

A Brief History of Balloon Catheters

THE PATH OF INNOVATION IN MODERN BALLOON
CATHETER APPLICATIONS

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The Path of Innovation in Modern Balloon Catheter Applications

Everyone knows that Benjamin Franklin invented the lightning rod, bifocals, and the Franklin stove.¹ But did you know that he also designed an early flexible urinary catheter? He worked with a local silversmith to devise a jointed, flexible catheter for his brother, who suffered from kidney stones.^{2,3} This was one of the first innovations on the path to developing modern balloon catheters.

Today's medical balloons are thinner, stronger, and smaller than ever before. The trend toward minimally invasive procedures has been the driving force behind the development of smaller, more complex catheter-based devices. Devices for vascular and other applications continue to reach deeper into the anatomy with more therapeutic technology.

This white paper will describe 4 balloon catheter uses, the historical milestones that contributed to their development, and some innovative medical balloon applications that resulted:

1. Occlusion
2. Dilatation
3. Ablation
4. Implant delivery

TIMELINE OF CATHETER INNOVATIONS:

3000 BCE

Ancient Egyptians used hollow reeds and rolled palm leaves to fashion urinary catheters.¹³ Other ancient civilizations made catheters from gold, iron, bronze, and wood,¹³ and began experimenting on cadavers to study the function of cardiac valves.¹⁴

1974

Dr Andreas Gruentzig, a German physician, first used a balloon-tipped catheter to perform a percutaneous transluminal angioplasty to re-open a severely narrowed femoral artery.⁵

1977

Gruentzig and colleagues performed the first coronary angioplasty procedure on a human, using a balloon catheter to expand narrowed blood vessels.⁶

1752

Benjamin Franklin worked with a local silversmith to devise a jointed, flexible catheter for his brother, who suffered from kidney stones.^{2,3}

1844

Charles Goodyear patented vulcanized rubber, from which bendable catheters could be mass-produced.²

1929

Dr Werner Forssmann, a German surgical trainee, performed the first right heart catheterization in a human—on himself.¹⁵

1964

US interventional cardiologist Dr Charles Dotter performed the first percutaneous transluminal angioplasty to dilate the superficial femoral artery of a patient with painful leg ischemia and gangrene.⁴

1939

David Sheridan started a catheter business and went on to invent the first single-use catheter, an innovation for which *Forbes Magazine* in 1988 dubbed him the “catheter king.”¹⁶

1935

Aided by the development of latex rubber, Dr Frederic Foley, a urologist in St. Paul, Minnesota, introduced the first urinary balloon catheter, which still bears his name.²

1986

Dr Jacques Puel and Dr Ulrich Sigwart implanted the first coronary stent into a patient in France. It was used as a scaffold to prevent the vessel from closing and to avoid restenosis in coronary surgery.⁹

1998

Dr Michel Haïssaguerre, a French cardiac electrophysiologist, first described the use of catheter ablation for patients with atrial fibrillation.^{7,8}

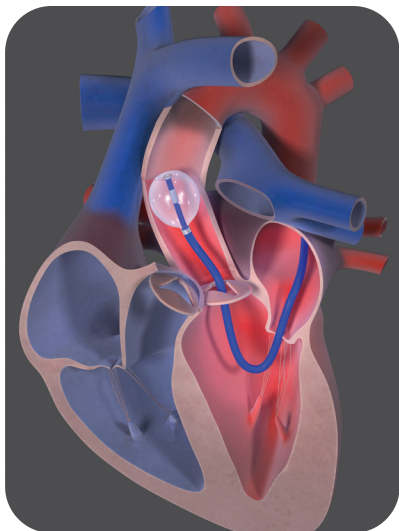
2002

French interventional cardiologist Dr Alain Cribier and colleagues performed the first transcatheter aortic valve implantation procedure on a patient with severe symptomatic aortic stenosis.¹⁰

1. Occlusion:

In 1935, Dr Frederic Foley, a urologist in St. Paul, Minnesota, introduced the first urinary catheter with an inflatable balloon, making it possible for the catheter to stay in place without tape. Although Dr Foley was unable to patent his device, this urinary catheter still bears his name.²

Beyond the urinary market, balloon catheters are used for occlusion in a wide range of other applications, including cardiovascular, gastroenterological, and neurovascular procedures. These balloon catheters are highly compliant so they conform to the anatomy and form a seal.

