Instructions for Use

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1 INTENDED USE

The Altius ProActiv+ Central Venous Catheter (CVC) is indicated for adult patients to permit short term central venous access (up to a maximum of 10 days, but may be replace and used cumulatively for 28 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)

Indicated for patients at risk of infection or in line with requirements of hospital protocols, the Altius ProActiv+ CVC is coated with an antimicrobial solution made of PHMB (polyhexamethylene biguanide) and copolymerised with PEG (Polyethylene Glycol), which is covalently bonded to the catheter.

The ProActiv+ technology provides protection against catheter related bloodstream infections (CRBI's) for the duration of use and is not intended for use against existing infections.

Altius ProActiv+ High Pressure (HP) CVC is also indicated for the following:

- Patients requiring Computerised Tomography (CT) imagery and the powerful injection/administration of contrast media where pressure may not exceed 300 psi.

Altius ProActiv+ High Flow (HF) CVC is also indicated for the following:

- Patients requiring rapid administration and /or, large volumes of blood or fluids.

2 INTENDED USERS

The device is intended for use by trained healthcare professional and includes but is not limited to the following.

Table 1. Intended user population

Insertion	In use / Maintenance	Removal

Intensivists	Nurses and doctors	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 trained to remove a central venous catheter
	Intensivists	

3 CLINICAL BENEFITS

The Altius ProActiv+, Altius ProActiv+ HP and Altius ProActiv+ HF CVC's provide the following clinical benefits;

- 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.
- Luersafe connectors are integrated to reduce the risk of infection and air embolism and remove the requirement for manual clamps
- Colour-coded lumens allow a clearer identification of the lumens
- Multitube technology using round lumens provides a consistent flow rate ensuring suitable drug delivery
- The ProActiv+ technology provides protection against catheter related blood stream infections(CRBI's) by means of polymer surface modification, preventing adhesion of pathogens and microbial colonization.

The different variations of the Altius ProActiv+ HP and HF CVC accommodate different therapeutic needs:

- The HP range includes a dedicated lumen for safe administration of Contrast Media by syringe or power injection (pressures of 300 psi and flow-rates of up to 10 ml s−1). These flow rates are only achieved for contrast media with a viscosity of 11.8 cP units if warmed to body temperature (37°C). This dedicated proximal lumen is clearly identified by the colour purple and reduces the need for additional canulation to administer contrast media.

- The HF range includes a medial lumen which can be used for routine administration of fluids or connected to rapid infusion devices for delivery of blood and fluids up to 9000 ml/ hr (150 ml/ minute) in the case of trauma emergencies, liver transplant or other conditions requiring rapid infusion of fluids. Use of this lumen reduces the need for additional canulation with large bore catheters.

The insertion kit provides the following clinical benefits;

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

- Echogenic needle supports improved visualisation under ultrasound to ensure accurate placement and to prevent posterior wall puncture.
- Hydrophilic dilator to provide effective and less traumatic dilation
- The guidewire dispenser with pre-loaded guidewire ensures controlled placement.

- The guiding syringe allows passage of the guidewire through the syringe for accurate placement of guidewire tip, there is no need to remove the syringe from the needle until the guidewire is in place, thus potentially reducing vessel trauma. The valved system of the syringe maintains a closed system preventing air embolism as the guidewire passes through the barrel and valve of the syringe.

4 DEVICE DESCRIPTION

Altius ProActiv+, Altius ProActiv+ HP and Altius ProActiv+ HF CVC sets are a combination of sterile, single use, surgically invasive devices. All configurations are radiopaque and made from polyurethane.

The catheters are composed of 1 to 7 lumens. Multiple lumens allow the administration of several drugs without them mixing:

They are also available in different length configurations from 11cm to 30cm and French sizes 5 to 12.5Fr.

