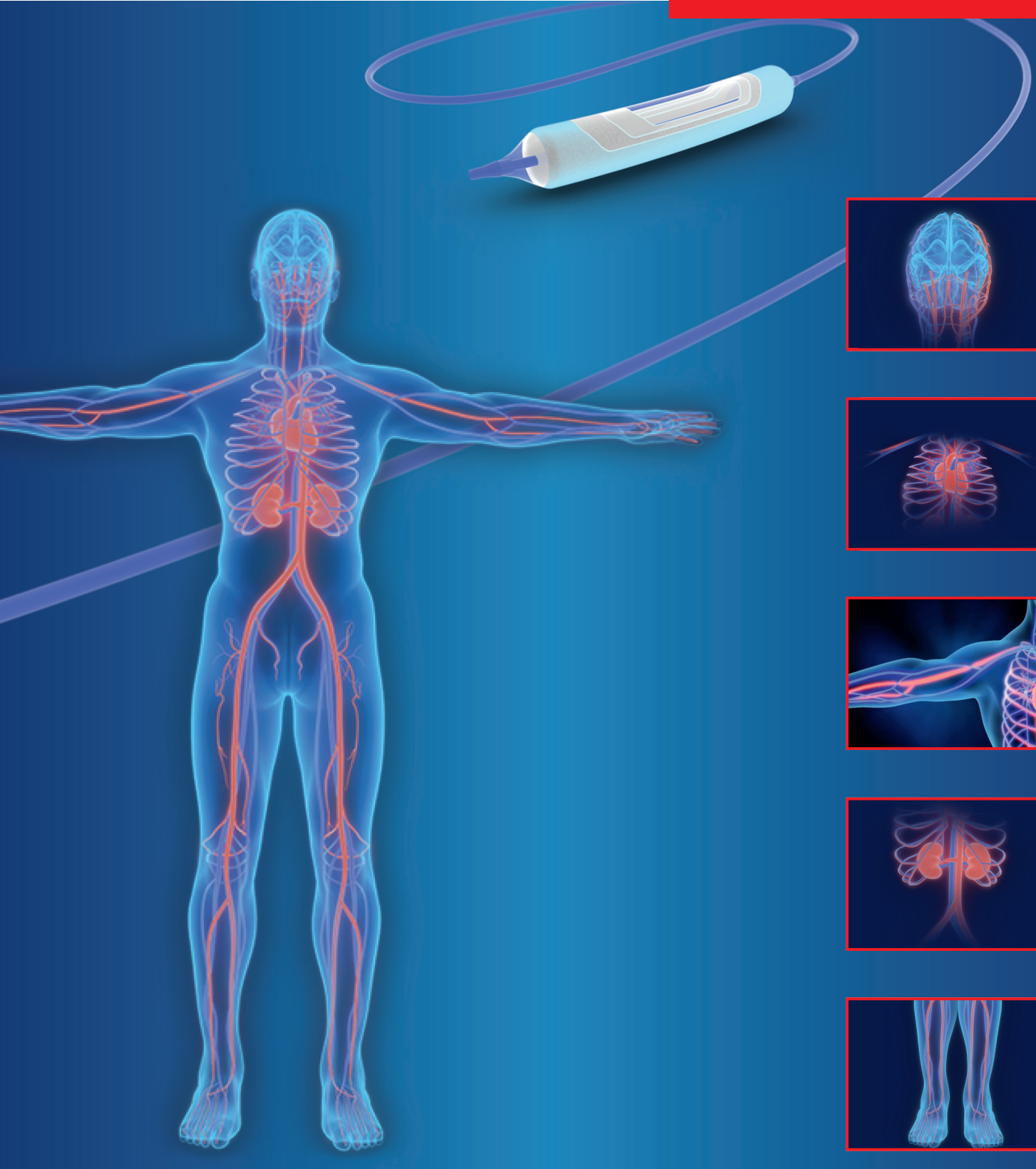
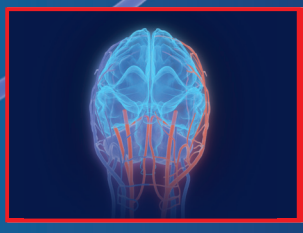
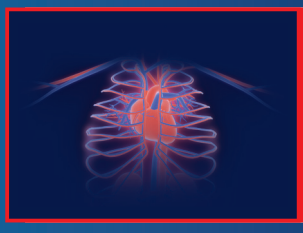
ELUTAX "3"

