

Background Paper for the Tissue Expert Committee:

How can the tissue donation and transplantation system
best ensure that supply aligns with demand?

Contents

1. Introduction	2
A. Background.....	2
2. Scope	3
3. Current State	3
A. Current State	3
B. Current Community Thinking.....	5
C. Other Models	6
4. Analysis	8
A. Analysis Approach.....	8
B. Analysis Findings.....	8
5. Options and Considerations.....	9
A. Options	9
B. Considerations.....	14
APPENDIX A	15

1. Introduction

A. Background

Recognizing the need to improve the organ and tissue donation and transplantation (OTDT) system in Canada, the federal, provincial (except Quebec) and territorial governments in April 2008 asked Canadian Blood Services to take on new responsibilities related to OTDT. This included the development of a strategic plan for an integrated OTDT system, in collaboration with the OTDT community. As part of this work, three committees were formed – the Steering Committee, Organ Expert Committee and Tissue expert Committee – to help develop the recommendations through a formal, structured planning process.

This document is one of a series of background documents developed to help the committees in their discussions. These documents focused on the critical issues within the system, describing the current state and examining potential options and solutions. Conclusions from the committee discussions were consolidated and incorporated in the final recommendations of the final report. The full report, ***Call to Action: A strategic plan to improve organ and tissue donation and transplantation performance for Canadians***, can be found at organsandtissues.ca, along with the other background documents in this series.

Limitations of these documents:

- These documents were intended for an audience familiar with the subject matter and contain terms and acronyms that may not be in common usage outside the field.
- In some cases, original documents referenced draft materials which have now been finalized. In these cases, where possible, references have been updated. These situations are clearly marked.

- These documents provided an overview of the issue for further discussion by experts in the field of OTDT. The findings and evaluations contained in these documents are not comprehensive—they reflect what was considered to be most applicable to the issue at the time.
- Information in these documents presents knowledge available at the time of the OTDT committee meetings. These documents have been edited for consistency in style and format, but have not been updated to reflect new information or knowledge. References and web links also remain unchanged and may no longer be accurate or available.
- As these are background documents to the ***Call to Action*** report which is available in both English and French, they are available in English only. Requests for translation can be made to Canadian Blood Services using the contact information below.

Note: Production of this document has been made possible through a financial contribution from Health Canada. The views expressed herein do not necessarily represent the views of the federal, provincial or territorial governments.

For more information on these documents or the ***Call to Action*** report, please contact:

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2. Scope

How can the TDT system best ensure that supply aligns with demand?

The alignment of supply and demand constitutes a range of current challenges in the current state of the Canadian TDT system. Ensuring supply is aligned with demand does not mean all demand is met, nor does it suggest a balance between Canadian supply and foreign supply. Ensuring the alignment of supply and demand within the Canadian TDT system means understanding product demand, optimizing the use of Canadian resources (e.g., recovered tissue, processing capacity) and assets (e.g., inventory) to meet demand, and having mechanisms to address potential risks related to obtaining the necessary domestic and international supply to meet demand.

This paper exploring various methods used in TDT systems and by organizations to ensure alignment of supply with demand; for example, customer relationships, demand forecasting, production flexibility and inventory management.

While the integral linkage between supply planning and source of supply is referenced, this document does not address production levels or the balance between Canadian- and foreign-sourced tissue. These topics are addressed in other papers in this series.

3. Current State

A. Current State

Canada has a competitive and relatively open tissue market in which end-users have the ability to purchase tissue from any supplier registered with Health Canada. In general, demand for tissue in Canada is met through this open access to various sources of supply. Although demand for cornea and tendons has been more difficult to meet due to cost and other factors, demand for all commonly used tissue types is either available through the Canadian tissue banking system or by importation from Health Canada-registered suppliers in the United States. In essence, importation bridges the gap between total demand and Canadian supply both in terms of quantity and type of product available.

The challenge is generally not that demand goes unmet, but rather that the Canadian TDT system is not currently capable of ensuring that demand would be met in the face of risks that may arise. The system as a whole does not have the relationships with end-users necessary to

understand the quantity and product attributes required; the result, among other consequences, is an inability to forecast demand on a national level. A lack of market intelligence and cooperation between jurisdictions has led to an inability to optimally leverage production resources. What's more, a lack of coordination and cooperation amongst tissue banks has led to uncoordinated national inventory management, which has meant historically that some provinces suffer shortages of certain tissue types while other provinces have excess tissue or the capacity to recover and produce the required tissue. The following sections explore the current state in greater depth.

