

# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

**No.**

**CE 540596**

**Issued To:**

**Teleflex Medical  
IDA Business and Technology Park  
Dublin Road  
Athlone  
Co. Westmeath  
Ireland**

In respect of:

**Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of non-active respiratory, non-active gynaecological, non-active regional anaesthesia, non-active surgical and non-active urology devices.**

**Those aspects of manufacturing relating to obtaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.**

**The manufacture of non-active and active surgical devices for adult and paediatric intraosseous infusion, bone marrow aspiration, bone marrow biopsy, bone lesion biopsy and non-active sterile urology catheters.**

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

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-01-13**

Date: **2020-06-09**

Expiry Date: **2024-05-26**

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Page 1 of 3

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.

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# EC Certificate - Production Quality Assurance

## Supplementary Information to CE 540596

Issued To:

**Teleflex Medical**  
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**Ireland**

Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
MD 0102	Sterile Intraosseous Vascular Access System	--
MD 1104	Non-sterile Intraosseous Vascular Access System	
MD 0102	Sterile Powered Bone Access	--
MD 1104	Non-sterile Powered Bone Access	
MD 0102	Sterile Sternal Intraosseous Device	--
MD 0101	Sterile Silicone Foley Catheter	--

First Issued: **2009-01-13**Date: **2020-06-09**Expiry Date: **2024-05-26**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Number	Device Name	Intended purpose per IFU
<b>Class Is</b>		
MD 0301	Intraosseous Vascular Access System Stabilizer	--
MD 0102	Powered bone access connector	--
MD 0101	Tracheostomy Tube Accessories	--
MD 0102	Tuohy Borst Adaptor	--
MD 0102	Syringe	--
MD 0101	Urology Dilator	--
MD 0101	Guedel Airway	--
MD 0101	Intrauterine Catheter Set	--
MD 0101	Sterile Container	--
MD 0101	Neckband	--
<b>Sterility aspects only</b>		
---	Procedure Packs under article 12	---

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# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

## List of Significant Subcontractors

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

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**Ireland**

Subcontractor:	Service(s) supplied
ArcRoyal Virginia Road Kells, Co. Meath Ireland	Manufacture
Arriol International Corporation Carretera San Isidro KM 17 Zona Franca San Isidro Santo Domingo Este Dominican Republic	ETO Sterilization Manufacture
Arrow International CR, a.s. Jamska 2359/47 Zdar Nad Sazavou 59101 Czech Republic	Manufacture
BBF Sterilisationsservice GmbH Willy-Rüsch-Straße 10/1 71394 Kernen Germany	Radiation (Gamma Sterilization)

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Subcontractor:	Service(s) supplied
CeMed GmbH Im Oberdorf 41 72419 Neufra Germany	Assembly Packaging
China Biotech Corporation No. 10, 33 rd., Road, Taichung Industrial Park Taichung Taiwan	Radiation (Gamma Sterilization)
Degania Silicone Limited Kibbutz 1513000 Degania Bet Israel	Manufacture
Donatelle Plastics, Inc. 501 County Road E-2 Extension New Brighton MN 55112 USA	Manufacture

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Subcontractor:	Service(s) supplied
Foremount Enterprise Co., Ltd. No. 17, Alley 15, Lane 5 Shenan Street Shengang Dist 42944 Taichung City Taiwan	<b>Manufacture</b>
Iotron Industries USA 4394 East Park 30 Drive Columbia City Indiana 46725 USA	<b>Radiation (E Beam Sterilization)</b>
Medical Service GmbH Luisenstraße 8 75378 Bad Liebenzell/Unterhaugstett Germany	<b>Assembly Packaging</b>

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Subcontractor:	Service(s) supplied
Medioplast Israel Ltd. 7 Hayarkon St. P.O. Box 13214 Industrial Zone Yavne 8122710 Israel	ETO Sterilization
Rose GmbH für Medizintechnik Gottbillstraße 25-30 54294 Trier Germany	ETO Sterilization
sfm medical devices GmbH Brückenstraße 5 63607 Wächtersbach Germany	ETO Sterilization Manufacture

