BIOPSY DEVICES - GLOBAL ANALYSIS AND MARKET FORECASTS
Executive Summary

The table below provides an overview of the global biopsy devices market during the forecast period from 2013–2019.

<table>
<thead>
<tr>
<th>Procedure Volumes (in millions)</th>
<th>2013</th>
<th>2019</th>
</tr>
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<tbody>
<tr>
<td>Global</td>
<td>13.2</td>
<td>18.2</td>
</tr>
<tr>
<td>US</td>
<td>4.2</td>
<td>5.8</td>
</tr>
<tr>
<td>5EU</td>
<td>2.3</td>
<td>2.9</td>
</tr>
<tr>
<td>South America</td>
<td>1.0</td>
<td>1.6</td>
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<tr>
<td>APAC</td>
<td>5.8</td>
<td>7.9</td>
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<table>
<thead>
<tr>
<th>Market Sales ($m)</th>
<th>2013</th>
<th>2019</th>
</tr>
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<tbody>
<tr>
<td>Global</td>
<td>$506.4</td>
<td>$602.4</td>
</tr>
<tr>
<td>US</td>
<td>$265.4</td>
<td>$248.8</td>
</tr>
<tr>
<td>5EU</td>
<td>$75.3</td>
<td>$102.8</td>
</tr>
<tr>
<td>South America</td>
<td>$19.5</td>
<td>$32.8</td>
</tr>
<tr>
<td>APAC</td>
<td>$146.2</td>
<td>$217.8</td>
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Market Drivers

- Inadequate screening tests for particular cancers (↑↑↑↑)
- Demand for minimally invasive biopsy techniques (↑↑↑)
- Increased adherence to certain cancer screening guidelines (↑↑)
- Aging patient population (↑↑)

Market Barriers

- Increased accuracy of cancer diagnostic tests (↑↑)
- Bundling of breast biopsy reimbursement (↑↑↑)
- Decreased adherence to certain cancer screening guidelines (↑↑)
- Benefits of mass prostate cancer screening outweighed by risks (↑↑)

Source: GlobalData Interviews with Leading Radiologists, Oncologists, and Marketing Executives from Current Players, 2013
Note: 5EU = France, Germany, Italy, Spain, and UK; South America = Brazil; APAC = Asia-Pacific (China, India, and Japan)
*Market Valuations are approximated. See accompanying forecast model for specific numbers.

Overview

GlobalData estimates that the biopsy devices market in 2013 was valued at $506.4m across the 10 regions covered in this report, which include the United States (US), France, Germany, Italy, Spain, the United Kingdom (UK), Japan, Brazil, India and China. By the end of the forecast period in 2019, sales will have grown to over $602.4m, with a Compound Annual Growth Rate (CAGR) of 2.93%.

Future Growth

GlobalData forecasts that the emerging economies included in this report will grow at much higher CAGR than the global growth rate. Countries in the Asia Pacific (APAC) region such as Japan and China and the South American country of Brazil will have growth rates that are more than double the global CAGR. This is primarily due to the increased market access of each country’s population to healthcare resources and the increased adoption of more expensive core needle biopsy devices over fine needle aspiration devices.
Executive Summary

The figure below illustrates the composition of global biopsy devices procedure volumes in 2013 and 2019.

Future Outlook

While the global biopsy devices market is expected to see growth over the forecast period, there are several barriers that are dampening the intervention's potential adoption levels. Notably in the US, reimbursement for image guided breast biopsies has undergone some restructuring. The 2014 Medicare Fee Schedule Final Rule imposed drastic reimbursement cuts for these procedures which will have a significant effect on the adoption of more expensive vacuum assisted biopsy (VAB) devices. Additionally, the US represents approximately 71% of the global VAB market. The benefit of routine screening for prostate cancer has come under scrutiny as sophisticated clinical trials reveal that it has minimal impact on the cancer related mortality. This is a huge setback for the adoption of biopsy devices in the diagnosis of prostate cancer given the market has immensely benefited from the inadequacies of the prostate specific antigen (PSA) test. Finally, the biopsy devices market faces substantial long term threats as startup companies and large medical device manufacturers try to make the diagnosis of cancer even less invasive without the need for target tissue extraction. Two such technologies include optical biopsies and liquid biopsies. Companies currently in the space and those looking to enter can harness the analysis in this report to better navigate this market.
Executive Summary

While there are significant barriers facing this market, current and future players can still position themselves to obtain a competitive advantage. The major European countries included in this forecast have general mass screening programs for breast cancer detection and they will be increasing their adoption of more expensive VAB devices. Additionally, the emerging economies will see an increased shift from fine needle aspiration devices to more expensive core biopsy devices over the forecast. These countries are working towards widespread cancer screening programs for their populations. This report expounds upon these topics and provides actionable insights for those currently in or looking to enter the biopsy devices market.

What Do Physicians Think?

