IA
INNATE ABILITY

onda

CLINICAL USER'S MANUAL

May 2019

DEKA
Innate Ability

Disclaimer

The present material is merely illustrative. The policy described is not of a suggestive nature, it is not intended to be exclusive and/or the best for the treatment of this case and it is not intended to substitute or influence in any way the diligence, prudence and expertise of the operator.

Although the present material is updated until the editing date and is considered reliable, the writer is not responsible for errors, omissions, imprecision, lack of completeness, punctuation errors or for the information herein contained.

The present document may contain technical imprecision and typographical errors or omissions.

Except for the rules bound by low, the writer specifically:

a) decline any responsibility for accident, damage or prejudicial consequence of any type and/or nature which could derive from the use of any device, system or technology described in the present material;

d) does not assume any responsibility for consequence deriving from the action, omission and/or errors of users/operators or for any loss or damage suffered or caused as a consequence of the use of the information published in one of these pages;

c) is not responsible for any damage, claim, request or legal action, whether direct or indirect, specific, incidental, consequential or punitive, resulting from the use of this document and/or the information herein contained.

The information contained in the present document:

a) is not intended to be a deal or proposal, nor does it constitute any contractual obligation towards those who read or use these pages;

b) can, at the exclusive and indisputable discretion of the writer, be deleted, modified and/or updated at any moment without notice.

All the information contained in this document is property of DEKA M.E.L.A. s.r.l.

1
Introduction:
Skin Imperfections Overview

Over the latest 30 years there has been a major increase in the demand for non-invasive methods for use in the medical and aesthetics sectors, to treat skin imperfections in general and in particular, and above all, to treat ***localized adiposity, cellulite*** treatment and ***skin laxity***.

1.1 Adipocyte Cells and Localised Adiposity

Plastic surgeons differentiate localized fat deposits from generalized fat deposits which are seen in obesity. Localised fat deposits, with their typical "trochanter cushion" or "saddle bag" appearance, consists of an increased accumulation of fat in the regions where fat deposits are physiologically present. Typical localized fat deposits are in the sides of the hips, buttocks, thighs and medial face of the knee in female, and the love handles in male. They tend to be stubborn to exercise and diet regimens. For women they can be considered as a secondary sexual characteristic since influenced by the female sex hormones. The adipocytes in these areas are in fact very rich in oestrogen receptors, hormones which exert an action that favours the accumulation of fat inside these cells. This "hormone-dependency" may therefore explain the scarce effectiveness that nutritional diets have in these areas.

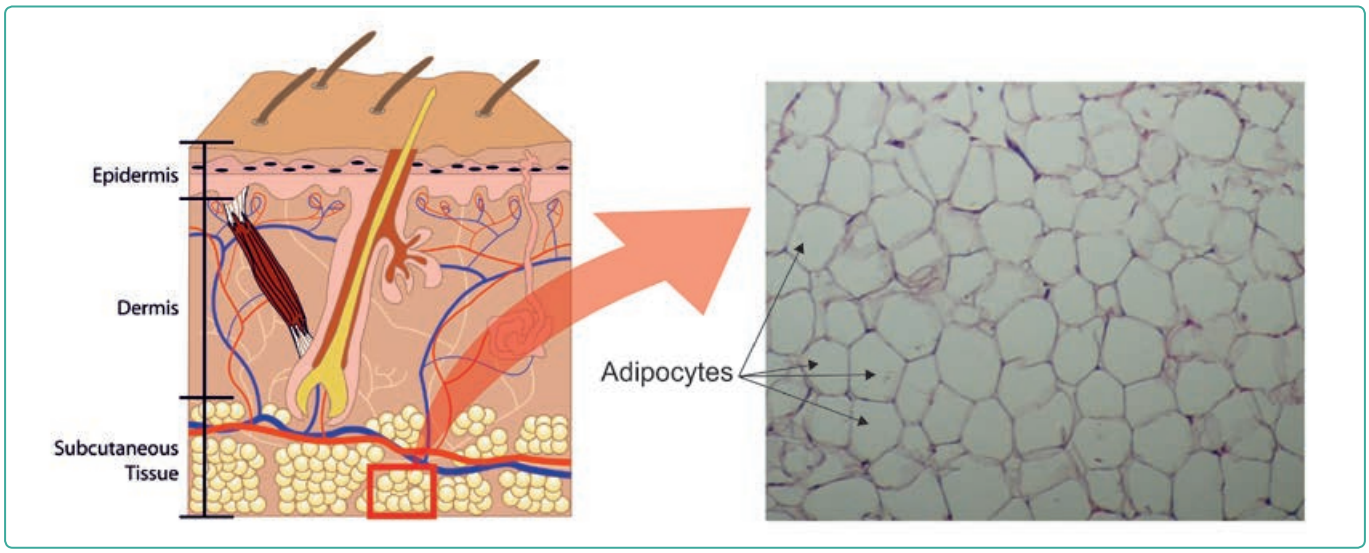


Figure 1. Structure of adipose tissue deep to the skin (subcutaneous fat tissue).

Localized fat deposits are created by an increase in the volume of the adipocytes (hypertrophy) as a consequence of increased fat deposits. On palpation, the area in question is compact but not painful. Frequently however, localized fatty tissue might coexists with cellulite (Oedematous Fibrosclerotic Panniculopathy) in the same area.

1.1.1 Android Morphotype

This is characterised by a distribution of subcutaneous fatty tissue, prevalent in the upper half of the body i.e. chest, lower cervical region, tricipital region, and abdomen.

Although typically masculine, this conformation, commonly defined "apple-shaped", may olso be found in the female sex and is quite frequent in women in menopause.

1.1.2 Gynoid Morphotype

This type usually has a more accentuated bone structure in the hip area than the shoulders (bitrochanteric greater than the bihumeral diameter) with subcutaneous fatty tissue distribution mainly in the lower half of the body, abdomen below the transverse umbilical line, trochanteric area, buttocks and lower third and medial areas of the thighs immediately above the knees. This morphological constitution, commonly defined "Pear-shaped", is typically feminine and is influenced by the female sexual hormones.

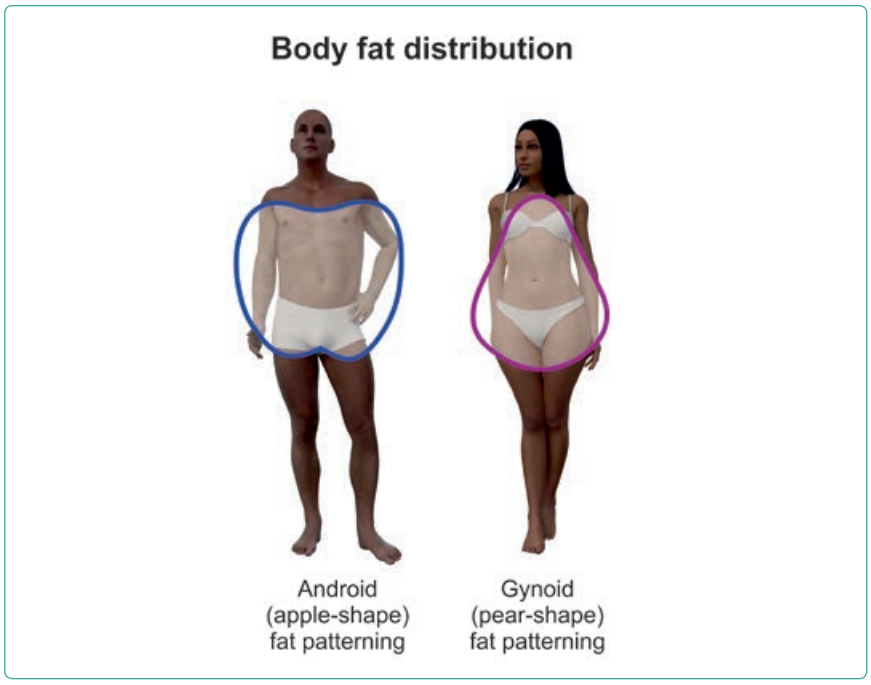


Figure 2. Android-shape vs. gynoid-shape morphotypes.

1.2 Cellulite (or Oedematous Fibrosclerotic Panniculopathy)

Cellulite, also known by the more correct term "Oedematous Fibrosclerotic Panniculopathy", identifies aesthetic changes in the subcutaneous adipose panniculum. It is prevalently, although not exclusively, found in gynoid subjects and located electively in the trochanter and supero-lateral areas of the thighs, inner parts of the knees and buttocks. Usually it is highlighted only when the skin is forcibly forced, otherwise it has a smooth appearance when relaxed.

Cellulite is caused by the alteration of the venous and lymphatic system that slows down the flow of blood causing water retention in between the fat cells that start modifying their conditions relating to dimension and composition. It is a sign of the derma-hypodermic structures chronic degenerative process.

