusion 3, although it is possible for this to sit directly on the flat surface of upper part 10 or for upper part 10 to slope upwards to form a
25 truncated peak on which spherical portion 2 is situated. The spherical portion 2 provides an excellent reference point for x-ray images, as its diameter remains unchanged regardless of the viewing angle. In addition the spherical portion 2 acts as a fixing means over which a
30 resilient attachment means can be snapped.

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Further embodiments are conceivable. Apart from single protruding edges or peaks, the subareas may also delimit projections of different shapes, e.g. the shape of a cube or Lego® block.

- 5 Further, the fixing means can comprise any alternative designs which allow a mechanical connection to be made with complementary attachment means.

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Claims

1. Invasive fastening device comprising an anchoring part for anchoring within the bone, whereby the fastening device is arranged for temporary or permanent placement in the palatal or retromolar region, said device being made of a biocompatible material and comprising fixing means for connection to a dental restoration device.
2. Invasive fastening device according to claim 1, whereby the fixing means comprises a slide rail or a slide member.
3. Invasive fastening device according to claim 2, whereby the slide rail or slide member has a dovetail configuration.
4. Invasive fastening device according to claim 1 wherein the fixing means comprises means for providing a snap fit connection to the dental restoration device.
5. Invasive fastening device according to any preceding claim, wherein the biocompatible material is radiopaque.
6. Invasive fastening device according to claim 5 whereby the biocompatible radiopaque material is selected from the group consisting of titanium, titanium alloys, ceramics and plastics.

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7. Invasive fastening device as claimed in any preceding claim wherein the anchoring part has a length of between 3-6 mm and a diameter of between 1-5mm.
8. Invasive fastening device as claimed in claim 7
5 wherein the overall length of the device is less than 9mm.
9. Invasive fastening device as claimed in any preceding claim, wherein the upper part of the device comprises a spherical portion.
- 10 10. Invasive fastening device as claimed in any preceding claim, wherein the upper part of the device comprises an edge.
11. A dental restoration device comprising attachment means for connecting said device to an invasive
15 fastening device located in the palatal or retromolar region.
12. A device as claimed in claim 11 wherein the attachment means are arranged to connect to a fastening device as claimed in any of claims 1 to 10.
- 20 13. A dental restoration kit comprising;

at least one invasive fastening device comprising an anchoring part for anchoring within the bone, whereby said fastening device is arranged for temporary or permanent placement in the palatal or retromolar
25 region, the device being made of a biocompatible material and comprising fixing means, and

a dental restoration device comprising attachment means,

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wherein said fixing means and attachment means
comprise complementary features which enable the
dental restoration device to be functionally
connected to the fastening means when the fastening
5 means is located in the palatal or retromolar region.

14. Use of at least one invasive fastening device
according to any of claims 1 to 10 located in the
palatal or retromolar region as a temporary or
permanent anchor for a dental restoration device.

10 15. Method of fitting a dental restoration device within
the mouth, comprising the step of

attaching said dental restoration device to at
least one invasive fastening element located in the
palatal or retromolar region.

