



EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 081681 0017 Rev. 02

Manufacturer

**Shanghai Kindly
Medical Instruments Co., Ltd.**

No.925 Jinyuan yi Road

201803 Shanghai

PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Sterile 'Inflation device, Pressure bandage, Angiography syringe' for single use, Infusion sets without needle, syringes without needle, Burette infusion sets without needle, Vaginal Dilator.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: BJ19703071

Valid from: 2019-10-29

Valid until: 2024-05-26

Date, 2019-10-29

C.D.h

Christoph Dicks
Head of Certification/Notified Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

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(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 081681 0017 Rev. 02

Facility(ies):

Shanghai Kindly Medical Instruments Co., Ltd.
No.925 Jinyuan yi Road, 201803 Shanghai, PEOPLE'S
REPUBLIC OF CHINA



Product Service

Certificate

No. Q5 081681 0020 Rev. 01

Holder of Certificate: Shanghai Kindly
Medical Instruments Co., Ltd.

No.925 Jinyuan yi Road
201803 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Shanghai Kindly Medical Instruments Co., Ltd.
No.925 Jinyuan yi Road, 201803 Shanghai, PEOPLE'S
REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design, Development, Production and Distribution of Sterile 'Inflation device, Pressure bandage, Angiography syringe, Infusion connector and accessory' for single use, Sterile Seldinger needle, Intervention accessories kit, Guidewire, Introducer tool kit, Introducer set, Bone cement syringe, Manifold kit, Stopcocks, Manifold for single use, Pressure transducer for single use, Infusion pumps for single use, Medical Wasting Containers, Infusion sets without needle, Syringes without needle, Burette infusion sets without needle, Extension tube, Y-connector Pack, Foley catheter, Vaginal Dilator, Safety syringe, Angiography Catheter, Guiding Catheter, Micro Catheter.

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.: BJ18703043

Valid from: 2019-03-18

Valid until: 2021-12-06

I. Purpur

Date, 2019-03-18

Stefan Preiß



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 081681 0021 Rev. 00

Manufacturer:

**Shanghai Kindly
Medical Instruments Co., Ltd.**

No.925 Jinyuan yi Road
201803 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Sterile Seldinger needle, Intervention accessories kit, Guidewire, Introducer tool kit, Introducer set, Bone cement syringe, Manifold kit, Stopcocks, Manifold, Infusion pumps, Pressure transducer for single use, Extension tube, Foley catheter, Safety syringe, Angiography Catheter, Y-connector Pack, Sterile Infusion connector and accessory for single use, Guiding Catheter, Micro Catheter.

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.:

BJ19703071

Valid from:

2019-10-29

Valid until:

2024-05-26

Date, 2019-10-29

C.D.H.

Christoph Dicks
Head of Certification/Notified Body



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 081681 0021 Rev. 00

Facility(ies):

Shanghai Kindly Medical Instruments Co., Ltd.

No.925 Jinyuan yi Road, 201803 Shanghai, PEOPLE'S
REPUBLIC OF CHINA



SHANGHAI
KINDLY
MEDICAL INSTRUMENTS CO., LTD.



To Win Universal Confidence With KDL Quality And Reputation

SHANGHAI KINDLY MEDICAL INSTRUMENTS CO., LTD.

Add: No.925 Jinyuan No.1 Road, Shanghai China

TEL: +86-21-59140056
FAX: +86-21-69000013

P.C.: 201803
Http: //www.kdl-interv.com

Professional Intervention Products Manufacturer

A white ECG (heart rate) line is superimposed on the blue wavy background at the bottom right of the page.



Enterprise Vision:

Become a globally-renowned interventional and implantable medical device group led by technology innovation!

Business Philosophy:

Get symbiosis, success and development together with customers, partners and all staff!

Enterprise Spirit:

Team is the cornerstone of enterprise! Innovation is the engine of development! Execution is the key to success!

Enterprise Mission:

Serve globally health industry with innovative technology and high quality products!

Company Introduction

Shanghai Kindly Medical Instruments Co., Ltd. (hereinafter referred to as "the Company") is a sub-company of KDL Group in Shanghai, China. As the holding company, KDL Group was set up in 1987, which has 12 subsidiaries and more than 3,500 employees in China. And KDL Group is one of the largest manufacturers of medical products in China, which always focus on R&D, production and global trade. It was awarded the vice president of China Association for Medical Devices Industry (CAMDI) and the president of Medical Polymer Product Branch of CAMDI.

The Company was established in 2006, and it focuses on R&D, production and global trade in high-tech intervention products. Since our establishment, the Company integrated quickly kinds of resources including mold design, mold processing, injection, assembling, packaging, sterilization and so on. The Company has strong ability for scientific research and development of high-tech medical products with independent intellectual property. And we obtained a number of awards, such as Shanghai Torch Plans, Shanghai High-tech Achievement Transformation Project, Shanghai Innovation Fund, Shanghai Patent Invention Award, National Innovation Fund, Shanghai Talent development fund, Shanghai High and New Tech Enterprise etc. With capacity of produce and ability of innovation, we built up our brand images of "Leading technology with medical-engineering cooperation and independent innovation".

With obtaining ISO9001, ISO13485 and CE certificates, the Company has extended its business to the United States, Europe, South America, the Middle East, South Africa, India, and other 40 countries and regions. Now we have become one of the most popular professional manufacturers in high-tech medical products in China. During 10 years developing, we formed the enterprise spirit of "Team is the cornerstone of venture; Innovation is the source of development; Execution is key to success". We will develop high quality medical products continuously to contribute to global human health services following the company's development philosophy of "To Win Universal Confidence with KDL Quality and Reputation".

C

Cardiology Intervention

- Inflation Device
- Inflation Device II
- Y-Connector Kit
- Angiography Syringe
- Manifolds Kit
- High Pressure Manifolds
- COMFORT High Pressure Manifolds
- Transradial Introducer Set I
- Transradial Introducer Set II
- Femoral Introducer Set
- Femoral Pressure Bandage
- Transradial Pressure Bandage I
- Transradial Pressure Bandage II
- PTFE Guide Wire
- Hydrophilic Guide Wire
- Seldinger Needle
- Angiography Catheter
- High Pressure Tubing
- Pressure Transducer

O

Orthopedic Intervention

- PVP Tool Kit
- Spine Tool Kit
- PKP Balloon Catheter
- Joint Intervention Kit
(ECTR Disposable Kit)
- Bone Biopsy Drill
- Bone Needle + Vacuum Lock Syringe

P

Peripheral Intervention

- Intestinal Balloon Catheter
- Multifunction Drainage Tube
- Foley Catheter with Hydrophilic Coating
- Pressure Monitoring System for Bladder
(Bladder Guard)
- Vaginal Speculum
- Automatic Umbilical Cord Clamps

I

Infusion & Injection

- Safety Syringe
- Vacuum Lock Syringe
- PC (Polycarbonate) Syringe
- Infusion Pump
- Disposable Analgesia Pump
- Electric Infusion Pump
- Burette Infusion Set
- Coiled Tube
- Positive Pressure Needle Free Connector
(with or without extension line)
- Needle free connector (with or without extension line)
- Anti-back Flow Needle Free Connector
(with or without extension line)
- Stopcock
- Manifolds for Anesthesiology



C

Cardiology Intervention

- Inflation Device
- Inflation Device II
- Y-Connector Pack
- Angiography Syringe
- Manifolds Kit
- High Pressure Manifolds
- COMFORT High Pressure Manifolds
- Transradial Introducer Set I
- Transradial Introducer Set II
- Femoral Introducer Set
- Femoral Pressure Bandage
- Transradial Pressure Bandage I
- Transradial Pressure Bandage II
- PTFE Guide Wire
- Hydrophilic Guide Wire
- Seldinger Needle
- Angiography Catheter
- High Pressure Tubing
- Pressure Transducer

Inflation Device



- Stable performance with ergonomically design
- Accurate inflation of interventional devices with pressure control
- 30cm high pressure extension tubing with male rotating luer assure pressure maintenance during inflation
- 3-way stopcock up to 500psi
- Volume: 20ml

Ref.NO.	Product Description
AI30	20ml, no leakage under 30atm
AI40	20ml, no leakage under 40atm

