



MEDICAL EQUIPMENT & SUPPLIES

Research Brief

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Research Brief

SASB's industry brief provides a summary of the material sustainability issues that are likely to impact shareholder value. The issues identified within are industry specific, and reflect how the associated companies rely on environmental, social, and human capital. Further, the brief identifies material sustainability issues that pertain to business model and innovation, and governance. SASB adheres to the U.S. Supreme Court definition of materiality, defined as "presenting a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." To identify material sustainability issues, SASB's research team examines three types of evidence; evidence of interest, evidence of financial impact, and forward looking impact. The research reflected within this document was conducted by SASB and an initial version of the document served as an input for the Industry Working Groups to evaluate the materiality of industry issues and potential accounting metrics. The industry brief is not the disclosure standard, but rather is intended to provide background context and evidence for the material sustainability issues that SASB identified for the given industry. SASB takes sole responsibility for errors and omissions.

Related Documents

- [Health Care Sustainability Accounting Standards](#)
- [Industry Working Group Participants](#)
- [SASB Conceptual Framework](#)
- [Example of Integrated Disclosure in Form 10-K](#)

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MATERIAL SUSTAINABILITY ISSUES

Environmental Capital

- Energy and Waste Efficiency

Social Capital

- Product Safety
- Ethical Marketing
- Affordability and Fair Pricing

Human Capital

Business Model and Innovation

- Product Design and Lifecycle Management

Governance

- Corruption and Bribery
- Manufacturing and Supply Chain Quality Management

INDUSTRY SUMMARY

The medical equipment and supplies industry researches, develops, and produces medical, surgical, ophthalmic, and veterinary instruments and devices. Products are used in hospitals, clinics, and laboratories and range from disposable items to specialized equipment.¹

The medical equipment and supplies industry is driven by the purchasing power of hospitals and distributors, as well as by demand for health care services. The increased prevalence of diseases associated with unhealthy lifestyles and an aging population will likely contribute to growth in this industry. In particular, the obesity epidemic will impact demand for electrophysiology and interventional cardiology devices, while an increase in the elderly population will correlate with orthopedic devices. Emerging markets and the expansion of health insurance in the U.S. will contribute to further growth. However, the extension of government insurance programs, provider and payer consolidation, and regulatory emphasis on reduced costs will create downward pricing pressure. In addition, a new sales tax imposed

¹ A list of the top five companies by revenue appears in Appendix I

on medical devices will present challenges to the industry. The impact of the tax will be largely dependent on the industry's ability to pass these costs on to purchasers.

The medical equipment and supplies industry provides an essential public good in the form of products that aid in the treatment of a range of medical conditions. However, companies in this industry will face challenges due to an evolving legislative and regulatory environment that is likely to align the interests of society with those of long-term investors. These developments will also emphasize how non-financial forms of capital contribute to market value. More specifically, the management of environmental, social, and human capital will increasingly affect traditional valuation by impacting revenue, cash flow, and cost of capital. The ability of companies to manage these issues while also addressing the associated risks and opportunities through business model and innovation, and governance will be strong indicators of management quality and long-term value.

To ensure that shareholders are able to evaluate performance in these areas, medical equipment and supplies companies should report on the sustainability issues that will have a material impact in the near and long term. Enhanced reporting will provide stakeholders with a more holistic (and comparable) view of performance that includes both positive and negative externalities and the non-financial forms of capital that medical equipment and supplies companies rely on to create long-term value.

The sustainability issues that will drive competitiveness within the medical equipment and supplies industry include:

- Improving resource efficiency in manufacturing and product life cycle management
- Ensuring product safety
- Marketing products ethically and eliminating corruption and bribery
- Providing access to products and transparent pricing for consumers
- Ensuring operational and supply chain standards

The extent to which these sustainability issues impact value will become increasingly apparent as the legislative and regulatory environment continues to evolve and emphasis is placed on patient safety, transparency, reduced costs, preventative care, and improved patient outcomes.

LEGISLATIVE AND REGULATORY TRENDS IN MEDICAL EQUIPMENT AND SUPPLIES

The regulatory environment that governs the medical equipment and supplies industry continues to evolve. Although the financial impact of these policies is yet to be determined, the following section provides a brief summary of

key legislative efforts and associated industry trends that are likely to affect shareholder value and sustainability performance.