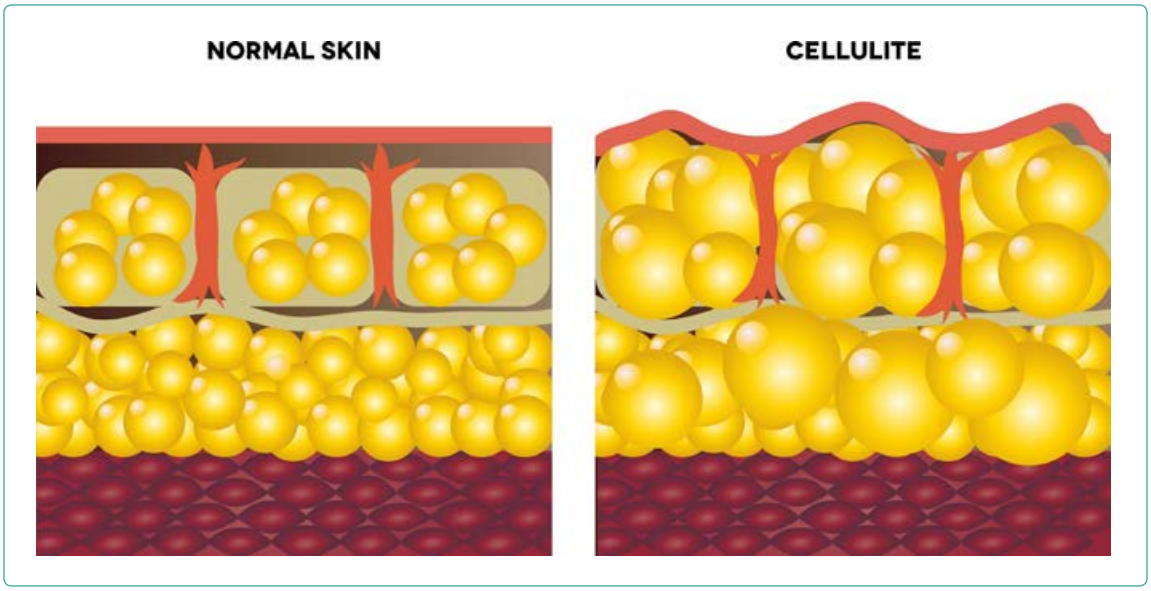


Figure 3. Schematic representation of healthy skin vs. skin with cellulite.

In details, the hematic stasis makes the adipocyte cells to suffer and increase their volume (oedema), it leads to a degeneration of the fundamental interstitial substances and collagen fibres with fragmentation of the elastic fibres, increase in the number (hyperplasia) and thickness (hypertrophy) of the reticular fibres, finally resulting in sclerosis.

Briefly cellulite is considered a "multi-factorial disease" involving genetic, constitutional, hormonal and vascular causes, often aggravate by concomitant causes such as bad eating and lifestyle habits, stress, tight clothing and high-heel shoes, intestinal disorders, hepatic disease and posture disorders.

If Cellulite it is left untreated, the process gradually and inexorably develops into the following phases:

- **Stage I – Oedema:** reversible, characterised by venous-lymphatic stasis, hypo-oxygenation and insufficient drainage of the interstitial fluids. This is followed by an expansion in the extracellular volume, hypertrophy of the adipocytes due to the accumulation of triglycerides, degeneration of the collagen and elastic fibres, and tissue distress due to a compromise of the metabolic exchanges, with an accumulation of catabolytes and free radicals. The skin becomes spongy and less elastic. Stage I cellulite, usually occurs at the ankles, calves, thighs and arms and is caused by an accumulation of fluid (edema) within the adipose tissue.

- **Stage II –Initial Fibrosis:** normally the fat cells are wrapped in a net of very fine reticular fibres. The persistence of conditions characterising Stage I gives rise to a breaking away of these fibres which react by increasing in number and thickness, while degeneration of the collagen and elastic fibres continues; at this point fibrosis starts developing. This progression leads to subversion of the normal lobular structure of the subcutaneous fatty tissue, accompanied by massive stasis. The skin becomes pallid, spongier, hypothermic, and hypoplastic, and paresthesia begin to manifest with the typical "orange peel" appearance.
- **Stage III – Fibrosclerosis and Micronodules:** stasis becomes accentuated and the entire skin structure breaks down. The collagen and reticular fibres degenerate and tend to create a fibrous, compact weft which encapsulates the fat cells and forms true micronodules. The progression towards sclerosis generates further compromise and distress of the tissues. The skin features described above are accentuated and pain is felt with palpation. In this type of cellulite there is a greater production of connective-fibrous tissue, and the adipose tissue is harder, with possible formation of small nodules.
- **Stage IV – Sclerosis and Macronodules:** the fusing together of several micronodules, leading to the appearance of large macronodules that are painful to the touch. The macronodules can also fuse together. At this stage, which is irreversible, the following events also manifest: the disappearance of typical lobulation of the fatty tissue, diffused liposclerosis, significant alterations of the microcirculation that becomes extensively ecstatic, phenomena of epidermal atrophy, zonal sclerosis of the derma with dermal introflexions. The skin takes on a typical "mattress" physiognomy. Skin streaks appear and there is pain, both spontaneous and with palpation. In this case the nodules that are created are larger and the adipose tissue becomes even harder.

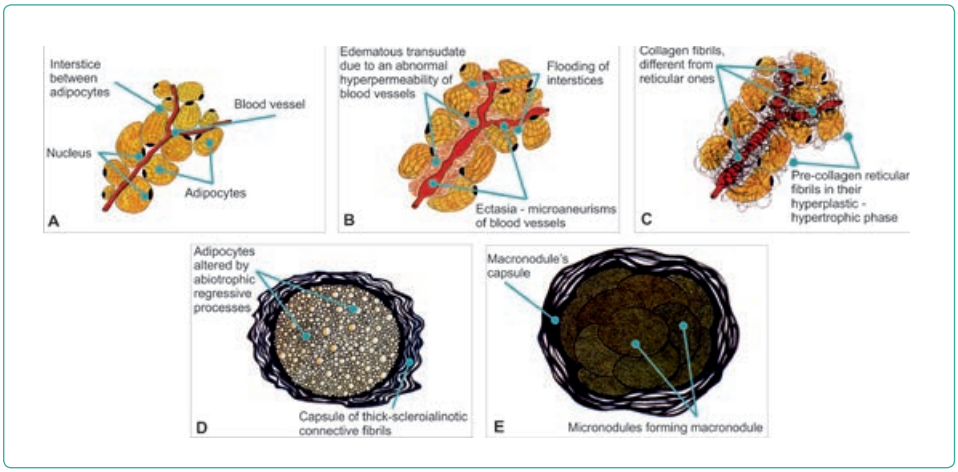


Figure 4. (A): Healthy fat tissue. (B) – (C) - (D): The 4 different stages of cellulite.

When this condition is associated with predisposing factors and persists over time, a chronic disorder occurs characterized by:

- venous-lymphatic stasis and fluid retention with expansion of the extracellular compartment (oedema);
- degeneration of the fundamental interstitial substance, breaking down and deterioration of the collagen and elastic fibres, hyperplasia and hypertrophy of the reticular fibres;
- hypertrophy of the fatty cells due to the accumulation of triglycerides and formation of characteristic hypertrophic lobules;
- skin with an "orange-peel" or "mattress" appearance.

Often during the initial stages, the cellulite, which already appears to be associated with a venouslymphatic insufficiency as well, besides aggravating the oedematous component typical of cellulite, is also associated with varying degrees of painful symptoms in the lower limbs.

1.2.1 Types of cellulite

Hard to the touch, Compact Cellulite can be either painful and it can cause stretch marks on the skin. It especially affects people in good physical shape with a toned musculature. It is the most common type of cellulite, but also the easiest to treat. It occurs more frequently on the knees, thighs and buttocks.

Soft cellulite

This type of cellulite presents sclerotic nodules, and often it occurs within the thighs and arms in people of mature age, who perform either little physical activity or who have sudden increases or decreases in weight.

Edematous cellulite

It is sign of a very advanced stage of cellulite evolution and it appears as swollen and spongy.

This type of cellulite is painful to the touch, it occurs especially on women's lower limbs (feet and ankles) and it is associated with both stagnation of fluids and venous insufficiency (venous and lymphatic circulation problems), which occurs mainly in the buttocks and the pelvis.

1.3 Skin Laxity

The skin laxity consists of the relaxation of the dermal-epidermal tissues and subcutaneous layer as a consequence of:

1. Underlying muscular mass hypotrophy: surface tissues lack their normal support;
2. Dermal elasto-collagenic components reduction;
3. Supporting fatty tissue reduction.

Condition 1) is typical of thighs and arms and it is generally due to scarce physical activity and dietary imbalances.

Conditions 2) and 3) may be related to factors like aging, photo-aging, diet imbalances and they involve all body areas including the face.

2
Technical Features and Principle of Action

Onda	
Source	Microwaves - Coolwaves®
Frequency	2.45 GHz
Power	200 W
Smart Handpieces (Patent Pending)	Deep: Ø 6.6 cm – 35 cm^2 Shallow: Ø 5.6 cm - 25 cm^2 LED system control to provide an intuitive guide to the operator during the procedure
Handpiece Cooling	Integrated Skin Cooler
Emission Control	Fingerswitch
Graphical User Interface	10,4" Colour Display Touch Screen
Data Base	Integrated tutorial with treatment protocol
Dimentions	397 (W) mm x 1104 (H) mm x 692 (D) mm
Weight	< 60 Kg
Electrical Requirements	100-240 Vac; 50-60 Hz; 1500 VA

Figure 5. Onda System.

Onda utilizes special microwaves (called **Coolwaves®**) to provide localized adiposity, cellulite treatment and skin laxity treatments all in one device, all over the body (excluding the face, neck and terminal part of the limbs).

