3D Printed Totally Bioresorbable Stents

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Tallinn And Helsinki
Feb. 05-11, 2018.

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- Introduction to AMT
- Novel 3D Printing Technology
- Totally Bioresorbable Stents
- Stent Delivery System
- Proposals

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Introduction

- **A leading company specialized in commercialization of 3D printed bioresorbable stents**
- **Found in 2011 in Beijing, China**
- **3800m² of Class 10K GMP Manufacturing facility and lab space**
- **With 43 employees**

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Introduction

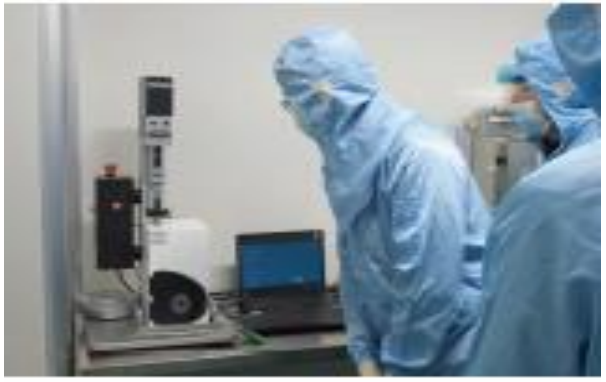
GMP Complained Manufacture facility

Stent Printing

Drug Eluting Coating

Stent Crimping

In-process Stent Inspection



Radial Force Testing

Analytical Lab

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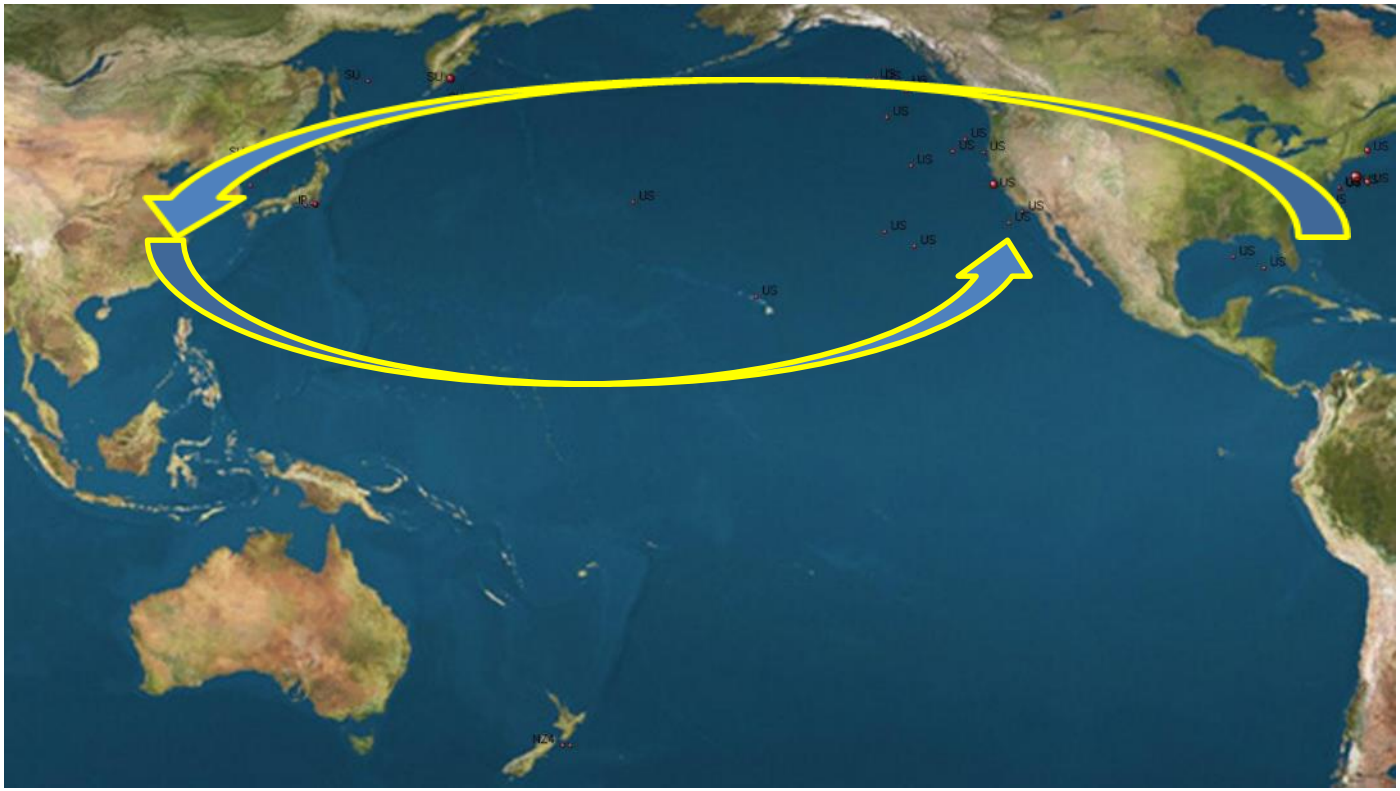
Introduction

- **Technology originally developed in 3D Biotek, NJ , US, and transferred to AMT in Beijing, China**



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Target Market I： Cardiovascular Disease

