

Eye drop dispensing system



The innovative and safe way for serum eye drop preparation



Serum eye drops

Safe preparation of serum eye drops in a functionally closed system

Dry eye disease is an increasing symptom patients are suffering from in many developed countries. It can be found as a result of pollution and noxious working environments as well as from special indications like GvHD, Sjögrens disease, etc...

Serum and other blood components (e.g. platelet lysate) have been proven to be an unrivalled therapeutic treatment with unique performance when applied as eye drops.

Features and Innovations

- vial production by injection moulding
- reduced preparation work of the filling process by pre-assembly of the vials in blister strips
- sealed vials providing an anti-tamper mechanism
- improved nozzle for better administering of drops
- an extended definition of the Inteded Use allows dispensing of different types of blood components from a regulatory aspect

Eye drop processing is usually time, labour and cost intensive. Our innovative dispensing approach allows for the production of serum eye drops to be carried out quickly and safely without the need for using clean room facilities. Dispensing the serum only needs a few working steps. The “second generation” product comes with improved handling for both users and patients. The vials are pre-assembled in blisters and the caps are individually sealed. The use of the filling rack is no longer necessary.

One single blood donation yields up to more than 130 single vials of serum eye drops, depending on the physical status of the patient or the donor. Dilution leads to an even higher yield respectively.

All vials may be labelled individually to ensure the highest possible safety level for patients. The high output of vials from one single blood donation offers the continuous supply of this unique therapy for an ambulant treatment of your patients.

Dispensing using the eye drop systems

After preparation (and a possible dilution) the serum can be dispensed using the ATS system. The integrity of the closed system can be ensured by using a sterile docking device. So dispensing may be performed outside of a clean room environment by using the following steps:

The eye drop system will be taken from the sterile wrapping, the blisters are combined to blocks and positioned with the flat side of the caps down.

A filter adapter for removing microaggregates (e.g. TFZ1) can be added to the filling line using a sterile docking device. For identification the vials are labelled according to the internal requirements.

For initiating the dispensing process the eye drop system is sterile docked to the serum bag. The serum bag will then be positioned on a hook (e.g. infusion stand) using the attachment eye at the bottom. After opening the docking site the dispensing process will start by gravity. The process is completed once the serum reaches the vent bag of the ATS.

For increasing the yield of vials the intermediate tubings may be vented by applying manual pressure to the vent bag at the end of the ATS.

Usually a full whole blood donation allows filling of several eye drop systems. These may be docked to the serum bag sequentially. Using a „short“ system (ATS12 or ATS12.1) should be considered for optimising the cost effectiveness.

For bacterial testing the content of readily filled vials can be used. Alternatively, some serum may be transferred to the vent bag when dispensing is completed. The vent bag provides transfusion ports which may be spiked with adequate adapters. A blood culture holder adapter (e.g. AD821.1) may be docked to the vent bag alternatively.


Dispensing process with ATS36


Separating the blister trays


Sealing of the vials


Readily filled and labelled vials ready for packing

Eye drop systems ATS

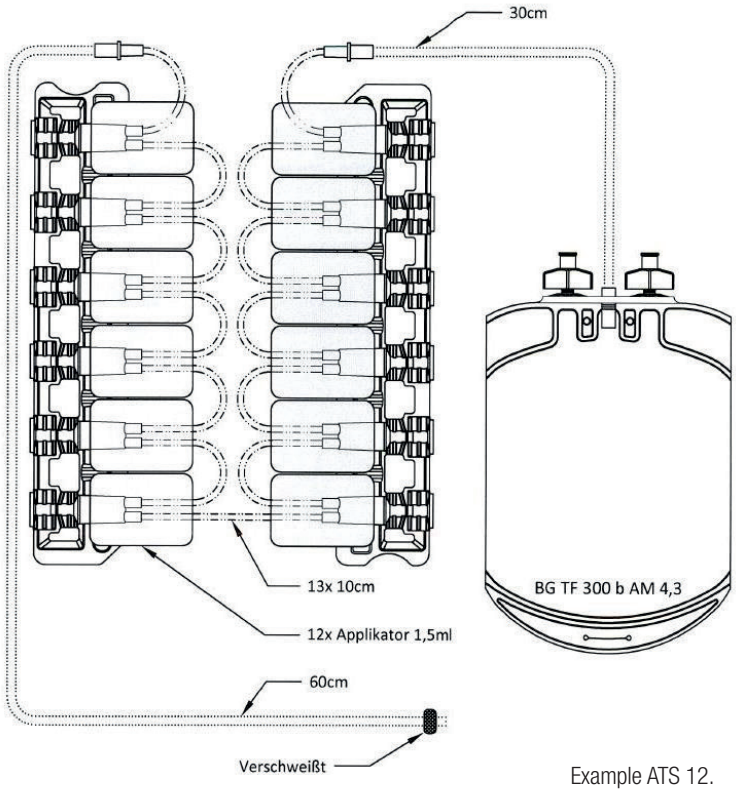
Dispensing, storage and application of blood components as a tear fluid substitute suitable for treatment of diseases of the human eye.

