Device for cauterising tissue and uses thereof

Field of the invention

The present invention relates to a device for cauterising tissue suitable to be mounted on a biopsy and/or sampling instrument.

Background of the invention

The sampling of a portion of a tissue is often necessary in many humans and animals, particularly in the diagnosis and treatment of patients with cancerous tumours, pre-malignant conditions and other diseases and disorders. In particular, it is used to exclude malignancy. A biopsy may be performed when a lesion, or an abnormal area within a tissue that could possibly represent cancerous changes, is detected. The biopsy is performed to determine the nature of the lesion or abnormal area.

Traditionally, biopsies have been performed using conventional, or 'open' surgery, which involves making a large incision on the skin and dissection down to the area in question and removing the lesion. Haemostasis is then achieved using diathermy, or an electrosurgical system, in direct contact with the bleeding tissue to stop further haemorrhage. With the advent of minimally invasive biopsy techniques, it is now possible to achieve tissue biopsy through small incisions in the skin, measuring 3 to 5 mm in length. A biopsy instrument is usually constructed as a needle-like instrument with a diameter of less than 5 mm or that which is equivalent to the intended size of the skin incision and is passed from the skin to the area in question under some form of image guidance. This is known as a percutaneous approach and is commonly performed using either ultrasound techniques or x-rays for guidance. A tract therefore needs to be created from the entry point on the skin to the lesion.

Sharp dissection of vascular tissue is usually involved in demarcating the tract and removing tissue. This often results in bleeding which may occasionally be uncontrolled. A technique of achieving haemostasis is therefore essential. It is evident that because of its approach, bleeding poses a challenge for image-guided minimally invasive biopsy techniques as haemostasis cannot be achieved in the traditional manner as would be possible in conventional biopsies.

There is a paucity of devices created to prevent uncontrolled bleeding in a consistent and effective manner following percutaneous minimally invasive biopsies. Depending on the type of tissue sampled, methods that have been employed include the application of physical pressure, adrenaline injection, argon laser coagulation, or the recent use biodegradable hydrogel polymers (http://www.surgery.arizona.edu/research/grants-research/biodegradable-hydrogels.htm) or fibrin glue which act as tissue sealants and form a physical bond with the cut surface of the tissue. Although some of these techniques have been proven useful in conventional surgery, the requirements for negotiating the tract from the skin to the lesion before its application precludes its accurate and effective use in the setting of minimally invasive percutaneous biopsy techniques. Based on current methods, effective haemostasis may not be achieved and continued bleeding or a large haematoma might result. This may require further treatment with conventional surgery. In such cases, the patient is subject to additional discomfort and distress and the advantage of a minimally invasive procedure is negated.

There is therefore a need in the art for a device that can achieve haemostasis soon after a biopsy and/or tissue sampling, so as to cause minimal bleeding and discomfort to the patient.

Summary of the invention

The present invention addresses the problems above, and in particular provides a new device for cauterising tissue.

According to one aspect, the present invention provides a device for cauterising tissue, the device arranged to be mounted to a biopsy and/or sampling instrument and comprising a conductive cauterising portion and means for heating the cauterising portion. The device may be hollow.

According to a further aspect, the cauterising portion of the device may be in the form of a ring or a part of a ring through which the biopsy and/or sampling instrument extends. According to another aspect, the cauterising portion may be at least a part of a conductive material, wherein the conductive material is in the form of any one of or a combination of a layer, a cylinder and/or a wire.

The device may also be in the form of a sleeve. The cauterising portion may be part of a conductive material. This conductive may be insulated by insulating material, leaving only the cauterising portion exposed.

The device of the present invention is to be mounted on a biopsy and/or sampling instrument such that the cauterising portion of the device is closer to the distal end of the instrument. Accordingly, the device may be mounted either permanently onto the biopsy and/or sampling instrument or be releasably removable from the instrument.

According to yet another aspect of the present invention, the device may comprise a telescoping assembly comprising at least two members, wherein the first member is co-operatively engaged with the second member.

According to a further embodiment, the device may be a sleeve having a C-shaped cross-section, said sleeve being sufficiently flexible to bend at least a portion of its length away from the instrument, whilst the remaining length

remains mounted to said instrument. The uncompleted part of the cross-section of the sleeve forms a gap in the sleeve. According to a further embodiment, at least part of the gap is closed by a resilient member. For the purposes of the present invention, the term 'resilient' will be understood to encompass flexible and/or elastic material. The resilient member may be at least one elastic band or an interwoven elastic fabric. However, any suitable resilient member may be used for the present invention.

The device may be as thin as possible, such as within the thickness range of between 0.1 to 0.5 mm. In so doing, on insertion of the instrument, the device may have a minimal "drag", or "snow plough" effect, on the adjacent tissue and skin, and instead promote a "clean" insertion of the device.

The device may further be arranged to mask at least a part of a biopsy and/or sampling lateral opening on the biopsy and/or sampling instrument.

The means for heating the cauterising portion comprises connection means connecting the cauterising portion to a power supply for heating the cauterising portion. In particular, the means for heating may be connected to the conductive material.

In a further aspect, the present invention provides a method for cauterising tissue comprising the steps of:

- mounting a cauterising device of the present invention on a biopsy and/or sampling instrument;

- inserting the biopsy and/or sampling instrument into a tissue mass;

- obtaining a tissue sample; and

- cauterising the tissue.

In a more preferred embodiment, the method may further comprise an additional step between the steps of mounting the device on the instrument and inserting the instrument into a tissue mass, wherein the additional step comprises acting on the device to mask at least a part of a lateral opening on the instrument. The method may also comprise a step of rotating the instrument such that the cauterising portion of the device is in a predetermined angular orientation. Further, the tissue may be cauterised while removing the device from the tissue mass.

