

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

SMITHS MEDICAL DEUTSCHLAND GmbH

Bretonischer Ring 3, D-85630 Grasbrunn, Germany

See appendix for additional sites and additional site scopes

has been registered by Intertek as conforming to the requirements of:

EN ISO 13485:2016

The management system is applicable to:

Design, manufacture, inspection, storage and distribution of
Pressure Monitoring, Infusion Disposables, Interventional
Imaging, Neurosurgery, Vascular Access.

The Servicing of active medical devices.

Certificate Number:

119-04 C

Initial Certification Date:

08 June 2004

Date of Certification Decision:

25 June 2018

Issuing Date:

25 June 2018

Valid Until:

24 June 2021



061

Calin Moldovean

President, Business Assurance

AMTAC Certification Services Limited, T/A Intertek;
Milton Keynes, UK

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UKAS accredited body under
schedule of Accreditation No. 061





CERTIFICAT DE ÎNREGISTRARE

Se certifică prin prezenta că sistemul de management al:

SMITHS MEDICAL DEUTSCHLAND GmbH

Bretonischer Ring 3, D-85630 Grasbrunn,
Germania

Pentru locații și domenii suplimentare, vedeți anexa

a fost înregistrată de către Intertek deoarece se
conformează cerințelor:

EN ISO 13485:2016

Sistemul de management este aplicabil pentru:

Proiectarea, fabricarea, inspectarea,
depozitarea și distribuirea Dispozitivelor de
Monitorizare a Tensiunii, a Dispozitivelor de
Injectare de Unică Folosință, a Dispozitivelor
pentru Intervenții, Imagistică, Neurochirurgie,
Acces Vascular.

Service-ul dispozitivelor medicale active.

Certificat Număr:

119-04 C

Data Certificării Inițiale:

08 Iunie 2004

Data Deciziei Certificării:

25 Iunie 2018

Data Emiterii:

25 Iunie 2018

Valabil Până la:

24 Iunie 2021



Semnătura - indescifrabilă

Calin Moldovean

Președinte, Business Assurance

AMTAC Certification Services Limited, T/A Intertek;
Milton Keynes, UK

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Certification Services Ltd sucursală deținută integral de
către Intertek Holdings Ltd”

Intertek Certification Limited este organism acreditat UKAS
conform graficului de Acreditare nr. 061

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înscrisului original în limba engleza, ce a fost vizat de mine.



Traducător autorizat
Nr. 2769/2015



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Epidural Anaesthesia

For the past 30 years PORTEX® has pioneered Epidural Systems. After being the first to produce epidural catheters for Obstetric anaesthesia in the early 1970s, PORTEX® went on to develop 'single use' devices in the early 1980s, quickly establishing a strong reputation for innovation, quality and reliability expected from a market leader. The PORTEX® MINIPACK was the first 'single-use' kit designed specifically for epidural procedures and included the first plastic, low friction Loss of Resistance Device. The success of this epidural kit has led to the trade name 'Minipack' being used generically within the medical profession to describe a basic single-use epidural pack.

Today PORTEX® continues to lead the field in epidural anaesthesia with a broad range of epidural procedure kits and components, including LOCKIT®, the unique catheter fixation device launched in 1999 in response to the well-documented incidence of epidural catheter migration during post-operative patient management.

Recognising that procedural techniques vary, PORTEX® has pioneered a custom kitting service, allowing clinicians to customise a procedure tray to suit individual needs.



Specification

Needle Gauge	Length	Product Code
18G Paediatric	50mm (clear hub)	100/395/018
19G Paediatric	50mm (clear hub)	100/395/019
16G	80mm	100/395/160
18G	80mm	100/395/180
17G	80mm (clear hub)	L727/61 *
18G	80mm (clear hub)	L728/61 *
16G	110mm (clear hub)	100/395/560
18G	110mm (clear hub)	100/395/580

Supplied sterile, individually packed in cartons of 10

* Supplied sterile, individually packed in cartons of 20

Specification

Needle Gauge	Length	Product Code
16G Winged	80mm	E522*

*Supplied sterile, Individually packed in cartons of 20

Tuohy Needles

Designed to provide accurate and reliable access to the epidural space.

- Optimised tip profile to maximise the all-important feel during insertion.
- Internal stylets minimise tissue coring during insertion.
- Optional snap on wings allow maximum flexibility in use.
- Depth of needle insertion is easily determined by clear 10mm graduations.
- Extra length and paediatric sizes available.

All Metal Tuohy Needle

Alternative design of epidural needle featuring an all-metal hub and stylet.

Sharps Safety Devices

Description	Product Code
Point-Lok*	4139



Supplied in packs of 10 x 100



Specification

	Capacity	Product Code
Epidural LORD	10ml	100/398/000

Supplied sterile, individually packed in cartons of 10



Specification

Tuohy Needle Gauge	Length	Product Code
16G	80mm	100/380/016
18G	80mm	100/380/018

Supplied sterile in packs of 10

Epidural 'Loss of Resistance' Device

The PORTEX® 'Loss of Resistance' Device is a single-use, low-friction syringe specifically designed to facilitate successful location of the epidural space.

- Designed with low and consistent frictional movement of the plunger to provide excellent sensitivity for epidural space detection.
- Graduated barrel indicates degree of plunger advancement.
- Suitable for use with both air and saline techniques with standard Luer slip connection to epidural needles.

Epidural Single Shot Packs

'Loss of Resistance' Device and Tuohy needle set. Ideal for use in chronic pain clinics for bolus injections into the epidural space.

Contents: (Tuohy Needle – length 80mm, with attachable wings, a 10ml plastic LORD and a 18G filter needle).



Epidural Catheter

- Manufactured from a clear blend of Polyether block amide for optimum clarity, strength and kink resistance.
- Available in various gauges with a choice of distal tip eye geometry.
- Smooth tip forming to minimise trauma during insertion.
- Standard 1cm catheter marking to facilitate accurate catheter positioning.
- Confirmed patency and consistent flow rates achieved through 100% flow testing after manufacture.
- Distal tip mark to aid visual confirmation of complete catheter on removal.
- Paediatric catheters available in 18G or 19G with option of closer, helically placed eyes for even distribution of drugs, reducing likelihood of multi-compartmental spread of local anaesthetic*.
- All catheters are supplied with a Luer lock connector.

* Collier C B. Gatt SP. A new epidural catheter. Closer eyes for safety? Anaesthesia 1993;48: 803-806.

Specification

Clear Catheter Type	For use with needle gauge	Length	Catheter ID Label	Catheter Guide	Catheter Connector	Nominal Diameter mm Internal External	Product Code
16G Closed End 3 Eyes	16G	915mm	•	•	•	0.55 1.03	100/382/116
16G 3 Closer Eyes	16G	915mm	•	•	•	0.55 1.03	100/382/816
18G Closed End 3 Eyes	18G	915mm	•	•	•	0.45 0.83	100/382/118
18G 3 Closer Eyes	18G	915mm	•	•	•	0.45 0.83	100/382/818
18GHD (Higher Stiffness) Closed End 3 Eyes	18G	915mm	•	•	•	0.45 0.83	100/382/218
19G Paediatric Open End	19G	650mm	•	•	•	0.38 0.63	100/382/019
Catheters gauged to suit the epidural needle through which insertion is intended.							Supplied in packs of 10
19G Open End	16G	915mm		•	•	0.55 1.01	G994/61
19G Closed End 3 Eyes	16G	915mm		•	•	0.55 1.01	G995/61
20G Open End	18G	915mm		•	•	0.46 0.86	G996/61
20G Closed End 3 Eyes	18G	915mm		•	•	0.46 0.86	G997/61

Actual catheter gauge.

Supplied in packs of 10



Specification

Size	Product Code
Tunnelling Device – 200mm & Handle	100/387/020
Tunnelling Device – 350mm & Handle	100/387/035

Supplied sterile and packed individually.

Subcutaneous Tunnelling Device

With the wider application of epidural analgesia in the management of long-term pain relief, the subcutaneous implantation of epidural catheters offers significant advantages to both clinician and patient.

The PORTEX® Subcutaneous Tunnelling Device is a quality, single-use surgical instrument designed to aid the subcutaneous placement of epidural catheters.

- The atraumatic tip prevents damage to the major blood vessels.
- The thin, smooth wall and large internal diameter allows easy passage of the catheter.
- Manufactured from polished surgical quality stainless steel, it can be gently curved to follow the desired pathway through the tissues.
- Offered in a choice of two lengths – 200mm and 350mm to suit individual techniques.
- Subcutaneous implantation reduces the risk of infection in the epidural space, provides security against catheter displacement, particularly in mobile patients, and sites the catheter connection conveniently for infusion of prescribed drugs.



Specification

Catheter Gauge	Product Code
16G	100/399/016
18G	100/399/018

Supplied sterile in packs of 20

LOCKIT® Epidural Catheter Fixation Device

LOCKIT® is a unique epidural catheter fixation device designed to prevent unwanted catheter migration. LOCKIT® ensures that pain control delivered via the epidural catheter is not compromised, providing increased confidence and peace of mind during post-operative pain management.

- Transparent locking mechanism maintains catheter patency and permits monitoring of catheter exit site.
- Foam adhesive pad makes application easy and minimises patient discomfort.
- Medical grade adhesive layer avoids skin irritation.
- Easy-to-peel backing makes application straightforward, even when wearing gloves.
- Available for both 16G and 18G catheters.

Flat



Disc



Specification

Filter Type	Membrane Pore Size	Maximum Pressure kg/cm ²	Filter Area cm ²	Priming Volume ml	Product Code
Flat	0.2µm hydrophilic 2-way	7.0	4.91	0.75	100/386/010
Disc	0.2µm hydrophilic 2-way	5.3	2.77	0.36	100/385/010
Flat	0.2µm	5.27	4.3	0.7	6556/61

Supplied sterile, individually packed in cartons of 10.

Epidural Filters, Disc & Flat, with Luer Lock connection

Smiths Medical low volume bacterial filters are available from PORTEX®. These filters may be used for the in-line filtration of low volume doses of aqueous solutions. These are especially suitable for filtration of drug solutions during injection into the epidural space in order to protect the patient from the transmission of infection or other particulate matter.

- The 0.2µm hydrophilic-supported membrane allows two-way filtration and the ability to test aspirate.
- Male and female Luer lock connections for maximum security.
- Flat profile for patient comfort (flat filter only).
- Transparent to allow visual monitoring of filtration and low priming volume.
- Suitable for 96 hours period of use (flat filter only).

N.B. We recommend use of these filters with a syringe no smaller than 10ml capacity to avoid undue pressure.



Epidural Minipacks System 1/2/3/4

A cost-effective and convenient procedure pack, containing all the essential components needed to perform an epidural procedure. Available in 4 variants providing flexibility and choice. All products are single-use and offered in space-saving packs.

Sharps Safety Devices

Description	Product Code
Point-Lok®	4139



Supplied in packs of 10 x 100

Specification Epidural Minipacks System 1

Tuohy Needle Gauge	Length	With Attachable Wings	Clear Catheter with Connector & Guide	Plastic LORD Size	Catheter Identification Label	0.2µm Epidural Filter	Product Code
16G	80mm	•	Open End	10ml	•	•	100/391/016
16G	80mm	•	Closed End 3 Eyes	10ml	•	•	100/391/116
16G	110mm	•	Closed End 3 Eyes	10ml	•	•	100/391/516
16G	80mm	•	Closed End 3 Closer Eyes	10ml	•	•	100/391/816
16G	80mm	•	Closed End 3 Eyes	7ml		•	M477*
17G	80mm	•	Open End	7ml		•	G747*
17G	80mm	•	Closed End 3 Eyes	7ml		•	G998*
18G	80mm	•	Open End	10ml	•	•	100/391/018
18G	80mm	•	Closed End 3 Eyes	10ml	•	•	100/391/118
18G HD (Higher Stiffness)	80mm	•	Closed End 3 Eyes	10ml	•	•	100/391/318
18G	110mm	•	Closed End 3 Eyes	10ml	•	•	100/391/518
18G	80mm	•	Closed End 3 Closer Eyes	10ml	•	•	100/391/818
18G	80mm	•	Open End	7ml		•	G749*
18G	80mm	•	Closed End 3 Eyes	7ml		•	G748*
19G	80mm	•	Open End	10ml	•	•	100/391/190

