KIMAL
delivering healthcare innovation

Altius CLASSIC

Instructions for Use
إرشادات الاستخدام
Инструкции за употреба
Návod k použití
Brugsanvisning
Gebruiksaanwijzing
راهنمای استفاده
Käyttöohjeet
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Bruksanvisning
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Pokyny na používanie
Navodila za uporabo
Instrucciones de uso
Bruksanvisning

Instructions for use in all languages are available by scanning this code

1. INTENDED USE

Altius classic central venous catheter set is indicated for adult patients to permit short-term central venous access (cumulatively for up to 28 days, but replaced every 7-10 days) for the treatment of diseases or conditions requiring central venous access, including, but not limited to the following:

- Lack of usable peripheral IV sites
- administration of vasoactive/inotropic drugs
- administration of incompatible medications
- administration of hypertonic solutions including total parental nutrition
- blood sampling
- blood transfusion
- monitoring of central venous pressure (CVP)

2. INTENDED USERS

The device is intended for use by the following trained professionals:

Insertion	In use/Maintenance	Removal
Intensivists	Nurses	Intensivists
Anaesthetists	Consultants	Anaesthetists
Advanced nurse practitioners	Radiologists	Advanced nurse practitioners
Other qualified health care professionals trained to insert a central venous catheter	Anaesthetists	other qualified health care professional
	Intensivists	

3. CLINICAL BENEFITS

Catheter:

- Provides access to the central circulation system through a single puncture site allowing short-term administration of medication, as well as blood sampling and central venous pressure monitoring.
- Separate lumens (extensions) allow the administration of multiple drugs/medicines without them mixing.
- The suture wings (fixation wings) ensure stability of the device and helps to prevent extravasation.

Set components:

The ready-to-use set, provides all the devices required to insert the catheter, using the Seldinger technique.

- The echogenic needle can be visualised under ultrasound guidance to ensure accurate placement.
- The hydrophilic dilator provides effective and less traumatic dilation.
- The guidewire dispenser with a pre-loaded guidewire ensures a controlled placement.

4. SPECIAL PATIENT POPULATIONS

For adults only. Controlled studies of this product have not been conducted in pregnant women or neonatal patients. Benefits of use of this catheter should be weighed against any possible risk.

5. DEVICE DESCRIPTION

Central Venous Catheter is a Sterile, non-pyrogenic, single use medical device made from radiopaque polyurethane. The catheter is available in multiple variations to accommodate different patient anatomical requirements and therapeutic needs. It can be available in 2 to 5 lumen and in French size between 7 and 8.5.

The body of the catheter is tapered at the tip and graduated to help in the safe placement of the tip. The hub is equipped with wings that can be fixed to the skin with sutures, 2 to 5 lumens emerge from the hub.

Each lumen is equipped with a flat clamp that can be slid to open or close position.

Altius Classic Central Venous Catheter is provided with a combination of accessories in a set which allows the catheter to be easily inserted percutaneously and safely placed in the correct anatomical location. These accessories are as follows:

Table 1 Altius Classic CVC Set content

No.	Item name	Quantity	Dimension
1	Central Venous Catheter	1	See label
2	Echogenic introducer needle	1	See label
3	Hydrophilic vessel dilator	1	See label
4	Fixation wing	1	/
5	Guidewire	1	See label
6	Guiding Luerslip syringe	1	5ml
7	Scalpel	1	Number 11

The catheter extensions are transparent to allow visualising the fluids that are administered through them.