In a most preferred embodiment, the method is such that the instrument is first positioned into the tissue mass, followed by the mounting of the device, enabling acting on the device to mask at least a part of a lateral opening on the instrument. The method may also comprise a step of rotating the instrument such that the cauterising portion of the device is in a predetermined angular orientation. Further, the tissue may be cauterised while sliding the device within the tissue.

In a preferred embodiment, the method of cauterising tissue may also be carried out such that the cauterising device is mounted on the biopsy and/or sampling instrument after the instrument has been removed from the body after a biopsy and/or tissue sampling, followed by re-inserting the instrument into the tissue mass which has been sampled, and cauterising the tissue.

In another aspect of the present invention is a biopsy and/or sampling instrument for obtaining tissue samples and cauterising the remaining tissue comprising:

- means for sampling tissue;

- a lateral opening for receiving the tissue samples;

- a conductive cauterising portion; and

- means for heating the cauterising portion.

In a more preferred embodiment, the sampling means includes a cauterising portion. In a most preferred embodiment, the sampling means may include a coaxial cutter internal to the instrument which may have a connection to a power supply such that the cutter both samples ad cauterises tissue.

Another further aspect is a method of obtaining tissue samples and cauterising the remaining tissue comprising the steps of:

- introducing the biopsy and/or sampling instrument as described above into a tissue mass to be sampled;

- severing a tissue sample from the tissue mass that has entered the lateral opening;

- transporting the severed tissue sample to the proximal end of the instrument;

- depositing the severed tissue sample; and

- cauterising the tissue.

Accordingly, the types of tissue cauterised in the present invention include mammalian tissue. In particular, the invention relates to cauterising human tissue. Even more in particular, the invention relates to cauterising breast tissue.

According to another aspect, the invention provides a method of assembly of an instrument for cauterising tissue comprising the steps of: attaching a sheath to a shaft of a biopsy and/or sampling instrument and connecting a diathermy pin to the instrument to cauterise a tissue.

In a preferred embodiment, the sheath may function as either a conductive or insulating sheath.

Another aspect of the invention is a kit comprising a device for cauterising tissue according to any aspect of the present invention, and a biopsy and/or sampling instrument.

The present invention also provides any one of the embodiments disclosed below and indicated with the numbers 1 to 54.

1. A device for cauterising tissue, the device arranged to be mounted to a biopsy and/or sampling instrument and comprising a conductive cauterising portion and means for heating the cauterising portion.

2. The device according to claim 1, wherein the device is hollow.

3. The device according to any one of claims 1-2, wherein the cauterising portion has an orifice through which the biopsy and/or sampling instrument extends, optionally said cauterising portion with orifice forming at least a part of a ring.

4. The device according to any one of claims 1-3, wherein the cauterising portion is at least a part of a conductive material.

5. The device according to any one of claim 4, wherein the conductive material is in the form of any one or a combination of a layer, a cylinder and a wire.

6. The device according to any one of claims 4-5, wherein the conductive material is further insulated by insulating material, leaving the cauterising portion exposed.

7. The device according to any one of claims 1-6, wherein the device is in the form of a sleeve.

8. The device according to any one of claims 1-7, wherein the device is mounted on a shaft of the biopsy and/or sampling instrument.

9. The device according to any one of claims 1-8, wherein the device is mounted on the biopsy and/or sampling instrument such that the cauterising portion is closer to a distal end of the biopsy and/or sampling instrument.

10. The device according to any one of claims 1-9, wherein the device is mounted on the biopsy and/or sampling instrument by frictional contact between the biopsy and/or sampling instrument and the device.

11. The device according to any one of claims 1-10, wherein the device further comprises mounting means for holding the device on the biopsy and/or sampling instrument.

12. The device according to any one of claim 11, wherein the mounting means comprises an O-ring at an interface between the device and the biopsy and/or sampling instrument.

13. The device according to any one of claim 11, wherein the mounting means comprises a locking mechanism between the device and the biopsy and/or sampling instrument, and wherein the mechanism comprises any one or a combination of a press-fit, interference fit or spring loaded mechanism.

14. The device according to any one of claim 11, wherein the mounting means comprises an adhesive layer for adhering the device to the biopsy and/or sampling instrument.

15. The device according to any one of claims 1-14, wherein the device is mounted permanently onto the biopsy and/or sampling instrument.

16. The device according to any one of claims 1-14, wherein the device is mounted releasably removable from the biopsy and/or sampling instrument.

17. The device according to any one of claims 8-16, wherein the device is slidable along the shaft of the biopsy and/or sampling instrument.

18. The device according to any one of claims 1-17, wherein the means for heating the cauterising portion comprises connection means connecting

the cauterising portion to a power supply for heating the cauterising portion.

19. The device according to any one of claims 1-18, wherein the means for heating is connected to the conductive material.

20. The device according to any one of claims 1-19, wherein the device is arranged to mask at least a part of a biopsy and/or sampling lateral opening on the biopsy and/or sampling instrument.

21. The device according to any one of claims 1-20, wherein the device comprises a telescoping assembly comprising at least two members, wherein the first member is co-operatively engaged with the second member.

22. The device according to any one of claims 1-21, wherein the thickness of the device is in the range of 0.1-0.5 mm.

23. The device according to any one of claims 1-22, wherein the device includes a sleeve having a C-shaped cross-section, said sleeve being sufficiently flexible to bend at least a portion of its length away from the instrument, whilst the remaining length remains mounted to said instrument.

