stryker

DuraMatrix® portfolio

Manufactured by Collagen Matrix

History

Since 2003, Stryker has partnered with Collagen Matrix, Inc. to provide our customers with quality products for the restoration of the dura mater.

Collagen Matrix, founded in 1997 by Shu-Tung Li, Ph.D., who has over 40 years of experience in connective tissue research and collagen based implant development, delivers a full line of high quality collagen and mineral based medical devices that support the body's natural ability to regenerate. The Company currently produces finished medical devices in the areas of Dental, Neurosurgical, Spine, Orthopaedic and Nerve Repair Surgery.

DuraMatrix line products are comprised of Type I collagen and intact dermis tissue derived from a bovine source.

DuraMatrix-Onlay PLUS

Collagen dura regeneration matrix
highly conformable and sutureless restoration

DuraMatrix-Onlay PLUS is derived from purified, bovine Achilles tendon. It is intended for use as a dura substitute for the repair of dura mater.

In addition to the thick, spongy texture, this fourth generation DuraMatrix product has a non-porous, collagen layer. This layer helps produce a lower liquid permeability rate compared to a competing dura substitute.[1, 3]

DuraMatrix-Onlay PLUS offers a balanced resorption profile that occurs over approximately 8 weeks.[2, 3]

Liquid permeability (ml/min/cm²)[1,3]

DuraMatrix-Onlay PLUS

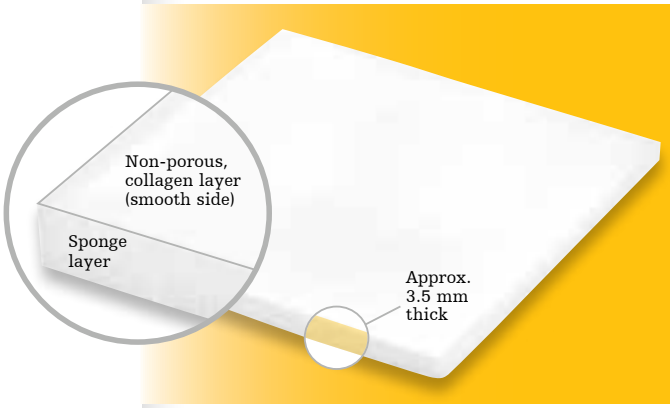
0.011±0.007

Comparison substitute

0.558±0.091

50x[1, 2, 3]

