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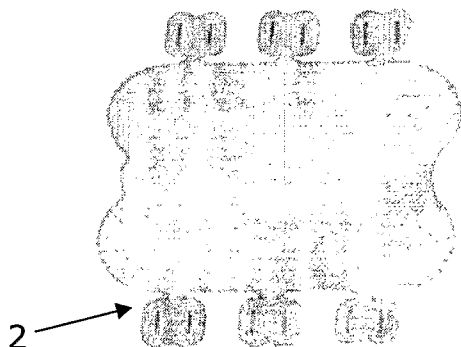
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD FOR PRODUCING ORTHODONTIC APPLIANCES AND ORTHODONTIC APPLIANCE



RAL SCALE 9003

(57) Abstract: Method for manufacturing orthodontic devices comprising a step of moulding an orthodontic device. The method comprises a further step in which the orthodontic device is coated with a polymeric film. The latter significantly reduces colour degradation of the same device during actual use, i.e. when it is used for a pre-determined period of time in the patient's mouth.



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**TITLE**

Method for producing orthodontic appliances and orthodontic appliance.

**DESCRIPTION**

5 The present invention relates to a method for producing orthodontic appliances and an orthodontic appliance.

It is known that brackets are widely used in orthodontic techniques, the brackets being bonded to  
10 the vestibular surface of teeth in an arch that requires orthodontic treatment. The brackets have slots accommodating a pre-shaped metal wire that passes through each slot. To prevent the wire from slipping out of these slots, each bracket is provided  
15 with a ligature device, commonly named "ligature", that, in its simplest form, consists of a ring made from an elastic material such as polyurethane. Examples of orthodontic ligatures are described in US 5540586, EP 289334, ES 1042372 and EP 1169977.

20 During orthodontic therapy, ligatures and other orthodontic components undergo changes in colour. These changes can be sudden or gradual depending upon a patient's oral hygiene and dietary habits and are caused by contact with oral liquids and other liquids  
25 containing caffeine, theine and other substances providing similar effects. The corresponding aesthetical worsening, which is particularly evident in the case of transparent ligatures applied to so-called "aesthetic" brackets and in the case of the  
30 same aesthetic brackets (brackets in substantially translucent materials like ceramics), is cause for a serious psychological disadvantage for patients who

may in fact be disinclined to undergo treatment.

The main aim of the present invention is to eliminate, or at least drastically reduce, the above-mentioned drawback.

5 This result has been achieved, according to the present invention, by adopting a method and providing a device having the characteristics described in the independent claims. Further characteristics of the present invention are the object of the dependent  
10 claims.

Thanks to the present invention it is possible to avoid, or at least drastically limit and delay, changes of colour that are typical of ligatures and other traditional orthodontic components, thus  
15 providing self-evident practical and psychological benefits to the patient. Furthermore, the present method is relatively simple and cost-effective and it provides extremely reliable orthodontic components in terms of colour stability.

20 Further disclosure, objects, advantages and aspects of the present application may be better understood by those skilled in the relevant art by reference to the following description of preferred embodiments taken in conjunction with the accompanying drawings,  
25 which are given by way of illustration only, and thus are not limitative of the present invention, and in which:

- Figs. 1 - 5 show examples of orthodontic ligatures which can be treated adopting the method according  
30 to the present invention;
- Fig. 6A shows a simplified block diagram

illustrating the operative steps of the method according to the present invention;

- Fig. 6B is a chart of the chemical changes that take place during the process;

5 - Fig. 7 shows a set of polyurethane ligatures made by traditional techniques before being used;

- Fig. 8 shows the same set of ligatures as in Fig. 7, after being treated according to the present method and after being subjected to an empirical test involving immersion in coffee for 14  
10 consecutive days;

- Fig. 9 shows a set of polyurethane ligatures, untreated and not subjected to the same test.

A method according to the present invention may be applied, for example, to the manufacture of  
15 orthodontic devices such as elastic polyurethane ligatures of the type shown in Figs. 1 - 5.