Cardiovascular Disease is the #1 Cause of Death in China

Rural Region

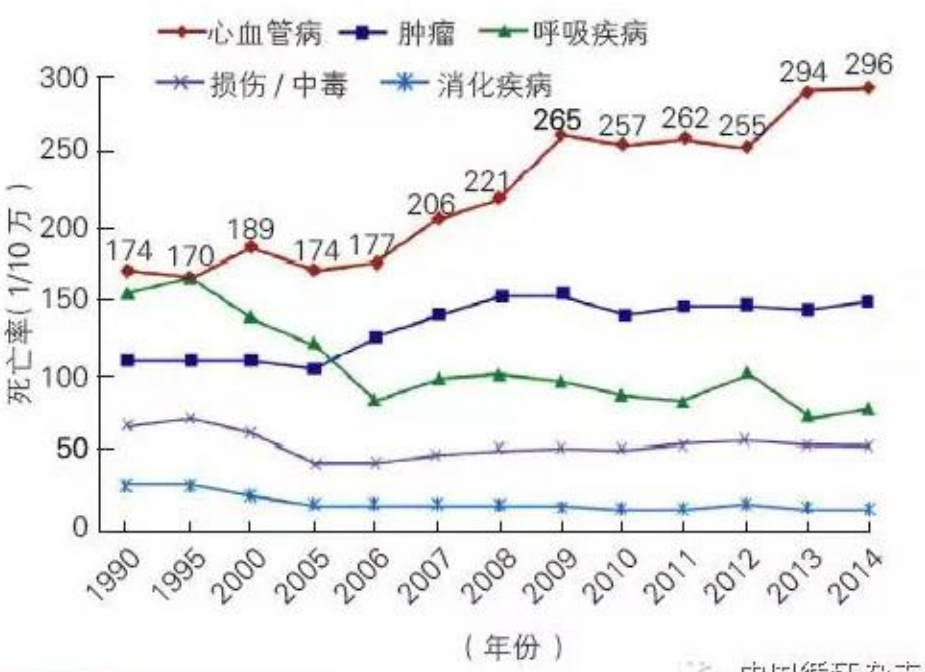

图 1 1990 年 ~2014 年中国农村居民主要疾病死亡率变化

Metropolitan Region

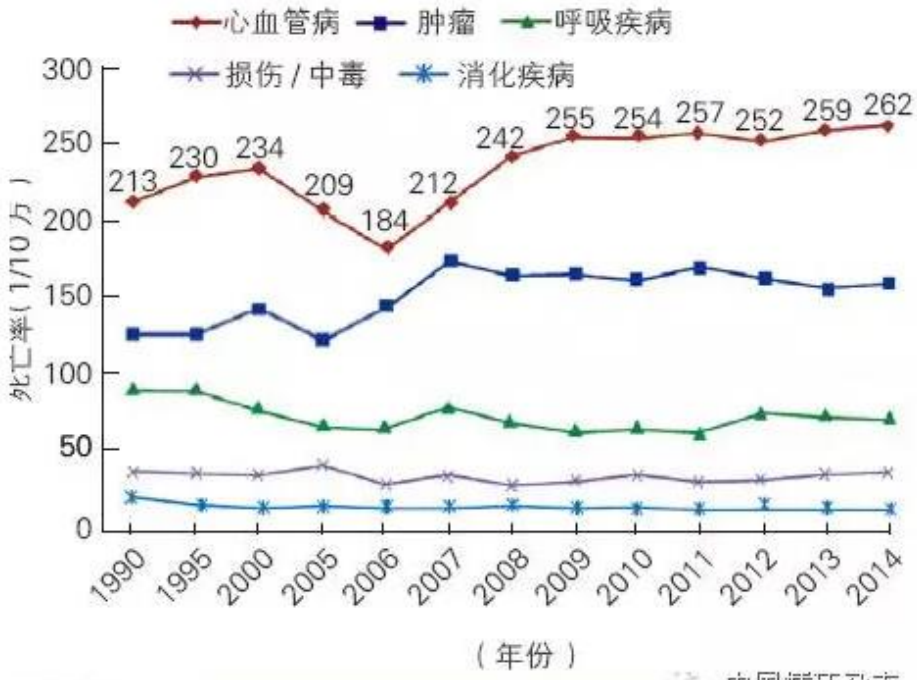

图 2 1990 年 ~2014 年中国城市居民主要疾病死亡率变化

# of Cardiovascular patients is expected to grow in the next 10 years

2015 Cardiovascular Disease Report of China

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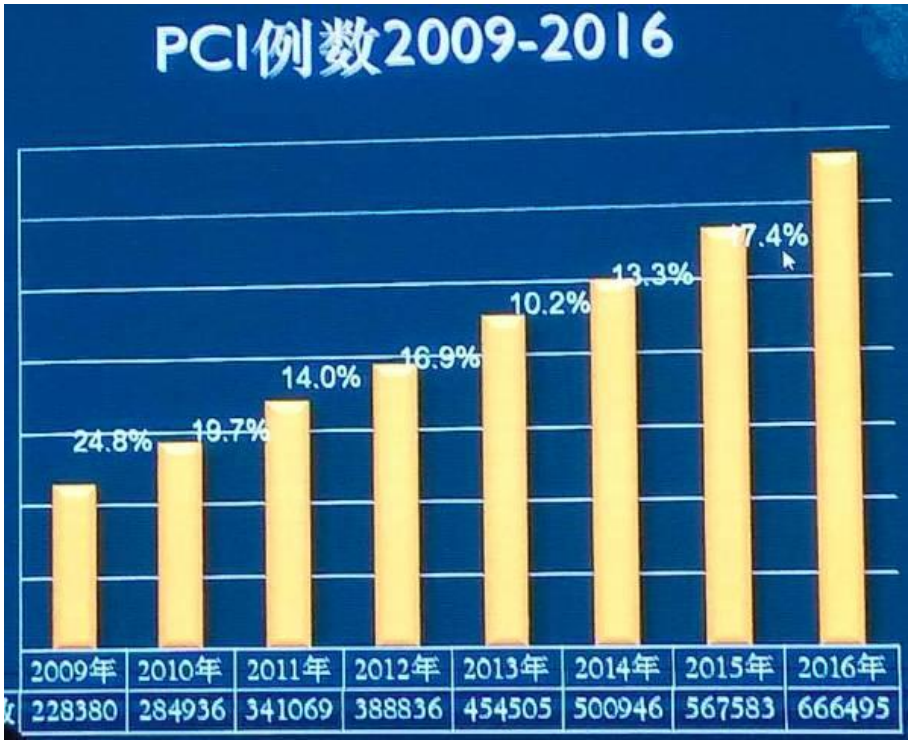
Coronary Stent Market and PCI Procedures

