



The United States Medical Device Industry Profile

2014



The United States
Food and Drug Administration

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About this Industry

Industry Definition

Medical devices regulated by the FDA range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices. In addition, medical devices include in vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits, which

may include monoclonal antibody technology. Certain electronic radiation emitting products with medical application and claims meet the definition of medical device. Examples include diagnostic ultrasound products, x-ray machines and medical lasers.

Data Sources

- CDRH Registration and Listing
- Dun and Bradstreet, Inc.
- U.S. Census Bureau

- Bureau of Economic Analysis
- U.S. Department of Commerce
- PricewaterhouseCoopers and the National Venture Capital Association

Medical Device Industry Classification

| NAICS Code | NAICS Description |
|-------------------|---|
| 325413 | In-vitro diagnostic substance manufacturing |
| 334510 | Electromedical and electrotherapeutic apparatus manufacturing |
| 334516 | Analytical laboratory instrument manufacturing |
| 334517 | Irradiation apparatus manufacturing |
| 339112 | Surgical and medical instrument manufacturing |
| 339113 | Surgical appliance and supplies manufacturing |
| 339114 | Dental equipment and supplies manufacturing |
| 339115 | Ophthalmic goods manufacturing |

UNITED STATES MEDICAL DEVICE INDUSTRY AT A GLANCE

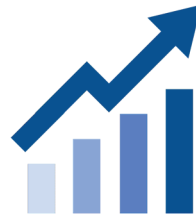
MEDICAL DEVICE MANUFACTURING IN 2014

\$391 BILLION IN SALES

U.S. MEDICAL DEVICE MARKET SIZE



Medical Devices Accounted For \$0.03 of Every \$1 Spent by U.S. Consumers



Medical Device Sales Grew 2.1 % Annually Between 2005 and 2014



Medical Devices Accounted For 5 % of All Venture Capital Funding



Medical Device Manufacturers Employ Approximately 400,000 workers



Approximately 17,500 Establishments Manufacture Medical Devices in the U.S.



The Medical Device Trade Surplus Grew To \$2.0 Billion

Sources: Bureau of Economic Analysis, Annual Survey of Manufacturers, Dun and Bradstreet, Inc., The MoneyTree™ Report by PricewaterhouseCoopers and the National Venture Capital Association, U.S. Department of Commerce and the U.S. International Trade Commission

COMPARING THE UNITED STATES AND EUROPE

COMPARISON FOR CALENDAR YEAR 2013

Population



(Millions)

Total Establishments



Total Employed



Total Sales



(Billions \$)

Total Patents



317

17,500

400,000

300

12,969



506

25,000

575,000

114

10,668

Sources: Dun and Bradstreet, Inc., Medtech Europe 2014, U.S. Patent and Trademark Office,

*Patents includes only domestic patents



Employment



The Medical Device Industry is a Large Employer

Approximately 400,000 people work in this industry



Small Businesses Make Up Most Establishments

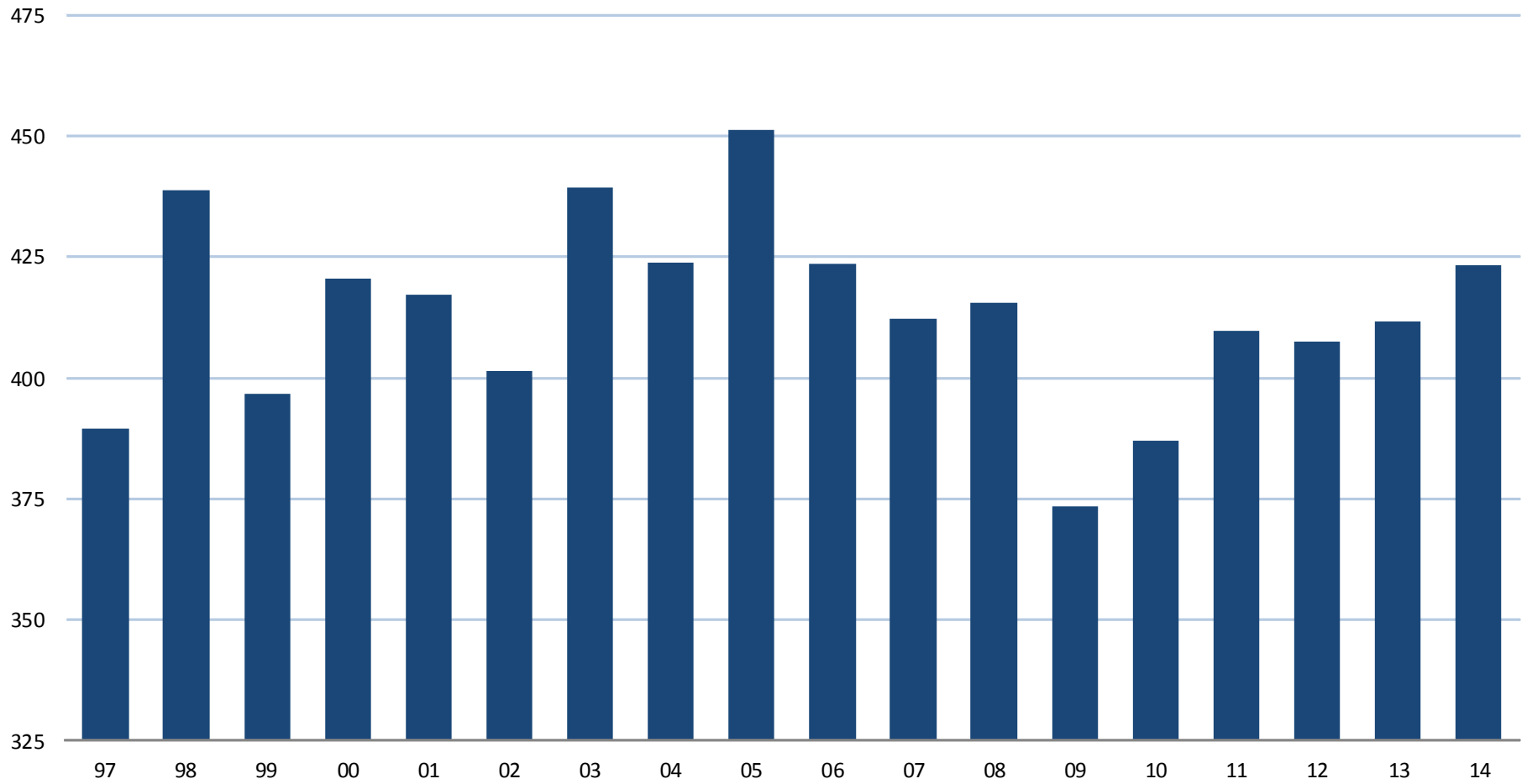
99% of firms are small businesses (employ under 500 employees)



