

**Bringing new dimensions
to vascular access**

Hemaport®

Vascular Access

Patients with End Stage Renal Disease (ESRD) need dialysis to survive. The removal of residual products and water from the blood stream with hemodialysis, where the blood is circulated through a filter in the dialysis machine, is a routine procedure in health care today. To be able to connect the patient to a dialysis machine there is a need of an access route to the circulation.

A well functioning blood access permits repeated access to the blood stream allowing extra corporeal circulation of large volumes of blood three to seven times a week. Accordingly, an access should allow easy connection and high blood flows at moderate pressure levels. Each dialysis session takes several hours to perform so the opportunity of moving freely in a chair or bed is a great advantage. High probability of success and easy handling also contribute to patients' comfort and trust in the procedure.

With Hemaport® a new dimension in vascular access is introduced. With channels no less than 4 mm in diameter, high blood flows with moderate pressures can be achieved. This needle free device allows fast and easy connection and disconnection. No lock solution is needed as blood flows continuously through the device between dialysis sessions.

Trends in Dialysis

The increasing number of patients undergoing hemodialysis today, and in the future, increases the demand for finding alternative solutions for performing the procedure. Home dialysis or limited care centres require a more active patient and at the same time offer a more flexible solution for the patient. Hemaport® was developed with this in mind. It is possible to make connection and disconnection with one hand, the access is needle free and there is no lock solution to be installed or hemostasis at the end of the procedure.

Daily and nocturnal dialysis regimens are proposed to increase quality of life and outcome. Since no skin puncture is required the Hemaport® access can be used as many times as desired without discomfort.



Hemaport[®] features

- an AV-access with continuous blood flow
- no needles
- fast and easy connection and disconnection
- high blood flows with low or moderate pressures
- no lock solution
- peripheral location

Indication for Hemaport

Hemaport[®] is intended for patients undergoing hemodialysis.

Hemaport[®] acknowledges the ambition of the medical community to increase the usage of AV-fistulas due to their relatively low risk for complications. As Hemaport[®] is a new device with unique design it offers an alternative solution in difficult clinical situations such as problems of creation, maturation and maintenance of an AV-fistula. It is also an alternative for patients with needle phobia, in patients with complications following central dialysis catheters and where a location in the peripheral vasculature is preferred. The design and function of Hemaport[®] makes it also suitable for situations where the patient is actively participating in the dialysis session such as home dialysis and limited care.

Unique design

Hemaport® is a transcutaneous device and requires a vascular surgical procedure before use. The in-growth of tissue into the perforated collar at the base of the device requires maturation. Normally, dialysis with Hemaport® can start after 7-10 days of healing but, if clinically necessary, dialysis can be performed with the device immediately after implantation.

Many patients with vascular accesses will experience problems with thrombosis and stenosis in the vasculature. The Hemaport® offers a distinct advantage as pharmacological and mechanical thrombolysis can be performed through the large bore channels of the device. Through the dialysis lid thrombolytic medication can be administered and contrast media injected for diagnostic angiography. Interventions such as thrombectomy (using a Fogarty catheter or similar type of device), balloon dilatation and/or placement of stents can be performed through the dialysis lid without open surgery.



Clinical data

Clinical experience with Hemaport® is limited. During clinical follow-up studies access flow and pressure have been measured.

Clinically used flows at dialysis sessions with 8 weeks of the implantation have been 326 ± 62 ml/min (range 180 to 450 ml/min; n=82 dialysis sessions). The corresponding pressures recorded on the dialysis machine monitor have been 101 ± 41 mmHg (30 to 220 mmHg) on the venous side and 18 ± 43 mmHg (-100 to 90 mmHg) on the arterial side.

At 500 ml/min flow (measured as speed of the blood pump) average venous pressure was 120 mmHg (range 95 to 200 mmHg) and on the arterial side the corresponding pressure was -22.5 mmHg (range -105 to +40 mmHg).

Hemapure AB has the ambition to follow the patency and performance of the devices and is conducting follow-up studies as well as documentation on clinically used devices. For updated clinical information and sales information, contact Hemapure AB or a representative.

Hemaport® Product Description

The main components of the system are the Housing device, which is permanently implanted, Fig. 1, and the disposable lids and applicators, Fig. 2.

