



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

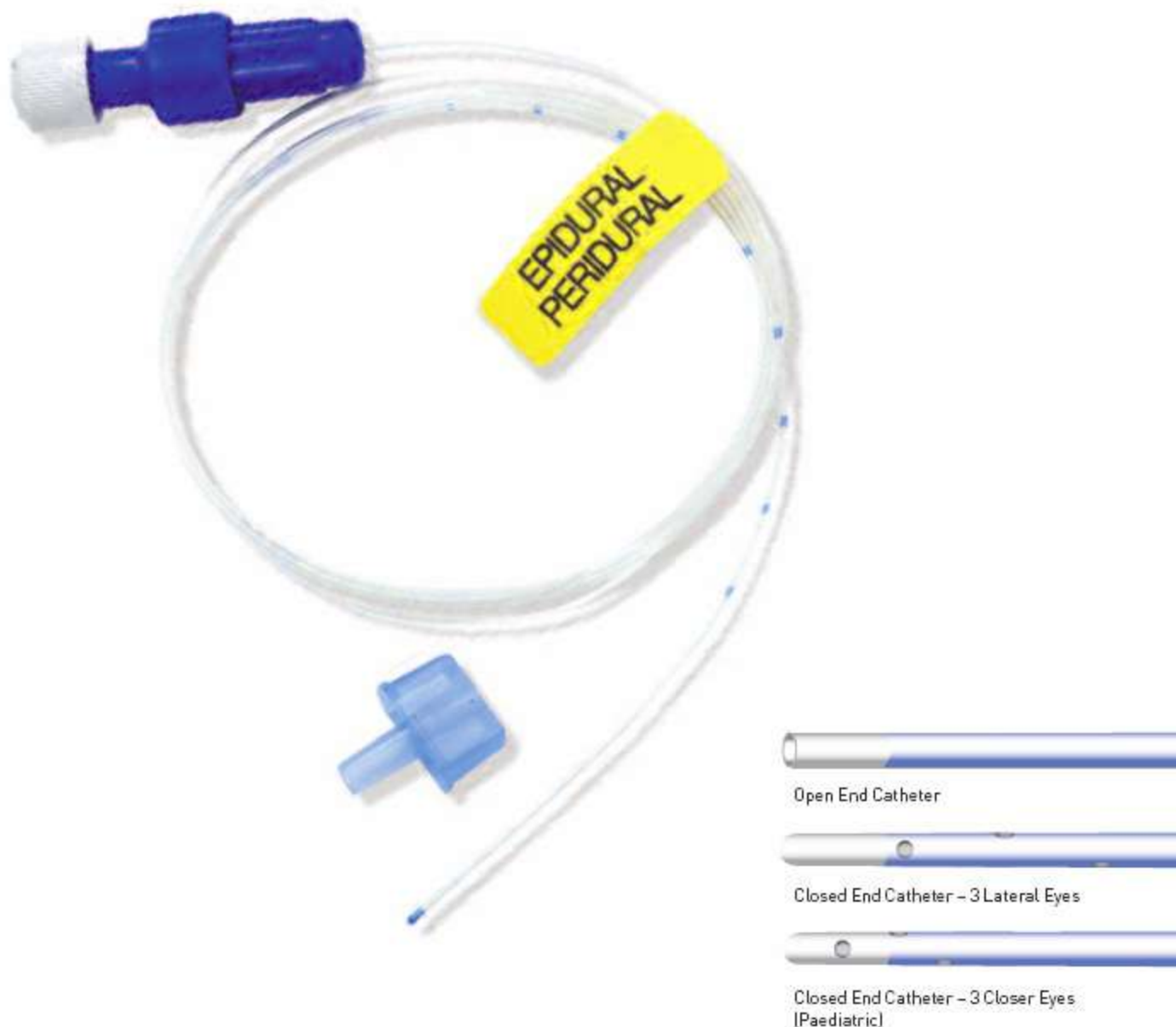
The PORTEX® 'Loss of Resistance' Device is a single-use, low-friction syringe specifically designed to facilitate successful location of the epidural space.

- 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

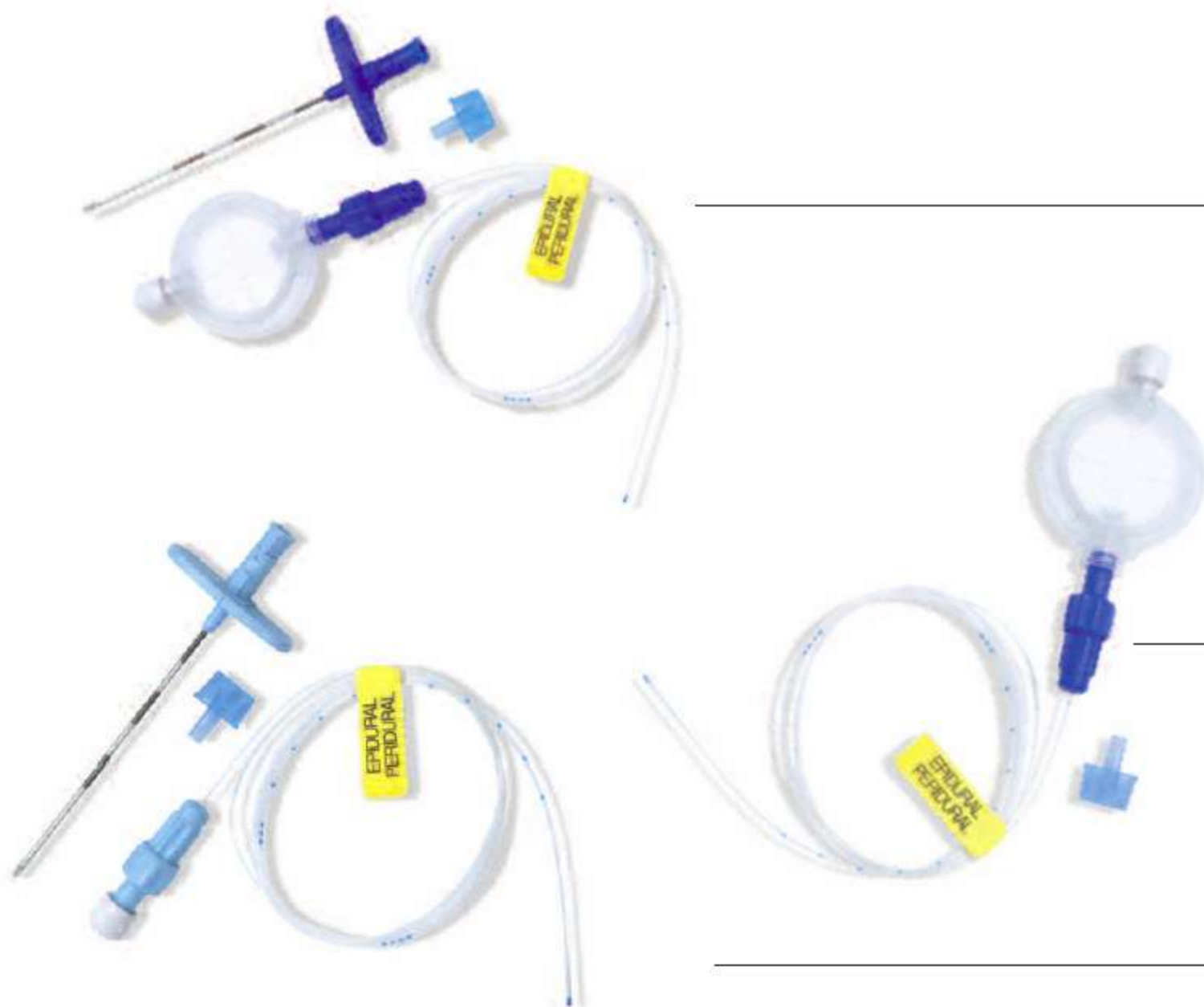
Tuohy Needle Gauge	Length	With Attachable Wings	Clear Catheter with Connector & Guide	Plastic LORD Size	Catheter Identification Label	0.2µm Epidural Filter	Product Code
18G	50mm	•	Closed End 3 Closer Eyes	10ml	•	•	100/391/180
19G	50mm	•	Open End	10ml	•	•	100/391/019

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" Trocar	Tuohy Needle (Blade 60mm) 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)

