Balloon Dilatation Catheter

3

Huajuan Mao, Junmin Bao, Zhiyong Chen, and Jian Dong

Abstract

Balloon catheters are main devices for endovascular treatment, and, based on the features of their delivery systems, they can be classified into two types, i.e., the over-the-wire (OTW) type and the rapid exchange system (RX) type. This chapter provides a tabular summary of the names, brands, compliances, and specifications of balloon catheters, as well as their adapter wires, adapter sheaths, bursting pressures, shafts, and other adapter devices. After that, it elaborates on their structures and features based on balloons of different brands.

Keywords

Balloon catheter · Adapter device · Structure and features
Model types

3.1 Introduction

The balloon dilatation catheter, short for balloon, is used for expanding the diseased portion and delivering endovascular devices for stents or as the support catheter to recanalize the diseased segments of the blood vessels. The balloon can be divided into four parts: the tip, balloon body, connecting segment, and delivery shaft.

H. Mao (✉) · J. Bao · J. Dong
Department of Vascular Surgery, Changhai Hospital, Second Military Medical University, Shanghai, China
e-mail: czymm8@163.com

Z. Chen
Department of Vascular Surgery, The First Hospital, Anhui Medical University, Anhui, China

3.1.1 Balloon Performance

Balloon dilatation catheter performance is evaluated usually with reference to the following parameters:

3.1.1.1 The Crossing Profile

The crossing profile refers to the outer diameter when the balloon is not expanded, currently taking the minimum outer diameter that the balloon can cross as the criteria, and it generally refers to the outer diameter of the balloon marker portion.

3.1.1.2 Flexibility

Flexibility refers to the ability that the balloon accesses through the lesions in natural vascular state.

3.1.1.3 Trackability

Trackability refers to the ability of the balloon to reach the lesions under the guidance of the wire.

3.1.1.4 Pushability

Pushability refers to the ability of the balloon tip to navigate through the lesions when the operator manipulates the balloon delivery unit in vitro.

3.1.2 Balloon Compliance

Balloon compliance refers to the ability that the balloon diameter changes along with the pressure change when the balloon is fully inflated, an index indicating the tensile capacity of the balloon. Balloon can be classified as non-compliant, semi-compliant, and compliant balloons according to the ratio of the final diameter with the rated diameter when the balloon reaches rated standard pressure and is continually compressed to the bursting pressure.

Z. Jing et al. (eds.), *Endovascular Surgery and Devices*, https://doi.org/10.1007/978-981-10-8270-2_3

3.1.2.1 The Non-compliant Balloon

The balloon with 100–110% ratio between final diameter and rated one is usually high-pressure balloon, featuring strong and even expansion force, not liable of dog-bone phenomenon (dog-bone phenomenon means that when the balloon is inflated to rated bursting pressure within a stent, both the proximal and distal diameters of the balloon are all larger than those of the stent, showing like a dog-bone under X-ray), and available for expanding hard plaques.

3.1.2.2 The Semi-compliant Balloon

Most balloons with 110–130% ratio between final and rated diameters are semi-compliant balloons, having a crossing profile smaller than that of the non-compliant ones and excellent crossability.

3.1.2.3 The Compliant Balloon

Compliant balloons are the ones with ratio between final and rated diameters exceeding 130% or even reaching several times their own volume. These balloons are mainly used for aortic dilatation and temporary closure or expansion of indwelling vascular prosthesis.

3.1.3 Types and Features of Balloons

Balloons are mainly classified into two categories: over the wire (OTW) and rapid exchange system (RX), according to the delivery system.

3.1.3.1 OTW

OTW (over the wire). The balloon dilatation catheter is mainly used for long-segment occlusive diseases and situations where the wire needs to be exchanged. This kind of balloon features excellent pushability, commonly used for the endovascular treatment for subclavian artery, iliac artery, femoral artery, popliteal artery, and infra-popliteal artery.

3.1.3.2 RX

RX (rapid exchange system). The balloon dilatation catheter often has a smaller outer diameter, facilitating the operator control, available for rapid exchange of the balloons, but disadvantaged in relatively poorer trackability and pushability than the OTW, thus making it inconvenient for wire exchange. This kind of balloon is often used for endovascular treatment of renal artery, carotid artery, and coronary artery, as well as for the retrograde puncture of lower extremity arteries.