End-user relationships

Effective end-user relationships provide insight into transplant establishment product needs and demands, thereby informing appropriate production. A survey conducted in 2003 found that, at the time, a notable portion of transplant

How can the tissue donation and transplantation system best ensure that supply aligns with demand?

establishments and end-users were unaware of Canadian sources for allograft products.¹

The environmental scan of the Canadian tissue programs in 2009 revealed that the majority of tissue banks focus distribution within their institution or health region, and are not engaged in the development of relationships outside their current scope of practice.² End-user engagement strategies were uncoordinated and bank-specific. Interaction with allograft end-users was mostly limited to informal conversations and basic customer satisfaction surveys.

Discussions with tissue banks indicate that at least one bank is considering partnering with a medical supply company to gain access to an established set of distribution channel relationships.

Some efforts to engage end-users are occurring successfully at the regional and provincial levels. One regional tissue bank has taken a more coordinated approach by engaging all end-users within their health region in a comprehensive review of demand and product requirements. Héma-Québec surveyed Quebec transplant establishments to quantify current use. No other examples of provincial or national level engagement of transplant establishments or end-users were identified.

Forecasting demand

Effective demand forecasting provides an informed estimate of short and longer-term consumer demand both in terms of type and quantity of products. This forecasting ensures that product-line, recovery, production and distribution planning have a basis in market reality.

The 2009 scan did not identify any demand-forecast initiatives or processes within Canadian tissue banks.³ In an effort to better understand demand, Canadian Blood Services asked three Canadian tissue banks to work with their operating

rooms to quantify total allograft use and demand within their hospitals. Two of the three tissue banks were unable to readily quantify allograft use—an illustration of how and why accurate demand forecasting is challenging within the current state.

While Quebec⁴ has employed methodologies to estimate demand on a provincial level, there is no mechanism in place to quantify and/or forecast demand for Canada as a whole.

Production flexibility

Production flexibility refers to the ability to adjust production levels and product lines in response not only to emerging technologies and techniques, but also end-user demand. There are two basic levers in tissue production: recovered tissue and production capacity and capability.

The environmental scan of the Canadian tissue programs in 2009 revealed that there was a limited ability to adjust production within musculoskeletal, cardiac and skin banks in support of demand and changing clinical needs. Production appears to be a function of donor supply rather than end-user demand. Two programs with established processing facilities indicated that their facilities were under-utilized due to lack of donor supply.

In the last few years, endothelial keratoplasty, which selectively replaces only the diseased layer of the cornea, has become the preferred procedure for Fuchs' Dystrophy or other endothelial disorders. In response to this trend, a few eye banks have begun providing pre-cut tissue for this procedure.

Inventory management

Inventory management and supporting information systems are unique to each tissue bank. Inventory is generally viewed as an institutional or regional resource. The majority of tissue banks support only institutional or regional demand. Two programs have focused on the distribution of allografts outside their provinces as a way to generate revenue.

¹ Canadian Council for Donation and Transplantation. Supply of Human Allograft Tissue in Canada; Final Report, April 2003

² Canadian Blood Services, Supply of Human Allograft Tissue in Canada: Final Report, 2010

³ Canadian Blood Services, Supply of Human Allograft Tissue in Canada: Final Report, 2010

⁴ Canadian Council for Donation and Transplantation. Human Tissue Importation Practices in Canada, October 2006.

How can the tissue donation and transplantation system best ensure that supply aligns with demand?

Transplant establishments have no single national point of access for Canadian tissue products. The scan revealed no coordinated or systematic approach by which to control stock levels and distribute inventory inter-provincially or nationally.

This lack of coordination between tissue banks means that, at times, there are tissue needs in a given region that could be met by a tissue bank in another region that has the required tissue in inventory. There is more often routine

communication between eye banks to ensure the allocation of available corneas. However, the lack of cost recovery practices in ocular programs was identified as a barrier to good inventory management.

Funding

The 2009 scan revealed no coordinated or systematic approach to funding donor supply, production and distribution. Cost recovery practices within tissue programs are inconsistent.

