

# 3D Printing in the Medical Device Industry – Final Report

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# Recommendations



- Do not pursue big med-device companies unless you are prepared to deal with the sawtooth demand curve
- Physicians and small med-device companies may be more sustainable marketing targets
- Focus marketing messages on speed and quality to build relationships med-device companies
- Focus marketing messages on speed, accuracy and value added services for physicians
- Leverage tradeshow, conferences, and trade groups to access both Med-device companies and physicians

# Primary Research: Key Themes & Learnings



- Speed of end to end process (quote to receiving parts) is the most critical factor for most companies
- Relationships are important in the outsourcing selection process
- Value added services like assembly, CT scan conversions or creation of appearance models may help cement relationships
- Large service bureaus were frequently mentioned partners due to speed and ease of service
- Many large Med-Device companies have cyclical relationships with outsourcing suppliers
- Many physicians are open to using 3D printed anatomy from CT scans for complex procedure planning
- There is a patient education benefit to physicians using 3D prints pre-surgery to explain the procedure
- Specialized materials (PEEK, titanium) or processes may also drive outsourcing in cases where the material is not available in house
- Specialization is key to maintaining competitive advantage



# BIG MED-DEVICE COMPANIES

# Big Med-Device Companies



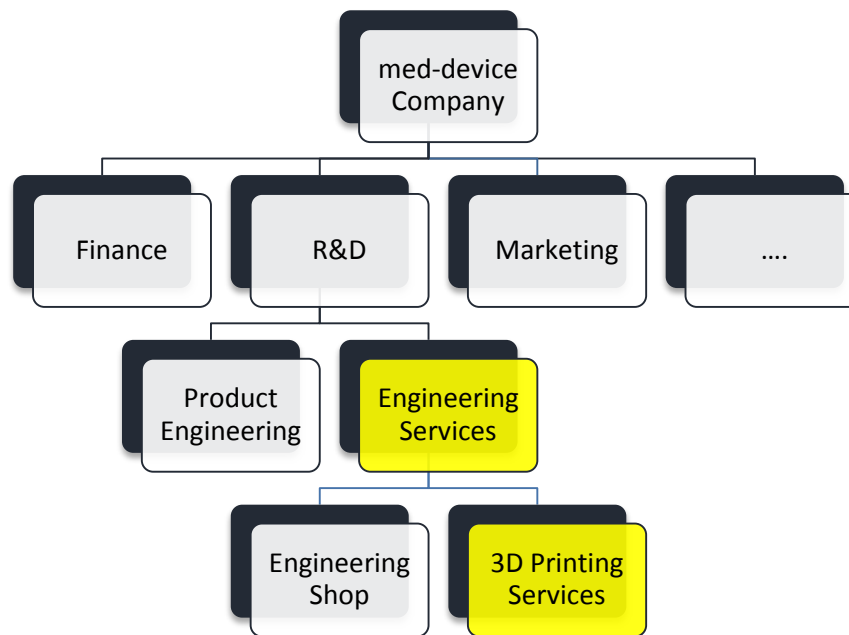
- These are the biggest players with annual revenue over \$500M
- They have the most money and do more development work compared to other companies in the med-device industry
- They are the most likely to have existing in-house 3D printing capability and expertise
- They would appear to be the most obvious target for marketing 3D printing in this industry

# Speed, Reliability, and Ease of Execution



- These companies rely heavily on relationships and tend to use the same service bureau for most prints
- Speed was the number one concern that drove selection of a service bureau
- Accuracy and having the right equipment/materials was a second driver of selection
- Overall these customers want an easy, reliable way to quickly make parts when their internal capacity is constrained

# Building Relationships



## Organizational Structure

- 3D Printing services are typically aligned to the R&D department, rather than specific product lines

## Product Engineering

- The management level is important to target as they typically approve outsourcing requests and often make recommendations

