


DIRECTIONS FOR USE



Continuous Cardiac Output Pulmonary Artery Catheter truCATH.ip

For use only with the OMEGA CRITICAL CARE Continuous Cardiac Output truCCOM†

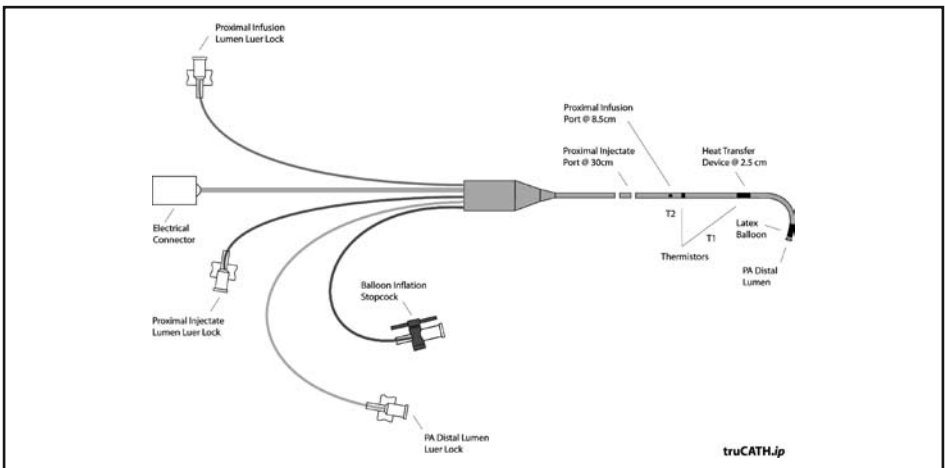
Caution:  This product contains Natural Rubber Latex which may cause allergic reactions.

 Material used for manufacture of this specific medical device contains Bis(2-ethylhexyl)phthalate (DEHP) as an integral part of the material formulation.

Caution: Only for use by appropriately qualified Clinical Personnel.

Sterile:  Do not reuse  Do not re-sterilise

The truCATH.ip is supplied heparin coated.



DESCRIPTION

The OMEGA CRITICAL CARE Continuous Cardiac Output Pulmonary Artery Catheter (Catalogue No. TCH-5100) is a flow-directed pulmonary artery catheter designed to enable the monitoring of hemodynamic pressures and to provide continuous measurement of cardiac output. Used with OMEGA CRITICAL CARE Continuous Cardiac Output Monitor (Catalogue No. TM), The truCATH.ip catheter allows for continuous calculation and display of cardiac output and provides an additional infusion lumen that allows for continuous infusion.

To measure cardiac output continuously, the continuous cardiac output system (truCOMMS†) uses thermal energy (heat) produced by the thermal coil located on the catheter to maintain a fixed temperature differential of 1-3°C above blood temperature. Cardiac output is calculated by determining the power required to maintain this temperature differential. Alternatively, cardiac output can be measured by the traditional bolus thermodilution method.

(† truCATH.*ip*, truCCOM and truCCOMS are trademarks of OMEGA CRITICAL CARE Ltd.)

Within the body of the truCATH.*ip* are six lumens, described as follows:

