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Feature Article

Micro-Needling 2.0

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Back in December 2012, I reviewed the market for 'dermarollers'; the manually operated, sterile, needle covered roller devices aimed at micro-medical skin-needling.

The treatment, which is used for indications ranging from skin rejuvenation and acne scar resolution to reducing stretch marks and encouraging follicular growth to treat hair loss, is now referred to by many names including medical skin needling, collagen induction therapy, percutaneous collagen induction, micro-needling or simply dermarolling.

However, man is never satisfied and is always looking to improve on a basic concept; upgrade it in some way. Thus we are now seeing a new crop of automated skin needling devices available in the marketplace; of course they are not automated rollers, but in fact automated needle bearing stamps fixed to a hand-held or pen-like unit which is operated in a continuous motion across the skin.



Designed to improve the ease-of-use, speed and flexibility of medical needling treatments, and to augment the achievable treatment results (when compared to dermarollers), these new devices also bring with them a new raft of names for the treatment, including electronic skin needling, automated skin needling, fractional skin needling and fractional micro-dermal needling,.

In addition, like every upgrade, they bring a whole new set of technical considerations for those who are deciding on which one to invest in.

The Problem With Dermarollers

The popularity of the dermaroller (and dermastamp) style devices has led to almost market saturation, with many companies now offering a solution to their clients. Similarly, this has also led to the market being flooded with cheap, generic products with poor design, build and quality of components, emanating mostly from the Far East, which could be detrimental to patient safety. As covered in my previous article, there are many factors to take into account when [choosing a dermaroller](#).

Micro-needling is designed to produce thousands of microscopic holes (with spaces in between) as the needles enter into the layers of the skin through the papillary and reticular dermis in order to stimulate a wound healing action to repair and regenerate collagen in the deeper dermal layers.

At the same time there is rapid closure of the incisions and the epidermis is thus left intact. This 'invasion' by the needles stimulates the dermis to produce growth factors and new collagen, all of which then remodels and improves the skin tone and texture.

Manual dermaroller devices have been around and in active use by clinicians for a number of years now, but they do come with some issues, aside from the vast differences in product quality, design and build.

From a practitioner perspective the biggest problem is their inflexibility. The fact that there is a fixed needle length to each roller and you have to put one down and get another one out to change that, plus the size and shape of the device means that you can't always reach the areas you want to as easily as you'd like to and may again have to switch to a dermastamp.

Similarly, actually getting the needles to break the skin's surface and penetrate into it can require a certain amount of force or pressure to achieve the depth of penetration required for effective dermal stimulation. These factors can have an impact on the intensity of the treatment which can be performed and thus the results achieved.

From a patient perspective, these same factors can also be a problem and patient discomfort with dermaroller treatments is often cited. The inflexibility of the device means that the intensity of the treatment may be compromised in more delicate or sensitive areas of the face as the patient simply can't tolerate the needle length or pressure required to treat; this of course may then lead to patient dissatisfaction when the results are not as dramatic as hoped for.

Also, depending on the build quality, design style and make-up of the dermaroller, the number of needles in it (some of the Chinese imports have far too many needles in them) and the angles at which the needles penetrate into the skin, there is potential for causing significant tissue damage through snagging and tearing as one set of needles exit the skin and another enters. This is less of a problem with the better designed, quality rollers available.

The Solution?

Thus, the industry came up with an answer – by making automated devices equipped with a head that had needles perpendicular to it, there is said to be more control, increased intensity of treatment application and it is quoted that this gives more patient comfort as the needles just go up and down in a vertical fashion and can be adjusted to vary the depth and speed of insertion in more sensitive areas of face.

Similarly there is a theory that the vibration that the needle plate head creates on the skin reduces the sensation of pain felt in the skin as it causes confusion in the nerve endings.

Most manufacturers also claim reduced tissue tearing when compared to traditional dermarollers but as is always the case, there are those who argue that this is not true and tissue tearing, at some degree, will occur with all.

Things to Consider When Choosing an Automated Needling Device

Automated skin needling systems are not without niggles themselves. It's important to know what key criteria to be looking for when choosing one, and there are a number of things you need to think about.

CE Mark

It may seem obvious but it's important to choose a system with a genuine European CE mark, preferably made in an ISO 13485 accredited factory. Currently, European medical device regulation treats these devices as two separate entities, the unit and the needle heads. The unit is a class I medical device, which can be self-certified or certified by an EU Notified Body, although this is not mandatory. The needles however require a mandatory class IIa medical device certification for commercialisation. All of the devices discussed in this article carry a CE Mark for a class IIa medical device for the single-use, sterile, disposable needle heads which are an integral part of the devices.

Please note that as yet there are no FDA approved automated needling devices (or manual dermaroller/stamp devices) as no one has as yet completed the pre-market approval required to register them correctly as Class II and III medical devices for USA compliance. This means, and it is something the FDA has been cracking down on in the last year, such devices cannot actually be sold or imported into America presently. Therefore any claims of FDA approval, clearance or registration are erroneous.

Motors

One of the criticisms, especially of early devices is that in some cases the needles simply couldn't penetrate the skin to the full depth specified when they are automated with poor quality or inadequate motors driving the needles.

Our skin is actually pretty tough; I mean it takes quite a bit of force to cut yourself or inflict an actual wound on it so getting a number of needles which are travelling quite fast (faster than your eyes could keep up with) to penetrate all the way to a depth of 2mm is quite a challenge for device manufacturers and designers, especially as the number of needles (in the head) increases the force required..

