University Hospitals Bristol NHS
NHS Foundation Trust

Application form for the Introduction of a New Technique or Medical Device

To be completed by the applicant in conjunction with the Directorate Manager

Name of Clinical Lead:	**Internal Contact Number (& Mobile)**
Name of Directorate Manager:	**Internal Contact Number (& Mobile)**
Directorate:	

Name/Title of New Technique/Medical Device:

SherLock 3CG Tip Location (TLS) and Tip Confirmation System (TCS).

Summary of clinical topic to be addressed by new Technique/Medical Device:

Peripherally inserted central catheters (PICCc) are vascular access devices utilised to deliver medium to long-term and/or thrombophlebitic intravenous therapy and are inserted in patients from all specialities within the Trust.

The vast majority of PICCs are inserted by the Oncology Team, who place in excess of 500 PICCs per year. The current practice for insertion by the team is ultrasound-guided venous puncture and the required length of catheter to be inserted is estimated based upon surface landmarks of the distal third of the superior vena cava (SVC), which is the desirable position for the PICC tip. The procedure is undertaken in the Oncology Department (based on the Day Ward at the Bristol Oncology Centre) or at the patient's bedside if too unwell for transfer.

Malposition is a complication of PICC insertion and can involve passage of the PICC into internal jugular vein, contra-lateral subclavian vein, lying too proximal in SCV or brachiocephalic vein or too distal with tip in the right atrium. PICC tip position is currently confirmed on a post-procedural chest X-ray (CXR) and the PICC cannot be accessed until confirmation of position. Current malposition rate has been calculated at 40%.

In some procedures clinicians are aware of, and unable to correct, malposition during insertion. In other cases, it is not evident until post-procedural CXR. Intra-procedural fluoroscopy can be used to guide the intravascular journey and final PICC position but involves radiation exposure. This is not electively available to the IV Access Team and has extremely limited availability when a difficult procedure occurs due to high demand within the Trust for access to interventional radiology theatres. Overall, malposition results in a suboptimal experience for the patient who can undergo repeated procedures and experience delays commencing urgent therapy.

The Oncology Team are hoping to obtain approval to introduce a new device to their clinical practice which allows magnetic and electrocardiographic real-time tracking of the PICC tip during insertion – the Sherlock 3CG TCS. With introduction of the device our short- to medium-term aims are to reduce malposition rates and delays to therapy, and

improve patient experience; and in the medium- to long-term to reduce the need for post-procedural CXR for confirmation of PICC tip position. Whilst the technologies employed are not novel (utilised since the 1990's), they would be a new introduction to the Trust and would represent a change in clinical practice for the Oncology Team. The PICC used with the Sherlock 3CG TCS is the POWERPICC Solo which is already in use within the Trust.

The SherLock 3CG system is unique in that it uses both tip location system as well as a tip confirmation system. It facilitates the guidance and placement of PICCs using magnetic tracking and cardiac electrical signals (ECG) technologies. The device displays ECG waveforms received from the patient's skin (baseline ECG) and from the tip of the catheter (intravascular ECG) on the graphical user interface. The signals are generated at the distal tip of the PICC and acquired in real-time. Through observation of the displayed P wave, a clinician can determine the PICC tip location as it travels through the superior vena cava (SVC), right atrial junction and right atrium – relative to the sino-atrial node. Both magnetic signal and ECG acquisition is accomplished using an integrated Sherlock 3CG Sensor. This system negates the use of confirmation X Ray for PICC placement in the majority of patients and allows an image to be printed for the patient's notes.

SherLock 3CG is safe and has been approved by the FDA as well has a CE mark approval for use in humans.

Your application will need to be supported by the following documentation. Please cross the relevant box to indicate that the specific document/s has/have been attached to your application form:

X	Sufficient detail about the new technique or device with reference to the advantages and the risks to the patient.
X	Current evidence available on research previously conducted – *to be reviewed by the applicant and attached.* Pittiruti. M. Sapiens* Tip Confirmation System (TCS) Post Market clinical Study, Catholic University hospital, Rome, Italy. 2010 Pittiruti. M. The EKG method for positioning the tip of PICCs: results from two preliminary studies. JAVA Vol 13 No 4 2008 Smith. B. Intravenous electrocardiographic guidance for placement of peripherally inserted central catheters. University of Utah, salt lake City USA. Journal of Electrocardiology 43. 2010 Pittiruti. M. The electrocardiographic method for positioning the tip of central venous catheters. Catholic University hospital, Rome, Italy. JVA 11 1004. 2011
	Possible technique/ device incidents and safety alerts have been researched using the following databases and resource tools. **Cochrane, MHRA, NICE, NPSA**. ***(Click on the respective title to access)*** Nil known
	Please liaise and obtain from the manufacturer any device or safety alerts related to the application. Nil known

X	CE mark/product license. ***Please provide number*** Power Injectable Picc catheters CE 551333 & CE 551344 SherLock 3CG Tip Confirmation System ISO13485 Quality System certificate FM 550143]

Training method of applicant/team (Please cross relevant box(s):			
X	Audio visual	**X**	Training demonstration/seminar
X	Trained by expert/ Centre of Excellence	**X**	Mentored by expert

Directorate Support

All signatures must be obtained before submission.
(Signatories are encouraged to attach additional recommendations/comments)

Directorate Accountant – Please cross appropriate box(s):

	Funding has been fully identified for all additional costs
	Funding has been identified to cover expected additional costs
	No funding identified but additional costs expected
	No additional costs expected (e.g. cost neutral)
	Additional financial implications/recommendations attached

Procedure

How many procedures and over what period of time are to be undertaken?

