Feature Article

The 'Nitty Gritty' of Medical Micro-Needling Derma Rollers
Do you know what you are you really buying?

Medical skin needling, also referred to as collagen induction therapy, percutaneous collagen induction or simply micro-needling is a treatment area which has grown exponentially in the last 5 years.

Aimed at stimulating the body's own collagen and elastin production for the treatment of everything from fine lines and wrinkles to stretch marks, scarring and hair loss, the treatment is performed through the insertion of a series of fine, sharp needles of varying lengths, mounted on a roller device which travel into the epidermis and/or dermis as the roller is moved over the skin's surface.

Skin needling rollers, also referred to as dermarollers (derma is the Greek for skin) are available in needle lengths categorised for clinical, medical, surgical or home use (cosmetic/personal).

In this article, we are not aiming to discuss the treatment methods, the actual effect on the skin structures, or indeed the effectiveness of treatment alone or as an adjunct to topical treatments or similar. As more and more clinicians are embarking on offering this service to their clients, both through in-clinic treatments and with at-home skincare products and home use rollers, so a myriad of devices has been launched to the UK marketplace through a number of wholesalers and distributors. That's not to forget the abundance of online providers of medical needling rollers busy touting their cheap and generic wares from far flung countries in Asia.

So what we really need to know, is the 'nitty gritty' of the difference between the devices, how are they made, what's good, what's bad and what do you, as an aesthetic practitioner need to consider when buying rollers to use on your patients.

With the help of various skin needling device manufacturers and distributors we have put together some of the key things to consider and suggest that this is an article that you really must read; despite its 'book like' nature, I urge you to get a cuppa and keep reading!

Design, Manufacture & Quality

This is the foundation of a micro-needling device, like anything you buy, a poorly designed and made product, using cheap materials will both not do the intended 'job' to the levels that you might expect, but in the worst case scenario could cause harm.

Whilst there is no specific definition of a micro-needle, they are generally fine needles with a shaft diameter of between 0.1mm and 0.25mm. Properly designed micro-needling devices require medical engineering, from the materials used to the number of needles created.

There are currently two main methods of manufacture; grinding and stamping.

Despite their application, micro- needles should in-fact be atraumatic, so a fully validated grinding and construction process is preferred over either a stamping or cutting production in the best quality rollers. Unfortunately we are unable to ascertain the exact needle processes used by each of the individual brands sold to the UK market, however generally it is thought that most needles produced globally are done so by mechanical pressing or stamping, with only a few key brands adopting the grinding method.

Grinding of the needles normally requires the stainless steel to go through a tempering/hardening process to enable each needle to be ground to an incredibly fine point, about 2 - 3 µm tip radius, in order to conserve tissue and minimise "tearing" or ripping of the tissue as they enter and leave it when the device is rolled over the skin.

Needles used in the needle disk system (such as in the DTS/GENOSYS roller) are stamped from metal sheets approximately 0.16 – 0.25mm thick. Essentially these are not needles but better described as spikes like those on a cog. The manufacturer makes the claim that the tip of the spike has a "mosquito" diamond shape that enhances penetration but a counter argument is that the fact that they are stamped and do not go through a secondary hardening and sharpening process means that the points are not considered to be sharp, plus they are also felt to be too close together.

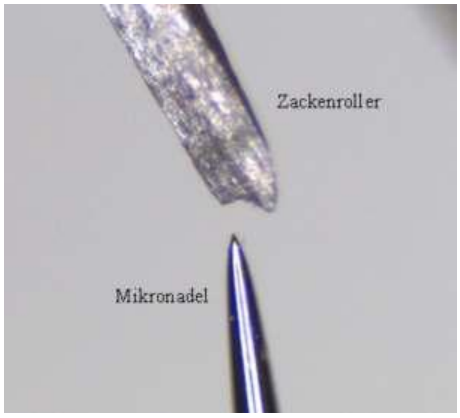
Image of a disk from a Disk Needle Therapy System (DTS) roller

This combined with the number of needles (more information on this below), means that their action on the skin is more traumatic as too much pressure is required in application, rather than the less traumatic performance of a ground micro-needle produced system.

Testing of needle disk systems by Dermaroller GmbH shows that the metal is softer and bends more easily than the steel used for grinding.

Pangaea Laboratories also noted that there have been no trials using this system and that they have concerns over the safety of this device.