This is also why traditional dermarollers need a certain amount of manual pressure to work otherwise it's like the skin is just pressed up against a bed of needles, like the magic 'bed of nails' tricks of old, with the needles not actually penetrating through the skin layers properly. Choosing a high quality and high powered device, whether powered by a motor or an electro-magnet should minimise this problem.

Of course claims about speed and how fast it works is not the same as how powerful a device is at making the necessary micro-holes.

Origins

Some of the automated needling devices available have evolved from semi-permanent tattoo or micropigmentation machines which have a fairly long history of use by semi-permanent make-up specialists for 'dry tattooing' as a treatment for skin rejuvenation and scar resolution.

These devices have therefore been adapted and modified, for the indication of micro-needling, to carry different heads with different bespoke needles to the original tattoo needles, which are often more closely aligned than on the new automated needling devices. In many cases the general principles of speed, needle depths and the number of needles on a head vary very little.

The correct term for dry tattooing is MCA (Multi-trepannic Collagen Actuation) Micro Needling, but many practitioners still refer to it as 'dry tattooing' with their clients and argue that it is the best option for treating scars.

Traditionally most clinics don't have an in-house micro-pigmentation specialist available to offer dry tattooing so have tended to either refer on externally, offer alternative treatment solutions themselves, or as we see now are investing in automated skin needling devices themselves. The notion of automated medical micro-needling over the terminology 'dry tattooing' may also be a more preferable marketing choice.

Other devices on the market have been designed from the ground up, citing that this avoids the limitations of adapting a device, which already has a primary function, to make it work for an alternative treatment indication; allowing developers to 'think outside the box'.

One of the key considerations quoted by developers is the concept of 'duty cycles' and the mechanics of the motor which operates a device.

Duty Cycle

The duty cycle refers to the percentage of time that the needles are in the skin during one in-and-out operation cycle of the head. This is important as it means that the higher the duty cycle, the longer the needles are actually embedded in the skin, rather than in a process of being pushed down or pulled up by the device and fully retracted. Lower duty cycle is said to be preferable since the device can be moved along the skin without the needles being embedded.

One of the easiest ways to picture this is to think about bicycle pedals, if you look at them sideways on. No matter how fast or slow the cyclist is pedalling (akin to different speed settings on an automated needling device), the pedals are either up, down or on their way up or down. This means that the pedals are downwards half of the time and upwards half of the time, since they are fixed by a chain to the feet (i.e. the motor/gearbox); the same is therefore true of the needles on most of these devices.

Some manufacturers therefore advocate a solution which has more of a piston like operation to reduce the amount of time the needles are in the skin. This is because the duty cycle of a device has a bearing on the chances of tissue tearing as the device head is moved in a continuous motion (horizontally or in small circles) over the surface of the skin.

By design there will always be some, albeit minute amount of additional tissue tearing with these automated needling devices except where the device is used on a single punch mode or has a duty cycle around 1%.

Tilting Heads

Some manufacturers claim to compensate for this by using tilting or articulating heads (like on modern-day razors) which allow the heads to move more smoothly along the contours of the skin, rather than a fixed end-plate. This is said by some to virtually eliminate the chance of skin dragging and others to simply allow the needles to penetrate vertically if the device is not held perfectly straight.

Others cite this as an unnecessary gimmick and something which could result in non-perpendicular micro-holes in the dermal layers as the head tilts around.

Needles

When looking at the heads, which of course fit onto the end of each automated pen-like device, as well as the ongoing consumable cost, some are significantly more expensive than others, there are a number of other things which you may wish to think about which could have a bearing on how well it can be used for treatments.

For example, questions such as:

- What are the needles made from?
- How are the needles sharpened during manufacture?
- What gauge or diameter are the needles? For example, 33 gauge needles will make smaller micro-holes than a 26 gauge, leading to more insertions per centimetre square, which is said to lead to more dermal stimulation and less epidermal trauma as the holes will close quicker. Yet, if the needles are too thin then they could in theory bend, which you do not want. The relationship between diameter and strength is such that a 25% increase in the diameter would lead to approximately 100% increase in needle strength.
- Are the needles tapered towards the end? This means that at a lower depth setting the diameter of the needle entering the skin will be reduced, compared to the full needle diameter or gauge, which reduces patient discomfort.
- How many needles are in each head?
- Are there different heads with different configurations or numbers of needles for different indications?
- Can it be used in a continuous motion across the face, just as a stamp or a combination?
- What about needle speed – can this be varied? Some argue that increased speeds are needed to effectively target dense scar tissue as compared to just treating for skin rejuvenation purposes.
- What is the minimum and maximum needle length (depth of penetration) and how are the increments spaced?
- Can the needle length be safely and easily changed?

One of the most talked about parameters is the mechanism by which the needles are withdrawn from the skin at the end of each cycle, and how quick and effective this is to fully retract the needles either before they are pushed down into the skin again or before the operator moves the hand piece head.

Many options are used by the various manufacturers from strong springs which push or pull the needles back, to magnets and cam wheels. Whichever system is in use it's important that it can keep in tune with the motor driving the unit and be able to fully retract the needles in the given time period available.

Topicals, Glide Mediums and Local Anaesthesia

Many of the devices use a topically applied proprietary 'glide serum' to facilitate easy movement across the skin (either in straight lines or in a small circular motion). With sufficient lubrication in place and the correct pre-set of needle depth and speed for the area being treated, dragging of the device heads which leads to tissue tearing should be minimised.

