

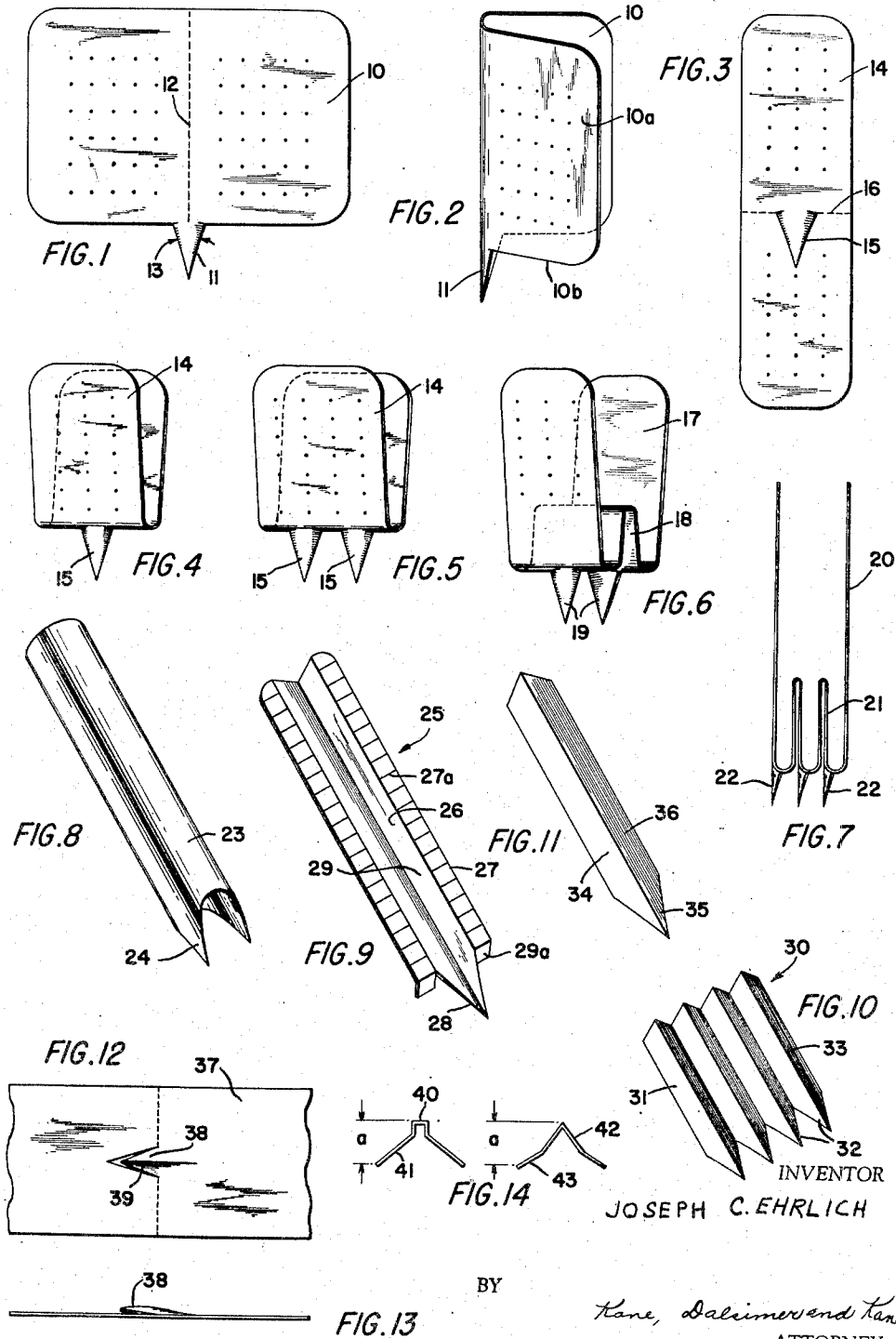
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LANCETS

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LANCETS

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The present invention relates to lancets for puncturing the finger or other skin areas of the body for letting blood for purposes of examination or for making various blood determinations.

