

# DuraStat®: Clinical Benefits Resulting in Net Cost Savings

	DURASTAT NET SAVINGS ANALYSIS	METRIC	QTY/MO.	QTY/YR.	\$ EACH	TOTAL	ADDITIONAL INFORMATION
ID INCIDENCE	<b>Lumbar Spine Procedures</b> Average Facility with 5-7 Surgeons	N/A	42	500	N/A	N/A	Volumes vary greatly. This average including instrumented and uninstrumented procedures.
	<b>Incidental Durotomies at a Typical Facility</b> Approximately 17% Incidence in Spine	17%	7	85	N/A	N/A	17% incidence across all spine surgery includes higher incidence in complex cases (revisions, etc.) and lower in routine cases (decompression, etc.). <sup>1,2,3</sup>
	<b>Difficult to Reach Tears</b> 1/3 Tears Require DuraStat	1/3	2.36	28	\$890	\$25,217	DuraStat is applicable in a subset of ID cases when tears are particularly challenging to access and treat, such as in MIS cases, or when far lateral tears occur in open cases.
OPERATIVE TIME	<b>Additional Exposure Time for Access</b> 6 Min. at \$93/Min. <sup>4</sup>	6	14	170	\$93	\$15,810	Soft tissue dissections and bone removal to access the tear are the biggest time drivers. In MIS cases, there is potential to convert to an open exposure.
	<b>Wait Time for Sterile Tray &amp; Preparations</b> 4 Min. at \$93/Min.	4	9	113	\$93	\$10,540	The data cites a range of 30-60 minutes / dural tear. <sup>5,6</sup>
	<b>Manual Closure Time (Loading, Supination, etc.)</b> 5 Min. at \$93/Min.	5	12	142	\$93	\$13,175	Sterile availability, access without additional exposure and ease of operation are time savings drivers for DuraStat. <sup>7</sup>
COMPLICATIONS	<b>Unplanned In-Patient Days</b> <sup>8</sup> 15% Require Additional Flat Best Rest	15%	0.35	4.25	\$2,517	\$10,697	If a direct, mechanical closure is not achieved, post-operative ID protocols call for flat bed rest as a first-line of defense against persistent CSF leaks. <sup>9,10</sup>
	<b>CSF Leak Treatment</b> <sup>11</sup> 5% of Cases (Drains, Antibiotics, etc.)	5.0%	0.12	1.42	\$6,479	\$9,179	Non-operative treatments when a CSF leak is initially identified. Persistent CSF leaks occur in 9-21% of ID cases. <sup>12</sup>
	<b>Ongoing CSF Leak Treatments</b> 2.5% Treatments for ~2 Years	2.5%	0.06	0.71	\$7,479	\$5,298	Fistulas and fluid masses result in long-term on-going treatment. <sup>13</sup>
	<b>Reoperations to Repair Persistent CSF Leaks</b> One per Year — No Reimbursement	1	0.08	1	\$18,000	\$18,000	Severe leaks that are not closed required re-operation for direct mechanical closure. <sup>14</sup> Superior quality of repair enabled with DuraStat <sup>15</sup> can help mitigate the risk of leaks from poor or inadequate repair.
COST AVOIDANCE	Estimated Annual Cost Avoidance (Time)					\$39,525	<b>Other potential savings opportunities not considered in this model</b> <ul style="list-style-type: none"> <li>• Patient satisfaction scores</li> <li>• Litigation expenses and outcomes</li> <li>• Comorbidities associated with unplanned flat bed rest and immobilization during recovery</li> <li>• Additional degenerative spinal conditions resulting from the complication</li> <li>• Reduced usage of sealants and on-lays as a result of mechanical repair</li> </ul>
	Estimated Annual Cost Avoidance (Complications)					\$43,173	
	Total Estimated Annual Cost Avoidance					\$82,698	
	Total Annual Cost of DuraStat					\$25,217	
	<b>Net Estimated Annual Cost Savings</b> Average Savings After the Cost of DuraStat						

## REFERENCES

1,2,3 ID Incidence (17%): Ghobrial GM, et al. (2015). *Neurosurgical focus*, 39(4), E8.; Sin AH, et al. (2006). *Journal of Neurosurgery: Spine*, 5(3), 224-227; Smorgick Y, et al. (2015). *Journal of Neurosurgery: Spine*, 22(5), 483-486.  
4 OR Cost (\$93/min): Watkins IV RG, et al. (2010). *The open orthopaedics journal*, 4, 228.  
5,6 OR Time (30-60 min.): Schroeder GD, et al. (2016). *Spine*, 41(19), 1548-1553; Desai A, et al. (2011). *Journal of Neurosurgery: Spine*, 14(5), 647-653.  
7 DuraStat Time Savings: McKenzie JC, et al. (2019). Evaluation of a Novel Dural Repair Device in a Simulated Durotomy Model.  
8 In-Patient Cost (\$2,517): "Hospital Adjusted Expenses per Inpatient Day." *The Henry J. Kaiser Family Foundation*, 21 Feb. 2020, www.kff.org/health-costs/state-indicator/expenses-per-inpatient-day.