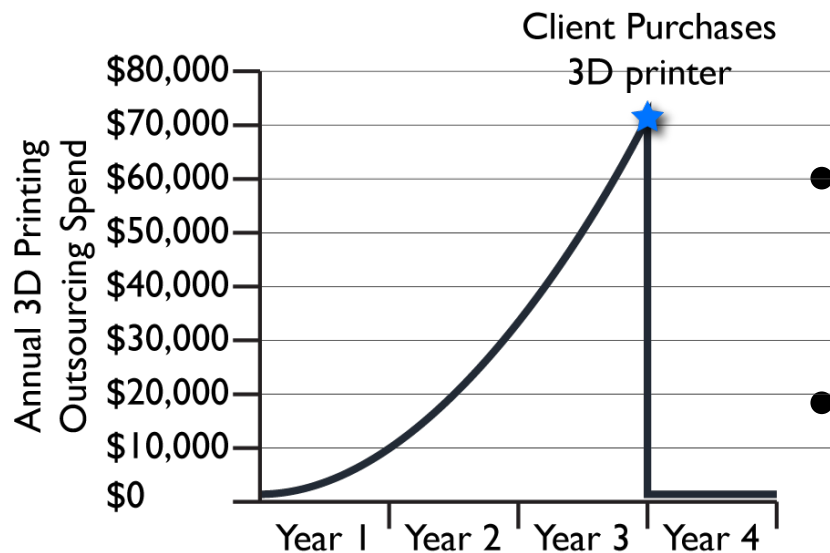
## Engineering Services

- Internal 3D Print Services Technicians often make recommendations when demand exceeds capacity

## Titles to Target

- Engineering Manager/Director Level
- Engineering Services Manager
- Engineering Technician

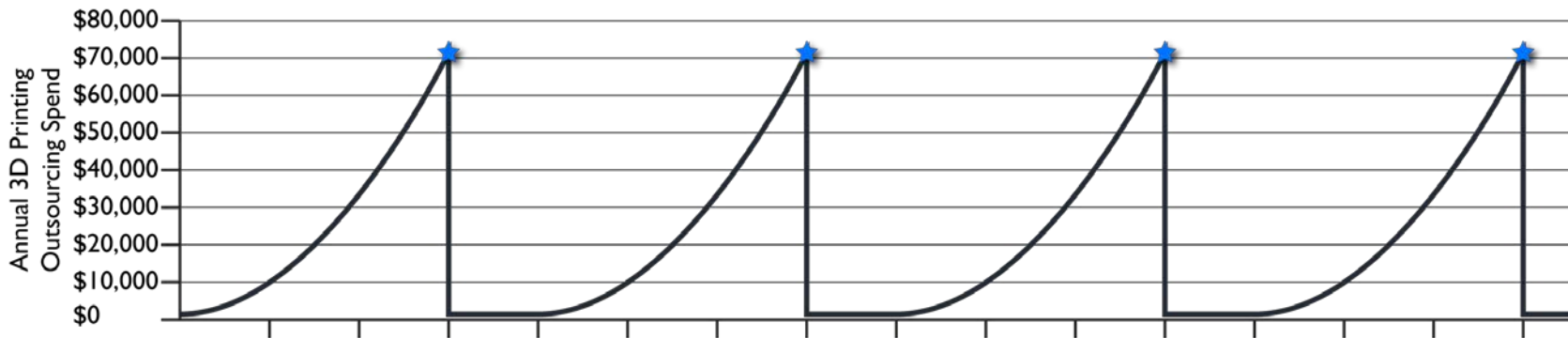
# Cyclical Relationships



- As companies start using 3D printing they tend to outsource
- Over time their use increases until it reaches a tipping point
- At somewhere around \$50-80K of outsourcing a year many companies will purchase a machine for internal use



# Cyclical Relationships



- This process may repeat many times over longer or shorter timeframes
- This means that strong customers may suddenly drop their volume to very low levels
- This makes the larger scale Med-Device companies a challenging target market
- Building strong relationships helps secure business but the cyclical nature is still a serious issue

# Marketing Strategy



- To pursue these clients focus on relationship building
- Attending conference may be a good option to initiate new relationships
- Focus messaging on speed, ease of use, and reliability
- Be prepared for customers demand to peak and drop sharply in a cyclical fashion
  - This will necessitate continual efforts to establish new leads and relationships