Cardiovascular Disease is the #1 Cause of Death in China

Annual # of PCI Procedures



Annual PCI Procedure Growth Rate

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Target Market II: Peripheral Artery Disease (PAD)

Diabetic patients are often having PAD

Diabetic Patients in China： ～ 113 million
PAD patients： ～22 million
Amputation： > 1 million

Stenting is an effective way of treating PAD

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Traditional Stent Fabrication Technology

Laser Cut Technology

Polymer Tubing Extrusion

Laser Cutting

- Multi-step process
- 80-90% material wasted
- Patent protected, no freedom to operate (FTO)

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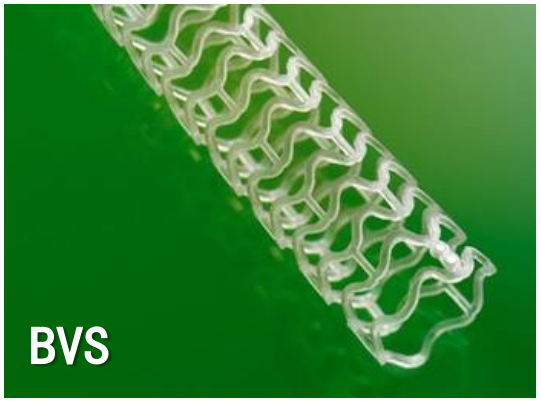
Vascular Bioresorbable Scaffold Using 3D Printing?

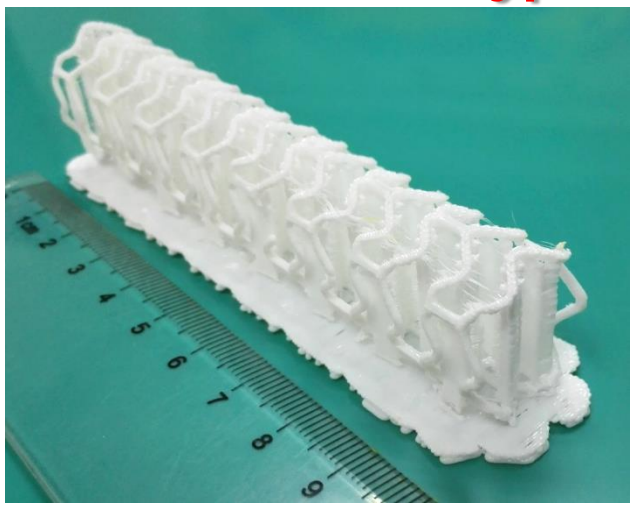
feasibility： traditio[X] 3D printing

Reference standard

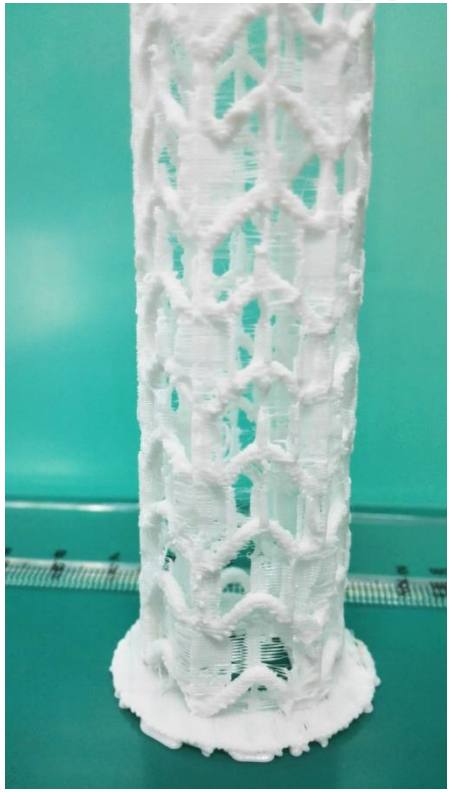
Abbott's Absorb BVS



Horizontal type



Vertical type



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Multi-axial 3D Printing Technology

