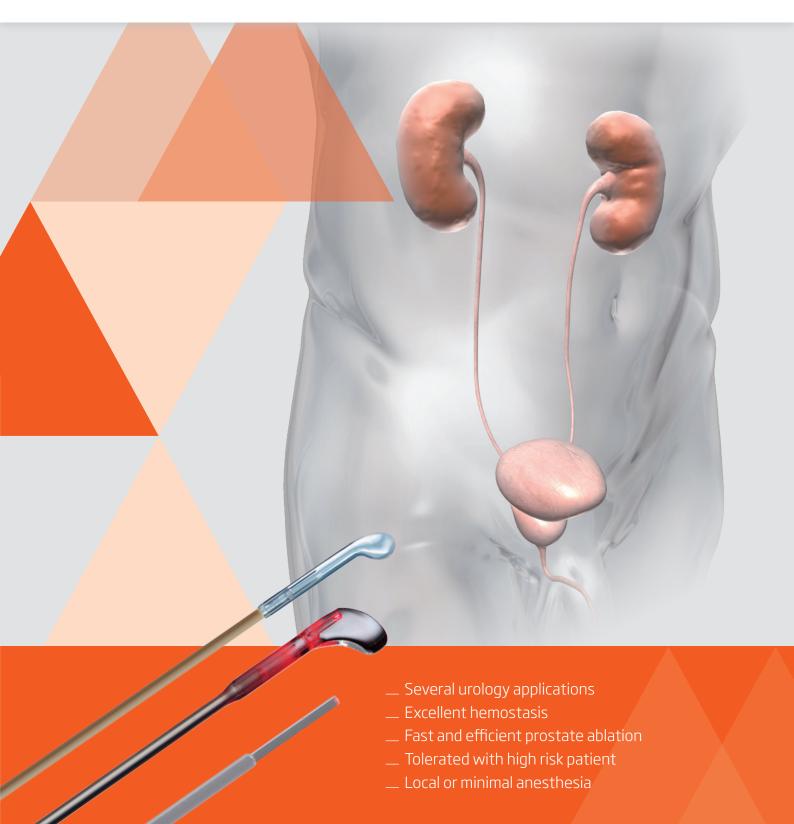
biolitec® in Urology TWISTER, XCAVATOR®



Minimally invasive laser therapy of BPH, tumors, condylomas, strictures and more



BPH – Benigne Prostatic Hyperplasia

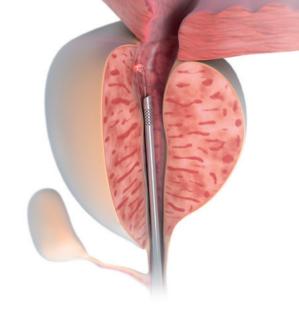
Contact fiber approach with the XCAVATOR® and the TWISTER fibers

Our contact fibers are developed to reach out for unmatched ablation rates and excellent reliability. Working in contact mode offers direct and high energy delivery exact on the area where you want to ablate or vaporize. The results are smooth intrasurgical surfaces. Special developed glass tips assure working without fiber degradation and consistently high performance. More fiber control through tactile feedback shows the best outcome and permits outstanding treatment.









XCAVATOR®

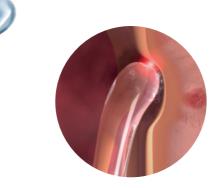
Time is precious, so we designed the XCAVATOR® as the first true Laser-TURP to combine the efficacy of trans-urethral resection with the unmatched safety and hemostasis of the LEONARDO® laser system series. The patent pending glass tip of the XCAVATOR® fiber ensures a safe treatment of benign prostate hyperplasia powered by optimized absorption in water and hemoglobin.



- Unique glass tip makes the XCAVATOR® as the first choice treating prostate glands from small to quite large
- Increased contact surface area results in a wider area of tissue resection
- ___ Efficient vaporization, coagulation and resection
- Specially designed resectoscope decreases likelihood of costly optic damage
- Optimized field of view due to vapor bubbles concentrated at fiber tip only
- ___ Tissue resection with possible histological diagnosis
- Short learning curve

TWISTER

The new TWISTER XL fiber is designed to increase the well known ablation rates of the TWISTER L and improve precision fiber handling by optimizing rigidity. Larger fiber tip design increases the surface area to almost 20 % larger than the TWISTER L. A specially designed coating enhances the rigidity and handling of the fiber tip while increasing durability.

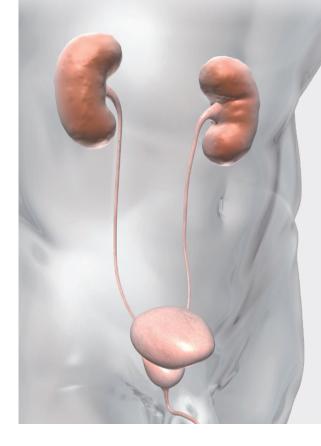


- __ Increased fiber tip surface area for fast and efficient ablation
- Contact mode for tactile feedback
- Increased control of the fiber tip
- Excellent hemostasis
- Short catheter time and fast recovery
- Cystoscope compatibility in line with TWISTER L



Several other urological laser applications

efficient - smooth - gentle



Upper tract tumors

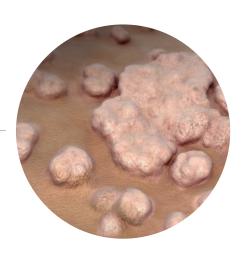
- Comfortable treatment of upper tract tumors with a very thin fiber via a flexible cystoscope
- __ This avoids an open or laparoscopic surgery
- Fast and minimal invasive surgery

