

CRYONEEDLE APPARATUS AND METHODS OF USE

TECHNICAL FIELD

[0001] The invention relates to needles used in connection with cryosurgical procedures, and to systems and methods for effecting the same. More specifically, the invention relates to various specially designed needle apparatuses that are usable to perform intralesional cryotherapy procedures for treatment of keloids and hypertrophic scarring, and to systems and methods employing the same.

CROSS REFERENCE TO RELATED APPLICATIONS

[0002] This application claims the benefit under 35 U.S.C. §119(e) or other applicable patent law of U.S. Provisional Patent Application No. 63/592,274, filed October 17, 2023; U.S. Provisional Patent Application No. 63/592,286, filed October 17, 2023; and, U.S. Provisional Patent Application No. 63/592,293, filed October 17, 2023. The disclosures of each of the three foregoing provisional applications are incorporated by reference herein in their entireties for all purposes.

BACKGROUND OF THE INVENTION

[0003] Keloids and hypertrophic scars are representative of abnormally healing skin that is resistant to multiple surgical and non-surgical treatments. These abnormal, fibroproliferative scars exhibit aggressive dermal growth which can be painful and may cause undesirable cosmetic appearance of the skin, physical deformities, restriction of joint mobility, or other undesirable effects.

[0004] Intralesional cryotherapy has emerged as an effective treatment method for reducing the size of keloids and hypertrophic scars. Earlier treatment options involved topical application of a cryogen to the keloid mass, exposing only the surface of the keloid mass. These treatments did not reach the core of the keloid mass, were minimally effective, and required many rounds of treatments. Conversely, intralesional cryotherapy involves passing a very low temperature cryogen fluid, typically liquid nitrogen, through a specially designed needle assembly (referred to herein as a cryoneedle) that has been injected into or through the core of the scar tissue mass. Intralesional techniques treat the keloid mass from the inside out, exposing a much larger, internal volume of the mass to the freezing effect of the cryogen. Freezing leads to necrosis of the scar tissue, which reduces the overall size of the keloid as the area heals.

[0005] Cryoneedle assemblies implement certain design features making them suitable for use for intralesional cryotherapy. More specifically, cryoneedles comprise a component configuration that creates a flow path along the length of the cryoneedle for the cryogen fluid to pass through. Received cryogen is routed through the cryoneedle assembly while it is inserted within the keloid mass, then is expelled from the cryoneedle via an exhaust port of the cryoneedle disposed at a location that is kept external to the patient's body.

[0006] Existing cryoneedle designs implement a two-tube assembly for creating the desired flowpath. The first tube is an inner lumen comprising an open-ended channel through which cryogen fluid from a cryogen source is received and routed. The inner lumen tube is encapsulated within an outer sheath comprising a longer and diametrically wider tube than that of the inner lumen. The outer sheath is closed at its far end to form a sharp tip used to insert the cryoneedle assemble into and through the keloid mass. The outer sheath has an exhaust port at the end opposite the sharp tip through which spent cryogen is expelled into the surrounding environment. This arrangement creates a cryogen flow along the length of the inner lumen to the tip of the outer sheath, then back along the length of the outer sheath to the exhaust port. This known cryoneedle design and operation is described and shown in U.S. Patent No. 6,503,246 to Har-Shai. There has been insubstantial improvement to cryoneedle design since Har-Shai.

[0007] Several problems exist with prior art cryoneedles. First, existing designs create a risk of exposing a patient's healthy tissue to cryogen fluid and unintended freezing from cryogen fluid leaving the exhaust port and can cause unsafe exposure to cryogen that has been exhausted into the surgical environment. Second, existing designs cause uneven cooling along the working length of the cryoneedle assembly, leads to inefficient cryogen use, and causes points of frozen buildups within and around the cryoneedle that require pauses during the cryotherapy to eliminate. Each of the foregoing has the undesirable effect of reducing the effectiveness of the treatment and wasteful, inefficient use of cryogen. Third, prior art cryoneedles are unwieldy and difficult for physicians to place and manipulate due to their non-ergonomic designs. Finally, prior art cryoneedles are devoid of safeguards to prevent their re-use by physicians to perform multiple cryotherapy procedures, in violation of FDA single-use guidelines. Cryoneedle re-use creates a risk of infection to patients that would not exist otherwise.

[0008] Improvements are presented in the various embodiments disclosed herein to address one or more of these problems. In some embodiments, improvements are implemented with the

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

[0009] Several improvements to existing cryoneedle assembly designs are presented in the various embodiments 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

when not held in place by a latch protrusion engaging a flange. An end of the latch protrusion may extend into an opening for receiving the one or more posts upon assembly of the cryoneedle components. In such embodiments, upon coupling, interference from the post may cause the latch protrusion to deform and disengage, permitting the movable sleeve insert to move to its second orientation. While in its second orientation, portions of the movable sleeve insert may fill the one or more openings of the needle attachment to prevent reattachment of the needle attachment to the handle, once removed.