Differently from existing technologies, **Onda** focalizes its action on the subdermal fat by means of **Coolwaves®** delivered to the subdermal layers from two specially designed handpieces able to drive all the energy right to the selected target (Patent Pending Delivery mode).

The synergy in between the two patent pending handpieces allows for:

- Regression of the cellulite;
- Reduction of localised fat deposits;
- Toned, elastic skin with a reduction in flabbiness;
- Harmonious remodelling of the body contours.

Since the first session in a virtually painless way.

2.1 Onda Handpieces Description and Features

The Patent pending design allows limiting any possible electromagnetic field dispersion. The continuous cooling incorporate in the contact-handpieces, make it possible to preserve the more superficial layers of the skin from unwanted overheating.

Onda system consists of the following handpieces:

- Shallow handpiece → For skin tightening and superficial cellulite
- Deep handpiece → For targeting fat and deep cellulite.

2.1.1 Shallow Handpiece

The shallow handpiece induces a most concentrate and superficial heating that produces a controlled hyperthermia aimed to solubilising the fibrous collagen and inducing the shrinkage of most superficial collagen fibres in order to get both tightening and remodelling effect on the superficial connective tissue.

Features

- 5.6 cm large
- LED indicators:

  Green = optimal coupling

  Yellow = less 70% of coupling

  Red = no coupling (microwaves retired in the handpiece and the system provide to stopping the erogation in 10 seconds)
- 0.7 cm deep focalisation of the heating
- integrated cooling (till 5°C)
- Recommended for skin tightening & superficial cellulite

Figure 6. Shallow Handpiece.

2.1.2 Deep Handpiece

The deep handpiece induce a largest and deep heating that produces a controlled hyperthermia which causes a molecular oscillation on the adipocytes and solubilising the deeper collagen fibres to induce the lipolysis of the fat cells and the remodelling of the collagen fibres by the fibroblasts activation.

Features

- 6.6 cm large
- LED indicators:

  Green = optimal coupling

  Yellow = less 70% of coupling

  Red = no coupling (microwaves retired in the handpiece and the system provide to stopping the erogation in 10 seconds)
- 1.2 cm deep focalisation of the heating
- Integrated cooling (till 5°C)
- Recommended for localised fat & deep cellulite

Figure 7. Deep Handpiece.

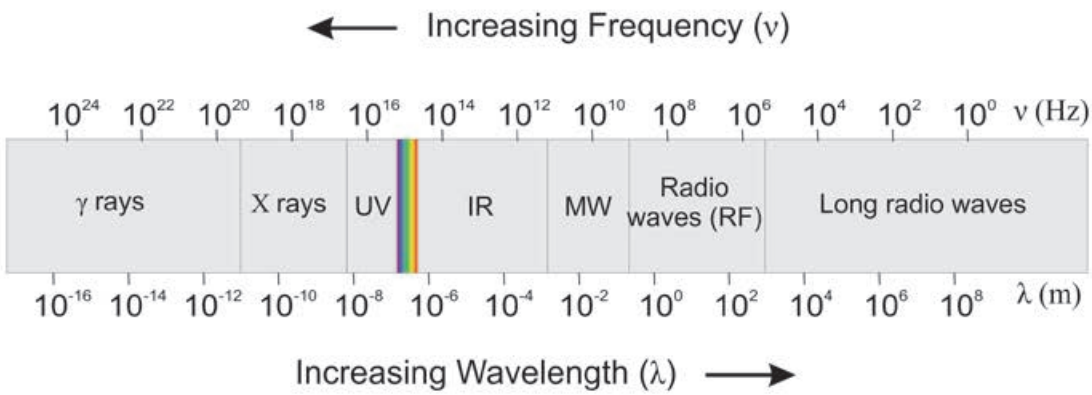
2.2 Coolwaves®: the Foremost in Microwave Technology

Microwave technology is very popular in the modern society and it is not a new comer in medical applications either. It has been widely used in many branches of medicine up to now including Oncology. It has been proven to be highly safe for use on humans too. The selective microwave frequency **Onda** works at, is 2.45GHz. Such a frequency it has been discovery to make skin tissue to be almost "transparent" to the passage of the energy so to make it free to work almost totally over the subdermal fat layer specifically. This makes the superficial layers of the dermis to be preserved from unwanted heating and to stay cool. For this reason the microvawes **Onda** works with, are now denominated **Coolwaves®**.

2.2.1 Coolwaves® Rationale

The reason why **Coolwaves®** target fat cells in a safe, effective and non-invasive way depends on the frequency **Coolwaves®** works at.

In fact microwaves, radiofrequencies, lasers owns their own frequencies as per the following scheme:



- **Radiofrequencies range from 30 kHz to 1 GHz, i.e. between 10^4 and 10^9 Hz**
- **Microwaves range from 1 GHz to 100 GHz, i.e. between 10^9 and 10^{11} Hz**
- **Lasers range from 10^{11} Hz and 10^{15} Hz**

Figure 8. The Electromagnetic Spectrum.

In simple terms, skin behaves differently when submitted to different frequencies (technically: dielectric behaviour). For instance, the skin is either more available to let some energy with certain frequencies to pass through it or it is less available to let the same energy, with a different frequency, to pass through it again. In other words, frequency discriminates the passage properties.

Technically speaking, "Skin Conductivity" is a physic characteristic that identifies the property of a biological tissue to transfer the energy received from an outer source (microwave handpiece) to surroundings tissues.

Conductivity is a function of the applied frequency of energy. Simply speaking skin offers more resistance to low frequency energies (less conductivity) instead skin offers less resistance (more conductivity) to higher frequency energies.

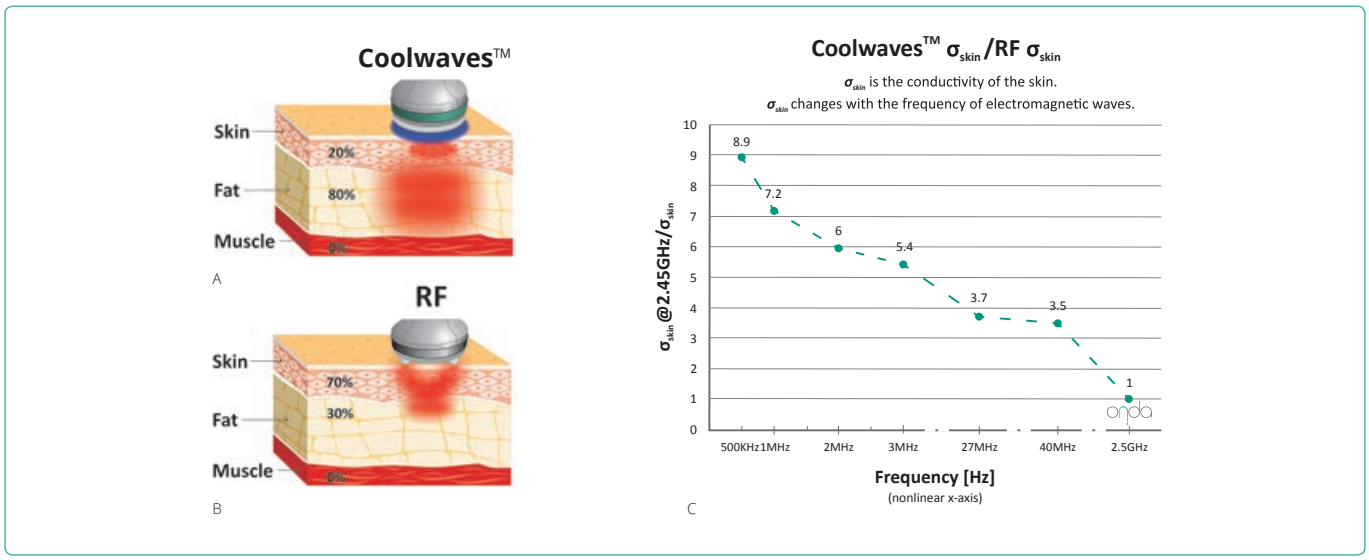


Figure 9. (A): Onda smart handpieces (patent pending) are designed so that only 20% of the energy goes to the dermis, and this is in any case counterbalanced by the integrated cooling system that annuls the effects of such heat on the epidermis. The remaining 80% of the energy penetrates into the fat, acting effectively on the lipocytes. (B): the situation is quite different with RF handpieces. For Coolwaves®, the conductivity of the outermost layers of skin is at least 3.5 times higher than that of the commonly-used RF irradiation systems in aesthetic medicine (Graph C). That means that most of the RF energy gets stuck in the epidermis and dermis, heating them up to such an extent that there is a risk of tissue damage. Moreover, as the RF energy remains close to the surface, it fails to reach the hypodermis where the fat cells are located, and whose membranes must be broken in order for the treatment to be effective.

In summary, lower frequency means more skin resistance, more skin resistance corresponds to more energy absorption and more energy absorption means to generated heating in the site of absorption.

That's why **Coolwaves®** (2.45GHz = very high frequency = microwaves) pass through the skin without generating substantial heating and they can target directly the subdermal fat tissue.

