Atrion
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Balloon Catheter Inflation Devices:

SUPPORTING CARDIOVASCULAR, GASTROINTESTINAL, UROLOGICAL, AND STRUCTURAL INTERVENTIONS

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Supporting Cardiovascular, Gastrointestinal, Urological, and Structural Interventions

Introduction

Inflation devices are recommended for use with balloon catheters to create and monitor the pressure in the balloon and to deflate the balloon.

Balloon catheters are critical tools in interventional medical procedures. They are used to mechanically dilate specific anatomical structures and to deliver stents, drugs, therapeutics and implants.

Balloon catheter inflation devices provide precise, controlled delivery of fluid volume and pressure to ensure that balloons achieve the desired diameter and shape without causing vessel or structural damage.

Therapeutic Applications

Balloon catheters that require high pressure balloon inflation and pressure monitoring are used in a wide range of interventional procedures

CORONARY ANGIOPLASTY (PERCUTANEOUS CORONARY INTERVENTION)

Balloon catheters are used to open stenotic (narrowed) or blocked coronary arteries in patients with atherosclerosis or coronary artery disease. After a pre-dilation to open the blocked artery, a second balloon catheter is often used to deploy/expand a stent into the vessel. A stent is a small, mesh-like tube implanted to keep the artery open and improve blood flow. A third balloon can be used to post-dilate the stent to optimize stent expansion, improve stent apposition and potentially reduce the risk of complications such as stent thrombosis and restenosis. Drug coated balloons (DCBs) are an emerging alternative to permanent stent implantation. DCBs are coated with a drug-excipient matrix that delivers anti-proliferation medication directly to the vessel wall during balloon inflation.

PERIPHERAL ARTERY DISEASE (PAD)

Balloon catheters are used to treat blockages in the legs (i.e. femoropopliteal or below-the-knee) and arms (i.e. arteriovenous fistula/graft). Similar to coronary angioplasty, the balloon dilates narrow vessels to improve blood flow. Peripheral balloons are often longer in length and larger in diameter vs. coronary balloons to accommodate bigger peripheral vessels. The larger balloons require more fluid volume to inflate and, in some cases, have a rated burst pressure up to 40ATM.

STRUCTURAL HEART

Transcatheter heart valve replacement is a minimal invasive procedure to replace diseased heart valves with an artificial heart valve. In balloon expandable transcatheter aortic valve replacement (TAVR), the artificial valve is mounted on a metal frame which is crimped on a balloon catheter and the artificial valve is then guided into the aortic annulus via a transfemoral catheter. The balloon is inflated to expand the metal frame and anchor the heart valve implant, replacing the stenotic (narrowed) or regurgitant (leaky) valve. In some cases, valvuloplasty, a balloon dilation to expand the valve leaflet and widen the opening, is performed prior to valve replacement.

ESOPHAGEAL

An esophageal stricture is a narrowing of the esophagus that leads to difficulty swallowing foods and liquids. Esophageal balloon dilation involves inserting a large balloon catheter into the esophagus and inflating it to stretch the narrowed area.

GASTROINTESTINAL

Balloon dilation is performed during endoscopic retrograde cholangiopancreatography (ERCP) procedures to widen narrowed or obstructed bile or pancreatic ducts. It involves inserting a balloon catheter through the endoscope and inflating it to expand the duct, allowing for stone removal, stent placement, or other interventions.

UROLOGY

Balloon dilation for urethral stricture treatment is a minimally invasive procedure that uses a balloon catheter to widen the urethra, relieving the narrowing caused by scar tissue. It's an effective treatment for short strictures and can be a good option for recurrent strictures, particularly when combined with DCBs, which can reduce the risk of recurrence. DCBs are also used to treat Benign Prostatic Hyperplasia (BPH). In these procedures, a balloon catheter coated with an antiproliferation drug is used to treat lower urinary tract symptoms (LUTS) caused by an enlarged prostate.

KYPHOPLASTY

Kyphoplasty is a minimally invasive procedure used to treat vertebral compression fractures in the spine, often caused by osteoporosis. A balloon is inserted into the fractured vertebra and inflated to compact the surrounding bone to create a defined cavity for cement injection. The space is filled with bone cement to stabilize the fracture and restore vertebral height.

BALLOON SINUPLASTY

Balloon sinuplasty is a minimally invasive procedure used to treat chronic sinusitis by widening the sinus openings and improving drainage. It involves inserting a small balloon catheter into the nasal passages, inflating it to reshape the sinus, and then deflating and removing the balloon. This technique aims to restore normal sinus function without the need for cutting or removing bone and tissue like traditional sinus surgery.

