

HEMOSTASIS VALVE SETS

Features

- Various types to meet the clinician's habits
- Pressure resistance and good sealing valve to reduce the blood loss.

Contents

- Hemostasis Valve
- Guide Wire Insertion Tool
- Torque Device



Product No.	Description	Product No.	Description
42.03.10000	Twist Y Connector	42.03.10002	Push pull Y Connector with 25 cm extension line and stopcock
42.03.10001	Push pull Y Connector	42.03.10006	Y Click Type with 25 cm extension line and stopcock
42.03.10004	Y Click Type	42.03.10003	Push pull Y Connector with 45 cm extension line and stopcock
42.03.10005	Twist Y Connector with 25 cm extension line and stopcock	42.03.10012	Y click Connector with 45 cm extension line and stopcock:

BALLOON INFLATION DEVICES – GUN TYPE

Features

- Easy to inflate even at high temperatures
- Pressure is released quickly
- The modified humanized design fits comfortably when operation



Product No.	Volume (ml)	Contents
42.04.30104	20	Balloon inflation device, Stopcock("RIGHT ON")
42.04.30103	20	Balloon inflation device, Stopcock("RIGHT OFF")
42.04.40051	20	Balloon inflation device, Stopcock("Right OFF")+Hemostasis Valve Set (Twist Type with 25cm Extension line & Stopcocks)
42.04.40052	20	Balloon inflation device, Stopcock("Right ON")+Hemostasis Valve Set(Push pull with 25cm Extension line & Stopcocks)
42.04.40053	20	Balloon inflation device, Stopcock("Right OFF")+Hemostasis Valve Set(Push pull with 25cm Extension line & Stopcocks)

BALLOON INFLATION DEVICES

Features

- Accurate reading, reliable inflation and deflation.
- Modified humanized design handle facilitates doctor's operation.
- Locking design enables one handed operation in deflation.



Product No.	Volume (ml)	Contents
42.04.30000	20	Balloon inflation device, Stopcock("RIGHT ON")
42.04.30001	20	Balloon inflation device, Stopcock("RIGHT OFF")
42.04.30002	30	Balloon inflation device, Stopcock("RIGHT ON")
42.04.30003	30	Balloon inflation device, Stopcock("RIGHT OFF")

Product No.	Volume (ml)	Contents
42.04.40000	20	Balloon inflation device, Stopcock("RIGHT ON")+ Hemostasis valve set (Twist)
42.04.40001	20	Balloon inflation device, Stopcock("RIGHT OFF")+ Hemostasis valve set (Twist)
42.04.40002	30	Balloon inflation device, Stopcock("RIGHT ON")+ Hemostasis valve set (Twist)
42.04.40003	30	Balloon inflation device, Stopcock("RIGHT OFF")+ Hemostasis valve set (Twist)
42.04.40012	20	Balloon inflation device, Stopcock("RIGHT ON")+Hemostasis valve set(Push Pull)
42.04.40013	20	Balloon inflation device, Stopcock("RIGHT OFF")+Hemostasis valve set(Push Pull)
42.04.40014	30	Balloon inflation device, Stopcock("RIGHT ON")+Hemostasis valve set(Push Pull)
42.04.40015	30	Balloon inflation device, Stopcock("RIGHT OFF")+Hemostasis valve set(Push Pull)
42.04.40004	20	Balloon inflation device, Stopcock("RIGHT ON")+Hemostasis valve set(Push Pull with 25cm extension line&stopcock)
42.04.40005	20	Balloon inflation device, Stopcock("RIGHT OFF")+Hemostasis valve set(Push Pull with 25cm extension line&stopcock)
42.04.40006	30	Balloon inflation device, Stopcock("RIGHT ON")+Hemostasis valve set(Push Pull with 25cm extension line&stopcock)
42.04.40007	30	Balloon inflation device, Stopcock("RIGHT OFF")+Hemostasis valve set(Push Pull with 25cm extension line&stopcock)
42.04.40026	20	Balloon inflation device, Stopcock("RIGHT OFF")+Hemostasis valve set(Twist type with 25cm extension line&stopcock)
42.04.40027	20	Balloon inflation device, Stopcock("RIGHT ON")+Hemostasis valve set(Twist type with 25cm extension line&stopcock)
42.04.40017	30	Balloon inflation device, Stopcock("RIGHT ON")+Hemostasis valve set(Twist type with 25cm extension line&stopcock)
42.04.40016	30	Balloon inflation device, Stopcock("RIGHT OFF")+Hemostasis valve set(Twist type with 25cm extension line&stopcock)