It is the general object of the present invention to provide a lancet which is so constructed that the skin can be punctured therewith practically without pain, or at least with a greatly reduced degree of pain, and in such manner that an adequate quantity of blood for the purpose of diagnostic medical studies is caused to flow naturally and without squeezing from the wound, the structure being also such that it can be made so cheaply that it can be discarded after a single use.

It has been the practice in drawing blood from the finger or other part of the body to employ a sharp instrument for puncturing the skin to cause blood to flow. With the instruments heretofore in use, the puncturing of the skin was always accompanied by considerable pain, and in order to obtain a sufficient quantity of blood for examination, and especially for making a number of blood determinations, it was the practice to squeeze the area around the wound. This was highly undesirable because the pressure exerted forced tissue fluids into the blood, so that the latter became diluted and failed to show a true picture of the condition of the blood. A circumstance that militated against the flow of blood out of the wound and made necessary the application of pressure was that with the instruments heretofore employed, the puncture was of such character that the normal tension of the skin tended to close the wound, and the trauma produced tissue juices which promoted rapid clotting. Thus, with the usual needle or pointed blade type of lancet, either a round puncture or a straight line puncture was produced, which tended to close quickly and stop the flow of blood.

Moreover, in order to give the lancets of known construction the necessary rigidity and strength, they were made of substantial thickness or diameter which, as I have found, unnecessarily increased the pain upon puncture of the skin. With the known lancets, also, it was difficult to judge or control the depth of penetration of the instrument, so that the point of the lancet either penetrated beyond or failed to reach the region of most abundant capillary blood supply.

Because of the relatively heavier construction of known lancets, their cost is considerable, so that they are continually re-used. Aside from the expense of cleaning and sterilizing them after each use, there is always the danger that through carelessness or haste, the sterilization will not be complete, so that the danger of infection and transmission of disease is always present.

It is accordingly a more specific object of the present invention to provide a lancet of such construction that the skin is pierced therewith very easily and with a minimum or substantial absence of pain.

It is a further object of the invention to construct a lancet of extremely thin gauge metal; in fact of such thinness that it would normally be likely to buckle when

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pressed into the skin, but to shape the same in such manner that it possesses the necessary rigidity.

It is a still further object of the invention to provide a lancet which can be made at such extremely low cost that it can be thrown away after a single use, and can be easily packaged in sterile condition.

Other objects of the invention are to provide a lancet in which the penetrating point projects for a distance of only about 1 to 3 mm. from the main body of the instrument, so that greater rigidity can be imparted to the point, while at the same time providing a gauge for the depth of penetration of the point; to provide a lancet having stop elements limiting the depth of penetration of the point to the region of the most abundant blood supply beneath the skin; to provide a lancet having a penetrating point so shaped that the puncture is neither circular nor rectilinear, but rather arched or angular, or consists of two or more spaced points, so that the punctures remain open for a longer period of time; to provide a lancet wherein by the combination of the thinness of the metal of which the lancet is composed and the angle at which the sharp point and edge of the lancet enters the skin, an easy and practically painless puncturing of the skin can be effected; to provide a lancet which enters the skin so easily that there is a minimum of tissue juice, or lymph produced, thus making possible a longer bleeding time and the yield of larger amounts of blood; to provide a lancet whose puncturing end portion is coated with a film of an anticoagulant to discourage clotting and thereby increase the time of blood flow, and to provide a unit which will not require an edge-sharpening operation.

Other objects and advantages of the invention will become apparent as the description thereof proceeds, and the features of novelty will be set forth in the appended claims.

I have found that whereas the lancets commonly used today are made of tubular or cylindrical metallic structures having relatively large diameters and require machining and finishing operations, or are made of sheet metal having a minimum thickness of about 0.004 inch in order to give the instrument the necessary rigidity and to insure against breakage of the point as it punctures the skin, a much cheaper and more efficient lancet can be produced by the simple operation of stamping sheet metal stock having a thickness of 0.0025 inch or less (and even down to about 0.0015 inch), provided that certain configurations are given to the penetrating portion of the instrument. According to the invention, a lancet made of such thin sheet metal can be given sufficient strength and rigidity and the puncture made practically painless, while insuring an adequate flow of blood without the application of pressure, if the point is suitably arched, bent, or ridged in such manner that the point (that is, the part of the instrument which penetrates the skin), forms an angle of about 25° or less when viewed from the side. The arching, bending or ridging of the central longitudinal surface of the point makes such point area sufficiently rigid and strong to insure against buckling or breaking in use. This rigidity may be increased by limiting the length of the penetrating point itself to about 1 to 3 mm. By reason of such thinness of the sheet metal, the reinforcing configuration, and the limited angularity, the skin, as I have found by actual use of my improved lancet, is easily punctured and the point enters the skin with a minimum destruction or displacement of tissue, so that the pain is greatly reduced as compared with prior structures. Moreover, by reason of the fact that the incision is of arched or V-shaped or similar form, the wound tends to pout or gape, so that the flow of blood is not interrupted by the