Supplied in packs of 10 *Supplied in packs of 20

Specification Epidural Minipacks System 1 Paediatric

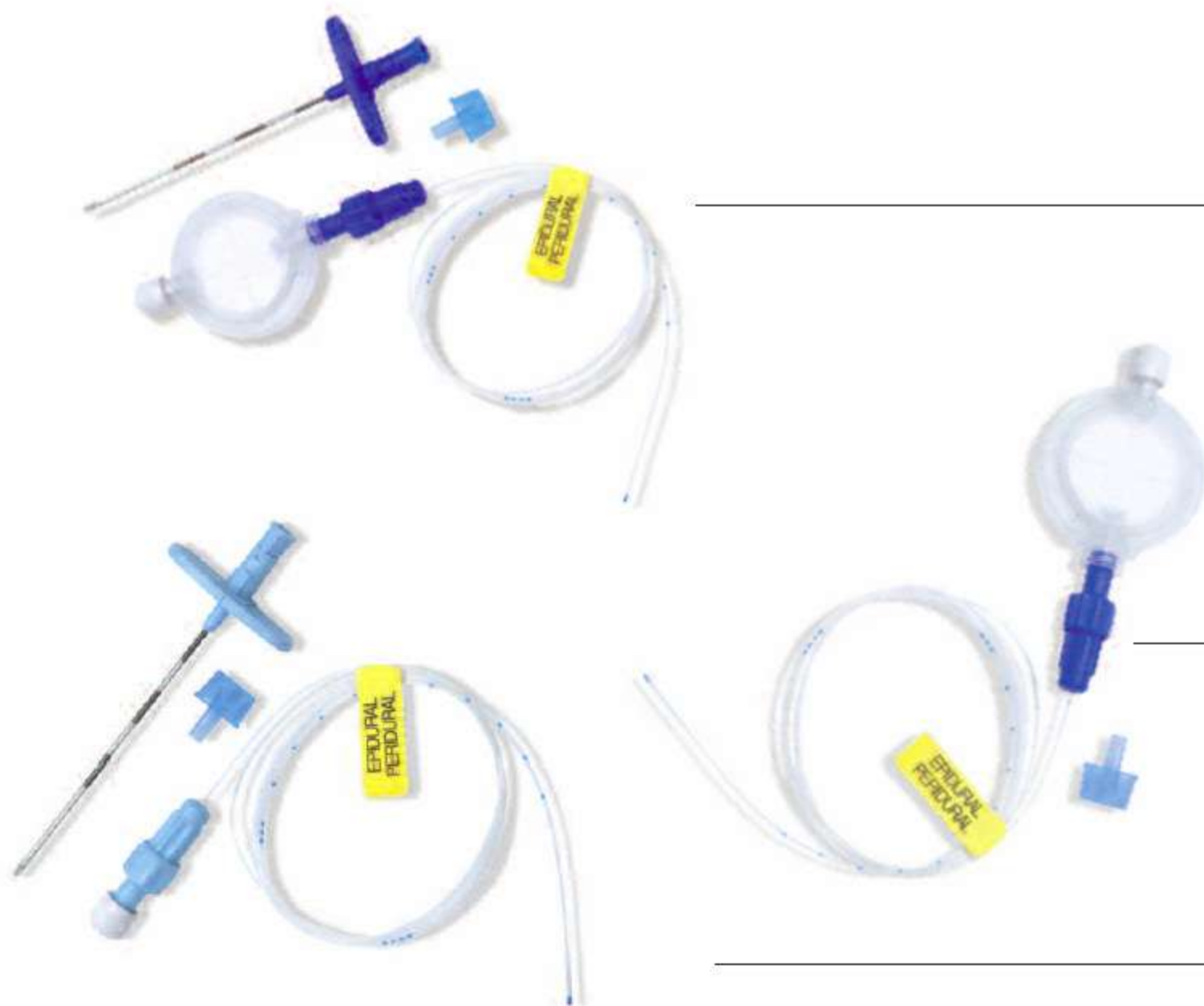
Tuohy Needle Gauge	Length	With Attachable Wings	Clear Catheter with Connector & Guide	Plastic LORD Size	Catheter Identification Label	0.2µm Epidural Filter	Product Code
18G	50mm	•	Closed End 3 Closer Eyes	10ml	•	•	100/391/180
19G	50mm	•	Open End	10ml	•	•	100/391/019

Supplied in packs of 10

Specification Epidural Minipacks System 1 with LOCKIT® Fixation Device

Tuohy Needle Gauge	Length	With Attachable Wings	Clear Catheter with Connector & Guide	Plastic LORD Size	Catheter Identification Label	0.2µm Epidural Filter	Product Code
16G	80mm	•	Closed End 3 Eyes	10ml	•	•	100/391/716
18G	80mm	•	Closed End 3 Eyes	10ml	•	•	100/391/718

Supplied in packs of 10



Sharps Safety Devices

Description	Product Code
Point-Lok®	4139



Supplied in packs of 10 x 100

Epidual Minipacks System 2

Specification

Tuohy Needle Gauge	Length	With Attachable Wings	Clear Catheter with Connector & Guide	Catheter Identification Label	0.2µm Epidural Filter	Product Code
16G	80mm	•	Clear Closed End 3 Eyes	•	•	100/392/116*
17G	80mm	•	Clear Open End		•	E623
17G	80mm	•	Clear Closed End 3 Eyes		•	F948
17G	80mm	•	Radio Opaque Closed End 3 Eyes		•	F950
17G	80mm	•	Clear Closed End 3 Eyes		•	M123
18G	80mm	•	Clear Closed End 3 Eyes	•	•	100/392/118*
18G	80mm	•	Clear Closed End 3 Eyes		•	G746
18G	80mm	•	Clear Closed End 3 Eyes		•	F949
18G	80mm	•	Clear Closed End 3 Eyes		•	M125

Supplied in packs of 20 *Supplied in packs of 10

Epidual Minipacks System 3

Specification

Clear Catheter with Connector & Guide	Catheter Identification Label	0.2µm Epidural Filter	Product Code
16G Closed End 3 Eyes	•	•	100/393/116
18G Closed End 3 Eyes	•	•	100/393/118

Supplied in packs of 10

Epidual Minipacks System 4

Specification

Tuohy Needle Gauge	Length	With Attachable Wings	Clear Catheter with Connector & Guide	Catheter Identification Label	Product Code
16G	80mm	•	Closed End 3 Eyes	•	100/394/116
18G	80mm	•	Closed End 3 Eyes	•	100/394/118

Supplied in packs of 10



Specification

Patient Preparation															Procedure Components						
Tuohy Needle	Sterile Field	Hand Towels x 2	Fenestrated Drape	Gauze Swabs x 5	Applicator Sponges x 2	Solution Prep Wells x 2	Filter Kwill	3ml Luer Slip Syringe	20ml Luer Slip Syringe	25G x 5/8" Hypodermic Needle	22G x 5/8" Hypodermic Needle	18G x 5/8" Hypodermic Needle	16G x 5/8" Hypodermic Needle	Tuohy Needle (Blade 80mm) With Attachable Wings	LORD	Clear Catheter & Connector	Catheter Identification Label	0.2um Epidural Filter	Catheter Fixation Sponge	Product Code	
16G	•	•	•	•	•	•	•	•	•	•	•	•	•	16G	•	10ml Plastic	Closed End 3 Eyes	•	•	•	100/390/116
17G	•		•	•	•		•	•	•		•			17G	•	10ml Glass L/L	Open End		•		E622
17G	•		•	•	•		•	•	•		•			17G	•	10ml Plastic	Open End		•		G455
18G	•	•	•	•	•	•	•	•	•	•	•	•	•	18G	•	10ml Plastic	Closed End 3 Eyes	•	•	•	100/390/118
18G	•		•	•	•		•	•	•		•			18G	•	10ml Glass L/L	Open End		•		G745
18G	•		•	•	•		•	•	•		•			18G	•	10ml Glass L/L	Closed End 3 Eyes		•		G895
18G	•		•	•	•		•	•	•		•			18G	•	10ml Plastic	Closed End 3 Eyes		•		L794
17G Single Shot	•		•	•	•	•	•	•	•		•			17G	•	10ml Glass L/L					E621

Maxipacks supplied in packs of 10

Epidural Maxipacks

A convenient, single-use procedure pack offered in a logical two-layer format with the upper tray containing a selection of patient preparation components and the lower tray containing all the essential epidural procedure components. Available in 16G, 17G and 18G.

Sharps Safety Devices

Description	Product Code
Point-Lok®	4139



Supplied in packs of 10 x 100



Spinal Anaesthesia

Complementing the epidural systems products, Smiths Medical applies the same meticulous attention to detail and quality to a range of precision-engineered spinal needles. Included in the spinal needle range is the RapID® brand of needles. Designed to provide maximum performance without compromising safety, the RapID® spinal needle selection delivers the high performance demanded by today's healthcare professionals. Spinal needles are available in Lancet (Quincke), Atraumatic and Pencil (Whitacre) tip designs, and offered as either individual

needles supplied with a matched introducer needle or in convenient procedure trays.

Recognising that procedural techniques vary, the RapID® range of spinal needles are also available through the SELECT custom kitting service, allowing clinicians to customise a spinal procedure tray to suit individual needs.

Supporting the spinal needle range is the 28g Spinal Micro-catheter System designed to facilitate effective regional anaesthesia through continuous intrathecal administration.



Pencil Point Spinal Needle Sets (Whitacre)

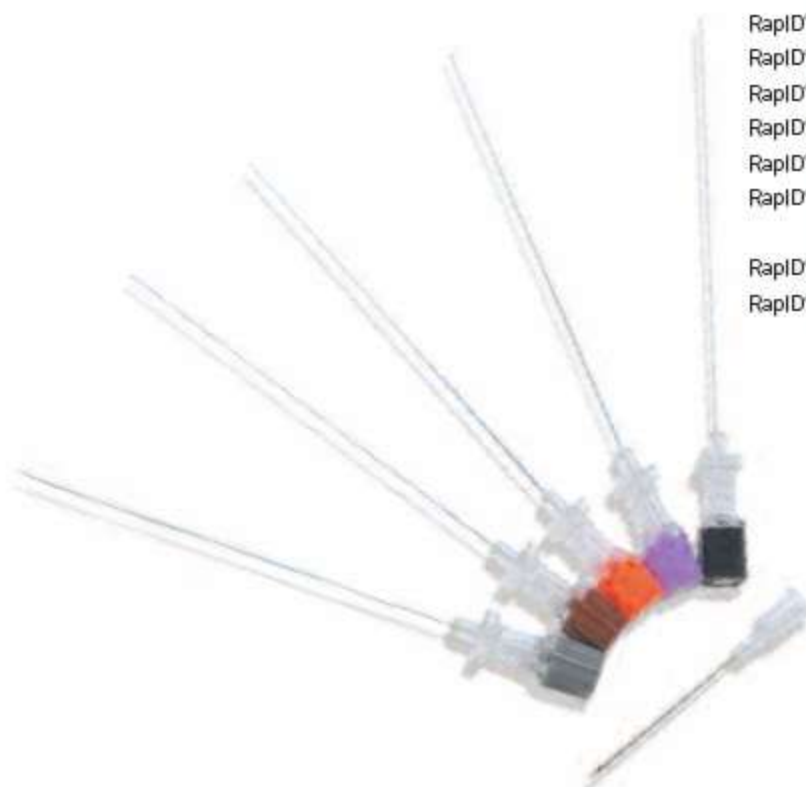
Specification

	Spinal Needle	Length	Introducer Needle	Product Code
RapID®	22G	90mm	18G	100/496/122
RapID®	24G	90mm	20G	100/496/124
	24G	90mm		L742**
	24G	90mm	20G	M121*
RapID®	25G	90mm	20G	100/496/125
	25G	90mm		L741**
	25G	90mm	20G	M122*
RapID®	25G	115mm		100/493/815
RapID®	25G	115mm	20G	100/492/815
RapID®	26G	90mm	20G	100/496/126
RapID®	26G	115mm		100/493/816
RapID®	26G	115mm	20G	100/492/816
RapID®	27G	90mm	20G	100/496/127
	27G	90mm	22G	M729*
RapID®	27G	115mm	20G	100/492/817
RapID®	27G	115mm		100/493/817

Supplied in packs of 20

**Supplied in packs of 50

*Supplied in packs of 60



RapID® Spinal Needle Sets and Midi-Trays

The RapID® range of Spinal Needles is available either as a needle set or in a Midi-Tray format.

The Midi-Tray provides a systematic presentation of the key components necessary for the administration of single-shot Spinal Anaesthesia.

- Available in both Pencil and Lancet tip variants from 22G through to 29G depending on patient and procedural requirements. Extra length needles available in 25G, 26G and 27G.
- Pencil tip needles incorporate precision-engineered tip and eye geometry for atraumatic insertion and reduction in Post Dural Puncture Headache (PDPH).

