PicoWay®

Remove Boldly.
Treat Lightly.

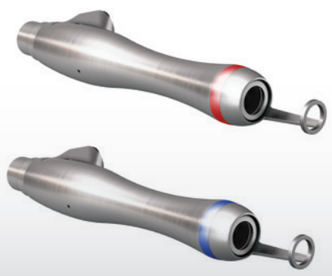
CANDELA™

Science. Results. Trust.

The PicoWay® system is a versatile picosecond platform intentionally designed for your practice.

PicoWay® is a true 3-wavelength picosecond platform for the treatment of wrinkles, acne scars, benign pigmented lesions and tattoos.

With high peak power and the shortest pulse durations,* PicoWay delivers a photoacoustic effect to transform skin.[1-5]



Four handpieces for versatility and treatment customisation

PicoWay® Zoom

- Full beam 532nm and 1064nm[3-5]
- Tattoo removal, benign pigmented lesions[3-5]

Spot sizes

PicoWay® 785

- Titanium Sapphire Crystal[13]
- 785nm[5]
- Tattoo removal (blue and green)[5]

Spot sizes

PicoWay® Resolve

- Two handpieces: 532nm and 1064nm[1-2]
- Acne scars and wrinkles[1-2]

Spot sizes

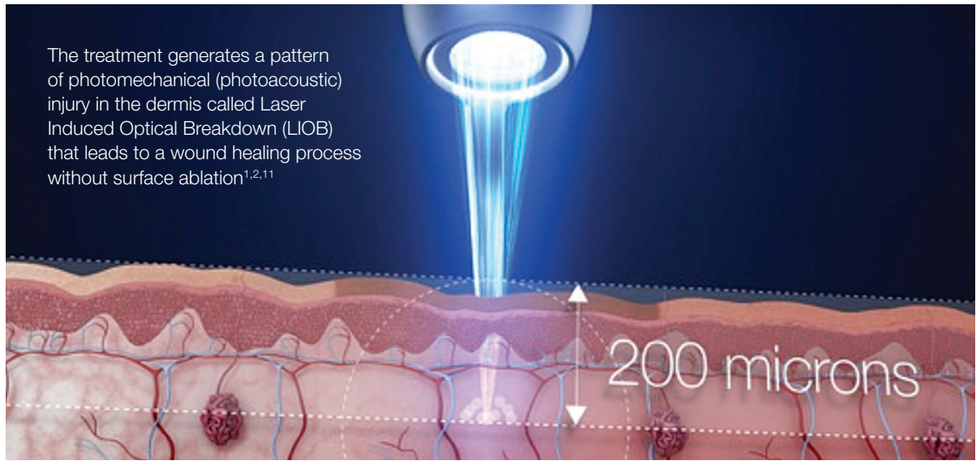
6x6 mm with 100 identical beams for uniform treatment[11, 13]

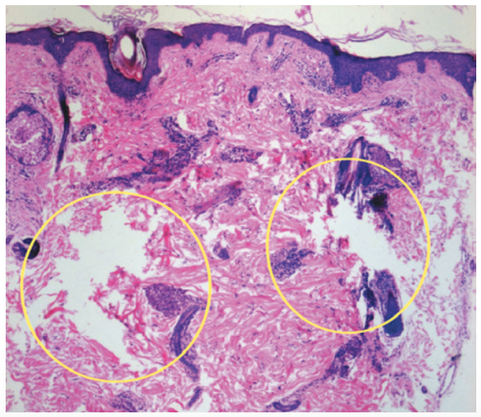
*Based on available 510(k) summaries as of October 2017.

PicoWay® Resolve handpiece acts at the dermis without breaking the epidermis[1,2,11,13]

Picosecond lasers have been demonstrated to build collagen and elastin[14-16]

The PicoWay® Resolve photoacoustic effect creates cavitations and a wound healing response in the dermis[2,11]

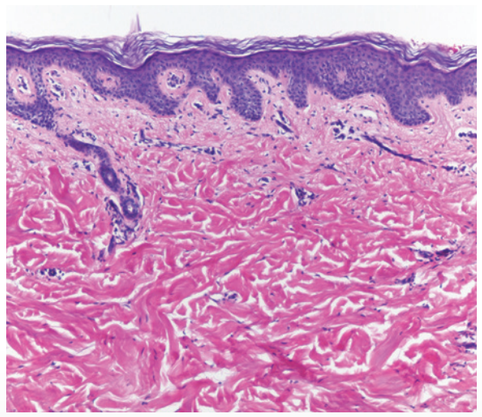




One day post treatment

Cavitations created in the upper dermis (Resolve 1064 nm, 2 mJ/µbeam).