6. PERFORMANCE CHARACTERISTICS

Table 2 Performance figures per each Altius Classic CVC code

Code	CVC Catheter Size	Priming Volume / Flow Rate														
		PROXIMAL			DISTAL			MEDIAL 1			MEDIAL 2			MEDIAL 3		
		P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr
Double Lumen																
KCS115702	7 Fr, 15 cm	0.35	18 G	1,600	0.40	14 G	8,500									
KCS120702	7 Fr, 20 cm	0.42	18 G	1,350	0.45	14 G	7,200									
KCS130702	7 Fr, 30 cm	0.50	18 G	1,100	0.53	14 G	6,250									
KCS115802	8 Fr, 15 cm	0.38	16 G	3,200	0.43	14 G	8,500									
KCS120802	8 Fr, 20 cm	0.45	16 G	2,750	0.50	14 G	7,200									
Triple Lumen																
KCS115703	7 Fr, 15 cm	0.24	18 G	1,600	0.31	14 G	5,800	0.27	18 G	1,600						
KCS120703	7 Fr, 20 cm	0.30	18 G	1,350	0.38	14 G	5,100	0.29	18 G	1,350						
KCS130703	7 Fr, 30 cm	0.35	18 G	1,100	0.45	14 G	4,300	0.35	18 G	1,100						
KCS115853	8.5 Fr, 15 cm	0.26	16 G	3,200	0.35	12 G	10,200	0.28	16 G	3,200						
KCS120853	8.5 Fr, 20 cm	0.32	16 G	2,750	0.40	12 G	8,500	0.33	16 G	2,750						
Quadra Lumen																
KCS115854	8.5 Fr, 15 cm	0.28	18 G	1,600	0.45	12 G	10,200	0.35	16 G	2,500	0.28	18 G	1,600			
KCS120854	8.5 Fr, 20 cm	0.32	18 G	1,350	0.53	12 G	8,500	0.40	16 G	1,700	0.32	18 G	1,350			
KCS130854	8.5 Fr, 30 cm	0.40	18 G	1,100	0.60	12 G	8,100	0.48	16 G	1,350	0.40	18 G	1,100			
Penta Lumen																
KCS115855	8.5 Fr, 15 cm	0.25	20 G	780	0.35	12 G	10,500	0.28	18 G	1,250	0.26	18 G	1,250	0.25	20 G	780
KCS120855	8.5 Fr, 20 cm	0.28	20 G	600	0.40	12 G	8,500	0.32	18 G	1,050	0.30	18 G	1,050	0.28	20 G	600
KCS130855	8.5 Fr, 30 cm	0.33	20 G	550	0.48	12 G	8,100	0.40	18 G	850	0.36	18 G	850	0.33	20 G	550

7. RELATIVE CONTRAINDICATIONS

The inserter of the catheter shall apply their clinical judgement prior to the insertion of the catheter. Instances where the catheter might not be suitable are:

Table 3 Patient evaluation prior to access placement

Consideration	Relevance
History of vascular access	Previously failed vascular accesses will limit available sites for access; the cause of a previous failure may influence planned access if the cause is still present. Previous placement of a CVC is associated with central venous stenosis
History of pacemaker use	There is a correlation between pacemaker use and central venous stenosis
History of diabetes mellitus	Diabetes mellitus is associated with damage to vasculature necessary for internal accesses
History of anticoagulant therapy or any coagulation disorder	Abnormal coagulation may cause clotting or problems with haemostasis of access site
History of previous arm, neck or chest surgery/ trauma/ Allergy	Vascular damage associated with previous surgery or trauma may limit viable access sites
Presence of another device related infection	When the presence of another device related infection, bacteraemia or septicaemia is known or suspected
Severe chronic obstructive lung disease	If severe chronic obstructive lung disease exists

8 INSTRUCTIONS FOR USE

8.1 Method of insertion

8.1.1 General preparation to obtain central access

The basic preparation and equipment which are required for venous cannulation are the same regardless of the route or technique chosen. Any Clinician who inserts central catheters should be taught the technique by an experienced colleague.

8.1.2 Equipment required for venous access

- Sterile dressing
- Syringes and needles
- Facility for chest X-ray
- Sterile pack and antiseptic solution
- Appropriate central venous catheter
- Local anaesthetic (e.g., lignocaine 1% solution)
- Saline or heparinised saline to prime and flush all lumens on the line after insertion
- Shaving equipment for the area if very hairy (especially if femoral access is required)
- Suture in case of fixation by suturing is determined (e.g., 2/0 silk on a straight needle)

8.1.3 General insertion technique for all routes

1) Using a strict aseptic technique, prepare and check all the equipment for use.
2) Prime the catheter lumens by flushing all of the lumens.
3) Prepare the guidewire syringe by advancing the tip of the guidewire dispenser into the valve of the syringe. This mechanical action releases the silicone of the valve to receive the Nitinol guidewire.
4) Monitor the marks on the guidewire to know the length of its advanced part. Generally, 20 cm for traditional Seldinger technique or 30 cm if using the guidewire introduction syringe.

