INSTRUCTION FOR USE CENTRAL VENOUS CATHETER

CENTRAL VENOUS CATHETER KIT-SINGLE

Intended Use:
Central venous catheter are intended to provide venous access to superior vena cava or inferior vena cava, for administration of intravenous fluids and medications.

Clinical benefits:
1. Longer duration of venous access compared to peripheral access for delivery of Iv. fluids and medications - The selection of the type of catheter use for a patient depends on the treatment and duration of use. The peripheral venous catheter, which is the most widely used venous access device, can only be used for a short term (3-5 days). The incidence of complications like extravasation, thrombophlebitis, etc., increases with the use of peripheral intravenous access. In critical care patients, though catheters are used for shorter duration, it is not always possible to establish peripheral access. Repeated peripheral insertions can be difficult in critical care patients due to difficult venous access. A percutaneously inserted central catheters for short duration (<14 days) provides a longer-term access as compared to the peripheral intravenous access.
The longer dwell time as compared to peripheral line will help in avoiding complications associated with repeated peripheral line procedures. This reduces unnecessary patient discomfort and unnecessary costs associated with it.
2. Safe and effective conduit for parenteral nutrition and vasopressor medications - Parenteral nutrition and vasopressor medications are high osmolar solutions. Use of peripheral intravenous catheters for transfusion of such solutions is associated with incidence of extravasation of events in peripheral intravenous catheters. The percutaneously inserted non tunnelled central venous catheter prevents this, by providing access to a larger central vein.
3. Safe access to perform hemodynamic monitoring and blood sampling- The non-tunneled central venous catheters have multiple lumens. Availability of multiple lumens helps the user to dedicate a lumen for collection of blood or for hemodynamic monitoring by introducing a probe into the right atrium. The device under evaluation helps by providing such access.

Contents:
a. Radiopaque Polyurethane indwelling catheter (with marking to verify position) with soft tip.
b. Guide wire with length marking and flexible" J" tip on one end — straight tip on other end, dispenser.
c. Introducer needle / Y — site introducer needle
d. Dilator
e. Luer lock syringe/ guiding syringe
f. Long handle Scalpel, blade No. 11
g. Catheter holder to secure the catheter
h. Catheter holder clamp with adjustable fixation wing to secure the catheter by suture the insertion site.
I. Injection caps /Clave Connector
j. Extension line clamps
k.3 ways stop cock, lipid resistant.
Contents are provided sterile & non-pyrogenic. Do not use if package has been previously opened or damaged. Sterilized by ethylene oxide. For single use only. Do not re-sterilize or reuse. For short-term use of less than 30 days. Contains no medication.

Materials Used:
ABS, HDPE, PUR, PP, PC, Poly isoprene, SS 304, Nylon or Nitinol

Indications:
The device does not diagnose, prevent monitor, treat alleviate, modify, or control any medical condition. The access provided by the device under evaluation is used for the following in critical care patients; Infusion of vasopressor medications or other vein irritating/ highly osmolar solutions, infusion of parenteral nutrition, continuous or intermittent monitoring of central venous pressure, blood sampling.

Contraindications:
Use of this product is contraindicated in patients with past irradiation at the site of puncture, severe chronic obstructive lung disease, clotting disorders e.g. in therapy with anticoagulants or anatomical anomalies e.g. enlarge struma, tumors in the neck region., post operative changes at the site of puncture. Inflammation of the skin at the site of puncture. Not to be used in patients with known hypersensitivity to any of the materials used and avoid use in vessels with known thrombosis.

Target patient population:
All critically ill patients.

Intended User Group:
The product should be used by Qualified Healthcare professionals e.g., Registered Medical practitioners (AMP) or physicians, Radiologists, Trained Advanced Nurse practitioner (ANP), Trained Registered Nurse (RN), certified nurse specialist (CNS) trained on insertion of central lines, Surgeons etc.

Dwell time: <14 days

Adverse Reactions and Possible Complications:
This section typically lists all known potential undesirable side effects and residual risks associated with the use of the device:
Hematoma at the site of puncture, catheter sepsis, cardiac arrhythmia due to incorrect intracardiac placement of the catheter, arterial injuries due to incorrect punctures, extravasation due to tip malposition, catheter induced thrombosis, thromboembolism of the superior vena cava, pneumothorax/ hemothorax, catheter occlusion, myocardial perforation /cardiac tamponade, and catheter breakage.