[0012] According to certain alternative embodiments, a cryoneedle may be implemented with an inner lumen comprising an elongated tube having plurality of apertures through the surface of the inner lumen along some or all its length for venting cryogen fluid into the outer sheath. In varying embodiments, the apertures may comprise a circular cross section, an oval cross section, an elongated, substantially rectangular cross section, or other shape. The apertures may be disposed at various orientations around the circumference of the tube structure comprising the inner lumen.

[0013] According to further alternative embodiments, a cryoneedle may be implemented with an outer sheath comprising an elongated tube comprising a sharpened, trocar tip usable to penetrate into and through keloid tissue. The trocar tip may comprise a hollow body or a solid body, and may be affixed to the outer sheath at its distal end. The trocar tip may form a block at the distal end of the outer sheath to limit cryogen fluid flow and insulate the distal portion of the trocar tip from freezing during use. Additionally, or alternatively, the outer sheath may be implemented with one or more ridge features disposed along its outer surface near its closed, distal end. The one or more ridges may trap excised tissue during use of the cryoneedle and thereby militate against the likelihood of re-use of at least a needle attachment comprising the outer sheath.

[0014] In addition to the foregoing, methods for using the improved cryoneedle embodiments disclosed herein to perform interlesional cryotherapy procedures are presented. According to one exemplary method, a cryoneedle is assembled by coupling a housing assembly to a needle attachment. A portion of the cryoneedle assembly comprising an outer sheath surrounding an inner lumen is inserted into the affected tissue of a patient. A supply of cryogen fluid is connected to the cryoneedle along with an exhaust line. Cryogen fluid is routed through the cryoneedle for sufficient time to cause freezing of the affected tissue in contact with and proximal to the outer sheath, at which time the cryogen fluid flow is stopped and the supply is removed. The needle attachment may be removed from the patient's body, detached from the handle, and discarded. Alternative

methods of use may involve performance of additional or different steps for performing interlesional cryotherapy procedures using cryoneedles according to the many novel embodiments disclosed herein.

[0015] Informed by the following detailed description of certain exemplary embodiments, a person of ordinary skill in the art will readily appreciate that various modifications to the embodiments disclosed are contemplated and may be implemented within a cryoneedle assembly while remaining within the spirit and scope of this disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] For a more complete understanding of the present invention and the advantages thereof, reference is now made to the following Detailed Description taken in conjunction with the accompanying drawings, in which:

Figure 1 is an isometric view of an exemplary embodiment of a cryoneedle 10;

Figure 2A is a partial section view of exemplary cryoneedle 10 showing handle 100, along section A-A of Fig. 1;

Figure 2B is a partial section view of exemplary cryoneedle 10, along section A-A of Fig. 1;

Figure 2C is a section view of exemplary cryoneedle 10, along section B-B of Fig. 1;

Figure 3 is an isometric view of a manifold 110 within the exemplary cryoneedle 10;

Figure 4 is an isometric view of a needle attachment 200 of exemplary cryoneedle 10;

Figure 5A is a section view of needle attachment 200 of exemplary cryoneedle 10, along section A-A of Fig. 4;

Figure 5B is a section view of needle attachment 200 of exemplary cryoneedle 10, along section B-B of Fig. 4;

Figure 6 is an exploded view of needle attachment 200 of exemplary cryoneedle 10;

Figure 7A is an isometric view of needle attachment 200 of exemplary cryoneedle 10, according to its unused configuration;

Figure 7B is an isometric view of needle attachment 200 of exemplary cryoneedle 10, according to its configuration after use;

Figure 8 is a partial section view of exemplary cryoneedle 10, at detachment of the needle attachment 200 from handle 100, along section A-A of Fig. 1;

Figure 9A is a side view of an inner lumen 280 of exemplary cryoneedle 10;

Figure 9B is a section view of inner lumen 280 of exemplary cryoneedle 10, along section A-A of Fig. 9A;

Figure 9C is a detail view 'A' of inner lumen 280 of Fig. 9A;

Figure 10A is a view of an outer sheath 220 of exemplary cryoneedle 10;

Figure 10B is a section view of outer sheath 220 of exemplary cryoneedle 10, along section A-A of Fig. 10A;

Figure 10C is detail view 'A' of outer sheath 220 of Fig. 10A;

Figure 10D is detail view of outer sheath 220 of Fig. 10B; and,

Figure 11 is a flowchart of an exemplary method of using exemplary cryoneedle 10 to perform intralesional cryotherapy on a keloid.

