

World's First and ONLY FDA Clearance for **True Regeneration™**

LANAP® = LAR™
PERIODONTAL REGENERATION PROTOCOL LASER ASSISTED REGENERATION

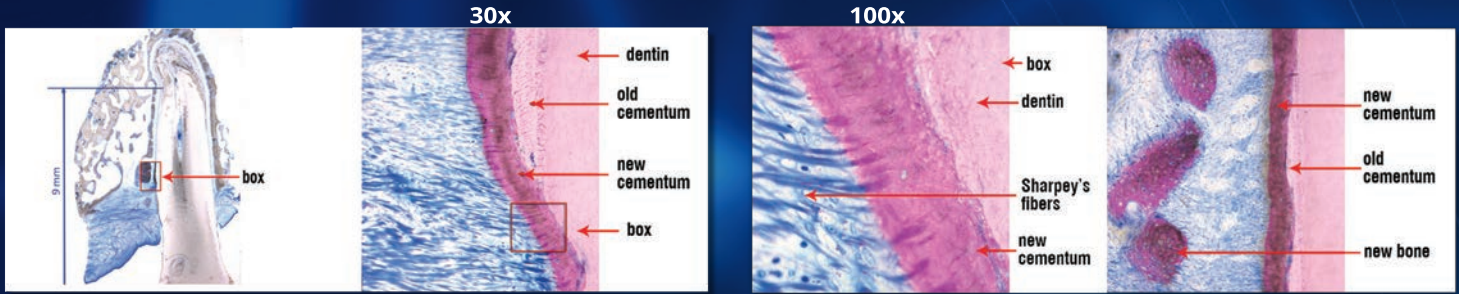
- First FDA clearance of functional tissue regeneration as a result of a protocol and device
- True Regeneration™ of periodontal tissue lost to gum disease – new alveolar bone, new cementum, new periodontal ligament
- 85% of U.S. adults have some level of periodontal disease
- 50% of U.S. adults have moderate to severe gum disease. Of this group, 40% don't know they have the disease, and only 3% accept traditional treatment.
- True Regeneration only achievable with the LANAP® protocol
- LANAP protocol = LAR (Laser Assisted Regeneration)

The LANAP=LAR procedure with the PerioLase MVP-7 achieve these results with:

- No biologics
- No growth factors
- No exogenous bone grafts
- No foreign membranes
- No scaffolding
- No stitches

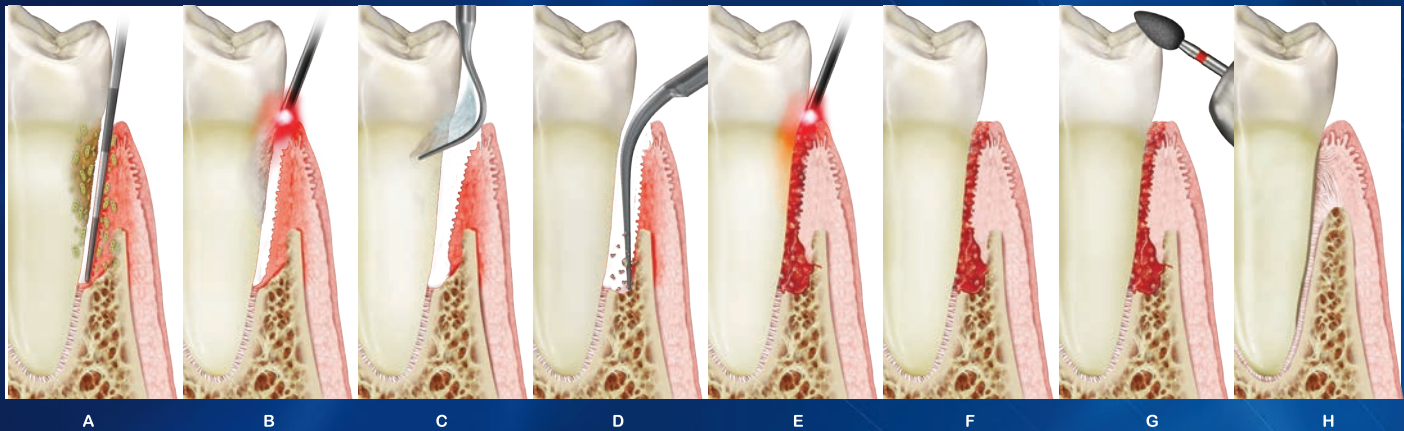
Proven with Human Histology

The LANAP protocol has been proven with two human histology studies; the presence of new bone can clearly be seen in the histological review.



LANAP Protocol Treatment Procedure

A key to the consistent positive results obtained with the LANAP protocol is the standardized protocol. Every LANAP specialist must complete 3 days of training before they are shipped a PerioLase MVP-7.