Surgical Devices is the Largest Employer

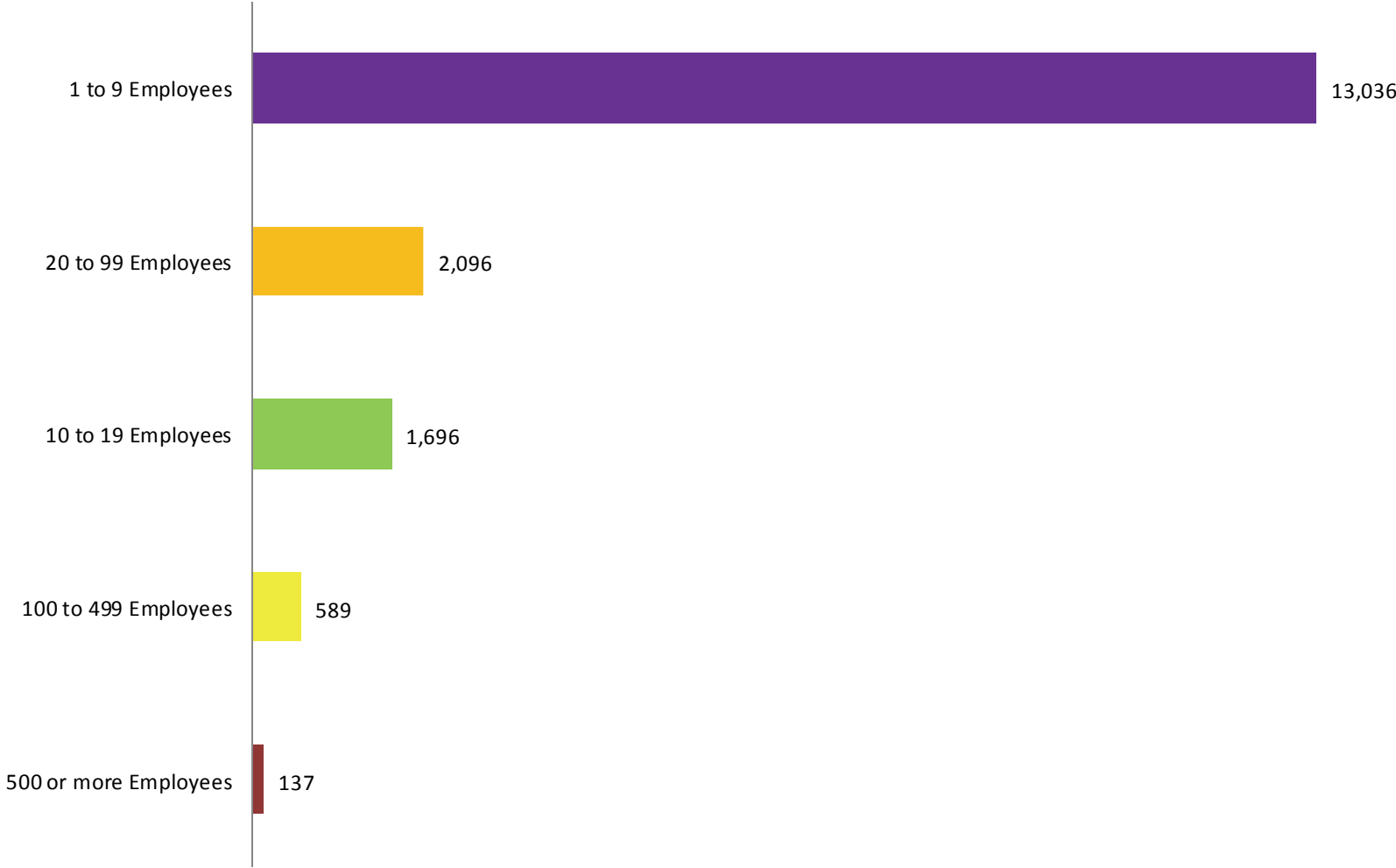
50% of employees manufacture surgical devices