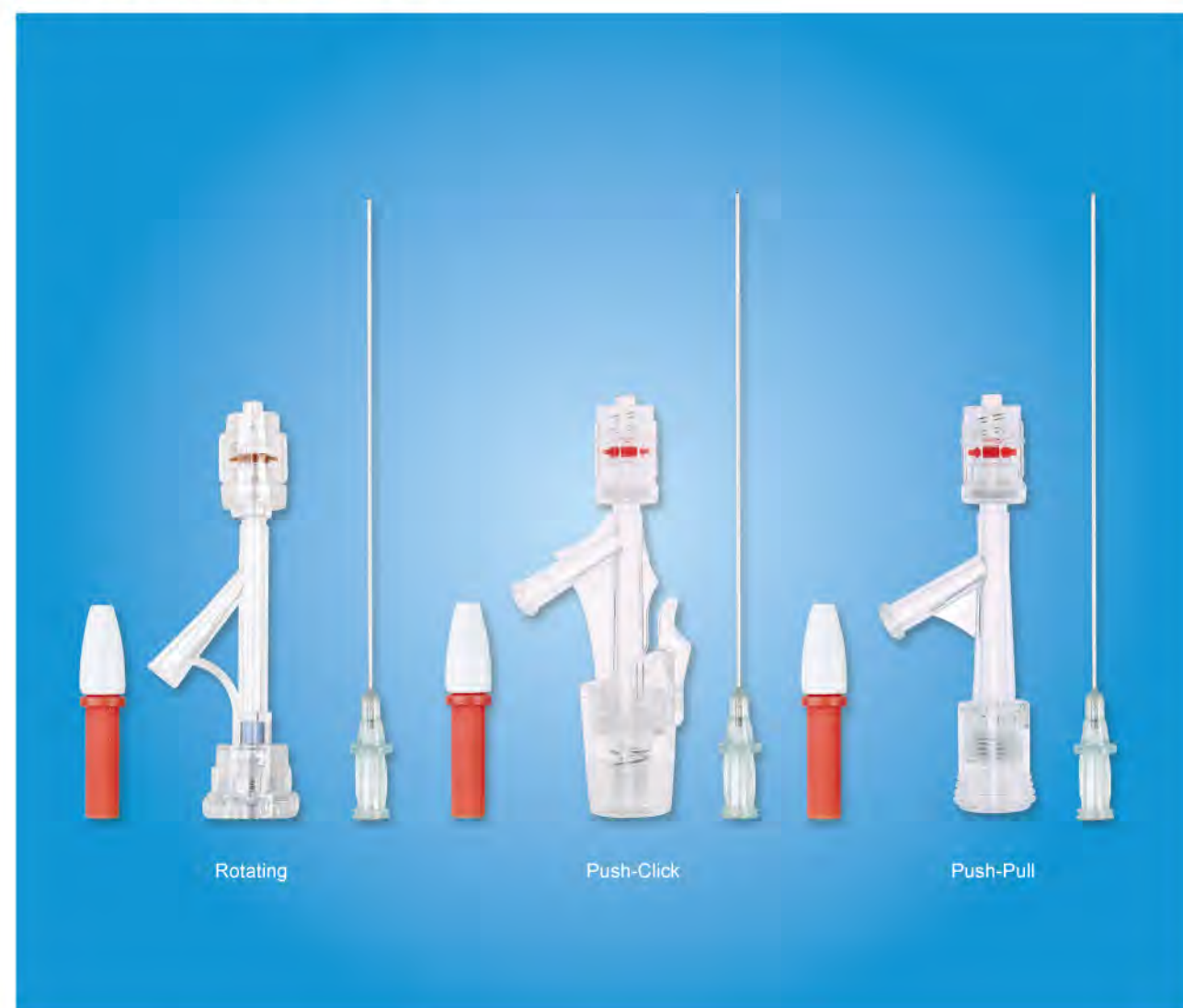
Inflation Device II



- Accurate and easy pressure control with ergonomically designed handle
- Inflate speed 50% faster compared to previous version
- 30cm high pressure extension tubing with male rotating luer assure pressure maintenance during inflation
- 3-way stopcock up to 500psi
- Volume: 20ml

Ref.NO.	Product Description
AI25	20ml, no leakage under 30atm

Y-Connector Pack



- Large lumen: 9Fr, 3.0mm for various device compatibility
- One-hand operation with 3 types: Rotating, Push-Click, Push-Pull
- No leakage under 80 Kpa

Ref.NO.	Product Description	Type
YCK111	Y-Connector (1), Insertion Tool (1), Torque Device (1)	Rotating
YCK111A	Y-Connector (1), Insertion Tool (1), Torque Device (1), Extension tube with stopcock (1)	
YCK113F	Y-Connector (1), Insertion Tool (1), Torque Device (1)	
YCK113G	Y-Connector (1), Insertion Tool (1), Torque Device (1), Extension tube with stopcock (1)	Push-Click
YCK113J	Y-Connector (1), Insertion Tool (1), Torque Device (1)	
YCK113k	Y-Connector (1), Insertion Tool (1), Torque Device (1), Extension tube with stopcock (1)	Push-Pull

Angiography Syringe



- Ring Plunger and Grip for easy and accurate dosage control
- Rotating adapter or fixed luer lock available across all volume
- Latex-free

Ref.NO.	Product Description	Ref.NO.	Product Description
AS0601	6ml, Rotating Adapter	AS0801	8ml, Rotating Adapter
AS0602	6ml, Fixed Adapter	AS0802	8ml, Fixed Adapter
AS1001	10ml, Rotating Adapter	AS1201	12ml, Rotating Adapter
AS1002	10ml, Fixed Adapter	AS1202	12ml, Fixed Adapter

Manifolds Kit



- Manifolds with pre-installed extension lines and infusion, help saving time
- Luer lock design for secure connection
- Latex-free

Ref.NO.	Product Description
AM0350	Manifolds 3-port ON (1), Angiography syringe 12ml (1), infusion set (2), High pressure tubing 120cm (1)
AM0351	Manifolds 3-port OFF (1), Angiography Syringe 12ml (1), infusion set (2), High Pressure tubing 120cm (1)
AM0352e	Manifolds 3-port ON (1), PC Syringe Red (1), Yellow (1), Blue (1), Green (1), White (1), infusion set (2), High pressure tubing 120cm (1)

* Kits customization upon request is available.

High Pressure Manifolds



- Pressure rating up to 500psi (34bar)
- Smooth rotation with low torque
- Handle color customization and built-in-logo on the manifold housing is available

Ref.NO.	Product Description
AM0201	2 ports with rotating adapter, right port orientation
AM0202	2 ports with rotating adapter, right port orientation
AM0301	3 ports with rotating adapter, right port orientation
AM0302	3 ports with rotating adapter, right port orientation
AM0303	3 ports with pressure line, right port orientation
AM0303A	3 ports with pressure line, right port orientation
AM0307	3 ports with rotating adapter, left port orientation
AM0308	3 ports with rotating adapter, left port orientation
AM0401	4 ports with rotating adapter, right port orientation
AM0402	4 ports with rotating adapter, right port orientation

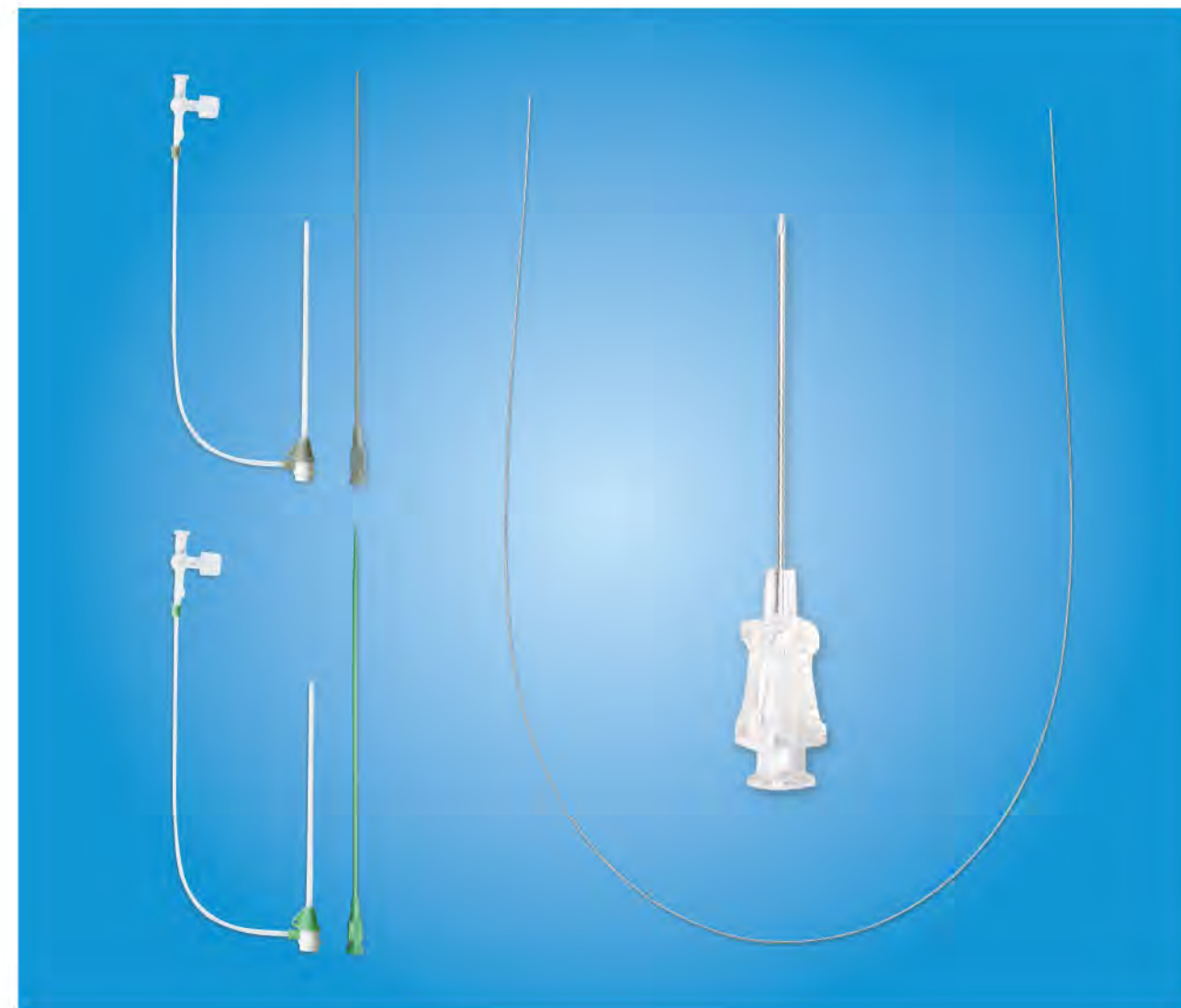
COMFORT High Pressure Manifolds



- TPE-over-molding provides soft touch handle
- Pressure rating up to 500psi (34bar)
- Smooth rotation with extended handle and low torque
- Handle color customization is available

Ref.NO.	Product Description
AM0209	2 ports with rotating adapter, right port orientation
AM0210	2 ports with rotating adapter, right port orientation
AM0309	3 ports with rotating adapter, right port orientation
AM0310	2 ports with rotating adapter, right port orientation

