Wiki section

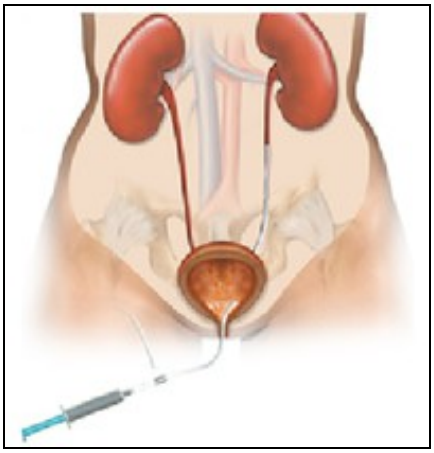
This is a landscape report on the Ureteral stent market, including key company profiles, products, patents and relevant clinical trails.

- ***What is it?*** A ureteral stent is a specially designed hollow tube, made of a flexible plastic material that is placed in the ureter.
- ***Need for a ureteral stent:*** In patients who have, or might have, an obstruction (blockage) of the kidney, an internal drainage tube called a ?stent? is commonly placed in the ureter, the tube between the kidney and the bladder. This is placed there in order to prevent or temporarily relieve the obstruction.

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Background



Ureteric Stent

Ureteral stents are used in urological surgery to maintain patency of the ureter to allow urine drainage from the renal pelvis to the bladder. These devices can be placed by a number of different endourological techniques. They are typically inserted through a cystoscope and may also be inserted intraoperatively. Indwelling ureteral stents help to reduce complications and morbidity subsequent to urological and surgical procedures. Frequently, ureteral stents are used to facilitate drainage in conjunction with Extracorporeal Shock Wave Lithotripsy (ESWL) and after endoscopic procedures. They are also used to internally support anastomoses and prevent urine leakage after surgery. Ureteral stenting may almost eliminate the urological complications of renal transplantation. An antimicrobial ureteral stent, which inhibits encrustation and bacterial colonization while maintaining patient comfort.

- Ureteral stent: resists migration, resists fragmentation, is kink resistant and radiopaque.
- Bacterial colonization: antimicrobial activity for up to two weeks.
- Patient Comfort: stent has a low coefficient of friction (value) for ease of insertion and will soften on implant at body temperature to maintain patient comfort.

more on background...

Market Overview

Market for ureteral stent can be analyzed by estimating market for each of Ureteral Stent?s fundamental use. Other uses of Ureteral Stent include Post-surgical swelling/infection of uterus, Active kidney infection etc.

