

DuraMatrix[®] Suturable Value Analysis Brief

Description of Product:

DuraMatrix Suturable is a white, nonfriable, conformable, resorbable, collagen membrane consisting of highly purified collagen derived from bovine dermis. The product is intended for use as a dura substitute for the repair of dura mater.

Value Proposition:

DuraMatrix Suturable is a third generation of DuraMatrix product designed to include the desired handling characteristics with high conformability. It has a rapid 1 minute hydration time and can be cut in the dry or hydrated state¹. The product utilizes crosslinking technology in order to control the in vivo resorption & degradation profile, control handling characteristics, and enhance mechanical strength¹. Below you will find a summary of the mechanical and in vivo testing completed on the product.

Suture Pull Out Strength¹:

DuraMatrix Suturable shows significantly higher suture pull out strength that permits it to be firmly anchored to surrounding tissue with minimal risk of membrane tear or detachment.

Product	Suture Pull Out Strength
DuraMatrix Suturable	20.40 ± 1.54 N
Durepair	11.67 ± 4.12 N

Implant Resorption and New Collagen Formation²:

The total resorption time, defined as ≤ 5% implant remaining, is approximately 38-40 weeks for DuraMatrix Suturable compared to 20-22 weeks for Durepair. The application of DuraMatrix Suturable appeared to potentially prevent CSF leakage.

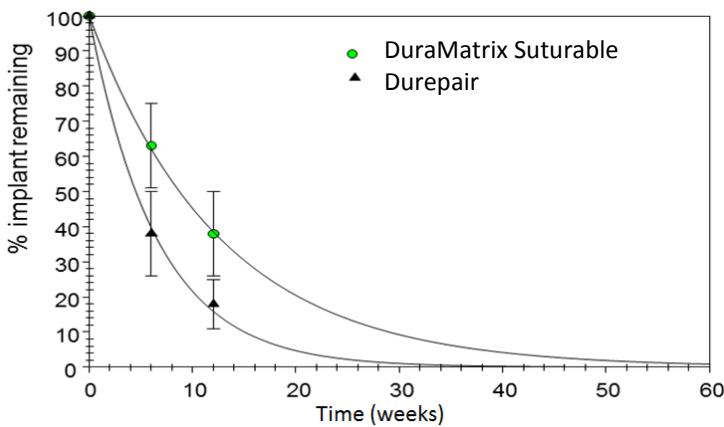


Figure1: Percent Implant Remaining of DuraMatrix Suturable vs. Durepair.

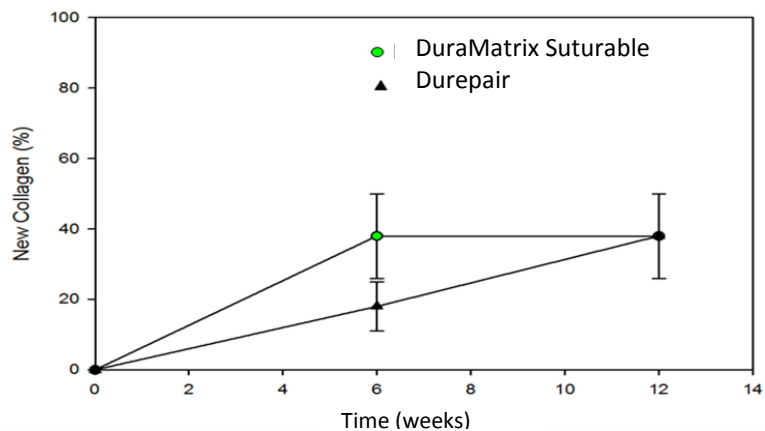


Figure 2. Percent New Collagen Formation of DuraMatrix Suturable and Durepair.



Reconstructive

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Spinal Implants

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area

1: Collagen Matrix Internal Testing

2: In vivo evaluation of resorption in a rabbit duraplasty model. Data on file.