

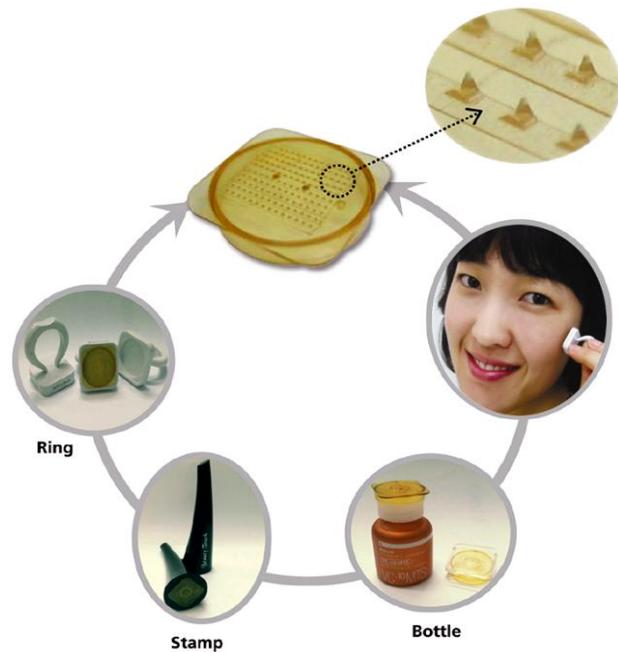
MiTi Systems

Brief Description

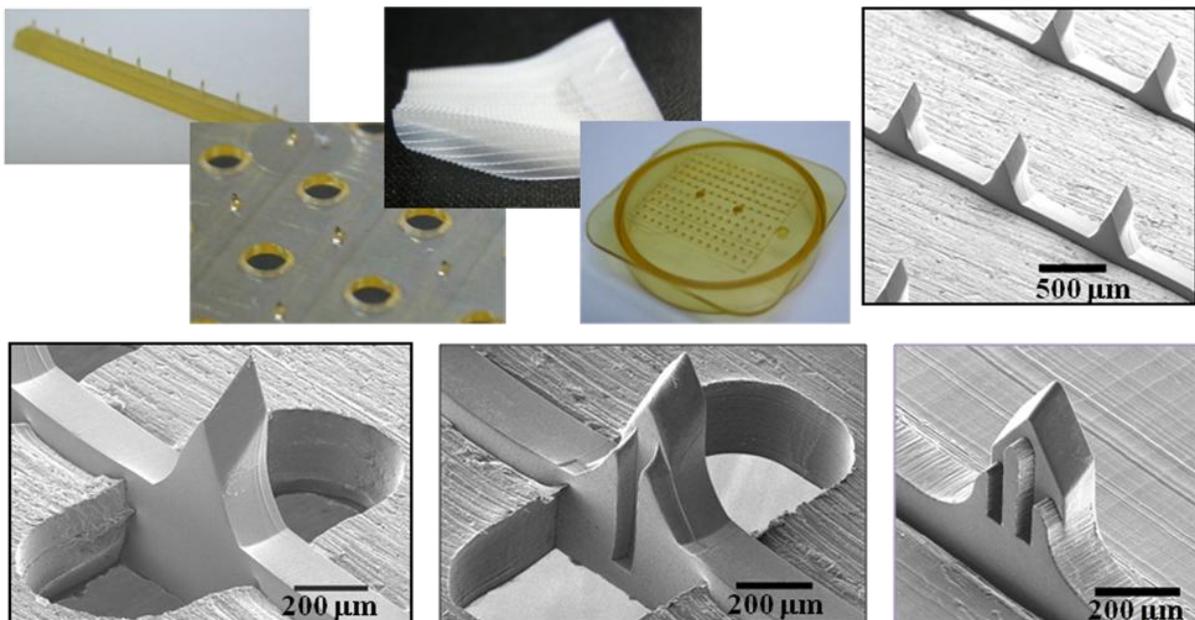
MITI Systems has not only developed various prototypes of microneedles but also commercialized two types of polymer-based microneedle systems, Mi-Roll and Beauty Cap. These items can be used for **skin care, medical treatment, cosmeceutical delivery, and pharmaceutical delivery.**



[Mi-Roll]



[Beauty Cap]



[Various microneedles by MITI Systems]

Technology Overview

Introduction

Stratum Corneum(SC), the outermost thin layer of the skin, is the main barrier preventing cosmeceuticals and pharmaceuticals from being absorbed into skin. Microneedles make very tiny paths in the SC. Therefore, cosmeceuticals and pharmaceuticals can be easily absorbed into the skin or delivered into the body through the paths. The paths are totally recovered in a few hours, so it is safe from infection.