24. A method of cauterising tissue comprising the steps of:

- mounting the cauterising device of claims 1-23 on a biopsy and/or sampling instrument;

- inserting the biopsy and/or sampling instrument into a tissue mass;

- obtaining a sample of said tissue; and

- cauterising the tissue.

25. The method according to claim 24, further comprising the step of masking at least a part of a lateral sampling opening of the instrument between the steps of mounting the cauterising device and inserting the instrument. .

26. The method according to claim 24, further comprising the step of masking at least a part of a lateral sampling opening of the instrument after inserting the instrument.

27. The method according to any one of claims 24 to 26, further comprising the step of rotating the biopsy and/or sampling instrument such that the cauterising portion of the device is in a predetermined angular orientation.

28. The method according to any one of claims 24 to 27, further comprising the step of cauterising the tissue while sliding the biopsy and/or sampling instrument within the tissue mass.

29. The method according to any one of claims 24 to 28, wherein the tissue is mammalian tissue.

30. The method according to claim 29, wherein the mammalian tissue is human tissue.

31. The method according to claim 30, wherein the human tissue is breast tissue.

32. A method of cauterising tissue comprising the steps of:

- mounting the cauterising device of claims 1-23 to a biopsy and/or sampling instrument after the instrument has been removed from the body after a biopsy and/or tissue sampling;

- inserting the biopsy and/or sampling instrument into a tissue mass which has been sampled; and

- cauterising the tissue.

33. The method according to claim 32, further comprising the step of rotating the biopsy and/or sampling instrument such that the cauterising portion of the device is in a predetermined angular orientation.

34. The method according to claim 32 or 33, further comprising the step of cauterising the tissue while sliding the instrument within the tissue mass.

35. The method according to any one of claims 32 to 34, wherein the tissue is mammalian tissue.

36. The method according to claim 35, wherein the mammalian tissue is human tissue.

37. The method according to claim 36, wherein the human tissue is breast tissue.

38. A biopsy and/or sampling instrument for obtaining tissue samples and cauterising the remaining tissue comprising:

- means for sampling tissue;

- a lateral opening for receiving the tissue samples;

- a conductive cauterising portion; and

- means for heating the cauterising portion.

39. The instrument according to claim 38, wherein the means for sampling comprises the conductive cauterising portion.

40. The instrument according to claim 39, wherein the conductive cauterising portion comprises a cutting member for cutting a sample of the tissue, said

cutting member being internal to, and co-axial with, an insertion shaft of the instrument;

and a power supply connection attached to said cutting member to facilitate the means for heating the cauterising portion.

41. The instrument according to any one of claims 38 to 40, wherein the cauterising portion is between a distal end of the biopsy and/or sampling instrument and the lateral opening for receiving the tissue sample.

42. The instrument according to any one of claims 38 to 41, wherein the cauterising portion is at least a part of a ring around the means for sampling.

43. A method of obtaining tissue samples and cauterising the remaining tissue comprising the steps of:

- introducing a biopsy and/or sampling instrument according to any one of claims 38 to 42 into a tissue mass to be sampled;

- severing a tissue sample from the tissue mass which has entered a lateral opening of the instrument;

- transporting the severed tissue sample to a proximal end of the instrument;

- depositing the severed tissue sample; and

- cauterising the tissue.

44. The method according to claim 43, further comprising the step of rotating the instrument such that the cauterising portion of the instrument is in a predetermined angular orientation.

45. The method according to claims 43 or 44, further comprising the step of cauterising the tissue while removing the instrument from the tissue mass.

46. The method according to any one of claims 43 to 45, wherein the tissue is mammalian tissue.

47. The method according to any one of claim 46, wherein the mammalian tissue is human tissue.

48. The method according to any one of claim 47, wherein human tissue is breast tissue.

49. A kit comprising a device for cauterising tissue according to claims 1-23 and a biopsy and/or sampling instrument.

50. A method of assembly of an instrument for cauterising tissue comprising the steps of: attaching a sheath to a shaft of a biopsy and/or sampling instrument and connecting a diathermy pin to the instrument to cauterise a tissue.

51. The method according to claim 50, wherein the sheath is an insulating sheath.

52. The device according to claim 23, wherein the uncompleted part of the cross-section of the sleeve forms a gap in the sleeve, and wherein at least part of the gap is closed by a resilient member.

53. The device according to claim 52, wherein the resilient member is at least one elastic band.

54. The device according to claim 52, wherein the resilient member is an interwoven elastic fabric.

Brief description of the figures

Figure 1A is a side elevation view of the cauterising device according to one aspect of the invention. Figure 1B is a cross sectional view of Figure 1A.

Figures 2A and 2B are cross sectional views of the cauterising device in the form of a sleeve.

Figures 3A and 3B are cross sectional views of a cauterising device in the form of a sleeve according to another aspect of the invention.

Figures 4A and 4B are the cross sectional views of alternative aspects of the invention, wherein the cauterising device comprises a telescopic assembly.

Figure 5 shows a perspective view of a cauterising device.

Figures 6A and 6B shows a side elevation and Figures 6C, 6D, 6E and 6F show a perspective view of an aspect of the present invention.

Figure 7 illustrates how the cauterising device of the present invention may be mounted on a biopsy and/or sampling instrument.

Figure 8 shows how the cauterising device according to the present invention may be arranged to mask a part of the lateral opening of the biopsy and/or sampling instrument.

Figures 9A, 9B, 9C and 9D show side views of alternatives of a biopsy and/or sampling instrument with means for cauterisation present in the instrument.

Detailed description of the invention

It will be convenient to further describe the present invention with respect to the accompanying drawings that illustrate possible arrangements of the invention. Other arrangements of the invention are possible, and consequently the particularity of the accompanying drawings are not intended to be limiting of the present invention.

