shown to be safe and effective, even in the hands of low-level health care workers, the equipment is not necessarily suitable to be widely dispersed. Indeed, cryotherapy tools can be expensive, technically complex, lacking portability, and difficult to repair in the field.

Currently, the developing world utilizes cryoguns, see, for example, USPN 4,377,168 which discloses expanding pressurized CO_2 (or N_20 in some instances when a country or program can afford the added expense of the N_20) against a thermally conductive tip. The expansion of the CO2 in this closed system creates a temperature of approximately -50 to -70 degrees C on the surface of the tip which is in contact with a lesion. Meanwhile, the industrialized world also utilizes cryoguns, but they are of a very different nature; see USPPNs 2008/0119839 and 2013/0079761. These disclose much more complex and costly devices that, for example, continually circulate a cryogenic liquid that is never allowed to reach a temperature where it solidifies or freezes and becomes anything like a spray of cryogenic snow.

With carbonated beverage manufacturers being widely dispersed in the developing world, and often using carbon dioxide to produce their carbonated beverages, carbon dioxide manufacturers are also widely dispersed in the developing world. This has led to cryoablation being conducted with carbon dioxide as the primary source of coolant.

The current design of cryotherapy tools suffers from several flaws when utilized with carbon dioxide tanks, including: water vapor leaving the tank causes tip blockages, non-medical grade carbon dioxide may have particulates, which cause tip blockages, and a pressure drop may occur in the cylinder through the cooling process during extended use which results in warmer and less effective tip temperatures.

Additionally, the equipment was never originally designed for use within the extreme conditions of the developing world where there are high volumes of ablations along with environmental abuse of the product. First, the tips on the current cryotherapy tools are manufactured with gold or chrome plating, which not only makes the tip expensive, at approximately three hundred dollars per tip, but these tips also suffer from corrosion from the chlorine disinfection method - the widely available method for sterilization in the developing world.

Improper cleaning and storage of these tips also leads to clogs, requiring replacement. Additionally, the overall cost of the equipment is around thirteen hundred to two thousand dollars per device. Moreover, with the complexity of this equipment's engineering design, there is a lack of repair knowledge and backup parts

when the equipment breaks down. Unfortunately, when the cryotherapy equipment malfunctions in the field, the device becomes unused and is rarely capable of being easily fixed.

Finally, the amount of carbon dioxide required per treatment limits the portability of the device. A tank containing 22.7 kg of CO_2, weighs approximately 72.6 kg total, and treats only about 10 to 15 patients. These large tanks are therefore difficult to transport to the rural areas where women need to be screened and treated, either in the context of health centers, mobile health vehicles or organized screen & treat camps. Therefore, these characteristics of current cryotherapy equipment prohibit its massive scale-up for widespread impact on reducing the burden of cervical cancer.

It would therefore be advantageous to provide a device and method that could safely, effectively, and in a low-cost manner treat, destroy or ablate cervical, precancerous lesions in order to prevent cervical cancer.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Before explaining at least one embodiment of the present invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and to the arrangements of the components or elements set forth in the following description or illustrated in the drawings. This invention is capable of being practiced and carried out in various ways. Therefore, it is to be understood that the present invention is not to be limited to the specific embodiment disclosed herein, and that its many variants are intended to be included within the scope of the appended claims. Also, it is to be understood that the phraseology and terminology employed herein are for the purpose of description and should not be regarded as limiting. In the accompanying drawings, like numbers refer to like elements throughout.

A preferred embodiment in accordance with the present invention 1 provides an apparatus or device and method that utilizes cryotherapy to treat, destroy or ablate a patient's abnormal tissues or lesions, e.g., for the ablation of cervical, precancerous lesions for the prevention of cervical cancer. The device includes an auxiliary piping assembly 10 that is configured to be connected to the typically horizontally-directed outlet of a pressurized, carbon dioxide tank in the bottom of which resides liquid carbon dioxide, CO_2, or other suitable fluid that freezes at a comparatively low temperature (i.e., a low-temperature liquid).

The purpose of this piping assembly and its configuration is adapted to yield the proper flow conditions for the beginning of the creation of the CO_2 snow from the distal end of the piping assembly when the pressurized tank of carbon dioxide is allowed to exhaust through the piping assembly at operating pressures in the range of 52.7-59.8 kg/cm^2 and the CO_2 freezes as it exits the assembly. See US Patent Number (USPN) 6,543,251 and European Patent Number (EP) 1,046,614B1 for background technology related to the creation of CO_2 snow. One variant for the configuration of this piping assembly 10 includes a distal end 12 that has an adapter 14 which allows the piping assembly to be connected and firmly affixed to the tank's outlet 2, while also reducing the diameter of the pipe through which the exhaust is flowing. See

FIG. 1(a).