▪ Fig. 1 shows an orthodontic bracket (1) with a base (10) for bonding it to the vestibular surface of a  
20 tooth and a body (11) from which two wings (12) emerge. The wings (12) delimit a slot (13) and offer a securing point for the ligature (2). The latter is of the type providing two rings intended to be secured to said wings and a central body (20)  
25 intended to be positioned above the slot (13);

▪ Fig. 2 shows a simple pre-curved ring ligature (2);

▪ Figs. 3 and 4 show further examples of (2) with a central body (20);

▪ Fig. 5 shows another example of ligature (2) with  
30 two separate rings, a central body (20) and pre-shaped curves (21) resulting in correspondence of

the points where the rings join the central body (20). This figure also shows the bracket (1), having the same shape as that in Fig. 1, and the pre-shaped wire (14) passing through the said slot.

5 The present method involves a step of moulding an orthodontic device, e.g. a polyurethane ligature, and a subsequent operative step during which the device is coated with a polymeric film that significantly reduces the colour degradation of the device during  
10 its actual use, i.e. when it is used for a predetermined period of time in the patient's mouth.

Since moulding of orthodontic devices is a well-known technique, further details concerning the above-mentioned first operative step are not provided. The  
15 documents listed above illustrate examples regarding the manufacturing of orthodontic devices to which the second step of the present method may be advantageously applied.

Particularly satisfying results have been achieved by  
20 realizing a Parylene coating by means of plasma deposition on polyurethane ligatures.

The coating consists of a film that is particularly well-bonded to the substrate and that, despite its thinness (only a few microns), prevents direct  
25 contact between the polyurethane substrate and oral liquids. Without this coating, the polyurethane substrate would be subject to imbibition and a subsequent colour change from clear to dark would occur over relatively short time spans.

30 For example, referring to Figs. 6A and 6B, the said coating can be obtained as follows.

In a first step (A), the di-monomer (diparaxylylene)

in powder form at room temperature is brought up to 150°C at atmospheric pressure and vapourised.

In a second step (B), the substance thus obtained is brought to 690°C under a depressurised atmosphere (half the pressure used in the previous step) and the monomer converts to gaseous form.

In a second third step (C), the gas thus obtained is conducted to a vacuum coating chamber (pressure between 0.07 and 0.1 atm.) at room temperature (23°C - 35°C) where the items to be coated are positioned. The coating chamber can be of the fixed or slowly rotating type. During this step, the gas particles become solid without forming a liquid and the polymer adheres to the items positioned in the chamber.

In a fourth step (D), any excess gas exits the coating chamber, is cooled and brought to its liquid form.

The film deposited on the substrate is particularly continuous, uniformly spread and perfectly takes up the geometry and shape of the substrate.

The above-mentioned process allows both Parylene N (with no chlorine atoms) and Parylene C (with one chlorine atom on the benzene ring) to be produced. Parylene C deposits more quickly on the substrate (0.2 micron/min) but the polymeric film is less uniform.

The following empirical test was carried out in the applicant's laboratories. A set of polyurethane ligatures (2) of the same shape as those in Fig. 5 was subjected to the procedure outlined above and a coating of Parylene N of approximately 2.5 microns was obtained (Fig.7). After the colour had been

graded according to the RAL scale (value recorded 9003), the set was immersed in liquid coffee for 14 consecutive days. When the set was removed from the coffee, the colour grading had not changed from when the set was first immersed. The same test was also carried out on a set of ligatures (2) made of the same material and of the same shape, but not coated with Parylene. Evaluation of the colour acquired by the non-coated set after 14 days immersion in liquid coffee was determined as 1011 on the RAL scale (dark yellow almost brown).

The use of Parylene is known in the biomedical sector as it is used to lubricate human implant devices to reduce resistance to blood flow (see US patent US 5632771). According to the present invention, the use of Parylene proved surprisingly effective in preventing, or at least drastically delaying, colour degradation in orthodontic appliances.

The above-mentioned procedure can also be applied with the same advantages to orthodontic brackets, especially the so-called aesthetic types, e.g. polycarbonate brackets.