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Subcontractor:	Service(s) supplied
Sparton Onyx, LLC 2920 Kelly Avenue Watertown South Dakota 57201-7249 USA	Manufacture
Sterigenics Germany GmbH Kasteler Straße 45 Wiesbaden 65203 Germany	ETO Sterilization
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	ETO Sterilization

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**Ireland**

Subcontractor:	Service(s) supplied
Steritec, Inc. P.O. Box 1969 1705 Enterprise Street Athens, TX 75751 United States of America	ETO Sterilization
Synergy Health Sterilisation UK Ltd 1 Alpha Court Capitol Park Thorne Doncaster DN8 5TZ United Kingdom	ETO Sterilization
Synergy Sterilisation (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	ETO Sterilization

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Subcontractor:	Service(s) supplied
Teleflex Medical Sdn. Bhd. Lot PT 2577, Jalan Perusahaan 4 34600 Kamunting Perak Malaysia	ETO Sterilization Manufacture
Viant San Antonio, Inc. 7027 Fairgrounds Parkway San Antonio TX 78238 United States of America	Manufacture
Viant Upland, Inc. a.t.a. (formerly) Lake Region Medical 2052 West 11th Street Upland CA 91786 USA	Manufacture
Willy Rüschi GmbH Willy-Rüsch-Straße 4-10 71394 Kernen i.R., Germany	Manufacture

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# EC Certificate - Production Quality Assurance

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Date	Reference Number	Action
13 January 2009	7245725	First issue.
17 March 2009	7325720	Company address amended. Extension to scope. Addition of Willy Rüsç, Germany as subcontractor for design and manufacture.
25 August 2009	7399908  7439096	Addition of SFM as significant subcontractor for manufacture. Addition of 'design' services supplied by Teleflex Medical, Malaysia, Arrow International CR, a.s. and Arrow International, Inc., Czech Republic. Correction of History page header. Intrauterine catheter added to scope.
08 September 2010	7558507	Scope reworded in accordance with generic device groups. Activity of 'Design' removed from all subcontractors and 'Control of Sterilisation' added. Certificate renewal.

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Page 1 of 5

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Date	Reference Number	Action
23 February 2011	7635647	Scope extended to include, 'Those aspects of manufacturing relating to securing and maintaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.' Addition of subcontractor, 'ArcRoyal Ltd., Virginia Road, Kells, Co. Meath, Ireland' for Manufacture and Control of Sterilization activities.
23 May 2012	7778468	Correction of significant subcontractor address.
04 February 2013	7932595	The addition of significant subcontractors Foremount Enterprise Co Ltd and Bidoia SAS Di Gianfranco Didia EC.
13 July 2015	8334933	Extension to scope to include 'The manufacture of non-active and active surgical devices for adult and paediatric intraosseous infusion, bone marrow aspiration, bone marrow biopsy and bone lesion biopsy.' Significant subcontractor changes: Addition of Vidacare LLC, Lake Region Medical, Arriol International Corporation, Coastal Life Technologies, Inc & Sparton Onyx. LLC.

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Date	Reference Number	Action
28 August 2015	8406492	Certificate renewal. Removal from scope of 'those aspects of Annex V relating to securing and maintaining sterility in the manufacture of non-active digestive tract devices' and 'Those aspects of Annex V related to metrology in the manufacture of non-active respiratory devices'.
10 February 2016	8455693	Removal of Vidacare LLC from list of significant subcontractors. Service(s) supplied for Arriol International Corporation, Coastal Life Technologies Inc. and Lake Region Medical changed from crucial suppliers to Control of Sterilization, Manufacture. Service(s) supplied for Sparton Onyx. LLC changed from crucial supplier to Manufacture. Removal of repeated use of word 'devices' from scope.
28 July 2017	8762518	Change of address for Coastal Life Technologies. Addition of Donatelle Plastics Inc., 55112 New Brighton to list of significant subcontractors.
04 March 2019	7779566	Traceable to NB 0086.