A pressure gauge **16** that is sized to measure and read pressures up to approximately 49.2 – 70.3 kg/cm^2 is included in this piping assembly so as to check to ensure that the tank pressure is adequate to support the creation of CO_2 snow. It also includes a valve **18** that regulates flow through the piping assembly, a ninety degree elbow **20** that is used to redirect the normal direction of the flow from the tank from being horizontal to vertical, and a proximal end **22** to which is attached a nozzle **24** whose outlet or orifice **24a** diameter is critical to the efficient operation of the piping assembly and it's on-demand, capability to begin the creation of CO_2 snow.

A preferred variant of this piping assembly's distal end has the diameter of the pipe to which the nozzle connects being 3.2mm and the diameter of the nozzle's orifice **24a** being in the range of 0.13-1.3mm, with a preferred value of 0.4mm. Downstream from this nozzle and its orifice **24a** is a snow horn **26** which has a boundary wall **26c** and a configuration adapted to create the final flow conditions for the collection of CO_2 snow having a desired density.

Alternatively, the snow horn has a configuration adapted to create the proper flow conditions at the snow horn's proximal end so as to enable a prescribed mass of the snow of a desired density to be collected in a specified period of time. See FIG. 1(b). This snow horn has a distal end **26a** that has a configuration that allows it to be locked to a comparable fitting (e.g., 1/8 inch NPT tap) on the proximal end **22** of the piping assembly. The proximal end **26b** of this snow horn has a special fitting or coupling **28** that allows for it to be easily connected to and disconnected from the distal end **34** of the device's applicator **30.** This coupling **28** is also configured as the element of the device which has the least structural strength. The purpose of this is to ensure that the device will break apart at this coupling during a situation in which an accident were to occur and an excess CO_2 pressure were to be applied to the device.

The CO_2 snow's desired density is chosen so that the mass of CO_2 snow collected is sufficient to provide the needed low temperature reservoir while also allowing the scale of the device to be such that it is appropriate for the desired

cryotherapy procedure. Experimentation has shown that a CO_2 snow density in the range of 0.5-0.7 g/cm^2 allows the required mass of snow to be in the range of 8-10g for a normal preventive, ablation of cervical, precancerous lesions procedure.

The present invention also includes a hollow, tubular applicator **30** which has proximal **32** and distal **34** ends. As its name implies, this part of the present invention is used by a health care provider to help precisely locate the point/s on a patient where the invention's cryotherapy will be applied. This applicator **30** has a configuration that is adapted to collect and temporarily store in its interior **36** and proximate its distal end the mass **6** of CO_2 snow that is required (i.e., sufficient to allow the mass of collected snow to serve as the low temperature thermal reservoir for the device after the applicator's distal end has been disconnected from the snow horn and the applicator's tip attached so the applicator and its tip together can be used to perform a cryotherapy ablation).

See FIG. 1(c). See also FIG. 2 which is an exploded, perspective view of the elements of the present invention that are shown in FIG. 1(c).

A flow-through fitting **40** is provided at the applicator's distal end that is configured to allow for, among other things, the attachment and detachment of the applicator's distal end to and from the coupling **28** on the distal end of the snow horn during the part of the process in which the applicator is filled with CO_2 snow. This same fitting **40,** upon being decoupled from the snow horn, is also configured to allow it to be used for attaching to the applicator's distal end an especially designed applicator cap or tip **50** which is the part of the device that actually comes into contact with a patient's body where it is desired to freeze and ablate targeted tissues or cells.

The proximal end **32** of the applicator has an opening **38** that allows access to the applicator's interior from this proximal end. This opening allows for a base **66** at the distal **64** end of a retractable, push rod **60** to be inserted to different distances into the applicator. The outer boundaries of this base have a configuration that is adapted to allow them to provide a sliding seal against the applicator's interior wall **42.** The distal portion of this base, when the push rod is adjustably inserted into the applicator, thus forms the furthest boundary at which CO_2 snow

may accumulate in the applicator. The wall **42** of the applicator is also provided with a number of vent holes **44** by which gases can be vented during the CO_2 snow filling process.

In the alternate venting pattern, channels running parallel to the axis of the cylinder allow gas venting to the atmosphere at both the proximal **32** and distal **34** ends of the applicator. The opening to each of the channels is sufficiently small such that the particles of snow do not coagulate in this region in such a way as to block the channels. The channels may also serve to vent the sublimating gas during a cryotherapy treatment procedure and thereby prevent accumulation of the sublimate in the vaginal cavity which inhibits the device operator's ability to see the distal end of the applicator.