(Courtesy of A. Ribe, M.D.)



Two months post treatment

Complete healing with the empty vacuoles filled by the wound healing process.

(Courtesy of A. Kauvar, M.D.)

PicoWay® Resolve transforms skin with **little to no downtime**[1,2]

- Brief 15 to 20 minute treatment sessions
- Tolerable, mild side effects: 8 to 36 hours of mild erythema
- Little post-procedure discomfort
- Epidermis is intact2

PicoWay®: Benign Pigmented Lesions

The PicoWay® system visibly improves benign pigmented lesions (Zoom 532 nm and 1064 nm)[3]

The PicoWay® device treats benign pigmented lesions including solar lentigines, freckles, café au lait and hyperpigmentation[3]

The PicoWay® device is successful across a broad range of skin types (Fitzpatrick Skin Types I-IV)[3]

The PicoWay system works from the inside out[1-5]

- Targets chromophores below the surface of the skin[6]
- Breaks the pigment into miniscule particles[3-6]
- Successfully minimises the appearance of benign pigmented lesions[3]

Investigator assessments

- Clearance grade of benign pigmented lesions was assessed on a 5-point scale[3]
- After two treatments for all pigmented lesions, 87% of the lesions had at least good response (>50% had good response or better)[3]

Blinded assessments (primary endpoint)[3]

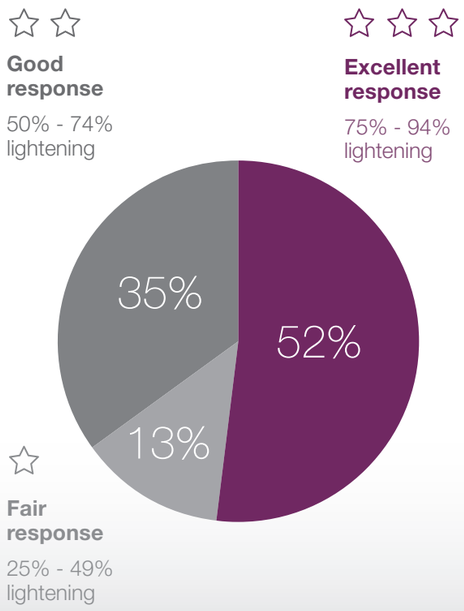
96% of the pigmented lesions had at least 50% clearance (Grade 3-5) after two treatments by blinded evaluation.

Study design

- Two clinical sites: USA and Hong Kong
- Treatments with PicoWay 532 nm or 1064 nm
- n=29 pigmented lesions on face and body
- Up to nine treatment sessions (two to six weeks interval)
- Mean four treatments
- Three follow-up visits (4, 8, and 12 weeks post-last treatment)

Study demographics[3]

- 26 subjects (1 male, 25 females)
- 46% Asian (n=12)
- 54% Caucasian (n=14)
- Mean age: 48±10 years, range 21-66
- Fitzpatrick Skin Types I-IV



Demonstrated success with both 532 nm and 1064 nm wavelengths

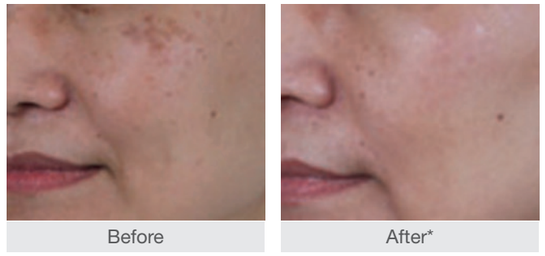
The PicoWay® system noticeably clears benign pigmented lesions[3]

The PicoWay® device successfully removes benign pigmented lesions with visible results after 1-2 treatment sessions.[3]

