

# Microneedles for drug delivery

## Patent Landscape Analysis – August 2020

*Are microneedles mature enough to replace hypodermic needles?  
Who are the top players and who is best placed in the race against COVID-19?*

### REPORT OUTLINE

- Microneedles for drug delivery
- Patent landscape analysis
- August 2020
- Ref.: KM20006
- PDF >140 slides
- Excel file > 2,450 patent families
- €3,990 for a multi-user license



### REPORT'S KEY FEATURES:

- **IP trends**, including time-evolution of published patents, and countries of patent filings
- Patents' **legal status**
- Ranking of **main patent assignees**
- **Key players' IP position** and **relative strength** of their patent portfolios
- **Summary of the IP related to applications:** Cancer therapy, Cosmetic, Diabetes, Ophthalmic, Pain management and Vaccine.
- **Summary of the IP related to technologies:** Applicators, housing & others, Coated, Hollow, Porous, Soluble, Hydrogel and Solid microneedles.
- **Analysis of patent oppositions (Europe) and review of key patents.**
- **Excel database** containing all patents analyzed in the report, including applications and technologies segmentations

### LINKED REPORTS

- [Circulating Tumor Cells: isolation & detection Patent Landscape](#)
- [Microfluidics Startup Identification](#)
- [Artificial Intelligence in Medical Diagnostics Patent Landscape](#)
- [Other reports](#)

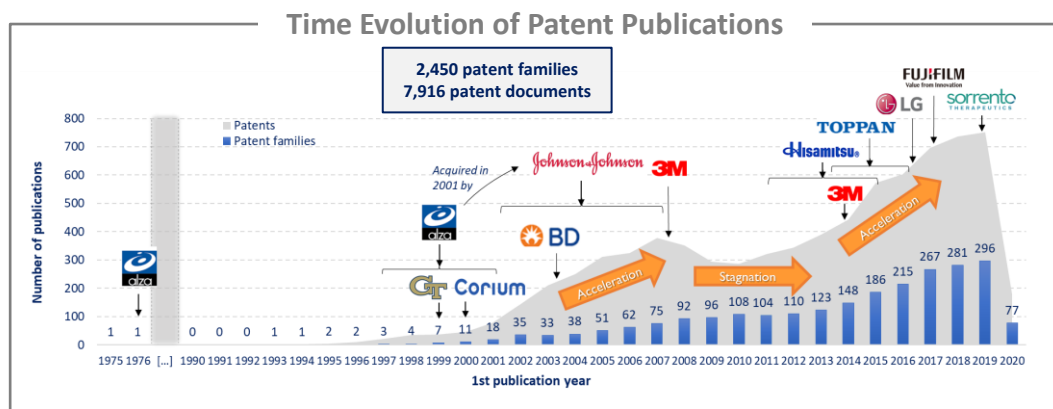
### Microneedles for drug delivery, a new way to deliver drugs through the stratum corneum

The global drug delivery market has been observed to be as large as USD 440.5 billion in 2018. Hypodermic needles are known to be very efficient and they have been used immensely in the delivery of biological macromolecules, insulin, vaccines, etc. However, their invasive nature, stability issues, and non-compliance have always been the issues of concern and led to the requirement of highly skilled medical practitioners for administration.

In this context, microneedles have shown immense potential, since they can easily, painlessly and safely deliver drugs without special storage infrastructure. Hence, they can be self-administered by anybody, thereby eliminating the need for a clinic visit and the assistance of skilled medical practitioners. This serves as an important advantage, especially in the emerging markets. Moreover, microneedles do not create sharp waste, thereby eliminating the problem of discarding needles and hazardous risks. Patients suffering from needle phobia can easily use microneedles. Indeed, according to a study published in Behavioral Neurology, 2014, around 3-4% of the world population faces needle phobia.

Microneedles for drug delivery are attracting interest from big companies and start-ups alike and show immense potential that could transform the global transdermal market. Furthermore, in the actual race to find a COVID-19 vaccine, numerous companies (e.g. Kindeva (3M), Debiotech, Verndari, NanoPass, Bioserentach, Sorrento Therapeutics, Merck, etc.) have developed or shared their microneedle delivery system and promising results have already been released. Other fields, like cosmetic, ophthalmic and diabetes showed important technological progress in the past few years that could disrupt the existing market and replace the current standard drug delivery system.

In this evolving context, it is crucial to understand the intellectual property position and strategy of these different players. Such knowledge can help detect business risks and opportunities, anticipate emerging technologies, and enable strategic decisions to strengthen one's market position.