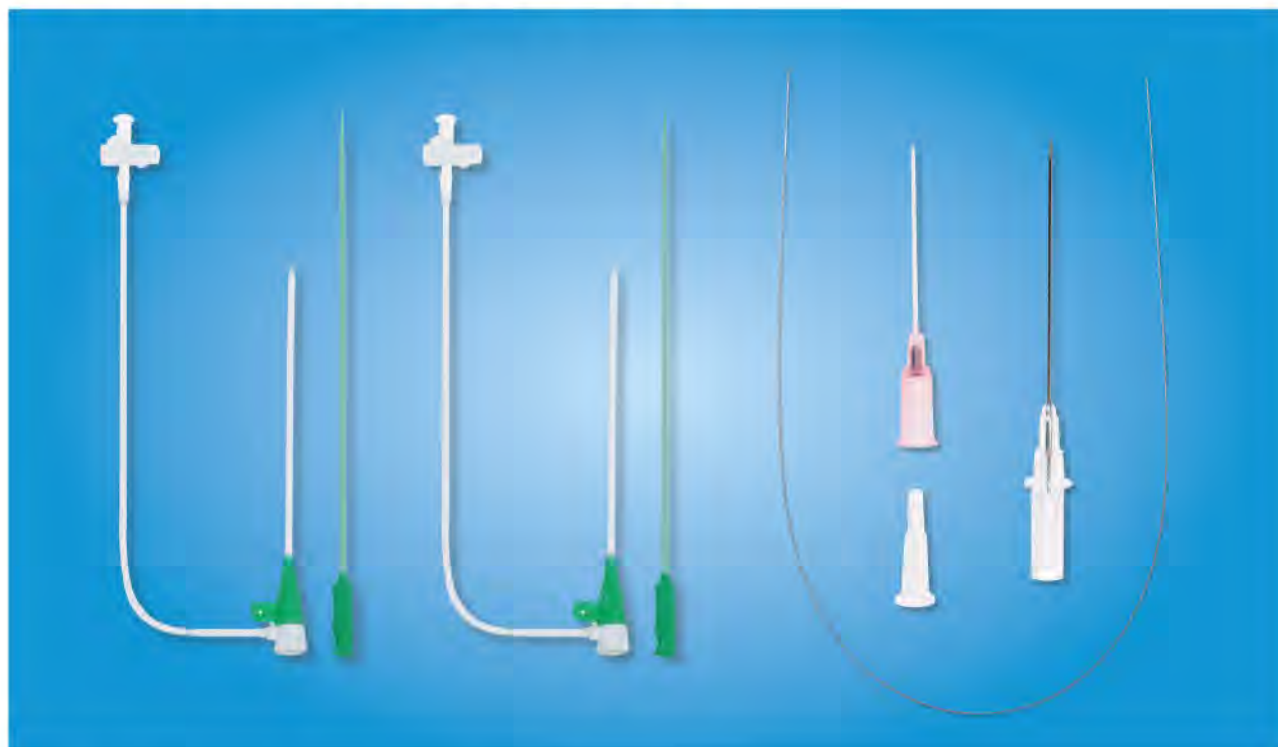
Transradial Introducer Set I



- Longer taper ensure smooth transition between sheath and dilator
- Excellent pushability, flexibility and radiopacity
- 0.021" stainless steel guide wire, hydrophilic guide wire available upon request

Ref.NO.	Type	Sheath		Dilator		Guide wire	Needle(G/mm)
		I.D. (mm)	L (mm)	I.D. (mm)	L (mm)	O.D. (inch)	
TR01	5F	1.9	110	0.68	168	0.021"	21/45
TR02	6F	2.1	110		168		
TR02A	6F	2.1	160		218		

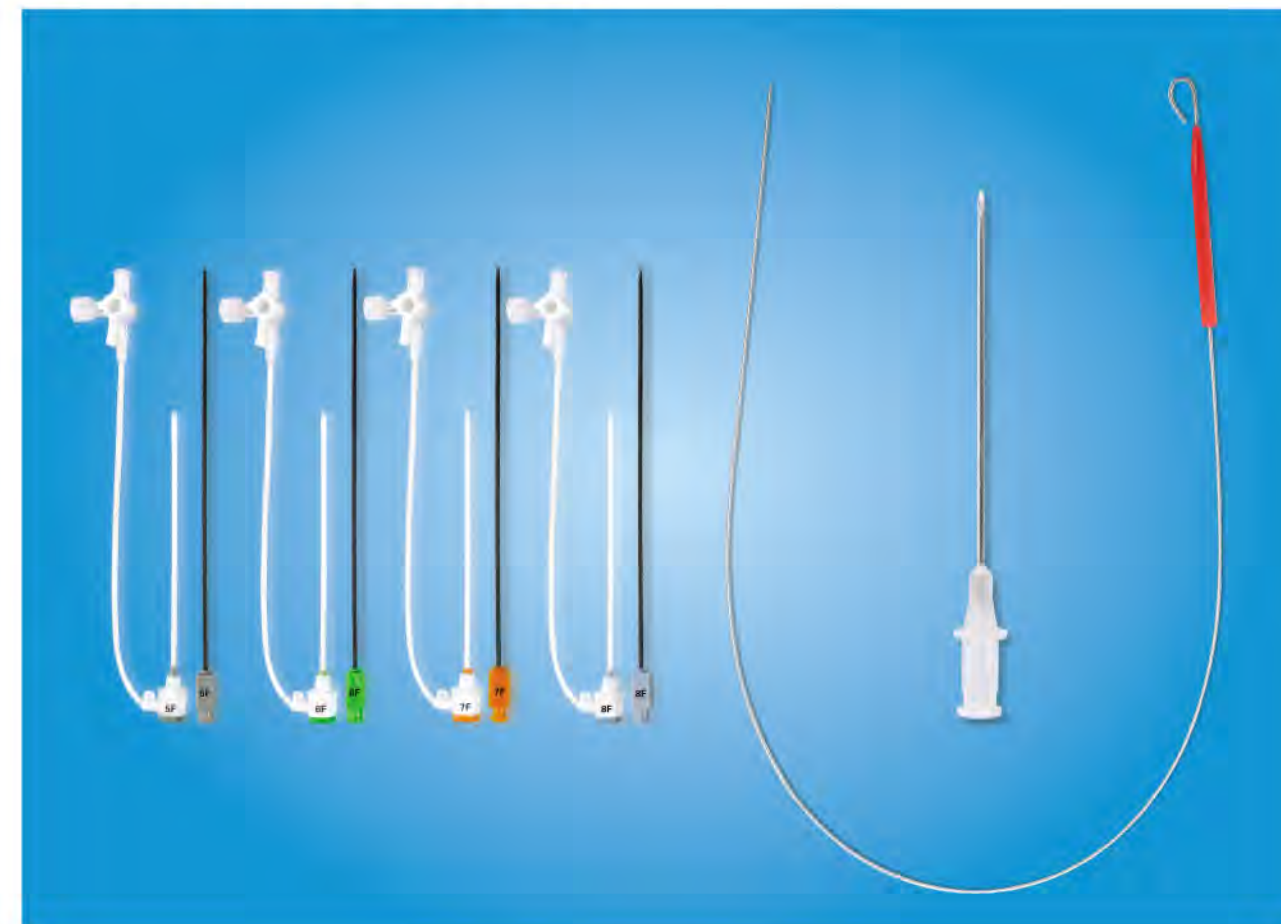
Transradial Introducer Set II



- Longer taper ensure smooth transition between sheath and dilator
- Excellent pushability, flexibility and radiopacity
- Hydrophilic guide wire with cannula needle is available
- Hydrophilic coated sheath available

Ref.NO.	Type	Sheath		Dilator		Guide wire	Needle (G/mm)	Hydrophilic Guide Wire	Hydrophilic Coating
		I.D. (mm)	L (mm)	I.D. (mm)	L (mm)	O.D. (inch)			
TR03	5F	1.86	110	1.1	170	0.021"	21/45	No	No
TR03A	5F	1.86	160		218				
TR04	6F	2.18	110		170				
TR04A	6F	2.18	160		218				
HTR03	5F	1.86	110	1.1	170	0.025"	20/31 cannula needle	Yes	No
HTR03A	5F	1.86	160		218				
HTR04	6F	2.18	110		170				
HTR04A	6F	2.18	160		218				
CTR03	5F	1.86	110	1.1	170	0.021"	21/45	No	Yes
CTR03A	5F	1.86	160		218				
CTR04	6F	2.18	110		170				
CTR04A	6F	2.18	160		218				
CHTR03	5F	1.86	110	1.1	170	0.025"	20/31 cannula needle	Yes	Yes
CHTR03A	5F	1.86	160		218				
CHTR04	6F	2.18	110		170				
CHTR04A	6F	2.18	160		218				

Femoral Introducer Set



- Excellent pushability, flexibility and radiopacity
- Smooth transition between sheath and dilator
- No leakage under 80kpa
- Hydrophilic coated sheath available

Ref.NO.	Type	Sheath		Dilator		Guide wire	Needle (G/mm)	Hydrophilic Coating
		I.D. (mm)	L (mm)	I.D. (mm)	L (mm)	O.D. (inch)		
IS01	5F	2.0	110	1.1	170	0.038"	18/70	No
IS02	6F	2.3						
IS03	7F	2.6						
IS04	8F	3.0						
HIS01	5F	2.0		1.1				Yes
HIS02	6F	2.3						
HIS03	7F	2.6						
HIS04	8F	3.0						

Femoral Pressure Bandage



- Unique design prevent unintended movement of the bandage
- The transparency ensures complete visualization of the puncture site

Ref.NO.	Product Description
FPB01	Bandage I: 55cm*6cm(±0.5cm), Bandage II: 70.7cm*6cm(±0.5cm) Pressure indication 0-60N

Transradial Pressure Bandage I



- The transparency ensures complete visualization of the puncture site
- Dual-balloons enhance precise compression over the radial artery
- Standard luer lock connector

Ref.NO.	Product Description
PB04A	Bandage:24cm*4cm Balloon:3.5cm*3.5cm
PB04B	Bandage:27cm*4cm Balloon:3.5cm*3.5cm

Transradial Pressure Bandage II



- Good flexibility, favorable contact
- No effects on venous blood circulation
- Pressure indication, convenient to adjust compression pressure
- Curved surface silicone available, much more comfortable for patient

Ref.NO.	Product Description
PB01	Flat surface, Bandage 18cm*3cm(±0.5cm), Pressure indication 0-20N
PB02	Flat surface, Bandage 22cm*3cm(±0.5cm), Pressure indication 0-20N
PB03	Flat surface, Bandage 26cm*3cm(±0.5cm), Pressure indication 0-20N
PB01A	Curved surface, Bandage 18cm*3cm(±0.5cm), Pressure indication 0-20N
PB02A	Curved surface, Bandage 22cm*3cm(±0.5cm), Pressure indication 0-20N
PB03A	Curved surface, Bandage 26cm*3cm(±0.5cm), Pressure indication 0-20N

