

# THERE IS A WIDESPREAD CONCERN OVER HEALTH HAZARDS ASSOCIATED WITH THE USE OF NEEDLES

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## TRANSDERMAL DELIVERY OF CLOSTRIDIUM BOTULINUM TOXIN TYPE A

*New studies demonstrate that Clostridium Botulinum Toxin Type A can now be transdermally delivered using Mattioli Engineering's newest device, the Transderm Ionto® System.*

By **LINDSAY DONLAN**

The Transderm Ionto® System is the only device on the market FDA cleared as an alternative to injections that is capable of delivering high molecular weight drugs. It is possible to transdermally deliver solutions into the body using the Transderm Ionto® System because this device combines both microdermabrasion and a patented, proprietary technology from Mattioli Engineering called Dermoelectroporation®. First, Microdermabrasion is performed prior to the treatment to exfoliate the stratum corneum for better penetration of the solution. The second step is to use Dermoelectroporation, which utilizes the skins water-based channels to allow ionic drug solutions to penetrate due to controlled "electroporation-like" continuous, reversed polarity, electrical pulses. The vibration feature located on the Transderm Ionto probe minimizes the perception of electrical pulses resulting in a very pleasant treatment, with no pain or bruising normally associated with injections. Performing both microdermabrasion and Dermoelectroporation technology, it is possible to get a delivery rate five times that of a topical solution.

Botulinum toxin is composed of a neurotoxin and is classified immunologically into types A to G, and non-toxic components including hemagglutinin. Type A botulinum toxin has a molecular weight ~150,000 Da. The therapeutic possibilities of botulinum toxin type A are manifold and certainly not yet fully exhausted. The toxin is now being administered not only in focal dystonia and focal spasticity, but also in several other medical fields. Tremors, hyperhidrosis, rhinitis, achalasia,

hemifacial spasm, blepharospasm, anal fissure and aesthetic corrections are only several of the numerous fields where this neurotoxin can be used. The classical method of administering botulinum toxins was by injection, until now. Injections may be the cause of both physical and psychological discomfort for patients with a low tolerance for pain or history of other problems associated with needles. This safe and proven machine uses electric currents and ionic technology to deliver therapeutic ingredients directly into the body.

Mattioli Engineering presented a scientific poster on the Transdermal Delivery of Clostridium Botulinum Toxin Type A at the 2007 American Academy of Dermatology.

### TRANSDERM IONTO SYSTEM:

The Only Needles Free Injection System

The Transderm® Ionto System, using Mattioli Engineering's newest technology – Dermoelectroporation®, is the only transdermal delivery device FDA-cleared as an alternative to injections.

### FDA-CLEARANCE

The intended use of the Transderm® Ionto System is "as a powered drug delivery system that is indicated for the local administration of ionic drug solutions into the body for medical purposes and can be used as an alternative to injections (510k number – k042590)".

### TECHNOLOGY DESCRIPTION

The Transderm® Ionto System, when connected to an Ultrapeel® microdermabrader (microderma-



## PATIENTS REQUIRE NON-INVASIVE, PAIN-FREE ALTERNATIVES

abrasion is used prior to transdermal delivery to exfoliate the stratum corneum to allow better penetration of the ionic drug solution) – along with Dermoelectroporation® technology, allows the principle to enter the dermis by means of low-energy, electrical pulses.

### WHAT IS DERMOELECTROPORATION?

Dermoelectroporation® is a new patented, proprietary technology from Mattioli Engineering. It utilizes the skins water based “channels” to allow ionic drug solutions to penetrate due to controlled “electroporation-like” continuous reversed polarity electrical pulses. Because of this, it is able to control the average pulse value and vary the pulse shape according to the skins specific electrical impedance. So, even though these pulses are similar in shape to the electroporation ones, these are instead completely different from them in value, time duration, and electrical characteristics. The pulse shapes in Dermoelectroporation® operate at a low energy and penetrate even under high skin impedance conditions. These factors allow the transdermal delivery of drugs to occur as in classical iontophoresis, even if the average current value on the patient is zero. This means that there is no change to the pH of the ionic drug solution and that all the ions – both positive and negative – are delivered through the skin. Dermoelectroporation® also enables macromolecules to be transdermally delivered.

Doctors in the US are using the Transderm® Ionto system for:

- Skin Texture Enhancements
- Dermal Fillers
- Cellulite Treatments
- Needles Free Mesotherapy Applications
- Pre Laser Treatments
- Pain Management
- Skin Bio Revitalization Treatments
- Skin Resurfacing

### Features of the Needle Free Injection System

- Capability to transdermally deliver ionic drug solutions

- Capability to transdermally deliver micro and macromolecules (greater than 800,000Dalton)
- No electrolysis of ionic drug solutions or variation in the ionic drug solution pH
- Both positive and negative ions of the drug are transdermally delivered at the same time
- Performing microdermabrasion first promotes the transdermal delivery rate
- Reproducibility of dose delivered
- Patient's perception of electrical pulses is significantly decreased due to the vibration feature
- Non-invasive action
- No trauma from injections

Needles Free Injection System® controls

The Needles free injection system® can control all the parameters concerning:

- Reproducibility on any skin condition
- Optimizing absorption characteristics
- Amount of drug to be delivered
- Time of delivery
- Digitally controlled exfoliation accuracy

### About Mattioli Engineering

Mattioli Engineering is a global, research-driven company dedicated to providing state of the art technology to the medical community; specifically in the field of dermatology, skin care, cosmetic and general surgery. Thanks to Research and Development team, Mattioli Engineering is the leader in the future of medicine.

Since our establishment in 1992, we have installed products all over the world. Mattioli Engineering has been a pioneer and leader in microdermabrasion for more than a decade, introducing the Aesthi Peel, Pepita, Crystal and Ultra Peel II to the United States. Since then Mattioli launched a newest technology – Dermoelectroporation. This technology will change the dermatology practice in the coming years.

Mattioli Engineering is a privately owned medical device company headquartered in McLean, Virginia. ■