

# ANALYSIS OF THE PERIPHERAL NERVE REPAIR MARKET IN THE UNITED STATES

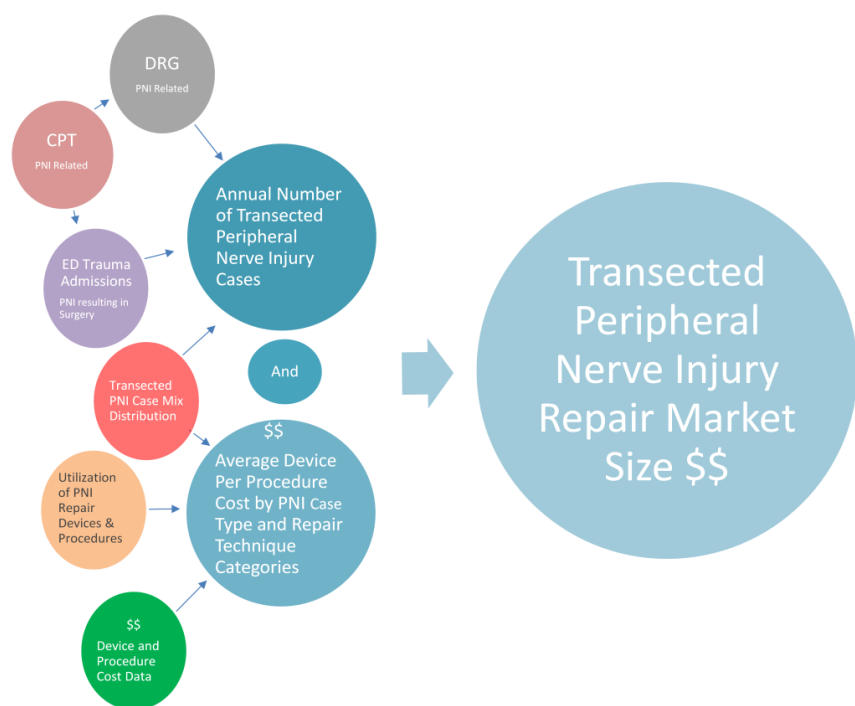
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## Overview/Summary

Based on research and analysis, the U.S. market for the repair of transected peripheral nerves in the extremities is \$1.32 to \$1.93 billion dollar per year. (See Figure 1.)

Figure 1. Overview of the Transected Peripheral Nerve Repair Market Model



**Disclosure:** The content of this document is based on the results of third party research conducted by Magellan Medical Technology Consultants, a Minneapolis, MN company, which was made possible by funding from AxoGen, Inc. headquartered in Alachua, FL. The information contained herein does not necessarily represent the opinions of AxoGen, Inc.

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**Importance of Transected Gap Length** – Transected peripheral nerve injury (PNI) repair involves sizing up each patient’s capacity to regain the use of their damaged nerve and the risk associated with the repair attempt. To be sure, every repair approach technique or device carries with it the potential for failure at a cost of life-long morbidity. This risk of morbidity is not confined to the nerve injury site alone since having a paralysis or loss of sensation leaves the patient more vulnerable to other risks such as falling or an inability to sense skin trauma. The risk of a poor outcome is greatest with transected nerve injuries, which is the focus of this paper and market estimation model. Compression type injuries where blood supply and cellular organization remain intact at some level carry with them a greater likelihood of recovery with repair or protection interventions. With each millimeter of a gap separation on a transected nerve there are associated greater repair challenges and more complicated treatment decisions.

**“No Gap” or “Short Gap” Length Repairs** - Short or no gap transected nerve repairs can be attempted by approximating the nerve ending margins with suture. This may also include the use of protective wraps or coaptation aids to strengthen the repair area. In joining the transected nerve endings directly, the surgeon must decide how much tension to place on the nerve which may be shortened by the gap length amount. Stress on the nerve from tension must be assessed not only in a neutral anatomical position (no flexion or extension) but also for range of motion in the region of the body during flexion and extension. Stress on a repaired nerve can also result from surrounding tissue edema and vascular supply compromises – thus the direct suturing together of the damaged transected nerve ends is not without risk of poor outcome.

**“Small Gap” and “Large Gap” Repairs** - For transected nerve injuries where the surgeon feels it would be risky to directly join the nerve-endings together with suture; there are various techniques and device options. A hollow tube or connector device may be placed as a simple conduit to grossly align the nerve endings in an attempt to allow for peripheral nerve re-generation without the stress of pulling the nerve endings together. It is

generally accepted that the hollow tube method has limitations in terms of gap length, with the longer gap lengths having less efficacious outcomes when repaired by connector or hollow tube devices. For gap lengths beyond acceptable hollow tube lengths, the surgeon may elect to harvest nerve from elsewhere in the body and place it in the gap – this is called an autograft. As a nerve tissue specific material, autograft provides well suited scaffolding for nerve re-generation. This technique is currently used for the longer gap repairs and is well received by the injured tissue area as it is the patient's own tissue (autologous), thus minimizing inflammation and scarring to the area while providing a re-generative optimal conduit. For large diameter nerve repairs, the surgeon may bundle smaller diameter nerve grafts together creating a larger conduit for the re-generation process to take place. But, the price of autograft is steep as the harvested nerve site is now rendered permanently damaged creating new life-long morbidity where there was none. At best, this is a trade-off of morbidities if, and only if, the autograft works. If the repaired site isn't able to re-generate then the patient is left with two injuries, one from the initial injury and the other iatrogenic (treatment induced) as a result of the autograft. Newer technologies strive to address the significant drawbacks of autologous tissue harvest as an alternative option.

**Emerging and Disruptive Technologies** - Newer technologies, such as processed nerve allograft, offer the scaffolding of human nerve tissue without creating additional morbidity caused by harvesting nerve elsewhere on the patient. Further, processed nerve allograft eliminates the need for anti-rejection medications required with whole allograft. Processed nerve allograft is an emerging technology that has begun to expand the list of tenable options in peripheral nerve repair and as such is a disruptive technology. Nerve repairs that were once considered off-limits due to the complexity or severity of the injury may be back on the table for discussion. Nerve repairs however sometime get the lowest priority because tissue viability is first and foremost on the surgeon's mind. Vascular repair, organ integrity and bone repair are taken care of immediately and nerve repairs are more often than not handled later on or last if at all. This is in part because of the dilemma associated with some of the peripheral nerve repair options, e.g. autograft leading to other morbidity.

