PHS MEDICAL®

Patient Information

The port system

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VO (EU) 2017/745 MDR CERTIFIED

The MDR (Medical Device Regulation) is a strict regulation that manufacturers must comply with if they want to place a medical device on the EU market.

SD-001005m Rev. C 09/24

Introduction

Dear patient,

your doctor has prescribed a port system from PHS Medical GmbH for your intravenous treatment. This implantable port system enables infusion therapy to be carried out without having to repeatedly puncture the veins in the arm or wrist with a cannula.
During your treatment, this port system should help you to lead as normal a life as possible.

Please read this patient information leaflet carefully.

The information will help you to better understand treatment with a port system.

If you have any questions after reading this handbook, your doctor will be happy to answer any questions you may have!

IMPORTANT!

Your doctor should inform you about the port system, its application and the associated risks in a preliminary consultation.

We wish you a successful treatment and a good recovery!
YOUR PHS MEDICAL TEAM

IMPORTANT!

This port system comes with a patient ID card, which your doctor must give you. Please always carry it with you and show it to the medical staff before each treatment. The card identifies the type of port you have received and contains important information and safety instructions for use.

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What is an implantable port system?

Port systems are medical devices that are implanted under the skin, usually in the chest area, to provide permanent access to the vascular system. These systems were developed for patients who need to receive medication repeatedly or regularly via the vein.

They provide an easy-to-find location for medical staff to insert a cannula to administer fluids or drugs into the vascular system or to take blood samples. The port is accessed by puncture (insertion) with a (non-coring) port cannula.

Port systems are intended for single use and are usually explanted and disposed of at the end of therapy. The port system is removed in a similarly simple manner as the implantation.

C-Port®-CT (CTKP-...)

NuPort®-LP (LPA-...)

NuPort®-CT (CTP-...)

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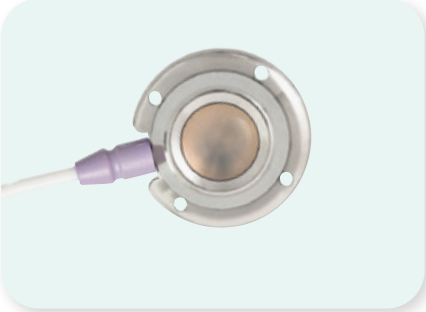
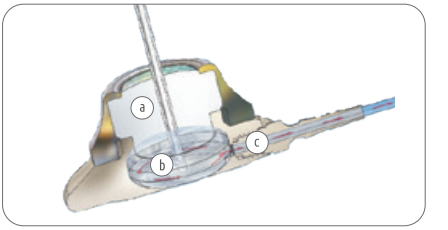


C-Port® (SPB-...)

How is a port system constructed?

A port system is a small device which is inserted under the skin in a short procedure. It consists of a port made of titanium or polysulfone (PSU) with a hollow space (port chamber) which is sealed by a silicone septum. The septum is manufactured to withstand a very high number of applications with a non-coring cannula.

A flexible tube (catheter) made of silicone or polyurethane (PUR) is connected to the port. The catheter is inserted into a large, central vein that transports blood to the heart. This ensures rapid dilution of the administered medication or fluids.



Port

(a) Clear septum
(b) Port chamber
(c) Outlet

The port system

(1) Port
(2) Catheter fixation
(3) Catheter

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When is a port system needed?

The port systems are intended for use for patients who require:

- repeated access to the vascular system for injections,
- infusion of drugs,
- administration of blood or blood products and/or collection of blood as part of therapy.

Areas of application are e.g:

- Parenteral nutrition
- Chemotherapy
- Pain therapy
- Endocrinological therapy
- Substitution of coagulation factors
- Contrast medium infusion in radiation diagnostics
- Treatment of severe asthma or cardiac arrhythmia
- Blood collection and transfusion

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When should a port system not be used?

The port systems are not to be used under the following conditions (contraindications):

- Patients with known or suspected allergic reactions to the materials contained in the implant
- Patients with known infection, bacteremia or sepsis
- Patients with body tissue that cannot adequately support the port or catheter
- Patients with chronic obstructive pulmonary disease (COPD)
- In patients with previous venous thrombosis or surgical procedures at or near the site of intended use
- If a potential access site has been irradiated
- If the patient's tissue factors prevent proper stabilization of the port system and/or access

IMPORTANT!