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Date	Reference Number	Action
Current	3124053	<p>Certificate renewal.</p> <p>Addition of supplementary product information table.</p> <p>Update to scope to include non-active sterile urology catheters.</p> <p>Name change from Coastal Life Technologies to Viant San Antonio, Inc., Name change from Lake Region Medical to Viant Upland, Inc</p> <p>Removal of Control of Sterilization from Service(s) supplied for ArcRoyal Ltd., Arrow International CR, a.s. (Zdar), Viant San Antonio, Inc., Donatelle Plastics, Inc., Foremount Enterprise Co., Ltd., Viant Upland, Inc., sfm medical devices GmbH, Teleflex Medical Sdn. Bhd., and Willy Rüschi GmbH.</p> <p>Addition of ETO Sterilization to Service(s) supplied for sfm medical devices GmbH and Teleflex Medical Sdn. Bhd.</p> <p>Administrative correction of details for ArcRoyal, Arriol International Corporation, Arrow International CR, a.s., Donatelle Plastics, Inc., Foremount Enterprise Co., Ltd., Sparton Onyx. LLC, sfm medical devices GmbH, Teleflex Medical Sdn. Bhd. and Willy Rüschi GmbH.</p> <p>Removal of Arrow International CR a.s. (Hradec Kralove) and Bidoia SAS Di Gianfranco Didoia E.C.</p> <p>Addition of CeMed GmbH and Medical Service GmbH for Assembly and Packaging.</p>

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Date	Reference Number	Action
	3124053	Addition of Degania Silicone Limited for Manufacture Addition of Steritec, Inc., Sterigenics US, LLC, Rose GmbH für Medizintechnik, Synergy Health Sterilisation UK Ltd, Sterigenics Germany GmbH, Medioplast Israel Ltd., and Synergy Sterilisation (M) Sdn Bhd. for ETO Sterilization Addition of Iotron Industries USA for E-beam Sterilization Addition of China Biotech Corporation and BBF Sterilisationsservice GmbH for Gamma Sterilization.

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The management system of

## Teleflex Medical

2917 Weck Drive, Research Triangle Park, NC, 27709, United States

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 11 September 2018 until 14 July 2023  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 27 May 2021


Issue 29. Certified since 26 September 2000

Certification is based on reports numbered WWW/MC/06866

Multiple certificates have been issued for this scope

The main certificate is numbered US97/10879.00

Authorised by



SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK  
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

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# Teleflex Medical

## Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 29

Detailed scope

Sterile Hem-o-lok Ligation Clips.  
Sterile Deknatel® PTFE pledgets.  
Sterile Polyester Nonabsorbable Surgical Sutures (POLYLENE/ "cottony"™ II, "silky" II POLYDEK®, TEVDEK® II, NextSitch®, Capio™, Fx®, NiceLoop™, TEVDEK®).  
Sterile DEKLENE® II, DEKLENE® MAXXTM, CAPIOTM and FIXT® polypropylene non-absorbable surgical sutures.  
Sterile BONDEK® and BONDEK® Plus Polyglycolic Acid Synthetic Absorbable Surgical Sutures.  
Sterile Polyglytone 6211™ Monofilament Absorbable Surgical Sutures.  
Sterile MONODEK® Polydioxanone Absorbable Surgical Sutures.  
Sterile Hem-o-lok Automatic Clip Appliers.  
Metal Ligation System.

Sterile External stapling system (including stainless steel staples, staplers and removers), Sterile, Efx endo fascial closuresystem (abdominal access), Sterile, Efx shield fascial closure system (abdominal access), Sterile, Efx classic fascial closuresystem (abdominal access)

Sterile stainless steel surgical Sutures

Sterile FORCE FIBER® surgical sutures.