- The proximal injectate lumen terminates at a port located 30cm from the distal tip. When the distal tip is located in the pulmonary artery, the proximal injectate port resides in the right atrium or vena cava, allowing for bolus cardiac output injections, right atrial pressure monitoring, blood sampling, or infusion of solutions.
- The proximal infusion lumen terminates at a port located 8.5cms from the distal tip. When the distal tip is located in the pulmonary artery the proximal infusion port resides in the right ventricle allowing for right ventricular pressure waveform observation, blood sampling and infusion of solutions (not for thermodilution cardiac output injections).
- The pulmonary artery (PA) distal infusion lumen terminates at the distal tip. During insertion, this port is used to monitor catheter location, via transitional pressure measurements. At full insertion this port resides in the pulmonary artery allowing for pulmonary artery and pulmonary artery wedge pressure measurements, infusion of solutions or mixed venous blood sampling.
- The distal and proximal thermistor lumens contain the electrical leads for the thermistor which are positioned on the catheter surface, approximately 2.5cm and 6.5cm respectively from the distal tip. The thermistors are used to measure temperatures and in conjunction with the thermal coil generate data used to calculate cardiac output. The distal thermistor is located immediately below the thermal coil.
- The thermal coil lumen contains leads for the thermal coil which is located 2.5cm from the distal tip. The thermal coil generates the heat necessary for maintenance of a constant temperature differential between the proximal and distal thermistors. The energy required to maintain the fixed temperature differential is used to calculate cardiac output continuously.
- The balloon inflation lumen has a one-way stopcock at its proximal end and terminates in a latex balloon at the distal tip. When the catheter is properly positioned in the pulmonary artery, intermittently the balloon is inflated for the measurement of pulmonary artery wedge pressure. The balloon is inflated using the 1.5cc volume-limited syringe supplied.

INTENDED USE

The truCCOMS intended use is for assessment of a patient's hemodynamic condition through direct intracardiac (right heart) and pulmonary artery pressure monitoring, cardiac output determination and for infusing solutions. The distal port on the catheter also allows for sampling of venous blood and provides an additional infusion lumen that allows for continuous infusion.

INDICATIONS

The primary indications for the truCATH.*ip* are for the hemodynamic monitoring of critically ill patients. Conditions in which PA catheters have been routinely used are given in table 1.

CONTRA-INDICATIONS

There are no absolute contra-indications to the use of flow-directed pulmonary artery catheters. However patients with either recurrent sepsis or hyper-coagulopathy in which the catheter could serve as a focal point for septic or bland thrombus formation should not be considered candidates for a balloon flotation catheter. Also, the truCATH.*ip* is contraindicated in patients with a known sensitivity to heparin. A patient with a left bundle branch block may develop a right bundle branch block during catheter insertion, resulting in complete heart block. In such patients, the capability for temporary pacing modes should be immediately available.

Table (1) Clinical indications that may require PA catheters

A. Primary indications:

- Acute heart failure
- Severe Hypovolemia
- Complex circulatory situations
- Medical emergencies
- Adult respiratory distress syndrome
- Gram negative sepsis
- Drug intoxication
- Acute renal failure
- Hemorrhagic pancreatitis
- Intra and post-operative management of high risk patients
- History of pulmonary or cardiac disease
- Fluid shifts (e.g. extensive intra-abdominal operations)
- Management of high-risk obstetric patients
- Diagnosed cardiac disease
- Toxemia
- Premature separation of placenta
- Cardiac output determinations
- Different diagnosis of mitral regurgitation and ventricular septal rupture
- Diagnosis of cardiac tamponade

B. Secondary indications:

- Blood sampling
- Infusion of saline and dextrose solutions

INSERTION

Catheter insertion should be performed by personnel experienced with this procedure.

EQUIPMENT

1. truCATH.*ip*
2. Percutaneous sheath introducer and contamination shield, size 8.5fr (2.85mm)
3. Sterile pressure flush system and pressure transducers
4. Injectate temperature sensing probe (if performing bolus thermodilution measurements)
5. truCCOM
6. Connecting cables
7. Bedside ECG and pressure monitoring system
8. Syringe driver/infusion pump if required

In addition, the following items should be immediately available in case of complications during catheter insertion: anti-arrhythmic drugs, defibrillator, respiratory assist equipment and a transvenous pacing catheter.

CATHETER PREPARATION

Use aseptic technique

Caution: Avoid forceful wiping or stretching of the catheter during testing and cleaning so as not to break the thermistor wires or circuitry or detach thermal coil leads. Wiping the catheter before insertion may cause removal of the heparin coating.

Prior to catheter insertion, the following procedure should be performed:

1. Flush catheter lumens with a sterile solution to ensure patency and to remove air.
2. Prior to insertion into the sterile catheter sheath, check balloon integrity by inflating* it to the recommended volume by using the 1.5cc volume limited syringe supplied. Check for major asymmetry and for leaks by submerging in sterile saline or sterile water. Deflate balloon before insertion.