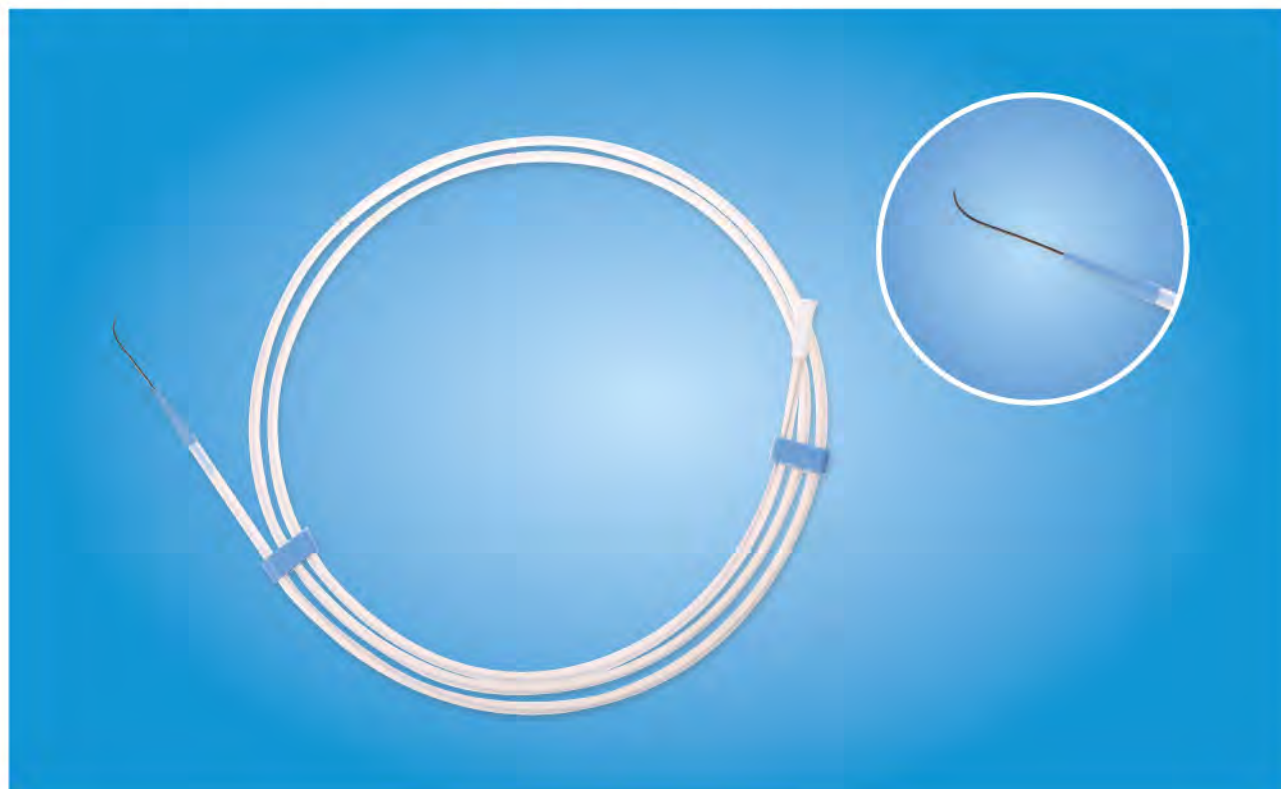
PTFE Guide Wire



- Special designed dispenser to achieve easy flush
- High quality 304 stainless steel with PTFE coating
- J tip radius : 3mm

Ref.NO.	Product Description		
	O.D. (inch/mm)	Length (cm)	Tip Form
GW351JF	0.035" (0.89mm)	150	J
GW352JF		180	
GW353JF		260	
GW351SF		150	Straight
GW352SF		180	
GW381JF	0.038" (0.97mm)	150	J
GW382JF		180	
GW383JF		260	
GW381SF		150	Straight
GW382SF		180	

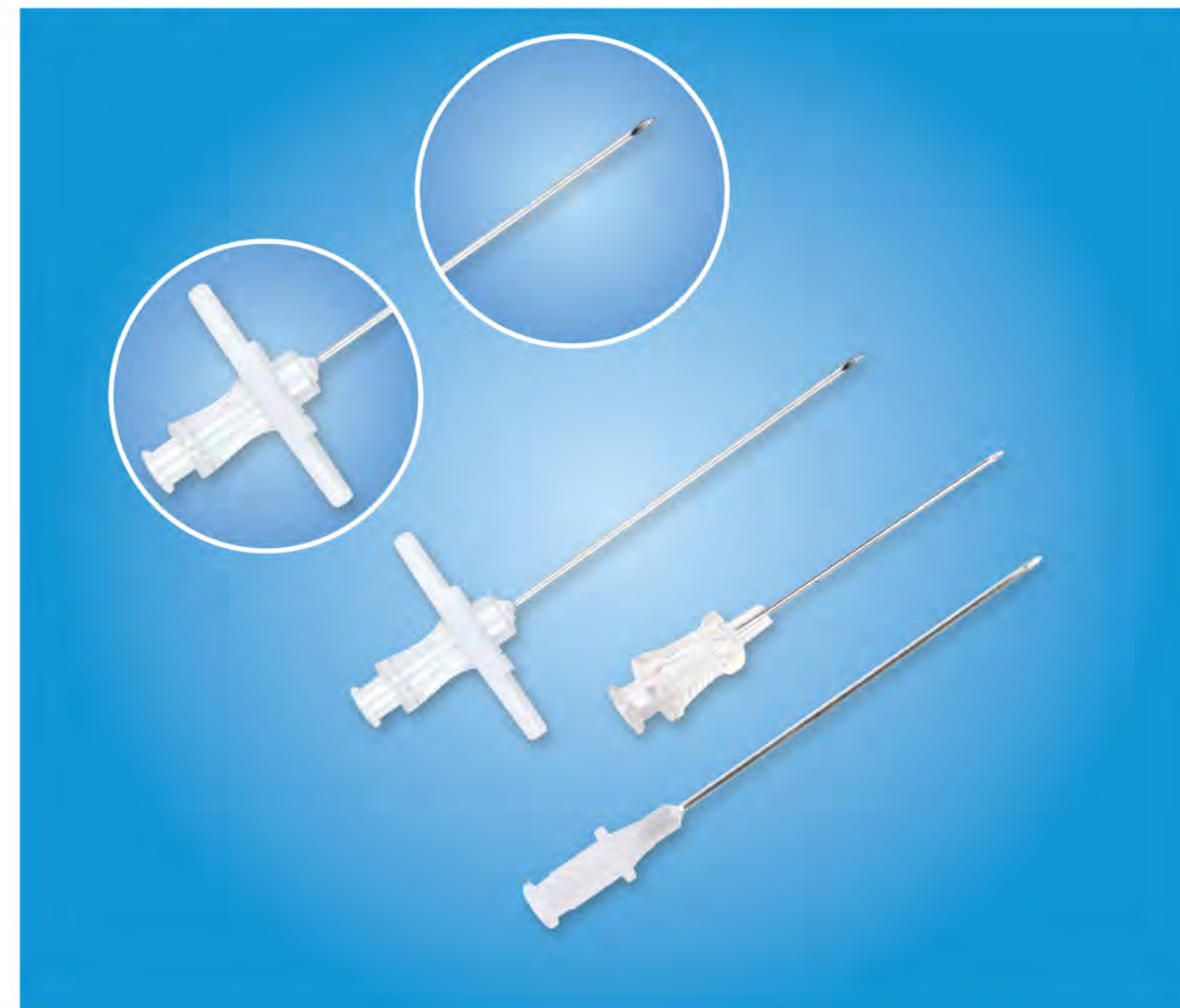
Hydrophilic Guide Wire



- High quality Niti core wire enables 1:1 torque control for better navigation and faster vessel selection
- TPU jacket with tungsten providing excellent visibility under X-ray.
- Unique coating technology ensure a lubricant surface durable

Ref.NO.	Product Description		
	O.D. (inch/mm)	Length (cm)	Tip Form
HG353AF	0.035" (0.89mm)	150	45° Angled
HG354AF		180	
HG355AF		260	
HG353JF		150	J tip
HG354JF		180	
HG355JF		260	
HG383AF	0.038" (0.97mm)	150	45° Angled
HG384AF		180	
HG385AF		260	
HG383JF		150	J tip
HG384JF		180	
HG385JF		260	

