Method for producing a pricking element

Description

The invention concerns a process for producing a lancing element in particular for withdrawing a body fluid in which a flat shaped member is formed from a flat material by applying a mask and allowing an etching agent to act upon it wherein at least a part of the flat shaped member is shaped as a tip for piercing into a body part of a test subject.

Lancing elements of this type allow the analysis of very small amounts of fluid especially in bioanalytics, such as for example those which are withdrawn in situ as capillary blood for blood glucose determinations. Such microfluidic systems, in addition to the microscopic volumes (microliters and less) are also characterized by structural elements of increasingly smaller dimensions which allow capillary forces to be utilized and can be implemented in so-called disposables in a suitable manner for mass production. Although manufacturing processes especially in the form of mask etching (photochemical etching) are known from the field of semiconductor technology for highly integrated systems; the materials used can hardly be used for mechanically stressed structures especially because of their brittleness. When biocompatible materials such as steel are etched, a problem occurs with conventional shaped-complementary etch masking that the generated lancing structures are rounded off and thus do not allow a particularly optimal puncture.

An etching process for producing surgical needles is known from US 4 777 096 A, in which the etch mask extends beyond the tip to be formed in a distally blunted shaping area which should prevent rounding. However, this mask overhang is shorter than the undercutting range of the etching agent so that the tip is shaped by a

combined lateral and frontal etching action which only slightly reduces the problem of blunting.

From this starting point the object of the invention was to avoid the disadvantages occurring in the prior art and to improve a production process of the type mentioned above such that sharp lancing structures for optimal lancing into a body part are created in a process sequence suitable for mass production without requiring complicated post-processing steps.

The combination of features stated in the independent patent claims is proposed to achieve this object. Advantageous embodiments and further developments of the invention are derived from the dependent claims.

The idea behind the invention is to produce a sharp tip solely by means of lateral mutually converging etching agent fronts. Accordingly it is proposed according to the invention that the mask is provided with a shaping area for the tip to be formed and with a screening area which extends distally beyond this shaping area to prevent the tip from being etched off at the front, and that a sharp tip is exposed by laterally undercutting the side flanks of the shaping and screening area. This can prevent the contour in the area of the tip from being rounded off whereby the etching process is terminated as soon as the bridge of material located between the side flanks of the etching mask is broken through. This allows optimized tips to be created in order to reduce the lancing pain and to enable body fluid to be picked up with the smallest possible dimensions. Moreover, the required propulsion forces for the lancing can be minimized and traumatization of the body tissue can be substantially avoided.

The shaping area of the etching mask advantageously narrows towards the screening area to produce a lancing shaft that tapers towards the tip. For this it is advantageous when the shaping area is linearly chamfered at least on one side.

Another advantageous embodiment provides that at least one side flank is bent or concavely curved in the junction between the shaping area and screening area so that the substrate material in the area of the tip to be produced only has to be removed from the side.

In any case it should be ensured that the screening area has a constant or increasing width over a given screening length where it connects with the shaping area. The screening length should be larger than the proximal undercutting width due to the action of the etching agent. This reliably prevents the tip from being centrally etched off.

The tip is preferably shaped as a result of a constriction in the mask where the width of the constriction should be less than twice the lateral undercutting width so that the substrate material under the constriction is completely etched away.

The screening area is advantageously widened again after the constriction. Also in order to improve the stability of the etching mask, it is advantageous when the screening area has a widening bridge section distal to the tip that is to be formed.

Whereas etching processes in steel mainly proceed isotropically, it is also conceivable that the lateral undercutting width is larger or smaller than the etching depth. Anisotropy for example occurs when the etching agent is applied at an overpressure relative to the surroundings in order to ensure a particularly effective action. The etching agent can be applied in a dipping bath or by being sprayed onto the flat material.

For a high throughput it is advantageous when the flat material that is preferably formed from stainless steel sheet metal is processed from roll to roll by photo-

chemical mask etching. However, it is also possible to use a semiconductor wafer as a flat material.

The thickness of the flat material is advantageously between 1 mm and 0.01 mm.

According to a further preferred embodiment the lancing element is provided with a semi-open capillary channel to transport the body fluid that is formed by a channel slot in the mask where the distal ends of the channel walls form a sharp tip. In this connection the screening areas for the tips of the channel walls are delimited on one side by the channel slot.