Number of People Employed by the Medical Device Industry (in 1,000's)
Between 1997 - 2014



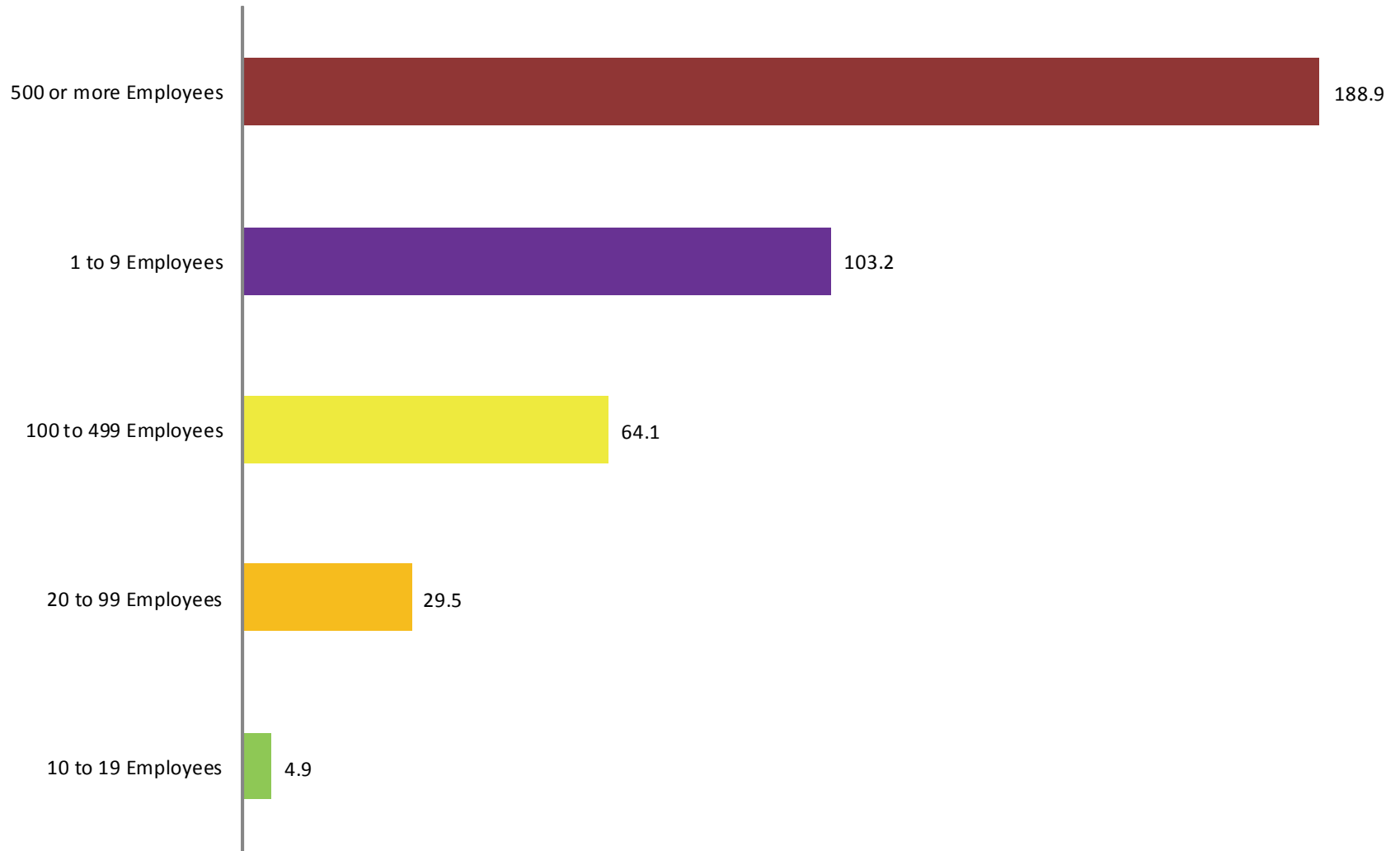
Source: Dun and Bradstreet, Inc.

Medical Device Manufacturing Establishments by Number of Employees, 2014



Source: Dun and Bradstreet, Inc.

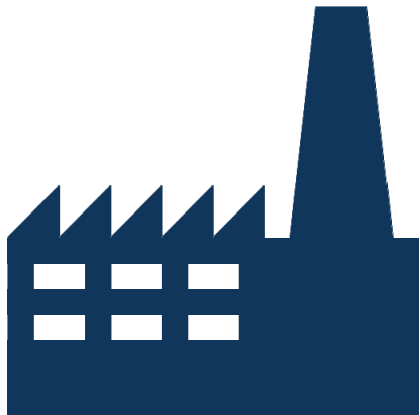
US Medical Device Sales (in Billions of \$) by Employment Size of Manufacturing Establishment, 2014



Source: Dun and Bradstreet, Inc.



