



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 14 10 54466 017

Manufacturer: **Royal Fornia Medical Equipment Co., Ltd.**

Fornia Tech Park, No.18, Kejiyi Road,
Hi-tech Innovation Coast, Tangjia Bay
519085 Zhuhai, Guangdong Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Disposable Infusion Pump, Disposable central venous catheter and kit, Disposable laryngeal mask, Endotracheal Tube, Endobronchial Blocker Tube, Reinforced Endotracheal Tube, Double lumen Endobronchial Tube, Disposable Airway Management Intubation Kit, Endoscopy Mask.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: BJ1486607

Valid from: 2015-01-10

Valid until: 2020-01-09



Hans-Heiner Junker

Date, 2014-11-24

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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REPUBLIC OF CHINA

COPY-Original file at FORNIA

CERTIFICAT – CE

Sistemul de Asigurare a Calității

(Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa II exclusiv (4))

(Dispozitive în Clasa IIa, IIb sau III)

Nr. G1 14 10 54466 017

Producător: **Royal Fornia Medical Equipment Co., Ltd.**
Fornia Tech Park, Nr. 18, Kejiyi Road
Hi-tech Innovation Coast, Tangjia Bay
519085 Zhuhai, Provincia Guangdong
REPUBLICA POPULARĂ CHINEZĂ

Reprezentant – CE **Shanghai International Holding
Corp. GmbH (Europa)**
Eiffestrasse 80
20537 Hamburg
GERMANIA

Categorie(i) **Pompă infuzare de unică folosință, Cateter venos central de unică**
Produs: **folosință și kit, Mască laringiană de unică folosință, Tub Endotraheal,
Tub Blocator Endobronhial, Tub Endotraheal Ranforsat, Tub
Endobronhial cu Lumen Dublu, Kit Intubare pentru Managementul
Căilor Respiratorii, Mască Endoscopie.**

Organul de Certificare al TÜV SÜD Product Service GmbH declară că producătorul mai sus menționat a implementat un sistem de asigurare a calității pentru proiectarea, producerea și inspecția finală a produselor respective / categorii de produs, în conformitate cu Anexa II MDD. Numitul sistem de asigurare a calității se conformează cerințelor Directivei și se supune unei supravegheri periodice. Pentru comercializarea dispozitivelor din clasa III un Certificat Anexa II.4 este obligatoriu. Vedeți notele de pe pagina următoare.

Raport Nr.: 7BJ1486607

Valabil de la: 10-01-2015

Valabil până la: 09-01-2020

**TÜV
572844**

Data, 24-11-2014

Hans-Heiner Junker
Semnătura – indescifrabil

TÜV SÜD Product Service GmbH este Organism de Notificare cu nr. de identificare 0123.



CERTIFICAT – CE

Sistemul de Asigurare a Calității

(Directiva 93/42/CEE cu privire la Dispozitivele Medicale, Anexa II exclusiv (4))

(Dispozitive în Clasa IIa, IIb sau III)

Nr. G1 14 10 54466 017

Unități Producție: Royal Fornia Medical Equipment Co., Ltd.
Fornia Tech Park, Nr. 18, Kejiyi Road, Hi-tech Innovation Coast, Tangjia
Bay, 519085 Zhuhai, Provincia Guangdong
REPUBLICA POPULARĂ CHINEZĂ

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

Traducător autorizat
Nr. 2769/2015





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The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: BJ1486607

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Hans-Heiner Junker

Date, 2014-11-24

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Royal Fornia Medical Equipment Co., Ltd.
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Tangjia Bay, 519085 Zhuhai, Guangdong Province, PEOPLE'S
REPUBLIC OF CHINA

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Product Service

C E R T I F I C A T E

No. Q1N 16 10 54466 018

Holder of Certificate: Royal Fornia Medical Equipment Co., Ltd.

Fornia Tech Park, No.18, Kejiyi Road
Hi-tech Innovation Coast, Tangjia Bay
519085 Zhuhai, Guangdong Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Royal Fornia Medical Equipment Co., Ltd.
Fornia Tech Park, No.18, Kejiyi Road, Hi-tech
Innovation Coast, Tangjia Bay, 519085 Zhuhai,
Guangdong Province, PEOPLE'S REPUBLIC OF
CHINA

**Certification Mark:****Scope of Certificate:**

Design, Development, Production and Distribution
of Disposable Infusion Pump, Disposable Electronic
Infusion Pump, Disposable Central Venous Catheter
Kit, Insulin Pump, Disposable Infusion Set(only used
for insulin pump), Disposable Anaesthesia Kit
(epidural, spinal), Disposable laryngeal mask,
Endotracheal Tube, Endobronchial Blocker Tube,
Reinforced Endotracheal Tube, Double
lumen Endobronchial Tube, Disposable Airway
Management Intubation Kit, Endoscopy Mask.