One area of controversy and confusion is the concept of using automated needling devices to drive or push topically applied agents (e.g., hyaluronic acid or vitamin style meso ingredients) into the skin.

The MHRA has determined that there is a clear definition as to what is a 'topical' or becomes a 'topical' once applied to the surface of the skin and what is a 'systemic' product. An issue would occur if a dermal (pin-point) bleed is created and a topical is thus introduced into the systemic circulation. Clinicians would be running a high risk of prosecution in court if they needled topical products into the reticular dermis and then had an adverse reaction, e.g., septicaemia or anaphylaxis etc.

However, the MHRA does not view the products used as glide mediums in the same way and although a small amount of these may be pushed into the skin during treatment, it does not see an issue with their use! For this reason most manufacturers only recommend the use of their proprietary glide medium serums during treatment with the needles. Of course many of these glide mediums themselves have been produced to incorporate HAs and other ingredients which it could be argued make them much more than just a simple gliding lubricant.

Other options include the use of sterile proprietary and non-proprietary solutions (class III medical devices) which are preloaded into the needle cartridge (via a syringe) and delivered as a continuous flow through the head during needle operation.

Many practitioners will of course want to and choose to apply a topical local anaesthesia to further aid patient comfort and interestingly it has been noted to me that not all of these are 'friendly' towards these needling devices, particularly if they create a film of any kind on the surface of the skin and aren't removed completely before treatment commences. In the worst case scenario which was reported to me, and as is believed to have happened with some of the earlier devices, a build up of product can cause a gluing effect in the head and is thought to have been the cause of the device motor burning out. This causal link is however unproven.

For this reason effective removal of topical anaesthetics, before initiating treatment, has been reported to have a significant impact on the movement (glide ability) of the needle cartridge head over the skin, and some manufacturers of these devices make a recommendation based on which topical anaesthetics they believe work best with their device.

It is noted that there are other factors that should be considered when choosing a topical anaesthetic brand for your patients and specific questions regarding the method of use and the product's characteristics should be referred to the specific product manufacturer/distributor for detailed and accurate information which is not being covered in this article.

Ergonomics

As well as the technical specifications for the device, with anything which you will be operating for a length of time, it's important to 'get a feel for it' and look for something light-weight and ergonomic. Take an opportunity, at trade shows and conferences or when the sales rep comes knocking to pick up and hold the devices. Their size, shape and weight plus your own physical specifications will have a bearing on which one fits snugly in your hand and feels comfortable for repeated in clinic use.

The method of operation may also be worth considering. Some devices use digital control panels on a separate table top unit, followed by foot pedal or hand operation, whilst others are pre-set and adjustable directly on the handset and may or may not then need a prolonged button press for continuous operation. These factors all add to the ease of use, flexibility during treatment and practitioner fatigue.

Needle Stick Prevention

Similarly, as well as the operating mechanisms, what happens when the device isn't operating and more specifically do the needles retract into the head for safety and prevention of needle stick injuries? Currently only one device (the Dermadart) offers and markets an 'auto-retraction system', they're so confident of this that if anyone at a trade show demonstration can make the device leave the needles out after stopping the device or physically pulling the plug from the wall to simulate a power cut, they will give them a free device!

Other devices, like the eDS, did tell me that when the power to their device is cut (intentionally or not) the needle plate returns to its starting position, with the needles all contained within the needle cartridge tip; however they do not promote this as a feature (perhaps they will now).

Having such a feature means that the device can also be safely put down mid-treatment should the practitioner need to obtain another item or alter their position at the patient's side without the risk of scratching themselves when reaching for the device. Most devices will tend to leave the needles out half of the time (referring back to the duty cycle) and it may simply be luck and a mathematical probability as to which occurs. It is hoped that more manufacturers will look to incorporating this kind of safety feature as needle stick injuries are a common risk for medical practitioners.

Insurance

Don't forget to tell your insurance company – being already insured for traditional dermarollers might not be cover enough as you move to an automated version which is mains powered and thus carries different risk factors. You may need alterations to your policy so be sure to check prior to investing in equipment.

Similarly all the devices covered are generally sold only for use by medical professionals (doctors, nurses, dermatologists, dentists, surgeons etc.). However, in some cases (and sometimes dependent on the specific model or needle heads) some are sold for use by aestheticians (beauty therapists), but it's worth bearing in mind that they may find it difficult to obtain medical indemnity provision to cover them for treating using such a device, especially if it is one which can go up to 2mm deep into the skin.

Support

Finally, it's important to consider the support that will be provided to you by the company post-sale. This includes device warranties (ideally a couple of years), product and part guarantees, training and marketing support and provision, as well as ease of contact, particularly if there is no direct UK base for all of these.

Devices Available on the Market

There are now a good handful of manufacturers and distributors supplying automated skin needling devices to the UK aesthetic industry. The following information is designed to give a brief overview of the main brands (a non-exhaustive list in alphabetical order) including details of their construction, their licensing and any claims that they make in their marketing. For more details of each device, we would recommend visiting the associated website and contacting suppliers listed.

Amiea Med Revive MN

The Amiea Med Aesthetics Revive MN is made in Germany by MT.DERM GmbH and uses needles supplied by another German company, Dermaroller GmbH. It is distributed in the UK by Schuco International (London) Ltd.

