

**Market Overview of Hemostats & Sealant segment
of Baxter India**

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TO WHOMSOEVER MAY CONCERN

This is to certify that HIMANSHU RAO student of Post Graduate Diploma in Pharmaceutical Management (PGDPM) from Institute of Health Management Research, Jaipur has undergone internship training at LINTAC SOLUTIONS & CONSULTANTS from 3rd FEBRUARY, 2014 to 30 APRIL, 2014.

The Candidate has successfully carried out the study designated to him during internship training and his approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish him all success in all his future endeavors.



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CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled MARKET OVERVIEW OF HEMOSTATS AND SEALANT SEGMENT OF BAXTER INDIA submitted by HIMANSHU RAO Enrollment No.184 under the supervision of MR. ABHISHEK DADHICH for award of Postgraduate Diploma in Hospital and Pharmaceutical Management of the Institute carried out during the period from 2012 to 2014 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.

Himanshu Rao

Signature

Market Overview of Hemostats and Sealant segment of Baxter India

Abstract:

The industry of topical hemostat and sealants market is very interesting. Hemostats, sealants, and adhesives are gaining increasing acceptance in surgical practice everywhere and presently represent a multi-billion dollar industry. A hemostat is designed to cause blood to clot and requires the presence of blood in the operative field to be effective. Sealants work by creating a sealing barrier. They polymerize independently and may work best when blood is not present in the field.

New products are in development and practice patterns of surgical adhesives are evolving, as clinicians familiarize themselves with the capabilities of each product. Tissue sealants and adhesives have some distinct advantages. However they are expensive and approved by the FDA for specific Indications only⁴. Topical hemostats are comparatively less expensive and more acceptable to surgeons. They also have a proven well-established clinical record. There are concerns over topical hemostats derived from animal source products. Before these concerns affect the industry, it is expected to move toward developing more advanced, safer, effective and preferably humane tissue products in the future. Due to slightly restricted growth opportunities within the low growth Indian topical hemostats market, in the later part of the forecast period is likely to witness more competition within the industry resulting insignificant market share shifts to advanced products.

Baxter and has demonstrated considerable aggression in competing for market share, particularly in the recent past. As a result, if companies have to retain and grow its position in the Indian market, which is becoming increasingly attractive due to the rapid growth in the segment, it is essential that other companies obtain a detailed understanding of the current position and future strategy of these two companies including their current sales, breakdown of sales by region, type of customer and by procedure, distribution of sale by product group, organization structure for the Hemostats and Sealants business, pricing and channel strategy, new products that the companies are planning to launch to accelerate their growth, sales, marketing, communication and positioning strategy, breakdown of marketing and promotional spend and future objectives.

Abhinav
27/5/14

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INTRODUCTION:

Hemostats are medical devices which find extensive applications in a wide range of surgical procedures to control bleeding during or after a surgical procedure. Sealants are also used to stop internal bleeding which can occur because of an injury or during a surgical procedure. There are a fairly large number of international and Indian companies that also operate in the same segment⁴.

<u>Company</u>	<u>Key Brands</u>
J&J Medical	Sugicel®, Evicel®
Baxter	Floseal®, Tissel®
Sri Gopal Krishna Labs	AbGel® (Sterile Surgical Haemostatic Sponge)

Baxter has demonstrated considerable aggression in competing for market share, particularly in the recent past. As a result, if J&J Medical has to retain and grow its position in the Indian market, which is becoming increasingly attractive due to the rapid growth in the segment, it is essential that J&J Medical obtains a detailed understanding of the current position and future strategy of Baxter India including their current sales, breakdown of sales by region, type of customer and by procedure, distribution of sale by product group, organization structure for the Hemostats and Sealants business, pricing and channel strategy, new products that the companies are planning to launch to accelerate their growth, sales, marketing, communication and positioning strategy, breakdown of marketing and promotional spend and future objectives

Definition:

Topical Hemostats –

These are devices used for surgical procedures, wherein bleeding is difficult to control with conventional methods such as suturing, stapling, or placement of pads or gauze at the bleeding site. Topical hemostats are placed at the bleeding site to soak excess blood and to accelerate hemostasis. Without such products, patients can lose large amounts of blood and require transfusions that involve the risk of contracting blood-borne diseases.

Collagen-based Topical Hemostats –

Collagen is a helical protein found in mammalian connective tissue. It is found in every major tissue, which requires strength and flexibility such as skin, tendon, bone, and fascia. As a result of its abundance in animal tissue and its biocompatibility, collagen has been used extensively to formulate medical materials.

Oxidized Regenerated Cellulose-based Topical Hemostats –

Cellulose is a plant-derived polysaccharide and is the most abundant organic compound in the biosphere. Because of its physical properties, cellulose serves in a structural capacity for plant support. Oxidized regenerated cellulose is a knitted fabric produced by the controlled oxidation of regenerated cellulose. It is used in the clinical environment as a hemostat.

Gelatin-based Topical Hemostats –

Gelatin is a biopolymer derived from bovine sources. It has a wide range of applications, which includes its use in the coating of tablets used for oral consumption, cosmetics, photography, and other technical applications. However, in the clinical environment, gelatin is used primarily as a topical hemostat.

Thrombin-based Topical Hemostats –

Thrombin is a protein in the blood's plasma involved in the body's physiological blood-clotting mechanism. Thrombin is a component of the clotting cascade known as Factor IIa. Commercially, thrombin is prepared by reacting tissue thromboplastin and prothrombin of bovine origin in the presence of calcium chloride. Thrombin-based products are used in the United States for procedures in which blood clotting must be accelerated. For example, thrombin is often used in organ transplant procedures where a hemostat is required and where the field of vision must be kept clear to continue surgery.

Combination Topical Hemostats –

Products using a combination of either collagen, cellulose, gelatin, or thrombin are defined as combination products.

Tissue Sealants –

Tissue sealants consist of either biologic or synthetic materials. They serve primarily as a physical barrier to provide continence of fluid or air. Tissue sealants are used in a variety of surgical specialties and applications typically as an adjunct product for more effective surgeries. Tissue sealants can be categorized as follows on the basis of their composition:

- a) Fibrin sealants
- b) Collagen-based sealants
- c) Synthetic polymer-based sealants
- d) Protein-based tissue sealants

Fibrin Sealants –

Fibrin sealants consist of biologic components of the natural clotting system. A fibrin sealant is formed when fibrinogen and thrombin are combined in the presence of Factor XIII and calcium as catalysts. Other factors affecting the formation of fibrin sealants include pH, fibronectin, and exogenous plasmin. There are several types of fibrin sealants based on the sources from which the fibrin is prepared:

- a) Autologous fibrin sealants
- b) Pooled or homologous fibrin sealants
- c) Human recombinant fibrin sealants

Autologous Fibrin Sealants –

Autologous fibrin sealants are formed using the patient's own blood.

Pooled or Homologous Fibrin Sealants –

Pooled plasma or homologous fibrin sealants are formed using blood from multiple donors.

Human Recombinant Fibrin Sealants –

Human recombinant fibrin sealants consist of recombinant components produced from transgenic animals. This is performed by genetically engineering the DNA (Deoxyribonucleic Acid) of the production species, so that it is able to produce human

fibrinogen or thrombin. The components are then harvested and used to manufacture tissue sealants.

Human recombinant technology enables the collection of human fibrinogen and thrombin in a controlled environment, instead of through blood donors.

Collagen-based Sealants –

Collagen-based sealants consist of biologic components. They are formed from collagen alone or collagen combined with other active compounds such as thrombin. Collagen is a helical protein found in mammalian connective tissue. It consists of bundles of tiny fibers that form connective tissue, including white inelastic fibers of the tendons, ligaments, bones, and cartilage.