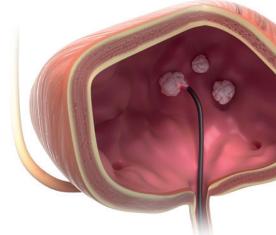
Condyloma

- Smooth and gentle laser condyloma treatment
- Smooth surface after the treatment
- __ No scars

Stricture

- No or very low bleeding
- Always a good view during the procedure
- Easy and comfortable handling





Tumor surgery

Our specialty fibers ensure a safe treatment of bladder tumors powered by optimized absorption in water and hemoglobin when utilizing the LEONARDO® DUAL 200 Watt or LEONARDO® DUAL 45 Watt.

Bladder tumors

The ability of simultaneous cutting and coagulation offers a simple and safe method with a minimal to non loss of blood. Different methods are possible, the standard procedure in an operating room with general/regional anesthesia or outpatient procedure which is even tolerate of high risk patient. The outpatient procedure using a flexible cystoscopy and different kinds of bare fibers does not require general/regional anesthesia and is a gentle way of treating bladder tumors. Both laser treatments for bladder tumors reduce risks for the patient and can be performed quickly.

- Outpatient procedure using flexible cystoscopy
- Tolerated with high risk patient
- Can be performed safely and effectively in the office



Partial nephrectomy

Cutting and coagulation properties of our optical fibers contribute to a successful nephron sparing surgery securing better overall renal function. Our high-tech fibers would be the fiber of choice to ensure best results. Cutting and coagulating at the same time provides minimal bleeding with a good view on the tissue. Use of our special diode lasers for (open, laparoscopic or robotic) partial nephrectomy offers benefit of no or shorter warm ischemia time with more effective tissue coagulation, hemostasis and reduced parenchymal damage.

- Less bleeding
- No need of suppressing feeding arteries no time pressure
- Cutting and coagulating at the same time
- Laparoscopic or open procedure







LEONARDO®

Model	LEONARDO® DUAL 200	LEONARDO® DUAL 45
REF	SL980+1470nm200W	SL980+1470nm45W
Wavelength	980 nm and 1470 nm	980 nm and 1470 nm
Max. power	200 Watt (1470 nm/40 Watt + 980 nm/160 Watt) individually adjustable	45 Watt (1470 nm/15 Watt + 980 nm/30 Watt), individually adjustable
Fiber diameter	≥ 360 µm	≥ 360 µm
Aiming beam	532 nm and 635 nm, green 1 mW, red 4 mW, user-defined intensity	532 nm and 635 nm, green 1 mW, red 4 mW, user-defined intensity
Treatment mode	CW, pulse mode, ELVeS® signal, ELVeS® segment, derma mode	CW, pulse mode, ELVeS® signal, ELVeS® segment, derma mode
Pulse duration /-break	0.01 – CW / 0.01 – 60 sec	0.01 – CW / 0.01 – 60 sec
Power supply	110 – 240 VAC, 50 / 60 Hz, 850 VA	110 – 240 VAC, 50 / 60 Hz, 450 VA
Dimensions (H×W×D)	approx. 20 cm × 37 cm × 26 cm	approx. 28 cm × 37 cm × 9 cm
Weight	approx. 15 kg	approx. 8.5 kg



LEONARDO® DUAL 200 RWYSIBLE LASER RADIATION AVID EYE OR SIGN ERPOSIURE TO DIECT OR HORBIECT FRAZIATION CLASS 4 LASER PRODUCT Coded-Laser 260 + 430 m/cm 24 00 W/HALL Coded-Laser 2470 + 430 m/cm 24 00 W/HALL CECORES 1-2007 18 CECORO 2-22 2007

VISIBLE LASER RADIATION
AVOID EYE EXPOSURE TO DIRECT RADIATION

CLASS BR LASER PRODUCT
Diode-Laser 535 +/-10 nm CW 4 mW (Max.) (Alming)
Diode-Laser 532 +/-10 nm CW 1 mW (Max.) (Alming)

LEONARDO® DUAL 45

INVISIBLE LASER RADIATION
AVOID EYE OR SKIN EXPOSURE TO
DIRECT OR INDIRECT RADIATION

CLASS 4 LASER PRODUCT
Diode-laser 980 + 7.30 mmcW 30 W(Max.)
Diode-laser 1470 + 7.30 mmcW 15W (Max.)

VISIBLE LASER RADIATION
AVOID EYE EXPOSITION TO DIRECT RADIATION
CLASS 3R LASER PRODUCT
Olode-Laser 635 +/-10 mm CW 4 mW (Max.)(Alming)
Olode-Laser 532 +/-10 mm CW 1 mW (Max.)(Alming)

LEONARDO Mini Dual

INVISIBLE LASER RADIATION
AVOID EYE OR SKIN EXPOSURE TO
DIRECT OR INDIRECT RADIATION

CLASS 4 LASER PRODUCT

Didde-Laser 1870-4-30 nm (W 4W (Max.)