发 明 专 利 证 书

发 明 名 称：用于制备三维多孔管状支架的方法及设备

发 明 人：刘营;王宗鑫;刘永强

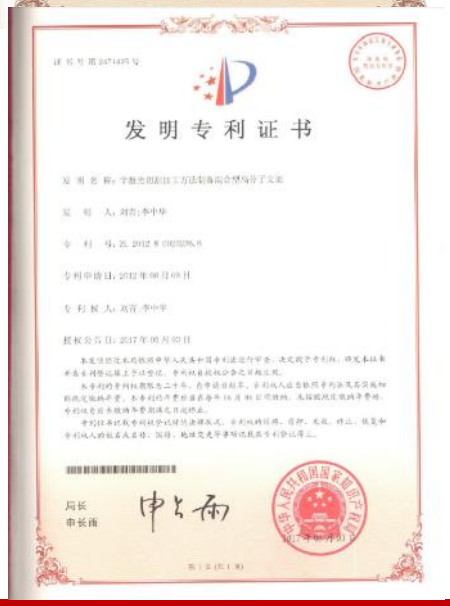
专 利 号：ZL 2010 1 0002569.1

专利申请日：2010 年 06 月 25 日

专 利 权 人：北京阿迈特医疗器械有限公司

授权公告日：2015 年 08 月 26 日

局长
申长雨



发 明 专 利 证 书

发 明 人：刘营;李中华

专 利 号：ZL 2012 1 0303256.6

专利申请日：2012 年 08 月 08 日

专 利 权 人：刘营;李中华

授权公告日：2017 年 05 月 03 日

局长
申长雨

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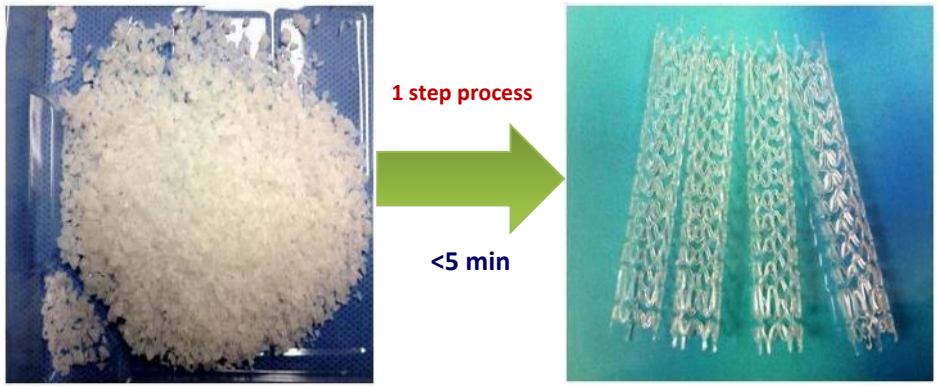
Comparison of Fabrication Technologies

3D Printing Technology



- One step process (<5 min)
- Highly efficient in using materials
- Capable producing complicated structure
- Proprietary Technology, FTO

Laser Cut Technology

- Multi-step process
- Lower yields, high cost
- Most material wasted(>90%)
- No FTO

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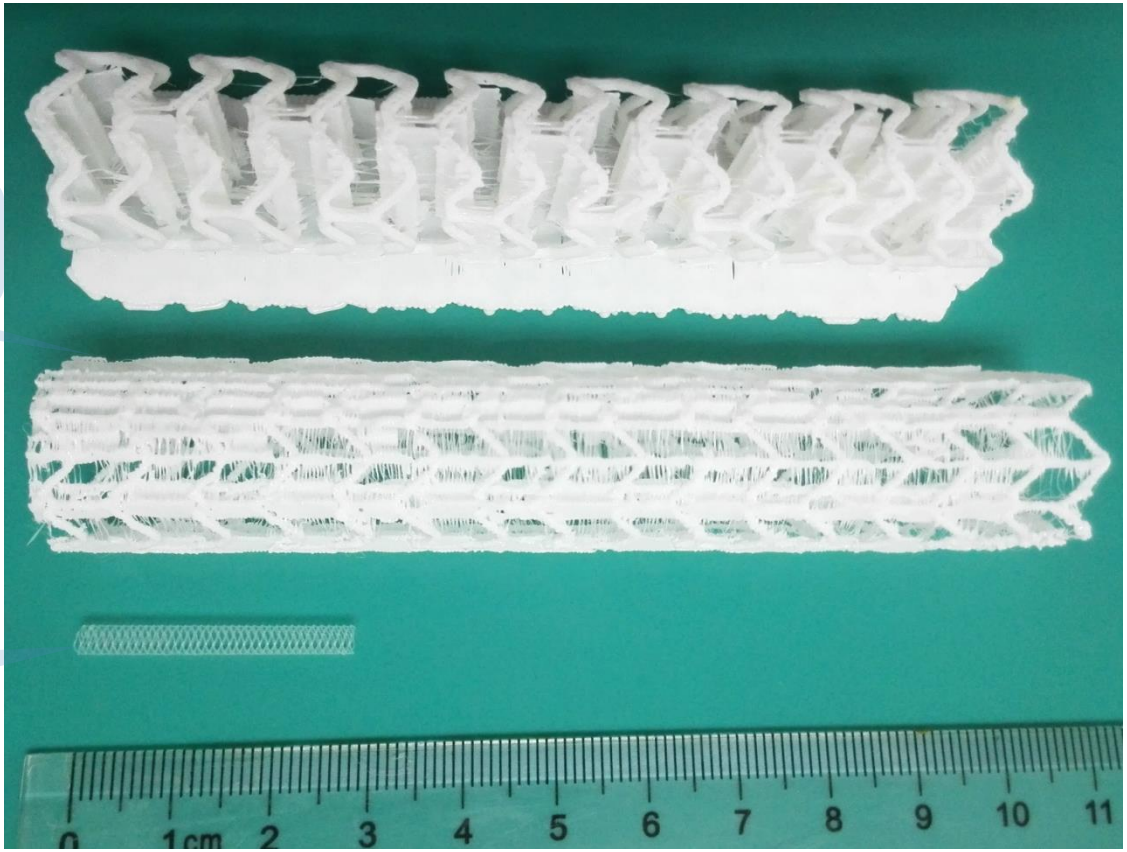
Innovative Fabrication Technology

BRS using 3D printing

Traditional 3DP

Novel 3DP



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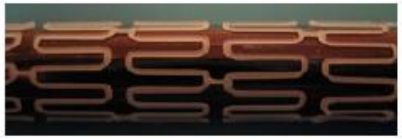
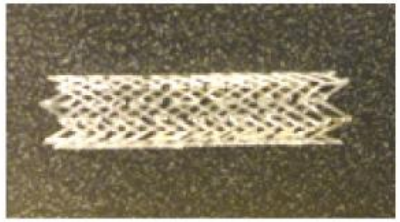
Stents With Various Materials