Establishments



The Medical Device Industry is a Large Industry

Approximately 17,500 establishments manufacture medical devices



Most Establishments are Small Businesses

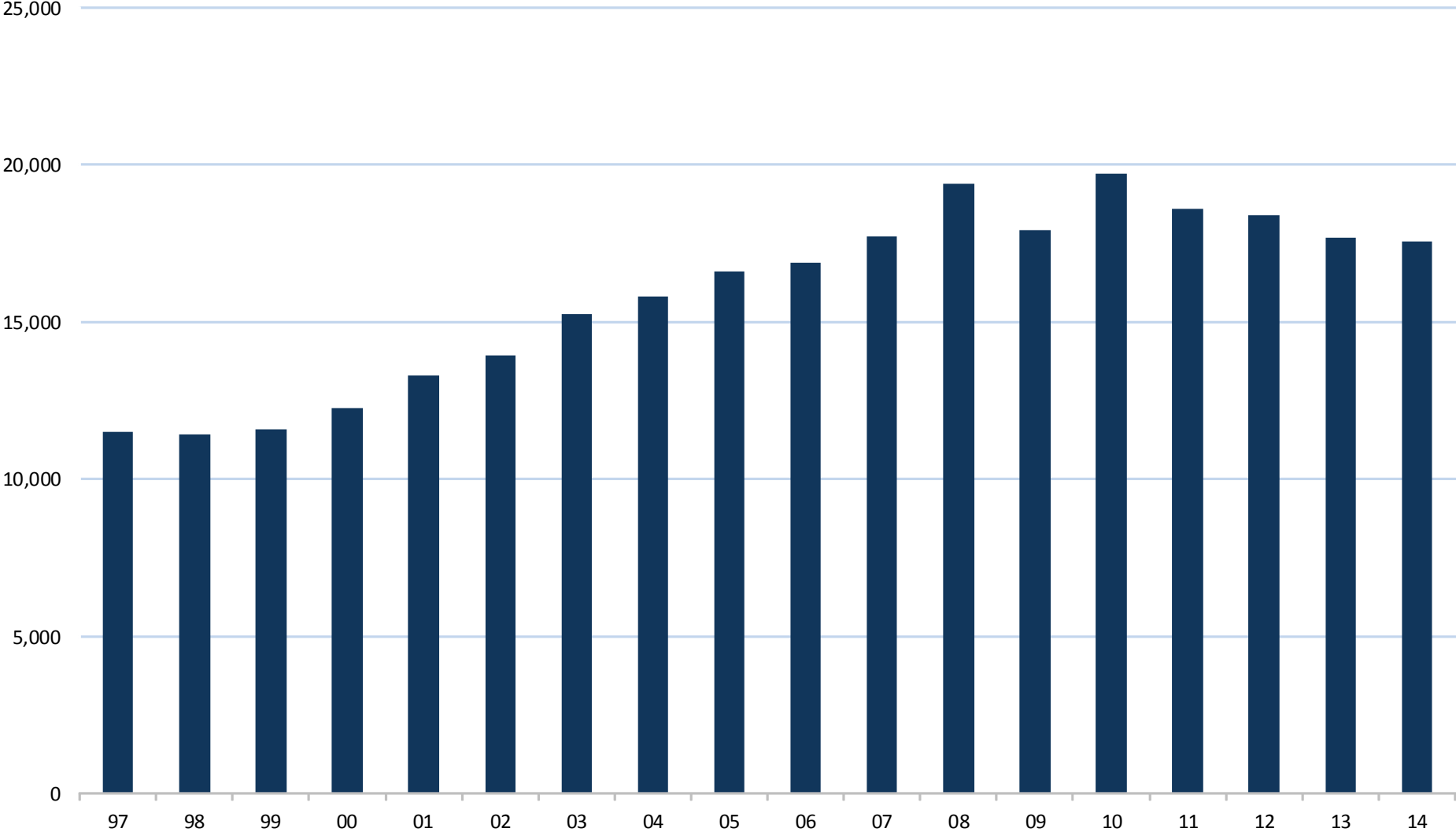
Approximately 13,000 establishments employ 1 - 9 workers



Most Establishments Manufacture Surgical Devices

Slightly less than 9,500 establishments manufacture surgical devices

Number of Medical Device Manufacturers, 1997 - 2014



Source: Dun and Bradstreet, Inc.



Sales



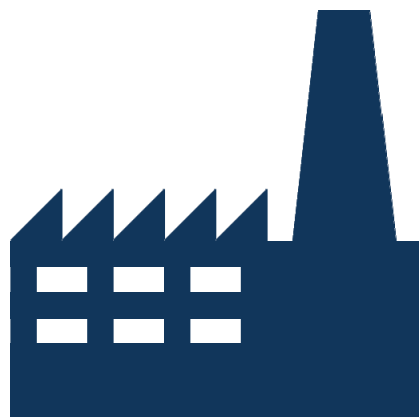
Medical Device Sales Continue to Rise

Total Sales rose from approximately \$200 billion in 1997 to \$400 billion in 2014