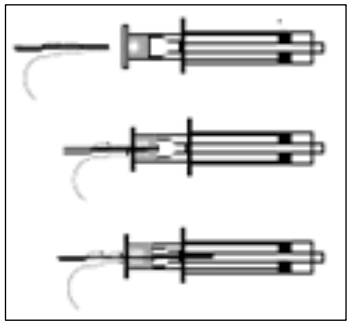


Figure 1 Guiding Syringe

5) Before inserting the dilator, dip it into saline solution to activate the hydrophilic coating.
6) TAKE CARE not to allow the wire to be pushed further into the vein whilst advancing the catheter. Advance the catheter to the length determined anatomically or to the length determined through the use of ECG lead if used. Remove the guidewire once the catheter is fully advanced. The catheter position should be confirmed with chest X-ray. Rotating the catheter may make insertion easier.
7) Aspirate blood up to the syringe to check that blood can be aspirated freely from all lumens of the catheter, flush with saline following push pause flushing technique and a positive disconnection technique.
8) Secure the catheter in place with the suture and cover with a sterile dressing. Tape any redundant tubing, carefully avoiding any kinking or loops which may snag and pull out the catheter.

⚠ **WARNING**

- **This product is sterile and for single use only. DO NOT reuse, reprocess or re-sterilise. Reuse of the device creates a potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality.**
- **DO NOT USE catheter or accessories if any sign of damage is visible.**
- **The catheter does not have any metallic components and can be exposed to various environmental conditions**

including thermal ignition source (during MRI) as long as no metal component is attached to it.

- **DO NOT USE the catheter for high pressure applications and contrast media injection otherwise the catheter may rupture and leak.**
- **The catheter should not be cut to alter its length.**
- **The catheter should be in place no longer than 28 days from the date of insertion. Cumulatively for up to 28 days, but replaced every 7-10 days. DO NOT USE for any purposes other than indicated.**
- **The insertion technique has a significant influence on the complications and outcome of the patient.**
- **Insertion must be performed by a competent and experienced catheter insertion team.**
- **Be sure that you are familiar with the possible complications that may occur and emergency measures are known and available.**
- **Patients requiring ventilation support are at greater risk of pneumothorax during subclavian vein cannulation.**
- **DO NOT advance the guidewire or catheter if unusual elastic resistance is encountered. DO NOT insert or withdraw the guidewire forcibly from any component. The wire could break or unravel, in which case both the catheter and guidewire must be removed simultaneously.**
- **In the rare event that a hub or connector separates from any component during insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove the catheter immediately.**
- **If any resistance is felt, then the needle should be pulled out with the wire still inside and the procedure repeated. This reduces the risk of entangling of the guidewire or its end being cut off by the needle tip.**
- **Over advancement of the guidewire (or catheter) can result in serious injuries or arrhythmias.**
- **Use the marking on the catheter to determine the advanced length.**
- **Use 10 ml or greater syringe to flush the catheter to reduce risk of exceeding the pressure capacity of the**

catheter. If resistance is felt during flushing, no further attempt should be made. Further flushing could result in catheter rupture with possible leakage or immobilisation.

- **Always be sure that the catheter tip is in the superior vena cava and has not entered into the right atrium to avoid possible arrhythmias or mural injury.**

8.1.4 Fixation using the secondary fixation wing

1) Place the white part of the secondary fixation wing and place it as close as possible to the venopuncture.
2) Snap the blue part of the moveable wing over the white wing.
3) Suture the wings through the holes to the skin of the patient.

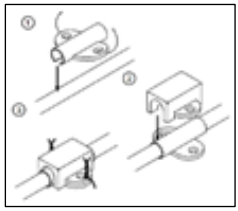


Figure 2

PRECAUTIONS

- **Ultrasound should be used in the placement of catheters.**
- **The position of the tip of any central venous catheter should be verified by radiological means (e.g., X-ray) and monitored routinely as per institution policy.**
- **DO NOT use absolute alcohol or acetone-based products on the catheter. 2% chlorhexidine or iodine-based solution is recommended as antiseptic solution.**
- **It is not recommended to use antimicrobial ointments or solutions on catheters as it may cause degradation of catheter materials.**
- **DO NOT use sharp instruments near the extension line or tubing. DO NOT use scissors to remove dressing, as this could possibly cut or damage the catheter. DO NOT suture through any part of the catheter. Catheter tubing can tear when subjected to excessive force or rough edges.**
- **It is recommended that only luer lock (threaded) connections be used with the catheter (including syringes, bloodlines, IV tubing and injection caps).**
- **Repeated over-tightening of bloodlines, syringes and caps will reduce connector life and could lead to potential**

connector failure. Inspect the catheter frequently for nicks, scrapes and cuts, etc. which could impair catheter performance.

