

## HELICOLL® COMPARISON WITH OTHER FDA APPROVED PRIME PRODUCTS

| PRODUCT   | HELICOLL®   | APLIGRAF®<br>/DERMAGRAFT®   | PURAPLY®<br>/PURAPLY® AM   | XWRAP®   | OASIS™  | INTEGRA™<br>/PRIMATRIX  | EPIFIX™<br>/AMNIOFIX™  | CYTAL™  |
|---|---|---|--|--|---|---|--|---|
| Manufacturer  | ENCOLL Corp.  | Organogenesis Inc.  | Organogenesis Inc.   | Applied Biologics  | Smith & Nephew  | Integra<br>LifeSciences   | MiMedX   | Acell   |
| Matrix  | Patented high purity bovine Type-I collagen                       | Human fibroblast - on bovine Type I collagen/polyglactin mesh     | Porcine intestinal cross-linked type-III collagen                          | Amniotic Membrane Derived Allograft with Carcinogenic Elastin <sup>1</sup> | Porcine small intestinal submucosa (SIS) with 10% Carcinogenic Elastin <sup>2</sup> | Collagen with or without glycosaminoglycan and a silicone layer | Dehydrated Human Amnion/Chorion Allograft with 42% Carcinogenic Elastin <sup>1</sup> | Porcine urinary Bladder Xenograft with 9% Carcinogenic Elastin <sup>3</sup> |
| Size/shape  | 5x5 cm to 60x60 cm & Custom sizes                                 | Circular, 8 cm dia, disc / 5 cm x 7.5 cm                          | 1.6 cm disc to 8x16 cm sizes   | 2x2 cm to 4x8 cm sizes   | 3x3.5 cm to 7x20 cm in sizes  | 2x2 cm to 20x25 cm in sizes                                     | 2x2 cm to 4x6 cm in sizes  | 3x3.5 cm to 10x15 cm in sizes   |
| Sterilization   | Terminal sterilization  | Aseptically processed   | Terminal sterilization using gamma that might denature/cross-link collagen | Terminal Sterilization   | Terminal sterilization  | Aseptically processed   | Terminal sterilization   | Terminal sterilization  |
| Shelf life  | 3 years at room temperature                                       | 5 days at room temperature  | Greater than 2 years   | 2 years & Requires Refrigeration   | 2 years at room temperature   | 1 year at room temp.  | 5 years at room temperature  | 2 years at room temperature   |
| Handling  | Rehydrates in saline in 5 min.; easily handled, sutured & stapled | Shipped on a nutrient medium/frozen; difficult to handle; fragile | Rehydrates in saline   | Rehydrates in saline   | Rehydrates in saline; easily sutured & stapled                                      | Can be sutured & stapled; easily handled                        | Can be sutured & stapled; easily handled   | Can be sutured & stapled; easily handled                                    |
| Large presence of immunogenic Elastin/ adverse biomolecules               | No  | No  | Yes (significant amnt of Type-III Collagen)                                | Yes (>15% elastin presence)  | Yes (>15% elastin presence)   | Yes (significant amnt of GAGs)                                  | Yes (>15% elastin presence)  | Yes (>15% elastin presence)   |
| Bioactivity expressed via neo-vascularization & granulation               | Within 4 to 5 days after application (Clinically proven)          | No report indicates lesser than 9 days                            | No such fast infiltration of blood vessels is reported                     | No report indicates lesser than 9 days                                     | No report indicates lesser than 9 days  | No report indicates lesser than 9 days                          | No report indicates lesser than 9 days   | No report indicates lesser than 9 days                                      |
| Applications to Heal  | 1-4 applications  | Up to 5 applications  | variable   | variable   | variable  | variable  | variable   | variable  |
| Control of hyper glycosylation of Diabetic Foot Ulcer Wounds to heal fast | Yes   | No  | No   | No   | No  | No  | No   | No  |
| <b>Total Advantages of the product</b>                                    | <b>9 of 9</b>   | <b>1 of 9</b>   | <b>3 of 9</b>  | <b>2 of 9</b>  | <b>2 of 9</b>   | <b>1 of 9</b>   | <b>3 of 9</b>  | <b>2 of 9</b>   |

Note: Intact tissue-based membrane products (like OASIS™, EPIFIX™, AMNIOFIX™, CYTAL™) naturally contain at least 15% of high immunogenic compound namely Elastin, besides other allergenic biological molecules like glycosaminoglycans and certain types of collagen other than Type-I collagen.

Ref 1. <https://pubmed.ncbi.nlm.nih.gov/16968153/> 2. <https://link.springer.com/article/10.1007/s10029-020-02238-y> 3. <https://pubmed.ncbi.nlm.nih.gov/9852359/>