closing of the wound. The blood so obtained contains a minimum of tissue juice and accordingly the tendency to clotting is reduced. To a certain degree, a similar effect is obtained by providing the lancet with a plurality of spaced points for more or less simultaneous puncture of the skin at two or more points. Where a rather large amount of blood is required, say of the order of 0.5 cc. or more, I may provide the surface of the points with an anticoagulant, such as heparin or heparin substitute, to further delay the clotting of the blood at the incision.

I have found that by limiting the point of the lancet to about 1 to 3 mm., and by providing suitable stop elements, as will be described more fully hereinafter, I am able also to strengthen the point and prevent it from buckling or breaking, despite its extremely thin gauge, while at the same time insuring that the point will enter the region of the skin which has the densest supply of capillaries to a sufficient depth so that an adequate flow of blood is obtained.

With these and other objects in mind, reference is had to the attached sheet of drawings illustrating practical embodiments of the invention, and in which:

Fig. 1 shows a blank of one form of my improved lancet construction in which it can be sterilized and packaged for marketing;

Fig. 2 shows the blank of Fig. 1 as bent by the physician prior to use;

Fig. 3 shows another form of blank in which the point of the lancet is struck from the body of the blank and given a curved or arched outline;

Fig. 4 shows the blank of Fig. 3 bent into the form for use;

Fig. 5 shows a modification of the structure of Fig. 4 wherein two points are provided for making two spaced punctures, the two points being positioned along the same bend of the blank;

Fig. 6 shows a further modification of the structure of Fig. 4 wherein two spaced points are provided and located upon spaced bends of the blank;

Fig. 7 is a diagrammatic side view of a still further modification wherein three points are provided at three bends of the sheet metal blank;

Fig. 8 shows a modification in which the lancet is of tubular form and provided with two points which are more or less diametrically opposed to each other;

Fig. 9 shows an alternative and in certain respects preferred structure wherein the body of the lancet is given a pre-formed V-shaped cross section and is provided with stops for limiting the depth of the penetration of the point;

Fig. 10 shows a still further modification in which points are provided on corrugated sheet metal which can then be cut to form lancets having 1, 2 or more points;

Fig. 11 shows a single-point lancet cut from the structure shown in Fig. 10;

Fig. 12 shows a blank similar to Fig. 3, but in which the point struck from the body of the blank is given a pre-formed central, sharp longitudinal bend;

Fig. 13 shows an end view of the structure of Fig. 12; while

Fig. 14 shows other forms of cross section that can be given to the point member.

Referring to the drawing, and particularly to Fig. 1, there is shown a blank 10 made of sheet metal of a thickness not greater than about 0.0025 in., and which may be as thin as about 0.0015 in. Projecting more or less centrally from one side of the blank 10 is a V-shaped point member which is centrally arched. The blank is stamped from any suitable material such as stainless steel, or nickel- or chrome-plated steel, or any other proper sheet metal or alloy having the necessary degree of flexibility and hardness, so that the blank can be readily bent into the shape in Fig. 2. As in that figure, upon bending of the blank by the physician, (which bending may be facilitated by the provision of a score line 12), there is pro-

vided a lancet having two wings 10a which can be readily gripped by the fingers, with the point 11 projecting from one corner thereof. As will be understood, the bottom edges 10b of the wings 10a can serve as stops to limit the degree of penetration of the point 11. In the final form of the lancet shown in Fig. 2, the point 11 will have a curved cross section and on being pressed into the skin will form an arcuate incision. The wings 10a may be provided with a non-slip surface as is indicated by the stipling.