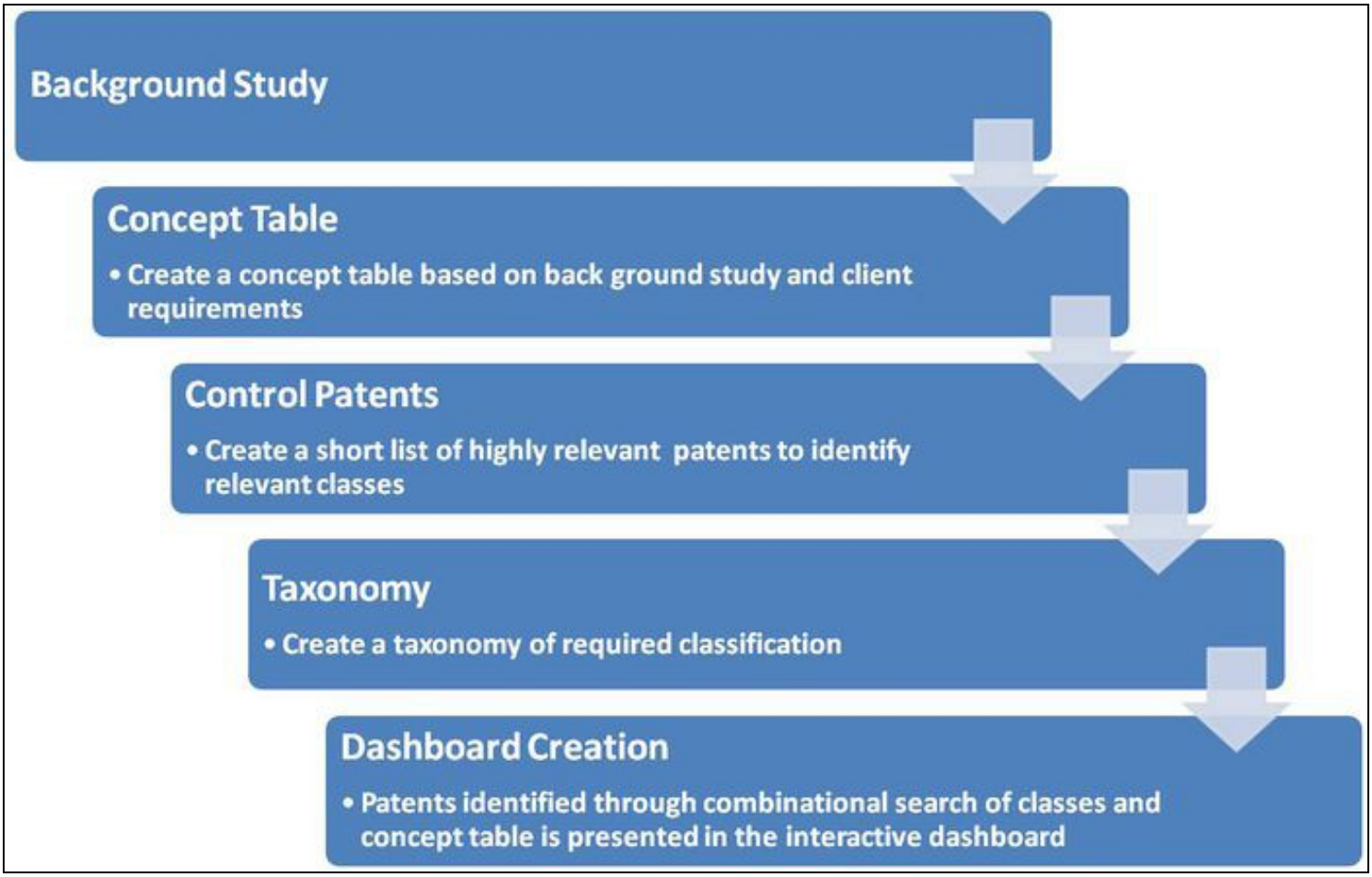
more on market overview...

Interactive Mind Map

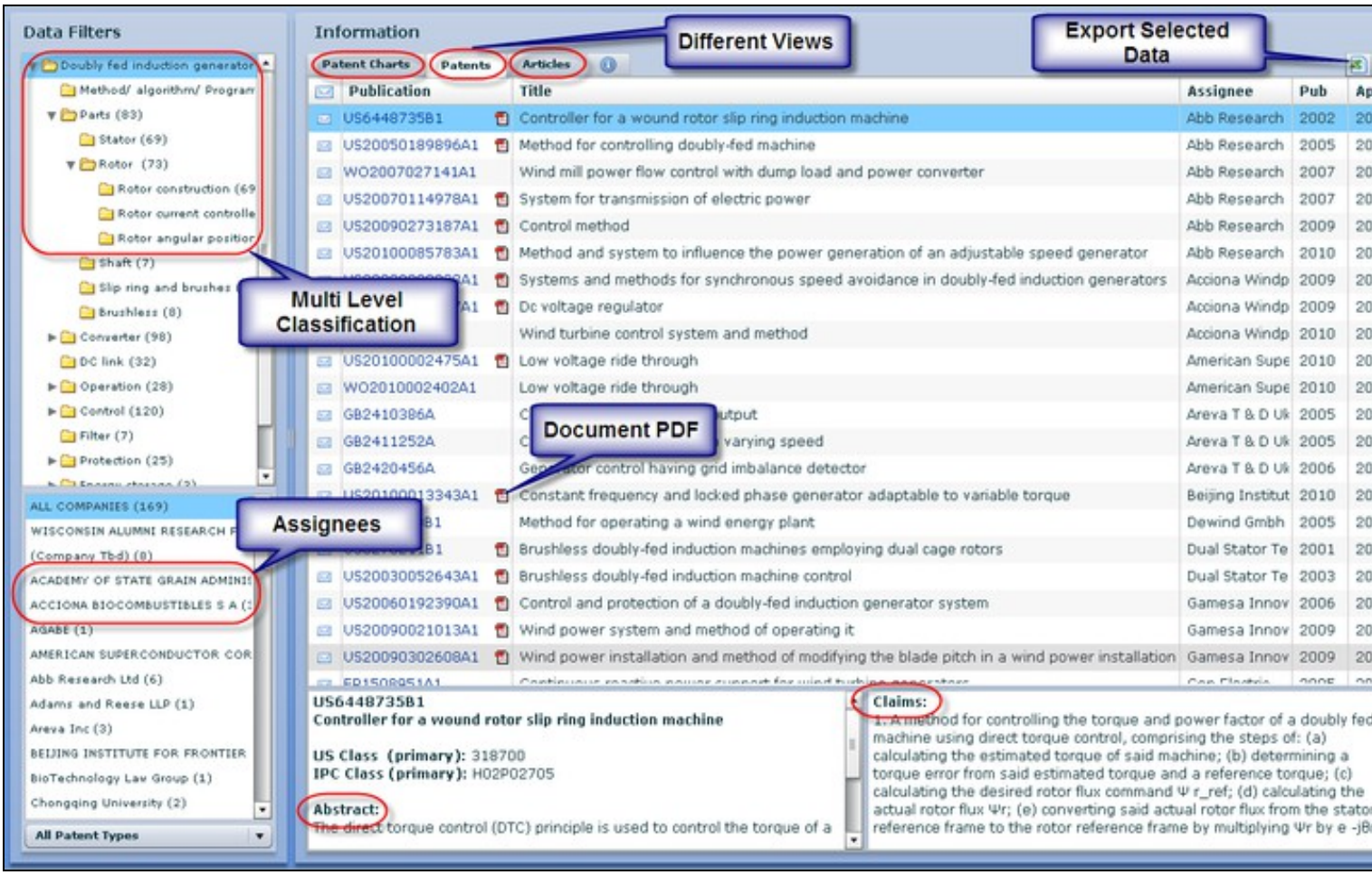
- To access the Dashboard you have to signup. You can do so by clicking **here**
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- *Click on the red arrow adjacent to the node name to view the content for that particular node in the dashboard*
- *Click on the "+" sign to zoom the mindmap and "-" sign to shrink the mindmap*