- **The selection of the appropriate catheter length is at the sole discretion of the physician. To achieve proper tip placement, proper catheter length selection is important. Routine X-ray should always follow the initial insertion of the catheter to confirm proper placement prior to use.**
- **Early product failure might be as result of:**
  - **improper positioning of the catheter tip-**
  - **improper flushing and disconnection after use**
  - **aggressive insertion of male luer which may cause cracking of female luer.**
- **Always ensure there is secure fixation of the catheter to the patient.**
- **Always ensure that the fixation is not causing catheter obstruction.**

8.1.5 Procedure after insertion before using the catheter

Ensure that fluid runs in freely and that blood draws back freely.

WARNINGS

Practical problems common to most insertion techniques

The table below lists some problems that may occur with any of the routes for central venous access.

Table 4 Problems during central venous cannulation

Problem	Description
Arterial puncture	Usually obvious but may be missed in a patient who is hypoxic or hypotensive. Withdraw the needle and apply firm direct pressure to the site for at least 10 minutes or longer if there is continuing bleeding. If there is minimal swelling, then retry or change to a different route.
Suspected pneumothorax	If air is easily aspirated into the syringe (note that this may also occur if the needle is not firmly attached to the syringe) or the patient starts to become breathless.

Problem	Description
	Abandon the procedure at that site. Obtain a chest radiograph and insert an intercostal drain if confirmed. If access is absolutely necessary, then try another route ON THE SAME SIDE or femoral vein. **DO NOT** attempt either the subclavian or jugular on the other side as bilateral pneumothoraxes are produced.
Arrhythmias during the procedure	Usually from the catheter or wire being inserted too far (into the right ventricle). The average length of catheter needed for an adult internal jugular or subclavian approach is 15cm. Withdraw the wire or catheter if further than this.
Air embolus	This can occur, especially in the hypovolaemic patient who is breathing spontaneously, if the needle is left in the vein whilst open to the air. It is easily prevented by ensuring that the patient is positioned in the Trendelenburg position (for jugular and subclavian routes) and that the guidewire is passed down the needle promptly.
The wire will not thread down the needle	Check that the needle is still in the vein. Flush it with saline. Try angling the needle so the end of it lies more along the plane of the vessel. Carefully rotate the needle in case the end lies against the vessel wall. Reattach the syringe and aspirate to check that you are still in the vein. If the wire has gone through the needle but will not pass down the vein it should be very gently pulled back. If any resistance is felt, then the needle should be pulled out with the wire still inside and the procedure repeated. This reduces the risk of the end of the wire being cut off by the needle tip.
Persistent bleeding at the entry	Apply firm direct pressure with a sterile dressing. Bleeding should usually stop unless there is a coagulation abnormality. Persistent severe bleeding may require surgical exploration if there is an arterial or venous tear.

8.2 Possible complications

The table below lists some of the possible complications that can occur during the early and late stages of central venous cannulation.

Table 5 Potential early and late complications

Early	Late
Extravasation	Infection
Haemorrhage	Hydrothorax
Pneumothorax	Air embolism
Arterial puncture	Haemothorax
Catheter embolism	Venous stenosis
Cardiac tamponade	Venous thrombosis
Cardiac arrhythmias	Vascular perforation
Injury to the thoracic duct	Pulmonary embolism
Injury to surrounding nerves	Catheter colonisation
Intra-arterial placement of the catheter	Line fracture and Embolism

8.2.1 Prevention and treatment of catheter dysfunction

Causes of early catheter dysfunction

- Mechanical compression (pinch off syndrome in subclavian catheter)
- Malposition of catheter tip
- Kinks
- Catheter migration
- Occlusion of side holes due to clotting or fibrin sheath formation or drug precipitation (some antibody locks or IV IgG)
- Patient position, especially if the catheter has not been well positioned and secured
- Loss of catheter integrity by infection

- Malpractice/ incorrectly use of the catheter by the staff.

Methods that should be used to treat dysfunctional or non-functional catheter include

- Repositioning of a mispositioned catheter.
- Use of thrombolytics, as per hospital protocol.
- All catheter-related infections, except for catheter exit-site infections, should be addressed by initiating parenteral treatment with an antibiotic(s) appropriate for the organism(s) suspected. Definitive antibiotic therapy should be based on the organism(s) isolated.
- Catheters should be exchanged as soon as possible and within 72 hours of initiating antibiotic therapy in most instances, and such exchange does not require a negative blood culture result before the exchange. Follow-up cultures are needed 1 week after cessation of antibiotic therapy.