In numbers:

- 80% **Coolwaves®** energy targeting the **fat cells**
- 20% Energy absorbed by the epidermal and dermal layers

2.2.2 Metabolic Effect on Adipocyte Cells

Coolwaves® targeted action on adipose tissue, it produces the following effects:

1. Remodeling of the connective tissue matrix with consequent modification of the microenvironment that regulates the Adypocites metabolism. The homeostatic balance between the adipocytes and the connective interstitium that defines the vital conditions of the adipose tissue is therefore altered.
2. Adypocite metabolic changes by induced thermal stress. Adypocites are therefore stimulated to release a quantity of lipids much higher than their physiological capacity in the outer environment.

Action on the fat:

Coolwaves™ intense stimulation, put adipocytes under a strong stress condition so to induces metabolic changes. These modifications lead the adipocytes to release part of their lipid content outside, in the cellular interstitium, through a mechanism called "blebbing": the droplets of fat reach the plasma membrane where they are surrounded by evaginations of the membrane which give the cell a bubble-like appearance. The bubbles once detached from the adipocyte, bring the lipid content to the outer interstitial connective tissue. This mechanism is so intense that it initiates a process of lysis of fat cells with adipocyte membrane rupture. The large amount of droplets of fat that are poured into the interstitial connective, stimulates the recall of the macrophages from the blood that have the task of "cleaning" the cellular interstitium from the excess of fatty acids, engulf the excess free fat. When the condition of normality is restored, the macrophages migrate into the lymphatic system.

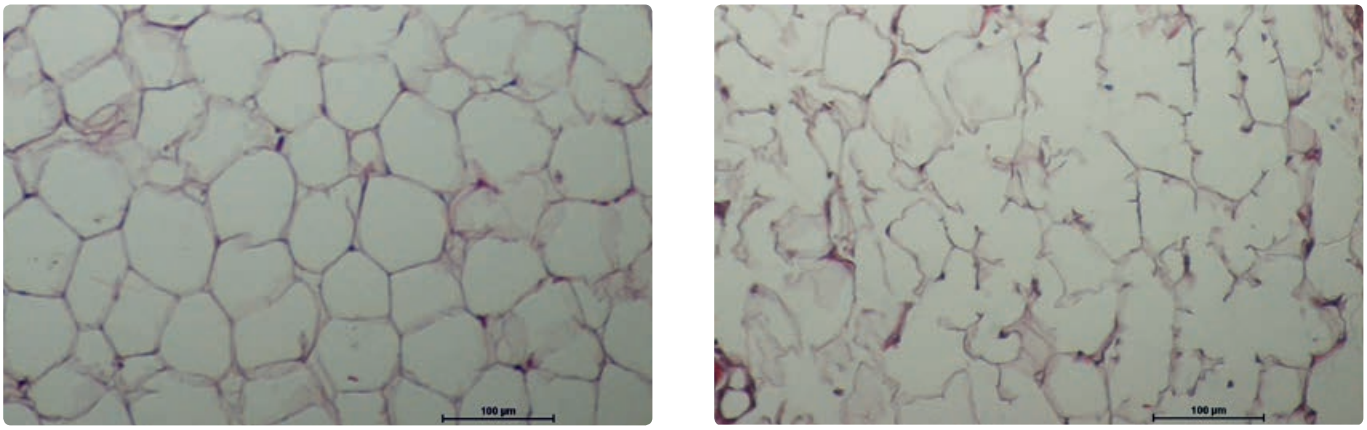


Figure 10. Histological images of tissue with human abdominal fat (magnification x20). (A): Control. (B): Sample from the same patient immediately after treatment with Onda Coolwaves®. Image (B) clearly shows the ruptured lipocytes and initial hyperaemia with dilatation of the blood vessels. *Courtesy of Prof. R. Perrotta, M.D. and M.S. Tarico, M.D., Catania - Italy.*

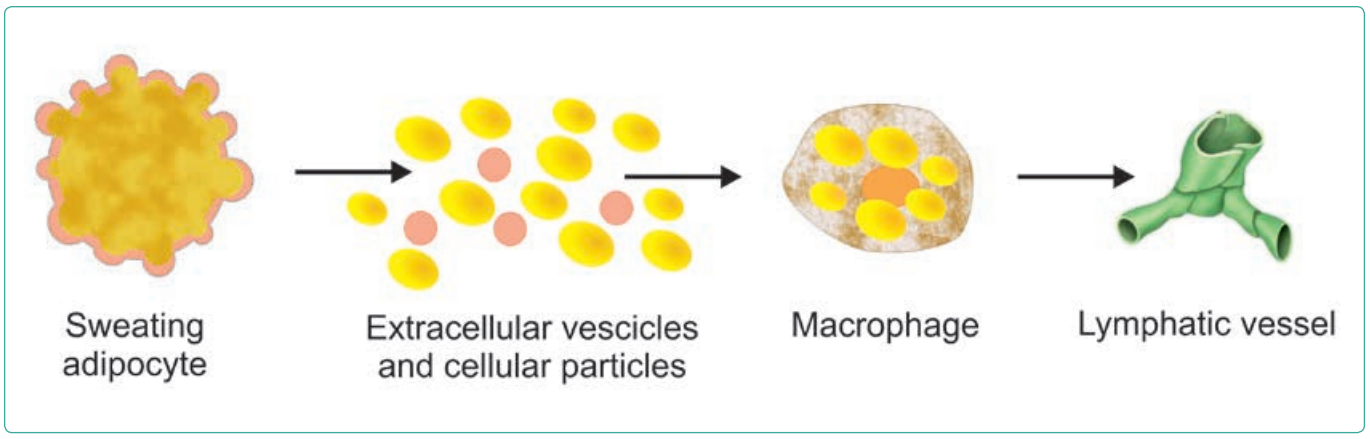


Figure 11. Scheme of the lysis of an adipocyte that is digested by a macrophage, which transports the fat into the lymphatic system to be metabolized.

Action on the cellulite:

The typical "orange peel" texture of cellulite is determined by the consistent presence of large fibrous collagen septae that lead to a constriction of the natural lobulation of adipose tissue, as well as adipocyte hypertrophy and water retention. The energy of the **Coolwaves®**, absorbed by fibrous connective branches, causes the solubilization of the collagen to take place, with consequent debridement of the tight non-elastic weft that strangled the lobules. The solubilization of collagen, in addition to producing the loss of the pitted appearance of the skin, also makes it possible to reactivate the fibroblasts which are stimulated to produce new, more elastic collagen.

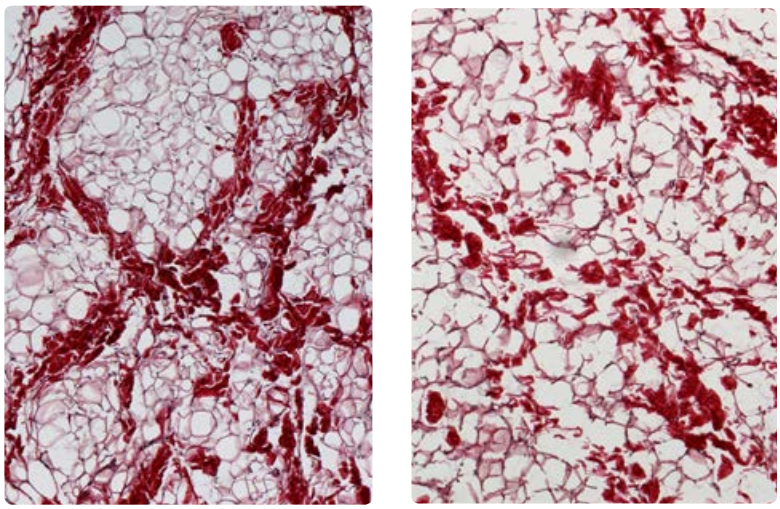


Figure 12. Picrosirius Red staining image, magnification10X, before (on the left) and after (on the right) treatment with the Coolwaves®. In the pre-treatment image is visible the organized structure of the collagen fibers while in the post-treatment picture is possible to observe the collagen fibers solubilization.

Action on the Skin Laxity

The heat produced by the **Coolwaves®** in the dermis it causes either an immediate collagen shrinking and a consequent tightening.

