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(71) Applicant (for all designated States except US): DEUY (IRELAND) [IE/IE]; Loughbeg, Ringaskiddy, County Cork (IE).

(72) Inventors:
Beedall, Duncan [GB/GB]; c/o DePuy International Limited, St Anthonys Road, Beeston, Leeds, West Yorkshire LS11 8DT (GB).

Reason, Mark [GB/GB]; c/o DePuy International Limited, St Anthonys Road, Beeston, Leeds, West Yorkshire LS11 8DT (GB).


(54) Title: MANUFACTURING METHOD AND PRODUCT

(57) Abstract: A method of manufacturing a surgical instrument or prosthesis and a surgical instrument or prosthesis so manufactured are described. A first material is injected into a first mould to form an interim component. Portions of the interim component define at least one channel. The maximum wall thickness of the interim component is less than a first threshold determined by the injection moulding properties of the first material. The maximum width of the at least one channel is less than a second threshold determined by the injection moulding properties of a second material. The second material is injected into a second mould containing at least part of the channel of the interim component so that the channel is at least partially filled with the second material.

FIG. 2
The present invention relates to a manufacturing method and a product produced by the manufacturing method. In particular, the present invention relates to methods of making surgical instruments and prostheses.

Surgical instruments and prostheses are typically formed from a relatively small number of materials, which are selected for their properties, including biocompatibility, strength and resilience. Typical materials include metals such as stainless steel and plastics. The chosen materials, and the methods by which the instruments are formed, vary according to the particular function of the instrument or prosthesis.

Certain surgical instrument may be required to withstand significant forces which are generated during normal use, for instance a surgical impactor which is used to transfer an impaction force to an orthopaedic implant. It is clear that an impactor must be relatively strong to withstand the impaction force without damage. It is known to form such an impactor from a single block of plastic, for instance Radel® (Polyphenylsulfone) which has been machined to the required shape. Under high loads such a machined plastic component may fracture. Machining plastic is also a relatively expensive manufacturing method.

Alternatively, surgical instruments which are required to withstand high loads may be formed partly from plastic and partly from metal. However, while this may prove stronger than machined plastic, the high stress experienced during loading may cause the separate components to come apart due to vibration. Forming surgical instruments from multiple components, in particular where metal is used, is relatively expensive.

It is a requirement of reusable surgical instruments that they must be easy to clean. A machined plastic instrument may offer a relatively easy to clean solution as its exterior surface may be relatively smooth. Instruments formed from a combination of plastic and metal however may be relatively difficult to clean due to the interfaces between the components (or at least users may perceive the instrument as being difficult to clean).
It is an object of embodiments of the present invention to obviate or mitigate one or more of the problems associated with the prior art, whether identified herein or elsewhere.

According to a first aspect of the present invention there is provided a method of manufacturing a surgical instrument or prosthesis comprising: injecting a first material into a first mould to form an interim component, portions of the interim component defining at least one channel, the maximum wall thickness of the interim component being less than a first threshold determined by the injection moulding properties of the first material, and the maximum width of the at least one channel being less than a second threshold determined by the injection moulding properties of a second material; and injecting the second material into a second mould containing at least part of the channel of the interim component so that the channel is at least partially filled with the second material.

An advantage of the first aspect of the present is that by producing a surgical instrument or prosthesis using two plastic injection moulding steps an instrument or prosthesis comprising a substantial thickness of plastic may be produced with a reduced risk of surface sinking or voids being left within the mould. Furthermore, the second injection moulding step may be arranged to produce an instrument with a smooth exterior surface, which is easy to clean. The instruments may also be cheaper than equivalent instruments manufactured through machining plastic or metal or coupling together multiple plastic or metal components.

The first and second thresholds may be determined by the maximum thickness of the respective material that can be injection moulded without significant slumping or voids forming within the mould. The first and second thresholds may be less than 5mm.

The interim component may comprise at least two ribs each having a thickness less than the first threshold, the at least one channel being defined between the ribs.
The interim component and the second mould may be arranged such that the maximum width of the cavity between the interim component and the mould wall is less than the second threshold.

5 The first and second materials may be different colours.

The first and second materials may comprise plastics. The first and second plastics may have substantially similar structural properties. The first and second plastics may comprise the same plastic. At least one of the first and second plastics may further comprise at least one additive. The or each plastic may comprise a high or ultra high performance polymer, or silicone.