RECOMMENDED INSERTION PROCEDURE SELDINGER TECHNIQUE:
Follow aseptic technique and employ universal precautions and procedure per institutional protocols.
1. In preparation for the placement of central venous catheters, use aseptic techniques (e.g., hand washing) and maximal barrier precautions (e.g., sterile gowns, sterile gloves, caps, masks covering both mouth and nose, fullbody patient drapes, and eye protection).
2. Position patient in a slight Trendelenburg (head-down) position to reduce the risk of air embolism.
3. Prepare and drape the puncture site, as required.
4. Prepare the indwelling catheter for insertion by flushing catheter lumen with sterile solution to confirm patency and priming.
5. Clamp extension lines or attach injection caps to the appropriate Extension lines, leaving the distal extension line uncapped for guide wire entry.
6. Locate and puncture the vein using the introducer needle mounted on syringe for aspiration. Remove the syringe.
7. Remove the protective cap from the guide wire dispenser. Retract the guide wire into guide wire dispenser to straighten its J-tip. Gently advance guide wire through introducer needle into vein. Use the length markings to check the insertion depth. First band indicates 10cm, second band 20cm and third band 30cm.
8. Once the guide wire is in place, make a controlled 3-mm stab incision in the skin at the entry site with a #11 blade to prevent the dilator from catching.
9. Hold guide wire in the desired position and remove guide wire dispenser and introducer needle.
10. By rotating slightly, insert vessel dilator over the guide wire into the blood vessel to enlarge the puncture site. Retaining the position of guide wire, remove the vessel dilator in order to insert indwelling catheter.
11. Insert tip of indwelling catheter over the guide wire. Holding catheter near skin, advance the catheter up to the desired position with slightly twisting movement.
12. Centimeter marks on indwelling catheter can be taken as reference points to finalize indwelling catheter position.
13. Hold indwelling catheter in the desired position and remove the guide wire.
14. Verify that the entire guide wire is intact upon removal.
15. Check lumen placement by attaching a syringe to each extension line and aspirating until free flow of blood is observed. Connect all extension lines to appropriate luer lock lines as required. Unused port may be locked using injection caps. Extension line clamps are provided on extension lines to occlude flow through lumen during line and injection cap changes.
16. Secure and dress catheter temporarily.
17. Verify catheter tip position by chest x-ray immediately after placement.
18. Secure catheter to the skin either with integrated junction hub or with the moveable catheter holder. Catheter holder clamp can be fixed on catheter holder to secure the catheter before suturing the catheter holder and catheter holder clamp together on patient's skin.

RECOMMENDED INSERTION PROCEDURE SELDINGER TECHNIQUE USING GUIDING SYRINGE:
1. In preparation for the placement of central venous catheters, use aseptic techniques (e.g. hand washing) and maximal barrier precautions (e.g., sterile gowns, sterile gloves, caps, masks covering both mouth and nose, full body patient drapes, and eye protection).
2. Position patient in a slight Trendelenburg (head-down) position to reduce the risk of air embolism.
3. Prepare and drape the puncture site, as required.
4. Prepare the indwelling catheter for insertion by flushing catheter lumen with sterile solution to confirm patency and priming. Clamp extension lines or attach injection caps to the appropriate extension lines, leaving the distal extension line uncapped for guide wire entry.
5. Puncture the vein using the introducer needle and with the special guiding syringe attached for aspiration.
6. Remove the protective cap from the guide wire dispenser. Retract the guide wire to the guide wire dispenser to straight its J-tip. Then attached the dispenser with the guide wire to the hole in the guiding syringe thump rest. Use your thumb to advance the guide wire into the vein. Use the length markings to check the insertion depth. First band indicates 10cm, second band 20cm and third band 30cm. Once the guide wire is in place, make a controlled 3-mm stab incision in the skin at the entry site with a #11 blade to prevent the dilator from catching.
7. Hold guide wire in the desired position and remove guide wire dispenser and introducer needle with guiding syringe.
8. By rotating sightly, insert vessel dilator over the guide wire into the blood vessel to enlarge the puncture site. Retaining the position of guide wire, remove the vessel dilator in order to insert indwelling catheter.
9. Insert tip of indwelling catheter over the guide wire. Holding catheter near skin, advance the catheter up to the desired position with slightly twisting movement.
10. Centimeter marks on indwelling catheter can be taken as reference points to finalize indwelling catheter position.
11. Hold indwelling catheter in the desired position and remove the guide wire.
12. Verify that the entire guide wire is intact upon removal.
13. Check lumen placement by attaching a syringe to each extension line and aspirating until free flow of blood is observed. Connect extension line to appropriate luer lock lines as required. Unused port may be


Cautions


See Instructions for use

Product reference/Art. No.