Seldinger Needle

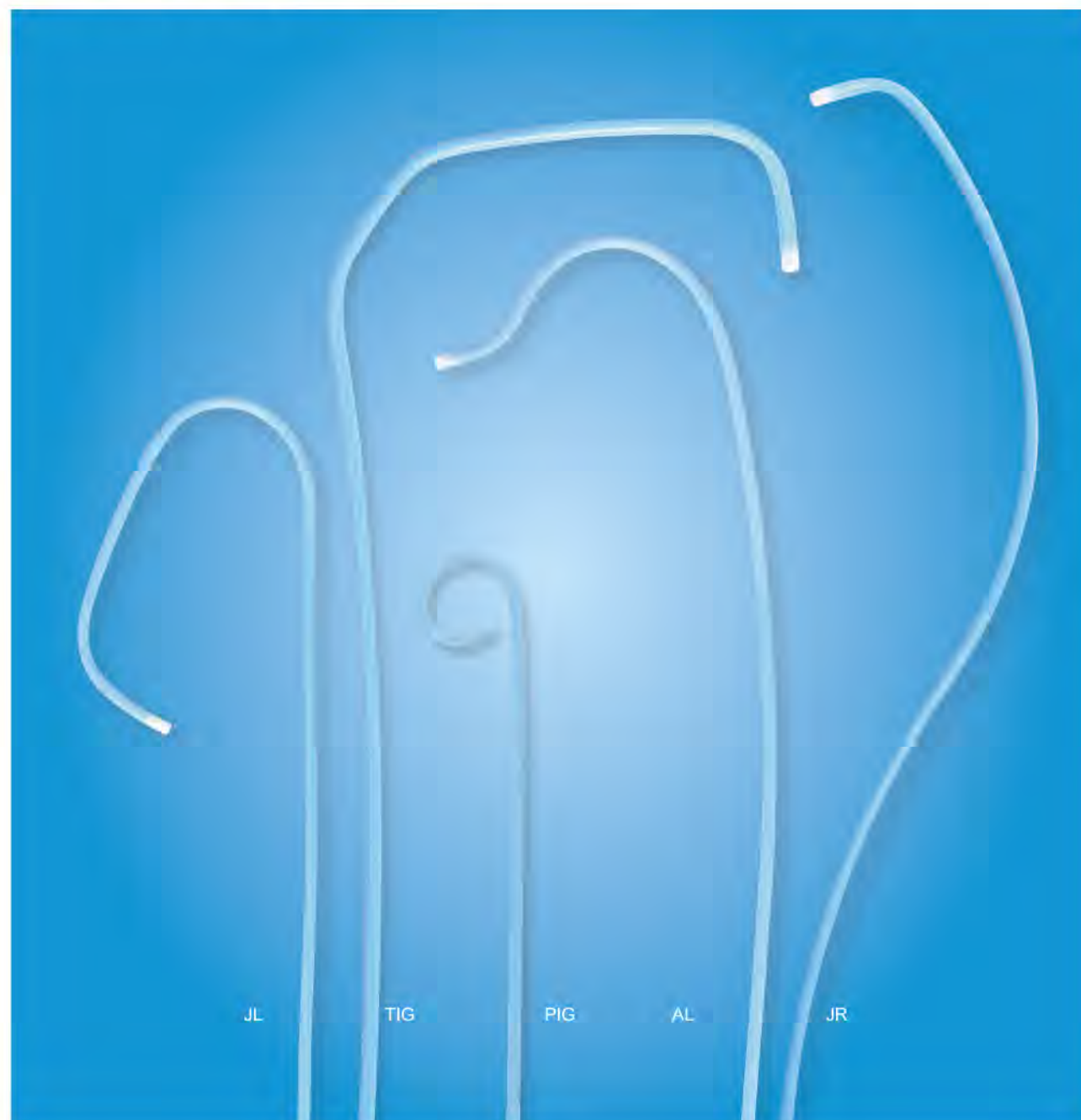


- Thin wall, large bore with polished inner surface
- High quality 304 Stainless Steel
- Sharp needle tip for lower penetration force
- Bevel up orientation

Ref.NO.	O.D. (mm/G)	Length(mm)
SN03	1.20mm/18G	70mm with wings
SN03A	1.20mm/18G	70mm without wings
SN06	0.80mm/21G	45mm without wings

Other Types According to Customer's Requirement

Angiography Catheter



- Soft tip reduces potential for vessel trauma
- Double braided stainless steel for 1:1 torque control
- Maximum pressure: 1200psi / 84 bar
- Maximum Guide wire: 0.038" / 0.97mm

Shape	Fr size	Product code	Shape Name	Length (cm)	Side holes	Shape Illustration
TIG	5F	ACTIG15F	Radial TIG	100	1	
	6F	ACTIG16F	Radial TIG	100	1	
Pigtail	5F	ACPIG5F	Straight Pigtail	110	6	
	5F	ACPIG5F20M10H	Straight Pigtail with 20 marker band	100	10	
	5F	ACPIGA5F	145° Angled Pigtail	110	6	
	6F	ACPIGA6F	145° Angled Pigtail	110	6	
Judkins Left	5F	ACJL355F	JL 3.5	100	/	
	6F	ACJL356F	JL 3.5	100	/	
	5F	ACJL405F	JL 4.0	100	/	
	6F	ACJL406F	JL 4.0	100	/	
	5F	ACJL505F	JL 5.0	100	/	
	6F	ACJL506F	JL 5.0	100	/	
Judkins Right	5F	ACJR355F	JR 3.5	100	/	
	6F	ACJR356F	JR 3.5	100	/	
	5F	ACJR405F	JR 4.0	100	/	
	6F	ACJR406F	JR 4.0	100	/	
	5F	ACJR505F	JR 5.0	100	/	
	6F	ACJR506F	JR 5.0	100	/	
Amplatz	5F	ACAL15F	AL 1	100	/	
	6F	ACAL16F	AL 1	100	/	
	5F	ACAL25F	AL 2	100	/	
	6F	ACAL26F	AL 2	100	/	

High Pressure Tubing



- Unique braiding technology provides clear visualization of air bubbles inside the tubing
- Length customization is acceptable

Ref.NO.	Type	Production Description	Ref.NO.	Type	Production Description
PMT0101	30cm	Female-Male Luer Lock No Leakage under 500psi Pressure	PMT0501	30cm	Rotating adapter No Leakage under 1200psi Pressure
PMT0102	60cm		PMT0502	60cm	
PMT0103	90cm		PMT0503	90cm	
PMT0104	120cm		PMT0504	120cm	
PMT0105	150cm		PMT0505	150cm	
PMT0106	180cm	3-way stopcock-Male Luer lock No Leakage under 40psi Pressure	PMT0509	180cm	Female-Male Luer Lock No Leakage under 1200psi Pressure
PMT0201	30cm		PMT0301	30cm	
PMT0202	60cm		PMT0302	60cm	
PMT0203	90cm		PMT0303	90cm	
PMT0204	120cm		PMT0304	120cm	

Pressure Transducer



- Consistent and accurate pressure monitoring with pressure range: -4~40kPa (-30~300mmHg)
- With built-in flush device to simplify priming the tube and flushing
- Sensitivity: 5μV/V/mmHg±2%

Ref.NO.	Cable	Monitor cable connector	Optional accessories	Ref.NO.	Cable	Monitor cable connector	Optional accessories
DPT0101	I-Type	BD	Flush Set	DPT0403	IV-Type	Argon	Pressure monitoring tubing (1200mm), Flush Set
DPT0102			Pressure monitoring tubing (1200mm), Flush Set, Infusion set (1500mm)	DPT0404			Flush Set, Infusion set (1500mm)
DPT0103			Pressure monitoring tubing (1200mm), Flush Set	DPT0501	V-Type	ACE	Flush Set
DPT0104			Flush Set, Infusion set (1500mm)	DPT0502			Pressure monitoring tubing (1200mm), Flush Set, Infusion set (1500mm)
DPT0201	II-Type	Philip	Flush Set	DPT0503			Pressure monitoring tubing (1200mm), Flush Set
DPT0202			Pressure monitoring tubing (1200mm), Flush Set, Infusion set (1500mm)	DPT0504			Flush Set, Infusion set (1500mm)
DPT0203			Pressure monitoring tubing (1200mm), Flush Set	DPT0601	VI-Type	Utah	Flush Set
DPT0204			Flush Set, Infusion set (1500mm)	DPT0602			Pressure monitoring tubing (1200mm), Flush Set, Infusion set (1500mm)
DPT0301	III-Type	Abbot	Flush Set	DPT0603			Pressure monitoring tubing (1200mm), Flush Set
DPT0302			Pressure monitoring tubing (1200mm), Flush Set, Infusion set (1500mm)	DPT0604			Flush Set, Infusion set (1500mm)
DPT0303			Pressure monitoring tubing (1200mm), Flush Set	DPT0701	VII-Type	ELS	Flush Set
DPT0304			Flush Set, Infusion set (1500mm)	DPT0702			Pressure monitoring tubing (1200mm), Flush Set, Infusion set (1500mm)
DPT0401	IV-Type	Argon	Flush Set	DPT0703			Pressure monitoring tubing (1200mm), Flush Set
DPT0402			Flush Pressure monitoring tubing (1200mm), Flush Set, Infusion set (1500mm)	DPT0704			Flush Set, Infusion set (1500mm)



B

Orthopedic Intervention

- PVP Tool Kit
- Spine Tool Kit
- PKP Balloon Catheter
- Joint Intervention Kit (ECTR Disposable Kit)
- Bone Biopsy Drill
- Bone Needle + Vacuum Lock Syringe

PVP Tool Kit



- Percutaneous Vertebroplasty (PVP) Therapies
- Rotating injection of bone cement provides accurate dosage control
- Different tip configurations (Diamond, Bevel and Trocar) are available

Ref.NO.	Product Description	Product Name
ZT01I	O.D. 3.0mm, W.T. 0.5mm, Length 100mm	Bone Needle
ZT01J	O.D. 3.0mm, W.T. 0.5mm, Length 130mm	
ZT01K	O.D. 3.0mm, W.T. 0.5mm, Length 150mm	
ZT06A	10ml, Fixed connector	Bone Cement Injector
ZT06B	10ml, with high pressure tubing and rotating luer connector	

Spine Tool Kit



- Percutaneous Kyphoplasty (PKP) Therapies
- Rotating injection of bone cement provides accurate dosage control
- Different tip configurations (Diamond, Bevel and Trocar) are available

Ref.NO.	Product Description	Product Name
ZT01I	O.D. 3.0mm, W.T. 0.5mm, Length 100mm	Bone Needle
ZT01J	O.D. 3.0mm, W.T. 0.5mm, Length 130mm	
ZT01K	O.D. 3.0mm, W.T. 0.5mm, Length 150mm	
ZT02A	O.D. 3.4mm, W.T. 0.275mm, Length 190mm	Bone Cement Filler
ZT03A	O.D. 4.2mm, W.T. 0.3mm, Length 125mm	Dilator
ZT04A	O.D. 3.4mm, Length 180mm	Bone Drill
ZT05	O.D.1.55mm, Length 268mm	Guide wire

PKP Balloon Catheter



- Percutaneous Kyphoplasty (PKP) Therapies
- Burst pressure ≥ 16 atm
- Platinum-iridium marker band provides better visibility during operation

