Schedule

Proposed Amended Claims for EP (UK) 3 760 143

1. A device for removing a stone, a stone fragment or a foreign body from a patient comprising:

(i) a suction evacuation assembly (10) which includes a sheath (20) and one or more side arms (50, 60);

said sheath (20) having a proximal end (21) and a distal end (22);

(ii) an obturator (90) having a straight or tapered distal end (92) which is inserted into a proximal end (21) of the sheath (20) and which extends beyond the distal end (22) of the sheath (20) and is releasably secured to the proximal end (21) of said sheath (20);

(iii) a side arm (50) emanating from the outer surface (24) of said sheath (20), wherein said side arm (50) further comprises a pressure regulating mechanism (110) in the form of a longitudinal slit in respect of the axis of the side arm (50) which allows a person using the suction evacuation assembly (10) to increase the negative pressure within the suction evacuation assembly (10) by covering the pressure regulating mechanism (110) or decrease the negative pressure within the suction evacuation assembly (10) by uncovering the pressure regulating mechanism (110);

(iv) optionally, an accessory side arm (60) emanating from the outer surface (34) of said sheath (20);

(v) said sheath (20) having a lumen (23) which is the same diameter as a lumen (53) of said side arm (50) and if present as a lumen (63) of said accessory side arm (60);

(vi) a flexible cap (100) releasably secured to the proximal end (21) of the sheath (20);

(vii) a proximal end of a primary tube (76) releasably secured to said side arm (50) or if present said accessory side arm (60) and a distal end (72) of said primary tube (76) releasably secured to a collection container (80); and

(viii) a proximal end of a secondary tube (78) releasably secured to said collection container (80) and a distal end of said secondary tube (78) releasably secured to a negative pressure system (120);

(ix) wherein said obturator (90) can be withdrawn from said sheath (20) and a scope can be inserted into the sheath (20) through the flexible cap (100) and into said patient in order to visualize said stone or foreign body using said scope; and

(x) wherein the negative pressure system (120) can be activated in order to remove said stone or foreign body from said cavity if a diameter of said stone or foreign body is narrower than an inside diameter of said sheath (20) and said side arm (50), or lithotripsy can be performed on said stone or said foreign body in order to create fragments with a decreased diameter which allow the passage of said fragments within the inside diameter of said sheath (20) and said side arm (50); and the stone, foreign body and/or fragments can be collected in said collection container (80).

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2. The device of claim 1 further including

a guide wire which can be introduced into a lumen or cavity of a patient's body containing one or more stones or foreign bodies prior to inserting said sheath (20) into a lumen or cavity of a patient's body in order to aid in the positioning the distal end (22) of said sheath (20) in a position in close proximity to said stones or foreign bodies; and

a needle assembly which includes a needle sheath with an inner channel and an outer surface and a needle shaft which are releasably secured to one another;

wherein the needle shaft can be inserted into the needle sheath which can be inserted into the obturator (90) which can then be inserted into the suction evacuation sheath allowing the guide wire to pass through the needle assembly while positioning the distal end of said sheath in a position in close proximity to said stones or foreign bodies.

31. **A device for removing a stone, a stone fragment or a foreign body from a patient comprising:**

(i) a suction evacuation assembly (10) which includes a sheath (20) and one or more side arms (50, 60);

said sheath (20) having a proximal end (21) and a distal end (22);

(ii) an obturator (90) having a straight or tapered distal end (92) which is inserted into a proximal end (21) of the sheath (20) and which extends beyond the distal end (22) of the sheath (20) and is releasably secured to the proximal end (21) of said sheath (20);

(iii) a side arm (50) emanating from the outer surface (24) of said sheath (20), wherein said side arm (50) further comprises a pressure regulating mechanism (110) in the form of a longitudinal slit in respect of the axis of the side arm (50) which allows a person using the suction evacuation assembly (10) to increase the negative pressure within the suction evacuation assembly (10) by covering the pressure regulating mechanism (110) or decrease the negative pressure within the suction evacuation assembly (10) by uncovering the pressure regulating mechanism (110);

