

An Advanced Breakthrough Therapy to Treat Foot Ulcer: EpiFix® – a skin substitute clinically proven for effective healing of DFUs and VLU.

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Q1 Why is choosing an advanced therapy, like EpiFix, important to Ontarians?

Millions of people are living with diabetes in Canada. *Diabetes Canada* and *Wounds Canada* are leaders in highlighting key issues that affect Canadians living with diabetes and, more importantly, in guiding Canadians to important treatment remedies for insidious complications of diabetes like Diabetic Foot Ulcers (DFU).

In Ontario, for example, as a direct result of DFUs, there is one amputation every four hours, according to *Diabetes Canada*, and the majority of these amputations are the direct result of foot ulcers that do not heal. More importantly, diabetics are more likely to be hospitalized for limb amputation - almost 25 times more likely than non-diabetics. Furthermore, the complications from DFUs costs the system almost half a billion dollars annually.

Q2 Why EpiFix, a human allograft consisting of dehydrated Human Amnion/Chorion Membrane (dHACM), and how does it help as an advanced wound care therapy?

Human amniotic membrane has been noted in clinical literature for over a century. *In vivo* studies show that the barrier properties of amniotic membrane help reduce scar tissue formation and enhance wound healing, and physicians have been using amniotic membrane for wound repair for years.

Since 2006, MiMedx has optimized its PURION® Process, a proprietary processing methodology that employs aseptic processing techniques in addition to terminal sterilization to produce EpiFix, a skin substitute consisting of dehydrated Human Amnion/Chorion Membrane (dHACM) allograft.

Q3 Can EpiFix be used in Canada?

Since its introduction in the United States, MiMedx has processed and distributed in excess of 1 million tissue allografts for the treatment of wound care. MiMedx has had a license registration in Canada since 2011.

In several peer-reviewed publications MiMedx PURION® Processed dHACM allografts demonstrated recruitment of stem cells, promotion of cell migration, and modulation of stem cell activity *in vitro* and *in vivo* compared to appropriate controls. Numerous published randomized, controlled, clinical trials have demonstrated that the PURION Processed dHACM is an effective therapy for treatment of chronic wounds and to promote healing.

Q4 How does EpiFix compare from an economic standpoint?

According to *Diabetes Canada*, it has been demonstrated that the cost for chronic wound management to the health care system in Canada is high in terms of resource utilization and the negative impact to the quality of life of the patient.

In a complex Markov Model approach used in a recent Ontario study comparing the costs and outcomes of EpiFix with the costs and outcomes associated with standard of Care (SOC) and off-loading, the model found that EpiFix used in DFU treatments resulted in superior wound healing and reduced costs. Moreover, the model showed that costs associated with EpiFix over SOC were more cost effective and most importantly dominated SOC in quality of life years.



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