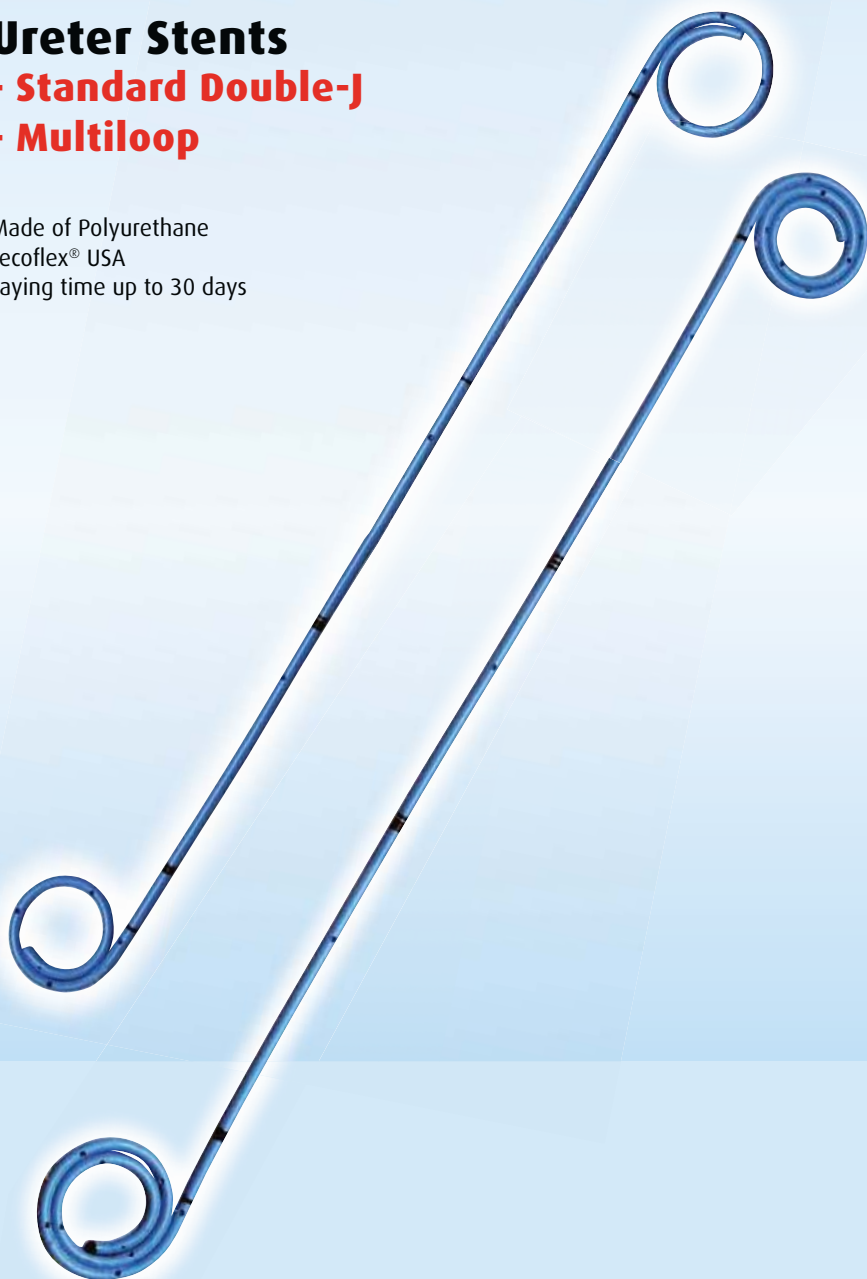


Ureter Stents

- Standard Double-J
- Multiloop

Made of Polyurethane
Tecoflex® USA
Laying time up to 30 days



Ureter Stents

Set consists of stent, pusher, suture and clamp. Made of Polyurethane Tecoflex® USA

Standard Double-J

One side open	Both sides open	Size (Fr/CH)	Length (cm)	Guidewire
SS-4716	SOT-4716	4.7	16	0.032"
SS-4724	SOT-4724	4.7	24	0.032"
SS-4726	SOT-4726	4.7	26	0.032"
SS-4728	SOT-4728	4.7	28	0.032"
SS-4730	SOT-4730	4.7	30	0.032"

SS-516	SOT-516	5	16	0.035"
SS-524	SOT-524	5	24	0.035"
SS-526	SOT-526	5	26	0.035"
SS-528	SOT-528	5	28	0.035"
SS-530	SOT-530	5	30	0.035"