LEGGROSS. 1970-77 FEF. FGROIL-29-29-007

VISIBLE LASER RADIATION
AVOID EYE EXPOSURE TO DIRECT RADIATION

CLASS 3R LASER PRODUCT
DIAGRAGE - 1.30 nm CW 4 mW (Max.) (Alming)
DEF 60825 - 1.2007
DEF 60825 - 1.2007

LEONARDO Mini 1470 nm

INVISIBLE LASER RADIATION
AVOID EYE OR SKIM EXPOSURE TO
DIRECT OR INDIRECT RADIATION

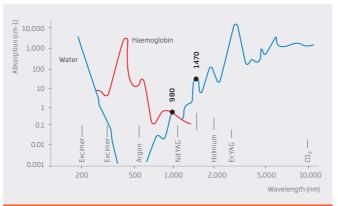
CLASS 4 LASER PRODUCT
DIGGO-12801 12700 + 7000 m CW 8 W (Max.)
IEC 60825 - 127007 IEC 606012 - 22-2007

VISIBLE LASER RADIATION
AVOID EYE EXPOSURE TO DIRECT RADIATION
CLASS 3R LASER PRODUCT
Diode-Laser 635 +/-10 nm CW 4 mW (Max.)(Alming)



1470nm14W 30 nm) / 4 W (1470 nm)	SL1470nm12W
30 nm) / 4 W (1470 nm)	
00 mm) / 4 W (14/0 mm)	12 W (1470 nm)
m	≥ 360 µm
max. 4 mW	635 nm, max. 4 mW
e mode (optional)	CW, pulse mode (optional), ELVeS® signal
30 sec / 0.01 – 180 sec	0.01 – 180 sec / 0.01 – 180 sec
0 VAC, 50 - 60 Hz (12 VDC @ 65 W)	110 – 240 VAC, 50 – 60 Hz (12 VDC @ 100 W)
atteries	Li-ion Batteries
cm × 21.5 cm	6 cm × 9 cm × 21.5 cm
	80 sec / 0.01 – 180 sec 0 VAC, 50 – 60 Hz (12 VDC @ 65 W) atteries

All laser sets comprise 3 safety goggles, foot switch, interlock connector, power cord and manual in a carrying case. The LEONARDO® DUAL 45 Watt is only suitable for the treatment of vesical tumours, partial kidney resection and other low-grade applications with low wattage settings. The standard device in urology primarily used for BPH treatment and all other applications is the LEONARDO® DUAL 200 Watt. The LEONARDO® DUAL 45 is the suitable laser system for partial nephrectomy, bladder tumors, strictures, condylomas etc. The LEONARDO® Mini is the suitable laser system for bladder tumors, strictures, condylomas, etc.



LEONARDO® DUAL 200 Watt – Unique combination of two simultaneous wavelengths

LEONARDO® DUAL 200 Watt combines the wavelengths of 980 nm and 1470 nm with high absorption in H₂O and hemoglobin for multiple applications not only in urology. Wavelength of 980 nm provides high absorption in hemoglobin and is therefore well suited for applications in urology. Due to absorption properties the emitted laser beam does not affect the bladder.



Handpieces and instruments

REF	Product
500400355	Storz Laser Cystoscope Set (blue) OD 23 Fr ID 7.5 Fr, no optics, incl. external and internal sheath and obturator
400400250	XCAVATOR® Resectoscope 360° Rotating and Continues Irrigation Set OD 26 Fr, no optics
AB2731	ASAP 30° Optics Hopkins II, compatible Storz Laser Cystoscope blue and XCAVATOR® Resectoscope
400100100	Universal Dual Luer Handpiece, for ø 600-1000 µm fibers
400400110	Laparoscopic sheath 30 cm, ID ø 1.4 mm, OD ø 5 mm
400400115	Laparoscopic sheath 40 cm, ID ø 1.4 mm, OD ø 5 mm

Fibers for LEONARDO®

	B. J. J. FRANKERSON			
	Product LEONARDO®	Length [m]	Core ø[Fr]	ADø[µm]/[Fr]
ВРН				
503200250	XCAVATOR® Fiber	3	1.8	_
503200220	TWISTER Large Fiber	3	1.8	3100/9.3
503200235	TWISTER XL Fiber	3	1.8	3300/9.3
Other Application	ons			
503200744	Bare Fiber 400 µm, Flat Tip, IC	3	400/1.2	750/2.3
503200740	Bare Fiber 600 µm, Flat Tip, IC	2.6	1.7	860/2.6
503300400	Bare Fiber 1000 µm, Flat Tip, IC	2.6	2.9	1400/4.2
503200750	Bare Fiber 600 µm, Ball Tip, Adj. Luer, IC (1 × 6 h)	2.5	1.7	860/2.6
503300410	Bare Fiber 1000 µm, Ball Tip, IC	2.6	2.9	1400/4.2
503200741	Bare Fiber 600 µm, Conical Tip, IC	2.6	1.7	860/2.6
503300405	Bare Fiber 1000 µm, Conical Tip, IC	2.6	2.9	1400/4
Enucleation				
503200745	Bare Fiber 600 µm, Flat Tip, Adj. Luer, ID (1 × 6 h)	3	565/1.7	860/2.6
503300415	Bare Fiber 1000 μm, Flat Tip, Adj. Luer, ID (1 × 6 h)	2.6	945/2.9	1400/4
A II 6'b				dt

All fibers are free of latex and DEHP. Our fibers are single use products (unless otherwise indicated), delivered sterile for immediate use.