(iv) optionally, an accessory side arm (60) emanating from the outer surface (34) of said sheath (20);

(v) said sheath (20) having a lumen (23) which is the same diameter as a lumen (53) of said side arm (50) and if present as a lumen (63) of said accessory side arm (60);

(vi) a flexible cap (100) releasably secured to the proximal end (21) of the sheath (20);

(vii) a proximal end of a primary tube (76) releasably secured to said side arm (50) or if present said accessory side arm (60) and a distal end (72) of said primary tube (76) releasably secured to a collection container (80); and

(viii) a proximal end of a secondary tube (78) releasably secured to said collection container (80) and a distal end of said secondary tube (78) releasably secured to a negative pressure system (120);

(ix) wherein said obturator (90) can be withdrawn from said sheath (20) and a scope can be inserted into the sheath (20) through the flexible cap (100) and into said patient in order to visualize said stone or foreign body using said scope; and

(x) wherein the negative pressure system (120) can be activated in order to remove said stone or foreign body from said cavity if a diameter of said stone or foreign body is narrower than an inside diameter of said sheath (20) and said side arm (50), or lithotripsy can be performed on said stone or said foreign body in order to create fragments with a decreased diameter which allow the passage of said fragments within the inside diameter of said sheath (20) and said side arm (50); and the stone, foreign body and/or fragments can be collected in said collection container (80);

~~T~~the device ~~of claim 1~~ further comprising:

a flexible, deflectable tip secured to the distal end (42) of the distal sheath (40) which will enable the user to adjust the direction of suction, irrigation, instrument placement, or removal of a stone, stone fragment or any other foreign body or tissue from a patient.

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~~4~~2. The device of claim 1 further comprising an expandable distal sheath (20).

~~5~~3. The device of claim 1 further comprising a balloon that can be inflated to hold the sheath (20) in place within the body cavity or an anchoring mechanism operationally associated with the distal portion of the distal shaft.

~~6~~4. The device of claim 1 wherein said side arm (50) and said accessory side arm (60) each further comprise a pressure regulating mechanism (110) which allows a person using the suction evacuation assembly (10) to increase or decrease the negative pressure within the suction evacuation assembly (10).

~~7~~5. The device of claim 1 wherein the scope has a diameter which is smaller than an inner diameter of the sheath (20) of the suction evacuation assembly (10) resulting in an open channel within the lumen (23) of the sheath (20) which permits the passage of stones, pieces of stones or other foreign objects through the lumen (23) of the sheath (20) and through said side arm (50) and/or accessory side arm (60).

~~8~~6. The device of claim 1 wherein the suction evacuation assembly (10) further comprises:

a secondary sheath (130) secured to the outer surface (24) of the sheath (20), now a primary sheath;

said secondary sheath (130) allows the passage of a guide wire through the secondary sheath (130) while positioning the distal end (22) of said primary sheath (20) in a position in close proximity to said stones or foreign bodies.

~~9~~7. The device of claim ~~8~~6 wherein said secondary sheath (130) may be used to guide additional irrigation, a catheter, a foreign body basket, a backstop, an instrument or device to the position in close proximity to said stones or foreign bodies simultaneously with the scope and/or irrigation, catheter, foreign body basket, backstop, instrument or device through the primary sheath (20).

~~10~~8. The device of claim ~~9~~7 wherein said secondary sheath (130) has a proximal end (131) which is located near the proximal end (21) of the primary sheath (20) and a distal end (132) which extends beyond the distal end (22) of the primary sheath (20) in order to allow irrigation, a catheter, a foreign body basket, a backstop, an instrument or device to be passed beyond a stone, a stone fragment or other foreign body during a procedure to remove them.

~~11~~9. The device of claim 1 wherein the suction evacuation assembly (10) further includes the addition of two, three or four barrels which are integral to the structure of the sheath (20) and wherein the additional barrels may be used to guide additional irrigation, a catheter, a foreign body basket, a backstop, an instrument or device to the position in close proximity to said stones or foreign bodies simultaneously with the scope and/or irrigation, catheter, foreign body basket, backstop, instrument or device through the primary sheath (20).