Synthetic Polymer-based Sealants –

These sealants consist of a variety of artificial components such as polyethylene glycol, synthetic peptides, and protein polymers. They are chemical compounds formed by linking a number of small monomers, and can be made up of different monomers or from many units of the same. The material is free of protein and other contaminants.

Protein-based Tissue Sealants –

These sealants contain purified bovine serum albumin (BSA) and glutaraldehyde, and are used as adjuncts to seal anastomoses for large vessel repair and to reinforce friable tissue in the repair of acute thoracic aortic dissections.

ABBREVIATIONS:

ITEMS	DESCRIPTIONS
AOC	Alkylene oxide copolymer
ASM	Area Sales Manager
BU	Business unit
CAGR	Compound annual growth rate
CFA/C&F	Carrying & forwarding agent
CME	Continuing medical education
CSF	Cerebro spinal fluid
CTVS	Cardiothoracic vascular surgery
DCGI	Drugs Controller General of India
GI	Gastrointestinal
IV	Intravenous
J&J	Johnson & Johnson
KAM	Key Account Manager
KOL	Key opinion leader
LBL	Leave behind literature
MNC	Multinational Corporation
MRSA	Methicillin-resistant Staphylococcus aureus
MRP	Maximum retail price
OD	Outpatient Department

OT	Operation theatre
RTM	Round table meeting
RC	Rate contract
PTS	Price to stockiest
PTR	Price to retailer
PG	Postgraduate
USP	Unique selling proposition

LITERATURE REVIEW:

The industry of topical hemostat and sealants market is very interesting. Hemostats, sealants, and adhesives are gaining increasing acceptance in surgical practice everywhere and presently represent a multi-billion dollar industry. A hemostat is designed to cause blood to clot and requires the presence of blood in the operative field to be effective. Sealants work by creating a sealing barrier. They polymerize independently and may work best when blood is not present in the field³.

New products are in development and practice patterns of surgical adhesives are evolving, as clinicians familiarize themselves with the capabilities of each product. Tissue sealants and adhesives have some distinct advantages. However they are expensive and approved by the FDA for specific Indications only⁴. Topical hemostats are comparatively less expensive and more acceptable to surgeons. They also have a proven well-established clinical record. There are concerns over topical hemostats derived from animal source products. Before these concerns affect the industry, it is expected to move toward developing more advanced, safer, effective and preferably humane tissue products in the future. Due to slightly restricted growth

opportunities within the low growth Indian topical hemostats market, in the later part of the forecast period is likely to witness more competition within the industry resulting in significant market share shifts to advanced products⁶.

While some key participants exited, the market still remains competitive with manufacturers

employing aggressive marketing strategies and financial resources. King Pharmaceuticals was

the major participant in the thrombin-based hemostats market. With Surgicel, Ethicon Inc. is

the sole player in the cellulose-based hemostats segment.

Applications of hemostats:

Surgeons use topical hemostats to control mild to moderate bleeding when conventional means, such as suture or ligature, are ineffective. Hemostats are indicated in most surgical procedures as adjunctive or complementary. Hemostats come in a variety of forms and each of them have specific applications and use. Fibrillar material, similar to cotton, can be applied in a thin layer or can be balled up and placed on the specific site. Pads and sponges are often held in place against the bleeding site while hemostasis is attained. Liquids may be

sprayed at the site using a syringe. Surgeons also use hemostats in powder form by applying

it on the bleeding site. Figure 3-2 lists some of the available forms with their advantages and drawbacks.

Type of Hemostat Classification Approval Mechanism

- a) Collagen-based Class III medical device PMA
- b) Cellulose-based Class III medical device PMA
- c) Gelatin-based Class III medical device PMA
- d) Thrombin-based Biologic PLA/ELA
- e) Collagen + Thrombin Combination Class III medical device PMA

Practice patterns of tissue sealants use are evolving as clinicians familiarize themselves with

the capabilities of each product with the introduction of multiple agents. At least five families of tissue adhesives and tissue sealants now exist. traces of fibrin sealants usage go back to the development of Cohn fractionation in the 1940s, and to the method of cryoprecipitation in 1960s. However, in 1977, the FDA (Food and Drug Administration) revoked the license for commercial use of fibrin sealants prepared from pooled human plasma, fearing the possible transmission of Hepatitis-B virus (HBV) in particular. Fibrin sealants have a long and successful history in Europe since 1970s.

While these products were not commercially available, clinicians and hospitals realized the importance of such products and developed "home-brew" fibrin sealants. The blood bank tissue sealants (commonly known as "home-brew" tissue sealants) include a mix of cryoprecipitated human plasma, and bovine thrombin. These products were not subject to strictly defined specifications governed by the FDA, in terms of consistency, purity, availability, and cost. Until recently, blood bank tissue sealants were quite popular in the United States. The introduction and approval of commercial alternatives provided greater assurance of consistent quality.

The FDA decided to allow commercial production of fibrin sealants as a result of increasing

pressure from physicians and manufacturers. In May 1998, Baxter became the first company

to receive FDA approval to commercially market its fibrin sealant, Tisseel VH, in the United

States. The launch of Tisseel VH paved the way for introduction of more tissue sealant products in the market. The U.S. tissue sealants market generated only \$138.8 million in 2002. However, it reached \$153.2 million in 2003 at 10.4 percent revenue growth rate over the previous year. The compound annual growth rate (CAGR) for this market during 2003-2010 period is estimated at 6.0 percent.

Application & Use:

Tissue sealants can be used to close incisions, seal, and secure skin flaps, and to promote hemostasis. These products are used in a variety of surgical specialties and applications, typically as an adjunct product for the purpose of more effective surgeries. Tissue sealants consist of either biological or synthetic materials².

Fibrin sealants contributed to 73 percent of total tissue sealant revenues in 2003. Proteinbased

tissue sealants had a revenue share of 22 percent while synthetic polymer-based tissue sealants accounted for about five percent revenues during 2003.

There are different types of tissue sealants, each categorized and subcategorized by their

substance of composition. These categories include⁶:

- a) Fibrin sealants
- b) Pooled fibrin sealants
- c) Autologous fibrin sealants
- d) Recombinant fibrin sealants
- e) Synthetic polymer-based sealants
- f) Protein-based tissue sealants
- g) Recombinant human collagen sealants

Tissue sealant delivery devices include:

- a) Syringe
- b) Spray bottle
- c) Tube
- d) Catheters
- e) Sponges
- f) Bandages

Tissue sealants are available in several formulation configurations, including the following:

- a) Liquid
- b) Gel
- c) Dry powder
- d) Bandage
- e) Foam
- f) Membrane

The choice of product formulation depends on the type of interventional procedure to be performed and a variety of other factors, including physician preferences. The future market

is expected to consist of products competing in various formulations to better meet the specific needs of certain procedures. These new formulations are likely to compete with liquid tissue sealants of all types, because they are unlikely to require the extensive preparation time and efforts involved in liquid sealants.