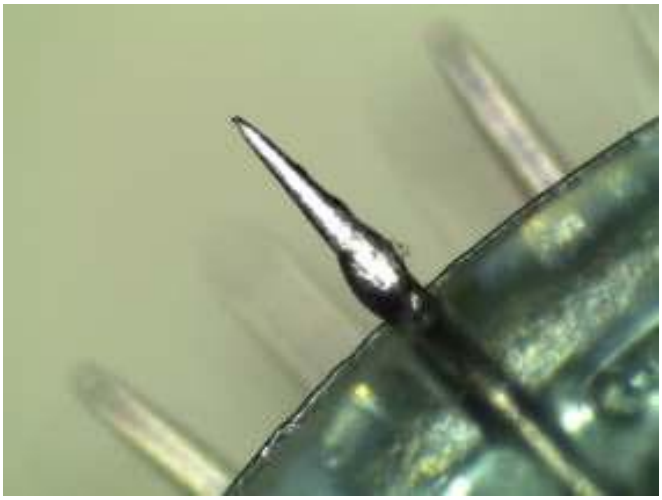
The needle lengths range from 0.8 to 3.0mm. The cutting edges of such needles can measure 0.16mm plus. This is 50 times wider than the 0.003mm tip radius of a ground, precision micro-needle as illustrated in this image.



Stamped versus ground needle

In many of the imported devices from the Far East, the finish tends to be quite rough and so the needles are often coated or plated and/or polished. This gives a smoother, shinier finish but will give a blunting effect to the needles. There is also uncertainty about the materials used, which can include copper and nickel which is used to avoid corrosion.

Most needles used in the wide range of generic rollers produced in China and India are more like industrial pins than needles. See example images below, for typical examples of rollers manufactured in China and India which clearly show irregularities in the needle shafts. These images show a brand from India called DERMAL ROLLER.



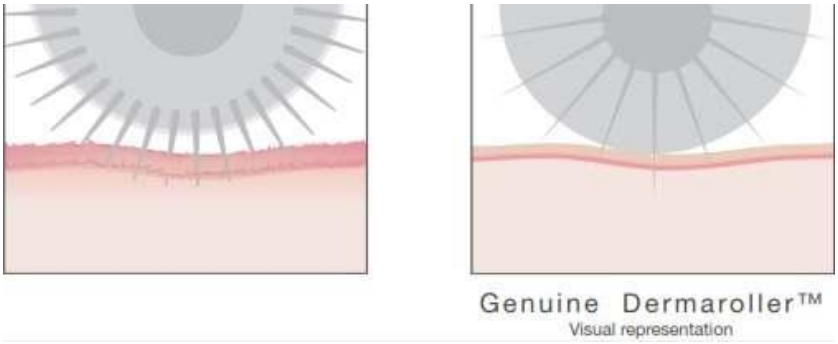
Number of Needles

Contrary to popular belief, having a greater number of needles in a medical skin roller is not beneficial. Having more needles actually requires a greater force to be applied to penetrate the skin; meaning the procedure will be more painful and/or proper needle penetration will be difficult to achieve. It also means that there are a greater number of needles trying to enter and exit the skin at any one time which increases the risk of tearing or shearing of the skin tissues. The main dermaroller brands available on the market do display a variety of different needle configurations but popular layouts include 192 needles, those manufactured from disks tend to have more.

It is also critical that every needle is the same length; a lack of uniformity in the length of the needles could lead to an inconsistency in the penetration and a reduction in the efficacy of the treatment. Assessment of a variety of rollers by Dermaroller GmbH has shown that needle length is not always consistent.

Angle of Needles

The optimum angle to have between each needle on a micro-needling device is between 15 and 20 degrees (for example, the Genuine Dermaroller™ brand has an angle of 20 degrees and the DTS/GENOSYS device declares an angle of 6 degrees on their website). At the optimum angle range, minimum penetration force is required as only one needle will be entering the skin at any one time, as shown in the image below.



The picture on the left hand side is a visual representation of a roller with a larger number of needles and consequently with a lower angle of separation between the needles. This angle will require greater force to be applied in order to get all of the needles into the skin. So essentially the greater the angle between the needles and the fewer there are (within reason) the better, as this requires the least pressure to apply treatment and will minimise any potential excessive trauma to the skin.

Materials, Construction & Quality Control

All skin needling devices have similar components; a plastic roller and micro-needles, which depending on the method of manufacture are either glued in place or embedded directly into the plastic roller. The preferred solution would be the embedded option as this method is believed to be more secure, in that there is less chance of the needles becoming loose.

Rollers manufactured using the needle disk system separate each of the stamped metal disks with a small disk of plastic.

High quality stainless steel is the appropriate material for micro-medical skin needles – alloying elements of chromium, nickel, molybdenum and titanium. The chromium enables the metal to maintain its scratch and corrosion resistant surface and the molybdenum and titanium increases the hardness of the metal and helps to maintain a cutting edge.