**Evolving Market** - Emerging disruptive technologies, like processed nerve allografts, may be re-shaping and expanding the market potential for

peripheral nerve repairs. In an evolving market with newer disruptive technologies, the question of market size is of keen interest. The market size for peripheral nerve injury repair and protection devices is therefore best evaluated in the context of an evolving market adopting newer technologies that bring opportunities for greater outcomes and patient satisfaction. This is even more so the case when the newer technologies can be cost neutral to the current standard of care options as healthcare cannot easily tolerate technologies that increase cost.

**Market Size Estimation Challenges** - The greatest challenge in a market estimate lies in the fact that data sources vary in terms of direct access to market space information. Thoughtful use and application of data sources are necessary to construct accurate market estimates. The adoption curve to newer nerve repair technologies can best be understood by assessing their receptiveness with industry experts and end-users.

**Nerve Repair Surgeons' Survey** - To gain a perspective on the adoption of technologies in peripheral nerve repair, an independent market research firm produced an on-line survey asking nerve repair surgeons for their opinions on current nerve repair techniques and devices as well as their future utilization of the currently available options. The analysis for the construction of the market model weighted each surgeon's responses to questions based on their per year number of peripheral nerve cases – annual caseload. Since the goal is to estimate the market size, using an annual caseload weighting system speaks directly to a procedure volume based model for characteristics and norms. Also, most often surgical specialty groups have members that sub-specialized in certain procedures and as such they are the leaders of the group – the ones we want to focus most on in understanding decision processes. The survey revealed among many things, that surgeons whose practice incorporated the use of nerve autografts were also most receptive to increasing their use of newer products such as processed nerve allografts. Furthermore, the 25 surveyed nerve injury surgeons (with a combined annual PNI repair caseload of 2,824 cases) strongly supported the incorporation of allograft procedures into their future practice. The surgeons also conveyed that in repairing a transected nerve, gap segment length is most important in their decision on which technique or device to utilize in the repair.

**Claims Codes and Admissions Rates as Data Sources for Number of Procedures** - For annual nerve repair and nerve protection procedure

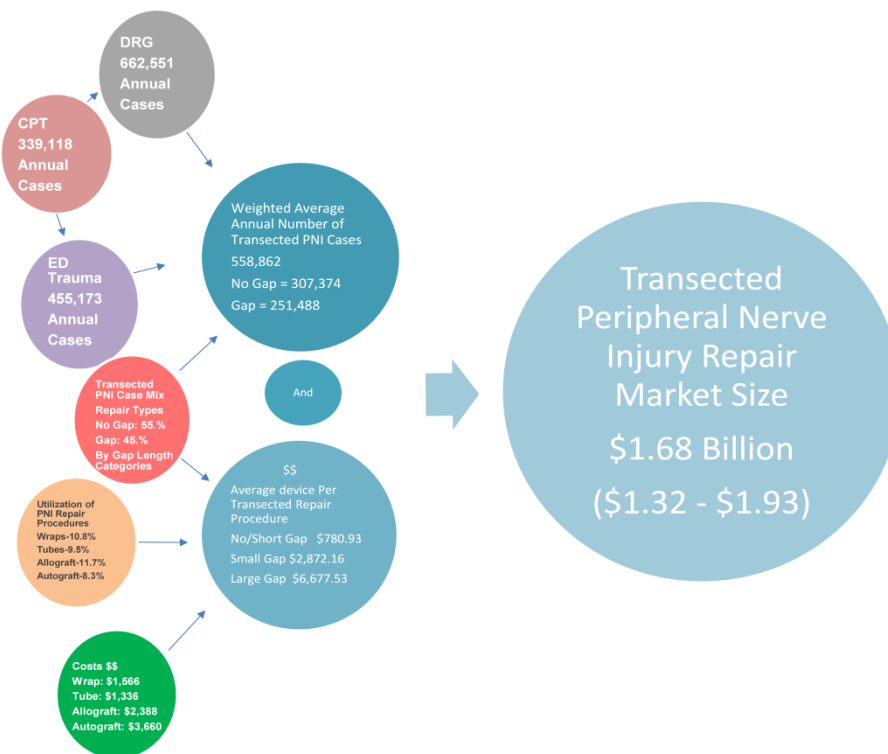
estimates, DRG codes and Emergency Department (ED) extremity trauma data were analyzed and showed that the number of potential peripheral nerve injury procedures was between 455,173 to 662,551 per year with an average number of 558,862. This assessment was focused only on extremity peripheral nerve trauma and did not include other evolving market opportunities such as breast reconstruction, carpal and tarsal tunnel repair, facial/oral nerve injuries, and torso nerve repairs – all part of the evolving peripheral nerve market but not utilized to estimate the market size in this analysis.

**Validation Check with CPT Claims Codes** - CPT codes from 2009 were also examined and found to substantiate the lower bound estimates of DRG coded nerve procedures and ED trauma admissions needing nerve repair surgery annual number of cases estimates. It is reasonable that CPT claims for nerve procedures would be low or underestimate the true number of annual procedures due to how reporting is typically handled. Some CPT codes are neglected in reporting and sampling routines for complex medical cases with multiple simultaneous procedures taking place such as in trauma surgery. CPT codes in sampling routines (such as the data for this model) are reported by a hierarchy of reimbursement rates with the top five highest reimbursable procedures getting listed and subsequent codes being left out of the sample listing.

**A Three Tiered Level of Transected Gap-Length for Pricing and Revenue Considerations** - By examining the distribution of transected gap lengths defined by peripheral nerve repair surgeons in relation to their decision making process for repair approach, a three tiered gap-length pricing model was developed: No/Short Gap, Small Gap and Long Gap.