THE INTELLIGENT DRUG COATED BALLOON

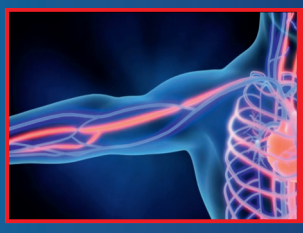




NEURO

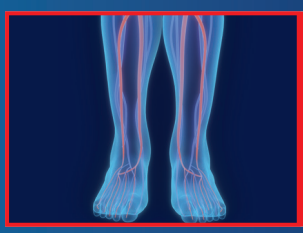


CORONARY



DIALYSIS

CENTRAL



PERIPHERAL

THE DRUG COATING BALLOON COMPANY

AR Baltic Medical

AR Baltic Medical

THE DRUG COATING BALLOON COMPANY

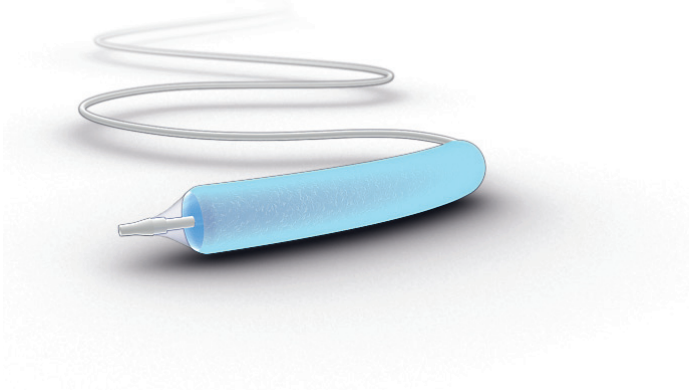
AR Baltic Medical was among the first companies, which developed drug coated balloons from 2006.

ELUTAX "3" our third generation Balloon is the newest of its kind to enable a long term Drug release over months - with only one single inflation.

The especially developed release system offers a sustained Drug persistence at the lesion and is the key for healing.

The versatile drug coating enables us to coat different catheter platforms, therefore we are actually the only company, which offers a range of Drug eluting Balloons with a diameter of 1.5 mm to 14 mm and a length of 1 cm to 25 cm.

The particular homogeneous coating is one of many other reasons why the product can be used in the different vascular territories: arterial as well as venous; peripheral as well as central, and especially in the supra-aortic territories.



TECHNOLOGY BACKGROUND

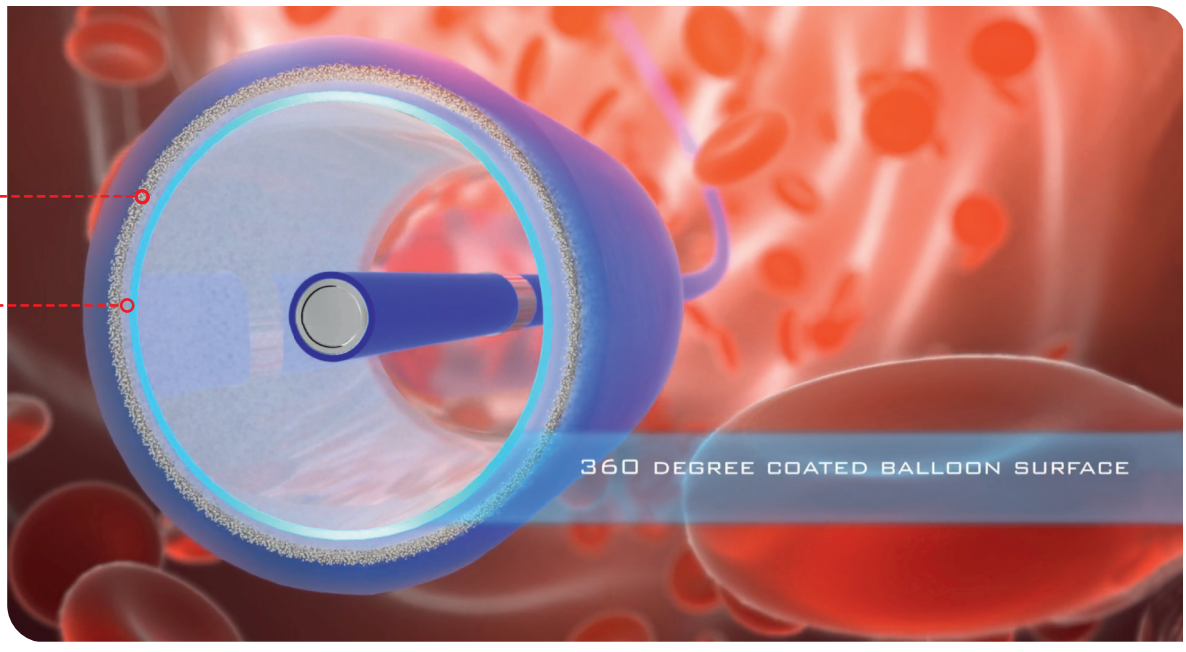
Balloon platform: Catheter produced in house

Sizes: length from 1 cm to 25 cm, diameter from 1,5 to 14 mm

High flexible balloon catheter with low profile due to our Vortex Technology.

Multi Purpose Drug Matrix

- Homogenous coating
- Even and Consistent coating of inflated Balloons
- Drug Matrix (3 Dimensional Dextran – Paclitaxel Formation)
- Balloon with 360 Degree coating coverage
- Minimal Drug lost during passage in the body
- Minimal Drug lost from the balloon surface during maneuver or inflation
- Reliable quantitative Drug deposition into the vessel wall
- Target deposition Modus TDM - Drug is only released at higher pressure and contact the vessel wall
- Long Lasting EFFECT -Drug concentration in the vessel wall (intima, media, adventitia) for several weeks
- No Drug “Chunk” spreading - during inflation



