

# + Bone Anchored Port for Hemodialysis.

The first bone anchored long-term vascular port for hemodialysis.

## Introduction.

In many medical disciplines, direct long-term access to the body's major blood vessels is a key issue. Such long-term ports are required, for example, for hemodialysis in patients with renal insufficiency and for long-term chemotherapy in cancer patients. In the case of hemodialysis the vascular port is used for extracorporeal blood cleansing for several hours at least three times a week. This therapy calls for perfect venous ports and also requires very high blood flow rates of up to 450 ml/min. Studies and long-term empirical data indicate that complications cost up to CHF 10,000 a year per patient. Apart from infections and thrombosis, the pain experienced by patients when their arteriovenous fistula is being punctured, is very unpleasant. In developing the BAP, the focus therefore lied on the following features: creation of a safe, long-term access with easy handling that allows the user to regain part of his freedom and quality of life.

## Background.

The idea of implanting a dialysis port on the head, originates from many years of experience with bone anchored hearing aids, which exhibit low skin infection rates around the implant. The reasons for this are the good circulation in the scalp and the fact that there is very little tissue in the skull between the skin and the bone. Bacterial infections (so-called soft-tissue infections) frequently occur where there are relatively thick layers of soft tissue under the skin (muscle tissue or fat tissue). That is why hemodialysis catheter patients and arteriovenous fistula patients are often confronted with such infections. It usually means the ports can no longer be used for hemodialysis.

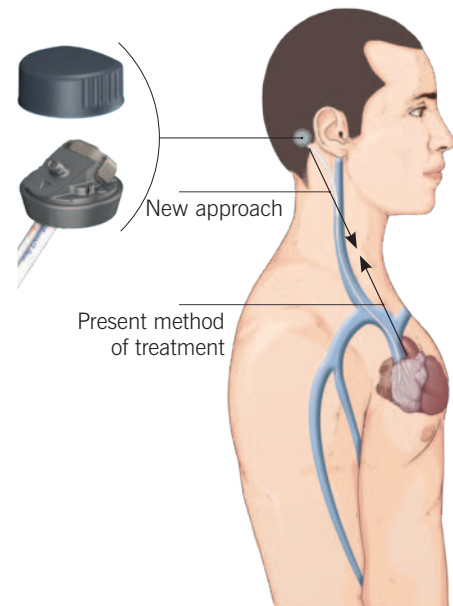


Fig 1: Bone Anchored Port – the first bone anchored percutaneous port for hemodialysis.

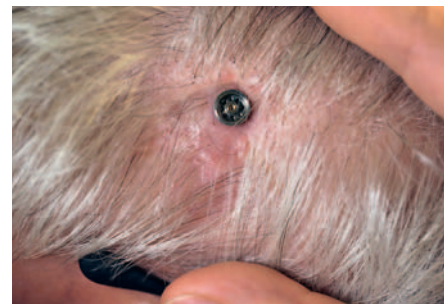


Fig. 2: A wearer of the Bone Anchored Hearing Aid (BAHA). The skin around the implant is well vascularized and nicely cicatrized.



Fig. 3: The fundamental benefits of the BAP – lower infection rates and good stability – are based on positive experiences in the field of auditory implantology.

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## The device.

The BAP is comprised of a casing (the actual implant), an ingenious valve system consisting of a main valve and a sub-valve in an internal housing, a catheter and a replaceable cap.

The catheter ends, like any other long-term hemodialysis catheter, in the right atrium of the heart. However, its course is straighter, which allows higher flow rates during dialysis and causes less turbulence in the catheter. This in turn has a positive impact on the durability of the port because fewer catheter occlusions occur. The internal housing contains a tubing system that is normally open. Only when the main valve is being exchanged it is closed from the outside with a clamping mechanism. The main valve protects the interior of the port and the catheter against air ingress and pathogens and it is changed regularly by dialysis nursing staff. Connection to the dialysis machine happens via an adapter that is simply clicked onto the port. After each dialysis the port is eventually protected with a new cap.

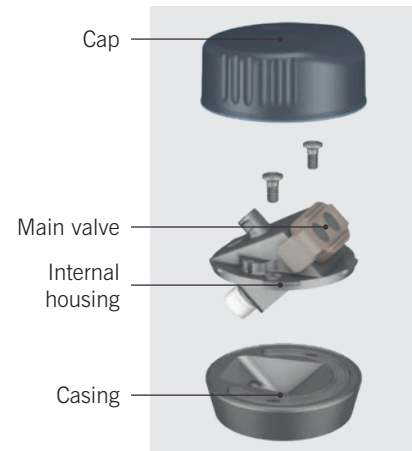


Fig 4: The modular design of the port permits flexible replacement of components without having to explant the baseplate – a major benefit in terms of hygiene!

## Benefits.

- Access site in a tissue zone with good circulation and reduced infection risk.
- No repeated painful vessel puncture, no postoperative bleeding.
- Self-contained system with replaceable components (better hygiene).
- Safety barrier between port and catheter tip (reduced risk of catheter infection).
- Fewer catheter blockages due to a straighter course of the catheter (hardly any turbulence).
- Stable anchorage in the bone allows first dialysis shortly after implantation (good primary stability).
- Better resistance to everyday influences.

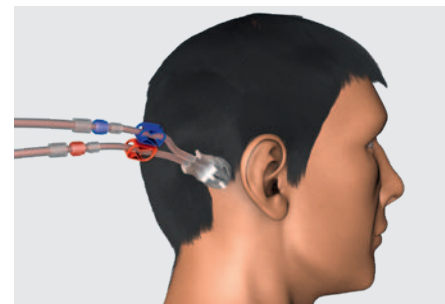


Fig. 5: The BAP adapter can easily be connected to the port and thus permits connection to any dialysis machine.

## Partnerships.

The Bone Anchored Port was developed in close collaboration with the following institutions.

**INSELSPITAL**  
UNIVERSITÄTSSPITAL BERN  
HOPITAL UNIVERSITAIRE DE BERNE  
BERN UNIVERSITY HOSPITAL

Clinic for Ear, Nose and Throat Diseases, Head and Neck Surgery  
University Clinic for Nephrology, Hypertension and Clinical Pharmacology

**u<sup>b</sup> ARTORG CENTER**  
BIOMEDICAL ENGINEERING RESEARCH

Research Unit for Artificial Hearing