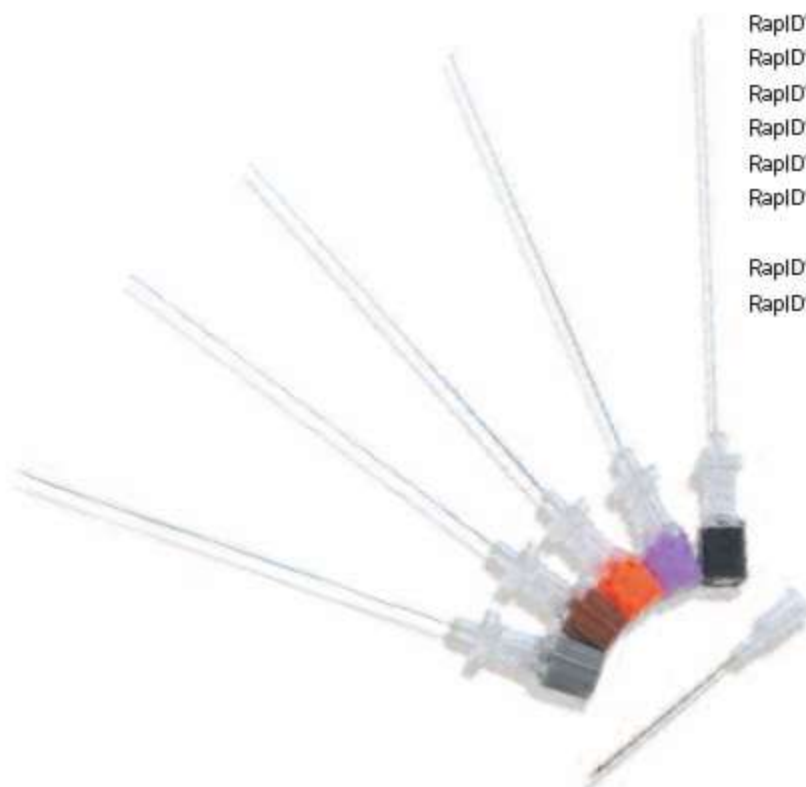
Specification

	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)

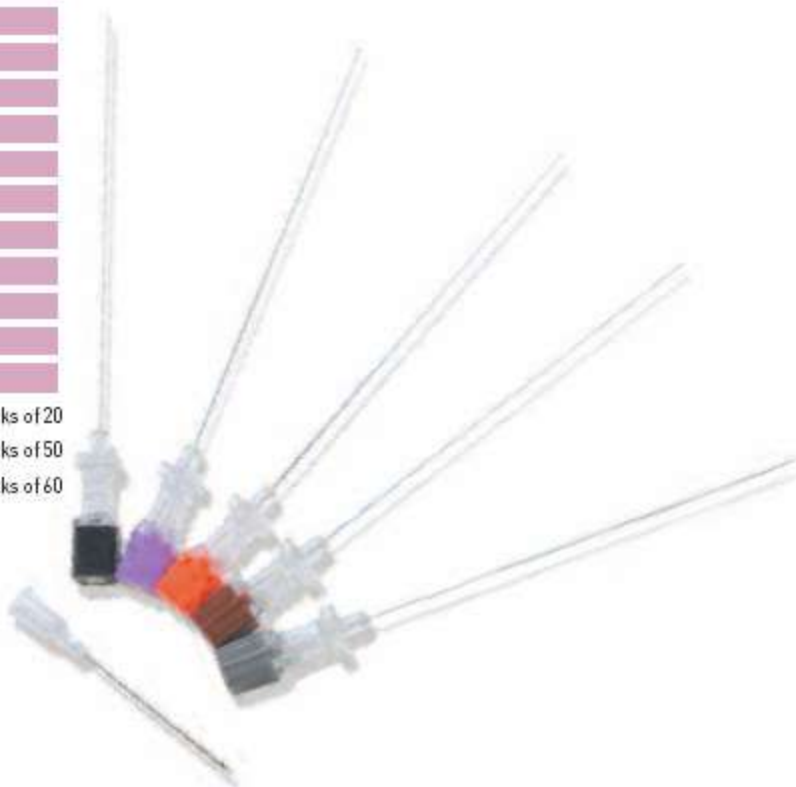
Specification

	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 Kwill	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	Spinal Needle Brand - R=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
----------------------	-------------

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
--------------	------

TRACER® III Replacement Leadset

Product Code	NLC3
--------------	------

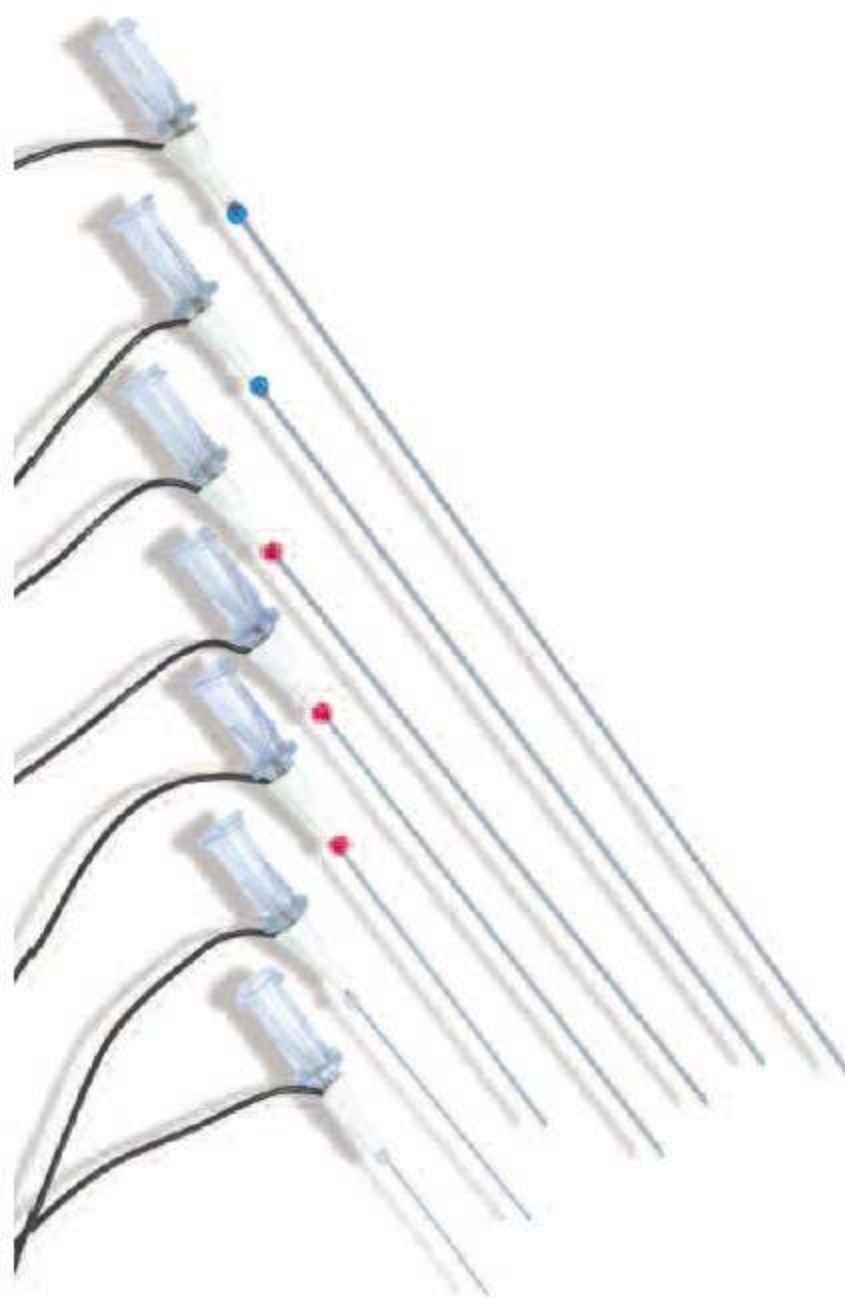
TRACER® III Adaptor Lead

Product Code	NLA3
--------------	------



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.