According to a first aspect, the present invention provides a device for cauterising tissue, the device arranged to be mounted to a biopsy and/or sampling instrument and comprising a conductive cauterising portion and means for heating the cauterising portion.

The biopsy and/or sampling instrument to which the device may be mounted to can be any biopsy and/or sampling instrument known in the art. For example, the instrument may be any one of the instruments as described by US Patent Nos. 5,526,822, 5,649,547, 5,769,086, 6,638,235, herein incorporated by reference.

According to a further aspect, the device is hollow. For the purposes of this invention, the term hollow refers to a body having a hole or space within, a cavity, opening or space in or within a body.

According to Figure 1A, it provides a cauterising device **10** comprising a conductive cauterising portion **15**, and means for heating **20** the cauterising portion **15** by a power supply (not shown). The cauterising portion **15** is in the form of a ring through which a biopsy and/or sampling instrument may extend. The cauterising portion **15**, however, may be a part of a ring. In this case, the remaining part of the ring, which does not act as the cauterising portion **15**, is insulated by suitable insulating material. The means for heating **20** is in the form of a wire running along the length of the device **10**. Alternatively, the

means for heating **20** may be in the form of a ring of conductive material (as seen in Figure 1A) attached to the cauterising portion **15** by means of a wire running along the length of the device **10**. However, the means for heating **20** may be any other means by which the cauterising portion **15** may be heated or connected to a power supply.

Figure 1A also provides an alternative arrangement of the cauterising device **10**. The device **10** may be in the form of a sleeve **12** comprising a cauterising portion **15** and means for heating **20** connected to the cauterising portion **15**.

In order to prevent the heat from being dissipated and ensuring that the heat is concentrated at the cauterising portion **15**, the means for heating **20** is surrounded by an insulating material **25**, as shown in Figure 1B. For the purposes of this invention, any suitable insulating material known in the art may be used. In particular, the insulating material **25** may be a biocompatible material, as it will be inserted into a tissue mass. Examples of biocompatible materials include plastic or epoxy.

Another aspect of the present invention is shown in Figures 2A and 2B. Figure 2A shows the cauterising device **30**, wherein the device **30** is in the form of a sleeve. The sleeve comprises a conductive layer **35** and means for heating **20** connected to a power supply (not shown). The conductive layer **35** is further insulated by an external insulating layer **40** to prevent heat from the conductive layer **35** from being dissipated to the surrounding. Another function of the external insulating layer **40** is to prevent the patient's skin to be burnt by the heat supplied by the power supply. The external insulating layer **40** however leaves a portion of the conductive layer **35** exposed. This exposed portion of the conductive layer **35** acts as the cauterising portion **38** of the device **30**, which is in the form of a ring around the sleeve. The advantage of exposing just a portion of the conductive layer **35** to act as the cauterising

portion **38** is to ensure that the heat supplied is concentrated at a point and therefore the cauterising of the tissue would be more effective.

Alternatively, the conductive layer **35** may be insulated by external insulating layer **45** such that a portion of the conductive layer **35** is exposed at either ends of the device **30**. The exposed portion of the conductive layer **35** at the distal end of the device acts as the cauterising portion **38**, while the other exposed portion at the proximal end of the device **30** may be used as the means for heating **20**, which is in turn connected to a power supply (not shown).

A further alternative of this aspect of the invention provides an inner insulating layer **45**, as shown in Figure 2B. This inner insulating layer **45** would be useful when the device **30** is mounted on a biopsy and/or sampling instrument with a shaft made of conducting material, so as to minimise heat from the conductive layer **35** from being dissipated to the shaft of the instrument.

The cauterising device **50** as shown in Figures 3A and 3B is similar to the device of Figures 2A and 2B. The device **50** comprises a conductive layer **55** and an external insulating layer **60**. The external insulating layer **60** leaves a portion of the conductive layer **55** exposed. This exposed portion of the conductive layer **55** forms the cauterising portion **58** of the device **50**. However, in the device **50**, the cauterising portion **58** forms just a part of a ring around the sleeve.

A further alternative is wherein the external insulating layer **60** leaves the conductive layer **55** exposed at either ends of the conductive layer **55**. The exposed portion of the conductive layer **55** at the distal end of the device **50** acts as the cauterising portion **58**, while the other exposed portion of the conductive layer **55** acts as the means for heating **20**, which is in turn connected to a power supply (not shown) to heat the cauterising portion **58**.

Another alternative of the present aspect is shown in Figure 3B. The device **50** further comprises an internal insulating layer **65**. This internal insulating layer **65** would be useful when device **50** is mounted on a biopsy and/or sampling instrument with a shaft made of conducting material, so as to minimise heat from being dissipated from the conductive layer **55** from being dissipated to the shaft of the instrument.

Accordingly, the conductive layer **55** may be extended at the end opposite the end with the cauterising portion **58** to permit the attachment of a diathermy pin (not shown).

Yet another aspect of the present invention is shown in Figures 4A and 4B. Figures 4A and 4B show a cauterising device **70** and **90** respectively comprising a telescoping assembly comprising three members, **78**, **79**, **80**, wherein the members are all co-operatively engaged with the adjacent member. In particular, member **78** is co-operatively engaged with member **79**, which is in turn co-operatively engaged with member **80**.

For the purposes of this invention, a telescoping assembly refers to members that fit together like a set of cylinders that slide into one another, allowing extension and shortening of the assembly. The telescoping assembly may contain any number of members, with a minimum of two members and wherein the first member is co-operatively engaged with the second member. The number of members may vary depending on the length desired to extend the device to.