For single use only

Do not Resterilize


Do not use if packaging or product has been damaged or contaminated

Batch Number


Date of Manufacturing


Use by / Expiry date

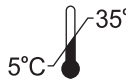
Sterilised by Ethylene Oxide


Single Sterile barrier system

European Authorised Representative


Manufactured by


Non Pyrogenic

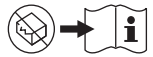


Storage Condition


Keep Away from direct Sunlight


Keep Dry

Medical Devices


Do not use if package (Sterile barrier system) is damaged and check IFU.

INSTRUCTION FOR USE CENTRAL VENOUS CATHETER

locked using injection cap. Extension line clamp is provided on extension lines to occlude flow through lumen during line and injection cap changes.
14. Secure and dress catheter temporarily.
15. Verify catheter tip position by chest x-ray immediately after placement.
16. Secure catheter to the skin either with integrated junction hub or with the moveable catheter holder. Catheter holder clamp can be fixed on catheter holder to secure the catheter before suturing the catheter holder and catheter holder clamp together on patient's skin.
17. 3-Way stopcock, lipid resistant may be in use if additional medication is required.

This product contains NO natural rubber latex
For providing feedback on this product write to customercare@polymedicure.com
In case of any serious incident occurred, please report it to the-Poly Medicure Ltd and/or its authorized representative and to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website:
https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en

WARRANTY:
Manufacturer warrants its products free from defects in workmanship and Materials under proper handling and use. This warranty voids if failure or defect is due to handling, storage as well as factors relating to the patient diagnosis, treatment, surgical procedures and other matters beyond manufacturers control directly affect manufacturers products and the results obtained from their use.

PRECAUTIONS/CAUTIONS:
1. Maintain catheter patency according to institutional policies, procedures and practice guidelines.
2. Always select smaller catheter size (i.e., outside diameter) and type considering to patient position and clinical situation.
3. Position cutting edge of scalpel away from guidewire.
4. If a resistance is encountered when attempting to remove the guide wire after placement withdraw the catheter 2 or 3 cm and attempt to remove the guide wire. If resistance is again encountered, remove the guide wire and catheter simultaneously.
5. Carefully clean the insertion site and position, the puncture may only be made after the disinfectant has been completely dried on the skin.
6. Cleaning of insertion site should be done with facility approved disinfectant such as Povidone —iodine or chlorhexidine (0.5 % in alcohol), be aware that organic solvent such as alcohol may interact with catheter materials and weaken it.
7. Marking symbology is referenced from catheter distal end as:
   • Numerical: 5, 10, 15 etc. denotes 50,100, 150mm intervals & so on.
   • Dots: each dot (".") denotes a 10mm interval.
8. When removing catheters, it is recommended to raise CVP by keeping the patient in a supine position or with their head down or Trendelenburg position to prevent air embolism.
9. Store in between 5°C to 35°C, avoid excessive heat protect from direct sunlight and moisture.
10. Inspect the catheter insertion site daily for signs of infection. Change or remove the catheter when catheter insertion site infection is suspected or No longer deemed clinically necessary or as per facility approved protocol and CDC guidelines.
11. Secure catheter to the skin either with integrated junction hub or with the moveable catheter holder.
12. Catheter holder clamp can be fixed on catheter holder to secure the catheter before suturing the catheter holder and catheter holder clamp together on patient's skin.
13. 3-Way stopcock lipid resistant may be in use if additional medication is required.
14. Use aseptic techniques during insertion and maintenance to reduce infection risk.
15. Safe use up to 14 days, reducing the need for frequent catheter changes and thereby decreasing patient discomfort and risk of thrombosis, infection, etc.
16. Discard the set after single use. The product should be disposed of as per facility approved protocol or CDC guidelines.
17. The Summary of Safety and Clinical Performance (SSCP), Document No.: PML/MD/SSCP/36 shall be made available to the public upon request without undue delay or can be downloaded from Eudamed public website: https://ec.europa.eu/tools/eudamed/#/screen/home

