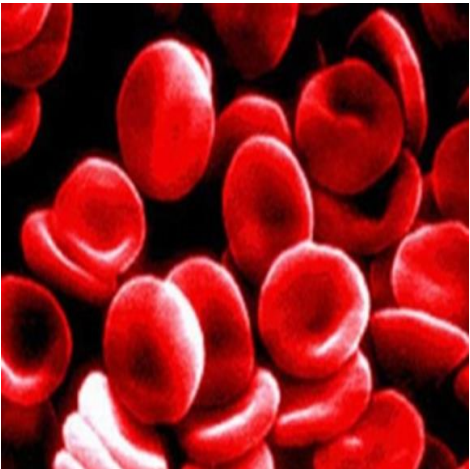


Abstract for Blood Bag Production

This abstract refers to blood bag production considering general and process information



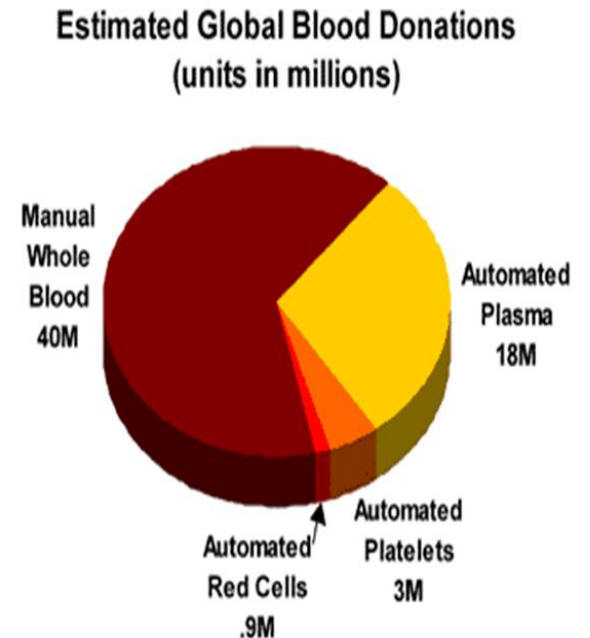
BLOOD BAGS



Blood donation and processing with these system is supplemented by further devices such as automated scales, automated blood separators, sterile docking systems, sealers and filtration racks.

Donor products are a growing part of the large, global blood collection market. The chart below shows the estimated number of blood collections.

Blood bag systems are fundamentals for worldwide blood supply by "classical" blood donation. More than 90 percent of all blood donations are processed in these systems that have up to six different bags with variable functions. A combination of PVC bags with retractable needles, pre-donation sampling pouches and different filtration devices form the basis for highly professional whole blood collection systems.



BLOOD COLLECTION PROCESS

The Manufacture of Blood Components

While donating, the donor's blood is collected into a plastic bag (the main bag), a part of a set consisting of three plastic bags connected with plastic tubes. The whole set is sterile and has never been used before. The tubes enable the transfer of parts of the blood from one bag to another without breaking the chain of sterility. The main bag contains matter preventing the blood from coagulating.

After the collection, the blood is centrifuged so that it is divided into three layers in the main bag according to the density of each part. After the centrifugation, the plasma, which is on top, is pressed

into an empty plastic bag (the plasma bag) through a plastic tube in the top of the bag. The red blood corpuscles, which are on the bottom, are lead into another plastic bag (the SAG-M bag), containing liquid with nutrients for the red blood corpuscles, through a tube in the bottom of the bag. The layer in between, which remains in the main bag, is called the buffy coat. It contains large amounts of blood platelets and white blood corpuscles, and it is used for producing concentrates of blood platelets. Thus, the collected whole blood is split into three different components in each their plastic bag.

In this way, it is possible to store the components separately under ideal

conditions, depending on their respective requirements.



BLOOD COLLECTION PROCESS

All blood components are labeled with a unique and clear collection number that makes it possible to trace where the blood has been collected from, where it has been stored, and to which patient it has been administered. All this information is registered in the blood bank's computer system.