lower liquid permeability rate when compared to a competing dura substitute



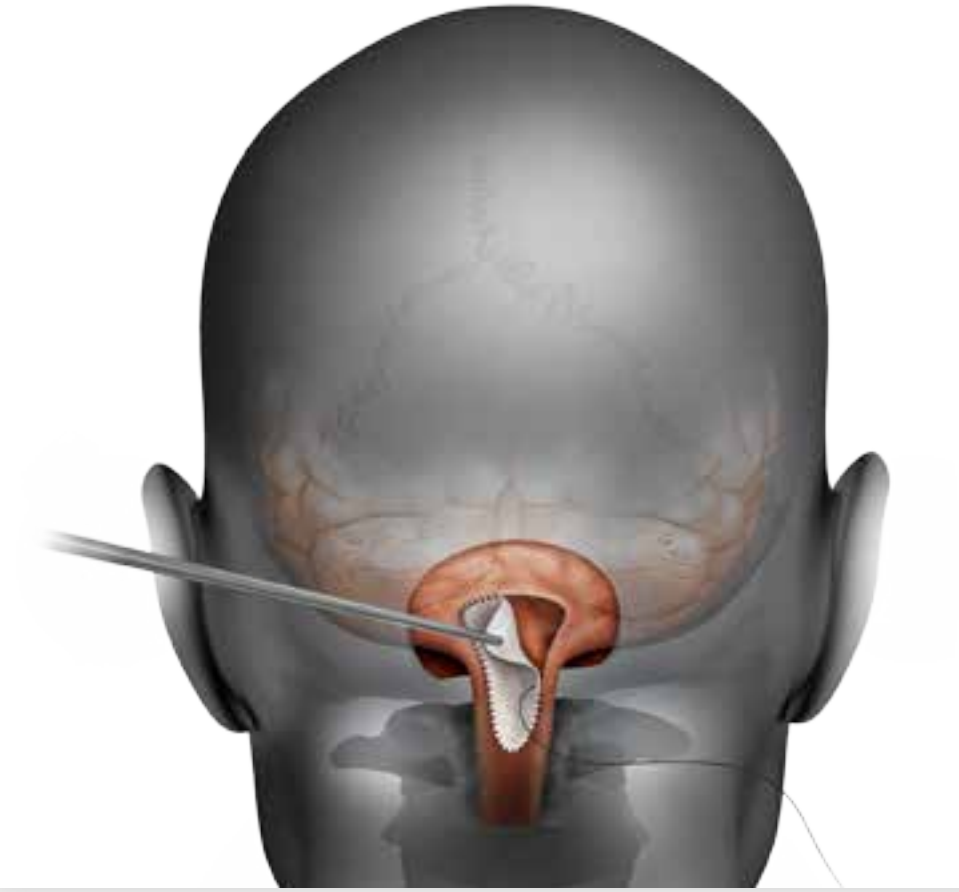
DuraMatrix Suturable

Collagen dura membrane
reinforced and reliable

DuraMatrix Suturable is a collagen dura membrane from purified intact bovine dermis tissue. It is intended for use as a dura substitute for the repair of dura mater.

The natural crosslinks inherent in the native bovine collagen are further biochemically reinforced through a proprietary cross-linking process to provide suturable strength. Furthermore, this results in a resorption time of 38-40 weeks based on the results of a rabbit duraplasty model,[2, 3] while new dura mater is regenerated to replace the membrance.

DuraMatrix Suturable shows high suture pull out strength.[1, 3] This permits the graft to be firmly anchored to surrounding tissue with minimal risk of membrane tear or detachment.



The total resorption time (defined as <5% implant remaining) is approximately 38-40 weeks for DuraMatrix Suturable. [2,3]

Suture pull out strength (N) [1,3]

DuraMatrix Suturable

20.40±1.54 N

Comparison substitute

11.67±4.12 N

74.8%

greater suture pullout strength when compared to a competing dura substitute.[1, 3]

DuraMatrix-Onlay

Collagen dura membrane, onlay **conformable and versatile**

DuraMatrix-Onlay is a purified, type I collagen membrane derived from bovine Achilles tendon. It is intended for use as a dura substitute for the repair of dura mater.

With a thickness of about 0.6mm, DuraMatrix-Onlay serves as a thinner onlay option than DuraMatrix-Onlay PLUS. DuraMatrix-Onlay can also be applied with minimal tension sutures if desired.

DuraMatrix-Onlay offers a balanced resorption that occurs over 6-9 months. [2, 3]

DuraMatrix

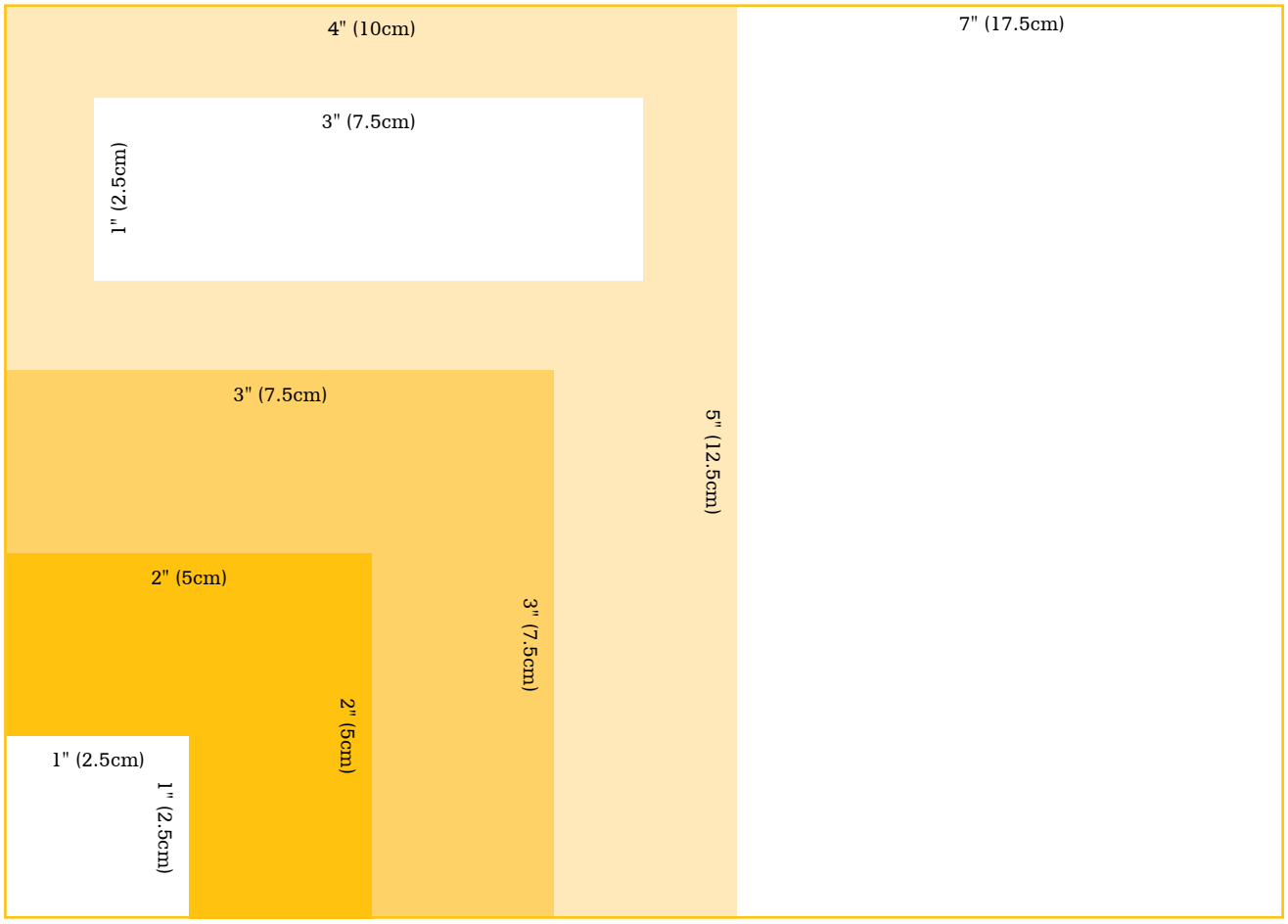
Collagen dura substitute membrane **strong and conformable**