Chromium and nickel are the primary alloys in the majority of corrosion and heat resistant stainless steels. The nickel is required to stabilise the structure and add to the material's strength, it is effectively locked in to the structure of the metal so that in most stainless steels there is virtually no risk of nickel allergy. (Care does need to be taken if a needle is "coated" and assurance that this does not contain nickel should be sought.) The molybdenum adds to the hardness primarily as it increases it's durability under high temperatures which are often required in the tempering/hardening process. When titanium is used as an alloying agent it is typically less than 1% (0.25 - 0.6%) and enhances the effect of the chromium and therefore corrosion resistance of the stainless steel.

This type of steel is ideal for medical instruments as it is strong, easy to sterilise and is resistant to corrosion. In terms of marketing claims, be aware that there is no such thing, from a legal standpoint, as 'medical grade stainless steel'. Various stainless steel 'recipes' have been created and have been used in medical equipment for many years, thus proving their long term safety, but there is no singular steel alloy claimed as medical grade. Any new proprietary formulas must satisfy various standards authorities before being granted a clearance for use in medical applications.

The steel needs to go through a strengthening and tempering process to provide the strength needed to enable them to be ground and processed to the required sharpness. This also means that they stay sharp and are not compromised during the procedure.

Titanium is stronger than some steels and approximately 45% lighter. Due to its biocompatible nature it is used in a range of surgical tools and surgical implants. Often mixed or alloyed with other metals, these alloys are very strong

and tough even at high temperatures. The high cost of the raw materials and their processing make them prohibitive for many applications and industries and also increases the brittle nature of this metal if too much is used. Traders from China often claim that their devices are made from titanium. There is no evidence to prove this and it would seem highly unlikely as the material cost would be far too expensive and very difficult to tool due to breakages. Some products do contain a small percentage of titanium as part of the stainless steel alloy however, but levels do vary.

The plastic roller or barrel are made from a number of differing plastics such as ABS and MABS plastic or resin, with the cheaper Chinese or Indian imported rollers using inferior plastic compounds. Many of the higher quality brands use Lexan®. Lexan is the brand name for polycarbonate sheet and resin in a wide range of grades. Lexan is mainly used in things like space and sports helmets, clear high-performance windshields and aircraft canopies, motor vehicle headlight lenses, and bullet-resistant windows! The Lexan grade of plastic allows for irradiation and other forms of sterilisation without degrading or discolouration so is favoured by leading brands. MABS is widely used in medical and diagnostic products and is also capable of sterilisation by irradiation.

Sterility

The credibility of claims regarding sterility also needs considering and it is wise to understand and be clear about the difference between cleaning, disinfecting and sterilising.

A sterile product is one that is free of viable microorganisms, including spores. The level/dose of the particular process used must be sufficient to eradicate all viable microorganisms and render the item sterile. This should be a validated process in which the known starting bio-burden has been rigorously tested at the process level/dose. The dose would need to also have been tested in the packaging and the format in which it is processed; this is normally done through dose mapping. The packaging seal/closure system around the device also needs to have been tested and validated, as should the claimed shelf life. Once validated, the starting bio-burden, the required dosing throughout the process and the packing configuration should be tested and approved for each batch/lot of production.

There are 4 main methods of sterilisation; irradiation, heat, gas and chemical.

Irradiation

Gamma rays and electronic beam processing are commonly used for the sterilisation of disposable medical equipment such as syringes, needles and cannulas. This should be done at an approved site at a validated dose and process.

Heat

When using heat to sterilise, the most commonly used method is an autoclave. Pressure sterilisation is the chosen method for medical sterilisation of heat resistant devices. For any method of moist heat sterilisation, biological indicators are used to validate and confirm the process. When using biological indicators, samples containing spores of heat-resistant microbes are sterilised alongside a standard load. A colour change in the control indicates the presence of bacteria as does the appearance of cloudiness which indicates light scattering by bacterial cells. Either of these changes is indicative of the fact that the sterilisation process has been ineffective.

Autoclaving can be done on an industrial or clinic scale. Again this process needs to be a validated one, from dosing through the process, to packaging and storage.

Gas

Gas sterilisation can be used for materials and items that are sensitive to higher temperatures or radiation i.e. plastics and electrics. Ethylene Oxide (EO) is a common gas used in this process as it penetrates well, kills all known viruses, bacteria and fungi, including bacterial spores and is compatible with most materials including medical devices, even after repeated applications.

The downsides are its highly flammable nature, levels of toxicity and the fact that it is a carcinogen. Because of this it is normally reserved for heat/gamma sensitive instruments. A typical sterilisation process using EO consists of three stages; pre-conditioning, sterilisation and a period of post-sterilisation aeration to remove all toxic residues. EO is still widely used by medical device manufacturers for larger scale sterilisation.