I have found that if the point 11, measured from the bottom edge 10b, is given a length of 1 to 3 mm., penetration of the point to the region of most abundant capillaries is insured. The skin structure in the finger tips is such that maximum blood flow is attained by penetrating the stratum corneum and epithelium into papillary layers of the cutis, where capillary loops are located. Deeper punctures reaching into the deep cutis and adipose layer do not add significantly to the yield of blood. The multiple punctures into the capillary layer are more effective as they open more capillaries to the surface. Once the capillaries are opened to the surface, the duration and volume of bleeding depend on:

1. The amount of trauma caused by the incision. Dull, traumatizing techniques increase the amount of tissue juice and are followed by early clotting. I have found that clean incisions by very sharp, thin, easily penetrating lances produce more profuse and longer bleeding.

2. The volume and pressure of the blood in the capillary area incised.

3. The natural clotting tendency of the blood, i. e., the bleeding time for the individual patient.

4. The shape of the incision. Needle punctures seal quickly, owing to the tendency of the local tissue tension to press together the walls of the puncture. On the other hand, curved or angular incisions overcome at least in part the tendency of the wound to close and operate to cause the wound to gape and stay open.

5. The introduction—where desired—of anti-clotting substances, such as heparin, with the puncture.

6. The area of the body in which the puncture is made.

I have found that with a point such as shown in Fig. 2, a clean curved incision can be made with minimum trauma, if the length of the point, as already indicated, is from 1 to 3 mm. in length. With a point made of sheet metal of 0.0025 in. or less, ease of penetration is promoted with avoidance of excessive trauma. As will be understood, by using metal of the very reduced gauge indicated, it will be unnecessary to grind or sharpen the edges of the pointed penetrating element.

I have found also that the angle of the point member has an important influence on the ease of penetration and reduction of pain. This angle should be no greater than about 25°, preferably about 20° and can be reduced below such value. The angle is measured from one of the inclined sides of the point member to the crown thereof, and is approximately half of the aggregate angle indicated by the numeral 13 in Fig. 1. This is the angle seen when the lancet is viewed from the side as in Fig. 2.

In the form of the invention shown in Fig. 3, the rectangular blank 14 has a point member 15 struck from the central area thereof, the point member being simultaneously or subsequently given an arched form as indicated in the drawing. This blank is bent along the score line 16 to form the lancet shown in Fig. 4, with the point extending transversely to the line of bend. As in Fig. 2, the point member of Fig. 4 has a maximum angularity of about 25°, measured as previously indicated, and preferably of about 20°.

Fig. 5 shows a lancet provided with two point members 15, spaced from each other along the central bend of the sheet metal strip 14. This type of structure is suitable where larger quantities of blood are required. In this, as well as most of the preceding and subsequently described forms, the base of the penetrating element of sharp-pointed V-shape is narrower than the adjoining

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portions of the finger-piece member. Accordingly, lateral shoulders or stops are formed which limit the depth of penetration of the pointed element.

In the structure of Fig. 6, two point members 19 are struck from the body of the blank 17 at such a distance from each other along the length of the metal strip that when the latter is bent twice, as shown in the drawing, to form a central bend 18 and two lateral bends, the points are spaced from each other. These points can be arched in the same or in opposite directions. As will be evident, the double bend acts to increase the rigidity of the instrument. There can also be struck, from the sheet metal strip, three or more point members spaced along the length of the strip, and the latter then bent to provide a three-point lancet as shown in Fig. 7 wherein the body of the lancet is indicated at 20, the bends at 21, and the point members at 22. A blank similar to that of Fig. 1 can be provided with two point members projecting from one of the edges thereof, and the blank then rolled into a tube as shown at 23 in Fig. 8. This tube will have considerable rigidity despite the thinness of the metal stock. The two points 24, which may be diametrically opposite each other, make a double puncture which insures a substantial flow of blood without the necessity for squeezing the area of puncture.

It will be noted that in all the previously described structures, the point members extend from edges or bends of the body of the lancet in such manner that such edges or bends act as stops which limit the degree of penetration of the point members. By limiting the length of the point members as above described, the maximum depth of penetration can be readily limited.