# SMALL AND MEDIUM SIZE MED-DEVICE COMPANIES

# What is a Small Med-device Company?



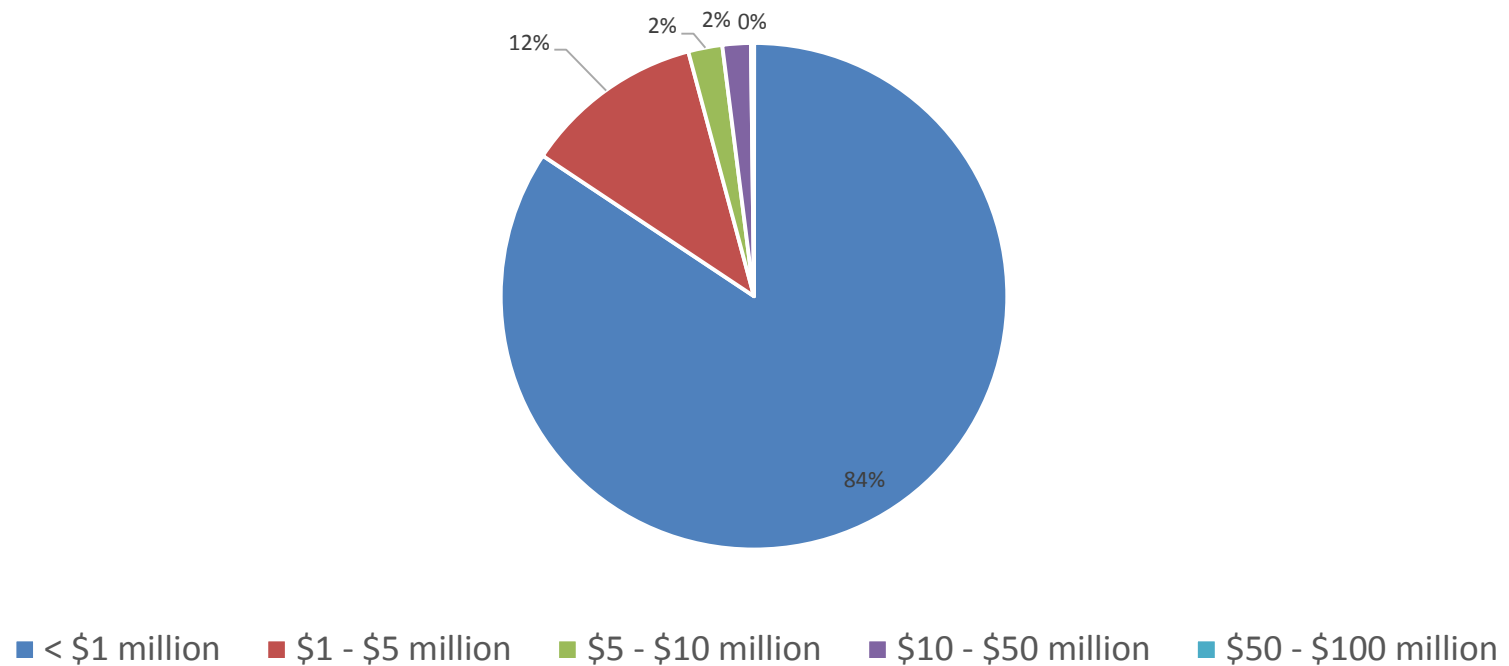
- “There are more than 6,500 medical device companies in the U.S., mostly small and medium-sized enterprises (SMEs). More than 80 percent of medical device companies have fewer than 50 employees, and many (notably innovative start-up companies) have little or no sales revenue.” - Select US<sup>1</sup>
- We consider any med-device company with under \$100M in revenue a small or medium company.
- The needs of these companies for prototyping and proof of principle models are similar to larger companies, but they rarely have internal capabilities
- Speed, reliability, and relationships are all still key drivers in selecting a 3D printing partner

# How Many of These Companies are There?



*Based on a search of the Hoover's business database there are over 6,780 small med device companies in the USA<sup>2</sup>*