Chemical

Chemical sterilisation is achieved using chemicals such as Chlorine releasing agents or Peracetic acid. These tend to be corrosive so are limited to materials that can resist such challenges and those that are intended for home use as this the most convenient method in such an environment e.g. baby feeding bottles and equipment. Less corrosive agents such as Gluteraldehyde require special handling and holding environments, they are usually limited to specialist hospital areas.

It should be noted that alcohol is not a sterilant but a disinfectant.

One needs to be careful when considering claims of sterility as it is an absolute status. For example, a claim to maintain sterility during re-use without the product going through a validated resterilisation process would be misleading and false.

Also when looking at the different methods of sterilisation is there one that suits all component parts of a device? Heat and chemicals may not be appropriate as they can damage or change the structure of certain plastics and metals and gamma radiation equipment is not readily available for most clinics! Some rollers do come apart to enable separate processes of sterilisation to be effectively achieved for the various parts but those rollers which are one, fixed unit are normally sold as single-use and advice given in training courses or by distributors to go against this should be avoided.

The dangers of re-using micro-needling devices, even on the same person, without adequate sterilisation or misusing a single use device on multiple people were highlighted by a piece in the Daily Mail (**Chinese women warned over 'potentially lethal' microneedle roller after beauty treatment takes Hong Kong by storm**) which described how beauty salons in Hong Kong were performing micro-needling treatments and using the same device (the MTS Roller) for numerous patients. The salons were not sterilising these devices leading to infections in a number of people having the treatments. Hong Kong's Consumer Council branded the treatment as 'potentially lethal' following a number of complaints. This simply gives the procedure an unnecessary bad dose of PR.

The responsible way to perform these treatments, if the roller cannot be re-cleaned by a validated procedure such as cold sterilisation or autoclaving which would mean that the same roller could be reused on the same patient, is in a clinical setting with a sterile, single use medical device by a suitably qualified, experienced and trained practitioner.

Home use rollers cause other issues with hygiene as many come with an often untested, proprietary sanitising solution, or offer no solution and suggest consumers use baby sterilising solution. The problem with the latter is that the roller has not been tested with baby sterilising products to ensure either proper cleaning or compatibility. It is widely known that baby bottle sterilising solutions use chemicals which are highly corrosive to metals while being gentle on the plastic of the typical baby bottle. It should be noted that home use roller should be specifically designed for that use and not penetrate beyond the epidermis and thus make contact with dermal tissue or blood supply, needles that are longer than 0.2-0.3mm will do this. Devices that are sold for home use greater than this length and make claims for re-sterilisation at home should be avoided

Medical Device Classification & General Product Safety

According to the European Union Medical Devices Directive; *'Medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:*

1. *Diagnosis, prevention, monitoring, treatment or alleviation of disease*
2. *Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap*
3. *Investigation, replacement or modification of the anatomy or of a physiological process*
4. *Control of contraception*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Medical devices are regulated under the provisions of a number of EU directives, covering different categories of medical device. The 4 categories are:

1. Class I = a plaster, a pair of glasses
2. **Class IIa** = disposable contact lenses, syringes, **micro-needling devices**
3. Class IIb = dermal fillers, gastric bands, lasers
4. Class III = breast implants, hip joints

A manufacturer of Class I devices can self certify their compliance to the EU directives. All other classes of device need assessment by an independent third-party organisation known as a notified body. A notified body is a private company regulated by the member states competent authority, in the UK the competent authority is the MHRA.

With the CE marking on a product, the manufacturer declares that the product conforms to the essential requirements of the applicable EU directives. When certified by a notified body, the notified body's number will be

displayed alongside the CE mark. Medical devices have to comply with ‘essential requirements’. They must be safe and must function in a medical-technical way as described in the manufacturer’s ‘intended purpose’.

CE marking is a validated process that documents how a product is manufactured. It also provides batch/lot traceability and ensures consistency across a batch. Having a CE mark should mean that the process of sterilisation and manufacture has been validated by the notified body.

Whilst CE marking is a good starting point when looking for a medical device it is neither a definitive solution nor a guarantee of quality. CE marking should assure sterility of the device and consistency through the manufacturing process but it unfortunately does not necessarily determine how good or effective a device or the method of manufacture is.

The CE mark is designed to give consumers the absolute assurance of medical quality. Ironically, while the principal of one standard for all of Europe is signified by the CE mark, there is regrettably a variance in standards of the various notified bodies. Some are more lax than others. We have seen recently, failures in the monitoring and surveillance by the notified body and competent authorities with the PIP breast implant scandal. Unlike with medicines, notified bodies or certifying bodies are one step removed from the competent authority in a given country. The MHRA conducts periodic audits of notified bodies; it does not conduct its own assessment of data on safety and effectiveness of devices.