SS-616	SOT-616	6	16	0.035"
SS-624	SOT-624	6	24	0.035"
SS-626	SOT-626	6	26	0.035"
SS-628	SOT-628	6	28	0.035"
SS-630	SOT-630	6	30	0.035"

SS-716	SOT-716	7	16	0.038"
SS-724	SOT-724	7	24	0.038"
SS-726	SOT-726	7	26	0.038"
SS-728	SOT-728	7	28	0.038"
SS-730	SOT-730	7	30	0.038"

SS-826	SOT-826	8	26	0.038"
SS-828	SOT-828	8	28	0.038"
SS-830	SOT-830	8	30	0.038"

Multiloop

One side open	Both sides open	Size (Fr/CH)	Length (cm)	Guidewire
SS-47ML+ML	SOT-47ML+ML	4.7	Multiloop 24-30	0.032"
SS-5ML+ML	SOT-5ML+ML	5	Multiloop 24-30	0.035"
SS-6ML+ML	SOT-6ML+ML	6	Multiloop 24-30	0.035"
SS-7ML+ML	SOT-7ML+ML	7	Multiloop 24-30	0.038"
SS-8ML+ML	SOT-8ML+ML	8	Multiloop 24-30	0.038"

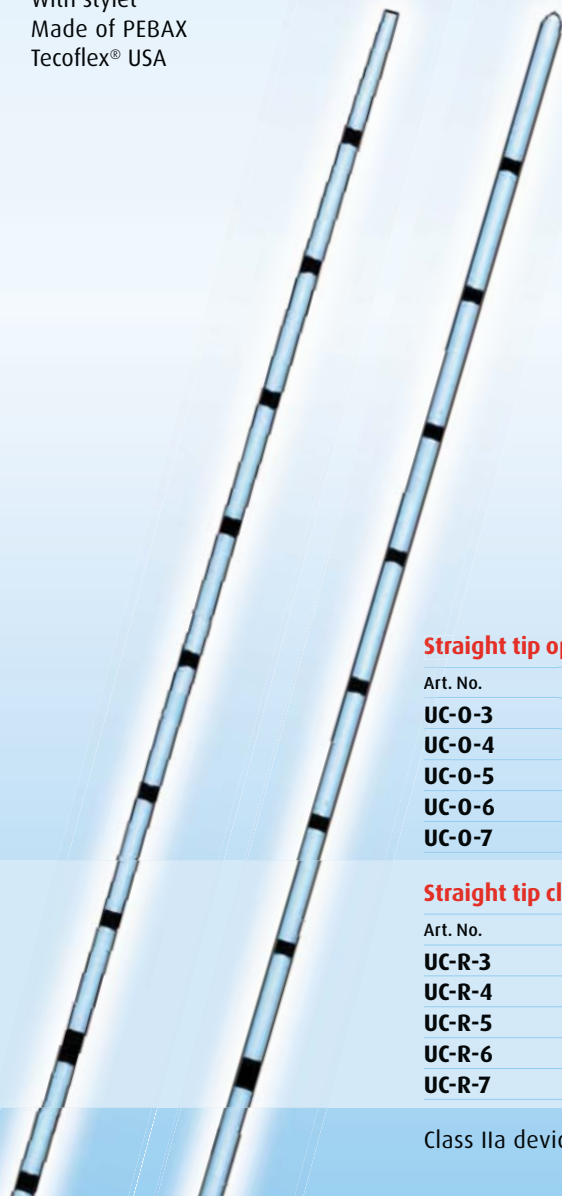
other sizes available

Set with stainless steel guidewire add +G (for example SS-4716+G).
Set with nitinol guidewire add +GHS (for example SS-4716+GHS).

Ureter Catheter

To inject contrast liquid

With stylet
Made of PEBAX
Tecoflex® USA



Straight tip open

Art. No.	Size (Fr/CH)	Length (cm)
UC-O-3	3	70
UC-O-4	4	70
UC-O-5	5	70
UC-O-6	6	70
UC-O-7	7	70

Straight tip closed

Art. No.	Size (Fr/CH)	Length (cm)
UC-R-3	3	70
UC-R-4	4	70
UC-R-5	5	70
UC-R-6	6	70
UC-R-7	7	70

Class IIa device – for single use only

Ureter Catheter

To inject contrast liquid

With stylet
Made of PEBAX
Tecoflex® USA



Angled tip open (Tiemann)