The Patient Protection and Affordable Care Act (PPACA) is expected to benefit the industry by expanding health insurance to 26 million people who were previously uninsured.^{i,2} In addition to increased utilization of health care services and, subsequently, medical supplies, the PPACA includes a 2.3 percent sales tax on medical devices sold after December 31, 2012. This is estimated to cost the industry \$20 billion over the next 10 years.ⁱⁱ Further, challenges could arise from downward pricing pressure, leading to increased merger activity in managed care and health care delivery. This consolidation can increase the ability of providers and payers to negotiate lower prices for equipment and supplies and prevent previously independent physician groups from choosing preferred supplies.

The American Recovery and Reinvestment Act of 2009 included provisions for \$1.1 billion dollars in funding for the advancement of comparative effectiveness research (CER). The framework is intended to provide health care providers with the necessary information to make value-based decisions. CER will encourage medical equipment and supplies companies to further substantiate the effectiveness of their products, which could result in increased emphasis on less expensive devices or alternative therapies.

SUSTAINABILITY RISKS AND OPPORTUNITIES

Recent legislation in the U.S. indicates an effort to increase health insurance coverage while reducing health care costs. Companies will, therefore, not be able to maximize financial capital unless they address material sustainability issues as well. Specifically, firms that are able to navigate new regulations while addressing all forms of capital and limiting negative externalities will be better positioned to protect shareholder value in the long term.

The following section provides a brief description of each sustainability issue that is likely to have material implications for the medical equipment and supplies industry. The description includes evidence of materiality, value impact, and timing. The issues are divided into five categories: Environmental Capital, Social Capital, Human Capital, Business Model and Innovation, and Governance. Tables outlining the type of evidence supporting materiality for each issue and the recommended disclosure framework appear in Appendices II and III, respectively. An analysis of the current state of reporting on material sustainability issues in the medical equipment and supplies industry appears in Appendix IV.

² Estimates range between 26 and 30 million for the number of people will become insured under the PPACA.

ENVIRONMENTAL CAPITAL

Medical equipment and supplies companies engage in research and manufacturing processes that rely heavily on environmental capital. Firms in this industry depend on the ability to utilize purchased resources (i.e., energy and water). In addition, companies have been afforded the opportunity to generate negative externalities through air emissions and waste. As resources become limited and legislation seeks to address these externalities, investors must understand how individual companies within this industry manage these risks and adhere to societal expectations.

Energy and Waste Efficiency

The manufacturing of medical equipment and supplies requires the use of energy, water, and material inputs in addition to the creation of waste. As concern over climate change and dwindling natural resources continues to impact pricing, medical equipment and supplies companies will be exposed to fluctuations in costs for these key inputs. Firms that are able to improve manufacturing efficiencies and limit dependence on resources are likely to enhance shareholder value.

Evidence

Medtronic reports that it has established goals to reduce its energy and water use by 10 percent by the year 2013, compared to a baseline of 2007. The company is also working to reduce both its regulated and non-regulated waste streams by five percent during the same period.

Thermo Fisher indicates that it “may incur unexpected costs from increases in fuel and raw material prices, which could reduce our earnings and cash flow.”

Value Impact and Timing

Innovative approaches to resource management allow companies to reduce operating costs, thereby increasing value for shareholders.

SOCIAL CAPITAL

Medical equipment and supplies companies are expected to deliver safe and accessible products. In addition, companies in this industry face opportunities and challenges associated with the ethical marketing of products. Firms that are able to effectively manage these aspects of social capital will be better positioned to protect shareholder value.

Product Safety

Information on product safety and side effects can surface after controlled clinical trials and approval. Subsequently, companies are exposed to the financial implications of recalls and other adverse events. Equipment failures, manufacturing defects, design flaws, or inadequate disclosure of product-related risks can lead to significant product liability claims. Medical equipment and supplies firms that limit the incidence of these claims will be better positioned to protect shareholder value.