DETAILED DESCRIPTION

[0017] The embodiments disclosed herein are presented as illustrative examples for the purpose of describing various aspects of the inventions disclosed. They are not exhaustive of every embodiment contemplated which could embody or practice the inventions disclosed. Accordingly, they should not be understood as limiting in nature. A wide range of variations, modifications, changes, and substitutions are contemplated. Many such variations and modifications may be considered desirable by those skilled in the art based upon a review of the following description of certain preferred embodiments. Accordingly, it is appropriate that the appended claims be construed broadly in a manner consistent with the scope of the invention.

[0018] **Figure 1** presents an isometric view of an exemplary embodiment of a cryoneedle 10 which may implement one or more of the innovations disclosed herein. According to the embodiment shown, cryoneedle 10 may comprise a handle 100 and a needle attachment 200. The handle 100 may comprise a generally L-shaped outer housing, as shown, to facilitate ease of handling, use, and manipulation of the cryoneedle 10 by a physician to perform intralesional cryotherapy. A person of ordinary skill in the art will appreciate that alternative ergonomic outer housing shapes and configurations of the handle 100 could be implemented.

[0019] In certain embodiments, handle 100 may be implemented with connections for receiving and coupling to one or more conduits for fluid flow. Such connections may comprise one or both of a cryogen supply line and an exhaust line. Further, such connections may be disposed internal

or external to the body of handle 100. According to the present embodiment, as best shown in **Figures 2A-2C**, the handle 100 may comprise internal connection ports 112, 114 for coupling to each of a supply line 102 and an exhaust line 104, respectively, disposed within an outer housing 106 of the handle 100. Supply line 102 may connect to a source of cryogen fluid and route the cryogen fluid to cryoneedle 10 for use in performance of intralesional cryotherapy. Spent cryogen fluid may be expelled from the cryoneedle 10 via the exhaust line 104 may be used to vent spent cryogen fluid from cryoneedle 10 following its use.

[0020] As shown, the connection ports 112, 114 for supply line 102 and exhaust line 104 may comprise barbed fittings for press-on tube connections. Connection ports 112, 114 may accommodate detachable coupling to the supply line 102 and/or exhaust line 104. In alternative embodiments, different connection means may be utilized, including interference fittings, threaded fittings, quick disconnects, compression fittings, or other known connection types suitable for use with cryogen fluids. In some embodiments, the connection ports may comprise a circular cross-section. Alternatively, different cross-sectional geometries may be implemented.

[0021] As shown, handle 100 further comprises a housing 106 which may define a volume and overall shape of the handle 100 to be substantially “L” shaped. According to this embodiment, connection ports 112, 114 are internal to the handle 100 and disposed within the substantially horizontally extending portion of the housing 100. In alternative embodiments comprising internally housed connections, the connection ports 112, 114 may be disposed at different locations within the handle 100, such as in substantially vertically extended section comprising its “L” shape.

[0022] As shown, connection ports 112, 114 comprise integral features of a manifold 110 within handle 100, best shown in **Figure 2A and Figure 3**. According to this embodiment, manifold 110 may be substantially vertically oriented, may abut one or more internal walls or support structures of housing 106, and may comprise a cross-sectional shape substantially coincident with that of housing 106, which may be substantially circular or disk-shaped. In an embodiment, manifold 110 may comprise any structure, position, orientation, and/or surface features suitable to accommodate connecting a supply and/or exhaust line, such as supply line 102 and exhaust line 104, to internal components of the cryoneedle 10.

[0023] According to the embodiment shown, manifold 110 may comprise a barbed connection port 112, extending outward and away from the main body of manifold 110 toward the rear of

handle 100. Connection port 112 may be centrally located with respect to the substantially circular cross-section of manifold 110. Manifold 110 may further be implemented with an additional coupling along its opposite, forward-facing surface that may align with the location of connection port 112. As shown, this forwardly extending coupling may comprise a cylindrically shaped, open-ended collar 116. Collar 116 may be configured to receive within it, and thereby connect to, an internal structure of the cryoneedle, such as the connector port 262 of needle attachment 200, shown in Figs. 2B, 2C, and Fig. 6. According to the configuration shown, collar 116 may accommodate a sealed, interference fit between its circular, inner wall surface and the connection port 262 and gasket 264. By doing so, connection port 112 and collar 116 of manifold 110 operate as an intermediary for placing the needle attachment 200 components of the cryoneedle 10 in fluid communication with supply line 102 for receipt of cryogen fluid during use.

[0024] In some embodiments, including the one shown, manifold 110 additionally comprises a second rearward facing connection port 114 for coupling to the exhaust line 104. Connection port 114 may comprise a barbed connection extending outward and away from the main body of manifold 110 toward the rear of handle 100. Connection port 114 may be disposed vertically adjacent to connection port 112 with respect to the substantially circular cross-section of manifold 110.

