

Title – Powder delivery device

This invention relates to improvements in a device for the dispensing of powder. In particular, the invention relates to an improvement in devices of the general type disclosed in International Patent Application WO2010/070333 (which is hereby
5 incorporated by reference). Such devices are of particular utility in surgical procedures or other medical applications, for the topical delivery of powder to an internal or external surface of the body.

10 In devices of the type disclosed in WO2010/070333, a flow of gas entrains powder that is to be dispensed and carries that powder out of the device via a barrel. The barrel serves to direct the powder to the desired application site.

In the devices illustrated in WO2010/070333, the barrels are rather short and are
15 of simple construction.

It has now surprisingly been found that the performance of devices of the type disclosed in WO2010/070333 may be substantially improved by modifications to the design of the barrel. In particular, elongation of the barrel and/or the
20 incorporation of certain structural features in the internal bore of the barrel may lead to an improvements.

Thus, according to the invention there is provided a device for the dispensing of powder, the device being of the type in which a generated gas flow entrains the
25 powder to be dispensed and carries the powder from the device via a barrel, the barrel having a bore including a main portion with a continuous internal surface, characterised in that

(a) the length of the main portion is at least fifteen times its maximum internal diameter; and/or

30 (b) the internal bore of the main portion is tapered; and/or

(c) the barrel has an outwardly flared outlet portion.

The device according to the invention is advantageous in that the form of the barrel may lead to certain improvements in performance. In particular, the form of the barrel may be chosen in such a way that the shape of the plume of powder emitted from the device is optimised for a particular application. Thus, the distribution of powder on the intended site of application may be made more uniform. In addition, the velocity of the powder plume may be increased, and this may result in the form of the plume being maintained over greater distances, so that the powder plume remains intact when projected over larger distances than those obtained with a conventional device, enabling the powder delivery device to be held a greater distance from the desired delivery site. This may be advantageous, for instance, in surgical procedures where it may not be possible to hold the device close to the intended site of application of the powder. In addition, fall-off of powder from the plume, under the influence of gravity, may be reduced, leading to reduced deposition of powder at undesired locations. In addition, the outlet may be less prone to clogging, improving performance and reducing the maintenance required. Dispersion of the powder as it leaves the device may also be improved. In general, the device according to the invention may operate effectively over a wide range of gasflow pressures, eg from about 0.5bar to about 7bar, though for most applications pressures in the range 0.5bar to 2bar are generally satisfactory, eg from 0.5bar to 1.5bar.

In some preferred embodiments of the device, the length of the main portion is at least fifteen times its maximum internal diameter; and the internal bore of the main portion is tapered.

In other embodiments of the device, the barrel has an outwardly flared outlet portion.

In some particularly preferred embodiments of the device,

- (a) the length of the main portion is at least fifteen times its maximum internal diameter; and
- (b) the internal bore of the main portion is tapered; and
- (c) the barrel has an outwardly flared outlet portion.

In embodiments in which the barrel is elongated, the barrel may be rigid or it may be flexible.

- 5 In rigid embodiments, the length of the main portion of the barrel is at least fifteen times, eg at least eighteen times or at least twenty times, its maximum internal diameter, or more.

- 10 In rigid embodiments, the length of the main portion is typically between about 30mm and 100mm, eg about 50mm or about 75mm. The maximum internal diameter of the main portion is typically from 1mm to 6mm, eg about 2mm or about 3mm.

- 15 In flexible embodiments of the barrel, the barrel is generally longer than for rigid embodiments, the length of the main portion of the barrel typically being between about 50mm and about 300mm, more commonly between about 50mm and about 200mm, and typically between about 100mm and 180mm, eg about 150mm. The internal diameter of the barrel in such embodiments is most commonly between about 1mm and about 6mm, typically between about 1.5mm and
20 about 4mm, eg about 2mm or about 3mm.