Small Businesses Account for a Quarter of Sales

In 2014, 26% of sales were from establishments employing 1 - 9 workers



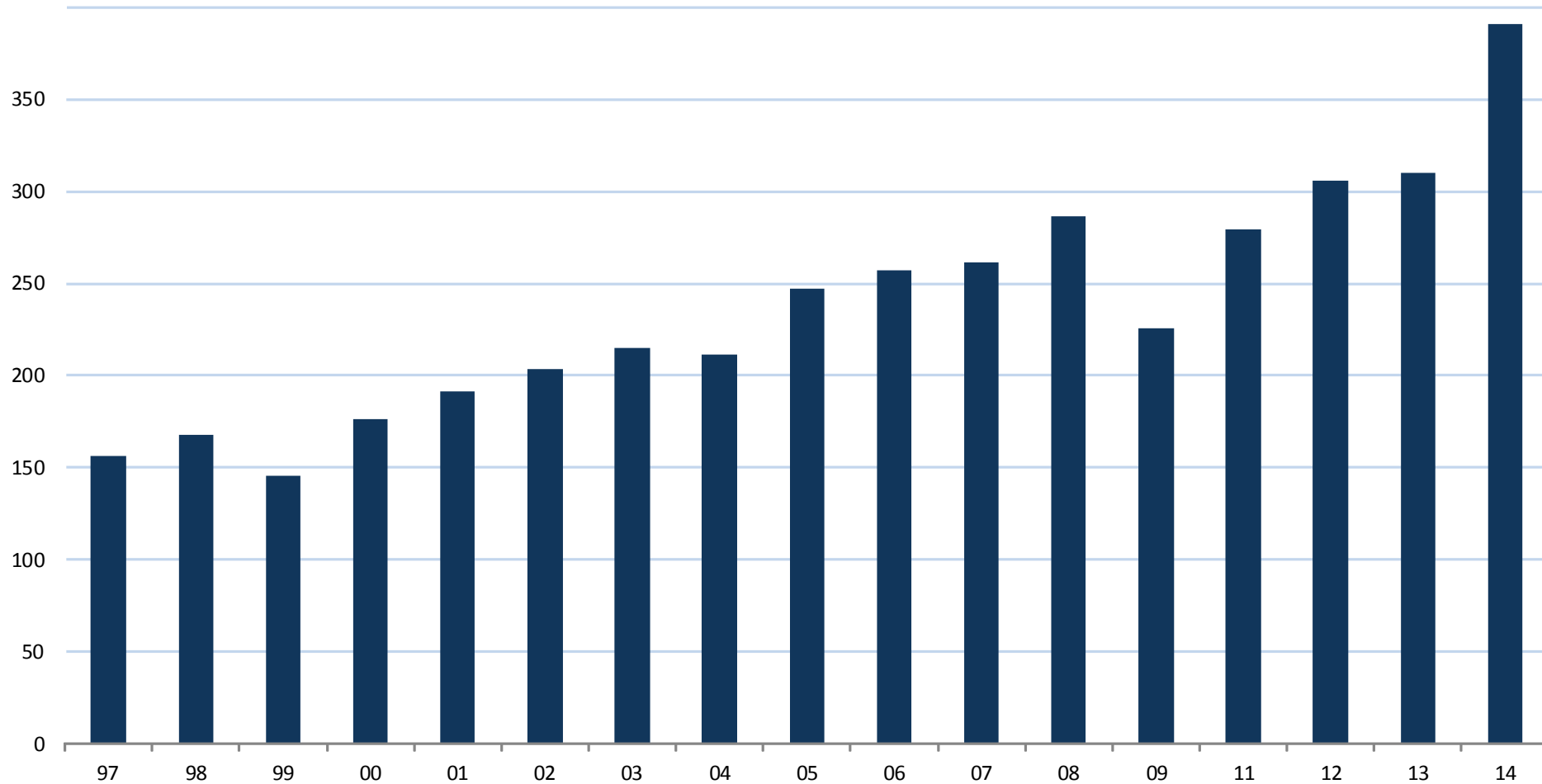
Large Businesses Account for Half of Sales

In 2014, 48% of sales were from establishments employing 500 or more workers

Source: Dun and Bradstreet, Inc.

