

CLAIMS

1. A process for preparing blood components from blood, by means of a biomedical device (16) comprising a first bag (2) connected to a second bag (11) and to a third bag (13), said process comprising the steps of:
 - a) Subjecting an isolated blood sample (1), contained within the first bag (2), to a first centrifugation at a speed of 250 rpm for a time of 10 minutes, so as to obtain a sediment consisting of red blood cells (3) and a supernatant consisting of platelet-rich plasma (4);
 - b) Transferring from the first bag (2) said platelet-rich plasma (4) obtained from step a) to the second bag (11);
 - c) Subjecting the first bag (2), connected to the second bag (11) and to the third bag (13), to a second centrifugation at a speed of 2000 rpm for a time of 15 minutes, so as to obtain a supernatant consisting of platelet-poor plasma (5) in an upper portion of the first bag (2) and a red blood cell concentrate (6) in a lower portion of the first bag (2), and a supernatant consisting of platelet-poor plasma (5) in an upper portion of the second bag (11) and a platelet pad (12) in a lower portion of the second bag (11);
 - d) Transferring the platelet-poor plasma (5) from the first bag (2) to the second bag (11) or to the third bag (13);
 - e) Separating the first bag (2) from the second bag (11) and from the third bag (13), and fluidly connecting the first bag (2) to a storage bag (7);
 - f) Transferring the platelet-poor plasma (5) from the second bag (11) to the third bag (13), minus a volume of platelet-poor plasma (5) such as to dilute the platelet pad (12), thus forming a re-suspended platelet

- concentrate (15) having a platelet concentration between 800,000 and 1,200,000 platelets per microliter;
- g) Diluting the red blood cell concentrate (6) by adding a volume of additive solution (8) so as to obtain a suspension of concentrated red blood cells having a hematocrit value over 60%;
- h) Removing the leukocytes contained in the suspension of concentrated red blood cells by filtration through a leukoreduction filter (14), thus obtaining a filtered concentrated red blood cell suspension (9), and collecting and storing the filtered concentrated red blood cell suspension (9) in the storage bag (7).
2. A process according to claim 1, wherein the additive solution (8) for storing the red blood cells consists of sodium-adenine-glucose-mannitol (SAGM), or a physiological solution.
3. A process according to claim 1 or 2, wherein the additive solution (8), prior to step g), is contained in a solution bag (10) which is removably fluidly connectable to the first bag (2).
4. A process according to claim 3, wherein step g) is carried out by fluidly connecting a tributary cannula (18) of the solution bag (10) to a secondary cannula (19), wherein the secondary cannula (19) branches off from a main cannula (17) fluidly connecting the first bag (2) to the storage bag (7) by a sterile connection.
5. A process according to any one of the preceding claims, wherein, before step a), a selection step a1) is included, in which a blood unit is selected according to the following parameters:
- TNC (total nucleated cells) $< 1.5 \times 10^9$;

- Volume without anticoagulant > 50 ml;
 - Platelet count in units with anticoagulant > 150,000 per microliter;
 - Beginning of the process within 48 hours from the blood unit collection;
 - optionally, compliance with local regulations.
6. A process according to claim 5, wherein, following the selection step a1) and before step a), a recording step a2) is included, in which the recording of the date and time of the delivery of the blood unit to be allocated to step a), and of the date and time of the beginning of step a), is carried out.
 7. A process according to claim 6, wherein following step a2) and before step a), an analysis step a3) is included, in which the net weight of the blood unit is determined and a blood count of the blood unit is performed, and following step a3), a transfer step a4) is included, in which the blood of the blood unit is transferred by a sterile connection into the first bag (2).
 8. A process according to any one of the preceding claims, wherein in step b) the platelet-rich plasma (4) is extracted from the first bag (2) and transferred to the second bag (11) by a manual plasma extractor.
 9. A process according to any one of the preceding claims, wherein the platelet-poor plasma (5) is extracted from the second bag (11) and transferred to the third bag (13) by a manual plasma extractor, and by a subsequent transfer from the second bag (11) to the third bag (13) through a siphon racking.
 10. A process according to any one of the preceding claims, wherein following the transfer of the platelet-poor plasma

(5) from the second bag (11) to the third bag (13), the net weight of the platelet pad (12) contained in the second bag (11) is calculated.