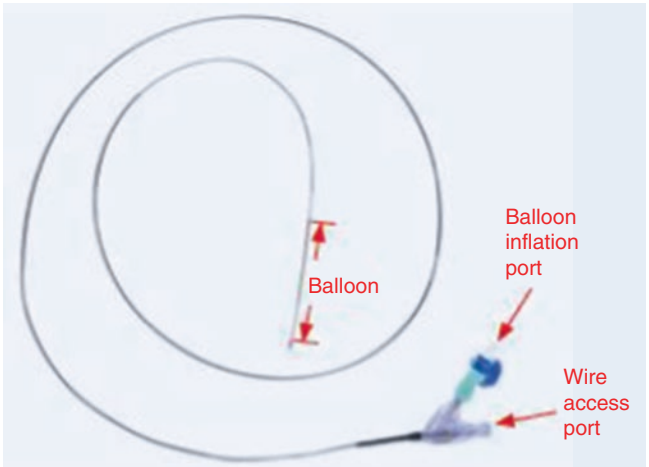

Fig. 3.1 OTW balloon dilatation catheter

3.2 OTW Balloon Dilatation Catheter

3.2.1 Product Structure

OTW balloon dilatation catheter consists of a double-lumen shaft lever with the balloon body connected at its distal end (Fig. 3.1). The double-lumen shaft lever is branched at its proximal end, one of the lumen functions as the port for the wire to enter the central lumen while the other lumen as a pathway to control the inflation and shortening of the balloon with the mixture of the contrast agent and the normal saline. A smooth, flexible, and noninvasive tip is located at the proximal end of the catheter, facilitating the advancement of the catheter through narrow portions. To ensure accurate positioning of the balloon under X-ray, two radiopaque marker bands are equipped on both ends of the work zones of the balloon.

3.2.2 Specifications and Models

At present, the brands of OTW balloon dilatation catheters include Boston Scientific, Medtronic, Bard, Cordis, Medtronic, Abbott, Biotronik, Optimed, Cook, Gore, etc. This section mainly introduces balloon dilatation catheters from such brands as Mustang (Boston Scientific), Admiral Xtreme (Medtronic), Reekross 35 (Bard), Savvy Long (Cordis), Evercross (Medtronic), Fox Sv (Abbott), Passeo-35 (Biotronik), Coda (Cook), and Tri-Lobe (Gore) (Table 3.1).

Table 3.1 Brand-specific OTW balloon specifications (for reference only)

Name	Brand	Compliance	Balloon diameter (mm)	Balloon length (mm)	Matching wire (in)	Matching sheath (F)	Burst pressure (atm)	Shaft (cm)
Mustang	Boston Scientific	Non-compliant	3–12	20–200	0.035	5–7	14–24	40, 75, 135
Sterling OTW	Boston Scientific	Semi-compliant	2–10	20–150	0.018	4	10–14	80, 90, 135, 150
Coyote	Boston Scientific	Semi-compliant	1.5–4	40–220	0.014	4	12–14	90, 150
XXL	Boston Scientific	Non-compliant	12–18	20–60	0.035	7	5–8	75, 120
Admiral Xtreme	Medtronic	Semi-compliant	3–12	20–300	0.035	5–7	17.76	80, 130
Pacific	Medtronic	Semi-compliant	2–7	20–300	0.018	4–5	24.67	90, 130, 180
Deep	Medtronic	Semi-compliant	1.5–4	20–210	0.014	5	15.79	120, 150
Reekross l4	Bard	Semi-compliant	25	40–220	0.014	4	13–16	140
Reekross18	Bard	Semi-compliant	2–5	40–220	0.018	4	13–16	130
Reekross 35	Bard	Semi-compliant	2–6	40–220	0.035	5–6	13–16	75, 110
Bantam	Bard	Semi-compliant	2–9	20–220	0.018	4–6	12–16	75, 90, 130
Bantam α	Bard	Semi-compliant	1.25–5	15–220	0.014	4	13–16	100, 130, 150
Powerflex P3	Cordis	Semi-compliant	4–12	10–100	0.035	5–7	15	40, 80, 110, 135
Powerflex Pro	Cordis	Semi-compliant	3–12	20–220	0.035	5–7	18	80, 135
Maxi LD	Cordis	Semi-compliant	14–25	40–80	0.035	8–12	5–6	40, 80
Savvy	Cordis	Semi-compliant	2–6	20–100	0.018	4–5	10	80, 120, 150
Savvy Long	Cordis	Semi-compliant	2–6	120–220	0.018	4–5	12–15	80, 120, 150
Sleek	Cordis	Semi-compliant	1.5–5	15–280	0.014	4	10–16	150
Evercross	Medtronic	Semi-compliant	3–12	20–200	0.035	5–7	10–20	80, 135
Powercross	Medtronic	Semi-compliant	2–6	20–200	0.018	4–6	14	90, 150
Nanocross	Medtronic	Semi-compliant	1.5–4	20–210	0.014	4	14	90, 150
Fox Sv	Abbott	Semi-compliant	2–5	15–120	0.018	4	16–22	90, 135, 150
Fox cross	Abbott	Semi-compliant	3–14	20–120	0.035	5–7	8–18	50, 80, 135
Armada 14	Abbott	Semi-compliant	1.5–4	20–200	0.014	4	14	90, 150
Armada 35	Abbott	Semi-compliant	4–14	20–250	0.035	5–7	7–25	80, 135
Passeo-35	Biotronik	Semi-compliant	3–10	20–200	0.035	5–6	16	80, 90, 130
Passeo-18	Biotronik	Semi-compliant	2–7	20–220	0.018	4–5	15	90, 130, 150
Passeo-14	Biotronik	Semi-compliant	1.5–4	20～220	0.014	4	14	90, 120, 150
Mars	Optimed	Non-compliant	3–10	40–100	0.035	5–6	17.76	75, 120
Coda	Cook	Compliant	32	40	0.035	10	/	100
Sanye	Gore	Compliant	16–45	40	0.035	18	/	104