B. Current Community Thinking

Reports and Papers

Final Report: Development and Evaluation of Options for Tissue Systems in Canada, 2006⁵

This report assessed previous Canadian Council for Donation and Transplantation reports and consultations, as well as international comparators to develop and evaluate options for tissue systems in Canada. The report identified the issues that drive, or have the most influence on, Canadian tissue banking, as well as the outcomes of our current system. Issues explored in the report

⁵ Canadian Council for Donation and Transplantation. Final Report: Development and Evaluation of Options for Tissue Systems in Canada, March 31, 2006.

included the consequences of lacking a national planning process.

Key elements of a successful TDT system included:

- development of a national tissue inventory database;
- establishment and monitoring of national targets for supply and demand of tissue products;
- facilitation of national group purchasing of advanced tissue products; and
- promotion of a national point of access to tissue for Canadian end-users.

Forums

Enhancing Tissue Banking in Canada — Phase 1: Sustainability (Canadian Council for Donation and Transplantation) November 23 to 24, 2006—Montreal, Quebec

The meeting focused on sustainability in tissue banking.⁶ Discussion groups identified several strategic actions that could help align supply and demand, including:

- Develop a strategy to engage transplant establishments and end-users;

- Develop a national strategy for managing long-term demand and processing of advanced tissue products;
- Establish a mechanism for the bulk purchase of external products, starting regionally and expanding nationally;
- Develop a national processing strategy that takes into account regional variations;
- Convene evidence-based consensus forums to identify best standardization practices in tissue production and distribution;
- Develop a centralized importation and distribution system (not necessarily at the national level);

⁶ Canadian Council for Donation and Transplantation. Enhancing Tissue Banking in Canada, Phase 1: Sustainability, Task Force Report, May 2007

How can the tissue donation and transplantation system best ensure that supply aligns with demand?

- Develop a national database or virtual tissue warehouse that includes a waitlist; and
- Establish interprovincial TDT billing agreements.

National Consultation: Organ and Tissue Donation and Transplantation (Canadian Blood Services) September 22 to 24, 2008—Gatineau, Quebec

A number of recommendations emerged from this consultation in relation to supply and demand alignment, including:⁷

- Perform a detailed market study to quantify demand, the drivers of demand, and user preferences;
- Create transplant-establishment and end-user advisory groups;
- Develop a supply strategy focused on specific tissue types or products;
- Implement standardized and harmonized product bar coding to support inventory management and traceability;
- Implement a nationwide tissue-bank information sharing network to show existing inventory levels; and
- Develop a national allocation model for tissues in short supply.

⁷ Canadian Blood Services. Executive Summary National Consultation, Organ and Tissue Donation and Transplantation, Ottawa, Ontario September 22-24, 2008

C. Other Models

Other healthcare systems, including TDT systems, adopt a variety of models to ensure alignment of supply with demand—or to mitigate the risks that may affect the ability to meet demand. Generally, these models fall into three categories:

- In a sole distributor model, product distribution is restricted to a single distributor. Supply and demand are monitored at the system level. Distribution channels and end-user relationships are managed centrally.
- In a coordinated model, tissue production and distribution are supported by multiple independent source establishments; however, systems and processes are in place to coordinate the alignment of supply and demand.
- In a competitive model, tissue production and distribution are supported by multiple independent source establishments in a competitive environment. There is no coordinated approach to aligning supply and demand or to allocating scarce tissue.

The following systems' approaches to ensure supply-and-demand alignment are described

briefly to illustrate ways to address the central question of this paper.

Australia

Tissue banks are state-based and function independently. The Australian Organ and Tissue Donation and Transplant Authority is developing a National Eye and Tissue Donation and Transplant Network. This network will deliver a coordinated, accountable, national tissue transplantation service and develop the data collection, analysis and reporting requirements, including a national eye and tissue donor database, and national eye and tissue allocation protocols.⁸ The network will also support national eye and tissue donation allocation protocols and processes, including a national eye and tissue donor database and outcome registry. Because the network is in development, specifics on supply and demand components have yet to be determined.

⁸ Australia Government Department of Health and Aging. A Worlds Best Practice Approach to Organ and Tissue Donation for Australia: Overview, Retrieved from www.health.gov.au on August 15, 2009.

How can the tissue donation and transplantation system best ensure that supply aligns with demand?**United Kingdom: National Health Service Blood and Transplant (NHSBT)- Tissue Services**

The NHSBT centralized and amalgamated a number of tissue banks within the UK tissue system. NHSBT - Tissue Services competes for market share with other UK tissue banks, as well as international tissue sources, and recovers its costs by invoicing end-users for allograft use. As NHSBT - Tissue Services is a single bank within a competitive environment, a national approach to aligning supply and demand is challenging. Eye banking is currently managed within NHSBT UK Transplant division, as opposed to NHSBT - Tissue Services, due to its historic ties to the organ donation program.