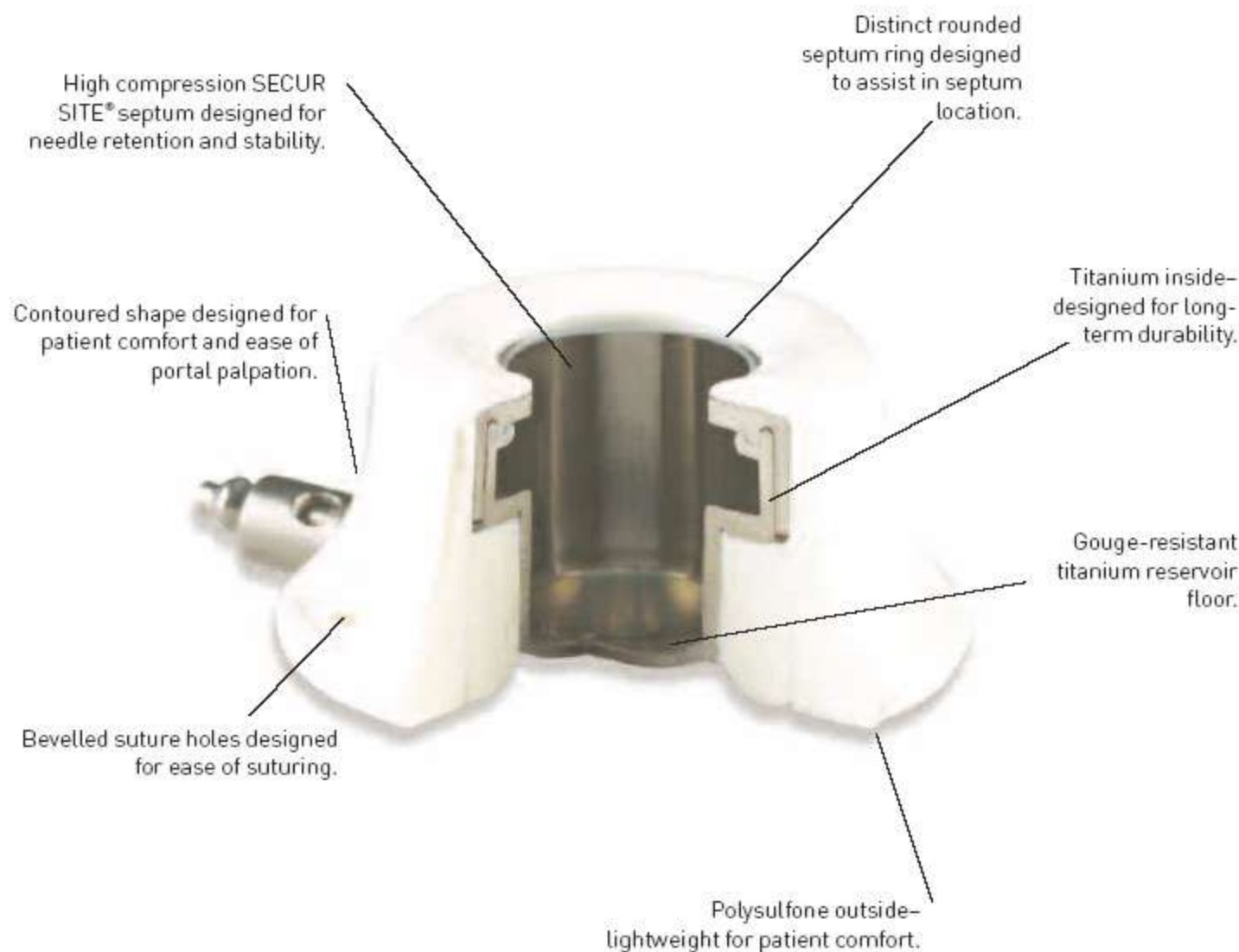


Epidural and Intra-Spinal Ports & Access Systems

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.



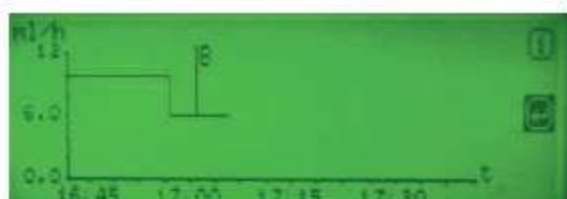
The Select Custom Kit process

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 Omnicare 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

Omnicare® PCA 0153-0001 (this part number refers to the UK variant).
Omnicare® 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*

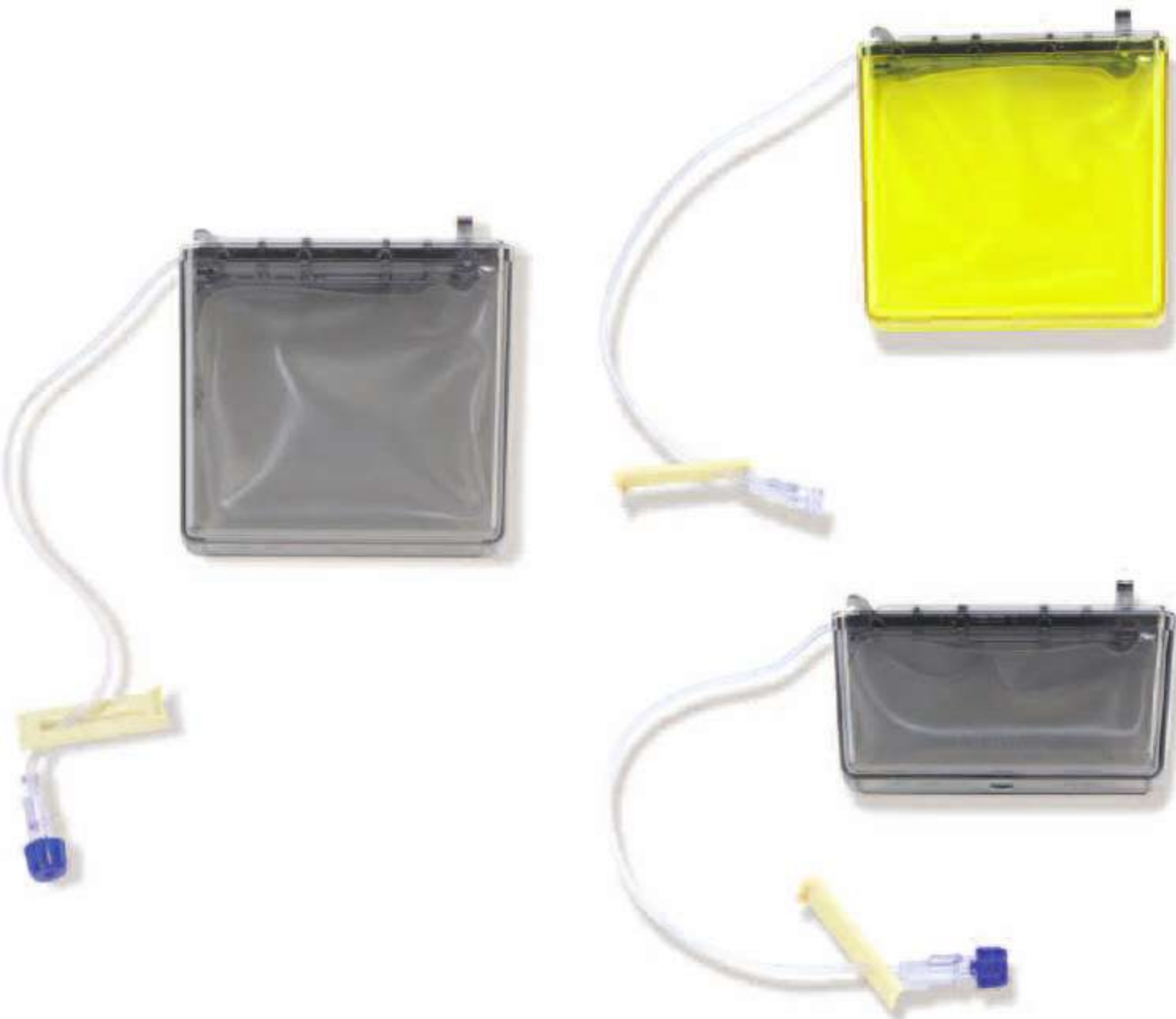
Resolution	0.050 ml per pump stroke
Size	4.4 cm x 10.4 cm x 14.1 cm (1.7 in. x 4.1 in. x 5.6 in.) excluding cassette or other accessories.
Weight	568 g (20 oz.) including 9-volt battery and empty 100 ml Medication Cassette reservoir, excluding other accessories.
Power Sources	9-volt alkaline or lithium 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® –

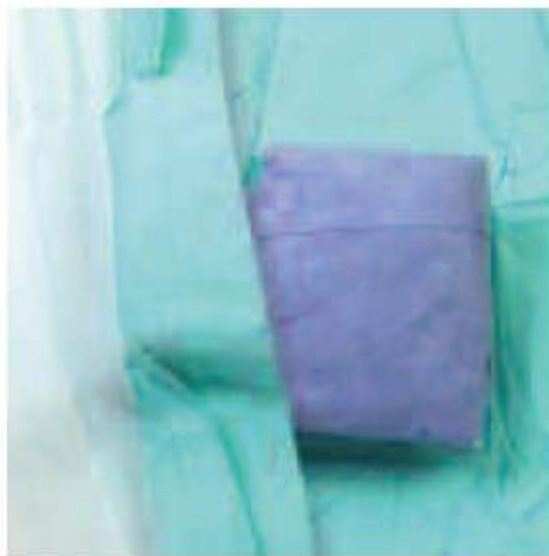
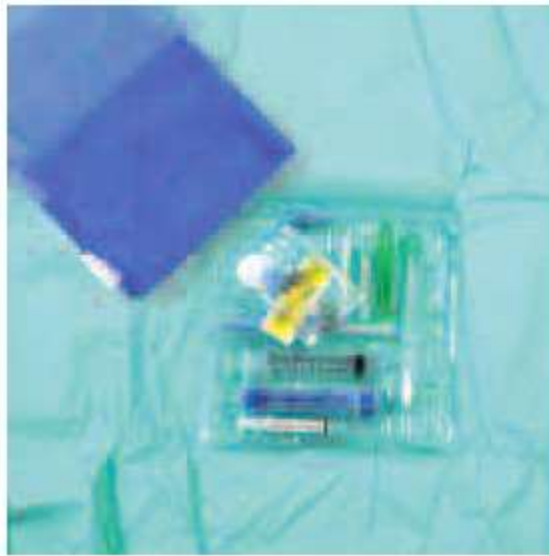
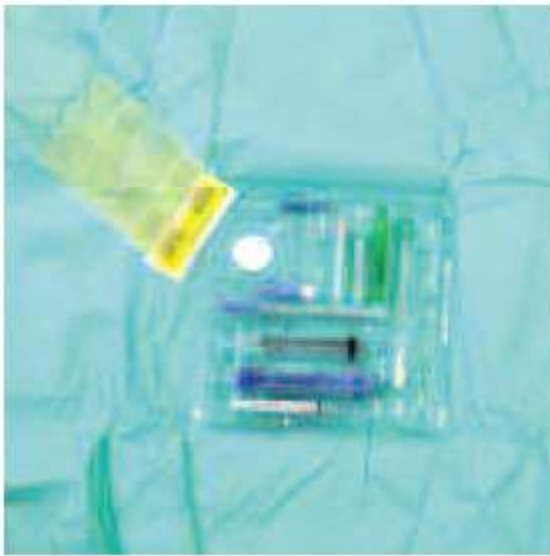
Needle with Needle Protection Device