MT.DERM GmbH hail from a background in designing and manufacturing micro-pigmentation or medical tattooing devices, so they adapted the technology to create an automated medical micro-needling system. The Amiea Med Aesthetics Revive MN and accompanying needle cartridges have a class IIa medical device CE certificate and are made in an ISO 13485 certified factory.

It consists of a base unit, fixed by magnets to a mount with a hand piece (weighing 100g) which can also be stored on the mount. Operation during treatment is by either foot pedal or via the hand piece, depending on preference. The makers claim that the device generates little noise and vibration and is an easy-to-clean unit. They also assert that other automated micro-needling methods which use a stand-alone hand piece with an integrated motor do not have the strength to penetrate into the dermis with minimal trauma.



It comes with options for a variety of needle cartridges, from a single needle for targeting deep scars to needles grouped in various shaped, linear or sloped configurations of 3, 5 and 7 needles which are a maximum of 2mm in length and appropriate for smaller, larger and curved scar tissue. The manufacturers note that the 7 needle (round configuration) head is unique to their device.

A 6 needle cartridge is the standard head and is recommended for skin rejuvenation treatments. It comes in maximum lengths of 1.5mm and 0.5mm and features a tilting head. All needle depths can be adjusted via the hand piece from 0.1mm to their maximum at increments of the same with speed variations of 50 to 150 hits per second. This provides the clinician with a wide variety of options to choose from.

Dry needling with the device is not recommended, ideally a glide medium should be used or the cartridges can be filled with their proprietary serums and solutions via a 'reservoir window'.

Interestingly the device is also able to be fitted with a different and unique hand piece which takes cartridges of plastic needles for use on extremely delicate and sensitive skin as a Mesotherapy treatment using their proprietary range of Vytal serums.

The Revive MN is available to doctors and nurse and aestheticians who can demonstrate qualifications and insurance cover to treat up to 2mm in depth. It is sold for £1,600 (ex. VAT), including a box of 8 of the 6 needle cartridges and comes with a 2 year warranty with training and marketing support available. Needle prices range from £70 to £140 (ex VAT) for boxes of 8, depending on the configuration.

For more information please visit www.amieamed.com and www.schuco.co.uk/aesthetics/micro-needling/revive-mn.html.

DERMADART®

The DERMADART® is unlike any of the other devices on the market because it uses an electro-magnetic linear drive system, as opposed to a motor, which it is claimed means no friction or loss of power during use, and also produces a much lower duty cycle than other devices on the market to appreciably reduce tissue tearing.

It has two patents pending for this technology.

According to the developers this not only makes it one of a kind but a first of a kind.

The new Dermadart device has been developed by Barnet Medical Devices Ltd (a sister company to Pangaea Laboratories, known for the Medik8 range of professional skincare) in collaboration with Turkish medical device company ALA Kosmetic, who manufacture their product in their ISO 13485 certified factory. It is distributed in the UK through Skin Brands Ltd. The device has been in trials with a selected number of UK clinics since last summer and is due for market launch in April 2014.

As well as being CE Mark certified as a class IIa device for the needle heads, the Dermadart device itself has also been certified through a notified body (rather than self certified) as a class I medical device. In addition Barnet Medical Devices Ltd chose to have the device vetted by a UK specialist medical device testing house to check it for electrical safety and compliance with EU standards on accessible parts. The device passed with flying colours and I have been supplier with a copy of the report.

The device was originally launched on the European market by ALA Kosmetic, in very much a prototype form, and branded as the Dermajet. Barnet Medical Devices Ltd later negotiated a collaborative deal with the Turkish manufacturer and spent a year working with them to redevelop and refine the inner and outer workings of the prototype device and its needle heads, as well as taking it through CE mark medical device certification.

Allegations which can be found on the Internet which defame the developers and discredit the Dermadart device and its safety, based on assumptions from the original Dermajet machine are untrue and legal action is pending against the author for these falsehoods.



The Dermadart inserts the needles at high speed using a high powered electromagnet which goes from zero to maximum speed in milliseconds and then also retracts very quickly using a spring and magnet mechanism. It comes with a single needle head comprised of 12 (0.25mm tapered, equivalent to 32 gauge) sterile medical grade stainless steel needles on a tilting plate. There are plans to produce other configurations in the future. The needle head also have a nice safety feature whereby the needles will fully retract to a safe position when the device is switched off or if the power is cut during treatment. This automatic retraction avoids any risk of needle-stick injuries caused by needles simply stopping at whichever point they are in during a cycle when the power is stopped or the operator decides to switch it off and put it down.

The Dermadart also has adjustable speeds and three different speed options to include a single pulse, a burst mode and a continuous mode; it also features a noticeable one second delay or pause between cycles as an option. The needle depth is also adjustable from 0.2mm to 2.0mm at increments of 0.2, 0.5, 1.0, 1.5 and 2.0mm using a changeable guard system whilst the needles are fully retracted into the cartridge.



The operation of the device is via the hand piece which features a main button which can be clicked or double-clicked to choose initial settings, alongside a smaller 'burst' button and dial at the rear to adjust the speed settings.