Sharps Safety Devices

Description	Product Code
Point-Lok®	4139



Supplied in packs of 10 x 100



Lancet Point Spinal Needle Sets
(Quincke)

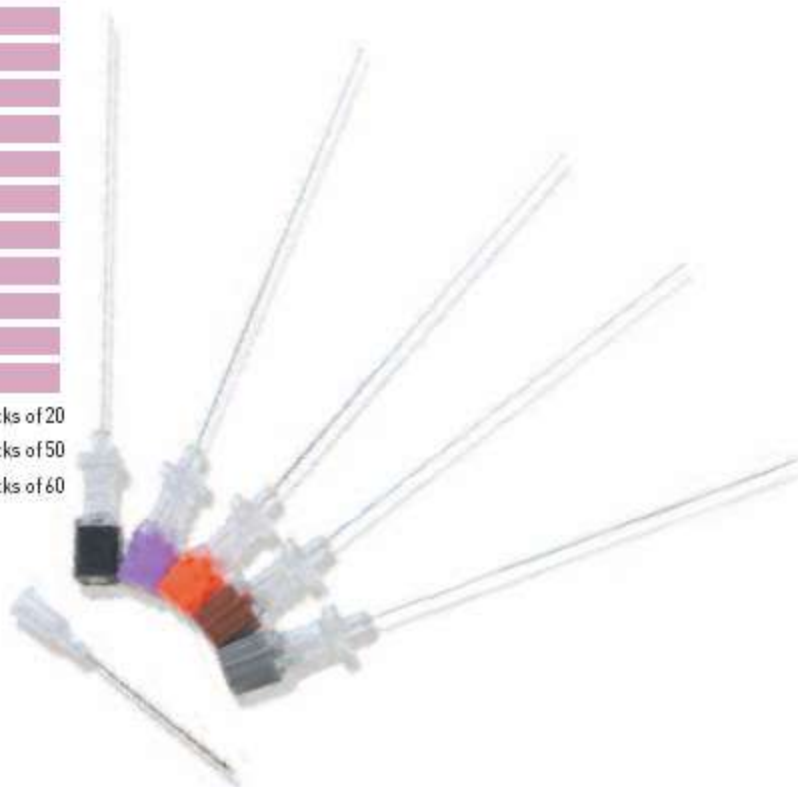
Specification

	Spinal Needle	Length	Introducer	Product Code
RapID*	22G	90mm	18G	100/496/022
	22G	90mm		L746**
RapID*	24G	90mm	20G	100/496/024
RapID*	25G	90mm	20G	100/496/025
	25G	90mm	20G	M118*
RapID*	26G	90mm	20G	100/496/026
	26G	90mm	20G	M119*
RapID*	27G	90mm	20G	100/496/027
	27G	90mm		L743**
	27G	90mm	22G	M120*
	29G	90mm	22G	M341*

Supplied in packs of 20

**Supplied in packs of 50

*Supplied in packs of 60



- Size and positioning of the lateral eye minimises the potential for 'transdural positioning'. This ensures accurate delivery in the subarachnoid space.
- Clear hubs and excellent cerebrospinal fluid flashback performance provides rapid identification of correct needle placement.
- Colour-coded stylets allow easy identification of needle size.
- Supplied with a matched introducer needle to ensure accurate and safe needle placement within the subarachnoid space.



Specification

Spinal Needle	Length	Introducer Needle	Intradermal Needle	Hypodermic Needle	Syringe	Filter Kwill	Product Code
22G	90mm	18G	25G	22G	3ml & 5ml	•	100/497/122
25G	90mm	20G	25G	22G	3ml & 5ml	•	100/497/125
26G	90mm	20G	25G	22G	3ml & 5ml	•	100/497/126
27G	90mm	20G	25G	22G	3ml & 5ml	•	100/497/127

Supplied in packs of 10

Midi-trays

Midi trays are available in pencil point format, containing a spinal needle and introducer, supported by the key components necessary for administration of the local anaesthetic prior to needle insertion.

Filter kwill (5µm, priming volume of 0.3ml) removes particulate matter when drawing up, maximising patient safety.

Sharps Safety Devices

Description	Product Code
Point-Lok*	4139



Supplied in packs of 10 x 100



Patient Preparation												Procedure Components						Product Code
Spinal Needle Gauge	Sterile Field	Hand Towels x 2	Fenestrated Drape	Gauze Swabs x 5	Applicator Sponges x 2	Solution Prep Wells x 2	Filter Kwik	3ml Luer Slip Syringe	22G x 1 1/2" Hypodermic Needle	25G x 5/8" Hypodermic Needle	16G x 5/8" Trocar	Spinal Needle Gauge	Spinal Needle Type - P=Pencil, L=Lancet, A=atraumatic	Re-Rapid, A=Abbott, BD	6ml Luer Lock Syringe	5ml Plastic Syringe	Introducer Needle	
22G	*	*	*	*	*	*	*	*	*	*	*	22G	P	R	*		18G	100/389/822
22G	*	*	*	*	*	*	*	*	*	*	*	22G	L	R	*		18G	100/389/022
22G	*	*	*	*	*	*	*	*	*	*	*	22G	L	BD	*		18G	E619
24G	*	*	*	*	*	*	*	*	*	*	*	24G	A	A	*		19G	G888
25G	*	*	*	*	*	*	*	*	*	*	*	25G	P	R	*		18G	100/389/825
25G	*	*	*	*	*	*	*	*	*	*	*	25G	L	R	*		18G	100/389/025
25G	*	*	*	*	*	*	*	*	*	*	*	25G	P	A	*		19G	G973
25G	*	*	*	*	*	*	*	*	*	*	*	25G	L	BD	*		19G	E620
26G	*	*	*	*	*	*	*	*	*	*	*	26G	P	R	*		18G	100/389/826
26G	*	*	*	*	*	*	*	*	*	*	*	26G	L	R	*		18G	100/389/026
26G	*	*	*	*	*	*	*	*	*	*	*	26G	L	BD	*		20G	G421
27G	*	*	*	*	*	*	*	*	*	*	*	27G	P	R	*			100/389/827
27G	*	*	*	*	*	*	*	*	*	*	*	27G	L	R	*			100/389/027
27G	*	*	*	*	*	*	*	*	*	*	*	27G	L	BD	*		20G	G972

All Spinal Maxipacks supplied in packs of 10

Spinal Maxipack, Pencil Point Needle & Lancet Tip Needle

The spinal Maxipack provides all the essential components required for spinal anaesthesia in a single pack.

Presented in a logical two-layer format, the upper tray contains a selection of patient preparation components and the lower tray contains the essential components to perform the spinal block.

Available in 22G to 27G pencil tip or lancet tip format, dependent on the patient and procedure requirements, high performance and safety are assured.



Specification
Spinal Microcatheter Kit

Pack Contents	Product Code
23G Crawford Spinal Needle	100/384/023
28G Styletted Microcatheter	
18G Introducer Needle	
1ml Syringe	
Microcatheter Fixation Device	
Luer Lock Connector	
Microcatheter Guide	
Spinal Catheter Label	
0.2µm Syringe Filter	

Supplied in packs of 2

The System Includes

- 23G Crawford Spinal Needle with optimised 30° angle of bevel.
- Needle bevel heel and sides blunted to minimise risk of potential catheter shearing.
- 28G Styletted Microcatheter.
- Graduated markings permit accurate catheter positioning.
- PTFE coated stylet aids easy withdrawal from catheter.
- Correct catheter placement may be confirmed by aspiration of CSF.
- Supplied with catheter identification label to avoid confusion with epidural catheters or other infusion lines.
- Supplied with Luer lock connector.
- 1ml syringe for accurate dose delivery.
- Compact 0.2µm syringe filter .



Single Packed Filter

0.2µm Syringe Filter	100/385/020
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Supplied in packs of 10

Microcatheter System

The Spinal Microcatheter System for continuous spinal anaesthesia is considered appropriate for a wide range of surgical and pain management applications, providing a rapid and controlled response. The technique permits precise dose titration and allows minimal amounts of local anaesthetic to be used, minimising the risk of systemic toxic reactions.

Sharps Safety Devices

Description	Product Code
Point-Lok®	4139



Supplied in packs of 10 x 100



Combined Spinal Epidural Systems

Bringing together the well documented advantages of epidural and spinal anaesthesia, the Smiths Medical range of Combined Spinal Epidural products includes the unique CSEcure® locking needle system.

Launched in 1998, the CSEcure® needle system provides a safe and effective solution to needle control during the CSE procedure, without compromising the all-important feel. CSEcure® is available in a wide range of pack options from individual sets of needles through to full procedure packs.

Recognising that procedural techniques vary, the CSE needle range is also available through the SELECT custom kitting service, allowing the clinician to customise a CSE procedure tray to suit their individual needs. In addition, the CSE range offers a selection of traditional non-locking needle systems supplied as either matched needle sets or in full procedure trays. Now offered in the traditional 'needle-through-needle' CSE range is a back-eye design of Tuohy needle to facilitate spinal needle placement.

Needle Sets

Specification
CSEcure® Needle Sets

Tuohy Needle	With Attachable Wings	Spinal Needle	Spinal Needle Type	CSEcure® Lock	Product Code
16G	•	26G	Pencil	•	100/396/916
16G	•	27G	Pencil	•	100/396/716
18G	•	27G	Pencil	•	100/396/718

Needle Sets supplied in packs of 10



Specification
CSEcure® Minipacks

(contains CSEcure® needle set with lock, catheter (3 eyes) and connector, Filter (0.2µm), LORD, Fixation sponge, catheter ID label)

Tuohy Needle	With Attachable Wings	Spinal Needle	Spinal Needle Type	Product Code
18G	•	27G	Lancet	100/491/318
16G	•	26G	Pencil	100/491/916
16G	•	27G	Pencil	100/491/716
18G	•	27G	Pencil	100/491/718

Portex CSE Minipacks supplied in packs of 10



CSE Needle Systems

- Providing the rapid onset and reliability of a spinal block, allowing anaesthesia to be prolonged both intra and post-operatively via an epidural catheter.
- Designed for optimal performance, minimising drag of needle through needle and maximising feel of dural puncture.
- Rapid CSF flashback to confirm correct needle tip position.
- CSEcure's® unique needle hub locking feature enables tip relationships to be maintained after dural puncture, providing increased confidence of correct spinal needle tip position during injection of the anaesthetic.

Sharps Safety Devices

Description	Product Code
Point-Lok®	4139



Supplied in packs of 10 x 100

Traditional (non-locking) Needle Sets

Specification

Traditional (non-locking) Needle Sets

Tuohy Needle	With Attachable Wings	Spinal Needle	Spinal Needle Type	Back Eye	Product Code
18G		25G	Pencil	•	M145*
16G	•	26G	Lancet		100/396/116
16G	•	26G	Pencil		100/396/816
16G	•	27G	Pencil		100/396/616
18G	•	27G	Pencil		100/396/618

Supplied in packs of 10

*Supplied in packs of 20



Specification

Traditional (non-locking) CSE Minipacks

(contains CSE needle set, catheter (3 eyes) and connector, Filter (0.2µm), LORD, Fixation sponge, catheter ID label)

Tuohy Needle	With Attachable Wings	Spinal Needle	Spinal Needle Type	Product Code
18G		25G	Pencil	M146*
16G	•	26G	Lancet	100/491/116
18G	•	26G	Lancet	100/491/118
18G	•	27G	Pencil	100/491/618
16G	•	26G	Pencil	100/491/816
18G	•	26G	Pencil	100/491/818

Supplied in packs of 10

*Supplied in packs of 20 (back eye needle, no catheter label, no fixation sponge)



- Maximum of 15mm spinal needle tip protrusion from Tuohy needle.
- In locked position the spinal needle is free to rotate, enabling 360° freedom for drug dispersal in preferred direction.
- Pencil point needles provide a satisfactory solution to the problem of Post Dural Puncture Headache and atraumatic entry into the subarachnoid space.

- Excellent drug distribution is achieved through three helically-located lateral eyes within the clear catheter, minimising the potential for the localised pooling of drug solutions within the epidural space.



Plexus Anaesthesia

Supporting the growing interest in Plexus Anaesthesia for Pain Management, Smiths Medical's Plexus Anaesthesia Systems offer the Anaesthetist a more targeted approach to Pain Management.

The TRACER® III nerve stimulator is a light-weight portable system, allowing easy confirmation of needle placement to target nerves for procedures where a motor response can be elicited. The small micro current delivered by the TRACER® III stimulates the larger A Alfa motor fibres before the smaller A Delta or C fibres responsible for pain, thereby achieving a motor response without eliciting pain.

TRACER® III automatically compensates for patient resistance and displays the actual current being delivered at the tip of the needle. As well as current intensity, the easy-to-read screen displays the maximum current range, pulse frequency, the pulse width and current battery life status.



TRACER® III

Ref Code	NL3
Dimensions	2.9" (7.3cm) x 5.5" (14.0cm) x 1.4" (3.4cm)
Weight	9.6 oz (275g) with 9v battery
Output Current	0.05-5.0mA ± 1% (into a load of 12 kOhms or less)
Pulse Frequency	Programmable 1 Hz/2Hz ±2%
Pulse Width	50, 100, 300, 500, 1000 microseconds ±10%
Pulse Risetime	Less than 5 microseconds open circuit
Power	One 9v Alkaline Battery
Regulatory	CE marked to MDD EC93/42, UL 2601-1, CSA 22.2 no.601.1

Plexus Anaesthesia

TRACER III® also features:

- Volume control with audible tone changes.
- Audio open-circuit alarm.
- Automatic shut-off after 20 minutes of non use to preserve battery life.
- Two pulse frequency options 1Hz and 2Hz.
- Five pulse width settings 0.05, 0.1, 0.3, 0.5, and 1.0 msec.