BALLOON INFLATION DEVICES

Introduction

SCW balloon inflation device provide reliable and accurate inflation for your most demanding cases. Ergonomically designed with accuracy and quality in mind, easy to control and finish the inflation and deflation procedures, SCW balloon inflation devices are also available in custom kit configuration.

Features

- Max Pressure: 30 Bar , 40 Bar
- Accurate;
- Stable performance;
- Simple operation



Max Pressve: 30 Bar

Product No.	Volume (ml)	Contents
42.04.10000	20	Balloon inflation device, Stopcock("RIGHT ON")
42.04.10001	20	Balloon inflation device, Stopcock("RIGHT OFF")
42.04.20000	20	Balloon inflation device, Stopcock("Right ON")+Hemostasis Valve Set(Twist Type)
42.04.20001	20	Balloon inflation device, Stopcock("Right OFF")+Hemostasis Valve Set (Twist Type with 25cm Extension line & Stopcocks)
42.04.20002	20	Balloon inflation device, Stopcock("Right ON")+Hemostasis Valve Set(Push pull with 25cm Extension line & Stopcocks)
42.04.20003	20	Balloon inflation device, Stopcock("Right OFF")+Hemostasis Valve Set(Push pull with 25cm Extension line & Stopcocks)

Max Pressve: 40 Bar

Product No.	Volume (ml)	Contents
42.04.10009	20	Balloon inflation device, Stopcock("RIGHT ON")
42.04.10010	20	Balloon inflation device, Stopcock("RIGHT OFF")
42.04.10011	20	Balloon inflation device, Stopcock("Right ON")+Hemostasis Valve Set(Twist Type)
42.04.20006	20	Balloon inflation device, Stopcock("Right OFF")+Hemostasis Valve Set (Twist Type with 25cm Extension line & Stopcocks)
42.04.20007	20	Balloon inflation device, Stopcock("Right ON")+Hemostasis Valve Set(Push pull with 25cm Extension line & Stopcocks)
42.04.20008	20	Balloon inflation device, Stopcock("Right OFF")+Hemostasis Valve Set(Push pull with 25cm Extension line & Stopcocks)

DOSE-CONTROL SYRINGES



Features

- Clear body provides excellent clarification and smooth as glass feeling
- Solid piston barrel Maintains stable and persistent under pressure
- Rotating and Fixed Luers , in luer connection it allows for flexibility and dependence
- Safety of space ,Intended to reduce the potential of air bubbles getting into the catheter
- Safety of reservoir,available with 0.5 mL taking precautions against bottoming out during injection

Product No.	Description	Tip Style	Product No.	Description	Tip Style
42.07.10001	10ml Thumb Ring&Finger Rings	Rotator Tip	42.07.20001	10 Thumb Ring&Finger Rings	Fixed Tip
42.07.10002	12ml Thumb Ring&Finger Rings	Rotator Tip	42.07.20002	12 Thumb Ring&Finger Rings	Fixed Tip
42.07.10003	20ml Thumb Ring&Finger Rings	Rotator Tip	42.07.20003	20 Thumb Ring&Finger Rings	Fixed Tip



COLORED PISTON SPECIALTY SYRINGES

Features

- Clear body provides excellent clarification
- Smooth operation
- Safety increased that reduces incidence rate of syringe exchange