Art. No.	Size (Fr/CH)	Length (cm)
UC-AO-3	3	70
UC-AO-4	4	70
UC-AO-5	5	70
UC-AO-6	6	70
UC-AO-7	7	70

Angled tip closed (Tiemann)

Art. No.	Size (Fr/CH)	Length (cm)
UC-AR-3	3	70
UC-AR-4	4	70
UC-AR-5	5	70
UC-AR-6	6	70
UC-AR-7	7	70

Cone tip open

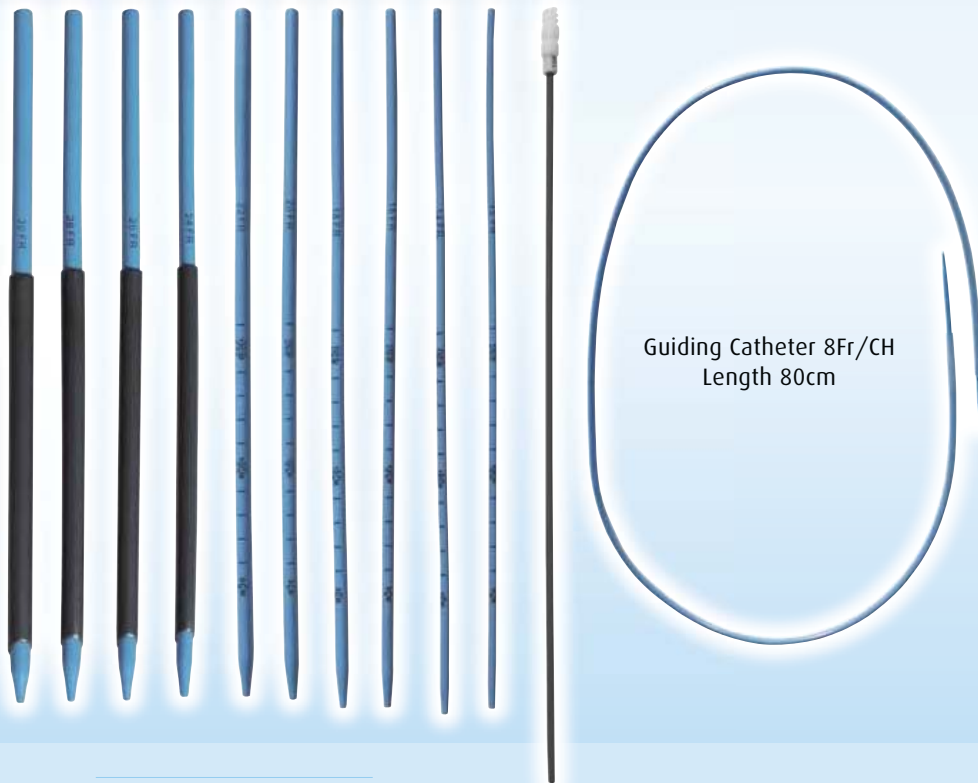
Art. No.	Shaft (Fr/CH)	Cone (Fr/CH)	Length (cm)
UCC-5/8	5	8	70
UCC-6/10	6	10	70
UCC-7/12	7	12	70

Class IIa device – for single use only

Amplatz Renal Dilation Set

Hydrophilic coated

Used for progressive dilation of the nephrostomy tract prior to percutaneous stone removal. Radiopaque dilators.



Art. No.	Size (Fr/CH)
ARDS 8/30	8 to 30

Amplatz Renal Dilators

Hydrophilic coated

Used for progressive dilation of the nephrostomy tract prior to percutaneous stone removal. Radiopaque dilators.

Single

Art. No.	Size (Fr/CH)	Length (cm)
RD 18	18	30
RD 20	20	30
RD 22	22	30
RD 24	24	30
RD 26	26	30
RD 28	28	30
RD 30	30	30

Amplatz Sheath

Hydrophilic coated

Used during renal dilatation to provide atraumatic working tracks after removal of the dilator.