PCL stents



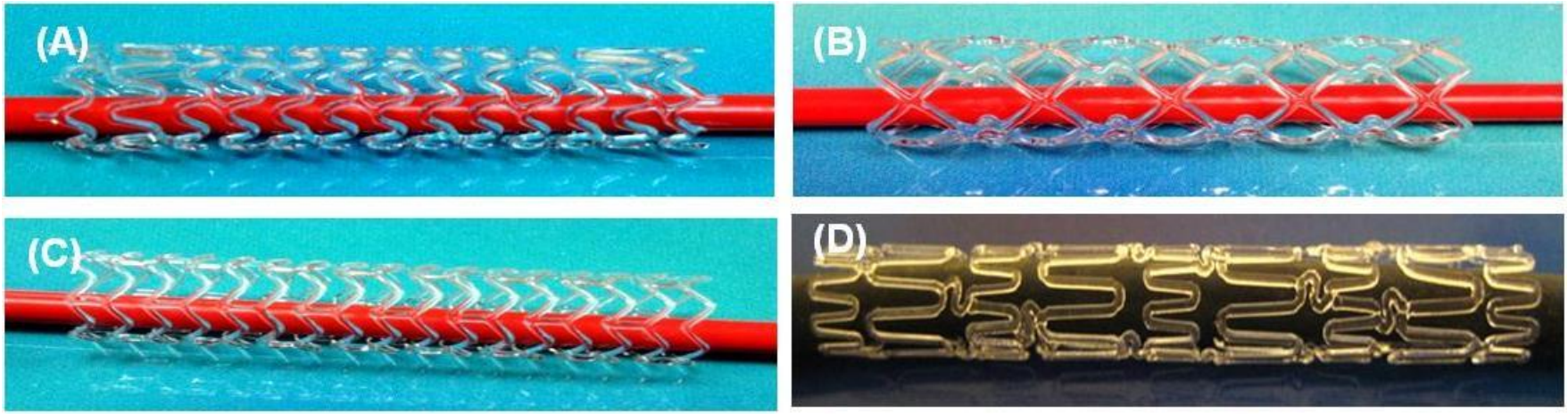


A B C

A. Polyglycolide (PGA) stents; B. Poly(lactide –co –glycolide) 50/50 stents; C. Polyurethane stents.

Stents with Various Designs

Stent with various structures



PLLA stents: (A) helical; (B) closed-cell; (C) zig-zag; (D) complex。

PCL stents

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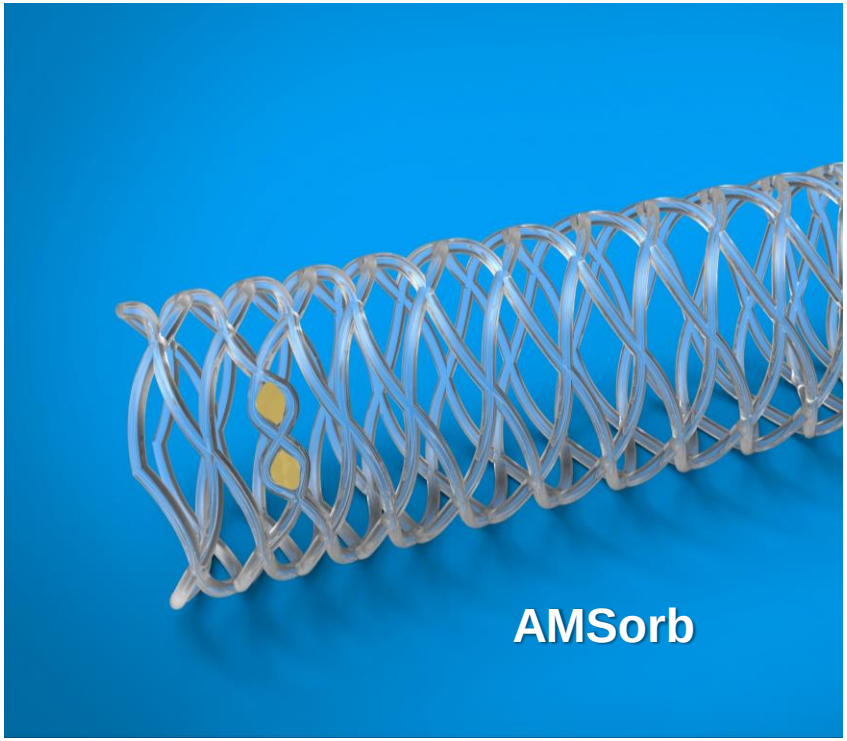
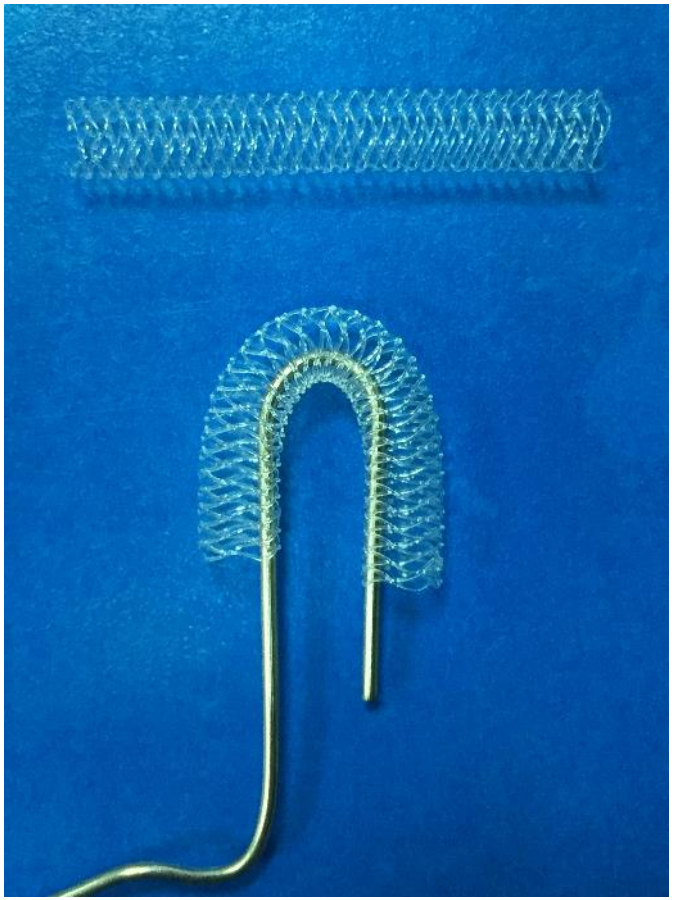
AMSorb™, 3D Printed Coronary Stents With An Innovative Design