Product No.	Description	Product No.	Description	Product No.	Description	Product No.	Description
42.15.10000	3ml White	42.15.20000	6ml White	42.15.30000	10ml White	42.15.40000	20ml White
42.15.10001	3ml Red	42.15.20001	6ml Red	42.15.30001	10ml Red	42.15.40001	20ml Red
42.15.10002	3ml Green	42.15.20002	6ml Green	42.15.30002	10ml Green	42.15.40002	20ml Green
42.15.10003	3ml Blue	42.15.20003	6ml Blue	42.15.30003	10ml Blue	42.15.40003	20ml Blue
42.15.10004	3ml Yellow	42.15.20004	6ml Yellow	42.15.30004	10ml Yellow	42.15.40004	20ml Yellow
						42.15.40005	20ml Purple



EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60144232 0001

Report No.: 17047213 010

Manufacturer: SCW Medicath Ltd.
No. 4 Baolong 6th Road
Baolong Industrial Town
Longgang District, Shenzhen
518116 Guangdong
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60139711 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-05-26

Date: 2020-05-26

Notified Body

Fuxiu Sheng



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60144232 0001
Report No.: 17047213 010

Manufacturer: SCW Medicath Ltd.
No. 4 Baolong 6th Road
Baolong Industrial Town
Longgang District, Shenzhen
518116 Guangdong
P.R. China

Products:

- Disposable Pressure Transducers
- Introducer Sets
- Guide Wires
- Angiographic Syringes
- Hemodialysis Catheterization Kits
- Patient-Controlled Analgesic Infusion Pumps
- Disposable Infusion Pumps
- Tracheostomy Tube Kits
- Percutaneous Nephrostomy Sets
- Ureteral Stent Sets
- Drainage Catheter Sets
- Transradial Introducer Sets
- Introducer Needles
- I.V Cannulas
- Cervical Ripening Balloon
- Postpartum Balloon

Date: 2020-05-26

Notified Body



Fuxiu Sheng



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60144232 0001
Report No.: 17047213 010

Manufacturer: SCW Med cath Ltd.
No. 4 Baolong 6th Road
Baolong Industrial Town
Longgang District, Shenzhen
518116 Guangdong
P.R. China

Products:

- Locking Drainage Catheters
- Percutaneous Access Sets
- ERCP Guidewires
- Manifolds
- Stopcocks
- Manifold Sets
- Connecting Tubings

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Dose-control Syringes
- Balloon Inflation Devices
- Colored Piston Specialty Syringes
- Infusion Sets with Needleless Adapters
- Pressure Bandages
- Hemostasis Valve Sets
- Injection Caps

Date: 2020-05-26

Notified Body



Fuxiu Sheng



Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2095157-1

Organization: SCW Medicath Ltd.
No. 4, Baolong 6th Road, Baolong
Industrial Town, Longgang District
Shenzhen
518116 Guangdong
P.R. China

Scope: Design and Development, Manufacture and Distribution of Disposable Pressure Transducers, Introducer Sets, Guide Wires, Angiographic Syringes, Hemodialysis Catheterization Kits, Patient-Controlled Analgesic Infusion Pumps, Disposable Infusion Pumps, Tracheostomy Tube Kits, Percutaneous Nephrostomy Sets, Ureteral Stent Sets, Drainage Catheter Sets, Transradial Introducer Sets, Introducer Needles, I.V Cannulas, Cervical Ripening Balloon, Postpartum Balloon, Manifolds, Stopcocks, Manifold Sets, Connecting Tubings, Dose-control Syringes, Balloon Inflation Devices, Colored Piston Specialty Syringes, Infusion Sets with Needleless Adapters, Pressure Bandages, Hemostasis Valve Sets, Locking Drainage Catheters, Percutaneous Access Sets, ERCP Guidewires, Injection Caps

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10918574-100
Effective date: 2021-07-09
Expiry date: 2024-07-08
Issue date: 2021-07-05



A handwritten signature in blue ink, appearing to be 'W. Hsu'.

Dipl.-Ing. W. Hsu

TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02