Accordingly, when using the device **70** or **90**, even though the telescoping assembly comprises of three members **78**, **79** and **80**, only member **80**, comprising a cauterising portion **75**, may be extended out of member **79** without the need to extend member **79** out from member **78**. The members **78**, **79** and **80** are made of any suitable insulating material so as to prevent the heat supplied to the cauterising portion **75** from dissipating to the

surrounding. The members **78**, **79** and **80** are preferably made of insulating biocompatible material. For example, plastic or epoxy.

The assembly further comprises a cauterising portion **75** which is connected to the power supply (not shown) by a wire **85**. In Figure 4A, there are two wires **85** running along the length of the assembly to connect the cauterising portion **75** to the power supply, whereas in Figure 4B, there is only one wire **85** running along the length of the assembly to connect the cauterising portion **75** to the power supply. The wire **85** is insulated by suitable insulating material **77**, leaving only the cauterising portion **75** exposed.

An alternative aspect of the invention is a telescoping assembly as described above, comprising at least two members and wherein each member comprises at least a conductive material in the form of a layer, and an external insulating layer. The member may further comprise an internal insulating layer. The conductive material of all members is arranged in such a way that the conductive material of all members of the assembly are in continuous contact. A person skilled in the art would have the relevant knowledge on how the members should be arranged such that the conductive layers of all the members are in continuous contact.

According to another aspect of the present invention is the device **100** as shown in Figure 5. The cauterising device **100** is mountable on a biopsy and/or sampling instrument. The cauterising device **100** has an orifice through which a biopsy and/or sampling instrument extends, comprising three layers: the inner layer **111** with a proximal extension, the middle conducting layer **110** with a protrusion **108** of the middle conducting layer **110** proximal to a ledge **115** and the outer layer **105**. The protrusion **108** may be in the form of any one of or a combination of a layer, a cylinder and/or a wire. The device **100** further comprises a ring **120** of conductive material connected to the protrusion **108** through the middle conducting layer **110**. The outer layer **105**

and inner layer **111** are made of insulating material while the middle layer **110**, and its protrusion **108**, is made of conducting material. The three layers are such that a part of the middle conducting layer **110** is sandwiched between the inner insulating layer **111** and the outer insulating layer **105**. This exposed distal part of the inner conducting layer **110** which forms the ring **120** acts as the cauterising portion when the device **100** is connected to a power supply (not shown). A possible way of connecting the device **100** to a power supply may be by attaching the power supply to conducting layer **110** either directly or through its protrusion **108**. Accordingly, the device **100** is mounted on a biopsy and/or sampling instrument such that the ring **120** of the device **100** is at the distal end of the instrument, while the exposed protrusion **108** of the middle conducting layer **110** is at the proximal end of the instrument. The ledge **115**, made of insulating material serves the purpose of preventing the skin from coming into contact with the conducting layer **110**. The ring **120** may be a part of the middle conducting layer **110** which is not covered by the outer insulating layer **105**. The middle conducting layer **110** and/or its protrusion **108**, when connected to a power supply acts as the means for charging or heating ring **120**, which is the cauterising portion. This middle conducting layer **110** serves as connection means between the ring **120** and the power supply to allow an electric current to charge the cauterising portion and allow heat dissipation for cautery when the ring **120** is in contact with tissue.

According to a further aspect, a diathermy pin (not shown) may be curled over the exposed protrusion **108** of the middle conducting layer **110** to be used for electric current conduction. When a user of the device **100** activates the power supply, heat is supplied to the cauterising portion, either connecting the middle conducting layer **110** or its exposed protrusion **108** directly to a power supply, or by using a diathermy pin attached (not shown) to the protrusion **108**. The inner insulating layer **111** extends proximally beyond the middle

conducting layer **110** creating a shelf for stable placement of such a diathermy pin.

Another aspect of the present invention is a device **130** for cauterising tissue, as shown in Figures 6A, comprising a conductive cauterising portion **140** which is in the form of a part of a ring with two arms **135** and **145**, through which a biopsy and/or sampling instrument extends. The device **130** may be mounted to a biopsy and/or sampling instrument according to any suitable method known in the art. The device **130** further comprises a means for heating **150**, which connects the cauterising portion **140** to a power supply (not shown). The power supply heats the cauterising portion **140** when it is required to do so. Accordingly, the power supply may be controlled by the user of the device **130**.

According to a further aspect, the two arms **135** and **145** may be made of flexible conductive material, such that when the device **130** is mounted to a biopsy and/or sampling instrument, the two arms **135** and **145** may be adjusted by either pressing the arms **135** and **145** closer together, in the case of a biopsy and/or sampling instrument with a smaller diameter, or pushing the arms **135** and **145** further apart, in the case of a biopsy and/or sampling instrument with a larger diameter.

As an alternative to Figure 6A, Figure 6B provides a cauterising device **132**, comprising a conductive cauterising portion **140** which is in the form of a part of a ring at one end of the device **132** with two arms **135** and **145**, through which a biopsy and/or sampling instrument extends. The device **132** comprises another ring with two arms **136** and **146** at the other end of the device. The device **132** further comprises a means for connection **152**, which connects the two rings at either ends of the device **132**. The power supply needed to heat the cauterising portion **140** may be connected to either arm **146** or **136** of the device **132**. The power supply heats the cauterising portion

140 when it is required to do so. Accordingly, the power supply may be controlled by the user of the device **132**. Similar to the device **130** of Figure 6A, the arms **135**, **136**, **145** and **146** may be made of flexible conductive material. The rings of device **130** and **132** may be split-rings.