Warnings:
1. Read warnings, cautions and instructions prior to use.
2. Do not place the catheter into or allow it to remain in the right atrium or right ventricle Failure to follow these Instructions can result in severe patient injury or death.
3. Do not use if the product packaging (sterile barrier system) or product has been damaged or contaminated.
4. The internal jugular vein, common femoral vein, and subclavian veins are the preferred sites for temporary central venous catheter placement using the Seldinger technique. However, the decision of where to place a central line and device selection is typically based on the patient considerations, clinical situation, as well as individual physician experience and preference. Position patient as appropriate for insertion site.
5. Subclavian or Jugular approach: Place patient in slight Trendelenburg position as tolerated to reduce risk of air embolism and enhance venous filling.
6. Femoral approach: Place patient in supine position.
7. Do not suture directly to the outside diameter of the catheter to avoid cutting or damaging the catheter or restricting flow through catheter lumen.
8. Do not bring catheter into contact with acetone or similar solvents, which can weaken the catheter and can cause it to leak or break.
9. Do not connect the catheter to pressure of more than 3 bars. Use of pressure more than 3 bars, may cause catheter rupture, Infiltration, extravasation etc.
10. Do not re-sterilize and reuse the product. Reuse of this product may change its mechanical or biological features and may cause device failure, allergic reactions or Infection due to microbial contamination.
11. The product should not be used after its expiry date.
12. Do not kink or use forceps to clamp the lumen tubing during line changes, avoid potential problem of cutting catheter by not using scissors to remove dressing etc.
13. Never pull back or withdraw the guidewire while the needle is in place. This could damage the wire on the needle bevel. If any resistance is felt to the advancement of the guidewire, do not persist, withdraw both needle and the guidewire simultaneously.
14. Improper placement or handling of the catheter may result in life-threatening complications such as cardiac tamponade or pneumothorax.
15. Always confirm catheter tip location using imaging techniques before use.
16. The product should be used only by Qualified Healthcare Professionals.
17. Gas supply line, Enteral Feeding bags, Suction line or any other non-compatible connectors should not be connected with this device.
18. Poly Medicure Limited will not be responsible for any direct incidental or consequential damages resulting from wrong use of product.

Performance Characteristics:
Below are the performance characteristics of Central Venous Catheter kit:
1. Catheters are made from biocompatible, radiopaque polyurethane allowing for precise positioning which ensures minimal risk of irritation and allergic reaction, as well as visibility under x-ray imaging to prevent misplacement.
2. The kit components are sterile and non-pyrogenic to prevent infection and pyrogenic reactions.
3. Catheters are sterilized using ethylene oxide gas to ensure sterility without compromising material integrity.
4. Catheters withstand mechanical stresses during insertion, dwell time, and removal without kinking, fracturing, or collapsing.
5. Soft, tapered tips to minimize the risk of vascular trauma. Clear markings on the catheter and guide wire assist in accurate placement.
6. Lumen design (single) to accommodate various clinical needs such as medication administration or parenteral nutrition.
7. Luer connectors are conform to the ISO 80369-7 to prevent misconnections.
8. Safe use up to 14 days, reducing the need for frequent catheter changes and thereby decreasing patient discomfort and infection risk.
9. Packaged in a manner that maintains sterility and integrity until the point of use. Clear labeling on the packaging includes instructions, contraindications, and warning.

This IFU is applicable for: Central venous catheter kit single lumen for all variants (Novocent, Novocent Pro & Novocent Protekt.

Differences between Novocent, Novocent Pro & Novocent Protekt is provided in below table-

Key Differences between CVC brands				
Central Venous Catheter kit				
S. No.	**Name of Component**	**Used in Novocent**	**Used in Novocent Pro**	**Used in Novocent Protekt**
1	Indwelling catheter	√	√	√
2	Extension line clamp	√	√	√
3	Scalpel	√	√	√
4	Dilator	√	√	√
5	Catheter Holder	√	√	√
6	Catheter Holder Clamp	√	√	√
7	Injection cap (as per requirement)			
7.1	Heparin Cap OR	√	√	—
7.2	Clave connector	—	—	√
8	Syringe-5 cc (as per requirement)			
8.1	Luer lock syringe OR	√	√	√
8.2	Guiding syringe	√	√	√
9	Introducer Needle (as per requirement)			
9	Introducer Needle OR	√	√	√
9.1	Y site Introducer Needle	√	√	√
10	Guide Wire (as per requirement)			
10.1	Guide wire (SS-304) OR	√	—	—
10.2	Guide Wire (Nitinol)	—	√	√
11	3 Way Stopcock	√	√	√

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Email: customercare@polymedicure.com,
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E-mail : mail@obelis.net

CE 0123

INSTRUCTION FOR USE CENTRAL VENOUS CATHETER

CENTRAL VENOUS CATHETER KIT- DOUBLE/ TRIPLE/ QUADRUPLE

Intended Use:
Central venous catheter kit are intended to provide venous access to superior vena cave or inferior vena cave, for administration of intravenous fluids and medications.