The exact dimensions of such an applicator will obviously be a function of the type of cryotherapy procedure that is desired to be performed using the present invention. For a normal preventive, ablation of cervical, precancerous lesions procedure, typical dimensions for this applicator are: outer diameter = 15.9 mm, wall thickness = 1.6mm when polycarbonate extruded tubing is being used as the material from which to fabricate the tube, length in the range of 152-203 mm, vent holes: diameters in the range of 0.5-0.8 mm and 15 — 20 in number and spaced at 6.4 mm intervals along the length of the tube. For an applicator sized in this manner, typical snow horn dimensions would then be: length = 178-229 mm, inside tube diameter = 9.5 mm and where it may be fabricated from an assortment of plastics, including polycarbonate, acrylic, polysulfone, ABS, acetal copolymer, or polypropelene.

Once the applicator is sufficiently filled with CO_2 snow, the applicator is disconnected from the snow horn and an applicator cap or tip **50** is attached to the fitting **40** on the applicator's distal end **34.** During a cryotherapy treatment process, the mass or plug **6** of CO_2 snow must be continually pressed up against the inner side **52** of the applicator cap to ensure that the plug has good thermal contact with the applicator cap **50.** An appropriately sized spring or other suitable biasing means **70** is fitted around the push rod and travels along with the push rod and up into the applicator's interior. The distal end **72** of this spring presses against the back side

CLAIMS

We claim:

1. A device (1), that is adapted to connect to the outlet of a tank that is pressurized in the range of 52 - 60 kg/cm^2 and contains liquid carbon dioxide, for providing a patient with a cryotherapy process that is directed to the ablation of cervical, precancerous lesions to prevent cervical cancer, said device comprising:

a piping assembly (10) having a distal (12) end and a proximal (22) end and a configuration adapted to allow said distal end (12) to connect to said pressurized tank outlet, a nozzle (24) having a diameter in the range of 0.13 - 1.3 mm so as to create a spray of carbon dioxide snow as a result of the freezing of said liquid carbon dioxide upon its exhaustion from said piping assembly (10),

a tubular, snow horn (26) having a distal (26a) end and a proximal (26b) end, a boundary wall (26c) extending between said ends and enclosing the interior region of said snow horn, said snow horn also having a configuration adapted to allow said snow horn distal end (26a) to connect to said piping assembly proximal (22) end and having a length between said ends in the range of approximately 170 - 230 mm and an inner diameter of approximately 10 mm,

a tubular applicator (30) having a distal (34) end and a proximal (32) end and a wall extending between said ends and enclosing the interior region of said tubular applicator, with said tubular applicator (30) also having a length between said ends in the range of approximately 150 - 200 mm and an outer diameter of approximately 16 mm, a wall thickness of approximately 1.6 mm, and wherein said wall has a plurality of vent holes which have a diameter in the range of approximately 0.5 - 0.8 mm and wherein said applicator distal (34) end is configured to temporarily connect to said snow horn proximal (26b) end,

wherein said configurations of the tubular snow horn (26) and the tubular applicator (30) are adapted to allow for the collection in said applicator of a prescribed mass of said carbon dioxide snow in the range of approximately 8 - 10 grams and having a density in the range of 0.5 - 0.7 g/cm^3,

an applicator tip (50) having an inner (52) surface and an outer (54) surface that includes a metal portion and a configuration adapted to allow said applicator tip to connect to said applicator distal (34) end during said process of providing said cryotherapy ablation and to allow said metal portion of said outer (54) surface of said applicator tip to come into contact with said patient, and

a push rod (60) having a distal (64) end and a proximal (62) end and a base (66) attached to said push rod distal (64) end and having a configuration adapted to allow said push rod distal (64) end to variably extend into said tubular applicator (30) from said applicator proximal (32) end so as to allow said push rod base to serve as the furthest point in said applicator from said applicator distal (34) end that said spray of carbon dioxide snow can collect.

2. The device as recited in Claim 1, further comprising:

a handle (80) having a configuration adapted to allow said handle to be hand-operated to control the positioning of said distal end (34) of said tubular applicator during said process of providing said cryotherapy ablation.

3. The device as recited in Claim 1, further comprising:

a means for biasing (70) said push rod (60) so as to cause said push rod base (66) to push said prescribed mass of collected carbon dioxide snow towards and against said applicator tip (50) during said cryotherapy ablation process.

4. The device as recited in Claim 2, further comprising:

a means for biasing (70) said push rod (60) so as to cause said push rod base (66) to push said prescribed mass of collected carbon dioxide snow towards and against said applicator tip (50) during said cryotherapy ablation process.

5. The device as recited in Claim 1, wherein:

said push rod (60) configuration further adapted to interact with said handle (80) to control the location of said base (66) relative to said applicator distal (34) end.

6. The device as recited in Claim 4, wherein:

said push rod (60) configuration further adapted to interact with said handle (80) to control the location of said base (66) relative to said applicator distal (34) end.