Each catheter set consists of a Altius ProActiv+ CVC and insertion kit. The insertions kits include the following components:

- 1 × Echogenic introducer needle
- 1 × 5 ml guiding syringe
- 1 × Nitinol guidewire in a guidewire advancer with cap
- 1 × Hydrophilic coated dilator
- 1 × Scalpel
- 1 x Fixation wing

5 PERFORMANCE CHARACTERISTICS

Single Lumen		Priming Vol./Flow Rate		
Catheter Size		DISTAL		
C.V.C Catheter		P.V CC	Gauge	ml/hr
5 Fr	15 cm	0.20	16 G	3,640
5 Fr	20 cm	0.30	16 G	3,240
7 Fr	15 cm	0.40	14 G	8,000
7 Fr	20 cm	0.50	14 G	7,600
7 Fr	30 cm	0.60	14 G	6,600

Single HP		Priming Vol./Flow Rate		
Catheter Size		DISTAL		
C.V.C Catheter		P.V CC	Gauge	ml/hr
5 Fr	15 cm	0.30	16 G	3,000
5 Fr	20 cm	0.30	16 G	2,800
6 Fr	20 cm	0.35	15 G	4,900
7 Fr	15 cm	0.55	14 G	9,300
7 Fr	20 cm	0.60	14 G	7,500
8 Fr	20 cm	0.65	12 G	10,200

Double Lumen		Priming Volume / Flow Rate					
Catheter Size		PROXIMAL			DISTAL		
C.V.C Catheter		P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr
7 Fr	15 cm	0.35	18 G	1,600	0.40	14 G	8,500
7 Fr	20 cm	0.42	18 G	1,350	0.45	14 G	7,200
7 Fr	30 cm	0.50	18 G	1,100	0.53	14 G	6,250
8 Fr	15 cm	0.38	16 G	3,200	0.43	14 G	8,500
8 Fr	20 cm	0.45	16 G	2,750	0.50	14 G	7,200
8 Fr	30 cm	0.50	16 G	2,350	0.55	14 G	6,250

Double HP		Priming Volume / Flow Rate					
Catheter Size		PROXIMAL			DISTAL		
C.V.C Catheter		P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr
7 Fr	15 cm	0.30	17 G	2,500	0.35	14 G	5,800
7 Fr	20 cm	0.30	17 G	2,050	0.35	14 G	5,100
8 Fr	15 cm	0.30	16 G	3,200	0.40	14 G	6,600
8 Fr	20 cm	0.30	16 G	2,700	0.40	14 G	6,100

Triple Lumen		Priming Volume / Flow Rate								
Catheter Size		PROXIMAL			DISTAL			MEDIAL		
C.V.C Catheter		P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr
7 Fr	11 cm	0.21	18 G	2,000	0.26	14 G	6,000	0.21	18 G	2,000
7 Fr	15 cm	0.24	18 G	1,600	0.31	14 G	5,800	0.27	18 G	1,600
7 Fr	20 cm	0.30	18 G	1,350	0.38	14 G	5,100	0.29	18 G	1,350
7 Fr	30 cm	0.35	18 G	1,100	0.45	14 G	4,300	0.35	18 G	1,100
8 Fr	15 cm	0.26	16 G	3,250	0.35	14 G	6,000	0.28	16 G	3,250
8 Fr	20 cm	0.32	16 G	2,750	0.40	14 G	5,100	0.33	16 G	2,750
8 Fr	30 cm	0.38	16 G	2,350	0.45	14 G	4,200	0.38	16 G	2,350
8.5 Fr	15 cm	0.26	16 G	3,200	0.35	12 G	10,200	0.28	16 G	3,200
8.5 Fr	20 cm	0.32	16 G	2,750	0.40	12 G	8,500	0.33	16 G	2,750
8.5 Fr	30 cm	0.38	16 G	2,350	0.45	12 G	8,100	0.38	16 G	2,350
8.5 Fr	65 cm	0.76	16 G	1,500	0.90	12 G	5,700	0.76	16 G	1,500