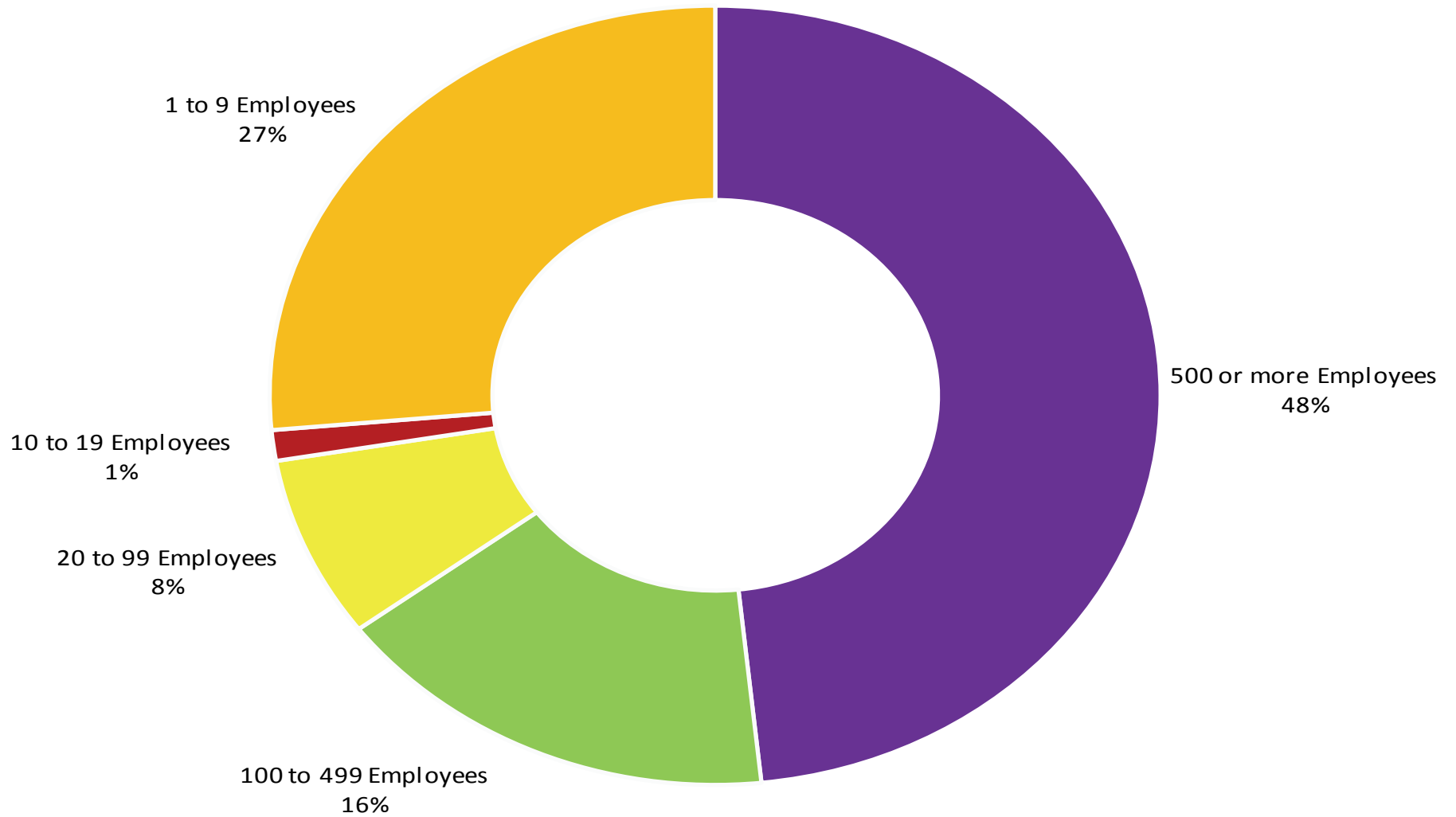
Medical Device Sales, in 2014 dollars, 1997-2014

\$400 Billion

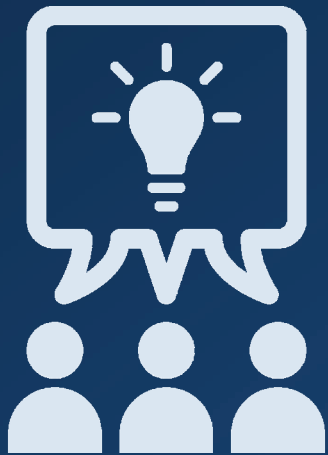


Source: Dun and Bradstreet, Inc.

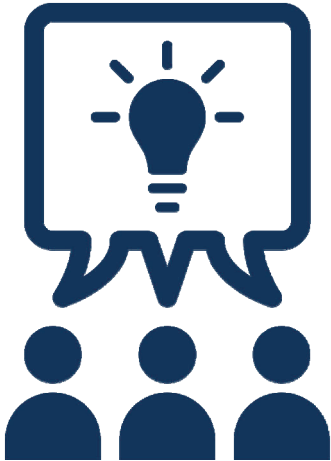
Medical Device Sales by Employment Size of Establishment, 2014



Source: Dun and Bradstreet, Inc.



Innovation



Domestic Patents Continue to Rise

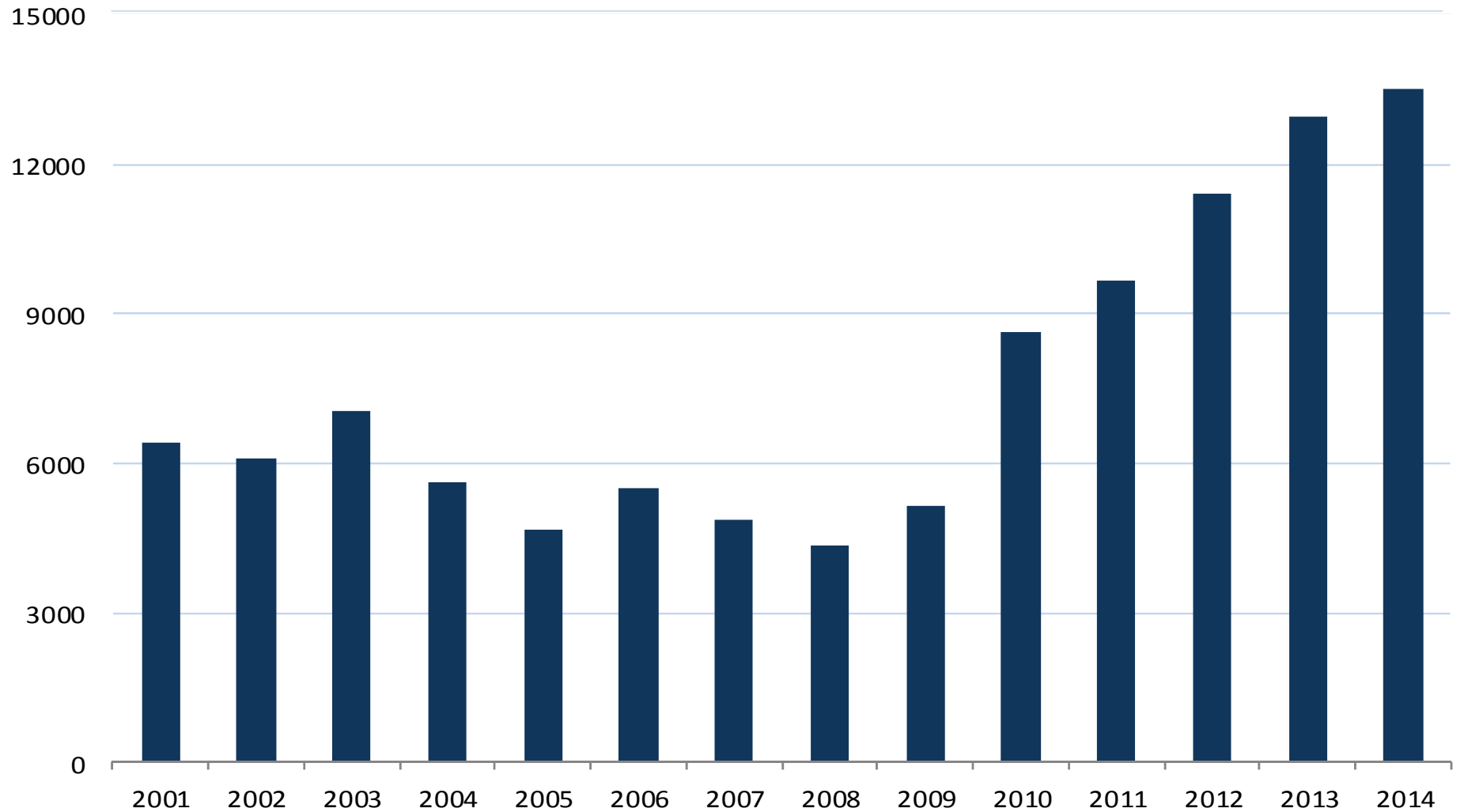
Total Domestic Patents rose from roughly 5,000 in 2005 to 14,000 in 2014



