objective of preventing re-use of the cryoneedle to perform more than one intralesional cryotherapy procedure. Additionally, or alternatively, in some embodiments, improvements are implemented with the further objective of causing uniform cryogen temperature exposure and freezing effect along the working length of the outer sheath surface of the cryoneedle. In yet further embodiments, improvements are implemented for improved ergonomics and/or to reduce or eliminate the risk of unwanted exposure to exhausted cryogen fluid as it leaves the cryoneedle.

SUMMARY OF THE INVENTION

[008a] According to a first aspect of the present invention, there is provided a cryoneedle assembly for performing intralesional cryotherapy, comprising a handle and a needle attachment. The handle comprises: an outer housing; a receptacle for receiving and coupling the handle to the needle attachment; a supply channel through which cryogen fluid is routed through the handle to the needle attachment; and an exhaust channel through which cryogen fluid is routed through the handle from the needle attachment. The needle attachment comprises: an inner lumen operatively connected to the supply channel of the handle at a first end of the inner lumen while the needle attachment is coupled to the handle, and comprising at least one opening through which cryogen fluid exits the inner lumen; and an outer sheath surrounding the inner lumen and having a closed end formed into a sharp point and an open end operatively connected to the exhaust channel of the handle while the needle attachment is coupled to the handle. The needle attachment and handle are configured to detachably couple to one another, thereby forming a flow path for cryogen fluid in which the cryogen fluid from the supply channel of the handle is routed to the inner lumen of needle attachment and cryogen fluid exiting the needle attachment is routed to the exhaust channel in the handle.

[008b] According to a second aspect of the present invention, there is provided a cryoneedle assembly for performing intralesional cryotherapy, comprising a handle and a needle attachement. The handle comprises: an outer housing; a supply channel through which cryogen fluid is routed through the handle to a needle attachment; and an exhaust channel through which cryogen fluid is routed through the handle from the needle attachment. The needle attachment comprises: an inner lumen operatively connected to the supply channel and comprising at least one opening through which cryogen fluid exits the inner lumen; and an outer sheath surrounding the inner lumen and having a closed end formed into a sharp point and an open end operatively connected to the exhaust

channel. The inner lumen comprises a plurality of openings through its axial surface and disposed along its length through which cryogen fluid exits the inner lumen and enters the outer sheath.

[008c] According to a third aspect of the present invention, there is provided a cryoneedle assembly for performing intralesional cryotherapy, comprising a handle and a needle attachment. The handle comprises an outer housing; a supply channel through which cryogen fluid is routed through the handle to the needle attachment; and an exhaust channel through which cryogen fluid is routed through the handle from the needle attachment. The needle attachment comprises: an inner lumen operatively connected to the supply channel and comprising at least one opening through which cryogen fluid exits the inner lumen; and an outer sheath surrounding the inner lumen and having a closed end formed into a sharp point and an open end operatively connected to the exhaust channel. The outer sheath comprises a tip attachment comprising: solid body permanently affixed to the outer sheath; and a sharp point at the closed end of the outer sheath comprising a trocar configuration. The tip attachment blocks cryogen fluid flow within the outer sheath to insulate the closed end of the tip attachment from exposure to the cryogen fluid.

[0009] Several improvements to existing cryoneedle assembly designs are presented in the various emobiments disclosed herein. According to one embodiment, a cryoneedle assembly for performing intralesional cryotherapy is disclosed which comprises a handle and a needle attachment. The handle may comprise internal channels and connection ports for coupling to supply and exhaust lines for introducing and expelling cryogen fluid from the cryoneedle assembly during use. The needle attachment may comprise a detachable assembly configured to couple to the handle. The needle attachment may comprise an inner lumen operatively coupled to the supply line to receive cryogen fluid during use which may then be routed through the inner lumen to an outer sheath surrounding the inner lumen. The outer sheath may comprise a closed end formed into a sharp point usable for penetrating hypertrophic scar tissue. Cryogen fluid may be routed to the interior of the outer sheath during use to effect freezing of the surrounding tissue, before the cryogen fluid is expelled from the cryoneedle through the exhaust line.

[0010] In certain embodiments, a cryoneedle assembly may comprise a handle to which a detachable needle attachment may be affixed. The needle attachment may comprise a configuration causing it to transition from an unused state to a used state. According to such embodiments, the needle attachment may be rendered unusable for continued use to perform

intralesional cryotherapy or become incapable of re-attaching to the handle upon transitioning to its used state.