Triple Lumen HP		Priming Volume / Flow Rate								
Catheter Size		PROXIMAL			DISTAL			MEDIAL		
C.V.C Catheter		P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr
7 Fr	20 cm	0.25	18 G	1,350	0.30	16 G	2,800	0.25	18 G	1,350
7 Fr	30 cm	0.25	18 G	1,100	0.30	16 G	2,350	0.25	18 G	1,100
8 Fr	15 cm	0.25	18 G	1,600	0.25	14 G	6,600	0.30	18 G	1,600
8 Fr	20 cm	0.25	18 G	1,350	0.25	14 G	5,100	0.30	18 G	1,350

Quadra Lumen		Priming Volume / Flow Rate											
Catheter Size		PROXIMAL			DISTAL			MEDIAL 1			MEDIAL 2		
C.V.C Catheter		P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr
8.5 Fr	11 cm	0.25	18 G	1,800	0.35	12 G	10,500	0.30	16 G	2,600	0.25	18 G	1,800
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
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
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

Quadra Lumen HP		Priming Volume / Flow Rate											
Catheter Size		PROXIMAL			DISTAL			MEDIAL 1			MEDIAL 2		
C.V.C Catheter		P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr
8 Fr	15 cm	0.25	18 G	1,250	0.35	16 G	4,200	0.25	18 G	1,250	0.25	18 G	1,250
8 Fr	20 cm	0.25	18 G	1,020	0.35	16 G	3,800	0.25	18 G	1,020	0.25	18 G	1,020
9 Fr	15 cm	0.25	17 G	1,600	0.25	14 G	6,600	0.25	17 G	1,600	0.25	17 G	1,600
9 Fr	20 cm	0.25	17 G	1,350	0.25	14 G	6,050	0.25	17 G	1,350	0.25	17 G	1,350

Catheter Size		Priming Volume / Flow Rate														
Penta Lumen		PROXIMAL			DISTAL			MEDIAL 1			MEDIAL 2			MEDIAL 3		
C.V.C Catheter		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
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
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
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
9 Fr	15 cm	0.26	18 G	1,250	0.45	14 G	8,500	0.26	16 G	3,200	0.26	18 G	1,250	0.26	18 G	1,250
9 Fr	20 cm	0.30	18 G	1,050	0.53	14 G	7,200	0.30	16 G	2,750	0.30	18 G	1,050	0.30	18 G	1,050

Catheter Size		Priming Volume / Flow Rate														
Penta Lumen HP		PROXIMAL			DISTAL			MEDIAL 1			MEDIAL 2			MEDIAL 3		
C.V.C Catheter		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
9 Fr	15 cm	0.20	18 G	1,250	0.30	16 G	3,200	0.20	18 G	1,250	0.20	18 G	1,250	0.20	18 G	1,250
9 Fr	20 cm	0.20	18 G	1,100	0.30	16 G	2,800	0.20	18 G	1,100	0.20	18 G	1,100	0.20	18 G	1,100
9 Fr	30 cm	0.20	18 G	840	0.30	16 G	2,200	0.20	18 G	840	0.20	18 G	840	0.20	18 G	840

Catheter Size		Priming Volume / Flow Rate											
Seven Lumen		PROXIMAL			DISTAL			MEDIAL 1			MEDIAL 2		
C.V.C Catheter		P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr
8.5 Fr	15 cm	0.20	21 G	800	0.30	14 G	3,200	0.20	21 G	800	0.20	21 G	800
		MEDIAL 3			MEDIAL 4			MEDIAL 5					
		P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr			
		0.20	21 G	800	0.20	21 G	800	0.20	21 G	800			

Catheter Size		Priming Volume / Flow Rate											
Seven Lumen		PROXIMAL			DISTAL			MEDIAL 1			MEDIAL 2		
C.V.C Catheter		P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr
8.5 Fr	20 cm	0.20	21 G	620	0.33	14 G	2,800	0.20	21 G	620	0.20	21 G	620
		MEDIAL 3			MEDIAL 4			MEDIAL 5					
		P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr			
		0.20	21 G	620	0.20	21 G	620	0.20	21 G	620			