- In order for the barrel to be flexible, its main portion is typically formed as a plastics tube, the plastics material being such that the tube may be manually deformed to the required shape without occlusion of the internal bore. The nature
25 of the required shape will generally be dictated by the circumstances of the procedure in which the device is being used. Most commonly, a single bend may be introduced into the barrel by the user of the device, but in other situations it may be necessary to form the barrel into a more complex shape, eg with a double bend (ie an "S"-shape or the like). It has surprisingly been found that, even when
30 bent into shapes as extreme as are ever likely to be required in practice (eg two 90° bends), the pattern of powder dispensed from the device can remain satisfactory in terms of the geometry of the plume of powder emerging from the distal end of the barrel and the pattern of deposition of the powder.

The nature of the plastics material from which the flexible elongate barrel is formed may be such that the tube retains the shape into which it is deformed, at least for as long as is required during normal use. Preferably, however, the barrel

5 incorporates one or more malleable elongate members that can be readily deformed, and which have the effect of retaining the barrel in the desired configuration until it is once again manually deformed to another configuration. Such members may take the form of wires or rods of metal or other malleable material that are incorporated into the barrel. Most commonly, such wires or rods

10 are disposed parallel to the longitudinal axis of the barrel. In some embodiments, the main portion of the barrel is a tube having more than one lumen, one lumen (normally the one having the greatest cross-sectional area) constituting the bore of the barrel along which powder is dispensed, and at least one lumen accommodating one or more wires or rods. In other embodiments, one or more

15 wires or rods are embedded in the plastics material from which the barrel is formed. There may be just one such wire or rod, or there may be two, three, four or more such wires. Where there are more than one wire or rod, those wires or rods are most commonly equiangularly spaced around the main portion of the barrel.

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Forms of material that are suitable for the malleable wires or rods are copper wire and copper-coated steel wire. In one currently preferred embodiment, a single such wire is embedded in the wall of the tube that constitutes the main portion of the barrel. In other embodiments, two, three or four such wires may be used.

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In other embodiments, another form of malleable material may be used to enable the form of the barrel to be altered. For instance, the main portion of the barrel may be provided, along the whole or part of its length, with a sheath of material that holds its shape when deformed, eg a foam material of the type known as

30 memory foam or visco-elastic foam..

In embodiments in which the internal bore of the main portion is tapered, the internal diameter of the bore may decrease from the upstream to the downstream

end of the main portion, ie the internal bore of the main portion may converge. Alternatively, the internal diameter of the bore may increase from the upstream to the downstream end of the main portion, ie the internal bore of the main portion may diverge. The taper angle may typically be in the range 0.5° to 3° , more commonly 0.5° to 2° .

Embodiments in which the main portion of the barrel is flexible typically have a main portion that is considerably longer than is the case for rigid embodiments. Those flexible embodiments are typically formed by extrusion and in such cases will therefore have an internal bore of constant cross-section. Embodiments in which the main portion of the barrel is rigid are more commonly formed by injection moulding, in which case the internal bore of the main portion of the barrel may have a uniform cross-section or may, more preferably, be tapered.

In embodiments in which the barrel has an outwardly flared outlet portion, the outlet portion typically has a length of between 5mm and 25mm, more commonly between 5mm and 10mm. The internal diameter of the outlet portion may increase from its upstream to its downstream end by a factor of two or more. As will be readily appreciated, where the outlet portion is "flared", that term refers to the internal shape of the outlet, ie to a widening of the outlet from its upstream to its downstream end. That widening may or may not be reflected in the external shape of the outlet.

Apart from the modifications to the barrel described above, the device according to the invention may be as described in WO2010/070333, in particular in relation to Figures 3 to 12 of that document. Briefly summarised, such a device has a main body that may comprise upper and lower housing components formed in plastics material by injection moulding. The main body may have the general form of an elongate cylinder that is adapted to be held in a user's hand, the underside of the lower component being shaped to facilitate such grip. A push button-type actuator may be mounted in the top of the main body such that, when the device is held by the user, the actuator can be depressed by the thumb of the hand that holds the device. A flexible tube may extend from the rear end of the device and

may be adapted to be connected to a gas source, eg a source of compressed air. A connector may be provided at the distal end of the tube. A vial containing the powder that is to be dispensed from the device may be coupled to the device, eg via an upstanding spigot that is received within the mouth of the vial. The
5 barrel may extend from the front end of the device.