The present 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 and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

**CLAIMS**

- 1) Method for manufacturing orthodontic devices comprising a step of moulding an orthodontic device, characterised by the fact that it comprises  
5 a further step in which the orthodontic device is coated with a polymeric film that significantly reduces colour degradation of the same device during actual use, i.e. when it is used for a pre-determined period of time in the patient's mouth.
- 10 2) Method according to claim 1 characterised by the fact that the said orthodontic device is made of polyurethane.
- 3) Method according to claim 1 characterised by the fact that said orthodontic device is an elastic  
15 ligature.
- 4) Method according to claim 1 characterised by the fact that said orthodontic device is an orthodontic bracket.
- 5) Method according to claim 4 characterised by the  
20 fact that said orthodontic bracket is a polycarbonate bracket.
- 6) Method according to claim 1 characterised by the fact that said polymeric film is a parylene film.
- 7) Method according to claim 6 characterised by the  
25 fact that said film is a parylene N film.
- 8) Method according to claim 6 characterised by the fact that said film is a parylene C film.
- 9) Method according to claim 1 characterized by the fact that the thickness of said coating film is  
30 about 2.5 microns.
- 10) Method according to claim 6 characterized by the fact that the thickness of said coating film is

about 2.5 microns.

- 5 11) Orthodontic device characterised by the fact that it is coated with a polymeric film that significantly reduces colour degradation of the same device during actual use, i.e. when it is used for a pre-determined period of time in the patient's mouth.
- 12) Device according to claim 11 characterized by the fact that it is made of polyurethane.
- 10 13) Device according to claim 11 characterized by the fact that it is an elastic ligature (2).
- 14) Device according to claim 11 characterized by the fact that it is an orthodontic bracket.
- 15 15) Device according to claim 11 characterized by the fact that said polymeric film is a parylene film.
- 16) Device according to claim 15 characterized by the fact that said film is a parylene N film.
- 17) Device according to claim 15 characterized by the fact that said film is a parylene C film.
- 20 18) Device according to claim 11 characterized by the fact that the thickness of said coating film is about 2.5 microns.
- 25 19) Device according to claim 15 characterized by the fact that the thickness of said coating film is about 2.5 microns.