For a special design of the shaped member the flat material is provided on both sides with a mask wherein a pointed lancing shaft is etched free on one side and a semi-open capillary channel with pointed channel walls that extends towards the lancing shaft is etched free on the other side.

According to another aspect of the invention the etching mask is provided with a compensation opening at a lateral distance from an undercut edge section, and an edge contour of the flat shaped member is etched away from the edge through the compensation opening under the action of the etching agent. This allows undesired undercuts on the shaped member to be chemically milled off without additional manufacturing effort.

In order to remove the edges it is advantageous when the compensation opening preferably runs as a slot or chain of holes in the mask along the edge section. The compensation opening should have a smaller inner width than a cut-away in the mask adjoining the edge section.

In order to achieve a combined undercutting effect on a bridge of material extending between the edge of the mask and the compensation cut-out, the width of the overlying mask bridge should be less than the undercutting width of the etching agent measured from the edge of the mask.

Depending on the desired shape of the contour the invention provides that the compensation opening is arranged in a shaping area and optionally in a screening area of the mask for the tip to be formed. In particular it is advantageous when the compensation opening is laterally spaced apart from a bent or concavely curved side flank of the mask.

In order to also in this case protect the tip from being etched away at the front, it is of special advantage when the compensation opening is introduced at the side of a central axis running towards the tip that is to be formed so that a strip of the mask is retained in front of the tip along the central axis and at least beyond the undercutting width. In principle the same considerations apply here with regard to avoiding a frontal action of the etching agent as already setforth with regard to the edge of the mask. In any case a V-shaped contour of the compensation opening should be avoided.

The invention is elucidated in more detail in the following on the basis of the embodiment examples shown schematically in the diagram.

Fig. 1 shows a lancing element with a tip and a capillary channel for withdrawing blood in a top-view.

Fig. 2 shows the rear-side of an etching mask for producing the tip of the lancing element in a top-view.

Fig. 3 shows the front face of an etching mask for producing the capillary channel in the area of the tip in a top-view.

Fig. 4 shows an enlarged section of the etching mask in the distal end region of the capillary channel in a top-view.

Fig. 5 shows a section along the line 5 – 5 of fig. 4.

Fig. 6 shows a section along the line 6 – 6 of fig. 4.

Figs. 7 to 9 show another embodiment example with a compensation slot in the etching mask in representations corresponding to figs. 4 to 6; and

Fig. 10 shows a top-view of an etching mask for producing a tip according to the prior art.

The lancing and sampling element 10 shown in the drawing is used as a disposable article to withdraw and to capillary transport a small amount of blood from a body part of a test subject especially in order to carry out blood glucose measurements. For this purpose it comprises a flat shaped member 12, a lancing member 14 shaped thereon having a tip 16 and a semi-open capillary channel 18 for capillary blood transport from the tip 16 to an analytical site 20.

The flat shaped member 12 is made of a stainless steel metal sheet 22 having a thickness of about 100 to 300 µm. Its proximal end section forms a holding area for handling during the lancing process whereas the lancing member 14 which is shaped as one piece at the distal end, generates a small wound in the skin of the user in order to remove microscopic volumes of blood. In this connection the capillary channel 18 has a groove shape or is semi-open over its length so that, as described

below, it can be produced by photolithography. The withdrawn blood sample can for example be analysed by reflection spectroscopic or electrochemical detection methods in a known manner.

The material of the sheet metal or substrate is structured by means of the photo-chemical machining or milling method. In this process an etching mask 24 is applied, preferably to both sides, of the substrate 22 which covers the structure of the shaped member that is to be uncovered in a subsequent etching step. The mask is formed by coating the substrate 22 with a photoresist and it is exposed through a photomask having the desired pattern that is arranged in front of the mask whereby the photoresist is polymerized or hardened in the covered areas while the other areas are rinsed away after development.

An etching agent to the substrate 22 is subsequently applied over the (double-sided) etching mask 24 generated in this manner so that the masked areas are etched away according to the basic shape. In the case of an isotropic etching action, the depth of the removed material corresponds to the lateral etching rate for the undercutting of edge contours of the mask 24. The etching process can also take place anisotropically due to external influencing parameters or material properties of the substrate i.e. the lateral undercutting rate is then larger or smaller than the depth etching rate.