The barrel may be provided with a mounting that enables its orientation relative to the main body of the device of which it forms part to be varied. For instance, the barrel may engage the main body of the device in the manner of a ball-and-socket
10 connector, so that the orientation of the barrel may be adjusted, eg manually by the operator.

In presently preferred embodiments, however, the barrel is connected to the main body of the device in a fixed orientation. The barrel may be connected to the main
15 body by a threaded connection, or by a suitable quick release connection such as a bayonet fitting. Other forms of connection may alternatively be used, eg a luer lock-type connection, or an interference fit or the like.

The device according to the invention may be manufactured using medical grade
20 materials, most components being most conveniently manufactured in plastics by techniques such as injection moulding and extrusion. Where appropriate, components may be manufactured in other materials, eg glass or metal.

The device according to the invention may be used to deliver a wide variety of
25 powders to a surface of the body. Such powders include agents intended to have a therapeutic effect, either in terms of a pharmacological effect on the body or as disinfectants or the like useful in the prevention or treatment of infections. One particular field in which the device of the invention is useful, however, is for the delivery of haemostatic powder compositions to internal tissues exposed during
30 surgical procedures or after traumatic injury. Such haemostatic compositions, which may also be described as tissue sealants, may for instance comprise dry powder mixtures of fibrinogen and thrombin. Such a mixture is essentially inert when formulated in the dry state, but once hydrated, eg upon application to a

bleeding wound, the mixture leads to the production of fibrin which cross-links to form a blood clot.

Thus, according to a further aspect of the invention, there is provided a method of
5 delivering a haemostatic composition to an internal tissue exposed during surgical procedures or after traumatic injury, which method comprises providing a device as described above, which device is charged with a quantity of a haemostatic composition in dry powder form, and dispensing said composition from said device onto said tissue.

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The invention will now be described in greater detail, by way of illustration only, with reference to the accompanying drawings, in which

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Figure 1 is a perspective view of a first embodiment of a powder delivery device according to the invention;

Figure 2 is a side view of the device of Figure 1;

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Figure 3 shows a barrel that forms part of the device of Figure 1;

Figure 4 is a cross-sectional view of the barrel of Figure 3;

Figures 5(a) and (b) illustrate the range of vertical movement of the barrel;

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Figures 6(a) and 6(b) illustrate the range of lateral movement of the barrel;

Figure 7 is a perspective view of a second embodiment of a powder delivery device according to the invention, showing the barrel separated from the main body of the device;

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Figure 8 is a perspective view from behind of the barrel of the device of Figure 7;

Figure 9 is a cross-sectional view of the barrel of Figure 8;

Figure 10 is a perspective view of a third embodiment of a powder delivery device according to the invention, comprising the main body of the second embodiment with an alternative form of barrel attached to it;

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Figure 11 is a perspective view of the barrel shown in Figure 10; and

Figure 12 is a cross-sectional view of the barrel of Figure 11.

10 Referring first to Figures 1 and 2, a first embodiment of a powder delivery device in accordance with the invention is generally designated 20. Save for the inventive modification described in greater detail below, the device 20 is of similar form to the device illustrated in Figures 3 to 12 of WO2010/070333. Briefly summarised, the device 20 has a main body that comprises upper and lower housing
15 components 23a,23b that are formed in plastics material by injection moulding. The main body has the general form of an elongate cylinder that is adapted to be held in a user's hand, the underside of the lower component 23b being shaped to facilitate such grip. A push button-type actuator 27 is mounted in the top of the main body such that, when the device 20 is held by the user, the actuator 27 can
20 be depressed by the thumb of the hand that holds the device 20.

A flexible tube 25 extends from the rear end of the device 20 and is adapted to be connected to a gas source, eg a source of compressed air (not shown). A suitable connector 26 is provided at the distal end of the tube 25.