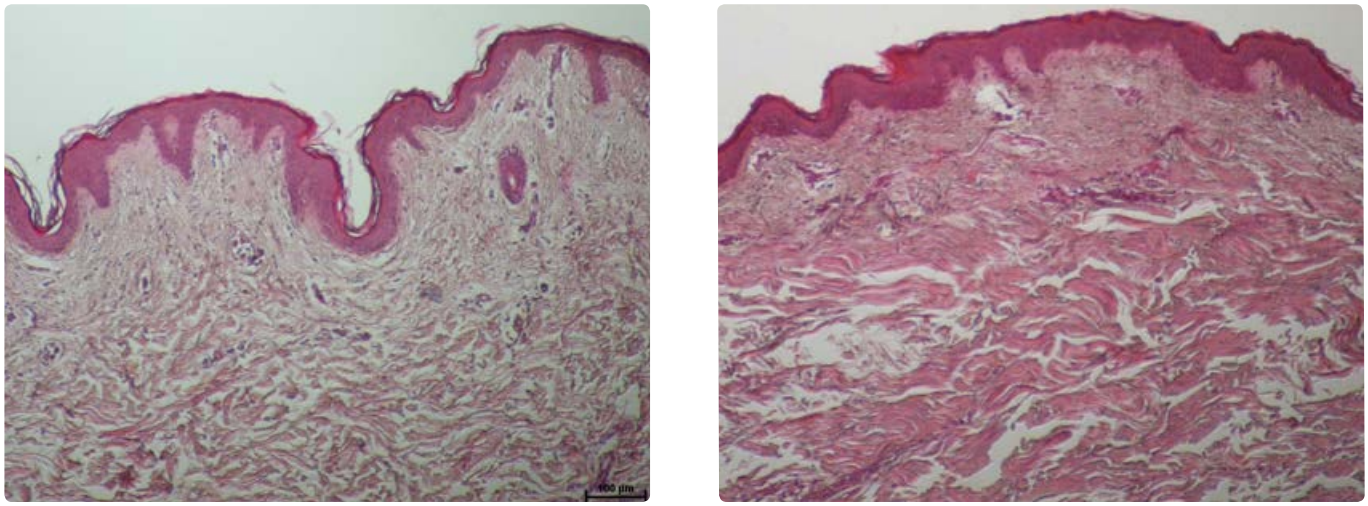


Figure 13. H&E histological image before (on the left) and after (on the right) treatment with Onda. In the post picture, collagen in the dermis appears pinker (eosinophilus) indicating its greater concentration. The heat causes in fact the shrinking and tightening of collagen that aggregates leaving free white spaces, clearly visible in an H&E image.

2.2.3 Safe and Controlled Delivery to the Fat Layer

As describide in the paragraph 2.2.1, **Coolwaves®** are preferentially absorbed by fat molecules rather than the skin molecules in which they do not create substantial heating.

For further safety and improved patient comfort, the handpieces are equipped with an integrated cooling system that acts as a barrier between the **Coolwaves®** delivery source and the skin. This creates a thermal cushion which protects the epidermis and the dermis, allowing the action to be concentrated deep down in the skin on the targeted fat. **Coolwaves®** therefore do not risk causing hot spots on the skin, unlike the electrodes used in radiofrequency systems.

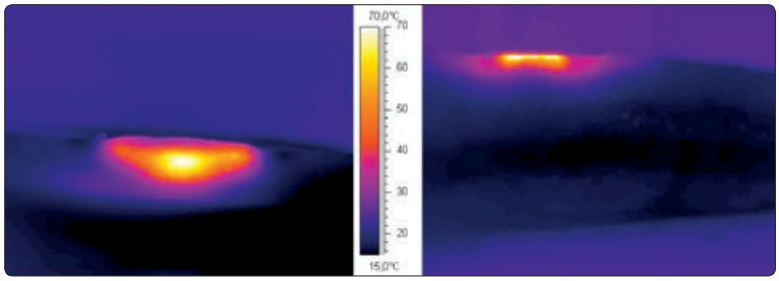


Figure 14. (A) Thermographic image of ex-vivo tissue, seen in section, treated with an Onda handpiece. A "hot zone" can clearly be seen just below the top layers of the skin, which stay cold and are therefore displayed in blue. The image next to it (B) corresponds to a similar ex-vivo tissue treated with bipolar radiofrequency. The tip effect where the electrodes and the skin come into contact clearly creates a strong rise in temperature on the surface, while deeper the tissue remains cold, which proves that it is not possible to reach the correct treatment temperatures in the subcutaneous fat.

3
Clinical Procedure

3.1 General Guidelines

This manual provides information on how to use the system but it cannot replace the physician's clinical judgement. General rule is to preserve the skin. The treatment should not have a strong effect on the skin. The higher levels of power and energy must be selected with extreme caution in order to prevent damage to the skin.

The user must keep note and be familiar with each type of treatment before proceeding with setting the parameters.

The information contained in this manual has to be considered as a suggested use of the device. It cannot be considered an exhaustive and comprehensive guide for the use of **Onda** device and cannot in anyway substitute for operator experience and observation.

DEKA recommends that all qualified personnel who operate the system first seek training that includes, but is not limited to, the following aspects:

Training for this device is provided by DEKA M.E.L.A srl or people authorized by DEKA M.E.L.A srl.

NOTE: For more detailed indications about "how to use the system" and "safety recommendations" please refer to the Onda Operator's Manual received with the system.

3.1.1 Indications for use

The **Onda** system is a medical device intended for deep heating of the adipose tissue tor the treatment of lipodystrophy, edematous fibrosclerotic panniculopathy and for body contouring in dermatological, plastic surgery and aesthetic medicine environments.

NOTE: This device can only be used by users/operators having gained specific expertise in all such disciplines and medical applications the device is intended and used for. In addition an adequate training and experience in the type of treatment to be carried out.

The user/operator must also ensure, under his/her own responsibility, that he/she fulfils the requirements and qualifications required by laws and current local regulations enabling to operate the device according to its specific indications for use.

3.2 Patient Examination

First and foremost, it is important for the professional to carry out an examination and an anamnesis of the patient in order to determine the most appropriate protocol.

The main information to take into account for drawing up the most suitable treatment plan includes:

- Patient's anamnesis
- Patient's inspection
- Patient's motivations and expectations

The patient must be suitably informed about the treatment procedure, the results that he can expect according to his individual characteristic, the probable number of sessions necessary for achieving the desired results, the steps to follow before and after each treatment session and any possible side effects.

3.2.1 Anamnesis

Anamnesis makes it possible to discover any illnesses, risk factors and possible causes in the patient's history that could be responsible for the onset of localized adiposities problems, cellulite, fluid retention, obesity, etc. (for example: hormonal imbalances, metabolic alterations, life style, use and abuse of alcohol, smoking etc.)

3.2.2 Inspection

This consists of a careful examination of the subject's general physical condition:

- morphotype (gynoid or android)
- overweight or obesity
- signs of venous insufficiency in the lower limbs
- identification of any asymmetries between the body segments

At this stage, a general analysis of the physical state of the patient is carried out to identify the areas to be treated and to evaluate, for each of the areas, the type and condition of the imperfection / pathology (localized adiposity, cellulitis, skin laxity). Once verified this, the suitability for treatment with **Onda** and the most appropriate protocol will be defined.

It is important to carry out a careful objective examination of the whole area to be treated in order to determine either a qualitative and quantitative evaluation of the tissue. Information regarding skin hydration, the possible presence of edema, muscle tone and any abnormalities or lesions must be acquired and carefully evaluated too. Perform a preventive ultrasound examinations before starting the treatment in order to identify any possible presence of lipomas, nodules, pre-existing fibrotic tissue or any other possible anomaly.

It is also recommended to proceed with blood tests (or other instrumental examinations depending on the case) before proceeding with the **Onda** treatment, so as to be able to exclude any injuries and diseases that could be contemplated onto the treatment contraindications list.

In case of pain detected during preliminary palpation screening (often associated with the more advanced stages of cellulitis) the cause must be both identified with certainty and evaluated.

Recommendation: In case of localized fat treatment, make sure to identify areas with skinfold thicker than 2 cm (the sub-dermal fat layer must be at least 1 cm thick) and thinner than 5.5 cm.

The thickness should be assessed with the aid of instrumental examinations like a plicometer.

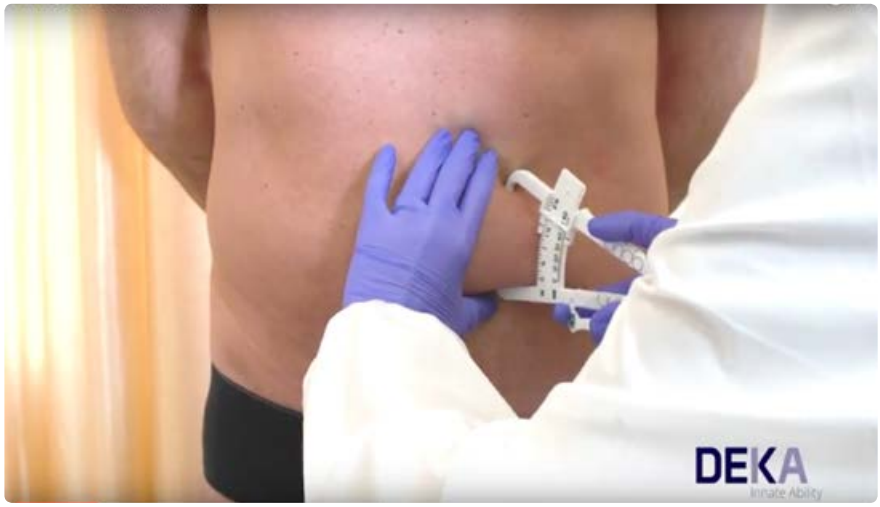


Figure 15. How to mesure the skin fold with a plicometer. The correct skin fold value is readeble in the scale of measurement of the instrument as shown in the picture.

3.2.3 Motivations and Expectations

During the patient's interview and inspection, detailed information has to be collected not only in relation to the symptomatology but also about motivations and goals that have made the subject contacting the medical or aesthetics centre.

3.3 Contraindications

After the preliminary interview with the patient, the physician should assess whether the treatment is appropriate or whether to postpone or exclude it completely. In order to correctly identify the treatment inclusion criteria, it is advisable to also do blood tests for the contraindications given below.