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

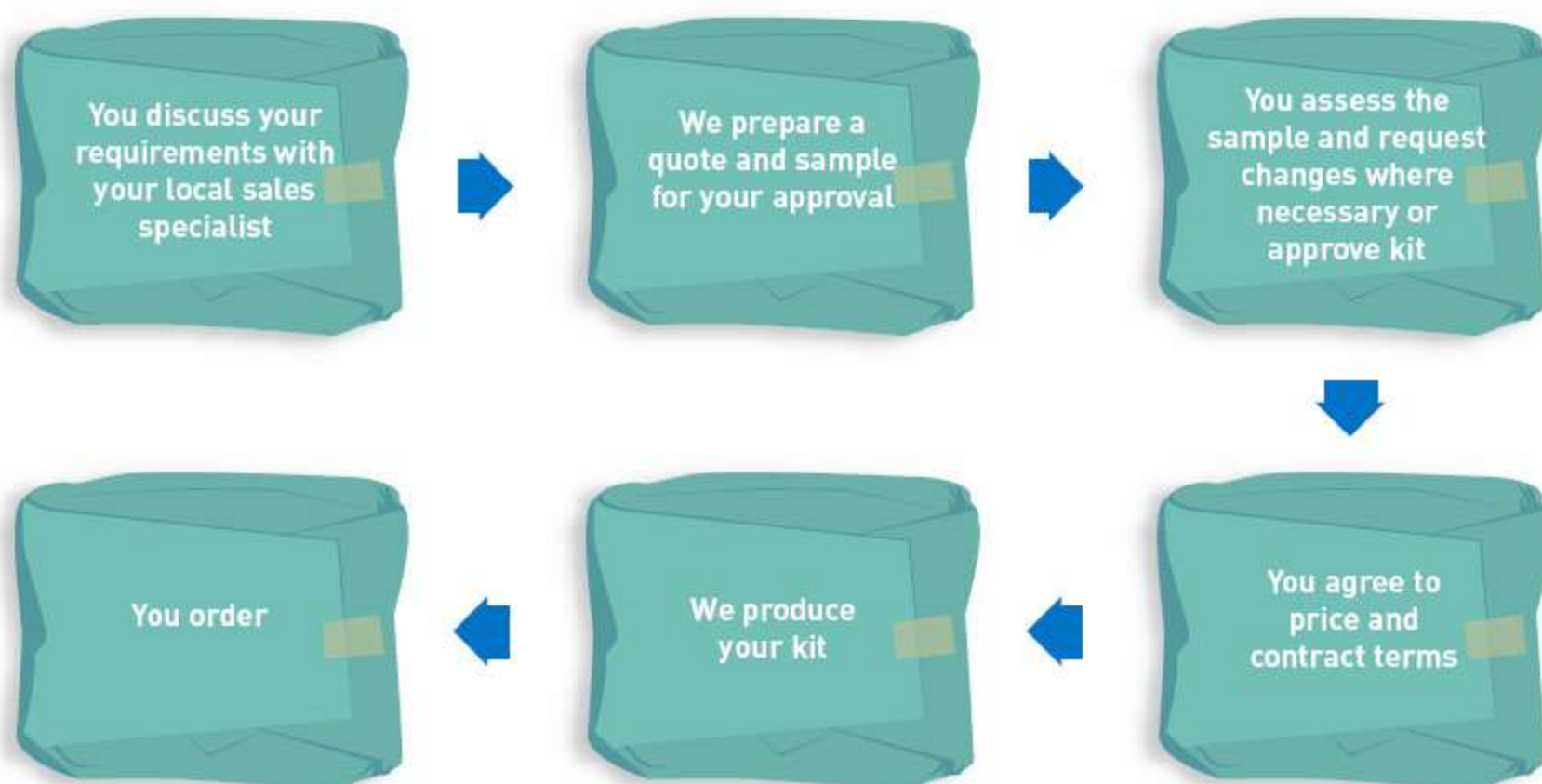
SELECT CUSTOM KITS

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

Smiths is a trademarks of Smiths Group plc.
Literature No. LIT/PM/2563

smiths

Smiths Medical - a part of Smiths Group plc

EC Design-Examination Certificate

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

No.**CE 660825****Issued To:**

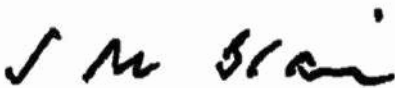
Smiths Medical ASD, Inc.
10 Bowman Drive
Keene
New Hampshire
03431
USA

In respect of:

Spinal and combined spinal/epidural needles including Correct Inject Spinal Needles

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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: **2017-06-16**

Date: **2017-06-16**

Expiry Date: **2022-06-15**

...making excellence a habit.™

Page 1 of 9

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

EC Design-Examination Certificate

Supplementary Information to CE 660825

Issued To:

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

Item Number:	Description:
100/389/022	SPINAL MAXIPACK 22G
100/389/725CS	CORRECTINJECT SPINAL MAXIPACK 25G PENCIL POINT
100/389/726CS	CORRECTINJECT SPINAL MAXIPACK 26G PENCIL POINT
100/389/825	SPINAL MAXIPACK PENCIL POINT NEEDLE SIZE 25G
100/389/826	SPINAL MAXIPACK PENCIL POINT NEEDLE SIZE 26G
100/396/116	SPINAL/EPIDURAL SET LANCET SPINAL NEEDLE 26G/16G
100/396/318	SPINAL/EPIDURAL NEEDLE SET WITH LOCK 27G LANCET 18G TUOHY
100/396/716	SPINAL/EPIDURAL NEEDLE SET WITH LOCK 27G P/PNT 16G TUOHY
100/396/718	SPINAL/EPIDURAL NEEDLE SET WITH LOCK 27G P/PNT 18G TUOHY
100/396/816	SPINAL/EPIDURAL SET PENCIL POINT SPINAL NEEDLE 26G/16G
100/396/916	SPINAL/EPIDURAL NEEDLE SET WITH LOCK 26G P/PNT 16G TUOHY
100/491/116	SPINAL/EPIDURAL MINIPACK LANCET POINT NEEDLE 26G/16G
100/491/318	SPINAL/EPIDURAL MINIPACK WITH LOCK 27G LANCET 18G TUOHY
100/491/618	SPINAL/EPIDURAL MINIPACK PENCIL POINT NEEDLE 27G/18G
100/491/716	SPINAL/EPIDURAL MINIPACK WITH LOCK 27G P/PNT 16G TUOHY
100/491/718	SPINAL/EPIDURAL MINIPACK WITH LOCK 27G P/PNT 18G TUOHY
100/491/816	SPINAL/EPIDURAL MINIPACK PENCIL POINT NEEDLE 26G/16G
100/491/818	SPINAL/EPIDURAL MINIPACK PENCIL POINT NEEDLE 26G/18G
100/491/916	SPINAL/EPIDURAL MINIPACK WITH LOCK 26G P/PNT 16G TUOHY
100/492/815	25G PENCIL POINT SPINAL NEEDLE+ INTRODUCER, EXTRA LENGTH
100/492/816	26G EXTRA LENGTH SPINAL NEEDLEWITH 20G INTRODUCER NEEDLE
100/492/817	27G PENCIL POINT SPINAL NEEDLEWITH 20G INTRODUCER NEEDLE
100/492/715CS	CORRECTINJECT SPINAL NEEDLE SET 25G EXTRA LENGTH PENCIL POINT
100/492/716CS	CORRECTINJECT SPINAL NEEDLE SET 26G EXTRA LENGTH PENCIL POINT
100/492/717CS	CORRECTINJECT SPINAL NEEDLE SET 27G EXTRA LENGTH PENCIL POINT