[0025] During cryotherapy procedures, the cryogen fluid source is sufficiently cooled such that it is supplied in its liquid state. The cryogen fluid warms and evaporates during cryotherapy whereby expelled cryogen is typically in a completely gaseous state. Accordingly, in certain embodiments, including the one shown, manifold 110 may not be implemented with a separate coupling opposite the connection port 114 on its forward-facing surface for directing a flow of spent cryogen from the system. Instead, the cryogen fluid will expand as it warms in ambient conditions. This expansion induces free-flow egress of cryogen from the outer sheath 220 to within the internal volume created by the coupled cap 210 and housing 106, before exiting through the opening provided at connection port 114 into exhaust line 104. Connection port 114 may provide the only opening for venting cryogen fluid from the coupled cap 210 and housing 106 due to the presence of annular interference fit between outer surface 120 of the manifold 110 and the inner surface of housing 106 creating an otherwise sealed internal volume.

[0026] In some embodiments, manifold 110 may comprise one or more posts, for example the two posts 118 shown in Fig. 3, extending outward from the surface of manifold 110 opposite from

connection ports 112, 114. As shown, posts 118 may comprise raised structures disposed adjacent to collar 116 and protruding outward from the disk-shaped, vertically oriented body of manifold 110. Posts 118 may protrude out farther from the body of manifold 110 than the circular wall structure forming collar 116. As shown, post 118 may comprise a crescent-like cross-section. In alternative embodiments, additional or fewer posts, or other structures, may be present. Further, such structures may comprise sizes, shapes, and locations differing from that shown, to include, for example, protrusions having square, oval, circular, or other shapes that may have greater or less depth than posts 118. Regardless, in embodiments including these or similar alignment features, at least one such alignment feature may be configured with a suitable size, shape, and location to cause it to engage a corresponding feature of the needle attachment 200 when the handle 100 and needle attachment 200 are coupled to one another. By way of example, in the embodiment shown, post 118 may be configured to engage a latch 238 of sleeve insert 230 (best shown in **Figures 6 and 7**) when cryoneedle 10 is assembled.

[0027] As described above, in some embodiments, housing 106 and manifold 110 are permanently affixed to one another via adhesives, fasteners, welding, or any known coupling means suitable for withstanding exposure to cryogen fluids. Alternatively, housing 106 and manifold 110 are integrally formed as a one-piece assembly. In further alternative embodiments, housing 106 and manifold 110 are detachably coupled to one another via an interference fit, removable fasteners, or other suitable coupling method.

[0028] In some embodiments, including that shown in Fig. 2A, housing 106 may be implemented with one or more couplings disposed at or near its forwardmost edge which may provide means for coupling handle 100 to needle attachment 200. As shown in the embodiment of Figs. 2A and 2B, housing 106 may comprise hook-shaped retaining lips 122, 124 protruding outward from the forwardmost edge of housing 106. In alternative embodiments, additional, fewer, or different couplings may be implemented and may have different sizes, shapes, or locations than those shown.

[0029] Turning to **Figures 4-6**, in an embodiment, cryoneedle 10 may comprise a needle attachment 200 which may be configured to permit detachable coupling to and subsequent removal from handle 100. As shown, needle attachment 200 may comprise a cover 210 which may comprise one or more couplings 214; an outer sheath 220 comprising an elongated, hollow tube structure with a closed, sharp end 226; a sleeve insert 230 configured to rotate from a first to a second

orientation; an internal frame 250; and, tube gland 260 affixed to an inner lumen 280 comprising an elongated, hollow tube structure having one or more openings through it. Alternative embodiments may comprise additional, fewer, or different components than those shown. Further, in an embodiment, one or more components shown may be integrated with one or more other components to form a single, combined structure.

[0030] In operation, needle attachment 200 may accommodate receipt of supply cryogen through one or more connections to supply line 102 via manifold 110, and the flow of cryogen fluid through the inner lumen 280 and outer sheath 220 while coupled to handle 100 during use. According to the exemplary embodiment of Figs. 4-6, cryoneedle 10 may comprise a component configuration suitable for discouraging or preventing re-use of the needle attachment 200 following its first attachment to handle 100 and use to perform an intralesional cryotherapy procedure.