Warning: Care must be taken when introducing the catheter into sterile catheter sheath as damage may occur to the balloon.

Warning: Do not use catheter if either asymmetry or leaks are present.

3. Prior to insertion into the patient the catheter's electrical continuity must be tested. When testing, the Heat Transfer Device (HTD) and T2 thermistor must be fully immersed in sterile saline greater than 25°C. Connect the truCATH.*ip* to the patient cable. The catheter test is carried out from the 'SYSTEM' menu. Press the 'SYSTEM' key then using the 'SELECT' key move the cursor to the 'System Test' item. 'ENTER' will start the test. Testing will last approximately 5 seconds and once it is complete one of two messages will be displayed:
 1. 'truCATH.*ip* connected' indicates that the test has been successful.
 2. 'Catheter fault!' Code *n*' indicates that a fault has been detected with the catheter where *n*' refers to the type of fault discovered.

Code	Fault Source
0	EEPROM
1	T1 thermistor
2	T2 thermistor
3	Coil

In the event of a fault occurring the catheter must not be used.

4. Connect the Proximal infusion and Distal pressure monitoring lumens to flush system and pressure transducers. Ensure that the lines and transducers are free of air.

***Warning:** Air should never be used for balloon inflation in any situation where it may enter the arterial circulation, e.g. in adults with suspected right to left intra-cardiac or intra-pulmonary shunts (Ref.10). Bacteria-filtered carbon dioxide is the recommended inflation medium because of its rapid absorption into the blood in the event of a balloon rupture within the circulation. Carbon dioxide diffuses through the latex balloon, diminishing the balloon's flow directed capability after two to three minutes of inflation.

Before re-inflation completely deflate the balloon by removing the syringe and opening the stopcock. Do not forcefully aspirate with the syringe as damage to the balloon may result. After deflation, re-attach the syringe to the stopcock.

Warning: Do not leave the catheter in a permanent wedge position. Furthermore, avoid lengthy balloon inflation while the catheter is in a wedge position; this occlusive manoeuvre may result in pulmonary infarction.

CATHETER INSERTION PROCEDURE

truCATH.*ip* can be inserted at the patients bedside, without the aid of fluoroscopy, guided by continuous pressure monitoring.

Caution: It should be assured pressure transducers are fully functional prior to commencing insertion procedure. This should be completed in line with manufacturers recommended guidelines.

Pressure waveform observations using the Proximal Infusion Lumen will be limited when the patients suffer from certain conditions e.g. Pulmonary Valve Insufficiency or Stenosis.

Caution: The catheter should pass easily through the right ventricle and pulmonary artery and into a wedge position in less than a minute.

Caution: truCATH.*ip* is heparin coated and hence must never be wiped or cleaned prior to insertion.

Note: Should the catheter require stiffening during insertion, slowly perfuse the catheter with 5ml to 10ml cold sterile solution as the catheter is advanced through a peripheral vessel.

Although a variety of techniques can be used for insertion, the following guidelines are provided as an aid to the physician:

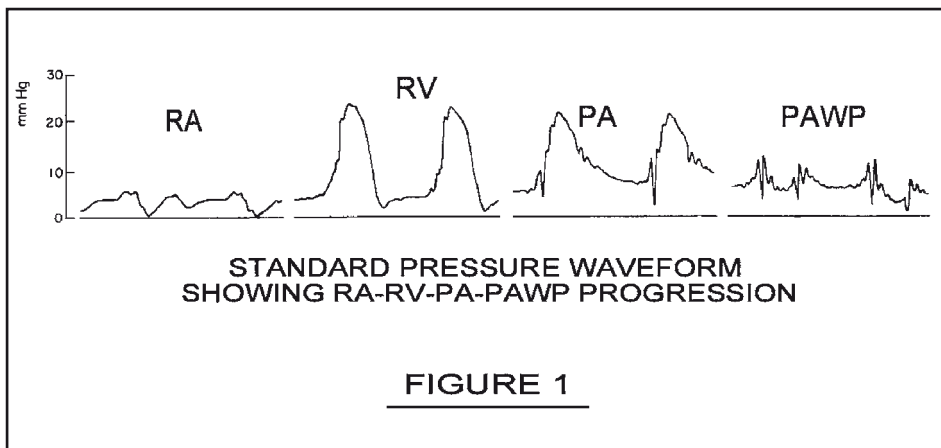
1. Introduce the catheter into the vein by percutaneous insertion using the Seldinger technique, by venous cutdown or via a percutaneous sheath introducer.

