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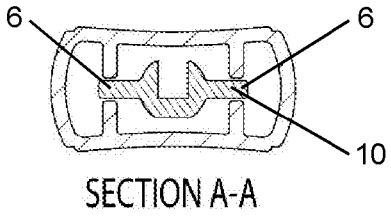

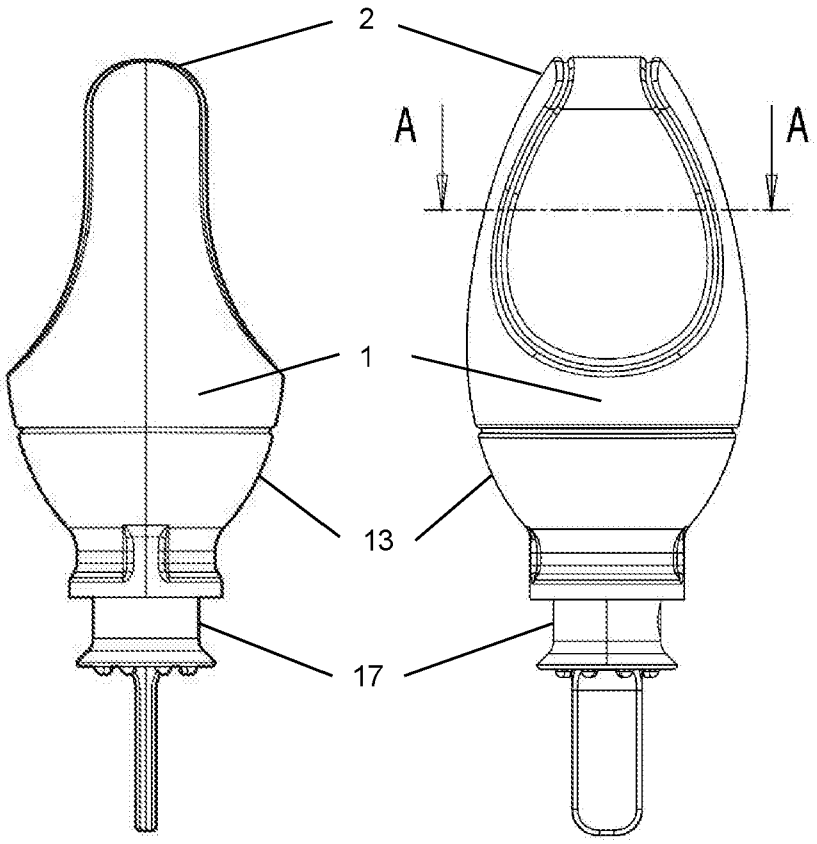

Figure 1

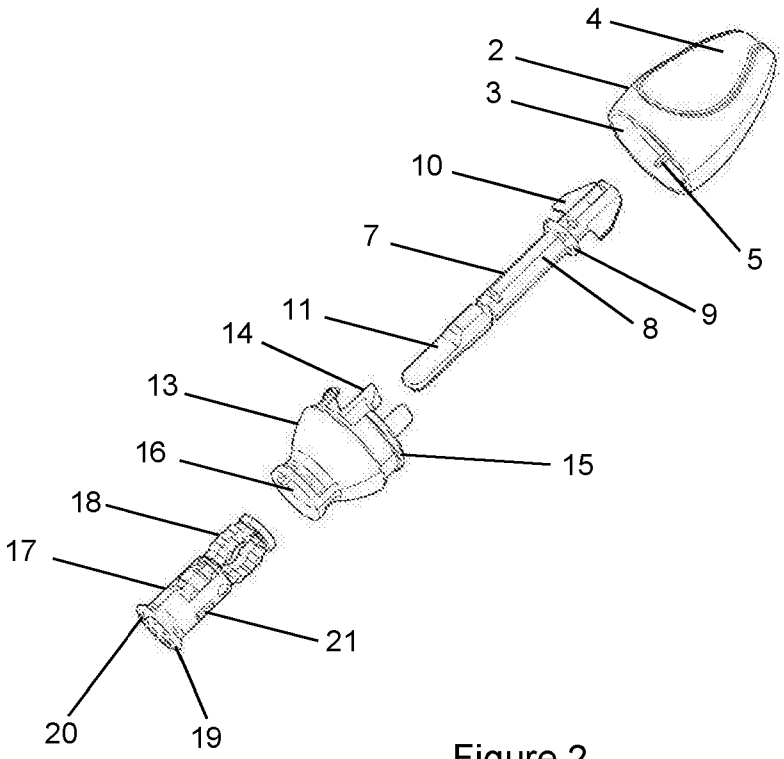

Figure 2

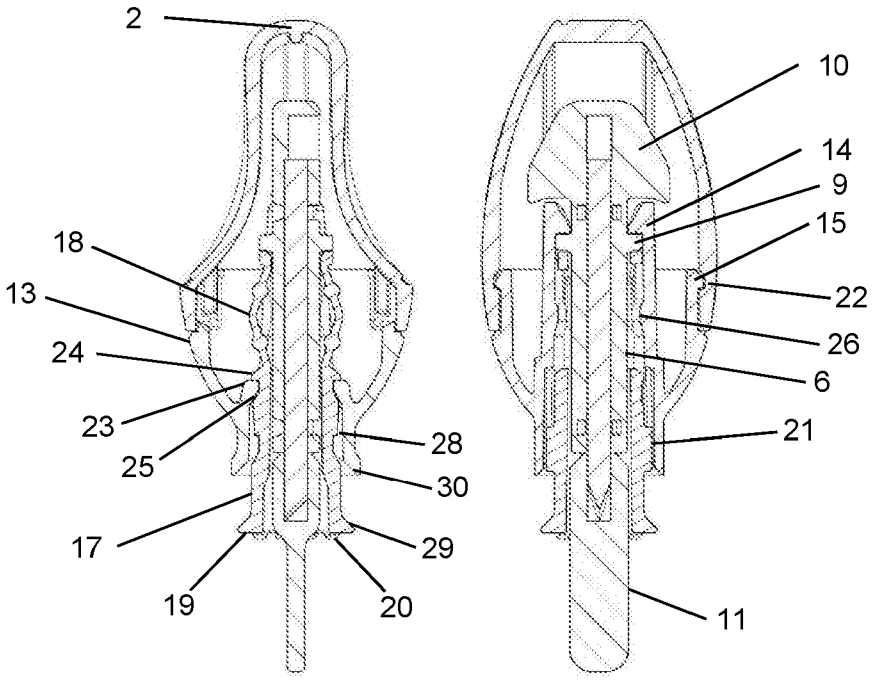

Figure 3

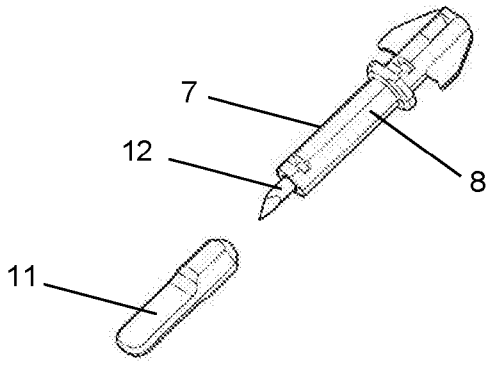

Figure 4

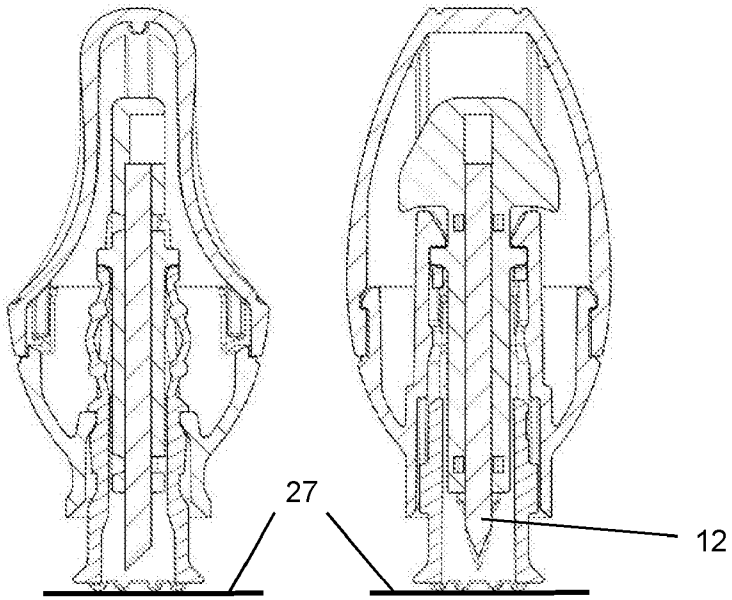

Figure 5

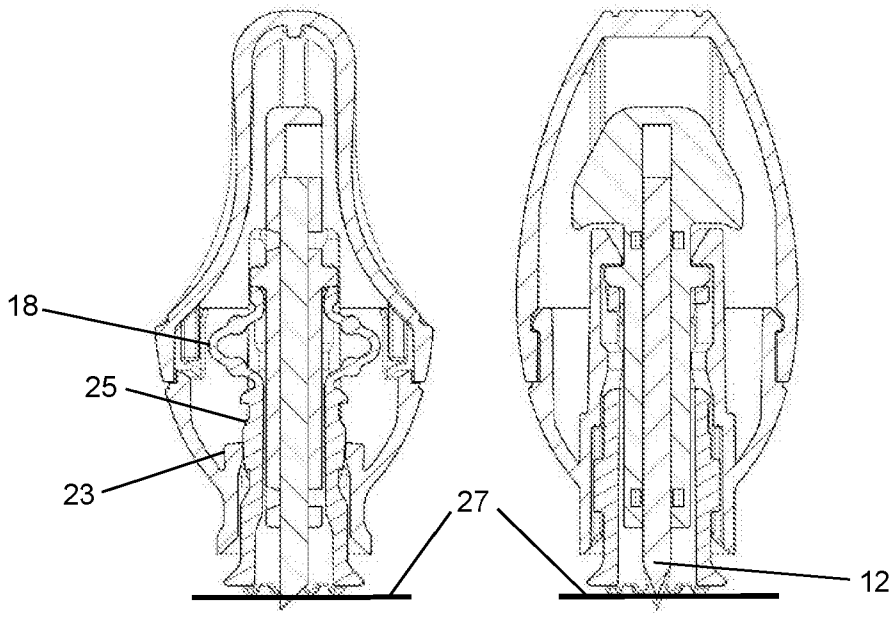

Figure 6

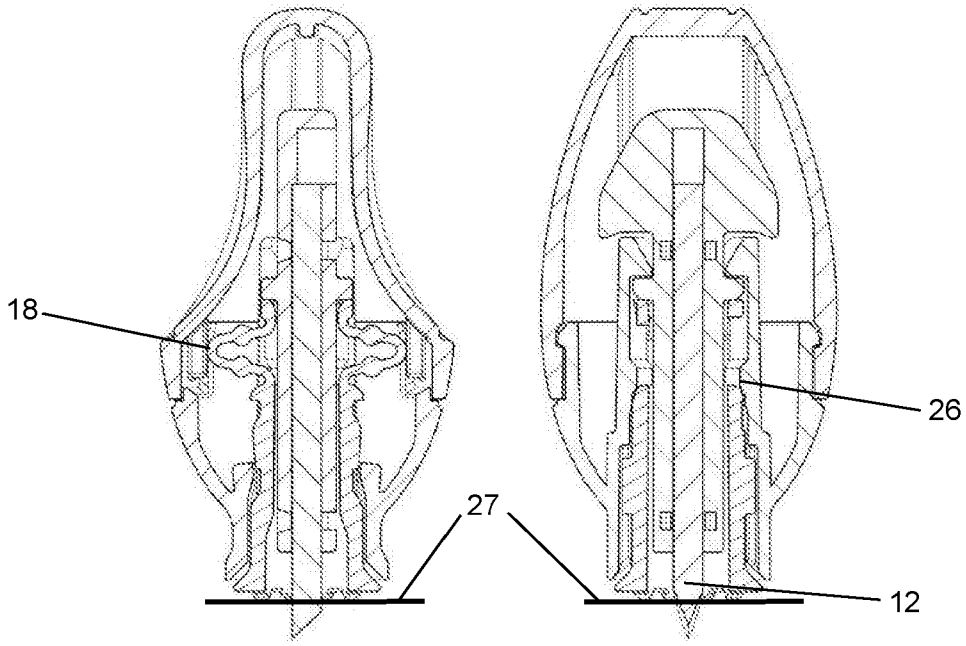

Figure 7

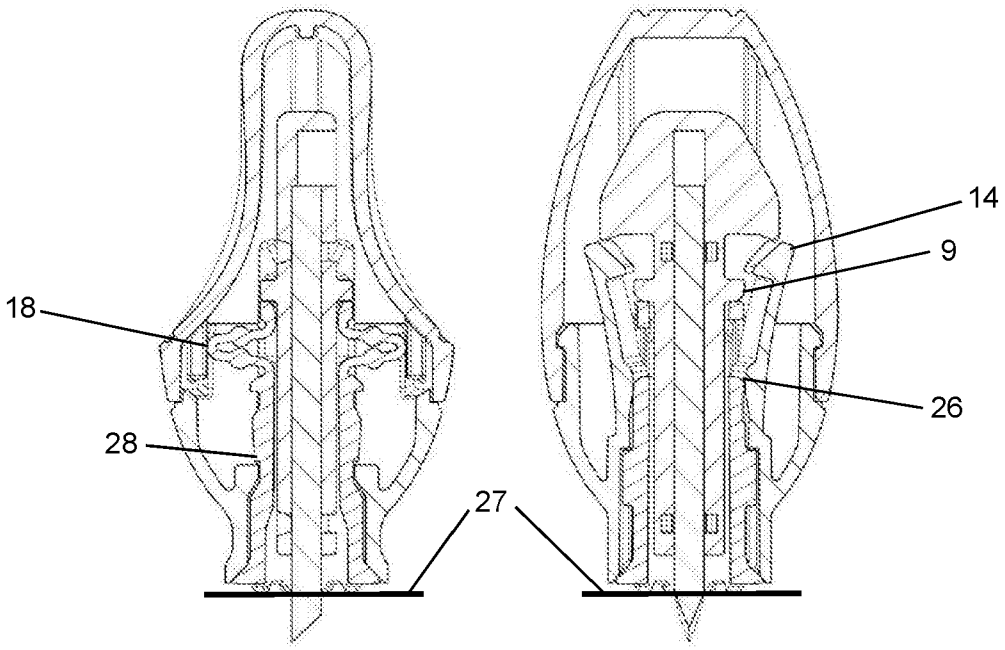

Figure 8

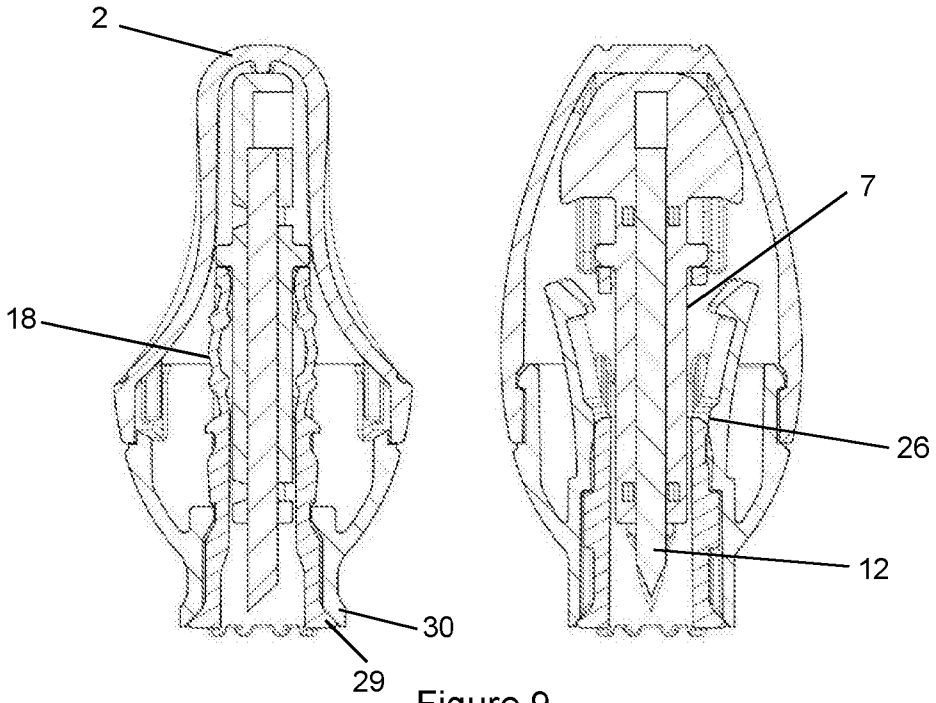

Figure 9

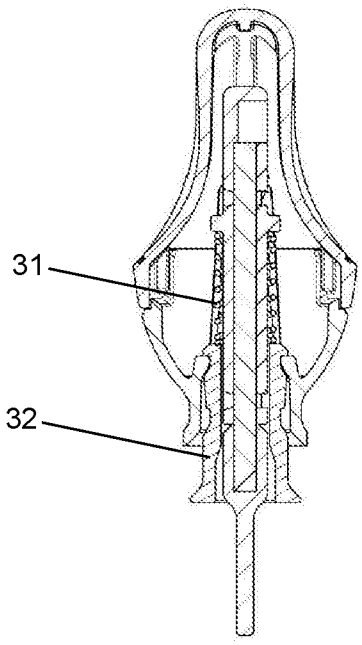

Figure 10

Single Use Lancing Device

