

Debiotech named as finalist of the Medical Design Excellence Award competition for its DebioJect™ Intra-Dermal micro-needle injection device.



DebioJect™

Lausanne, Switzerland, April 3, 2014. Debiotech is proud to announce that it has been named as finalist for the prestigious Medical Design Excellence Award for its DebioJect™ intra-dermal micro-needle injection device. The winning Award ceremony will take place on June 11th in New York, at the Jacob K. Javits Convention Center.

The DebioJect™ micro-needle injection device has been developed to address the unmet need for intra-dermal injection of vaccines and other drugs. It has been made to precisely target an injection site, whose depth can be defined between 200 and 650 µm, while securing a leakage free and easy to use procedure. Thanks to a dedicated insertion device, an injection of up to 0.5 ml can be reached in only few seconds in all types of skin.

The DebioJect™ micro-needle is the result of the partnership collaboration with Pr. Göran Stemme at KTH (Royal Institute of Technology, Stockholm) who is one of the original inventors of the specific micro-needle design.

Note: the previously used "NanoJect" trade-name was changed to DebioJect™ to better reflect Debiotech's engagement in intra-dermal drug and vaccine delivery.



“The Medical Design Excellence Award is a prestigious step in our team’s fascinating journey over the last 5 years in the field of intra-dermal injection,” says Frédéric Neftel, MD, President and CEO of DEBIOTECH SA. “The DebioJect™ micro-needle injection device has been conceived to deliver drugs and/or vaccines very precisely, in a new intra-dermal territory which offers numerous opportunities for therapeutic improvements. In the field of Vaccines, numerous studies are suggesting improved immunological responses, which could also be associated with reduced dosage and less pain or needle-phobia. In the field of drugs, it represents an opportunity to reach more specifically the lymphatic tissue and/or potentially modify the specific pharmacokinetics of a drug, such as insulin. We are extremely excited about these new opportunities and believe DebioJect™ represents today’s easiest and most secured way to ensure properly targeted dosage of any given drug in the intra-dermal space”.

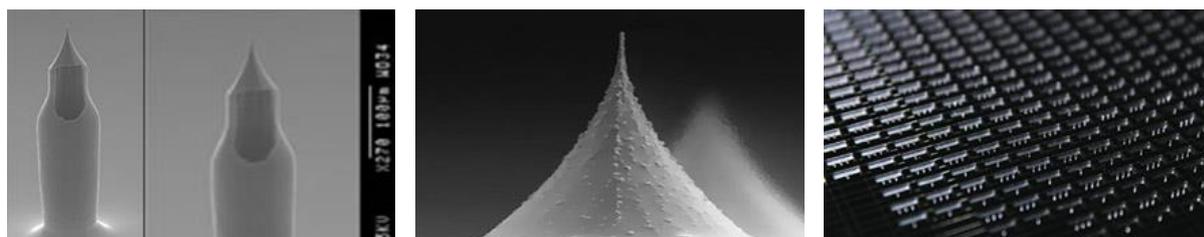
“The DebioJect™ micro-needle injection device is currently used in several clinical studies and has shown excellent injection repeatability and efficacy, with more studies to begin very soon,” says Paul Vescovo, PhD, DebioJect™ Project Leader at DEBIOTECH S.A. “We are now also considering the DebioJect™ micro-needles as a method for sustained drug or vaccine delivery, in which every micro-needle can be loaded with a significant amount of a specific drug (in a dry form or as a gel), where DebioJect™ is applied as a patch onto the skin until the drug is fully released in the intra-dermal space. As such, DebioJect™ represents a unique platform of opportunities for drug and/or vaccine delivery.”

“This micro-needle design has been made to address very specific concerns of conventional micro-needles, which can hardly penetrate the upper layer of the skin without coring (blocking of the channel), and a great difficulty to inject at the apex of the micro-needle, where the pressure on the tissue is very high,” says Dr. Göran Stemme, professor of micro- and nanosystems at KTH and member of the Royal Swedish Academy of Sciences (KVA). “We therefore used the properties of MEMS (Micro-Electro-Mechanical-System) to design micro-needles with a side-hole and a very sharp tip, which ultimately resulted in unique injection characteristics, such as the absence of leakage during injection and a painless, very precisely targeted injection. The collaboration with Debiotech, who played an essential role in the development of the final device, makes it now possible to serve the interest of many people worldwide suffering from life threatening diseases or risks.”