Sterile Chest drainage and autotransfusion systems,

Sterile Thoracic Catheters,

Sterile and Non-sterile Aortic Punch,

Non-sterile Self Retaining Tissue retractor/blades

Non-sterile Anaesthesia and respiratory Circuits including breathing bags and water traps, Non-sterile Heated Humidifiers, Non-sterile Non-Pre-filled Humidifiers and Nebulizers, Non-sterile Small Volume Nebulizers, Sterile Pre-filled Humidifiers and Nebulizers (saline or water) with adaptors, Sterile Pre-filled unit dose vial /solution for nebulisation, Non-sterile Respiratory therapy Adaptors and connectors, Sterile Column and Reservoirs including adaptors, Non-sterile Nasal cannula (including gas sampling), Non-sterile Cannula and Supply Tubing, Nonsterile CPAP Cannula System, Non-sterile Manual resuscitators and PEEP valves, Non-sterile Respiratory and anaesthesia masks, Non-sterile Gas scavenging mask, Sterile Endotracheal tubes, Sterile Endobronchial tubes, Non-sterile Suction and Aspirating Tubes, Sterile Ventilated Thoracic Chest Seal, Sterile Operative Cholangiogram Catheters, Sterile Abdominal Access and Insufflation devices, Sterile Capillary drains, Sterile Percutaneous Surgical System (MiniLap and Grip graspers), Sterile Percutaneous Surgical System (Mini Polar electrosurgical probe and MiniGrip Bipolar Graspers), Percutaneous surgical System (Interchangeable electrosurgical tool tips) for laparoscopic surgery, Non-sterile Heat and Moisture Exchangers

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market





# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Teleflex Medical  
IDA Business and Technology Park  
Dublin Road  
Athlone  
Westmeath  
Ireland

Holds Certificate No:

**FM 544574**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design and manufacture of non-active digestive tract devices; non-active gynaecological devices, non-active regional anaesthesia devices, non-active respiratory devices, non-active surgical devices, non-active urology devices and active surgical devices.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2009-03-09

Latest Revision Date: 2020-02-12

Effective Date: 2020-02-12

Expiry Date: 2023-02-11

Page: 1 of 1



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Catheter Diameter: 14 Ga., 2.2 mm

Priming Volume: 0.55 mL

Priming volumes are approximate and are done without the injection cap. Injection cap priming volume is 0.17 mL.

Flow Rate: 4900 mL/hr

Flow rates are done with normal saline, room temperature, 100 cm head height and represent approximate flow capabilities.

#### Contents:

- 1: ..... Indwelling Catheter:  
14 Ga. x 8" (20 cm) Radiopaque  
Polyurethane with Blue FlexTip®,  
Integral Extension Line,  
Extension Line Clamp, Side Holes,  
Integral Suture Wing
- 1: ..... Spring-Wire Guide, Marked:  
.032" (0.81 mm) dia. x 23-5/8" (60 cm)  
(Straight Soft Tip on One End — "J" Tip  
on Other) with Arrow Advancer™
- 1: ..... Introducer Needle:  
18 Ga. x 2-1/2" (6.35 cm) XTW
- 1: ..... Syringe: 5 mL Luer-Slip
- 1: ..... Tissue Dilator
- 1: ..... Clamp: Catheter
- 1: ..... Fastener: Catheter Clamp

#### Rx only.

**Warning: Read all package insert warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.**

Sterile. Single use — do not resterilize. Sterilized by ethylene oxide. Do not use if package has been previously opened or damaged. Does not contain natural rubber latex. Fluid path components are non-pyrogenic. Contains no medication.