Ref.NO.	Product Description		
	Type	Balloon Initial Length	Max Volume
CBT103A	I	10mm	4CC
CBT153A		15mm	4CC
CBT203A		20mm	6CC
PKPQ01	Y	10mm	4CC
PKPQ02		15mm	4CC
PKPQ03		20mm	6CC

Joint Intervention Kit (ECTR Disposable Kit)



- Endoscopic carpal tunnel release (CTR) Therapies, for pressure on the median nerve releasing and carpal tunnel syndrome symptoms relieving.
- Minimized incision compared to Open CTR
- To be associated with minimal pain and scarring due to minimal incision, a shortened recovery period and a high level of patient satisfaction

Ref.NO.	Product Description
LRK01	Dilator O.D. 6mm, Dilator O.D. 7mm, Slotted cannula O.D. 6mm, Slotted cannula O.D. 7mm, Probe knife, Hook Knife, Dissector
LRK02	Dilator O.D. 6mm, Dilator O.D. 7mm, Slotted cannula O.D. 7mm, Probe knife, Hook Knife, Dissector
LRK03	Dilator O.D. 7mm, Slotted cannula O.D. 7mm, Probe knife, Hook Knife, Dissector
LRK04	Dilator O.D. 6mm, Slotted cannula O.D. 6mm, Probe knife, Hook Knife, Dissector

Bone Biopsy Drill



- Small amount of bone biopsy, reducing the injury
- Ergonomic handle design enhance ease of use
- Clockwire cutting trephine teeth to optimize incremental sampling tip, easier for rotary cutting of bone tissue
- With probe for sampling

Ref.NO.	Description
BN01	O.D. 3.0mm, W.T. 0.5mm, Length 100mm
BN01A	O.D. 3.0mm, W.T. 0.5mm, Length 65mm
BN01B	O.D. 3.0mm, W.T. 0.5mm, Length 150mm

Bone Needle + Vacuum Lock Syringe



- Connect the vacuum lock syringe to the bone needle once it is entered into the right position
- To setup the syringe to lock, move the plunger completely back and turn the plunger so that the locking fins can engage the stop pin
- Vacuum lock syringe is designed to minimize hand fatigue and increase procedure efficiency
- Different size of needle is available upon request

Ref.NO.	Description
BNV01	Bone needle(O.D. 1.8mm W.T. 0.25mm Length 65mm)+Vacuum lock syringe 30ml
BNV01A	Bone needle(O.D. 1.8mm W.T. 0.25mm Length 45mm)+Vacuum lock syringe 30ml



A

Peripheral Intervention

- Intestinal Balloon Catheter
- Multifunction Drainage Tube
- Foley Catheter with Hydrophilic Coating
- Pressure Monitoring System for Bladder (Bladder Guard)
- Vaginal Speculum
- Automatic Umbilical Cord Clamps

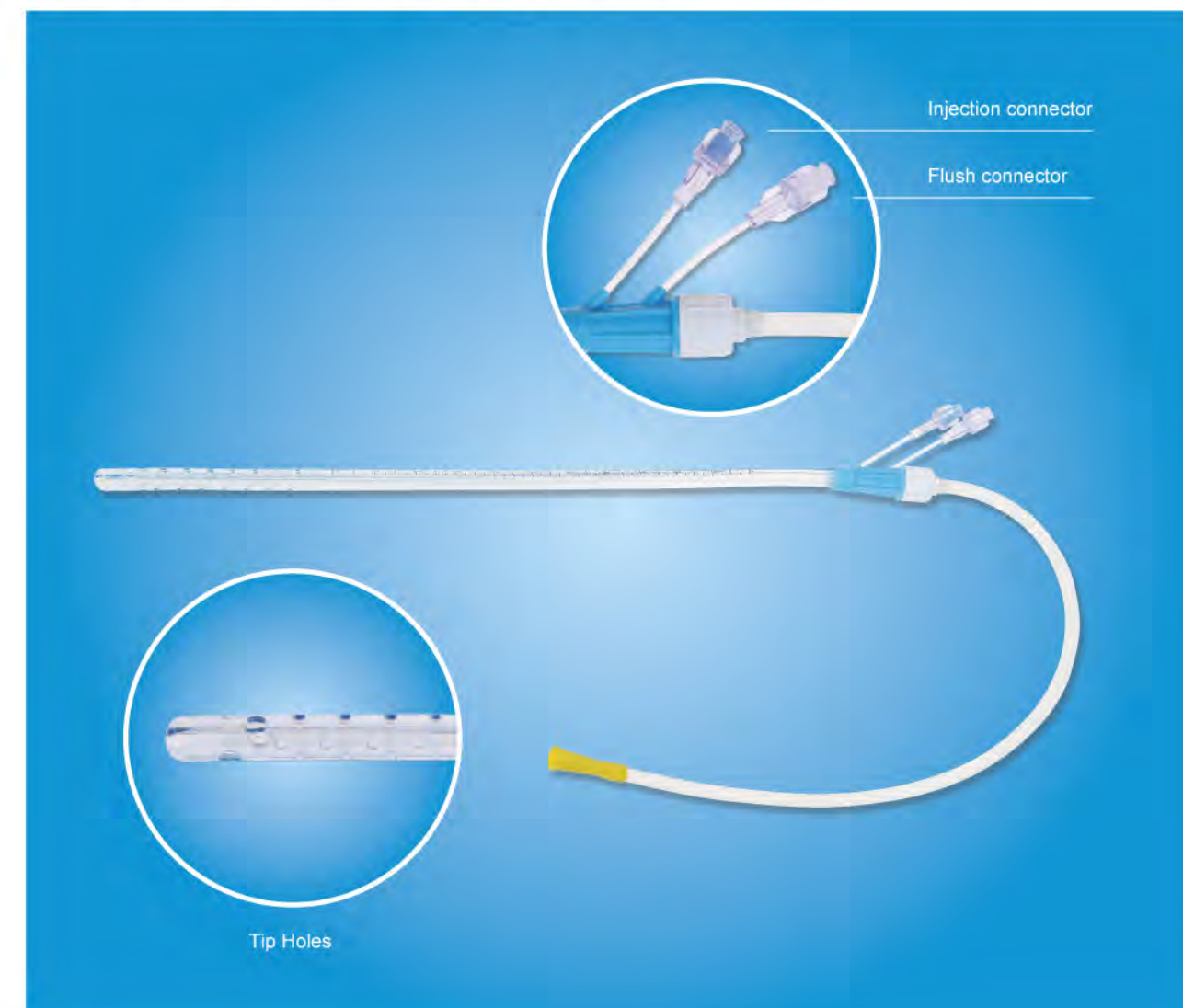
Intestinal Balloon Catheter



- During CT/MRI inspection for patients with complex anal fistula or tumor, the balloon can be either inflated by air or liquid to improves CT/MRI imaging quality
- Enema or medicine can be directly injected into intestine, use the inflated balloon to seal off the potential leakage
- Stop acute bleeding of internal hemorrhoids by the balloon compression
- Replacing normal anal tube for elder patients or patients with external anal sphincter dysfunction to avoid an episode of incontinence
- Apply for insulating of intestinal anastomosis to protect from anastomotic infection

Ref.No.	Length of catheter (mm)	Length of balloonL (mm)	Max O.D. of balloon (mm)	Sketch
CQ1-A	200	150	40	
CQ1-B	200	100	40	
CQ2-A	200	150	40	
CQ2-B	150	70	40	
CQ2-C	150	70	40	
CQ2-D	200	2*70	40	

Multifunction Drainage Tube



- For medicine injection, douche, and drainage therapies
- Flush connector on the distal end for douching
- Pull the inner tube out to clean blood clotting inside the hollow tube
- Providing negative pressure connector to reduce block and infection
- High dose pressured irrigation enables eliminating greater omentum-wrapped block in abdominal cavity

Ref.No.	Product Description
YLG01	4 way connector, cap, inner tube, hollow tube, connecting tube, needle free connector, Cone connector

Foley Catheter with Hydrophilic Coating



- Biomedical grade silicone, safer than latex
- Hydrophilic coating provides superb pushability
- Unique coating technology ensure a long-lasting lubricant surface

Ref. No.	Specification	Type	Cavity Type	Balloon capacity (ml)	Care package (Yes/No)
DNG03	Silicone	6F-26F	2	1.5,5,10,15,30	Y/N
DNG06	Hydrophilic silicone	6F-26F	2	1.5,5,10,15,30	Y/N

Note: Please indicate the foley catheter in exact Ref.No.—Type—Cavity type—balloon Capacity—with or without care package, for example: DNG03—7F—2—5 —Y

Pressure Monitoring System for bladder (Bladder Guard)



- Record and custom setting the bladder pressure for urination
- Record the frequency and temperature of urination
- Lithium battery provide more than 14 days of use with single charge
- Emergency switch button for urgency

Ref. No.	Specification	Type	Cavity Type	Balloon capacity (ml)	Care package (Yes/No)
DNG01	Pressure Monitoring	6F-26F	2	1.5,5,10,15,30	Y/N
DNG02	Temperature & Pressure Monitoring	8F-26F	3	5,10,15,30	Y/N
DNG04	Hydrophilic Pressure Monitoring	6F-26F	2	1.5,5,10,15,30	Y/N
DNG05	Hydrophilic Temperature & Pressure Monitoring	8F-26F	3	5,10,15,30	Y/N

Note: Please indicate the foley catheter in exact Ref.No.—Type—Cavity type—balloon Capacity—with or without care package, for example: DNG01—7F—2—5 —Y

Vaginal Speculum



- Dual smooth edge leaf with locking fins, for safe vaginal check
- Adaptable LED light source eliminates the need for positioning a light source independently
- Self-holding in various positions

Ref.No.	Length(mm)	Width(mm)	Height(mm)
KYQ01	115	50	33
KYQ02	105	40	28
KYQ03	95	30	20

Automatic Umbilical Cord Clamps



- Reducing the blood exposure of newborn
- Recording the separating moment of infant & mother
- Talking clock system
- Birthday reminder system

Ref.No.	Product Description
EUCC-V	Umbilical clamp, handle, blade, electronic watch
UCC-V	Umbilical clamp, handle, blade