SoloStim® Foot Control

Product Code	NLP3
Dimensions	8" (20.3cm) x 3.75" (9.4cm) x 2.75" (7.0cm)
Weight	2.1lbs (0.96kg)

TRACER® III Protective Case

Product Code	NLB3
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TRACER® III Replacement Leadset

Product Code	NLC3
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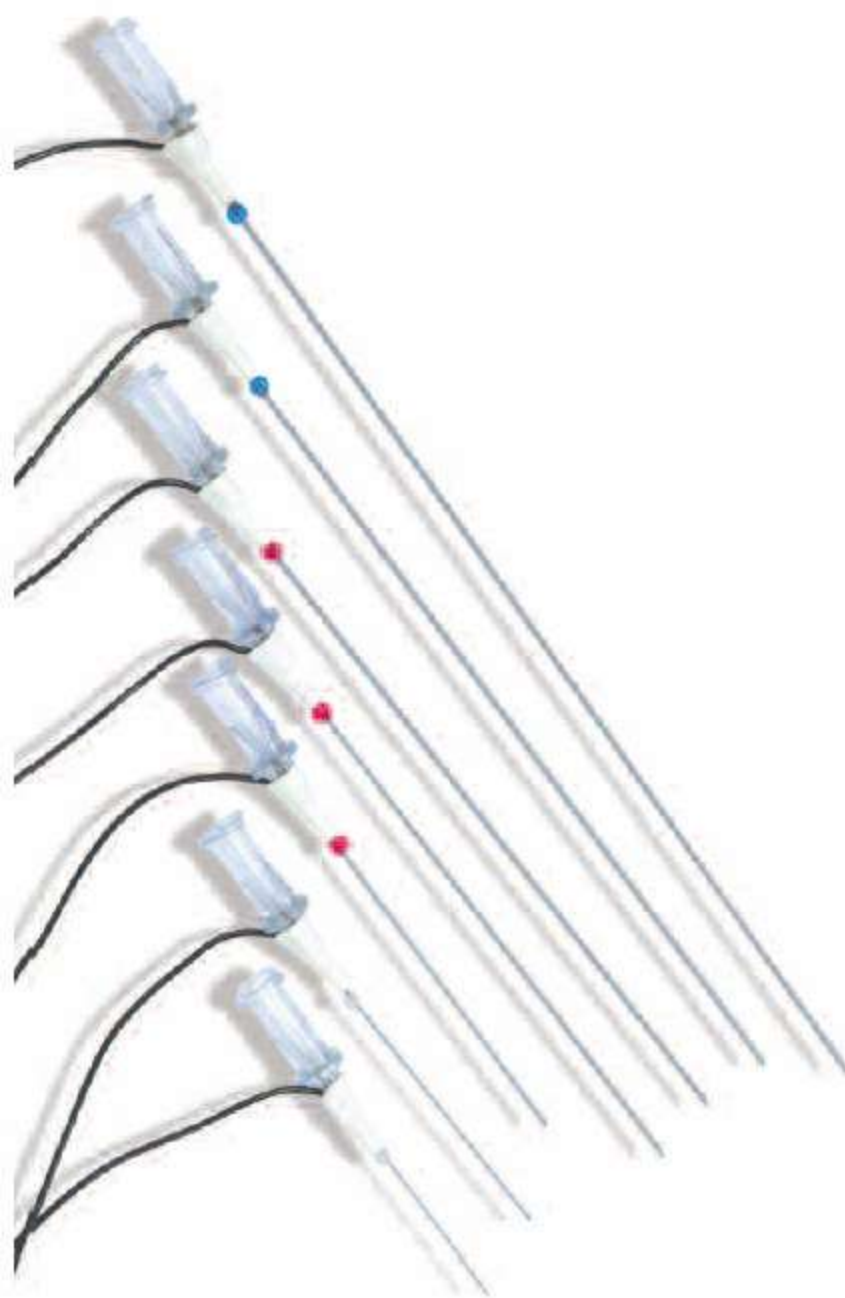
TRACER® III Adaptor Lead

Product Code	NLA3
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Unique to Smiths Medical's Plexus Anaesthesia System is the SOLOSTIM™ foot control. Used in conjunction with the TRACER III® Nerve Stimulator, it allows hands-free operation and control of the stimulating current, enabling the clinician to use both hands for accurate needle placement and nerve location.

- Two operating ranges can be selected. 0.05-5.0 mA and 0.05-1.5mA.



Single Shot Needles

Needle Gauge	Needle Length	Product Code
25	25mm	25/025/PB
25	40mm	25/040/PB
22	50mm	22/050/PB
22	80mm	22/080/PB
20	100mm	20/100/PB
20	120mm	20/120/PB
20	150mm	20/150/PB

Bevel: 30° B Block

Insulation: >50 kOhms resistance

Hub: Transparent female Luer fitting

Lead Wire: 18" long with 1.5mm touch proof connector

CONTINUOUS PROLONG™ Sets

Needle Gauge	Needle Length	Product Code	Tuohy style needle	Continuous Block Catheter
19	40mm	19/040/PL		yes
19	50mm	19/050/PL		yes
19	100mm	19/100/PL		yes
19	150mm	19/150/PL		yes
18	40mm	18/040/PLT	•	yes
18	50mm	18/050/PLT	•	yes
18	100mm	18/100/PLT	•	yes
18	150mm	18/150/PLT	•	yes

(supplied with 21G catheter)

Bevel:

30° B Block for 19 gauge

tuohy tip for 18 gauge

Insulation: >50 kOhms resistance

Hub: Transparent female Luer fitting

Lead Wire: 18" long with 1.5mm touch proof connector

Catheter: 21G closed end 3 lateral eyes Radio opaque

A full range of insulated needles and catheter sets support the TRACER III® and SOLOSTIM™ System. Ranging from short needles suitable for upper extremity blocks, the needles incorporate an advanced Hydro-Slick teflon coating which is laser-stripped at the tip to ensure a high degree of insulation and accuracy.

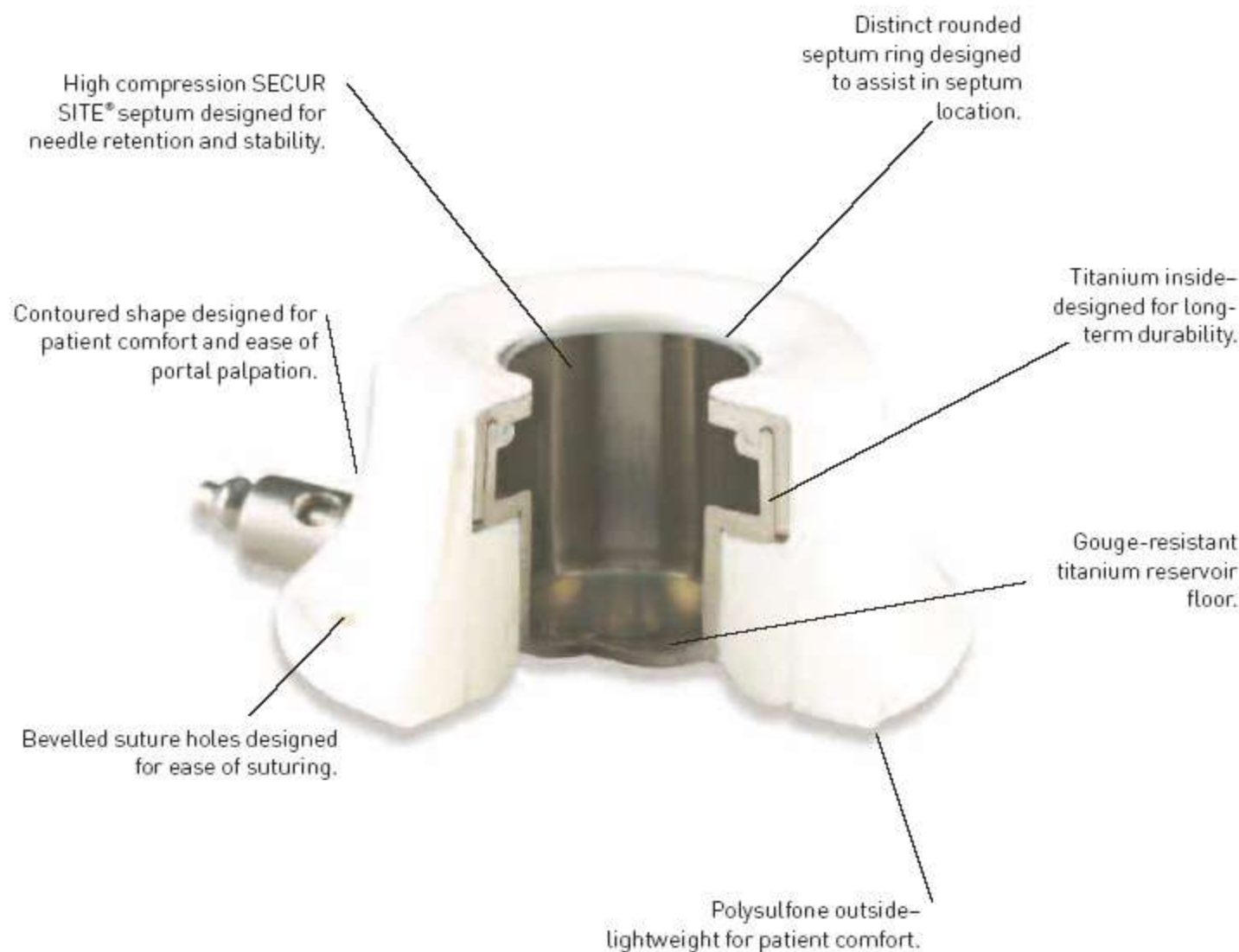


Epidural and Intra-Spinal Ports & Access Systems

Recognising the need for effective Chronic Pain Management, the PORT-A-CATH® brand of implantable Epidural and Intra-spinal Ports from Smiths Medical, provide an effective and reliable means of administering Pain Management Therapies over extended periods of time. Setting standards in excellence and innovation, the Deltac PORT-A-CATH® brand of Epidural and Intra-spinal Ports offer unsurpassed performance and reliability.

Smiths Medical also provides a comprehensive range of Vascular Access Ports for Intravenous and Intra-arterial Therapies. Please see our Vascular Access Catalogue for more details.

EPIDURAL AND INTRA-SPINAL PORTS



Specification

	Catheter material	OD (mm)	ID (mm)	Length (cm)	Product Code
Epidural Port	Polyurethane Open ended	1.2	0.5	91	21-1501-24
Spinal Port	Polyurethane Closed end with side hole	0.9	0.5	91	21-1500-24

Manufactured from a lightweight polysulfone body incorporating a gouge-resistant titanium base, PORT-A-CATH® II is designed for long-term durability and patient comfort. The compressed silicone septum provides secure needle retention when accessing the port, allowing up to 2000 needle punctures. All ports are supplied with a polyurethane catheter in a full procedure tray.



GRIPPER® Needles

Specification

Gauge	Length (mm)	Product code with Y-site	Product code without Y-site
22G	19	21-2939-24	21-2733-24
22G	25	21-2940-24	21-2714-24
22G	32	21-2941-24	21-2715-24
20G	19	21-2947-24	21-2734-24
20G	25	21-2948-24	21-2717-24
20G	32	21-2949-24	21-2718-24
19G	19	21-2955-24	21-2735-24
19G	25	21-2956-24	21-2720-24
19G	32	21-2957-24	21-2721-24
20G	16	21-2746-24	21-2736-24
22G	16	21-2738-24	21-2737-24

Supplied in packs of 12



GRIPPER® Plus Safety Needles

Specification

Gauge	Length (mm)	Product code with Y-site	Product code without Y-site
19G	19	21-2868	21-2768
19G	25	21-2869	21-2764
19G	32	21-2870	21-2765
20G	16	21-2864	21-2769
20G	19	21-2865	21-2767
20G	25	21-2866	21-2762
20G	32	21-2867	21-2763
22G	16	21-2860	21-2770
22G	19	21-2861	21-2766
22G	25	21-2862	21-2760
22G	32	21-2863	21-2761

Supplied in packs of 12

Supporting the Epidural and Intra-spinal Ports is the GRIPPER® and GRIPPER® PLUS range of non-coring Huber needles for accessing ports. The removable contoured grip provides confident needle placement, while the low profile design eliminates the need for bulky dressings. When in situ, the cushioned needle platform stabilises the needle and increases patient comfort. The new GRIPPER® PLUS needle offers access to the port in one easy and safe motion. Featuring an effective needle stick protection system, GRIPPER® PLUS provides improved clinical safety when removing the needle from the port.

All GRIPPER® and GRIPPER® PLUS access needles have integrated extension lines featuring needle-less Y-site access, and secure Luer lock connectors allowing connection to an appropriate infusion pump if required.

- A wide variety of gauges and lengths to accommodate most ports.
- Colour-coded C-clamp for ease of needle gauge identification.

With over 400,000 implantations during the last 10 years the Smiths Medical range of ports and needles gives you and your patients the confidence and security you deserve.