Caution: Use of an introducer is recommended, as the heparin complex coating may delay haemostasis in the cutdown area.

2. Gently advance the catheter into the right atrium. Entry of the catheter tip into the thorax is signalled by an increased respiratory fluctuation in pressure. Figure 1 shows the characteristic intracardiac and pulmonary pressure waveforms.

Note: When the catheter is near the junction of the right atrium and the superior or inferior vena cava of the typical adult patient, the tip has been advanced approximately 40cm from the right or 50cm from the left antecubital fossa, 15 to 20cm from the jugular vein, 10 to 15cm from the subclavian vein, or about 30cm from the femoral vein.

3. Using the 1.5cc volume limited syringe provided, inflate the balloon with CO₂ or air* to the maximum recommended volume. Do not use liquid.



Warning: Pulmonary complications may result from the improper inflation technique. To avoid damage to the pulmonary artery and possible balloon rupture, do not inflate above the recommended volume. Use the 1.5cc volume-limited syringe provided in the catheter package.

4. Advance the catheter until the pulmonary artery wedge pressure (PAWP) is obtained, then passively deflate the balloon by removing the syringe from the stopcock. Do not forcefully aspirate as this may damage the balloon. After deflation, re-attach the syringe.

Caution: Failure of a balloon flotation catheter to enter the right ventricle or pulmonary artery is rare, but may occur in patients with an enlarged right atrium or ventricle, particularly if the cardiac output is low or in the presence of tricuspid or pulmonary incompetence or pulmonary hypertension. Deep inspiration by the patient during advancement may also facilitate passage.

Caution: If a right ventricular pressure tracing is still observed after advancing the catheter several centimetres beyond the point where the initial right ventricular pressure was observed, the catheter may be looping in the ventricle which can result in kinking or knotting of the catheter (see Complications). Deflate the balloon and withdraw the catheter into the right atrium. Re-inflate the balloon and re-advance the catheter to the pulmonary artery wedge position, then deflate the balloon.

5. Re-inflate the balloon to determine the minimum inflation volume necessary to obtain a wedge tracing. If a wedge is obtained with less than the maximum recommended volume, the catheter must be withdrawn to a position where full inflation volume produces a wedge tracing.
6. Reduce or remove any excessive length or loop in the right atrium or ventricle by slowly pulling the catheter back approximately 2 to 3cm. The catheter tip may slip back into the ventricle causing arrhythmias. In this event, either re-inflate the balloon and reposition the catheter or deflate the balloon completely and withdraw the catheter.

Caution: Do not pull the catheter across the pulmonary valve while the balloon is inflated.

7. In order to ensure proper positioning of the HTD in the main PA, observe the pressure trace from the Distal Lumen and also the Proximal Infusion Lumen. If catheter is floated until a wedge waveform trace is observed and the balloon is deflated, the proximal infusion lumen might show a PA waveform trace. In this case, the catheter should be withdrawn slowly until the waveform just turns into a RV waveform trace.

Caution: If distal or proximal pressure trace shows irregularities or dampened signal withdraw catheter slightly and observe if irregularity of waveform disappears. If it does not disappear flush lumens and then re-insert.