Patents

Patent Search Strategy



Dolcera Dashboard



Dashboard Link

Ureteral Stent - Dashboard	

- Flash Player is essential to view the Dolcera Dashboard
- To access the Dashboard you have to signup. You can do so by clicking **here**

Patent Heat Map

This is supposed to be a flash animation. You'll need the flash plugin and a browser that supports it to view it.

more on patent analysis...

Clinical Trials

New trials

1	Assessment of Drug-Eluting Ureteral Stent on Bacterial Adherence and Biofilm Formation	Renal Calculi, Ureteral Obstruction	Ureteral Stent	Lawson Health Research Institute, Boston Scientific Corporation
2	Memokath® 044TW Stent for Treatment of Urethral Stricture	Urethral Stricture	Memokath stenting	Engineers & Doctors Wallsten Medical Group
3	Study to Determine if There Are Specific Clinical Factors to Determine Stent Encrustation	Kidney Stones	N\A	University of California, Irvine
4	Ureteral Stent Length and Patient Symptoms	Kidney Stones	Ureteral Stent	Emory University
5	Drainage of Malignant Extrinsic Ureteral Obstruction Using the Memokath Ureteral Stent	Ureteral Obstruction	Memokath 051 Ureteral Stent	Mayo Clinic Engineers & Doctors Wallsten Medical Group
6	A Prospective Comparison Between Ureteral Stent and Nephrostomy Tube for an Urgent Drainage of Obstructed Kidney (JJVsPCN08)	Kidney Disease	Nephrostomy tube and ureteral stent	Rabin Medical Center