Sirolimus Drug Eluting PLLA Stents from AMT





Strut Thickness: ~0.14 mm
Strut Cross-Section: Round (~0.015 mm²)

Ability To Adapt To Anatomic Shape Of The Vessels

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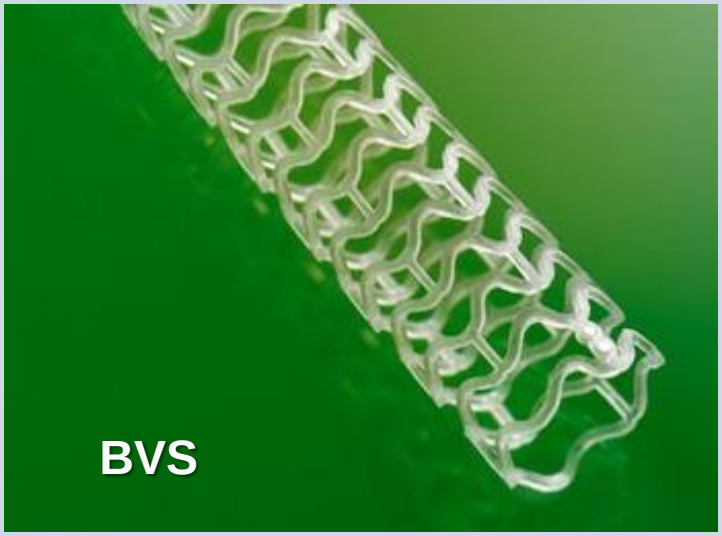
Comparison Between BRS and Metallic Stent (Coronary)

Manufacture	Abbott	AMT
BRS Design		
Structure	Open Cell, Multi-Link	Closed Cell
Material	PLLA	PLLA
Processing	Laser Tube Cutting	3D Multi-Axial Fabrication
Strut Thickness	0.15~0.17 mm	0.13~0.15 mm

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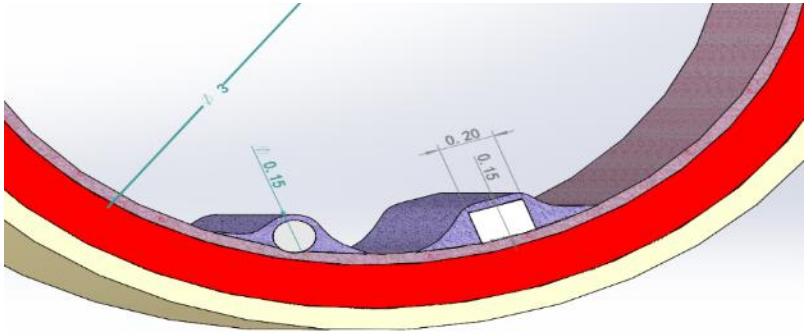
Advantages of AMsorb™