Balloon Catheter Inflation Devices

FEATURES AND FUNCTIONS

Balloon catheters that require high pressure balloon inflation and pressure monitoring are used in a wide range of interventional procedures:

LOCKING MECHANISM

Balloon catheter inflation devices feature a locking mechanism, integrated into the inflation syringe, allowing clinicians to engage and disengage the screw-driven plunger threads. The plunger threads are unlocked/disengaged to fill the syringe with fluid and to prepare the device for use. To generate the high pressure required by many balloon catheters, the screw driven plunger must be locked/engaged, allowing the user to rotate the screw plunger clockwise to precisely deliver fluid to dilate the balloon. Once balloon dilation is complete, the threads are disengaged/unlocked so the user can pull a vacuum to quickly deflate the balloon catheter.

PRESSURE MEASUREMENT

Balloon diameter is often correlated to a specific inflation pressure. Two critical specifications that define the operational limits of a balloon during interventional procedures are nominal pressure and rated burst pressure. Nominal pressure is the pressure at which the balloon catheter achieves a specified diameter or shape as designed by the manufacturer for optimal performance. The rated burst pressure is the maximum pressure the balloon is designed to withstand before there is a risk for significant failure or balloon rupture. Inflation devices have a pressure gauge to measure and display the balloon pressure so the clinician can properly dilate the balloon.

CLEAR SYRINGE BARREL

A clear syringe barrel allows clinicians to see fluid levels during device preparation to ensure all air bubbles have been cleared prior to use and then to monitor fluid dispensing during balloon dilation. The syringe must have durable construction to accommodate high pressure balloon catheter dilation.

TUBING AND CONNECTOR

High-pressure braided tubing connects the device to the balloon catheter with a Luer-lock ensuring a secure, leak-free interface. The rotating luer-lock connection should be ISO 80369 compliant.

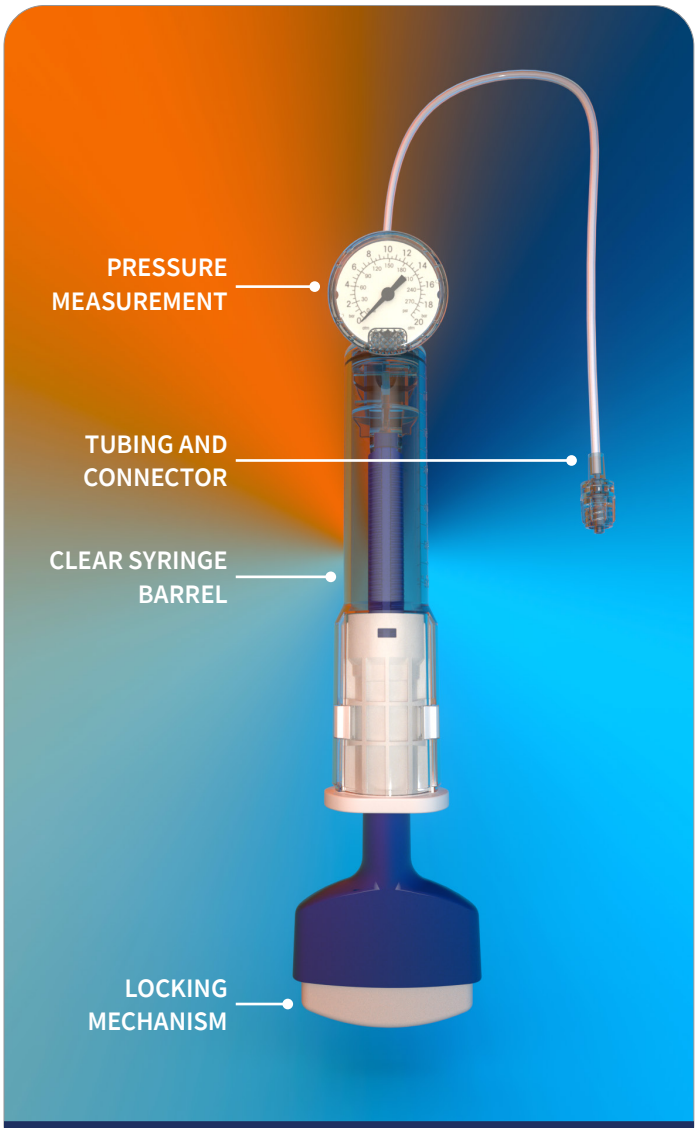

FIGURE 1: Inflator features

Balloon Catheter Inflation Devices

CRITICAL PERFORMANCE CHARACTERISTICS

One device does not fit all applications. Specialty clinical applications have unique inflation device requirements.

INFLATION/DEFLATION SPEED

Balloon catheters used in heart valve replacement procedures must be rapidly inflated and deflated as the expanded balloon blocks blood flow through the heart valve. The need for speed prohibits users from engaging the locking mechanism and dilating the balloon with the use of the threaded plunger. The inflation device must have a small-bore diameter to minimize user input force and allow the balloon to be dilated manually. In addition, heart valve balloons are often large diameter and require up to 45ccs of fluid volume to fully dilate at pressures up to 15ATM. In order to meet the large capacity requirement of these balloon catheters, while still allowing for rapid manual inflation, the length of the device must increase, complicating the design requirements and manufacturing processes. A quick latch locking mechanism, that allows the plunger threads to remain in the unlocked/disengaged position, is often preferred for structural heart procedures versus a spring-loaded locking mechanism that automatically returns to the locked position.