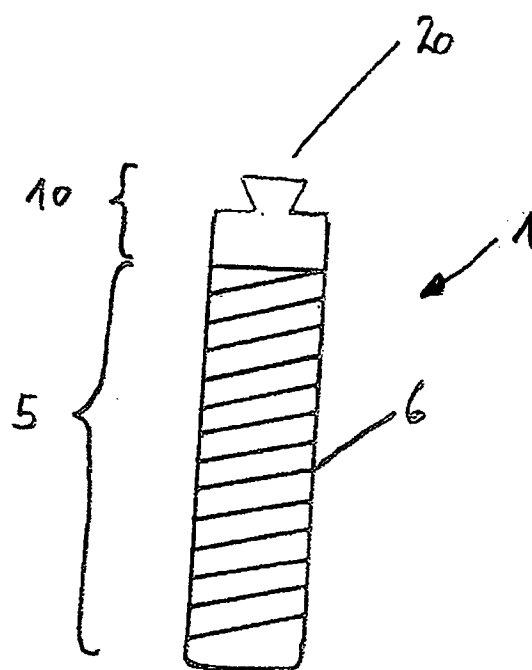


Fig. 1



Fig. 2

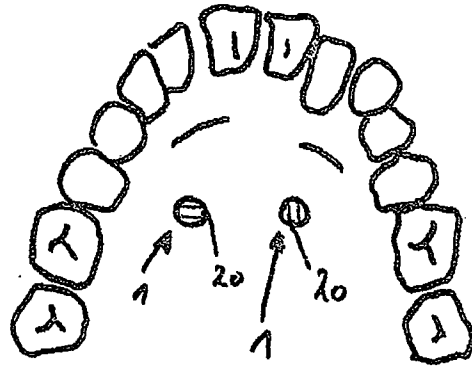


Fig 3

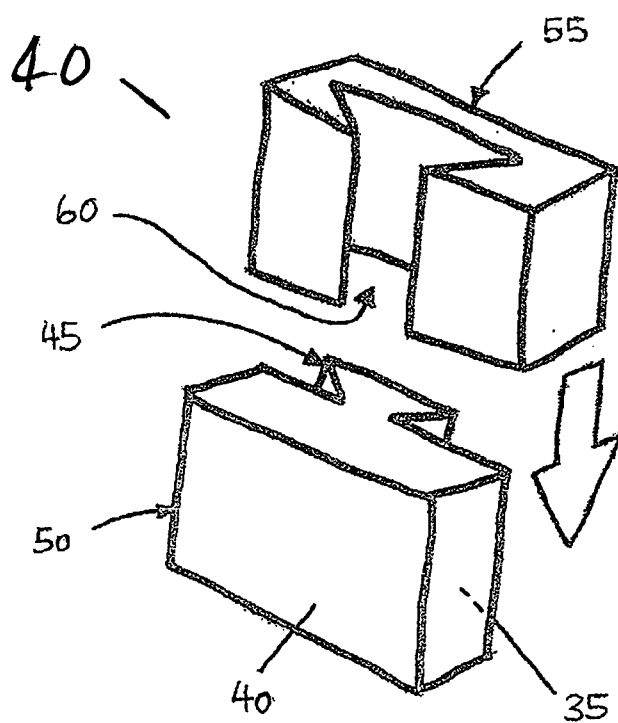


Fig. 4

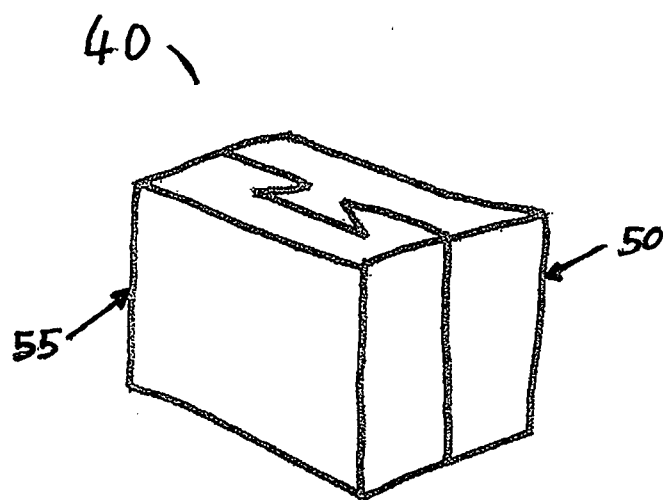


Fig. 5

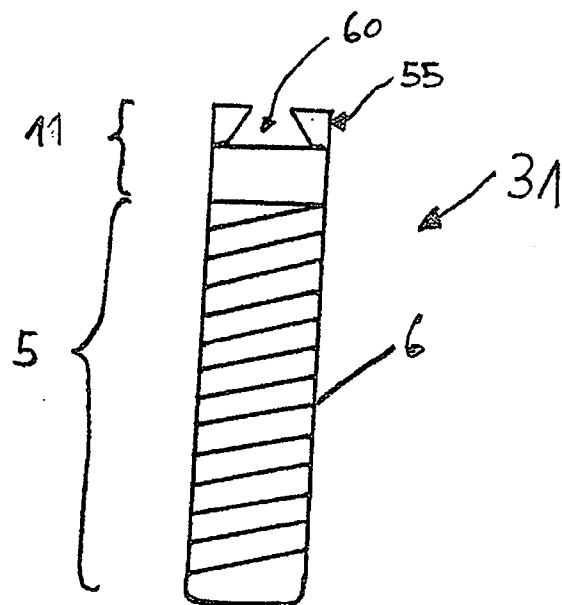


Fig. 6

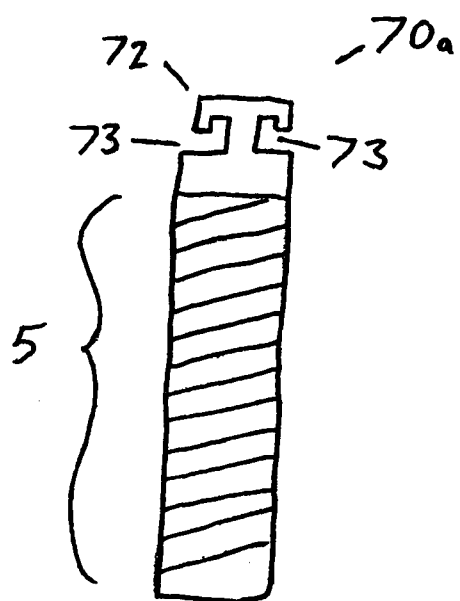


Fig 7A

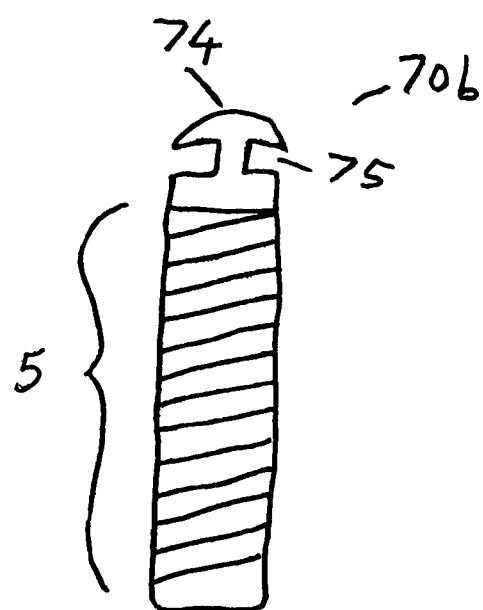


Fig 7B

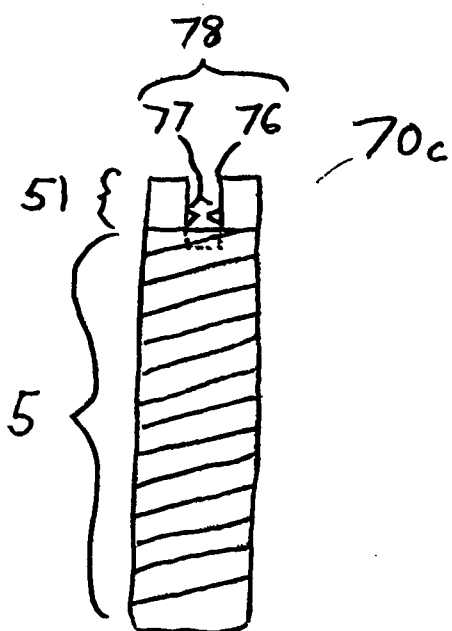


Fig 7C

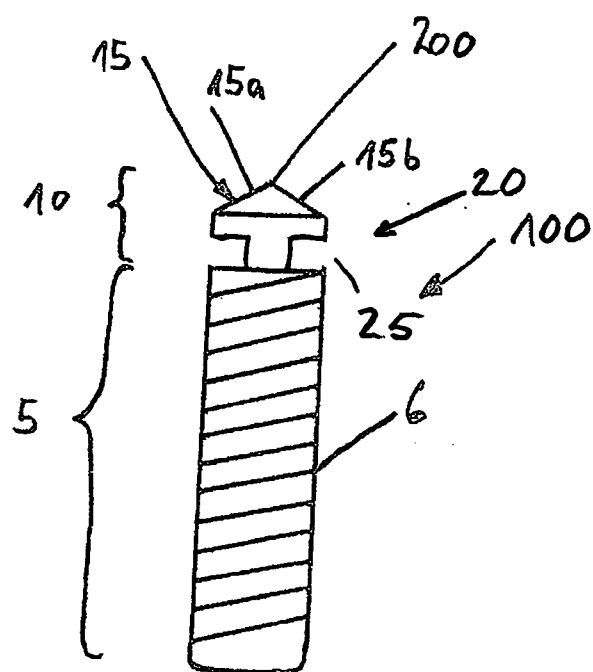


Fig. 8

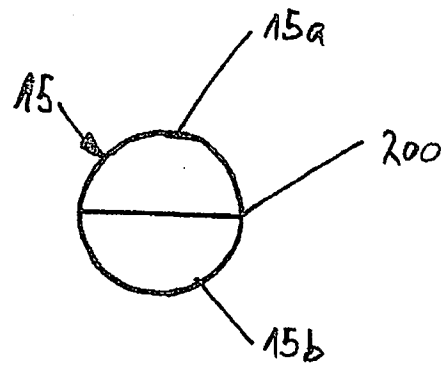


Fig. 9a

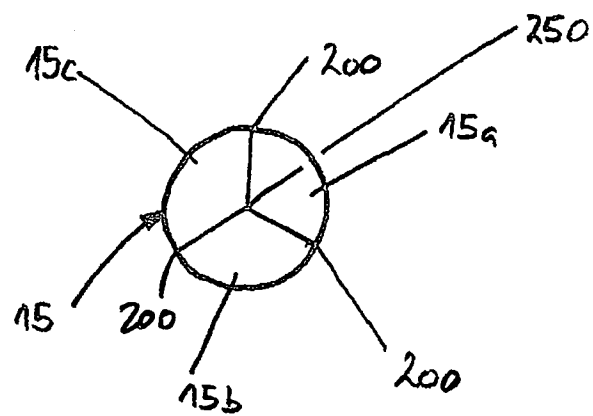


Fig. 9b

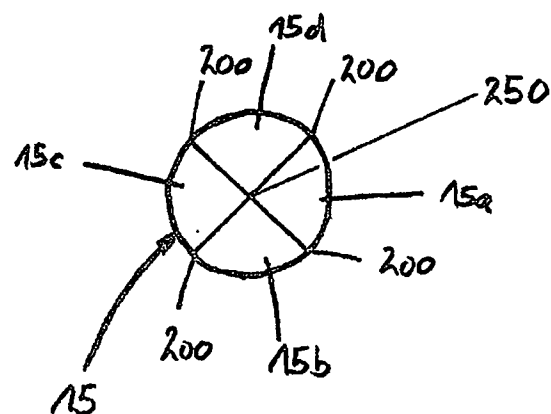


Fig. 9c

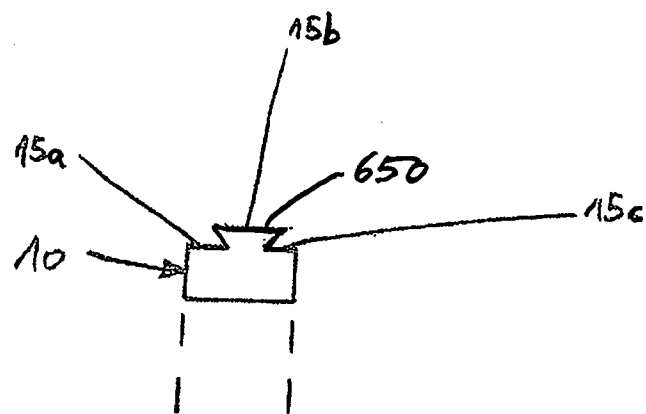


Fig. 10

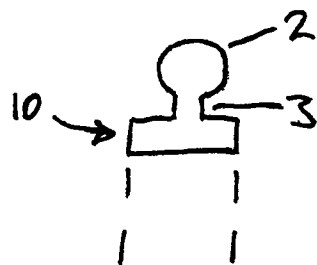


Fig. 11

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2011/001863

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61C8/00

ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, COMPENDEX, INSPEC, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/027772 A1 (BREDENT DENTALGERAETE UND MATE [DE]; WICHMANN MANFRED [DE]; BERGLER MI) 31 March 2005 (2005-03-31)	1,4-6, 9-13
Y	page 3, line 13 - page 19, line 30; figures 1-4	2,3,7,8