Clinical benefits:
1. Longer duration of venous access compared to peripheral access for delivery of Iv. fluids and medications - The selection of the type of catheter use for a patient depends on the treatment and duration of use. The peripheral venous catheter, which is the most widely used venous access device, can only be used for a short term (3-5 days). The incidence of complications like extravasation, thrombophlebitis, etc., increases with the use of peripheral intravenous access. In critical care patients, though catheters are used for shorter duration, it is not always possible to establish peripheral access. Repeated peripheral insertions can be difficult in critical care patients due to difficult venous access. A percutaneously inserted central catheters for short duration (<14 days) provides a longer-term access as compared to the peripheral intravenous access.
The longer dwell time as compared to peripheral line will help in avoiding complications associated with repeated peripheral line procedures. This reduces unnecessary patient discomfort and unnecessary costs associated with it.
2. Safe and effective conduit for parenteral nutrition and vasopressor medications - Parenteral nutrition and vasopressor medications are high osmolar solutions. Use of peripheral intravenous catheters for transfusion of such solutions is associated with incidence of extravasation of events in peripheral intravenous catheters. The percutaneously inserted non tunneled central venous catheter prevents this, by providing access to a larger central vein.
3. Safe access to perform hemodynamic monitoring and blood sampling- The non-tunneled central venous catheters have multiple lumens. Availability of multiple lumens helps the user to dedicate a lumen for collection of blood or for hemodynamic monitoring by introducing a probe into the right atrium. The device under evaluation helps by providing such access.

CONTENTS:
a. Radiopaque Polyurethane indwelling catheter (with marking to verify the position) with soft tip.
b. Guide wire with length marking and flexible" J" tip on one end — straight tip on other end in dispenser.
c. Introducer needle / Y — site introducer needle.
d. Dilator
e. Luer lock syringe/ guiding syringe
f. Long handle Scalpel, blade No. 11
g. Catheter holder to secure the catheter
h. Catheter holder clamp with adjustable fixation wing to secure the catheter by suture the insertion site.
I. Injection caps /Clave Connector
j. Extension line clamps
k. 3 way stop cock, lipid resistant.
Contents are provided sterile & non-pyrogenic. Do not use if package has been previously opened or damaged. Sterilized by ethylene oxide. For single use only. Do not re-sterilize or reuse. For short-term use of less than 30 days. Contains no medication.

Materials Used:
ABS, HDPE, PUR, PP, PC, Stainless steel, Polyisoprene, SS 304, Nylon or Nitinol.

Indications:
The device under evaluation does not diagnose, prevent, monitor, treat, alleviate, modify, or control any medical condition. The access provided by the device under evaluation is used for the following in critical care patients; Infusion of vasopressor medications or other vein irritating/ highly osmolar solutions, infusion of parenteral nutrition, continuous or intermittent monitoring of central venous pressure, blood sampling.

Contraindications:
Use of this product is contraindicated in patients with past irradiation at the site of puncture, severe chronic obstructive lung disease, clotting disorders e.g. in therapy with anticoagulants or anatomical anomalies e.g. enlarge struma, tumors in the neck region., post operative changes at the site of puncture. Inflammation of the skin at the site of puncture. Not to be used in patients with known hypersensitivity to any of the materials used and avoid use in vessels with known thrombosis.

Target patient population:
All critically ill patients.

Intended User Group:
The product should be used by Qualified Healthcare professionals e.g., Registered Medical practitioners (RMP) or physicians, Radiologists, Trained Advanced Nurse practitioner (ANP), Trained Registered Nurse (RN), certified nurse specialist (CNS) trained on insertion of central lines, Surgeons etc.

Dwell time: <14 days

Adverse Reactions and Possible Complications:
This section typically lists all known potential undesirable side effects and residual risks associated with the use of the device:
Hematoma at the site of puncture, catheter sepsis, cardiac arrhythmia due to incorrect intracardiac placement of the catheter, arterial injuries due to incorrect punctures, extravasation due to tip malposition, catheter induced thrombosis, thromboembolism of the superior vena cava, pneumothorax/ hemothorax, catheter occlusion, myocardial perforation /cardiac tamponade, and catheter breakage.

