دائـــــرة الــصــحـــة DEPARTMENT OF HEALTH



Health Technology Review		
Technology Name:	Epifix	
Approvals by International Bodies:	The regulation in the USA allows AMA Products to be marketed without prior approval or clearance from the FDA.	
Company name:	Medlab Medical Equipment Trading LLC	
Agent in UAE:	Motaz Abusamra	
Email:	m.abusamra@medlabuae.com, admin@medlabuae.com	

Short Description	Epifix is one of the Amniotic membrane allograft (AMA) products that is
of the Technology:	used for reducing inflammation and scar tissue formation, as well as for
of the rechnology.	enhancing wound healing of soft tissues

Health Technology Assessment Team Recommendation	Approved	
Summary of Review:		
After reviewing the researches provided by the applicant and the information we gathered around this technology, we came to conclude that the researches have shown improvements in wound healing after using this technology in one controlled study including 22 patients treated with Epifix		
healing after using this technology in one controlled study including 32 patients treated with Epifix,		

however, these are small improvements that were not compared to similar technologies in terms of clinical effectiveness. The National Institute for Health and Care Excellence (NICE) have studied this technology and advices the use of the least costly dressing that meet the required clinical performance characteristics as there is not enough evidence to determine whether advanced dressings are more clinically effective than conventional dressings.

Advantages	Disadvantages	
Safe to use	No comparison to similar technologies	
Slight Improvement to conventional ways of	Expensive as it requires multiple	
dressings	applications along with regular dressings	

## We recommend an **approval of using this technology** with the following conditions:

The approval on using the product in Abu Dhabi.

- 1. Disapprove its inclusion in the insurance coverage.
- 2. Any other documents or information requested regarding the product.
- 3. Compliance with the conditions and regulations of the Department of Health regarding the products marketing and advertising in the health sector.
- 4. Compliance with the relevant laws and standards of the Department of Health.

**Moreover,** DOH has the right to stop the product at any stage if deemed necessary, initial Conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.







**Technology Image** 

## The New Foundation for Tissue Regeneration



## Simple. Effective.

## An Amniotic Membrane Allograft for Chronic and Acute Wound Care

- Delivers Essential Wound Healing Growth Factors
   Enhances Healing
- Enhances Healing
- Reduces Inflammation and Scar Tissue Formation
  Stores at Room Temperature for up to 5 Years
- Available in Multiple Sizes

Ordering Information Customer Service: 866.477.4219 customerservice@mimedx.com

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