

# Tissue Engineering Functional Human Lips

## CLINICAL NEED

Tissue engineering and regenerative medicine face several barriers preventing translation of *in vitro* technology to the clinical arena: (1) the inability to create composite soft tissue structures that contain striated muscle, skin, and mucosa with a mucocutaneous junction (lip) and (2) difficulty in developing an *in vivo* perfusion system (blood vessels) to supply nutrition for large segments of tissue created *in vitro*. Lack of tissue perfusion is a major limitation of survival of implanted *in vitro* produced complex composite soft tissue implants.

## SOLUTION

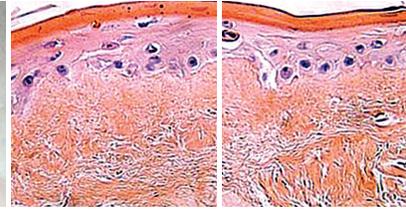
A team of researchers at the University of Michigan led by Dr. Stephen E. Feinberg has developed a tissue engineering approach in conjunction with the surgical technique of prelamination, to create an innervated pre-vascularized prelaminated composite soft tissue microvascular free flap based on the latissimus dorsi muscle for use in functional reconstruction of human lips.

## COMPETITIVE ADVANTAGE

This approach addresses the issues of creating autogenous complex composite soft tissue structures with an adequate perfusion system. In addition, this approach provides a platform technology for fabrication of autogenous mucocutaneous junctions in the body such as the anus, vagina, and eyelid that circumvents the need for immunosuppression required from allotransplants.

## ITP SUPPORT

With the overall objective of using mucocutaneous constructs to restore soft tissue, support from the ITP program will be used for preparatory and follow-through events surrounding IND discussions with the FDA for initiation of a first-in-human clinical trial.



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*“The success gained from the proposed first-in-human Phase I multicenter clinical trial to tissue engineer functional human lips will establish a platform technology that will create a paradigm shift on how the surgeon may reconstruct composite soft tissues that have a mucocutaneous junction, i.e., lips, vagina, eyelids, and anal sphincter. It will also validate a method to fabricate autogenous composite soft tissue grafts that will supplant procedures requiring lifetime immunosuppression.”*

## CLINICAL TRANSLATION PATHWAY

### Publications:

*In Vitro* Development of a Mucocutaneous Junction for Lip Reconstruction. J Oral Maxillofac Surg. 2016.

Tissue engineering of lips and muco-cutaneous junctions: *in vitro* development of tissue engineered constructs of oral mucosa and skin for lip reconstruction. Tissue Eng Part C. 2012.

### Intellectual Property:

US 7,887,829 Mucosal cell composites and methods  
US 8,835,169 Compositions, methods and systems for preparation of a stem cell-enriched cell population

### Regulatory Pathway:

Anticipated: Biologic, IND to enable BLA

### Commercialization Strategy:

In development with the MPWRM Commercialization/Market Needs Core

### Product Launch Strategy:

In development with the MPWRM Commercialization/Market Needs Core

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