RECOMMENDED INSERTION PROCEDURE SELDINGER TECHNIQUE:
Follow aseptic technique and employ universal precautions and procedure per institutional protocols.
1. In preparation for the placement of central venous catheters, use aseptic techniques (e.g., hand washing) and maximal barrier precautions (e.g., sterile gowns, sterile gloves, caps, masks covering both mouth and nose, full body patient drapes, and eye protection).
2. Position patient in a slight Trendelenburg (head-down) position to reduce the risk of air embolism.
3. Prepare and drape the puncture site, as required.
4. Prepare the indwelling catheter for insertion by flushing catheter lumen with sterile solution to confirm patency and priming.
5. Clamp extension lines or attach injection caps to the appropriate Extension lines, leaving the distal extension line uncapped for guide wire entry.
6. Locate and puncture the vein using the introducer needle mounted on syringe for aspiration. Remove the syringe.
7. Remove the protective cap from the guide wire dispenser. Retract the guide wire into guide wire dispenser to straighten its J-tip. Gently advance guide wire through introducer needle into vein. Use the length markings to check the insertion depth. First band indicates 10cm, second band 20cm and third band 30cm.
8. Once the guide wire is in place, make a controlled 3-mm stab incision in the skin at the entry site with a #11 blade to prevent the dilator from catching.
9. Hold guide wire in the desired position and remove guide wire dispenser and introducer needle.
10. By rotating slightly, insert vessel dilator over the guide wire into the blood vessel to enlarge the puncture site. Retaining the position of guide wire, remove the vessel dilator in order to insert indwelling catheter.
11. Insert tip of indwelling catheter over the guide wire. Holding catheter near skin, advance the catheter up to the desired position with slightly twisting movement.
12. Centimeter marks on indwelling catheter can be taken as reference points to finalize indwelling catheter position.
13. Hold indwelling catheter in the desired position and remove the guide wire.
14. Verify that the entire guide wire is intact upon removal.
15. Check lumen placement by attaching a syringe to each extension line and aspirating until free flow of blood is observed. Connect all extension lines to appropriate luer lock lines as required. Unused port may be locked using injection caps. Extension line clamps are provided on extension lines to occlude flow through lumen during line and injection cap changes.
16. Secure and dress catheter temporarily.
17. Verify catheter tip position by chest x-ray immediately after placement.
18. Secure catheter to the skin either with integrated junction hub or with the moveable catheter holder. Catheter holder clamp can be fixed on catheter holder to secure the catheter before suturing the catheter holder and catheter holder clamp together on patient's skin.

RECOMMENDED INSERTION PROCEDURE SELDINGER TECHNIQUE USING GUIDING SYRINGE:
1. In preparation for the placement of central venous catheters, use aseptic techniques (e.g. hand washing) and maximal barrier precautions (e.g., sterile gowns, sterile gloves, caps, masks covering both mouth and nose, full body patient drapes, and eye protection).
2. Position patient in a slight Trendelenburg (head-down) position to reduce the risk of air embolism.
3. Prepare and drape the puncture site, as required.
4. Prepare the indwelling catheter for insertion by flushing catheter lumen with sterile solution to confirm patency and priming. Clamp extension lines or attach injection caps to the appropriate extension lines, leaving the distal extension line uncapped for guide wire entry.
5. Puncture the vein using the introducer needle and with the special guiding syringe attached for aspiration.
6. Remove the protective cap from the guide wire dispenser. Retract the guide wire to the guide wire dispenser to straight its J-tip. Then attached the dispenser with the guide wire to the hole in the guiding syringe thump rest. Use your thumb to advance the guide wire into the vein. Use the length markings to check the insertion depth. First band indicates 10cm, second band 20cm and third band 30cm.
7. Once the guide wire is in place, make a controlled 3-mm stab incision in the skin at the entry site with a #11 blade to prevent the dilator from catching.
8. Hold guide wire in the desired position and remove guide wire dispenser and introducer needle with guiding syringe.
9. By rotating sightly, insert vessel dilator over the guide wire into the blood vessel to enlarge the puncture site. Retaining the position of guide wire, remove the vessel dilator in order to insert indwelling catheter.
10. Insert tip of indwelling catheter over the guide wire. Holding catheter near skin, advance the catheter up to the desired position with slightly twisting movement.
11. Centimeter marks on indwelling catheter can be taken as reference points to finalize indwelling catheter position.
12. Hold indwelling catheter in the desired position and remove the guide wire.
13. Verify that the entire guide wire is intact upon removal.