The analysis of the time evolution of patent publications shows that using microneedles for drug delivery were first filed in the 1971 by ALZA corporation patent (US3964482). However, it was not possible to make such microstructure devices until the 1990s, with the advent of high-precision microelectronics industrial tools. Hence, no patent families were published until 1993 and publications increased from 2001/2002, mainly due to the patenting activity of ALZA Corporation and Becton and Dickinson. A stagnation phase was observed between 2007 and 2012, followed by a second acceleration phase related to the patenting activities of 3M, Toppan Printing and Hisamitsu Pharmaceutical. Patent publications then accelerated from 2015 with the entry of numerous newcomers and the expansion of the cosmetic and soluble microneedles field. The main patent assignees are Asian industrial players that develop an international intellectual property strategy. Asia (CN, JP and KR) and US are the main territories of protection, which appear to be strategic territories for these applicants.

**Analysis by segment**

Microneedles for drug delivery can be applied to different fields and use different technologies (i.e. type of microneedles). Therefore, a technological segmentation was made for this IP landscape, as follows:

**Applications:**

- **Cancer therapy:** microneedle patches present advantages in terms of controllability, easy applicability and predominant synergistic effect.
- **Cosmetic:** microneedles make it possible to enhance skin permeation to deliver cosmeceuticals.
- **Diabetes:** painless delivery of insulin transdermally into the stratum corneum through the miniature pores created by the microneedles.
- **Ophthalmic:** microneedles make it possible to deliver drug formulations to the target ocular tissues with great precision.
- **Pain management:** Injecting a vaccine strategically into the skin through microneedles can produce a significantly more intense immune response.

**Technologies:**

- **Applicators, housing & others:** a key feature is the reliability that is required for applicators for consistent application/penetration of the microneedles.
- **Coated microneedles:** the coated drug formulation of the microneedle dissolves and deposits in the skin.
- **Hollow microneedles:** they make it possible to deliver continuously a large amount of drugs through the inserted hollow needles.
- **Porous microneedles:** they are a single-unit-drug delivery system, containing either a liquid or a dry drug formulation.
- **Soluble microneedles:** they dissolve upon contact with skin interstitial fluid and release the drug over time.
- **Hydrogel microneedles:** Once inserted, hydrogel microneedles rapidly take up interstitial fluid from the tissue, thus inducing the diffusion of the drug.
- **Solid microneedles:** they are creating transient aqueous microchannels through which the drug can be delivered through the stratum corneum.

**Identifying the companies that have recently emerged in the IP landscape**

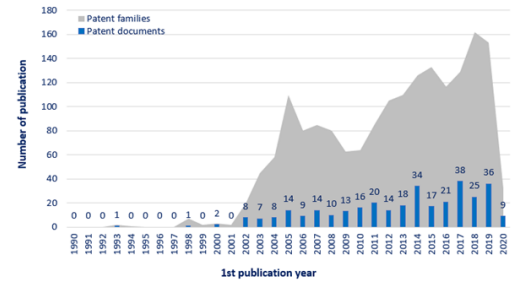
Among the players that have filed patents related to microneedles for drug delivery, **over 40 newcomers** were identified. These companies are established companies and start-up firms developing their first products in the microneedle sector. Numerous IP newcomers are based in Asia and in the US with only a few in Europe. It is possible that one of these innovative companies could become one of the next healthcare unicorns that the big corporations will be tempted to acquire.

**Key patent analysis**

This IP study includes the selection and description of key patents. The key patent analysis includes the legal state of the family for each of the main territories, the number of received citations, the review of the main claim(s), the description of interesting features about the innovation disclosures and relevant figures illustrating how the innovation works. The description also contains information about the fact that the patent family was involved in patent litigation in the USA.

**Segment Analysis**

Time Evolution of Patent Publications



Assignee (Top assignees ranked by strength score)	Player country	No of patent families	No of patent publications	% of top 100's publications	Number of granted patents							Number of pending patents					
					All countries	USA	Europe	Japan	China	Korea	All countries	USA	Europe	China	Korea	WO	
3M	US	26	38	195	89	22	17	7	14	5	28	5	10	2	2	7	2
HISAMITSU PHARMACEUTICAL	JP	19	22	104	51	6	6	14	5	7	24	3	5	2	2	2	2
BECTON DICKINSON	US	15	34	166	66	16	9	5	2	2	5	3	1	1			
CORIUM	US	12	41	98	40	9	7	6	2		41	6	8	4	1	3	1
SORRENTO THERAPEUTICS	US	10	37	125	49	11	8	6	4	3	42	6	4	2	2	2	1
CLEARSIDE BIOMEDICAL	US	11	85	83	22	11	1	3	1	0	43	5	9	3	4	2	
JUVIC	KR	14	88	41	21	5	1	3	2	10	9	1	3	2	2	2	1
YONSEI UNIVERSITY	KR	13	41	46	21	4	2	2	3	10	9	2	2	1	3	1	1
GEORGIA TECH	US	8	28	41	2	2					29	5	6	4	3	1	1
JOHNSON & JOHNSON	US	14	21	161	4	2	1				21	1	1				
UNIVERSITY OF PITTSBURGH	US	6	100	38	8	3					23	6	3	3	1	2	
NANOMED	US	5	71	23	14	5	3	1	2	1							
UNIVERSITY OF NORTH CAROLINA	US	10	48	25							16	4	2	1	3	1	3
LABRADOR DIAGNOSTICS	US	1	100	39	32	5	3	5	1	6	4	1	1				
NITTO	JP	4	67	46	13	0	1	2	1	2	3	3	1				
RAPRAS	KR	5	29	15	7	1	1	1	4								
QUADMEDICINE	KR	5	68	10	7	1	1	1	5	3	3						
CARNEGIE MELLON UNIVERSITY	US	3	100	31	7	2					20	3	3	3	1	2	
VAKKAS	AU	4	40	28	12	6	1				7	3	1				

For each segment, the patent publication timeline and the patent portfolios of main players were analyzed.