Technical Field

The present disclosure relates to single-use lancing devices, for example for use in providing a sample of blood.

Background

Lancing devices are used to obtain blood samples from a person by piercing the skin on a finger or other body part with a small needle or blade. Such blood samples are required for many medical tests, for example glucose tests for diabetes management. To make the process of drawing the blood sample convenient and safe to the user, lancing devices need to satisfy high standards. For example, in order to avoid infection and contamination, lancing devices are preferable single-use disposable products. They must therefore be small and simple, to be economic, and preferably should use a sustainable design to minimise waste and environmental impact through their life cycle.

Disposable lancing devices typically include a needle connected to a holder, collectively referred to as a lancet, and a trigger mechanism. When the trigger is activated the lancet is propelled from a retracted position within the housing of the device to an extended position wherein the needle projects from the housing to prick the subject's skin. Usually the lancet is driven by a metal spring which is cocked during the assembly of the device and released by the trigger. A problem with these devices is that the use of metal springs contributes to the device's environmental impact during disposal. Furthermore, metal springs require additional space within the device, increasing the amount of plastic required and the size of the packaging. Another problem with current designs is that storing a lancing device with a cocked spring can cause parts to become misshapen through tension, impairing its operation.

Summary

The present invention has been devised to overcome the problems described above; in particular, to address the need for a lancing device which is more sustainable than current designs.

