CLAIMS

1. A device for the processing and separation of biological fluids into components, comprising:

- a hollow centrifugal processing chamber (10) rotatable about an axis of rotation, the processing chamber having an inner cylindrical wall (16) enclosing a space (19) for receiving biological fluids to be processed and having an inclined upper wall (12) leading to a narrower neck (14) that extends axially from the cylindrical wall (16) and its inclined upper wall (12) and that has an inlet/outlet (29) for biological fluid to be processed and for processed components of the fluid, the cylindrical wall (16), its inclined upper wall (12) and the narrower neck (14) all being in one piece, wherein the space (19) in the hollow processing chamber for receiving biological fluids occupies the entire volume across the hollow processing chamber (10) between facing parts of the inner cylindrical wall (16) and along the length of the cylindrical wall, said space (19) having a given volume delimited by a bottom (10B) of the hollow cylindrical chamber, or a variable volume delimited by the position of an axially movable member (18) within the cylindrical wall (16) ; and

- a dynamic/static inlet/outlet head (20) mounted on the neck (14) of the processing chamber (10), the inlet/outlet head having a first part (22) rotatable with the processing chamber and a second part (24) that remains stationary, the first and second parts of the inlet/outlet head being connected by a sealing means (26) allowing rotation of the first part relative to the second part, the inlet/outlet head having a central through-passage for the inlet of biological fluid to be processed and the outlet of processed/separated components of the fluid;

Characterized in that the device further comprises a flow guide (30) inserted in and rotatable with the processing chamber (10), the flow guide being located adjacent to, spaced slightly apart from and in shape-matching relationship to the inclined upper wall (12) of the processing chamber to define with the inclined upper wall of the processing chamber an inclined flow passage (32), the flow guide (30) being disposed above said space (19) for receiving biological fluids to be processed with its inclined flow passage (32) leading into a top part of the inner cylindrical wall (12) of the processing chamber; and wherein the inlet/outlet head (20) comprises:

- a first inlet/outlet (29) and a second inlet/outlet (40), the first and second inlets/outlets being disposed on the stationary second part (24) of the inlet/outlet head (20) at a top end and/or at a lateral side thereof, and
- an axial separator (28a, 28b) in the central through-passage of the inlet/outlet head (20), the axial separator defining separate first and second axially-directed passages in the inlet/outlet head,
- an upper part of one of the first and second axially-directed passages communicating with one of the first and second inlets/outlets (29, 40), and an upper part of the other of the first and second axially-directed passages communicating with the other of the first and second inlets/outlets (29, 40),
- a lower part of one of the first and second axially-directed passages communicating with said space (19) in the processing chamber for receiving biological fluids to be processed, and a lower part of the other of the first and second axially-directed passages communicating with the inclined flow passage (32) between the flow guide (30) and the inclined upper wall (12) of the processing chamber,

arranged so the device is operable in a continuous flow mode in which biological fluid to be processed can be inlet via one of the first and second inlets/outlets (29, 40), while processed biological fluid is simultaneously outlet via the other of the first and second inlets/outlets (29, 40).

2. The device according to claim 1, wherein the stationary second part (24) of the inlet/outlet head (20) comprises an external generally cylindrical body said first inlet/outlet is an axial inlet/outlet (29) in the inlet/outlet head (20), and said second inlet/outlet is a lateral inlet/outlet(40) located in a lateral side of the generally cylindrical body.

3. The device according to claim 2 wherein the processing chamber has an upwardly-projecting elongated central neck (14) that extends into the inside of the rotatable first part (22) of the inlet/outlet head (20) up to adjacent the level of the lateral inlet/outlet (40)..

4. The device according to claim 2 or 3, wherein the sealing means (26) of the inlet/outlet head comprise a first seal located axially on one side of the lateral inlet/outlet (40) and a second seal located axially on the other side of the lateral inlet/outlet (40).

5. The device according to any preceding claim wherein said axial separator is a central tube (28a, 28b) that comprises a stationary axially-outer part (28b) extending in the stationary second part (24) of the inlet/outlet head, and a rotatable axially-inner part (28a) connected to a central part of the flow guide (30), said rotatable axial-inner part of the central tube communicating with the space (32) between the flow guide (30) and said inclined upper wall (12) of the processing chamber.

6. The device according to any preceding claim wherein the rotatable first part (22) of the inlet/outlet head (20) is located inside the stationary second part (24) of the inlet/outlet head (20).