According to another further aspect, the cauterising device **160** is in the form of a hollow sleeve **165** as shown in Figure 6C. The device **160** comprises a conductive cauterisation portion **140**, which is a part of a ring through which the biopsy and/or sampling instrument extends. The sleeve **165** of the device **160** is made of flexible insulating material, while the cauterising portion is made of flexible conductive material, such that a tighter fit can be achieved when the device **160** is mounted to a biopsy and/or sampling instrument, depending on the diameter of the biopsy and/or sampling instrument. Further, there is a means for heating **150** running within the sleeve **165**, through the length of the sleeve **165**, which is connected to a power supply (not shown) to supply heat to the cauterising portion **140** when required.

Another further aspect is shown in Figure 6D. The device **170** works similarly to the device **160** of Figure 6C. However, the device **170** is in the form of a hollow sleeve of conductive material **174**. The device **170** comprises a cauterising portion **172**. A power supply (not shown) is connected to the conductive material **174** by means of heating **173**. The cauterising portion **172** is therefore heated by the power supply via the conductive material **174**. The device **170** further comprises an external insulating layer **175** which covers the conductive material **174**, leaving the cauterising portion **172** exposed. Similar to the device **160** of Figure 6C, the cauterising portion **172**, external insulating layer **175** and the layer of conductive material **174** is made of flexible material to achieve a better fit of the device **170** on the biopsy and/or sampling instrument when the device **170** is mounted on the instrument.

A further aspect of the present invention is shown in Figure 6E. The device **300** of Figure 6E works similarly to device **160** of Figure 6C. As with device **160**, the device **300** comprises a hollow sleeve **165** and a conductive cauterisation portion **140**, which is part of a ring through which the biopsy and/or sampling instrument extends. The sleeve **165** of the device **300** is made of flexible insulating material, while the cauterising portion is made of flexible conductive material, such that a tight fit can be achieved when the device **300** is mounted to a biopsy and/or sampling instrument, depending on the diameter of the biopsy and/or sampling instrument. There is also a means for heating **150** running within the sleeve **165**, through the length of the sleeve **165**, which is connected to the power supply (not shown) to supply heat to the cauterising portion **140** when required. The device **300** further comprises an elastic band **302** to close the gap between the sleeve **165** of the device **300** at at least one part of the sleeve **165**. The elastic band **302** may be attached to the cauterising portion **140** as shown in Figure 6E. Alternatively, the elastic band **302** may be placed at any position along the length of the sleeve **165**. As another alternative, there may be more than one elastic band **302** placed along the length of the sleeve **165**. The elastic band **302** can be of any suitable material such that it enables the sleeve **165** to fit snugly around a biopsy and/or sampling instrument and also allow the sleeve **165** to be able to stretch beyond its original diameter without the device **300** detaching itself from the biopsy and/or sampling instrument on which it is mounted. For example, the elastic band **302** may be made of a resilient material such as rubber. However, any other suitable material may be used for the elastic band **302**. The elastic band **302** may be attached to the sleeve **165** by an adhesive such as glue or the like. Alternatively, there may be means provided on the cauterising portion **140** and/or the sleeve **165** for the connection of the elastic band(s) **302**.

Another further aspect of the present invention is provided in Figure 6F. The device **310**, as shown in Figure 6F, is similar to the device **300** of 6E. However, instead of the use of elastic band(s) **302**, the device **310** uses a resilient material **312** to cover the gap between the sleeve **165**. The resilient material **312** may be in the form of an interwoven elastic material, or any suitable elastic and/or flexible material may be used. For example, an interwoven elastic fabric may be used as the resilient material **312**. The resilient material **312** can be of any suitable material such that it enables the sleeve **165** to fit snugly around a biopsy and/or sampling instrument and also allow the sleeve **165** to be able to stretch beyond its original diameter without the device **300** detaching itself from the biopsy and/or sampling instrument on which it is mounted. The resilient material **312** may be attached to the sleeve **165** by a suitable adhesive such as glue or the like. Alternatively, means may be provided on the sleeve **165** and/or the cauterising portion **140** to attach the resilient material **312** to itself.

Another aspect of the present invention is shown in Figure 7. Figure 7 shows how the device **30** may be used together with a biopsy and/or sampling instrument **185**. However, this aspect of the invention is not limited to the device **30** but any device which is within the scope of the present invention. Figure 7 is also not limited to the use of biopsy and/or sampling instrument **185**, but any suitable biopsy and/or sampling instrument may be used according to this aspect of the invention. The device **30** is mounted to the biopsy and/or sampling instrument **185** such that the cauterising portion **38** of the device **30** is closer to the distal end of the instrument **185**. According to Figure 7, the device **30** is mounted to a shaft **190** of the instrument **185**. The instrument **185** further comprises a lateral opening **180** for receiving tissue samples.

The device **30** can be mounted on instrument **185** by any suitable method. The device **30** may be mounted either permanently or releasably removable

from the instrument **185**. For example, the device **30** may be mounted on instrument **185** by frictional contact between the instrument **185** and the device **30**. This can be done by passing the instrument **185** through the hollow device **30**, and the device **30** will consequently be held in place by frictional contact. Therefore, according to this aspect, no further mounting means are required.