The hemostat, sealant, and adhesive components of the surgical toolbox continue to evolve and enter clinical practice at a rapid rate. The goal of this comprehensive, sequential review is to update these components to include those now available (February 2012) as well as to explore cost and regulatory factors that impact the development and use of these materials. A unique system of definitions for organizing these components based on group, category, and class is used as a means of improving the understanding and appropriate use of these materials. The system will be used here to present the most recent additions to the toolbox, which are evaluated based on safety, efficacy, usability, and cost. These new additions include pooled human plasma fibrinogen and thrombin embedded in an equine collagen patch for cardiac surgical hemostasis, polyethylene glycol (PEG) and human serum albumin for lung surgical pneumostasis, modified PEG and trilycine amine for spinal sealing, octyl and butyl lactoyl cyanoacrylate for vascular sealing, and a variety of octyl and butyl cyanoacrylates with or without dyes and/or polyester mesh for skin closure with the creation of a bacterial barrier. The system of definitions will also be used to clarify key strategies in the current health care environment for reducing costs and for increasing understanding of Food and Drug Administration regulatory decisions for these materials.

When surgical ligation of bleeding fails, or is not possible, surgeons rely on a number of hemostatic aids, including thrombin¹. This review discusses the history, pharmacology and clinical application of thrombin as a surgical hemostat. The initial thrombin was bovine in origin, but its use has been complicated by the formation of antibodies that cross react with human coagulation factors. This has been associated with life threatening bleeding and in some circumstances anaphylaxis and death. Human thrombin, isolated from pooled plasma of donors, has been developed in an effort to minimize these risks, but its downside is the potential of transmitting blood-borne pathogens and limited availability. Recently a recombinant thrombin has been developed and approved for use by the FDA. It has the advantage of being minimally antigenic and devoid of the risk of viral transmission. Thrombin is often used in conjunction with other hemostatic aids, including absorbable agents (like gelfoam, collagen, and cellulose), and with fibrinogen in fibrin glues. The last part of this review will discuss these agents in detail, and review their clinical applications.

OBJECTIVES:

1. To find out the Current (2013), estimated (2014) and forecast (2015) sales of hemostats and sealants and breakdown of sales by:
 - i. Region wise
 - ii. Type of surgical procedure
 - iii. Category of customers:
 - a) Government institutions
 - b) Corporate hospitals (group and stand-alone)
 - c) Others
2. To find out the Product portfolio within sealants and hemostats of Baxter India.
3. To find out the Distribution model of Baxter India.
 - i. Distribution channels and margins at each level.
4. To study the organization structure of the company.
5. To find out the Sales Structure of Baxter India.
6. To find out the Marketing and promotional strategy of Baxter India.
7. To find out their new product introductions over 2-5 years.
8. SWOT analysis.

RESEARCH METHODOLOGY:

- 1.) Type of Study Design: The type of study design used for this research is cross sectional study design.
- 2.) Research Instrument: a.) Interviews: Respondents were interviewed on hemostats and sealant segment of Baxter India
- 3.) Data Collection Source: a.) Primary Data Source: Interviews
b.) Secondary Data Source: Newspapers, Journals & Internet
- 4.) Approach: Draw each respondent into a discussion by reviewing areas of general interest in the sealants and haemostats segment and slowly bringing in key questions

<u>Respondent Categories</u>	<u>No. of Interviews</u>
Channel partners and distributors of the target companies	30
Customers	30
Other companies supplying Hemostats and Sealants	10
Local Manufacturers of Hemostats and Sealants including Strategic Alliance Partners to the Target companies	10
Medico-marketing companies	10
Regulatory authorities	5
Others such as Associations and Experts	5
Total	100

ANALYSIS:

Competitor Profile:

BAXTER:

- i. Baxter India is a wholly-owned subsidiary of Baxter International
- ii. Baxter India has been present in India for past 15 years
- iii. It is a leading manufacturer and supplier of innovative surgical technologies and pharmaceutical products in India
- iv. Key operational therapeutic segments are:
 - a) Anesthesia
 - b) Bio-surgery (includes hemostats and sealants)
 - c) Clinical nutrition
 - d) Critical care
 - e) Hemophilia
 - f) Infusion systems
 - g) Pharmaceuticals & IV solutions
 - h) Renal care

Leading Brands:

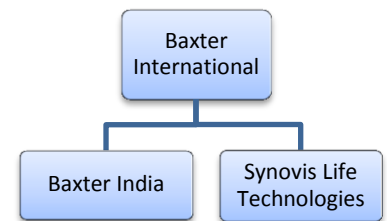
<u>Category</u>	<u>Leading Brands</u>
Bio Therapeutics	Flexbumin
Biosurgery	Floseal & Tisseel
Hemophilia	Feiba Stim 4 and Recombinate

Baxter initiated its Indian operations in 1997

- In its Biosurgery portfolio, Tisseel was launched in 2004, followed by Floseal in 2007
- Coseal was launched in 2011

In 2011, Baxter acquired Synovis Life Technologies for US\$325 million

- Acquisition expanded Baxter's regenerative medicine and Biosurgery portfolio with addition of Synovis' biological and surgical products, used for soft tissue repair and microsurgery in several procedures
- Following DCGI guidelines, Baxter India has initiated the process for registering Synovis brands under its Indian flagship

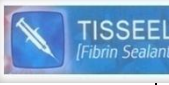


KEY SPECIALITY SURGICAL APPLICATION MATRIX :

Products	CTV S	Neurosurgery	Orthopedic/Spinal	Oncosurgery	GI & Bariatric
Peri Strips Dry	√				√
Flo-thru	√				

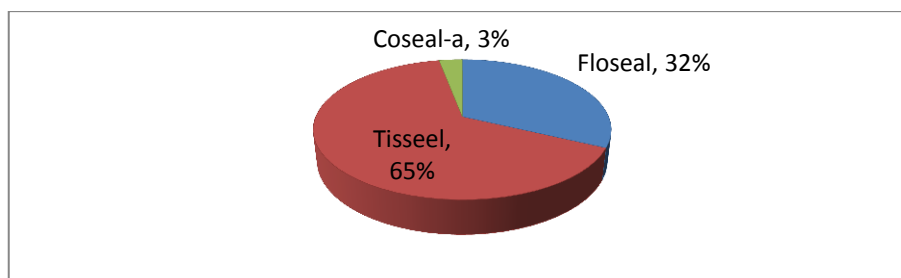
Shunt					
Flo-Rester	√				
Vascular Probe	√				

Breakdown of key brands for each division:

Brands	Type	Description	Key communication message	Key target clinicians	Sales revenue, 2012 (INR million)
	Gelatin-based hemostatic matrix	Indicated in surgical procedures (other than ophthalmic) as an adjunct to conventional hemostatic measures	• Pure hemostat which stops bleeding very rapidly, even in 2 minutes • Two-way action, initiating as well as completing the coagulation cascade	• CTVS surgeons • Neurosurgeons • Spinal surgeons • Onco surgeons • General surgeons	66
	Fibrin sealant	Indicated for use as an adjunct to hemostasis in surgeries involving cardiopulmonary bypass and	• Natural fibrin-based sealant which offers effective sealing • Tissue-	• CTVS surgeons • Neurosurgeons • Spinal surgeons • Onco surgeons • General/gastric &	112

		treatment of splenic injuries due to trauma to the abdomen	to-tissue growth	bariatric surgeons • Orthopedic surgeons • Ophthalmic surgeons	
 Coseal <i>Surgical Sealant</i>	Synthetic hydrogel	Biocompatible hydrogel that rapidly cross-links with the proteins in tissue to immediately adhere to the area to which it is applied, and stops bleeding	• Synthetic hydrogel sealant developed to withstand pressure of up to 660 mmhg	• CTVS surgeons • Onco surgeons	22

Sales breakdown for Biosurgery segment, 2013: INR 165 Million:



Tisseel

- Leading brand in Biosurgery segment; in 2013, it accounted for 65% of total sales
- Neurosurgery was the key consuming segment since it effectively prevents CSF leakage

- Neuro and spinal surgeries generated more than half of total Tisseel sales at INR 112 million
- Tisseel is the only product in Baxter's bio-surgery division indicated for ophthalmic surgical use accounting for 5% share by value. It is primarily used for corneal graft surgeries where sutures are avoided.