If you have any of the above-mentioned contraindications, please inform your doctor.
If you have allergies to certain medications, e.g. heparin, or other substances, please also pass this information to your doctor.

What are the advantages of a port system?

- The port system only needs to be implanted once for the entire treatment period
- No dressing is required after the implantation suture has healed
- As the port system is implanted under the skin, there is no need for daily care
- Apart from a small prick when inserting the cannula, use of the port system is painless
- Outpatient use is possible
- The port systems are suitable for standard computer tomography (CT) and magnetic resonance imaging (MRI) examinations
- You are not restricted in your choice of clothing
- Many types of sport are still possible, but movements that cause bruising in the area of the port system should be avoided; ask your doctor about special activities such as diving
- Air travel is also possible; please always carry your patient ID card with you in case the port system triggers the safety alarm
- The port system is not affected by microwaves, magnetic waves, electrical currents, etc.

What are the risks of using a port system?

The use of port systems involves risks that are normally associated with the insertion or use of an implant or indwelling catheter. Your doctor should inform you about this.
Contact your healthcare professional if you believe you are experiencing any side effects associated with the product or its use, or if you are concerned about any risks.

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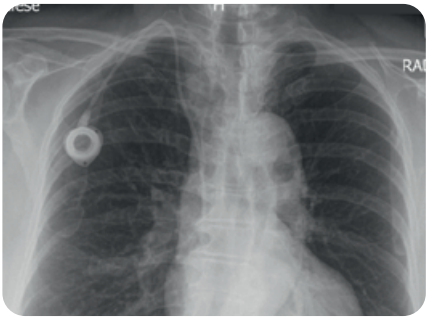
What is the procedure for implanting a port system?

The port system is implanted as an in-patient or out-patient procedure under local anesthesia in approx. 30 minutes. A small incision is made in the chest area for this purpose. The catheter is inserted through this into a large vein leading to the heart. The port chamber is connected to the catheter and placed in the tissue under the skin so that it can be easily felt for the application. The incision is sutured. There will be a small scar and a slight bulge in the skin around the port chamber.



Follow your doctor's instructions on how to care for the small incision. No water, creams or similar solutions should come into contact with the wound during the first week after implantation. Once the incision has healed, your port system does not require any special care.

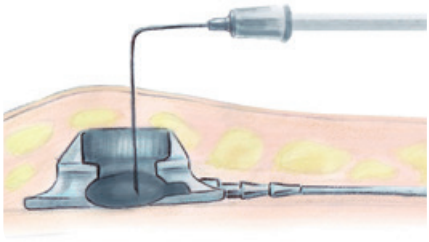
Avoid physical exertion and contact with people with infectious diseases in the first few days after implantation.

After healing, you can resume your normal daily activities. However, try to avoid pressure, friction or other external influences, e.g. direct sunlight, in the area of the port system. If the car seat belt presses on the implantation site, you can be exempted from wearing a seat belt.

IMPORTANT!

If fever, pain, redness or inflammation occur after implantation or while the port system is in the body, please inform your doctor immediately.

How is the port system used after implantation?



IMPORTANT!

If fever, pain, redness or inflammation occur after implantation or while the port system is in the body, please inform your doctor immediately!

The skin in the area of the port system is disinfected before use. A special (non-coring) cannula is used to pierce the septum of the port through the skin. This establishes access to the bloodstream. Medication and fluids can be administered and blood samples taken. The septum is designed in such a way that it contracts again after the cannula is removed and is therefore sealed. If you are receiving a continuous infusion, a dressing may be applied to protect and stabilize the cannula.

Much more detailed information can be found in the patient section of our Summary of Safety and Clinical Performance. This can be found on the homepage of PHS Medical in the 'Download area' or you can obtain this via this QR code:

www.phs-medical.de/K07V12F03_P

The PHS Medical Team wishes you a successful treatment and all the best for your future!

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