11. A process according to any one of the preceding claims, wherein following step d), the first bag (2) containing the red blood cell concentrate (6) is sealed, the net weight of the first bag (2) containing the red blood cell concentrate (6) is determined, a blood count on the red blood cell concentrate (6) contained in the first bag (2) is performed, and the first bag (2) containing the red blood cell concentrate (6) is cooled and stored at a temperature between 2°C and 6°C.
12. A process according to any one of the preceding claims, wherein the volume of the platelet-poor plasma (5) adapted to form a re-suspended platelet concentrate (15) of predetermined concentration of platelets per microliter is calculated by multiplying the total number of platelets in the starting blood unit by the average percentage of platelets recovered in the platelet-rich plasma (4) separated in step b).
13. A process according to any one of the preceding claims, wherein following the formation of the re-suspended platelet concentrate (15), a blood count on the re-suspended platelet concentrate (15) contained in the second bag (11) and a blood count on the platelet-poor plasma (5) contained in the third bag (13) are performed, and the second bag (11) containing the re-suspended platelet concentrate (15) and the third bag (13) containing the platelet-poor plasma (5) are then cooled and stored at temperatures below -25°C.
14. A process according to any one of the preceding claims,

wherein the additive solution (8) is added to the red blood concentrate (6) by directing the flow of the additive solution (8) in the opposite direction to the flow of the red blood cell concentrate (6) directed towards the storage bag (7).

15. A biomedical device (16) for preparing blood components, comprising:
- a first bag (2), said first bag (2) being connected to a second bag (11) and to a third bag (13); said second bag (11) being adapted to contain plasma (4) and a platelet pad (12) and a re-suspended platelet concentrate (15); said third bag (13) being adapted to contain platelet-poor plasma (5);
 - a storage bag (7), fluidly connected to the first bag (2) by a main cannula (17);
 - a solution bag (10), comprising a tributary cannula (18);
- said solution bag (10) being separated from the main cannula (17) and being fluidly connectable to the secondary cannula (19), branching off from the main cannula (17), by means of a sterile connection of the tributary cannula (18) to the secondary cannula (19);
- wherein the first bag (2) is adapted to contain a blood sample (1) and a red blood cell concentrate (6),
- wherein the solution bag (10) is adapted to contain an additive solution (8) for red blood cell storage,
- and wherein the storage bag (7) is adapted to contain a filtered concentrated red blood cell suspension (9).
16. A biomedical device (16) according to claim 15, comprising a siphon fluidly connecting the second bag (11) to the third bag (13).

17. A biomedical device (16) according to claim 15 or 16, wherein the second bag (11) comprises a connecting tube (20) connected to the second bag (11) at an upper region of the second bag (11).
18. A biomedical device (16) according to claim 17, wherein the second bag (11) comprises a blind tube (21) placed at the upper region of the second bag (11), and the connecting tube (20) is inserted with a "Y" fitting on the blind tube (21).
19. A biomedical device (16) according to any one of claims 15 to 18, wherein the tributary cannula (18) is configured to input the additive solution (8) into the main cannula (17) by directing the flow of the additive solution (8) in the opposite direction to the flow of the red blood cell concentrate (6) directed from the first bag (2) towards the storage bag (7).
20. A biomedical device (16) according to any one of claims 15 to 19, comprising a leukoreduction filter (14) arranged in the main cannula (17), said leukoreduction filter (14) being adapted to filter the concentrated red blood cell suspension directed towards the storage bag (7).
21. A biomedical device (16) according to claim 20, wherein the leukoreduction filter (14) is placed upstream, with reference to the flow of the concentrated red blood cell suspension from the first bag (2) to the storage bag (7), of the intersection between the main cannula (17) and the secondary cannula (19).
22. A biomedical device (16) according to claim 20, wherein the leukoreduction filter (14) is placed downstream, with reference to the flow of the red blood cell concentrate (6) from the first bag (2) to the storage bag (7), of the

intersection between the secondary cannula (19) and the tributary cannula (18).

23. A biomedical device (16) according to claim 20, wherein a first and a second secondary cannula (19', 19'') branch off from the main cannula (17), and the leukoreduction filter (14) is between the intersection between the main cannula (17) and the first secondary cannula (19'), and between the intersection between the main cannula (17) and the second secondary cannula (19'').
24. A biomedical device (16) according to any one of claims 15 to 23, wherein the first bag (2), the second bag (11) and the third bag (13) are made of a flexible material which is resistant to a 2000 rpm centrifugation with a duration of 15 minutes.
25. A biomedical device (16) according to any one of claims 15 to 24, wherein:
- the first bag (2) has an inner volume of 150 ml,
 - the second bag (11) has an inner volume of 60 ml,
 - the third bag (13) has an inner volume of 60 ml,
 - the solution bag (10) has an inner volume of 50 ml,
 - the storage bag (7) has an inner volume of 150 ml.
26. A system for preparing blood components, comprising:
- a biomedical device (16) according to one of claims 15 to 25,
 - at least one centrifuge,
 - at least one plasma extractor.
27. A system according to claim 26, wherein at least one centrifuge comprises a protective tubular flexible casing and cylindrical adapters made of solid plastic.