In Fig. 9 there is shown an alternative and in certain respects preferred structure having a different form of stop member for limiting the degree of penetration. In this construction, indicated generally at 25, the central portion of the elongated instrument is centrally sharply bent, as indicated at 26, to form a body portion of V-shaped cross section. Extending laterally from the sides of the V-structure, at the free ends thereof, are lateral wing members 27, which may be corrugated as shown at 27a, to provide a non-slip surface. The point member 28 is formed by cutting the central body portion of the instrument at an angle, or is can be formed originally of a blank in a manner similar to Fig. 1, except that in the structure of Fig. 9 the point member is not arched but is centrally sharply bent in continuation of the bend of the body of the instrument. The wing members 27 are provided with tabs or flaps 29a which are bent approximately at right angles thereto, so as to provide transversely extending stop elements at each side of the point member to arrest penetration by the latter beyond a certain depth. It will be clear from the foregoing that the angle between an inclined side of the point member 28 and the central longitudinal bend will have a maximum value of about 25°, preferably about 20°. The sides of bend 26 may be about 1.2 mm. wide.

Fig. 10 illustrates a suitable method of manufacture of another form of the invention by forming a corrugated metal strip, indicated at 30, having more or less sharp bends 31 and more or less flat, inclined sides 33 which terminate at the tapered point members 32 whose sides, like those of the points or spikes shown in the other figures of the drawing, are preferably slightly curved. From a long corrugated sheet metal strip of this kind, lancets having one or more points can readily be cut. A single-point lancet cut from such a strip is shown in Fig. 11, wherein the inclined flat sides are shown at 34 and 36, and the point at 35.

In the embodiment shown in Figs. 12 and 13, the metallic strip 37 is centrally punched or stamped similarly to the structure of Fig. 3, except that the point or spike 38 is drawn into a centrally sharp-ridged or ribbed structure indicated at 39, the drawing and bending operation continuing for some distance into the body of the lancet as more clearly indicated in exaggerated fashion in Fig. 13.

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In this way, the punched or stamped-out point member is reinforced by the central ridge in the same manner as the corrugated lancets shown in Fig. 10 and 11.

Fig. 14 shows other suitable cross sections for the point member on an enlarged scale, and also, if desired, of the body of the lancet itself. The channel shaped ridge 40 terminating in the flaring sides 41 can be stamped from flat stock, as can the more sharply peaked ridge 42, and its less sharply inclined sides 43. In the several forms where a ridge is included, it extends longitudinally of the penetrating element and reinforces the structure. Also, it serves to provide a non-rectilinear incision.

It will be understood that as the end of the point member is approached, the channel 40 becomes narrower until it disappears at the point. In both of the structures shown in Fig. 14, the maximum height *a* of the point member is so related to the length of such member that the inclined and preferably slightly curved sides of the member form an angle of no more than about 25° with the upper edge of the channel or ridge.

As will be apparent in considering the penetrating elements shown in the several figures, they are preferably not flat. In other words, viewed in a transverse cross-section, the main portion of the element is non-rectilinear. Accordingly, as the skin is penetrated by the element, the edges of the epidermis are forced apart to promote bleeding.

In general, where the body of the lancet is formed by doubling the sheet metal stock, as in Figs. 2, 4, 5, 6, 7, and 12, such stock can have a thickness as low as about 0.0015 in.; however, where the body of the lancet is formed of only a single thickness of metal stock, such stock is preferably of somewhat higher thickness, as from about 0.0018 to 0.0025 in. Also, in lancets having two or more points, these points may be made of different lengths, so as to penetrate to different depths to insure that the region of densest capillaries is opened up to the surface.

I have found that a suitable shape for the point member is one whose projection on a plane parallel to the plane of the slanting free edges of the member is approximately an equilateral triangle (as shown most clearly in Fig. 9), the angle of the ridge in the structures shown in Figs. 9, 10, 11 and 12 being approximately 60°, while the point is about 2.4 mm. long. The projection of the point member may, however, have an angle somewhat less than 60°, as indicated in Figs. 4 to 6, and even be of the order of 30°. As will be understood, at least one cutting edge defines this point.

To insure a flow of blood for an adequate period of time, I provide the point members with a coating of an anticoagulant, such as heparin and the like, by dipping the points in the heparin solution, or by placing a drop of such solution on the points and allowing the same to dry.