8. Alternatively if the patient's condition prevents wedge pressure or is contra-indicated the catheter can be positioned as follows:
 - a) Check the pressure trace of Proximal Infusion Lumen shows RV pressure waveform, then gently inflate the balloon and advance slowly until Proximal Infusion Lumen pressure trace changes to show PA trace.
 - b) Deflate the balloon and withdraw the catheter slowly until the pressure trace returns to RV trace, withdraw the catheter another 1cm and stop (the HTD is now correctly positioned in the mid main PA).
9. When the catheter is in position the Proximal Injectate Lumen can also be used for monitoring CVP. This can be achieved by connecting the Proximal Injectate Lumen and Proximal Infusion Lumen to a 3 way stopcock on the pressure transducer, this will allow monitoring of CVP and RVP.
10. If the Proximal Infusion Lumen shows a PA pressure waveform or low CCO is observed, this would indicate that the catheter may have migrated into the PA branch. To correct, ensure that the balloon is deflated and withdraw the catheter until the Proximal Infusion Lumen pressure waveform changes to a RV pressure waveform, then withdraw a further 1cm. If the length of the catheter withdrawn is less than one internal marking i.e. < 10cm, then the catheter may have wedged early due to PA vasoconstriction. It is recommended in this instance to withdraw the catheter fully.
11. If the clinician believes the PA vasoconstriction will abate and decides to leave the catheter within the patient it should be noted CO value will be significantly reduced until the proper positioning is completed.
12. However, if the length of the catheter withdrawn is greater than one interval marking i.e. > 10cm then the catheter should be re-floated back into wedge position, ensuring the Proximal Infusion Lumen indicates RV pressure waveform.
13. Confirm the final catheter tip position with chest X-ray.

Note: If the Proximal Infusion Lumen shows a PA pressure waveform or low CCO is observed, this would indicate that the catheter may have migrated into the PA branch. To correct, ensure that the balloon is deflated and withdraw the catheter until the Proximal Infusion Lumen pressure waveform changes to a RV pressure waveform, then withdraw a further 1cm.

Note: After deflation, the catheter tip may tend to recoil towards the pulmonary valve and slip back into the right ventricle, requiring that the catheter be repositioned.

Maintenance and Use *in situ*

The catheter should remain indwelling only as long as is required by the patient's condition.

Caution: The incidence of complications increase significantly with indwelling periods longer than 72 hours (Ref. 8).

Catheter Tip Position

Keep the catheter tip centrally located in a main branch of the pulmonary artery near the hilum of the lungs. Do not advance the tip too far peripherally. The tip should be kept where full or near full inflation volume is required to produce a wedge tracing. The tip migrates towards the periphery during balloon inflation (ref. 11).

Catheter Tip Migration

Caution: Anticipate spontaneous catheter tip migration towards the periphery of the pulmonary bed. Continuously monitor Proximal Infusion Lumen pressure to verify that it shows RV pressure trace. If it shows PA trace then withdraw the catheter until RV pressure trace is observed.

Spontaneous catheter tip migration towards the periphery of the lungs occurs during cardiopulmonary bypass (Ref. 4). Partial catheter withdrawal (3 to 5cm) just before bypass should be considered, as it may help reduce distal migration and prevent permanent catheter wedging post bypass (Ref. 4). After termination of bypass, the catheter may require repositioning. Check the distal pulmonary artery tracing before inflating the balloon. Daily chest X-rays may be used to verify position.

Balloon Inflation and Wedge Pressure Measurement

Caution: Over a period of time, the catheter tip may migrate towards the periphery of the pulmonary bed and lodge in a small vessel. Damage may occur either by prolonged occlusion or by over distension of the vessel upon reinflation of the balloon (see complications section).

Caution: Reinflation of the balloon should be performed gradually while monitoring pressures. Inflation is usually associated with a feeling of resistance. If no resistance is encountered, it should be assumed that the balloon has ruptured. Discontinue inflation at once. The catheter may still be used for hemodynamic monitoring, however take precautions against infusion of air or liquids into the balloon lumen. During normal catheter use, keep inflation syringe attached to the stopcock to prevent inadvertent injection of liquid into the balloon inflation lumen.