**Applied
Standard(s):**

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned
above has established and is maintaining a quality management system, which meets the
requirements of the listed standard(s). See also notes overleaf.

Report No.:

BJ1686604

Valid from:

2017-01-01

Valid until:

2019-12-31

Date, 2016-12-20

Stefan Preiß

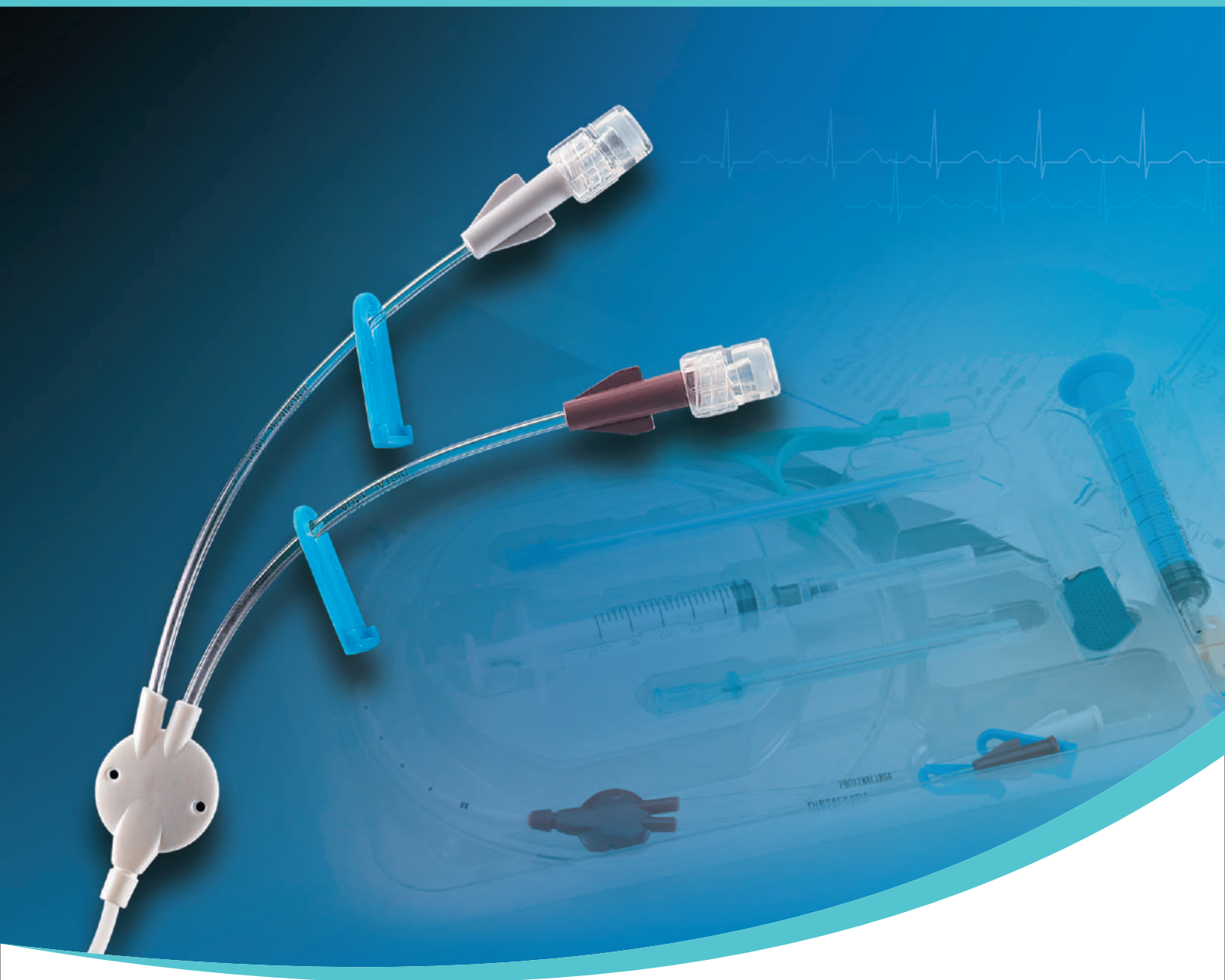


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DAKKS
Deutsche
Akkreditierungsstelle
D-27411-01-00