The company notes that one of the unique features of the Dermadart is that it has a low duty cycle due to the electro-magnetic linear driven needles and the pulse delay, as low as 1% (operating at 1Hz in single pulse mode), which means that at that speed the needles are in the skin 1% of the time and out the skin 99% of the time. They state that other motor driven devices, which have a fixed gearbox-driven system, have a 50% duty cycle and mean that the needles are in the skin 50% of the time. The device offers speeds of 1Hz to approximately 35Hz thus creating duty cycles from 1% to 35%, with the most commonly used during treatments being 25Hz (25 cycles per second). The developers chose not to increase the speed as high as 50Hz as it was found to be unnecessary and counter-productive during testing.

Use of the Dermadart is recommended in a linear pattern of movements and either dry or using a non-proprietary sterile, class III medical device solution in combination with the device. The company is currently developing a proprietary hyaluronic acid product, in conjunction with a pharmaceutical company, which will also be a class III medical device to be used during treatment and will be sterilised on application.

It is acknowledged that the hand piece is not as lightweight as others on the market and operator fatigue could be an issue. The makers are building a stand which will help to support the weight of the device and make it almost weightless.

Since Dermadart is brand new to the market, the developers are keen to see the reaction from the wider market after the launch and then look at what features to work on going forward, although they do have some developments in the pipeline which may come as early as 2015. A home use device with lower power, speed, and depth is also envisaged.

The Dermadart comes in a complete boxed kit which costs £795 (ex. VAT) and includes a one year warranty, with an option to upgrade to a 2 year warranty for an additional £50. Dermadart needle cartridges (in a sterile pack) are sold in boxes of 10 for £80.00 (ex. VAT) and are available direct from SkinBrands Ltd and through Wigmore and Med-fx pharmacy suppliers. Training and marketing support is available through SkinBrands Ltd.

For more information, please visit <http://dermadart.com>.

Derma FNS

The Derma FNS (Fractional Needling System), also referred to as the Derma Finesse is manufactured in Korea in an ISO 13485 certified factory by Dong Bang, a well known and established producer of acupuncture needles, on behalf of the British company SkinMed Ltd who oversee the product design and specifications, as well as distributing direct to the UK market.



The device's needle assembly has a CE mark (class IIa) certificate from a UK notified body and is sold only to medical professionals.

The needle heads come in a variety of configurations of 1, 3, 5 and 7 needles with a 9 needle (33 gauge) head provided as standard. The device can operate the head both in a stamp or continuous motion via a direct CAM driven up and down mechanism which is supported with a spring system to cushion the needle head movement. Starting at 0mm, the needles have a maximum depth of over 2mm, although such depth is rarely required, even in the hands of medics. This can be modified by turning a depth control on the tip of the pen-like device (when on or off) to give a continuous change in depth of increments of 0.1mm or less. The use of a proprietary erythema reducing glide medium on the skin is recommended during the needling treatment.

The speed of the Derma FNS has three settings which range from 6,000 (setting 1) to 8,000 (setting 3) RPM; this is said to help with effective gliding of the needle head. The speed setting can be altered by tapping a button on the hand piece. It claims to produce 1,200 micro holes per second. The supplier notes also that the hand piece is made from a metal alloy, and not plastic, making it a unique feature, which helps to make it lightweight to operate.

The Derma FNS comes with a 2 year warranty and a 10,000 hours warranty on the motor. Anyone wishing to purchase the device will need to be certified by SkinMed Ltd before they can be sold a machine. They provide training at multiple venues with free and paid for options available depending on location and whether you are existing clients or not. Full marketing support is also provided.

The cost of a Derma FNS ranges from free to £1,000 (ex VAT); this includes a starter pack of perioperative products and glide medium, plus a box of 30 needle heads. A 'lease for free' option is available to existing Enerpeel protocol users. Needle heads are available direct from SkinMed Ltd or through Cosmedic Pharmacy.

SkinMed Ltd have also completed and have current research and clinical trials underway by dermatologists and surgeons using the Derma FNS on acne scarring, hypertrophic scars, operation scars (caesarean and breast augmentation), stretch marks, as well as comparing devices and rollers post-accident and injury for insurance claim treatments. They have three other pens in trials which have a number of unique features, currently undisclosed, which they expect to launch through 2014 and 2015.

For more information, please visit www.dermafns.co.uk.

Dermapen 3MD

Dermapen™ claims the mantle as being the original device that started this revolution for automated pen-like devices in the needling world. As such they claim to have moved on to their next generation technology (from Dermapen 1 and 2), with the third iteration of their device; whereas they believe that their competitors are still marketing their first generation systems or have just chosen to produce an OEM version of an existing device.

The Dermapen devices are manufactured in South Korea in an ISO 13485 certified factory, on behalf of Equipmed of Australia who own all the tooling and have control over the design, specifications and quality control. The Dermapen needles are class IIa certified medical devices. The final units are assembled in Australia. They produce several Dermapen devices which are branded as Personal, Professional (for salon use by aestheticians up to 1mm) and Medical (for use by doctor and nurses only, up to 2.5mm).

The latest Medical Dermapen, launched at this year's AAD meeting, is the 3MD, which Equipmed say has been redesigned and rebuilt from scratch to withstand the rigours that a clinic will put a device under. It also claims to be 30% faster than its predecessor, the Dermapen 2, producing 1,300 micro-holes per second, compared to 990.



The pen-like hand piece (weighing 82 grams) comes with a needle head incorporating one more needle than previous models with 12 needles (33 gauge) which are adjustable at any increment between 0mm and 2.5mm by adjusting a rotating dial on the pen tip. The needle head operates using a very strong spring which pushes the shaft of the needles back into the cartridge with significant force after each insertion of the needles.