DuraMatrix is a purified, type I collagen membrane derived from bovine Achilles tendon. It is intended for use as a dura substitute for the repair of dura mater.

DuraMatrix has a thickness of approx. 0.3 mm which can be considered similar to the thickness of native dura.

The conformability properties of the membrane combined with its mechanical strength allow DuraMatrix to be applied as either an onlay membrane or sutured in place.

DuraMatrix offers a balanced resorption that occurs over 6-9 months. [2, 3]



DuraMatrix-Onlay PLUS

Part number	Size	Units per
DMOP11	1 in x 1 in (2.5 cm x 2.5 cm)	1
DMOP13	1 in x 3 in (2.5 cm x 7.5 cm)	1
DMOP22	2 in x 2 in (5 cm x 5 cm)	1
DMOP33	3 in x 3 in (7.5 cm x 7.5 cm)	1
DMOP45	4 in x 5 in (10 cm x 12.5 cm)	1
DMOP57	5 in x 7 in (12.5 cm x 17.5 cm)	1

DuraMatrix Suturable

Part number	Size	Units per
DMS11	1 in x 1 in (2.5 cm x 2.5 cm)	1
DMS13	1 in x 3 in (2.5 cm x 7.5 cm)	1
DMS22	2 in x 2 in (5 cm x 5 cm)	1
DMS33	3 in x 3 in (7.5 cm x 7.5 cm)	1
DMS45	4 in x 5 in (10 cm x 12.5 cm)	1

DuraMatrix-Onlay

Part number	Size	Units per
CDSLM11	1 in x 1 in (2.5 cm x 2.5 cm)	1
CDSLM13	1 in x 3 in (2.5 cm x 7.5 cm)	1
CDSLM22	2 in x 2 in (5 cm x 5 cm)	1
CDSLM33	3 in x 3 in (7.5 cm x 7.5 cm)	1
CDSLM45	4 in x 5 in (10 cm x 12.5 cm)	1
CDSLM57	5 in x 7 in (12.5 cm x 17.5 cm)	1

DuraMatrix

Part number	Size	Units per
CDSM11	1 in x 1 in (2.5 cm x 2.5 cm)	1
CDSM13	1 in x 3 in (2.5 cm x 7.5 cm)	1
CDSM22	2 in x 2 in (5 cm x 5 cm)	1
CDSM33	3 in x 3 in (7.5 cm x 7.5 cm)	1
CDSM45	4 in x 5 in (10 cm x 12.5 cm)	1

References: 1. In vitro data on file at Collagen Matrix, Inc. **2.** Rabbit duraplasty study. Data on file at Collagen Matrix inc. **3.** The results of preclinical in vitro studies may not be indicative of human clinical outcomes **4.** In vivo evaluation of resorption in a rabbit duraplasty model. Data on file.

Craniomaxillofacial

CMFBR75EN_Rev. None_12764
SDL 07/2020
2019-23407

stryker.com

Collagen Matrix, Inc.
15 Thornton Road Oakland,
NJ 07436 USA

CE 2797

EC REP

MDSS GmbH
Schiffgraben 41
D-30175 Hannover
Germany

Distributed by:
Stryker Leibinger GmbH & Co. KG
Bötzinger Straße 41
79111 Freiburg
Germany