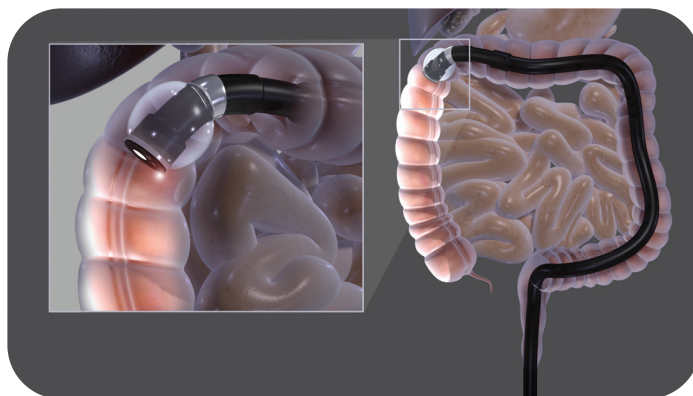


MYOCARDIAL PROTECTION:

During cardiopulmonary bypass procedures when blood is not circulating through the heart, cardioplegia solution is delivered to the heart to induce hypothermia and lower the metabolic rate, protecting the heart from cell death. Cardioplegia can be delivered in the direction of normal blood flow (antegrade), in the

reverse direction of blood flow (retrograde), or in a combination of both. A balloon catheter is used in retrograde cardioplegia delivery to occlude the coronary sinus, forcing the cardioplegia into the coronary vessel and preventing the flow back into the right atrium. These balloons must be strong and compliant to fully occlude the anatomy and redirect the blood flow.

COLONOSCOPY:



In a colonoscopy procedure, an endoscopic camera on a flexible tube is used to examine the large colon and the distal part of the small bowel to look for ulcers, colon polyps, tumors, and areas of inflammation or bleeding. A balloon catheter act as a bumper, helping to center and position the endoscope and making it easier to advance to the affected area. Colonoscopy balloons are typically soft and compliant, with large diameters and thin walls.

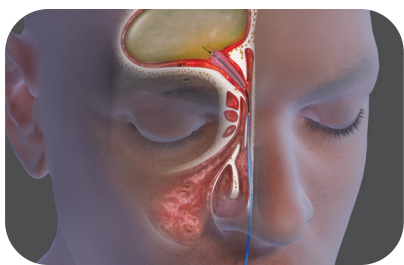
2. Dilatation:

In 1964, US interventional cardiologist Dr Charles Dotter performed the first percutaneous transluminal angioplasty, dilating the superficial femoral artery of a patient with painful leg ischemia and gangrene who had refused leg amputation.⁴ Dotter's work was foundational to Dr Andreas Gruentzig's technique for percutaneous transluminal balloon angioplasty, first performed in 1974.⁵ Gruentzig went on to perform the first percutaneous coronary balloon angioplasty in 1977.⁶

Angioplasty techniques and devices have advanced to include balloon-expandable stents, drug-coated stents, and drug-coated balloons. These techniques have also been adapted for dilatation in other areas of the body, including orthopedics and ENT.

Characteristics of balloons used for dilatation include:

- Controlled compliance to open to a precise diameter
- High tensile strength to allow thin walls and low profiles
- High inflation pressures to open blocked passageways



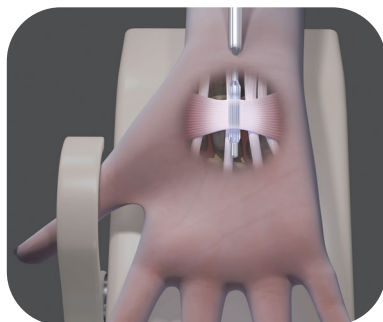
SINUPLASTY:

This minimally invasive procedure for chronic sinusitis uses a thin, high-pressure balloon to dilate sinus passages and facilitate drainage of accumulated mucus

for easier breathing. Sinuplasty balloons often have an abrasion-resistant coating to guard against puncture during the procedure.

CARPAL TUNNEL PLASTY:

This application uses a balloon to expand and stretch the transverse carpal ligament, which reduces compression on the median nerve in the wrist and relieves severe pain or numbness in the hand. This is a minimally invasive alternative to a surgical approach involving cutting the transverse carpal ligament to relieve nerve pressure.



