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maXimus™  
Powered by TriLipo™

## TriLipo™ - A Novel Non Invasive Technology for Body Shaping Using the Maximus™ System

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March 2010

## Abstract

Aesthetic procedures aiming at non-invasive localized fat reduction, circumference reduction, cellulite improvement and skin tightening are desired worldwide to substitute surgical, invasive procedures. Non-invasive treatments using RF, laser, IR light, ultrasound or muscle toning procedures are common practice but do not provide the optimal solution in terms of efficacy and drainage of the internal released fat. The Maximus™ is a novel medical grade non invasive system that uses cutting edge TriLipo™ technology, for the purpose of body shaping by reducing and removing localized fat.

The TriLipo™ technology combines thermal RF effect for fat reduction and skin tightening with simultaneous active drainage. This triple action enables patients to benefit from visible, immediate and long term results using a simple "walk-in, walkout" pleasant treatment.

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## Introduction

Excess localized fat and cellulite are caused by the enlargement of hypodermal fat cells, lymphatic stagnation and the weakening and thinning of dermal connective tissue. Although significant clinical improvement may be achieved through surgical procedures, these are not without risk, and there is a growing demand for pain-free, non-invasive solutions that offer effective body shaping. The mechanism of operation involves stimulating the fat metabolism and increasing collagen regeneration in a gradual, safe, painless 'lunch time' clinical process.

Several aesthetic treatment options are currently available for non invasive fat reduction procedures. These include professional devices based on optical energy, Radio Frequency (RF) or ultrasound, devices based on vacuum, massage, or on muscles toning procedures and devices based on combination of the above mentioned technologies.

The Maximus™, powered by the TriLipo™ technology is a novel system for non-invasive body shaping developed and marketed by Pollogen® Ltd, which provides effective and fast fat reduction and collagen remodeling simultaneously.

## TriLipo™ Technology

TriLipo™ technology uses a combination of focused TriLipo™ RF energy and TriLipo™ muscle energy which are delivered into the skin in a unique simultaneous application.

The triple action of TriLipo technology consists of RF deep volumetric heating combined with internal muscle contraction and external mechanical force which together yield maximum fat removal and lymphatic drainage as well as skin tightening.

The RF energy generates heat through tissue resistance in both the dermal and subcutaneous layers. Selective and focused electro-heating of the skin stimulates and increases fat metabolism in the subcutaneous fat layer and collagen remodeling in the dermal layer.

In the subcutaneous fat layer, the thermal effect accelerates the natural fat metabolism process and the release of liquid fat from the fat cells into the extra-cellular matrix (Figure 1).

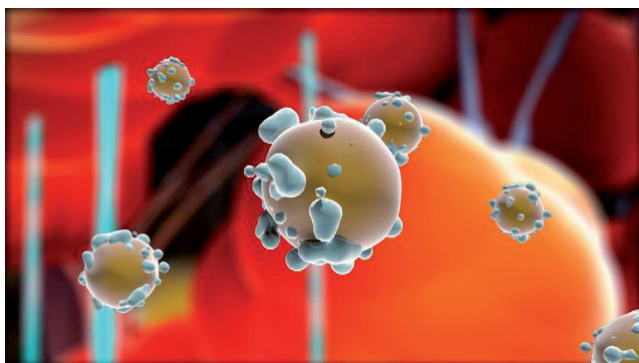


Figure 1: Liquefied fat released from fat cells

Drainage of the released liquid fat is accelerated by simultaneously applying internal and external pressure on the fat layer. Internally, TriLipo™ muscle energy pulses stimulate the muscle layer causing the muscle to contract. This contraction elevates the muscle and pushes the fat cells up towards the surface. Simultaneously, the mechanical pressure of the applicator presses the skin from above. The combined internal and external pressure increases the removal of the liquid fat via accelerated lymphatic drainage (Figure 2).

The simultaneous effect of the RF and the forced drainage results in the homogenous heating and in accelerated blood and lymph circulation that optimizes tissue oxygenation and detoxification.

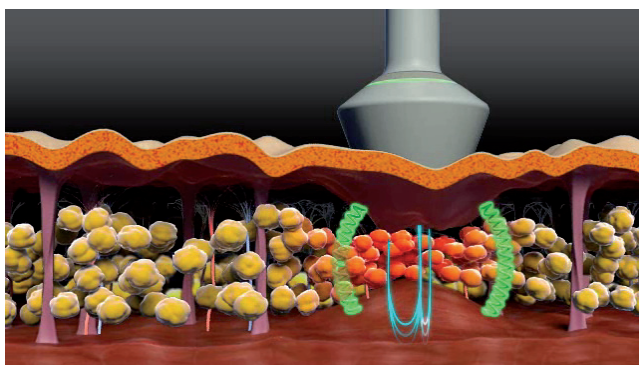


Figure 2: External and internal pressure yielding optimal drainage

In the dermal layer, focused RF energy heats the collagen fibers causing them to contract, resulting in immediate skin tightening and smoothing.