Art. No.	Size (Fr/CH)	Length (cm)
AM 10	10	30
AM 24	24	17
AM 26	26	17
AM 28	28	17
AM 30	30	17

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)

1. Land: Schweizerische Eidgenossenschaft, Kanton Zürich
Country: Swiss Confederation, Canton of Zürich
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has been signed by Andreas Bachmann

3. in seiner Eigenschaft als
acting in the capacity of Notary Public

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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 [Signature]



S. Overkott



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

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9. Stempel/Siegel, Stamp/seal 10. Unterschrift / Signature



[Handwritten signature]

S. Overkott



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

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

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Legalization see reverse side

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
 ZERTIFIKAT ♦ CERTIFICATE ♦ 認證書 ♦ CERTIFIKAT ♦ CERTIFICADO ♦ CERTIFICAT

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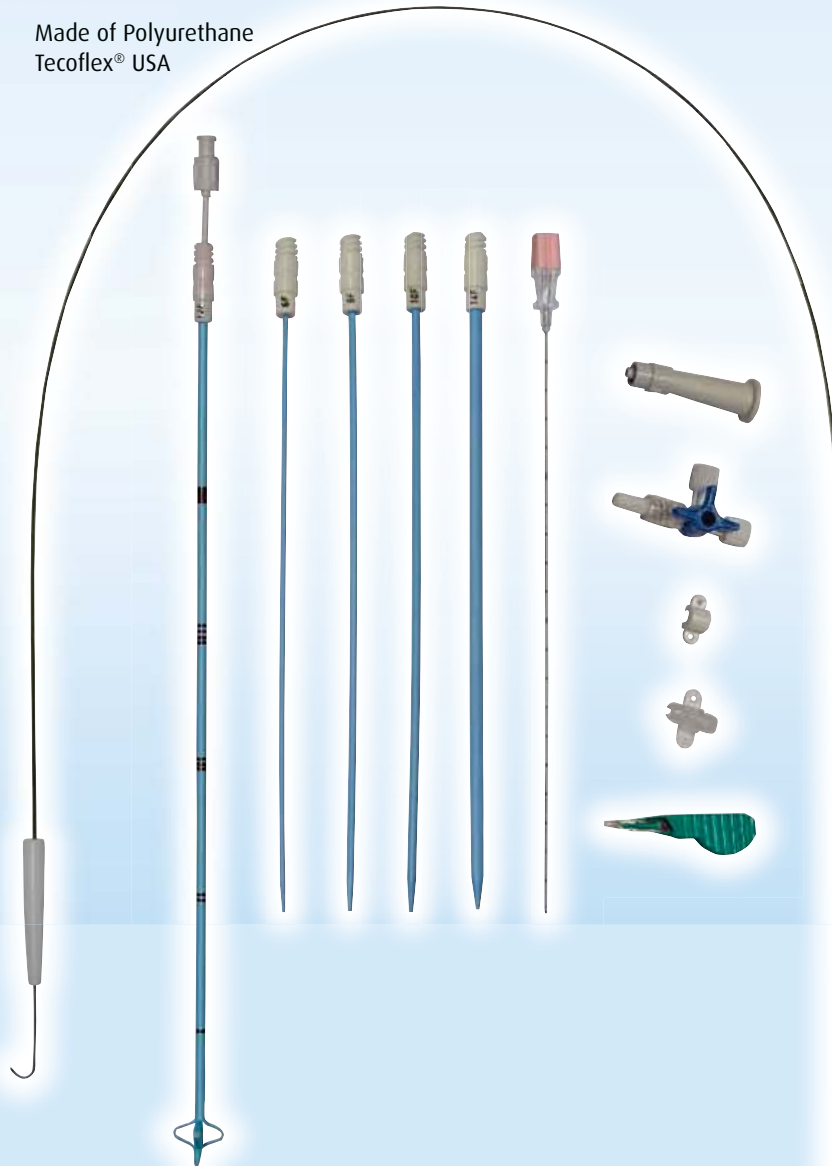
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S. Overkott

Nephrostomy Drainage Set with Malecot Catheter

Made of Polyurethane
Tecoflex® USA



Nephrostomy Drainage Set with Malecot Catheter

A convenient complete set for percutaneous placement of drainage catheter. Soft polyurethane material provides superior biocompatibility and drainage. Highly radiopaque for precise placement. Laying time up to 30 days

1 Set consists of:

- MALECOT – Drainage Catheter 35cm, usable length 30cm, 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 MALECOT Catheter

Catheter hydrophilic coated

Art. No.	Catheter Size (Fr/CH)	Fascial Dilators (Fr/CH)
PDS-M10	10	6 – 8 – 10 – 12
PDS-M12	12	6 – 8 – 12 – 14
PDS-M14	14	8 – 12 – 14 – 16
PDS-M16	16	8 – 12 – 14 – 16

PDS-M18 / M20 / M22 available

MALECOT Catheter only

Art. No.	Size (Fr/CH)
PCN-M10	10
PCN-M12	12
PCN-M14	14
PCN-M16	16

PCN-M18 / M20 / M22 available