Concluded trials

1	Long-term outcome of permanent urethral stents in the treatment of detrusor-sphincter dyssynergia	To evaluate the long-term efficacy of a permanently implanted urethral stent in the treatment of spinally injured patients with detrusor-sphincter dyssynergia.	13	Detrusor-sphincter dyssynergia	Stenting is an effective alternative to sphincterotomy in the long-term, although secondary bladder neck obstruction is a frequent problem.
2	Nephrostomy Tube or 'JJ' Ureteric Stent in Ureteric Obstruction: Assessment of Patient Perspectives Using Quality-of-Life Survey and Utility Analysis	Upper urinary tract obstruction is often relieved by either a percutaneous nephrostomy tube (PCN) or a ureteric stent. Both can cause considerable morbidity and reduce patient's health-related quality of life (QoL). We have compared the QoL in these 2 groups.	34	Upper urinary tract obstruction	Patients with 'JJ' stents have significantly more irritative urinary symptoms and a high chance of local discomfort than patients with nephrostomy tubes (PCN). However, based on the EuroQol analysis, there is no significant difference in the gross impact on the health-related QoL or the utility between these groups indicating no patient preference for either modality of treatment.
3	Impact of stents on urological complications and health care expenditure in renal transplant recipients: results of a prospective, randomized clinical trial.	A randomized, prospective trial to compare the incidence of early urological complications and health care expenditures in renal transplant recipients with or without ureteral stenting.	201	Renal transplant recipient	Using a ureteral stent at renal transplantation significantly decreases the early urinary complications of urine leakage and obstruction. However, there is a significant increase in urinary tract infections, primarily beyond 30 days after transplantation. Stent removal within 4 weeks of insertion appears advisable.

Adverse Events

S.No.	Brand Name	Adverse Event	Date FDA Received
1	Cook Urologicals Cook Urological Stent	Stent broke into pieces while removing it from the patients body.	12/14/2005
2	Boston Scoientific Boston Scientific Ureteral stent System	Fractured stent seen under Fluroscopy	10/17/2007
3	Boston Scoientific Boston Scientific Ureteral Stent System Kit 8 FR X 24 CM	During insertion of ureteral stent, the stent broke into multiple parts which were retained in the patient.	10/14/2005
4	Boston Scientific Corp Boston Scientific 8 FR X 28 CM Ureteral Stent System Kit	Breakage of the upper loop of the ureteral stent while trying to insert it.	01/05/2005
5	Boston Scientific Bostoon Scientific Micro Vasive Contour VL Ureteral Stent	Broken stent observed during x-ray procedure.	12/12/2003

Pre-Market Notification

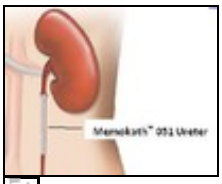
Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance, also known as Premarket Notification. This premarket submission demonstrates to the FDA that the device to be marketed is atleast as safe and effective, that is, *substantially equivalent*, to a legally marketed device. Parties required to submit a 510(k) to the FDA include domestic or foreign manufacturers introducing a device to the U.S. market, as well as specification developers and repackers/relabelers.

A 510(k) is required when:

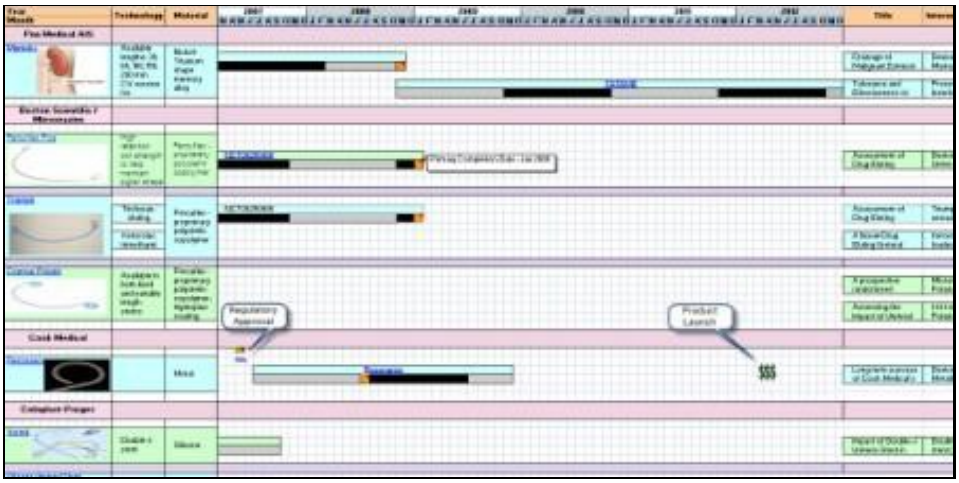
- Introducing a device into commercial distribution (marketing) for the first time.
- Proposed different intended use for a device already in commercial distribution.
- Change or modification of a legally marketed device.

510(k) ?Substantial Equivalence? Decision Making Process

Some of the companies active in the field of ureteral stents have been represented in the table below.