According to a first aspect of the present invention there is provided a lancing device comprising a housing and a lancet. The lancet comprises a needle and is configured to be movable rearwardly within the housing from an initial operational position to a retracted position. The lancing device further comprises a shroud coupled movably to the housing and at least partially covering and extending forwards beyond a forward end of the needle before use of the lancing device, and a biasing member coupled between the lancet and the shroud. The shroud is configured to, when pressed against skin around a sampling site, move rearwards relative to the housing, prime the biasing member during the rearward movement, and, at a first point of the rearward movement, allow the needle to contact the sampling site and subsequently, at a second point of the rearward movement, release energy stored in the biasing member to drive the lancet from the operational position to the retracted position. The housing comprises deflectable legs. The deflectable legs extend from an inner surface of the housing and are configured to engage with a shoulder of the lancet to restrict a rearward movement of the lancet with respect to the housing until the shroud reaches the second point of the rearward movement. The shroud is further configured to, at the second point of the rearward movement, deflect the legs so that rearward movement of the lancet is no longer restricted and energy stored in the biasing member is released to drive the lancet from the operational position to the retracted position.

The biasing member may comprise one or more springs that are compressed during the rearward movement. The or each spring may be a plastic spring. The or each plastic spring may be formed integrally with the shroud. The or each plastic spring may be a flexible leg.

The housing may comprise one or more fingers configured to resist an initial rearward movement of the shroud until a level of force applied by the user exceeds a predefined threshold force. The housing and the shroud may comprise cooperating snap-fit fastening features for preventing resetting of the shroud, after the shroud reaches the second point of the rearward movement.

The housing may comprise a lower housing part and an upper housing part in snap-fit engagement with one another. The lower housing part may be configured to couple the shroud moveably to the lower housing. The lower housing part may comprise the deflectable legs, one or more fingers configured to resist an initial rearward movement of the shroud until a level of force applied by the user exceeds a predefined threshold force, and snap-fit fastening features for cooperatively engaging with features of the shroud for preventing resetting of the shroud, after the shroud reaches the second point of the rearward movement.

Components of the device may be configured to facilitate assembly of the device by installing the shroud into the lower housing part by inserting the shroud from a lower end of the lower housing part and pushing the shroud rearwards into the lower housing part until the or each finger restricts further rearward movement of the shroud; installing the lancet into the lower housing part by inserting the lancet from an upper end of the lower housing part and fastening the lancet into the deflectable legs, and joining the upper housing part with the lower housing part by snap-fit engagement.

Brief Description of the Drawings

Figure 1 shows a side, a front and a horizontal cross-section view of an assembled lancing device;

Figure 2 is an exploded view of the lancing device of Figure 1;

Figure 3 shows cross-sectional side and front views of the lancing device of Figure 1;

Figure 4 is a view of a lancet of the lancing device of Figure 1 after the needle cap has been removed from the lancet;

Figure 5 shows cross-sectional side and front views of the lancing device of Figure 1 after removal of the needle cap;

Figure 6 shows cross-sectional side and front views of the lancing device of Figure 1 in use where a needle is inserted into the skin;

Figure 7 shows cross-sectional side and front views of the lancing device of Figure 1 in use where the needle is further inserted into the skin;

Figure 8 shows cross-sectional side and front views of the lancing device of Figure 1 in use where the needle reached a predetermined skin penetration depth;

Figure 9 shows cross-sectional side and front views of the lancing device of Figure 1 after usage; and

Figure 10 shows a cross-sectional side of an alternative embodiment including a compression spring.

Detailed Description

The Figures illustrate the components and operation of a single use lancing device designed for pricking a person's skin to, for example, provide a blood sample. The references to "lower", "upper", "horizontal" and "vertical" have been chosen for convenience, and refer to the orientations as shown in Figure 1 and Figures 4-9.

Referring to Figure 1, a lancing device 1 is shown in an assembled state. As further illustrated in the exploded view of Figure 2, the lancing device 1 has a lower housing part 13, an upper housing part 2, a lancet 7 and a shroud 17. The shroud 17 comprises a generally tubular shaped section and two spring legs 18 extending away from the tubular section in a substantially coaxial direction. The spring legs 18 serve as respective compression springs. In a relaxed state, both spring legs 18 include a central portion of convex shape with respect to the central axis. The lower end of the shroud 17 has a generally ring-shaped skin contacting surface 19. Projections 20 on the skin contacting surface are intended to "confuse" the nerves in the area of the prick to make the prick less painful to the user. The shroud 17 comprises two ribs 21 which extend laterally from an outer surface of the shroud 17.