The length of the body of the lancet is such as to provide for convenient gripping between the fingers and can be from about ½ in. to 1½ in. It will be understood that the point members are shown in enlarged form in the drawing, for clarity of illustration.

It will be seen from the foregoing that I have provided a lancet construction which can be manufactured in large quantities at low cost, so much so that the same can be discarded after a single use.

By reason of the thinness of the stock and the limited angularity of the tapered point members, the skin can be penetrated with a minimum of pain and a relatively abundant flow of blood contained. Whereas with prior lancets only about 1 or 2 drops of blood could be obtained without squeezing the lancets of the present invention can yield as much as 6 drops of blood without pressure, and even as much as 10 or more. By reason of the provision of the stops formed by sides or shoulders, the depth of penetration can be accurately controlled, so that by the use of lancets with point members varying in length from 1 to 3 mm. (0.04" to 0.12"), the region of richest blood

supply can be opened up with patients of different ages or skin thicknesses. The lancets can be easily sterilized and individually packaged in paper, cellophane or other wrappers.

Various other modifications will suggest themselves to those skilled in the art, pursuant to the disclosure hereinabove.

Thus, the tabs 29a can be omitted from the structure of Fig. 9, in which case the ends of the wing portions 27 will serve as stops. Also, a lancet may be constructed in accordance with the invention having the general configuration of Fig. 1, but of smaller width and made of a single, non-folded strip of metal, the point member being curved or ridged as shown for example in Figs. 1, 9, 11 and 12. In such case, the metal will be of the higher range of thicknesses, say from 0.0018 to 0.0025 in.

From the foregoing it will be understood that, among others, the objects of the invention are achieved. Obviously numerous changes in construction and rearrangements of the parts may be resorted to without departing from the spirit of the invention as defined by the claims.

I claim:

1. A lancet comprising a finger-piece member made of flexible sheet metal of a thickness no greater than about 0.0025" and having a skin-penetrating element integral therewith and extending therefrom, said element being of tapered form and terminating in a sharp point, and forming a penetration angle of less than 25°.

2. A lancet according to claim 1, wherein the transverse cross-section of the main portion of said penetrating element is non-rectilinear.

3. A lancet according to claim 1, wherein the skin-penetrating element is from about 0.04" to 0.12" long.

4. A lancet according to claim 3, including a shoulder for limiting the depth of penetration of said element.

5. A lancet according to claim 1, including a shoulder for limiting the depth of penetration of said element.

6. A lancet according to claim 1, wherein the finger-grip is formed of a folded-over piece of sheet metal, the penetrating element being in line with the bend of said finger grip, and the bend of the latter continuing into the penetrating element, whereby the incision made by the lancet is non-rectilinear.

7. A lancet according to claim 1, wherein the finger-grip is formed of a folded-over piece of sheet metal, the penetrating element being struck from the body of said finger-piece and extending transversely of the bend of said finger-piece.

8. A lancet according to claim 7, wherein the penetrating element is bent transversely thereof, whereby the incision made by the lancet is non-rectilinear.

9. A lancet as defined in claim 1, wherein the finger-piece is formed of a corrugated sheet metal, the penetrating element forming an extension of a corrugation, and being itself longitudinally bent for at least a portion of the length thereof.

10. A lancet comprising an elongate centrally bent finger-piece member made of flexible sheet metal of a thickness no greater than about 0.0025", and having a skin-penetrating element forming an extension of said member, said element being tapered and sharp-pointed and having a penetration angle of less than 25°, said element having a length of about 0.04" to 0.12", the base of said element being narrower than the adjoining portion of said finger-piece member, whereby lateral shoulders are formed which limit the depth of penetration of said element.

11. A lancet comprising an elongate, centrally bent finger-piece member made of flexible sheet metal of a thickness no greater than about 0.0025", and having a skin-penetrating element forming an extension of said member, said element being tapered and sharp-pointed and having a penetration angle of less than 25°, said element having a length of about 0.04" to 0.12", and tabs extending transversely of said element and acting as stops to limit the depth of penetration of said element.

12. A lancet according to claim 1, wherein the skin-penetrating element is provided with a coating of an anti-coagulant preparation.