Accessories

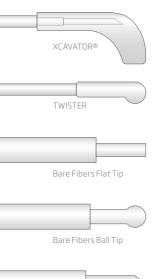
REF	Product
LA1371	Laser safety goggles 950 – 110 L4 + 1470 L2 (FULL) type: earpiece
LA5199	Laser safety goggles DIR 804 – 1755 L3 (FULL), type: basket, clear
LA5165	Sticker Laser warning 20 × 20 cm
400100115	Medi Strip 0.7/1.2 BF 600 μm, autoclavable – Fiber stripper for Bare Fiber 600 μm
AB1323	Stripping tool for fibers 0.3 – 1 mm
AB1908	Touhy Borst adapter
AB2594	Biopsy needle (for the handpiece)
400400200	Camera Filter HPD 980 nm and 1470 nm, small, OD 24 mm*

^{*} With high wattages (100 watt) for a good view on the screen

Fibers for holmium laser systems

REF	Product	Length [m]	Coreø [µm]/[Fr]	ADø [µm]/[Fr]	Connector	NA
Single-use Fibe	r					
500200326	Megabeam HBFSF 230 - 253, OD 420 μm	3.1	272	420	SMA905	0.28
500200327	Megabeam HBFSF 365 - 403, OD 550 μm	3.1	365	550	SMA905	0.22/0.37
500200328	Megabeam HBFSF 550 - 603, OD 750 μm	3.1	550	750	SMA905	0.22/0.37
Multiple use						
500200789	Megabeam RHBFSF 230/253-3	3.0	272	420	SMA905	0.22/0.36
500200790	Megabeam RHBFSF 365/400-3	3.0	365	550	SMA905	0.22/0.36
500200791	Megabeam RHBFSF 550/605-3	3.0	550	750	SMA905	0.22/0.36
500200792	Megabeam RHBFSF 945/1000-3	3.0	945	1400	SMA905	0.22/0.36
Side Fiber						
500300451	Megabeam SF - 2100 - H	3.2	550	950	SMA905	0.22

All fibers are free from latex and DEHP. Our fibers are designed for single use only (unless otherwise indicated), delivered sterile for immediate use. Fibers are compatible with, but not limited to: StoneLight®, COHERENT®, Deka, LUMENIS®, Dornier MedTech and NewStarLasers systems.



Bare Fibers Conical Tip

Single-use Fiber

Multiple use



Side Fiber

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Contact us

to learn more about a whole new world of minimally invasive laser therapies



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Biolitec Biotecnologia Comércio, Importação, Exportação LTDA

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CeramOptec GmbH

Bonn, Germany Phone: +49 228 979670

Ceram Optec SIA

Riga, Latvia

Phone: +371 653 25 994



All fibers are free of latex and DEHP. Our fibers are single use products (unless otherwise indicated) delivered sterile for immediate use.

Imprin

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LEONARDO®

Model	LEONARDO® DUAL 200	LEONARDO® DUAL 45
REF	SL980+1470nm200W	SL980+1470nm45W
Wavelength	980 nm and 1470 nm	980 nm and 1470 nm
Max. power	200 Watt (1470 nm/40 Watt + 980 nm/160 Watt) individually adjustable	45 Watt (1470 nm/15 Watt + 980 nm/30 Watt), individually adjustable
Fiber diameter	≥ 360 µm	≥ 360 µm
Aiming beam	532 nm and 635 nm, green 1 mW, red 4 mW, user-defined intensity	532 nm and 635 nm, green 1 mW, red 4 mW, user-defined intensity
Treatment mode	CW, pulse mode, ELVeS® signal, ELVeS® segment, derma mode	CW, pulse mode, ELVeS® signal, ELVeS® segment, derma mode
Pulse duration /-break	0.01 – CW / 0.01 – 60 sec	0.01 – CW / 0.01 – 60 sec
Power supply	110 – 240 VAC, 50 / 60 Hz, 850 VA	110 – 240 VAC, 50/60 Hz, 450 VA
Dimensions (H×W×D)	approx. 20 cm × 37 cm × 26 cm	approx. 28 cm × 37 cm × 9 cm
Weight	approx. 15 kg	approx. 8.5 kg



LEONARDO® DUAL 200 **NVISIBLE LASER RADIATION** AVIDIE YEO 8 SOIR EXPOSURE TO DIBLE TO 10 RIBBOR TO ARADATION **CLASS 4 LASER PRODUCT** Coded-Laser 2600 - 4.30 mmcW 400 W(Max.) Diode-Laser 2600 - 4.50 mmcW 400 W(Max.) ECCOSES 1,2007 | IECCOSES 1,2007 | IECCOSES

VISIBLE, ASSER MOUAT IND

CLASS 3R LASER PRODUCT

Diode-Laser 635 +/-10 mm CW 4 mW (Max.) (Aliming)

IEC60825-1:2007 IEC60601-2-22:2007

LEONARDO® DUAL 45

INVISITE LOSSE MADUAL TON
AVOID EYE OR SXINE EXPOSURE TO
DIRECT OR MORRECT RADIATION

CLASS 4 LASER PRODUCT

Didd-Laser 980 +/-30 mm (W 30 W (Max.)
Didd-Laser 1470 +/-30 mm (W 13 W (Max.)
EM60825-12-2008 EM60801-2-22-2007