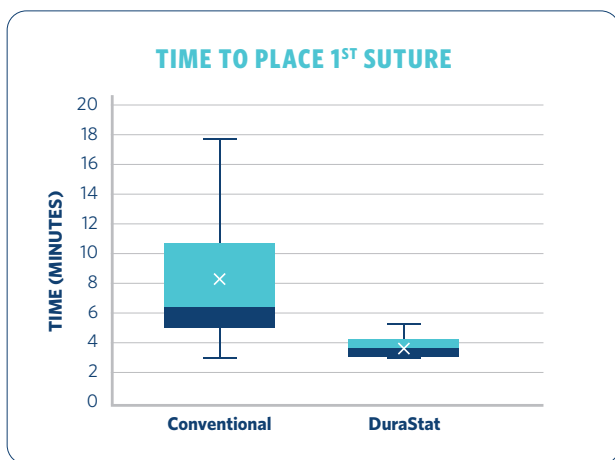
9,10 Flat Bed Rest: Ruban D, et al. (2011). *Neurosurgical focus*, 31(4), E15.; Radcliff KE, et al. (2013). *J Spinal Disord Tech*.  
11 CSF Leak Treatment Cost (\$6,479): Jallo J, et al. Presented at the 2009 Annual Meeting of the Congress of Neurological Surgeons (CNS).  
12 CSF Leak Rate (9-21%): Jankowitz BT, et al. (2009). *European Spine Journal*, 18(8), 1169-1174.  
13 On-Going Treatment: Guerin P, et al. (2012). *Injury*, 43(4), 397-401.  
14 CSF Leak Re-Operation: Wong AP, et al. (2014). *World neurosurgery*, 81(3-4), 634-640.  
15 DuraStat Repair Quality: Mangan J, et al. (2019). Superior Tissue Handling and Dural Tear Closure with DuraStat: A Comparative Analysis.

# DuraStat® vs. Conventional Durotomy Repair

## OVERVIEW

Using a validated anatomical model with enhancements to simulate flowing cerebrospinal fluid, blood and realistic nerve roots, DuraStat yielded higher quality, safer, faster dural repairs when compared to traditional suturing technique across multiple surgeon participants and studies.

## FASTER & MORE REPRODUCIBLE



### TIME SAVINGS

When an Incidental Durotomy (ID) occurs, DuraStat saves time over Conventional Suturing Technique

- 57% time savings for 1<sup>st</sup> suture placement—most critical to an efficient repair<sup>1</sup>
- 36% less time to complete the repair overall<sup>4</sup>

### REPRODUCIBILITY

When compared to conventional suturing tools DuraStat showed far less variation in time to complete a repair<sup>2</sup>

- 100% of surgeon participants agreed DuraStat is easy to use<sup>3</sup>

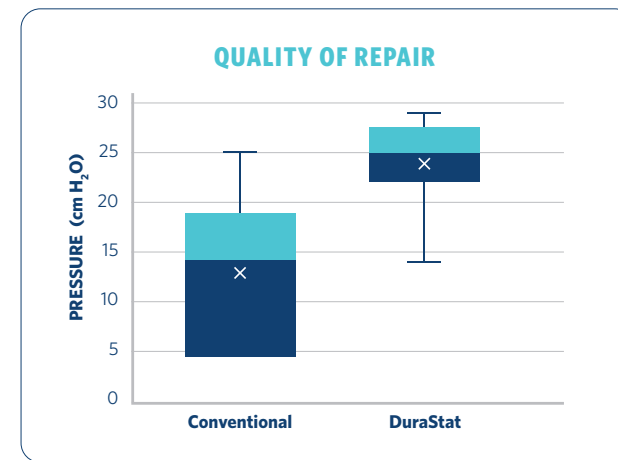
## SAFER



### PATIENT SAFETY

DuraStat was safer than conventional techniques. Conventional Suturing resulted in 30% occurrence of trapped simulated nerve roots, while DuraStat entrapped none - 0%<sup>5</sup>

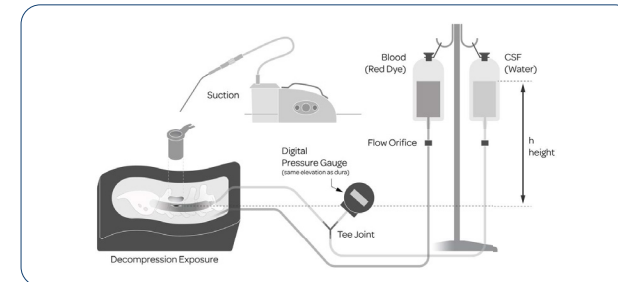
## HIGHER QUALITY



### BETTER QUALITY REPAIR

Using DuraStat resulted in a more consistent and higher quality repair when compared to Conventional Suturing<sup>5</sup>

## SURGICAL TRAINING MODEL SCHEMATIC



1,2,3 Evaluation of a Novel Dural Repair Device in a Simulated Durotomy Model - In this study DuraStat was evaluated alongside conventional manual suturing tools in a validated anatomical training model. DuraStat took 57% less time and with less variation to place the 1<sup>st</sup> suture compared to conventional technique. The results were statistically significant.

89% of surgeons agreed DuraStat is safer than conventional techniques.

100% agreed DuraStat is safer than using adjuncts alone. 100% agreed DuraStat is easy to use.

4,5,6 Superior Tissue Handling and Dural Tear Closure with DuraStat: A Comparative Analysis - This study was designed to assess the differences in intraoperative management of incidental durotomy repair utilizing DuraStat compared to conventional techniques in a controlled model. To evaluate this, surgeons completed one repair each with DuraStat and conventional technique. Time to Repair was statistically significantly faster with DuraStat taking 36% less time to complete the repair. Quality of Repair was statistically significantly higher with DuraStat as measured by the change in pressure back to baseline after the repair. Safety was statistically significantly superior with DuraStat as nerve root entrapment did not occur, whereas 3 surgeons with conventional technique entrapped nerve roots in the repair.