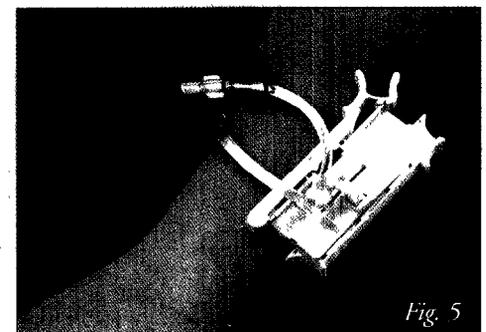
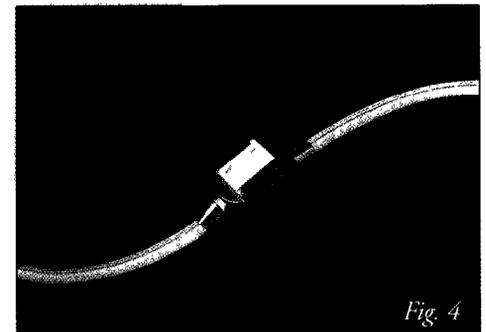
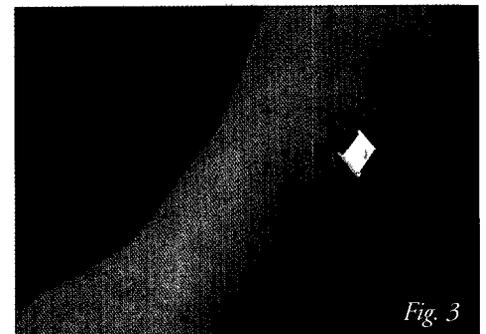
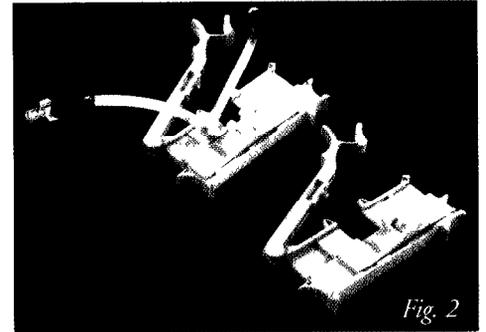
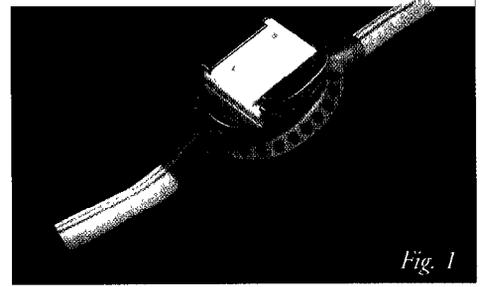
The Housing is surgically implanted at a suitable location, usually the upper arm or the leg, see Fig. 3. Blood is circulated to it through synthetic grafts, which form the connection between the inflow, an artery, and the return, a vein, see Fig. 4.

With the Sealing Plate in position, blood is continuously flowing through the implant, from artery to vein.

Prior to treatment, the Sealing Plate is exchanged for the Dialysis Lid using the applicator that attaches to the Housing making an easy and secure transfer possible, Fig. 5.

When the Dialysis Lid is correctly in position, the applicator and Sealing Plate can be removed and discarded, see Fig. 6.

The Hemaport® is then connected, via the blood tubing, to the dialysis machine. When the dialysis treatment is finished, the Dialysis Lid is exchanged for a new Sealing Plate.



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The Hemaport® is marked by the CE which indicates compliance of this specific device to all applicable essential requirements of the MDD (93/42/EEC) of the European Community.

Hemapure AB operates a quality management system certified to the requirements of EN ISO 9001 and EN 46001

Hemaport® is a registered trademark of Hemapure AB.

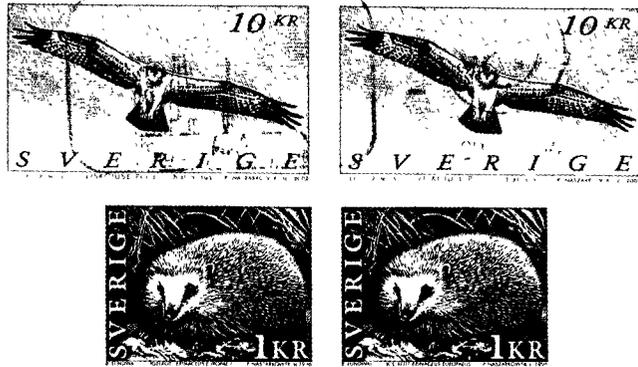
We reserve the right to make alterations of the product and the specifications therefore change at any time without notice.

This brochure is intended to provide an overview of Hemaport® and its benefits. For clinical use, we refer to Instructions for Use, enclosed in the product packaging.

Hemaport® is protected by Swedish patent no 9703839-2, other countries and pending.

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