Measure wedge pressure only when necessary and only when tip is properly positioned (see above). Avoid prolonged manoeuvres to obtain wedge pressure and keep wedge time to a minimum (two respiratory cycles or 10-15 seconds), especially in patients with pulmonary hypertension. If difficulties are encountered, discontinue wedge measurements. In some patients, pulmonary arterial end-diastolic pressure can often be substituted for pulmonary artery wedge pressure if the pressures are nearly identical (Refs. 12 & 13), obviating the need for repeated balloon inflation.

Patency

All pressure monitoring lumens should be filled with sterile, heparinized saline solution (e.g., 500 I.U. heparin in 500ml saline) and flushed at least once each half hour or by continuous slow infusion. If loss of patency occurs and cannot be corrected by flushing, the catheter should be removed.

General

Keep pressure monitoring lumens patent by intermittent flush or continuous slow infusion with heparinized sterile saline. Infusion of viscous solutions (e.g. whole blood or albumin) is not recommended, as they flow too slowly and may occlude the catheter lumen.

Warning: Never flush the catheter when the balloon is wedged in the pulmonary artery.

Periodically, check IV lines, pressure lines and transducers to keep them free of air. Also ensure that connecting lines and stopcocks remain tightly fitted.

Caution: Magnetic Resonance Imaging (MRI) compatibility: truCATH.jp has not been tested for MRI compatibility, however due to the presence of conductive wires within the catheter there is a potential risk to induced currents, excessive heating or other potentially hazardous conditions when performing MRI examination.

Caution: Do not use an electromagnetic flow probe around the pulmonary artery as this may cause interference with the heat transfer device on the catheter.

Cardiac Output Determination

Continuous

Continuous cardiac output measurement is made by continuously monitoring the power needed to maintain a constant temperature differential of 1-3°C between the proximal thermistor and the distal thermistor under the thermal coil. Using the power required to maintain the temperature differential, truCCOM computes the cardiac output. This measurement is conducted without additional instrument calibration, material preparation or operator intervention. Refer to the truCCOM Operator's Manual for additional details.

Thermodilution Mode (TDCO)

TDCO should only be performed by appropriately qualified personnel.

To determine cardiac output by thermodilution, a known amount of sterile solution of known temperature is injected into the right atrium or vena cava, and the resultant change in blood temperature is measured in the pulmonary artery by the catheter thermistor. Cardiac output is inversely proportional to the integrated area under the resulting curve. This method has been shown to provide good correlation with the direct Fick method and dye dilution technique for cardiac output determination.

Correlation factors or computation constants needed to correct for indicator heat transfer are given in the specifications at the back of this booklet. truCCOM requires that a computation constant be used to correct for injectate temperature rise as it passes through the catheter. The computation constant is a function of injectate volume, temperature and catheter dimensions. The computation constants listed in the specifications have been determined (in-vitro).

The proximal injectate lumen can be used to carry out TDCO if required using an injectate kit compatible with the Omega TD probe supplied. Non-compatible injectate kits will require a Flow-Through Housing adapter which can be obtained from Edwards Lifesciences ref: 93505.

Refer to the truCOMM Operator Manual for detailed information on monitor operation in Thermodilution mode.

COMPLICATIONS

Invasive procedures may involve some patient risks. Although serious complications associated with pulmonary artery catheters are relatively uncommon, the physician is advised before deciding to use the catheter, to consider and weigh potential benefits and risks associated with the use of the catheter against alternative procedures.

The general risks and complications associated with indwelling catheters are described in the literature (see References). Strict adherence to the foregoing instructions and the awareness of risks reduces the incidence of complications. Several known complications include:

Perforation of the Pulmonary Artery

Factors associated with the development of fatal pulmonary artery rupture during the use of flow directed balloon-tipped catheters are pulmonary hypertension, advanced age (Refs. 1 & 5), cardiac surgery with hypothermia and anticoagulation (Ref. 14) and distal catheter tip migration (Ref. 1 & 4), arteriovenous fistula formation and other vascular traumas.