DRUG MATRIX PACLITAXEL+DEXTRAN

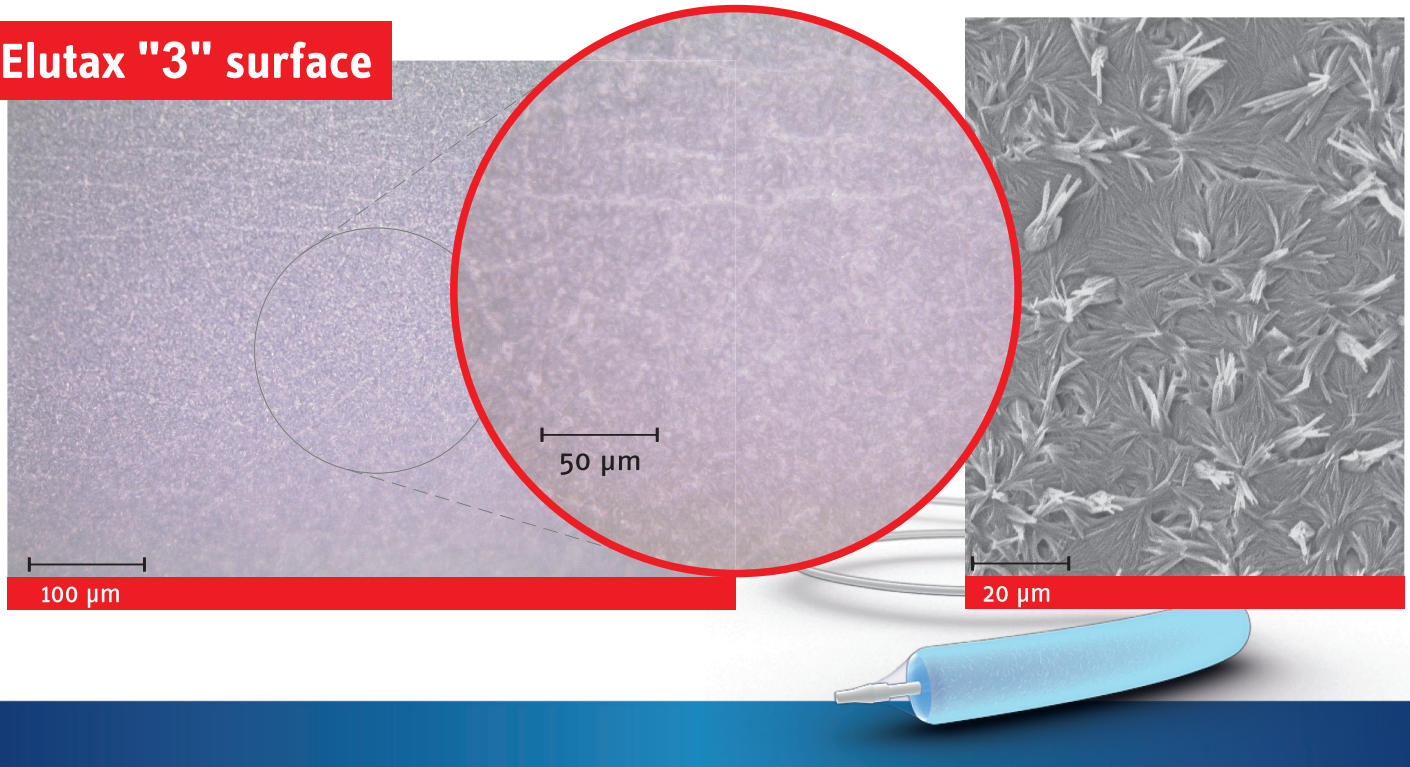
1. Seals the drug at the vessel
2. Therapeutic action time is longer

+ Better mechanical stability
+ Anti thrombogenic
+ Lesion protection
+ Reservoir Matrix
+ Local stability
+ Lowest wash off after deposition

Paclitaxel Tissue levels of different Drug eluting Balloons over 30 days

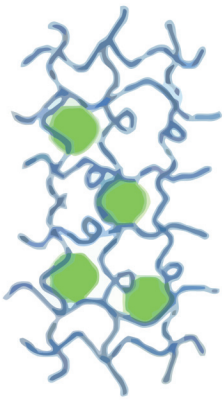
Coronary PORCINE	Elutax "3"	Competitor A	Competitor B
uniform coating	yes	no	no
360 degree	yes	no	no
Drug Dose 1 hour Drug Dose 7 days Drug Dose 30 days	~ 250 µmol/ml ~ 70 µmol/ml ~5-10 µmol/ml	~ 200 µmol/ml ~ 0 µmol/ml ~0 µmol/ml	~ 200 µmol/ml ~ 10 µmol/ml ~0,1 µmol/ml
Drug lost during maneuver	max 5%	high	up to 30% every 10 sec.

Elutax "3" surface

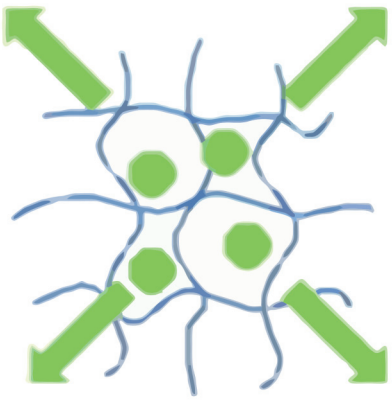


SUSTAINED VALUE

PRINCIPLE OF DRUG MAINTENANCE IN THE VESSEL WALL



Paclitaxel trapped in DEXTRAN structure.
In this configuration the Drug is coated onto the balloon surface and pressed against the inner lumen of the vessel after inflation.