3.3.1 Absolute Contraindications

- Cardiac insufficiency or disorders;
- Severe vascular diseases;
- Heart implants/pacemakers;
- Neoplasia in progress or in the past 5 years;
- Kidney and liver failure/dysfunction;
- Active phlebitis, thrombophlebitis, phlebothrombosis;
- Pregnancy and breast-feeding (until 10 months after delivery);
- Infectious diseases (especially hepatitis B and C);

- Subjects with clotting disorders/ haemorrhagic diathesis
- Patients with a transplanted organ;
- Subjects with decompensated diabetes type I and II;
- Patients with deep brain stimulation implants;
- Recognised sensitivity to the device.

3.3.2 Relative contraindications

Listed below are conditions and/or diseases which, based on their specific anatomic position, severity and characteristics, may be a reason to exclude the patient from treatment. Patients with the following conditions have to consult their physician prior to undergoing Onda treatment.

- Skin pathologies;
- Skin disorders stimulated by heat, such as recurrent Herpes Simplex in the treated area (assess the use of a prophylaxis);
- Neoplasia more than 5 years before;
- Anticoagulant and antiaggregant treatments (possibility of persistent erythema);
- Use of anti-inflammatory drugs with steroids one week before the treatment (it is advised against taking these drugs also in the week after the treatment);
- Use of retinoids, antioxidants, skin nutrition supplements within a month from the treatment;
- History of phlebitis or thrombosis;
- Presence of telangiectasias in the area to be treated;
- Presence of lipomas in the area to be treated;
- Subjects with autoimmune diseases;
- Breast-feeding (beyond 10 months after delivery);
- Varicose veins;
- Diabetes;
- Predisposition for formation of keloids or abnormal healing;
- Patients with unrealistic expectations;
- Patients with BMI >30 (Onda treatment is recommended only for localised adiposity and not for obesity);
- Hypertriglyceridemia and hypercholesterolemia;
- Alteration of blood pressure;
- Presence of fibrotic tissue and particularly lax tissue;
- Under-age patients;
- Menstruation.

In the case of patients undergoing pharmacological therapy, always check for the possible contraindications and side effects to evaluate, if appropriate, to stop the therapy before treatment with the **Onda** system.

3.3.3 Areas to be excluded from the treatment

- Head and neck;
- Cardiac, décolleté and breast areas;
- Tattoos or permanent make-up in the treated area;
- Genitalia;
- Mucous membranes;
- Bone protrusions;
- Fractures (even if in the process of healing);
- Tissue with limited thickness of the subdermal fat layer (< 1cm);
- Varicose veins;
- Areas with acute inflammatory processes (as rashes, inflammation, infection, hematoma, wounds, etc.)
- Open wounds;
- Permanent implant in the treated area, such as metal/plastic plates, prosthesis and screws or injected chemical or autologous substance, fat injections or prosthesis;
- Subjects with any body piercing in the treatment area;
- Lymph nodes stations;
- Femoral, subclavian and brachial arteries and veins;
- Pharmacologically anaesthetised areas (absence of patient feedback on pain);
- Areas with sensibility reduced or absent;
- Ischaemic tissues of patients with vascular disorders whose blood circulation is insufficient to cover increased metabolic requirements (risk of necrosis);
- Spine areas subjected to laminectomy;
- Hernias;
- Lipomas;
- Fibrotic tissue and particularly lax tissue.

3.4 Pre-Treatment Procedure

3.4.1 Recommendations

- Given the high degree of absorption of microwaves by water, it is recommended to suspend the use of moisturizing and softening creams in the area to be treated at least one week before the session with **Onda**. In this way it is avoided to have a greater absorption of the **Coolwaves®** in the superficial layers of the skin and, at the same time, the penetration to the adipose tissue is increased.
- The patient should drink 2 litres of water a day to facilitate the drainage of interstitial fluids. It is recommended to start this the day before the treatment and continue the following day.

3.4.2 Photographic Monitoring

Acquiring photographic images of patient, before and after every treatment session, helps to monitor the effectiveness of the treatment. For ensuring the best photographic quality it is necessary to standardise the shots in order to reproduce the same position of the patient, the same lighting conditions and biometric reference points.

3.4.3 Just Before Starting with the Treatment

- Before starting the treatment, the area concerned must be cleansed of any impurities that could interact with the Coolwaves® or obstruct handpiece sources. Remove any make up, lotions, deodorants or ointments with a gentle soap, then rinse with plenty of water.
- Shave any dense hair on the area to be treated to improve the coupling between handpiece and skin.
- Divide the treatment area into sub-areas of 15x15cm.
- In case of localized fat, take the measure of skinfold inside the square sub areas with the standing patient.
- The patient should lie on the bed in the appropriate position. To increase the adipose tissue thickness and move away from the muscle surface in treatment of the abdomen, it is advisable to position the patient with the torso slightly bent forward.
- Spread a thin film of pure vaseline oil (pharmaceutical grade) over the entire treatment area for proper contact of the handpiece with the skin, better coupling and grater fluidity of the movements. Use minimal quantity! During the treatment, it may be necessary to repeat application of the product.

NOTE: For more detailed indications about "how to use the system", "warning" and "safety recommendations" please refer to the Onda Operator's Manual received with the system.

3.5 Treatment Procedure

Based on patient's evaluation, select the most suitable protocol to treat the area and the condition of interest.

3.5.1 Performing the Treatment Step by Step

- Switch the system on, access to the Home menu (please refer to the **Onda** Operator's Manual received with the system), connect the handpiece required and enter the treatment parameters. **Onda** system has an internal database with pre-programmed treatment protocols. You can chose to use this database or to set parameters as you like. In both cases it is recommended to start the treatment with conservative parameters (low power) and then gradually increase them (if necessary) checking tolerability to the treatment as indicated in the protocols. The aim is to gradually and homogeneously increase the subcutaneous temperature. It is advisable to treat the area with limited power in order to homogeneously heat it for an extended period, rather than sharply increasing the temperature for a limited time. In addition, high power could result in less control over the temperature increase and side effects.
- Set a skin cooling temperature of 5°C. The use of skin cooling of the **Onda** handpieces allows comfortable treatment execution other than protecting the epidermis and the dermis from sharp temperature increases. Moreover it optimises the deep thermal effect and promote the oedema reabsorption.
- Identify the area to be treated and position the handpiece on it. Press the READY key and then press the finger switch/foot switch. Keep the handpiece perpendicular and always in contact with the skin surface. A system of LED lights enables smart handpieces (patent pending) to provide an intuitive guide to the operator during the procedure, which ensures that treatment is both safe and effective. (Please refer to the **Onda** Operator's Manual received with the system for more details).
- Make smooth and continuous movements on the treatment area and never stop on one point: preferably make circular and linear movements on sub-areas not larger than 15x15 cm for at least 7-10 minutes so as to homogeneously cover the entire area (the total treatment time may change according to the selected power and dose). Hold the handpiece "vertically" in contact with the skin exercising very light pressure in such a way that the handpiece is always in contact with the skin.
- If the area to be treated is less than 15X15 cm, decrease the dose and/or power proportionally.
- According to the selected values for power and dose parameters, the system automatically displays the time needed for treatment. During treatment, both the selected dose and treatment time decrease. When both values reach zero, the system remains READY but the treatment is interrupted. Even by pressing the foot switch\finger switch the treatment will not restart until you enter the dose selection pop-up and select the dose value for treating another sub-area.

3.5.2 Monitoring the Treatment

During the treatment, the patient can feel slight discomfort, a slight tingle and you can observe a temporary reddening due to the passage of the **Coolwaves®** that causes subcutaneous heating. The power delivered should be adapted to the patient's sensitivity to pain and the tissue to be treated: the treatment should be effective but not excessively painful!

As just told, the use of **Coolwaves®** induces a localised increase in temperature and can cause slight discomfort which must be monitored through the following symptoms:

- Slight erythema and a sensation of slight heat. In case of intense erythema, an intense sensation of heat, blistering and intense pain, immediately interrupt the treatment.
- Tissue softer to the touch as demonstration of fat melting.
- During passage of the handpiece, placing your hand on the skin, you will feel homogeneous heating of the treated area.
- Do not extend the movements beyond each single area as this would make the treatment ineffective. The subcutaneous tissue can in fact be heated in more or less time depending on the power used, but it is also related to the extent of the movements. if you irradiate too large areas (or for too short a time), the temperature increases locally but without ever reaching the end point threshold and the treatment may be little effective.
- On the contrary if the handpiece irradiates too small areas, the temperatures indicated are exceeded and this may lead to undesired effects. Movements which are spaced closer together and high power could quickly increase both pain and the temperature.

3.6 Treatment Cycle

On average, the complete cycle consists of 4 sessions, 4 weeks spaced each other. It is strongly suggested to perform lymph drainage massages in between 2 following **Onda** sessions and at the end of the cycle of treatment.

3.6.1 Possible Side Effects

Mild side effects including itching, numbness, hardness, warmth, tenderness, redness, swelling, burns, bruising, nodules and blisters at the treatment area are usually transient and resolve within a few days from the treatment.

Adverse effects at the treatment area such as skin and fat tissue necrosis, skin contour irregularities and asymmetry could occur after improper use of the system, such as excessive energy levels or incorrect fat tissue evaluation.

