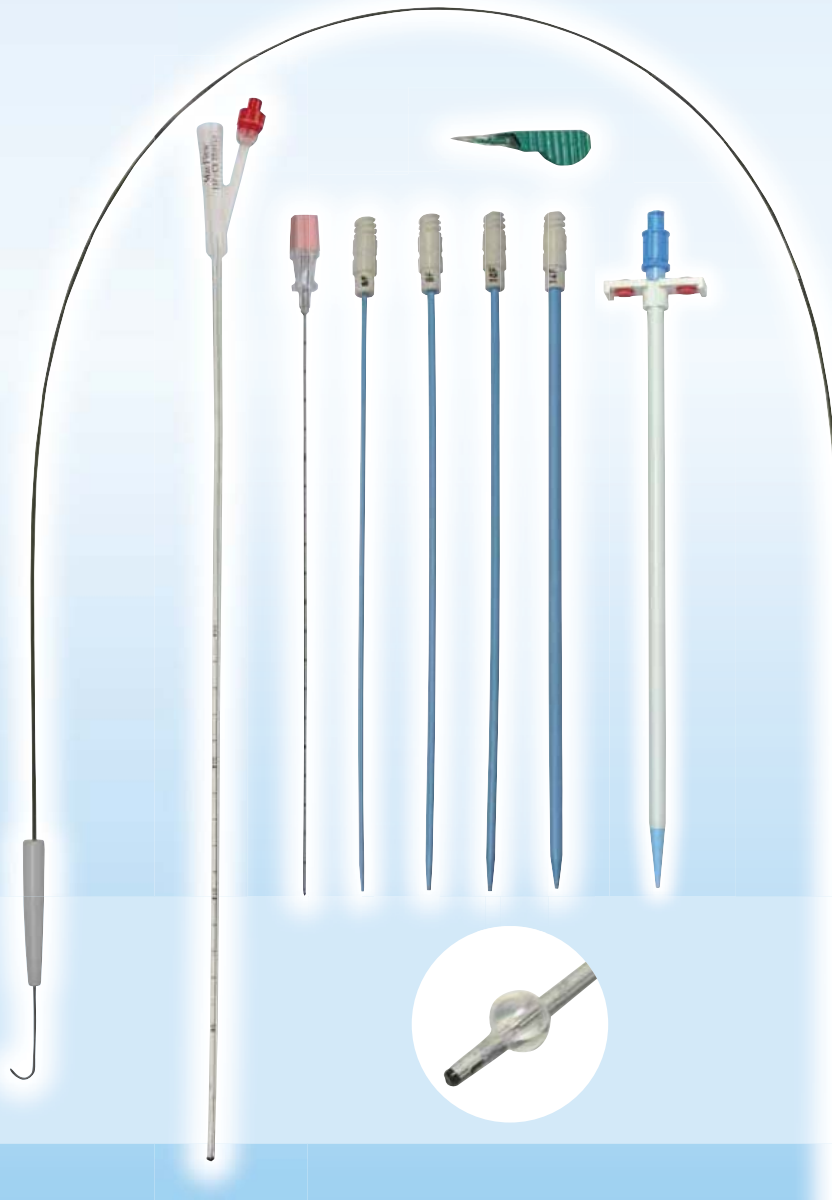


Nephrostomy Drainage Set with 100% Silicone Integral Catheter



Nephrostomy Drainage Set with 100% Silicone Integral Catheter

A convenient complete set for percutaneous placement of a 2-way Silicone Integral Balloon Catheter. Excellent biocompatibility and drainage. Laying time up to 30 days

1 Set consists of:

- Drainage Catheter 40cm, usable length 35cm, plus straightener
- 2-part puncture needle 1,3mm (18 GA)
- Lunderquist Guidewire 80cm J-Tip, fixed core, stainless steel, 0.035"
- Fascial Dilators 20cm, ABS
- Urine Bag connector