Paclitaxel Long-term diffusion out of DEXTRAN from the inner lumen into the vessel wall.

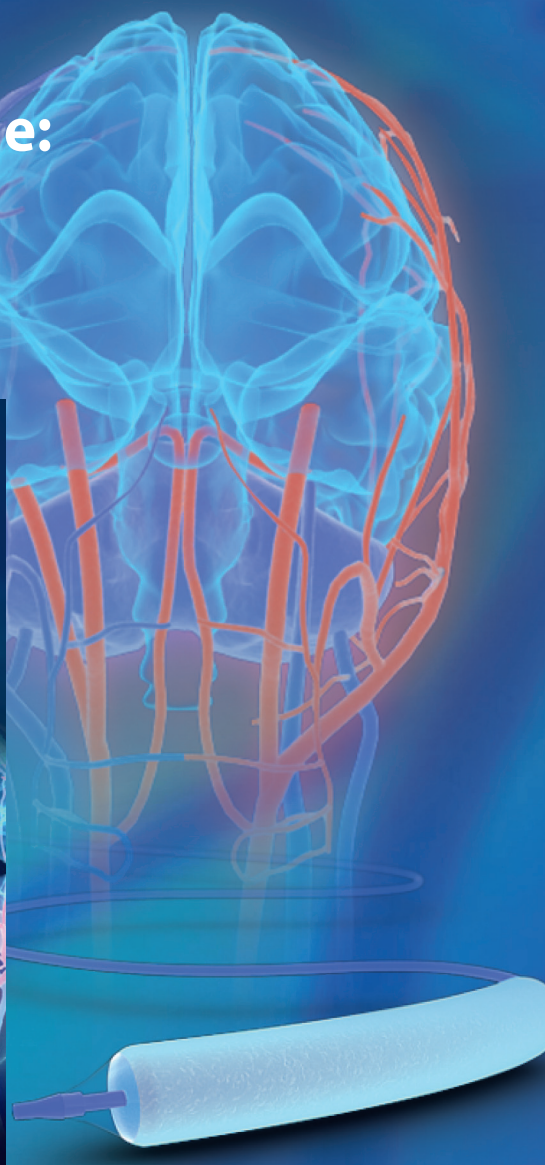
The special coating structure enables effective drug tissue levels up-to 60 days after intervention.

ELUTAX "3"

NEURO

NEW sizes available:

THE ONLY DRUG ELUTING BALLOON CERTIFIED FOR THE TREATMENT OF INTRA-CRANIAL AND CAROTID LESIONS



NEURO

Purpose:	Supraaortic lesions
Lesion location (if not to tortuous):	carotid a., vertebral a., basilar a., middle cerebral a. (M1)
Tip:	flexible, sof0,017"
MAX Catheter profile:	less than 1 mm
Catheter design:	Rx
Catheter material:	Pebax/Nylon
Usable catheter length:	Minimum 144 cm and 155 cm
GW length:	Recommended 180-250 cm
Max. recommended GW:	0,014"
Introducer sheath compatibility:	4F
Guiding catheter compatibility:	5 F
Balloon characteristic:	semi compliant
Balloon nominal diameter:	1,5-6,0 mm
Balloon nominal length:	10-40 mm
Balloon coating:	3D-Dextran-Paclitaxel Matrix
Nr. of folds:	3
Crossing profile:	less than 1 mm
Transition Zones:	6
Inflation time recommended:	15 sec
Nominal pressure:	6 atm
RBP:	14 atm
Need of predilatation:	NO