Experience has shown that the MHRA essentially takes the position that it has no jurisdiction or control over devices used for ‘cosmetic indications’.

This would not be the case for a medicine, which would be classified as such by its ingredients, mode of action and safety and raises questions over how well the supply of devices into the aesthetics industry is policed and how the reliability of suppliers can be guaranteed.

If we return to the specifics of skin needling, the MHRA have made it clear they have no interest or jurisdiction if the device is used for ‘cosmetic indications’ regardless of the fact that it is attempting to achieve a physiological and anatomical change to the human body and is thus deemed by many to be ‘medical’.

Currently any person can perform a procedure and any device, which does not make a medical claim, can be sold outside of any medical regulatory control. Thus this then falls under **General Product Safety Regulations 2005**, which requires that a producer does not place a product on the market, supply a product or offer or agree to do so for another entity unless the product is a safe product. This level of general regulation is much harder to police and validate.

If we look at the procedure, in-clinic needling requires; surface anaesthesia using a pharmaceutical product, multiple needle penetrations into the dermis, clinical end points including pin point bleeding, a pre-treatment consultation regarding patient suitability and contra-indications and potential management of complications.

The treatment goal is collagen stimulation and regeneration, angiogenesis and extra-cellular matrix regeneration.

Surely a responsible position is that these activities should be carried out in a clinical setting with a medical device and by a suitably qualified, experienced and trained practitioner. We do however have to remember CE marking is only a starting point and is open to, on occasion, fraudulent or misleading claims. For those that do not carry legitimate CE mark medical device classification there is virtually no policing of claims made by manufacturers. Broad technical and methodological claims can be made without verification.

General Product Safety regulation falls under the remit of local authorities and Trading Standards, many argue that it is very questionable as to whether they are appropriate bodies to investigate or monitor these issues.

Examples to justify this point of view would be claims regarding the materials of manufacture, the sterility, the methods of use, e.g., which needle lengths are appropriate for home use/professional use, re-use (with or without validated cleaning and sterilisation processes and proof of product quality maintenance), who can use them, as well as the management of potential adverse events and complications. It’s easy to see that this could well be a task too far for Trading Standards.

Interestingly, as a comparison, according to the Canadian equivalent of our MHRA regulator, Health Canada, dermal rollers make health claims about what their products do, so that places them in the same class as a medical device requiring a license. They do not consider them to be cosmetic. Thus, a roller without a license from them cannot legally be sold.

Brands

Naming conventions and trademarks are also an issue for this area; the word ‘dermaroller’ cannot be trademarked alone as it is deemed to be a generic term to describe the item; as mentioned previously dermaroller equals skinroller which is an exact definition of the item, much like ‘Hoover’ is a trademarked brand but ‘vacuum cleaner’ which describes the item is not.

The German Dermaroller GmbH company claim to be the first to have used the ‘Dermaroller’ name and to have registered the first web domain using the word in 2000, a patent was submitted in Germany in the same year and granted in 2005.

According to them, the name quickly became a descriptive term for the similar devices that soon followed with widespread use on the Internet. In Europe there is a registered Dermaroller trademark combining the word with a logo design, as used on the Dermaroller GmbH packaging. In the UK the trade mark Genuine Dermaroller™ has also been used alongside this to try and differentiate the devices. The Dermaroller company does own a registration of the Dermaroller trademark as a word in the USA but the widespread use of dermaroller as a descriptive term and the high cost of litigation to protect the mark has resulted it in it becoming the ‘Hoover’ of the skin-needling market where the only winners are lawyers lining their pockets with cash. A variety of combinations of brands do exist featuring similar wording like ‘derma roller’, ‘dermal roller’ or ‘dermarollers’ to avoid potential legal confrontations as have happened in the past.

There are now a large number of distributors supplying skin needling rollers 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 brand, we would recommend visiting the associated website and contacting suppliers listed.

DermaPure Pure Roller

The DermaPure Pure Roller is distributed in the UK by DermaPure Ltd, through their Hop Clinic Essentials operation. The rollers are not CE marked. They are marketed on the packaging as ‘*the pure titanium micro roller system*’ and their website claims they use ‘*ultra fine titanium needles*’; however, the use of high levels of titanium within the needles is doubted within the industry and independent testing has shown that the level does not conform with a medically approved stainless steel grade.

The rollers use 200 needles (of 0.07mm diameter) with home use products available from 0.25mm. The supply of longer needle lengths, up to 3mm is to clinics only.

www.purerollers.com

Dermal Roller SR™

Dermal Roller SR™ is manufactured by Prollenium Medical Technologies Inc. who are based in Canada and distributed in the UK by Boston Medical Group Ltd. Their single-use professional rollers have 192 needles and are made from Japanese surgical steel with a nickel percentage of around 1.5%, which the manufacturers claim makes incidents of allergic reaction almost impossible.