Comparison of cross sections of struts of the two types of stents

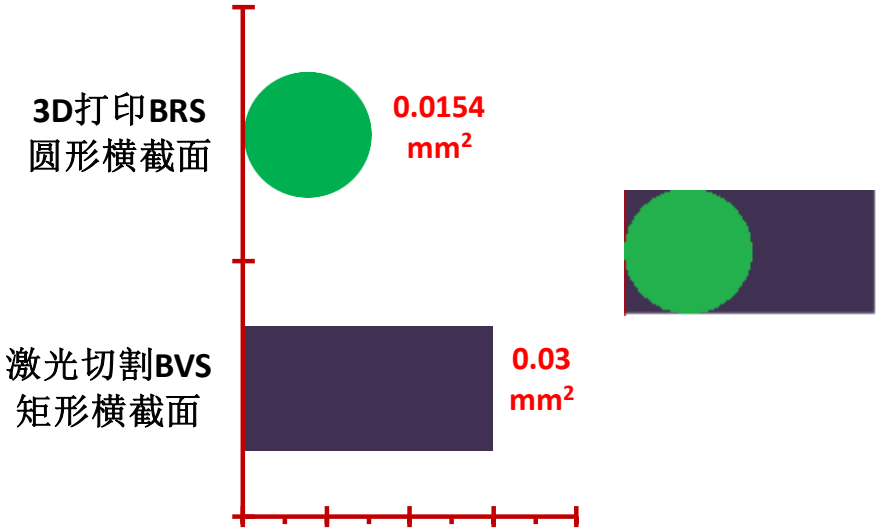


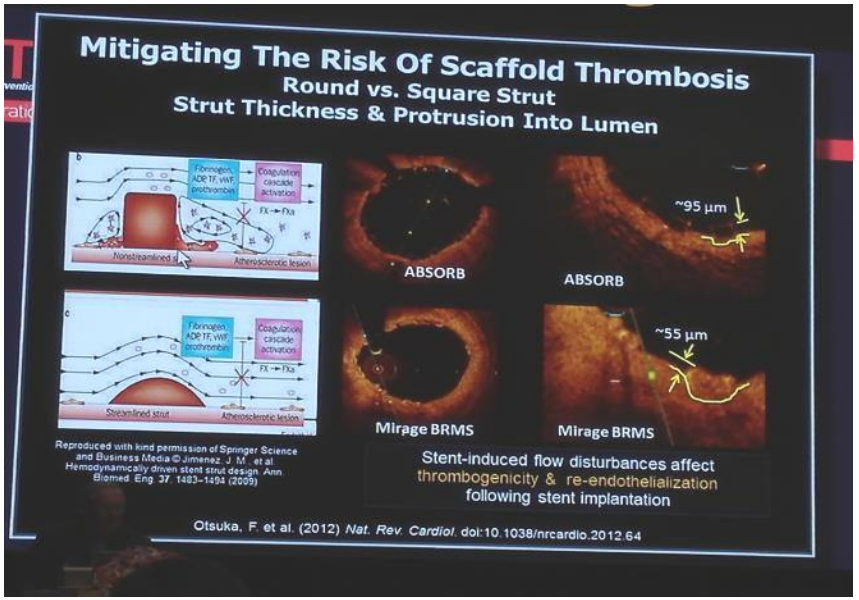
Cross section reduced 41%.

Advantages:

1. **Less blood flow disturbance**
2. **Fast endothelization**
3. **Reduced total resorption time.**

支架杆横截面积比较





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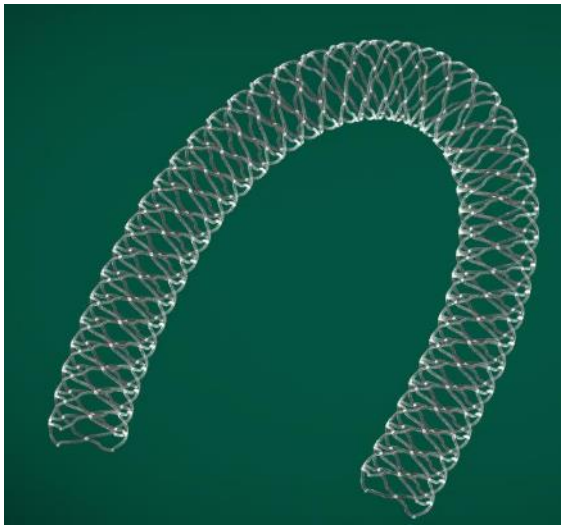
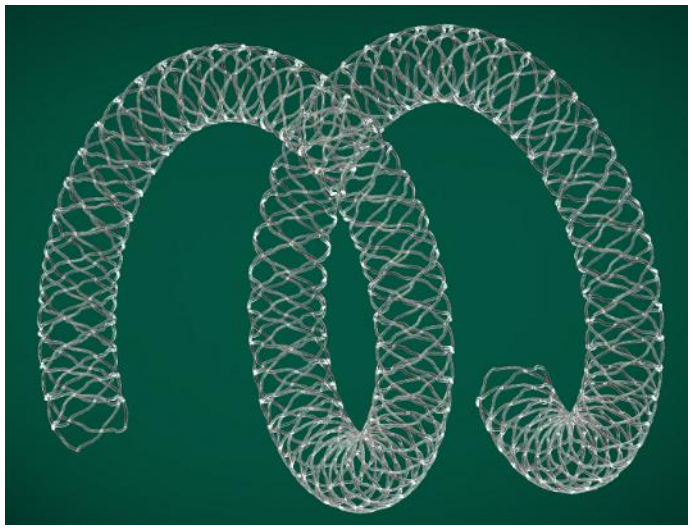
Perisorb™, 3D Printed Peripheral Stents With An Innovative Design

Paclitaxol Drug Eluting PLA based Stents

- Modified PLLA polymer with better fatigue resistant properties
- Asymmetric Drug Eluting Coating for Targeted Drug Delivery
- Super Flexible Structure design





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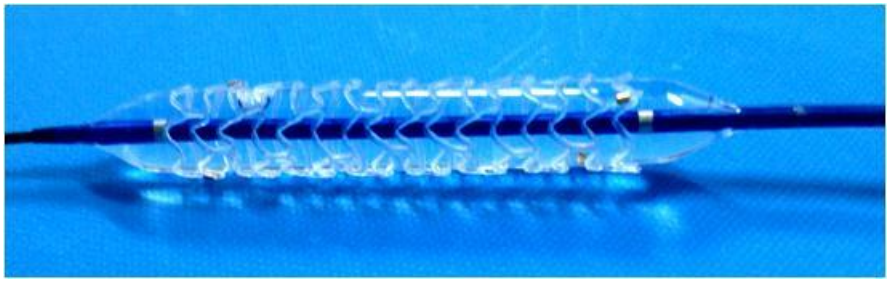
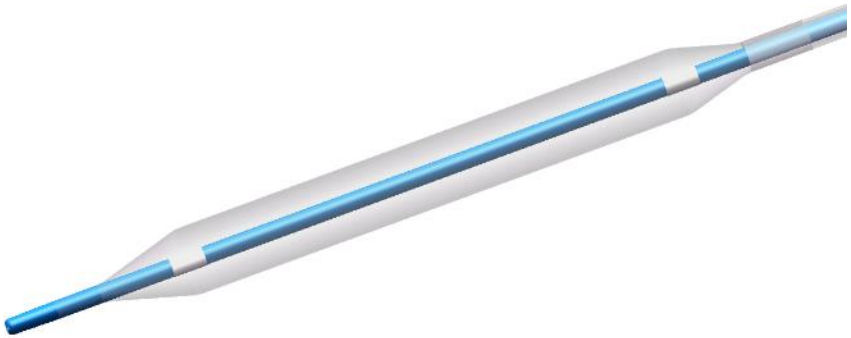
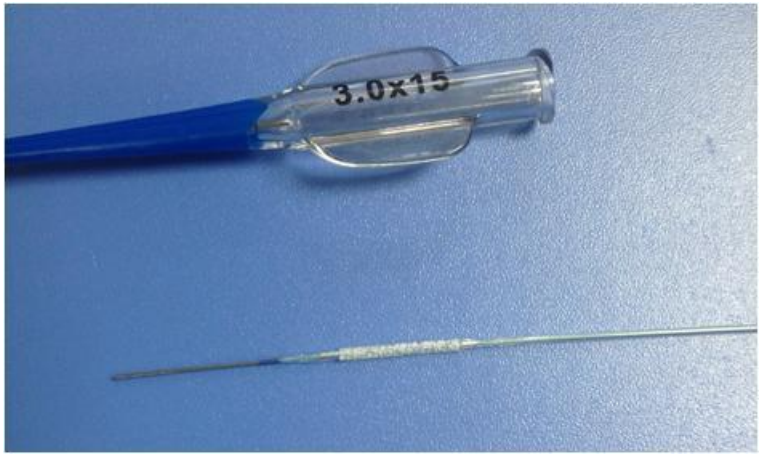
AMT BRS Delivery Systems