ORDER-CODE: N-ELUTAX"3"-XXXXX

Extra-Long Shaft: N-ELUTAX-L

NEURO

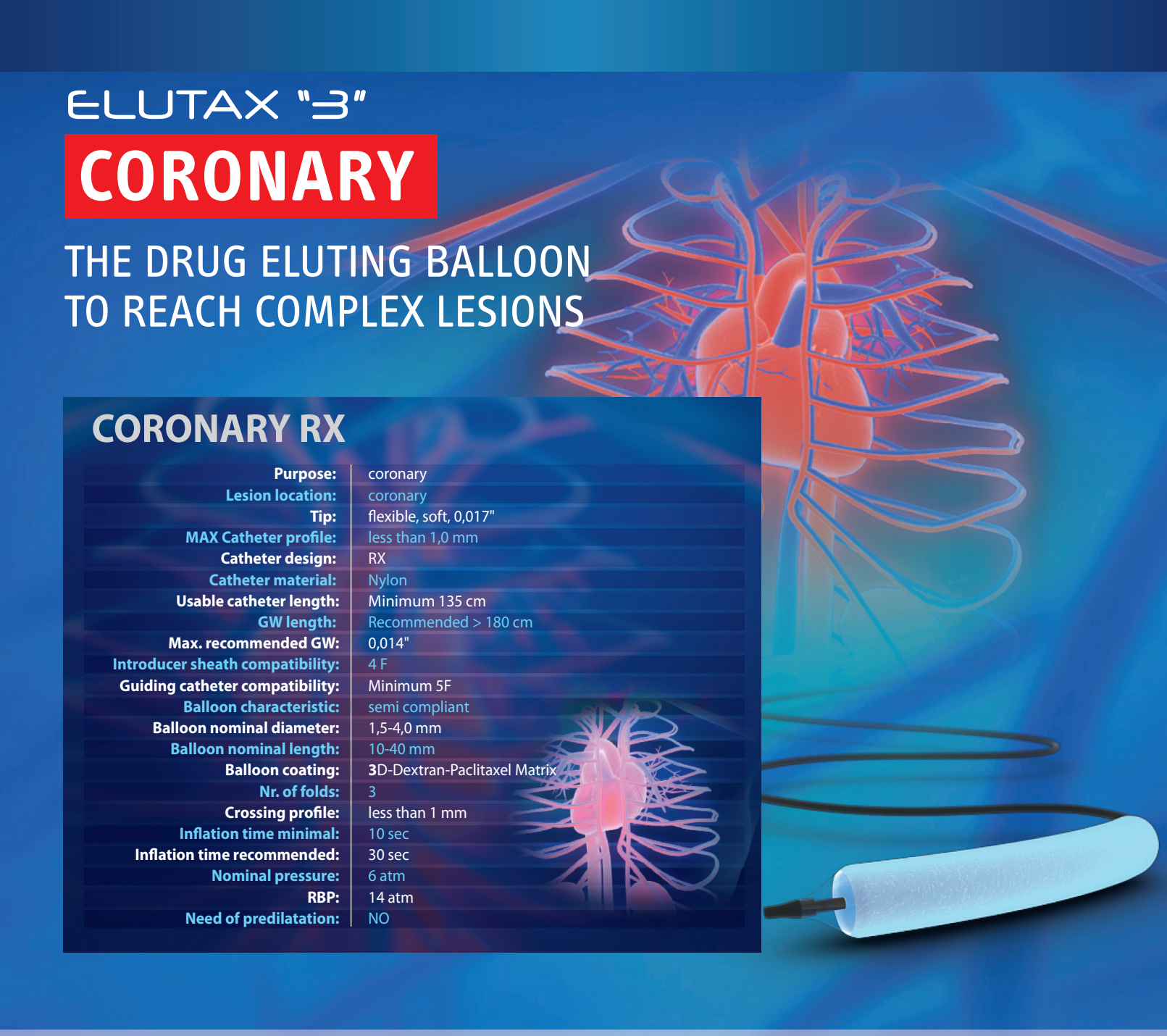
length mm	10	13	15	20	25	30
1.50	10150	13150	15150	20150	25150	30150
2.00	10200	13200	15200	20200	25200	30200
2.25	10225	13225	15225	20225	25225	30225
2.50	10250	13250	15250	20250	25250	30250
2.75	10275	13275	15275	20275	25275	30275
3.00	10300	10300	10300	10300	10300	10300
3.25	10325	13325	15325	20325	25325	30325
3.50	10350	13350	15350	20350	25350	30350
4.00	10400	13400	15400	20400	25400	30400
4.50	10450	13450	15450	20450	25450	30450
5.00	10500	13500	15500	20500	25500	30500
5.50	10550	13550	15550	20550	25550	30550
6.00	10600	13600	15600	20600	25600	30600

diameter

ELUTAX "3"

CORONARY

THE DRUG ELUTING BALLOON TO REACH COMPLEX LESIONS



CORONARY RX

Purpose:	coronary
Lesion location:	coronary
Tip:	flexible, soft, 0,017"
MAX Catheter profile:	less than 1,0 mm
Catheter design:	RX
Catheter material:	Nylon
Usable catheter length:	Minimum 135 cm
GW length:	Recommended > 180 cm
Max. recommended GW:	0,014"
Introducer sheath compatibility:	4 F
Guiding catheter compatibility:	Minimum 5F
Balloon characteristic:	semi compliant
Balloon nominal diameter:	1,5-4,0 mm
Balloon nominal length:	10-40 mm
Balloon coating:	**3**D-Dextran-Paclitaxel Matrix
Nr. of folds:	3
Crossing profile:	less than 1 mm
Inflation time minimal:	10 sec
Inflation time recommended:	30 sec
Nominal pressure:	6 atm
RBP:	14 atm
Need of predilatation:	NO

The Dextran excipient enables a prolongated and more efficient drug uptake.

CORONARY RX

length

mm	10	13	15	20	25	30	40
1.50	10150	13150	15150	20150	25150	30150	
2.00	10200	13200	15200	20200	25200	30200	40200
2.25	10225	13225	15225	20225	25225	30225	
2.50	10250	13250	15250	20250	25250	30250	40250
2.75	10275	13275	15275	20275	25275	30275	
3.00	10300	13300	15300	20300	25300	30300	40300
3.50	10350	13350	15350	20350	25350	30350	40350
4.00	10400	13400	15400	20400	25400	30400	40400