3.6.2 Post Treatment Recommendations

- It is suggested to perform a lymphatic drainage massage immediately after the Onda treatments.
- It is advisable not to treat again the same area before 3-4 weeks.
- The patient should avoid direct exposure to the sun after the treatment (for erythema ab igne) for 2 days.
- If the skin is slightly pink or red in areas following the treatment, the patient has to avoid hot water when washing until any erythema has subsided.
- It is suggested, for the patient, to follow an appropriate healthy diet and do a moderate physical activity.

3.7 Database Protocol

Onda system has an internal database with pre-programmed treatment protocols with 3 different main applications: Localized Fat, Cellulite and Tightening. Simply following the indications on the Graphic User Interface (G.U.I) you can easily set system parameters according to the patient's specificity (please refer to the Onda Operator's Manual received with the system for more details).

For all protocols we suggest to start setting the skin cooling temperature at 5°C.

3.7.1 Localized Fat

Gender	Area	Skinfold (mm)	Handpiece	Power (W)	Dose (J)
Woman	Stomach	20	Deep	120	70000
		25		120	70000
		30		130	80000
		35		130	80000
		40		140	90000
		45		140	90000
		50		140	100000
		55		140	100000
	Abdomen	20		120	70000
		25		120	70000
		30		130	80000
		35		130	80000
		40		140	90000
		45		140	90000
		50		140	100000
		55		140	100000

NOTE: Refer to the figure 15 for the correct way to measure the skinfold.

Gender	Area	Skinfold (mm)	Handpiece	Power (W)	Dose (J)
Woman	Arm	20	Shallow	110	50000
		25		110	60000
		30		110	60000
		35		120	60000
		40	Deep	120	80000
		45		130	80000
		50		140	90000
		55		140	90000
	Inner Thigh	20	Deep	120	60000
		25		120	60000
		30		130	70000
		35		130	70000
		40		140	80000
		45		140	80000
		50		140	90000
		55		140	90000

Gender	Area	Skinfold (mm)	Handpiece	Power (W)	Dose (J)
Woman	Knee	20	Shallow	110	50000
		25		110	50000
		30		120	60000
		35		120	60000
		40		120	70000
		45		120	70000
		50		120	80000
		55		120	80000
	Back	20	Deep	120	70000
		25		120	70000
		30		130	80000
		35		130	80000
		40		140	80000
		45		140	80000
		50		140	90000
		55		140	90000

Gender	Area	Skinfold (mm)	Handpiece	Power (W)	Dose (J)
Woman	Trochanter	20	Deep	120	70000
		25		120	70000
		30		130	80000
		35		130	80000
		40		140	80000
		45		140	80000
		50		140	90000
		55		140	90000
	Side	20	Deep	120	70000
		25		120	70000
		30		120	80000
		35		130	80000
		40		130	80000
		45		140	80000
		50		140	90000
		55		140	90000

Gender	Area	Skinfold (mm)	Handpiece	Power (W)	Dose (J)
Man	Stomach	20	Deep	120	70000
		25		120	70000
		30		130	80000
		35		130	80000
		40		140	90000
		45		140	90000
		50		140	100000
		55		140	100000
	Abdomen	20	Deep	120	70000
		25		120	70000
		30		130	80000
		35		130	80000
		40		140	90000
		45		140	90000
		50		140	100000
		55		140	100000

Gender	Area	Skinfold (mm)	Handpiece	Power (W)	Dose (J)
Man	Arm	20	Shallow	110	50000
		25		110	60000
		30		110	60000
		35		120	60000
		40	Deep	120	80000
		45		130	80000
		50		140	90000
		55		140	90000
	Inner Thigh	20	Deep	120	60000
		25		120	60000
		30		130	70000
		35		130	70000
		40		140	80000
		45		140	80000
		50		140	90000
		55		140	90000

Gender	Area	Skinfold (mm)	Handpiece	Power (W)	Dose (J)
Man	Knee	20	Shallow	110	50000
		25		110	50000
		30		120	60000
		35		120	60000
		40		120	70000
		45		120	70000
		50		120	80000
		55		120	80000
	Back	20	Deep	120	70000
		25		120	70000
		30		130	80000
		35		130	80000
		40		140	80000
		45		140	80000
		50		140	90000
		55		140	90000

Gender	Area	Skinfold (mm)	Handpiece	Power (W)	Dose (J)
Man	Trochanter	20	Deep	120	70000
		25		120	70000
		30		130	80000
		35		130	80000
		40		140	80000
		45		140	80000
		50		140	90000
		55		140	90000
	Side	20	Deep	120	70000
		25		120	70000
		30		120	80000
		35		130	80000
		40		130	80000
		45		140	80000
		50		140	90000
		55		140	90000

3.7.2 Cellulite

Gender	Area	Stage	Handpiece	Power (W)	Dose (J)
Woman	Stomach	1	Shallow	110	70000
		2		110	80000
		3		120	90000
		4		120	90000
	Inner Thigh	1	Shallow	110	60000
		2		110	70000
		3		120	80000
		4		120	90000
	Lateral Thigh	1	Deep	120	70000
		2		130	80000
		3		140	90000
		4		150	90000
	Knee	1	Shallow	110	60000
		2		110	60000
		3		120	70000
		4		120	80000

Gender	Area	Stage	Handpiece	Power (W)	Dose (J)
Woman	Posterior Thigh	1	Deep	120	70000
		2		130	80000
		3		140	90000
		4		150	90000
	Gluteus	1	Deep	120	70000
		2		130	80000
		3		140	90000
		4		150	90000
	Trochanter	1	Shallow	110	60000
		2		120	70000
		3		130	80000
		4		130	90000

Gender	Area	Stage	Handpiece	Power (W)	Dose (J)
Man	Stomach	1	Shallow	110	70000
		2		110	80000
		3		120	90000
		4		120	90000
	Inner Thigh	1	Shallow	110	60000
		2		110	70000
		3		120	80000
		4		120	90000
	Lateral Thigh	1	Deep	120	70000
		2		130	80000
		3		140	90000
		4		150	90000
	Knee	1	Shallow	110	60000
		2		110	60000
		3		120	70000
		4		120	80000

Gender	Area	Stage	Handpiece	Power (W)	Dose (J)
Man	Posterior Thigh	1	Deep	120	70000
		2		130	80000
		3		140	90000
		4		150	90000
	Gluteus	1	Deep	120	70000
		2		130	80000
		3		140	90000
		4		150	90000
	Trochanter	1	Shallow	110	60000
		2		120	70000
		3		130	80000
		4		130	90000

3.7.3 Tightening

Gender	Area	Handpiece	Power (W)	Dose (J)
Woman Man	Stomach	Shallow	120	6000
	Abdomen			
	Arm			
	Inner Thigh			
	Lateral Thigh			
	Posterior Thigh			
	Gluteus			
	Back			
	Trochanter			
	Side			

Appendix

Practice Name

Medical History Form Template*

FOR ONDA BODY TREATMENT

*DISCLAIMER: THIS MEDICAL HISTORY FORM TEMPLATE IS PROVIDED "AS IS" AND IT IS INTENDED FOR INFORMATIONAL PURPOSES ONLY. THIS TEMPLATE MAY NOT MEET ALL LEGAL OR REGULATORY REQUIREMENTS FOR USE WITH PATIENTS. DEKA COMPANY DOES NOT MAKE ANY REPRESENTATION, GUARANTEE OR WARRANTY, EXPRESS OR IMPLIED OR ASSUME ANY LIABILITY OR RESPONSIBILITY FOR THE ACCURACY, COMPLETENESS, OR USEFULNESS OF THE CONTENTS OF THIS SAMPLE FORM. PHYSICIANS USING THIS TEMPLATE ARE RESPONSIBLE FOR ENSURING THE INFORMED CONSENT FORM USED WITH PATIENTS MEETS ALL APPLICABLE LEGAL AND REGULATORY REQUIREMENTS, AND ARE INVITED TO CONSULT WITH THEIR ATTORNEY.

Last Name: _____ First Name: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Telephone: Home: _____ Work: _____ Cell: _____

Date of Birth: _____ Sex: Female _____ Male _____

Family Doctor: _____ Phone: _____

Pharmacy: _____ Phone: _____

Emergency Contact: _____Phone: _____

Which body area/areas would you like treated?

_____

_____

Please answer all of the following questions YES NO

1. Do you have ANY current or chronic medical illnesses? YES NO

Disclose any history of heat urticaria, diabetes, autoimmune disorders or any immunosuppression, blood disorders, cancer, bacterial or viral infections, medical conditions that significantly compromise the healing response, cardiac insufficiency or disorders, vascular diseases, kidney and liver failure/ dysfunction, phlebitis, thrombophlebitis, phlebothrombosis, infectious diseases, clotting disorders/ haemorrhagic diathesis, severe hyperglycaemia and hypercholesterolemia, alteration of blood pressure, infectious diseases (especially hepatitis B and C), or any other condition or illness.

Please List: _____

_____

2. Do you have ANY current or chronic skin conditions? YES NO

Also disclose any history of eczema, psoriasis, allergic dermatitis, any diseases affecting collagen, scleroderma, skin cancer, or any other skin condition.