3.2.3 Brand Information

3.2.3.1 Mustang Balloon Dilatation Catheter

Product Structure

Mustang balloon dilatation catheter, the US Boston Scientific-produced high-pressure non-compliant balloon, consists of a balloon, bumper tip, an inner tip, a reducer tube, a stain relief, Y connector, and the catheter shaft. The balloon has hydrophilic coating applied on both ends of the work zones and platinum-iridium radiopaque marker bands.

Features and Models

The Mustang balloon dilatation catheter is indicated for percutaneous transluminal angioplasty (PTA) in the peripheral vasculature. The balloon matches well with 0.89 mm (0.035 in) wire and 5–7F vascular sheath, available with 3–12 mm in diameter, 20–200 mm in length, 14–24 atm of bursting pressure, and 40 cm, 75 cm, and 130 cm in shaft length.

3.2.3.2 Admiral Xtreme Balloon Dilatation Catheter

Product Structure

Admiral Xtreme balloon dilatation catheter, the US Medtronic-produced semi-compliant balloon, consists of a

coaxial dual-lumen catheter and a balloon, wherein the coaxial dual-lumen catheter is made of the polyamide elastomer, and the balloon of polyamide material, surfaced with hydrophilic coating. On both ends of the work zones of the balloon are two radiopaque metal marker bands.

Features and Models

The balloon dilatation catheter is indicated for percutaneous transluminal angioplasty (PTA) in the peripheral vasculature. The balloon matches well with 0.89 mm (0.035in) wire, and 5–7F vascular sheath, available with 3–12 mm in diameter, 20–300 mm in length, 17.76 atm of bursting pressure, and 80 cm and 130 cm in shaft length.

3.2.3.3 Reekross 35 Balloon Dilatation Catheter

Product Structure

Reekross 35 balloon dilatation catheter, the US Bard-produced semi-compliant balloon, consists of a rigid shaft (extending from the proximal handle to the distal tip) with a separate rigid inflation lumen. The balloon is made of a blend of nylon and polyamide elastomer and the rigid shaft of 304 V stainless steel. The catheter shaft is surfaced with Silx hydrophilic coating, and by virtue of Quadflex Technology, the balloon can perform multiple inflations, while the catheter is advanced through long, occluded lesions. Platiniridium marker bands are equipped on both ends of the work zone of the balloon, ensuring accurate positioning under X-ray.

Features and Models

The balloon dilatation catheter is indicated specially for the treatment of highly difficult seriously calcified artery lesions of lower extremity, suitable for both transluminal and endovascular angioplasty. The balloon matches well with 0.89 mm (0.035 in) wire and 5–6F vascular sheath. The balloon diameter is 2–6 mm, length 40–220 mm, burst pressure 13–16 atm, and 75 cm and 110 cm in shaft length.