Dermapen use their proprietary AOVN™ technology which stands for Advanced Oscillating Vertical Needling; this is based on using a combination of the best frequency, size of needles and speed of the motor to oscillate the needles into the skin, which they claim allows the device to run smoothly across the surface of the skin and not cause tissue tearing. The device operates in a continuous motion at variable speeds, depending on the indication being treated, by using the AOVN technology.

Dermapen offer a variety of proprietary topical serum products which have a hyaluronic acid base to target hydration, pigment stabilisation, skin lightening, scar correction and stretch mark minimisation which are for use during treatment, to avoid dry application.

Dermapen were unable to disclose price or warranty information. Training and marketing support is available. Equipmed UK is in charge of direct sales within the UK & Ireland.

For more information, please visit www.dermapenworld.com.

eDermastamp™ (eDS®™)

The eDermastamp™ or eDS®™ as it is also trademarked is distributed in the UK by AesthetiCare®, supplier of the Genuine Dermaroller™ brand of manual micro-needling devices. eDS® Skin Rejuvenation using the eDermastamp™ won the Gold Award for *Best Product Innovation* at the Aesthetic Awards 2013-2014.

The eDS®™ system combines German medical device electrical mechanisms from (MT.DERM GmbH) with the German Dermaroller GmbH company's 6-stage processed Medizinisch Nadel Technik™ medical-needle technology, found in the Genuine Dermaroller™ devices, to make the needles and needle plate head, which are class IIa CE certified medical devices. Both are produced in ISO 13485 certified factories.

The eDermastamp™ was designed on the basis of an existing micro-pigmentation medical device manufactured by MT. DERM GmbH.

According to the distributor;

"The original medical devices (from MT.DERM) were high specification, had a high level of power and needle speed control and the needle cartridge designs were high quality and prevented any flow back from the cartridge head into the device hand piece when performing procedures. All deemed critical features to Dermaroller GmbH and AesthetiCare® and so collaboration was deemed to be the most efficient manner of delivering the high quality medical device specification product we felt the market required.

The commercial agreement was made between Dermaroller GmbH and MT.DERM GmbH to co-brand the device, i.e. MT.DERM would market an Amiea Med brand and Dermaroller GmbH would market a separate brand, the eDermastamp."

The hand piece, needle cartridge head and micro skin-needles all needed adaptation as the required features for these elements had some different requirements when compared to a micro-pigmentation device."

The eDermastamp system has a separate electronic control unit, which powers the hand piece and motor; this minimises the weight of the hand piece (it weighs 100g) and reduces the risk of overheating in the hand piece itself. Both the stainless steel hand piece and control panel sit on a stainless steel table-top pedestal. Once programmed on the control unit, the hand piece on/off mechanism is operated either by a button on the control unit or by foot pedal.

Currently there is one type of needle cartridge available which is a 6 needle head to a maximum depth of 1.5mm, which includes a tilting mechanism on the needle plate to allow smooth movement over uneven areas of skin. The needle tip plate moves up and down, driven by the oscillation of a tumbler plate within the hand piece, in a continuous operation.

The manufacturers note that this occurs with a full stroke length of up to 3mm meaning that the needle can be fully retracted from the skin, whilst in operation, thus minimising dragging and tissue tearing.

The needle cartridge also has a back flow resistance mechanism to prevent any fluids present during the treatment contaminating the hand piece.

The needle length is adjustable throughout the course of the treatment in increments of 0.1mm by twisting the upper portion of the hand piece. The needle speed is also adjustable via the display on the control unit ranging from 50 to 150 insertions per second, adjusted in increments of 10.



It is recommended that the eDermastamp™ is used with a proprietary glide medium.

The needle cartridge itself contains a 'window' and 'reservoir' allowing the input of proprietary and non-proprietary sterile serums or solutions via a syringe which is then released in a steady flowing stream during treatment.

This is said to be particularly useful when treating around the peri-orbital and peri-oral areas; whereas on the rest of the face direct application of topicals is found to be quicker in practice.

AesthetiCare® recommend using their proprietary Dermaroller™ CIT Solution which is a validated sterile HA solution that is classified as a CE marked Class III sterile medical device. It contains 1% (10mg/ml) pure hyaluronic acid and other skin enhancing ingredients, designed to hydrate and rejuvenate dry and ageing skin.

The eDermastamp is available for £1,250 (+ VAT), with needle cartridges costing £82.50 (+ VAT) for a box of 5.

The Dermaroller™ CIT solution costs £250 (+VAT) for a box of 10 x 5ml vials. AesthetiCare® Esteem Club discounts apply and special terms and bundle offers are regularly announced.

The device comes with a 2 year warranty with training provided free of charge upon purchase and full marketing support as approved providers.

AesthetiCare® told me that the eDS® II and associated products are in development with further announcements being made in Q3/4 2014. These will incorporate enhancements based on clinical user feedback and on-going medical engineering and design development.

Currently the collaboration between the two companies, Dermaroller and MT.DERM, means that the devices and the needle cartridges marketed by the two companies are the same but differently branded.

For more information, please visit www.genuinedermaroller.co.uk

Comparison Chart

To make it easier to compare some of the key features of the automated needling devices reviewed, please click on the image to see a handy comparison chart (in a PDF).