Select Custom Kit Service

Smiths Medical recognises that health professionals are as individual as their patients. The Select Custom Kitting service allows clinicians the opportunity to customise their own kits to suit their personal component preferences and operational needs. The service offers the following benefits to both users and purchasers:

- With a simple ordering system, custom kits ensure you receive exactly the right components for each individual, with no extras to assemble and nothing wasted.
- Considerable time-saving gained from set-up to procedural application as all the items are present in one package.
- Risk of infection is reduced as all items are only handled once.
- Stockholding is reduced as packs can be held by your local distributor according to forecast and demand.



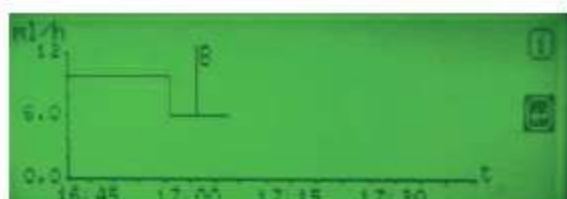
The Select Custom Kit process

It is quick and easy to create and produce any kit to suit your exact requirements.

- 1 Select kit components with our Product Specialist.
- 2 Our Custom Kit Unit prepares sample(s) for approval in 3 days.
- 3 Sample(s) approved and order placed.
- 4 Our Custom Kit Unit produces initial stock.
- 5 Usage forecast agreed and 2-3 months stock produced to be held by distributor.
- 6 Standing order placed by hospital with distributor with extra supplies available for call-off at all times.



Pumps



OMNIFUSE® PCA

Designed with safety in mind, OMNIFUSE® PCA breaks new ground in syringe pump design. Specifically developed for Patient Controlled Analgesia (PCA), OMNIFUSE® PCA meets the needs of today's demanding Pain Management Therapies.

The intuitive point and select user interface, combined with a wide range of features which can be enabled or disabled, provides a high degree of operational flexibility and the desired balance between simplicity and sophistication.



Specification

Dose Range	0.1ng – 99.9mg
Dose Duration	1 second – 15 minutes
Clinician Override Dose Range	0.1ng – 99.9mg
Loading Dose Range	0.1ng – 99.9mg
Background (Dose) Rate Range	0.1ng/h – 500mg/h
Background Rate Range (with boluses)	0.1 – 20ml/h
Background Rate Range (no boluses)	0.1 – 800ml/h
Bolus Rate Range	0.1 – 800ml/h
Bolus Rate Range (timed)	1 second – 15 minutes
Dose Limit Range by Mass	1ng – 9999mg
Dose Limit Range by Volume	1 – 9999ml
Dose Limit Range by Demands	1ng – 50 demands
Dose Limit Period	1 – 8 hours or variable
Accuracy	Volumetric: $\pm 2\%$ Linear: $\pm 0.25\%$ using the Braun Omnifix 50ml syringe
Syringe Sizes	2ml – 60ml
Purge Rate	0 – 800ml/h
KVO Rate	0 – 2ml/h

Occlusion Pressure Alarm Limits	5 levels between 180 and 1250mmHg
History	3000 events
Battery Type	Sealed Lead Acid
Battery Life	10 hours @ 5ml/h
Battery charge time	10 hours to full charge
AC Power Supply	100 – 240V at 50/60Hz 50W
Weight	3.5kg (not including pole clamp)
Dimension	384 x 170 x 92mm (not including locking pole clamp)
Fluid Ingress Protection	IPX4
Electrical Safety	Class 1, Type CF
Design Standards	EN 60601-1, EN 60601-2 EN 60601-4, EN 60601-2-24

Part numbers

OmniFuse® PCA 0153-0001 (this part number refers to the UK variant).
OmniFuse® Drug Protocol Management System 0153-0084.

- Supplied with Drug Protocol Software as standard to help minimise Medication Errors during programming.
- Large display screen can illustrate the current infusion profile in a graphical format.
- Infusion history which can be viewed over 1 hour periods.
- Displays showing graphical representations of patient profiles when pain, nausea and sedation parameters are entered into the pump.

- Electronic Patient Handset illuminates when a bolus is available.
- The 'ASLEEP' function allows the pump to be programmed and left in a dormant state awaiting use.

Confidence and safety when connecting the patient to OMNIFUSE® PCA can be achieved using the FLO-SAFER™ range of extension sets designed to suit every individual patient requirement.



FLO-SAFER™ Extension Set System

- Include line clamps with an option of an integral Anti-Syphon Valve.
- Available with a fluid path of PVC or PE medical grade plastics.
- Yellow extension sets that are colour-coded to conform with the internationally recognised colour for epidural use.
- Wastage and consequent drug expenditure reduced by low volume sets that incorporate narrow-bore tubing, reducing priming volume by 75%.
- Integral Roberts Clamp giving the confidence of a safer and convenient method of flow control.

Specification
PVC Extension Sets & R Clamp

Length (cm)	Priming	Product Code
50	0.5ml	0128-0196
100	1.0ml	0128-0197
150	1.5ml	0128-0122
200	2.0ml	0128-0198

Sets supplied in packs of 50

Specification
PVC Extension Sets & ASV & R Clamp

Length (cm)	Priming	Product Code
50	0.5ml	0128-0251
100	1.0ml	0128-0252
150	1.5ml	0128-0253
200	2.0ml	0128-0254

Sets supplied in packs of 50

Specification
PE Lined Extension Sets & ASV & R Clamp

Length (cm)	Priming	Product Code
50	0.5ml	0128-0255
100	1.0ml	0128-0256
150	1.5ml	0128-0257
200	2.0ml	0128-0258

Sets supplied in packs of 50

Specification
PE Lined Extension Sets (narrowbore 0.5mm) + ASV + R Clamp

Length (cm)	Priming	Product Code
100	0.25ml	0128-0259
150	0.4ml	0128-0260

Sets supplied in packs of 50

Specification
Yellow Epidural PU Extension Sets + ASV + R Clamp

Length (cm)	Priming	Product Code
150	1.5ml	0128-0261
200	2.0ml	0128-0262

Sets supplied in packs of 50

Specification
Yellow Epidural PU Extension Sets + S Clip

Length (cm)	Priming	Product Code
150	1.5ml	0128-0263
200	2.0ml	0128-0264

Sets supplied in packs of 50

Specification
150cm PVC Extension Sets + Y Set + ASV +
Non-Return Valve and Loop

Product Code
Primary Line - 1.5ml/ Secondary Line - 2.0ml
0128-0121

Sets supplied in packs of 50

Specification
150cm PVC Extension Sets + Pressure Sensing Disc

Priming	Product Code
2.2ml	0130-0041

Sets supplied in packs of 50

ASV – Anti-Syphon Valve
PVC – Polyvinylchloride
PE – Polyethylene

PU – Polyurethane
R Clamp – Roberts Clamp
S Clip – Slip Clip



CADD-Legacy® PCA

CADD Legacy® PCA is safe, reliable and durable.

Specifically dedicated to PCA applications, the CADD Legacy® PCA pump is particularly suited for Pain Management Therapies via the intravenous, intra-arterial, subcutaneous, intraperitoneal, epidural and intrathecal routes.

CADD Legacy® PCA is capable of continuous, demand dose and clinician bolus infusions that can be used independently or in combination with each other.

- Enhanced keypad and message display screen, providing easy-to-read information for programming adjustments and troubleshooting.
- Built-in safety features allowing you and your patient to be alerted to any undesirable events in the pump's operation.
- Air-in-line detector indicating the presence of air administration set tubing and the upstream and downstream occlusion sensors detecting any interruptions of fluid delivery.



Specification

Product Code	21-6300-51
Delivery Modes	Continuous, Demand Dose, Clinician Bolus (modes can be used independently or in combination).
Indications	Pain management infusion therapies.
Delivery routes	Intravenous, Intra-arterial, Subcutaneous, Intraperitoneal, Epidural, Intrathecal.
Programming	
Programming Units	ml,mg,mcg
Reservoir Volume	1 ml – 9,999ml or not in use
Drug Concentration	0.1 – 100mg/ml, 1–500 mcg/ml
Continuous Rate	0–50ml/hr, 0–5,000 mg/hr, 0 – 25,000 mcg/hr*
Dose Volume	Demand dose – 0 – 9.9ml, 0 – 990 mg, 4,950mcg. Clinician Bolus – 0–20ml, 0 – 2,000mg, 0 –10,000mcg*
Demand Dose Lockout	5 min – 24 hr
Demand Doses/hour	1 – 12
Reporting	
Reservoir Volume	0 – 9,999ml* (ml only)
Drug Concentration	
Given (volume delivered)	0 – 99,999.95ml
Doses Given	0 – 999
Doses Attempted	0 – 999

- The capacity to store the last 500 events in its memory. This information can be downloaded either directly or remotely (using a modem) to a PC or a printer using the CADD Diplomat® PC Communications System.
- Filled medication cassettes or pole-mounted fluid bags, allowing the clinician flexibility to choose medication delivery option that best suits Pain Management needs.
- Optional security shells safeguard against undesired tampering with the pump during use.
- CADD Legacy® offers a high degree of strength and durability, making it the ideal choice for ambulatory patients with an active lifestyle.



Simply Safer, The CADD-Prizm® PCS II Pain Management Pump

The CADD-Prizm® PCS II pump uses 20 years of proven ambulatory infusion system experience to provide an easy- to-use pump that optimises safety, security and pain control, whilst offering the pump information and patient reports that your Acute Pain Team needs for effective Pain Management.

Each component in the CADD Acute Pain Management System complements and supports the safe and reliable delivery of pain medication. Use of the pumps across multiple patient areas increases clinician familiarity, whether used for an ambulatory, pole-mounted, post- operative, epidural or IV infusion.

The effectiveness of delivery reaches a higher level when combined with Medication Delivery Management Software that reduces the risk of medication errors via electronic programming of the pump with standardised protocols.

- When combined with the CADD-Prizm® PCS II pump, the software will help reduce programming errors, save time and provide consistent, high quality Pain Management.
- Electronic protocol programming, archived pump and patient data and printable documentation whenever required.
- Helps reduce the risk of medication errors.
- You can quickly select and accurately program pain



General Pump Specifications*

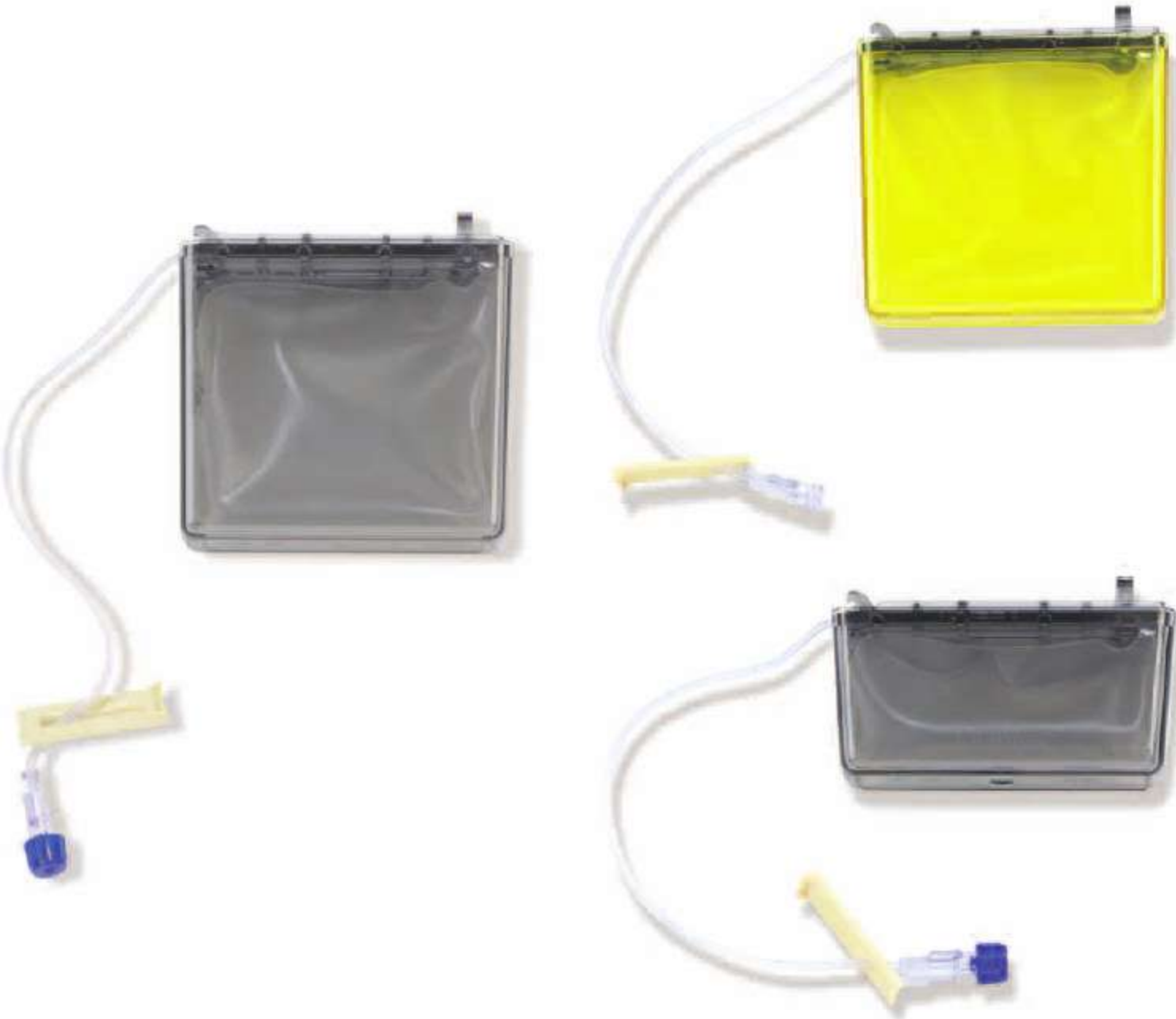
Resolution	0.050 ml per pump stroke
Size	4.4 cm x 10.4 cm x 14.1 cm (1.7 in. x 4.1 in. x 5.6 in.) excluding cassette or other accessories.
Weight	568 g (20 oz.) including 9-volt battery and empty 100 ml Medication Cassette reservoir, excluding other accessories.
Power Sources	9-volt alkaline or lithium battery such as DURACELL® Alkaline MN 1604 or ULTRALIFE® Lithium U9VL; AC adaptor.
Upstream Occlusion Sensor	Fluid is not flowing from the reservoir to the pump.
Pump Alarms	Pump has many notifications and visual/audible alarms, including low/depleted power status, low/depleted reservoir volume, cassette detached/attached, high pressure, and others related to specific pump conditions. Refer to the Operators Manual for listing of pump alarms.
Bolus Volume at Occlusion Alarm Pressure	0.050 ml resolution sets/reservoirs: < 0.25 ml.
System Delivery Accuracy	±6% (nominal)
High Pressure Alarm	18 ± 9 psi
Air Detector Alarm	Single bubble greater than 0.100 ml.