Breakdown of Small med-device Companies by Annual Revenue



# Why Small Med-Device Matters

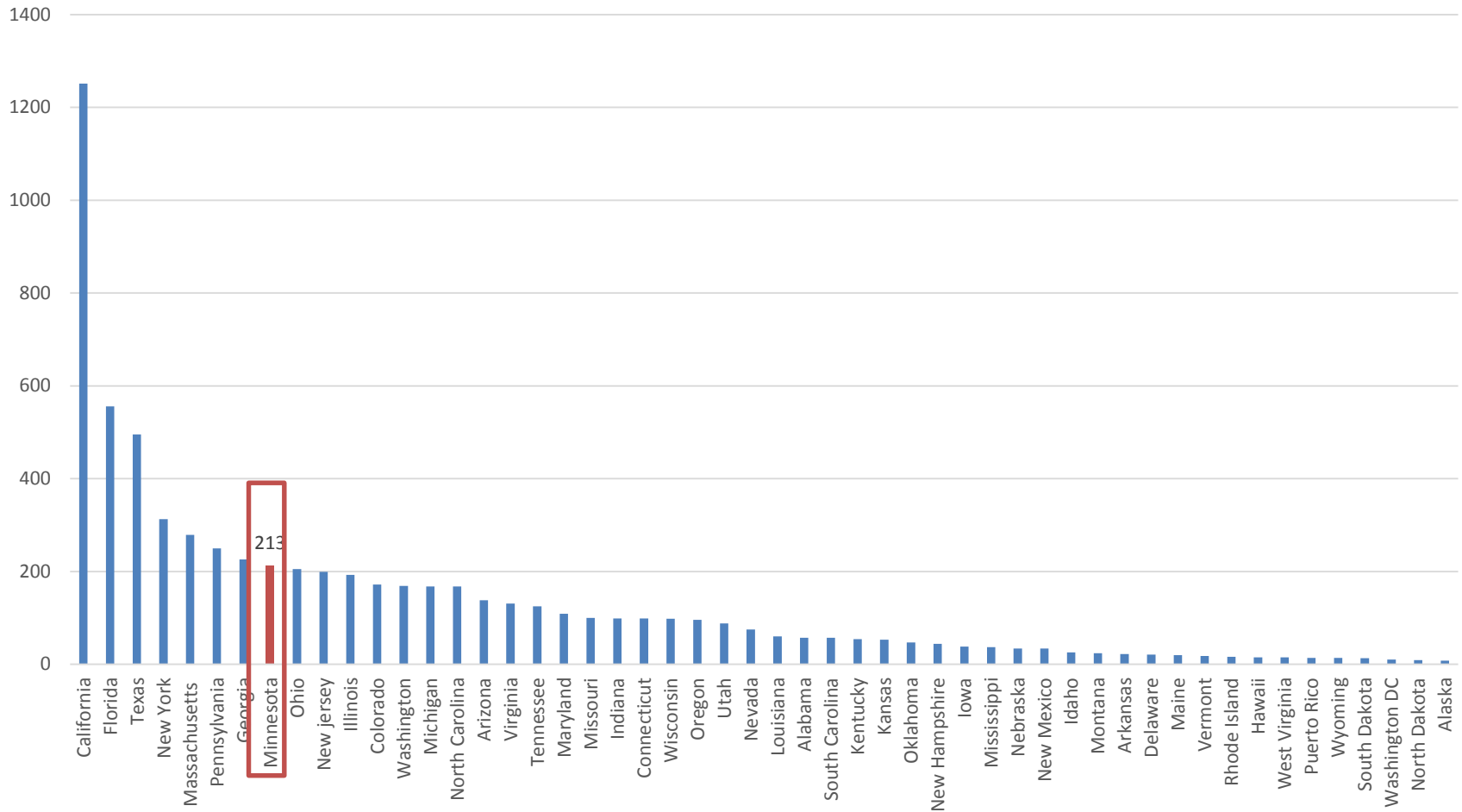


- Similar need for 3D printing compared to large companies
- Similar selection criteria and reliance on relationships compared to large companies
- Our research shows that unlike large med-device companies small companies don't always see the value is buying 3D printers
- The amount of use and the speed at which printing technology is advancing makes buying a printer a less attractive investment
- Small med-device companies are more likely to have a less drastic sawtooth demand profile as result
- However as many of these companies are start-ups there may be more demand instability related to company failures