VISIBLE LASER RADIATION
AVOID EYE EXPOSURE TO DIRECT RADIATION
CLASS 3R LASER PRODUCT
Didde-Laser 635 +/-10 mm CW 4 mW (Max;)(Alming)
Didde-Laser 532 -/-10 mm CW 1 mW (Max;)(Alming)
PROPS-1, 79-7907
PROPS-1, 79-7907

LEONARDO Mini Dual

INVISIBLE LASER RADIATION
AVOID EVE OR SKIN EXPOSURE TO
DIRECT OR INDIRECT RADIATION

CLASS 4 LASER PRODUCT
Diode-Laser 180 +/- 30 nm CW 10 W (Max.)
Diode-Laser 1470 +/- 30 nm CW 4 W (Max.)
ECGOREST-12007 ECG 606 UK 2-22-2007

VISIBLE LASER RADIATION
AVOID EVE EXPOSURE TO DIRECT RADIATION

CLASS 3R LASER PRODUCT
DIAGRAGE - 1.20 nm CW 4 mily (Max.) (Alming)
1EC60825 - 1.2007 1EC60601-2.22007

LEONARDO Mini 1470 nm

INVISIBLE LASER RADIATION
AVOID EYE OR SKIM EXPOSURE TO
DIRECT OR INDIRECT RADIATION

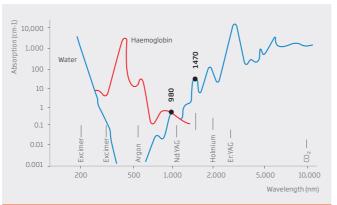
CLASS 4 LASER PRODUCT
Dided-laser 1470 4-730 m (W) 8 W (Max.)
IEC 60825 - 122007 EC 60601-2-22:2007

VISIBLE LASER RADIATION
AVOID EYE EXPOSURE TO DIRECT RADIATION
CLASS 3R LASER PRODUCT
Diode-Laser 635 +/-10 nm CW 4 mW (Max.)(Alming)



Model	LEONARDO® Mini Dual	LEONARDO® Mini 1470 nm
REF	SL980+1470nm14W	SL1470nm12W
Power/Wavelength	10 W (980 nm) / 4 W (1470 nm)	12 W (1470 nm)
Fiber diameter	≥ 360 µm	≥ 360 µm
Aiming beam	635 nm, max. 4 mW	635 nm, max. 4 mW
Treatment mode	CW, pulse mode (optional)	CW, pulse mode (optional), ELVeS® signal
Pulse duration/-break	0.01 – 180 sec / 0.01 – 180 sec	0.01 – 180 sec / 0.01 – 180 sec
Power supply	110 – 240 VAC, 50 - 60 Hz (12 VDC @ 65 W)	110 – 240 VAC, 50 – 60 Hz (12 VDC @ 100 W)
Batteries	Li-ion Batteries	Li-ion Batteries
Dimensions (H × W × D)	6 cm × 9 cm × 21.5 cm	6 cm × 9 cm × 21.5 cm
Weight	900 g	900 g

All laser sets comprise 3 safety goggles, foot switch, interlock connector, power cord and manual in a carrying case. The LEONARDO® DUAL 45 Watt is only suitable for the treatment of vesical tumours, partial kidney resection and other low-grade applications with low wattage settings. The standard device in urology primarily used for BPH treatment and all other applications is the LEONARDO® DUAL 200 Watt. The LEONARDO® DUAL 45 is the suitable laser system for partial nephrectomy, bladder tumors, strictures, condylomas etc. The LEONARDO® Mini is the suitable laser system for bladder tumors, strictures, condylomas, etc.



LEONARDO® DUAL 200 Watt – Unique combination of two simultaneous wavelengths

LEONARDO® DUAL 200 Watt combines the wavelengths of 980 nm and 1470 nm with high absorption in H₂O and hemoglobin for multiple applications not only in urology. Wavelength of 980 nm provides high absorption in hemoglobin and is therefore well suited for applications in urology. Due to absorption properties the emitted laser beam does not affect the bladder.



Handpieces and instruments

REF	Product
500400355	Storz Laser Cystoscope Set (blue) OD 23 Fr ID 7.5 Fr, no optics, incl. external and internal sheath and obturator
400400250	XCAVATOR® Resectoscope 360° Rotating and Continues Irrigation Set OD 26 Fr, no optics
AB2731	ASAP 30° Optics Hopkins II, compatible Storz Laser Cystoscope blue and XCAVATOR® Resectoscope
400100100	Universal Dual Luer Handpiece, for ø 600-1000 μm fibers
400400110	Laparoscopic sheath 30 cm, ID ø 1.4 mm, OD ø 5 mm
400400115	Laparoscopic sheath 40 cm, ID ø 1.4 mm, OD ø 5 mm