Set with 2-way INTEGRAL Balloon Catheter

Art. No.	Catheter Size (Fr/CH)	Balloon (cc/ml)	Facial Dilators (Fr/CH)
CH-PCNL 10	10	1.5	6 - 8 - 10
CH-PCNL 12	12	2	8 - 10 - 12
CH-PCNL 14	14	3	10 - 12 - 14
CH-PCNL 16	16	5	10 - 12 - 14 - 16

INTEGRAL Exchange Set

Same as drainage set without puncture needle

CH-PCNL 10-E	10	1.5	6 - 8 - 10
CH-PCNL 12-E	12	2	8 - 10 - 12
CH-PCNL 14-E	14	3	10 - 12 - 14
CH-PCNL 16-E	16	5	10 - 12 - 14 - 16

INTEGRAL Balloon Catheter only

CH-PCNL 10-S	10	1.5
CH-PCNL 12-S	12	2
CH-PCNL 14-S	14	3
CH-PCNL 16-S	16	5
CH-PCNL 18-S	18	5
CH-PCNL 20-S	20	5

Class IIb device - for single use only

Ureter Access Sheath Standard

Made of Polyurethane
Tecoflex® USA
Dilator: PEBAX

Provides **ureteral dilation** and
a **continous working channel**
for the introduction of Endoscopes
and Instruments during ureteral
access procedures.

Art. No.	Sheath Inner Diameter Size (Fr/CH) = mm	Sheath Length
UAS 10-13	10 = 3.3	13
UAS 10-20	10 = 3.3	20
UAS 10-28	10 = 3.3	28
UAS 10-30	10 = 3.3	30
UAS 10-35	10 = 3.3	35
UAS 10-45	10 = 3.3	45
UAS 12-13	12 = 4	13
UAS 12-20	12 = 4	20
UAS 12-28	12 = 4	28
UAS 12-30	12 = 4	30
UAS 12-35	12 = 4	35
UAS 12-45	12 = 4	45
UAS 14-13	14 = 4.7	13
UAS 14-20	14 = 4.7	20
UAS 14-28	14 = 4.7	28
UAS 14-30	14 = 4.7	30
UAS 14-35	14 = 4.7	35
UAS 14-45	14 = 4.7	45

Class IIa device – for single use only

Ureter Access Sheath Braided

Made of Polyurethane (braided)
Tecoflex® USA
Dilator: PEBAX
Silver part: Stainless steel, braided tube

Provides **ureteral dilation** and
a **continous working channel**
for the introduction of Endoscopes
and Instruments during ureteral
access procedures.

Art. No.	Sheath Inner Diameter Size (Fr/CH) = mm	Sheath Length
UAS-B 10-13	10 = 3.3	13
UAS-B 10-20	10 = 3.3	20
UAS-B 10-28	10 = 3.3	28
UAS-B 10-30	10 = 3.3	30
UAS-B 10-35	10 = 3.3	35
UAS-B 10-45	10 = 3.3	45
UAS-B 12-13	12 = 4	13
UAS-B 12-20	12 = 4	20
UAS-B 12-28	12 = 4	28
UAS-B 12-30	12 = 4	30
UAS-B 12-35	12 = 4	35
UAS-B 12-45	12 = 4	45
UAS-B 14-13	14 = 4.7	13
UAS-B 14-20	14 = 4.7	20
UAS-B 14-28	14 = 4.7	28
UAS-B 14-30	14 = 4.7	30
UAS-B 14-35	14 = 4.7	35
UAS-B 14-45	14 = 4.7	45

UAS-BH hydrophilic coated

Class IIa device – for single use only

TUR Electrodes

For Prostate Surgery



Sphere Electrode (5mm Ball)



Cutting Loop for 30° Optic



Necklace Electrode



Cold Knife Electrode



Roller Electrode



Kriloktrode Electrode
(Simultaneous Cutting & Vaporization)