# Where are These Companies?



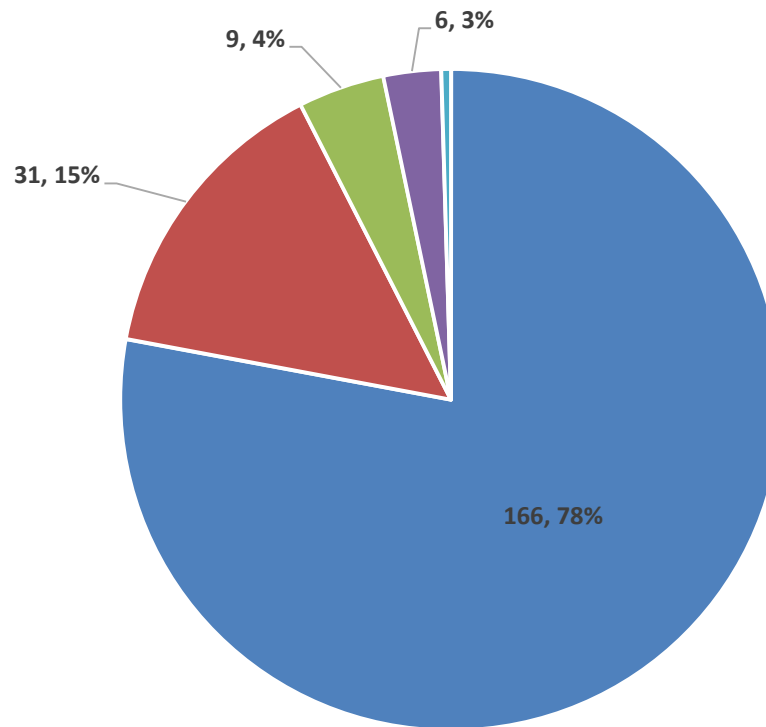
Number of Small Med-Device Firms by State<sup>2</sup>



# How Many are Based in MN?



Breakdown of Small med-device Companies in Minnesota by Annual Revenue<sup>2</sup>



■ < \$1 million   ■ \$1 - \$5 million   ■ \$5 - \$10 million   ■ \$10 - \$50 million   ■ \$50 - \$100 million



# Marketing Strategy



- Pursue a strategy with the same type of messaging as for large med-device companies
  - This will require preparing new focused marketing materials to sell 3D Ally effectively
- Look to join industry groups like Medical Alley Association to gain access to companies in this sector:
  - Largest healthcare trade organization in Minnesota
  - Membership fee for 3D Printing Ally: \$500-1000 annual
  - Provides access to exclusive networking event
- Use the provided complete list of the Minnesota based companies from our Hoover's search with company revenue and phone numbers
  - This could be used as a lead base to start targeting local players in this market



# PHYSICIANS

# What is the opportunity for 3D printing for physicians?



- Doctors have begun utilizing CT scans (or other images) to create patient-specific models, which are used for the following:
  - Pre-surgical planning
  - Resident training
  - Patient or parent education
- The most prevalent use is for pre-surgical planning for complex procedures, the majority of the examples are from the following specialties:
  - Orthopedics
  - Neurology
  - ENT
  - Cardiac
  - Transplant
  - Pediatrics
- Estimate 1-5% of total procedures could benefit from 3D printed models