Fibers for LEONARDO®

REF LEONARDO® BPH	Product LEONARDO®	Length [m]	Coreø[Fr]	AD ø [μm]/[Fr]
503200250	XCAVATOR® Fiber	3	1.8	_
503200220	TWISTER Large Fiber	3	1.8	3100/9.3
503200235	TWISTER XL Fiber	3	1.8	3300/9.3
Other Application	ns			
503200744	Bare Fiber 400 µm, Flat Tip, IC	3	400/1.2	750/2.3
503200740	Bare Fiber 600 µm, Flat Tip, IC	2.6	1.7	860/2.6
503300400	Bare Fiber 1000 μm, Flat Tip, IC	2.6	2.9	1400/4.2
503200750	Bare Fiber 600 µm, Ball Tip, Adj. Luer, IC (1 × 6 h)	2.5	1.7	860/2.6
503300410	Bare Fiber 1000 μm, Ball Tip, IC	2.6	2.9	1400/4.2
503200741	Bare Fiber 600 µm, Conical Tip, IC	2.6	1.7	860/2.6
503300405	Bare Fiber 1000 µm, Conical Tip, IC	2.6	2.9	1400/4
Enucleation				
503200745	Bare Fiber 600 μm, Flat Tip, Adj. Luer, ID (1 × 6 h)	3	565/1.7	860/2.6
503300415	Bare Fiber 1000 μm, Flat Tip, Adj. Luer, ID (1 × 6 h)	2.6	945/2.9	1400/4

All fibers are free of latex and DEHP. Our fibers are single use products (unless otherwise indicated), delivered sterile for immediate use.

Accessories

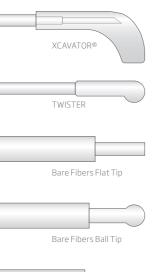
REF	Product
LA1371	Laser safety goggles 950 – 110 L4 + 1470 L2 (FULL) type: earpiece
LA5199	Laser safety goggles DIR 804 – 1755 L3 (FULL), type: basket, clear
LA5165	Sticker Laser warning 20 × 20 cm
400100115	Medi Strip 0.7/1.2 BF 600 μm, autoclavable – Fiber stripper for Bare Fiber 600 μm
AB1323	Stripping tool for fibers 0.3 – 1 mm
AB1908	Touhy Borst adapter
AB2594	Biopsy needle (for the handpiece)
400400200	Camera Filter HPD 980 nm and 1470 nm, small, OD 24 mm*

^{*} With high wattages (100 watt) for a good view on the screen

Fibers for holmium laser systems

REF	Product	Length [m]	Coreø [µm]/[Fr]	ADø [µm]/[Fr]	Connector	NA
Single-use Fibe	r					
500200326	Megabeam HBFSF 230 - 253, OD 420 μm	3.1	272	420	SMA905	0.28
500200327	Megabeam HBFSF 365 - 403, OD 550 μm	3.1	365	550	SMA905	0.22/0.37
500200328	Megabeam HBFSF 550 - 603, OD 750 μm	3.1	550	750	SMA905	0.22/0.37
Multiple use						
500200789	Megabeam RHBFSF 230 / 253 - 3	3.0	272	420	SMA905	0.22/0.36
500200790	Megabeam RHBFSF 365/400-3	3.0	365	550	SMA905	0.22/0.36
500200791	Megabeam RHBFSF 550/605-3	3.0	550	750	SMA905	0.22/0.36
500200792	Megabeam RHBFSF 945/1000-3	3.0	945	1400	SMA905	0.22/0.36
Side Fiber						
500300451	Megabeam SF - 2100 - H	3.2	550	950	SMA905	0.22

All fibers are free from latex and DEHP. Our fibers are designed for single use only (unless otherwise indicated), delivered sterile for immediate use.Fibers are compatible with, but not limited to: Stone Light@, COHERENT@, Deka, LUMENIS@, Dornier MedTech and NewStar Lasers systems.



Bare Fibers Conical Tip

Single-use Fiber

Multiple use





TULA® DUAL

Trans Urethral Laser Ablation of Recurring Bladder Tumors



TULA® DUAL – DUAL Laser Technology

Staying true to its tradition in pioneering new minimally invasive treatments, biolitec® combines DUAL wavelengths of 980 nm / 1470 nm to provide excellent and efficient intra and post-operative results. Dual diode lasers with high quality fiber optics make procedures safe and cost effective for both healthcare professionals and patients.

Literature TULA® DUAL

Introduction and Objectives: Non-invasive bladder cancer is often recurrent. 5-10% of patients will have recurrences that are small and few. Treating these recurrences causes morbidity to patients because of the frequent resections under general anesthesia that are needed to control the disease, (...)

This project aims to prove the safety and efficacy of receiving outpatient laser treatment under local anesthetic. Laser vaporization of small bladder tumors has several advantages over standard electrocautery techniques. The lack of electrical conduction reduces discomfort to patients, bleeding is almost absent and even patients on anticoagulation therapy can be treated. (...)

Methods: (...) The diode 1470 nm (1 mm depth of penetration) offers improved hemostasis over the Holmium (0.2 mm) and limits the reported bladder perforation risk with the deeper ND;YAG and diode 980 nm (5 - 10 mm). As such the diode 1470 nm may represent the ideal 'urothelial' laser. We kept a prospective dataset of patients receiving TULA treatment over a five year period. Parameters recorded include number of patients/procedures, patient age, comorbidities, procedure time, pain perception, complications, readmission rates, and patient satisfaction.

Results: Between 1st May 2012 and 28th December 2016, there were a total of 454 laser ablations performed on 306 different patients. The median age was 75 (range 24-99 years old). Median procedure time was 10 minutes, mean energy 759 J. Out of 306 patients, 192 had pre existing TCC (141 Ta, 34 T1, 4 T2 (following DXT), 6 CIS, 7 unknown/ historical NMIBC). 102 Laser ablations were conducted whilst the patient was on anticoagulants: (25 aspirin, 22 clopidogrel, 53 warfarin, 1 dabigatran, 1 tinzaparin). No complications were recorded secondary to bleeding. (...)