[0031] In certain embodiments, the cryoneedle 10 may comprise a two-piece design in which needle attachment 200 may be attachable to, and removable from, handle 100. According to the particular embodiment shown in Fig. 5A, cap 210 may comprise one or more couplings along its rearward facing edge for this purpose. As shown, these couplings may comprise one or more hook-shaped retaining lips 214. As shown best in Fig. 2B, retaining lip 214 may comprise a size, shape, location, and orientation suitable for engaging with and affixing to corresponding retaining lip 124 of handle 100 upon the needle attachment 200 being pressed into and received within the handle 100. According to the embodiment shown, these components may be disassembled via application of pinching force to the cap 210 on its sides, which will cause outward deflection in the areas proximal to retaining lips 214 and disengagement. In alternative two-piece embodiments, additional, fewer, or different couplings than those shown may be implemented.

[0032] As discussed above, according to the embodiment shown, coupling of the needle attachment 200 to handle 100 may cause insertion of connector port 262 (shown in Figs. 2B, 2C, and Fig. 6) into collar 116 to form a sealed connection around gasket 264. Gasket 264 may comprise an O-ring and may be made using rubber, PTFE, Nitrile, Neoprene, and/or Fluorocarbon, or other similar suitable material. This connection may cause inner lumen 280 to be in fluid communication with supply line 102 via sealed connections at connection port 112 and collar 116, whereby cryogen fluid may be routed through the cryoneedle 10 upon assembly to perform intralesional cryotherapy.

[0033] In some embodiments, including the embodiment shown in Fig. 6, tube gland 260 is included, and comprises a sleeve 274 along the axial length of tube gland 260. As shown, sleeve 274 of tube gland 260 may have a substantially cylindrical shape that may enclose a channel extending through the entire axial length of tube gland 260. An inner lumen 280 comprising an elongated, hollow tube which may be affixed along a portion of its outer surface to the interior channel formed by sleeve 274 of tube gland 260. In some embodiments, sleeve 274 may shield the inner lumen 280 and strengthen its resistance to deformation under stress. The sleeve 274 may additionally operate as an alignment aid securing inner lumen 280 in a desired position and orientation.

[0034] In some embodiments, the tube gland 260 and inner lumen 280 may be configured to co-terminate at, or adjacent to, the connection port 262. This co-planar termination may facilitate the simultaneous disengagement of the coupling of the inner lumen 280 and tube gland 260 from collar 116 upon disassembly of cryoneedle 10. The placement of gasket 264 may prevent escape of cryogen fluid that may otherwise result from an imperfect coupling of connection port 262 and inner lumen 280 to the collar 116 while cryoneedle 10 is in use.

[0035] As shown in the embodiment of Fig. 6, sleeve 274 may be disposed within a circular channel through the entire axial length of sleeve insert 230, which in turn may be disposed within a central channel passing through the entire length of internal frame 250. Internal frame 250 may, in turn, be fixedly restrained in a desired orientation and position within cap 210 via engagement of alignment tabs 218 of cap 210 by groove 258 of internal frame 250, as best shown in Figs. 6-8. According to this nested configuration, each of these needle attachment 200 structures may aid in securing inner lumen 280 in a fixed position within the needle attachment 200. These components may work in concert to secure inner lumen 280 in a preferred position and orientation with respect to outer sheath 220.

[0036] The position and orientation of outer sheath 220 may, likewise, be fixed. As shown in the embodiment of Figure 5B, for example, outer sheath 220 may be fixedly attached to cap 210 at a coupling forming a collar 212 extending into and through the forward-facing surface of cap 210. The size, position, and orientation of collar 212 may be suitable for contacting and tightly encircling outer sheath 220 along the portion of its outer surface disposed within collar 212. The connection may be sealed via overmold inserted along and around the contact area between outer sheath 220 and collar 212.

[0037] As shown, outer sheath 220 may comprise an elongated, hollow tube structure. Alternatively, outer sheath 220 may be implemented with an oval-shaped cross-section, a square-shaped cross-section, or other cross-sectional geometry known in the art. Outer sheath 220 may extend outward and away from the handle 100 of cryoneedle 10 and may comprise a closed or otherwise blocked distal end. Outer sheath 220 may be manufactured out of stainless steel, carbon steel, titanium, silicon, polymers, or any other material approved for use to perform intralesional cryotherapy known by those skilled in the art. Similarly, inner lumen 280 may likewise be manufactured from any of the foregoing materials.

[0038] In some embodiments, the inner lumen 280 and outer sheath 220 may be oriented in a substantially concentric configuration. Outer sheath 220 may comprise inner dimensions sufficiently large to permit it to completely surround and encapsulate the portion of inner lumen 280 extending outward beyond the forward-facing surface of cap 210. It is along this outwardly extended portion of its length that one or more openings through the surface of inner lumen 280 may be present. Alternatively, inner lumen 280 may comprise an open distal end with or without any additional openings along its length. In some embodiments, a distal end of the inner lumen 280 terminates near to the distal end of the outer sheath 220.