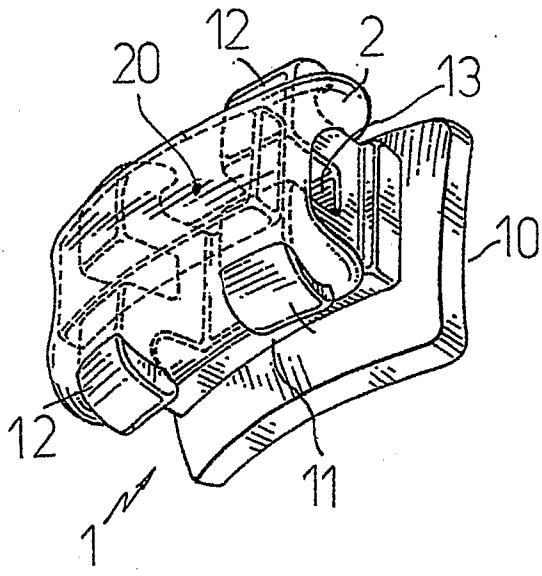


FIG. 1

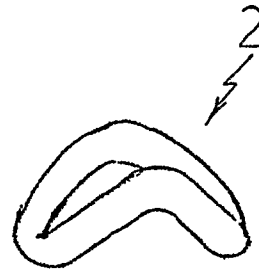


FIG. 2

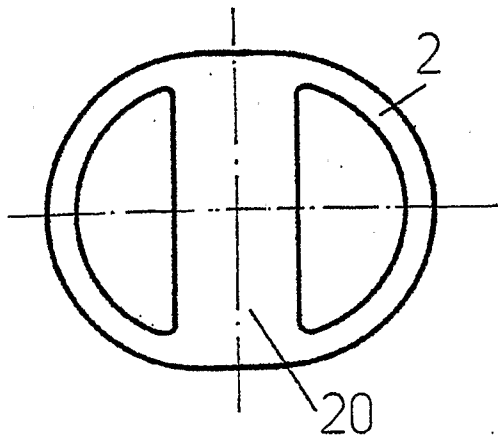


FIG. 3

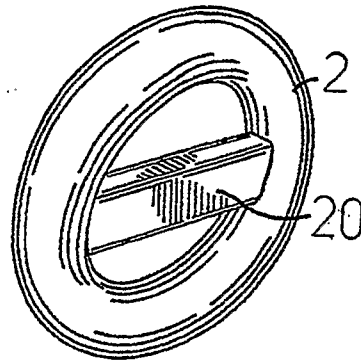


FIG. 4

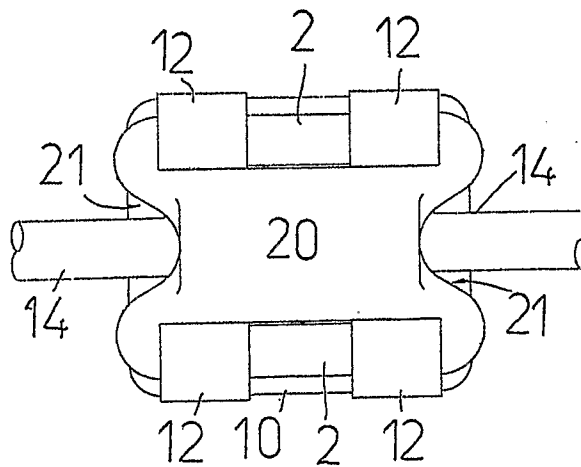


FIG. 5

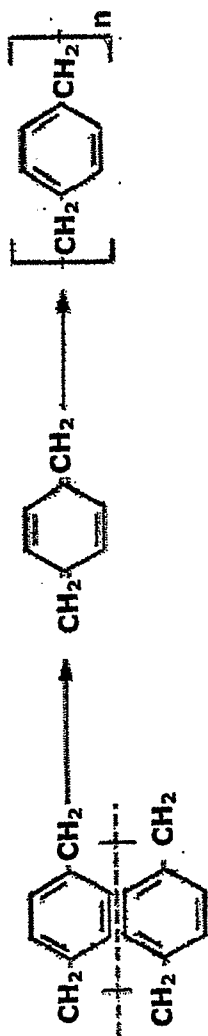


FIG.6B

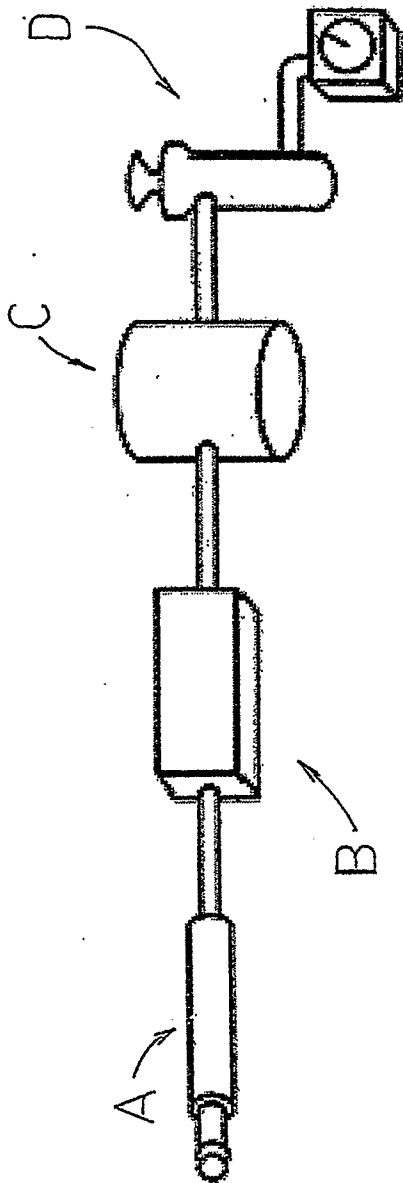
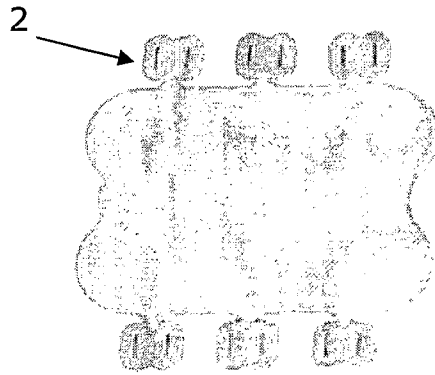