**Market Model Results** - Applying a case-mix formula based on transected extremity nerve injuries within the three tiered gap-length level categories to the estimated number of applicable procedures per year, the U.S. market size was found to be \$1.32 to \$1.93 billion dollars with a mean of \$1.68 billion dollars per year. (See Figure 2.)

Figure 2. Market Estimate Model for U.S. Transected PNI Repairs



### Methodology

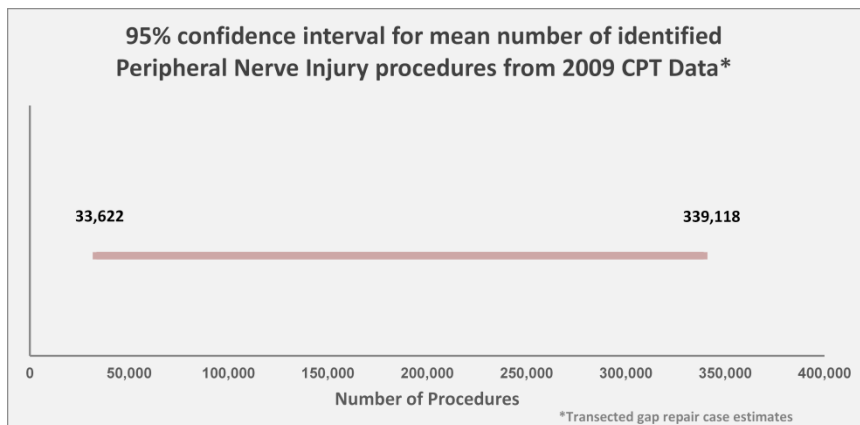
**Incorporating Known and Evolving Aspects into the Market Model** - The purpose of this paper is to determine the current size of the peripheral nerve injury repair device market for transected nerves. New technologies for peripheral nerve repair and nerve protection have been developed and are being introduced to and adopted by the industry. Like most evolving markets, early adopters have led the way by embracing new and disruptive technologies as well as allowing for fundamental changes in their approach to transected PNI repairs with the goal of improved patient outcomes and improved patient satisfaction. The determination of market size in an evolving market requires building on the market's known aspects with

information about the adoption and incorporation of process changing philosophies that convey confidence about its conclusions.

**Annual Number of Procedures Estimates** - The market size estimate was predicated on per year procedure numbers of well-known diagnostic/billing claim systems (CPT and DRG codes) as well as U.S. emergency department admission statistics (ED trauma). Combining these data resources, then allows for the construction of a market size estimate model that utilizes statistical distributions to substantiate its results and conclusions. To guard against over dependence of any one source or claims code within a source, analysis was first employed to define the variability (or error) associated with each data source's distribution using statistical bootstrapping sampling method procedures. 95% confidence intervals were constructed along with means for each data source. The final procedures per year value used in the market model was determined by a weighted (on number of annual procedures) average of the DRG and ED-trauma admissions needing surgery estimates.

**The Use of CPT Codes** - CPT codes were sampled and analyzed to establish a minimum current baseline level of known and reported nerve repair procedures for the purpose of validating the use of DRG and ED trauma admissions distributions in our market size model. CPT codes expectantly will underestimate the market, as explained in the overview section, and as such are not applied directly as a parameter in the final market size estimate model. (See Figure 3.)

Figure 3. CPT Code Data for U.S. Annual Case Number Distribution



**Adoption Rate Considerations** - We recognize that surgeons are a product of their training and experience and so current practices don't assess receptivity or future embracement or adoption rates of newer technologies. Assessing and utilizing receptiveness to adoption of newer technologies is an important component in understanding the potential market size in a rapidly evolving industry such as this one. The on-line nerve repair surgeon survey was used to define current receptivity and adoption trends for use in the market estimate model.

**Applying a Pricing Model to Number of Procedures** – A pricing model was constructed based on the cost of techniques and average sale prices (ASP) of devices or supplies used in transected PNI repairs. This cost data was then applied to a three tiered gap-length level system. The within gap-length tier average cost per procedure was calculated by apportioning utilization of techniques and devices statistics as reported by the nerve repair surgeons' survey responses.

**Gap-Length Tier Levels** – The overall strategy in defining an average price per procedure by gap length levels is to base the market model on clinical decision factors that drive the selection of repair technique and device selection. The dollar value of technique and device options can then be applied to the distribution of PNI repairs in a manner that best reflects the surgeon's decision making process.

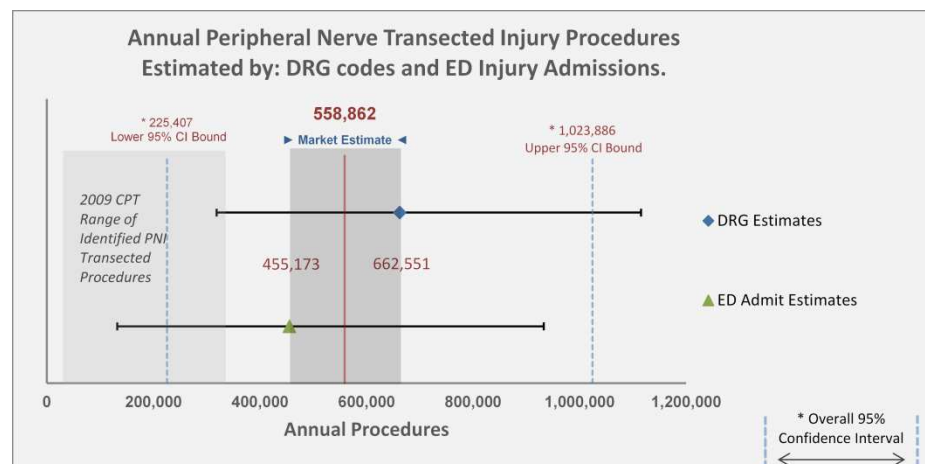
- The first gap-length tier level: 'No/Short Gap' was defined as a gap length of 0 millimeters up to the upper 95% confidence interval of transected gap lengths where it was deemed by surveyed surgeons as too long for suturing the nerve endings together directly because direct suturing would cause too much tension on the repaired nerve.
- The second gap-length tier level: 'Small Gap' was defined as a gap length longer than the first gap-length tier's maximum length up to the upper 95% confidence interval of transected gap lengths where it was deemed by surveyed surgeons as too long for use of a hollow tube or connector to repair the nerve.
- The third gap-length tier level: 'Large Gap' was then defined as gap lengths longer than the second gap-length tier's maximum length.