8.3 Care of central venous catheter

- Use an aseptic technique with maximal sterile barrier precautions when inserting the catheter and any subsequent injections or changing fluid lines.
- DO NOT use absolute alcohol or acetone-based products on the catheter. 2% chlorhexidine or iodine-based solution is recommended as antiseptic solution.
- When accessing LuerSafe (female luer) wipe it in accordance with local hospital protocol but never use disinfectants with alcohol content higher than 70% or higher and neither use ethanol or propanol alcohols.
- DO NOT apply aggressive twisting force to the line while wiping it for disinfection.
- While connecting or wiping the female luer always grasp the luer itself, not from the extension tube below it.
- Keep the entry site covered with a dry sterile dressing and following the protocol of the hospital. Some hospitals' protocol also advise to put biopatch on the insertion site or a specific dressing.

- Change the catheter if there are signs of infection at the site.
- Remember to remove the catheter as soon as it is no longer needed. The longer the catheter is left in, the greater the risks of sepsis and thrombosis.
- When changing the dressing, if using an alcohol-based cleaning solution (with concentration not higher than 70%), ensure the site is dry by either waiting for 20 to 30 seconds or by drying with a clean, sterile swab before applying a dressing.
- For lumens not in use, check at least once a day their patency by aspirating the lumen and flushing it with saline solution using a push-pause flushing followed by a positive disconnection.

8.4 Catheter removal

Remove any dressing and suture material. It is recommended that the patient is in a supine or Trendelenburg position. Ask the patient to take a breath and fully exhale. Remove the catheter with a steady pull while the patient is holding their breath and apply firm pressure to the puncture site for at least 5 minutes to stop the bleeding. Excessive force should not be needed to remove the catheter. If it does not come out, try rotating it whilst pulling gently. If this still fails, cover it with a sterile dressing and ask an experienced person for advice.

8.5 Catheter disposal

Used catheters should be disposed of in a sanitary container or according to hospital protocol to prevent possible contamination and cross infection.

9 CONNECTIONS

All connector ports in the Altius classic CVC Set are standard 6% (luer) taper in compliance with BS EN ISO 80369-7.

10 DESCRIPTION OF THE MARKING SYSTEM

To achieve the required length, the catheter tube is marked with numerical numbers every 5 cm with dots every 1 cm in between, apart from the first 5 cm which is not marked.

5 • • • • 10 • • • • 15 • • • • 20 • • • • 25 • • • •

Illustration purposes only, not to scale.

11 CODING CONVENTION

Altius Classic Central Venous Catheter Sets included in this range are coded as “KCS1XXYYZ”, where:

- KCS1 stands for first generation uncoated CV catheter,
- XX stands for the catheter length in centimetre,
- YY stands for the French size of the tube and
- Z stands for the number of lumens of the catheter.

12 SERIOUS ADVERSE EVENTS

If a serious adverse event occurs, please report it to Kimal at: vigilance@kimal.co.uk and to your national competent authority.

This is the “Kimal Altius Classic CVC Set” Summary of Safety and Clinical Performance (SSCP) location after the launch of the European Database on Medical Devices/Eudamed:

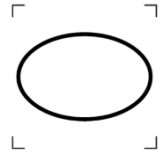
https://ec.europa.eu/tools/eudamed

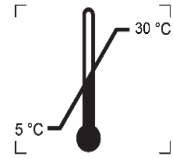
For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized 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://ec.europa.eu/growth/sectors/medical-devices/contacts_en

13 SYMBOL GLOSSARY

en	Symbol Glossary: Symbols are in compliance with ISO 15223-1 and BS EN 15986. Some symbols may not apply to this product. Refer to product labelling for symbols that apply specifically to this product.

				
Caution	Medical device	Fragile, handle with care	Do not reuse	Do not resterilize
				
Not made with natural rubber latex	Keep away from sunlight	Single sterile barrier system	Date of manufacture	Sterilized using ethylene oxide
				
Catalogue number	Batch code	Use-by date	Manufacturer	Keep dry

				CE 0476
Do not use if package is damaged and consult instructions for use	This way up (To indicate correct upright position of the transport package)	Consult instructions for use or consult electronic instructions for use	Temperature limit (Store between 5°C and 30°C)	CE marking of conformity with European notified body identification number (KIWA Cermet Italia)

EC REP	Advena Ltd. Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013, Malta	MD
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