Key Opinion Leaders (KOL) do not expect to the adoption levels of CNB and FNA devices to shift dramatically over the forecast in the diagnosis of prostate cancer.

“"I don’t see that as being appropriate unless there is a significant change in the pathology workup of the specimen because the pathologist usually needs histology rather than cytology. I’m not expecting this to change in the foreseeable future.”

- Key Opinion Leader

KOLs also don’t expect to see any changes in the adoption levels of various biopsy devices and procedures in the diagnosis of lung cancer.

“No. I expect for the whole field to stay the same for the next 10-15 years.”

- Key Opinion Leader

European KOLs indicated that vacuum assisted biopsy devices and core needle biopsy devices are predominately utilized in the diagnosis of breast cancer.
“Vacuum assisted biopsy is encouraged. Core needle biopsies with high caliber needles like 14 gauge and 16 gauge with bigger diameters than 18 gauge or 20 gauge while that is compulsory to do more than one biopsy using more than 18g and its encouraged for them to utilize vacuum assisted biopsy but still the minority of ladies are undergoing vacuum assisted biopsy but that number is increasing.”

-Key Opinion Leader

KOLs indicated that ultrasound imaging is the most frequently utilized imaging technique when diagnosing cancer.

“Ultrasound is not limited to be used by radiologists but it’s available to surgeons, physicians, pediatricians, gynecologists, and almost any medical specialty. It’s cheap, easy and quick.”

-Key Opinion Leader

Additionally KOLs don’t expect a significant change in the imaging modality preferences for breast cancer biopsies.

“I don’t expect a significant change. I think that high quality ultrasound is not going to improve further and stereotactic biopsy has its role for lesions which can’t be identified in ultrasound and this is micro-calcification again.”

-Key Opinion Leader
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2 Introduction

2.1 Overview

Cancer is the uncontrolled growth of abnormal cells in the body. It can affect numerous organs and tissues of the body. It can spread to neighboring tissues, or remain localized. When a patient is suspected of having a particular type of cancer, a biopsy procedure is performed to extract a target tissue sample for histological analysis. This intervention typically provides a definitive cancer diagnosis for the patient. Given that these procedures play such an important role in the diagnostic pathway for various cancers, medical device manufacturers have worked to develop devices that maximize the volume and quality of the tissue samples, as well as decrease their negative impact on the patient’s body. As seen with other medical device markets, less invasive biopsy techniques have entered the market and have established a new gold standard in many global regions.

For this market analysis, the biopsy devices market is segmented by cancer indication and by the type of biopsy procedure performed. Beyond providing a general analysis and forecast for each device segment in different global regions from 2010–2019, this report offers a more granular approach by assessing the adoption patterns of the different biopsy procedure types for specific cancer indications in specific geographies. This report and forecast focus on the adoption patterns of surgical biopsies, fine needle aspiration (FNA) devices, core needle biopsy (CNB) devices, and vacuum-assisted biopsy (VAB) devices in the diagnosis of breast, prostate, lung, liver, and thyroid cancers. Additionally, this report and forecast focus on these adoption patterns in the 10 major global markets, which include the United States, France, Germany, Italy, Spain, the United Kingdom, Japan, Brazil, China, and India. This segmentation provides better business intelligence, so that more effective actions can be taken.
Introduction

2.2 Catalyst

While the biopsy devices market has matured quite significantly, there are still significant barriers to overcome and opportunities for growth. While the US has seen the rapid adoption of VAB devices in the diagnosis of breast cancer, this market segment will be subjected to immense pricing pressure during the forecast period covered in this report. Changes in the reimbursement rates for image-guided breast biopsy procedures will affect both the average selling prices (ASPs) of these devices and the adoption levels of alternative tissue-extraction devices and procedures, including CNBs and open surgical biopsies. Additionally, the emerging economies will provide opportunities for growth as access to healthcare improves, adoption of FNA decreases, and governments work towards implementing cancer screening programs. This report is intended to elaborate on these market opportunities and barriers to help current and future competitors navigate the market.

2.3 Related Reports

- MediPoint: Diagnostic Ultrasound Imaging – Global Analysis and Market Forecasts
- MediPoint: Colorectal Cancer Screening Tests - Global Analysis and Market Forecasts
Appendix

12.7 About MediPoint

MediPoint is the flagship product for GlobalData’s Medical team. Each MediPoint report is built from the ground up by our team of healthcare analysts in the US and UK. Each report includes input from experienced physicians and leading key opinion leaders (KOLs). Running throughout each report in the series, “What Physicians Think” quotes provide a unique insight into how healthcare professionals are reacting to events within the industry, and what their responses could mean for industry strategists.

12.8 About GlobalData

GlobalData is a leading global provider of business intelligence in the healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports, and forecasts. Our analysis is supported by a 24/7 client support and analyst team.

GlobalData has offices in New York, San Francisco, Boston, London, India, Korea, Japan, Singapore, and Australia.

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