Evidence

Depending on the classification of a medical device, products can be required to undergo extensive tests governed by the Medical Device Safety Division (MDSB) of the Federal Drug Administration (FDA). According to the FDA, 4,343 medical devices were recalled between 2005 and 2010.ⁱⁱⁱ

In 2010, Johnson & Johnson recalled a hip implant that had been used in an estimated 93,000 patients worldwide.^{iv} The company reports that it spent \$800 million on the recall over the last two years. However, Johnson & Johnson is currently facing 8,000 lawsuits relating to the hip implant, which could cost the company an additional \$2 billion.^v

Value Impact and Timing

Companies that fail to manage the safety of their products are exposed to product recalls, regulatory fines, diminished brand reputation, and litigation, impacting both profits and liabilities.

Ethical Marketing

Medical equipment and supplies companies face challenges associated with marketing of specific products. Consumer-directed advertisements for medical devices in the U.S. and outreach to physicians provide opportunities for increasing market share. However, challenges arise from the potential for marketing off-label uses. In 2011, the federal government collected \$1.45 billion in fines from pharmaceutical and medical equipment and supplies companies to settle charges, the majority of which focused on the promotion of off-label use. Corporate disclosure of legal and regulatory fines and the codes of ethics that govern interactions with health professionals will allow shareholders to monitor performance in this area.

Evidence

In 2009, Synthes and four of its executives were indicted for marketing Norian XR for off-label use in certain spinal surgeries. At least five deaths have been attributed to this off-label use, and the company was required to pay \$23 million in fines, while four executives were sentenced to up to nine months in prison.^{vi}

Medtronic reports that “failure to comply with ‘off-label’ promotion restrictions can result in significant administrative obligations and costs, and potential penalties from, and/or agreements with, the federal government.”

Value Impact and Timing

Recent examples of fines associated with illegal marketing demonstrate the potential for such practices to impact both profits and liabilities.

Affordability and Fair Pricing

Legislative emphasis in the U.S. and abroad on health care cost containment and increased access will continue to place downward pricing pressures on the medical equipment and supplies industry. This pressure will be further articulated by continued consolidation among health care providers and the increasing role of government-sponsored insurance programs. As a result, companies that have relied on contractual advantages to protect profits may be challenged to enhance value as the government seeks to reduce its Medicare and Medicaid spending. Firms that are able to ensure access and fair pricing are likely to limit the negative impact of cost containment while recognizing the potential revenue opportunities associated with expanded access.

Evidence

A recent report by the Government Accountability Office found significant price differences for the same medical devices at different hospitals. For example, the difference between the highest and lowest price reported for the same automated implantable cardioverter defibrillator was \$8,723. Similarly, a primary total knee construct ranged in price from \$5,200 to \$9,500.^{vii}

Stryker reports that “cost containment measures in the United States and other countries resulting in pricing pressures could have a negative impact on our future operating results. Initiatives

sponsored by government agencies, legislative bodies, and the private sector to limit the growth of health care costs, including price regulation and competitive pricing, are ongoing in markets where we do business.”

Value Impact and Timing

Medical equipment and supplies companies that engage in unfair pricing schemes are likely to experience reduced profits and increased cost of capital in the long term as regulations seek to limit health care expenditures.

HUMAN CAPITAL

Medical equipment and supplies companies rely on human capital to maintain value. However, relative to other industries in the health care sector, this industry does not face specific and material risks or opportunities associated with human capital.

BUSINESS MODEL AND INNOVATION

In addition to the development of safe and accessible products, medical equipment and supplies companies have the opportunity to meet consumer demand for products that address environmental and human health concerns associated with product lifecycle.

Product Design and Lifecycle Management

Medical equipment and supplies companies face increasing challenges associated with the human and environmental impact of the industry's products. Companies will likely face consumer and regulatory pressure to limit the use of toxic and/or scarce material inputs while also addressing issues such as the energy efficiency and end-of-life disposal of specific products. Firms that are able to limit these externalities will be better positioned to meet consumer demand and reduce future liabilities.

Evidence

Medical equipment accounts for an estimated 18 percent of hospitals' total energy use, indicating a significant opportunity for improved efficiency. In 2010, Kaiser Permanente announced a sustainability scorecard for medical products. The initiative will require its suppliers to provide environmental data for equipment and supplies used in the company's facilities. Kaiser Permanente spends an estimated \$1 billion on medical products annually; and, with its supply chain partners, could influence \$10 billion in medical purchasing.