The device **30** is also able to slide along the shaft **190** of the instrument **185**. This enables the device **30** to mask at least a part of the lateral opening **180** when such a large opening is not required for tissue sampling. For example, in a breast biopsy which uses a breast biopsy instrument such as that described in US Patent 5,526,822, in many patients an adequate thickness with compression of the breast may not be achieved to carry out the biopsy procedure. For example, stereotactic percutaneous vacuum-assisted breast biopsy of the breast requires the breast to be compressed before the biopsy. The vacuum biopsy device has a fixed biopsy chamber (aperture) length and a requirement for a minimum compression. As a result, there are occasions when the lesion is too close to the skin or when the compression is too narrow to accommodate the biopsy detail of the instrument. In the first instance there will be a portion of the aperture that extends beyond the skin and leaves it open to the air. Vacuum suction therefore cannot be achieved. In the second instance, biopsy is often aborted and the patient would have to subject to conventional 'open' surgery. Other examples in which only a part of the lateral opening would be required include when only the distal part of the instrument needs to be inserted into the breast, only a small tissue sample is required or if the area to be sampled is found very near to the skin. It would therefore be advantageous to be able to use the device to mask a part of the lateral opening in order to reduce the size of the lateral opening on the instrument. This can be seen in Figure 8, which shows device **30** masking a part of the lateral opening **180** on the shaft **190** of the instrument **185**.

According to a further aspect, the device **30** may also be held firmly in place on the instrument **185** by using any suitable mounting means known in the art. In particular, the mounting means comprises an O-ring at an interface between the device **30** and the instrument **185**. Other mounting means comprise a locking mechanism between the device **30** and the instrument **185**, wherein the mechanism comprises any one of the following or a combination thereof, but not limited to, a press-fit, interference fit or spring loaded mechanism. Yet another example of mounting means is an adhesive layer for adhering the device **30** to the instrument **185**. The adhesive layer may be a layer of glue or any other suitable means of adhering two surfaces together.

Another aspect of the present invention is the use of the device according to any aspect of the present invention to cauterise tissue, wherein the method of cauterising tissue comprises the steps of:

- mounting the cauterising device to a biopsy and/or sampling instrument;

- inserting the biopsy and/or sampling instrument into a tissue mass;

- obtaining a tissue sample; and

- cauterising the tissue.

The device may be mounted to a biopsy and/or sampling instrument as shown in Figure 7 or 8. Accordingly, the device **30** may be mounted to the instrument **185** before a tissue sample has been obtained, followed by inserting the instrument **185** with the device **30** into a tissue mass which is desired to be sampled. The tissue sample can then be obtained by any suitable method. For example, the method as described in any one of US Patents Nos. 5,526,822, 5,649,547, 5,769,086, 6,638,235. Once the tissue sample has been obtained, the cauterising portion **38** is heated via the means for heating **20** which heats the cauterising portion **38**, for example by connecting the

means for heating **20** to a power supply (not shown). For example, the cauterising portion **38** may be heated by induction. However, the cauterising portion **38** is heated only when the tissue is to be cauterised. Therefore, the power supply is controlled by the user who is able to switch on the power supply only when it is required.

The method of cauterising the tissue may further comprise an additional step between the steps of mounting the cauterising device **30** to the instrument **185** and inserting the instrument **185** into a tissue mass. This additional step comprises acting on the device **30** to mask at least a part of the lateral opening **180** on the instrument **185**, as shown in Figure 8. The method may further comprise another step of rotating the instrument **185** such that the cauterising portion **38** of the device **30** is in a predetermined angular orientation. According to a further aspect, the tissue may be cauterised while removing the instrument **185** from the tissue mass.

The method is not restricted to biopsy procedures but any tissue, which has been sampled, may be cauterised. The tissue may be mammalian tissue. In particular, the tissue may be human tissue and even more in particular, the tissue may be breast tissue. The method may also be used for cauterising kidney or liver tissues.

According to another aspect of the present invention, the method of cauterising tissue comprises the steps of:

- mounting the cauterising device to a biopsy and/or sampling instrument after the instrument has been removed from the body after a biopsy and/or tissue sampling;

- inserting the biopsy and/or sampling instrument into a tissue mass which has been sampled; and

- cauterising the tissue.

The difference between the present method and that described above is that in the present method, the device **30** is mounted on the instrument **185** after the biopsy and/or tissue sampling procedure has been carried out. After the device **30** has been mounted, the instrument **185** is re-inserted into the tissue mass which has been sampled. The tissue is then cauterised to stop secure haemostasis. The cauterisation portion **38** is heated only when the user switches on the power supply and when the user wishes to carry out cauterisation of the tissue.

Another aspect of the invention is a kit comprising a device for cauterising tissue according to any one aspect of the present invention and a biopsy and/or sampling instrument.

Another aspect of the present invention is a biopsy and/or sampling instrument for obtaining tissue samples and cauterising the remaining tissue comprising:

- means for sampling tissue;

- a lateral opening for receiving the tissue samples;

- a conductive cauterising portion; and

- means for heating the cauterising portion.

An example of such an instrument is as shown in Figure 9A. The instrument **200** comprises a pointed distal end **230**, a lateral opening **220** along its hollow shaft **215**, a cauterising portion **225** made of conductive material, and a wire **210** connecting the power supply to the cauterising portion **225**. The instrument **200** may further comprise other features similar to instruments as described in US Patent Nos. 5,526,822, 5,649,547, 5,769,086, 6,638,235, the comments of which are incorporated herein by reference. In particular, the means of sampling include the shaft **215** and the pointed distal end **230**. The

means of heating and connection means need not be restricted to the use of a wire. However, any suitable means of heating and connection means known in the art may be used.

The cauterising portion **225** is between the distal end **230** of the instrument **200** and the lateral opening **220** for receiving the tissue sample. The cauterising portion **225** is in the form of a ring around the shaft **215** of the instrument **200**. The cauterising portion **225** is heated by means for heating the cauterising portion **225**. In this case, a wire **210** running along the length of the shaft **215** within the shaft **215** is used to connect the power supply to the cauterising portion **225**. In order to ensure effective cauterisation of the tissue, it would be advantageous to concentrate the heat at the cauterising portion **225**. Therefore, the wire **210** is covered with insulating material (not shown) to prevent heat from being dissipated to the shaft **215**, particularly if the shaft **215** is made of conducting material.