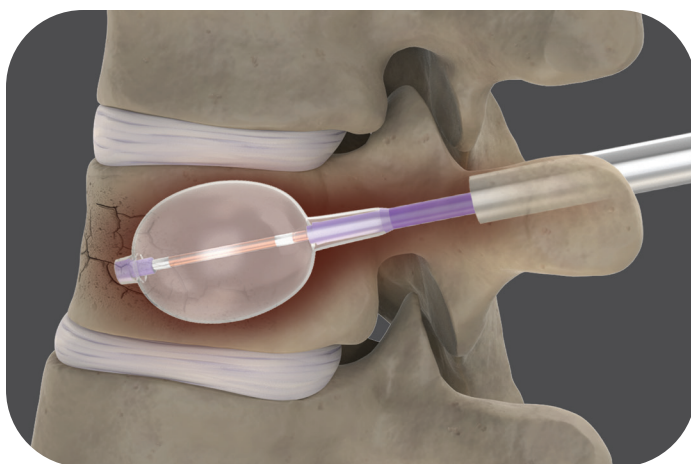
This balloon is a unique offset (one-sided) shape. Integrated with a cannula, it provides directional dilatation, or pushes only on one side.

KYPHOPLASTY:

This application is a treatment for vertebral compression fracture to reduce back pain and repair spinal fracture.

A balloon catheter is used to create a cavity in the bone before injecting bone cement to prevent further vertebral collapse.

Kyphoplasty balloons differ from other dilatation balloons. They are compliant and have a relatively low burst pressure, unconstrained. However, they still generate very high pressures for cavity creation because they are constrained in use by the surrounding vertebral body. They also must be puncture resistant because of their use in cancellous bone that can have sharp edges.



3. Ablation:

In 1998, Dr Michel Haïssaguerre, a French cardiac electrophysiologist, first described the use of catheter ablation for patients with atrial fibrillation.⁷ Haïssaguerre and his colleagues applied radiofrequency (RF) energy via a catheter to create scar tissue that “isolated” the pulmonary veins and prevented electrical disturbances from traveling through the heart.⁸

Balloon-based ablation catheters serve several functions:

- Help position the device to ensure precise treatment
- Contain the energy source
- Allow transmission of energy from catheter to tissue

Characteristics of these balloons include:

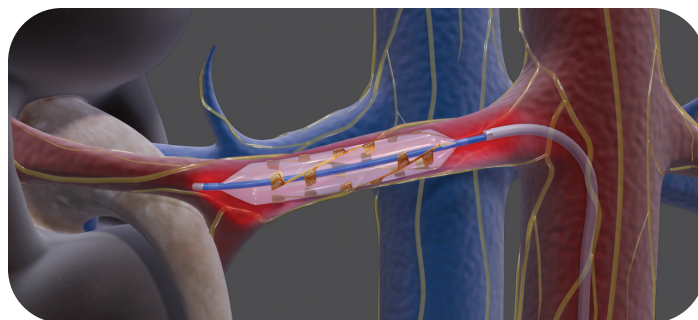
- Noncompliant/semicompliant, to maintain a fixed shape for precise treatment
- Ultrathin wall to ease delivery and facilitate energy transfer
- High tensile strength

RADIOFREQUENCY (RF) CATHETER ABLATION APPLICATIONS:

RF energy is used to ablate tumors or other dysfunctional tissue using heat generated from medium-frequency alternating current. It can be precisely targeted to ablate the diseased tissue without significant damage to surrounding tissue.

Balloons used for RF applications have some compliance to ensure they conform to the anatomy and enable precise energy delivery. RF energy is typically delivered via electrodes on the surface of the balloon, unlike cryoablation or laser ablation applications in which energy is delivered through the balloon itself. Balloons used in RF ablation procedures must therefore be able to withstand the temperatures that the energy source generates.