Comparison Chart - Key Features of Automated Medical Skin Needling Devices

Manufacturer/ Distributor	Country of Manufacture	Design/ Protection	Device CE Marked/ Class/ Approval/ Lic	Wax	Needle Material	Needle Configuration	Needle Material	Needle Length/ Diameter	Needle Material	Can attach to Syringe	Adjustability/ Manual	Feed of Wax/ Paste	Can handling be automatic	Needle Block/ Protection	Warranty	Cost per Vial
Active Medical Review																
MT DERM (Dermaroller) & AesthetiCare (AesthetiCare)	Germany (CE)	Adaptation of standard technology using a special design	Yes - Class for Medical CE/Marked CE/II Approved for digital skin needling	Plastic (PC)	Cartridge	10 needles fixed in cartridge	10 needles fixed in cartridge	1.5mm x 0.25mm	10 needles fixed in cartridge	Yes by adjusting wax amount	Yes, response automatic	Feed of wax on piston	Can handle automatic in its handling in the mechanism	Yes	2 years	Device CE 2009 Medical device and as a series of 50 range from CE 01 to CE 05 (100 needles CE 01 to CE 05) (100 needles CE 01 to CE 05)
DermaDerm																
DermaDerm (DermaDerm)	Italy (CE)	Designed and approved for use	Yes - Medical Class I Certified CE/II Approved for digital skin needling	Plastic (PC)	Cartridge	10 needles fixed in cartridge	10 needles fixed in cartridge	1.5mm x 0.25mm	10 needles fixed in cartridge	Yes by adjusting wax amount	Yes, response automatic	Feed of wax on piston	Can handle automatic in its handling in the mechanism	Yes	2 years	Device CE 2009 Medical device and as a series of 50 range from CE 01 to CE 05 (100 needles CE 01 to CE 05)
Normal Final Professional Needling Systems																
DermaDerm (DermaDerm)	Italy (CE)	Designed and approved for use	Yes - Medical Class I Certified CE/II Approved for digital skin needling	Plastic (PC)	Cartridge	10 needles fixed in cartridge	10 needles fixed in cartridge	1.5mm x 0.25mm	10 needles fixed in cartridge	Yes by adjusting wax amount	Yes, response automatic	Feed of wax on piston	Can handle automatic in its handling in the mechanism	Yes	2 years	Device CE 2009 Medical device and as a series of 50 range from CE 01 to CE 05 (100 needles CE 01 to CE 05)
DermaDerm 360																
DermaDerm (DermaDerm)	Italy (CE)	Designed and approved for use	Yes - Medical Class I Certified CE/II Approved for digital skin needling	Plastic (PC)	Cartridge	10 needles fixed in cartridge	10 needles fixed in cartridge	1.5mm x 0.25mm	10 needles fixed in cartridge	Yes by adjusting wax amount	Yes, response automatic	Feed of wax on piston	Can handle automatic in its handling in the mechanism	Yes	2 years	Device CE 2009 Medical device and as a series of 50 range from CE 01 to CE 05 (100 needles CE 01 to CE 05)
DermaDerm 360																
DermaDerm (DermaDerm)	Italy (CE)	Designed and approved for use	Yes - Medical Class I Certified CE/II Approved for digital skin needling	Plastic (PC)	Cartridge	10 needles fixed in cartridge	10 needles fixed in cartridge	1.5mm x 0.25mm	10 needles fixed in cartridge	Yes by adjusting wax amount	Yes, response automatic	Feed of wax on piston	Can handle automatic in its handling in the mechanism	Yes	2 years	Device CE 2009 Medical device and as a series of 50 range from CE 01 to CE 05 (100 needles CE 01 to CE 05)



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What Users Say

Many would agree that it doesn't matter what you're embarking on purchasing, there is nothing like some first-hand reviews from those who have been there before you and have experience of the product or service. Thus, here is a selection of thoughts which have been passed on to me as I researched this sector from genuine, UK based aesthetic practitioners actively using many of the automated needling devices currently available.

Automated Versus Roller

A Cosmetic Doctor from Bournemouth told me;

"We were asked by AesthetiCare® to do a split-face study on the use of the eDS system vs Genuine Dermaroller last year. The results showed:

1. *eDS is much more comfortable for the patient*
2. *Post treatment erythema was less on eDS side*
3. *Post treatment marks on the skin was less with eDS*
4. *Patient satisfaction was much higher with eDS*
5. *9 months post treatment there was equal benefits seen to both sides of the face.*

The advantage of the eDS system is being able to vary the depth of the needle which is very important in bony or thin areas of the face."

Nikki Zanna, RGN & NIP, Owner of Halo Aesthetics told me;

"I switched to the eDS about 6 months ago having used the Dermaroller for a few years. I mainly use it for sun damage, fine lines and wrinkles, elastosis etc., but also for scarring (acne scarring, surgical scars, trauma scars etc). I have found that the eDS is significantly less painful than the Dermaroller, however the 'downtime' for eDS is slightly longer (seems to cause more erythema). The results I see for scarring are better with the eDS. I find the eDS is much more flexible due to the variable needle depth/speed meaning that very delicate areas (e.g., eye lids, peri-orbital lines, peri-oral area etc.) can be treated effectively. I have seen good results with both treatments but predominantly choose eDS as clients tolerate the treatment much better."