X	WO 01/37752 A1 (NICOS SAS DI DE TONI NICOLETTA [IT]; MAINO BORTOLO GIULIANO [IT]) 31 May 2001 (2001-05-31)	1-3,5-10
Y	page 3, line 17 - page 4, line 28; figures	2,3
A	1-5	4,11-13
X	US 5 234 341 A (JOHANSEN RAYMOND J [US]) 10 August 1993 (1993-08-10)	1-3,5,6, 9-13
Y	column 3, lines 12-58; figures 1-6	2,3
A		4,7,8
	-/--	

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

28 July 2011

Date of mailing of the international search report

04/08/2011

Name and mailing address of the ISA/

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Authorized officer

Kunz, Lukas

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2011/001863

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/037206 A1 (COSTA ANTONIO [IT]) 8 May 2003 (2003-05-08)	1,5-8,10
Y	page 6, line 1 - page 7, line 16; figures	7,8
A	1-4 -----	2-4,9, 11-13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2011/001863

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 14, 15
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 14, 15

Independent claim 14 defines a use of an invasive fastening device for attaching a dental restoration device thereto. The term "invasive fastening device" implies that this fastening device must have been previously fixed in the palatal or retromolar region using a surgical treatment. A treatment of the body by surgery is excluded from search and examination (Articles 17 (2) a) i) and 34 (4) a) i) PCT, as well as Rules 39.1 iv) and 67.1 iv) PCT). Independent claim 15 defines a method of attaching a dental restoration device to an invasive fastening device. The term "invasive fastening device" implies that this fastening device must have been previously fixed in the palatal or retromolar region using a surgical treatment. A treatment of the body by surgery is excluded from search and examination (Articles 17 (2) a) i) and 34 (4) a) i) PCT, as well as Rules 39.1 iv) and 67.1 iv) PCT).

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2011/001863

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2005027772 A1	31-03-2005	EP 1663051 A1 RU 2339336 C2 US 2007077535 A1	07-06-2006 27-11-2008 05-04-2007
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WO 0137752 A1	31-05-2001	AT 291390 T AU 2001401 A DE 60018965 D1 DE 60018965 T2 EP 1235529 A1 ES 2239628 T3 IT VI990241 A1 US 6669473 B1	15-04-2005 04-06-2001 28-04-2005 23-03-2006 04-09-2002 01-10-2005 28-05-2001 30-12-2003
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