The eye drop system includes twelve, thirty or thirty six reclosable vials with 1.5 ml or 3.0 ml volume (3.0 ml with ATS12.1, ATS30.1 and ATS36.1). The vials are linked by short tubings. The medium to be dispensed will be sterile docked to the feed tubing of the eye drop system. The vent bag at the very last vial of the system will catch the sterile air during the dispensing process. The vials are pre-assembled in groups of six pieces to a blister tray. Before dispensing, the blister trays may be combined twofold each to form a self-standing block of vials.

All ATS models are gamma-sterilised and come with a shelf life of 35 months. The vials provide a thermal stability down to – 80°C. The average drop size is 0,045 ml.

MODEL	ATS12	ATS30	ATS36	ATS12.1	ATS30.1	ATS36.1
product code	152002	152001	152000	152003	152004	152005
vials/unit	12	30	36	12	30	36
filling volume	1,5 ml	1,5 ml	1,5 ml	3,0 ml	3,0 ml	3,0 ml
units/box	30	15	15	30	15	15

ATS



Example ATS 12.

Empty bag configurations TF304ff

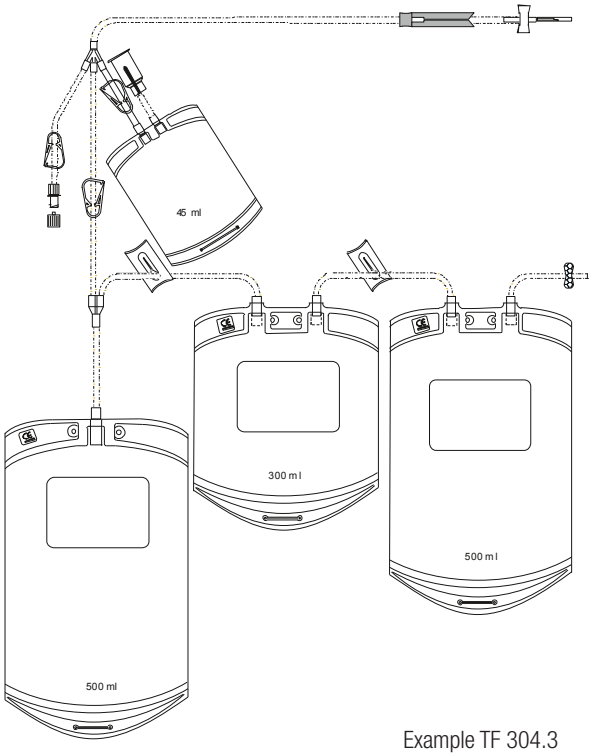
Collection of whole blood for preparation of serum eye drops

Transfer bags TF 304ff provide a blood collection tube and the combined empty bags. The connection tubings are equipped with slide clamps. The products provide either a 17G size needle for puncture or a luer lock site for connecting an individually chosen cannula. All configurations provide a predonation-sampling site with adapters of either Holdex or Sarstedt type as well as a site for connecting a container with volume substitution media for the patient/donor.

The product is gamma-sterilised and comes with a shelf life of 35 months.