Storing the Blood Component

Distinct rules have been laid down regarding the storage of the individual blood components. The rules take the storage temperature into special account because the shelf life is particularly dependent on the temperature. The requirement for correct and constant temperature when storing blood is due to the fact that the

blood has to stay as fresh as possible. When storing blood, the temperature must be measured all the time and registered continuously so that the storage temperature can be documented.

Blood Bag Manufacturing Process

The core of the lines is the full automatic bags manufacturing line, provided with computerized shuttles which perform all the assembly processes. In brief:

- A special high Frequency welding machine is perimetralling welding the calendared PCVC film (not collapsible) with the pipes.
- An operator brings the bags to the automatic shuttle.
- Another operator loads the

different stations with the necessary components for the bags (needles, pre-donation bags, connectors, etc)

- In case of KITS (double / triple bags) each operator inserts the bags onto a shuttle, which takes the bags to the following assembling stations.
- The bags are then filled with anticoagulants (25 – 45 ml each, depending on different formulations).
- An automatic labeling sticks special labels onto the bags.
- A vacuum overwrapping machine performs the overwrapping in special alu-foils. Before loading the overwrapping trays, an operator inspects the quality of the bag.

BLOOD BAG MANUFACTURING PROCESS

- Then the overwrapped bags are laid onto the trays of the autoclave and sterilized with a semi air automatic process.

This base process could then be optionally integrated, in future investment steps as follows:

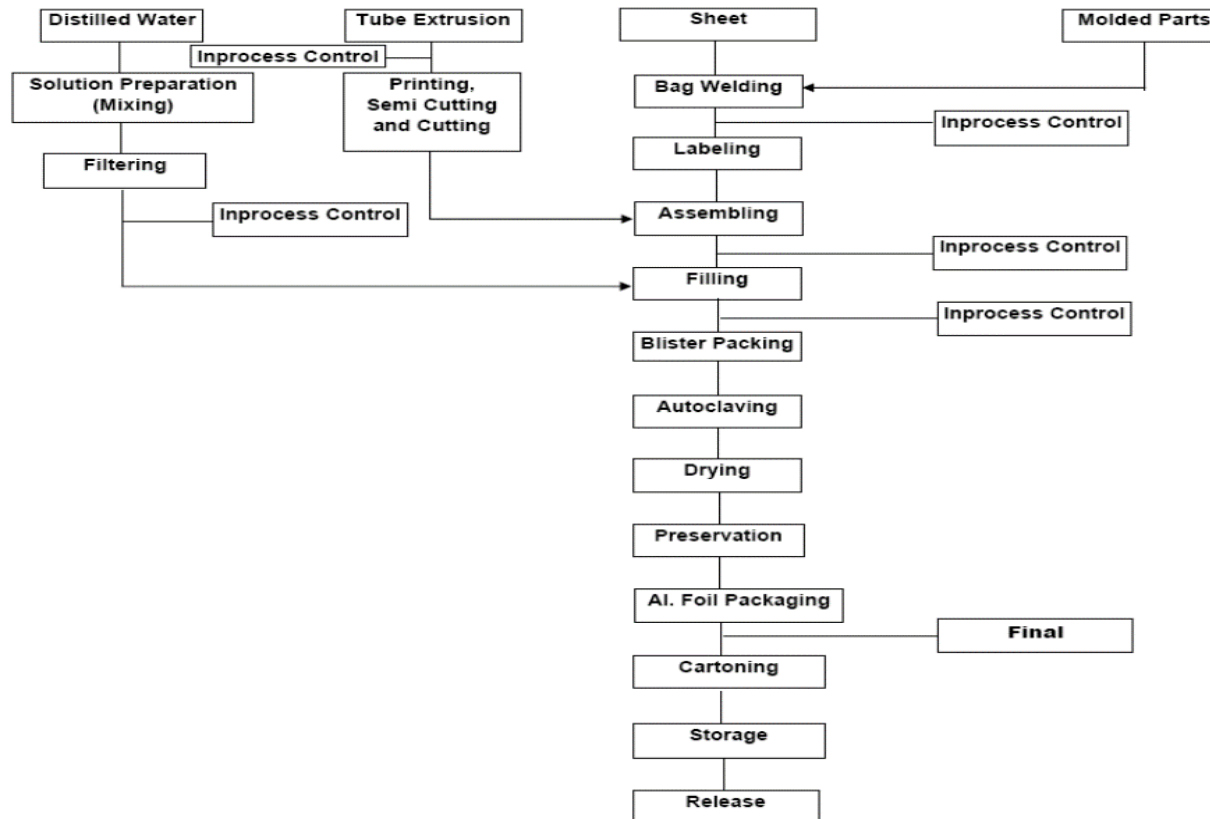
- A. The project shall be optional provided with an Injection Molding Department with several presses and molds, allowing the project to be independent in the manufacturing of all of the plastic blood bag components.
- B. The Optional Division of Leukocyte Filter will produce the shells of the filters, purchase the pre-cut and washed Filtering Tissue from