3.2.3.4 Savvy Long Balloon Dilatation Catheter

Product Structure

The Savvy Long balloon dilatation catheter, the US Cordis-produced semi-compliant balloon, consists of a seat, strain relief, a catheter, and a balloon (2 mm balloon is twofold and 3–6 mm threefold). The catheter is surfaced with Silx hydrophilic coating. The catheter is made of nylon blend, balloon of nylon blend and Pebax. On both ends of the work zones of the balloon are hydrophilic coating and radiopaque platiniridium marker bands.

Features and Models

The balloon dilatation catheter is indicated for endovascular dilatation treatment for the superficial femoral artery of lower extremity, deep femoral artery, popliteal artery, and infrapopliteal artery. The balloon matches well with 0.46 mm (0.018in) wire and 4–5F vascular sheath. The balloon diameter is 2–6 mm, length 120–220 mm, burst pressure 12–15 atm, and 80 cm, 120 cm and 150 cm in shaft length.

3.2.3.5 Evercross Balloon Dilatation Catheter

Product Structure

The Evercross balloon dilatation catheter, the US Medtronic-produced semi-compliant balloon, consists of a dual-lumen catheter with a distally mounted semi-compliant inflatable balloon. The material for the balloon is polyamide and that for the catheter is polyamide and Pebax. A layer of hydrophilic coating of light-sensitive sodium sulfonate and polyvinylpyrrolidone is applied at the distal portion of the catheter. On both ends of the work zones of the balloon are a radiopaque marker band used for balloon positioning.

Features and Models

The balloon dilatation catheter is indicated for endovascular dilatation treatment of lower extremity artery and renal artery and other vascular stenoses. The balloon matches well with 0.89 mm (0.035in) wire and 5–7F vascular sheath. The diameter of the balloon is 3–12 mm, the length 20–200 mm, the burst pressure 10–20 atm, and 80 cm and 135 cm in shaft length.

3.2.3.6 Fox Sv Balloon Dilatation Catheter

Product Structure

The Fox Sv balloon dilatation catheter, the US Abbott-produced semi-compliant balloon, consists of a dual-lumen catheter and a balloon, made of polyamide, and surfaced with hydrophilic coating on the catheter, a balloon tip and wire lumen, except on the balloon. On both ends of the work zones of the balloon are platiniridium marker bands used for positioning the relative position of the balloon and vascular stenosis.

Features and Models

The balloon dilatation catheter is indicated for endovascular dilatation treatment for atherosclerosis obliteration of lower extremity and restenosis following the stent placement. The balloon is suitable with 0.46 mm (0.018in) wire and 4F vascular sheath and available with 2–5 mm diameter, 15–120 mm length, 16–22 atm burst pressure, and 90 cm, 135 cm and 150 cm in shaft length.

3.2.3.7 Passeo-35 Balloon Dilatation Catheter

Product Structure

The Passeo-35 balloon dilatation catheter, the German Biotronik-produced semi-compliant balloon, consists of a balloon, a catheter, and an operation handle. The material for the balloon is polylaurylamide, and that for the catheter is Pebax and that for the Y joint portion of the operation handle is Polycarbonate. The catheter is surfaced with hydrophilic silicon coating and the balloon with hydrophilic patching coating. On both ends of the work zones of the balloon is a radiopaque marker band used for balloon positioning.

Features and Models

The balloon dilatation catheter is indicated for endovascular dilatation treatment of lower extremity artery, renal artery, and other vascular stenoses. The balloon fits well with 0.89 mm (0.035in) wire and 5–6F vascular sheath. The balloon is available with 3–10 mm diameter, 20–200 mm length, 16 atm burst pressure, and 80 cm, 90 cm, and 130 cm in shaft length.

3.2.3.8 Coda Balloon Dilatation Catheter

Product Structure

The Coda balloon dilatation catheter, the US Cook-produced compliant balloon, consists of a balloon, a catheter, and a catheter seat (Fig. 3.2). The material for the balloon is polyurethane, and that for the catheter is polyurethane, barium sulfate, and yellow dye, that for the catheter seat is polyurethane, and that for the balloon lumen joint is polycarbonate. On both ends of the work zones of the balloon is a radiopaque platiniridium marker band used for balloon positioning under X-ray.

