Prokera®

A Vision of Modern Healing

Prokera biologic corneal bandages help empower the eye's healing abilities to expedite a return to normal.

Healing Vision. Restoring Life.

Early intervention is critical in eye care. Prokera corneal bandages are designed for treating damaged cornea(s) by creating an environment for regenerative healing.

They are easy-to-use and can be inserted in the office by a trained eye care professional. Because Prokera contains cryopreserved amniotic membrane tissue to promote healing, it excels at restoring a normal and healthy epithelium while minimizing the risk of scar tissue formation. Early intervention with Prokera supports restoration of the cornea's own healing capabilities, reducing inflammation, improving corneal health, and optimizing long-term outcomes.[1-7]

Seeing a Difference

Prokera is the only FDA-cleared cryopreserved amniotic membrane product. It supports the corneal-healing process without harmful side effects.[1,4,6] Our proprietary CryoTek preservation method maintains full biologic components including a key protein complex HC-HA/PTX3, and sturctural integrity equivalent to fresh tissue, which helps rapidly restore the cornea's own healing capabilities.[13,14]

Alternative amniotic membrane solutions that are dehydrated lack crucial biologic components, which risks repeated epithelial defects or erosions, chronic inflammation, scarring, vision loss or pain.[1,8]

The Challenge with Conventional Treatments

Corticosteroids

Increased ocular pressure, cataract formation, and infection risk[1,9]

Eye Drops

Ocular surface changes, inflammation, and fibrosis[10]. May rely on a single molecule to address inflammation in multi-factorial diseases[11,12]

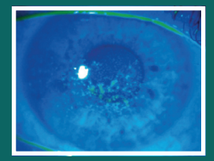
Bandage Contact Lenses

No therapeutic benefits, relies on body's ability to heal itself

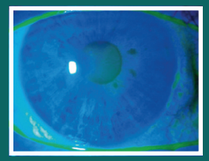
Proven Outcomes

- Improves corneal nerve regeneration and accelerates ocular-surface health recovery[2,3,5]
- Shown to significantly improve both corneal nerve density and sensitivity ($P = 0.015$; $P < 0.001$)[2,*]
- Halts fibrosis, facilitating faster re-epithelialization[1,6]
- Superior outcomes vs bandage contact lens (BCL)[1,†]:
  - 70% of eyes re-epithelialized by day 5 with Prokera Slim vs. only 20% with BCL
  - 90% of eyes achieved absolute corneal clarity by Day 7 with Prokera Slim vs. 0% with BCL

93% of patients with moderate- to-severe dry eye disease reported improvement after one Prokera treatment.[15]

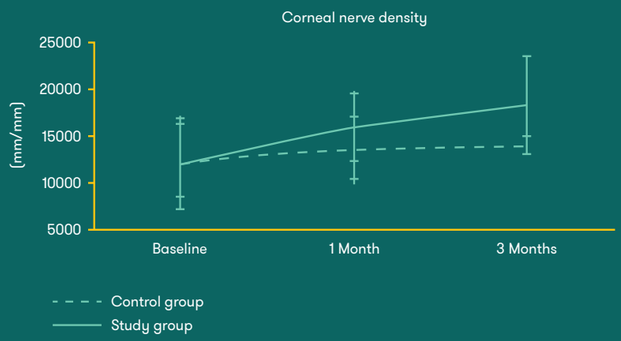


Before Prokera



After Prokera

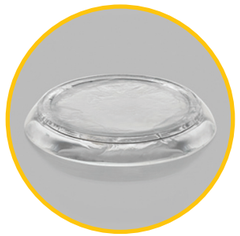
After Prokera photo taken 3 months after treatment. Standard treatment window for Prokera is 3-7 days.



Prolong re-epithelialization and corneal healing[1-3,9,10]

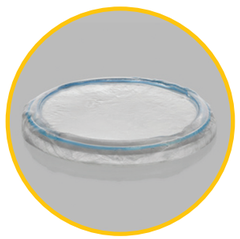
The Right Healing. The Right Product.

We are in a race against time to heal chronic wounds. BioTissue products provide the natural healing properties of human birth tissue to the wound. The BioTissue proprietary CryoTek cryopreservation process is the only tissue processing method shown to produce an allograft comparable to the native tissue.[13-14]



Prokera® Classic

Maintain orbital space with a symblephoron ring for cases where prevention of closure or adhesion is a concern.

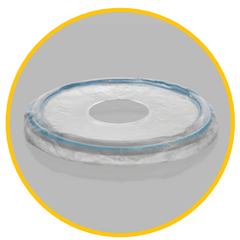


Prokera Slim

Use our ComfortRing™ technology for a lower profile device that contours to the ocular surface to maintain comfort in treatment.

Prokera Plus

Maximize the therapeutic benefit with a double layer of cryopreserved amniotic membrane tissue, for patients who need intensive treatment.



Prokera Clear

Provide your patient with some visual acuity during treatment with a 6mm ClearView™ aperture. This is crucial in monocular needs.