Value Impact and Timing

Medical supplies and equipment companies that are able to address the lifecycle of their products will be positioned to capitalize on long-term consumer and supply chain demand, providing the potential for additional revenue sources.

GOVERNANCE

Strict regulatory environments and competition in the medical equipment and supplies industry increase the importance of strong governance. Management structures must be able to negotiate international laws while avoiding the risks associated with issues such as corruption and bribery. Further, companies must establish standards of excellence within their supply chain and internal manufacturing operations. Information on governance performance is essential for shareholders to understand management quality and a company's ability to protect value.

Corruption and Bribery

Medical equipment and supplies companies are subject to various state, federal, and international laws pertaining to health care fraud and abuse. Anti-kickback laws and the U.S. Foreign Corrupt Practices Act generally prohibit companies from making payments for the purpose of obtaining or retaining business. The ability of companies to ensure compliance both in the U.S. and abroad is likely to have material implications.

Evidence

Biomet was fined \$23 million in 2012 for paying surgeons in Argentina, Brazil, and China to use its artificial hips.^{viii} The same year, Orthofix

International agreed to pay \$5.2 million to settle the Securities and Exchange Commission's charge that it had violated the Foreign Corrupt Practices Act by bribing officials in Mexico to gain sales contracts with government hospitals.^x In 2011, Medtronic agreed to pay \$23.5 million in fines for illegal kickbacks to doctors who implanted its pacemakers and defibrillators.^x

Value Impact and Timing

Recent settlements demonstrate how corruption and bribery can lead to significant fines that impact profits and liabilities.

Manufacturing and Supply Chain Quality Management

Manufacturing and supply chain quality is essential to protecting consumer health and corporate value. Medical equipment and supplies firms that fail to manage quality in these areas are susceptible to significant fines, lost revenue associated with manufacturing stoppages, and the potential loss of independence. Disclosure of Federal Drug Administration enforcement actions and supply chain audit programs provide shareholders with an understanding of how companies in this industry are managing the associated risks.

Evidence

Since 2009, the FDA has increased its oversight of companies and the number of warning letters issued. In 2013, Hospira received a warning letter over problems with the company's Plum A+ infusion pump. The letter followed the company's decision to retire three pumps after regulatory trouble. The decision to retire those pumps is expected to reduce annual sales by two to four percent. In addition, the company's Symbiq devices manufactured in Puerto Rico were banned by the FDA after manufacturing concerns, resulting in between \$50 and \$100 million in lost annual sales.^{xi}

Value Impact and Timing

A failure to ensure operational excellence can result in fines and decreased revenue associated with manufacturing stoppages and plant closures. In addition, this issue can expose companies to shareholder action and decreased consumer confidence. Subsequently this issue has the potential to impact profits, liabilities, assets, and cost of capital.

APPENDIX I: Top Five Companies by Revenue | Medical Equipment & Supplies

- Johnson & Johnson
- Medtronic Inc.
- Thermo Fisher Scientific Inc.
- Abbot Laboratories
- Stryker Corp.

APPENDIX II: Evidence of Materiality | Medical Equipment & Supplies

The following table provides a summary of the evidence of materiality for each issue in the medical equipment and supplies industry

MATERIAL SUSTAINABILITY ISSUES		EVIDENCE OF INTEREST					EVIDENCE OF FINANCIAL IMPACT				FORWARD-LOOKING IMPACT			
		MM	IWGs		Other	EI	Revenue / Cost	Asset/ Liability	Cost of Capital	EFI	Probability	Magnitude	Timing	FLI
			%	Priority										
ENVIRONMENTAL CAPITAL	Energy, Water, and Waste Efficiency	58%	93%	4		Low	•			Med	•	•	Near	Yes
SOCIAL CAPITAL	Product Safety	95%	100%	1		High	•	•		High				
	Ethical Marketing	60%	100%	5		Med	•	•		High				
	Affordability and Fair Pricing	75%	-	-	•	Med	•		•	Med	•	•	Near	Yes
BUSINESS MODEL AND INNOVATION	Product Design and Lifecycle Management	60%	100%	2		Med	•			Low	•	•	Near	Yes
GOVERNANCE	Corruption and Bribery	85%	100%	3		High	•	•		Low				
	Manufacturing and Supply Chain Quality Management	35%	-	-	•	Low	•	•	•	High				

MM: Materiality Map, a percentile score of the relative importance of the issue among SASB's initial list of 43 generic sustainability issues. The score is based on the frequency of relevant keywords in documents (i.e., 10-Ks, shareholder resolutions, legal news, news articles, and corporate sustainability reports) that are available on the Bloomberg terminal for the industry's publicly listed companies.

