

LIFECATH / LIFECATH EXPERT

Codes 2191., 2193. / 8191., 8193.

Instructions for use.

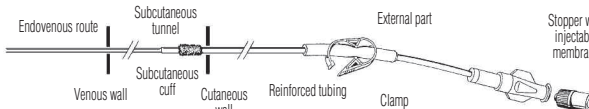
Read all instructions and warnings carefully before use.
The insertion of a LIFECATH must be performed under sterile surgical technique (using masks, gloves, gloves, sterile patient working field and equipment).

DESCRIPTION
LIFECATH is a XRO (or a radiopaque) long term central venous silicone catheter for parenteral nutrition and for the administration of drugs, antibiotics and cancer chemotherapy.

It exists in two different versions:
- a kit containing only the catheter and a tunnelling rod.
- a complete set including the catheter, a Deslit introducer with peel-apart sheath (code 1146) and a tunnelling rod.

a/ LIFECATH (catheter only)
XRO silicone catheter with a subcutaneous cuff for long-term secure access.

Code	Int. Ø - Ext. Ø mm	Ch./Fr.	Total length cm	Useful length cm	Max. working press. Kg/cm²
2191.27	8191.28	0.5 - 1.0	2.7	75	50 3.5
2191.42	8191.43	0.7 - 1.4	4.2	75	50 3.5
2191.50	8191.51	0.95 - 1.7	5.0	75	50 3.5
2191.66	8191.67 / 668	1.10 - 2.2	6.6	90	55 3.5
2193.90	8193.90 / 97	1.6 - 3.2	9.6	90	55 3.5



b/ LIFECATH - Kit for percutaneous introduction

The LIFECATH kit consists of the catheter, a Deslit introducer (code 1146) with a peel-apart sheath for percutaneous introduction of the catheter and a tunnelling rod.

Code	Int. Ø - Ext. Ø mm	Ch./Fr.	Total length cm	Useful length cm	Max. working press. Kg/cm²	Deslit Introducer Code
2191.273	8191.28	0.5 - 1.0	2.7	75	50 3.5	-
2191.425	8191.43	0.7 - 1.4	4.2	75	50 3.5	-
2191.506	8191.507	0.95 - 1.7	5.0	75	50 3.5	1146.06
2191.667	8191.67 / 668	1.10 - 2.2	6.6	90	55 3.5	1146.07
2193.90	8193.90 / 961	1.6 - 3.2	9.6	90	55 3.5	1146.10

IMPORTANT CAUTIONS

- Only use Luer-Lock type connections.
- Be careful not to exceed the maximum working pressures indicated above (see description). Do not use springs with a volume of less than 10 ml. Small volume springs lead to excessive injection pressures that can cause the catheter to migrate from the site of the split.
- Lates gloves must be washed with sterile water to remove any talc residues before handling the catheter.
- To avoid any reflux of blood into the catheter, it is recommended that syringes containing the heparinized solution should not be connected directly to the catheter hub. The hub should first be occluded with an injectable membrane then flushed with saline and the heparinized solution should be administered through the membrane. The needle must be withdrawn while continuing the injection of heparinized solution.
- When flushing the catheter and performing a heparin-lock do not advance the needle too deeply into the injectable membrane.

INDICATIONS

- Long-term catheter indicated for:
 - prolonged, permanent or intermittent parenteral feeding, in hospital or at home,
 - chemotherapy,
 - transfusions of blood products, in hospital,
 - blood sampling,
 - organ transplants,
 - various treatments administered to AIDS patients (antiviral drugs, nutrition, etc.).

INSERTION OF LIFECATH

This catheter is inserted under local anaesthesia in adults and under general anaesthesia in children.
Preparation of the patient psychologically by explaining the aims and benefits of the technique:
- Oral premedication is desirable.
- This type of catheter is best inserted into the superior vena cava.
- If possible, a few hours before LIFECATH is to be inserted prepare the insertion site (washing, shaving, cautious disinfection of the area which is then covered by sterile drapes).
There are two insertion methods for LIFECATH:
A A surgical cut-down technique.
B Percutaneous technique by venous puncture.