Collins Knife



Spike Roller Electrode

TUR Electrodes MONOPOLAR

STORZ, 2 Stem, 30° Degrees, 24Fr

Cutting Loop **W-DC-24Fr**
 Collin's Knife **W-DZ-24Fr**
 Roller Electrode **W-DR-24Fr**
 Ball Electrode 3mm **W-DB-24Fr**

Ball Electrode 5mm **W-DS-24Fr**
 Kriloktrode **W-DK-24Fr**
 Cold Knife **W-DP-24Fr**
 Necklace **W-DN-24Fr**

Spike 3mm **W-DW-24Fr**
 Spike 5mm **W-DV-24Fr**

OLYMPUS, 1 Stem, 12° Degrees, 24Fr

Cutting Loop **W-OC-24Fr**
 Collin's Knife **W-OZ-24Fr**
 Roller Electrode **W-OR-24Fr**

Ball Electrode 3mm **W-OB-24Fr**
 Sphere Electrode 5mm **W-OS-24Fr**
 Kriloktrode **W-OK-24Fr**

WOLF, 1 Stem, 15° Degrees, 24Fr

Cutting Loop **W-WC-24Fr**
 Collin's Knife **W-WZ-24Fr**
 Roller Electrode **W-WR-24Fr**

Ball Electrode 3mm **W-WB-24Fr**
 Sphere Electrode 5mm **W-WS-24Fr**
 Kriloktrode **W-WK-24Fr**

STORZ, 1 Stem, 30° Degrees, 24Fr

Cutting Loop **W-SC-24Fr**
 Collin's Knife **W-SZ-24Fr**
 Roller Electrode **W-SR-24Fr**
 Ball Electrode 3mm **W-SB-24Fr**

Ball Electrode 5mm **W-SS-24Fr**
 Kriloktrode **W-SK-24Fr**
 Cold Knife **W-SP-24Fr**
 Necklace **W-SN-24Fr**

Spike 3mm **W-SW-24Fr**
 Spike 5mm **W-SV-24Fr**

OLYMPUS, 1 Stem, 30° Degrees, 24Fr

Cutting Loop **W-LC-24Fr**
 Collin's Knife **W-LZ-24Fr**
 Roller Electrode **W-LR-24Fr**

Ball Electrode 3mm **W-LB-24Fr**
 Sphere Electrode 5mm **W-LS-24Fr**
 Kriloktrode **W-LK-24Fr**

ACMI

Cutting Loop **UAC 24**
 Cutting Loop **UAC 26**
 Cutting Loop **UAC 28**

Class IIb device – for single use only

TUR Electrodes BIPOLAR

STORZ, 2 Stem, 30° Degrees, 24/26Fr

Cutting Loop **UBSCP**
 Cutting Loop **UBSCP40** (0.40mm wire)

Cutting Loop **UBSC**
 Cutting Loop **UBSC30** (0.30mm wire)
 Cutting Loop **UBSC40** (0.40mm wire)

Cutting Loop **UBSCDV** (small)
 Cutting Loop **UBSCD** (small)
 Cutting Loop **UBSCB** (straight)

OLYMPUS, 12° Degrees, 24Fr

Cutting Loop **UBOC12-S** (small)
 Cutting Loop **UBOC12-M** (medium)

OLYMPUS, 12° and 30° Degrees, 24Fr

Angeled Loop **UBOCA-S** (small)
 Angeled Loop **UBOCA-M** (medium)

OLYMPUS, 12° and 30° Degrees

Roller Electrode **UBOR**
 Loop Electrode **UBOC12-D**, 12° large
 Loop Electrode **UBOC30-D**, 30° large

Band Electrode **UBOC12-T**, 12° large
 Band Electrode **UBOC30-T**, 30° large

Button for Plasma **UBOB**

STORZ, 2 Stem, 30° Degrees, 24/26Fr

Coagulation Electrode **UBSCL** (pointed)
 Coagulation Electrode **UBSCLV** (pointed)

Half moon Vaporization
 Electrode, ball-shaped **UBSB**

OLYMPUS, 30° Degrees, 24Fr

Cutting Loop **UBOC30-S** (small)
 Cutting Loop **UBOC30-M** (medium)

OLYMPUS, 12°, 30° and 45° Degrees

Needle,
 Angeled Loop
UBOL

Bladder Evaquator

Used to perform irrigation and tissue collection during TUR prostate or bladder surgery

ELICK



Art. No.

