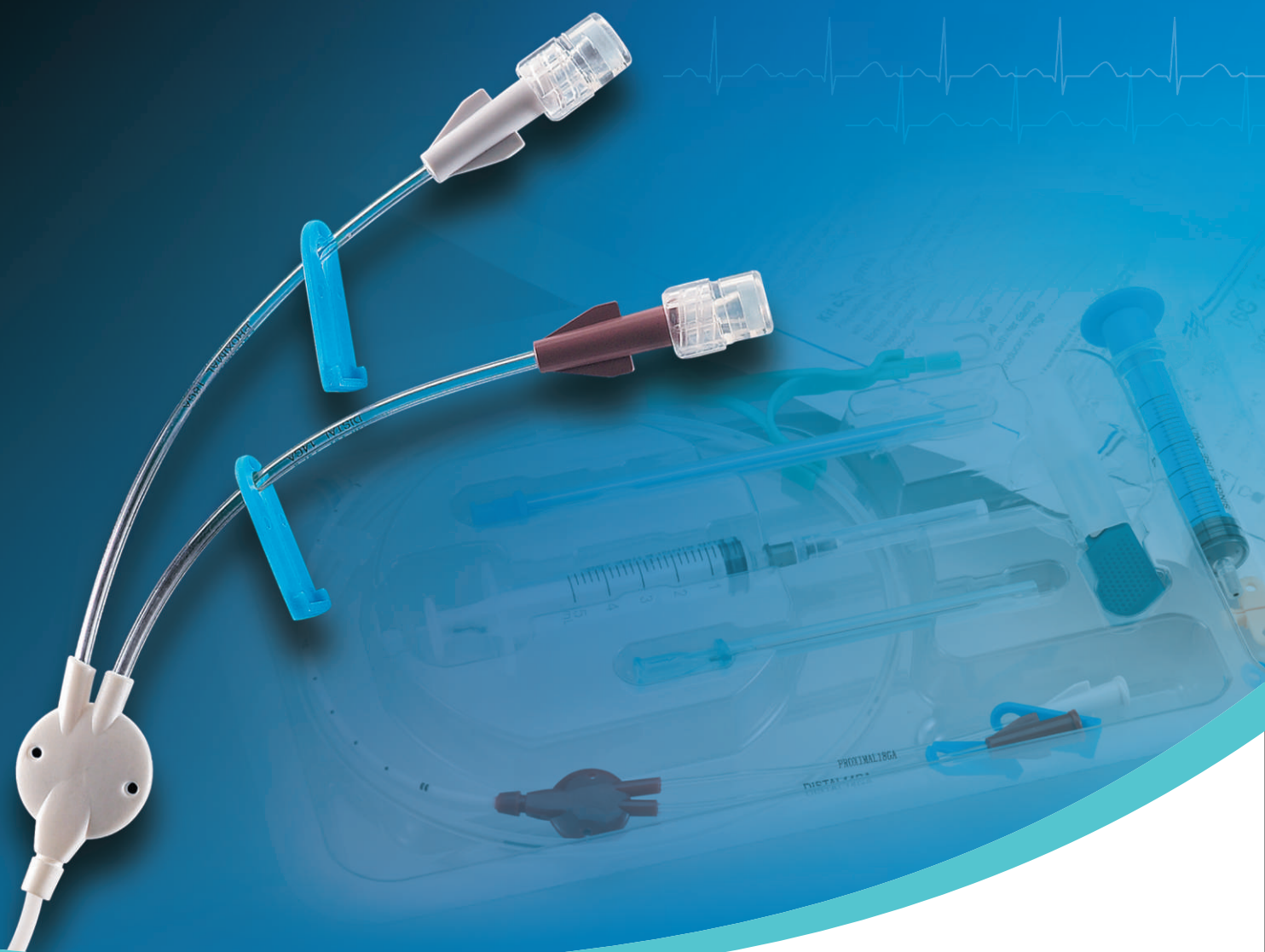




Disposable Central Venous Catheter Kit

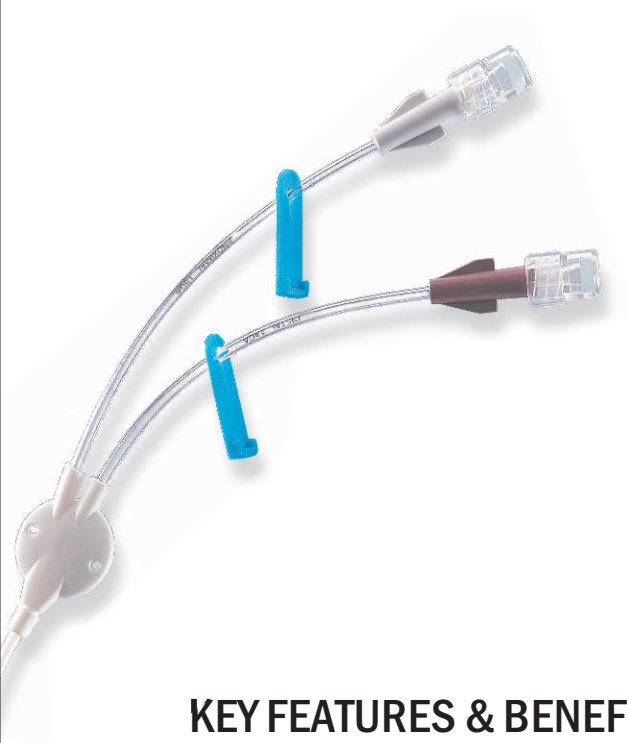


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Health care for better future



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

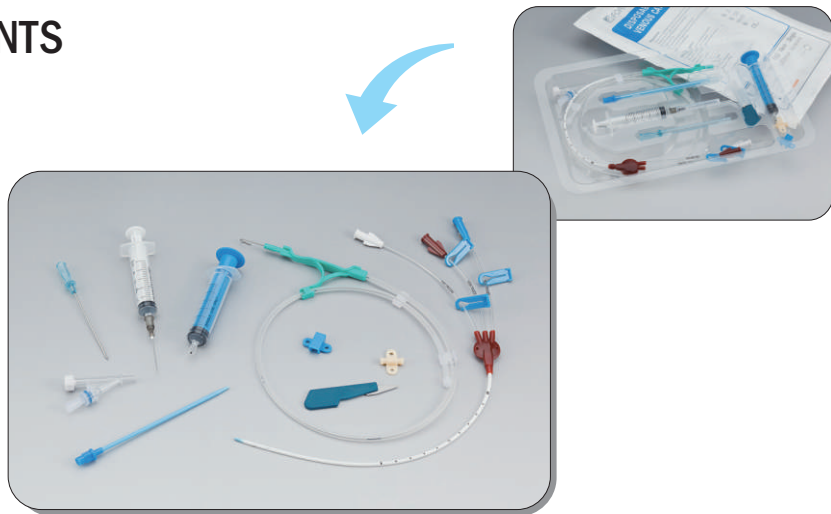
REF NO	Catheter		Lumen size			Lumen Section	Guidewire	Vessel Dilator	Introducer Needle
	Size	Length*	Media	Distal	Proximal				
CVC-3151	5.5 F	5 cm	22 G	18 G	22 G		0.021"x50cm	6.5Fx7cm	20Gx4.5cm
CVC-3152	5.5 F	8 cm	22 G	18 G	22 G		0.021"x50cm	6.5Fx7cm	20Gx4.5cm
CVC-3153	5.5 F	10 cm	22 G	18 G	22 G		0.021"x50cm	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

Royal Fornia Medical Equipment Co., Ltd.

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E-mail : fornia@rforia.com
Web : www.rforia.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.



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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 054466 0017 Rev. 01

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

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

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.:

BJ1986607

Valid from:

2019-06-28

Valid until:

2024-05-26

Date,

2019-06-28

Stefan Preiß

Head of Certification/Notified Body



Product Service

Certificate

No. Q5 054466 0020 Rev. 01

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, and Endoscopy Mask.

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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.: BJ19086603

Valid from: 2020-01-01

Valid until: 2022-12-31

Date, 2019-12-13

Christoph Dicks
Head of Certification/Notified Body