According a second aspect of the present invention there is provided an injection moulded surgical instrument or prosthesis comprising: a body having a minimum thickness which exceeds a first threshold determined by the injection moulding properties of a first material and a second threshold determined by the injection moulding properties of a second material; wherein the body is formed in a two shot injection moulding process using said first and second materials respectively, the body comprising interlaced portions of said first and second materials arranged such that the maximum thickness of any portion of the first material is less than the first threshold and the maximum thickness of any portion of the second material is less than the second threshold.

The present invention will now be described, by way of example only, with reference to the accompanying figures, in which:

25 Figures 1 and 2 illustrate front and rear views respectively of an interim component formed using a manufacturing method in accordance with a first embodiment of the present invention; and

30 Figures 3 and 4 illustrate front and rear views respectively of a surgical instrument formed using a manufacturing method in accordance with the first embodiment of the present invention.
It is known to manufacture products, including surgical instruments and prostheses, through injection moulding. A material such as thermoplastic or thermosetting plastic is heated and mixed to ensure a uniform consistency. The molten material is forced under pressure into a mould cavity where it cools and hardens. The amount of material required to fill the cavities of the mould is called a shot.

It is known that for a particular selected plastic material there is a maximum wall thickness (that is, the maximum thickness of any portion of the moulded article taking the shortest possible distance between exterior surfaces of the moulded article) that can be achieved before significant surface sinking or voids within the mould cavity occur. The maximum achievable wall thickness is dependent upon the material properties of the selected plastic and can be determined empirically for a given plastic. The skilled person will be able to readily determine though empirical testing the maximum wall thickness that can be achieved for a desired moulded article using any suitable plastic. A typical maximum thickness is 5mm. Although for certain materials the maximum could be larger, in the majority of applications 5mm is considered to be a sensible limit. Furthermore, the maximum thickness of different portions of a complex shape may vary. There are a number of "rules of thumb" which have been determined through empirical testing. For instance, to increase the strength of a thick wall of material, thinner ribs may be applied running perpendicular to the plane of the wall. To prevent sinking on the outside of the wall it is desirable to limit the thickness of the ribs to approximately 40% to 60% of the thickness of the wall.

It is known to use injection moulding to apply a layer of a plastic material over part or the whole of an existing interim component. This technique may be referred to as over-moulding or two shot moulding. One known application of this is to couple together two different forms of plastic having different material properties. For the example of a toothbrush, a first, stiff plastic may form the body of a handle, while a second, softer plastic forms a hand grip. Two shot moulding is also known for coating other materials such as metals with plastic, and for joining together two separate components.
Surgical instruments and prostheses, which may otherwise be suitable for manufacturing using injection moulding, may require a maximum wall thickness which exceeds the achievable limits for suitable plastics. Consequently, the use of injection moulding for surgical instruments and prostheses has been limited.

5 Referring to figures 1 to 4, these illustrate a two shot moulding method for manufacturing a surgical impactor in accordance with a first embodiment of the present invention. Figures 1 and 2 illustrate an interim component 10 formed through a first injection moulding step. Figures 3 and 4 illustrate a finished impactor 12 formed through a second injection moulding step, where part or the whole of the interim component 10 is present in the mould during the second injection moulding step. Figures 1 and 3 comprise first perspective views of the interim component or impactor and figures 2 and 4 comprise second, alternative perspective views of the interim component or impactor.

10 Figures 1 and 2 show that the shape of the mould in the first injection moulding step is chosen such that the interim component 10 comprises a series of walls and ribs, for instance ribs 14. Each wall or rib has a maximum thickness which is less than or equal to the maximum thickness achievable for an injection moulding step using the plastic material selected for the interim component 10. Channels, for instance channel 16, are defined between adjacent pairs of ribs. It can be seen that the ribs 14 substantially define the shape and size of the finished impactor 12.

It may be that the interim component 12 could have the required strength to use as an impactor, dependent upon the arrangement of walls and ribs, without further processing.

20 However, it is clear that an impactor having numerous channels, as is the case for the interim component 10, would be difficult to clean, and therefore would be unacceptable in a medical environment.

25 By positioning the interim component 10 in a suitable mould, a second injection moulding step can be used to substantially or fully fill the channels 16 with plastic to form the finished impactor 12. The plastic material applied in the second injection moulding step may substantially or fully cover the interim component 12, or the second injection
moulding step may be restricted to filling the channels 16. Either way, to ensure that the second injection moulding step does not result in surface sinks or voids, the maximum width of the channels 16 in the interim component is arranged to be less than or equal to the maximum thickness achievable for an injection moulding step using the plastic material selected for the second injection moulding step. Furthermore, for portions of the interim component 10 completely covered by the plastic applied in the second injection moulding step, the thickness of covering plastic is less than or equal to the same maximum thickness. It will be appreciated that the result of this is that the ribs forming the interim component 10 define the three dimensional shape of the finished component to within a limit set by the maximum thickness of the plastic injected in the second injection moulding step.