MITI Systems has developed various prototypes of microneedles that were considered impossible to make with traditional manufacturing processes, to bring human to health, comfort, and beauty with a cutting-edge technology of microneedles. We successfully have produced disposable polymer-based microneedle systems that are not only as strong as the previous metal products but also cheaper than them. Now, we are manufacturing Mi-Roll, the polymer microneedle roller, and Beauty Cap, the polymer microneedle cap. These items can be used both for skin care and medical treatment. Mi-Roll and Beauty Cap are appropriate to a large area and a local spot, respectively.

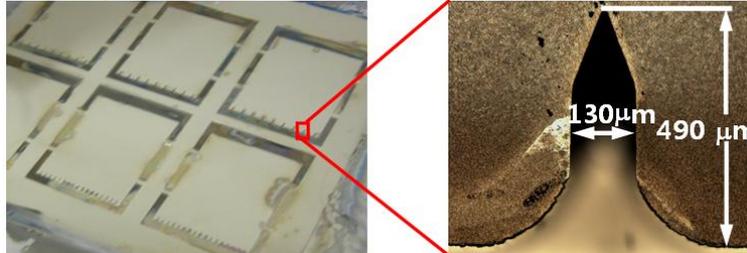
We put our ceaseless effort to reach out to the global market with Mi-Roll and Beauty Cap and to develop next generation products. In the short term, we are developing a microneedle film, which is flexible enough to be used as a beauty mask or a transdermal patch. In the longer term, MITI Systems aims to develop the microneedle drug delivery systems (DDS) and the micro diagnosis system. The microneedle based DDS can deliver various drugs, especially protein drug, gene drug or vaccines through the skin without pain. Through the micro diagnosis system, the process of diagnosis will be possible with only a small fraction of blood and become painless.

If pharmaceuticals are preloaded on a microneedle system, the FDA certification of the system is similar to that of a new drug. To save time and money for commercialization, we have produced microneedle systems as medical/cosmetic devices for now. We also approach the pharmaceutical markets with microneedle systems as devices. We are looking for partners of pharmaceutical/cosmetic companies who intend to apply our products to theirs. If they have their own concepts of microneedle systems, we can also give some solutions about manufacturing processes, even though the systems are preloaded pharmaceuticals.

Technology Platform

1. Mass production technology using polymer molding

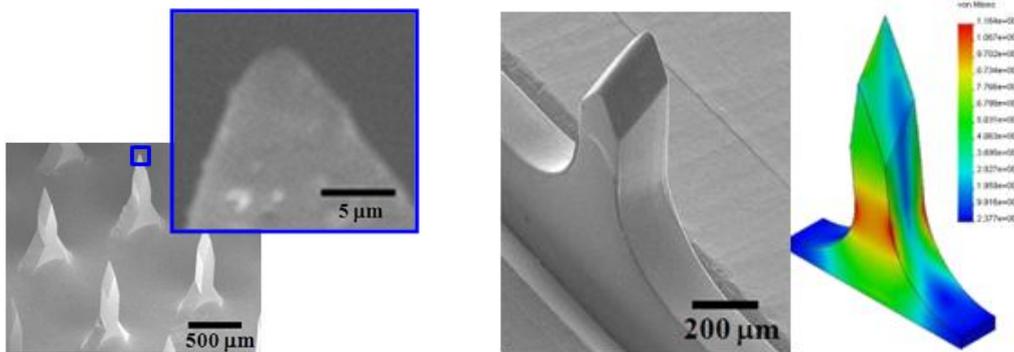
- Mass-production at low cost with injection molding process
- Made of biocompatible polymer
- Micro-stamper fabricated with MEMS process



[Ni Micro-stamper of microneedle]