# Case Study of the Benefits of 3D Printed Models



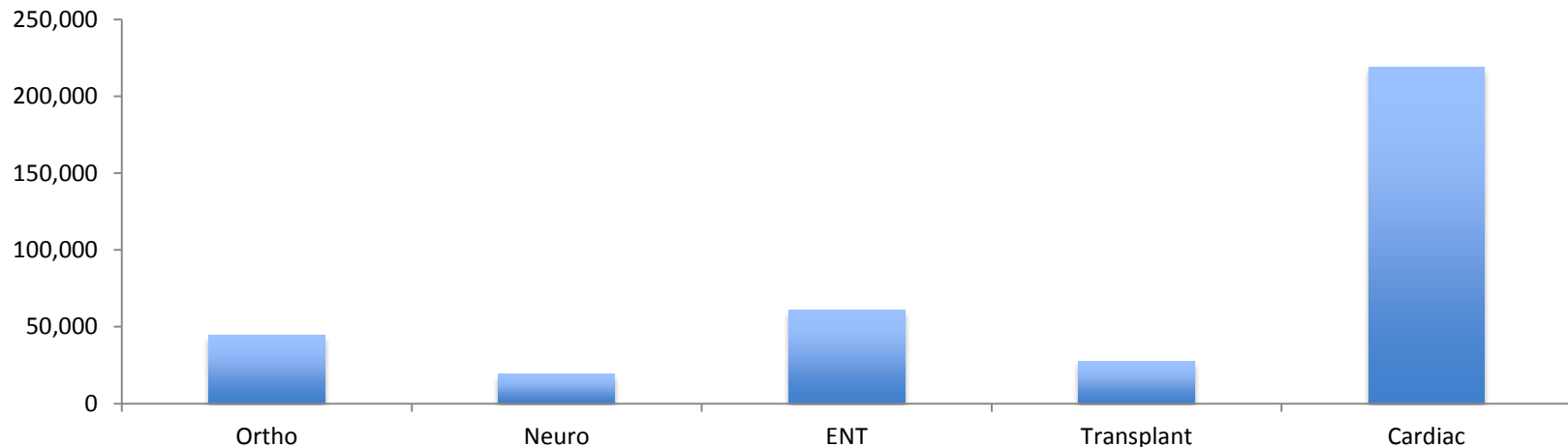
- Experiment Design:
  - Looked at Lumbar Discectomy procedures
  - Patients split into groups with and without 3D printed models
  - Outcomes tracked for 3 months following the procedure
- Experiment Results<sup>3</sup>:
  - Statistically significant differences found for:
    - Operating Time (107 min vs 132 min): 25 minutes OR time savings
    - Blood Usage (342 mL vs 467 mL): 123 mL blood savings
  - Outcomes and complications did not show statistically significant differences between the 2 groups
- Conclusion:
  - 3D printed models for pre-surgical planning can provide cost savings both in terms of OR time and blood usage