[0039] In operation, the relative sizing and placement of inner lumen 280 and outer sheath 220 may create a cavity between the outer surface of inner lumen 280 and the inner surface of outer sheath 220. Inner lumen 280 is operatively connected to receive supply cryogen fluid and to route it along its length. Cryogen fluid escapes from inner lumen 280 through one or more openings into the cavity formed between the outer surface of inner lumen 280 and the inside of outer sheath 220. The cryogen fluid is sufficiently cooled to effect freezing in the area in contact with and proximal to the external surface of the outer sheath 220. Accordingly, when inserted into a keloid or other afflicted tissue of a patient, cryogen fluid flowing through cryoneedle 10 may induce freezing and necrosis of the surrounding tissue near the outer sheath 220.

[0040] The efficiency, safety, and therapeutic effect of intralesional cryotherapy can be further improved through adoption of certain innovative features of the inner lumen 280 and the outer sheath 220, in accordance with exemplary embodiments disclosed below.

[0041] According to the embodiment shown in **Figures 9A-C**, inner lumen 280 may be implemented with one or more apertures 286 disposed along a portion of its length. As shown, for example, inner lumen 280 may be implemented with a series of apertures 286 disposed near its

distal end 284 and spanning a portion of its length back toward its proximal end 282. Apertures 286 may additionally be disposed at several orientations around the circumference of inner lumen 286, as shown in the embodiment of Fig. 9B. In an exemplary embodiment, apertures may comprise an elongated slit shape, as shown in Fig. 9C, providing openings for cryogen fluid to exit the inner channel 288 of inner lumen 280.

[0042] According to the particular embodiment shown, inner lumen 280 may comprise a hollow tube having a circular cross section and a closed distal end 284. Inner lumen 280 may comprise a series of three slit shaped apertures at each of three different orientations, evenly spaced from one another about the circumference of inner lumen 280. The apertures may each comprise approximately 0.012" tall by 0.1" wide slits, separated from one another by 0.25" of linear distance and/or 120 degrees of the cross-sectional circumference.

[0043] Using an inner lumen with the foregoing aperture pattern has been shown to cut the time needed to cool the external surface of an outer sheath to -40C by more than half in free-flow testing. Additionally, thermal testing showed near uniform cooling along the length of the outer sheath. Conversely, inner lumen designs comprising an open distal end with no apertures along the length of the inner lumen exhibited highly localized cooling at a location corresponding to the distal end of the inner lumen. Similar testing was conducted on raw poultry. The inner lumen 280 according to Fig. 9 was found to cause freezing of the poultry along the entire length of the portion of the outer sheath injected into the poultry over two minutes faster than accomplished using a prior art cryoneedle design. Additionally, the zone of frozen tissue that resulted from use of the improved design disclosed herein reached farther into the tissue and exhibited near uniform freezing effectiveness across the entire working length of the outer sheath.

[0044] In alternative embodiments of an improved inner lumen, the inner lumen 280 may be implemented with more or less apertures 286 than shown, which may be disposed over a shorter, greater, or different span along the length of inner lumen 280 than shown. Additionally, or alternatively, apertures 286 may comprise a different shape than shown, such as circular, oval, or other geometric shape. Apertures 286 may differ in size or shape from that shown, and may be of uniform or differing sizes along the length of inner lumen 280. In some embodiments, the plurality of apertures 286 may be circular in shape and may increase in diameter for those disposed farther along the length of the inner lumen 286. This gradient may allow for the flow of cryogen fluid to be substantially uniform along the length of the inner lumen 280.

[0045] In additional embodiments, the inner lumen 280 may terminate further from the distal end of the outer sheath 220. Inner lumen 280 may terminate having its distal end 284 flatly sealed, resembling the end of a cylinder, but may also terminate by having its distal end 284 come to a point, resembling a needle. In yet another embodiment, the inner lumen 280 may terminate with its distal end 284 open, further allowing cryogen fluid to escape. Other shapes and configurations will be known to those skilled in the art. Additional embodiments may comprise apertures 286 comprising slits that may spiral along the length and around the circumference of inner lumen 280.

[0046] When implemented, the inner lumen 280 according to these improved configurations may permit greater cryogen fluid flow through it into the outer sheath 220. Other improvements include a reduced likelihood of components within the cryoneedle freezing during use, thereby allowing the cryoneedle to achieve a lower temperature and more evenly distributed cooling effect. Both outcomes increase the effectiveness of intralesional cryotherapy treatment. Reducing the likelihood of components within the cryoneedle freezing also reduces the risk of a significant decline in performance or complete failure of the cryoneedle, which may result in directly exposing the patient's skin to cryogen fluid. In addition, cryotherapy may take less time to complete as time is no longer wasted waiting for a frozen cryoneedle to unfreeze to permit removal and reinsertion during ongoing treatment.