Infusion & Injection

- Safety Syringe
- Vacuum Lock Syringe
- PC (Polycarbonate) Syringe
- Infusion Pump
- Disposable Analgesia Pump
- Electric Infusion Pump
- Burette Infusion Set
- Coiled Tube
- Positive Pressure Needle Free Connector
(with or without extension line)
- Needle free connector (with or without extension line)
- Anti-back Flow Needle Free Connector
(with or without extension line)
- Stopcock
- Manifolds for Anesthesiology

Safety Syringe



- Retractable needle technology – manual retraction, reduce needle exposure and increase users control and safety
- Snap off the plunger after needle retraction, to encapsulating the used needle
- Safe disposal after use and further prevention of reuse or needlestick injury

Ref.NO.	Product Description	
	Type	With needle size
SS03	3ml	21G, 22G, 23G, 24G, 25G, 26G, 27G, G28G, G29G, G30G, 31G
SS05	5ml	
SS10	10ml	
SS20	20ml	

Vacuum Lock Syringe



- Multiple locking positions, designed ease of use
- PC barrel and ABS plunger provides high strength

Ref.NO.	Product Description
ZZSQ30	30ml dosage, 6 lock positions

PC (Polycarbonate) Syringe



- The color coded syringes help prevent potentially dangerous medication errors
- Polycarbonate material provides clear and smooth visualization of fluid and air bubbles
- Luer lock tip, latex-free

Ref.NO.	Product Description	Ref.NO.	Product Description	Ref.NO.	Product Description
ZSQ1R	1ml, Red plunger	ZSQ3LG	3ml, Light Green plunger	ZSQ10P	10ml, Purple plunger
ZSQ1B	1ml, Blue plunger	ZSQ3DG	3ml, Dark Green plunger	ZSQ10Y	10ml, Yellow plunger
ZSQ1W	1ml, White plunger	ZSQ6R	6ml, Red plunger	ZSQ10DG	10ml, Dark Green plunger
ZSQ1P	1ml, Purple plunger	ZSQ6B	6ml, Blue plunger	ZSQ10LG	10ml, Light Green plunger
ZSQ1Y	1ml, Yellow plunger	ZSQ6W	6ml, White plunger	ZSQ20R	20ml, Red plunger
ZSQ1LG	1ml, Light Green plunger	ZSQ6P	6ml, Purple plunger	ZSQ20B	20ml, Blue plunger
ZSQ1DG	1ml, Dark Green plunger	ZSQ6Y	6ml, Yellow plunger	ZSQ20W	20ml, White plunger
ZSQ3R	3ml, Red plunger	ZSQ6LG	6ml, Light Green plunger	ZSQ20P	20ml, Purple plunger
ZSQ3B	3ml, Blue plunger	ZSQ6DG	6ml, Dark Green plunger	ZSQ20Y	20ml, Yellow plunger
ZSQ3W	3ml, White plunger	ZSQ10R	10ml, Red plunger	ZSQ20DG	20ml, Dark Green plunger
ZSQ3P	3ml, Purple plunger	ZSQ10B	10ml, Blue plunger	ZSQ20LG	20ml, Light Green plunger
ZSQ3Y	3ml, Yellow plunger	ZSQ10W	10ml, White plunger		

Infusion Pump



- Elastic balloon provides constantly infusion pressure
- Air-eliminate-filter can filtering particles $\geq 2\mu\text{m}$
- Patented pressure stabilizing valve can maintain the pressure at 10 kPa (Regular infusion pressure)
- The elastomeric pump does not run by gravity as a regular IV does. It is totally portable and can be carried in a pocket or pouch
- Flow rate: 30 ~ 250 ml/h

Ref No.	Description	Configuration
IP60WR	60ml ; pressure balancer; flow regulator	
IP100WR	100ml ; pressure balancer; flow regulator	
IP200WR	200ml ; pressure balancer; flow regulator	
IP300WR	300ml ; pressure balancer; flow regulator	

Disposable Analgesia Pump



- Elastic balloon provides constantly infusion pressure
- Air-eliminate-filter can filtering particles $\geq 2\mu\text{m}$
- Microbore tube provides stable and accurate flow rate
- Bolus volume: 0.5ml/15min, 1ml/15min
- Flow rate: 1 ml/h~10 ml/h

Ref No.	Description	Configuration
IP6020	60ml; 2ml/h	
IP10020	100ml; 2ml/h	
IP20020	200ml; 2ml/h	
IP30020	300ml; 2ml/h	
IP6020B	60ml; 2ml/h; 0.5ml/15min	
IP10020B	100ml; 2ml/h; 0.5ml/15min	
IP20020B	200ml; 2ml/h; 0.5ml/15min	
IP30020B	300ml; 2ml/h; 0.5ml/15min	

Electric Injection Pump



- Convenient to install and use
- Used for micro-injection(IP-I) and liquid transfer(IP-II)
- Easier for nurses to transfer the liquid medication into the disposable analgesia pump or infusion pump (IP-II)
- Variety of operating modes with overpressure protection and alarm system

Ref.NO.	Type	Product Description
103IPI	IP-I	Used for micro-injection with 5ml syringe, flow rate: 1ml/h~150ml/h 10ml syringe, flow rate: 1ml/h~300ml/h 20ml syringe, flow rate: 1ml/h~600ml/h 30ml syringe, flow rate: 1ml/h~900ml/h 50ml syringe, flow rate: 1ml/h~1200ml/h
103IPII	IP-II	Used for liquid transfer

Burette Infusion Set



- Needle free injection site provides safer application environment
- Auto-stop floating valve inside enables safe infusion
- Flexible, transparent drip chamber with various dropper: 10/20/60 drops per ml

Ref.NO.	Product Description
XDP04	150ml with needle free Y connector
XDP10	150ml with Injection site
XDP13	150ml with straight tube

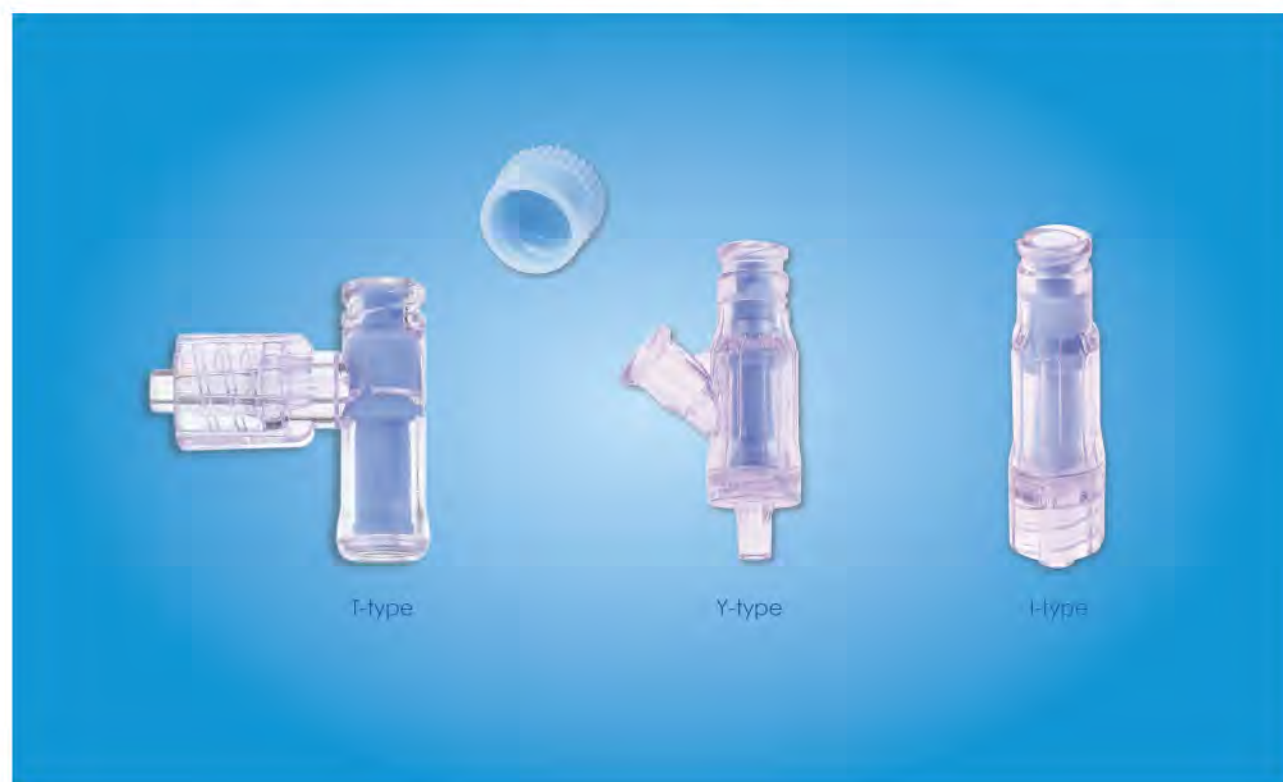
Coiled Tube



- The tubing stretches and retracts when needed during procedure
- DEHP free and Latex free
- Back check valve is available upon request