 Arrow International, Inc.  
2400 Bernville Road  
Reading, PA 19605 USA

 Teleflex Medical  
IDA Business and Technology Park  
Athlone, Ireland



**REF CV-04701**

# Central Venous Catheterization Set with Blue FlexTip® Catheter

# ARROW®

- CS** Centrální žilní katetrizační set s katetrem Blue FlexTip
- DA** Kateteriseringssæt med Blue FlexTip kateter til centrale vener
- NL** Centraal-veneuze katheterisatieset met Blue FlexTip katheter
- FR** Jeu de cathétérisme veineux central avec cathéter Blue FlexTip
- DE** Besteck für zentralen Venenkatheter mit Blue-FlexTip-Katheter
- EL** Σετ κεντρικού φλεβικού καθετήρα Blue FlexTip
- HU** Centrális vénás katéterező felszerelés Blue FlexTip katéterrel
- IT** Set per cateterismo della vena centrale con catetere Blue FlexTip
- PL** Zestaw do cewnikowania żył centralnych z cewnikiem Blue FlexTip
- PT** Conjunto de Cateterização Venosa Central com Cateter Blue FlexTip
- RU** Комплект для катетеризации главных вен с катетером Blue FlexTip
- SK** Centrálna venózna katetrizačná sada s katétrom Blue FlexTip
- SL** Komplet za centralno vensko katetrizacijo s katetrom Blue FlexTip
- ES** Conjunto de cateterización venosa central con catéter Blue FlexTip
- SV** Set för central venkatetrisering med Blue FlexTip-kateter
- TR** Santral Venöz Kateterizasyon Seti, Blue FlexTip Kateter ile

1V04701-1308 (6/12)

**ARROW®**  
INTERNATIONAL

REF  
CV-04701

14<sup>Ga.</sup> 20<sup>cm</sup> catheter length .032<sup>inch dia.</sup> spring-wire guide

Central Venous Catheterization Set with Blue FlexTip® Catheter

Peel to  
Open

Dimensions:  
Width: 6-9/64" (15,6 cm)  
Length: 8-21/32" (22 cm)

PB-50014-100B  
PBZ-50014-103A

T50014100A6 Dimensions: 5 7/8" x 7 5/8"

ARROW®



REF CV-15802 (IPNXXXXXX)

8 Fr. 2 Lumen 20 cm catheter length .032 inch dia. spring-wire guide

## Two-Lumen Central Venous Catheterization Set with Blue FlexTip® Catheter

### Contents:

- Two-Lumen Indwelling Catheter: 8 Fr. x 20 cm Radiopaque Polyurethane with Blue FlexTip®, Extension Line Clamps
- Spring-Wire Guide, Marked: .032" (0.81 mm) dia. x 23-5/8" (60 cm) (Straight Soft Tip on One End - "J" Tip on Other) with Arrow Advancer with ECG Mark
- Introducer Needle: 18 Ga. x 2-1/2" (6.35 cm) XTW
- Syringe: 5 ml Luer-Slip
- Tissue Dilator: 9 Fr. (3.0 mm) x 10.2 cm
- Dust Cap: Non-Vented
- SecondSite™ Adjustable Hub: Fastener
- SecondSite™ Adjustable Hub: Catheter Clamp

All components are CE 0086 unless otherwise noted.

Rx only. **Warning:** Read all package insert warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.

California Prop. 65

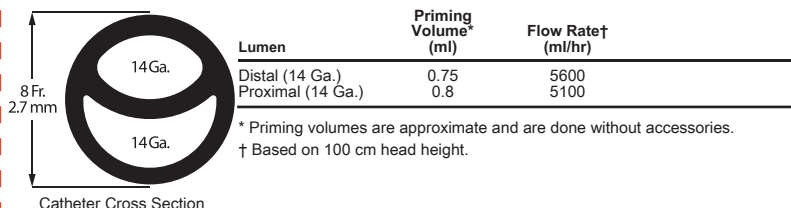
⚠ **WARNING:** Cancer and Reproductive Harm.

www.P65Warnings.ca.gov

Not made with natural rubber latex.

Fluid path components are non-pyrogenic.