For the particular exemplary surgical instrument illustrated in figures 1 to 4 it can be seen that the interim component defines an upper and lower flanges 18, 20. The second injection moulding step may comprise inserting the interim component 10 into a mould which seals to the flanges 18, 20 such that the channels 16 are filled by plastic in the second injection moulding step between the flanges 18, 20.

It may be that exactly the same plastic is used in the first and second injection moulding steps, in which case it may be difficult or impossible to discern from the finished product whether the product has been formed through two injection moulding steps. In such a situation it is clear that the maximum permissible thickness of the ribs and walls and the maximum width of the channels will be the same, as both are defined by the material properties of the same plastic material (though clearly, in practice, the ribs and channels may vary in dimensions up to those limits). However, it may be that different, though similar, plastics are used. In certain applications, dissimilar plastics may be used, though typically the same or similar plastics will be required for functional reasons associated with the use of the instrument or prosthesis. Consequently, it may be that the thresholds for wall thickness and channel width are different. By "similar" it is intended that the plastics used in each injection moulding step are generally the same, with similar chemical, structural or function properties. In particular embodiments of the present invention, where different but similar plastics are used, each plastic may be within the group of plastics known in the plastics industry as "high performance polymers" and "ultra high
performance polymers" as these generally have high resistance to chemicals, moisture and temperature as well as high stiffness. Alternatively, types of silicone may be used.

While embodiments of the present invention described above generally relate to surgical instruments, and methods of manufacturing such instruments, the invention defined by the claims is not limited to this. The same manufacturing techniques may also be applied to manufacturing surgical prostheses. In particular, the manufacturing techniques described above may be applied whenever there is a requirement to form a component with a thick section, which cannot be achieved in a single injection moulding step, and where there is a need to produce an easy to clean finished article. The above described techniques are particularly suited to applications where a finished article capable for bearing large loads is required. Advantageously the manufacturing cost may be reduced significantly compared with previously known alternative manufacturing techniques.

Other applications of, and modifications to, the present invention will be readily apparent to the appropriately skilled person from the teaching herein, without departing from the scope of the appended claims.
CLAIMS:

1. A method of manufacturing a surgical instrument or prosthesis comprising:
   injecting a first material into a first mould to form an interim component, portions
   of the interim component defining at least one channel, the maximum wall thickness of the
   interim component being less than a first threshold determined by the injection moulding
   properties of the first material, and the maximum width of the at least one channel being
   less than a second threshold determined by the injection moulding properties of a second
   material; and
   injecting the second material into a second mould containing at least part of the
   channel of the interim component so that the channel is at least partially filled with the
   second material.

2. A method according to claim 1, wherein the first and second thresholds are
   determined by the maximum thickness of the respective material that can be injection
   moulded without significant slumping or voids forming within the mould.

3. A method according to claim 1 or claim 2, wherein the first and second thresholds
   are less than 5mm.

4. A method according to any one of the preceding claims, wherein the interim
   component comprises at least two ribs each having a thickness less than the first threshold,
   the at least one channel being defined between the ribs.

5. A method according to any one of the preceding claims, wherein the interim
   component and the second mould are arranged such that the maximum width of the cavity
   between the interim component and the mould wall is less than the second threshold.

6. A method according to any one of the preceding claims, wherein the first and
   second materials comprise plastics.
7. A method according to claim 6, wherein the first and second plastics have substantially similar structural properties.

8. A method according to claim 7, wherein the first and second plastics comprise the same plastic.

9. A method according to claim 8, wherein at least one of the first and second plastics further comprise at least one additive.

10. A method according to any one of claims 6 to 9, wherein the or each plastic comprises a high or ultra high performance polymer, or silicone.

11. An injection moulded surgical instrument or prosthesis comprising:
   a body having a minimum thickness which exceeds a first threshold determined by the injection moulding properties of a first material and a second threshold determined by the injection moulding properties of a second material;
   wherein the body is formed in a two shot injection moulding process using said first and second materials respectively, the body comprising interlaced portions of said first and second materials arranged such that the maximum thickness of any portion of the first material is less than the first threshold and the maximum thickness of any portion of the second material is less than the second threshold.
**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**

INV. B29C45/16

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)

B29L B29C A61F A61B

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 practicable, search terms used)

EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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<th>Relevant to claim No.</th>
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Name and mailing address of the ISA:

European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel: (+31-70) 340-2040,
Fax: (+31-70) 340-3016

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Zattoni, Federico
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