1	Bard Urological	 InLay Optima	FDA 510(k)	Dec 2004	Silicone	Double pigtail with monofilament suture loop	365
2	Boston Scientific	 Polaris Loop	FDA 510(k)	Mar 2003	Dual Durometer Percuflex with HydroPlus Coating	Bladder loop design	365
3	Cook Medical	 Resonance	FDA 510(k)	May 2007	Metal	Temporary stenting	365
4	Fossa Medical	 Stone Sweeper	FDA 510(k) CE Mark	Aug 2002 Sep 2005	Polyurethane	Spiral radially expanding stent	13
5	Pnn Medical A/S	 Memokath 051	CE Mark	1995	Nickel-titanium shape memory alloy	Double fluted ended spiral stent	240

Timeline Visualization



Ureteral Stent Timeline

Products

The FDA classifies a ureteric stent as follows:

- TITLE 21 - FOOD AND DRUGS
- CHAPTER I - FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

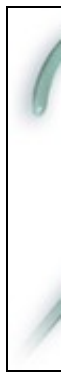
- SUBCHAPTER H - MEDICAL DEVICES
- PART 876 - GASTROENTEROLOGY-UROLOGY DEVICES
- Subpart E - Surgical Devices
- Sec. 876.4620 - Ureteral stent.
- Classification - class II device Code of Federal Regulations

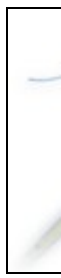
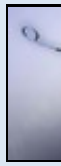
Sr. No.	Company	Device(s)	Approval	Approval Date	Material	Technology	Indwelling Time (days)	
1	Allium, Israel	URS	CE Mark	Jul, 2007	Nickel-titanium shape memory alloy covered by polymer	Self-expanding stent		
2	Pnn Medical A/S	Memokath 051	CE Mark	1995	Nickel-titanium shape memory alloy	Double fluted ended spiral stent	240	 M
			FDA Listing	Mar, 2004				
3	Fossa Medical	Stone Sweeper	CE Mark	Sep, 2005	Polyurethane	Radially expanding stent	13	 St
			FDA 510(k)	Aug, 2002				
		Open lumen stent	FDA 510(k)	Nov, 2003	Polyurethane	Pigtail-tipped stent with ?Pusher?		 C
			CE Mark	Sep, 2005				
		Expanding Ureteral Stent	FDA 510(k)	Jun, 2002	Polyurethane	Double pigtail stent with ?Pusher?		
4	Boston Scientific	Contour			Percuflex - proprietary polyolefin copolymer; Hydroplus coating	Fixed and variable length; Tapered tip	365	
		Percuflex			Percuflex	Pigtail	365	
		Polaris Ultra	FDA 510(k)	Jan, 2001	Dual Durometer Percuflex with HydroPlus Coating; soft Nautilus Bladder Coil.	Double pigtail	365	 P

		Polaris Loop	FDA 510(k)	Mar, 2003	Dual Durometer Percuflex with HydroPlus Coating	Bladder loop design	365	
		Retromax Plus			Percuflex material and Hydroplus coating	Endopyelotomy stent	Post-procedure healing	
		Stretch VL Flexima			Hydroplus Coating	Variable length coil on distal and proximal ends	90	
		Drug-Eluting Stent			Percuflex - proprietary polyolefin copolymer	Ketorolac trimethamine loaded stent		
5	Cook Medical	Resonance	FDA 510(k)	May, 2007	Metal		365	
		Sof-flex			AQ® Hydrophilic Coating	Radiopaque tip and tether for repositioning	180	
		Endo-Sof			AQ® Hydrophilic Coating	Double pigtail	365	
		C-Flex				Double Pigtail	180	

		Smith Universal				Nephrostomy tube + Ureteral stent	60	 Sm
		Endo-Sof Radiance	Launch	Dec, 2007	Heparin-bonded stent			
6	Q Urological	pAquaMedicina? Pediatric Ureteral Stent	FDA 510(k)	Jan, 2010	Hydrogel	Differentially larger end (no pigtail)	30	 pA
7	Bioteque Corp.	Ureteral Stent Set	FDA 510(k)	Apr, 2010			30	
8	Applied Medical Resources, CA, USA	Mesh	FDA 510(k)	Jul, 2001	Polyester mesh	Double-pigtail		
		Silhouette			Coil-reinforced; SL-6® hydrophilic coating	Patency Device		
		Applied Standard	FDA 510(k)	Jun, 1999	Proprietary thermoplastic elastomer material; SL-6® hydrophilic coating	Unique wall construction and enlarged drainage holes		 Ap
		7-10 endopyelotomy			Proprietary thermoplastic elastomer material; SL-6® hydrophilic coating	Dual Diameter stent		 Endo
		InLay Optima	FDA 510(k)	Dec, 2004	Silicone	Double pigtail with monofilament suture loop	365	 I