Catheter Size		Priming Volume / Flow Rate					
Double Lumen HF		PROXIMAL			DISTAL		
C.V.C Catheter		P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr
8.5 Fr	11 cm	0.33	16 G	3,360	0.45	12 G	12,100
8.5 Fr	15 cm	0.38	16 G	3,200	0.48	12 G	11,400
8.5 Fr	20 cm	0.45	16 G	2,750	0.50	12 G	10,500
8.5 Fr	25 cm	0.48	16 G	2,610	0.55	12 G	10,200

Catheter Size		Priming Volume / Flow Rate								
Triple Lumen HF		PROXIMAL			DISTAL			MEDIAL		
C.V.C Catheter		P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr
8.5 Fr	11 cm	0.33	16 G	3,360	0.45	12 G	12,100	0.33	16 G	3,360
8.5 Fr	15 cm	0.38	16 G	3,200	0.48	12 G	11,400	0.38	16 G	3,200
8.5 Fr	20 cm	0.45	16 G	2,750	0.50	12 G	10,500	0.45	16 G	2,750
8.5 Fr	25 cm	0.48	16 G	2,610	0.55	12 G	10,200	0.48	16 G	2,610

Catheter Size		Priming Volume / Flow Rate											
Quadra Lumen HF		PROXIMAL			DISTAL			MEDIAL 1			MEDIAL 2		
C.V.C Catheter		P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr	P.V CC	Gauge	ml/hr
12 Fr	11 cm	0.33	16 G	3360	0.55	12 G	12,100	0.45	12 G	12,100	0.33	16 G	3,360
12 Fr	15 cm	0.38	16 G	3,200	0.50	12 G	11,400	0.48	12 G	11,400	0.38	16 G	3,200
12 Fr	20 cm	0.45	16 G	2,750	0.48	12 G	10,500	0.50	12 G	10,500	0.45	16 G	2,750
12 Fr	25 cm	0.48	16 G	2,610	0.45	12 G	10200	0.55	12 G	10,200	0.48	16 G	2,610

Catheter Size		Priming Volume / Flow Rate														
Penta Lumen HF(HP)		PROXIMAL			DISTAL			MEDIAL 1			MEDIAL 2			MEDIAL 3		
C.V.C Catheter		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
12.5 Fr	15 cm	0.35	18	1,600	0.38	16	3,200	0.48	12	11400	0.48	12	11400	0.38	16	3,200
12.5 Fr	20 cm	0.42	18	1,350	0.45	16	2,750	0.50	12	10500	0.50	12	10500	0.45	16	2,750
12.5 Fr	25 cm	0.50	18	1,100	0.48	16	2,610	0.55	12	10200	0.55	12	10200	0.48	16	2,610

6 HOW SUPPLIED

All contents are supplied STERILE and non-pyrogenic in unopened and undamaged packaging. The devices are sterilised by ethylene oxide.

⚠ **WARNING** Do not use any unit if sterile package has been damaged or opened. DO NOT RE-USE OR RE-STERILISE the device. Do not re-sterilise, reprocess, or reuse. Reuse, reprocessing or re-sterilisation may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or re-sterilisation may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

Storage

⚠ Protect from direct sunlight, any source of heat, and moisture. Store at room temperature and do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that devices are used prior to expiration date on package label.

7 SPECIAL PATIENT POPULATIONS

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

8 CONTRA-INDICATIONS

The inserter of the catheter shall apply their clinical judgement prior to the insertion of the catheter. The device is contraindicated in the following circumstances:

- Patients with a known or suspected Polythylene Glycol (PEG) allergy.
- Patients with bleeding disorders.
- When the presence of another device related infection, bacteraemia or septicaemia is known or suspected.
- Post irradiation of prospective insertion site.
- Previous episodes of venous thrombosis or vascular surgery at the prospective placement site.
- Local tissue factors that prevent proper device stabilization and/or access.
- For central venous access >28 days
- Thrombus of the target vein

9 INSTRUCTIONS FOR USE

The Altius ProActiv +, Altius ProActiv+ HP and Altius ProActiv+ HF CVC is indicated for adult patients to permit short term central venous access (up to a maximum of 10 days but may be replaced and used cumulatively for 28 days) for the treatment of diseases or conditions requiring central venous access.