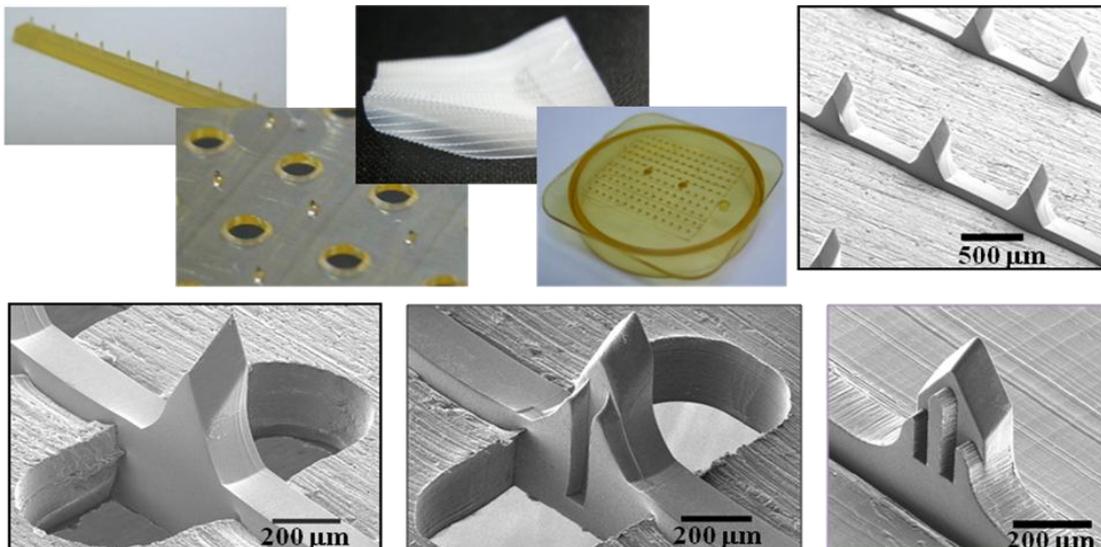
2. 3-dimensional sharp tip & strong shape

- Sharp tip for low insertion force
- Various shaft length for painlessness or effectiveness
- Round base for strength



[SEM images of microneedles]

3. Various types of polymeric microneedles



Supporting Evidence

1. Journal of Drug Targeting, Vol.18, pp.15-20, 2010

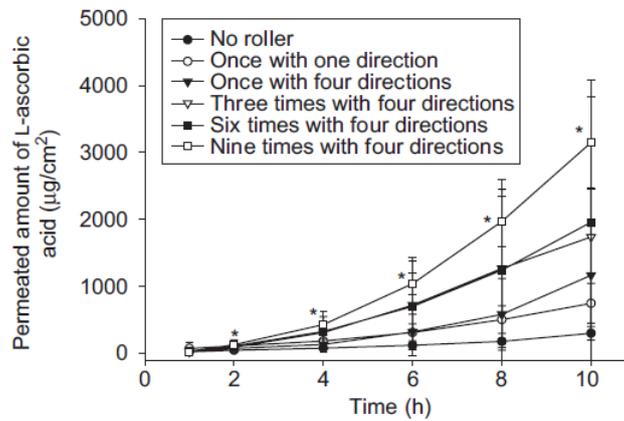


Figure 2. Effects of application modes of the polymer microneedle-roller on the permeation of L-ascorbic acid through the excised rat skin according to the rolling direction and frequency. Mean \pm SD, $n=3$. * $P<0.05$, significant difference compared to the value of L-ascorbic acid alone without pretreatment of the polymer microneedle-roller.

2. International Journal of Pharmaceutics Vol.397, pp.201–205, 2010

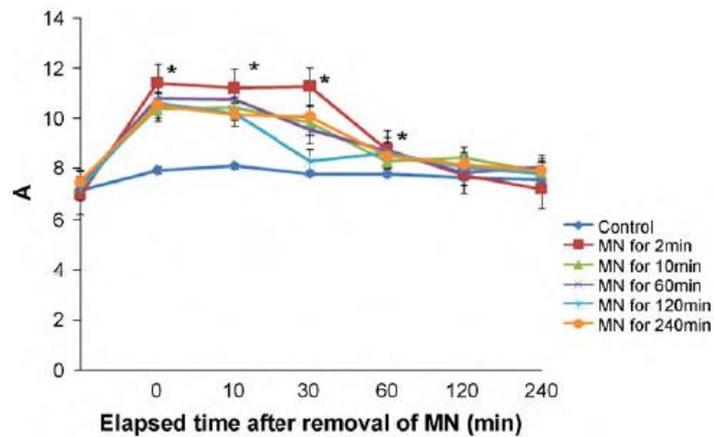


Fig. 4. Skin irritation by reflectance spectrophotometer according to MN application time and elapsed time after removal of MN.

