

Celsite® Access Port Systems

Patient guide



Patient Information

Patient name: _____

Patient address: _____

Patient phone number: _____

Hospital name: _____

Hospital address: _____

Doctor name: _____

Doctor phone number: _____

Date of insertion: _____

Site of insertion: _____

Celsite® model inserted: _____

Silicone catheter Polyurethane catheter

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A Glossary

Your physician has decided that you will need to undergo a therapy which requires continuous or intermittent vascular access. To make this access easier, he/she has advised you to have a Celsite® access port implanted. To help you understand your treatment you will find below a glossary providing you with the most common terms which will be used by your doctor or nurse when they refer to your access port or your treatment.

If some phrases used by your doctor are missing here, you should ask the medical staff looking after you for explanations.

ACCESS PORT	Device which consists of a catheter connected to a reservoir. It is implanted subcutaneously and used to deliver drugs into the blood stream.
BOLUS	Injection given over a short period of time.
CATHETER	Thin tube, placed into a vein, an artery, intra-thecal space or inside an organ (pleural and peritoneal spaces).
CENTRAL VEINS	Large, deep veins, close to the heart.
FLUSH	Rinse with a fluid.
HEPARIN	Drug which helps to prevent blood clotting.
IMPLANTATION	Operation performed by the physician when the access port is placed.
INFUSION/PERFUSION	Flow of fluid into the vein, artery...over a period of time, coming from a bag, a bottle of fluid or a pump, connected to a needle.
INTRA-VENOUS	Into a vein.
INTRA-THECAL	Inside the spinal space.
ORAL	By mouth.

PERIPHERAL VEINS	Small superficial veins of the arms and legs.
PERITONEAL	The peritoneal cavity is the fluid filled gap between the wall of the abdomen and the abdominal organs.
PHLEBITIS	Inflammation of a vein.
PLEURAL	Relates to the pleura: the membrane surrounding the lungs.
PORT	Access port.
RIGHT ATRIUM	Right upper chamber of the heart.
SEPTUM	Self-sealing membrane through which the needle passes to administer the drugs.
SUB-CUTANEOUS	Under the skin.
SODIUM CHLORIDE	Saline solution for injection (NaCl 0,9%).
THROMBOSIS	Formation or presence of a blood clot inside a blood vessel.
THROMBOPHLEBITIS	Venous inflammation with blood clot.

B My Celsite® access port

For an individualized management of your treatment, your doctor has recommended that you have an implanted access port.

1-Definition

Your Celsite® access port consists of an implantable catheter linked to a reservoir. The device is placed subcutaneously and can be used over a long period of time for any type of continuous or intermittent infusion.

The advantages of an access port are numerous:

- Decrease in number of puncture in peripheral veins which could be damaged by chemotherapy and are then less accessible
- Easier and less painful venous access, which is more comfortable
- Home care treatment facilitated
- Possibility to go on with everyday activities

Celsite® access ports are designed to improve your comfort.



2-Why do I need an access port ?

Lots of people each year have an access port implanted. Some of them will wear the port for a few months only, others, for a longer time. Your port's length of use will depend upon the duration of your treatment.

The reason why your doctor decided you should have an access port is to avoid having repeated injections or infusions into one of your peripheral veins. It will make your treatment and infusion much easier.

Frequent and long infusions into peripheral veins (chemotherapy for example) can lead to painful phlebitis. Celsite® access ports make it possible to preserve your peripheral veins and make the infusions the most convenient for you.

3-How does my Celsite® access port work?

The access port is composed of 2 main parts:

- the catheter, which is placed into one of your central veins, usually in the area around the collar bone, the neck or in the arm. The tip of the catheter is placed at the entrance to the heart.
- the port, connected to the catheter, is placed under the skin. To inject the drugs, the nurse punctures the septum of the access port using a special needle dedicated for access ports. The treatment is injected into the port and along the catheter into the blood stream.