Place the patient in the Trendelenburg position. Expose the upper thorax, turn the head to the side away from the catheter insertion site.
Disinfect a wide area around the site chosen for catheter insertion (area of vein exposure in the case of surgical insertion, site of venous puncture in the case of percutaneous introduction), the tunnelling path and the intended cut-down site of the catheter.

A. SURGICAL CUT-DOWN TECHNIQUE

Carry out a local anaesthesia of the skin (at the area of vein exposure and along the tunnelling path).

• Vein preparation

- Cutaneous incision and dissection of the chosen vein over a length of 2 to 3 cm (cephalic vein in the deltopectoral groove, external or internal jugular vein in the cervical region).

Place two clips under the exposed vein and ligate.

• Subcutaneous tunnelling and catheter insertion

- Make a small incision into the skin at the point chosen for the catheter exit point.
- Tunnelling with the tunnelling rod provided with LIFECATH: the subcutaneous path starts at the catheter exit point and continues as far as the point of introduction of the catheter into the vein (exposed area).

Gently and steadily pull on the tunnelling rod, the catheter follows the tunnelling rod in its subcutaneous track.

The cuff must be placed in the subcutaneous tunnel in the immediate proximity of the exit point (where the catheter emerges).

Estimate the length from the rod by cutting the catheter close to the tunnelling rod. Be careful to make a clean cut.

Disinfect the length of the catheter needed so that the distal end will be situated at the junction of the **superior vena cava and right atrium** and in the catheter to the required length with a clean, vertical cut.

Make a venotomy and introduce the catheter that has been previously flushed with heparinized saline.

Check for the absence of subcutaneous knots or loops on the catheter.

Remove the clips.

Carry out a radiological examination to confirm the correct positioning of the catheter (location of the distal end, absence of false route, no intravascular loops on the catheter, etc.).

Do not fix the catheter to the vein - such suturing is unnecessary if the catheter is correctly placed (distal end at the junction of the superior vena cava and right atrium). The attachment of the catheter to the vein wall could be dangerous when the catheter is removed.

Close the cut-down site with two layers of sutures.

B. PERCUTANEOUS TECHNIQUE

This technique involves using the Deslit introducer with peel-apart sheath (code 1146) available separately. It also consists of a kit consisting of a LIFECATH and its introducer.

Important caution: Before placing the peel-apart Deslit, check that the catheter can be

introduced without difficulty through the sheath of the Deslit.

The most frequently used veins are the internal and external jugular or the subclavian vein.

- Prepare (shave) and disinfect the areas chosen for the insertion site, tunnelling and the catheter exit site.

- Perform local anaesthesia at the insertion site of the chosen vein.

• Introduction of the peel-apart Deslit

- Fill the Deslit needle onto a syringe filled with 1 to 2 ml of saline.
- Puncture the vein. Maintain a vacuum in the syringe manually while you pass the needle through the layers of skin.

- As soon as blood flows back into the syringe, introduce the "J" shaped guide into the needle using the "J" straightener. The guide must slide through the needle without difficulty.

Important recommendations: To avoid any risk of the guide accidentally entering the cardiac cavities, do not push this too deeply into the vein. Be careful to leave a sufficient length outside the patient so as to be able to manipulate the guide without risk. **Never pull back or withdraw the guide** through the needle. **This can damage the wire on the needle level.**

- Remove the introducer needle. Maintain hold on guide. To aid insertion of the Deslit dilator and sheath assembly, carefully use a scalpel and rollers to enlarge the puncture site.

- Thread the Deslit assembly onto the guide.

- Slide the assembly along the guide wire in the vein lumen. This can be made easier by slightly twisting the dilator and sheath on the guide wire.

- Withdraw the guide leaving the dilator and Deslit sheath in the vein.

- Close the hub of the dilator with the male Luer stopper of the Deslit.

• Tunnelling the catheter

- Fit the distal end of the catheter to the tunnelling rod. In the case of a jugular approach (internal or external) the passage of the tunnelling rod over the clavicle is simplified if care is taken to bend the rod beforehand.
- Tunnelling with the rod provided with LIFECATH: the subcutaneous track runs from the catheter exit point to the point of entry of the Deslit into the vein.