A London based Cosmetic Doctor told me;

*"I have been using a dermaroller for more than 5 years and **Dermapen** for more than a year now The reason why I decided to add Dermapen to my practice is because it is more specific in difficult to access areas, such as the infra-nasal or infra-orbital area. I've also used it on years old striae with a good degree of patient satisfaction. In my experience, I have found less discomfort reported by the patient, and better clinical results than with a dermaroller."*

A West Country based Cosmetic Doctor told me;

*"I have started using the **Derma FNS** with excellent results. The treatment is better tolerated by patients and much more intensive (than Dermaroller). Erythema can last 2-3 days at least. The results with hypertrophic scarring are exceptional and for photo-ageing and fine lines the results after 3-4 treatments are as good as ablative treatments."*

Tissue Tearing and Device Dragging

Dr. Fab Equizi, Owner of The Lip Doctor Ltd told me;

*"Dragging is inevitable beyond needle depths of 1.5mm with electric micro-needling devices, more so with **Derma FNS** as opposed to **Dermapen 2**, but this is because I don't believe Dermapen 2 had the power to punch the needles in beyond 1.5mm. Derma FNS has an uprated motor so for a specified depth it is punching deeper than Dermapen. For example, I have to turn Derma FNS down to 0.8mm on the forehead which gives the same clinical endpoints as 1.5mm on Dermapen 2."*

A Cosmetic Doctor from Edinburgh told me;

*"I personally prefer the eDS I find with a high speed and plenty of serum or PRP it doesn't drag. My colleague prefers the **Dermapen** and I use the eDS. The only negative for the EDS is the gauge does not have depths on it so you have to count up or down by 0.1 to know the height of your needle."*

Nikki Zanna, RGN & NIP, Owner of Halo Aesthetics told me;

"The eDS only goes up to a maximum needle depth of 1.5mm which may be why there isn't so much 'dragging' with this device."

Conclusion

To many who have been using dermarollers for a number of years, the concept of automated skin needling is just an evolution from a manual to an electronically controlled option. It takes away some of the 'elbow grease' needed to perform traditional dermaroller treatments, whilst also making it a less macabre treatment for the client.

The basic principles of the needling are just the same. To others, perhaps as they have listened to many of the marketing pitches from the various companies, it is a magic wand which will allow them to treat a multitude of indications from scarring and stretch marks to lines, wrinkles and sun damage.

As with a lot of 'new' concepts in aesthetics, the theoretical notion sounds great but the studies, evidence and protocols are missing and many clinicians find themselves effectively trialling and dare I say 'dabbling' with treatment combinations including needling + topicals + PRP therapy as a means of making automated skin needling work to satisfactory results for them and their clients.

Without significant guidance it's all too easy for everyone to jump on the band wagon; let's face it compared to other capital investments, such as lasers, it's a cheap bit of kit, but it's unlikely that it really can effectively be used to treat as many indications as is often marketed. One cosmetic doctor I spoke to expressed his concerns that the marketing of these devices, and their relatively low price-point, was leading to a '*level of indiscriminate use by inexperienced medical practitioners*' who were using it for '*everything and anything*' with no evidence to hand.

Similarly, there is a fear that inexperienced practitioners may actually 'over needle' the skin, by re-passing an area too many times. This is also a worry particularly if we see a trend for ever increasing speeds with these devices, which then try to compete with each other by claiming to punch more and more holes per second. Remember this modality is supposed to be non-ablative and leave epidermal bridges between the holes. If the operator is unable to move the head of the device quickly enough between the motorised needle insertions then this could result in fewer of the neatly spaced micro-holes, with healthy, untouched tissue in between, that is the desired endpoint and more situations where the tissue has been as good as ablated by the needle repeatedly reinserting in the same small area. The availability of cheap Chinese imports, openly sold to the public and therapists online could also pose issues for patient outcomes and safety.

Some may question whether you really need to even invest in these new devices; if you already have a micro-pigmentation machine (and/or technician in-house), you may wish to test if dry tattooing is right for you and your clients (particularly for scarring) before you invest in alternative automated needling devices or whether moving away from traditional dermarollers is required at all to achieve the desirable results and client satisfaction at your practice.

It's true that we need more robust and independent studies, especially looking at the use of automated needling devices for skin rejuvenation, with or without the addition of other agents (topicals, HAs, PRP etc) to firmly evaluate the efficacy of the treatment, as well as determining the best protocols for use. But, will that ever happen? Most likely not.

Similarly, more comparative studies are needed to truly evaluate the differing devices. Many of the systems have been compared directly with dermaroller use but not across platforms. I'm told that early proposals are in place and protocols are being discussed for an independent comparison study of the Dermadart, Derma FNS and eDS. If this comes to fruition it will certainly be a paper worth reading and I for one will be popping the kettle on ready to sit down and read it.

I hope this article has given you an insight into the complexity of what seem on the face of it to be simple devices. Do your research, ask your peers and choose the right device for you and your clients.



Lorna Jackson

Lorna has been Editor of The Consulting Room™, the UK's largest aesthetic information website, for over a decade, since 2003. She has become an industry commentator on a number of different areas related to the aesthetic industry, collating and evaluating statistics, plus researching, investigating and writing feature articles, blogs, newsletters and reports for The Consulting Room™ and various consumer and trade publications, including *Cosmetic News*, *Journal of Aesthetic Nursing*, *Body Language*, *PMFA News*, *Aesthetic Medicine* and *Aesthetic Dentistry Today*. Lorna has also been asked to present at various industry events, including Smart Ideas, BACN and Merz Aesthetics Business Workshops, the FACE Conference and the Clinical, Cosmetic & Reconstructive Expo.



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