

## SPECIFICATIONS

MacoPharma continually aims for maximal safety of use, providing fully equipped systems; secure needle caps, needle covers to avoid needlestick injuries, pack property overwrap.



### Needle

Due to an high quality manufacture, 100% sharpness quality control with an individual visual control, and an individual mechanic control.  
(Each needle is test in a latex membrane, and should not resist to pression defined as an equivalent resistance of the skin)

The black line guides the nurses for the way of use of the needle.  
Ergonomically shaped hub.

The caps on the needle guarantee the closed system.



### SECUVAM™

Prevention of needle stick injury  
Lockable needle protector  
Round shape for ease of use  
Integrated device

No lockable protector if the cap is on the needle.



### BACTIVAM™ - Pre-donation sampling touch

- Diversion of first few ml of blood
- Guaranteed sample availability
- Reduction of bacterial contamination
- Optimised donation & sampling

A study underlines the value of systematic implementation of a pre-sampling pouch for the reduction of prevalence of contamination by cutaneous flora.  
Allows reducing bacterial contamination (75/90%). (Appendix 1)

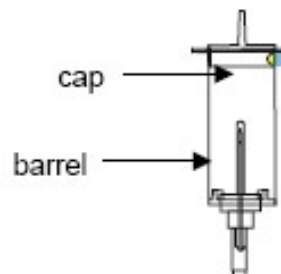


- No waste of blood : first derivated ml for screening and typing.
- No waste of time : withdrawing of sampling tubes during donation.
- Better traceability : labelling of testing tubes after filling them and the labelling of the blood pack.
- Better quality of samples for blood testing (before donation = exact donor figures).
- High confidence in procedures : nurses succeed all the key steps at the beginning of donation, in a short time.
- Better use of donor beds : no more acts after blood pack filling è better availability of nurses
- Better security : in case of fainting, nurses can quickly withdraw the needle from the donor's arm.
- Tubes are always available.
- Filling of vacuum tubes easier and painless for the donor : no collapsed tubes.
- Vacuum sampling on the Bactivam bag ► Better access.

Addition of a unitary traceability number in the center of each Bactivam at the moment of sealing.

### VACUVAM

- Sampling with vacuum tubes
- Sampling in a closed system
- Hygienic and safe procedure
- Integrated device
- Latex Free



- Cap sealed with a single ultrasonic weld-point.
- Removal of external locking-piece from barrel.
- Single-hand opening possible.

### Clamp

In conclusion of microbiological test on the effectiveness of the MacoPharma non-reopening clamp:  
The MacoPharma non-reopening clamp provides a real sealing capacity.  
There is no risk of contamination by closing the non reopening clamp, and there is no damage on the tube that can provide contamination from the outside.

Integration of an inviolable clamp directly on the sample tubing.  
*Device approved by the EFS (Appendix 2)*



## Traceability

Blood packs are becoming more and more complex ! Therefore, MacoPharma has developed an unique system for the complete traceability of Blood Pack systems and their individual components. This system is based on 3 different levels:

### 1<sup>ST</sup> LEVEL : LOT NUMBER OF THE PACK

Products of the same code, filled with the same batch of solution, sterilised on the same day.

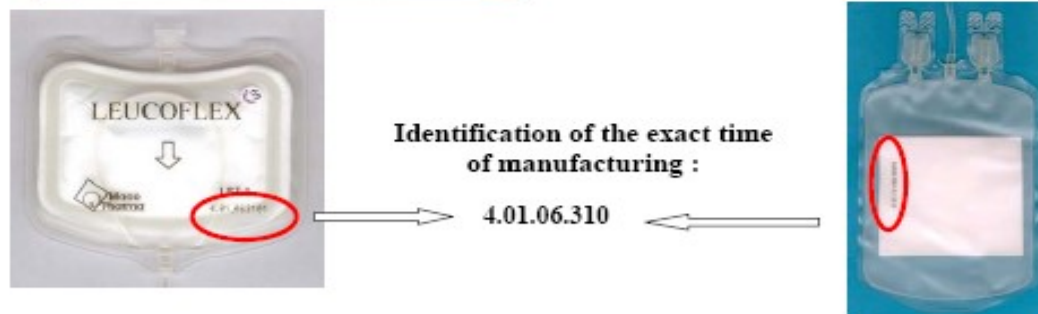
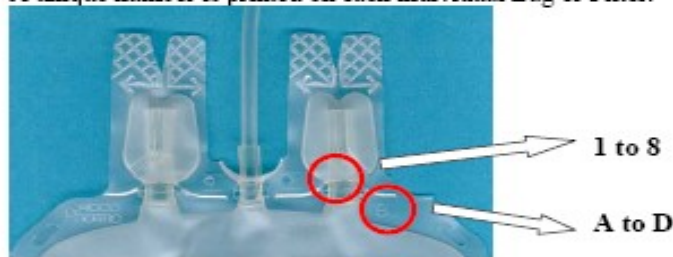


### 2<sup>ND</sup> LEVEL: IDENTIFICATION OF MANUFACTURING TOOL

Each tool is engraved in order to identify all possible combinations.

### 3<sup>RD</sup> LEVEL: IDENTIFICATION OF TIME OF MANUFACTURE (FILTERS, BAGS)

A unique number is printed on each individual Bag or Filter.



Notification of the observations from the supplier to the control laboratory leads immediately to a request for corrective action and contributes to the resolution of any problems within a few hours. The traceability system developed at MacoPharma allows the application of different expertise and also allows us to put into quarantine only a limited number of packs, where necessary.

