Collagen Dura Membrane

RESODURA®\textsuperscript{matrix suturable} is a resorbable collagen dura repair membrane designed with high mechanical strength. RESODURA®\textsuperscript{matrix suturable} is derived from highly purified intact bovine dermis. It is indicated for use as a suturable dura membrane for the repair of the dura mater and requires only a short hydration with sterile saline prior to implantation. It can be cut in either the dry or hydrated state, and can be placed with either side toward the brain. RESODURA®\textsuperscript{matrix suturable} has a thickness similar to that of native dura and a high suture retention strength (20.40 ± 1.54 N) that enables it to be sutured to surrounding tissue with minimal risk of membrane tear or detachment.

- Highly purified collagen
- Strong, yet flexible
- High suture retention strength
- Leak resistant material for protection against cerebrospinal fluid leakage
- Controlled resorption for effective dural repair
- Excellent handling characteristics
- Quick hydration time

\textsuperscript{1}Data on file with Collagen matrix.
In vivo Evaluation of RESODURA® matrix suturable Collagen Dura Membrane as a Dura Membrane in a Rabbit Duraplasty Model*

RESODURA® matrix suturable Collagen Dura Membrane and Durepair® (Medtronic) were implanted in twenty-six New Zealand White strain rabbits. A single 10 x 10 mm defect was created over the midline in the skull of each rabbit. The bone flap covering the defect was elevated and placed in saline. A critical sized defect, approximately 8 x 8 mm, was created in the dura. The dural defect was then covered by either the RESODURA® matrix suturable Dura Membrane or Durepair®. Both dura membranes were sutured in place. The bone flap was then placed, and the surgical site was sutured closed with non-resorbable suture.

This study demonstrated the safety and efficacy of RESODURA® matrix suturable Dura Membrane as a collagen dura substitute membrane in a rabbit duraplasty model compared to Durepair®. Efficacy was demonstrated macroscopically, histologically, and microscopically after 6 and 12 weeks. All of the rabbits survived the procedure and gained weight over the succeeding 12 weeks after local implantation of the implants onto a dura incision. The application of the RESODURA® matrix suturable Dura Membrane and the application of the Durepair® appeared to prevent CSF leakage. Microscopically, both the RESODURA® matrix suturable Dura Membrane and Durepair® were present at 6 and 12 weeks. Cellular responses to the implants were assessed histologically at these time points and it was determined all of the groups had similar inflammatory response, indicative of normal tissue repair response. There were no safety issues with regard to inflammatory response or negative cellular changes at the implant site. Both RESODURA® matrix suturable Dura Membrane and Durepair® were resorbed over time and aided in new collagen formation. As a first order approximation, the total resorption time is approximately 9 months for the RESODURA® matrix suturable Dura Membrane. Overall, it can be concluded that RESODURA® matrix suturable is a safe and effective collagen dura membrane in this duraplasty model.

Durepair® is a registered trademark of TEI Biosciences, Inc.

* Lee N, Yuen D, and Li ST, Two Novel Collagen Based Dura Repair Membranes: Solutions for the Multifaceted Needs in Duraplasty Part II: In Vivo Rabbit Duraplasty Studies (abstract). In: 10th World Biomaterials Congress, 2016 May, Montreal, Canada. Abstract nr 3315

DUMS2525  2.5 x 2.5 cm  1 membrane
DUMS2575  2.5 x 7.5 cm  1 membrane
DUMS0505  5 x 5 cm  1 membrane
DUMS7575  7.5 x 7.5 cm  1 membrane
DUMS10125  10 x 12.5 cm  1 membrane

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