Safety

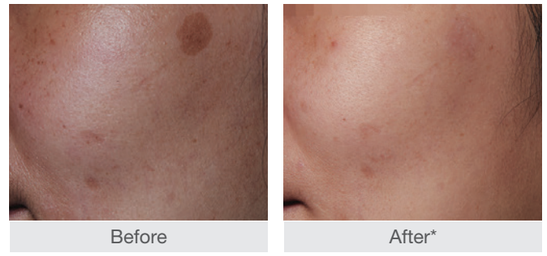
- No device related serious adverse events and no study withdrawals due to adverse events[3]
- Of the 107 treatments performed in the study, only three adverse events were reported for two subjects. These events were not severe and resolved or improved during the study[3]
- Immediate post-treatment subject ranking of pain sensation during treatment on 10-point pain Visual Analog Scale VAS) (0=no pain, 10=worst possible pain)
- 2.8±2.2 (mild pain sensation)[3]
- In 86% of treatments, patients reported none to moderate discomfort[3]

Nevus of Zygomaticus



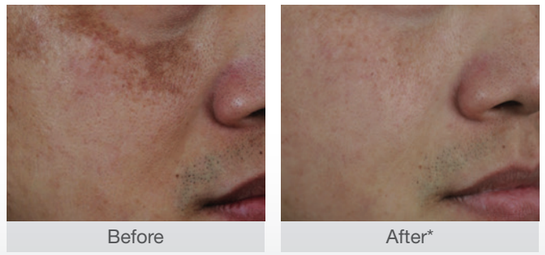
Four PicoWay 1064nm and 532nm treatments.
Photos courtesy of Cheng Kuo-Liang, M.D.

Solar Lentigines



Three PicoWay 1064nm and 532nm treatments.
Photos courtesy of Lee Sang Ju M.D.

Pigmented Lesions



Three PicoWay 1064nm and 532nm treatments.
Photos courtesy of Cheng Kuo-Liang M.D.

Solar Lentigines

Three PicoWay 1064nm and 532nm treatments.
Photos courtesy of Lee Sung Ju M.D.

References: **1.** PicoWay 510(k) clearance for wrinkles (K170597), May 2017. **2.** PicoWay 510(k) clearance for acne scars (K162454), February 2017. **3.** PicoWay 510(k) clearance for benign pigmented lesions (K150326), April 2015. **4.** PicoWay 510(k) clearance for tattoos (K142372), October 2014. **5.** PicoWay 510(k) clearance for tattoos with 785 nm wavelength (K160607), July 2016. **6.** Data on file. Syneron Candela.

*All photos are unretouched. Individual results may vary.

PicoWay®: Acne Scars

Acne scars are often associated with a loss of collagen (Resolve 1064 nm)

Acne scars are a common condition that can result from deficiencies in collagen.[7] About 40% of acne patients develop scars[8] and may suffer from psychological issues, low self-esteem and distress, regardless of the clinical severity of the scarring.[9]

Picosecond lasers have been demonstrated to build collagen and elastin.[9]

The PicoWay® Resolve handpiece works from the inside out[1-5]

- Treats acne scars using sub-surface ablation, designed to maintain an intact stratum corneum[2,6]
- Splits the laser wavelength into 100 identical beams for uniform treatment over a 6 x 6mm area[2,6]
- The handpiece is gently passed over the skin in a series of brief 15 to 20 minute sessions with the ultimate goal of transforming skin

Study design

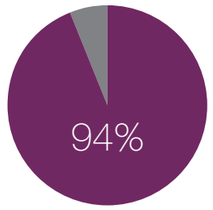
- Treatments with PicoWay® Resolve 1064 nm handpiece
- 36 facial areas treated
- Up to five treatment sessions (3-8 week intervals)
- Mean four treatments
- 12-week post-treatment follow up

Study demographics

- 36 male and female subjects
- Mean age: 44±13 years
- Fitzpatrick Skin Types II-V

PicoWay® is successful in a broad range of skin types (Fitzpatrick Skin Types II-V)[2]

Significant improvement in acne scar severity[2]



Treated area improvement*

High physician and patient satisfaction (at final 12-week follow-up)[2]