It is estimated that the IV Team could place 400+ in the first 12 months post training.

How many procedures are currently carried out? **[600+]**

Will the new technique/ device impact the Trust's activity volume? Yes– If yes, how?

The burden on the Radiology department in terms of carrying out a confirmation X Ray every time a PICC is placed and the time required to report the actual tip location will be greatly reduced.

With the current practice a misplaced PICC would require intervention to adjust the tip location and associated costs will be required by the Radiologist time or Oncology Team for the consumables to carry out this procedure.

In most cases of malposition, transfer of the patient to Interventional Theatres is not possible, either due to the condition of the patient or the demand for theatre space with fluoroscopy. Therefore withdrawal, repositioning with flushing techniques, removal and/or re-insertion on other the arm are the usual outcomes. However in some cases inserting a PICC, on the opposite arm is not an option due to lymph node clearance, vein preservation for potential fistula creation and/or co-morbidities.

Management of malposition always results in additional operator (Oncology Nurse placer) time. Additional equipment is usually required, of which the costs can vary greatly but can

frequently exceed twice the cost of an uncomplicated PICC insertion. Sometimes it is necessary to have the Picc tip position confirmed out of normal working hours incurring additional costs.

Capital Costs

Please provide details of any items that will require sterilisation e.g. containers / trays.

None

Please provide details of capital costs of any new equipment.

The SherLock 3CG consists of a netbook, SherLock tip confirmation system sensor, portable printer and hand held remote control. This will be placed on loan with a contract in place for the hardware and disposables for 3 months.
Thereafter the purchase price of SherLock 3CG System with Printer and roll stand is £9,990 plus VAT @ 20%

What would the maintenance arrangements be? Are there any additional costs? Yes/No. If yes, please provide details.

For the first 3 months the equipment would be placed in the hospital on a loan basis free of charge with a contract in place for the consumables. Maintenance will be covered by Bard Ltd.

Impact on Revenue Costs

Details of current consumables (price (£) and volume)	**£: Current cost to place a PICC with sterile pack is £149.82** (average cost; single lumen and dual lumen and placement tray) **Groshong PICC s/l £99, d/l £166.75** **SOLO s/l full tray £142.50 d/l £166** **X Ray confirmation is £75 per patient @ 400 patients is £30,000** **Volume: 400 PICC insertions + CXR = £89,928** **Total cost for Piccs and X Rays = £119,928** Please note calculatations are based on an average cost of all PICCs used with dressing pack.
Details of future consumables (price (£) and volume)	**£: Picc, sterile pack, tip confirmation system: £177.00** (average cost; single and double lumen Power PICC Solo with full placement tray) **Volume: 400 PICC = £70,800** Please note that the Power PICC SOLO has the additional capacity of power injecting contrast. Therefore additional savings may exist due to a potential redution in cannula insertions, prior to scan.

Are additional consumables required? Yes/No If Yes – please specify.

The PowerPicc SOLO is loaded with a stylet and magnet which is the tip location and confirmation system. The sterile placement pack currently comes separately will be included with the PowerPicc SOLO with this system.

Is there an additional impact on theatre time? Yes If Yes – please specify.

PICCs are currently placed by the Oncology Team. Time is expected to be reduced in not having to re position misplaced Piccs.

If additional theatre sessions are required please provide details.

This will reduce sessions in Radiology – see below

Please detail any other impact on staff time or numbers.

Not having to carry out an X Ray to confirm tip position in the majority of patients will free up time in the Radiology department (400+ patient chest X Rays per annum)
Reduction in time and associated costs in adjusting malplaced Picc catheters by the IV Team or Radiology. Radiologist will not have to dedicate time to report on these X Rays and portering costs will be greatly reduced.

Summary of financial impact (To be completed by the Divisional or Directorate Accountant).

Signature of Directorate Accountant …… ……. Date ……..

Clinical Lead (Applicant)

	Additional recommendations/comments attached.

Signature of Clinical Lead. …… Date …….……

Directorate Manager

	Additional recommendations/comments attached.

Signature of Directorate Manager…… …….. Date …….

Clinical Director

	Additional recommendations/comments attached.

Signature of Clinical Director …… …….. ……. Date …….

(If the applicant is the Clinical Director the signature of the Divisional Associate Medical Director is required)

New Technique/Device Evaluation Form	
Name of Lead Clinician:	
Designation:	**Directorate:**
Name/Title of New Technique/Medical Device:	

Feedback process ***to be agreed at new product meeting***

Written report/presentation to new product meeting *delete as appropriate
After [ ] number of procedures or
After [ ] months

Feedback to include:
Total number of procedures
Complications
Method of training
Financial analysis (cost benefit)

Clinical Audit Required: Yes/No - If yes, please complete audit proforma (include link)

Anticipated date initial evaluation findings to be reported to the Techniques and Medical Devices group. ***To be agreed in conjunction with TaMDg on approval of application.***

Applicant Signature

Signature: …… Date ……..…..

Chair of New Product group Signature

Signature: …….. ……..…Date……..…

Department Reference no. (Leave blank)

Application Outcome

	Approved		Not Approved		Approved subject to changes

Recommendations:

Signed by Chair of new product group ……. …….Date……