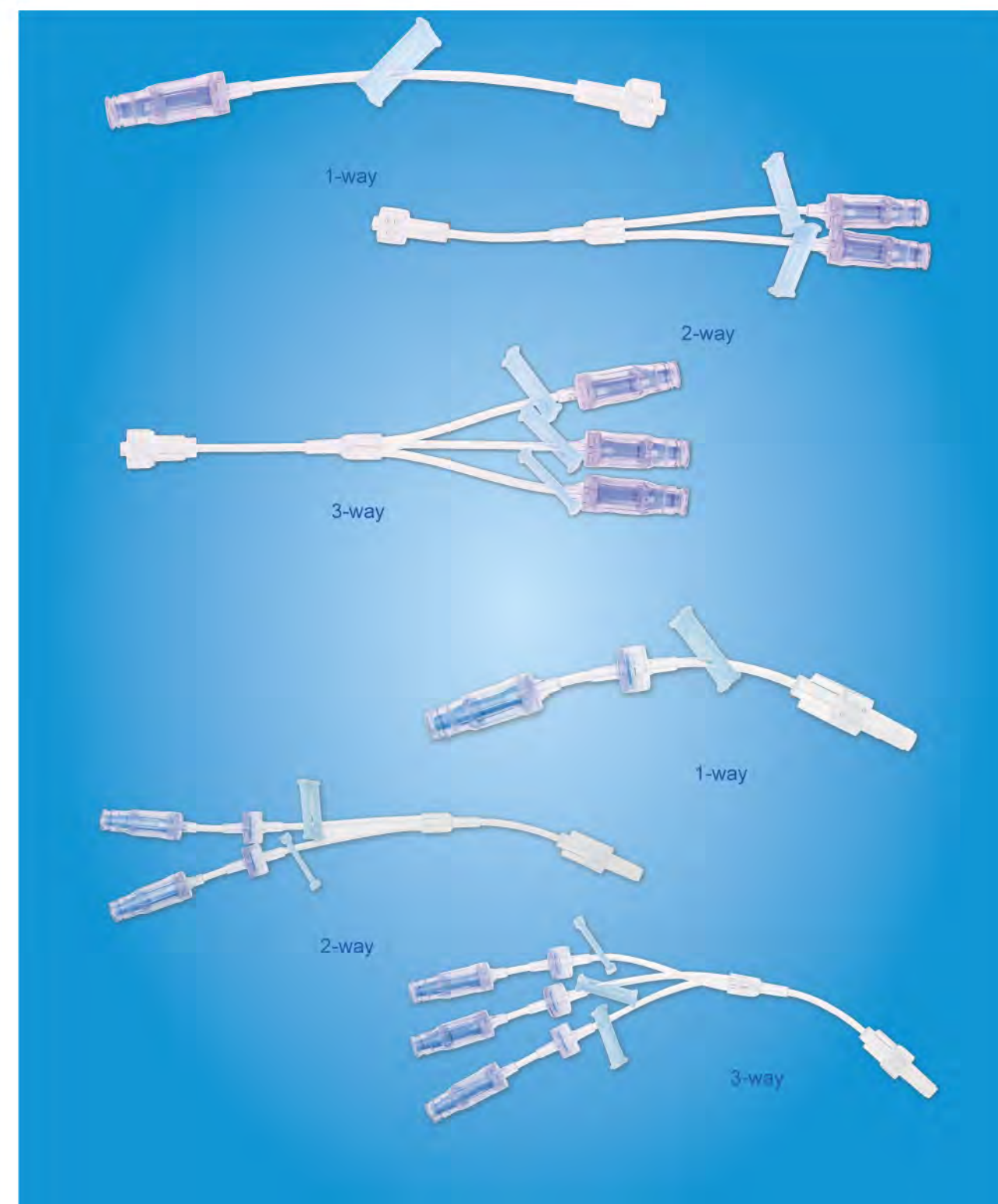
Ref.NO.	Length (cm)	Mpa (PSI)	Description
PMT0107	150	500	PVC, 1.8*3.3mm, Female-male luer lock
PMT0108			PVC, 1.8*3.3mm, Female-male luer lock, 2-way
PMT0109			PVC, 1.8*3.3mm, Female-male luer lock, 2- way with 1 check valve
PMT0110			PVC, 1.8*3.3mm, Female-male luer lock, 2- way with 2 check valve
ET0501A	200	350	PU, 1*2mm, Female-male luer lock
ET0501			PU, 1*2mm , Female-male luer lock
ET0501B			PU, 1.3*2.3mm, Female-male luer lock
ET0502			PU, 1*2mm, Female-male luer lock with needle free connector

Positive Pressure Needle Free Connector (with or without extension line)



- Special designed stem provides enhanced positive flushing
- Clear housing enables visibility of the inside liquid flow
- Disposable safety cap provides better infection control
- Made of biomedical grade silicone without metal components makes it compatible to MRI
- No leakage under 100 kPa /300 kPa

Ref.NO.	Product Description	Mpa
NFC08A	Y-port type, lipid-resistant	/
NFC08B	Female-Tube ends 1.3*2.3mm, lipid-resistant	/
NFC08C	Male-Female ends, lipid-resistant	/
NFV0107	1-way 1.3*2.3mm	100 kPa
NFV0207	2-ways 1.3*2.3mm	
NFV0307	3-ways 1.3*2.3mm	
NFV0105	1-way 1.3*2.3mm, with check valve	300 kPa
NFV0206	2-ways 1.3*2.3mm, with check valve	
NFV0305	3-ways 1.3*2.3mm, with check valve	



Needle free connector (with or without extension line)



- No leakage under 300 kPa
- Flow rate: > 100ml/min
- Latex-free

Ref.NO.	Product Description	Mpa
NFC01	Male-Female ends	/
NFC01A	Male-Female ends, lipid-resistant	/
NFC02	Female-Tube ends 1.3*2.3mm	/
NFC02A	Female-Tube ends 1.3*2.3mm, lipid-resistant	/
NFC04A	Tube-Tube ends Y-port type, lipid-resistant	/
NFC05	Female-Tube ends 3*4mm	/
NFC05A	Female-Tube ends 3*4mm, lipid-resistant	/
NFC06	Tube-Tube ends H-port type	/
NFC06A	Tube-Tube ends H-port type, lipid-resistant	/
NFV0101	1-way 1.3*2.3mm	100 kPa
NFV0102	1-way 3.0*4.0mm	
NFV0201	2-ways 1.3*2.3mm	
NFV0202	2-ways 3.0*4.0mm	
NFV0301	3-ways 1.3*2.3mm	
NFV0302	3-ways 3.0*4.0mm	
NFV0106	1-way 1.3*2.3mm, with check valve	300 kPa
NFV0203A	2-ways 1.3*2.3mm, with check valve	
NFV0306	3-ways 1.3*2.3mm, with check valve	



Anti-back Flow Needle Free Connector(with or without extension line)



- Needle free connector integrated with back check valve
- No leakage under 300 kPa
- Flow rate: > 10ml/min
- Latex-free

Ref.NO.	Product Description
NFC20	Female- Male ends
NFC21	Male-Female ends
NFC22	Female-Tube ends 1.3*2.3mm
NFV0108	1-way 1.3*2.3mm
NFV0208	2-ways 1.3*2.3mm
NFV0308	3-ways 1.3*2.3mm

Stopcock



- No Leakage under 45/500/1000psi
- Smooth rotation, easy to use
- Lipid-resistant material specialized for anesthesiology drugs

Ref.NO.	Product Description	Mpa	Lipid-resist
AM0101	"ON" Type, with luer fitting,	/	Available
AM0102	"OFF" Type, with luer fitting,	/	
AM0103	"ON" Type, without luer fitting, for tube connecting	/	
AM0104	"OFF" Type, without luer fitting, for tube connecting	/	
AM0108	"ON" Type, rotating Adapter,	500PSI	Available
AM0110	"OFF" Type, rotating Adapter,	500PSI	
AM0106	"ON" Type, rotating Adapter	1000PSI	
AM0109	"OFF" Type, rotating Adapter	1000PSI	

Manifolds for Anesthesiology



- 3 ways infusion available
- Lipid-resistant material specialized for anesthesiology drugs
- No leakage under 500 psi

Ref.NO.	Product Description
AM0311	"ON" type with 360° rotating adapter, right port orientation





Needle free connector (with or without extension line)

- No leakage under 300 kPa
- Flow rate: > 100ml/min
- Latex-free

Ref.NO.	Product Description	Mpa
NFC01	Male-Female ends	/
NFC01A	Male-Female ends, lipid-resistant	/
NFC02	Female-Tube ends 1.3*2.3mm	/
NFC02A	Female-Tube ends 1.3*2.3mm, lipid-resistant	/
NFC04A	Tube-Tube ends Y-port type, lipid-resistant	/
NFC05	Female-Tube ends 3*4mm	/
NFC05A	Female-Tube ends 3*4mm, lipid-resistant	/
NFC06	Tube-Tube ends H-port type	/
NFC06A	Tube-Tube ends H-port type, lipid-resistant	/
NFV0101	1-way 1.3*2.3mm	100 kPa
NFV0102	1-way 3.0*4.0mm	
NFV0201	2-ways 1.3*2.3mm	
NFV0202	2-ways 3.0*4.0mm	
NFV0301	3-ways 1.3*2.3mm	
NFV0302	3-ways 3.0*4.0mm	
NFV0106	1-way 1.3*2.3mm, with check valve	300 kPa
NFV0203A	2-ways 1.3*2.3mm, with check valve	
NFV0306	3-ways 1.3*2.3mm, with check valve	





Anti-back Flow Needle Free Connector (with or without extension line)

- Needle free connector integrated with back check valve
- No leakage under 300 kPa
- Flow rate: > 10ml/min
- Latex-free

Ref.NO.	Product Description
NFC20	Female- Male ends
NFC21	Male-Female ends
NFC22	Female-Tube ends 1.3*2.3mm
NFV0108	1-way 1.3*2.3mm
NFV0208	2-ways 1.3*2.3mm
NFV0308	3-ways 1.3*2.3mm





Stopcock

- No Leakage under 45/500/1000psi
- Smooth rotation, easy to use
- Lipid-resistant material specialized for anesthesiology drugs

Ref.NO.	Product Description	Mpa	Lipid-resist
AM0101	"ON" Type, with luer fitting,	/	Available
AM0102	"OFF" Type, with luer fitting,	/	
AM0103	"ON" Type, without luer fitting, for tube connecting	/	
AM0104	"OFF" Type, without luer fitting, for tube connecting	/	
AM0108	"ON" Type, rotating Adapter,	500PSI	Available
AM0110	"OFF" Type, rotating Adapter,		
AM0106	"ON" Type, rotating Adapter	1000PSI	
AM0109	"OFF" Type, rotating Adapter		



Manifolds for Anesthesiology

- 3 ways infusion available
- Lipid-resistant material specialized for anesthesiology drugs
- No leakage under 500 psi

Ref.NO.	Product Description
AM0311	"ON" type with 360° rotating adapter, right port orientation