United States

The successful alignment of supply and demand in the US is a consequence of a consistent supply surplus that is exported to other countries around the world. The US tissue system operates in a competitive, private-sector market. Success at procurement, processing and distribution is dependent on the strength of business relationships developed based on efficacy, cost and quality of service and product. Tissue procurement agencies generate revenue from the tissue they procure and supply to tissue banks and distributors. Tissue and eye banks and distributors generate revenue from the tissue they process and distribute to transplant establishments. Distribution channels are well developed by tissue banks, tissue distributors and medical supply companies. (Appendix A features one research organization's forecast of US demand through 2013.)

Allograft processors, in partnership with academia, are at the forefront of allograft research and development, including stem cell use and bioengineering. By developing advances in the clinical efficacy of allografts, through research and development, US processors are essentially creating new demand and markets as clinicians adopt these advances.

Canada: Héma-Québec

In Quebec, tissue and tissue products are being centralized provincially within an evolving sole-source distribution model. Héma-Québec, a provincially funded provider of blood and tissue, successfully piloted a centralized tissue production, importation and distribution model at a hospital in Montreal. Demand and supply are aligned; about one-sixth of Quebec's demand is being satisfied with imported tissue.

Based on information obtained via an interview with representatives from Héma-Québec in February 2008, the organization has partnered with an American processor with the intention of becoming the Quebec distributor for their products. Héma-Québec is also considering partnering with a medical supply company to access an established distribution channel into the Quebec allograft market. The long-term goal for Héma-Québec is to become the sole distributor of allograft products in the province.

Canada: Canadian Blood Services (blood operations)

Blood and blood products have been centralized in a national sole source distribution model. Blood and its derivatives are viewed as a national resource and distributed accordingly with no fees to end-users. Canadian Blood Services, which is funded by the provinces and territories, has been able to meet product demand more than 95 per cent of the time using supply held in a national inventory.

Hospital liaison specialists are located within centres of significant product use to support and manage distribution. Information systems support real-time national inventory management with products routinely shipped between jurisdictions to help meet demand. Demand forecasting models are used in both short- and long-term planning and operations. Supply and demand analysis informs product collection, production, and distribution. This analysis is also used to identify misalignments of supply and demand.

4. Analysis

A. Analysis Approach

Analysis of existing research and opinion papers has been conducted to provide the basis for this document. An environmental scan of the Canadian tissue bank community further enhanced data considered. The scan included quantitative surveys, site visits and qualitative interviews.

A pilot survey of a small number of Canadian transplant establishments indicated that data on allograft use was not readily available or accessible. As a result, data from a 2003 survey of Canadian end-users was used to inform demand assumptions.

A high level SWOT analysis of current models (domestic, international tissue systems, other healthcare systems) and related mechanisms was

used to evaluate the status quo and potential options.

Assumptions underlying the analysis include:

1. The final decision about mechanisms to ensure supply and demand alignment must integrate with the other elements of the TDT system strategy and, more specifically, with decisions regarding the balance of foreign and domestic tissue recovery and processing.
2. Funding agents (e.g., provincial and territorial governments, RHAs, LHINs and OPOs) are willing to consider adjustments to current funding and operational approaches.

B. Analysis Findings

- Canadian programs account for a significant amount of ocular demand.
- Canadian programs account for only a portion of basic bone, skin and cardiac allograft demand.
- Canadian programs do not produce demineralized and mineralized products

and machined bone products, which comprise the greatest component of demand. Canadian capability and capacity would need to increase dramatically to supply these types of products.

- There is lack of product standardization within Canadian tissue banks.

How can the tissue donation and transplantation system best ensure that supply aligns with demand?

5. Options and Considerations

A. Options

What is the best model to help align Canadian supply with demand?

Status quo

Individual banks continue to supply tissue products independently in a competitive and uncoordinated business environment. There continues to be a lack of demand planning, especially at an aggregate level.

Strengths	Weaknesses
<ul style="list-style-type: none"> • No additional resources required. • No change management required. • Allows free market principals to govern supply attributes such as price and vendor selection. 	<ul style="list-style-type: none"> • Does not ensure alignment between supply and demand across Canada. • There is no coordinated long-term planning for national demand or coordinated supply risk mitigation. • Existing processing capacity is not optimized. • Optimal use of current inventory is not supported. • A focus on supplying institutions or regions does not take advantage of potential economies of scale. • No control or ability to manage supply disruptions or shortages at the national level.