		Bardex® Double Pigtail Soft Stent	FDA 510(k)	Jan, 2003	Silicone	Attached with suture for ease of removal	
		Fluoro-4 Silicone Ureteral Stent			Silicone/tantalum		
		Figure-4 Silicone Ureteral Stent			Silicone	Three dimensional design	
		InLay Ureteral Stent	FDA 510(k)	Dec, 1998	Silicone	Tapered tip and lubricious hydrophilic coating	
		Urinary Diversion Stent	FDA 510(k)	Apr, 1991	Silicone		 Uri
10	Coloplast-Porges	Vortek	FDA 510(k)	Oct, 1998	Silicone	Double coating for easy maneuverability as well as flexibility	
		Biosoft	FDA 510(k)	Oct, 1998	Silicone	Extreme flexibility	

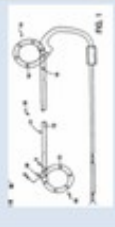
		Polyurethane			Hard or soft Polyurethane	Designed for short-term use	90	
		Silicone	FDA 510k)	Oct, 2002	Silicone	*Pyatiprofilnaya* technology		
11	Teleflex Medical	Rüsch Superglide DD	FDA 510(k)	Jul, 1999	WIRUTHAN® (polyurethane) with hydrogel coating	Directable and detachable		
		Classic closed-tip	FDA 510(k)	Dec, 1986		Classic Closed Tip		
		Classic Double pigtail	FDA 510(k)	Mar, 1996	Tecoflex® construction	Balanced-curled double pigtail design		
		Double-J	FDA 510(k)	Apr, 1988	Silicone	Double-J closed-tip		
		Lithostent			Tecoflex®	Grooved design		
12	Gyrus ACMI/Cabot/Acromed/Circon/Surgitek							

		Lubri-flex	FDA 510(k)	Nov, 1991	Tecoflex®	?Rememberance? of shape with a chemically bonded wettable solution		
		Multi-flex			Tecoflex®	Two durometers with helical kidney curls		
		Quadra-Coil multi-length	FDA 510(k)	Mar, 1996	Tecoflex®	Accomodate ureteral lengths from 22cm to 28cm		
		Sof-curl			Tecoflex®	Dual-durometer design and exclusive soft bladder helix		
		Uroguide			Silicone	Classic Double J with open tip		
13	Ameco Medical Industries	Amecath			Nitinol; Available with hydrophilic coating	Double loop stent	Short-term and long-term	
14	Angiomed-Movaco (C.R. Bard subsidiary)	Ureteral Stent Set	FDA 510(k)	Jan, 1987	Nitinol	Self-expanding stent		