In reference 25 (which considered the following risk factors: female postmenopausal, presence of cardiovascular disease, pulmonary hypertension, sepsis or hypothermia, surgical history of cardiopulmonary bypass, treatment with anticoagulation therapy and multiple insertions of PAC's, frequent manipulation or migration of the catheter) the most significant risk group was post menopausal female patients. For the patient with high risk factors, insertion of a PA catheter should be done under fluoroscopic guidance.

Extreme care should therefore be exercised during the measurement of pulmonary artery wedge pressure in patients with pulmonary artery hypertension. In all patients, balloon inflation should be limited to two respiratory cycles or 10-15 seconds.

Pulmonary Infarction

Tip migration with spontaneous wedging, air embolism and thromboembolism can lead to this complication (Ref. 3 & 15).

Cardiac Arrhythmias

Cardiac arrhythmias may occur during insertion (Ref. 6, 16, 17), but are usually transient and self-limited. Premature ventricular contractions are the most commonly observed arrhythmias. Ventricular tachycardia and atrial tachycardia (Ref. 8) have been reported. Use of prophylactic lidocaine should be considered to decrease the incidence of ventricular arrhythmias during catheterization (Ref. 7). ECG monitoring and immediate availability of antiarrhythmic drugs and defibrillator equipment is recommended.

Kinking, Looping and Knotting

If a right ventricular pressure tracing is still observed after advancing the catheter 15cm beyond the point where the initial right ventricular pressure tracing was observed, the catheter may be looping in the right ventricle which can result in kinking or knotting of the catheter. Deflate the balloon and withdraw the catheter into the right atrium. Re-inflate the balloon and re-advance the catheter to a pulmonary artery wedge position, then deflate the balloon.

Should knotting occur, the patient should be placed under fluoroscopy. Pull the knot tight and under fluoroscopic guidance, gently withdraw the catheter with the balloon deflated.

Sepsis/Infection

Preventive measures are recommended to guard against infection, including the use of sterile technique, application of topical antibiotic ointment and frequent sterile dressing changes.

The duration of catheterization should not exceed 72 hours.

Other Complications

Other complications include right bundle branch block, complete heart block (Ref. 9), tricuspid and pulmonary valve damage (Refs. 18 & 19), thrombo-cytopenia (Refs. 20 & 21), pneumothorax (ref. 2), thrombophlebitis (Ref. 2), thrombosis (Refs. 22 & 23) and heparin-induced thrombocytopenia (ref. 21).



Latex

In addition, allergic reactions to latex have been reported. Physicians should identify latex sensitive patients and be prepared to treat allergic reactions promptly.

Falsely elevated levels of sodium and potassium were reported in blood specimens collected through heparin-coated catheters and analysed with ion-selective electrodes (ISEs) (Ref. 24). This phenomenon is due to the presence of benzalkonium heparin to which some ISEs are sensitive. Samples exhibiting suspect sodium and/or potassium levels from instruments using ISEs should be assayed by flame photometry.



DEHP Phthalates

This product contains phthalates. The potential effects of phthalates on pregnant/nursing women or children have not been fully characterised and there may be concern for reproductive and development effects.

Long-term Monitoring

The duration of catheterization should be the minimum required by the patient's clinical state since the risk of thromboembolic and infectious complications increase with time. The incidence of complications increases significantly with indwelling periods longer than 72 hours (Ref. 8). Although the catheter is coated with a heparin complex, prophylactic systemic anticoagulation and antibiotic protection should be considered when long-term catheterization (i.e. over 48 hours) is required, as well as in cases involving increased risk of clotting or infection.

Sterility

The truCATH.*ip* is supplied as a single use sterile product. Do not re-use.

The MHRA is aware of serious incidents relating to reuse of single-use devices.