- A. Perio probe indicates excessive pocket depth and bone defects
- B. PerioLase® MVP-7™ laser energy vaporizes bacteria, diseased tissue, pathologic proteins, and alerts the practitioner to the presence of tartar
- C. Ultrasonic scaler and specialized tips are used to remove root surface tartar and calculus
- D. Bone is modified at time of surgery, Laser Tissue Regeneration (LTR™) initiated
- E. PerioLase MVP-7 is used to form a gel-clot containing stem cells from bone and soft tissue collagen
- F. Adherence of reté ridges, stem cells, RBCs to clean root surface, with a stable fibrin clot at the gingival crest to create a 'closed system'
- G. Bite trauma is adjusted
- H. True periodontal tissue regeneration occurs

Predictable Positive Results

In this instance, the occlusal adjustment impacted the patient's amalgam significantly. The choice was the patient's — destroy the crown to keep the tooth in your mouth or keep the crown and have the tooth extracted. The tooth remains, stable, in the patient's mouth.



R. H. Gregg, DDS, Cerritos, CA - General Dentist

Initial Pocket Depths:
10, 13, 15 mm

Post-Op Pocket Depths:
4, 3, 6 mm

PR Newswire, CERRITOS, CA, March 30, 2016

This world's first FDA clearance for tissue regeneration is groundbreaking in that Millennium Dental has demonstrated that **tissues lost to disease can be fully regenerated, including return to functional health.** www.TrueRegeneration.com

The pathway of tissue regeneration researched and cleared was tissues lost and destroyed as a result of infectious, inflammatory periodontal disease. This suggests there may be other pathways to tissue regeneration in the body that could now be investigated.

"Our preliminary understanding is that we are able to **stimulate and activate stem cells, in particular fibroblasts**, to form the necessary cellular components that turn into regenerated tissues. This is the first example of functional regeneration as a result of a protocol and device, where regeneration would otherwise not occur," states Robert H. Gregg II, DDS, co-founder of MDT, Inventor of the LANAP® protocol, co-developer of the PerioLase® MVP-7™. "If we can **regenerate tissues destroyed by infection** and inflammation in a cesspool of saliva and bacteria, the implications for what else could be regenerated elsewhere in the body are worth investigation."

The PerioLase® MVP-7™ received regulatory clearance using the LANAP®=LAR™ protocol for:

"Periodontal regeneration – true regeneration of the attachment apparatus (new cementum, new periodontal ligament, and new alveolar bone) on a previously diseased root surface when used specifically in the LANAP® protocol." (FDA 510(k)-151763).

True Regeneration returns function to diseased areas

Repair, for example, is not regeneration. Regeneration is return to normal architecture and functional health; repair is not. True Regeneration™ can be obtained despite the presence of periodontal disease – one of the most stubborn, persistent, and widespread infectious diseases according to the Surgeon General and the CDC 2010 NHANES report in the Journal of Dental Research on the prevalence of periodontal disease. (J Dent Res 89(11): 1208-1213, 2010).

Over 2,000 LANAP Regenerative Specialists

MDT has trained 2,000 credentialed LANAP regenerative specialists, that include general practitioners and periodontists alike. LANAP regenerative specialists are found in every U.S. state and major metropolis area, as well as Puerto Rico, the U.S. Virgin Islands, and Guam.

As Chair of the Periodontics Department of Rutgers School of Dental Medicine, I was delighted to learn Millennium has received acknowledgment from the FDA that LANAP can achieve the "Gold Standard" in periodontal therapy – true periodontal regeneration. Rutgers periodontal residents are trained in the most advanced techniques, including the LANAP protocol.



Andrew Sullivan, DDS
Chair of Periodontics
at Rutgers

THIS IS THE FIRST EXAMPLE OF FUNCTIONAL REGENERATION AS A RESULT OF A PROTOCOL AND DEVICE, WHERE REGENERATION WOULD OTHERWISE NOT OCCUR.

This new FDA indication for use **changes the meaning of 'return to periodontal health.'** No longer is return to periodontal health defined by filling holes or cutting away tissue. The FDA clearance reflects what we understood from two human histological studies – the LANAP protocol produces both periodontal tissue regeneration and function to previously diseased tissues.



Dawn M. Gregg, DDS
Director of Training for
the Institute for Advanced
Laser Dentistry

QR Codes to Online Videos

youtube.com/PerioLase4LANAP



PerioLase MVP-7™

The PerioLase MVP-7 is the only dental laser specifically designed for the LANAP protocol, optimized to target and destroy the bacteria causing gum disease for minimally-invasive, highly effective treatment.

LANAP Protocol Timeline

- 1999 ● PerioLase I (Analog, Dual-Pulse)
- 2001 ● PerioLase® MVP-7™ Introduced
- 2002 ● Ongoing Research & Development
- 2003 ● Raymond Yukna, DMD, MS, Abstract in IADR
- 2004 ● FDA Clearance Received; IADR Yukna Abstract II
- 2007 ● Yukna Histology Manuscript Published in IJPRD
- 2012 ● Lloyd Tilt, DDS, MS 12-Year Peer-Reviewed Retrospective Study Published in General Dentistry
- 2012 ● Marc Nevins Peer-Reviewed Histology Published in IJPRD
- 2013 ● LANAP Case Studies Published by I. Stephen Brown, Mangot and Braga
- 2014 ● Five-Site Multi-Centered Clinical Study Peer-Reviewed Published Manuscript; Marc Nevins 2nd Peer-Reviewed Published Manuscript in IJPRD
- 2016 ● FDA Clearance for True Regeneration™