Physician satisfaction

Subject satisfaction

References: **1.** PicoWay 510(k) clearance for wrinkles (K170597), May 2017. **2.** PicoWay 510(k) clearance for acne scars (K162454), February 2017. **3.** PicoWay 510(k) clearance for benign pigmented lesions (K150326), April 2015. **4.** PicoWay 510(k) clearance for tattoos (K142372), October 2014. **5.** PicoWay 510(k) clearance for tattoos with 785 nm wavelength (K160607), July 2016. **6.** Data on file. Syneron-Candela. **7.** Kravvas G, Al-Niaimi F. A systematic review of treatments for acne scarring. Part I: non-energy-based techniques. Scars Burns Healing. 2017; 3:1-17. **8.** Dreno B, Tan J, Kang W, Rueda M, Lozada VT, et al. How people with facial acne scars are perceived in society: an online survey. Dermatol Ther. 2016;6:207-218. **9.** Werschler WP, Herdener RS, Ross EV, Zimmerman E. Treating acne scars: What's new? Consensus from the experts. J Clin Aesthet Dermatol. 2015;8(8):S2-S8. **10.** Brauer JA, Kazlouskaya V, Alabdulrazzaq H, Bae YS, Bernstein LJ, et al. Use of a picosec- ond pulse duration laser with specialized optic for treatment of facial acne scarring. JAMA Dermatol. 2015;151(3):278-284.
11. Schomacker K, Bhawalkar JD. PicoWay Resolve Clinical Bulletin. 2016. Data on file. Syneron-Candela.

*94% of treated areas showed improvement in acne scar appearance following 3-4 treatment sessions (blinded evaluation of photographs) (n=36)[2]

Visual improvement in appearance of acne scars[2]

Safety

- No anesthetic was used[2,11]
- Most subjects reported mild levels of pain during treatment and no or mild discomfort following treatment[2,11]
- There were no adverse events during the course of the study[2]
- Anticipated treatment responses such as erythema, edema, tingling, pinpoint bleeding, crusting and acne breakout following treatment were observed and these effects resolved within days after treatment without medical intervention[2]
- Low to no downtime[2]

Acne Scars

Before | After*

Three Resolve 1064nm treatments.
Photos courtesy of Arielle Kauvar, M.D.

Acne Scars and Pores

Before | After*

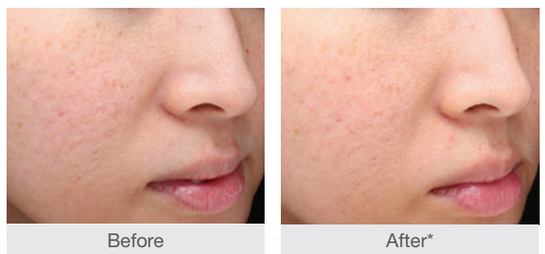
Three PicoWay 1064nm and 532nm treatments.
Photos courtesy of Cheng Kuo-Liang, M.D.

Post Acne PIH

Before | After*

One PicoWay 1064nm treatment.
Photos courtesy of Renita Rajan, M.D.

Acne Scars and Pores



Before | After*

One PicoWay 1064nm 532nm treatment.
Photo courtesy of inhouse evaluations, Syneron Candela

*All photos are unretouched. Individual results may vary.

PicoWay®: Wrinkles

The PicoWay® Resolve handpiece significantly reduces wrinkles (Resolve 532 nm and 1064 nm)

The PicoWay® Resolve handpiece is successful across a broad range of skin types (Fitzpatrick Skin Types I-IV)[1]

An alternative to current wrinkle treatments

Every year, millions of people receive treatments for wrinkles.[7] PicoWay® Resolve laser treatment provides an option to treat wrinkles using a picosecond laser that reaches the dermis without breaking the epidermis.[6,8]

The PicoWay® Resolve handpiece works from the inside out

- Treats wrinkles using sub-surface ablation, designed to maintain an intact stratum corneum[1,2,6]
- Splits the laser beam into 100 identical beams for uniform treatment over a 6 x 6 mm area[1,2,6]
- The handpiece is gently passed over the skin in a series of brief 15 to 20 minute sessions with the ultimate goal of transforming skin[1,2,6]
- Either a single or double pass treatment paradigm can be used[1]

Treatment results in high rates of improvement in wrinkle severity with low to no downtime.[1]

Picosecond lasers have been demonstrated to build collagen and elastin[9]

Study design

- Treatment with 1064 nm and/or 532 nm to each side of the face (n=52)[1,6]
- Treatment at one study site used double passes of both 1064 nm + 532 nm (two passes each) in the same treatment session (n=20; 80 treatments)[1,6]
- Topical anesthesia applied at these double-pass treated areas[1,6]
- ≤6 treatment sessions (three to eight weeks interval)