**Data Sampling for Number of Procedures per Year Estimates** - Sample data from three sources were obtained and used in a meta-analysis to determine the overall distribution of the number of transected nerve injury procedures in the U.S. The three sources of transected PNI procedure estimates are:

- (1) MS-DRG's from Claim Volume 2011 for Musculoskeletal, Nerve & Trauma (including carpal tunnel).
- (2) CPT code Claim Volume for Inpatient and Outpatient.
- (3) Emergency Department Admissions for Trauma (including brachial plexus and digital injuries), USDHHS, 2008-2009.

Each CPT and DRG claim code sampling result was given a percentage weight (0% to 100%) to reflect the portion of transected peripheral nerve repair cases within a given claim code. Thus some sampled claim codes were not used at all and had a 0% weight in the market estimate model. The Emergency Department data was adjusted from all trauma admissions to reflect only the percentage likely to require peripheral nerve repair surgery. (See Figure 4.)

Figure 4. Annual U.S. Transected Peripheral Nerve Injury Case Estimates



**Nerve Repair Surgeons' On-line Survey** – An on-line survey was established to obtain practice demographics, caseloads as well as surgical approach

philosophies of nerve repair surgeons. This survey data was then used to refine or build on estimate parameters in the market model and construct pricing breakpoints that related to the surgeon's selection criteria for treatment options. The survey was produced and implemented by a third party market research firm. Results were tabulated using SAS 9.3 and outcomes were applied to the market analysis model where appropriate. The application to the market model of the survey results was weighted by the surgeon's reported annual caseload thereby relying more on surgeons with more active practices or caseloads in peripheral nerve repair procedures.

**Pricing Model** – The first gap-length tier level ("No/Short Gap") breakpoint is at 8.90 mm. This gap-length tier level would encompass the entire direct repair (suture only as a primary intervention) approach spectrum of lengths as described by the nerve surgeons' survey responses. Thus 55% of U.S. transected PNI repairs would apply to this gap-length tier level leaving the remaining 45% of annual transected PNI cases for the other gap-length tier levels. Other interventions would also be utilized at the first gap-length tier level under 8.90 mm in length. The remaining two gap length tier levels were created by defining a point above where surgeons agreed that a direct (suture only) repair is not a risk reasonable option. While at the first tier level we see utilization of devices and techniques beyond suturing alone, there is agreement among the surgeons surveyed that at these gap lengths autograft would not be considered (presumably because of the morbidity caused at the donor site) whereas processed nerve allograft is considered. The breakpoint for "Small Gap" versus "Large Gap" was defined to be at 20 mm. 20 mm is the point where the surgeons agreed that use of a hollow tube or connector was too risky in terms of likely successful outcome. Thus, the gap length where surgeons surveyed agree that the only options are graft (autograft or processed allograft) or no repair at all. Using the gap length breakpoints, the average price for each of the three gap-length tier levels was determined, in part, by surveying three nerve repair product manufacturers (AxoGen®, Integra® and Stryker®) for ASP information and applying their product lines to appropriate repair techniques and device type categories as advertised by the manufacturer. (See Table 1.)

Table 1. List Price Ranges for Three Gap Length Levels of Transected PNI Repairs

Manufacturer		Wrap			Hollow Tube/Connector			Processed Nerve Allograft		
AxoGen	3-Tier Gap-Length Levels	AxoGuard	Low	High	AxoGuard	Low	High	Avance	Low	High
	No Gap or Short Gap	\$1,400	\$1,400	\$1,400	\$700	\$700	\$700	\$1,300	\$1,300	\$1,300
	Small Gap	\$1,400	\$1,400	\$1,400	\$700	\$700	\$700	\$2,388	\$1,950	\$2,825
	Large Gap	\$1,725	\$1,725	\$1,725	NA	NA	NA	\$3,125	\$2,825	\$3,425
Integra	3-Tier Gap-Length Levels	NeuraWrap	Low	High	Neuragen	Low	High			
	No Gap or Short Gap	\$1,470	\$1,470	\$1,470	\$1,470	\$1,470	\$1,470	NA	NA	NA
	Small Gap	\$1,470	\$1,470	\$1,470	\$1,670	\$1,470	\$1,870	NA	NA	NA
	Large Gap	\$2,015	\$2,015	\$2,015	NA	NA	NA	NA	NA	NA
Stryker	3-Tier Gap-Length Levels	NeuroMend	Low	High	NeroMatrix/Neurof	Low	High			
	No Gap or Short Gap	\$1,828	\$1,828	\$1,828	\$1,838	\$1,691	\$1,985	NA	NA	NA
	Small Gap	\$1,828	\$1,828	\$1,828	\$1,838	\$1,691	\$1,985	NA	NA	NA
	Large Gap	\$1,985	\$1,985	\$1,985	NA	NA	NA	NA	NA	NA

The manufacturer's list price information was then used to come up with an average pricing for each of the devices and techniques used for nerve repair. Finally, using the gap lengths where the surgeons reported that they'd most likely consider using each technique and device, an average cost of a transected PNI repair for each gap-length tier level was calculated by apportioning technique and device utilization information reported in the nerve surgeons' survey. Estimates for the cost of autograft were based on the cost per minute of OR and staff time needed to harvest the nerve segment from the donor site. Cost of OR time per minute varies greatly across geographies and facilities. The range used in the market model was \$3,360 to \$7,320. (See Table 2.)