Please List: _____

_____

3. Are you currently under a doctor's care? If so, for what reason? YES NO

_____

4. Do you take/use ANY medications (prescriptions and non-prescriptions), vitamins, herbal or natural supplements, on a regular or daily basis? YES NO

Please List: _____

_____

5. Are there any topical products (both medical and non-medical) that you use on your skin on a regular or daily basis? YES NO

Please List: _____

6. Do you have ANY heart implants/pacemakers or any other implantable devices? YES NO

7. (For women) are you or could you be pregnant? YES NO

8. (For women) Are you breastfeeding? YES NO

If YES, when did you give birth? _____

9. Do you take/use ANY systemic/oral steroids (e.g., prednisone, dexamethasone)? YES NO

10. Do you have ANY allergies to medications, foods, latex or other substances? YES NO

Please List: _____

11. Do you have a history of skin disorders stimulated by heat, such as recurrent Herpes Simplex in the treated area? YES NO

12. Do you have any open sores or lesions? YES NO

13. Do you have any rashes, inflammation, infection or hematoma in the area to be treated? YES NO

14. Do you have any history of radiation therapy in the area to be treated? YES NO

15. In the last six months, have you used any of the following:

anti-inflammatory, anticoagulants or blood-thinning medications? YES NO

Please List product name and date last used: _____

_____

16. Do you have a history of surgery or other treatments, medical or cosmetic,

in the area to be treated? YES NO

If yes, please list _____

_____

17. Do you have or have you ever had a hernia? YES NO

18. Do you have any tattoo or permanent make-up in the treated area? YES NO

19. Do you have a history of fainting or passing out? YES NO

20. Have you had any unprotected sun exposure or used tanning beds or lamps YES NO

in the last week?

21. Do you consider yourself to have an anxious or nervous personality? YES NO

22. Do you consider yourself claustrophobic or have issues with confinement? YES NO

Signature: _____ Date: _____

Reviewed by: _____ Date: _____

Practice Name

Patient Informed Consent Form Template*

FOR ONDA BODY TREATMENT

*DISCLAIMER: THIS PATIENT INFORMED CONSENT TEMPLATE IS PROVIDED "AS IS" AND IT IS INTENDED FOR INFORMATIONAL PURPOSES ONLY. THIS TEMPLATE MAY NOT MEET ALL LEGAL OR REGULATORY REQUIREMENTS FOR USE WITH PATIENTS. DEKA COMPANY DOES NOT MAKE ANY REPRESENTATION, GUARANTEE OR WARRANTY, EXPRESS OR IMPLIED OR ASSUME ANY LIABILITY OR RESPONSIBILITY FOR THE ACCURACY, COMPLETENESS, OR USEFULNESS OF THE CONTENTS OF THIS SAMPLE FORM. PHYSICIANS USING THIS TEMPLATE ARE RESPONSIBLE FOR ENSURING THE INFORMED CONSENT FORM USED WITH PATIENTS MEETS ALL APPLICABLE LEGAL AND REGULATORY REQUIREMENTS, AND ARE INVITED TO CONSULT WITH THEIR ATTORNEY.

Please read carefully and understand the contents of this form. Ask us if you not understand.

I hereby authorize Dr._____ or _____, under Dr. ____'s supervision to perform Onda treatment on me.

I understand that this procedure works by using high-frequency electromagnetic waves (called Coolwaves®) delivered to the subdermal layers from two specially designed handpieces. Coolwaves™ damages the fat cells that are then eliminated by the body through your lymphatic system. Onda system provides also cellulite and skin laxity treatments. Onda performs treatment all over the body (excluding face, neck, cardiac area, décolleté, breast area, genitalia, terminal part of the limbs, lymph nodes stations, femoral, subclavian and brachial arteries and veins, and some other areas contraindicated for the treatment because of not healthy conditions) in a virtually painless way.

I understand I may experience some heating, tingling, prickling or squeezing sensations in the deep of the fat layer. These sensations are either normal and expected and they are the indication of the effective ONDA action on the subdermal fat layers as well as cellulite or skin laxity.

I understand that my skin may be slightly pink to red immediately after treatment. This may last for hours up to days. Following the Onda treatment I may experience swelling and tenderness that lasts approximately few weeks, but may last longer. I may also experience tissue firmness or nodules. Nodules can last for days to several months, depending on the size of the nodule. This side effect typically resolves on its own. While uncommon, some nodules may be permanent. Other less common side effects which can occur are pain, bruising, itching, skin contour irregularities, dimpling, hyperpigmentation /hypopigmentation, asymmetry, changes in skin laxity, numbness, blister or burn. Rare occurrences of fainting or dizziness have been noted during and/or after the treatment. In case of superficial capillaries in the treated area, a temporary worsening of this aspect can appear. There may be risks not yet known at this time.

I understand that, in the case of undergoing some pharmacological therapy, the physician will evaluate the possible contraindications and side effects and decide , if appropriate, to stop the therapy before treatment with the Onda system.

I understand that I will require several treatments to obtain a significant, long-term result. Usually monthly treatments provide the best outcome in most individuals. While it is expected to see an improvement in the treatment area after the 2nd to 4th treatment, results vary between individuals. Some people respond below expectations. Although good results are expected, with the focus on improvement and not perfection, every person is unique and it is impossible to guarantee results. Moreover Onda treatments cannot stop the formation of new cellulite or prevent future skin laxity or formation of new fat deposits.

Before and after treatment instructions have been discussed with me and I understand that there may be increased risk if I do not follow the aftercare instructions.

I understand that there are other options for treatment including not having the procedure.

The cost of treatment has been discussed with me and I agree to pay this amount (_____). I consent to photographs and digital images being taken and used to evaluate treatment effectiveness, for medical education, training, professional publications or sales and marketing purposes. No photographs or digital images revealing my identity will be used without my written consent. If my identity is not revealed, these photographs and digital images may be used, shared, and displayed publicly for such stated purposes without my permission.

☐ Yes ☐ No Initials: _____

ACKNOWLEDGMENT:

BY MY SIGNATURE BELOW, I acknowledge that I have read this document carefully. I have had an opportunity to ask questions and all of my questions have been answered satisfactorily. I accept the risks and possible complications of the procedure.

Before each treatment I will inform the Physician if I have taken any new medications or my health state is changed since my last treatment.

This Agreement constitutes the complete agreement and understanding between Client and Office and will not be changed or modified in any way unless agreed to by both parties in writing.

PLEASE READ THIS DOCUMENT CAREFULLY. DO NOT SIGN THIS AGREEMENT BEFORE YOU HAVE READ IT COMPLETELY.

Consent for treatment of _____

_____	_____	_____
Signature-Patient or Guardian	Print Name/Relationship	Date
_____	_____	_____
Signature-Witness	Print Name	Date

Practice Name

Pre-Treatment / Post Treatment Instructions

FOR ONDA BODY TREATMENT

Onda pre-treatment instructions:

- Avoid direct sun exposure to the treatment area 7 days before the treatment.
- Given the high degree of absorption of microwaves by water, it is recommended to suspend the use of moisturizing and softening creams in the area to be treated at 48 hours before the session with Onda. In this way it is avoided to have a greater absorption of the Coolwaves® in the superficial layers of the skin and, at the same time, the penetration to the adipose tissue is increased.
- You should drink 2 litres of water a day to facilitate the drainage of interstitial fluids. It is recommended to start this 2-3 days before the treatment and continue the following days.
- Shower or bathe the day of treatment. Your skin must be free of all makeup, lotions, creams and body oils.
- Remove all jewelry and piercings pertinent to the treatment area.
- If you have very thick & dense hair in the treatment areas please trim or shave the areas at home before your appointment.
- Be sure to discuss your medical history and medications you take with your treatment provider.

Onda post-treatment instructions:

- You may experience mildly pink or red skin, tenderness or discomfort, swelling, tissue firmness or nodules in the treated areas. These are all expected side effects which usually resolve without medical intervention.
- Tenderness may occur as early as the day of treatment and can last two weeks or even longer.
- If needed, use a cold compress to help relieve tenderness.
- For body areas, if nodules occur, they typically last for days or 6 (six) months or longer, depending on the size of the nodule. While uncommon, some nodules may be permanent.
- In case of superficial capillaries in the treated area, a temporary worsening of this aspect can appear.

- Gently massage the area twice a day for 5-10 minutes. Massage should be continued until your next treatment or for 12 weeks if you have only one treatment.
- The patient should avoid direct exposure to the sun after the treatment (for erythema ab igne) for 2 days.
- If the skin is slightly pink or red in areas following the treatment, the patient has to avoid hot water when washing until any erythema has subsided.
- It is suggested, for the patient, to follow an appropriate healthy diet and do a moderate physical activity. You may resume your normal daily activities, including exercise, immediately after your Onda treatment.
- Staying well hydrated and engaging in light physical activity helps mobilize the disrupted fat for processing through the lymphatic system. We encourage you to drink at least 2 liters of water a day and take a daily walk or continue your regular exercise routine.
- It is advisable not to treat again the same area before 3 – 4 weeks.
- Contact your physician if you have any concerns about your treatment areas such as increasing tenderness or swelling several days after your treatment, or if you develop blisters, hardened areas or nodules.

DEKA
Innate Ability

DEKA M.E.L.A. s.r.l.
Via Baldanzese, 17 - 50041 Calenzano (FI) - Italy
Ph. +39 055 88.74.942 - Fax +39 055 88.32.884

www.dekalaser.com

© DEKA 055-0112-20-020 Rev.1.3

© DEKA M.E.L.A. s.r.l. - All rights reserved - In order to improve its products the company reserves the right to modify these specifications without prior notice.
Document Reserved for Health Professionals Only.