Critical Mechanisms	Presence
End-user relationships	Regional
Demand forecasting	Regional
Production flexibility	Regional
Inventory management	Regional

Sole-source provincial distribution

Provinces centralize the distribution of all produced and imported tissue through a sole source distributor. This option would facilitate the development of provincial distribution channels and demand forecasting. Production flexibility and inventory management would be coordinated through the sole provincial distributor.

How can the tissue donation and transplantation system best ensure that supply aligns with demand?

Strengths	Weaknesses
<ul style="list-style-type: none"> • In comparison to the status quo, where tissue banking is predominantly regional, this model would provide: <ul style="list-style-type: none"> ◦ Greater ability to manage supply distribution or shortages through a larger inventory; ◦ Coordinated end-user relationships that generate market intelligence; ◦ Greater ability to negotiate favourable pricing on foreign processing and imported tissue; ◦ Greater ability to mitigate supply shortfalls; and ◦ Greater opportunities for economies of scale. • Delivery of service remains within the provincial health system. 	<ul style="list-style-type: none"> • Access to allografts will not be consistent as Canadian product supply will vary provincially. • Demand planning will not occur at a national level without independent aggregation of data. • Excess inventory or processing capacity in one or more provinces may be wasted instead of being redirected to meet the demand of provinces experiencing product shortfall. • Shifts in product demand due to changing needs or advances in technology would be difficult to meet in a sole-source distribution model. • The list of products available for use is determined provincially, which may limit options for end-users.

Barriers
<ul style="list-style-type: none"> • Transplant establishments and end-users may be concerned with the loss of supply control to a sole distributor. • Existing tissue banks have evolved mostly in response to institutional demand and may be uncomfortable transitioning to a different approach. • Resources would be required to centralize (if only virtually) regional tissue banks into a single province model.

Critical Mechanisms	Presence
End-user relationships	Exclusively provincial
Demand forecasting	Exclusively provincial
Production flexibility	Exclusively provincial
Inventory management	Exclusively provincial

How can the tissue donation and transplantation system best ensure that supply aligns with demand?

Centralized provincial distribution in an open market

Provinces centralize the distribution of tissue they produce and compete for market share with external producers, such as other provinces and the American producers. The central distributor would develop provincial distribution channels and forecast demand provincially. Production flexibility and inventory management would be coordinated through the central distributor.

Strengths	Weaknesses
<ul style="list-style-type: none"> Allows free market principles to govern supply attributes such as price, diversity of available product and vendor selection. The competitive environment may support product development within the Canadian supply system. Provides provincial tissue banks advantages over the current regional tissue-banking state. Advantages include broader market intelligence and end-user relationships, greater economies of scale, greater ability to respond to supply risks, and greater ability to adjust production to align with demand. 	<ul style="list-style-type: none"> Effectiveness and efficiency of the provincial banks in market intelligence, forecasting, adjusting production and managing inventory will be diminished by open market factors. Demand planning will not occur at a national level without aggregation of data. Excess inventory or processing capacity in one or more provinces may be wasted instead of being redirected to meet the demand of provinces experiencing product shortfall. Shifts in product demand due to changing needs or advances in technology would be difficult to meet in a sole-source distribution model.

Barriers

- Existing tissue banks have evolved mostly in response to institutional demand and may be challenged to adopt a more systematic approach.
- Resources would be required to centralize (if only virtually) regional tissue banks into a single provincial model.

Critical Mechanisms	Presence
End-user relationships	Provincial
Demand forecasting	Provincial
Production flexibility	Provincial
Inventory management	Provincial

How can the tissue donation and transplantation system best ensure that supply aligns with demand?**Sole-source Canadian distribution**

Centralize the production and distribution of all produced or imported tissue through a sole Canadian source. The sole distributor would develop national distribution channels and forecast national demand. Production flexibility and inventory management would be coordinated across Canada.