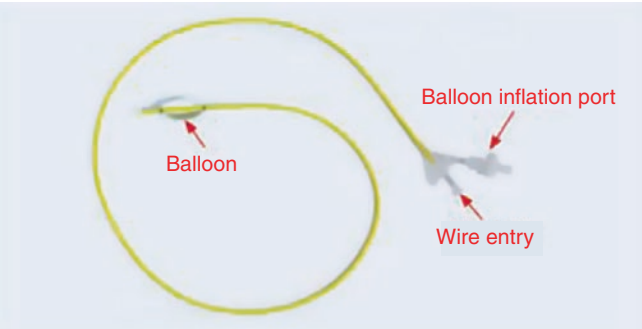

Fig. 3.2 Coda balloon dilatation catheter (Cook)

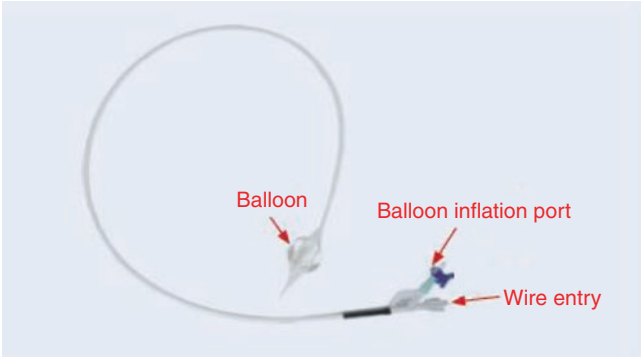

Fig. 3.3 Tri-lobe balloon catheter (Gore)

Features and Models

The balloon is indicated mainly for aortic (thoracic and abdominal aorta) dilatation and temporary closure or endovascular dilatation treatment of vascular prosthesis. The balloon is used in conjunction with 0.89 mm (0.035in) wire and 10F vascular sheath (11–12F recommended according to clinical experience). The balloon is 32 mm in diameter, 40 mm in length, and 100 cm in delivery shaft length.

3.2.3.9 Tri-Lobe Balloon Dilatation Catheter

Product Structure

The Tri-Lobe balloon dilatation catheter, the US Gore-produced compliant balloon (Fig. 3.3), consists of three polyurethane balloons distally mounted on a dual-lumen catheter and radiopaque marker bands along the edge of the balloon. The three inflation lumens are connected with a balloon, and the proximal inflation port is connected with all inflation lumens by a Luer joint. The tri-lobe design of the balloon dilatation catheter ensures that the aortic blood flow will not be completely obstructed when the balloon is fully inflated.

Features and Models

The balloon dilatation catheter is indicated for assisting the self-expanding stent graft with endovascular dilatation treatment for large-diameter blood vessels (thoracic and abdominal aorta). The balloon is used in conjunction with 0.89 mm (0.035in) wire and 18F vascular sheath. The balloon can be divided into large and small ones: the inflated diameter of the small balloon is 16–34 mm and that for large balloon 26–45 mm, with 104 cm in delivery shaft length.

3.3 RX Balloon Dilatation Catheter

3.3.1 Product Structure

RX balloon dilatation catheter consists of a proximal lumen used for balloon inflation and a coaxial push-in wire mounted at its distal end (Fig. 3.4). The catheter has a tapered tip so as to facilitate the insertion and crossing of the wire into the vascular stenosis. On both ends of the balloon are two radiopaque marker bands for accurate balloon positioning.

3.3.2 Specifications and Models

At present, the brands for RX balloon dilatation catheters mainly include Boston Scientific, Bard, Medtronic, Cordis, etc.; the features and models of which are shown in Table 3.2. This section mainly introduces Sterling Monorail (Boston Scientific), LitePAC (Bard), and Submarine Rapido (Medtronic) balloon dilatation catheters.

3.3.3 Brand Information

3.3.3.1 Sterling Monorail Balloon Dilatation Catheter

Product Structure

The Sterling Monorail balloon dilatation catheter, the US Boston Scientific-produced semi-compliant balloon, has a thin tip fixed on the distal RX catheter. The inner layer material of the wire lumen is made of high density polyethylene (hdpe) and dye. The balloon catheter has a tapered tip, facilitating the access through vascular stenosis. On both ends of the balloon are two marker bands available for observation and balloon catheter positioning under X-ray.