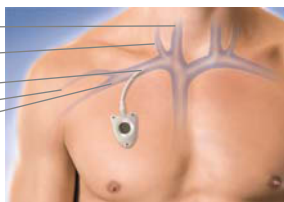
internal jugular vein

external jugular vein

sub-clavian vein

cephalic vein

axillary vein



4-Non venous Indications

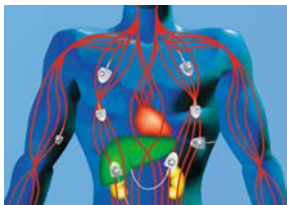
Celsite® access ports are not only **venous access ports**. The Celsite® access port range offers many other possibilities:

Arterial access ports: to be used for intra-arterial administration of chemotherapy

Spinal access ports: to be used for spinal administration of pain relieving drugs

Peritoneal access ports: to be used for intra-peritoneal administration of chemotherapy

Peritoneal/pleural access ports: to be used for intra-peritoneal administration of chemotherapy, hydration, drainage of malignant pleural ascites or drainage of malignant pleural effusion



C Implantation of the Celsite® access port

The following descriptions are based on general experience and therefore constitute only values for orientation.

1-How is my Celsite® access port implanted?

The implantation is performed in an operating theatre (or catheter lab) under local anesthesia. The operation is simple and takes only around 30 minutes. The doctor punctures the vein to introduce the catheter and incises the skin to make a pocket to place the Celsite® access under the skin. The port pocket is made as small as possible (about 2.5 cm). A dressing is then placed to protect the incision.

If treatment is required right after your port placement, it is possible for the physician to place a needle into your port to administer the treatment.

2-Before the implantation

You will have had an appointment with your doctor and with the clinic nurses to discuss your treatment. You will have been told about the advantages of your Celsite® access port. If you play a lot of racket sport such as tennis or squash, or if you practice in a rifle shooting club or a contact sport, you should mention it to your doctor before the implantation. Your physician will then be able to choose to implant the port in a place that will not affect your activities.

The week before the implantation, the doctor may need to perform blood tests. If you have any question, your doctor or nurse will be able to answer it.

3-The day of the implantation

Whenever it is possible, the access port is implanted under local anaesthetic in the day hospital. This, however, may vary from one hospital to the other and should be discussed with the nurse or doctor beforehand.

Before you leave the hospital, a chest X-ray is taken to confirm the correct position of the catheter.

Driving is not recommended right after the implantation, it is thus advised that you should be accompanied.

4-After the implantation

Healing is usually complete after a few days only and your Celsite® access port can be used immediately after the implantation. The port might be visible as a little bump under the skin. The bump can be easily felt under the fingers and can be more or less visible and sensitive.

If your treatment requires a few days infusion, a special needle will be put in place and covered with a sterile dressing. This needle does not need to be changed every day but every 7 days is the recommended maximum duration (unless otherwise stated by your doctor).

When you are not receiving regular treatment through your Celsite® access port, it is recommended to be flushed every 4 weeks (unless otherwise stated by your doctor). This is to make sure that the catheter and port are still functional.

The Celsite® access port will enable you to go on with your daily activities. Once the small scar from the operation has healed you can swim, bath, run and do anything you enjoyed before. After you leave the hospital, you should always keep your patient card with you. Your patient card gives all the important information anytime it is needed.

5-Potential complications

After the implantation, pain should only be moderate and can be treated with analgesics. The pain will disappear quickly as the port is not painful.

In most cases, there are no complications. However, immediate complications or delayed complications can appear. Your doctor will inform you about possible complications.

If the port is painful, please inform your doctor or nurse immediately.

C Implantation of the Celsite® access port

6- Maintenance

Maintenance

Check the access port site daily to confirm the absence of redness, or swelling.

Hygiene

Unless otherwise stated by your Doctor, you can have a bath or shower after the post-operative period.

No special care is needed if there is no needle inserted into the port.

If a needle is inserted into the port, take care not to wet the area around the port or the protective dressing.

If the port is not used, the dressing is not required.

If the dressing is dirty, it is recommended that you ask your nurse to change it so as to avoid any risk of infection.

Activities

After the implantation your access port is not painful. You can go back to your normal activities.