Peripheral BRS System (6.0x36mm)





Coronary BRS System (3.0x15mm)



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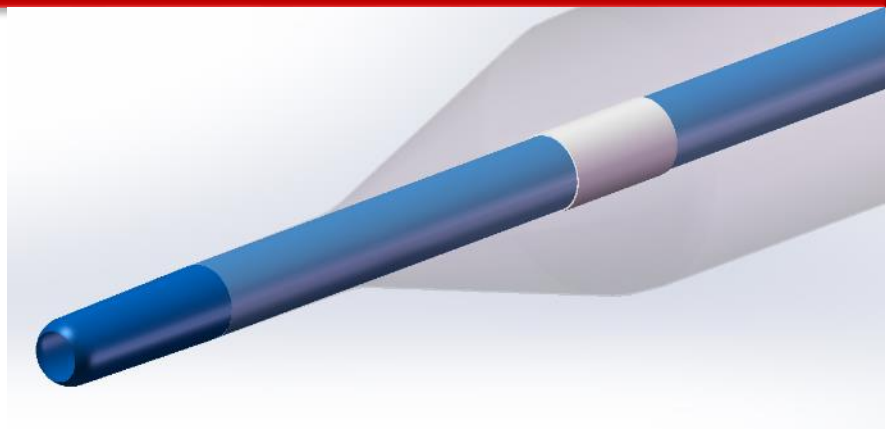
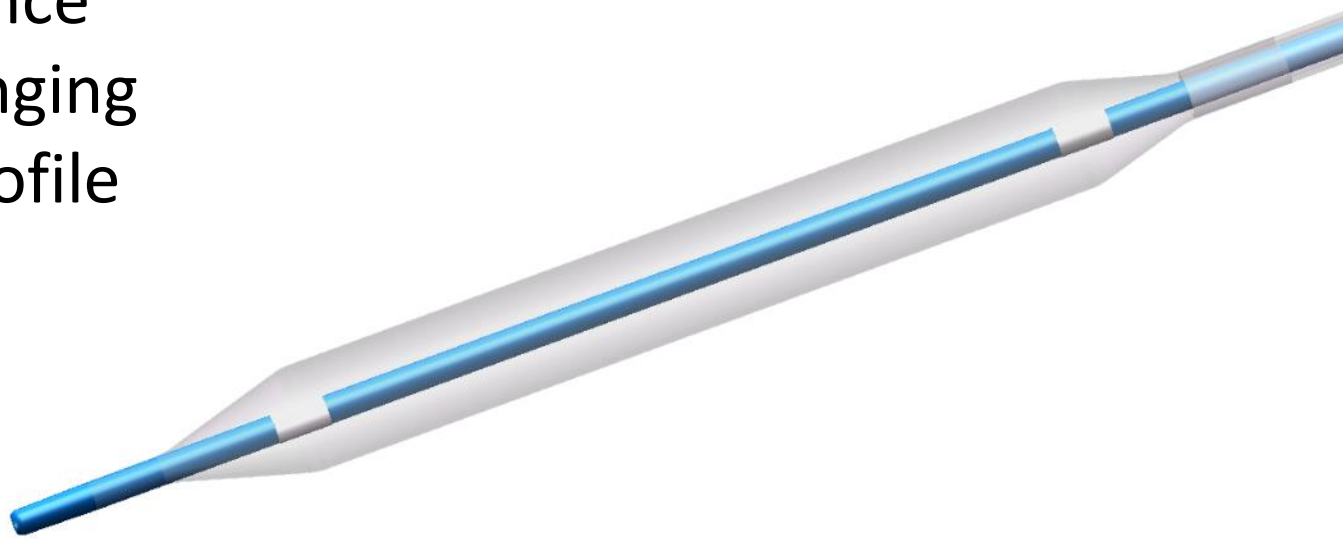
AMT Stent Delivery Systems

-Atraumatic tip
- Sturdy, pushable proximal shaft
- Soft distal shaft
- Low crossing profile
- High pressure rating
- Durable, rugged balloon material
- Optimal compliance

-Three balloon winging
-Small tip entry profile





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Proposals:

1. Marketing and Sales of AMT Products
2. Collaboration in New Product Development
3. OEM of Balloon Catheters

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