If replaced cumulative use of 28 days should not be exceeded. Repeated cannulation to change lines on a routine basis, rather than based on clinical need, can increase the risks to the patient.

The catheter should be inserted using Seldinger technique that includes using a guidewire and a vessel dilator to facilitate the insertion of the catheter.

9.1 Insertion site

Inserted in the right internal and external jugular veins, the left internal and external jugular veins or the subclavian veins and inserted into the Superior Vena Cava (SVC) with the tip resting at the lower third of the SVC.

9.2 Insertion procedure

Ultrasound should be used to ensure the catheter is correctly placed in the vein and to avoid arterial puncture.

Equipment required:

- Sterile gloves and gown
- Sterile pack
- Antiseptic solution (2% chlorhexidine solution) and sponge stick
- Local anaesthetic – e.g., 1% lidocaine
- Appropriate catheter for size of patient / purpose
- Syringes and needles
- Saline or heparinised saline to prime and flush the line after insertion
- Suture material if fixation by suturing is preferred – e.g., 2/0 silk on a straight needle.
- Sterile dressing
- Shaving equipment for the insertion site if applicable
- Facility for chest X-ray

General insertion technique for all sites

1. Confirm that central venous access is needed and select the most appropriate site. Explain the procedure to the patient.
2. Shave the insertion site if required.
3. Using a strict aseptic technique, prepare and check all the equipment for use.
4. Prime all lumens with saline prior to insertion.
5. Prepare the skin and drape the area. Allow insertion site to dry completely prior to skin puncture.
6. Infiltrate the skin and deeper tissues with local anaesthetic. In cases where difficulty is anticipated use the small local anaesthetic needle to locate the vein before using the larger needle. This reduces the risk of trauma to other structures.
7. Position the patient for the specific route selected – avoid long periods of head down, particularly in breathless patients.
8. Connect the introducer needle to the guiding syringe
9. Identify the anatomical landmarks for the chosen route using ultrasound guidance and insert the needle at the recommended point. After the needle has penetrated the skin, aspirate gently whilst advancing the needle as directed until the vein is entered. If the vein is not found, slowly withdraw the needle whilst gently aspirating; often the vein has been collapsed and transfixed by the entry of the needle.
10. Connect the guidewire dispenser to the guiding syringe and advance the guidewire (Seldinger technique) using the dispenser roller, into the vein.

⚠ **WARNING** The valve of the guidewire syringe should be opened by the guidewire advancer tip. Do not attempt to pass the guidewire before opening the valve by the advancer tip otherwise the wire may become kinked or damaged.

WARNING 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.

11. Advance the guide wire equivalent length to the desired position of the catheter tip. Remove the needle, syringe, and guidewire dispenser together.

WARNING Maintain grip on guidewire at all times. Ensure sufficient guidewire length is exposed for handling purposes. A non-controlled guidewire may lead to wire embolus.

12. It is necessary to dilate up the hole in the vein. Make a small incision in the skin and fascia where the wire enters the patient.
13. Activate the hydrophilic dilator by immersing in normal saline. Thread the dilator over the wire into the vein with a twisting motion. Excessive force should not be needed. Remove the dilator taking care not to dislodge the guidewire.
14. Thread the catheter over the guide wire until the end of the wire protrudes from the end of the catheter and whilst holding the wire advance the catheter into the vein.

WARNING Take care not to allow the wire to be pushed further into the vein whilst advancing the catheter. Over advancement of guidewire can result in serious injuries or arrhythmias.

WARNING Do not apply undue force to guidewire to reduce risk of possible breakage. If resistance is encountered when attempting to remove guidewire after catheter placement, guidewire may be kinked around tip of catheter within vessel. In this circumstance, pulling back on guidewire may result in undue force being applied resulting in guidewire breakage. If resistance is encountered, withdraw catheter relative to guidewire about 2-3 cm and attempt to remove guidewire. If resistance is again encountered, remove guidewire and catheter simultaneously.