[0047] Additionally, or alternatively, improvements to the prior art outer sheath design in the manners disclosed herein may provide further advantages. Referring to **Figures 10A-D**, for example, in an embodiment, an improved outer sheath 220 may comprise a proximal end 222 and a closed distal end comprising a solid sharp tip 226. Sharp tip 226 may be manufactured from stainless steel, carbon steel, titanium, silicon, polymers, and other materials known by those skilled in the art. Sharp tip 226 may be made using thermally resistant materials, such as nickel-based alloys, and may further comprise thermally resistant coatings known to those skilled in the art.

[0048] As shown, sharp tip 226 may comprise a trocar configuration. A freezing zone 224 may be disposed along a portion of the outer sheath 220 length. In operation, the solid body configuration of the trocar tip end 226 may operate to block cryogen fluid flow and effectively insulate the tip 226 to reduce or eliminate the incidence of it freezing during use.

[0049] These improved features may have several advantages. A “freeze ball” would routinely develop at the distal tip of prior art outer sheaths during use, requiring that the cryotherapy

procedure be halted to allow the freeze ball to thaw before cryoneedle extraction and replacement. This waste of time and resources is avoided using the improved outer sheath 220 disclosed herein.

[0050] Outer sheath 220 may additionally comprise one or more external ridge features 228 near its sharp tip 226. Ridge features 228 may cause tissue build up to collect on the surface of outer sheath 220, rendering outer sheath 220 more difficult to sanitize and therefore less likely to be re-used. Avoiding re-use eliminates certain risks to the patient of infection.

[0051] As shown, the outer sheath 220 does not comprise an opening through it for expelling spend cryogen fluid. In alternative embodiment, the outer sheath 220 may be implemented with an exhaust port for this purpose disposed near its proximal end 222.

[0052] In certain embodiments, cryoneedle 10 can be further improved by implementing it with a component configuration preventing re-use of needle attachment 200 to perform more than a single intralesional cryotherapy procedure. As shown in the particular embodiment of **Figures 6-8**, components comprising needle attachment 200 may be configured such that the needle attachment 200 may transition from a “new” state to a “used” state upon detachment from handle 100. Following this transition, needle attachment 200 may comprise a changed component configuration that physically prevents subsequent re-attachment of needle attachment 200 to a handle 100.

[0053] The “new” state is depicted in the view shown in Figure 7A. In this configuration, a circular flange 266 of tube gland 260 is shown. According to this embodiment, circular flange 266 is disposed within a circular opening 252 disposed at the rear-most section of internal frame 250. Circular flange 266 may be held in the position and orientation shown via alignment features of internal frame 250, which may include an annular ridge abutting circular flange 266. Circular flange may comprise cutout sections 268 disposed on opposite sides and passing completely through the body of circular flange 266 to form openings. The openings formed by cutout sections 268 may permit access to the internal volume comprising an oval shaped section 254 of internal frame 250. Such access may only be available while the needle attachment 200 remains in the “new” state, as shown in Fig. 7A.

[0054] While in the “new” state, latch connector 238 may be visible through one of the cutout sections 268. Latch connector 238 may comprise a deformable protrusion having a hook shape at its end. This is best shown in Figure 6. Also best shown in Figure 6 are recesses 234 of sleeve insert 230. Latch connector 238 may be disposed such that it occupies a portion of the volume

within one of the recesses 234. Further, as shown, recesses 234 may be in a rotational orientation when needle attachment is in its “new” state such that their positions are substantially coincident with those of cutout sections 268 of flange 266.

[0055] When in this relative positioning, latch connector 238 may engage a notch 272 disposed along the inward facing surface of flange 266 immediately adjacent to a cutout section 268. The hook connection between these components fixes the orientation of sleeve insert 230 relative to tube gland 260 to maintain the configuration shown in Fig. 7A.

[0056] This relative positioning may be maintained until the exemplary cryoneedle 10 is assembly via coupling needle attachment 200 to handle 100. When so coupled, a post 118 within handle 100 may engage latch connection 238 at its forward extended surface, which may protrude deep enough into the inner volume of handle 100 to cause latch connection 238 to deform and lose contact with notch 272. As shown in Figure 6, a torsion spring 242 may be disposed along an internal surface of sleeve insert 230 and may be configured to cause rotation of sleeve insert 230 by approximately a quarter turn about its longitudinal axis when insert sleeve is not being held in its first position by latch connector 238 engaging notch 272. According to this exemplary embodiment, therefore, upon subsequent detachment of needle attachment 200 from handle 100, sleeve insert 230 will rotate and place needle attachment in its “used” state, shown in Fig. 7B.