Strengths	Weaknesses
<ul style="list-style-type: none"> Ability to manage supply disruption or shortages would occur with the broadest inventory possible. Nationally centralized distribution channels provide market intelligence to forecast Canadian demand. Ability to conduct long-term planning and risk mitigation at a national level. Realizes the greatest potential for economies of scale. Standardization of at least domestic products to centrally managed specifications. Greatest buying power with which to negotiate favourable pricing on imported tissue and foreign processing contracts. 	<ul style="list-style-type: none"> The list of products available for use is determined nationally, which may limit options for end-users.
Barriers	
<ul style="list-style-type: none"> Transplant establishments and end-users may be concerned with the loss of supply control to a sole distributor. Infrastructure investment would be required to centralize (if only virtually) mechanisms for ensuring alignment of supply and demand. Services are currently funded and delivered provincially; the funding for tissue services would need to change to a national model. 	

Critical Mechanisms	Presence
End-user relationships	Exclusively national
Demand forecasting	Exclusively national
Production flexibility	Exclusively national
Inventory management	Exclusively national

How can the tissue donation and transplantation system best ensure that supply aligns with demand?**Coordinated National Distribution**

This option would coordinate the production and distribution of Canadian tissue through a virtual national inventory. Tissue banks would still compete for market share with international producers. National demand forecasting and coordination of excess processing capacity would be the responsibility of the coordinating body. Financial exchanges between source and transplant establishments would occur on a cost recovery basis. The use of excess processing capacity would be paid for by the tissue bank receiving the processed tissue. Interprovincial partnerships in support of processing and distribution efficiencies would be pursued independently.

Strengths	Weaknesses
<ul style="list-style-type: none"> • No change to independent status of programs. • Allows free market principals to govern supply attributes such as price, diversity of available product, and vendor selection. • Allows for the alignment of domestic supply to end-user demand on a national scale. • Aggregate data on inventory and production allows for supply and demand planning and supply risk mitigation at a national level. 	<ul style="list-style-type: none"> • Coordinating the use of excess processing capacity within a network of independent banks may be logistically challenging, and may not be optimal compared to national coordination of processing. • Lack of product-attribute standardization presents a challenge to distributing inventory inter-provincially. • Does not optimize the potential for economies of scale as production, storage, and distribution activities are duplicated throughout existing banks.

Barriers
<ul style="list-style-type: none"> • Infrastructure investment would be required to centralize (at least virtually) mechanisms for ensuring alignment of supply and demand. • Existing services are funded and delivered provincially; the funding for tissue services would need to change to fit this option. • Existing tissue banks have evolved mostly in response to institutional demand and may be uncomfortable transitioning to a more forward-looking approach.

Critical Mechanisms	Presence
End User Relationships	National
Demand Forecasting	National
Production Flexibility	National
Inventory Management	National

How can the tissue donation and transplantation system best ensure that supply aligns with demand?

B. Considerations

- To achieve the goal of ensuring the alignment of supply and demand across Canada will require certain coordinated mechanisms
- Recommendations may differ by tissue type (e.g. ocular versus bone)
- End-user relationship recommendations may differ by transplant establishment type (e.g. surgical versus dental)
- Detailed business cases may be required to model the cost of any given option

How can the tissue donation and transplantation system best ensure that supply aligns with demand?

APPENDIX A

The following chart details demand forecasting for the US.

Global Orthobiologics Market (\$ Millions)

Category	2007	2008	2013	Growth Rate%
Allograft	750	826	1,050	4.95%
Growth factors	750	920	1,550	11.0%
Demineralized bone matrix	400	484	780	10.0%
Synthetics (bone substitutes)	400	502	880	11.9%
Blood-based and orthopedic stem cells	200	245	414	11.0%
Total	2,500	2,977	4,674	9.4%

US Sales of Bone Allografts by Type Through 2013 (\$ Millions)

Category	2007	2008	2013	Growth Rate%
Base tissue	375	414	529	5.0%
Machined implants	200	245	368	8.5%
Demineralized bone	200	230	407	12.1%
Total	775	889	1,304	8.0%

US Corneal Transplant Market Through 2013

Category	2007	2008	2013	Growth Rate%
Number of transplants	39,391	40,900	45,000	1.9%
US market (\$Millions)	906	1,006	1,310	5.4%

US Heart Valve Transplant Market Through 2013

Category	2007	2008	2013	Growth Rate%
US allograft market	1,100	1,217	1,570	5.2%
US total grafts (\$Millions)	2,700	2,950	3,680	4.5%

US Market of Human Skin-Based Products Though 2013 (\$ Millions)*

Category	2007	2008	2013	Growth Rate%
Human skin-based products	188	280	750	21.8%

* Based on data from the National Centre for Health Statistics and the American Society for Aesthetic Plastic Surgery.