Floseal

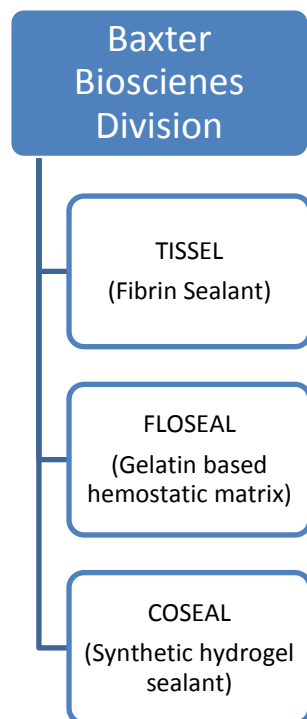
- Accounted for almost one-third of Biosurgery's revenue at INR 66 million
- CTVS is the primary application area and accounted for 32% of total sales by value; neurosurgery generated 30% sales
- Spinal surgery and surgical oncology were the other critical applications.

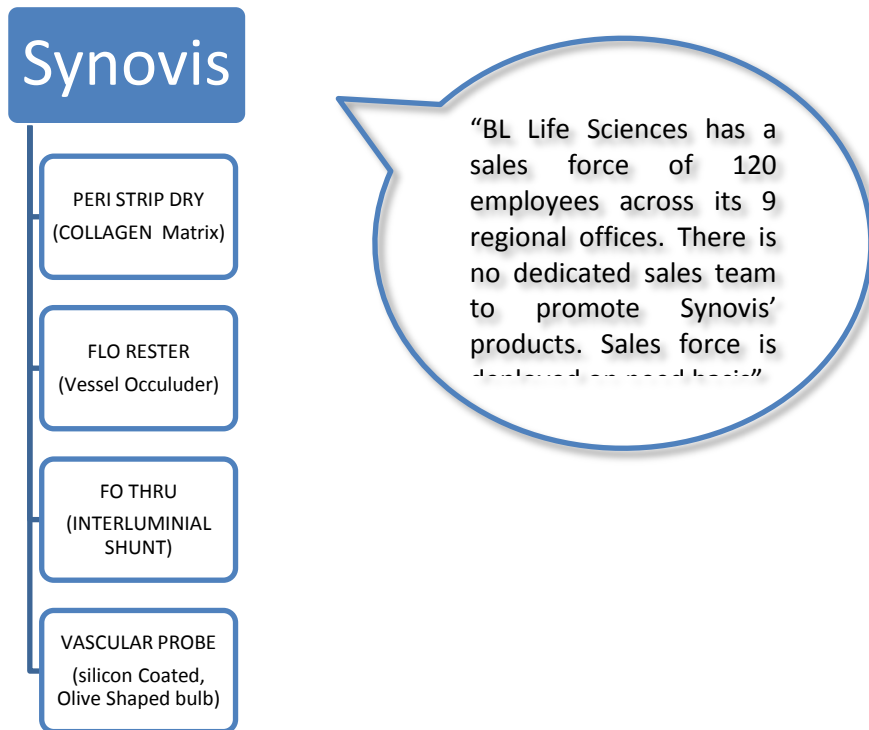
Coseal

- Primarily indicated for cardio and vascular surgeries; sold INR 22 million in its first year after launch
- it is not used in neurosurgery indications

Baxter's Biosciences division managed current product portfolio of hemostats and sealants. With completion of acquisition of Synovis, Baxter India's portfolio will include Synovis' four current brands.

- Until its acquisition, Synovis Life Technologies had a marketing tie-up with a Delhi-based distribution firm, BL Life Sciences





Business overview

- Baxter's Biosciences division handles Biosurgery segment which includes Tisseel, Floseal and Coseal in its hemostats/sealants product portfolio

Regional overview

- Southern region accounted for largest portion of total Biosurgery revenue, followed by northern region
- Eastern zone lagged behind—generated only 8% revenue on account of limited regional centers for critical surgeries and limited acceptance of premium-priced products

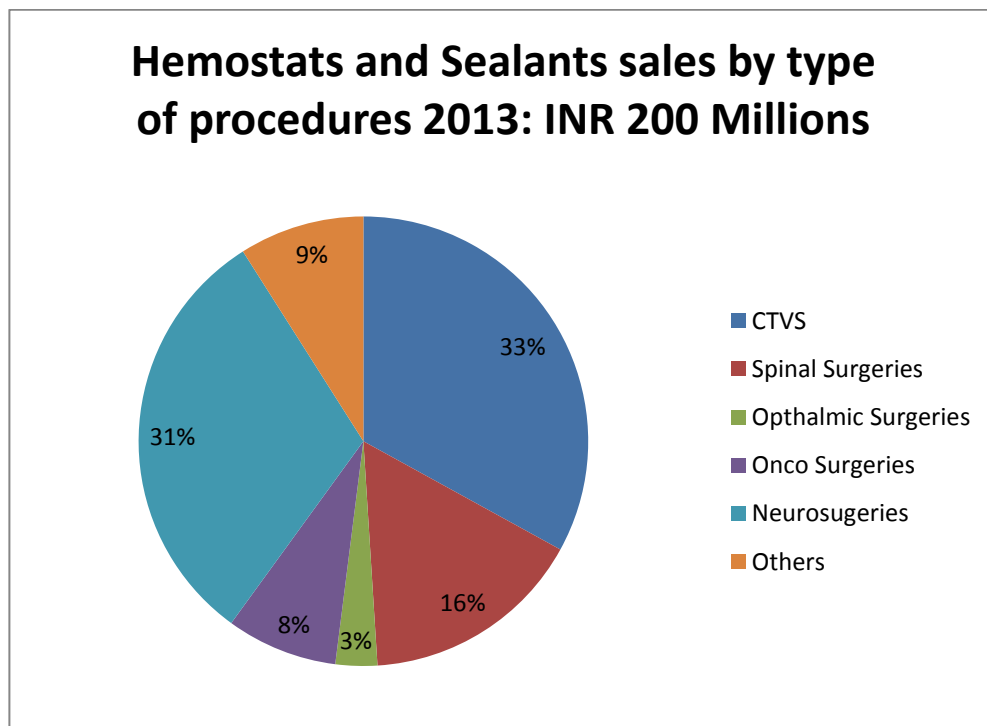
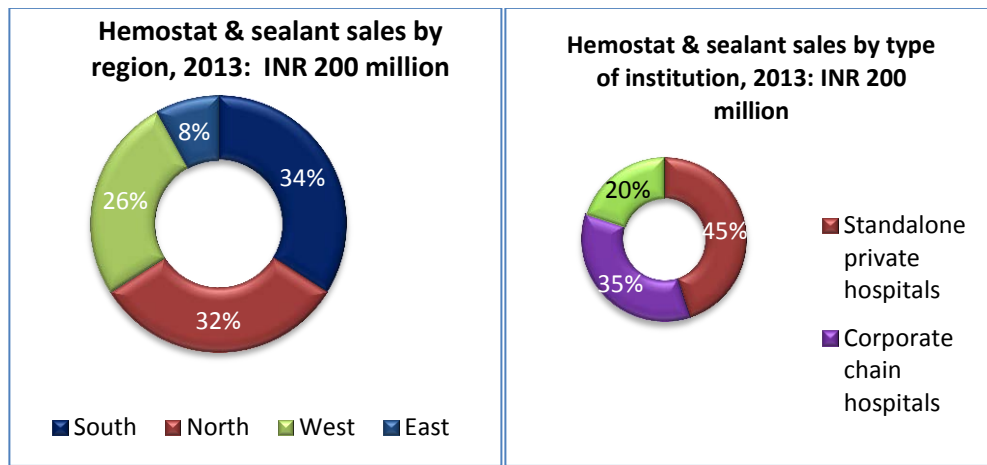
Customer overview