Professional use rollers are available in lengths of 0.5mm, 1mm, 1.5mm, 2mm, 2.5mm and 3mm. Training is provided to registered medical professionals and beauty therapists at NVQ level 2 & 3. Home use or cosmetic rollers are also available in lengths 0.2 and 0.3mm to be used in conjunction with a sanitising solution.

The device has courted some controversy in respect of its licensing and registration both in Europe and in Canada. At various points both packaging and instructions for use documentation contained within the packaging had included a CE mark, alongside the number for two notified bodies, SGS and **MED/CERT**, both of whom deny ever issuing a CE mark to any of the companies involved in the production or distribution of the product. When questioned about this, Boston Medical Group said; “as soon as we became aware of this issue, the entire batch was withdrawn although a small amount had already been dispatched. This was a printing error as the CE mark related to an injectable product.” (They also distribute the Revanesse® and Redexis® brands of dermal filler from Prollenium.) Both Boston Medical Group and Prollenium have confirmed that the Dermal Roller SR does not have a CE mark.

Additionally, in Canada, the device had its medical device license withdrawn in September 2010 due to “a lack of assurance of sterility”; therefore it can no longer be sold in Canada. The company’s response is that in order to comply with Health Canada, it would have been necessary for the product to be blister packed sealed. The decision was taken that as 99.9% of sales are generated throughout Europe, Asia and South America where the manufacturer compliance was acceptable in all these regions, it was therefore felt that there was no need to change manufacturing/packing process to satisfy the Canadian market. They also wanted to point out that there has not been even one case of infection or complication associated with this manufacturing process and safety of their clients is their utmost priority.

www.boston-medical-group.co.uk

Environ Roll-CIT™

Often considered as the father of all medical skin needling rollers, due to the invention of the dermaroller concept by Dr Des Fernandes, a South African Plastic Surgeon who conceived the idea originally using a needle stamp in the mid-1990s, the Roll-CIT™ (the abbreviation of Collagen Induction Therapy) is designed to be a reusable device.

However, it is noted in the promotional materials from the manufacturer Environ that they are to be used for the same patient. The roller heads are detachable and are sterilised with a chemical sterilant between uses. The handle can be sterilised by using an autoclave.

Rollers are available for cosmetic use and include an innovative, patent pending, two headed roller (the Body Roll-CIT™) with a needle length of 0.2mm.

Professional use rollers for medical procedures are split into a medical model with needle lengths of 1mm and a surgical model of 3mm. Both of which have supply restricted to doctors and trained medical staff.

www.environ.co.za/products/medical-roll-cit

GENOSYS

Developed in 2008 and originally known as the DTS (Diskneedle Therapy System), it was rebranded as GENOSYS in 2010 and is manufactured in South Korea. It is CE marked through the notified body SGS.

The GENOSYS dermarollers are manufactured using the disk needle system with 9 disks, each housing 60 needles, giving a total of 540 needles. Needle lengths of 0.25mm for personal use and 0.5mm, 1mm and 1.5mm for professional use are available and sold to licensed skin professionals only. A vibrating roller is also available. Expect to pay about £35 per roller.

www.genosys.info

Genuine Dermaroller™

Known as the market leader, Genuine Dermaroller™ makes the claim of being the first micro-needle device to be CE marked as a medical device. It is manufactured in Germany by Dermaroller GmbH using their Medizinish Nadel Technik™ medical-needle technology and distributed in the UK by Aestheticare, a division of Ferndale Pharmaceuticals Ltd. Dermaroller GmbH is **ISO13485** certified for the production of Dermarollers by the notifying body Med/Cert.

Needles in the Genuine Dermaroller are ground from high strength stainless steel. The stainless steel needles go through a 6 stage process to ensure this strength and sharpness is achieved. All medical and home use devices manufactured by them use an inter-self locking system to minimise as much as is technically possible the risk of needles detaching from the roller head. They claim this to be a further advanced technology than glue which is used in other ground micro-needling devices.

The 1.5mm medical roller has 9 needles per row, with 18 rows, making a total of 162 needles in the device. Needle lengths are available for 0.5mm, 1mm, 1.5mm and 2.5mm. The angle between the rows of needles is 20 degrees which is greater than most devices, this is claimed to enhance penetration and minimise surface trauma.

Supply in the UK is restricted to trained and authorised medical aesthetic clinics and practitioners. Home use products are also available and supplied to the public through authorised clinics. Expect to pay around £50 per roller. In-house training is available.