More than 300,000 Prokera Applications

Doctors around the country are using Prokera successfully across a wide range of applications, including moderate-to-severe cases of:

	Indications	ICD-10
Defect	• Corneal ulcer	H16.0
	• Central corneal ulcer	H16.01
	• Corneal ulcer with hypopyon	H16.03
	• Marginal corneal ulcer	H16.04
	• Mycotic corneal ulcer	H16.06
	• Dendritic corneal ulcer	B00.52
Delayed Healing	• Neurotrophic keratoconjunctivitis	H16.23
	• Exposure keratoconjunctivitis	H16.21
	• Punctate keratitis	H16.14
	• Filamentary keratitis	H16.12
Dystrophy	• Epithelial corneal dystrophy	H18.52
	• Recurrent corneal erosions	H18.83
Degeneration	• Band keratopathy	H18.42
	• Nodular corneal degeneration	H18.45
Damage	• Chemical burn	H18.42
	• Thermal burn	H18.45
	• Acid burn	T26.60XA
	• Steven-Johnson Syndrome	L51.1

For more details on how Prokera can help, visit www.BioTissue.com/Prokera.

Integration Made Easy

Prokera can be easily incorporated into any eye care practice to optimize outcomes.

Effective, Easy Treatment

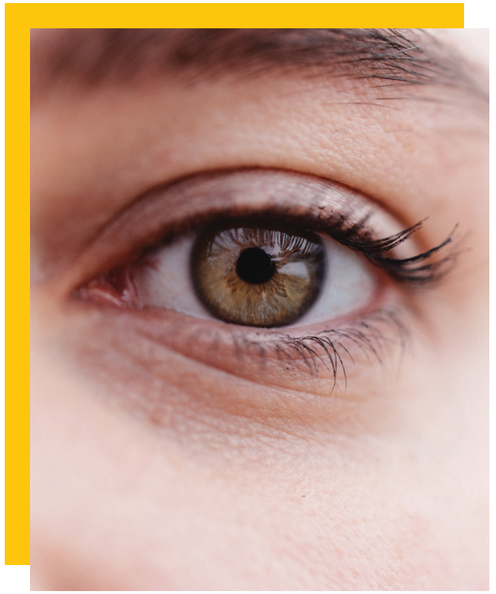
- Can be easily placed during a regular office visit or used with surgical interventions
- May reduce the need for additional visits for slow-or-poor-healing patients

Highly Reimbursed

- Medical device classification ensures high reimbursement
- Average Medicare reimbursement: $1,458
- Minimizes a patient's cost-burden of treatment

Minimal Storage Needs

- Easy-to-use packaging
- Conveniently stored in any on-site refrigerator or freezer



“Before the Prokera I did not have crystal vision. Everything was blurry, had a hue to it, difficulty focusing on things. Now my vision is crystal clear, and I can see things I couldn’t see before. This is incredible. I’m just blown away.”

- Prokera Patient, *Allentown, PA*

References

1. Desai NR. A comparison of cryopreserved amniotic membrane and bandage contact lens in their ability to provide high-quality healing after superficial keractectomy. Rev Ophthalmol. September 2014:1-6.
2. John T, Tighe S, Sheha H, et al. Corneal nerve regeneration after self-retained cryopreserved amniotic membrane in dry eye disease. J Ophthalmol. 2017:6404918 (Epub).
3. McDonald MB, Sheha H, Tighe S, et al. Treatment outcomes in the Dry Eye Amniotic Membrane (DREAM) study. Clin Ophthalmol. 2018;12:677-681.
4. Pachigolla G, Prasher P, Di Pascuale MA, et al. Evaluation of the role of PROKERA in the management of ocular surface and orbital disorders. Eye Contact Lens. 2009;35(4):172-175.
5. Cheng AM, Zhao D, Chen R, et al. Accelerated restoration of ocular surface health in dry eye disease by self-retained cryopreserved amniotic membrane. Ocul Surf. 2016;14(1):56-63.
6. Morkin MI, Hamrah P. Efficacy of self-retained cryopreserved amniotic-membrane for treatment of neuropathic corneal pain. Ocul Surf. 2018;16(1):132-138.
7. Tseng SC. HC-HA/PTX3 purified from amniotic membrane as novel regenerative matrix: Insight into relationship between inflammation and regeneration. Invest Ophthalmol Vis Sci. 2016;57(5):1-8.
8. Rumpakis J. Amniotic membranes—the perfect cover. Rev Ophthalmol. April 2016:49-54.
9. Baudouin C, Irkeç M, Messmer EM, et al. Clinical impact of inflammation in dry eye disease:proceedings of the ODISSEY group meeting. Acta Ophthalmol. 2018;96(2):111-119.
10. Baudouin C , Labbé A, Liang H, Pauly A, Brignole-Baudouin F. Preservatives in eyedrops: the good, the bad and the ugly. Prog Retin Eye Res. 2010;29(4): 312-334.
11. Abidi A, Shukla P, Ahmad A. Lifi tegrast: A novel drug for treatment of dry eye disease. J Pharmacol Pharmacother. 2016;7(4):194-198.
12. Colligris B, Alkozi HA, Pintor J. Recent developments on dry eye disease treatment compounds. Saudi J Ophthalmol. 2014;28(1):19-30.
13. Tan EK, Cooke M, Mandrycky C, et al. Structural and biological comparison of cryopreserved and fresh amniotic membrane tissues. J Biomater Tissue Eng. 2014;(4):379–388.
14. Cooke M, Tan EK, Mandrycky C, et al. Comparison of cryopreserved amniotic membrane and umbilical cord tissue with dehydrated amniotic membrane/chorion tissue. J Wound Care. 2014;23(10):4 65-476.
15. Data on file, BioTissue.

www.biotissue.com
7300 Corporate Center Drive, Suite 700, Miami, FL 33126 | 888.296.8858

BioTissue® Ocular

www.biotissue.com/ocular