15. Advance the catheter to the desired length. The catheter body is marked in centimetres. The first 5 cm of the catheter is not marked. The optimal tip location once inserted is at the junction of the superior vena cava and right atrium.
16. Gently remove the guidewire.
17. Aspirate and flush all lumens. A blood gas may be used to identify venous blood.
18. Secure the catheter in place using the primary suture wings.

The position of the catheter tip should be verified by radiological means. X-ray must show the catheter located in the right side of the mediastinum in the SVC with the distal end of the catheter parallel to the vena cava wall and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized. If catheter tip is malpositioned, reposition and re-verify.

Use a chest X-ray to also exclude a pneumo, hydro or haemothorax. An early radiograph may not show up abnormalities and it may be best to wait 3-4 hours unless symptoms develop.

WARNING Take care not to cause damage to the catheter with the suture needle.

WARNING Sure only the wings. Do not suture or wrap suture around the catheter body.

19. A secondary suture wing is provided if required. Detach the blue cover. Secure the white wing section to the catheter body by gently flexing the wing to open. Once in the desire location replace the blue cover, press gently until it snaps into place.

WARNING Ensure the secondary suture wing is fitted correctly and not pinching the catheter which may lead to occlusion.

⚠ **WARNING** Take care not to cause damage to the catheter with the suture needle.

20. Cover with a sterile dressing according with hospital protocol.

⚠ **WARNING** Never secure, staple and/or suture catheter body or extension lines directly to prevent catheter damage or impeding catheter flow.

21. Once the catheter is secured and position confirmed, it may be connected as required. If not to be used immediately connect catheter to a bag of intravenous fluid or flush all lumens with appropriate anti thrombotic.

⚠ **WARNING** Complications may arise during the insertion of a CVC, see below for further details.

The table below highlights problems that may occur with any insertion route for central venous access.

Table 2. 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. 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.

9.2 High pressure injection

Altius ProActiv+ High Pressure (HP) CVC is suitable to be used for the power injection of contrast media. Contrast media should only be injected through the purple distal lumen (marked PRESSURE).

⚠ **WARNING** Lumens other than the identified purple lumen are not suitable for the injection of contrast media. Injection may cause catheter rupture and / or tip displacement.

The Altius ProActiv+ HP CVC is compatible with contrast media with a viscosity rating of up to 11.8 cP at 37°C at a maximum of 300 psi to deliver a maximum of 10 ml/sec.

⚠ **WARNING** Using viscosity, pressures, or flow rates higher than those stipulated may cause catheter rupture and / or tip displacement. Contrast Media must be warmed to 37°C to ensure acceptable viscosity

Connecting to a high-pressure injector

1) Clean the LuerSafe connector of the purple distal lumen (marked PRESSURE).

Table 3. Lumen colours for the Altius ProActiv+ HP CVC range

Number of lumens	Distal	Medial 1	Medial 2	Medial 3	Proximal
One lumen	Purple	-	-	-	-
Two lumen	Purple	-	-	-	White
Three lumen	Purple	Blue	-	-	White
Four lumen	Purple	Blue	Grey	-	White
Five lumen	Purple	Blue	Grey	Green	White

2) Aspirate then flush the lumen to confirm the lumen is patent.
3) Connector the contrast media lines with a screwing action whilst pushing gently.
4) Administer the contrast as required.
5) Disconnect when the procedure is finished.
6) Aspirate then flush the lumen to confirm the lumen is patent.

9.4 High flow

The Altius ProActiv+ High Flow (HF) CVC provides a larger lumen that allows the administration of fluids at higher flow rates of up to 9000 ml per hour or higher. This supports the rapid administration of blood or fluids. Higher flow rates are achieved only when using the distal lumen.

Table 4. Lumen colours for the Altius ProActiv+ HF CVC range

Number of lumens	Distal	Medial 1	Medial 2	Medial 3	Proximal
Two lumen	Red	-	-	-	White
Three lumen	Red	Brown	-	-	White
Four lumen	Red	Brown	Blue	-	White
Five lumen	Red	Brown	Blue	Grey	White

9.5 Care of the catheter

- Use an aseptic technique with maximal sterile barrier precautions when inserting the catheter and any subsequent injections or changing fluid lines.