Table 2. Averaged Cost Procedure/Device Price for each Gap-Length Tier Level

Average Cost Based On (Up To) Three Manufacturers' ASP Listings				Average Cost Not Manufacturer Based	
Three-Tier Gap Length Levels	Wrap	Hollow Tube or Connector	Processed Nerve Allograft	Suture as additive supply	Autograft
No/Short Gap	\$1,566.00	\$1,336.00	\$1,300.00	\$11.61	NA
Small Gap	\$1,566.00	\$1,402.67	\$2,387.50	\$23.23	\$3,660.00
Large Gap	\$1,908.33	NA	\$3,125.00	\$34.84	\$7,320.00

## Results

The online survey obtained information from 26 US nerve repair surgeons however one of the surgeons was dropped as they indicated they do 600 procedures a year and appeared to be an outlier both in the data statistically and based on anecdotal reports. The remaining 25 surgeons had a combined annual caseload of 2,824 and an average annual nerve repair caseload of 112.97. (See Figure 5.)

Figure 5. Average Yearly Caseload for PNI Repairs

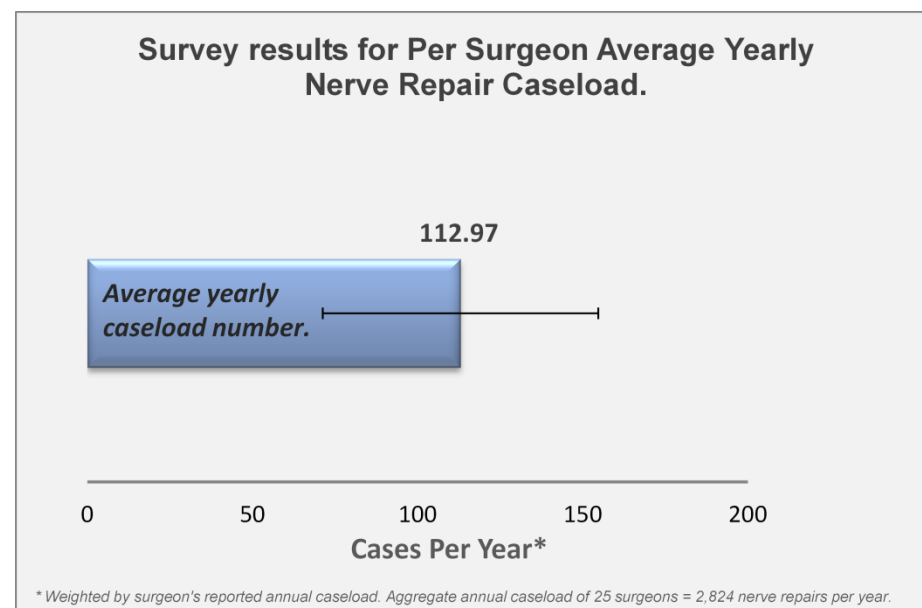
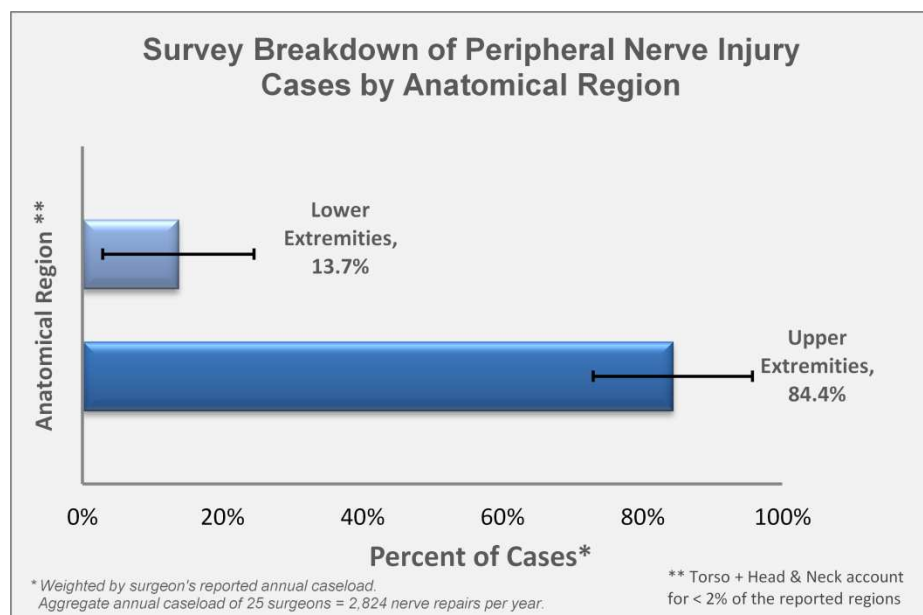




Figure 6. Anatomical Region of PNI Repairs

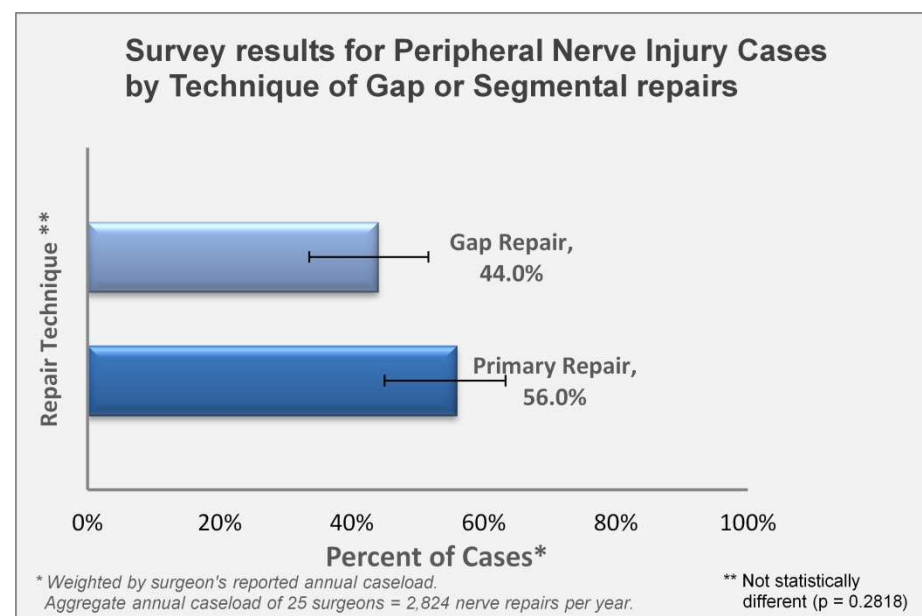


The online survey results are consistent with publications on anatomical region percentages of nerve repairs; namely Upper Extremities 84.4% (72.9% to 95.7%), Lower Extremities 13.7% (2.8% to 24.5%). Head & Neck as well as Torso comprised less than two percent of the adjusted caseloads per year. Of note, these sample results represent current body regions by caseload volume percentages and are not a substitute for future market potential opportunities in terms of revenue growth areas. (See Figure 6.)