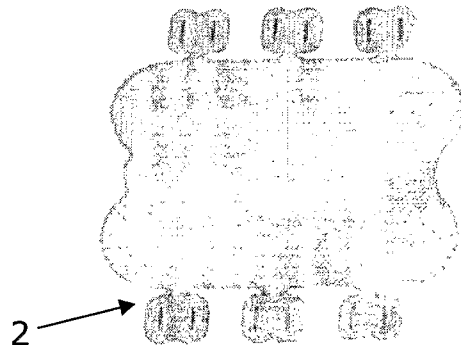
FIG.6A

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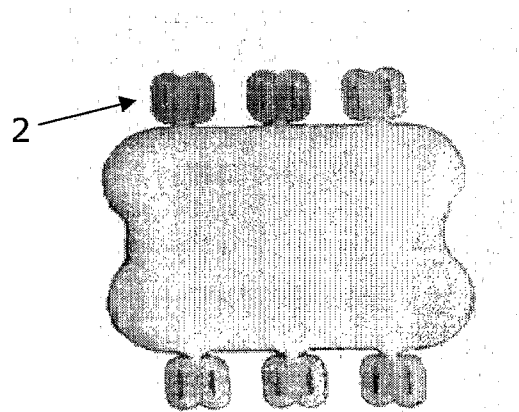
RAL SCALE 9003

FIG. 7



RAL SCALE 9003

FIG. 8



RAL SCALE 1011

FIG. 9

**INTERNATIONAL SEARCH REPORT**

International application No  
PCT/IT2005/000631

**A. CLASSIFICATION OF SUBJECT MATTER**  
A61C7/00

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, PAJ, WPI Data

| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b> |   |                              |
|---|---|------------------------------|
| Category*                                     | Citation of document, with indication, where appropriate, of the relevant passages                | Relevant to claim No.        |
| X   | US 5 230 619 A (WONG ET AL)<br>27 July 1993 (1993-07-27)<br>column 1, line 14 - line 15           | 1,4,5,<br>11,14              |
| Y   | column 2, line 29 - line 40<br><br>column 3, line 44 - column 4, line 10                          | 6-10,<br>15-19               |
| Y   | WO 03/051241 A (CENTRI)<br>26 June 2003 (2003-06-26)<br><br>column 3, line 30 - column 4, line 11 | 6,7,9,<br>10,15,<br>16,18,19 |
|   | -/--  |                              |

Further documents are listed in the continuation of Box C.

See patent family annex.

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Date of the actual completion of the international search  
  
14 March 2006

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## INTERNATIONAL SEARCH REPORT

International application No  
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
|-----------|--|-----------------------|
| Y         | EP 1 501 331 A (MATSUSHITA ELECTRIC INDUSTRIAL CO)   | 8,17                  |
| A         | 26 January 2005 (2005-01-26)<br>paragraph [0010] - paragraph [0011]<br><br>paragraph [0020]<br>claims 3-5  | 9,10,18,<br>19        |
| X         | -----<br>US 5 378 146 A (STERRETT)<br>3 January 1995 (1995-01-03)<br>column 1, line 27 - line 42<br>column 1, line 53 - line 67<br>column 2, line 12 - line 44 | 1-3,<br>11-13         |
| A         | -----<br>US 6 442 785 B1 (ROBINSON)<br>3 September 2002 (2002-09-03)<br>column 7, line 23 - line 25; claim 16<br>-----   | 6,15                  |

# INTERNATIONAL SEARCH REPORT

Information on patent family members

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| Patent document cited in search report | Publication date | Patent family member(s) | Publication date  |
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