- Keep the entry site covered with a dry sterile dressing and following the protocol of the hospital. Specific dressing types may be used as per hospital policy such as BIOPATCH or impregnated film dressings.
- Ensure the line is well secured to prevent movement (this can increase risks of infection and clot formation).
- Change the catheter if there are signs of infection at the site.
- Catheter shall be kept clean (sterile injections and connections) with no signs of systemic sepsis.
- 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.
- 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.
- When accessing LuerSafe (connectors) 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.

⚠ **WARNING** DO NOT apply aggressive twisting force to the line while wiping it for disinfection.

⚠ **WARNING** While wiping the LuerSafe (connectors) always grasp the luer itself, not from the extension tube below it.

- Some disinfectants used at catheter insertion site contain solvents which can weaken the catheter material. Alcohol, acetone, and polyethylene glycol can weaken the structure of polyurethane materials. These agents may also weaken the adhesive bond between catheter stabilization device and skin.

⚠ **WARNING** Do not use absolute alcohol or acetone-based product on the catheter. 2% chlorhexidine or Iodine based solution is recommended as antiseptic solution.

⚠ **WARNING** Do not use alcohol to soak catheter surface or allow alcohol to dwell in a catheter lumen to restore catheter patency or as an infection prevention measure.

⚠ **WARNING** Do not use polyethylene glycol containing ointments at insertion site.

Catheter dressing changes

Catheter dressings should be changed as per hospital protocol. The site should be cleaned as per the above guidance. 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.

⚠ **WARNING** Do not use sharp instruments near the extension line or tubing. Do not use scissors to remove dressings, as this could possibly cut or damage the catheter. Take care when cleaning catheter tubing may be damaged when subjected to excessive force or rough edges.

9.6 Routine use

Indwelling catheters should be routinely inspected for correct positioning, desired flow rate, security of dressing, and, for secure Luer-Lock connection. Use centimetre markings to identify if the catheter position has changed. Always ensure catheter patency prior to use.

⚠ **WARNING** Do not use syringes smaller than 10 ml to reduce the risk of intraluminal leakage or catheter rupture.

⚠ **WARNING** Do not use excessive force when flushing to try and clear any blockage or obstruction as this may lead to catheter rupture.

Check lumens not in use daily to assess patency by aspirating the lumen and flushing it with saline using a push-pause flushing followed by a positive disconnection.

LuerSafe connectors

Lines or syringes may be connected directly to the LuerSafe connector on the end of each lumen. Whilst connecting and disconnecting there is no requirement to clamp or pinch extension lines.

⚠ **WARNING** Do not clamp the body of the catheter or extension lines. Never use serrated forceps to clamp the extension lines.

1. Clean LuerSafe connector prior to use as per hospital protocol.
2. To attach a male slip luer or male luer lock grasp the body of the connector and push the luer / syringe into the silicone valve with an anticlockwise twisting motion.

⚠ **WARNING** Do not attempt to insert the luer / syringe at an angle as this may damage the connector.

3. Flush the lines after each use, in accordance with hospital protocol, using a push-pause and positive pressure disconnection technique.
4. To disconnect from the LuerSafe connector, grasp the body of the connector and twist clockwise until loose. The valve will seal automatically.

⚠ **WARNING** Over tightening of syringes and lines may lead to failure or damage of the LuerSafe connector.

⚠ **WARNING** Do not twist the LuerSafe connectors, this may lead to catheter damage.

9.7 Prevention and correction of catheter dysfunction

Catheters should be evaluated when they become dysfunctional.

Causes of catheter dysfunction

- Mechanical compression (pinch off syndrome in subclavian catheter)
- Malpositioning of catheter tip and catheter migration
- Kinks
- Side hole occlusion due to clotting or fibrin sheath formation or attachment to vein wall
- Drug precipitation (some antibody locks or IV IgG)
- Patient position especially in poorly secured catheter
- Loss of catheter integrity from infection

<u>Correction of dysfunctional or non-functional catheter</u>

Repositioning a malpositioned catheter

- Change patient position, ask him to cough or vigorous flush (if no resistance is felt) to try to dislodge side holes a way from vein wall.