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A glass vial 31 is coupled to the device 20 via an upstanding spigot (not visible) that is received within the mouth of the vial 31. A pair of clips 35 engage with a peripheral lip of the vial 31, so as to hold it securely in place. In other embodiments, the vial 31 may simply engage the spigot or similar formation with
30 an interference fit and/or the spigot or similar formation may have a degree of resilience enabling a clip-type fitting to the vial. To facilitate sealing engagement of the vial 31 with the device 20, the formation that receives the mouth of the vial 31 may incorporate or be formed from a suitable elastomeric material (eg a

thermoplastic elastomer). A device 20 having such a fitting may be produced using a two-shot moulding process.

As for the device described in WO2010/070333, the front end of the device 20 is provided with a tubular barrel 29, through which powder is dispensed from the device 20. The barrel 29 in the present invention, however, is rather different in form to that described in the earlier patent application, as is discussed in greater detail below.

10 The base of the spigot with which the vial 31 is engaged is closed by a perforated plate, such that when the device is in the operative orientation shown in Figures 1 and 2, powder contained within the vial 31 rests upon the perforated plate. When the actuator 27 is depressed, gas is caused to flow through the device 20, as described in WO2010/070333. The flow of gas has two, related, effects. First, the
15 gas flow drives a mechanical agitator in the form of a ball that is held captive within a circular track; rotation of the ball around the track induces vibrations in the device 20, the effect of which is to dislodge powder from the vial 31, through the perforated plate that constitutes the base of the spigot that is engaged by the vial 31. Secondly, a proportion of the the gas flow is directed at the underside of
20 the perforated plate, entrains the powder that is dislodged from the vial 31 and carries it from the device 20 via the barrel 29.

Thus, to dispense powder from the device 20, the user holds the device 20 in one hand, directs the barrel 29 at the intended site of application of the powder, and
25 depresses the actuator 27 with the thumb. This permits gas to flow through the device 20, causing the ball to rotate rapidly around the track and inducing a degree of mechanical vibration that is transmitted to the vial 31. Most of the gasflow is vented from the device 20. However, a small proportion of gas is directed at the underside of the perforated plate. The mechanical agitation of the
30 device 20 caused by rotation of the ball within the track facilitates the release of powder from the vial 31. The powder is entrained in the flow of air that escapes from the device 20 via the barrel 29. The powder is blown out of the device 1 and deposited on the site of application.

As noted above, the device 20 differs from that disclosed in WO2010/070333 in the form of the barrel 29. The barrel 29 is shown in Figures 3 and 4.

- 5 As can be seen in Figure 3, the barrel 29 is elongate and of circular cross-section, extending from a ball-type connector 291 at one end to a flared outlet 292 at the other. The ball-type connector 291 is captivated within an opening at the front of the main body of the device 20, between the upper and lower housing components 23a,23b, in the manner of a ball-and-socket joint.

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As can be seen from Figure 4, the barrel 29 has an internal bore having an entry portion 293 that is of constant diameter, a main bore 294 that is of reduced diameter relative to the entry portion 292, and an outlet portion 295 within the flared outlet 292. The diameter of the main bore 294 reduces along its length.

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- The overall length of the barrel 29 is approximately 70mm. The entry portion 293 of the internal bore has a diameter of approximately 5mm and a length of approximately 8mm. The diameter of the main bore 294, which has a length of approximately 48mm, reduces from approximately 3.5mm adjacent the entry portion 293 to approximately 2mm where the main bore 294 meets the outlet portion 295. The angle of convergence of the internal wall of the main bore 294 relative to its longitudinal axis is thus approximately 1°.

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- The entry portion 293 receives a tube (not visible in the drawings) by which the gasflow and entrained powder are fed from the main body of the device 20 to the barrel 29.