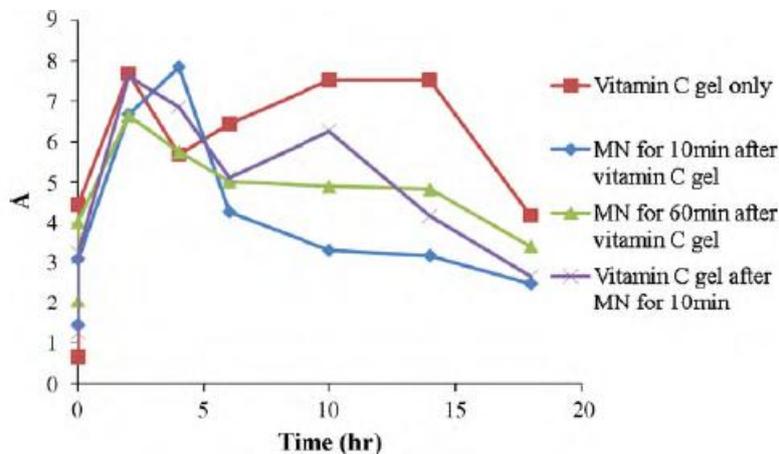


Fig. 5. The mitigating effect on UV-induced skin redness.

3. European Journal of Pharmaceutics and Biopharmaceutics, Vol.69, pp. 1040–1045, 2008

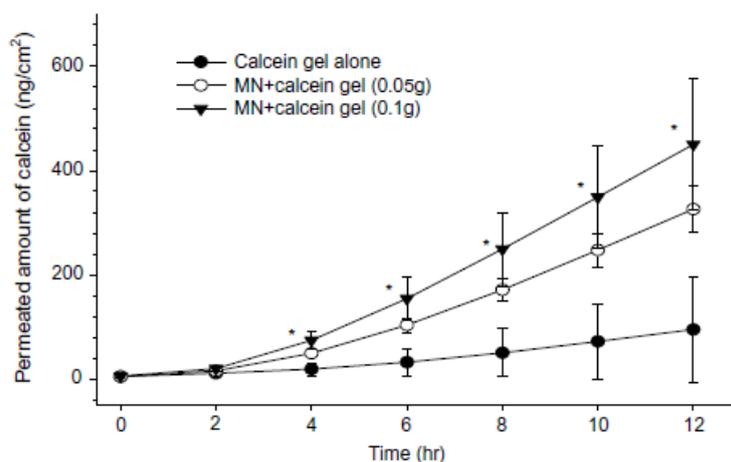


Fig. 3. The permeated calcein from the calcein gel coupled to the PC microneedle according to the amount of calcein gel.

Patent Information

	Title	Patent No./ Application No.
1	Microneedle roller and stamp with replaceable microneedles	KR 2008-0077360, PCT/KR09/1093, US 12/789,527
2	Structure of a micro-needle with channel therein side and manufacturing method thereof	KR 1004014, PCT/KR09/1146, US 12/895,378
3	Container for delivering effective ingredients to the skin using micro-needles	KR 2009-0004589, PCT/KR09/5741, US 12/826,009
4	Flexible microneedle patch system and method for manufacturing the same	KR 2009-0048582, PCT/KR10/1862
5	Microneedle drug delivery system including movable drug-containing capsule	KR 2009-0071572, PCT/KR10/3022, US 12/894,924
6	Lancet block and lancet device	KR 2009-0074550, PCT/KR10/3330, US 12/894,593
7	Microneedle roller-head system	KR 2010-0012619
8	Microneedle cap system enabling adjustment of outflow rate of active substance	KR 2010-0034850, PCT/KR10/3945
9	Hollow type microneedle for easy mass production and manufacturing method thereof	KR 2010-0040746
10	Ring-type microneedle system	KR 2010-0086796