Conclusions: Bladder cancer can re-occur in up to 50 % of patients over a 5 year period. This often requires multiple procedures and general anesthetics in patients with multiple medical issues. The Diode Laser vaporization of NMI bladder cancer has been proven to be well tolerated, less onerous on patients, and may reduce post operative complications.

Philip James, Sachin Agrawal, Aakash Pai (Ashford & St. Peter's NHS Foundation Trust)

Altaf Shamsuddin (Imperial College Healthcare NHS Trust)



Non muscle invasive bladder tumors

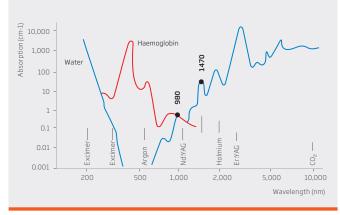
Non-muscle invasive bladder tumor normally has a high recurrence rate, leading to multiple treatments. Elderly patients with multiple morbidities are not fit for conventional treatment under general anesthesia. TULA® DUAL offers a technique using flexible cystoscopy for the treatment of bladder tumor under local or even no anesthesia in outpatient settings.

Advantages:

- Avoidance of the obturator-nerve reflex
- Specially designed fibers for best results
- Controlled and focussed penetration depth with less thermal spread
- Atraumatic fiber tip enables a smooth insertion and protects the working channel
- __ Dual concept for a matched penetration depth of tumor

Indications:

- Non muscle invasive bladder tumor
- __ Radiation cystitis





LEONARDO® DUAL with specially designed fibers combines the wavelengths of 980 nm and 1470 nm with high absorption in water and hemoglobin

LEONARDO®



Model	LEONARDO® Mini Dual	
REF	SL980+1470 nm14 W	
Power/Wavelength	10 W (980 nm)/4 W (1470 nm)	
Fiber diameter	≥ 360 µm	
Aiming beam	635 nm, max. 4 mW	
Treatment mode	CW, pulse mode (optional)	
Pulse duration/-break	0.01 – 60 sec / 0.01 – 60 sec	
Power supply	110 – 240 VAC, 50 – 60 Hz (7.2 VDC @ 36 W)	
Batteries	Li-ion batteries	
Dimensions (H x W x D)	6 cm × 9 cm × 21.5 cm	
Weight	900 g	

Fiber

REF	Product
503100410	TULA® Fiber, IC

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to learn more about a whole new world of minimally invasive laser therapies



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All fibers are free of latex and DEHP. Our fibers are single use products (unless otherwise indicated) delivered sterile for immediate use.

Imprint

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Non muscle invasive bladder tumors

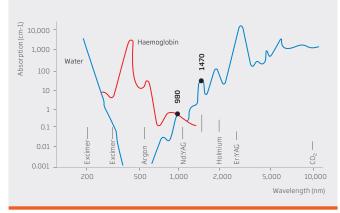
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Batteries	Li-ion batteries	
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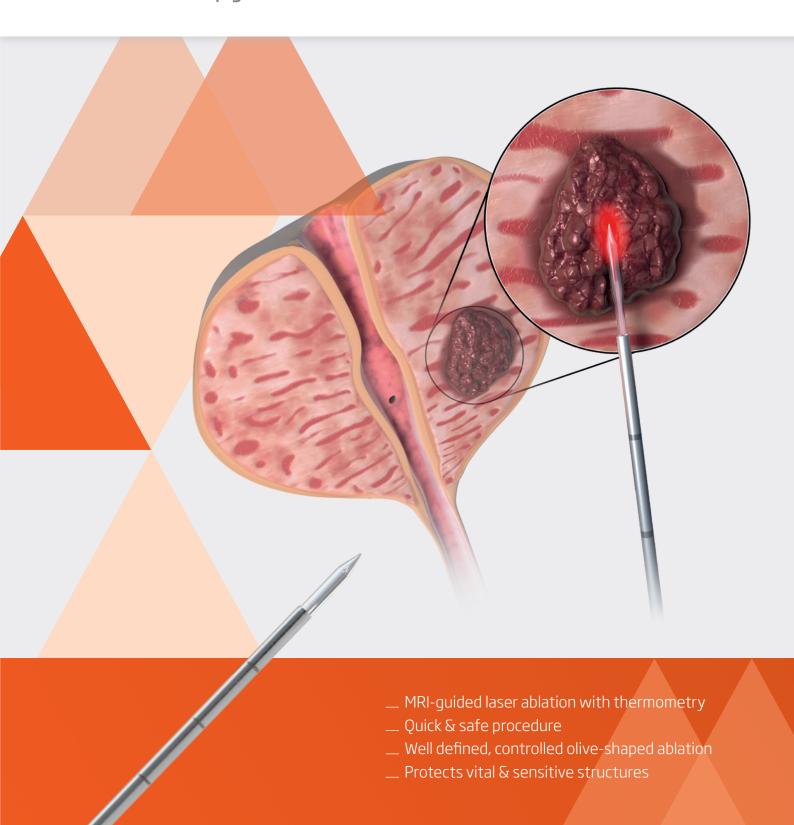
Fiber

REF	Product
503100410	TULA® Fiber, IC



Focal Laser Ablation

FLA Therapy of Prostate Tumors



A new dimension in the treatment of prostate tumors

No collateral damage to sensitive structures

The combination of real-time Magnetic Resonance Imaging (MRI) with Focal Laser Ablation (FLA) has led to a new and higher quality of prostate tumor treatment.