- fr** Jeu de cathétérisme veineux central à deux lumières avec cathéter Blue FlexTip
- de** Besteck für zweilumigen, zentralen Venenkatheter mit Blue FlexTip Catheter
- it** Set per cateterismo della vena centrale a due lumi con catetere Blue FlexTip
- pl** Zestaw do cewnikowania żyły centralnej z cewnikiem 2-kanalowym z końcówką Blue FlexTip
- pt** Conjunto de Cateterização Venosa Central com Lúmen Duplo e Cateter Blue FlexTip
- ru** Двухпросветный центральный венозный катетер с наконечником Blue FlexTip
- sl** Dvolumenski centralni venski pripor za katetrizacijo s katetrom Blue FlexTip
- es** Conjunto de cateterización venosa central de dos lúmenes con catéter Blue FlexTip
- sv** Set för tvåkanalig central venkatetrisering med Blue FlexTip kateter
- tr** İki Lümenli Santral Venöz Kateterizasyon Seti, Mavi esnek uçlu kateterli



LOT LotNumber  
YYYY-MM-DD



(01)XXXXXXXXXXXXXX  
(17)YYMMDD  
(10)LotNumber

CE Teleflex Medical  
IDA Business and  
Technology Park  
0086 Dublin Road, Athlone  
Co. Westmeath, Ireland

Arrow International, Inc.  
Subsidiary of Teleflex Incorporated  
2400 Bernville Road  
Reading, PA 19605 USA

teleflex®  
www.teleflex.com

LBL011264 (01/19)



REF CV-15802

Two-Lumen Central Venous Catheterization Set with Blue FlexTip® Catheter

8 Fr. 2 Lumen 20 cm catheter length .032 inch dia. spring-wire guide

ARROW®





REF CV-04701

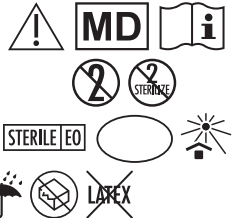
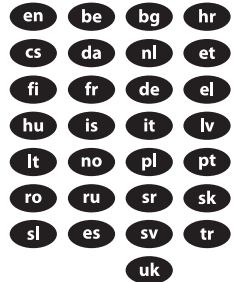
## One-Lumen CVC

### Contents:

- 1: One-Lumen Catheter: 14 Ga. (2.2 mm OD) x 20 cm, Side Holes
- 1: Spring-Wire Guide, Marked: .032" (0.81 mm) dia. x 23-5/8" (60 cm) (Straight Soft Tip on One End - "J" Tip on Other) with Arrow Advancer with ECG Mark
- 1: Introducer Needle: 18 Ga. x 2-1/2" (6.35 cm) XTW
- 1: Syringe: 5 mL Luer-Slip
- 1: Tissue Dilator: 7 Fr. (2.3 mm) x 10.2 cm
- 1: SecondSite™ Adjustable Hub: Fastener
- 1: SecondSite™ Adjustable Hub: Catheter Clamp

All components are CE 2797 unless otherwise noted.

**Warning:** Read all package insert warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death. [www.teleflex.com/IFU](http://www.teleflex.com/IFU) Not made with natural rubber latex. Fluid path components are non-pyrogenic.



Distal (14 Ga.)

Priming  
Volume\*  
(mL)

0.6

Gravity  
Flow  
Rate†  
(mL/hr)

5710

\* Priming volumes are approximate and are done without accessories.

† Flow rate values are approximate and are determined using deionized water at 100 cm head height.



EU Authorized  
Representative and  
Importer:

EC REP

Teleflex Medical  
IDA Business and  
Technology Park  
Dublin Road, Athlone  
Co. Westmeath, Ireland

Arrow International LLC  
Subsidiary of Teleflex Incorporated  
3015 Carrington Mill Blvd.  
Morrisville, NC 27560 USA

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[www.teleflex.com](http://www.teleflex.com)

LBL056978 (2021-03)

LOT



14 Ga.

1 Lumen

20 cm  
catheter  
length

.032 inch dia.  
spring-wire  
guide

REF CV-04701

## One-Lumen CVC