We learn from this survey that, on average, when surgeons perform a nerve repair on a transected nerve, 44% (33.6% to 51.6%) of the time it's a gap repair and 56% (45% to 63.3%) of the time it's repaired with no gap (direct repair). These statistics are used as a repair type case-mix parameter in our market model to grossly estimate the gap-length based repair type incidences in the U.S. population. For rounding simplicity in our model we will use a 45% gap repair rate and 55% no gap (sutured directly) repair rate – both well within the 95% confidence levels. These numbers reflect a caseload weighted average and not a per surgeon average. Using a caseload weighted average is more representative of the industry in terms

of numbers of procedures and what technique or device was used for the repairs. (See Figure 7.)

Figure 7. Transected PNI Repair Approach (Direct vs. Non-Direct).



The reported minimum and maximum transected gap length for each surgical repair technique and device option defines utilization patterns at each gap-length tier level. Figure 8 displays with the darker shaded regions, the overall agreed lengths of most often utilized technique or device. The lighter shaded regions display the currently available range of gap length products or technique usage. (See Figure 8.)

In Figure 9, we see the relationships between the three tier levels of repair categories (by gap length) and the utilization of transected PNI repair techniques or devices. For example in the 'No/Short Gap' tier level; 'Suture' is considered as the primary intervention 54.6% of the time, 'Hollow Tube/Connector' 27.7% of the time and 'Processed Nerve Allograft' 17.7% of the time for transected PNI lengths less than 8.90 mm. 'Autograft' is used 0% of the time at PNI gap lengths less than 8.90mm but 78.9% of the time at the 'Large Gap' tier level. Also displayed in Figure 8 are the proportions of the U.S. PNI transected repairs by each gap-length tier level

category. 55% of the PNI transected cases are in the 'No/Short Gap' tier level, 12.6% are in the 'Small Gap' tier level and 32.4% are in the 'Large Gap' tier level. (See Figure 9.)

Figure 8. Transected PNI Repair Techniques by Gap Length Levels.