Patients diagnosed with low to intermediate localized prostate tumors can be treated safely and precisely with no collateral damage to the adjacent structures with Focal Laser Ablation (FLA).



Example for location of a prostate tumor (© fotolia/blueringmedia)

Advantages

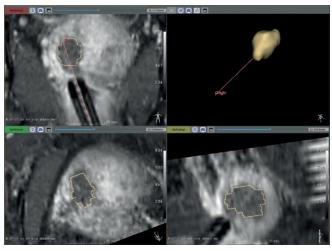
biolitec® FLA of Prostate Tumors

- Right penetration depth and energy absorption
- MRI compatible Litt fibers
 Procedure can be performend with different ablation zones
- Shorter hospital stay

- Protects critical structures around the prostate gland
- under local anesthesia
- Laser ablation can be repeated for recurring tumors

How is the intervention done? Transrectal or transperineal approach

- 1. After the confirmed diagnosis with PSA blood tests, MRI scans and prostate biopsy, the Focal Laser Ablation is performed under real-time MRI Guidance & Thermometry with the FLA Litt fibers by biolitec®
- 2. The Litt fiber is gently introduced and positioned into the core of the low to intermediate localized prostate tumors
- 3. The LEONARDO® Dual 45 laser and the Litt fiber deliver the energy to destroy the tumor in an olive-shaped ablation zone within minutes

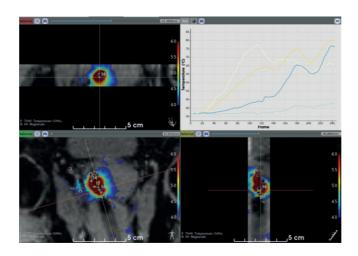


Post-Contrast T1-weighted image for thermal lesion confirmation

Images courtesy of Certis Therapeutics

Safety & precision

The Leonardo laser along with the specially designed Litt fiber produces well defined ablation to treat prostate tumors. A real time thermometry solution empowers clinicians with the next generation MRI-Guided Thermal Ablation. Certis Therapeutics with their advanced software provide solutions to monitor thermal energy under MRI Intervention with an unprecedented accuracy. The Certis software thermometry offers a complete solution for real-time MRI guided thermal ablations with utmost safety and precision in treating prostate tumors.



Temperature mapping during laser treatment

Thermometry during FLA with the biolitec® Litt laser fiber (relative temperature scale)

Darkblue	< 40°
Lightblue	40 - 45°
Green	45 - 50°
Yellow	50 - 55°
Orange	55 - 60°

The real-time MRI Mapping & Thermometry confirms the right and safe ablation during the laser procedure. The MRI scan shows proper destruction of tumor with sufficient safety margins.

The MRI-Focal Laser Ablation can be done either with a needle guide positioning (manual technique) or with a robotic needle guide positioning technique such as Soteria's Remote Controlled Manipulator (RCM; optional).



Medical BV Arnhem, The Netherlands)

The RCM positioned for treatment (© Soteria

Case images courtesy to Prof. Fütterer, University Hospital, Radboudumc, Nijmegen, The Netherlands

"I have used the biolitec® LEONARDO® Dual laser and the specially designed MRI compatible FLA Litt fibers since 2017. This is a special combination of precise and controlled technique for Focal Laser Ablation of Prostate Tumors. It helps to protect the vital structure from damage by minimizing the thermal spread, and at the same time achieve a safe and efficient ablation. biolitec® gives me this precision!"

Jurgen Fütterer MD PhD, Interventional Radiologist at Radboudumc, Nijmegen, and full professor at the Robotics and Mechatronics group, University of Twente, The Netherlands

Our products





LEONARDO®

Model	LEONARDO® DUAL 45		
REF	SL980+1470nm45W		
Wavelength	980 nm and 1470 nm		
Power	max. 45 Watt (1470 nm/15 Watt + 980 nm/30 Watt) separately adjustable		
Fiber diameter	≥ 360 µm		
Aiming beam	532 nm and 635 nm, green 1 mW, red 4 mW, user controlled intensity		
Treatment mode	CW, Pulse Mode, ELVeS® Signal, ELVeS® Segment, Derma Mode		
Pulse duration/-break	0.01 – 60 sec / 0.01 – 60 sec		
Power supply	110 – 240 VAC, 50 / 60 Hz, 450 VA		
Batteries	-		
Dimensions (H × W × D)	approx. 28 cm × 37 cm × 9 cm		
Weight	approx. 8.5 kg		

 $All\,laser\,sets\,incl.\,3\,safety\,goggles, foot\,switch, interlock\,connector, power\,cord\,and\,manual\,in\,a\,carrying\,case.$

Litt fibers

REF	Product	PU [Packaging unit]	length [m]	ø fiber [mm]	Ablation shape
503200270	Litt2B fiber	5	10	1.85	olive
503200280	Litt3B fiber	5	10	1.85	olive

Certis Therapeutics

REF	Product	Description	
CT-STK-1	Certis Solution Starter Kit	(laptop or mini desk) 32Gb PC with high-end graphic card	
	Certis Solution Starter Kit	MRI connection and parameters optimization	
CT-SFW-1.X	Certis Solution Annual License	12 months software license Includes upgrades	
		Includes maintenance and online support	

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