Venture Capital is Rising

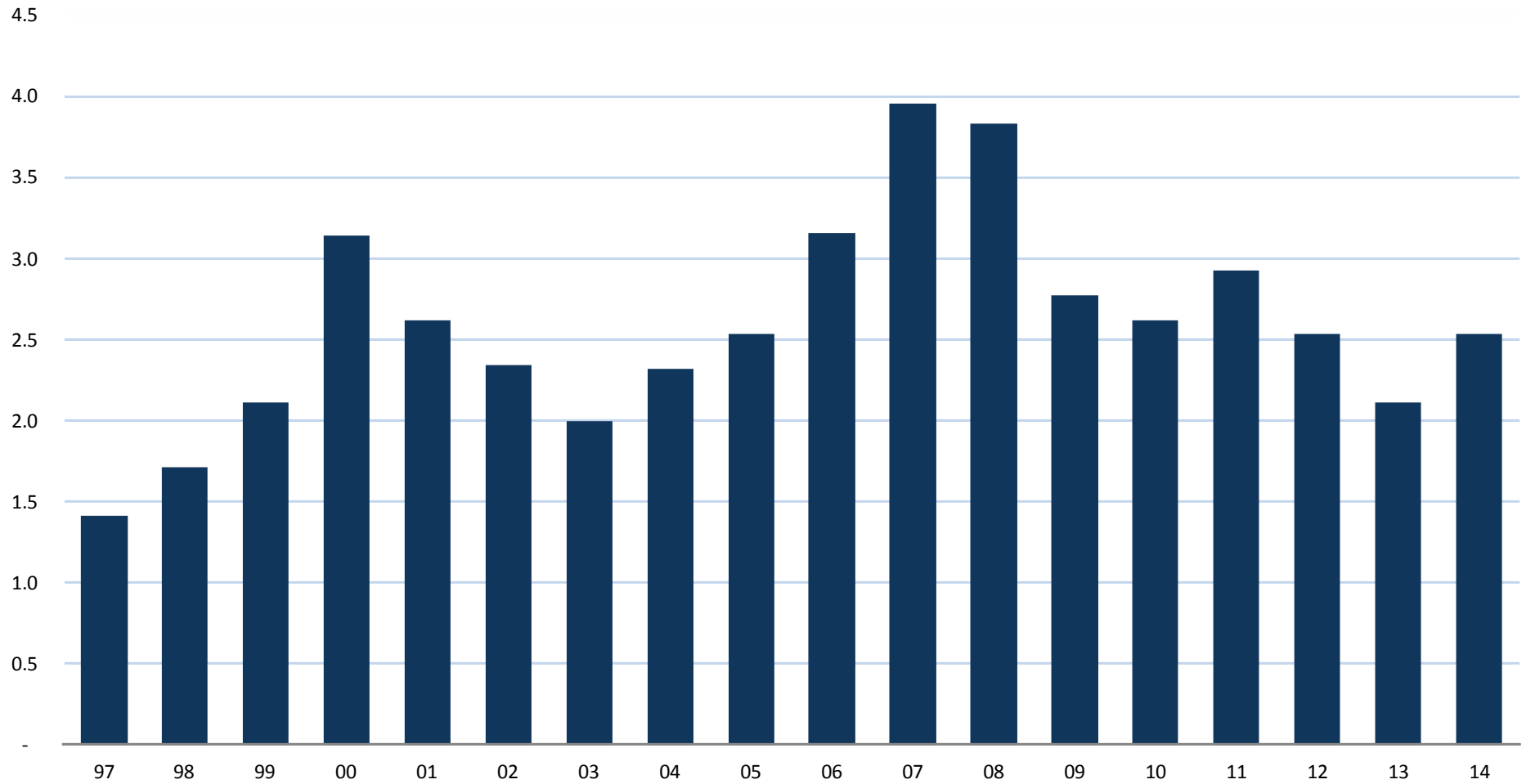
Total Venture Capital Investments in the Medical Device Industry rose from \$2.2 billion in 2013 to \$2.6 billion in 2014