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- The narrowing of the main bore 294 may cause an increase in velocity of the gasflow as it exits the device 20 and, together with the flared form of the outlet portion 295, this may help to maintain the shape of the powder plume emitted from the device 20, resulting in good coverage of the application site with powder. Fall off of powder from the emitted plume, under the influence of gravity, may be reduced, minimising the amount of powder that is dispensed onto sites other than

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to which the powder is intended to be delivered. The flared form of the outlet portion 295 also leads to a reduced likelihood of clogging.

In this embodiment, directional control over the emitted powder is achieved by virtue of the fact that the ball-type connector 291 permits the orientation of the barrel 290 relative to the main body of the device 20 to be varied over a wide range, both vertically (see Figures 5(a) and 5(b)) and laterally (Figures 6(a) and 6(b)).

Turning now to Figure 7, a second embodiment of a powder delivery device according to the invention is generally designated 30. The device 30 is broadly similar to the first embodiment 20 described above in that it comprises a main body 123 that receives vial 131 of powder. In this embodiment, the vial 131 is received within a ring 137 of thermoplastic elastomer that is moulded onto the upper component of the main body 123 in a two-shot moulding process.

Like the first embodiment 20, the device 30 comprises a tubular outlet barrel 39. In the second embodiment 30, however, the barrel 39 connects to the main body 123 by means of a bayonet fitting and has a fixed orientation relative to the main body 123.

As can be seen in Figure 8, the face of the barrel that abuts the main body 123 is formed with a male bayonet spigot 391 with a central recess that receives the open end of a tube 135 (see Figure 7) by which the gasflow and entrained powder are fed from the main body 123 of the device to the barrel 39. The barrel 39 is injection moulded in rigid plastics material (eg ABS) and (referring to Figure 9), like the barrel 29 of the first embodiment 20, is formed with an internal bore 394 that diminishes along its length (in this case from an internal diameter of approximately 2.9mm to an internal diameter of approximately 2mm). The barrel 39 has a flared outlet 392.

As for the first embodiment 20, the narrowing of the main bore 394 may cause an increase in velocity of the gasflow as it exits the device 30 and, together with the

flared form of the outlet 392, this may help to maintain the shape of the powder plume emitted from the device 30, resulting in good coverage of the application site with powder. Fall off of powder from the emitted plume, under the influence of gravity, may be reduced, minimising the amount of powder that is dispensed onto sites other than that to which the powder is intended to be delivered. The flared form of the outlet 392 also leads to a reduced likelihood of clogging.

Finally, Figure 10 depicts a third embodiment of a powder delivery device according to the invention, which is generally designated 40. This embodiment differs from the second embodiment 30 solely in the form of the outlet barrel 49. Indeed, the outlet barrel 39 of the second embodiment 30 and the outlet barrel 49 of the third embodiment 40 are interchangeable.

The form of the barrel 49 is shown in greater detail in Figures 11 and 12. The barrel 49 comprises three components: a bayonet hub 491, a flexible plastics tube 492 and an outlet tip 493.

The bayonet hub 491 is injection moulded in rigid plastics material (eg polyamide) and corresponds in overall shape to the proximal end of the rigid barrel 39 of the second embodiment 30. It has a central bore 495 that terminates in a socket within which one end of the flexible tube 492 is received. That end of the tube 492 may be fixed to the hub 491 by adhesive, by ultrasonic welding or by any other suitable means. The other end of the tube 492 is received within a similar socket formed in the outlet tip 493 (which is also formed by injection moulding of a suitable material, eg polyamide) and may be fixed by similar means. The distal (downstream) part of the outlet tip 493 has a flared internal bore.

The flexible tube 492 is formed by extrusion in polyurethane, a copper-coated steel wire 494 being embedded in the wall of the flexible tube 492 during manufacture. A user of the device may therefore form the flexible tube 492 into a desired configuration, the effect of the wire 494 being to retain the tube 492 in that configuration during use. The third embodiment 40 may be particularly useful in

surgical procedures in which it is desired to deposit the powder onto surfaces that are hidden and at which a straight barrel cannot be directed.