The cuff must be placed in the subcutaneous tunnel next to the exit point (where the catheter emerges).

Gently and steadily pull on the tunnelling rod, the catheter follows the tunnelling rod on its subcutaneous track.

The cuff must be placed in the subcutaneous tunnel next to the exit point (where the catheter emerges).

Remove the tunnelling rod.

• Introduction of the catheter

- Estimate the length of catheter needed so that the distal end will be situated at the junction of the superior vena cava and right atrium.
- Trim the excess length of catheter with a clean, vertical cut and flush the LIFECATH with heparinized saline.
- Withdraw the dilator and introduce the catheter into the vein through the Deslit sheath.
- Hold the wings of the Deslit hub with both hands and pull slowly to split the sheath. This must be done carefully to avoid removing the catheter from the vein.
- Suture the skin at the entry and exit points of the tunnelling path.
- Carry out a radiological examination to confirm the correct location of the distal end of the catheter, check on the absence of loops and false routing of the catheter.

FIXATION - MAINTENANCE

Warning: Silicone is a delicate material. Pay particular attention when manipulating sharp or pointed instruments (scissors, scalpel, needles, etc.) near the catheter.

Dressings

These should be replaced each time they become soiled or loose, at each infusion line change, or at least once a week in case of intermittent use.

Recommended technique:
- CAREFUL HAND WASHING.

- Use sterile gloves and equipment.

- Disinfect the skin with an antiseptic solution at the catheter exit point, then using a circular motion from the centre towards the outside continue disinfecting, never going over the same place twice with the same compass.

- Carefully dry the skin.

- Secure the external section of catheter. If it is long enough make a safety loop.

- Apply a sterile dressing covering the exit point of the catheter.

- Apply a second occlusive dressing covering the external part of the catheter.

Handling the catheter hub

- Ensure strict aseptic conditions each time that the catheter hub is handled, particularly when connecting infusion or injection accessories.
- If the catheter hub must be opened, it is recommended that the LIFECATH be clamped with the Roberts clamp provided.
- Check the exit point regularly to detect any signs of reddening, inflammation or local pain.
- All handling of the catheter (connection of infusion devices, blood sampling, etc.) must be carried out using a compass soaked in antiseptic.
- When the catheter is not in use, close the hub with an injectable membrane (code 891) or a Bionector® and make a heparin lock.

Flushing - Heparinisation

Flush the catheter with saline after each injection, infusion or blood sampling.

If several drug injections are needed, carry out a careful rinsing with saline between each one to avoid any precipitation of drug interactions.

Finally, inject 2 to 3 cc of 500 IU/ml of heparin solution (adults) or 100 IU/ml (children) through the injection membrane, continuing the injection while the needle is withdrawn to maintain a positive pressure.

For information: Priming volume

Code 2191.27 / 2191.273 / 8191.28 0.25 ml

Code 2191.42 / 8191.43 / 2191.425 / 8191.426 0.35 ml

Code 2191.50 / 2191.506 / 8191.51 / 8191.507 0.70 ml

Code 2191.66 / 8191.67 / 8191.67 / 8191.67 / 8191.668 1.10 ml

Code 2193.90 / 8193.90 / 8193.97 / 2193.90 / 8193.961 1.65 ml

IMPLANTATION

When inserting LIFECATH, you may need to cut the catheter. Note that each 10 cm section of catheter is equivalent to the following dead space:

Code 2191.27 / 2191.273 / 8191.28 0.04 ml

Code 2191.42 / 8191.43 / 2191.425 / 8191.426 0.06 ml

Code 2191.50 / 2191.506 / 8191.51 / 8191.507 0.10 ml

Code 2191.66 / 8191.67 / 8191.67 / 8191.67 / 8191.668 0.11 ml

Code 2193.90 / 8193.90 / 8193.97 / 2193.90 / 8193.961 0.21 ml

Ex. LIFECATH code 2191.66 on which 20 cm of catheter has been removed:
0.11 ml x 2
1.10 ml — 0.22 ml = 0.88 ml

Technical note for clearing obstruction from a silicone catheter (blood clot obstruction)

Clearance with Urokinase:

- 1500 U/ml solution.
- Aspirate, then inject 1 to 2 ml of the above solution from a 10 ml syringe (do not use a syringe with a long, thin needle).
- After clamping, leave in contact for 1 to 2 hours or even longer.
- Aspirate the Urokinase.
- Flush with saline, inject heparinized saline solution.