IWGs: SASB Industry Working Groups

%: The percentage of IWG participants that found the issue to be material. (-) denotes that the issue was added after the IWG was convened.

Priority: Average ranking of the issue in terms of importance. One denotes the most material issue. (-) denotes that the issue was added after the IWG was convened.

Other: Other evidence of interest including: in-depth 10-k analysis, shareholder resolutions, corporate sustainability reports, traditional financial analysis, impending regulation, and academic studies. This is primarily used in cases where the issue was added after the IWG or the issue received lower MM and IWG scores. However, this test is also used in some cases where there is significant additional evidence of interest.

EI: Evidence of Interest, a subjective assessment based on quantitative and qualitative findings.

EFI: Evidence of Financial Impact, a subjective assessment based on quantitative and qualitative findings.

FLI: Forward Looking Impact, a subjective assessment on the presence of a material forward-looking impact

APPENDIX III: Sustainability Accounting Metrics | Medical Equipment & Supplies

The following table provides a list of sustainability issues and the associated accounting metrics for the Medical Equipment and Supplies Industry.

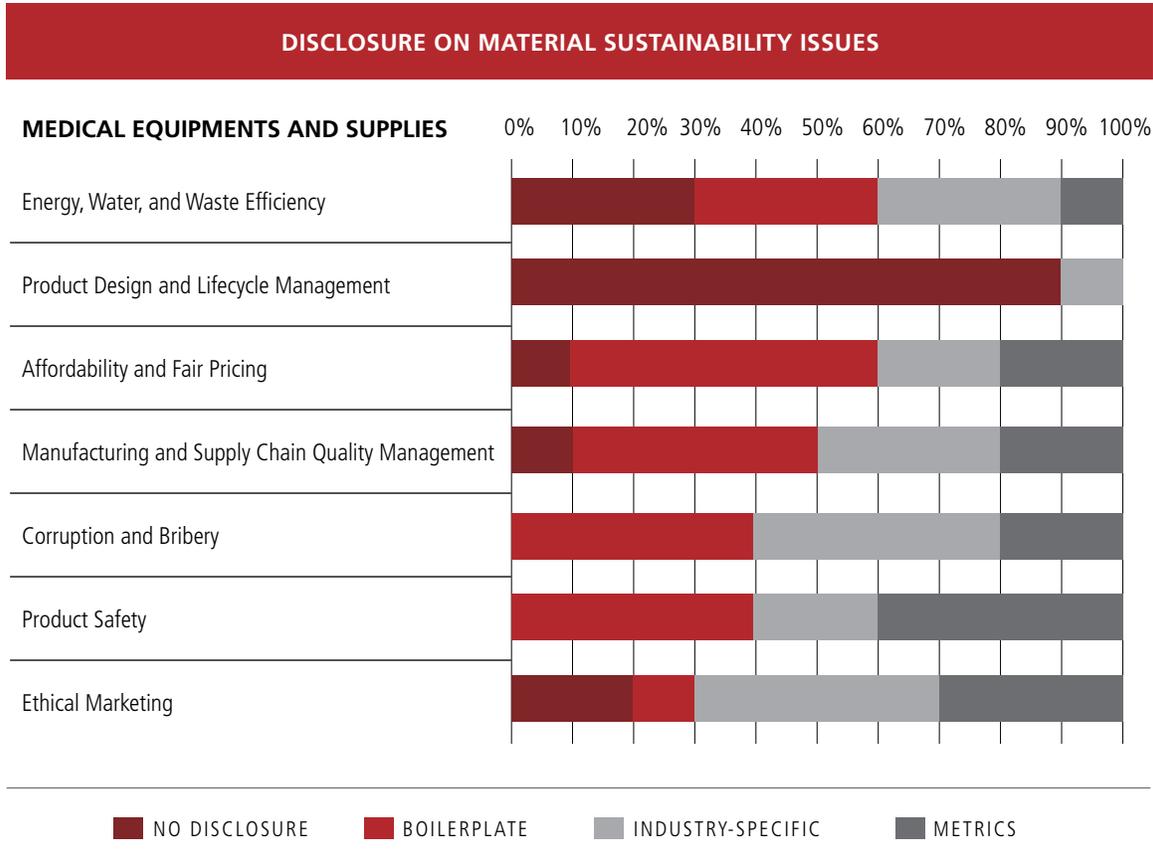
TOPIC	CODE	ACCOUNTING METRIC
Product Safety	HC0201-01	List of products recalled.
	HC0201-02	List of products listed in the FDA's MedWatch Safety Alerts for Human Medical Products (Medical Devices) database.
	HC0201-03	Number of fatalities related to products as reported in the FDA Adverse Event Reporting System.
Ethical Marketing	HC0201-04	Description of legal and regulatory fines and settlements associated with false marketing claims, including Federal Food, Drug, and Cosmetic Act violations for off-label marketing prosecuted under the False Claims Act. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events.
	HC0201-05	Description of code of ethics governing promotion of off-label use of products, including mechanisms to ensure compliance.
Affordability and Fair Pricing	HC0201-06	Ratio of weighted average rate of net price increases (for all products) to the annual increase in the U.S. Consumer Price Index.
	HC0201-07	Description of how price information (such as average and median) for each product is disclosed to customers or their agents (e.g., group purchasing organizations or consultants).
Energy, Water, and Waste Efficiency	HC0201-08	Total annual energy consumed (gigajoules) and percentage renewable (e.g., wind, biomass, solar).
	HC0201-09	Total water withdrawals and percentage from water-stressed regions – High or Extremely High Baseline Water Stress as defined by the WRI Water Risk Atlas; percentage of process water recycled.
