

BIOABSORBABLE ARTIFICIAL DURAL SUBSTITUTE

SEAMDURA



GUNZE

Codman
a Johnson & Johnson company

SEAMDURA

BIOABSORBABLE ARTIFICIAL DURAL SUBSTITUTE

Characteristics

SEAMDURA is a bioabsorbable artificial dural substitute made of a film from copolymer of L-lactide and ϵ -caprolactone (P(LA/CL)), and Polyglycolic acid (PGA) felt, that has the following characteristics.

Biodegradation

SEAMDURA is degradable and absorbable. It is finally replaced by natural dura-like tissue.

Artificial Material

SEAMDURA is made of synthetic materials which prevents the transmission of diseases.

Tear Resistance

SEAMDURA is tear resistant and elastic facilitating a good seal and reduced cerebrospinal leakage through the suture holes.

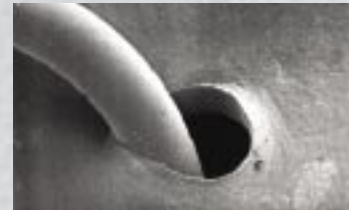
SEAMDURA is strong being reinforced with PGA felt.

Transparency

SEAMDURA is immediately transparent and non reflective to enable a clear line of view for the Neurosurgeon.



SEAMDURA



ϵ -polytetrafluoroethylene (Teflon)



Overview

SEAMDURA Component Parts

L-lactide copolymer and ϵ -caprolactone (P(LA/CL))

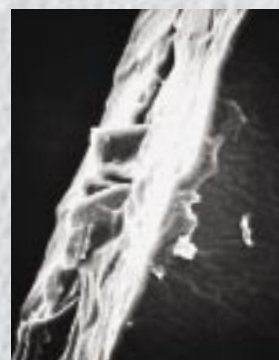
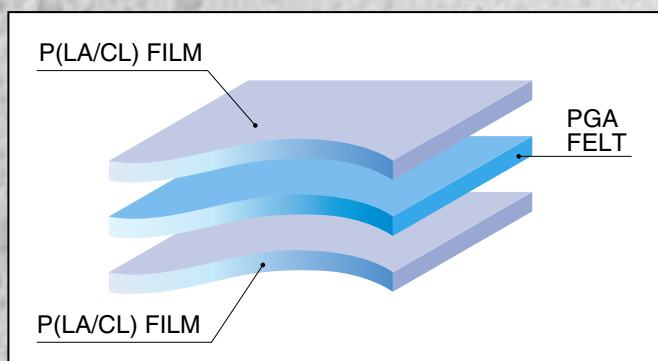
Polyglycolic Acid (PGA)

Solvent green 3 (Trace)

SEAMDURA Sheet Characteristics

A sheet of Seamdura consists of P(LA/CL) copolymer films layered with PGA felt to give strength, elasticity and a leak resistant seal.

SEAMDURA is available in four different sheet sizes and the largest size (5×15cm) is curved to follow the shape of the cranium.



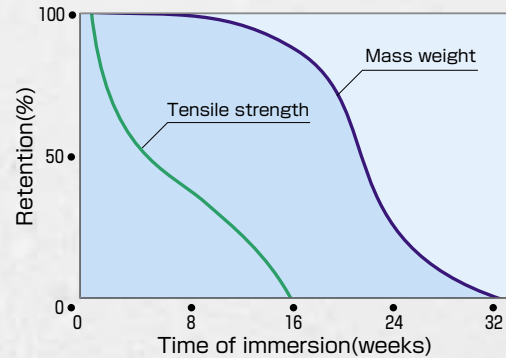
Microscopic side view

SEAMDURA is a bioabsorbable artificial dural substitute that aids dural regeneration with outstanding benefits to the patient and surgeon.

Absorption and Regeneration

SEAMDURA is progressively reduced by hydrolysis, absorbed and finally metabolised by the human body. SEAMDURA gradually reduces in strength and mass to be completely absorbed in approximately 32 weeks. In 3 to 4 weeks post procedure, the strength of SEAMDURA decreases to approximately 50% and in 12 weeks to nearly zero.

<Retention>



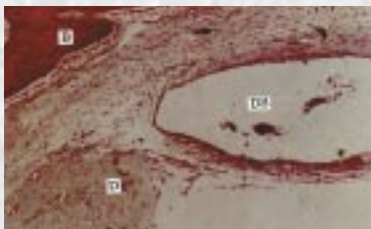
Indications

SEAMDURA is indicated for use in the repair of dura mater in the brain.

Tissue reaction

Tissue reactions for SEAMDURA on the rabbit's dura mater.

