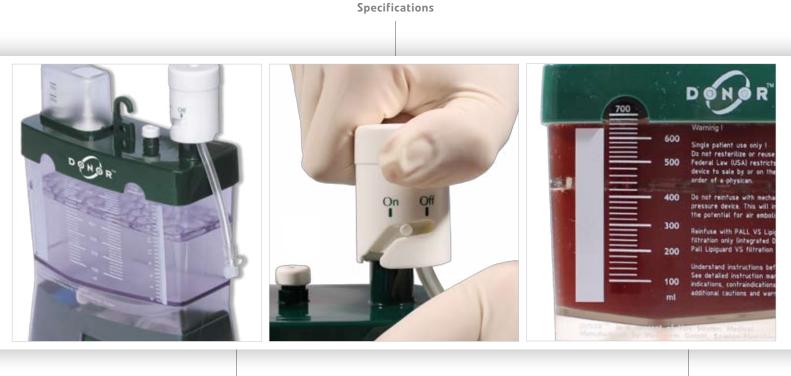
VAN STRATEN MEDICAL

'Providing Value To Life'

DONOR[™] – Pre-Evacuated Post-Operative Autologous Blood Reinfusion System

your partner in blood management



Instructions for Use

Pre-evacuated postoperative autologous blood reinfusion system

Introduction

Postoperative autologous blood reinfusion is very helpful in orthopaedics.

Studies show that reinfusing a patient's own blood reduce the need for standard allogeneic blood transfusion and thus minimise its related adverse reactions, including various types of infections^(1,2).

Postoperative autologous blood reinfusion ensures:

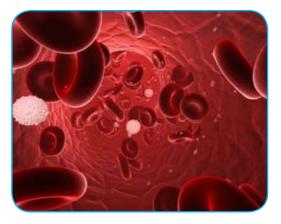
- patient recovers more quickly,
- prevents ageing of red blood cells,
- 100% direct oxygen transportation after autotransfusion,
- minimise patient's exposure to infectious factors,
- reducing any allergic reactions,
- psychological benefits for patients, who are receiving their own blood,
- no foreign bodies being infused,
- reduce pressure of blood banks, save blood for emergencies.

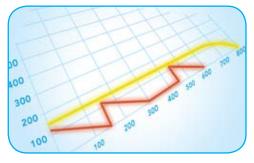
Your Partner in Blood Management

DONOR[™] is a premium device for postoperative drainage, collection, filtration and reinfusion of patient's own blood.

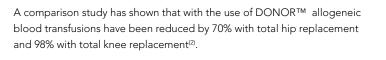
The DONOR[™] system is pre-evacuated with a unique vacuum regulator for constant low suction drainage. Thus, promoting the wound healing.

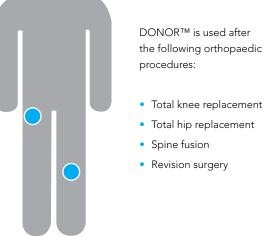
A validated LipiGuard blood filter ensures safe blood reinfusion of patient's own blood.





Constant Low Vacuum (DONOR™)
Bellow type (Intermittent suction)





Data on file:

- Cheng SC, et al. Investigation of the use of drained blood reinfusion after total knee arthroplasty: A prospective randomised controlled study, Journal of Orthopaedic Surgery .2005:13(2):120-124
- Hendriks HGE, et al. Less blood transfusion after the introduction of autotransfusion system in hip and knee replacement. [Minder bloedtransfusies na invoering van autotransfusiesysteem bij heup- en knievervanging]. Ned Tijdschr Geneeskd. (Dutch); 153:B187, 2009.



DONOR™:

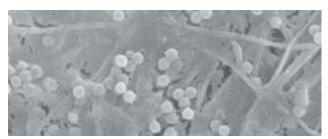
- completely sterile, single use, all-in-one system,
- 800 ml vessel,
- Y-drain connecting tube,
 - PUR wound drain lengths of 1100 mm and Ø 10 CH/FG,
 - Medifix screw connection (drain/trocar),
- trocar,
- LipiGuard filter and administration set,
- replacement low vacuum wound drainage bottle 600 ml to continue the wound drainage process as required.



Highlighted – Validated autologous blood filter

The LipiGuard filter significantly reduces the concentration of fat in the salvaged blood. Therefore, prophylactically protecting the patient against fat embolism syndrome. In-vitro testing of the DONOR™ system showed excellent performance characteristics and it has been concluded that DONOR™ is safe to use for collection and reinfusion of a patient's own blood (data on file).





SEM photograph-LipiGuard filter shows removal of active leukocytes, microaggregates and lipids (data on file).

Specifications



1. Break away cap, incl 0.2 µm hydrophobic filter



2. Vacuum indicator



To easily visualise the vacuum level inside the system.

To vent the system in

order to reinfuse the

blood.

3. 800 ml collection vessel



The system is pre-evacuated for constant suction.

The system is

ready to use.

Activate system and collection starts

automatically.

(Option) To

samples.

administer coagulant

or to take blood

To indicate at what

time the DONOR™

system has been

activated.

4. On/off switch, incl low vacuum regulator



5. Entry port



6. Time scale



7. Luer-Lock with closure cap



Enabling safe connection of the system to patient's connecting tube.

8. Entry port for filter spike



Located at base of container and facilitates easy connection of the filter spike.