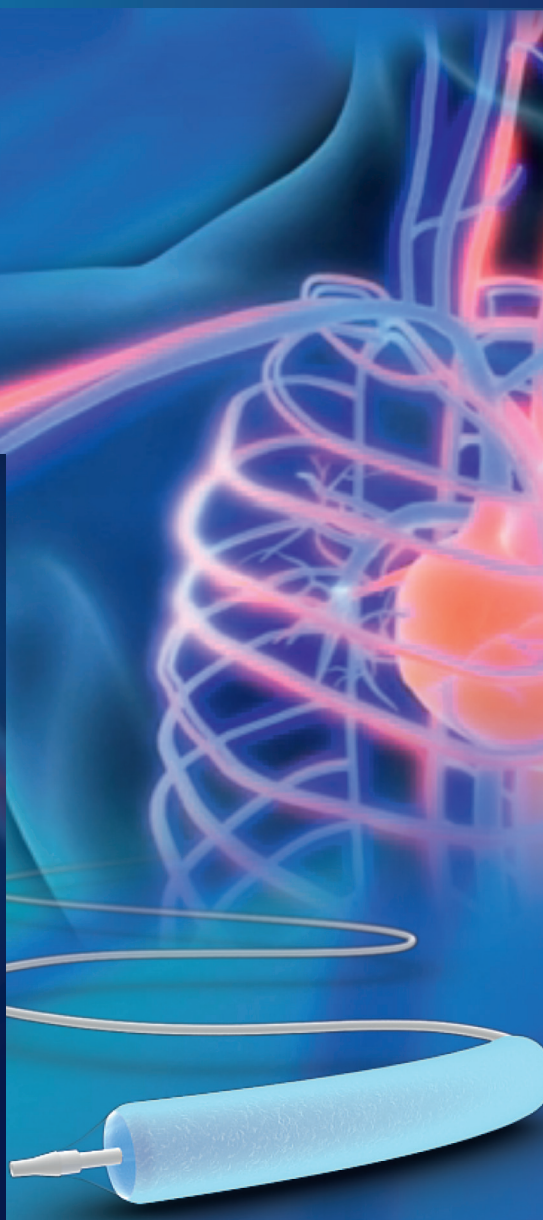
diameter

ORDER-CODE: ELUTAX "3"- RX-C-XXXX

ELUTAX "3"

DIALYSIS

HIGH PRESSURE CAPABILITIES AND SHORT SHAFT GIVES YOU SAFETY AND COMFORT



FISTULA OTW

Purpose:	Fistula treatment
Lesion location (if not to tortuous):	Dialysis: AV Fistula
Tip:	flexible, soft, 0,017"
MAX Catheter profile:	less than 1,1 mm
Catheter design:	OTW
Catheter material:	Nylon
Usable catheter length:	Max 50 cm
GW length:	> 120 cm
Max. recommended GW:	0,018"
Introducer sheath compatibility:	5-6 F depending on diameter
Balloon characteristic:	semi compliant
Balloon nominal diameter:	4,0 - 7,0 mm
Balloon nominal length:	20-40-60 mm
Balloon coating:	3D-Dextran-Paclitaxel Matrix
Nr. of folds:	3
Crossing profile:	less than 1,1 mm
Inflation time minimal:	10 sec
Inflation time recommended:	30 sec
Nominal pressure:	6 atm
RBP:	18 atm
Need of predilatation:	NO

HIGH PRESSURE DRUG ELUTING BALLOON

DIALYSIS

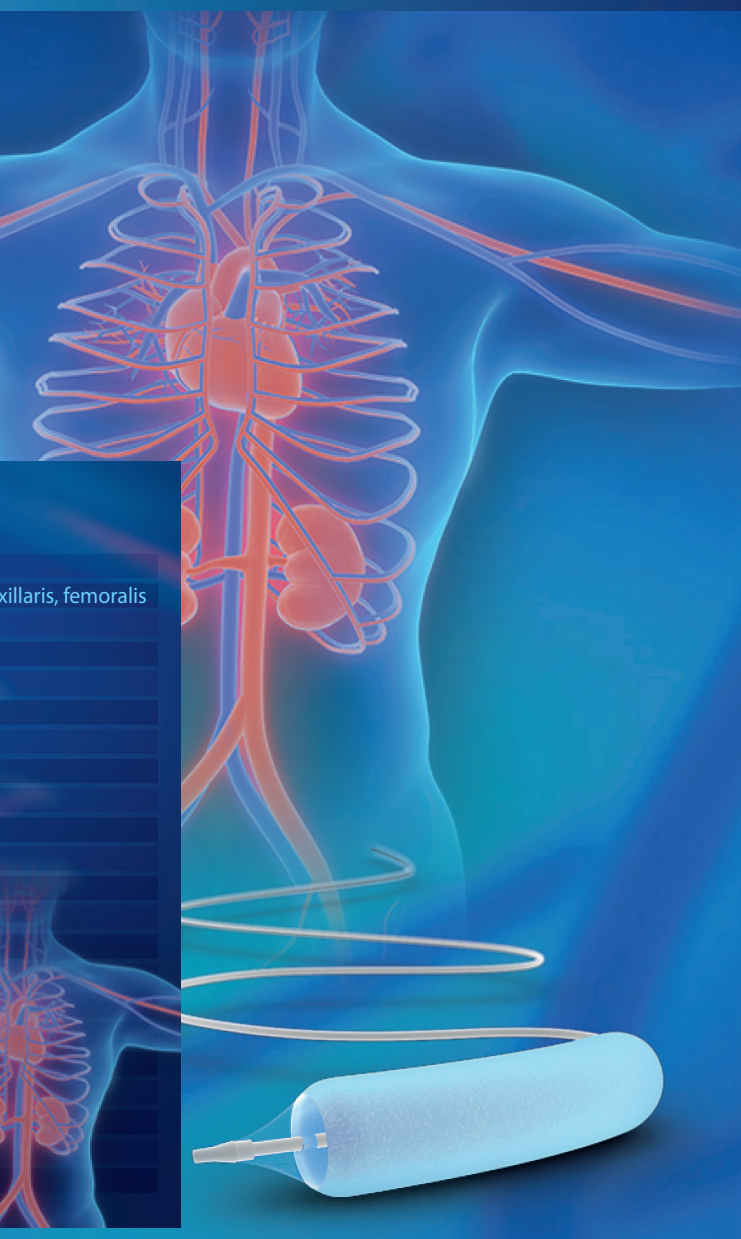
length mm / diameter	20	40	60
4.00	20400	40400	60400
5.00	20500	40500	60500
6.00	20600	40600	60600
7.00	20700	40700	60700