Reuse can be unsafe because of risk of:

- Cross-infection — inability to clean and decontaminate due to design.
- Endotoxin reaction — excessive bacterial breakdown products, which cannot be adequately removed by cleaning.
- Patient injury — device failure from reprocessing or reuse because of fatigue, material alteration and embrittlement.
- Chemical burns or sensitisation — residues from chemical decontamination agents on materials that can absorb/adsorb chemicals.
- Also, if you reuse a single-use device you may be legally liable for the safe performance of the device.

Caution:



Do not reuse.



Do not re-sterilise.

Shelf Life

The shelf life is indicated on the catheter tray and the outer box. Storage beyond the specified time may result in balloon deterioration, since the natural latex rubber in the balloon is acted upon and deteriorated by the atmosphere.



Do not re-sterilise.

Note: re-sterilisation will not extend the shelf life of the catheter.

Packaging and Storage

The packaging within is designed to avoid crushing of the catheter and to protect the balloon from exposure to the atmosphere. Therefore the catheter must remain inside the package until use. Store in a dry place between 15°C - 25°C, keep away from sunlight. Do not use if the package has been previously opened or damaged.

Caution:



Do not use if packaging is damaged



Keep away from sunlight



Catheter Disposal After Use

After use the truCATH.*ip* should be disposed of as biohazardous waste following the hospitals own standards and national legal requirements for handling healthcare waste.

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SPECIFICATIONS

truCATH.ip TCH 5100

Catheter body

Heparin coated	yes
Body colour	yellow
Usable length (cm)	110
Size (French)	7 (2.3mm)
Distance between markings (cm)	10
Required introducer size (French)	8.5 (2.8mm)

Balloon

Diameter of deflated balloon (French)	8 (2.6mm)
Diameter of inflated balloon (mm)	13
Balloon inflation capacity (cc)	1.5

Proximal Injectate Lumen

Proximal Injectate port (cm from tip)	30
Proximal Injectate volume (cc)	0.6
Proximal Injectate rate* (cc/hr – normal saline)	257

Distal Lumen

Distal Infusion lumen volume (cc)	0.8
Distal Infusion rate* (cc/hr – normal saline)	300

Proximal Infusion Lumen

Proximal Infusion port (cm from tip)	8.5
Proximal Infusion lumen volume (cc)	0.44
Proximal Infusion lumen rate* (cc/hr – normal saline)	77

Natural Frequency/Amplitude Ratio

Proximal Injectate lumen	18.7 HZ/2.50:1
Distal Infusion lumen	13.7 HZ/2.20:1
Proximal Infusion lumen	15.5 HZ/1.41:1

Thermistor/Thermal Coil

Distal thermistor location (cm from tip)	2.5
Proximal thermistor location (cm from tip)	6.5
Thermistor resistance at 37°C (ohms)	14,004
Resistance rate change (ohms/°C)	520
Thermal Coil location (cm from tip to mid-point)	2.5

Syringe

3cc balloon inflation syringe volume (cc)	limited to 1.5cc
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Sterilisation

Ethylene oxide

All specifications given are nominal values

* Using de-ionised water at room temperature 100cm above injection site, gravity drip.

Computation Constants

Injectate Temperature

0 - 5°C
19 - 22°C
23 - 25°C

Computation Constants at Indicated Injection Volumes

















5cc	10cc
.247	.542
.274	.578
.287	.595

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

U.S. Patent No. 5,682,899

Other Patents Pending

Symbol legend

	Do not reuse
	Contains Natural Rubber Latex
	Sterilised using Ethylene Oxide
	Do not use if package is damaged
	Manufacturer
	Lot Number
	Use By
	Catalogue Number
	Caution: Attention, see instructions for use
	The presence of this Symbol indicates that the material used for manufacture of this specific medical device contains phthalates 'DEHP' as an integral part of the medical device material formulation
	Do not re-sterilise
	Keep away from sunlight
	Temperature Limitation
	Quantity
	Exterior Diameter
	Usable length

Manufactured by:

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Scotland

UK

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Email: info@omegacriticalcare.com

For technical assistance, please call Omega Customer Services on the above numbers.

Made in the UK

CE 0123

Part # **801001**

Rev: **E**