Study demographics

- 72 patients (3 males, 69 females) treated on 92 facial areas[1,6]
- Mean age of 56±9 years (range 33-71 years)[1,6]
- Mild to moderate bilateral perioral and/or periorbital wrinkles[1,6]
- Fitzpatrick Skin Types I-IV[1,6]

Treated area improvement*

82%

Success with single-pass 1064 nm and/or 532 nm[1,6]

Treated area improvement**

92%

Success with single-pass 1064 nm and/ or 532 nm[1,6]

Improvement in Elastosis***

100%

Success with double-passes of both 1064 nm + 532 nm treatment[1,6]

High physician and patient satisfaction (at final 12-week follow-up)[1]

Investigator satisfaction

88%

Patient satisfaction

74%

*Of treated areas showed improvement in wrinkle appearance at final 12 week study visit after 3-6 treatment sessions (n=72[1] As measured by correct identification of the post treatment photograph and assessment of at least one Elastosis Score unit, Blinded evaluation
**Of treatment areas showed improvement in wrinkles appearance at final 12-week study visit (n=72)[1]
***Of treatment areas showed improvement in Elastosis score at final 12-week study visit (n=20)[1,13] Investigator evaluation [6]

Noticeable improvement in appearance of wrinkles across a broad range of skin types

Safety

- Most patients reported low levels of pain during treatment (mean pain level of 4.18±2.56 [range 0 to 10])[1,6]
- The most common immediate treatment responses reported in >2% of subjects were:[1,6]
  - Erythema.....**93%**
  - Crusting.....**4%**
  - Purpura.....**7%**
  - Pinpoint bleeding...**14%**
  - Edema.....**57%**
- All responses were expected from the treatment and resolved spontaneously within a few days[1,6]
- Low to no downtime[1,6]

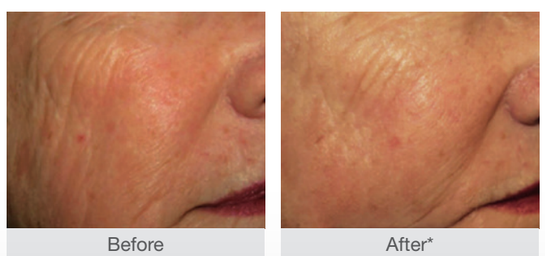
Wrinkles - Female

12 weeks post Resolve 1064nm treatment.
Photos courtesy of Eric Bernstein, M.D.

Wrinkles - Male

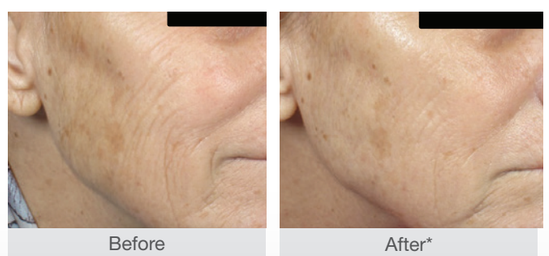
12 weeks post Resolve 1064nm treatment.
Photos courtesy of Eric Bernstein, M.D.

Wrinkles - Female



6 weeks post two PicoWay 1064nm and 532nm wavelength treatments.
Photos courtesy of David Friedman, M.D.

Wrinkles - Female



7 weeks post two PicoWay 1064nm treatments.
Photos courtesy of David Friedman, M.D.

References: **1.** PicoWay 510(k) clearance for wrinkles (K170597), May 2017. **2.** PicoWay 510(k) clearance for acne scars (K162454), February 2017. **3.** PicoWay 510(k) clearance for benign pigmented lesions (K150326), April 2015. **4.** PicoWay 510(k) clearance for tattoos (K142372), October 2014. **5.** PicoWay 510(k) clearance for tattoos with 785 nm wavelength (K160607), July 2016. **6.** Data on file. Syneron-Candela. **7.** ASAPS survey. https://www.surgery.org/sites/ default/files/ASAPS-Stats2016.pdf. Accessed August 28, 2017. **8.** American Academy of Aesthetic Medicine. What is aesthetic medicine? https://www.aaamed.org/aesthetic_med.php. Accessed August 28, 2017. **9.** Brauer JA, Kazlouskaya V, Alabdulrazzaq H, Bae YS, Bernstein LJ, et al. Use of a picosecond pulse duration laser with specialized optic for treatment of facial acne scarring. JAMA Dermatol. 2015;151(3):278-284.