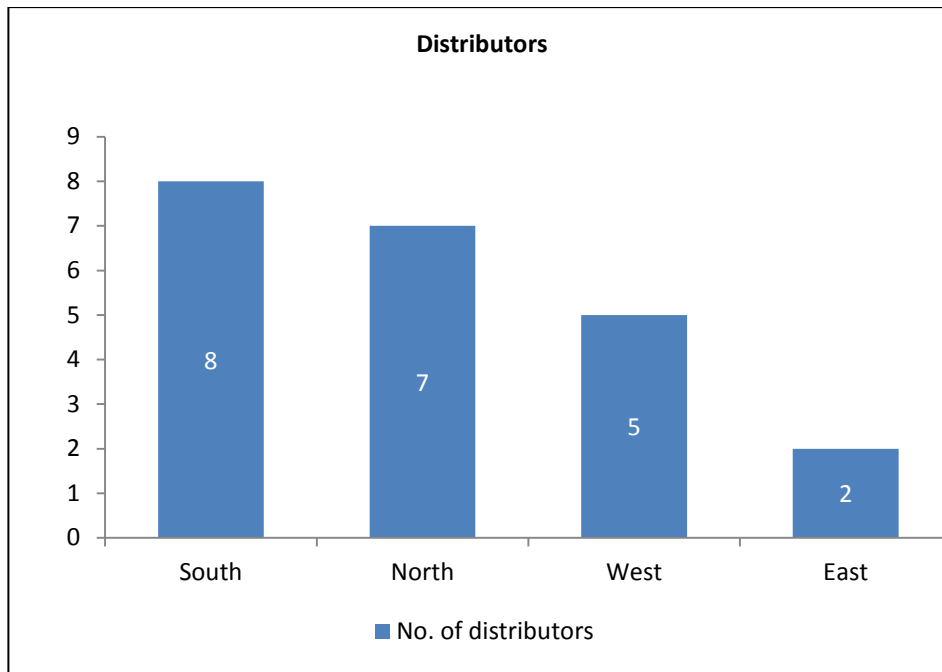
- Sales revenue was primarily generated from private market
 - Standalone surgical centers contributed highest portion to sales, contributing 45% to revenues
 - Corporate chain hospitals like Fortis hospitals, Apollo Hospitals, Max Hospitals, etc. accounted for 35% of total sales revenue
- Government institutions like defense, railways hospitals, state-owned institutions and so on accounted for around 20%
 - Included both tender and local purchases through registered distributors
 - Baxter offers up to 25% discount to governmental institutional accounts, in case of bulk procurement These discounts are given by supplying products

directly through CFAs, and passing on the supply chain margins as discounts.

Application overview

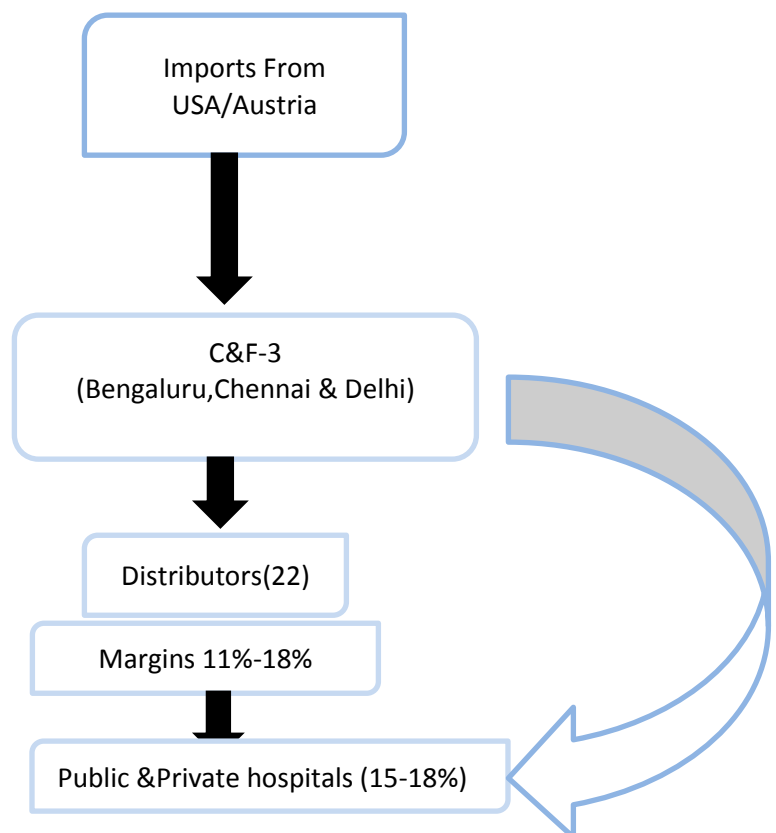
- Cardio-thoracic and vascular surgeries account for one-third of Baxter's biosurgery sales revenue, closely followed by neurosurgeries at 31%
- Spinal surgeries generated 16% revenue. Of this, 15% is contributed by neuro surgeons and remaining 85% is contributed by orthospinal surgeons





- Baxter's Biosurgery products are imported from Austria/USA and routed through distributors, spread all across the country
- Distributor margins–11%-18%; margins vary from product to product, for instance, margins offered on Coseal are up to 18% and on Tisseel–11%

For government institutional sales, Baxter offers 25% discounts to facilitate listing for bulk purchases. These margins are offered to institutions by circumventing distributors; margins are passed on as discounts



Key Responsibility Areas-Sales:

Key responsibility areas	Key Account Manager	Area Sales Manager	Sales Manager
Set sales targets		At territory level	At national and regional level
Meet sales targets	At territorial level	At area level/managing territory sales	Managed at regional and national level
Design sales tactics		Supports by providing information on specific accounts and about competitor moves	Develops sales tactics and regional campaigns to target key accounts and meet/combat the competition
Market assessment	At territorial level	At area level/managing territorial sales	Managed at regional and national level
Sales forecast		At area level/territorial level	At national and regional level
Distributor management /monitoring stock availability	At territorial level	At area level/regional level	Develops import schedule on basis of sales forecast

Key Account manager:

- Builds and maintains relationships with key users–cardio-thoracic surgeons, neurosurgeons, oncosurgeons, orthopedic surgeons and general surgeons
- Three to four calls per day
- Meets sales target in the assigned territory
- Organizes RTMs/CMEs for doctors
- Manages and implements the marketing and communication program
- Participates in industrial events and executes brand-building exercises
- Ensures product availability
- Monitors product distribution through CFAs to hospitals
- New business development
- Trains and educates technical staff and nurses on new products