ULTRA HIGH PRESSURE

Balloon catheters, used to dilate severely calcified lesions or compact bone material to create a cavity, often require 40ATM or 55ATM of pressure for the balloon to reach the proper diameter and shape. In some cases, the force required to inflate a balloon catheter could be as much as 300lbf (1300N). Therefore, inflation devices require reinforced plunger threads, braided tubing, high pressure gauges and a robust locking mechanism to accommodate inflating and deflating ultra high pressure balloons multiple times during a procedure.

LARGE FLUID CAPACITY

Large capacity balloon catheters require inflation devices to accommodate up to 60ccs of fluid volume and generate up to 20ATM of pressure, while promoting ergonomics and clinical usability. Deflating large balloons can prove to be especially challenging as the large diameter syringe requires higher user force to create negative pressure. The latching mechanism should be easy to activate so the user can lock the device in the vacuum position while the balloon is deflating.

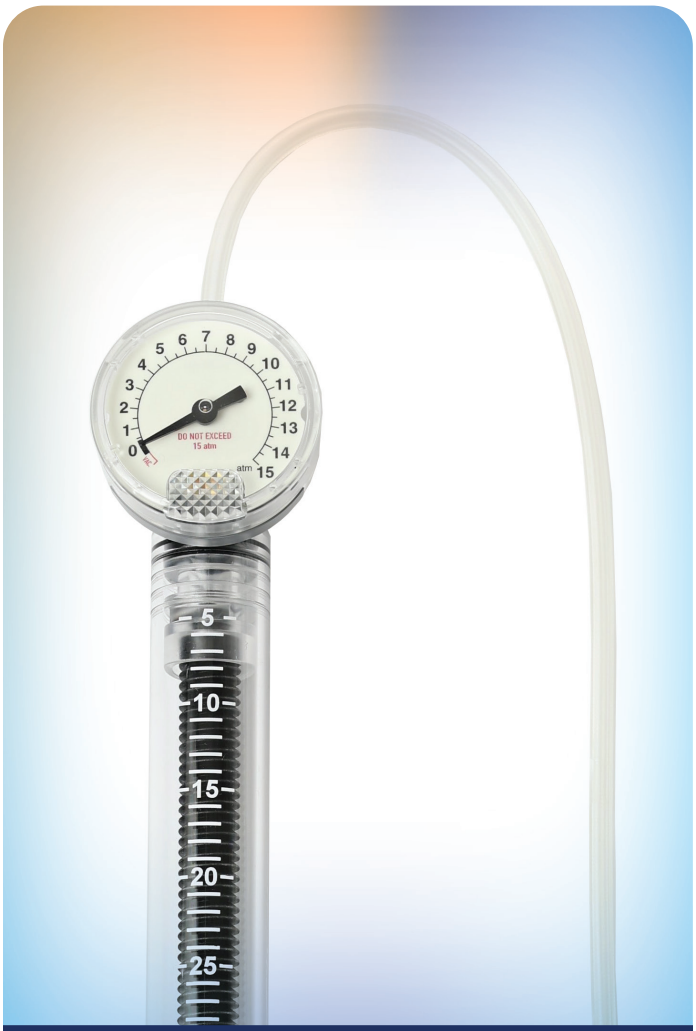

FIGURE 2: Detailed photo showcasing the gauge for precise measurements

PRESSURE GAUGE ACCURACY

To ensure balloon catheters are inflated to the appropriate shape and diameter, pressure accuracy is paramount. Premium pressure gauges have a minimum accuracy of +/- 1ATM over the pressure range and have a luminescent background to improve visibility in dark procedure rooms. Analog gauges are the most popular gauge type and serve as a practical, cost-effective and reliable tool to measure and display pressure.

Conclusion

Balloon catheter inflation devices play a critical role in a wide range of therapeutic procedures, from cardiovascular interventions to structural heart repairs and gastrointestinal treatments. Their design must meet the demanding requirements of high-pressure performance, rapid inflation and deflation, and precise fluid control to ensure optimal clinical outcomes. As medical applications continue to evolve, so too must the engineering behind these devices—tailoring features to meet the specific needs of each procedure. Understanding the nuances of inflation device functionality and performance characteristics is essential for clinicians and device developers alike, driving innovation and improving patient care across diverse therapeutic domains.

FIGURE 3: Atrion's inflators: A snapshot of innovation and versatility

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Nordson MEDICAL (Nasdaq: NDSN) is a global expert in the design, development, and manufacturing of complex medical device components. As a single-source partner, we enable our customers to save costs, speed time to market, and simplify supply chain management.

We work with companies at any point in the product life cycle, from concept to launch and beyond. With our flexible business model, we can provide a solution that meets the scope and scale of any project to bring innovative ideas to life.

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