Patent-Product-Clinical Trial Mapping

- To access the Dashboard you have to signup. You can do so by clicking **here**
- *Use the mouse(click and drag/scroll up or down/click on nodes) to explore nodes in the detailed taxonomy*
- *Click on the red arrow adjacent to the node name to view the content for that particular node in the dashboard*
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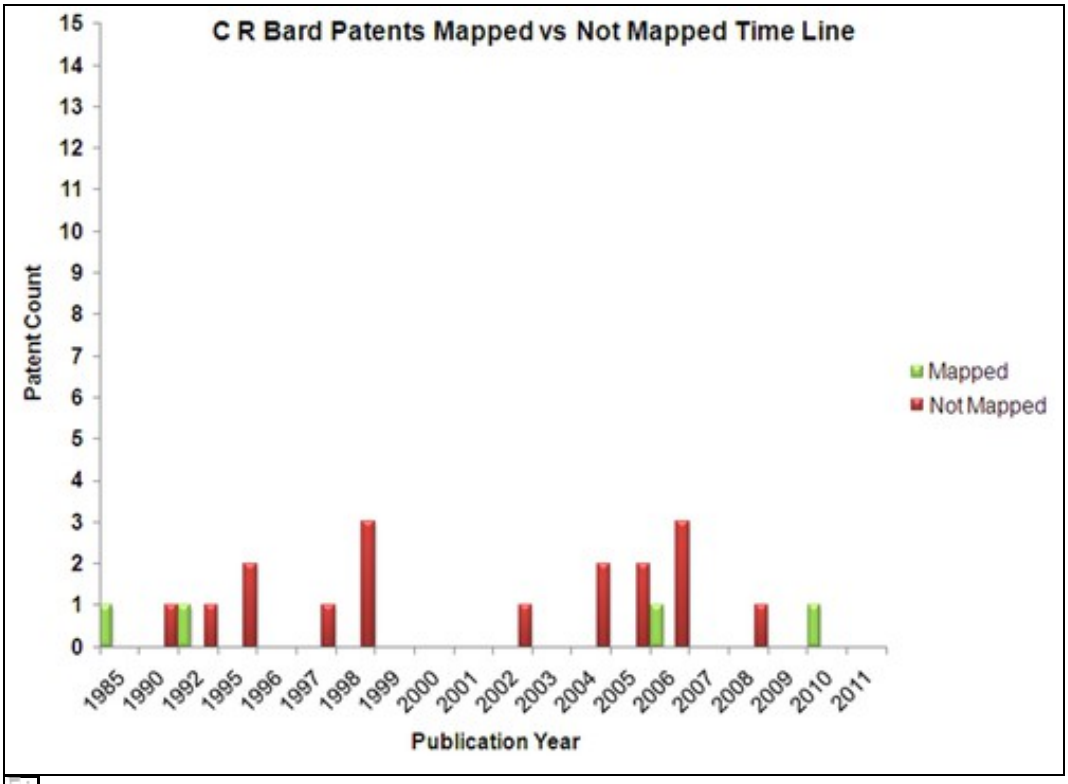
Product to Patent Mapping

S. No	Company	Product	Patent no.	Date of Publication	Assignee/Applicant	Title	Patent Figure	co
1	Boston Scientific	Percuflex® Ureteral Stent	US5401257	3/28/1995	Boston Scientific	Ureteral Stents, Drainage Tubes and the like		M pr er st m th po su
2	Boston Scientific	Percuflex® Plus Ureteral Stent	US6719804	4/13/2004	Boston Scientific	Medical Stent and Related Methods		M co m fir va se a
3	Boston Scientific	Polaris Ultra stent	US6719804	4/13/2004	Boston Scientific	Medical Stent and Related Methods		M co m fir va se a
4	Boston Scientific	Polaris™ Loop Ureteral Stent	US6991614	1/31/2006	Boston Scientific	Ureteral Stent for Improved Patient Comfort		M du pr

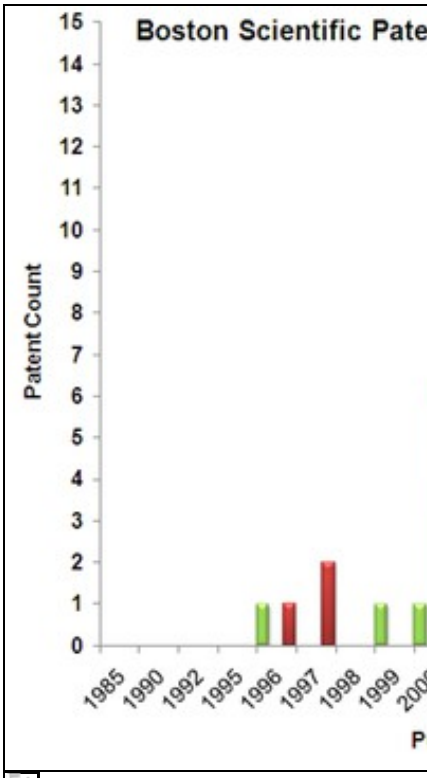


Screenshot for the product to patent mapping(Bard and Boston)

- Click **here** to download the excel file.
- Mapped Patent vs Not Mapped Patents



C R Bard



Boston Scientific

Concordance Dashboard



Concordance Dashboard

Insights

		Boston Scientific	C R BARD
Products	**Portfolio**	8 Products	6 Products
	Material	Percuflex - Biocompatible Polymer	Silicone
	Coating	Hydroplus	Licensed from pHreecoat