“The vaccine market, in particular, represents a huge opportunity for a product like DebioJect™ micro-needles, with over 1.5 billion dose injections worldwide every year”, says Laurent-Dominique Piveteau, PhD, Chief Operating Officer at DEBIOTECH S.A. “We believe that the DebioJect™ micro-needle device, with its unique and easy way to precisely inject up to 0.5 ml within a few seconds, will make a real difference in that specific market. Further opportunities of using the very particular design of our micro-needles are also very encouraging.”

The DebioJect™ logo, featuring the word "DebioJect" in a bold, sans-serif font. The "Debio" part is in red and the "Ject" part is in black. A red underline is positioned beneath the "Debio" portion. A small "TM" trademark symbol is located to the upper right of the "t" in "Ject".

Debiotech's innovative DebioJect™ micro-needle injection device has been designed to overcome the challenges of classical intradermal delivery techniques, while improving accurate site and dose delivery. Unlike other intradermal delivery systems, DebioJect™ is made of hollow micro-needles with a unique side protected delivery hole. By placing the hole on the side of the needle at a precise depth, the skin can be punctured without coring and without removing any tissue. Because the skin remains intact above the side hole, leakage during injection is prevented and healing is improved. Furthermore, by injecting through the side hole, where the needle does not apply direct pressure on the tissue, liquid can diffuse more easily at a better defined and controlled depth. This enables pain free injections of up to 0.5 ml in only 5 seconds.



Design of the DebioJect™ micro-needles and large scale wafer production (MEMS).

The innovation of DebioJect™ consists in the design of the micro-needles produced with MEMS (Micro-Electro Mechanical Systems) technology. By exactly controlling the position and orientation of the side hole on each micro-needle, it is possible to target a precise intradermal site and control drug or vaccine distribution. At the same time, the tip of the micro-needle can be made extremely sharp and without any protrusion to perfectly penetrate the skin at a 90 degree angle. These characteristics combined with a perpendicular insertion make the **insertion** virtually pain free for the patient.

The MEMS technology used to manufacture the micro-needles make them very strong and provides them with excellent biocompatibility properties. Thanks to the MEMS process, DebioJect™ micro-needles can be manufactured in high volumes, with high precision, and at low cost.

DebioJect™ is available in multiple possible configurations: one or several silicon micro-needles with injection depths ranging from 200 to 650 microns and having one or multiple hollow bores connected to a syringe. While every micro-needle is smaller than a 33G needle, the dimension of the bore is well adapted for delivery of large particles, suspensions, and long peptides.

The DebioJect™ is also easy to use and requires neither any complex technique nor professional healthcare personnel. It is for single-use only, thus avoiding any cross-contamination issues.

DebioJect™ is protected by over 7 patent families.



Different DebioJect™ configurations and comparison with conventional needle.

Debiotech's silicon micro-needles are currently manufactured by the CEA-LETI in Grenoble, France, one of the world's largest organizations for applied research in microelectronics and nanotechnology. It offers extensive facilities for micro- and nanotechnology research, including fabrication lines, 11'000 m² of cleanroom space, and first-class laboratories and equipment. The manufacturing process developed with the CEA-LETI is completely compatible with the major industrial MEMS foundries. Assembly is done in Switzerland, by Mecaplast, an ISO 13485 company active since more than 40 years in plastic injection moulding.

DebioJect™ will be available for clinical investigations under Debiotech's CE Mark. Companies interested should feel free to contact us directly.

More information is available at:

www.debioject.com

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"The Medical Design Excellence Award is based upon descriptive materials submitted to the jurors; the jurors and the competition operators did not verify the accuracy of any submission or of any claims made and did not test the item to which the award was given."