Referring to Figure 3, the shroud 17 comprises two hooks 24 which extend laterally from the outer surface of the shroud 17, and which provide generally flat and horizontal surfaces at their lower ends. The outer surface of the shroud 17 provides two tapered portions 25 located below the hooks 24. The tapered portions 25 are narrower at their upper ends than at their lower ends. The outer surface of the shroud 17 provides two laterally extending hooks 28 located below the tapered portions 25, providing generally flat and horizontal surfaces at their lower ends. At its lower end, the shroud 17 provides a tapered lip 29 on the outer surface. The lateral extent of the tapered lip 29 is greater at its lower end than at its upper end.

Referring to Figure 2, the lower housing part 13 is generally tubular shaped and provides an axial passage 16. The lateral extent of the lower housing part 13 is greater at its upper end than at its lower end. A plug 15 extends from an outer surface of the lower housing part 13. The plug 15 is generally annular shaped. Instead of forming a complete ring, the plug 15 may comprise two portions, which are arc shaped, as illustrated in Figure 2. As shown in Figure 3, the lower housing part 13 provides two deflectable fingers 23 which protrude from an inner surface of the lower housing part 13. Each finger 23 comprises an overhanging section which reduces the lateral extent of the passage 16.

The lower housing part 13 also provides two legs 14 which extend upwards from the inner surface of the lower housing part 13. The upper end of each leg 14 is shaped to serve as a hook of a snap-fit fastener. At the upper end of each leg 14, a generally triangular shaped hook protrudes towards the central axis of the lower housing part 13, providing a generally flat and horizontal surface at its lower end. The legs 14 are deflectable such that the unsupported upper ends of the legs flex away from the central axis of the lower housing part 13 when the legs 14 are deflected. Each of the legs 14 comprises a section 26 which protrudes towards the central axis of the lower housing part 13. As discussed in more detail below, the protruding

section 26 is configured to enable an interaction with the shroud 17 such that the shroud 17 deflects the legs 14 during operation of the lancing device. At its lower end, the inner surface of the lower housing part 13 further includes a tapered region 30. As discussed in further detail below, this tapered region 30 is configured to match the tapered lip 29 of the shroud 17.

Referring to Figure 2 again, the lancet 7 comprises an elongated body 8, and a needle 12 embedded within the body 8 and initially shrouded by a cap 11. The body 8 has a laterally extending shoulder 9 which provides generally flat and horizontal surfaces at its lower and upper ends. At an upper end, the body 8 comprises laterally extending ribs 10. The lateral extent of the ribs 10 is greater at its lower end than at its upper end. The cap 11 is moulded integrally with the body 8 but the cap 11 can be twisted off to expose the needle tip extending from a lower end of the body 8. The shape of the cap 11 is sufficiently flat and wide that it can be grasped by a user to facilitate twisting. An initial connection between the cap 11 and the body 8 is sufficiently weak that twisting of the cap 11 relative to the body 8 breaks the cap 11 free without damaging the body 8. Figure 4 shows the cap 11 and the lancet 7 after the cap 11 has been twisted off.

The upper housing part 2 is closed at its upper end and defines a generally circular opening 3 at its lower end. The lateral extent of the upper housing part 2 is greater at its lower end than at its upper end. The upper housing part 2 includes two portions of convex shape and two portions of concave shape with respect to the central axis, as illustrated respectively in the side and front views shown in Figure 3. Each concave shaped portion of the upper housing part 2 comprises a grip area 4 to assist a user in grasping the device during operation. Figure 2 shows only one grip area 4 as the second grip area is located on an opposite side of the upper housing device 2 and is not visible in this view. An inner surface of the opening 2 provides a socket 22 which is generally annular shaped. The socket 22 is configured to be cooperatively engageable with the plug 15 of the lower housing part 13 to join the two housing parts. The upper housing part 2 further comprises a rib 5 which extends downwards and is configured to be engageable with the lower housing part 13 to prevent rotation of the upper and lower housing parts 2, 13 in relation to each other when the two housing parts are joined. As shown in the horizontal cross section in Figure 1, the upper housing part 2 further defines slots 6 configured to receive the ribs 10 of the lancet 7.

The lower housing part 13, the upper housing part 2, the shroud 17 and the lancet body 8 are moulded components. Considering the lancet, the needle 12 is embedded into the lancet body 8 by over-moulding. It is an advantage that the main components of the lancing device 1,

including the spring legs 18, are manufactured from plastic materials. Moulded plastic springs enable designs which are highly compact and reduce waste.

The assembly of the lancing device comprises three simple steps. First, the shroud 17 is pushed into the passage 16 from the lower end of the lower housing part 13 until the fingers 23 restrict further rearward movement of the shroud 17. Second, the lancet 7 is installed in its operating position in the lower housing part 13 by inserting it into the passage 16 from the upper end of the lower housing part 13 and fastening the shoulder 9 into the two legs 14. Third, the upper housing part 2 is connected to the lower housing 13 part via the corresponding annular snap fit features 15, 22. NB. The lancet is sterilised prior to assembly.