Disposable Central Venous Catheter Kit

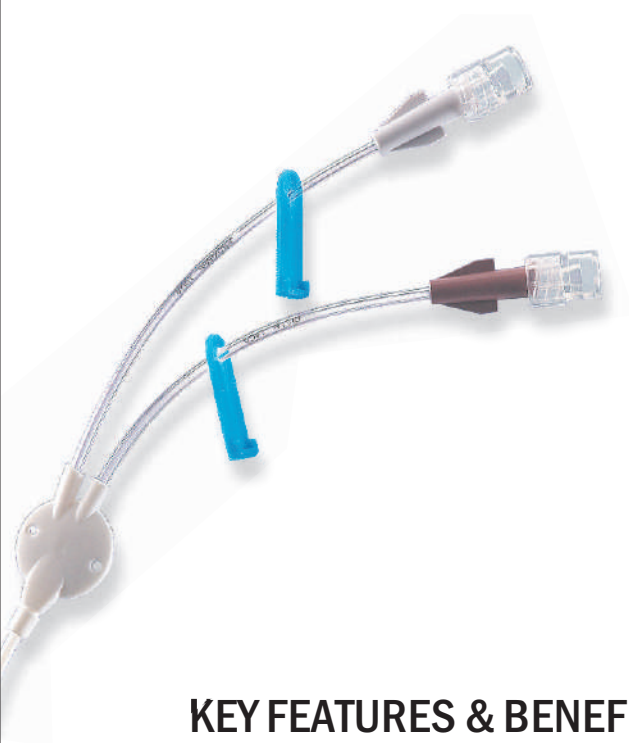


www.rfornia.com
Health care for better future



FORNIA® Disposable Central Venous Catheter Kit is for short term use of central venous access.

Safe
Reliable
Economical
Efficient



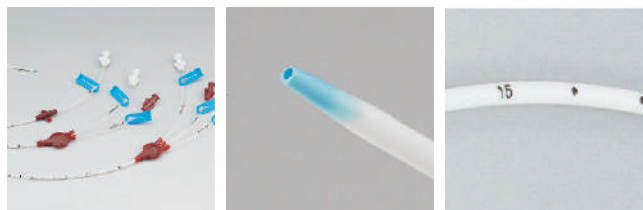
INTENDED USE

- ◆ Continual or discontinuous intravenous infusions
- ◆ Intravenous infusion of highly permeable or stimulative solutions
- ◆ Blood or blood product transfusion
- ◆ Blood sampling
- ◆ Continual or discontinuous central venous pressure monitoring
- ◆ Intravenous alimentation
- ◆ Unconscious patients unsuitable for venipuncturing
- ◆ Patients with injured limbs or peripheral vein access difficulty

KEY FEATURES & BENEFITS

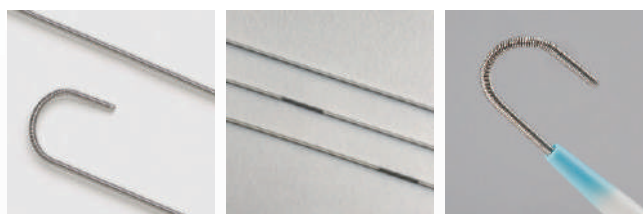
Catheter

- **Made of polyurethane(PU)**
 - Stiff to be inserted into vein at room temperature
 - Soften with warmth of blood stream
 - Reduce risk of irritating the intima of veins
- **Rounded, smooth and atraumatic catheter tip**
 - Ensure safety during insertion and placement
- **Graduation marking indicated in centimeters**
 - Precisely reveal the depth of insertion
- **Radiopaque**
 - Help check correct placement of catheter



Guidewire

- **Double-Ended (Straight & J tip) guidewire**
 - Flexible distal tips with dual purpose
- **Depth-indicator markings**
 - Distinct, permanent, 360° ringed bands
 - Facilitate proper placement
- **Superior wire-to-wire consistency**
 - Tight tolerance and special processing of tips
 - Ensure guidewire-to-catheter compatibility



Blue Introducer Syringe

- **Work in conjunction with introducer needle**
 - Load guidewire through hollow plunger into blood vessel
 - Withdraw blood to help confirm puncture point



Y Connector

- **Work in conjunction with introducer needle**
 - 5ml syringe attached to one port
 - Load guidewire through the second port into blood vessel



* Freely combine introducer needle with Blue Syringe or Y connector depending on doctor's preference.