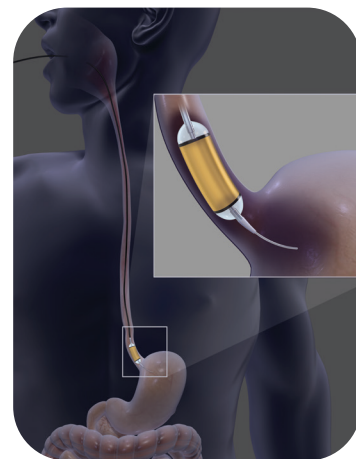
RENAL DENERVATION:



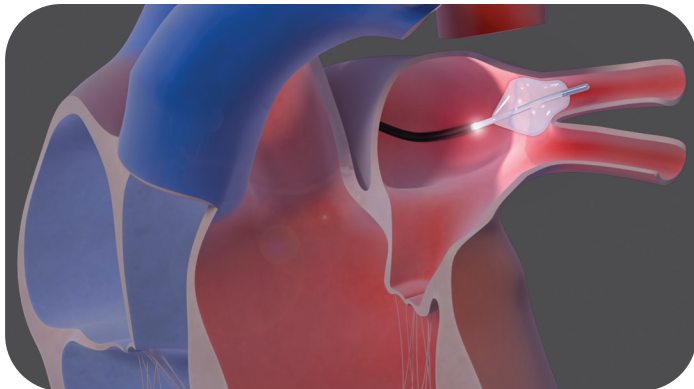
This minimally invasive procedure uses RF or ultrasound ablation to treat resistant hypertension. Renal artery nerves are ablated to reduce the sympathetic activity to the kidneys, which reduces blood pressure. Typically, semicompliant balloons are used to help ensure proper conformance to the anatomy.

ESOPHAGEAL ABLATION:

Balloon catheters have long been used for esophageal dilatation of strictures. An additional application is esophageal ablation. A 360° electrode array positioned on the surface of the balloon delivers a short burst of RF energy circumferentially to the esophagus to destroy precancerous cells associated with Barrett's esophagus.



ABLATION FOR ATRIAL FIBRILLATION (AF ABLATION):



In this application, an energy source is used to destroy a small amount of heart tissue to end the electrical disturbance causing arrhythmia. The most common type of AF ablation is accomplished via RF energy; however, that application involves a catheter without a balloon. Balloon catheters are used in 2 types of AF ablation: cryoablation, which removes heat to ablate tissue; and laser ablation, which applies heat to ablate tissue.

Balloons used in these applications feature large diameters with relatively small necks, which pushes the limits of balloon technology. However, each of these techniques uses balloons in a different way:

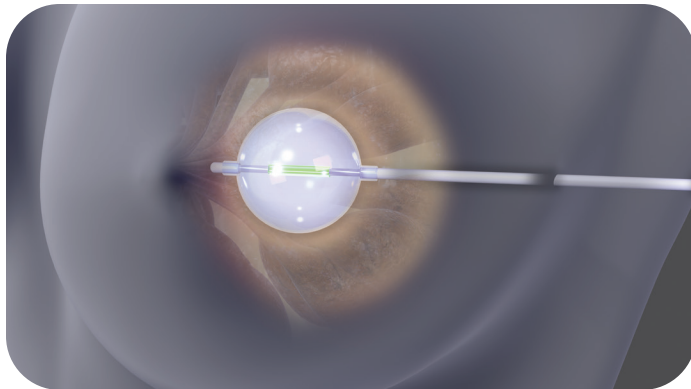
CRYOABLATION:

One unique design features an inner and an outer balloon. The refrigerant is delivered through the inner balloon, and the outer balloon is designed to serve as an added safety measure. This application requires a low-profile device with ultrathin walls that inflates to a very large diameter—a difficult technical challenge. In addition, the balloon has to withstand and remain flexible at very low temperatures.

LASER ABLATION:

This balloon contains the energy source and transmits energy from the catheter to the tissue. The balloon material is carefully chosen to ensure it is transparent to that wavelength of energy, so that the laser energy can pass through the wall of the balloon to the tissue.

BRACHYTHERAPY (RADIATION THERAPY):



In this application, the balloon is inflated to create a cavity that allows the physician to access the treatment area in order to precisely deliver localized doses of radiation to the affected area of the breast, prostate, cervix, or other tissues. As in laser ablation, the energy passes through the balloon to the treated tissue.

Balloons used in brachytherapy procedures are often more compliant than other ablation balloons. They have adjustable diameters to expand the space during therapy and inflate symmetrically to ensure uniform dosing. In addition, they have a low profile, but do not require as high tensile strength as other energy delivery systems.