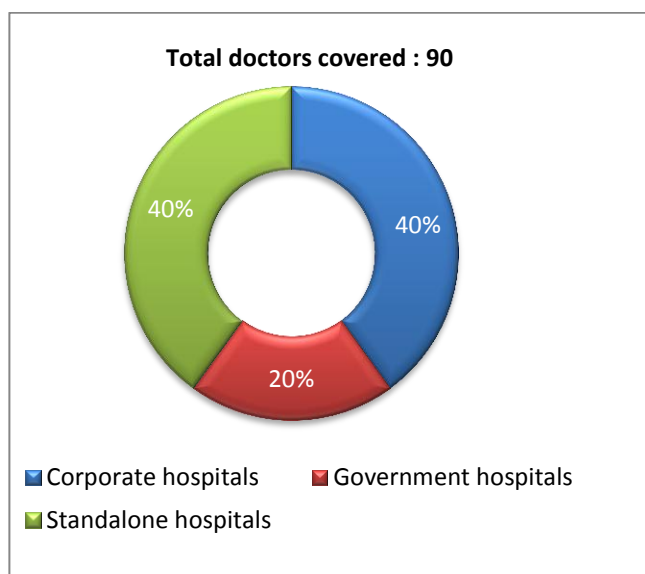
Distributes promotional material and conducts CMEs for paramedical staff

Area Manager:

- Strategic focus on leading surgeons and key accounts
- Provides monthly sales forecast to Sales Manager

- Monitors market conditions and competitor activities
- Supports KAM to organize RTMs and CMEs
- Leads and motivates KAMs through joint calls
- Builds and maintains strong relationships with key surgeons, hospitals and administrative staff to ensure smooth communication and supply
- Achieves monthly targets, both by volume and value for target focus products
- New business development
- Regularly follows up with hospital administration, Store and Purchase Managers and so on
- Monitors customer coverage
- Manages costs by devising optimum account coverage plans

Sales Strategy:



- I. Depending on business potential and differentiated strategy, surgeons of all indications are categorized as:
 - a. A-list surgeons: Include surgeons who have been regular users and are confirmed for high potential
 - b. B-list surgeons: Include surgeons who have just started using Baxter brands and are expected to provide high business value
 - c. C-list surgeons: Include surgeons that are either non-users or irregular users of Baxter's brands; however, are expected to offer good business value in future
- II. Each KAM is assigned 80-100 target doctors (15-18 hospital accounts) in the territory
- III. With given product category and level of competition, Baxter believes that OT calls (lasting up to 3 hours) at an interval of even more than a month result in better brand recognition and acceptance than frequent and short monthly visit

Daily call average	
Doctors	3-4 calls/day
All other key personnel of the hospitals such as Purchase Managers, Pharmacy Managers, Accounts Head/In charge, are also covered during the same call	

Category	specialist
Private standalone hospital	Cardiothoracic & vascular, neurology, spinal, gastrointestinal, general, orthopedic, oncology and ophthalmic surgeons
Corporate hospitals	Cardiothoracic & vascular, neurology, spinal, gastrointestinal/bariatric, general, orthopedic, oncology and ophthalmic surgeons
Government institutions	Cardiothoracic & vascular, neurology, spinal and oncology surgeons

Sales Strategy:

- I. Target customers: Baxter India's Biosurgery sales force is structured to reach key target accounts and clinicians. Target customers are segmented into two broad categories:
 - a. Sales strategy is differentiated on the basis of customer types—to market its entire product portfolio
 - Standalone hospitals: Account for the largest share of existing and potential customers. Focused on key surgeons and senior Purchase Department personnel
 - Corporate customers: Corporate chain hospitals are targeted. Leading surgeons and departmental heads are persuaded to use products
 - Institutional customers: key decision makers and leading KOLs are targeted in institutions since they have power to influence and finalize inclusion of the product in central or local formulary
 - Company does not have specific sales personnel for government institutions and private market accounts. Area Sales Manager and Key Account Manager are responsible for target hospitals covered in their territories
- II. Target segments: Sales team focuses on practitioners operating in the following therapeutic segments:
- III. Cardiothoracic, vascular, neuro and spinal surgeons are key target segments for Baxter's Biosurgery division
- IV. Since these categories include critical surgeries, and key target institutions clearly rate safety assurance above procedure cost, Baxter finds this category receptive to its premium-priced brands
- V. Approach:

- VI. Each representative focuses on entire chain of influencers—from lead surgeons to customer's Purchase Department personnel, including the Assistant Surgeons and resident surgery students
- VII. KOLs/Lead Surgeons: Primary focus remains on lead surgeons to include them as regular users, taking into consideration that their acceptance will highly influence the acceptance levels for products among other surgeon types

Category	Focus %
Cardio-thoracic surgeons	20-25
Neuro surgeons	20-25
Spinal surgeons	15-18
Oncosurgeons	10-12
GI/Bariatric surgeons	8-10
Ophthalmic surgeons	5-7
Others	10-15

- Surgeons: Sales team maintains its focus on surgical team in its existing and potential accounts, in order to develop these clinicians as confirmed users of its brands
- Resident surgeons/PG students: Sales team focuses its efforts on building this category of surgeons as its regular users by organizing CMEs and supporting their educational updates

Categorization of surgeons & influencers:

Depending on business potential and differentiated strategy, surgeons of all indications are categorized as:

- I. A-list surgeons: Include regular users and are confirmed for high potential
 - a. These surgeons are regularly invited for CMEs and RTMs to sharing their experiences about Baxter brands with other category surgeons
- II. B-list surgeons: Include surgeons who have just started using Baxter brands and are expected to offer high business value
 - a. These surgeons are regularly visited for OT/live promotion of products. Efforts are directed to enhance their acceptance of products, to maximum extent possible
- III. C-list surgeons: Include non-users or irregular users of Baxter's brands; however, are expected to offer good business value in future
 - a. Efforts are directed to influence these surgeons to experience the product efficiency

Purchase Department personnel of all major existing and potential accounts are targeted. Sales personnel handle tender business, and relationships with top administrative personnel in all key and relevant government institutions such as defense, railways, state-owned corporations and so on

Sales approach:

- I. In-clinic promotions: Sales team approaches surgeons with electronic tablets (I-Pad) to differentiate their brand communication approach from competitors

- II. Product detailing, indications, application method and benefits are presented using specifically designed videos. Sales personnel support the presentation by handling product related queries
- III. Use in OT: Sales personnel prefer promoting brands in OT than in OPD. To instill confidence and acceptance for products, the team carries out demonstrations of samples in OTs. **The representative insists that practitioners use the products in OT**. It also enables them to obtain immediate feedback
- IV. Sales personnel spend over 3 hours in general for each OT call
 - a. Each KAM handles the responsibility to target and manage around 80 surgeons. With an average of 3-4 calls per day and additional responsibility of organizing educational meets, the strategy is to make impactful and demonstrative calls, even if the duration between each call exceeds thirty days
 - b. Baxter believes that with the given product segment, comprehensive calls rather than regular and more frequent calls will add more value, as the emphasis is more on acceptance of product
- V. Baxter India provides pressure spray kits for Tisseel to institutions free of charge, on requirement basis. Presence of KAM or part-time OT technicians not only facilitates kit usage but it also provides a good platform to target class B & C surgeons to enhance acceptance in these categories
- VI. **Industrial and educational meetings:** Organizing and participating in promotional/industrial/educational meetings events:
- VII. National level events: Baxter India participated in various national level conferences to enhance its visibility, and to pursue its brand management and business development activities for its target surgical indications. Examples of the leading events are as follows:
 - a. 61st Annual Conference of Neurological Society of India–Neurocon 2012
 - b. 58th Conference of India Association of Cardio-vascular Thoracic Surgeons–IACTS, 2012
 - c. Annual Conference of Neuro Spinal Surgeons Association, India–Spine 2012
 - d. 47th Annual Conference of Association of Plastic Surgeons of India–APSICON, 2012
 - e. As part of its business development drive, company participated in 59th Annual conferences of IACTS, which is held in February, 2013
- VIII. For every major conference, Baxter sponsors 30-50 surgeons from across the country
- IX. Regional events
 - a. Sales team conducts RTMs for surgeons at territory level on a regular basis