PCA Delivery Mode Specifications

		Product Code
CADD-Prizm® PCS II ambulatory infusion pump Model 6101	Pump, carrying case, 50/100 ml pump pouch, pump key, remote dose cord, 9-volt battery, Operators Manual.	21-8951-51
CADD-Prizm® PCS II ambulatory infusion pump Model 6101 with yellow keypad	Pump, carrying case, 50/100 ml pump pouch, pump key, remote dose cord, 9-volt battery, Operators Manual.	21-8941-51

- protocols into the CADD-Prizm® PCS II pumps, reducing the risk of manual programming errors and saving programming time.

 - Use wireless technology to download to a PDA device, infusion history from the CADD-Prizm® PCS II pump and use the therapy report to help make patient management decisions. The stored information can later be archived on a PC for documentation.
 - The CADD system provides three choices of medication delivery – medication cassette reservoirs, IV bags or syringes.
- The tamper-resistant housing of the medication cassette reservoir provides security and durability, while reducing the risk of contamination associated with bag spikes.
 - An optional accessory, the secure and sturdy Lock Box, ensures that the pump and medication bag are locked away to prevent any tampering with the infusion. The option of colour-coded pumps, medication cassette reservoirs, administration lines and lock boxes all differentiate epidural and IV PCA delivery and enhance infusion safety.



Medication Cassette Reservoirs (must be used with Deltec Extension Set with Anti-siphon valve).

Product	Product Code	Unit
50-ml with Female Luer	21-7001-24	12/box
100-ml with Female Luer	21-7002-24	12/box
Yellow 100-ml with Female Luer	21-7100-24	12/box

Flexible Medication Reservoir

Product	Product Code	Unit
250-ml TOTM plasticised Medication Reservoir with Female Luer-activated valve	21-6167-24	48/box



CADD® Administration Sets

Product	Product Code	Unit
152 cm Tubing with Attached Bag Spike, Male Luer with Integral Anti-siphon Valve and Clamp	21-7022-24	12/box
152 cm Tubing with Attached Bag Spike, Male Luer Add-on Anti-siphon Valve and Clamp	21-7034-24	12/box
312 cm Yellow-striped with Attached Bag Spike, Male/Male Luers, Integral Anti-siphon Valve and Clamp	21-7024-24	12/box
229 cm TOTM-plasticised Tubing with Bag Spike, 0.2-micron Filter, Male Luer with Integral Anti-siphon Valve, and Clamp	21-7091-24	12/box
229 cm TOTM-plasticised Tubing with Female Luer, 0.2-micron Filter, Male Luer with Integral Anti-siphon Valve, and Clamp	21-7094-24	12/box
229 cm TOTM-plasticised Tubing with Bag Spike, In-line Anti-siphon Valve, Y-extension with One-way Female Checkvalve, Male Luer, and Clamps	21-7095-24	12/box
224 cm Yellow-striped Tubing, 0.2-micron Filter, Bag Spike, Male Luer with Integral Anti-siphon Valve and Clamp	21-7039-24	12/box

CADD® Extension Sets

Product	Product Code	Unit
76 cm with Male/Male Luers, Integral Anti-siphon Valve and Clamp	21-7045-24	50/box
	21-7060-24	12/box
114 cm with Male/Male Luers, Integral Anti-siphon Valve and Clamp	21-7046-24	50/box
	21-7061-24	12/box
152 cm with Male/Male Luers, Integral Anti-siphon Valve and Clamp	21-7047-24	50/box
	21-7062-24	12/box
140cm TOTM-plasticised Tubing with Male/Male Luers, 0.2-micron Filter, Integral Anti-siphon Valve and Clamp	21-7040-24	25/box
152cm TOTM-plasticised Tubing with Male/Male Luers, 0.2-micron Filter, Integral Anti-siphon Valve and Clamp	21-7106-24	50/box
173cm TOTM-plasticised Tubing with Male/Male Luers, In-Line Anti-siphon Valve Y-extension with One-way Female Checkvalve and Clamps	21-7092-24	12/box
229cm TOTM-plasticised Yellow-striped Tubing with Male/Male Luers, Integral Anti-siphon Valve and Clamp	21-7105-24	12/box
152cm TOTM-plasticised Microbore Tubing with Male/Male Luers, 0.2-micron Filter, Integral Anti-siphon Valve and Clamp	21-7052-24	50/box



Lock Boxes and Security Shells (for CADD-Prizm® pumps).

Product	Product Code	Unit
Security Shell Accommodates 250 medication bag, or several types of 30-ml pre-filled syringes; shell locks onto pump and may be pole-mounted using the pole-mount bracket (21-6120)	21-6117-24	each
Modified Security Shell For use with Flexible medication Reservoir (21-6127) and CADD® Administration Set with Male Luers (21-7059). Shell locks onto pump and may be pole-mounted using the pole-mount bracket (21-6120)	21-6117-24	each
Large Lockbox with Full Keypad, Air Detector Access Compatible with standard IV bags up to 500ml and pre-filled syringes up to 60ml	21-6186-51	each
Small Lockbox with Full Keypad, Air Detector Access Compatible with standard IV bags up to 100ml and pre-filled syringes up to 30ml	21-6185-51	each



Reusable Pouches

Product	Product Code	Unit
250-ml Pump Pouch Accommodates pump and up to 250-ml medication bag	21-2305-24	each
1-litre Pump Pouch Accommodates pump and 1-litre medication bag	21-2338-24	each
For CADD-Prizm® pumps		
Backpack (3-litre capacity) Accommodates CADD-Prizm® VIP pump, External Power Source (EPS) system, and up to a 3 litre, dual chamber medication bag	21-6123-24	each
Backpack (1-litre capacity) Accommodates CADD-Prizm® VIP pump, and up to a 1 litre, medication bag	21-6123-24	each
For CADD-Prizm® pumps		
50-/100-ml Pump Pouch Accommodates pump with 50/100-ml Medication Cassette reservoir	21-6122-24	each
250-/500-ml Pump Pouch with shoulder strap Accommodates pump with 250/500-ml medication bag, designed to be worn on the shoulder or round the waste	21-6127-24	each
250-/500-ml Pump Pouch Accommodates pump with 250/500-ml medication bag, designed to be worn round the waste	21-6124-24	each
For CADD-Legacy® pumps		
50-/100-ml Reusable Pouch Accommodates pump with 50/100-ml Medication Cassette reservoir	21-6260-24	each
250-/500-ml Reusable Pouch Accommodates pump with 50/100-ml medication Cassette reservoir	21-6265-24	each

Single-Use Pouches

Product	Product Code	Unit
For CADD-Prizm® pumps, all models		
Navy 50-/100-ml Pump Pouches	21-6129-24	10/box
Navy 250-/500-ml Pump Pouches	21-6131-24	10/box
For CADD-Legacy® pumps		
Multi-colour 50-/100-ml Pump Pouches	21-6161-24	10/box
Multi-colour 250-/500-ml Pump Pouches	21-6163-24	10/box

Pouch Straps

Product	Product Code	Unit
Shoulder Strap For use with 50-/100-ml pump pouch	21-2352-24	each
Shoulder Strap For use with 250-ml, 250-/500-ml, and 1 litre pump pouches; 50-/100-ml and 250-/500-ml dual pump pouches; Lock Box	21-2353-24	each
Backpack Shoulder Strap	21-6125-24	each

CADD PUMP ACCESSORIES

External Power Source Components (for CADD-Prizm® pumps, all models)

Product	Product Code	Unit
Power Pack with Rechargeable, Replaceable Battery	21-3801-04	each
AC adaptor required for use	21-3801-03	each
Ni-MH Replacement Battery	21-3801-04	each
For use with 21-3800 and 21-3801 power pack	21-3802-23	each
AC Adaptor 110volts (USA) Connector	21-3815-01	each
Note: This product is not CE marked		
AC Adaptor 220volts (Europlug) Connector	21-3807-22	each
AC Adaptor 220volts (UK) Connector	21-3809-20	each
AC Adaptor 240volts	21-3808-10	each
Note: This product is not CE marked		

CADD-Prizm® Pump Accessories

Product	Product Code	Unit
Pole-mount Bracket	21-6118-24	each
Slides into recess on back of CADD-Prizm® pump or security shell to allow pole-mounting of pump or pump and security shell.		
Power and Data In/Out Cover	21-6113-24	each
Replacement cover for power and data in/out jack		

CADD-Legacy® Pump Accessories

Product	Product Code	Unit
Polemount Bracket	21-6210-24	each
For use with pole-mount bracket (21-6118)		
For CADD-Legacy® 1, CADD-Legacy® PLUS and CADD-Legacy® PCA pumps		
AC Adaptor 220volts (Europlug) Connector	21-6206-26	each
AC Adaptor 220volts (UK) Connector	21-6204-20	each
AC Adaptor 240volts (Japan)	21-6208-09	each
Note: This product is not CE marked		
AC Adaptor 240volts (Australia)	21-6209-10	each
Note: This product is not CE marked		

Accessories

Product	Product Code	Unit
Battery Doors		
For CADD-Prizm® pumps – Standard	21-6110-24	each
For CADD-Legacy® pumps – Standard	21-6216-24	each
Pump Key for CADD-PCA®, CADD-Legacy® PCA and CADD-Prizm® pumps		
Pump Key	21-2303-24	each
Remote Dose Cords		
For use with CADD-Prizm® pumps	21-5814-22	each
For use with CADD-Legacy® PCA pumps	21-6220-24	each



PC to Pump Communications (For use with CADD-Prizm® and CADD-Legacy® pumps)

Product	Product Code	UCP Number	Unit
CADD-DIPLOMAT® System			
For Clinicians: (Must choose items from 1 and 2 for entire system)			
1 CD ROM for installing software on computer	21-6141-51	(01) 0 0610586 02224 4	each
2 For use with CADD-Prizm® pumps			
Interface cable/null modem cable to directly connect PC and CADD-Prizm® pump	21-6144-24	(01) 0 0610586 02590 0	each
For use with CADD-Legacy® pumps			
Interface cable/null modem cable to directly connect PC and CADD-Legacy® pump	21-6250-24	(01) 0 0610586 02177 3	each

Computer Requirements when using CADD-DIPLOMAT® System

- 486 or faster PC compatible computer (with an available 16 bit ISA slot for the internal modem) or an available RS232 serial port for an external modem.
- Windows® 95 or higher, or windows NT® 4.0.
- 8MB RAM (minimum).
- Hard Drive with at least 20MB available.



Sharps safety devices

Smiths Medical is helping to protect healthcare workers from exposure to sharps injuries through the introduction of a range of sharps safety devices.

At Smiths Medical, safety is the number one priority. The primary goal is to promote safety in every way and to create the safest possible environment for healthcare workers. Smiths Medical has been a leader in the prevention of blood-borne pathogen exposure and sharps safety for more than ten years. It continues to develop and introduce new

and improved products that make sharps use as safe as possible for clinicians and healthcare workers.

The Smiths Medical POINT-LOK® device is handy enough to slip into a pocket and can be supplied as an individual item or incorporated into Select Custom Kits, providing effective protection for sharps from 16-30 gauge.