Cautions


See Instructions for use

Product reference/Art. No.


For single use only

Do not Resterilize


Do not use if packaging or product has been damaged or contaminated

Batch Number


Date of Manufacturing


Use by / Expiry date

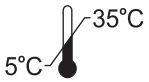
Sterilised by Ethylene Oxide


Single Sterile barrier system

European Authorised Representative


Manufactured by


Non Pyrogenic

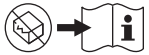


Storage Condition


Keep Away from direct Sunlight


Keep Dry

Medical Devices


Do not use if package (Sterile barrier system) is damaged and check IFU.

INSTRUCTION FOR USE CENTRAL VENOUS CATHETER

14. Check lumen placement by attaching a syringe to each extension line and aspirating until free flow of blood is observed. Connect extension line to appropriate luer lock lines as required. Unused port may be locked using injection cap. Extension line clamp is provided on extension lines to occlude flow through lumen during line and injection cap changes.
15.Secure and dress catheter temporarily.
16. Verify catheter tip position by chest x-ray immediately after placement.
17. Secure catheter to the skin either with integrated junction hub or with the moveable catheter holder. Catheter holder clamp can be fixed on catheter holder to secure the catheter before suturing the catheter holder and catheter holder clamp together on patient's skin.
18. 3-Way stopcock, lipid resistant may be in use if additional medication is required.

This product contains NO natural rubber latex
For providing feedback on this product write to customercare@polymedicure.com
In case of any serious incident occurred, please report it to the-Poly Medicure Ltd and/or its authorized representative and to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website:
https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en

WARRANTY:
Manufacturer warrants its products free from defects in workmanship and Materials under proper handling and use. This warranty voids if failure or defect is due to handling, storage as well as factors relating to the patient diagnosis, treatment, surgical procedures and other matters beyond manufacturers control directly affect manufacturers products and the results obtained from their use.

PRECAUTIONS/CAUTIONS:
1. Maintain catheter patency according to institutional policies, procedures and practice guidelines.
2. Always select smaller catheter size (i.e., outside diameter) and type considering to patient position and clinical situation.
3. Position cutting edge of scalpel away from guidewire.
4. If a resistance is encountered when attempting to remove the guide wire after placement withdraw the catheter 2 or 3 cm and attempt to remove the guide wire. If resistance is again encountered, remove the guide wire and catheter simultaneously.
5. Carefully clean the insertion site and position, the puncture may only be made after the disinfectant has been completely dried on the skin.
6. Cleaning of insertion site should be done with facility approved disinfectant such as Povidone —iodine or chlorhexidine (0.5 % in alcohol), be aware that organic solvent such as alcohol may interact with catheter materials and weaken it.
7. Marking symbology is referenced from catheter distal end as:
   • Numerical: 5, 10, 15 etc. denotes 50,100, 150mm intervals & so on.
   • Dots: each dot (".") denotes a 10mm interval.
8. When removing catheters, it is recommended to raise CVP by keeping the patient in a supine position or with their head down or Trendelenburg position to prevent air embolism.
9. Store in between 5°C to 35°C, avoid excessive heat protect from direct sunlight and moisture.
10. Inspect the catheter insertion site daily for signs of infection. Change or remove the catheter when catheter insertion site infection is suspected or No longer deemed clinically necessary or as per facility approved protocol and CDC guidelines.
11. Secure catheter to the skin either with integrated junction hub or with the moveable catheter holder.
12. Catheter holder clamp can be fixed on catheter holder to secure the catheter before suturing the catheter holder and catheter holder clamp together on patient's skin.
13. 3-Way stopcock lipid resistant may be in use if additional medication is required.
14. Use aseptic techniques during insertion and maintenance to reduce infection risk.
15. Safe use up to 14 days, reducing the need for frequent catheter changes and thereby decreasing patient discomfort and risk of thrombosis, infection, etc.
16. Discard the set after single use. The product should be disposed of as per facility approved protocol or CDC guidelines.
17. The Summary of Safety and Clinical Performance (SSCP), Document No.: PML/MD/SSCP/36 shall be made available to the public upon request without undue delay or can be downloaded from Eudamed public website: https://ec.europa.eu/tools/eudamed/#/screen/home