# How many of these procedures are performed annually?

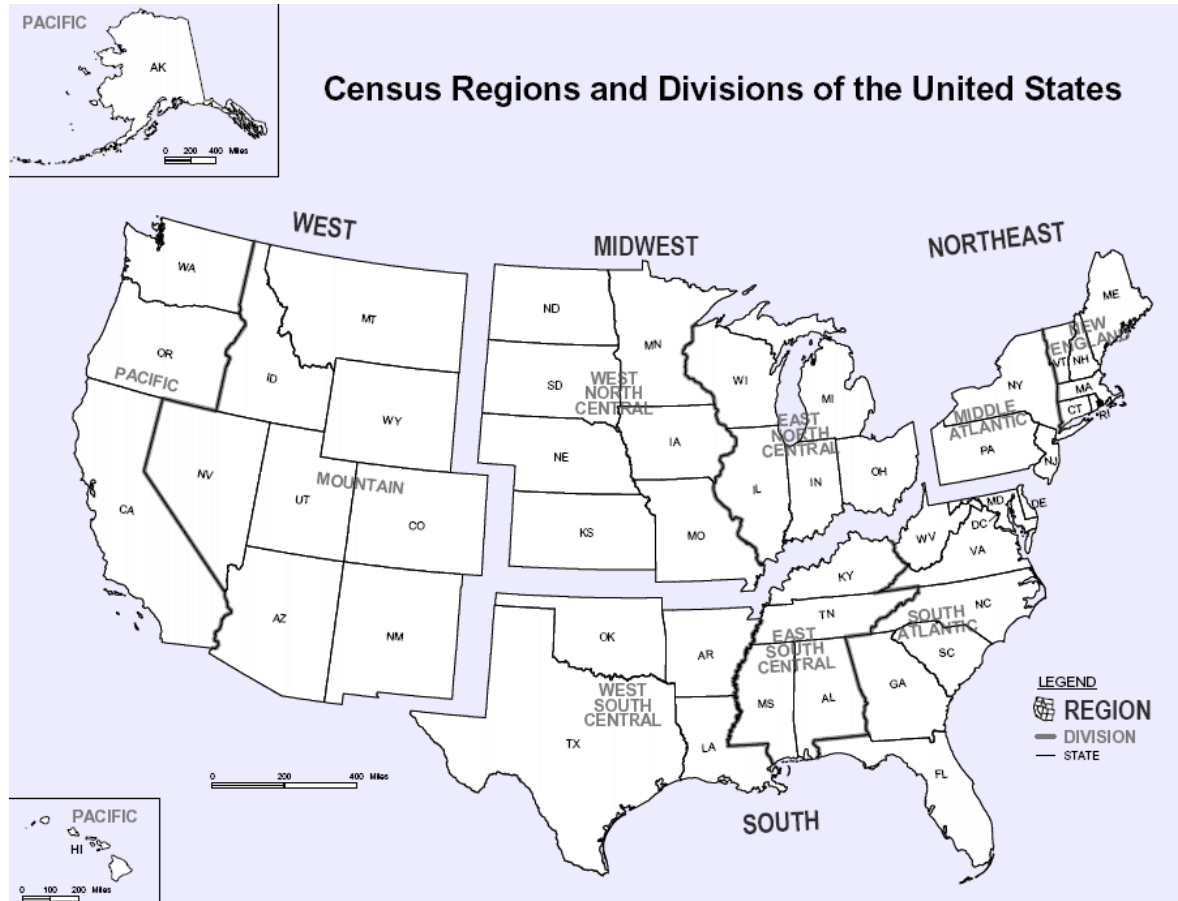


- Over 370,000 procedures performed annual in the US based on the DRG codes found in the appendix<sup>4</sup>

2013 Total Discharges



# Census Locations

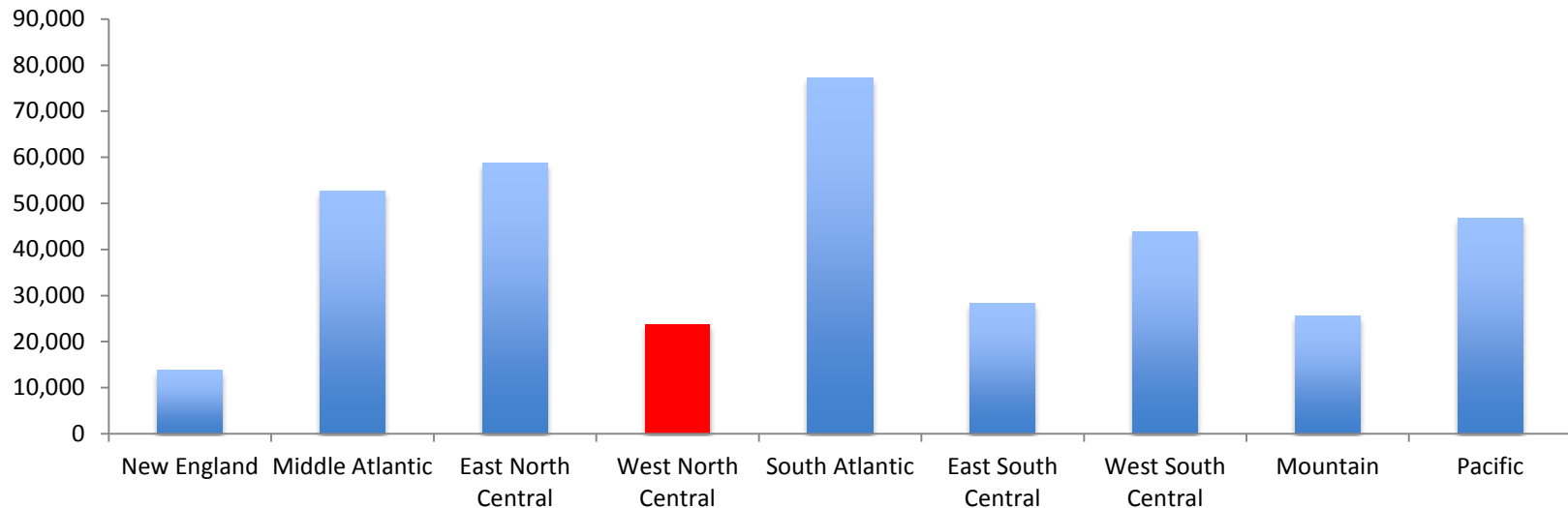


# How many of these procedures are performed locally?



- Nearly 24,000 procedures performed annual in the West North Central census region based on the DRG codes<sup>4</sup>