A new addition to the Genuine Dermaroller™ family has also been announced which will be available from January 2013, called the e-Dermastamp™. This CE certified medical device is an electronic micro-needling device using the same Medizinish Nadel Technik™ needle tips.

It consists of a handpiece with single-use tips, motor, keypad control and display which allows the needle length to be precisely adjusted (to a maximum of 1.5mm) and ensures that the speed is fully controllable. The tips also provide a "window" in the tip body to allow skin-enhancing topical serums and products to be infused around and via the micro-medical skin-needles if desired.

www.genuinedermaroller.co.uk

Lotus Roller®

The Lotus Roller® dermaroller is distributed in the UK by White Lotus Antiageing. The roller contains 192 stainless steel needles with a maximum needle length used of 1.5mm, as according to their philosophy of holistic micro-needling there is no need to induce the trauma caused by longer needles. They also have a minimum length of 0.5mm, noting that anything below that length doesn't induce collagen. Their needles are also quoted as 0.3mm in diameter.

In the past White Lotus have claimed in advertising that their roller is CE marked by the notifying body TUV Rhineland in Germany, yet when approached TUV said they do not record the Lotus Roller as a device, although they do certificate the Chinese manufacturer of the product. It is therefore felt that the labelling is not compliant with the CE marking process and certification; however TUV Rhineland are not taking matters further.

In-house training courses are open to beauty therapists with NVQ level 2 and above, those with level 2 must also have 3 years industry experience, as well as acupuncturists and medical professionals.

www.whitelotusantiaging.co.uk

Medik8® Titanium Dermaroller

The Medik8® Titanium Dermaroller is produced by UK based company Pangaea Laboratories who produce the Medik8 brand and is distributed in the UK by SkinBrands Ltd.

The needles used in the device are engineered and ground in Sweden from a titanium alloyed stainless steel. According to the manufacturer, the level of titanium in the Medik8 roller is deliberately small and precisely controlled (they wouldn't tell me how much as understandably it's a commercial secret). This, they claim, is to ensure that the properties of this stainless steel grade are maintained, resulting in a harder material which can be sharpened to a finer point, as well as a less corrosive material which reduces the amount of microscopic pitting, (especially useful on reusable home use rollers), than normal stainless steel. Controversies over marketing claims for the product such as statements stating '*engineered in Sweden from pure titanium*', and its actual brand name

have led the company to clarify the situation and any misunderstandings by saying; “our needles are not ‘pure’ titanium but made from ‘pure’ titanium (within the stainless steel)”.

The micro-needles are also gold plated to help maintain a clean surface. The roller consists of 24 needles in a row with 8 rows on the device, giving a total of 192 needles in a diamond pattern. It uses three independent fixing mechanisms including gluing, plastic embedding and disk riveting to ensure the needles stay in place.

Needle lengths are available at 0.2mm and 0.3mm for personal use, 0.5mm for clinic use by Beauty Therapists and 1mm, 1.5mm, 2mm and 3mm (the latter two being indicated for use on the body) are for medical use only, although some therapists do qualify to use a 1mm roller according to the distributor. Training is provided free of charge alongside an opening order. Expect to pay approximately £25 per roller.

Pangaea Laboratories gave us exclusive news that they will in fact be launching a newly designed and upgraded skin needling roller in the New Year (2013) under the brand name Medik8 Titanium Skinrölla®. There will also be a special edition for the scalp, for hair loss indications, called Nanogen Titanium Scalpröllа®. Both the medical and home use versions of the Skinrölla will be a CE mark certified medical devices (by a British notified body) along with the cleaning solution for the cosmetic roller. In fact, only the new Skinrölla offers a CE marked sanitising solution for use with the home roller, which is not the case with other proprietary solutions sold. Additionally the device comes with a detachable head design which allows people to buy one handle and refill it with roller heads. Pangaea Laboratories themselves will be certified to be an ISO13485 medical device manufacturer, whereby the production is fully audited and the products are made in ISO certified clean rooms.

Pangaea told us; “the rigorous and painstaking lengths we have gone to over two years to meet standards that are not even a legal requirement are testament to our commitment to safety, the industry and our brand reputation.”