First Issued: **2017-06-16**

Date: **2017-06-16**

Expiry Date: **2022-06-15**

...making excellence a habit.™

Page 2 of 9

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

EC Design-Examination Certificate

Supplementary Information to CE 660825

Issued To:

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

Item Number:	Description:
100/496/022	22G LANCET POINT SPINAL NEEDLESET
100/496/024	24G LANCET POINT SPINAL NEEDLESET
100/496/025	25G LANCET POINT SPINAL NEEDLESET
100/496/026	26G LANCET POINT SPINAL NEEDLESET
100/496/027	27G LANCET SPINAL NEEDLE SET
100/496/122	SPINAL NEEDLE SET 22G PENCIL POINT NEEDLE
100/496/124	24G SPINAL NEEDLE SET (PENCIL POINT)
100/496/125	SPINAL NEEDLE SET 25G PENCIL POINT NEEDLE
100/496/126	SPINAL NEEDLE SET 26G PENCIL POINT NEEDLE
100/496/127	27G PENCIL SPINAL NEEDLE SET
100/496/222CS	CORRECTINJECT SPINAL NEEDLE SET 22G PENCIL POINT
100/496/224CS	CORRECTINJECT SPINAL NEEDLE SET 24G PENCIL POINT
100/496/225CS	CORRECTINJECT SPINAL NEEDLE SET 25G PENCIL POINT
100/496/226CS	CORRECTINJECT SPINAL NEEDLE SET 26G PENCIL POINT
100/496/227CS	CORRECTINJECT SPINAL NEEDLE SET 27G PENCIL POINT
100/497/125	SPINAL MIDI-TRAY 25G PENCIL POINT SPINAL NEEDLE
100/497/126	SPINAL MIDI-TRAY 26G PENCIL POINT SPINAL NEEDLE
100/497/225CS	CORRECTINJECT SPINAL MIDI-TRAY 25G PENCIL POINT
100/497/226CS	CORRECTINJECT SPINAL MIDI-TRAY 26G PENCIL POINT
100/497/227CS	CORRECTINJECT SPINAL MIDI-TRAY 27G PENCIL POINT
921/025/0180	25G CUSTOM PACK
921/116/0121	CUSTOM RA TRAY
921/127/0198	16G/27G CSECURE CUSTOM KIT

First Issued: **2017-06-16**

Date: **2017-06-16**

Expiry Date: **2022-06-15**

...making excellence a habit.™

Page 3 of 9

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

EC Design-Examination Certificate

Supplementary Information to CE 660825

Issued To:

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

Item Number:	Description:
922/025/0163	25G SPINAL PACK, POOLE HOSPITAL 10/CA
922/025/0319	SET ANESTESIA ESPINAL PUNTA LAPIZ 25G
922/025/0564	25G SPINAL CUSTOM KIT
922/025/0604	25G SPINAL CUSTOM KIT
922/025/0665	25G SPINAL CUSTOM KIT
922/027/0285	27G SPINAL CUSTOM PACK
922/027/0319	27G SPINAL CUSTOM KIT
922/027/0415	27G SPINAL CUSTOM KIT
922/027/0593	27G SPINAL CUSTOM SET
922/116/0302	16G/26G COMBINED SPINAL EPI PK NORF/NORWICH HOSP
922/116/0412	16/26G CSE CUSTOM KIT
922/118/0412	18/26G CSE CUSTOM KIT
922/126/0382	16G/26G CSECURE CUSTOM
922/127/0272	16G/27G CSECURE CUSTOM KIT NORTHWICK PARK HOSPITAL
922/127/0323	6G/27G CSE CUSTOM KIT
922/127/0372	CSE CUSTOM PACK
922/127/0383	16G/27G CSE CUSTOM KIT
922/127/0441	16G/27G CSECURE CUSTOM KIT
922/127/0657	16/27G CUSTOM SET 10/BX
924/026/0123	SPINAL NEEDLE EXTRA LENGTH
924/027/0157	27G SPINAL N'DLE
928/118/0001	18G/27G CSECURE CUSTOM KIT
928/118/0008	18G/27G CUSTOM KIT + CSECURE

First Issued: **2017-06-16**

Date: **2017-06-16**

Expiry Date: **2022-06-15**

...making excellence a habit.™

Page 4 of 9

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

EC Design-Examination Certificate

Supplementary Information to CE 660825

Issued To:

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

Item Number:	Description:
931/127/0065	18G/27G/CSECURE CUS KIT
932/025/0022	25G SPINAL PACK
932/025/0157	25G SPINAL CUSTOM KIT
932/025/0162	25G SPINAL CUST KIT
932/025/0163	25G SPINAL CUSTOM KIT
932/025/0464	25G SPINAL PACK
932/025/0519	25G SPINAL CUSTOM KIT
932/025/0519CS	25G SPINAL CUSTOM KIT
932/025/0547	25g SPINAL CUSTOM KIT
932/026/0516	26G SPINAL CUSTOM PACK
932/026/0546	26g SPINAL CUSTOM KIT
932/027/0388	27G SPINAL CUSTOM KIT
932/027/0458	27G SPINAL CUSTOM KIT
932/027/0498	27G SPINAL CUSTOM KIT
932/027/0612	27G CUSTOM KIT
932/027/0657	27G SPINAL HELSINGER MODEL
932/116/0104	16G/26G CSECURE
932/116/0517	16G/26G CSECURE CUSTOM KIT
932/126/0668	16G/26G CSECURE CUSTOM KIT
932/127/0100	18G/27G EPIDURAL/SPINAL
932/127/0479	18G/27G CSECURE CUSTOM PACK
932/127/0696	18G/27G CSECURE CUSTOM KIT
934/024/0006	24G SPINAL PACK

First Issued: **2017-06-16**

Date: **2017-06-16**

Expiry Date: **2022-06-15**

...making excellence a habit.™

Page 5 of 9

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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
 A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 660825

Issued To:

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

Item Number:	Description:
934/027/0000	27G SPINAL KIT
934/127/0001	16/27G CSECURE EPIDURAL KIT
936/025/0205	25G SPINL CUST PACK
936/027/0205	27G SPINL CUST PCK
936/118/0130	18G/27G EPIDUL/SNL CUST KIT W/SECURE
936/118/0132	18G/27G CSECURE CUSTOM KIT
937/025/0047	25G SPINAL SET
937/025/0102	25G SPINAL KIT SUS LUND/REGIONAL SKANE
937/027/0096	27G SPINAL CUSTOM KIT
937/027/0108	27G SPINAL KIT SUS LUND/REGIONAL SKANE
937/127/0040	18G/27G CSEcure CUSTOM KIT
937/127/0048	18G/27G CSE CUSTOM KIT
9EPD-102002	SPINAL SET 25G
9EPD-102003	SPINAL SET 27G
9EPD-122001	SPINAL SET 25G
9EPD-122001EVKH	SPINAL SET 25G
9EPD-401002	SPINAL SET 25G
9EPD-502592	SPINAL SET 26G
9EPD-528002	SPINAL SET 25G
9EPD-590653	SPINAL SET 26G
9EPD-602001	SPINAL SET 25G
9EPD-740002	SPINAL SET 27G
9EPD-803604	CSE SET 16G/26G

First Issued: **2017-06-16**

Date: **2017-06-16**

Expiry Date: **2022-06-15**

...making excellence a habit.™

Page 6 of 9

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

EC Design-Examination Certificate

Supplementary Information to CE 660825

Issued To:

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

Item Number:	Description:
9EPD-803605	CUSTOM SPINAL SET 26 G
9EPD-833001	SPINAL CUSTOM PACK
9EPD-849002	SPINAL SET, 22G
9EPD-877501	SPINAL SET 26G
A3562-24	LUMBAR PUNCTURE (EDD) W/O DRUGS
A3808-24	LUMBAR TRAY (EDD) W/O DRUGS
A4062-22	LUMBAR TRAY (EDD) W/O DRUGS
A4075-22	LUMBAR TRAY (EDD) W/O DRUGS
E619 22G	22G SPINAL MAXIPACK
E620 25G	25G SPINAL MAXIPACK
EPSPCC0001	27G SPINAL SET
G421	26G SPINAL MAXIPACK
G888	24G SPINAL MAXIPACK ATRAUMATIC
G972	27G SPINAL MAXIPACK
G973	25G SPINAL MAXIPACK
J651/61	25G SPINAL CUSTOM MAXIPACK
J653/61	18/27G CSE CUSTOM MAXIPACK
J654/61	18/25G CSE CUSTOM MAXIPACK
L741-61	25G WHITACRE SPINAL NEEDLE SINGLE PACKED
L746-61	22G SPINAL NEEDLE -QUINCKE SINGLE PACKED
M121	24G ATRAUMATIC SPINAL NEEDLE INTRODUCER
M122	25G WHITACRE SPINAL NEEDLE WITH INTRODUCER

First Issued: **2017-06-16**

Date: **2017-06-16**

Expiry Date: **2022-06-15**

...making excellence a habit.™

Page 7 of 9

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

EC Design-Examination Certificate

Supplementary Information to CE 660825

Issued To:

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

Item Number:	Description:
M145	18/25G CSE NEEDLE SET WHITACRE
M146	18/25G CSE MINIPACK WHITACRE
M341	29G QUINCKE SPINAL NEEDLE WITH INTRODUCER
M729-61	27G WHITACRE SPINAL NEEDLE WITH INTRODUCER
MAX251	SPINAL MAXIPACK 25G
MAX261	SPINAL MAXIPACK 26G
MAX271	SPINAL MAXIPACK 27G
SPICC0001	SPINAL SET 27g
SPIFC00302	SPINAL SET 25G
SPIFC00902	SPINAL SET 25G
928/127/0016	18G/27G CUSTOM KIT SEQUENTIAL CSECURE C. HOSPITALAR 10/BX
EPICC0018	CSE PROCEDURESET - GENTOFTE
SPICC0017	SPINALSET SLL, 25G 10/BX
SPICC0012	Custom Spinal Sg ShotTray
922/025/0345	25G SPINAL CUSTOM KIT

First Issued: **2017-06-16**

Date: **2017-06-16**

Expiry Date: **2022-06-15**

...making excellence a habit.™

Page 8 of 9

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

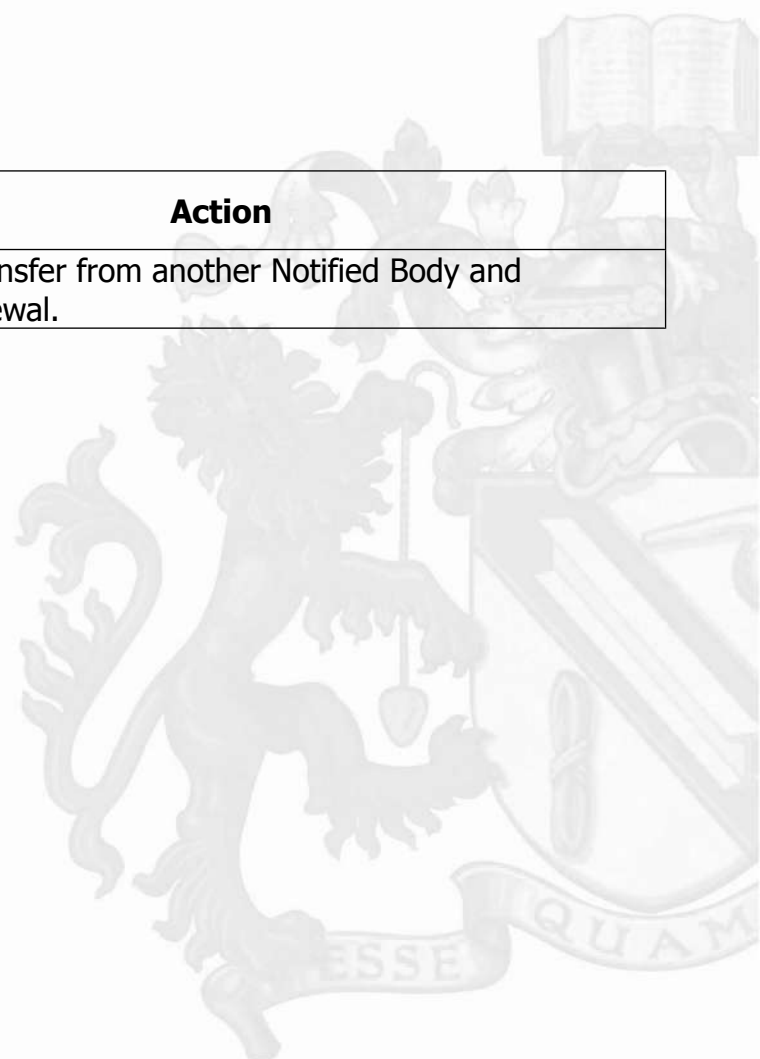
EC Design-Examination Certificate

Supplementary Information to CE 660825

Issued To:

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

Date	Reference Number	Action
Current	10166127	First issue. Transfer from another Notified Body and certificate renewal.

First Issued: **2017-06-16**Date: **2017-06-16**Expiry Date: **2022-06-15**

...making excellence a habit.™

Page 9 of 9

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

Certificat CE – Examinarea proiectului

Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa II, Secțiunea 4

Nr. **CE 660825**
Emis pentru: **Smith Medical ASD, Inc.**
10 Bowman Drive
Keene
New Hampshire
03431
SUA

Cu privire la:

Ace spinale si combinate – spinale/epidurale, incluzand ace spinale pentru injectie corecta.

BSI a examinat proiectul, conform cerințelor Directivei Consiliului 93/42/CEE, Anexa II, Secțiunea 4. Proiectul îndeplinește cerințele directivei. Pentru plasarea pe piață a acestor produse este necesar un certificat additional, prevazut de Anexa II secțiunea 4.

Pentru și în numele BSI, Organism de Notificare pentru Directiva de mai sus (Număr Organism de Notificare 0086):

Semnătura – indescifrabilă

Stewart Brain, Director Conformitate și Risc
Dispozitive Medicale

Prima emitere: 16-06-2017 Data: 16-06-2017 Data expirării: 15-06-2022

.. making excellence a habit.™

Pagina 1 din 9

Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate în conformitate cu cerințele Directivei așa după cum s-a demonstrat prin activitățile solicitate Organismului de Notificare. Această aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte în numele societății numită pe acest certificat, dacă nu s-a agreat în mod expres de către BSI.

Acest certificat a fost emis electronic și este în legătură cu condițiile contractuale.

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK Membră a Grupului de Societăți BSI.



...making excellence a habit.™



Certificat CE – Examinarea proiectului

Informatii suplimentare pentru CE 660825

Emis pentru:



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



Numarul articolului:	Descriere:
100/389/022	MAXIPACHET SPINAL 22G
100/389/725CS	MAXIPACHET SPINAL CORRECTINJECT 25G VARF CREION
100/389/726CS	MAXIPACHET SPINAL CORRECTINJECT 26G VARF CREION
100/389/825	MAXIPACHET SPINAL VARF CREION DIMENSIUNE AC 25G
100/389/826	MAXIPACHET SPINAL VARF CREION DIMENSIUNE AC 26G
100/396/116	SET SPINAL/EPIDURAL LANTETA SPINALA AC 26G/16G
100/396/318	SET AC SPINAL/EPIDURAL CU AMBOU 27G LANTETA 18G TUOHY
100/396/716	SET AC SPINAL/EPIDURAL CU AMBOU 27G P/PNT 16G TUOHY
100/396/718	SET AC SPINAL/EPIDURAL CU AMBOU 27G P/PNT 18G TUOHY
100/396/816	SET SPINAL/EPIDURAL VARF CREION AC SPINAL 26G/16G
100/396/916	SET AC SPINAL/EPIDURAL CU AMBOU 26G P/PNT 16G TUOHY
100/491/116	MINIPACHET SPINAL/EPIDURAL AC CU VARF LANTETA 26G/16G
100/491/318	MINIPACHET SPINAL/EPIDURAL CU AMBOU 27G LANTETA 18G TUOHY
100/491/618	MINIPACHET SPINAL/EPIDURAL VARF CREION AC 27G/18G
100/491/716	MINIPACHET SPINAL/EPIDURAL CU AMBOU 27G P/PNT 16G TUOHY
100/491/718	MINIPACHET SPINAL/EPIDURAL CU AMBOU 27G P/PNT 18G TUOHY
100/491/816	MINIPACHET SPINAL/EPIDURAL VARF CREION AC 26G/16G
100/491/818	MINIPACHET SPINAL/EPIDURAL VARF CREION AC 26G/18G
100/491/916	MINIPACHET SPINAL/EPIDURAL CU AMBOU 26G P/PNT 16G TUOHY
100/492/815	25G AC SPINAL CU VARF CREION+ INTRODUCATOR, EXTRALUNG
100/492/816	26G AC SPINAL EXTRALUNG CU 20G AC INTRODUCATOR
100/492/817	27G AC SPINAL CU VARF CREION CU 20G AC INTRODUCATOR
100/492/715CS	SET AC SPINAL CORRECTINJECT 25G EXTRALUNG VARF CREION
100/492/716CS	SET AC SPINAL CORRECTINJECT 26G EXTRALUNG VARF CREION
100/492/717CS	SET AC SPINAL CORRECTINJECT 27G EXTRALUNG VARF CREION

Prima emitere: **2017-06-16**

Data: **2017-06-16**

Data expirării: **2022-06-15**

Pagina2 din 9

Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate în conformitate cu cerințele Directivei așa după cum s-a demonstrat prin activitățile solicitate Organismului de Notificare. Această aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte în numele societății numită pe acest certificat, dacă nu s-a agreat în mod expres de către BSI.

Acest certificat a fost emis electronic și este în legătură cu condițiile contractuale.