Manufacture of the tip 16 is particularly critical for the function of the lancing element 10. According to fig. 10 an obvious approach according to the prior art would be to provide an appropriate etching mask with a pointed or triangular shaping area 26 corresponding to the desired contour of the finished part. However, it was observed in this case that the tip 28 formed in this manner is not sharp but is rounded off due to the etching agent that flows in from all sides during undercutting of the triangular mask 26.

In order to avoid this the etching mask 24 according to the invention has a shaping area 30 for the tip 16 to be formed and a distal – with regard to the lancing direction – adjoining screening area 32 preventing the front of the tip 16 from being etched off. The shaping area 30 narrows towards the screening area 32 and the side flanks 34, 36 of the mask 24 are bevelled with a linear slope. Starting at a constriction 38 the screening area 32 widens while forming a bridge section 40 towards the other areas of the mask so that the etching mask 24 remains overall more stable.

Hence, a sharp tip 16 is etched free by lateral undercutting of the side flanks 34, 36 of the shaping area and screening area 30, 32, the contour of which is shown by the dashed line in fig. 2. In this connection the screening area 32 has a larger screening length than the undercutting width viewed in the proximal direction whereas the width of the constriction 38 is less than twice the lateral undercutting width. In this manner the etched away material fronts converge at the constriction 38 until finally the tip 16 is uncovered when the etching process is completed.

The front side section of the mask 24 shown in fig. 3 is designed to be complementary to the desired capillary structure 18 in the area of the lancing member 14. Accordingly the mask 24 has a capillary slot 42 through which the channel 18 is etched in to form the channel walls 44. In order to also facilitate the lancing in this case the distal ends of the channel walls 44 are chamfered as sharp tips 16'. This is achieved in the manner described above by screening areas 32 positioned in front where in fig. 3 functionally identical parts have the same reference numerals so that reference can be made to the previous embodiments. In contrast to fig. 2 the side flanks 34, 36 in the area of the constriction 38 are not concavely curved on both sides but are rather bluntly angled on one side and on the opposite side thereto they are linearly delimited by the capillary gap 42 so that a wedge-shaped tip 16' is formed as shown by the dashed line.

The basic geometric effects of the etching process in the area of the channel tips 16' are illustrated in figs. 4 to 6. Figs 5 and 6 only show the upper substrate area after a certain etching time where the lateral etching contours 46 only describe a circular line in the case of an isotropic etching action. Thus lateral undercutting of the mask edges and side flanks 34, 36 of the mask 24 result in undercut edges of the shaped member 48, 50 as shown best in fig. 5. Such undercuts are indeed desirable in the area of the capillary channel 18 because they further improve the capillarity. However, the undercut 52 results in a barb (fig. 6) at the tip 16, 16' which can impair the lancing into the skin.

In order to rectify this, a compensation slot 54 can be kept free in the mask 24 according to figs. 7 and 8. This slot extends at a lateral distance to an undercut edge section 56 in the shaping area 30 of the mask 24 and ensures that the edges of the undercut 48 that would otherwise be formed are etched away. Hence, the etching agent which penetrates near to the edge via the compensation slot 54 results in a rounding of the edge 58 while avoiding a barb. The width of the mask strip 60 between the mask edge 56 and the compensation slot 54 is advantageously less than the lateral undercut width. This should ensure that the compensation slot 54 has a substantially smaller inner width compared to the neighbouring mask cut-out 62 so that the rounded edges 58 have a correspondingly smaller etching radius.

Claims

1. Process for producing a lancing element in particular for withdrawing a body fluid in which a flat shaped member (12) is formed from a flat material (22) by applying a mask (24) and allowing an etching agent to act upon it wherein at least a part of the flat shaped member (12) is shaped as a tip (16, 16') for piercing into a body part of a test subject, **characterized in that** the mask (24) is provided with a shaping area (30) for the tip to be shaped (16, 16') and with a screening area (32) which extends distally beyond this shaping area to prevent the tip from being etched off at the front (16, 16') and that a sharp tip (16, 16') is exposed by laterally undercutting the side flanks (34, 36) of the shaping area and screening area (32).

2. Process according to claim 1, **characterized in that** the shaping area (30) of the etching mask narrows towards the screening area (32).

3. Process according to claim 1 or 2, **characterized in that** the shaping area (30) is linearly chamfered at least on one side.

4. Process according to one of the claims 1 to 3, **characterized in that** at least one side flank (34) is bent or concavely curved in the junction between the shaping area (30) and screening area (32).