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PicoWay®: Tattoo Removal

The PicoWay® system successfully removes multicolour tattoos (Zoom 532 nm, Zoom 1064 nm and 785 nm handpieces)

PicoWay® Zoom

- 532 nm: red, yellow and orange (Fitzpatrick Skin Types I-III)[4]
- 785 nm: blue and green (Fitzpatrick Skin Types II-IV)[5]
- 1064 nm: black, brown, green, blue, and purple (Fitzpatrick Skin Types I-VI)[4]

Tattoos and their removal are expanding

- 40% of adults aged 26-40 years have at least one tattoo[6]
- 19% of people with tattoos have considered removal[6]
- 13% more tattoo removal procedures were performed in 2016 than 2015[7]
- Tattoo removal revenues are projected to reach $83.2 million by 2018[6]

The PicoWay® system works from the inside out[4-5]

- Targets tattoo ink particles below the surface of the skin[4-5]
- Breaks the pigment into miniscule particles[4-5]
- Successfully minimises the appearance of multicolour tattoos[4-5]

Study 1 - PicoWay® Zoom 532 nm or 1064 nm

- Three sites (USA)[4]
- 75 black or multicolour tattoos treated with up to 10 treatments[4,6]
- 2 to 10 week treatment interval[4]
- Mean entire treatment: 8-19 weeks[6]
- 60 subjects (23 males, 37 females)[4]
- Fitzpatrick Skin Types I-VI[6]
- In 62% of treatments, patients reported none to mild discomfort[4]

86% of patients had ≥50% clearance after three treatments[4]

≥50% clearance

86%

Study 2 - PicoWay® 785 nm

- One site (USA)
- Treatment with 785 nm wavelength for blue and green tattoos
- 22 tattoos were treated (18 were blue/green)
- Treatments administered at 6 to 16 week intervals up to two treatments (2-4mm spot, pulse repetition up to 5Hz)[5]
- 15 subjects (majority female)
- Fitzpatrick Skin Types I-VI[6]
- 22 tattoos were treated (18 were blue/green colour)[5,6]
- No serious adverse events[5]

83% (15/18) of blue/green tattoos achieved at least 50% clearance compared to baseline after just two treatments[5]

At least 50% clearance

83%

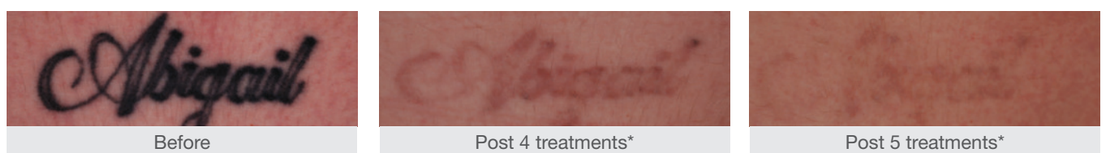
Clearance of black and multicoloured tattoo pigment with 1064nm wavelength

Multicoloured tattoo

Before | Post 1 treatment* | Post 3 treatments* | 8 weeks post treatment 7*

Skin type III treated with 1064nm. Photos courtesy of Eric Bernstein, M.D.

Multicoloured tattoo



Before | Post 4 treatments* | Post 5 treatments*

Skin type III treated with 1064nm. Photos courtesy of Eric Bernstein, M.D.

Black and red tattoo

Before | After*

Post four 1064nm treatments. Photos courtesy of Eric Bernstein, M.D.

Black and red tattoo

Before | After*

Post five 1064nm treatments. Photos courtesy of Eric Bernstein, M.D.

Black and red tattoo

Before | After*

Post four 1064nm treatments. Photos courtesy of Eric Bernstein, M.D.

Permanent eyebrow tattoo

Before | After*

Post one 1064nm treatments. Photos courtesy of Dr. Lee.

References: **1.** PicoWay 510(k) clearance for wrinkles (K170597), May 2017. **2.** PicoWay 510(k) clearance for acne scars (K162454), February 2017. **3.** PicoWay 510(k) clearance for benign pigmented lesions (K150326), April 2015. **4.** PicoWay 510(k) clearance for tattoos (K142372), October 2014. **5.** PicoWay 510(k) clearance for tattoos with 785 nm wavelength (K160607), July 2016. **6.** Data on file. Syneron Candela. 7. ASAPS survey. https://www.- surgery.org/sites/default/ files/ASAPS-Stats2016.pdf. Accessed July 7, 2017.