ORDERING INFORMATION



Single Lumen

REF NO	Catheter		Lumen size			Lumen Section	Guidewire	Vessel Dilator	Introducer Needle
	Size	Length*	Media	Distal	Proximal				
CVC-1111	24 G	5 cm	-	24 G	-		0.018"x50 cm	4Fx5cm	22Gx3cm
CVC-1112	24 G	8 cm	-	24 G	-		0.018"x50 cm	4Fx5cm	22Gx3cm
CVC-1121	22 G	5 cm	-	22 G	-		0.018"x50 cm	4Fx5cm	20Gx4.5cm
CVC-1122	22 G	8 cm	-	22 G	-		0.018"x50 cm	4Fx5cm	20Gx4.5cm
CVC-1123	22 G	10 cm	-	22 G	-		0.018"x50 cm	4Fx5cm	20Gx4.5cm
CVC-1131	20 G	5 cm	-	20 G	-		0.021"x50 cm	4Fx5cm	20Gx4.5cm
CVC-1132	20 G	8 cm	-	20 G	-		0.021"x50 cm	4Fx5cm	20Gx4.5cm
CVC-1134	20 G	13 cm	-	20 G	-		0.021"x50 cm	4Fx5cm	20Gx4.5cm
CVC-1142	18 G	8 cm	-	18 G	-		0.025"x50 cm	5.5Fx7cm	19Gx4.5cm
CVC-1144	18 G	13 cm	-	18 G	-		0.025"x50 cm	5.5Fx7cm	19Gx4.5cm
CVC-1145	18 G	16 cm	-	18 G	-		0.025"x50 cm	5.5Fx7cm	19Gx4.5cm
CVC-1155	16 G	16 cm	-	16 G	-		0.035"x60 cm	6.5Fx10cm	18Gx7cm
CVC-1156	16 G	20 cm	-	16 G	-		0.035"x60 cm	6.5Fx10cm	18Gx7cm
CVC-1157	16 G	30 cm	-	16 G	-		0.035"x70 cm	6.5Fx10cm	18Gx7cm
CVC-1165	14 G	16 cm	-	14 G	-		0.035"x60 cm	7.5Fx10cm	18Gx7cm
CVC-1166	14 G	20 cm	-	14 G	-		0.035"x60 cm	7.5Fx10cm	18Gx7cm
CVC-1167	14 G	30 cm	-	14 G	-		0.035"x70 cm	7.5Fx10cm	18Gx7cm



Double Lumen

REF NO	Catheter		Lumen size			Lumen Section	Guidewire	Vessel Dilator	Introducer Needle
	Size	Length*	Media	Distal	Proximal				
CVC-2141	4 F	5 cm	-	22G	22G		0.018"x50 cm	6.5Fx7cm	20Gx4.5cm
CVC-2142	4 F	8 cm	-	22G	22G		0.018"x50 cm	6.5Fx7cm	20Gx4.5cm
CVC-2143	4 F	10 cm	-	22G	22G		0.018"x50 cm	6.5Fx7cm	20Gx4.5cm
CVC-2144	4 F	13 cm	-	22G	22G		0.018"x50 cm	6.5Fx7cm	20Gx4.5cm
CVC-2145	4 F	16 cm	-	22G	22G		0.018"x50 cm	5.5Fx7cm	20Gx4.5cm
CVC-2151	5 F	5 cm	-	18G	20G		0.021"x50 cm	6.5Fx7cm	20Gx4.5cm
CVC-2152	5 F	8 cm	-	18G	20G		0.021"x50 cm	6.5Fx7cm	20Gx4.5cm
CVC-2153	5 F	10 cm	-	18G	20G		0.021"x50 cm	6.5Fx7cm	20Gx4.5cm
CVC-2154	5 F	13 cm	-	18G	20G		0.021"x50 cm	6.5Fx7cm	20Gx4.5cm
CVC-2155	5 F	16 cm	-	18G	20G		0.021"x50 cm	6.5Fx7cm	20Gx4.5cm
CVC-2156	5 F	20 cm	-	18G	20G		0.021"x50 cm	6.5Fx7cm	20Gx4.5cm
CVC-2175	7 F	16 cm	-	14G	18G		0.035"x60 cm	8.5Fx10cm	18Gx7cm
CVC-2176	7 F	20 cm	-	14G	18G		0.035"x60 cm	8.5Fx10cm	18Gx7cm
CVC-2177	7 F	30 cm	-	14G	18G		0.035"x70 cm	8.5Fx10cm	18Gx7cm
CVC-2185	8 F	16 cm	-	14G	14G		0.035"x60 cm	9Fx10cm	18Gx7cm
CVC-2186	8 F	20 cm	-	14G	14G		0.035"x60 cm	9Fx10cm	18Gx7cm