MODEL	TF304	TF304.1	TF304.2	TF304.3	TF304.4	TF304.5	TF304.6
product code	150021	150028	150038	150037	150040	150052	150053
17G needle with needle protector	●	●	○	●	●	●	●
sampling adapter	Holdex	Sarstedt	Holdex	Holdex	Sarstedt	Holdex	Sarstedt
volume serum bag	300 ml	300 ml	300 ml	500 ml	500 ml	300 ml	1000 ml
connection site for dilution	○	○	○	●	●	●	●
units/box	25	25	25	25	25	25	25

TF



Example TF 304.3

Products

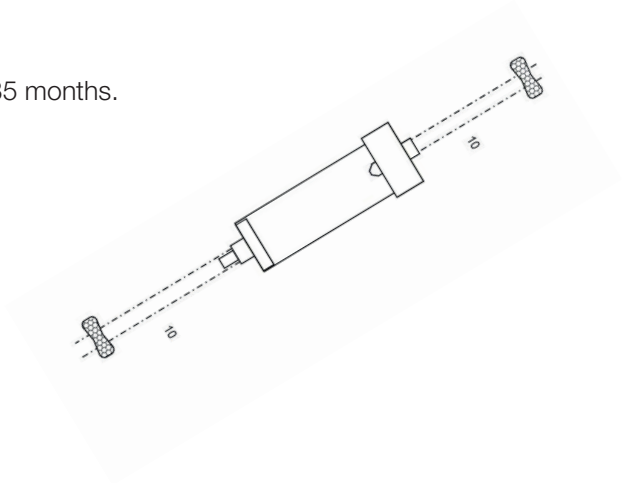
Filtration system TFZ1

TFZ1

Filter adapter for removing microaggregates during production of serum eye drops

The product consists of an infusion chamber with an integrated sieve (15µm) and two sealed tubing ends.

The product is gamma-sterilised and comes with a shelf life of 35 months.



MODEL	TFZ1
product code	140453
units/box	50

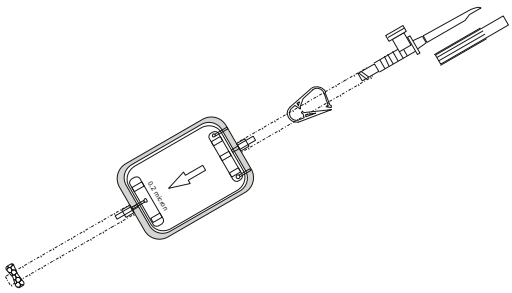
Filtration system TFZ2/TFZ3

TFZ2

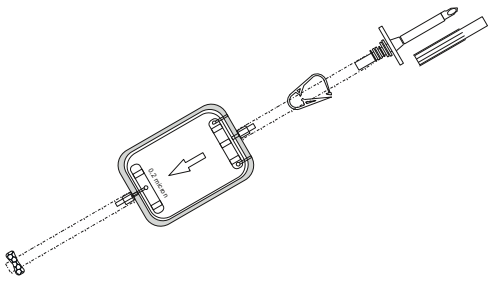
Filter adapter for sterile transfer of aqueous media from containers with transfusion ports for serum dilution

The product consists of a spike (vented: TFZ2 and non-vented: TFZ3) for connecting an aqueous medium, a sterile filter (0,2µm) and a sealed tubing end for connecting a blood component containing bag.

The product is gamma-sterilised and comes with a shelf life of 35 months.



TFZ3



MODEL	TFZ2	TFZ3
product code	140465	140466
Spike	vented	non-vented
units/box	50	50

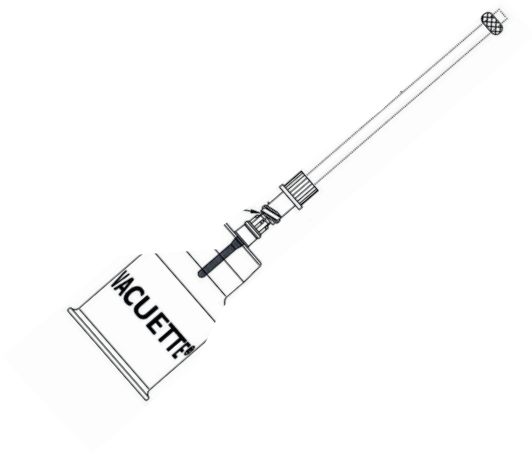
Sampling adapter AD821.1

Adapter for transferring blood or blood components into blood culture bottles

The product consists of a blood culture holder with a connected 10 cm tubing.
The product can be sterile connected to tubings of common bags for blood and blood components using a common sterile docking device.

The product is gamma-sterilized and come with a shelf life of 35 months.

MODEL	AD821.1
product code	140495
units/box	50



AD821.1