[0011] By way of example, in an embodiment, the cryoneedle housing may comprise one or more posts extending outwardly and toward the needle attachment. When in its unused state, a needle attachment may comprise one or more openings for receiving the one or more posts when the handle and needle attachment are coupled to one another. The needle attachment may additionally comprise movable sleeve insert that may be moved from a first to second orientation by a spring

CLAIMS

1. A cryoneedle assembly for performing intralesional cryotherapy, comprising:

a handle comprising:

an outer housing;

a receptacle for receiving and coupling the handle to a needle attachment;

a supply channel through which cryogen fluid is routed through the handle to the needle attachment; and,

an exhaust channel through which cryogen fluid is routed through the handle from the needle attachment;

the needle attachment comprising:

an inner lumen operatively connected to the supply channel of the handle at a first end of the inner lumen while the needle attachment is coupled to the handle, and comprising at least one opening through which cryogen fluid exits the inner lumen; and,

an outer sheath surrounding the inner lumen and having a closed end formed into a sharp point and an open end operatively connected to the exhaust channel of the handle while the needle attachment is coupled to the handle;

wherein the needle attachment and handle are configured to detachably couple to one another, thereby forming a flow path for cryogen fluid in which the cryogen fluid from the supply channel of the handle is routed to the inner lumen of needle attachment and cryogen fluid exiting the needle attachment is routed to the exhaust channel in the handle.

2. The cryoneedle assembly of Claim 1, wherein the inner lumen comprises a plurality of openings through its axial surface and disposed along its length through which cryogen fluid exits the inner lumen and enters the outer sheath.

3. The cryoneedle assembly of Claim 2, wherein the plurality of openings through the axial surface of the inner lumen comprise an elongated oval shape.

4. The cryoneedle assembly of Claim 1, wherein the outer sheath comprises a tip attachment forming the sharp point at the closed end of the outer sheath, and wherein the sharp point comprises a trocar configuration.

5. The cryoneedle assembly of Claim 4, wherein the tip attachment is solid body permanently affixed to the outer sheath, and wherein the end of the tip attachment at which it is affixed to the

outer sheath blocks cryogen fluid flow within the outer sheath to insulate the remainder of the tip attachment from exposure to the cryogen fluid.

6. The cryoneedle assembly of Claim 5, wherein the trocar tip comprises at least external facing ridge feature along its outer surface.

7. The cryoneedle assembly of Claim 1, further comprising:

at least one post disposed within the receptacle of the housing for receiving the needle attachment;

the needle attachment further comprising:

a connection interface core for engaging the supply channel of the handle, and comprising a flange having at least one recessed section;

a movable sleeve comprising a latching protrusion, wherein the latch protrusion is configured to engage a surface of the at least one recessed section to hold the movable sleeve in a first orientation;

a spring operatively coupled to the movable sleeve and configured to bias the movable sleeve to rotate to a second orientation;

an insertable body; and,

an outer cap;

wherein detachably coupling the needle attachment to the handle causes the at least one post to engage the latch protrusion and causing the latch protrusion to deform and disengage from the surface of the at least one recessed section to permit rotation of the movable sleeve under the spring force; and,

wherein the needle attachment is not reattachable to the handle once removed while the movable sleeve is rotated to its second orientation.

8. The cryoneedle assembly of Claim 1, wherein the handle comprises an L shape.

9. A cryoneedle assembly for performing intralesional cryotherapy, comprising:

a handle comprising:

an outer housing;

a supply channel through which cryogen fluid is routed through the handle to a needle attachment; and,

an exhaust channel through which cryogen fluid is routed through the handle from the needle attachment;

the needle attachment comprising:

an inner lumen operatively connected to the supply channel and comprising at least one opening through which cryogen fluid exits the inner lumen; and,

an outer sheath surrounding the inner lumen and having a closed end formed into a sharp point and an open end operatively connected to the exhaust channel;

wherein the inner lumen comprises a plurality of openings through its axial surface and disposed along its length through which cryogen fluid exits the inner lumen and enters the outer sheath.

10. The cryoneedle assembly of Claim 9, wherein the plurality of openings through the axial surface of the inner lumen comprise an elongated oval shape.