ORDER-CODE: ELUTAX "3"-OTWS-XXXXX

ELUTAX "3"

CENTRAL

NOW ALSO AVAILABLE WITH SHAFT LENGTH OF 90 CM



CENTRAL

Purpose:	Central lesions: large arteries and veins
Lesion location:	aorta, v. cava, iliac, subclavian, jugular, axillaris, femoralis
Tip:	flexible, soft
MAX Catheter profile:	less than 1,3 mm
Catheter design:	OTW
Catheter material:	Pebax/Nylon
Usable catheter length:	130 cm and 90 cm
GW length:	> 300 cm
Max. recommended GW:	GW: 0,018"
Introducer sheath compatibility:	5-7 F depending on diameter
Balloon characteristic:	semi compliant
Balloon nominal diameter:	7, 8, 10, 12, 14 mm
Balloon nominal length:	20, 40, 60, 80 mm
Balloon coating:	3D-Dextran-Paclitaxel Matrix
Nr. of folds:	3
Crossing profile:	less than 1 mm
Inflation time minimal:	10 sec
Inflation time recommended:	15-30 sec
Nominal pressure:	6 atm
RBP:	10 atm
Need of predilatation:	NO

NOW IT IS POSSIBLE TO TREAT LARGE VESSELS WITH DCB

ORDER-CODE: ELUTAX"3"OTW-XXXXX

Short Shaft : ELUTAX "3"-OTW-K

CENTRAL

length mm	20	40	60	80
7.00	20700	40700	60700	80700
8.00	20800	40800	60800	80800
10.00	201000	401000	601000	801000
12.00	201200	401200	601200	801200
14.00	201400	401400	601400	801400

diameter

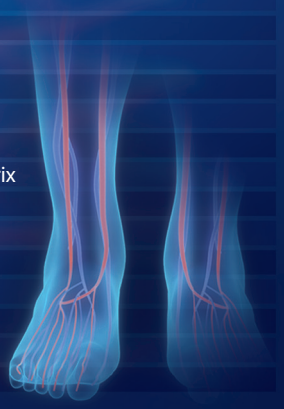
ELUTAX "3"

PERIPHERAL OTW

THE DRUG ELUTING BALLOON TO REACH COMPLEX LESIONS

PERIPHERAL OTW

Purpose:	Peripheral lesions
Lesion location (if not to tortuous):	femoral a., popliteal a., BTK. aa, plantar
Tip:	flexible, soft 0,017"
MAX Catheter profile:	less than 1,1 mm
Catheter design:	OTW, OTW-K, OTW-L
Catheter material:	Nylon
Usable catheter length:	Minimum 90 cm, 135 cm, 170 cm
GW length:	> 200, 300, 400 cm
Max. recommended GW:	0,018"
Introducer sheath compatibility:	4F
Guiding catheter compatibility:	6F
Balloon characteristic:	semi compliant
Balloon nominal diameter:	1,5-6,0 mm
Balloon nominal length:	10-250 mm
Balloon coating:	3D-Dextran-Paclitaxel Matrix
Nr. of folds:	3
Crossing profile:	less than 1 mm
Inflation time minimal:	10 sec
Inflation time recommended:	30 sec
Nominal pressure:	6 atm



PERIPHERAL OTW

length

mm	10	13	15	20	25	30	40	60	80	100	150	200	250
1.50	10150	13150	15150	20150	25150	30150							
2.00	10200	13200	15200	20200	25200	30200	40200	60200	80200	100200	150200	200200	250200
2.25	10225	13225	15225	20225	25225	30225							
2.50	10250	13250	15250	20250	25250	30250	40250	60250	80250	100250	150250	200250	250250
2.75	10275	13275	15275	20275	25275	30275							
3.00	10300	13300	15300	20300	25300	30300	40300	60300	80300	100300	150300	200300	250300
3.50	10350	13350	15350	20350	25350	30350	40350	60350	80350	100350	150350	200350	
4.00	10400	13400	15400	20400	25400	30400	40400	60400	80400	100400	150400	200400	
5.00				20500		30500	40500	60500	80500	100500	150500	200500	
6.00				20600		30600	40600	60600	80600	100600	150600	200600	