**2013 Procedure by Census Region**



# How many procedures could benefit from 3D printed models?<sup>4</sup>



	Discharges	1%	2%	3%	4%	5%
<b>TOTAL</b>	370,795	3,708	7,416	11,124	14,832	18,540
New England	13,860	139	277	416	554	693
Middle Atlantic	52,775	528	1,056	1,583	2,111	2,639
East North Central	58,705	587	1,174	1,761	2,348	2,935
West North Central	23,820	238	476	715	953	1,191
South Atlantic	77,160	772	1,543	2,315	3,086	3,858
East South Central	28,245	282	565	847	1,130	1,412
West South Central	43,825	438	877	1,315	1,753	2,191
Mountain	25,620	256	512	769	1,025	1,281
Pacific	46,785	468	936	1,404	1,871	2,339



# Who pays for the added cost of 3D printed models?



- Right now in the US, there is no reimbursement available for 3D printed models
- However, Japan's national health insurance recently approved reimbursement for 3D printed models<sup>3</sup>:
- “Japan's Central Social Insurance Medical Council, an organization of the Ministry of Health, Labour and Welfare, has announced that the cost of 3D printed organ models used to assist medical treatments and surgeries will be covered under the standard medical insurance payment range.”
  - Open BioMedical Initiative, January 2016

# Is it realistic for the US to follow Japan and reimburse 3D models?<sup>4</sup>



The average cost of the procedures evaluated greatly exceeds the cost of a 3D printed model

	Ortho Avg Cost	Neuro Avg Cost	ENT Avg Cost	Transplant Avg Cost	Cardiac Avg Cost
TOTAL	\$40,311	\$26,525	\$136,249	\$111,192	\$49,107
New England	\$42,162	\$32,042	\$163,290	\$235,195	\$57,689
Middle Atlantic	\$37,871	\$25,833	\$133,930	\$99,615	\$45,501
East North Central	\$37,445	\$23,955	\$127,136	\$123,217	\$47,059
West North Central	\$36,469	\$27,658	\$139,775	\$204,462	\$49,005
South Atlantic	\$38,509	\$23,620	\$124,402	\$111,677	\$44,747
East South Central	\$32,685	\$34,053	\$109,913	-	\$43,326
West South Central	\$35,109	\$24,816	\$129,078	\$122,613	\$44,512
Mountain	\$52,268	\$26,530	\$126,259	-	\$50,637
Pacific	\$54,875	\$31,365	\$198,226	\$184,988	\$67,461

# Marketing Strategy



- Pursue a strategy focused on the benefits for 3D printed surgical models
  - Tangible benefits: OR time savings, blood loss savings
  - Intangible benefits: training, education
- Look to attend trade shows and conferences where large groups of physicians will be in attendance
  - North American Spine Society, International Society for the Advancement of Spine Surgery
  - Aneurysm / AVM Conference
  - American Pediatric Surgical Association
  - American Academy of Facial Plastic and Reconstructive Surgery
  - American Society of Transplant Surgeons
- Leverage existing industry connections and network to gain introductions to physician thought leaders
  - Target professors of surgery at local universities
  - Target industry and association key opinion leaders
- Offer one-time free models to physician thought leaders to gain initial entry into the market and demonstrate the value added of 3D printer models
- Offer additional services and develop internal competencies that provide value to the physician market, e.g. processing CT scans into CAD files



# CONCLUSIONS

# Recommendations



- Do not pursue big med-device companies unless you are prepared to deal with the sawtooth demand curve
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- Focus marketing messages on speed and quality to build relationships med-device companies
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# Other Considerations



- Planned exit through acquisition
  - Maybe possible after long relationship with major player
  - Likely hard solicit this outcome
  - Probably not a good option
- Hard specialization
  - New machines – metal parts, PEEK material, Polyjet
  - Clean room
  - Production – custom implant production
  - All options are capital intensive

# Works Cited



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3. Open BioMedical Initiative. "Japanese Medical Insurance to Cover Cost of 3D Printed Organ Models | Open BioMedical Initiative - We Help." *Japanese Medical Insurance to Cover Cost of 3D Printed Organ Models*. Open BioMedical Initiative, 29 Jan. 2016. Web. 09 May 2016.
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