Promotional events and activities:

- a. One CME is targeted per Key Account Manager, for which 20-30 surgeons are invited
 - i. Class A surgeons (regular users of Baxter brands) are invited as speakers; event aims to improve acceptance of Baxter brands among surgeons with high business potential, however, use Baxter brands in a limited scope

- ii. CMEs are organized for various hospitals, which include surgeons from two to three government institutions or surgeons from a particular hospital chain; they are invited keeping in mind the acceptance of fellow invitees as colleagues
 - iii. Baxter's medical affairs team is a regular participant at these CMEs. Team also participates as speaker and shares new developments and global technology trends
 - b. RTMs are organized to target one RTM/month/KAM
 - i. These include surgeons from particular areas of specialization from one or two hospital accounts
 - ii. Each RTM has ten surgeons
- II. CME/RTM topics for various areas of specialization are:
 - a. CTVS
 - i. Hemostatic challenges specific to cardiac surgeries
 - ii. Existing recommendations to select hemostatic agents
 - iii. Existing practices in coagulation—achieving surgical hemostasis
 - iv. Peri-operative hemostasis management—aortic bleeding
 - b. Neurosurgery
 - i. Hemostasis management during craniotomy/dura repair
 - ii. Existing recommendations to manage CSF leakage
 - iii. Existing practices to manage dural leaks
- III. Each KAM conducts regular CMEs/training programs for OT and paramedical staff
 - a. These sessions are exclusively organized in the hospital

Channel strategies:

- I. Baxter India distributes its products through a network of its distributors located across each region of India
 - a. Distributor's margin ranges between 11%-18%
 - b. Margins offered to hospitals vary from 15%-28%, depending on order volume
 - c. In case of tender-based business, Baxter offers up to 25% discount to facilitate the listing for bulk purchases
- II. KAMs and AMs maintain healthy and friendly relationships with the distributors in the zone, so as to ensure adequate product availability
- III. Each AM is responsible for tracking and controlling account receivables
- IV. To maintain cold storage facilities at CFAs and distributors premises, Baxter has an agreement with service providers such as „Carrier“ and „Blue Star

Brand positioning:

- **FloSeal**

Indication

- I. Indicated in surgical procedures (other than ophthalmic) as an adjunct to hemostatic when bleeding control by ligature or conventional procedures is ineffective or impractical

Positioning

- a. Effective hemostasis:
 - i. Pure hemostat which stops bleeding very rapidly, even in 2 minutes
 - ii. Two-way action, initiating as well as completing the coagulation cascade

- b. Broad hemostasis:
 - i. Effective on both hard and soft tissue
 - ii. Proven to control bleeding from spurting to oozing
- c. Proprietary combination of two independent hemostasis promoting agent
 - i. The gelatin granules swell to produce a tamponade effect
 - ii. High concentrations of human thrombin convert fibrinogen into fibrin monomers accelerating clot formation
- d. Ease of application
 - i. Works on wet, actively bleeding tissue
- e. Confirms to irregular wound surfaces and can be applied directly to target site

Use pattern

- I. Key areas of specialization–CTVS, neuro, spinal and oncology surgeons
- II. Used to achieve hemostasis for peri-operative active bleeding
- III. Used specifically during spurting/pulsating/heavy bleeding. Not used in cases where hemostasis is achieved with hemostatic sponge
- IV. Highly preferred for vascular anastomotic/suture sites and in redo cases

• **Tisseel**

Indication

- I. Indicated for use as an adjunct to hemostasis in surgeries involving cardiopulmonary bypass and treatment of splenic injuries because of trauma to the abdomen
- II. Approved for general hemostasis

Positioning:

- I. Proven hemostasis- across all surgical specialties
- II. Proven sealing-prevent further leakages
- III. Versatile application- compatible with a full line of application and delivery devices for efficient and versatile application
- IV. Available Pre-mixed & pre-filled: No more mixing, no more drawing up, and no more vials

Use pattern

- a. Key specialties–neurosurgeons, CTVS, spinal, oncologists, gastrointestinal/bariatric and ophthalmic surgeons
 - i. GI/bariatric surgeons–prefer to use Tisseel in mesh fixation, sealing of staple line and as tacking device replacements
 - ii. Ophthalmic surgeons–prefer to use Tisseel primarily for corneal graft procedures to avoid sutures
- b. Prophylactic use to achieve hemostasis and prevent post-operative bleeding or leaks
- c. Primarily used to avoid inflammation and pain related to sutures/tacking devices and to reduce possibilities of infection associated with hemostatic sponge

• **CoSeal**

Indication:

- I. In vascular reconstruction to achieve adjunctive hemostasis by mechanically sealing leakage

Positioning:

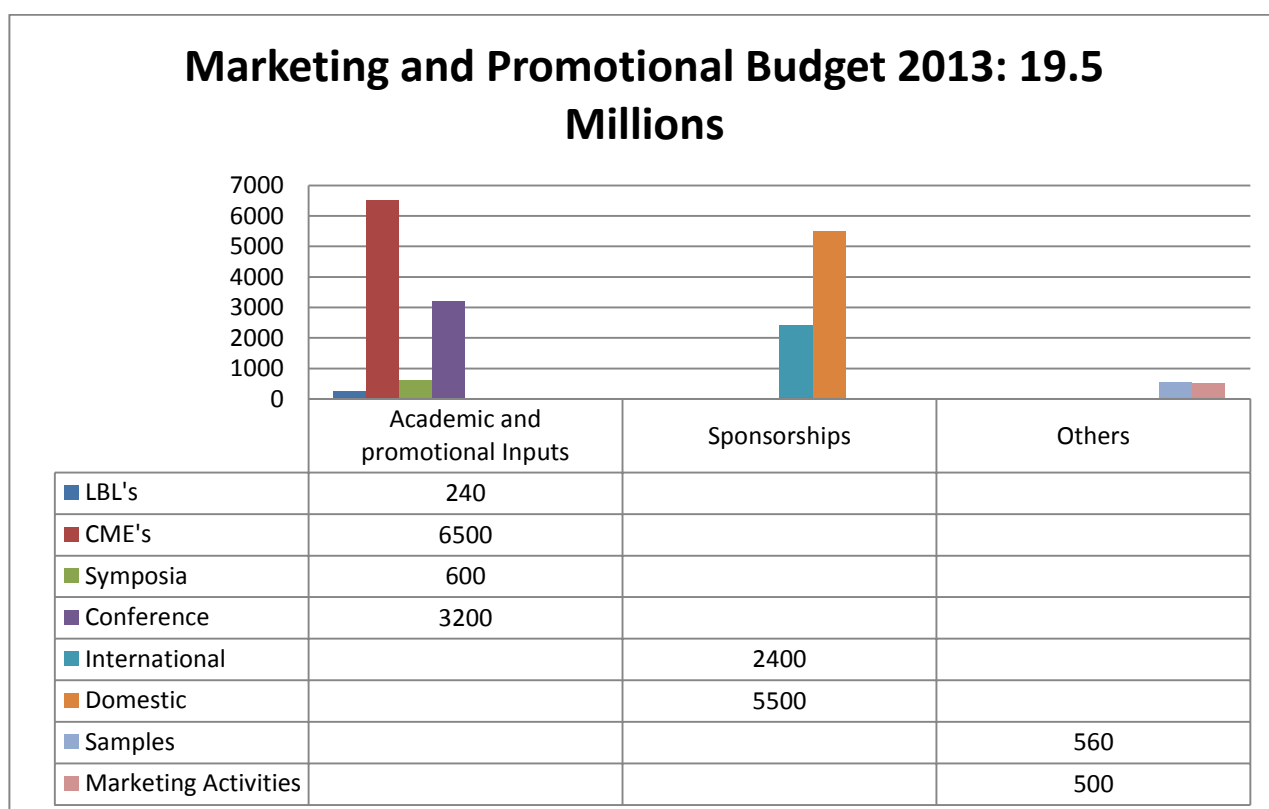
- I. Enhances healing process by 50%

- II. Fastens hemostasis: It polymerizes in 5 seconds of application and takes only 60 seconds to attain its maximum mechanical strength
- III. Does not interfere with natural healing process: It provides immediate intra-operative seal and maintains this during critical post-operative periods and therefore facilitates natural healing
- IV. Completely reabsorbed in 30 days
- V. Very flexible and more elastic than other graft material

Use pattern

- Key specialties–CTVS and oncosurgeons

Primarily used for sealing of vascular sites and in redo cases.