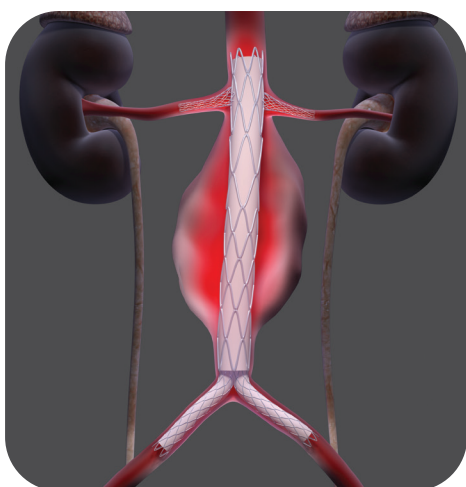
4. Implant Delivery:

In 1986, French physicians Dr Jacques Puel and Dr Ulrich Sigwart implanted the first coronary stent, used as a scaffold to prevent the vessel from closing and to avoid restenosis in coronary surgery.⁹

In 2002, French interventional cardiologist Dr Alain Cribier and colleagues performed the first transcatheter aortic valve implantation procedure on a patient with severe symptomatic aortic stenosis.¹⁰

Characteristics of balloons used to deliver implants include:

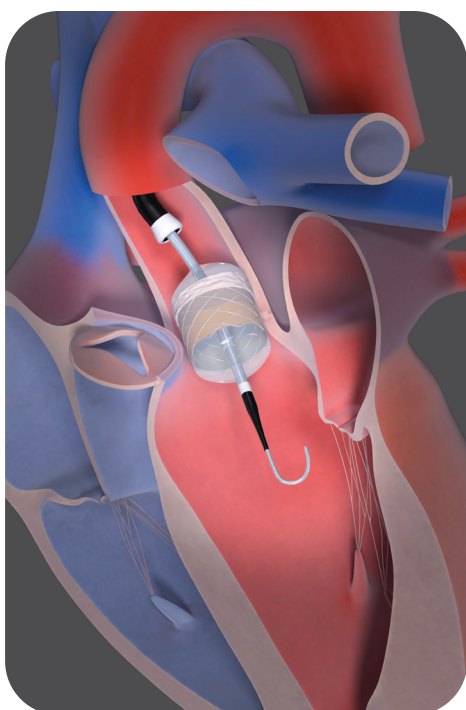
- High strength to open the device
- High durability to prevent damage from contact with the implant
- Low profile



ENDOVASCULAR GRAFT DELIVERY:

In this application, a balloon-based catheter is used to support delivery of a stent graft to treat an abdominal aortic aneurism or other cardiovascular disease. In some devices, the balloon opens the stent graft in the anatomy. In other cases, the balloon is used after deploying a self-expanding stent graft to ensure proper positioning and to prevent leakage. The graft supports the vessel and prevents it from bursting.

Balloons used to deliver stent grafts are typically noncompliant or semicompliant. Balloons used after deployment are typically very compliant to allow the graft to fully expand and seat in the vessel. These balloons can be high or low pressure.



VALVE REPLACEMENT:

Balloon-catheter-based devices are used in several minimally invasive procedures to replace diseased aortic valves. In these applications, balloons dilate the existing calcified valve (valvuoplasty), expand to deploy the new valve, and maintain the position of the new valve.

These balloons need to be more durable than many other balloons to resist damage in calcified valves. These balloons can have a variety of shapes, such as a “dog bone” shape with a narrowed space in the middle, to prevent migration of the valve during delivery and deployment.

CONCLUSION:

This white paper describes just a few of the many innovative applications for balloon catheters today. Others include implantable balloons for weight loss, heat transfer balloons for induced hypothermia treatment, and even balloons filled with bone cement to stabilize broken bones. Balloon technologies and applications will continue to expand as physicians and medical device designers collaborate to develop new minimally invasive surgical techniques and devices.

High-tech developments such as nanotechnology, electronic sensors, and artificial intelligence are among the next wave of innovation. These technologies will make “smart catheters”—catheters that provide physicians with real-time information about what is happening at the distal end—even smarter.¹¹

At the heart of medical device innovation is the creativity and perseverance of design engineers who tirelessly work to push the limits of technology in order to develop new breakthroughs in minimally invasive medical technologies. As Benjamin Franklin said, “Energy and persistence conquer all things.”¹²

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