[Experience has shown that this technique effectively clears catheters obstructed by a blood clot. It is obviously ineffective against crystals resulting from interactions between incompatible substances].

Warning

Alcohol such as ethanol and isopropyl alcohol do not change the physical properties of the silicone elastomer if it is used briefly without prolonged contact and if the silicone catheter is then dried fully.

The use of organic solvents such as acetone, chlorinated solvents, ethyl acetate, etc., is inadvisable. Do not expose this catheter to contact with iodine based solutions! These products can degrade or irreversibly deform the silicone elastomer.

Sterile. Ppyogen-free. Sterilized by ethylene oxide. Single use. Sterility guaranteed unless unit pack has been damaged or opened before use. Keep protected from heat, moisture and light. To dispose, of place the contaminated items in the appropriate receptacle. This device is not made with any dry natural rubber latex.

Caution: Federal Law (USA) restricts this device to be used by or on the order of a physician.

Caution: Do not expose this catheter to contact with iodine based solutions!

Caution: Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reactions or bacterial infections.

Caution: Do not bend the catheter at the extension line permanently to avoid damage to the catheter.

Caution: Do not use this product for monitoring, diagnosis, control or treatment of a defect of the heart or the central venous system.

Important caution: Before placing the peel-apart Deslit, check that the catheter can be

LIFECATH / LIFECATH EXPERT

Art.-Nr. 2191., 2193. / 8191., 8193.

Gebrauchsanweisung

Lesen Sie sorgfältig die Gebrauchsanweisung vor dem Kathetereinsatz.

Bei der Platzierung des LIFECATH müssen unbedingt sterile Kauteilen berücksichtigt werden (Mundschutz, Kittel, Handschuhe, sterile Patientenabdeckung).

PRODUKT-BESCHREIBUNG

LIFECATH sind einmalig, implantierbare Langzeitverweilkatheter aus röntgenkontrastgebenden Silikon für die parenterale Ernährung oder die Verabreichung von Medikamenten.

LIFECATH wird in 2 unterschiedlichen Varianten angeboten:

- Ein Katheter-Set, das nur den Katheter und eine Tunnelingnadel beinhaltet

- Ein Komplet-Set, das neben dem Katheter und der Tunnelingnadel auch ein INTRODUCTOR DESLIT „Break-Away“ mit Zubehör enthält.

- Entfernen Sie die Punktionsnadel.

- Fixieren Sie dabei den Dilator.

- Vergleichen Sie die Punktionsstelle durch eine Incision, damit der Dilator mit aufgestecktem INTRODUCTOR DESLIT „Break-Away“ eingeführt werden kann, ohne dass die Spitzengeometrie beschädigt wird. Der Guide darf bei diesem Vorgang ebenfalls nicht beschädigt werden.

- Führen Sie den Dilator mit aufgesteckter Schleuse über den Guide in die Vene ein.

- Leichte Drehbewegungen erreichen die Platzierung.

- Entfernen Sie den Guide. Der Dilator mit aufgesteckter Deslit verbleibt in der Vene.

- Verschließen Sie das Dilatorlumen mit einem Verschlussstopfen.

Tunnelung des Katheters

- Tunnelung mit der Tunnelingnadel. Führen Sie dabei die Nadel von der gewünschten Katheteraustrittsstelle zur Stelle an der das INTRODUCTOR DESLIT „Break-Away“ platziert ist.

- Ziehen Sie die Tunnelingnadel vorsichtig und gleichmäßig. Der Katheter folgt dem Tunnelwegweg. Die subcutane Manschette muss in Bereich der gewünschten Katheteraustrittsstelle subcutan platziert werden.

- Entfernen Sie den Dilator aus dem Deslit und schieben den Katheter durch das Deslit vor.