Certificat CE – Examinarea proiectului

Informatii suplimentare pentru CE 660825

Emis pentru:



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



Numarul articolului:	Descriere:
100/496/022	22G SET AC SPINAL CU VARF LANTETA
100/496/024	24G SET AC SPINAL CU VARF LANTETA
100/496/025	25G SET AC SPINAL CU VARF LANTETA
100/496/026	26G SET AC SPINAL CU VARF LANTETA
100/496/027	27G SET AC SPINAL CU VARF LANTETA
100/496/122	SET ACESPINAL 22G VARF CREION AC
100/496/124	24G SET ACESPINAL (VARF CREION)
100/496/125	SET ACESPINAL 25G VARF CREION AC
100/496/126	SET ACESPINAL 26G VARF CREION AC
100/496/127	27G SET AC SPINAL CU VARF CREION
100/496/222CS	SET AC SPINAL CORRECTINJECT 22G VARF CREION
100/496/224CS	SET AC SPINAL CORRECTINJECT 24G VARF CREION
100/496/225CS	SET AC SPINAL CORRECTINJECT 25G VARF CREION
100/496/226CS	SET AC SPINAL CORRECTINJECT 26G VARF CREION
100/496/227CS	SET AC SPINAL CORRECTINJECT 27G VARF CREION
100/497/125	TRAIECT SPINAL MEDIU 25G AC SPINAL CU VARF CREION
100/497/126	TRAIECT SPINAL MEDIU 26G AC SPINAL CU VARF CREION
100/497/225CS	TRAIECT SPINAL MEDIU CORRECTINJECT 25G VARF CREION
100/497/226CS	TRAIECT SPINAL MEDIU CORRECTINJECT 26G VARF CREION
100/497/227CS	TRAIECT SPINAL MEDIU CORRECTINJECT 27G VARF CREION
921/025/0180	25G PACHET PERSONALIZAT
921/116/0121	TRAIECT RA PERSONALIZAT
921/127/0198	16G/27G CSECURE SET PERSONALIZAT

Prima emitere: **2017-06-16**Data: **2017-06-16**Data expirării: **2022-06-15**

...making excellence a habit.™

Pagina3 din 9

Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate în conformitate cu cerințele Directivei așa după cum s-a demonstrat prin activitățile solicitate Organismului de Notificare. Această aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte în numele societății numită pe acest certificat, dacă nu s-a agreat în mod expres de către BSI.

Acest certificat a fost emis electronic și este în legătură cu condițiile contractuale.

Certificat CE – Examinarea proiectului

Informatii suplimentare pentru CE 660825

Emis pentru:



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



Numarul articolului:	Descriere:
922/025/0163	PACHET SPINAL, POOLE HOSPITAL 25G 10/CA
922/025/0319	SET SPINAL ANESTEZIE PUNTA LAPIZ 25G
922/025/0564	25G SET SPINAL PERSONALIZAT
922/025/0604	25G SET SPINAL PERSONALIZAT
922/025/0665	25G SET SPINAL PERSONALIZAT
922/027/0285	27G PACHET SPINAL PERSONALIZAT
922/027/0319	27G SET SPINAL PERSONALIZAT
922/027/0415	27G SET SPINAL PERSONALIZAT
922/027/0593	27G SET SPINAL PERSONALIZAT
922/116/0302	16G/26G PACHET COMBINAT SPINAL/EPIDURALPK NORF/NORWICH HOSP
922/116/0412	16/26G CSE SET PERSONALIZAT
922/118/0412	18/26G CSE SET PERSONALIZAT
922/126/0382	16G/26G CSECURE PERSONALIZAT
922/127/0272	16G/27G CSECURE SET PERSONALIZAT NORTHWICK PARK HOSPITAL
922/127/0323	6G/27G CSE SET PERSONALIZAT
922/127/0372	CSE PACHET PERSONALIZAT
922/127/0383	16G/27G CSE SET PERSONALIZAT
922/127/0441	16G/27G CSECURE SET PERSONALIZAT
922/127/0657	16/27G SET PERSONALIZAT 10/CUTIE
924/026/0123	AC SPINAL EXTRALUNG
924/027/0157	27G SPINAL N'DLE
928/118/0001	18G/27G CSECURE SET PERSONALIZAT
928/118/0008	18G/27G SET PERSONALIZAT + CSECURE

Prima emitere: **2017-06-16**Data: **2017-06-16**Data expirării: **2022-06-15**

Pagina 4 din 9

Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate în conformitate cu cerințele Directivei așa după cum s-a demonstrat prin activitățile solicitate Organismului de Notificare. Această aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte în numele societății numită pe acest certificat, dacă nu s-a agreeat în mod expres de către BSI.

Acest certificat a fost emis electronic și este în legătură cu condițiile contractuale.

Certificat CE – Examinarea proiectului

Informatii suplimentare pentru CE 660825

Emis pentru:



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



Numarul articolului:	Descriere:
931/127/0065	18G/27G/CSECURE SET PERSONALIZAT
932/025/0022	25G PACHET SPINAL
932/025/0157	25G SET SPINAL PERSONALIZAT
932/025/0162	25G SET SPINAL PERSONALIZAT
932/025/0163	25G SET SPINAL PERSONALIZAT
932/025/0464	25G PACHET SPINAL
932/025/0519	25G SET SPINAL PERSONALIZAT
932/025/0519CS	25G SET SPINAL PERSONALIZAT
932/025/0547	25g SET SPINAL PERSONALIZAT
932/026/0516	26G PACHET SPINAL PERSONALIZAT
932/026/0546	26g SET SPINAL PERSONALIZAT
932/027/0388	27G SET SPINAL PERSONALIZAT
932/027/0458	27G SET SPINAL PERSONALIZAT
932/027/0498	27G SET SPINAL PERSONALIZAT
932/027/0612	27G SET PERSONALIZAT
932/027/0657	27G SPINAL HELSINGER MODEL
932/116/0104	16G/26G CSECURE
932/116/0517	16G/26G CSECURE SET PERSONALIZAT
932/126/0668	16G/26G CSECURE SET PERSONALIZAT
932/127/0100	18G/27G EPIDURAL/SPINAL
932/127/0479	18G/27G CSECURE PACHET PERSONALIZAT
932/127/0696	18G/27G CSECURE SET PERSONALIZAT
934/024/0006	24G PACHET SPINAL

Prima emitere: **2017-06-16**Data: **2017-06-16**Data expirării:
2022-06-15

...making excellence a habit.™

Pagina 5 din 9

Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate în conformitate cu cerințele Directivei așa după cum s-a demonstrat prin activitățile solicitate Organismului de Notificare. Această aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte în numele societății numită pe acest certificat, dacă nu s-a agreeat în mod expres de către BSI.
 Acest certificat a fost emis electronic și este în legătură cu condițiile contractuale.

Certificat CE – Examinarea proiectului

Informatii suplimentare pentru CE 660825

Emis pentru:



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



Numarul articolului:	Descriere:
934/027/0000	27G SET SPINAL
934/127/0001	16/27G CSECURE EPIDURAL KIT
936/025/0205	25G PACHET SPINAL PERSONALIZAT
936/027/0205	27G PACHET SPINAL PERSONALIZAT
936/118/0130	18G/27G SET EPIDURAL/SPINAL PERSONALIZAT CU PROTECTIE
936/118/0132	18G/27G CSECURE SET PERSONALIZAT
937/025/0047	25G SET SPINAL
937/025/0102	25G SET SPINAL SUS LUND/REGIONAL SKANE
937/027/0096	27G SET SPINAL PERSONALIZAT
937/027/0108	27G SET SPINAL SUS LUND/REGIONAL SKANE
937/127/0040	18G/27G CSECURE - SET PERSONALIZAT
937/127/0048	18G/27G CSE SET PERSONALIZAT
9EPD-102002	SET SPINAL 25G
9EPD-102003	SET SPINAL 27G
9EPD-122001	SET SPINAL 25G
9EPD-122001EVKH	SET SPINAL 25G
9EPD-401002	SET SPINAL 25G
9EPD-502592	SET SPINAL 26G
9EPD-528002	SET SPINAL 25G
9EPD-590653	SET SPINAL 26G
9EPD-602001	SET SPINAL 25G
9EPD-740002	SET SPINAL 27G
9EPD-803604	CSE SET 16G/26G

Prima emitere: **2017-06-16**Data: **2017-06-16**Data expirării: **2022-06-15**

...making excellence a habit.™

Pagina 6 din 9

Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate în conformitate cu cerințele Directivei așa după cum s-a demonstrat prin activitățile solicitate Organismului de Notificare. Această aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte în numele societății numită pe acest certificat, dacă nu s-a agreat în mod expres de către BSI.

Acest certificat a fost emis electronic și este în legătură cu condițiile contractuale.