5. Process according to one of the claims 1 to 4, **characterized in that** the screening area (32) has a constant or increasing width over a given screening length where it connects with the shaping area (30).

6. Process according to claim 5, **characterized in that** the screening length is larger than the proximal undercutting width due to the action of the etching agent.

7. Process according to one of the claims 1 to 6, **characterized in that** the tip (16, 16') is shaped by a constriction (38) in the mask (24).

8. Process according to claim 7, **characterized in that** the width of the constriction (38) should be less than twice the lateral undercutting width.

9. Process according to claim 7 or 8, **characterized in that** the screening area (32) is widened again after the constriction (38).

10. Process according to one of the claims 1 to 9, **characterized in that** the screening area (32) has a bridge section (40) that widens in the distal direction relative to the tip (16, 16') that is to be formed.

11. Process according to one of the claims 1 to 10, **characterized in that** the undercutting etching width is larger or smaller than the etching depth.

12. Process according to one of the claims 1 to 11, **characterized in that** the etching agent is applied in a dipping bath or by being sprayed onto the flat material.

13. Process according to one of the claims 1 to 12, **characterized in that** the etching agent is applied at an overpressure relative to the surroundings.

14. Process according to one of the claims 1 to 13, **characterized in that** the flat material (22) that is preferably formed from stainless steel sheet metal is processed from roll to roll by photochemical mask etching.

15. Process according to one of the claims 1 to 14, **characterized in that** the thickness of the flat material (22) is selected to be between 1 mm and 0.01 mm.

16. Process according to one of the claims 1 to 15, **characterized in that** the lancing element is provided with a semi-open capillary channel (18) to transport the body fluid that is formed by a channel slot (42) in the mask (24), and that the distal ends of the channel walls (44) are shaped as a sharp tip (16').

17. Process according to claim 16, **characterized in that** the screening areas (32) for the tips (16') of the channel walls (44) are delimited on one side by the channel slot (42).

18. Process according to one of the claims 1 to 17, **characterized in that** the flat material (22) is provided on both sides with a mask (24) wherein a pointed lancing shaft (14) is etched free on one side and a semi-open capillary channel (18) with pointed channel walls (44) that extends towards the lancing shaft (14) is etched free on the other side.

19. Process according to one of the claims 1 to 18, **characterized in that** the mask (24) is provided with a compensation opening (54) at a lateral distance from an undercut edge section (56), and that an edge contour (48) of the flat shaped member (12) is etched away from the edge through the compensation opening (54) under the action of the etching agent.

20. Process for producing a lancing element in particular for withdrawing a body fluid in which a flat shaped member (12) is formed from a flat material (22) by applying a mask (24) and allowing an etching agent to act upon it wherein at least a part of the flat shaped member (12) is shaped as a tip (16, 16') for piercing into a body part of a test subject, **characterized in that** the mask (24) is provided with a compensation opening (54) at a lateral distance from an undercut edge section (56), and that an edge contour (48) of the flat shaped member (12) is etched away from the edge through the compensation opening (54) under the action of the etching agent.

21. Process according to claim 19 or 20, **characterized in that** the compensation opening (54) preferably runs as a slot or chain of holes in the mask (24) along the edge section (56).

22. Process according to one of the claims 19 to 21, **characterized in that** the compensation opening (54) has a smaller inner width than a cut-away in the mask (62) adjoining the edge section (56).

23. Process according to one of the claims 19 to 22, **characterized in that** a mask bridge (60) runs between the mask edge and the compensation opening (54), and that the width of the mask bridge (60) is less than the undercutting width of the etching agent measured form the edge of the mask.

24. Process according to one of the claims 19 to 23, **characterized in that** the compensation opening (54) is arranged in a shaping area (30) and optionally a screening area (32) of the mask (24) for the tip (16, 16') to be formed.

25. Process according to one of the claims 19 to 24, **characterized in that** the compensation opening (54) is laterally spaced apart from a side flank (34) of

the mask (24) that is bent or concavely curved distally beyond the tip (16, 16') to be formed.

26. Process according to one of the claims 19 to 25, **characterized in that** the compensation opening (54) is positioned at the side of a central axis running towards the tip (16, 16') that is to be shaped so that the mask is retained along the central axis beyond the tip (16, 16') and the tip (16, 16') is screened from being etched off at the front.