Triple Lumen

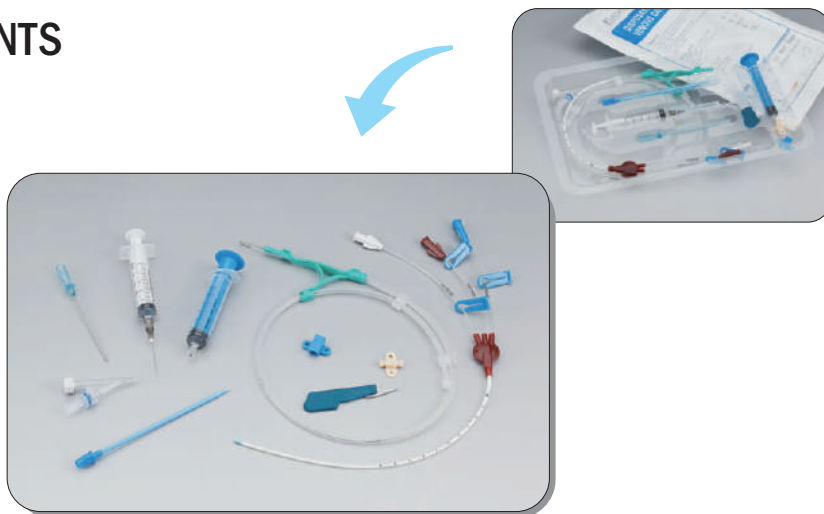
REF NO	Catheter		Lumen size			Lumen Section	Guidewire	Vessel Dilator	Introducer Needle
	Size	Length*	Media	Distal	Proximal				
CVC-3151	5.5 F	5 cm	22 G	18 G	22 G		0.021"x50cm	6.5Fx7cm	20Gx4.5cm
CVC-3152	5.5 F	8 cm	22 G	18 G	22 G		0.021"x50cm	6.5Fx7cm	20Gx4.5cm
CVC-3153	5.5 F	10 cm	22 G	18 G	22 G		0.021"x50cm	6.5Fx7cm	20Gx4.5cm
CVC-3154	5.5 F	13 cm	22 G	18 G	22 G		0.021"x50cm	6.5Fx7cm	20Gx4.5cm
CVC-3155	5.5 F	16 cm	22 G	18 G	22 G		0.021"x50cm	6.5Fx7cm	20Gx4.5cm
CVC-3156	5.5 F	20 cm	22 G	18 G	22 G		0.021"x50cm	6.5Fx7cm	20Gx4.5cm
CVC-3175	7 F	16 cm	18 G	16 G	18 G		0.035"x60cm	8.5Fx10cm	18Gx7cm
CVC-3176	7 F	20 cm	18 G	16 G	18 G		0.035"x60cm	8.5Fx10cm	18Gx7cm
CVC-3177	7 F	30 cm	18 G	16 G	18 G		0.035"x70cm	8.5Fx10cm	18Gx7cm
CVC-3185	8.5 F	16 cm	14 G	16 G	16 G		0.035"x60cm	9Fx10cm	18Gx7cm
CVC-3186	8.5 F	20 cm	14 G	16 G	16 G		0.035"x60cm	9Fx10cm	18Gx7cm
CVC-3187	8.5 F	30 cm	14 G	16 G	16 G		0.035"x70cm	9Fx10cm	18Gx7cm

* More catheter length from 5cm ~30cm is available upon customer's request.

STANDARD KIT CONTENTS

Each CVC kit contains:

- ◆ Central venous catheter
- ◆ Guidewire with advancer
- ◆ Vessel dilator
- ◆ Introducer needle
- ◆ Y connector
- ◆ 5ml syringe
- ◆ 22g syringe needle
- ◆ Catheter clamp
- ◆ Surgical scalpel
- ◆ Fastener: catheter clamp
- ◆ Blue introducer syringe



PACKAGE

Unit Package	Pieces per box	Pieces per carton	Carton dimension(cm)
Peel-open tray with Tyvek cover	10	120	71.5x57.2x48

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Web : www.fornia.com



ISO13485

Fornia constantly strives to improve quality and comply with regulatory requirements. Our Quality Management System is certified according to ISO 13485 and product is CE-proved.