Claims

1. A device for the dispensing of powder, the device being of the type in which a generated gas flow entrains the powder to be dispensed and carries the powder from the device via a barrel, the barrel having a bore including a main portion with a continuous internal surface, characterised in that
- 5 (a) the length of the main portion is at least fifteen times its maximum internal diameter; and/or
- (b) the internal bore of the main portion is tapered; and/or
- 10 (c) the barrel has an outwardly flared outlet portion.
2. A device as claimed in Claim 1, wherein the length of the main portion is at least fifteen times its maximum internal diameter; and the internal bore of the main portion is tapered.
- 15 3. A device as claimed in Claim 1 or Claim 2, wherein the barrel has an outwardly flared outlet portion.
4. A device as claimed in any preceding claim, wherein
- 20 (a) the length of the main portion is at least fifteen times its maximum internal diameter; and
- (b) the internal bore of the main portion is tapered; and
- (c) the barrel has an outwardly flared outlet portion.
- 25 5. A device as claimed in any preceding claim, wherein the barrel is rigid.
6. A device as claimed in Claim 5, wherein the length of the main portion of the barrel is at least fifteen times, or at least eighteen times or at least twenty times its maximum internal diameter.
- 30 7. A device as claimed in Claim 5 or Claim 6, wherein the length of the main portion is between about 30mm and 100mm, eg about 50mm or about 75mm.

8. A device as claimed in any one of Claims 5 to 7, wherein the maximum internal diameter of the main portion is from 1mm to 6mm, eg about 2mm or about 3mm.

5 9. A device as claimed in any one of Claims 1 to 4, wherein the barrel is flexible.

10. A device as claimed in Claim 9, wherein the main portion of the barrel has a length of between 50mm and 300mm, or between 50mm and 200mm, or between
10 100mm and 180mm.

11. A device as claimed in Claim 9 or Claim 10, wherein the internal diameter of the barrel is between 1mm and 5mm, or between 1.5mm and 3mm.

15 12. A device as claimed in any one of Claims 9 to 11, wherein the main portion of the barrel comprises a plastics tube.

13. A device as claimed in Claim 12, wherein the barrel incorporates one or more malleable elongate members.

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14. A device as claimed in Claim 13, wherein the elongate malleable members are wires or rods.

15. A device as claimed in Claim 14, wherein the wires or rods are embedded
25 in the plastics material from which the barrel is formed.

16. A device as claimed in Claim 14 or Claim 15, wherein the one or more elongate malleable members are one or more copper or copper-coated steel wires.

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17. A device as claimed in any preceding claim, wherein the internal diameter of the main portion decreases from the upstream to the downstream end of the main portion.

18. A device as claimed in any one of Claims 1 to 16, wherein the internal diameter of the main portion increases from the upstream to the downstream end of the main portion.

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19. A device as claimed in Claim 17 or Claim 18, wherein the internal diameter of the main portion increases or decreases at a taper angle of 0.5° to 3° , or a taper angle of 0.5° to 2° .

10 20. A device as claimed in Claim 3, wherein the outlet portion has a length of between 5mm and 25mm, or between 5mm and 10mm.

21. A device as claimed in Claim 20, wherein the internal diameter of the outlet portion increase from its upstream to its downstream end by a factor of two or
15 more.

22. A device as claimed in any preceding claim, which is a device described in WO2010/070333, in particular in relation to Figures 3 to 12 thereof.

20 23. A device as claimed in any preceding claim, wherein the barrel is provided with a mounting that enables its orientation relative to the main body of the device of which it forms part to be varied.

24. A device as claimed in Claim 23, wherein the mounting is a ball-and-socket
25 connector.

25. A device as claimed in any one of Claims 1 to 22, wherein the barrel is connected to the main body of the device in a fixed orientation.

30 26. A device as claimed in Claim 25, wherein the barrel is connected to the main body of the device by a bayonet fitting.

27. A method of delivering a haemostatic composition to an internal tissue exposed during surgical procedures or after traumatic injury, which method comprises providing a device as claimed in any preceding claim, which device is charged with a quantity of a haemostatic composition in dry powder form, and
- 5 dispensing said composition from said device onto said tissue.