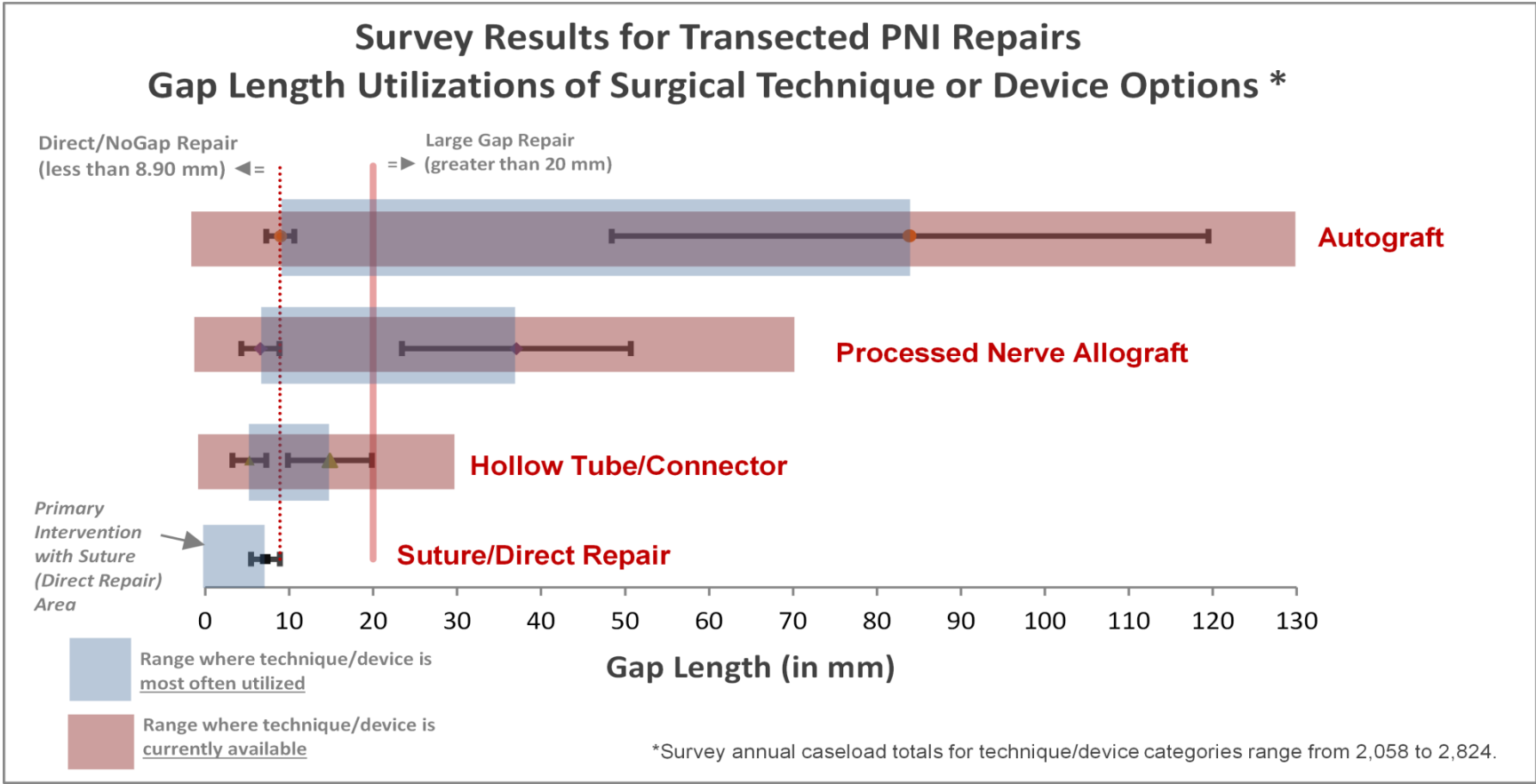
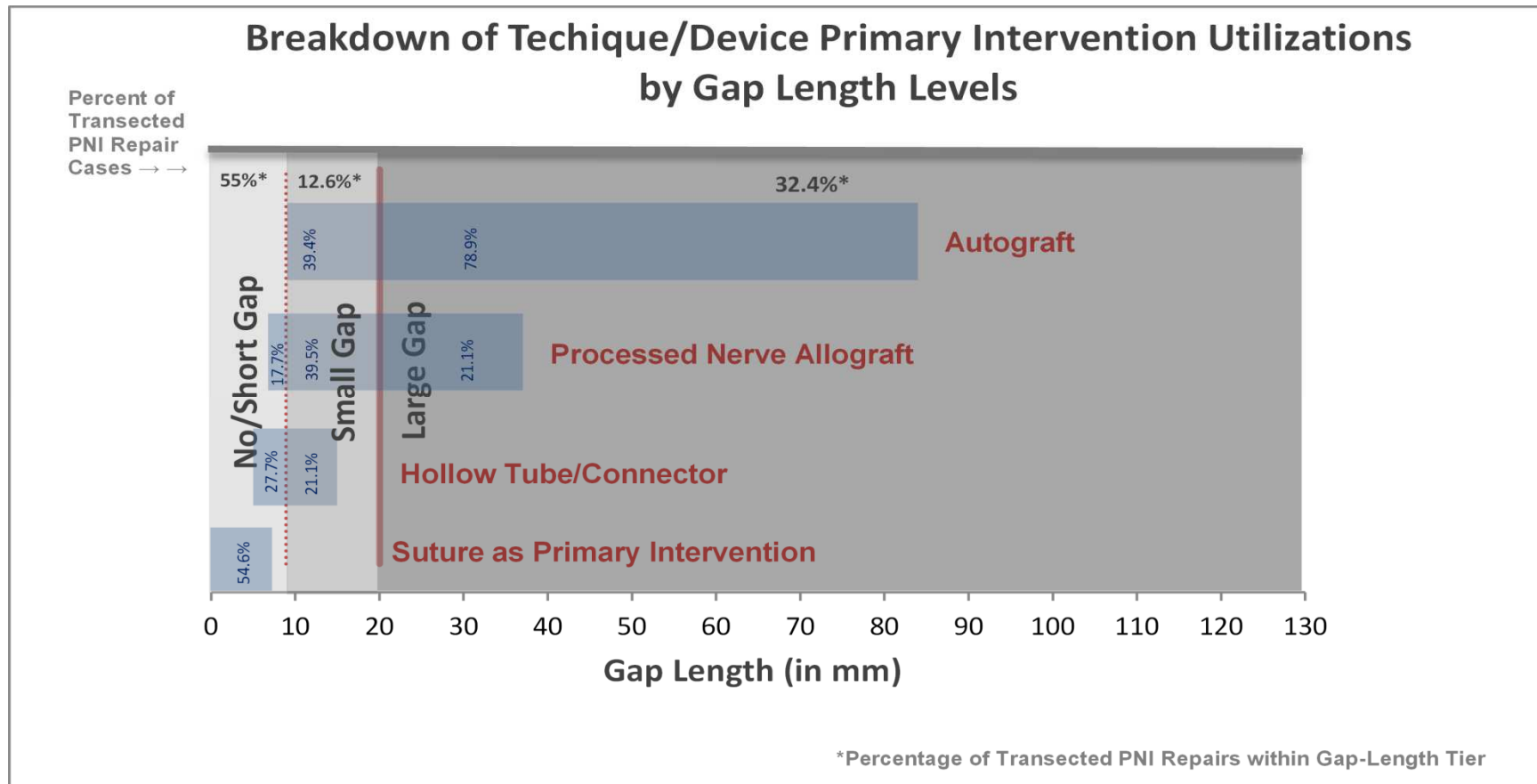




Figure 9. Primary Intervention Utilization by Gap Length Levels.



Broken down by gap-length tier level, table 3 lists the components and their apportioned cost contribution to the within tier level average cost of a procedure. (See Table 3.)

Receptivity to future increased use of processed nerve allograft technology was strongly indicated by the surgeons' survey showing a 75% affirmation of

processed nerve allograft procedures increasing in their practice ( $p < 0.0001$ ). (See Figure 10.) Figure 11 breaks down future increased processed nerve allograft usage percentages by the surgeon's current transected PNI repair case volume level. We note that the odds of indicating an increase in processed nerve allograft usage were seven times

Table 3. Average cost contribution of Technique or Device for transected PNI Procedures by Gap-Length Tier Levels

Technique or Device	No / Short Gap < 8.90 mm	Small Gap 8.9 - 20 mm	Large Gap > 20 mm
<b>Suture</b>	\$11.61 [Primary Intervention]	\$23.23 [Supply Only]	\$34.84 [Supply Only]
<b>Wrap</b>	\$168.94	\$168.94	\$205.87
<b>Hollow tube or Connector</b>	\$370.52	\$296.57	NA
<b>Allograft</b>	\$229.86	\$943.25	\$657.91
<b>Autograft</b>	NA	\$1,440.18	\$5,778.90
<b>Total</b>	<b>\$780.93</b>	<b>\$2,872.16</b>	<b>\$6,677.53</b>

higher for those surgeons who are in the upper 50th percentile of annual number of transected PNI repairs compared to those in the lower 50th percentile group. Since this is weighted by annual caseload, the results indicate that those surgeons most active and experienced in PNI repair strongly endorse increased future processed nerve allograft usage in their practice. (See Figure 11.)