13. A lancet comprising a finger-piece member formed of a folded-over piece of flexible sheet metal of a thickness no greater than about 0.0025" and having a skin-penetrating element integral therewith and struck from the body thereof and extending transversely of the bend, said element being of tapered form, having a sharp point and forming a penetration angle of less than 25°, said element having a longitudinal reinforcing ridge acting also to make the incision non-rectilinear.

14. A lancet blank comprising a substantially flat piece of flexible sheet metal of a thickness no greater than about 0.0025", and having intermediate of the ends thereof a skin-penetrating element of sharp-pointed V-shape integral therewith, said blank being adapted to be folded on itself to provide a finger-piece member from which said element projects.

15. A blank according to claim 14, wherein the V-shaped element is cut from the blank approximately centrally thereof, said blank having score lines extending laterally of the base of the V-shaped element to facilitate folding of the blank, said element being longitudinally bent to increase the rigidity thereof.

16. A blank according to claim 14, wherein the V-shaped element is ridged along its central longitudinal axis.

17. A lancet according to claim 1, wherein the finger-piece member is of tubular form.

18. A lancet according to claim 1, having a plurality of skin-penetrating elements.

19. A lancet comprising a finger-piece made of an elongate strip of flexible sheet metal of a thickness of 0.0018" to 0.0025" and centrally bent at an angle of approximately 60°, said finger-piece terminating in an integral sharp-pointed penetrating element having inclined sides making an angle of less than 25° with the central bend.

20. A lancet according to claim 19, wherein the inclined sides of the penetrating element make an angle of approximately 60° with each other.

21. A lancet comprising a body providing a manipulating portion, a pointed element extending from one end of said body, at least one cutting edge defining said point and extending at angles to the longitudinal axis of said body as well as to a plane normal to such axis, said body being formed of sheet metal of such thickness that it tends to collapse in response to a thrusting force such as is necessary to cause the point to penetrate the epidermis and the adjacent angular edge to cut through the latter, and said body being bent along a zone extending parallel to the axis of said lancet to provide a reinforcing structure forming an integral part of said body to prevent such collapse.

22. A lancet as specified in claim 21, an edge portion of said body extending adjacent said element and its cutting edge, and means whereby said edge portion provides—upon engaging the surface of the epidermis—a stop to limit the penetration of said lancet into the tissue.

23. A lancet comprising a strip of metal providing a manipulating body, a point projecting from said strip, the end area of said point having a thickness no greater than 0.0025" and said body being reinforced to prevent a deflection thereof as thrust is exerted upon said point to cause the latter to penetrate epidermis.

24. A lancet as specified in claim 23, said reinforcement comprising a central bend in said strip and extending into the point area to impart to the latter an arched configuration.

25. A lancet comprising a body providing a manipulating portion, a pointed element extending from one end of said body, at least one cutting edge defining said point and extending at angles to the longitudinal axis of said body as well as to a plane normal to such axis, said body being formed of sheet metal of such thickness that it tends to collapse in response to a thrusting force such as is nec-

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essary to cause the point to penetrate the epidermis and the adjacent angular edge to cut through the latter, and said point having a bulged-out portion extending substantially longitudinally of said point to provide a reinforcing structure forming an integral part of said point to prevent such collapse.

26. A lancet including a body comprising a narrow strip of material furnishing surfaces to be gripped between the thumb and finger of the user, a pointed element extending beyond one end of said strip and integral therewith, at least one cutting edge defining said point and extending at angles to the longitudinal axis of said body as well as a plane normal to such axis, an arresting surface forming a part of said strip and extending in a plane substantially normal to the axis of said body between one of its longitudinal edges and said element and said body being formed with a bulged-out portion extending into the area of said pointed element.

27. A lancet comprising a sheet metal body in the form of a strip providing a manipulating portion, said body having side edges, a pointed element extending from one end of said body and integral therewith, said element being defined by edges extending from its point towards said body and connecting therewith inwardly of the side edges of the latter, at least one edge of said

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pointed element extending at angles to the longitudinal axis of said body as well as a plane normal of such axis and a bulged-out portion extending into the area of both said pointed element and body.

28. In a lancet as defined in claim 21, in which the material in the point and defining the cutting edge is of the same thickness as the material of the body.

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