Ds:SEAMDURA, B:bone, D:dura mater, DT:dura like tissue, BT:brain tissue, S:suture, Abstract:K.Yamada, et al, Development of a duralsubstitute from synthetic bioabsorbable polymers, J Neurosurg 86:1997



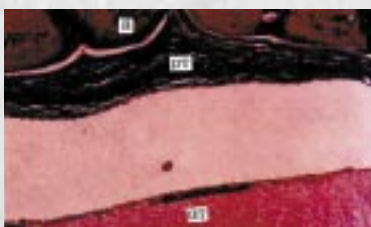
2 weeks after



4 weeks after



12 weeks after



24 weeks after

The tissue reaction was minimal and SEAMDURA had been completely absorbed after 24 weeks. Regeneration of the dura-like tissue due to thickening of collagen fibers was observed.

Case Study

A craniotomy was performed to reveal the area where artificial dural mater had been used and the subsequent regeneration of natural dura mater in a rabbit. After 30 months the site implanted with SEAMDURA (D2) was completely healed by regenerated dura-like tissue. No adhesion with the brain surface was noted.



After the operation



After 30 months
D1: Dried dura mater,
D2: SEAMDURA



[Contraindications]

- (1) Do not use this product to the operative field where is evidently contaminated. As these cases were excluded from studies, safety in these cases has not been established.
- (2) Do not use this product in necrotic tissue, in patients with serious infection and those who have used steroids for a long period of time likewise.
- (3) Do not use this product in patients with potentially delayed wound healing; for example malnourished or debilitated patients or patients who may undergo radiation or chemotherapy within 3 weeks of implantation. If wound healing is markedly delayed, the product may be absorbed before adequate regeneration of the dural substitute takes place.
- (4) Do not use this product in patients who have undergone acute stage external decompression and who may receive another craniotomy within several months of implantation. If another craniotomy is performed too soon, re-suturing may be impossible. The newly formed membrane is still fragile and the strength of this product may be insufficient to endure suturing.
- (5) Do not use this product to cover:
 - large defects at the skull base following surgery; or
 - dural defects involving mastoid air cells.
- (6) Do not use this product for skull base surgery if there is a high likelihood of liquorrhea. Severe infection can occur with delayed wound healing and prolonged liquorrhea.
- (7) No data is available concerning the use of this product to repair the dura mater of the spine, nor is data available for use of this product in the following patient populations:
 - infants;
 - children;
 - pregnant women;
 - women during puerperium;
 - nursing women.

[Precautions]

Inspect the sterile package carefully. Do not use if:

- the package or seal appears damaged;
- the contents appear damaged; or
- the expiry date has passed.

Do not open the package until ready to use the product. This product undergoes hydrolysis, which gradually decreases its strength. Do not store this product after the package has been opened.

Prior to implantation, warm the dural substitute to body temperature in physiological saline to approximate the elasticity of natural dura. This elasticity allows contact between the dural substitute and the natural dura.

Prior to implantation, carefully trim the dural substitute to size, ensuring an overlap to cover the existing dura to avoid CSF leakage. If the area of the dural substitute is smaller than the area of the dural

defect and is sutured with excessively high tension, then the product can compress the brain surface or cause rupture of the dura mater or dural substitute.

If the area of the dural substitute is much larger than the area of the dural defect, then:

- watertight suturing may be difficult;
- adhesion may occur due to excessive contact of this product with the brain surface;
- compression of the brain surface may occur; or
- CSF pooling may occur.

Do not use this product for dural defects greater than 48 cm² in size. Discard of the unused portion of the product and the package.

Do not use this product in combination with adhesives containing cyanoacrylate.

Confine the use of biological tissue adhesives in combination with this product to cases in which watertight suturing is not possible. Consult the package insert accompanying the adhesive.

Treat postoperative infection, if any, immediately. If infection persists, remove the product.

Pay careful attention to the incidence of infection when using this product to repair dura mater of the skull base.

Provide long-term patient follow-up postimplantation, when this product is used for a 30 cm² or larger dural defect.

Provide long-term patient follow-up postimplantation, when implanting this product in elderly patients.

This product is bioabsorbable and if wound healing is markedly delayed may be absorbed before adequate regeneration of the dural substitute takes place.

[Adverse Events]

Possible adverse events can occur with any neurosurgical procedure and may include, but are not limited to:

- hematoma
- hemorrhage
- liquorrhea
- infection
- adhesion
- scarring

It is possible that allergic reaction and minimal inflammatory response occur to the implanted material as adverse events.

[Sterility]

SEAMDURA bioabsorbable artificial dural substitute is intended for SINGLE USE ONLY; DO NOT RESTERILIZE. Use aseptic technique in all phases of handling. Gunze Limited will not be responsible for any product that is resterilized, nor accept for credit or exchange any product that has been opened but not used.

As long as the inner unit is not opened or damaged, the product is sterile and nonpyrogenic.

[Storage]

Store at normal temperature, 1-27°C (34-80°F). Do not use after the expiration date.

Do not use this product if the temperature indicator on the outer container is green.

[Product Variation (sterilized by EOG)]

| Code | Size and Color | Package |
|---------|----------------|---------------|
| SD-0210 | 2 × 10cm | 1 sheet / box |
| SD-0505 | 5 × 5 cm | |
| SD-0510 | 5 × 10cm | |
| SD-0515 | 5 × 15cm | |



Manufacturer

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