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The PicoWay® system delivers four treatments in one platform

The PicoWay® system demonstrates statistically significant improvement in all studied use[1-5]

Acne Scars[2]	Wrinkles[1]	Benign Pigmented Lesions[3]	Tattoo Removal[4]
1064nm	532nm and/or 1064nm	532nm and/or 1064nm	532nm, 785nm, 1064nm
% treated areas improve primary clinical endpoint			
94% (n=36, blinded evaluation of photographs)	82% (n=72, blinded evaluation)	94% (n=26, blinded evaluation)	86% (n=60 subjects with 75 black or multicolour tattoos had at least 50% clearance after three treatments)
	92% (n=72, investigator evaluation at 12 week study visit)		83% (n=18, blue/green tattoos treated with 785nm had at least 50% clearance after two treatments)
Endpoint discussion			
Improvement in acne scar appearance following three to four treatment sessions (blinded evaluation of photographs) at week 12 follow-up.	% of treatment areas showing improvement in elastosis score at week 12 after three to four treatment sessions.	At least 50% clearance (Grade 3-5) after two treatments by blinded evaluation.	Blinded reviewer assessment (primary endpoint) after three treatments (532 nm or 1064 nm) or after two treatments (785 nm).

High rates of physician and patient satisfaction[1-3]

The system architecture is designed for treatment customisation and performance[1-5, 13]

Flexibility

- Flexible treatment parameters for physician control of wavelength, fluence, repetition rate and spot size for highly customisable treatments[13]
- Multiple energies per spot size[13]
- Open architecture for future upgradeability[13]

Power and Pulse Durations

- Three true picosecond wavelengths with high peak power and shortest pulse durations for a photoacoustic effect[1-5]
- No compromise of spot size for fluence

Stability

- Stable optical synchronisation for a reliable laser[13]
- Runs cool[13]

Conservation

- Fast warm-up time[13]
- No frequent costly flashmap replacement
- Uses only 10% of its capable energy[13]
- No consumables[13]

PicoWay®

Remove Boldly. Treat Lightly.

PicoWay Zoom

The PicoWay Zoom handpiece (532 nm, 1064 nm) treats benign pigmented lesions and tattoo removal.[3, 4]

PicoWay 785

The PicoWay 785 nm handpiece removes blue and green tattoos.[5]

PICOWAY: LASER SYSTEM SPECIFICATIONS			
Laser Type	Nd:YAG Frequency	Double Nd: YAG	Titanium Sapphire
Wavelength	1064nm	532nm	785nm
Maximum Energy	400mJ	200mJ	100mJ
Pulse Duration	450ps	375ps	300ps
Peak Power	0.90 Gigawatts	0.53 Gigawatts	0.33 Gigawatts
Spot Sizes	2mm, 3mm, 4mm, 5mm, 6mm, 7mm, 8mm, 9mm, 10mm		2, 3, 4mm
Repetition Rate	Single 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Hz		
Delivery System	Articulated arm with 2 wavelengths Zoom handpiece		Dedicated handpiece
Warm Up Time	2 minutes		
User Interface	Touchscreen with GUI		
Size	107cm H x 46cm W x 69cm D (42" H x 18" W x 27" D)		
Weight	275 lbs / 125 kg		
Power Requirements	200-240 VAC, 50/60 Hz, 30A, 4600 VA single		

Resolve by PicoWay®

PicoWay Resolve

Resolve handpieces in 532 nm and 1064 nm wavelengths treat wrinkles and acne scars.[1,2]

PICOWAY RESOLVE SPECIFICATIONS		
Laser Type	Nd:YAG Frequency	Double Nd: YAG
Wavelength	1064nm	532nm
Micro-beam Energy	Up to 2.9mJ	Up to 1.5mJ
Pulse Duration	450ps	375ps
Spot Size	6mm x 6mm	6mm x 6mm
Matrix	10 x 10 microbeam array	10 x 10 microbeam array
Repetition Rate	Single 1, 2, 3, 4, 5, 6, 7, 8, 9, 10Hz	
Delivery System	Articulated arm with Resolve handpiece	

For more information about how the PicoWay system may help achieve your practice goals, contact your local Candela sales professional or visit **candelamedical.com**

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