7. The device according to claim 5 wherein :

(i) the inclined upper wall (12) of the processing chamber (10) is frusto-conical as is the upper surface of the flow guide (30);

(ii) the flow guide (30) has a central sleeve (36) that fits in the neck (14) of the processing chamber leaving a space of several millimeters between the facing frusto- conical surfaces;

(iii) the lower end of the central tube (28a) fits in the central sleeve (36) of the flow guide (30) and communicates with said space (32) between the facing frusto-conical surfaces; and

(iv) the flow guide (30) comprises an aperture in the form of at least one through passage (34), preferably three equally-distributed through passages, in its central sleeve (36) that communicate(s) the inside of the processing chamber (10) with the central passage of the inlet/outlet head outside its central tube (28a, 28b).

8. The device according to any preceding claim wherein the flow guide (30) comprises a peripheral rim (38) of external cylindrical shape that extends from the periphery of a frusto-conical upper surface of the flow guide (30), said peripheral cylindrical rim (38) fitting in the inner cylindrical wall (16) of the processing chamber below the junction of the inner cylindrical wall and the inclined upper wall (12) of the processing chamber.

9. The device according to any preceding claim wherein the processing chamber (10) contains within its cylindrical wall (16) an axially movable member (18) such as a piston that defines a separation space (19) of variable volume wherein the biological fluid to be processed and separated is received.

10. The device according to any preceding claim wherein the processing chamber (10) is part of a disposable set comprising a set of containers (52, 54, 56) for receiving the biological fluid to be processed and separated and the separated components, and optionally one or more additional containers for additive solutions.

11. The device according to any preceding claim further comprising a cabinet (60) for receiving the processing chamber, the cabinet having drive means for driving the centrifugal processing chamber and preferably also means for controlling the axial position of an axially movable member such as a piston in the processing chamber.

12. The device according to claim 11, further comprising closure members for the inlet/outlet to the processing chamber, said closure members being clips or pinch valves that act on tubing of the disposable set, and/or stopcocks (58) included in the disposable set and/or fitted on a cabinet for receiving the processing chamber.

13. A system for the processing and separation of biological fluids into components, comprising the device of any one of claims 1 to 12 and further comprising at least one peristaltic pump (59) for pumping incoming biological fluid through one of the first and second inlets/outlets (29,40); and/or for pumping extracted processed biological fluid components through the other of the first and second inlets/outlets (29,40).

14. A non-therapeutic method of processing and separating biological fluids into components using the device according to any one of claims 1 - 12 or the system of claim 13, the non-therapeutic method comprising the following steps:

(a) filling the processing chamber (10) with a biological fluid via one of said inlets/outlets (29, 40) with the second inlet/outlet closed (29, 40);

(b) rotating the processing chamber (10) to centrifuge biological fluid in the chamber in order to separate different components of the biological fluid onto the inner cylindrical wall (16) of the processing chamber or into the inside (19) of the processing chamber;

(c) operating in a continuous processing mode wherein filling of the processing chamber (10) with a biological fluid is carried out while at the same time extracting, via the second inlet/outlet components that have separated into the inside of the processing chamber;

(d) closing the first inlet/outlet (29, 40) whereby the processing chamber is no longer being filled with biological fluid, and continuing to extract components that have separated into the inside of the processing chamber via said second inlet/outlet (29, 40) ; and

(e) closing said second inlet/outlet (29, 40) whereby processed components that have separated into the inside of the processing chamber are no longer extracted via said second inlet/outlet (29, 40), and extracting via said first inlet/outlet (29, 40) components that have separated onto the inner cylindrical wall of the processing chamber.

15. The non-therapeutic method according to claim 14 wherein filling of the processing chamber with a biological fluid is produced by or is assisted by pumping, preferably by an external peristaltic pump (59), and/or by displacing in the processing chamber an axially movable member such as a piston (18) to alter the volume of a separation space of variable volume defined by the axially movable member.

16. The non-therapeutic method according to claim 14 or 15 wherein components are extracted from the processing chamber by pumping, preferably with a peristaltic pump (59).

17. The non-therapeutic method according to any one of claims 14 to 16 wherein continuous processing in step (c) is continued to process/separate a volume of biological fluid that exceeds the maximum separation volume of the processing chamber (10).

18. The non-therapeutic method according to any one of claims 14 to 17 wherein just prior to and/or during step (e) the centrifugal processing chamber (10) is accelerated/decelerated and/or rotated in opposite directions to loosen and/or mix separated components that have adhered on the inner cylindrical wall of the processing chamber.

19. The non-therapeutic method according to any one of claims 14 to 18 wherein centrifuging during step (b) is continued during steps (c) and (d), continuously or discontinuously.