Certificat CE – Examinarea proiectului

Informatii suplimentare pentru CE 660825

Emis pentru:



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



Numarul articolului:	Descriere:
9EPD-803605	SETN SPINAL PERSONALIZAT 26 G
9EPD-833001	PACHET SPINAL PERSONALIZAT
9EPD-849002	SET SPINAL, 22G
9EPD-877501	SET SPINAL 26G
A3562-24	PUNCTIE LOMBARA (EDD) FARA MEDICAMENTE
A3808-24	TRAIECT LOMBAR (EDD) FARA MEDICAMENTE
A4062-22	TRAIECT LOMBAR (EDD) FARA MEDICAMENTE
A4075-22	TRAIECT LOMBAR (EDD) FARA MEDICAMENTE
E619 22G	22G MAXIPACHET SPINAL
E620 25G	25G MAXIPACHET SPINAL
EPSPCC0001	27G SET SPINAL
G421	26G MAXIPACHET SPINAL
G888	24G MAXIPACHET SPINAL ATRAUMATIC
G972	27G MAXIPACHET SPINAL
G973	25G MAXIPACHET SPINAL
J651/61	25G MAXIPACHET SPINAL PERSONALIZAT
J653/61	18/27G CSE MAXIPACHET PERSONALIZAT
J654/61	18/25G CSE MAXIPACHET PERSONALIZAT
L741-61	25G WHITACRE AC SPINAL AMBALAT INDIVIDUAL
L746-61	22G AC SPINAL -QUINCKE AMBALAT INDIVIDUAL
M121	24G ATRAUMATIC AC SPINAL INTRODUCATOR
M122	25G WHITACRE AC SPINAL CU INTRODUCATOR

Prima emitere: **2017-06-16**Data: **2017-06-16**Data expirării: **2022-06-15**

...making excellence a habit.™

Pagina7 din 9

Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate în conformitate cu cerințele Directivei așa după cum s-a demonstrat prin activitățile solicitate Organismului de Notificare. Această aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte în numele societății numită pe acest certificat, dacă nu s-a agreeat în mod expres de către BSI.
 Acest certificat a fost emis electronic și este în legătură cu condițiile contractuale.

Certificat CE – Examinarea proiectului

Informatii suplimentare pentru CE 660825

Emis pentru:

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

Numarul articolului:	Descriere:
M145	18/25G CSE SET ACE WHITACRE
M146	18/25G CSE MINIPACHET WHITACRE
M341	29G QUINCKE AC SPINAL cu INTRODUCATOR
M729-61	27G WHITACRE AC SPINAL cu INTRODUCATOR
MAX251	MAXIPACHET SPINAL 25G
MAX261	MAXIPACHET SPINAL 26G
MAX271	MAXIPACHET SPINAL 27G
SPICC0001	SET SPINAL 27g
SPIFC00302	SET SPINAL 25G
SPIFC00902	SET SPINAL 25G
928/127/0016	18G/27G SET PERSONALIZAT SECVENTIAL CSECURE C. HOSPITALAR 10/CUTIE
EPICC0018	CSE SET PROCEDURAL - GENTOFTE
SPICC0017	SET SPINAL SLL, 25G 10/CUTIE
SPICC0012	Traiect personalizat pentru injective, de unica folosinta
922/025/0345	25G SET SPINAL PERSONALIZAT

Prima emitere: **2017-06-16**Data: **2017-06-16**Data expirării: **2022-06-15**
...making excellence a habit.™

Pagina 8 din 9

Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate în conformitate cu cerințele Directivei așa după cum s-a demonstrat prin activitățile solicitate Organismului de Notificare. Această aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte în numele societății numită pe acest certificat, dacă nu s-a agreat în mod expres de către BSI.

Acest certificat a fost emis electronic și este în legătură cu condițiile contractuale.

Certificat CE – Examinarea proiectului

Informatii suplimentare pentru CE 660825

Emis pentru:

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

Data	Numar de referinta	Actiune
Curenta	10166127	Prima editie. Transfer de la alt organ de certificare si inoie certificat.

Subsemnata **MUSUROIA MIRELA**, traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traduceri cu textul înscrisului original în limba engleza, ce a fost vizat de mine.

Traducător autorizat
Nr. 2769/2015



Prima emitere: **2017-06-16**



Data expirării: **2022-06-15**

Pagina 9 din 9

Valabilitatea acestui certificat este condiționată de menținerea sistemului de calitate în conformitate cu cerințele Directivei așa după cum s-a demonstrat prin activitățile solicitate Organismului de Notificare. Această aprobare exclude toate produsele proiectate și/sau fabricate de o terță parte în numele societății numită pe acest certificat, dacă nu s-a agreat în mod expres de către BSI.

Acest certificat a fost emis electronic și este în legătură cu condițiile contractuale.

Informații și Contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, Tel.: +44 815 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK Membră a Grupului de Societăți BS

Intertek

Intertek

SMITHS MEDICAL CZECH REPUBLIC a.s.

a fost evaluat și înregistrat de AMTAC Certification Services Limited ca fiind conform cerințelor:

EN ISO 13485:2012

Proiectarea, asamblarea, fabricarea, ambalarea si furnizarea de:

Dispozitive și Accesorii pentru Obstetrică și Ginecologie,
 Dispozitive și Accesorii Intervenție Imagistică,
 Dispozitive de Management al Oxigenului și Umidității,
 Dispozitive și Accesorii de Management al Durerii,
 Dispozitive și Accesorii Invasive de Monitorizare a Tensiunii Pacientului,
 Dispozitive Traheotomie,
 Dispozitive de Unică Folosință pentru Injecții,
 Dispozitive Catetere Aspirare,
 Sisteme de Dispozitive de Intubare.

Certificat Număr: 1201-04 B
Data Inițială a Certificării: 10 Ianuarie, 2014
Data Efectivă a Certificatului: 22 Mai 2017
Data Expirării Certificatului: 28 Februarie 2019

Brian Johnson

AMTAC Certification Services Limited, Milton Keynes, UK

Acest Certificat este proprietatea AMTAC Certification Services Ltd



10.3



În emitera acestui certificat, Intertek nu asumă nicio răspundere față de altă Parte în afara de Client, și aceasta, numai în conformitate cu Acordul de Certificare agree. Validitatea acestui certificat depinde de păstrarea de către organizație a sistemului în conformitate cu cerințele Intertek pentru sisteme de certificare. Validitatea poate fi confirmată prin email la certificates.validation@intertek.com sau prin scanearea codului din dreapta cu un AMTAC Certification Systems Limited este deținută de AMTAC Certification Systems Holdings Limited, care este o succursală juridică integrală de Intertek UK Holdings Limited. AMTAC Certification Systems Limited este un organism acreditat înregistrat la UKAS cu numărul de identificare 001. În emitera acestui certificat, AMTAC nu-și asumă nicio responsabilitate față de nicio parte, altă decât Clientul, și aceasta numai în conformitate cu Termenii și Condițiile agree. Certificatul rămâne proprietatea Intertek, careia îi trebuie returnat la cerere.

CT-IS 9001:2008-UKAS-EN-17-P-04 12

Subsemnata **MUSUROIA MIRELA**, traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traduceri cu textul înscrisului original în limba engleza, ce a fost vizat de mine.

Traducător autorizat
Nr. 2769/2015



Certificate of Registration



Intertek

This is to certify that the quality management system of

SMITHS MEDICAL INTERNATIONAL LIMITED

Boundary Road, Hythe, Kent, CT21 6JL, UK

has been assessed and registered by AMTAC Certification Services Limited as conforming to the requirements of:

EN ISO 13485:2012

The quality management system is applicable to:

Design of:

Breathing Systems, Drainage Devices, Feeding Devices,
Filtration Devices, Infusion Disposables, Intubation Systems, Obstetrics and Gynaecology
Devices, Oxygen and Humidity Management Devices, Pressure Monitoring Devices,
Respiratory Mechanics Devices, Resuscitation Devices,
Suction Catheters, Tracheostomy Tubes, Vascular Access Devices, Cardio Thoracic
Catheters and Drapes

Additional Site:

Human Resources and Training, Shipping, Demand Planning, Post Market Surveillance,
Market Intelligence, E-Business, International Customer Services, Business Development,
Registrations, Finance, Wallace Women's Healthcare

Certificate Number:	053-01 B
Initial Certification Date:	20 October 2005
Certificate Effective Date:	23 July 2016
Certificate Expiry Date:	22 July 2019



061



Brian Johnson

AMTAC Certification Services Limited, Milton Keynes, UK

This certificate is the property of AMTAC Certification Services Ltd

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. AMTAC Certification Services Limited is owned by AMTAC Certification Services Holdings Limited, which is a wholly owned subsidiary of Intertek UK Holdings Limited. AMTAC Certification Services Limited is an accredited body registered under UKAS with the identification number of 061. In the issuance of this certificate, AMTAC assumes no liability to any party other than to the Client and then only in accordance with the agreed Terms and Conditions.



The certificate remains the property of Intertek, to whom it must be returned upon request.

Intertek

MINISTERUL JUSTITIEI
MUSUROIA
MIRELA
Act. Nr. 2769
2009
AUTORIZAT