an external source and automatically assemble the filters, to be installed on line on the blood bags kits.



BLOOD BAG PRODUCTION FLOWCHART

BLOOD BAG PRODUCTION FLOW CHART



TECHNOLOGY/PRODUCT SPECIFICATIONS

Product: Blood Bags

Single Blood Bag

- Designed for collection, storage and transfusion of whole blood
- Contains 63 ml CPDA-1 anticoagulant solution. Also available with CPD anticoagulant solution
- Capacity: 250, 350, 450 ml
- 16G tamper-proof needle and standard donor tubing
- Packing: 10 bags/ At foil Outer box: 10 x 10
Gross weight: 13 kg

Double Blood Bag

- Designed to separate whole blood into plasma and red cells. Eliminates the possibility of contamination
- Primary bag contains 63 ml CPDA-1 anticoagulant solution. Also available with CPD anticoagulant solution The 300 ml transfer bag contains no solution
- Capacity: 1 x 450 ml + 1 x 300 ml transfer bag
- 16G tamper-proof needle and standard donor tubing
- Packing: 6-bags/ Al. Foil
Outer box: 10 x 6
Gross weight: 10.5 kg

Triple Blood Bag

- Designed to separate whole blood into three parts:
 1. Red blood cells, platelets & plasma
 2. Red blood cells, leucocytes & plasma
- Primary bag contains 63 ml CPDA-I anticoagulant solution. Also available with CPD anticoagulant solution. The 300 ml transfer bags contain no solution
- Optional: Transfer bag with SAG-M solution/5 days platelets storage
- Capacity: 1 x 450 ml + 2 x 300 ml transfer bags

TECHNOLOGY/PRODUCT SPECIFICATIONS

- 16G tamper-proof needle and standard donor tubing
 - Packing :
4 bags/ Al. Foil
Outer box: 12 x 4
Gross weight: 10 kg
With CPD /SAG-M solution
Gross weight: 15.5 kg
- Quadruple Blood Bag**
- Designed to separate whole blood into four parts:
 1. Red blood cells, platelets, plasma & cryoprecipitate
 2. Red blood cells, platelets, plasma & leucocytes
 - Primary bag contains 63 ml CPDA-I anticoagulant solution. The 300 ml transfer bags contain no solution.
- Capacity: 1 x 450 ml + 3 x 300 ml transfer bags
 - The system is also available with 1 x 450 ml bag containing CPD solution, 2 x 300 ml bags with no solution & 1 x 300 ml bag with 100 ml SAG-M solution
 - 16G tamper-proof needle and standard donor tubing
 - Packing :
3 bags/ Al. foil
Outer box: 12 x 3
Gross weight: 8.5 kg
With CPD /SAG-M solution
Gross weight: 13 kg



TRANSFER BAG

- Designed to transfer specific blood components from whole blood
- Contains no anticoagulant solution
- Capacity: 300 ml
- Packing: 100 bags / Outer box
Gross Weight: 5 kg



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For further inquiries and quotes, please contact:

ensymm UG & Co.KG

Life Science Center Dusseldorf
Merowingerplatz 1
40225 Dusseldorf
Germany

Tel: 0049 2113367527

Project_assistant@ensymm.com

www.ensymm.com