In an assembled lancing device, as shown in Figures 1 and 3, the lower and upper housing parts 2, 13 are joined together by a snap-fit engagement of the plug 15 and socket 22. The rib 5 of the upper housing part 2 is engaged with the lower housing part 13 to prevent rotation of the upper and lower housing parts 2, 13 in relation to each other. The lancet 7 is retained in an operating position in the lower housing part 13 by the legs 14. An upper end of the shoulder 9 engages with the legs 14, restricting a rearward movement of the lancet 7 with respect to the lower housing part 13. Similarly, a forward movement of the lancet 7 is restricted by the engagement of the legs 14 with the ribs 10 of the body 8. The ribs 10 are received by the slots 6 in the upper housing, preventing axial rotation of the lancet 7. The lower end of the shoulder 9 contacts an upper end of the spring legs 18 of the shroud 17. The spring legs 18 serve as compression springs between the shroud 17 and the shoulder 9. In other words, the retraction spring legs 18 serve as biasing members coupling the lancet 7 and the shroud 17.

In an assembled lancing device, an upper end of the shroud 17 is located inside the lower housing part 13 and the shroud 17 extends outwardly from the passageway 16 of the lower housing part 13. The ribs 21 of the shroud 17 cooperatively engage with pockets in the lower housing part 13, preventing rotational movement of the shroud 17. The hooks 24 of the shroud 17 are cooperatively engaged with recesses in the lower housing part 13, preventing forward movement of the shroud 17. The fingers 23 are engaged with the tapered portions 25 of the shroud 17. The fingers 23 restrict the rearward movement of the shroud 17 until a level of force applied by the user exceeds a predefined threshold force and thereby prevent an accidental activation of the lancing device.

With reference to Figures 5 to 9, the operation of the lancing device will now be described. In order to prepare the lancing device 1 for use, a user holds the lancing device with the fingers of one hand by the grip areas 4, grips the cap 11 with the fingers of the other, and twists off

the cap 11 to break the connection allowing the cap to be pulled off the needle. As the ribs 10 of the lancet body 8 are located in the slots 6, the lancet 7 is prevented from rotating which allows a user to twist the cap 11 relative to the body 8 to break off the cap 11.

After removal of the cap 11, the user places the skin contacting surface 19 with projections 20 against skin 27 around a sampling site, as illustrated in Figure 5. At this stage, the shroud 17 extends forwards beyond a forward end of the needle 12, preventing contact of the skin 27 with needle 12. Pressing the lancing device against the skin 27, the user applies a level of force that exceeds the predefined threshold force. Due to the applied force, the tapered portions 25 of the shroud 17 deflect the fingers 23 outwardly, allowing the shroud 17 to move rearwards into the housing, as shown in Figure 6. Next, the force, which is still applied by the user, leads to a sudden rearward movement of the shroud 17. During the rearward movement of the shroud 17, the lancet remains retained in its operational position by the deflectable legs 14 of the lower housing part 13, and the spring legs 18 of the shroud 17 are compressed along their axes. As shown in Figure 6, the applied force bends the central portion of each spring leg 18 laterally away from the central axis of the shroud 17. A reliable and predictable deformation of the spring legs 18 upon compression is ensured by the design of the spring legs 18, and in particular by the convex shape of the central portion. Upon reaching a first point of the rearward movement of the shroud 17, the needle 12 contacts the sampling site.

The user then continues to press the lancing device 1 against the skin 27 and, as illustrated in Figure 7, the shroud 17 moves further rearwards, the needle 12 further penetrates the skin 27, and the spring legs 18 are further compressed. As illustrated in Figure 8, at a second point of the rearward movement of the shroud 17, the needle 12 reaches a predetermined skin penetration depth. The shroud 17 is now largely retracted into the housing parts 2, 12 while further rearward movement of the shroud 17 is prevented by the lip 29 contacting the tapered region 30 of the lower housing 12. At this stage, the hooks 28 of the shroud 17 engage with the fingers 23 of the lower housing 12, so that forward movement of the shroud 17 is also prevented. The shroud 17 is now essentially locked in place. It is an advantage that the lip 29 has a tapered shape and that the tapered region 30 is configured to match the lip 29 as this restricts access to pull the shroud 17 back out thereby preventing improper resetting of the device.

The legs 14 are now flexed away from the central axis of the lower housing part 13 by the shroud 17 engaging with the protruding section 26 of the legs 14. The upper ends of the legs 14 are no longer engaged with the lancet shoulder 9. The rearward movement of the lancet 7 is no longer restricted within the housing and the energy stored in the spring legs 18 is

released to drive the lancet 7 from the operational position to a retracted position. As shown in Figure 9, when the lancet 7 is in the retracted position, the needle 12 does not extend outwardly from the passageway 16 of the lower housing part 13. Retracting the needle 12 when the moveable shroud 17 reaches a predefined position provides the advantage of a consistent and well-defined skin penetration depth.