9. Self-levelling drip chamber



10. Roller clamp



11. LipiGuard blood filter



12. PUR drain



13. Single cut trocar



14. Medifix connection



15. Y-drain connector with anti-reflux valve



16. Replacement wound drainage system



To regulate the blood flow.

The drip chamber

primes automatically.

Validated filter with impressive filtration characteristics.

PUR exceeds PVC in material characteristics. PUR drains are more flexible and lead to smoother insertion and easier removal.

Requires 1,3 kg less force to penetrate skin compared to a standard bayonet type trocar.

A screw mechanism for easy (dis)connection and smooth transition of drain and trocar, minimizing perforation of the skin.

For insertion of either 1 or 2 drains. Located closely to the drain, the anti-reflux valve prevents backflow to the patient.

Low vacuum wound drainage bottle to continue wound drainage.

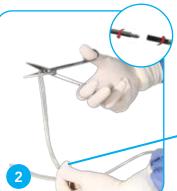
Instructions for Use

According to international (aaBB) guidelines, the reinfusion of the collected blood needs to start within 6 hours after the system has been activated.

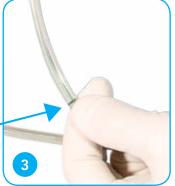
- steps 1 8 Operating Room (aseptic techniques)
 - steps 9 11 Recovery Room
 - steps 12 14 Nursery Ward (occassionaly also Recovery Room)



Ensure that package is undamaged and vacuum indicator is in "max" position. Remove DONOR system from peel-pouch using aseptic techniques.



Cut middle perforated drain (1100 mm length) drain in 2 equal lengths to facilitate 2 separate drains. The Medifix connector facilitates easy connection and disconnection of drain and trocar.



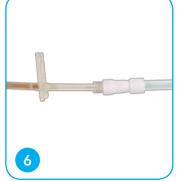
Insert and pass trocar/ wound drain into desired location until black line indicator appears just outside skin surface. Ensure air tight sealing of the perforated area of the drain.



With sterile scissors, cut wound drain at 45-degree angle for easier insertion into Y-drain connector.



Cut Y-drain connector to appropriate size for wound tubing and insert wound tubing firmly into drain connector. Cut only one part of Y-drain connector if one drain is used.



(Option)The wall suction line may be attached to the connecting tube to remove air; apply suction, and when exudates reaches sliding clamp, close sliding clamp.



Remove white protective cap.



Connect tubing to the DONOR™ reinfusion system using Luer-Lock.



Activate DONOR™ preferably 30 minutes* after wound closure/ tourniquet release by turning the vacuum regulator to "On".



Ensure sliding clamp on connecting tube has been opened in order to start wound drainage.



Indicate time of activation on front side (0 - 24 hours timescale).



When DONOR is full, drainage has stopped or it is time to start reinfusion, close the sliding clamp.

* Clamping off system (20 – 30 minutes) improves clotting cascade inside the wound. Thus, reducing blood clots in the collection device, minimizing blockages and improving reinfusion's flow rate.



Close the DONOR™ system by turning the vacuum regulator to "Off". Disconnect and place protective cap on the Luer-Lock (1).



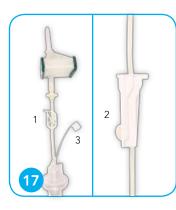
Connect replacement system. Turn vacuum regulator to "On" and open sliding clamp to continue drainage. Ensure green bellow is in "Max" position.



Release filter set by pressing both release buttons (front and back) of the green tray.



Break-off white aseptic spike entry port while holding the tubing firmly.



Close white tubing clamp (1) as well as roller clamp (2). Ensure that the white protective cap (3) is hanging freely.



Remove transparent protective cap from spike (1) and insert filter set spike firmly/ completely (2). Using a twisting motion will facilitate easier insertion of filter spike into tubing.



Vent the DONOR™ system by snapping off the breakaway cap.



Hang canister and attached filter set on drip stand, at least 3 feet or 1 metre above the patient. Prime system by opening the white tubing clamp (1). The automatic priming drip chamber should be hanging vertically (2).



Once blood flow into drip chamber has stopped completely, place protective cap (1) on the air vent of the drip chamber and tighten.



Remove white closing cap at the end of the giving set. Open roller clamp (1) and regulate flow. Ensure that the tubing has been filled completely with blood before connecting to the patient. Use proper size IV needle.



When the DONOR™ collection vessel is empty, reinfusion should be stopped by closing the roller clamp. Dispose the system according to local hospital guidelines.



When wound drainage is no longer required, close sliding clamp and turn switch to the "off" position to discontinue suction. Remove bottle, drain and tubing from patient according to your protocol and dispose in line with local hospital guidelines.

DONORTM Pre-Evacuated Post-Operative Autologous Blood Reinfusion System

Includes:

- DONOR™ collection vessel in size 800 ml
- Y drain connector and anti-reflux valve
- Middle perforated PUR drain 1100 mm length and trocar in Ø size 10 CH/FG
- LipiGuard VS autologous blood filter
- Administration set including self-levelling drip chamber
- Replacement wound drainage bottle in size 600 ml

Product descriptions and article codes are available in our catalogue or online on **www.vanstratenmedical.com**



Company information

Van Straten Medical is a family owned company, founded in 1975, and active in the development, sales, repair, modification and fixation of medical devices. Van Straten Medical has several divisions, including Export, and is founder & shareholder of the production facility Medinorm Medizintechnik GmbH in Germany.

Our export division offers surgical products and services to the international market through distributors and medical industry. Van Straten Medical is an ISO 9001 and ISO 13485 certified company.

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