Fibrin sheath stripping using a snare if a fibrin sheath is present

- Exchanging the thrombosed catheter over a guidewire if a fibrin sheath is present or if the catheter is malpositioned or of inadequate length.
- Use thrombolytics, as per hospital protocol.

Catheter infection

- Treatment of an infected CVC should be based on the type and extent of infection.
- 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.

9.8 Catheter removal

⚠ **WARNING** Only physician familiar with the technique should attempt the removal. Always review hospital protocols, possible complications and their treatments, precautions, and warning.

1. Remove any dressing and suture material.
2. Clean the catheter site as per hospital protocol.
3. Place the patient supine or into a Trendelenburg position
4. Ask the patient to take a breath and fully exhale. Remove the catheter with a steady pull while the patient is holding their breath.

⚠ **WARNING** 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.

5. Apply firm pressure to the puncture site for at least 5 minutes to stop the bleeding.
6. Cover catheter entry site with a sterile occlusive dressing.
7. Post removal assessment and documentation of insertion in medical notes.

⚠ **WARNING** 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.

10 POTENTIAL COMPLICATIONS

Observe patients for signs of potential early and late 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 Complication		Late
Pneumothorax	Inadvertent arterial puncture	Venous thrombosis
Bleeding	Air embolism	Exit site infection
Cardiac arrhythmias	Catheter embolus	Hydrothorax

Cardiac tamponade	Injury to surrounding nerves	Cardiac perforation
Catheter occlusion	Injury to the thoracic duct	Venous stenosis
Hematoma	Thoracic duct laceration	Bacteraemia
Haemorrhage	Catheter tip malposition	Septicaemia
Dysrhythmias	Brachial plexus injury	Fibrin sheath formation
Exsanguination	Intra-arterial placement of the catheter	Vessel erosion
Extravasation	Pleural (i.e., pneumothorax) and mediastinal injuries	Pulmonary embolism
		Catheter colonisation
		Line fracture and Embolism

11 CODING CONVENTION

The coding convention of the Altius ProActiv+, Altius ProActiv+ HP and Altius ProActiv+ HF CVC range is as indicated below.

Table 6. Coding convention description for CVC

Product Family	Coding Convention	Description
Altius ProActiv+	K2CS2**XXYY**Z	Standard Microbial CVC
Altius ProActiv+ HP	K2CS2**XXYY**Z**P**	P denotes High Pressure (HP)
Altius ProActiv+ HF	K2CS2**XXYY**Z**HF**	HF denotes High Flow (HF)
Altius ProActiv+ HP HF	K2CS2**XXYY**Z**PHF**	PHF denotes High Pressure (HP) & High Flow (HF)

- **K2CS** denotes the second generation of Kimal PLC Microbial CVC's,
- **XX** denotes the catheter length in centimetre,
- **YY** denotes the catheter French size.
- **Z** denotes the number of lumens of the catheter.

12 DEVICE DISPOSAL

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

13 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.

14 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.

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

15 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

This is the Altius ProActiv+ CVC, Altius ProActiv+ HP CVC, Altius ProActiv+ HF CVC and Altius ProActiv+ HF/HP CVC Summary of Safety and Clinical Performance (SSCP) location after the launch of the European Database on Medical Devices / EUDAMED:

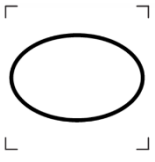
https://ec.europa.eu/tools/eudamed

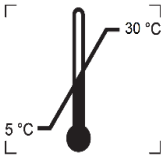
16 BASIC UDI-DI

Range	Description	Basic UDI-DI
Altius ProActiv+ CVC Set	Altius ProActiv+ CVC Set	5032932KSP-155DHX
Altius ProActiv+ HP & HF CVC Set	Altius ProActiv+ HP CVC Set	5032932KSP-155DHX
	Altius ProActiv+ HF CVC Set	
	Altius ProActiv+ HF HP CVC Set	

17 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 **1984**
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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