[0057] When in its “used” state, access to the internal volume of oval shaped section 254 of internal frame 250 may be physically blocked by portions of the insert sleeve 230. Accordingly, “used” needle attachment 200 may be incapable of being inserted into handle 100 sufficiently far for coupling. Interference between the forward edges of posts 118 with portions of the sleeve insert 230 may prevent coupling and creation of a sealed connection at collar 116 for receipt of cryogen fluid by the needle attachment 200. As such, the “used” needle attachment 200 is rendered unusable and may be discarded and replaced with a “new” needle attachment 200 before any further intralesional cryotherapy can be performed using cryoneedle 10.

[0058] Referring to **Figure 11**, in general, the foregoing concepts are applicable in the context of using cryoneedle 10 for performance of intralesional cryotherapy. According to one method for effecting such performance, at Step 1102, cryoneedle 10 may be assembled by coupling a needle attachment 200 with a handle 100. Upon coupling, an inner lumen 280 and outer sheath 220 may be operatively connected via the handle 100 to receive cryogen fluid from a source 102 upon it being connected to a connection port 112. At Step 1104, outer sheath 220 and inner lumen 280

may be partially inserted into or through the keloid tissue. At Step 1106, a cryogen fluid supply line may be connected to cryoneedle 10. According to certain exemplary methods of use, including the method shown in Fig. 11, an exhaust line 104 may additionally be connected to cryoneedle 10 in connection with Step 1106. Alternatively, cryoneedle 10 may be used in accordance with a method in which only a cryogen source is connected to cryoneedle 10, or in which one or more of the cryogen supply and exhaust connection(s) to cryoneedle 10 are made at connection ports of cryoneedle 10 disposed in locations other than at or within a handle 100.

[0059] At Steps 1108 and 1110, a cryogen fluid flow through cryoneedle 10 may be initiated to cause freezing of the volume of the keloid in contact with or near the portion of the outer sheath inserted into the keloid. Once freezing is complete, at Step 1112 the cryoneedle is disassembled by detaching needle attachment 200 from handle 100. At Step 1114, detached needle attachment 200 may be discarded and handle 100 sterilized. In alternative methods for use of cryoneedle 10, one or more of the foregoing Steps may be omitted, or may be performed in a different order than shown in Fig. 11. For example, in alternative embodiments, Steps 1102, 1104, and 1106 may be performed in any sequence while remaining within the scope of the present disclosure. Alternatively, in an embodiment, Step 1114 may partially or completely omitted, such as, for example, in instances in which the cryoneedle 10 is not implemented with a component configuration preventing re-use of needle attachment 200.

[0060] Those skilled in the art will recognize that further modifications, alterations, and substitutions to the embodiments shown and described will be necessary for certain implementations. Such modifications, alterations, and substitutions are within the scope of the present invention. While various preferred embodiments have been shown and described, it will be understood that there is no intent to limit the invention by such disclosure, but rather, it is intended to cover all modifications and alternate constructions falling within the spirit and scope of the invention. Applicant is entitled to claim all subject matter falling within the spirit and scope of the invention.

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.

22. A method for performing intralesional cryotherapy, comprising:

assembling a cryoneedle by coupling a re-usable housing to a needle attachment, wherein the needle attachment is operable for use to perform only one intralesional cryotherapy procedure;

inserting at least a portion of an outer sheath and inner lumen of the needle attachment into a keloid mass;

connecting a cryogen fluid supply to a first connection of the housing;

connecting an exhaust line to a second connection of the housing;
causing cryogen fluid to flow through the cryoneedle assembly until effect freezing of the keloid mass in the area in contact with and proximal to the portion of the outer sheath inserted into the keloid mass occurs;

ceasing the flow of cryogen fluid;

disconnecting the first and second connections;

removing the needle attachment from the keloid mass;

disassembling the cryoneedle by de-coupling the needle attachment from the housing; and,

discarding the needle attachment.

23. The method of Claim 22, wherein the needle attachment comprises an inner lumen having a plurality of openings through its axial surface and disposed along its length through which cryogen fluid exits the inner lumen.

24. The method of Claim 23, wherein the plurality of openings through the axial surface of the inner lumen comprise an elongated oval shape.

25. The method of Claim 24, further comprising:

wherein the needle attachment comprises an outer sheath further comprising a tip attachment forming the sharp point having a trocar configuration at the distal end of the needle attachment away from the handle; and,

using the sharp point of the tip attachment to penetrate the keloid mass to insert at least a portion of an outer sheath and inner lumen of the needle attachment into the keloid mass.

26. The method of Claim 24, further comprising:

wherein the tip attachment is solid body permanently affixed to the outer sheath;

wherein the end of the tip attachment nearest to the handle blocks cryogen fluid flow; and,

insulating the tip attachment from exposure to the cryogen fluid while cryogen fluid is flowing through the cryoneedle assembly.