EEC

For single use only

Class IIa device



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



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 106138 0002 Rev. 00

Manufacturer:

Marflow AG

Soodstrasse 57
8134 Adliswil, Zurich
SWITZERLAND

Product Category(ies):

Class IIb
Double J stent & set
Class IIa
PCN catheter & set
Ureteral catheter
Malecot catheter
Re-entry malecot catheter
Suprapubic catheter
Braided shaft catheter
Dual lumen catheter
Facial dilator
Amplatz dilator & set
Ureteral dilator & set
Ureteral balloon dilator
Double J stent & set
Mono J stent
Endopyelotomy stent
Guidewire
IP Needle
Chiba needle
Stone basket
Perk basket

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.:

IND20190101

Valid from:

2020-04-03

Valid until:

2024-05-26

T. Wacker

Page 1 of 3

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TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFICAT

Official Certification

Seen for authentication of the foregoing signature, acknowledged in our presence by

Ms. **Tracey WALTHER**, born 28th December 1958, Swiss citizen of Oberentfelden AG, according to her information residing at Brunaustrasse 17, 8002 Zürich, identified by identity card.

Zürich, 8th April 2020
BK no. 1027ff
Fee CHF 20.00



NOTARIAT ENGE-ZÜRICH

Andreas Bachmann, Notary Public

APOSTILLE

(Convention de la Haye du 5 octobre 1961)

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Country: Swiss Confederation, Canton of Zürich
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Notariat Enge – Zürich Kanton Zürich
5. In / at 8090 Zürich / Zurich
6. am / the 08.04.2020
7. durch die Staatskanzlei des Kantons Zürich
by the Chancellery of State of the Canton of Zurich
8. unter Nr. / under N° 1179274/2020
9. Stempel/Siegel, Stamp/seal
10. Unterschrift / Signature

S. Overkott



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Product Service

Certificate

No. Q5 106138 0001 Rev. 00

Holder of Certificate: **Marflow AG**
 Soodstrasse 57
 8134 Adliswil, Zurich
 SWITZERLAND

Facility(ies): Marflow AG
 Soodstrasse 57, 8134 Adliswil, Zurich, SWITZERLAND

Certification Mark:



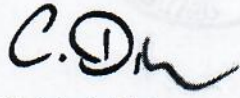
Scope of Certificate: Design and Development, Manufacture and Supply of Medical Disposables, Surgical Tools, Equipment & Accessories in the Field of Urology, Gastroenterology, Radiology, Gynaecology & Cardiology.

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.: IND20190101

Valid from: 2020-04-03
Valid until: 2023-04-02

Date, 2020-04-03 
 Christoph Dicks
 Head of Certification/Notified Body




A4 / 07.17

Official Certification

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Zürich, 8th April 2020
BK no. 1027ff
Fee CHF 20.00



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Andreas Bachmann, Notary Public

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6. am / the 08.04.2020
7. durch die Staatskanzlei des Kantons Zürich
by the Chancellery of State of the Canton of Zurich
8. unter Nr. / under N° 1179275/2020
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[Handwritten signature]

S. Overkott



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www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

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

No. G1S 106138 0003 Rev. 00

Manufacturer:

Marflow AG

Soodstrasse 57
8134 Adliswil, Zurich
SWITZERLAND

Product

Category(ies):

Class Is

Urine bag connector

Penile clamp

Evacuator

IUI catheter without syringe

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 II. 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.:

IND20190101

Valid from:

2020-04-03

Valid until:

2024-05-26

Date,

2020-04-03

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 2

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Zürich, 8th April 2020
BK no. 1027ff
Fee CHF 20.00



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S. Overkott