Warnings:
1. Read warnings, cautions and instructions prior to use.
2. Do not place the catheter into or allow it to remain in the right atrium or right ventricle Failure to follow these Instructions can result in severe patient injury or death.
3. Do not use if the product packaging (sterile barrier system) or product has been damaged or contaminated.
4. The internal jugular vein, common femoral vein, and subclavian veins are the preferred sites for temporary central venous catheter placement using the Seldinger technique. However, the decision of where to place a central line and device selection is typically based on the patient considerations, clinical situation, as well as individual physician experience and preference. Position patient as appropriate for insertion site.
5. Subclavian or Jugular approach: Place patient in slight Trendelenburg position as tolerated to reduce risk of air embolism and enhance venous filling.
6. Femoral approach: Place patient in supine position.
7. Do not suture directly to the outside diameter of the catheter to avoid cutting or damaging the catheter or restricting flow through catheter lumen.
8. Do not bring catheter into contact with acetone or similar solvents, which can weaken the catheter and can cause it to leak or break
9. Do not connect the catheter to pressure of more than 3 bars. Use of pressure more than 3 bars, may cause catheter rupture, Infiltration, extravasation etc.
10. Do not re-sterilize and reuse the product. Reuse of this product may change its mechanical or biological features and may cause device failure, allergic reactions or Infection due to microbial contamination.
11. The product should not be used after its expiry date.
12. Do not kink or use forceps to clamp the lumen tubing during line changes, avoid potential problem of cutting catheter by not using scissors to remove dressing etc.
13. Never pull back or withdraw the guidewire while the needle is in place. This could damage the wire on the needle bevel. If any resistance is felt to the advancement of the guidewire, do not persist, withdraw both needle and the guidewire simultaneously.
14. Improper placement or handling of the catheter may result in life-threatening complications such as cardiac tamponade or pneumothorax.
15. Always confirm catheter tip location using imaging techniques before use.
16. The product should be used only by Qualified Healthcare Professionals.
17. Gas supply line, Enteral Feeding bags, Suction line or any other non-compatible connectors should not be connected with this device.
18. Poly Medicure Limited will not be responsible for any direct incidental or consequential damages resulting from wrong use of product.

Performance Characteristics:
Below are the performance characteristics of Central Venous Catheter kit:
· Catheters are made from biocompatible, radiopaque polyurethane allowing for precise positioning which ensures minimal risk of irritation and allergic reaction, as well as visibility under x-ray imaging to prevent misplacement.
· The kit components are sterile and non-pyrogenic to prevent infection and pyrogenic reactions.
· Catheters are sterilized using ethylene oxide gas to ensure sterility without compromising material integrity.
· Catheters withstand mechanical stresses during insertion, dwell time, and removal without kinking, fracturing, or collapsing.
· Soft, tapered tips to minimize the risk of vascular trauma. Clear markings on the catheter and guide wire assist in accurate placement.
· Multiple lumen designs (double, triple, quadruple) to accommodate various clinical needs such as simultaneous medication administration, parenteral nutrition, and accurate hemodialysis monitoring.
· Luer connectors are conform to the ISO 80369-7 to prevent misconnections.
· Safe use up to 14 days, reducing the need for frequent catheter changes and thereby decreasing patient discomfort and infection risk.
· Packaged in a manner that maintains sterility and integrity until the point of use. Clear labeling on the packaging includes instructions, contraindications, and warning.

This IFU is applicable for: Central venous catheter kit double/triple/quadruple lumen for all variants (Novocent, Novocent Pro & Novocent Protekt).

Differences between Novocent, Novocent Pro & Novocent Protekt is provided in below table-

Key Differences between CVC brands				
Central Venous Catheter kit				
S. No.	**Name of Component**	**Used in Novocent**	**Used in Novocent Pro**	**Used in Novocent Protekt**
1	Indwelling catheter	√	√	√
2	Extension line clamp	√	√	√
3	Scalpel	√	√	√
4	Dilator	√	√	√
5	Catheter Holder	√	√	√
6	Catheter Holder Clamp	√	√	√
7	Injection cap (as per requirement)			
7.1	Heparin Cap OR	√	√	—
7.2	Clave connector	—	—	√
8	Syringe-5 cc (as per requirement)			
8.1	Luer lock syringe OR	√	√	√
8.2	Guiding syringe	√	√	√
9	Introducer Needle (as per requirement)			
9	Introducer Needle OR	√	√	√
9.1	Y site Introducer Needle	√	√	√
10	Guide Wire (as per requirement)			
10.1	Guide wire (SS-304) OR	√	—	—
10.2	Guide Wire (Nitinol)	—	√	√
11	3 Way Stopcock	√	√	√

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