According to a further aspect of the present invention, and with reference to Figure 9B, the cauterising portion **235** of the instrument **200** may be a part of a ring around the shaft **215**. The cauterising portion **235** is found between the distal end **230** of the instrument **200** and the lateral opening **220** of the shaft **215**. The cauterising portion **235** is connected to the power supply (not shown) by means of a wire **210** running along the length of the hollow shaft **215**. As described above, the wire **210** is covered by insulating material (not shown) to prevent the heat supplied to the cauterising portion **235** from dissipating to the shaft **215**, particularly if the shaft **215** is made of conductive material.

In Figure 9C, which is similar to Figure 9A, the instrument **200** is covered by an external insulating material **240** such that only the cauterising portion **225** and the lateral opening **220** are exposed. This would be particularly advantageous if the shaft **215** is made of conductive material, so as to prevent

the heat supplied to the cauterising portion **225** from dissipating to the rest of the shaft **215** and the surrounding. It should be noted that the external insulating material **240** may be used in any instrument **200** as shown in Figure 9A or 9B, particularly if the shaft **215** is made of conductive material.

Figure 9D shows an instrument **202** which works in a similar fashion as instrument **200** of Figure 9A. However, the instrument **202** is such that the means for sampling comprises an inner cutter **250** that acts as the cauterising portion. When heat is supplied to this inner coaxial cutter **250**, the tissue is cauterised.

Accordingly, the present invention also provides a method for the use of an instrument such as instrument **200** as shown in Figures 9A-C. A method of obtaining tissue samples and cauterising the remaining tissue comprising the steps of:

- introducing a biopsy and/or sampling instrument of the present invention into a tissue mass;

- severing a tissue sample from the tissue mass which has entered a lateral opening of the instrument;

- transporting the severed tissue sample to a proximal end of the instrument;

- depositing the severed tissue sample; and

- cauterising the tissue.

The tissue sample may be from any tissue. In particular, the tissue may be mammalian tissue. More in particular, the tissue may be human tissue and even more in particular, breast tissue. However, tissues such as kidney and liver tissues may also be sampled and cauterised.

The method, with reference to the instrument **200** (Figures 9A-C), may further comprise the step of rotating the instrument **200** such that the cauterising portion **225** (Figures 9A or C) or **235** (Figure 9B) of the instrument **200** is in a predetermined angular orientation. The method may further comprise the step of cauterising the tissue while sliding the instrument **200** within a tissue.

The cauterising portion **225** (Figures 9A or C) or **235** (Figure 9B) of the instrument **200** is heated by means of heat supplied by a power supply, to which the cauterisation portion **225** or **235** is connected. The power supply is switched on only when the cauterising portion **225** or **235** is to be used. Thus, the method also comprises the step of a user of the instrument **200** controlling the power supply so as to heat the cauterising portion **225** or **235** only when necessary, preferably after the cauterisation portion **225** or **235** is at or near the tissue mass that is to be cauterised.

The device as so described in its various embodiments may further support other peripheral uses. These may include catheter placement and marker placement. Catheter placement may be useful for the drainage of abscesses and placement of wires for ablation of tumour tissue. With respect to breast biopsies, a marker may be placed after the removal of the lesion to identify the site of the biopsy for purposes of further therapeutic surgery.

Conventionally, catheters are placed using the Seldinger technique. This involves the placement of a guidewire from a point in the skin to the area of concern under imaging guidance. Dilators of increasing diameters are then passed over the guidewire until such time that the tract is wide enough for the catheter to be introduced. The device according to any aspect of the invention may also serve to maintain the tract to facilitate the placement of a catheter, a means for further percutaneous therapy or marker where appropriate. If made of inert material, it may be left in situ in the tract itself to itself serve as a marker for a short time, perhaps while awaiting histological diagnosis. In

addition, if further development allows it to be made of biodegradable material, it may be left for longer periods.

According to another aspect, a radiologically visible marker may be attached to the cauterising portion so that the user of the device will be able to locate the cauterising portion under X-ray or ultrasound when inserted into a tissue mass, and appropriately position the cauterising portion.

Claims

1. A device arranged to be mounted to a biopsy and/or sampling instrument comprising a lateral opening for receiving tissue, wherein the device masks at least a part of the lateral opening to reduce the size of the lateral opening.

2. The device according to claim 1, wherein the device is in the form of a sleeve.

3. The device according to claim 1 or claim 2, wherein the device is arranged to be mounted on a shaft of the biopsy and/or sampling instrument.

4. The device according to any one of the preceding claims, wherein the device is mounted on the biopsy and/or sampling instrument by frictional contact between the biopsy and/or sampling instrument and the device.

5. The device according to any one of the preceding claims, wherein the device further comprises mounting means for holding the device on the biopsy and/or sampling instrument.

6. The device according to claim 5, wherein the mounting means comprises a locking mechanism between the device and the biopsy and/or sampling instrument, and wherein the mechanism comprises any one or a combination of a press-fit, interference fit or spring loaded mechanism.

7. The device according to claim 5, wherein the mounting means comprises an adhesive layer for adhering the device to the biopsy and/or sampling instrument.

8. The device according to any one of claims 3-8, wherein the device is slidable along the shaft of the biopsy and/or sampling instrument to mask at least a part of the lateral opening to reduce the size of the opening.

9. The device according to any one of claims 1 to 7, wherein the device is mounted releasably removable from the biopsy and/or sampling instrument.