Next, the user removes the lancing device from the sampling site and collects the blood sample, e.g. with a suitable swab. As the lancet 7 is now in the retracted position, the risk of accidental needle injuries is greatly reduced. The lancing device is now in a “used” state and can be disposed of. The retracted shroud 17 serves as a visual indicator to the user that the device has been used and thereby prevents any confusion by the user as to the state of the lancing device.

Those skilled in the art will appreciate that various modifications may be made to the above described embodiment without departing from the scope of the present invention.

In the embodiment shown in Figures 1 to 9, the needle 12 does not extend outwardly from the passageway 16 of the lower housing part 13 when the lancet 7 is in the retracted position. In another embodiment, the needle 12 may extend outwardly from the passageway 16 of the lower housing part 13 when the lancet 7 is in the retracted position. In this case, the forward end of the needle 12 is still covered by the shroud 17 which, even in the retracted position, extends slightly from the housing.

Figure 10 shows an alternative embodiment in which the biasing member coupled between the lancet 7 and a modified shroud 32 is a metal compression spring 31. The modified shroud 32 differs from the shroud 17 in that the modified shroud 32 does not include the spring legs 18.

In the above description, the pricking member that pierces the skin has been described as a “needle”. Those skilled in the art will appreciate that this term encompasses conventional needles, blades etc.

Reference numeral	Feature
1	Lancing device
2	Upper housing part

3	Opening
4	Grip areas
5	Rib
6	Slots
7	Lancet
8	Body
9	Shoulder
10	Lancet ribs
11	Needle cap
12	Needle
13	Lower housing part
14	Legs
15	Plug
16	Passageway
17	Shroud
18	Spring legs
19	Skin contact area
20	Projections
21	Shroud ribs
22	Socket
23	Finger
24	Hooks
25	Tapered portions
26	Protruding section
27	Skin
28	Lower shroud hooks
29	Shroud lip
30	Lower housing tapered region
31	Compression spring
32	Modified shroud

CLAIMS:

1. A lancing device comprising:

a housing;

a lancet comprising a needle, the device being configured to allow the lancet to move rearwardly within the housing from an initial operational position to a retracted position;

a shroud coupled movably to the housing and at least partially covering and extending forwards beyond a forward end of the needle before use of the lancing device; and

a biasing member coupled between the lancet and the shroud,

wherein the shroud is configured to, when pressed against skin around a sampling site, move rearwards relative to the housing, prime the biasing member during the rearward movement, and, at a first point of the rearward movement, allow the needle to contact the sampling site and subsequently, at a second point of the rearward movement, release energy stored in the biasing member to drive the lancet from the operational position to the retracted position, and wherein the housing comprises deflectable legs, the deflectable legs extending from an inner surface of the housing and being configured to engage with a shoulder of the lancet to restrict a rearward movement of the lancet with respect to the housing until the shroud reaches the second point of the rearward movement, and wherein the shroud is further configured to, at the second point of the rearward movement, deflect the legs so that rearward movement of the lancet is no longer restricted and energy stored in the biasing member is released to drive the lancet from the operational position to the retracted position.

2. A lancing device according to claim 1, wherein the biasing member comprises one or more springs that are compressed during the rearward movement.

3. A lancing device according to claim 2, wherein the or each spring is a plastic spring.

4. A lancing device according to claim 3, wherein the or each plastic spring is formed integrally with the shroud.

5. A lancing device according to claim 4, wherein the or each plastic spring is a flexible leg.

6. A lancing device according to any one of the preceding claims, wherein the housing comprises one or more fingers configured to resist an initial rearward movement of the shroud until a level of force applied by the user exceeds a predefined threshold force.

7. A lancing device according to any one of the preceding claims, wherein the housing and the shroud comprise cooperating snap-fit fastening features for preventing resetting of the shroud, after the shroud reaches the second point of the rearward movement.

8. A lancing device according to any one of the preceding claims, wherein the housing comprises a lower housing part and an upper housing part in snap-fit engagement with one another, said lower housing part is configured to couple the shroud moveably to the lower housing, and said lower housing part comprises:
the deflectable legs;
one or more fingers configured to resist an initial rearward movement of the shroud until a level of force applied by the user exceeds a predefined threshold force, and
snap-fit fastening features for cooperatively engaging with features of the shroud for preventing resetting of the shroud, after the shroud reaches the second point of the rearward movement.

9. A lancing device according to claim 8, wherein components of the device are configured to facilitate assembly of the device by:
installing the shroud into the lower housing part by inserting the shroud from a lower end of the lower housing part and pushing the shroud rearwards into the lower housing part until the or each finger restricts further rearward movement of the shroud;
installing the lancet into the lower housing part by inserting the lancet from an upper end of the lower housing part and fastening the lancet into the deflectable legs, and
joining the upper housing part with the lower housing part by snap-fit engagement.