



Health Technology Review	
Technology Ref.:	HTA 23073
Technology Name/Version/Model:	Interfyl® Human Connective Tissue Matrix -Interfyl
Approvals by International Bodies:	MoHaP, Saudi FDA, US FDA
Company name:	Celularity
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Short Description of the Technology:	INTERFYL® Human Connective Tissue Matrix is an allogeneic decellularized particulate human placental connective tissue matrix (CTM). It is an extracellular matrix (ECM). It is free of cells, cell debris, DNA & extraneous proteins.
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Health Technology Assessment Team Recommendation:	Approved
Summary of Review:	
Interfyl is a human connective tissue matrix (CTM), Intended use filler for soft tissue augmentation and replacement. Composition of ECM with structural proteins (collagen and elastin), functional biochemicals (fibronectin, laminin and GAGs), which provides structural support while maintaining its elasticity.	
Advantages	Disadvantages
Interfyl promote steady progress toward healing/closure and maintained tissue structure support and elasticity	series of experiments demonstrate significant differences in the response of tenocytes to different CTM preparations.
Do not use Interfyl for intravenous, intra-arterial, intra-ocular, or intrathecal applications.	
Room temperature storage and 10-year shelf life	
Easy to apply Conforms to irregular surfaces	
the product can remnant proteins, cytokines, and residual cell debris are eliminated, this prevents an inflammatory response and faster regeneration of the tissue	
patients will have shorter in-patient hospital stays, and will be able to return to work in shorter time	
The CTM filler derived exclusively from the chorionic plate of the human placenta only.	

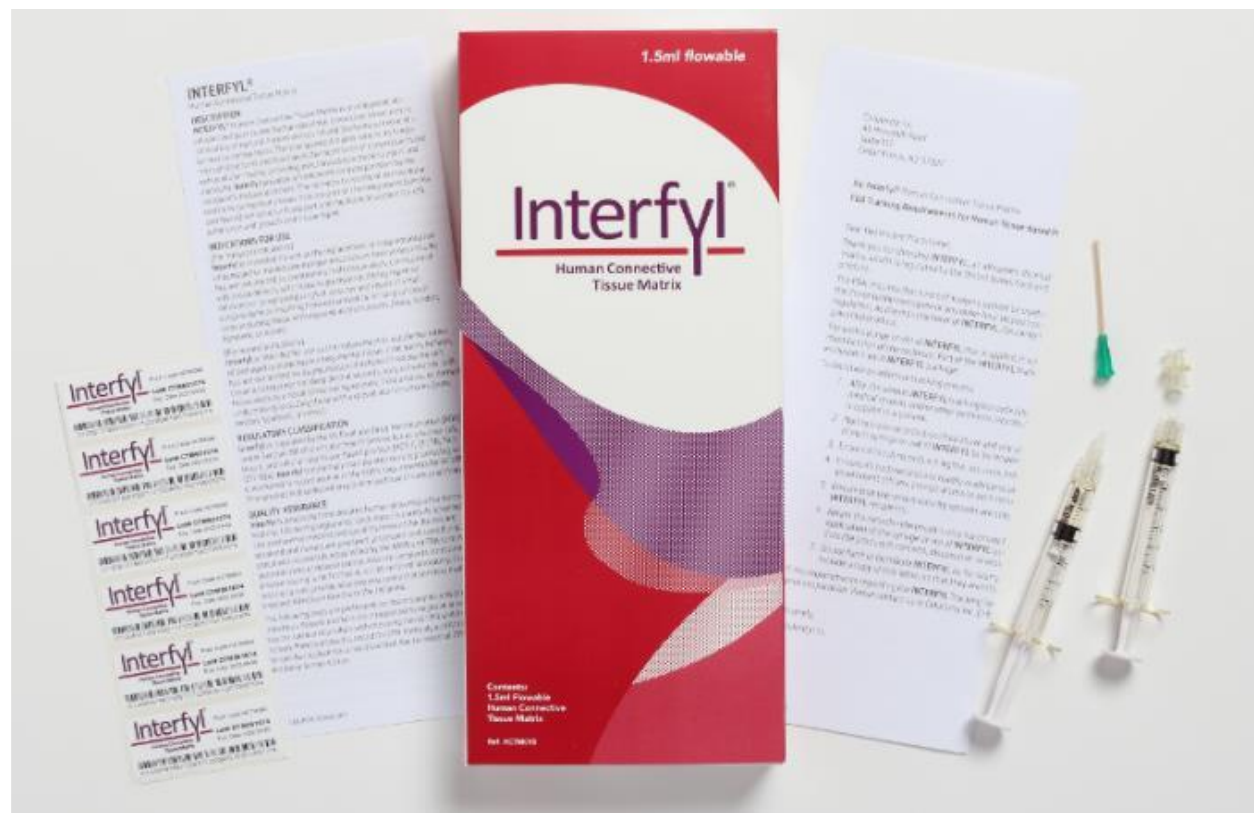


We recommend an **approval using this technology** for Market entry with the following conditions:

1. Interfyl® Human Connective Tissue Matrix -Interfyl.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.

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





Population, setting and intended user for Technology “Interfyl® Human Connective Tissue Matrix -Interfyl”

- **Population/ Intended User:**
 - Suited for a variety of surgical and wound applications where there is a need to replace or supplement damaged or inadequate integumental tissue.
 - Ideal solution for tunneling and satellite wounds
 - **To be performed by:**
 - Surgeons.
 - **Clinical Setting:**
 - Hospitals, special surgery centers.
 - **Condition of use:**
 - augmentation of deficient/inadequate soft tissue and treatment of deep dermal wounds; Tears.
 - surgical wounds; soft tissue voids as a result of tunneling wounds, fistula tracts.
 - dermal undermining including those with exposed vital structures (bone, tendon, ligament, or nerve).
 - Diagnosis with end stage joint arthritis.
 - exhausted all forms of conservative treatment.
 - elected to undergo foot and/or ankle arthrodesis.
 - **Exclusion criteria:**
 - use of post operative bone stimulator.
 - history of active target joint infection in 6 months prior to surgery.
 - malignant neoplasm.
- inadequate blood perfusion