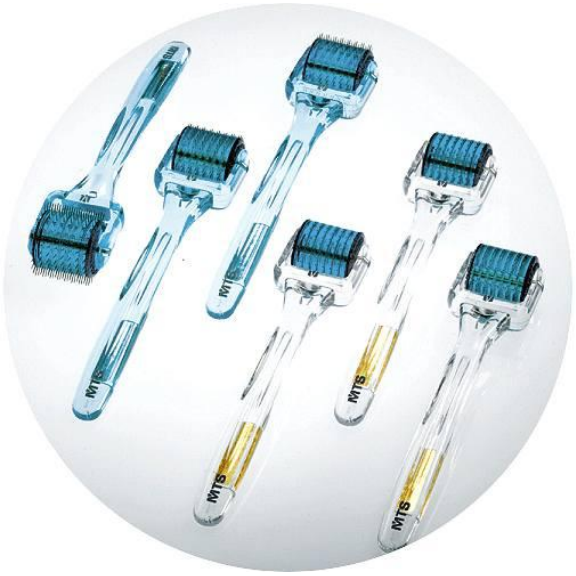
The barrel of the roller is made from the medical grade polycarbonate, Lexan®. This allows them to irradiate the product twice for ultimate sterility guarantees. The needles are again made from the titanium alloyed stainless steel. They use a triple needle lock system to ensure no needles can fall out; this comprises friction fits, medical glue and four rivets to hold the disks together. To test this claim they use a 10kg pull test on random samples which is an industry first.

Interestingly the handles of both devices (home and professional use) have a design-protected finger guard to protect the practitioner against accidental needle sticking. Following market research amongst Dermatologists, Pangaea found this to be a problem, so the guard, which is unobtrusive, effectively prevents practitioners from accidentally pricking themselves with the micro-needles. It has also been designed so that it can easily be put down on a clinical work surface without the needles touching anything. This preserves cleanliness and also prevents any deforming of the needles during the treatment session.

Pangaea announced that by the second quarter of 2013 all rollers they sell will be the new CE marked Skinrölla® product. Prices are not available until launch.

www.medik8.co.uk/roller/stamp-intro.html

MTS Roller™



The Microneedle Therapy System or MTS Roller™ was introduced in 2004 by an American based company called Clinical Resolution Laboratory and is distributed in the UK by Medical Aesthetic Group. The rollers are not CE marked.

The MTS Rollers are equipped with 200 needles (ground in Germany) mounted along a 21.5mm wide roller with 8 needles per horizontal row. The barrel is made from Lexan®. Needles lengths are available in 0.2mm and 0.3mm for personal use and 0.5mm for clinical use and 1mm, 1.5mm and 2.0mm for medical use.

MTS Rollers are sterilized with gamma radiation and sealed in a hermetic pouch and are guaranteed to be 100% contaminant-free upon delivery.

Supply of the full range is available to medical professionals, with those of 0.5mm and under available also to trained therapists. Expect to pay up to £40 per roller.

www.microneedle.com

Conclusion

Well done for sticking with this lengthy article! The subject of medical skin needling rollers, before you even touch on treatment protocols, evidence of effectiveness in terms of collagen induction from various needle lengths, along with their ability to target and treat various indications including those quoted such as acne scarring, stretch marks and hair loss, is indeed a confusing and complex one.

The UK market provides a broad range of products to the aesthetic clinician, all with varying degrees of unique claims and presentation. Trusted brands who can demonstrate quality and safety to you when asked and who provide appropriate and adequate levels of training and support should always be favoured over those with vague or unsubstantiated claims.

The myriad of different types and brands of rollers now available from China and India is mind boggling. One doesn't have to go far on the Internet to find companies who will ship devices over here for professional use, as well as the eye watering amount of shapes, sizes and configurations being sold direct to the public on sites such as eBay which no doubt have caused more harm than good to date. (This could fill another reference book!)

One **website** from China, which shocked me, illustrates the sheer range of products being manufactured by the Chinese and shipped worldwide due to the current inadequacies in the global regulation of these devices. You think we have a problem with too many CE marked Chinese dermal fillers entering Europe – then take a look at this, single, distributor based in China selling micro-needling devices from only $7 each! I would urge all aesthetic practitioners to steer clear of such cheap imports if you want to keep both your clients and your reputation.

Maybe it should fall to the medical aesthetic professionals in the UK to put together a code for the best practice of medical micro-needling treatments, including the preferred safety proven devices? Or maybe more lobbying needs to be done towards the MHRA to make skin needling rollers require a CE mark before sale. Who knows...*British Association of Micro-Needling* anyone?

Lorna Jackson
Lorna has been Editor of The Consulting Room™, the UK's largest aesthetic information website, for over nine years. She has become an industry commentator on a number of different areas related to the aesthetic industry, collating and evaluating statistics and writing feature articles, blogs, newsletters and reports for The Consulting Room™ and various consumer and trade publications, including *Aesthetic Medicine*, *Cosmetic News* and *Aesthetic Dentistry Today.*

I would like to thank Roger Bloxham, Managing Director and Georgina Farquhar, Marketing Executive from Aestheticare Ltd, Elliot Isaacs, Medical Director at Pangaea Laboratories Ltd and Jim O'Mahony, CEO of Boston Medical Group Ltd for their assistance with the more technical aspects of this feature article.