11. The cryoneedle assembly of Claim 9, wherein the needle attachment and handle are configured to detachably couple to one another, thereby forming a flow path for cryogen fluid in which the cryogen fluid from the supply channel of the handle is routed to the inner lumen of needle attachment and cryogen fluid exiting the needle attachment is routed to the exhaust channel in the handle.

12. The cryoneedle assembly of Claim 11, further comprising:

the housing further comprising a receptacle for receiving the needle attachment having at least one post disposed within the receptacle

the needle attachment further comprising:

a connection interface core for engaging the supply channel of the handle, and comprising a flange having at least one recessed section;

a movable sleeve comprising a latching protrusion, wherein the latch protrusion is configured to engage a surface of the at least one recessed section to hold the movable sleeve in a first orientation;

a spring operatively coupled to the movable sleeve and configured to bias the movable sleeve to rotate to a second orientation;

an insertable body; and,

an outer cap;

wherein detachably coupling the needle attachment to the handle causes the at least one post to engage the latch protrusion, causing the latch protrusion to deform and disengage from the surface of the at least one recessed section to permit rotation of the movable sleeve under the spring force; and,

wherein the needle attachment is not reattachable to the handle once removed while the movable sleeve is in its second orientation.

13. The cryoneedle assembly of Claim 9, wherein the outer sheath comprises a tip attachment forming the sharp point at the closed end of the outer sheath, and wherein the sharp point comprises a trocar configuration.

14. The cryoneedle assembly of Claim 13, wherein the tip attachment is solid body permanently affixed to the outer sheath, and wherein the end of the tip attachment at which it is affixed to the outer sheath blocks cryogen fluid flow within the outer sheath to insulate the remainder of the tip attachment from exposure to the cryogen fluid.

15. The cryoneedle assembly of Claim 14, wherein the trocar tip comprises at least external facing ridge feature along its outer surface.

16. The cryoneedle assembly of Claim 9, wherein the handle comprises an L shape.

17. A cryoneedle assembly for performing intralesional cryotherapy, comprising:

a handle comprising:

an outer housing;

a supply channel through which cryogen fluid is routed through the handle to the needle attachment; and,

an exhaust channel through which cryogen fluid is routed through the handle from the needle attachment;

the needle attachment comprising:

an inner lumen operatively connected to the supply channel and comprising at least one opening through which cryogen fluid exits the inner lumen; and,

an outer sheath surrounding the inner lumen and having a closed end formed into a sharp point and an open end operatively connected to the exhaust channel;

wherein the outer sheath comprises a tip attachment comprising:

solid body permanently affixed to the outer sheath; and,

a sharp point at the closed end of the outer sheath comprising a trocar configuration;

wherein the tip attachment blocks cryogen fluid flow within the outer sheath to insulate the closed end of the tip attachment from exposure to the cryogen fluid.

18. The cryoneedle assembly of Claim 17, wherein the trocar tip comprises at least external facing ridge feature along its outer surface.

19. The cryoneedle assembly of Claim 17, wherein the needle attachment and handle are configured to detachably couple to one another, thereby forming a flow path for cryogen fluid in which the cryogen fluid from the supply channel of the handle is routed to the inner lumen of needle attachment and cryogen fluid exiting the needle attachment is routed to the exhaust channel in the handle.

20. The cryoneedle assembly of Claim 17, further comprising:

the housing further comprising a receptacle for receiving the needle attachment having at least one post disposed within the receptacle;

the needle attachment further comprising:

a connection interface core for engaging the supply channel of the handle, and comprising a flange having at least one recessed section;

a movable sleeve comprising a latching protrusion, wherein the latch protrusion is configured to engage a surface of the at least one recessed section to hold the movable sleeve in a first orientation;

a spring operatively coupled to the movable sleeve and configured to bias the movable sleeve to rotate to a second orientation;

an insertable body; and,

an outer cap;

wherein detachably coupling the needle attachment to the handle causes the at least one post to engage the latch protrusion, causing the latch protrusion to deform and disengage from the surface of the at least one recessed section to permit rotation of the movable sleeve under the spring force; and,

wherein the needle attachment is not reattachable to the handle once removed while the movable sleeve is in its second orientation.

21. The cryoneedle assembly of Claim 17, wherein the handle comprises an L shape.