	Shape	Pigtailed and More	Figure 4 and more
Clinical Trials	**Current Trials**	Truimph Ureteral stent - Loaded with Triclosan Currently in Phase II (Canada)	None
Patents	**Coating**	Therapeutic / Medicinal coatings Magnetic nano particles for MRI Imaging Lubricious coatings helping easy insertion	Therapeutic coatings
	Structure	Multiple channels filled with therapeutic agent Multiple collapsible segments preventing fluid passing Renal coil with wick to prevent reflux Stent with beads on its surface Stent with reservoir indicating its release with change in color of urine Expandable and collapsible stent Stents with degradable barbs	Expandable stents for reducing discomfort
	Material	Elastically deformable stents Biodegradable polymer based stents Porous polymer for long term implantation Stent with variable hardness	Biodegradable polymers Shape memory alloys General polymer based

Inferences

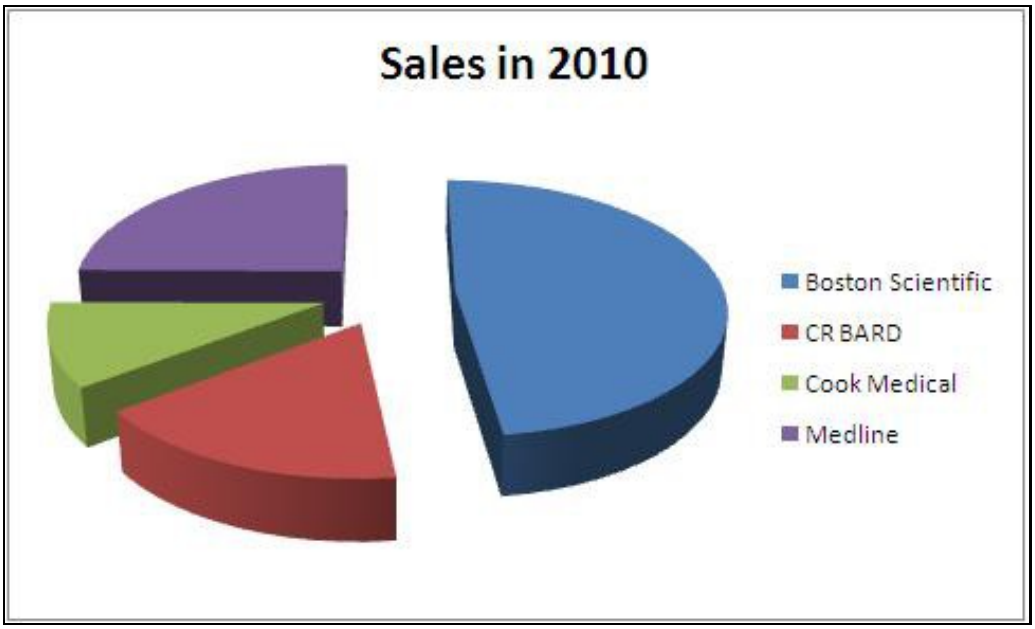
Boston Scientific	**C R BARD**
Relatively late entrant with patents filed post mid 90s	Early mover with patents filed in mid 80s
Increased patent activity since 2000	Patent activity never gained traction
Large number of patents yet to be "productized"	Few patents yet to be "productized"
Some products undergoing clinical trails	No products undergoing clinical trails
Diverse range of products with variation in material and structure	Small product portfolio
Seem to be strengthening they market position	Seem to be moving focus away from Ureteral stents market

Competitive landscape

Total Sales in 2010 - 4.04 Billion USD

Company	**Total Sales in 2010**	**Urological sales**	**Percentage share**	**Product portfolio**
Boston Scientific	7800	661	8.48	Boston_portfolio
CR BARD	2700	702	26.00	BARD_portfolio
Cook Medical	1700	-	-	Cook_portfolio
Medline	4040	-	-	Medline_portfolio

All figures in USD million



Boston Scientific

Company profile

Ureteral Stent portfolio

Net sales in 2010 ? USD 7.8 Billion

Share of Urology- 8.48 %

Net sales from Urology- USD 661 Million

Source BSsalesdata

CR BARD

Urology portfolio

Net sales in 2010 ? USD 2.7 Billion

Share of Urology- 26%

Net sales from Urology- USD 702 Million

Source ? CR BARD annual report

Cook Medical

Ureteral Stent portfolio

Total Sales - USD 1.7 Billion

Source

Medline

Ureteral Stent Portfolio

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Backup