	HC0201-10	Amount of waste (metric tons); percentage that is recycled, incinerated, and landfilled.
Product Design and Lifecycle Management	HC0201-11	Description of environmental and human health considerations made at product lifecycle stages such as design, procurement, manufacturing, distribution, use, and end-of-life and the type and percentage of products to which efforts apply.
	HC0201-12	Description of Extended Producer Responsibility (EPR) initiatives to promote manufacturer take-back, reuse, or proper safe disposal at the end of the lifecycle. Amount (by weight) of products accepted for take-back and reused, recycled, or donated, broken down by: (1) devices and equipment and (2) supplies.
Corruption and Bribery	HC0201-13	Description of legal and regulatory fines and settlements associated with bribery, corruption, or unethical business practices, including violations of the Foreign Corrupt Practices Act and those associated with providing kickbacks to physicians. Dollar amount of fines and settlements and a description of corrective actions implemented in response to events.
	HC0201-14	Description of code of ethics governing interactions with health care professionals including mechanisms to ensure employee compliance.

APPENDIX III: Sustainability Accounting Metrics | Medical Equipment & Supplies (Cont.)

TOPIC	CODE	ACCOUNTING METRIC
Manufacturing and Supply Chain Quality Management	HC0201-15	Number and type of FDA enforcement actions taken in response to violations of current good manufacturing practices (cGMP) including: product deemed adulterated, form 483s, suggested recall (Class I, II, III), Warning Letters, Border Alerts, license suspension or revocation, product seizure, Consent Decrees, criminal prosecution.
	HC0201-16	Percentage of facilities and Tier I suppliers participating in third-party audit programs for integrity of supply chain and products (e.g., materials, devices, packaging, etc.).
	HC0201-17	Description of efforts to maintain traceability within the distribution chain, particularly with respect to wholesalers, re-packagers, and/or contract distributors.
	HC0201-18	Discussion of any existing or projected risks or constraints with obtaining raw materials (or components) within the supply chain, including those related to restricted/limited availability, political situations, local labor conditions, natural disasters, climate change, or regulations.

APPENDIX IV: Analysis of 10-K Disclosures | Medical Equipment & Supplies

The following graph demonstrates an aggregate assessment of how the top ten companies in the medical equipment and supplies industry are currently reporting on material sustainability issues in the Form 10-K.



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