Figure 10. Embracing Future Use of Allograft.

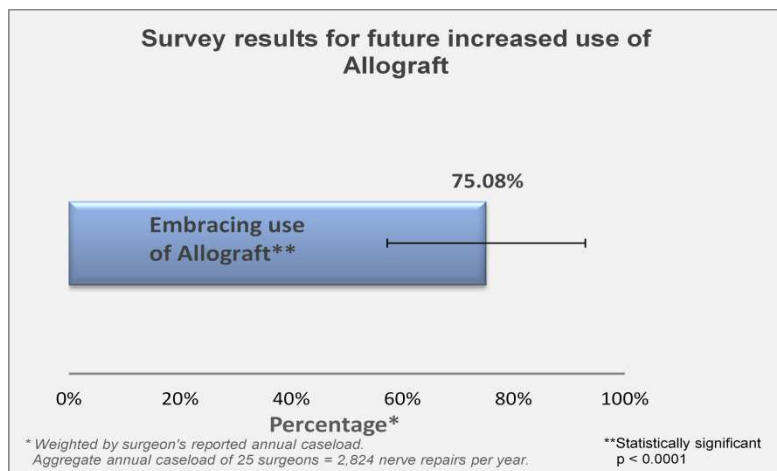
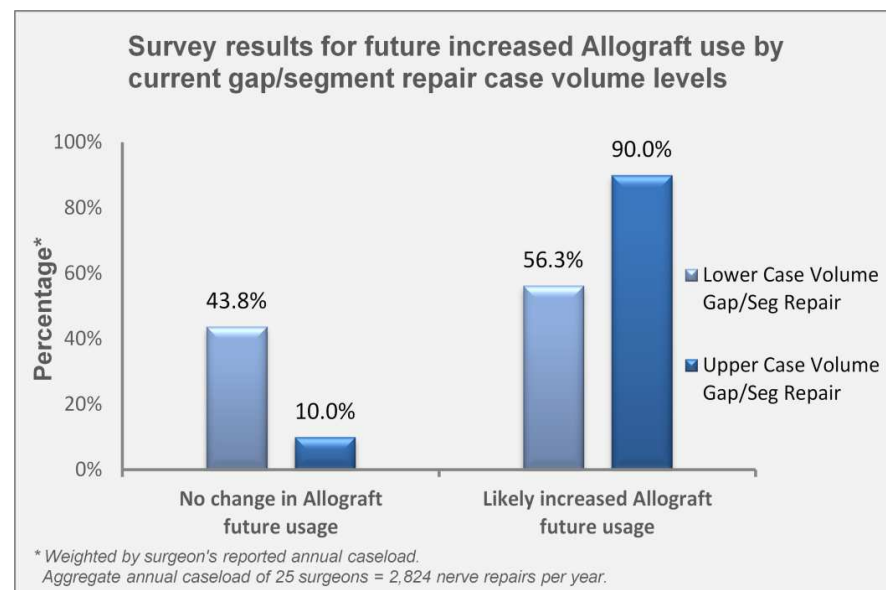
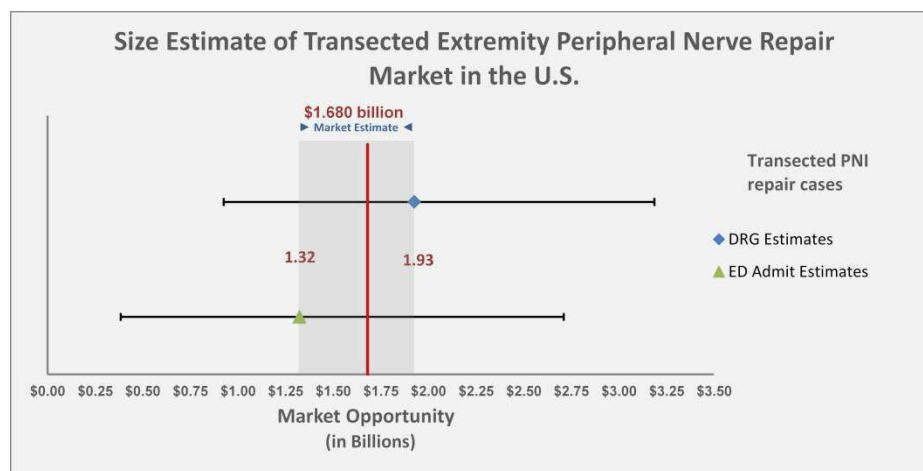


Figure 11. Future use of Allograft by caseload volume breakdown.



Applying the three gap-length tier levels and their associated average costs for techniques or devices utilized at the tier level to the number of annual transected PNI surgical cases gives us a conservative model estimate of \$1.32 billion to \$1.93 billion dollar market size with a mean of \$1.68 billion dollars per year. (See Figure 12.)

Figure 12. Market Estimate Model for U.S. Transected PNI Repairs.



### Conclusion

To estimate the size of the U.S. market for the repair of transected peripheral nerves demands assessing the impact of new technologies and consequently new opportunities. This market has products and technologies that have yet to run through their adoption cycles. The nerve repair surgeons' on-line survey results convincingly reported a high level of receptiveness to emerging and alternative technologies when asked about processed nerve allografts. This supports the notion of new market potential and favorable adoption rates for peripheral nerve repair products. The true picture of a market's potential must incorporate the impact of new and disruptive technologies to create a more robust analysis model that ensures completeness. To be sure, we've only scratched the surface of this market as we haven't included peripheral nerve repairs outside of the extremity regions of the body. As newer technologies are adopted and mature, it is reasonable to foresee expansion of the peripheral nerve market beyond the analysis presented here within. Using conservative and statistically based analytical techniques and methods, we are able to construct reasonable and sound-logic estimates for this evolving market. Claims data as well as ED admissions data have better defined the market space and information provided by nerve repair surgeons have defined the clinical decision process that leads to utilization of transected peripheral

nerve repair products. The summation of this research and analysis reveals a market estimate of \$1.32 to \$1.93 billion dollars per year.

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