- Sport: even if chest muscles are used, sport can be practiced moderately. For racket sports, the access port should be placed on the non-dominant side. You can go diving when the port is not being used.
- Travelling: There are no contra-indications. In a car, your seat belt must still be fastened. In a plane, your access port may activate the safety alarm. Keep your patient card with you and show it if necessary.
- Sunbathing: If you go out in the sun, protect the injection site with sunscreen cream.

D The use and maintenance of my Celsite® access port

To deliver your treatment, the nurse will puncture your Celsite® access port with a special needle. She will check the functionality and patency of the port by aspirating blood and flushing with saline solution.

The insertion of the needle into the port is generally painless. However local anaesthetic cream can be applied over the injection site to numb the area. Your nurse will tell you when to apply the cream.



The access, use and maintenance of your access port must be done according to strict aseptic rules and following approved local protocols.

D The use and maintenance of my Celsite® access port

This is why, to avoid any risk of infection your nurse will use:

- sterile gloves,
- mask,
- sterile gauze swabs,
- skin cleaning solution,
- sterile syringe,
- sterile needle.

The drugs can now be infused directly or via a pump or an infusion bag.

When the treatment is finished, the port is flushed and the needle removed. A small dressing can be put over the injection site for a few hours and then removed.

Keep your follow-up booklet with you to allow the medical staff to refer to it if necessary.

E Complications

In case you feel unwell, esp. have any of the following symptoms, you must contact your doctor:

- Fever
- Local pain
- Swelling around the access port
- Redness or discharge around the scar
- Breathing difficulties

F Questions-Answers

If you have any questions, contact your doctor.

■ **How long will my Celsite® access port be implanted?**

The Celsite® access port can stay in place for as long as your doctor determines that you need it. It is generally removed at the end of your treatment, after discussion with the medical staff.

■ **Do I have to stop wearing certain types of clothes?**

Ask your doctor or nurse because the answer depends upon where your Celsite® access port is placed.

■ **Will my Celsite® access port need to be accessed when not in use?**

We recommend to flush the system every 4 weeks with sodium chloride (NaCl) 0.9% (with or without heparin, according to local protocols), unless otherwise stated by your doctor.

■ **Can I get a CT procedure with a Celsite® access port?**

Yes, for all venous access ports (except with Celsite® Implantofix and ST301V/ST305V). Always show your patient card to clinicians who perform your CECT scan, it informs the medical staff that you have a power injectable Celsite® access port.



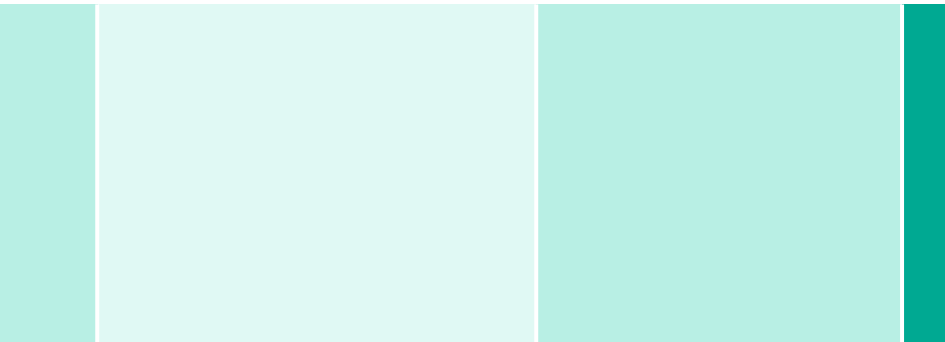
■ **Can I get a MRI procedure with a Celsite® access port?**

Non-clinical testing demonstrated that Celsite® Access Ports and Surecan®/Cytocan port needles (including Safety II and Ultrasite®) are MR Conditional. A patient with these devices can be scanned safely, immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla and 1.5-Tesla
- Maximum spatial gradient magnetic field of 710 Gauss/cm or less
- Maximum whole body averaged specific absorption rate (SAR) of 2.9 W/kg for 15 minutes of scanning.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the devices. Therefore, optimization of MR imaging parameters to compensate for the presence of these devices may be necessary.

Please see instructions for use for information for general information and information on MRI-related heating.



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