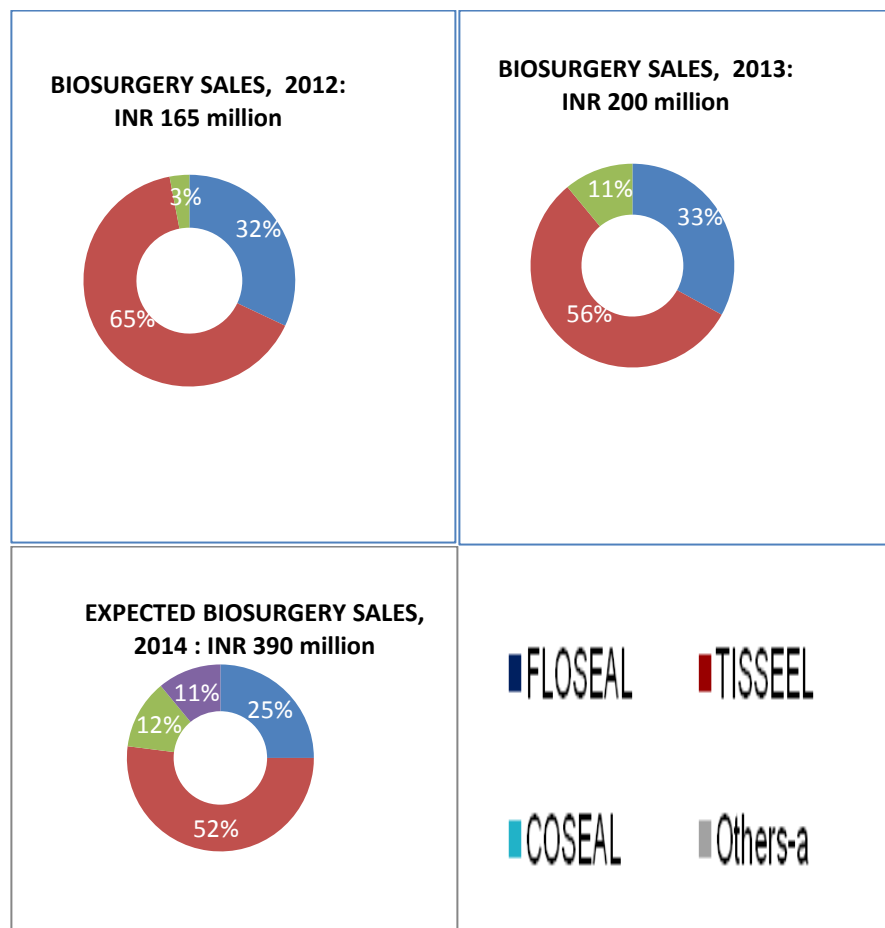


- Marketing and promotional budget breakdown is as follows:
 - a. In 2013, marketing and promotional spend was INR 19.5 million
 - i. 53% and 41% was allocated to Academic meetings and national & international sponsorships of key clinicians, respectively
 - b. Expense on visual aids and LBLs is very minimal as products are promoted through electronic media with audio-visual promotional aids

Current and Future Sales Overview:

- i. Hemostat and sealant market is anticipated to grow at 30%
- ii. Baxter's Biosurgery portfolio will experience 25% growth by 2015
- iii. In 2014, Biosurgery product sales were INR 200 million–21% growth over 2011. Tisseel accounted for 56% of total sales at INR112 million

- iv. Key growth drivers—increase in critical surgeries in cardio-vascular, neuro and orthopedics segments; health insurance coverage and increasing acceptability and use among surgeons
- v. With acquisition of Synovis Life Technologies and product approvals in process, Indian market is expected to generate INR 35 million revenue for Baxter by 2015
- vi. Baxter India intends to expand its Biosurgery product portfolio by introducing fibrin sealant(human) Artiss by mid-2013 and bone hemostat Ostene, by 2014



Baxter Product Pipeline:

Brands	Description	Year
Artiss	– Biologically active sealant comprises human fibrinogen and low concentration of human thrombin – Slow setting topical fibrin sealant indicated for; – Adherence of autologous skin grafts to surgically prepared wound beds resulting from burns – Adherence of tissue flaps during facial rhytidectomy surgery – Allows skin graft fixation without use of sutures or staples, thereby reducing post-operative complications – Target clinicians–plastic and reconstructive surgeons	2014
Ostene	– Bone hemostasis agent made of water-soluble alkylene oxide copolymers – Synthetic implant material, made from advanced AOC polymer blend and used to control bleeding from bone surfaces by acting as a mechanical barrier – Only available product designed to stop bone bleeding in surgery – Does not interfere with bone healing or increase the risk of surgical infections, including MRSA – Target clinicians–orthopedic and neurosurgeons	2015

SWOT Analysis

Strengths • Specialty product portfolio—hemostat and sealant products, comprising prophylactic use and instant hemostat and sealant products • Strong global reputation—globally acclaimed, innovative products available in over 100 countries • Efficient sales force focuses on defined target accounts and clinicians for enhanced sales generation • Addition of Synovis® portfolio to Baxter's existing range, as a part of its inorganic growth model	Weaknesses • High product prices limit the target accounts to select institutions and surgical applications to only critical procedures • Competition from low-cost substitutes such as haemostatic sponges, which are used for all surgical procedures • Lack of a specific brand positioning strategy for India, which makes it difficult for company to understand/meet local requirements of price-sensitive Indian market Lack of local manufacturing set up, resulting in additional operational
Opportunities • Extension of product line with similar products translating into strengthening of Biosurgery portfolio and solutions • Aggressive business expansion strategy and entry into tier II and other unexplored markets • Increasing medical tourism: India's medical tourism sector is expected to witness 30% annual growth. Key procedures include neuro, cardiac, orthopedic and oncology	Threats • Price advantage of competitive products leads to easy brand substitution • Pending approvals for brands of Synovis because of existing regulatory guidelines • Limited acceptance of premium-priced hemostats and sealants since these are non-essential products for procedures • Technological breakthrough: Introduction of new and advanced products may create resistance among clinicians to use of formerly used hemostat and sealant products e.g. Tri-Staple from Covidien

CONCLUSION:

- Hemostat and sealant market is anticipated to grow at 30%
- Baxter's Biosurgery portfolio will experience 25% growth by 2014
- In 2013, Biosurgery product sales were INR 200 million—21% growth over 2012. Tisseel accounted for 56% of total sales at INR112 million

- iv. Key growth drivers—increase in critical surgeries in cardio-vascular, neuro and orthopedics segments; health insurance coverage and increasing acceptability and use among surgeons
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