**Key Patent Analysis**

<b>Title</b>	Solvent-cast microneedle arrays containing active		
<b>Assignee(s)</b>	Corium International		
<b>1<sup>st</sup> priority date:</b>	16/04/2007	<b>Publication number of a representative member of the family :</b>	WO2008130587
<b>1<sup>st</sup> publication date:</b>	30/10/2008		

**Abstract:**

In an aspect of the invention, an array of microprotrusions is formed by providing a mold with cavities corresponding to the negative of the microprotrusions, casting atop the mold a first solution comprising a biocompatible material and a solvent, removing the solvent, casting a second solution atop the first cast solution, removing the solvent from the second solution, and demolding the resulting array from the mold. The first solution preferably contains an active ingredient.

**Key figures:**

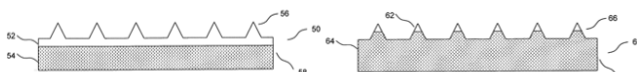


Figure 5A of the patent depicts schematically in cross-section two exemplary microprojection arrays of the invention. In microprojection array 50, there is a base 58 and a plurality of microprojections such as 56. The microprojection array comprises two layers 52 and 54 (shaded). As may be seen, the microprojections themselves fall entirely within layer 52, so that layer 54 does not contain any microprojections.

In microprojection array 60 there is also a plurality of microprojections such as 66. The microprojection array comprises two layers 62 and 64 (shaded). However, in array 60 the layer 62 encompasses only a portion of the microprojections which comprises their tips or distal ends. The layer 64 encompasses the portion of the microprojections not contained in layer 62 and also encompasses the totality of the base 68.

<b>Legal status</b>	<b>Granted</b>	US, AU
	<b>Pending</b>	EP, US
	<b>Received citation count</b>	121
	<b>Number of citing assignees</b>	61

**Claims (US9452280 Granted claims):**

1. A method of making a microstructure array, comprising: dispensing onto a mold having an array of microstructure cavities a formulation comprising a polymer, a therapeutic agent and a solvent, said formulation being dispensed in an amount sufficient to at least partially fill the microstructure cavities, said dispensing being carried out in presence of a gas having a solubility in the formulation or the mold that is greater than the solubility of air in the formulation or the mold; drying the formulation; and demolding from the mold a microstructure array.

**US10238848 (Granted claims):**

1. A microprotrusion array, comprising: an approximately planar base and a plurality of microprotrusions, wherein the microprotrusions comprise at least a first and a second layer arranged roughly parallel to the plane of the planar base, the first and second layers formed of different polymers, the first layer is contained in a distal end of the microprotrusions and comprised of (i) a biodegradable polymer, (ii) one or more components to facilitate biodegradation selected from sugars, sugar alcohols, cyclodextrins and waterswellable polymers, and (iii) an active ingredient, wherein a ratio of weight percent of the biodegradable polymer to weight percent of the one or more components to facilitate biodegradation is in the range of about 6.25:1 to about 1:3.75.

Moreover, the report also includes an **Excel database** with the **>2450 patent families** analyzed in this study. This useful patent database allows for **multi-criteria searches** and includes patent publication numbers, hyperlinks to the original documents, priority dates, titles, abstracts, patent assignees, each patent's current legal status and segmentation to which it belongs.

#### Companies mentioned in this report (non-exhaustive list)

JOHNSON & JOHNSON; 3M; BECTON DICKINSON; HISAMITSU PHARMACEUTICAL; CORIUM; TOPPAN PRINTING; ZEALAND PHARMA; PROCTER & GAMBLE; COSMED PHARMACEUTICAL; FUJIFILM; NANOPASS TECHNOLOGY; BIOSERENTACH; SORRENTO THERAPEUTICS; THERAJECT; KIMBERLY CLARK; SILICON MICRODEVICES; ALTEA; NITTO; RAPHAS; ZOSANO PHARMA; BOEHRINGER INGELHEIM; NISSHA; VAXXAS; NANOMED; CLEARSIDE BIOMEDICAL; LG HOUSEHOLD & HEALTH CARE; LTS LOHMANN THERAPY SYSTEMS

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Patent Landscape Analysis – August 2020

Ref.: KM20006

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