

## HELICOLL® COMPARISON WITH OTHER FDA APPROVED PRIME PRODUCTS

PRODUCT	HELICOLL®	APLIGRAF® /DERMAGRAFT®	PURAPLY® /PURAPLY® AM	XWRAP®	OASIS™/GRAFIX	INTEGRA™ /PRIMATRIX	EPIFIX™ /AMNIOFIX™	CYTAL™
Manufacturer	ENCOLL Corp.	Organogenesis Inc.	Organogenesis Inc.	Applied Biologics	Smith & Nephew	Integra 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> / Placental membrane with 49% Carcinogenic Elastin <sup>4</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 amt of Type-III Collagen)	Yes ( >15% elastin presence)	Yes ( >15% elastin presence)	Yes (significant amt 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/>

3. <https://pubmed.ncbi.nlm.nih.gov/9852359/>

2. <https://link.springer.com/article/10.1007/s10029-020-02238-y>

4. <http://www.liebertpub.com/doi/10.1089/ten.tea.2011.0738>