- Trennen Sie das Deslit durch vorsichtiges Auseinanderziehen an den Deslit-Griffplätzen.

- Schieben Sie den Katheter weiter vor. Ziehen Sie die Schleuse weiter aus dem Gefäß und spalten den Schleusenack weiter. Wiederholen Sie diese Prozedur so lange bis der Katheter platziert und die Schleuse entfernt ist.

- Verahren Sie die Hautinzision an beiden Seiten des Tunnelingwegs.

- Führen Sie eine Katheterplatzierungskontrolle mittels Röntgendurchleuchtung durch. (Position des distalen Katheterendes, Kontrolle auf intravasculäre Schleifenbildung des Katheters).

b/ LIFECATH Komplet-Set

Das LIFECATH Komplet-Set beinhaltet den Silikonkatheter, eine Tunnelingnadel und ein INTRODUCTOR DESLIT „Break-Away“ mit Zubehör.

Art.-Nr.	Innen Ø - Außen Ø mm	Ch./Fr.	L. ges. cm	L. intravas. cm	Max. Bolusdruck bar	Einführungs- beschl. Art.-Nr.
2191.273	8191.28	0.5 - 1.0	2.7	75	50 3.5	-
2191.425	8191.43	0.7 - 1.4	4.2	75	50 3.5	-
2191.506	8191.507	0.95 - 1.7	5.0	75	50 3.5	1146.06
2191.667	8191.67 / 668	1.10 - 2.2	6.6	90	55 3.5	1146.07
2193.90	8193.90 / 961	1.6 - 3.2	9.6	90	55 3.5	1146.10

WICHTIGE HINWEISE

1. Verwenden Sie zur Konnektion nur Luer-Lock-Ansätze.

2. Beachten Sie den maximalen Bolus-Druck in den obigen Tabellen.

Verwenden Sie keine Spritzen mit einem kleineren Volumen als 10 ml.

Bei der Verwendung kleinerer Spritzen kann der Bolusdruck über-schritten werden, was zu Katheterschiebungen führen kann.

3. Latex-Handschuhe sollten mit sterilem Wasser gewaschen werden, damit Kalziumrückstände entfernt werden.

4. Um einen Blutrückfluss in den Katheter zu vermeiden, sollte die mit heparinisierter Lösung gefüllte Spritze nicht direkt an dem Katheter-ansatz angeschlossen werden.

5. Alle Handhabungen der Katheter müssen zunächst mit einem Injektionsverschluss durchgeführt werden.

6. Die Membran kann mit einer an der Spitze konnektierten Nadel durchstoßen und der Katheter mit der heparinisierten Lösung gefüllt werden. Die Nadel sollte bei fort-währender Injektion (Druck auf dem Spritzenkolben) aus dem Injektionsstopfen gezogen werden.

Flushing - Heparinisation

Flush the catheter with saline after each injection, infusion or blood sampling.

If several drug injections are needed, carry out a careful rinsing with saline between each one to avoid any precipitation of drug interactions.

Finally, inject 2 to 3 cc of 500 IU/ml of heparin solution (adults) or 100 IU/ml (children) through the injection membrane, continuing the injection while the needle is withdrawn to maintain a positive pressure.

INDIKATIONEN

LIFECATH ist ein Langzeitverweilkatheter für:

- längeres, permanentes oder intermittierendes Ernährung im Krankenhaus oder im privaten Umfeld.
- Chemotherapie zur Tumorentlastung.
- Transfusion von Blutprodukten.
- Blutprodukten.

Verschiedene andere Anwendungen zur Behandlung von Infektionskrankheiten

Bei Zirkulation der Nadel muss die Injektion fortgesetzt werden um einen Blutreflux in den Katheter zu vermeiden.

Zur Information: Totraumvolumen

Art.-Nr. 2191.27 / 2191.273 / 8191.28 0.25 ml

Art.-Nr. 2191.42 / 8191.43 / 2191.425 / 8191.426 0.35 ml

Art.-Nr. 2191.50 / 2191.506 / 8191.51 / 8191.507 0.70 ml

Art.-Nr. 2191.66 / 8191.67 / 8191.67 /