In addition, fibroblasts' metabolism is accelerated leading to collagen regeneration and long term skin tightening and firming (Figure 3).

The TriLipo™ triple action effect is visible from the first treatment. Long term body shaping is achieved in a reduced number of treatments.

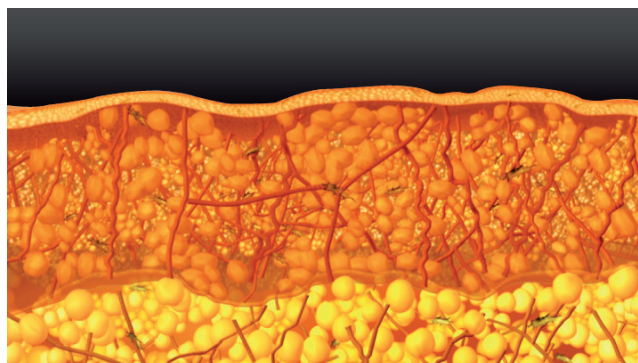


Figure 3: Collagen remodeling in the dermal layer leads to smoother skin surface

## The Maximus™ System

The Maximus™ system, powered by the TriLipo™ technology, is based on multiple electrodes that deliver TriLipo RF and TriLipo muscle energy simultaneously to the target tissues.

The TriLipo RF current is delivered at a frequency of 1 MHz and a maximum power of 50 watts to produce volumetric heating in the dermal and hypodermal layers.

The TriLipo™ Muscle Energy, uses the same multiple electrode array to deliver low frequency pulsed currents (LPC) to the underlying skin muscles.

The system uses biphasic mode with current regulation and is designed to limit combinations of current, pulse duration and frequency.

Sophisticated algorithms control the TriLipo™ energy output, providing maximum safety and efficacy.

The system consists of a main unit, three applicators, a foot switch and a bio-feedback control. The three applicators, ergonomically designed, differ in size and configuration to optimally accommodate treatment of different body and facial areas. Applicator No. 1 is indicated for the treatment of large body areas. Applicator No. 2 is indicated for the treatment of medium sized body areas and for facial areas. Applicator No. 3 is indicated for the treatment of very small and delicate facial areas.

The safety of the Maximus™ TriLipo™ system is maximized by a few unique technical features and clinical protocols: Multiple electrode modulation prohibits extended electrode heating and tissue over-heating at the electrode-tissue contact points; patented software limits the power density of the delivered energies; patient biofeedback control of pain sensation automatically terminates energy delivery; non-contact skin temperature monitoring during the treatment and a treatment protocol composed of multiple pass and multiple session routine.

The Maximus™ system is indicated for use in dermatologic procedures for non-invasive body shaping procedures, maximized by TriLipo™ technology.



Figure 4: The Maximus™ system

## Clinical Overview

Different treatment programs are available according to the treatment areas. For body areas such as the abdomen, thighs and buttocks, a program combining the TriLipo™ RF and TriLipo™ muscle energies is recommended. For the face, a stepwise program starting with TriLipo RF and followed by muscle activation at the cheeks area is suggested for optimal facial contouring results.

Default parameters are pre-programmed to facilitate treatment initiation. The parameters should be further adjusted by the operator from the user interface on the Main Unit according to patient reaction and skin tolerance. No active cooling of the electrodes or the skin is required.

Contraindications include pregnancy, any implantable electronic device, any active dermatological or vascular disorders and areas of sensory impairment such as in cases of nerve lesions and neuropathies.

Initial clinical evaluation of the new technology demonstrated safety and high efficacy in reducing localized fat deposits, circumference reduction and skin tightening.

Significant results were visible immediately after the first treatment. Long term clinical results are improved after a few treatments. Typically 4 treatments are suggested for long term results, according to individual patient condition. Clinical results are demonstrated in figures 5-8.

## Summary

The increasing demand for non invasive body shaping treatments that safely and effectively deliver measureable results has led to the development of combination treatment protocols. Combination modalities such as RF and ultrasound or other technologies, requires alternating use between several devices or different applicators. These combination treatments are successful since results are improved by the combination effect and sometimes the synergetic effect. However, the downside is the need for few devices and a complicated treatment protocol.

The TriLipo™ technology provides a unique alternative for the treatment of localized fat deposits and skin tightening by simultaneously applying two types of energies via the same applicator.

Maximus™, powered by TriLipo™ technology, is a safe and effective system for the treatment of excess localized fat and for non-invasive body shaping. The clinical effect of the RF component, designed to produce volumetric heating of the skin for fat reduction and skin tightening, is enhanced by the lymphatic drainage mechanism that accelerates the removal of the released fat from the treatment area. The combined effect maximizes circulation and drainage and results in optimal body contouring.

Treatments are suitable for body and facial areas, in patients of all skin types. Following a treatment session patients may benefit from measurable and visible results.