SHARPS SAFETY DEVICES

The Hypodermic Needle Pro® Ranges are available as individual items or pre-attached to syringes.

Specification

Hypodermic Needle Pro® –

Syringe and Needle with Needle Protection Device

Syringe	Needle Gauge	Colour	Product Code
1ml	25G x 25mm (1")	orange	4211
3ml	20G x 38mm (1 1/2")	yellow	4230
3ml	20G x 25mm (1")	yellow	4231
3ml	21G x 38mm (1 1/2")	deep green	4232
3ml	21G x 25mm (1")	deep green	4233
3ml	22G x 38mm (1 1/2")	black	4234
3ml	22G x 25mm (1")	black	4235
3ml	23G x 25mm (1")	deep blue	4236
3ml	25G x 16mm (5/8")	orange	4237
3ml	25G x 25mm (1")	orange	4238
5ml	20G x 38mm (1 1/2")	yellow	4250
5ml	20G x 25mm (1")	yellow	4251
5ml	21G x 38mm (1 1/2")	deep green	4252
5ml	22G x 38mm (1 1/2")	black	4254
10ml	20G x 38mm (1 1/2")	yellow	4260
10ml	20G x 25mm (1")	yellow	4261
10ml	21G x 38mm (1 1/2")	deep green	4262
1ml Luer slip with rotating Needle-Pro device	25G x 16mm (5/8")	orange	4310
1ml Luer slip with rotating Needle-Pro device	26G x 13mm (1/2")	brown	4312E
1ml Luer slip with rotating Needle-Pro device	27G x 13mm (1/2")	grey	4313

Supplied in packs of 400
Conforms to ISO Colour Codes

Specification

Hypodermic Needle Pro® –

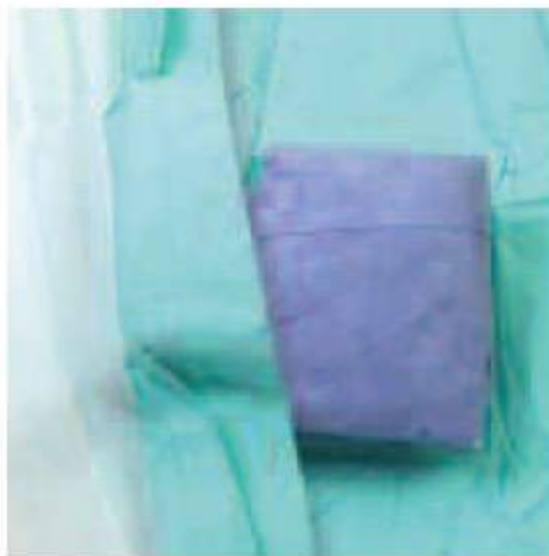
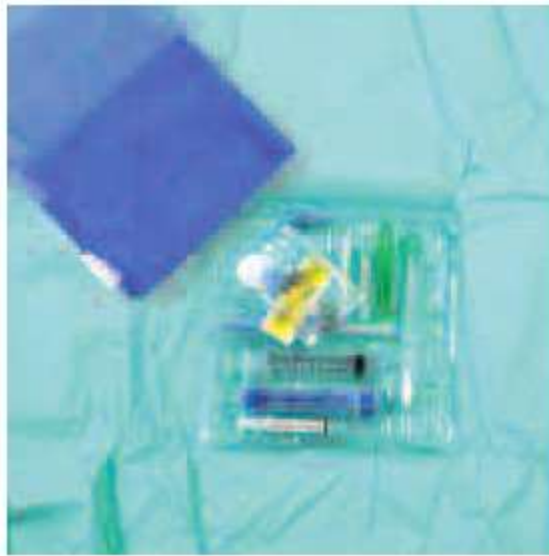
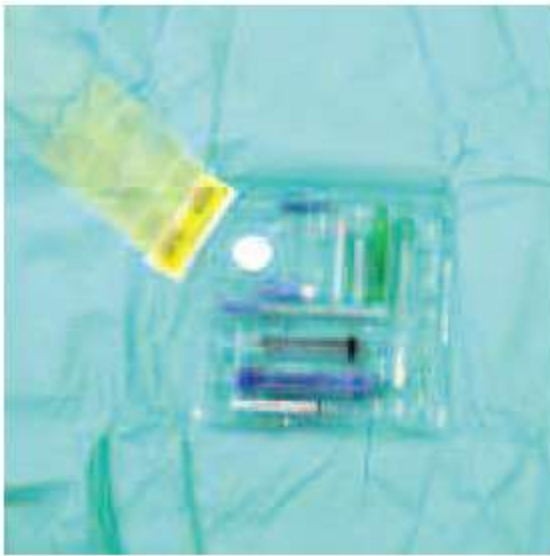
Needle with Needle Protection Device

Needle Gauge	Colour	Product Code
18G x 38mm (1 1/2")	pink	4280
18G x 25mm (1")	pink	4281
19G x 38mm (1 1/2")	cream	4282E
19G x 25mm (1")	cream	4283E
20G x 38mm (1 1/2")	yellow	4284
20G x 25mm (1")	yellow	4285
21G x 38mm (1 1/2")	deep green	4286
21G x 25mm (1")	deep green	4287
22G x 38mm (1 1/2")	black	4288
22G x 25mm (1")	black	4289
22G x 31mm (1 1/4")	black	4296
23G x 25mm (1")	deep blue	4290
23G x 31mm (1 1/4")	deep blue	4297
25G x 16mm (5/8")	orange	4291
25G x 25mm (1")	orange	4292
25G x 16mm (5/8") with rotating Needle-Pro device	orange	4320*
26G x 13mm (1/2") with rotating Needle-Pro device	brown	4322E*
27G x 13mm (1/2") with rotating Needle-Pro device	grey	4323*

* For use with Luer slip syringes only. Supplied in packs of 800
Conforms to ISO Colour Codes

Select Custom Kits

Selected by you, assembled by Smiths Medical



PAINMANAGEMENT

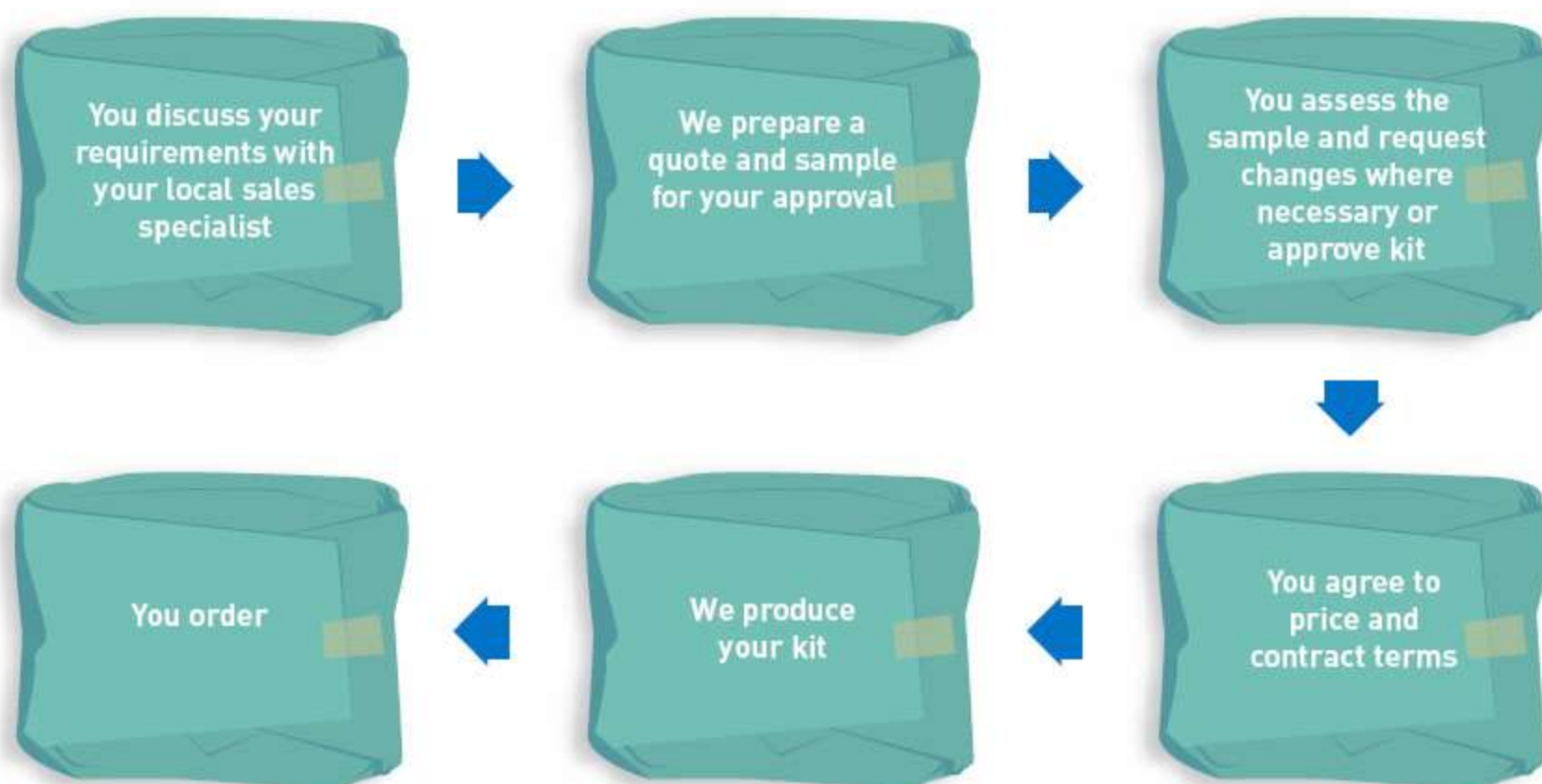
SELECT CUSTOM KITS

Just as all patients are individuals, so are the health professionals who care for them. Smiths Medical supplies standard ready-to-use packs for a number of procedures. We also supply Select Custom Kits, allowing us to treat our customers as individuals.

THE SELECT CUSTOM KIT service gives you the opportunity to customise your own kits to suit personal component preferences and operational needs.

With a Select Custom Kit all components are at hand ready for a procedure with the exact items specified in one convenient package. This reduces waste, and saves you time and money.

THE SELECT CUSTOM KITTING PROCESS



FOR MORE DETAILS CONTACT YOUR LOCAL SMITHS MEDICAL REPRESENTATIVE

THE DETAILS GIVEN IN THIS LEAFLET ARE CORRECT AT THE TIME OF GOING TO PRESS. THE COMPANY RESERVES THE RIGHT TO IMPROVE THE EQUIPMENT SHOWN.

For further information please call your local Smiths Medical distributor or Smiths Medical on +44 (0)1303 260551

Smiths Medical International Ltd

Hythe, Kent CT21 6JL UK

Tel: +44 (0)1303 260551 Fax: +44 (0)1303 266761

www.smiths-medical.com

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Literature No. LIT/PM/2563

smiths

Smiths Medical - a part of Smiths Group plc

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 661325****Issued To:**

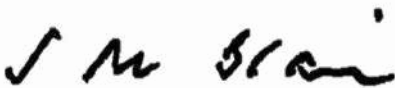
Smiths Medical International Ltd.
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2017-06-28**

Date: **2017-06-28**

Expiry Date: **2022-06-27**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 661325

Certificate Scope:

The design, development and manufacture of sterile:

Breathing Systems, Drainage Devices, Feeding Devices, Filtration Devices for Breathing Circuits, Infusion Disposables, Intubation Systems, Obstetrics and Gynaecology Sampling Devices, Oxygen and Humidity Management Devices, Pressure Monitoring Accessories, Resuscitation Devices, Suction Catheters, Tracheostomy Tubes, Vascular Access Devices

The design, development and manufacture of non-sterile:

Breathing Systems, Intubation Systems, Resuscitation Devices, Gynecologic Pessaries, Tracheostomy Tubes, Oxygen and Humidity Management Devices

First Issued: **2017-06-28**Date: **2017-06-28**Expiry Date: **2022-06-27**

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Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 661325**
Date: **2017-06-28**
Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
Brightwake Limited Lowmoor Business Park Kirkby-in-Ashfield Nottinghamshire NG17 7JZ United Kingdom	Manufacture
GaleMed Corporation No. 87, Li-Gong 2nd Road Wu-Jia YILAN 268 Taiwan	Manufacture
GE Medical Pollards Wood Nightingales Lane Chalfont Saint Giles HP8 4SP United Kingdom	Manufacture

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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 Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:

Service(s) supplied

Koo Medical Equipment (Shanghai)
 Co., Ltd
 100 Zhongde Road
 Dakun Industrial Park
 Songjiang, Shanghai 201614
 China

Manufacture

Pentair Filtration Solutions
 1350 Hammond Road
 St. Paul
 Minnesota
 55110
 USA

Crucial Supplier

Quadrant EPP Belgium N.V.
 Industriepark Noord
 Robert Tavernierlaan 2
 Tielt
 8700
 Belgium