diameter

ORDER-CODE: ELUTAX"3"OTW- K-XXXXX

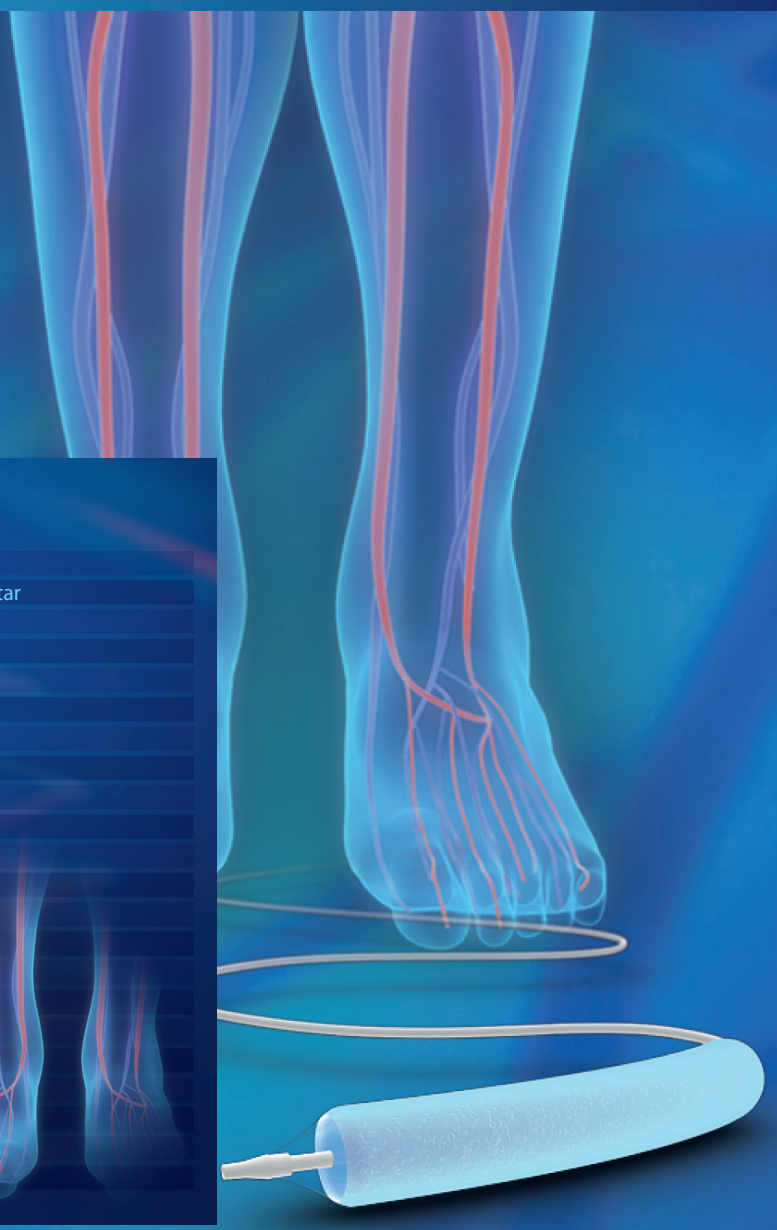
ORDER-CODE: ELUTAX"3"OTW-XXXXX

ORDER-CODE: ELUTAX"3"OTW- L-XXXXX

ELUTAX "3"

PERIPHERAL RX

THE DRUG ELUTING BALLOON TO REACH COMPLEX LESIONS



PERIPHERAL RX

Purpose:	Peripheral lesions
Lesion location:	femoral a., popliteal a., BTK. aa, plantar
Tip:	flexible, soft 0,017"
MAX Catheter profile:	less than 1,1 mm
Catheter design:	RX
Catheter material:	Nylon
Usable catheter length:	Minimum 135 cm
GW length:	Recommended > 180 cm
Max. recommended GW:	0,014"
Introducer sheath compatibility:	4F
Guiding catheter compatibility:	6F
Balloon characteristic:	semi compliant
Balloon nominal diameter:	1,5-6,0 mm
Balloon nominal length:	10-250 mm
Balloon coating:	3D-Dextran-Paclitaxel Matrix
Nr. of folds:	3
Crossing profile:	less than 1 mm
Inflation time minimal:	10 sec
Inflation time recommended:	30 sec
Nominal pressure:	6 atm
RBP:	14 atm
Need of predilatation:	NO

PERIPHERAL RX

length

mm	10	13	15	20	25	30	40	60	80	100	150	200	250
1.50	10150	13150	15150	20150	25150	30150							
2.00	10200	13200	15200	20200	25200	30200	40200	60200	80200	100200	150200	200200	250200
2.25	10225	13225	15225	20225	25225	30225							
2.50	10250	13250	15250	20250	25250	30250	40250	60250	80250	100250	150250	200250	250250
2.75	10275	13275	15275	20275	25275	30275							
3.00	10300	13300	15300	20300	25300	30300	40300	60300	80300	100300	150300	200300	250300
3.50	10350	13350	15350	20350	25350	30350	40350	60350	80350	100350	150350	200350	
4.00	10400	13400	15400	20400	25400	30400	40400	60400	80400	100400	150400	200400	
5.00				20500		30500	40500	60500	80500	100500	150500	200500	
6.00				20600		30600	40600	60600	80600	100600	150600	200600	

diameter

UNDISPUTED LENGTH

ORDER-CODE: ELUTAX "3"- RX-XXXXXX

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