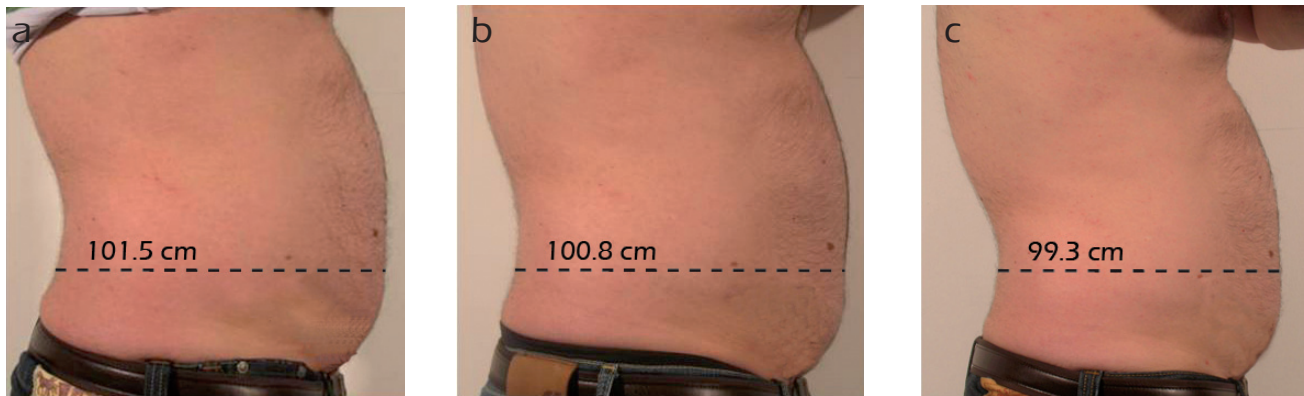


Figure 5: Male abdomen post 1 and 3 treatments: a- before, b- post 1 treatment, 0.7 cm circumference reduction, c- post 3 treatments, total reduction of 2.2 cm.

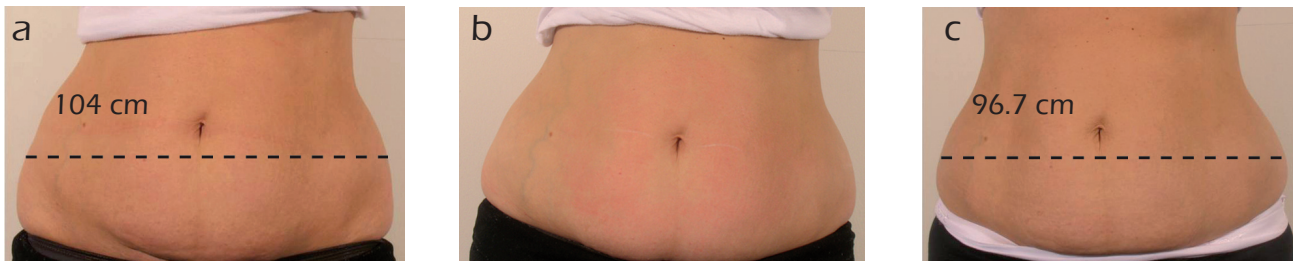


Figure 6: Female 7 months post pregnancy. a- before, b- immediately after 1 treatment - skin redness and tightening is noticeable, c- after 3 treatments, reduction of 7.3 cm.



Figure 7: Facial treatment, 51 year old patient. a – before, b -immediately after 1 treatment, c- after two treatments. Tightening effect on cheek area is visible.

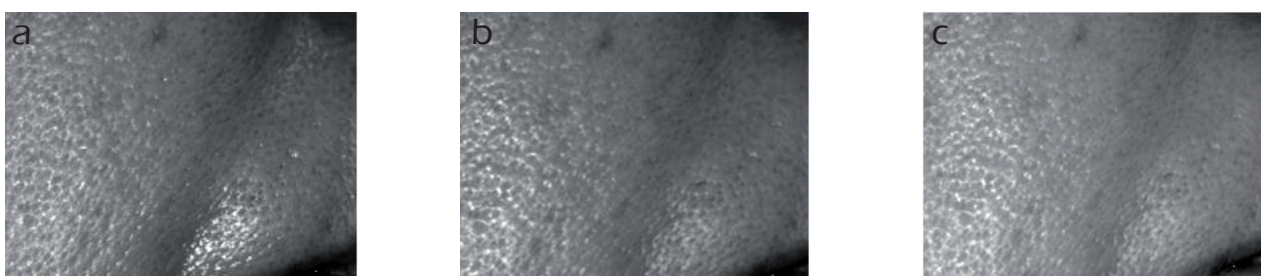


Figure 8: Primos 3D analysis of facial results.  
A - Nasolabial fold before treatment, b - Nasolabial fold immediately after 1 treatment, c: fold after 2 treatments