Total Patents Granted (U.S. Origin) 2001 - 2014



Source: U.S. Patent and Trademark Office

Venture Capital Financing for Medical Devices and Equipment (in Billion of dollars) 1997 - 2014



Source: The MoneyTree™ Report by PricewaterhouseCoopers and the National Venture Capital Association



Trade





Exports Continue to Exceed Imports

In 2014, Exports equaled \$54.5 billion while Imports equaled \$50.0 billion



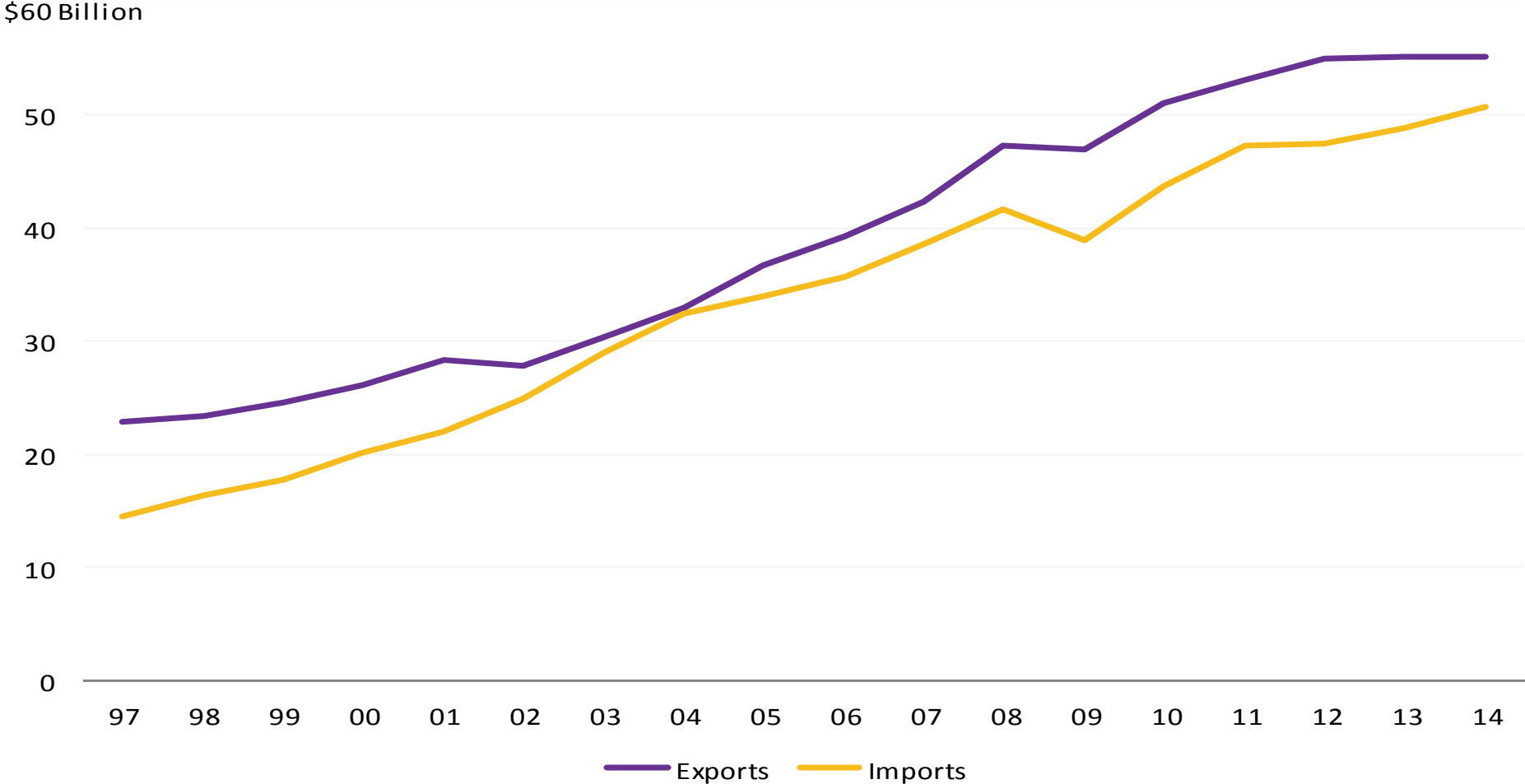
The Five Largest Importers of American Medical Devices
are (in order)

Japan, Netherlands, Canada, Belgium, and Germany

These Five Nations Account for 48 % of all U.S. Exports

Source: U.S. Department of Commerce and the U.S. International Trade Commission

U.S. Exports and Imports of Medical Devices (in 2014 dollars) 1997 - 2013



Source: U.S. Department of Commerce and the U.S. International Trade Commission