Manufacture

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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 Date: **2017-06-28**
 Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
Smiths Healthcare Manufacturing SA de CV Avenida Calidad No.4 Parque, Industrial Internacional Tijuana 22425 Mexico	Manufacture
Smiths Healthcare Manufacturing SA de CV Carretera Miguel Alemán Km 21.7 Parque Industrial Monterrey Apodaca Nuevo León 66603 Mexico	Manufacture

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
Smiths Medical ASD Inc. 10 Bowman Dr. Keene New Hampshire 03431 USA	Manufacture
Smiths Medical ASD Inc. 1265 Grey Fox Road St Paul Minnesota 55112 USA	Manufacture
Smiths Medical ASD Inc. 201 West Queen St., Southington Connecticut 06489 USA	Manufacture

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
Smiths Medical ASD Inc. 6250 Shier Rings Road Dublin Ohio 43016 USA	Manufacture
Smiths Medical ASD Inc. 9124 Polk Lane, Suite 101 Olive Branch Mississippi 38654 USA	Distribution
Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	Manufacture

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
Smiths Medical Gary 5700 W 23rd Ave Gary Indiana 46406 USA	Manufacture
Smiths Medical International Ltd 52 Grayhill Rd Cumbernauld Glasgow G68 9HQ United Kingdom	Manufacture
Smiths Medical International Nijmegen Bijsterhuizen 22-08 6604 LD Wijchen The Netherlands	Distribution

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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 Date: **2017-06-28**
 Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
Smiths Medical Italia Srl Via della Stazione, 2 Latina Scalo 04100 Italy	Packaging
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 B-4800 Verviers Belgium	ETO Sterilization
Sterigenics UK Limited Cotes Park Estate Somercoates Alfreton DE55 4NJ United Kingdom	ETO Sterilization

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	Gamma Sterilization
Sterigenics, LLC 1700 College Blvd. West Memphis Arkansas 72301 USA	Gamma Sterilization
Sterilization Services of Tennessee, Inc 2396 Florida Street Memphis Tennessee 38109 USA	ETO Sterilization

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Subcontractor:	Service(s) supplied
STERIS ISOMEDIX Services, Inc 7685 Saint Andrews Avenue San Diego California 92154 USA	ETO Sterilization
UPG Avenida La Cuspide #1 Parque Industrial Tecnomex Del. Playas de Tijuana Tijuana Baja California 22700 Mexico	Manufacture
Velcro USA Inc. 95 Sundial Avenue Manchester New Hampshire 03103-7206 USA	Crucial Supplier

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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 661325**
Date: **2017-06-28**
Issued To: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
United Kingdom

Date	Reference Number	Action
Current	8603100 8603169	First issue. Transferred from another Notified Body. Certificate renewal.

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

Nr. **CE 661325**
Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Obiect:

Consultati pagina cu obiectul certificatului.

pe baza examinarii noastre a sistemului de asigurare a calitatii conform cerintelor Directivei Consiliului 93/42/CEE, Anexa II excluzand Sectiunea 4. Sistemul de asigurare a calitatii indeplineste cerintele Directivei. Pentru lansarea pe piata a produselor din clasa III este necesar certificatul mentionat in Anexa II, Sectiunea 4.

Pentru si in numele BSI, organ de certificare in acceptiunea sus-mentionatei Directive (Organ de certificare cu numarul 0086):



Stewart Brain, Sef compartiment conformitate si risc

Dispozitive medicale

Prima editie: **2017-06-28**

Data: **2017-06-28**

Data expirarii: **2022-06-27**

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Pagina 1 din 2

Valabilitatea prezentului certificat este conditionata de mentinerea sistemului de calitate la cerintele Directivei dovedita de organul de certificare care supravegheaza compania. Prezenta aprobare exclude toate produsele proiectate si/sau fabricate de o terta parte on in numele companiei care detine prezentul certificat, cu exceptia unui acord contrar, incheiat cu BSI. Prezentul certificat a fost redactat electronic si este conditionat de respectarea caietului de sarcini.

Informatii si contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, inregistrata in Anglia sub numarul 7805321 in 389 Chiswick High Road, Londra W4 4AL, UK. A membra a grupului BSI.



Certificat nr.: CE 661325

Obiectul certificatului:

Proiectarea, dezvoltarea si fabricatia produselor sterile:

Sisteme de respiratie, Dispozitive de drenaj, Dispozitive de nutritie, Dispozitive de filtrare pentru Circuite respiratorii, Consumabile pentru perfuzii, Sisteme de intubatie, Dispozitive de prelevare a probelor pentru obstetrica si ginecologie, Dispozitive de gestionare a oxigenului si umiditatii, Accesorii de control al presiunii, Dispozitive de resuscitare, Catetere de absorbtie, Tuburi de traheostomie, Dispozitive de acces vascular

Proiectarea, dezvoltarea si fabricatia de produse nesterile:

Sisteme de respiratie, Sisteme de intubatie, Dispozitive de resuscitare, Supozitoare vaginale, Tuburi de traheostomie, Dispozitive de gestionare a oxigenului si umiditatii



Prima editie: 2017-06-28

Data: 2017-06-28

Data expirarii: 2022-06-27

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Pagina 2 of 2

Valabilitatea prezentului certificat este conditionata de mentinerea sistemului nde calitate la cerintele Directivei dovedita de organul de certificare care supravegheaza compania. Prezenta aprobare exclude toate produsele proiectate si/sau fabricate de o terta parte on in numele companiei care detine prezentul certificat, cu exceptia unui acord contrar, incheiat cu BSI.

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Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

Certificat nr.: **CE 661325**
 Data: **2017-06-28**
 Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:

Servicii prestate

Brightwake Limited
 Lowmoor Business Park
 Kirkby-in-Ashfield
 Nottinghamshire
 NG17 7JZ
 Marea Britanie

Fabricatie

GaleMed Corporation
 Nr. 87, Li-Gong 2nd Road
 Wu-Jia
 YILAN 268
 Taiwan

Fabricatie

GE Medical
 Pollards Wood
 Nightingales Lane
 Chalfont Saint Giles
 HP8 4SP
 Marea Britanie

Fabricatie

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Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

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Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:

Servicii prestate

Koo Medical Equipment (Shanghai)
Co., Ltd
100 Zhongde Road
Dakun Industrial Park
Songjiang, Shanghai 201614
China

Fabricatie

Pentair Filtration Solutions
1350 Hammond Road
St. Paul
Minnesota
55110
USA

Furnizor crucial

Quadrant EPP Belgium N.V.
Industriepark Noord
Robert Tavernierlaan 2
Tielt
8700
Belgia

Fabricatie

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Certificat CE - Sistem Integral de Asigurare a Calitatii

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

Lista subcontractantilor majori

Recunoscuti ca participanti la prestatii aferente produsului certificat prin:

Certificat nr.: **CE 661325**
Data: **2017-06-28**
Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:

Servicii prestate

Smiths Healthcare Manufacturing
SA de CV
Avenida Calidad Nr.4
Parque, Industrial Internacional
Tijuana
22425
Mexic

Fabricatie

Smiths Healthcare Manufacturing
SA de CV
Carretera Miguel Alemán Km 21.7
Parque Industrial Monterrey
Apodaca
Nuevo León
66603
Mexic

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Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:

Servicii prestate

Smiths Medical ASD Inc.
 10 Bowman Dr.
 Keene
 New Hampshire
 03431
 USA

Fabricatie

Smiths Medical ASD Inc.
 1265 Grey Fox Road
 St Paul
 Minnesota
 55112
 USA

Fabricatie

Smiths Medical ASD Inc.
 201 West Queen St.,
 Southington
 Connecticut
 06489
 USA

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Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:

Servicii prestate

Smiths Medical ASD Inc.
6250 Shier Rings Road
Dublin
Ohio
43016
USA

Fabricatie

Smiths Medical ASD Inc.
9124 Polk Lane, Suite 101
Olive Branch
Mississippi
38654
USA

Distributie

Smiths Medical Republica Ceha a.s.
Olomoucká 306
753 01 Hranice
Republica Ceha

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Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:

Servicii prestate

Smiths Medical Gary
5700 W 23rd Ave
Gary
Indiana
46406
USA

Fabricatie

Smiths Medical International Ltd
52 Grayhill Rd
Cumbernauld
Glasgow
G68 9HQ
Marea Britanie

Fabricatie

Smiths Medical International
Nijmegen
Bijsterhuizen 22-08
6604 LD Wijchen
Olanda

Distributie

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Certificat CE - Sistem Integral de Asigurare a Calitatii

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Data: **2017-06-28**
Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:

Servicii prestate

Smiths Medical Italia Srl
Via della Stazione, 2
Latina Scalo
04100
Italia

Ambalare

Sterigenics Belgium
(Petit-Rechain) SA
Zoning Industriel de Petit-Rechain
Avenue Andre Ernst 21
B-4800 Verviers
Belgium

Sterilizare ETO

Sterigenics UK Limited
Cotes Park Estate
Somercotes
Alfreton
DE55 4NJ
Marea Britanie

Sterilizare ETO

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Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzand Sectiunea 4

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 Data: **2017-06-28**
 Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:

Servicii prestate

Sterigenics US, LLC
 344 Bonnie Circle
 Corona
 California
 92880
 USA

Sterilizare cu raze gamma

Sterigenics, LLC
 1700 College Blvd.
 West Memphis
 Arkansas
 72301
 USA

Sterilizare cu raze gamma

Sterilization Services of
 Tennessee, Inc
 2396 Florida Street
 Memphis
 Tennessee 38109
 USA

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Certificat nr.: **CE 661325**
Data: **2017-06-28**
Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Subcontractant:

STERIS ISOMEDIX Services, Inc
7685 Saint Andrews Avenue
San Diego
California 92154
USA

Servicii prestate

Sterilizare ETO

UPG
Avenida La Cuspide #1
Parque Industrial Tecnomex
Del. Playas de Tijuana
Tijuana
Baja California
22700
Mexic

Fabricatie

Velcro USA Inc.
95 Sundial Avenue
Manchester
New Hampshire
03103-7206
USA

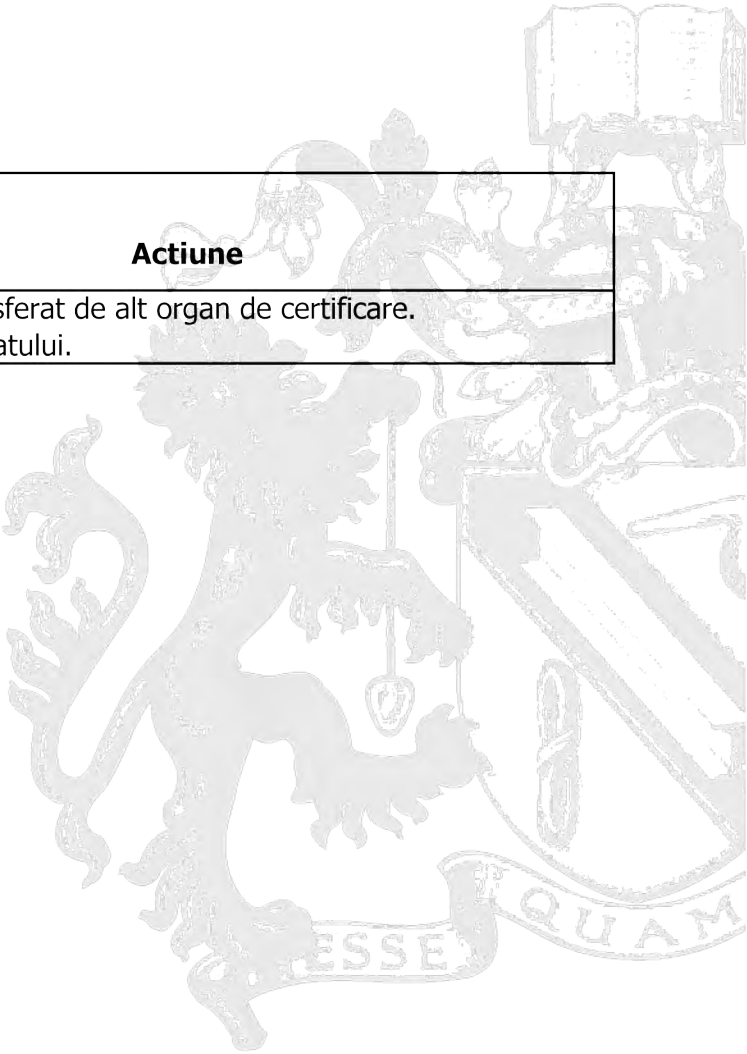
Furnizor crucial

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Certificat CE - Sistem Integral de Asigurare a Calitatii – Istoricul certificatului

Certificat nr.: **CE 661325**
Data: **2017-06-28**
Titular: **Smiths Medical International Ltd.**
Boundary Road
Hythe
Kent
CT21 6JL
Marea Britanie

Data	Numar de referinta	Actiune
Curenta	8603100 8603169	Prima editie. Transferat de alt organ de certificare. Reinnoirea certificatului.



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Traducător autorizat
Nr. 2769/2015