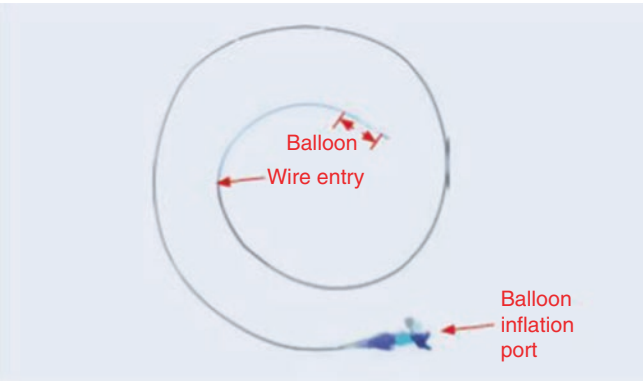

Fig. 3.4 RX balloon dilatation catheter

Features and Models

The balloon dilatation catheter is indicated for percutaneous transluminal angioplasty of such peripheral vessels as carotid, vertebral, and renal arteries. The balloon matches with 0.46 mm (0.018in) wire and 4–5F vascular sheath. The balloon is available with 5–8 mm diameter, 10–60 mm length, 14 atm burst pressure, and 80 cm and 135 cm in delivery shaft length.

3.3.3.2 LitePAC Balloon Dilatation Catheter

Product Structure

The LitePAC balloon dilatation catheter, the US Bard-produced semi-compliant balloon, has its proximal end made of 304 stainless steel and distal coaxial catheter made of nylon mixture. There are two radiopaque platiniridium markers on the balloon, facilitating balloon positioning under X-ray. A transparent axle is mounted at the proximal end of the catheter, facilitating the observation of air bubbles and removal of air bubbles during balloon preparation.

Features and Models

The balloon dilatation catheter is indicated for endovascular dilatation treatment for such peripheral vessels as carotid, vertebral, and renal arteries. The balloon matches with 0.36 mm (0.014 in) wire and 4–5F vascular sheath. The balloon is 2–7 mm in diameter and 15–220 mm in length, available with 12–16 atm burst pressure and 150 cm and 155 cm in delivery shaft length.

3.3.3.3 Submarine Rapido Balloon Dilatation Catheter

Product Structure

The Submarine Rapido balloon dilatation catheter is the US Medtronic-produced semi-compliant balloon. The proximal end of the balloon catheter shaft is a 2.3F single-lumen Hypotube surfaced with PTFE coating and connected with the distal lumen of the catheter. The distal shaft is

Table 3.2 Brand-specific RX balloon specifications (for reference only)

Name	Brand	Compliance	Balloon diameter (mm)	Balloon length (mm)	Matching wire (in)	Matching sheath (F)	Burst pressure (atm)	Delivery shaft (cm)
Sterling Monorail	Boston scientific	Semi-compliant	5–8	10–60	0.018	4–5	14	80, 135
LitePAC	Bard	Semi-compliant	2–7	15–220	0.014	4–5	12–16	150, 155
Submarine Rapido	Medtronic	Semi-compliant	2–7	20–80	0.018	4–5	16.7	135
Aviator plus	Cordis	Semi-compliant	4–7	15–40	0.014	4	12–14	142

3.5F. Catheter shaft and the balloon are all applied with hydrophilic coating. When the catheter gets moist, the hydrophilic coating functions as lubrication to the catheter.

Features and Models

The balloon dilatation catheter is specially used for endovascular dilatation treatment for carotid and renal artery lesions. The balloon matches with 0.46 mm (0.018in) wire and 4–5F vascular sheath. The balloon is 2–7 mm in diameter and 20–80 mm in length, available with 16.7 atm burst pressure and 135 cm in delivery shaft length.

3.4 Special Balloon Dilatation Catheter

3.4.1 Peripheral Cutting Balloon Dilatation Catheter

3.4.1.1 Product Structure

The Peripheral Cutting Balloon dilatation catheter (Fig. 3.5), the US Boston Scientific-produced non-compliant balloon, consists of 3–4 atherotome blades (microsurgical blade) mounted lengthwise on the balloon surface. The balloon is made of nylon. When the peripheral cutting balloon inflates, atherotome blades can cut the angiosclerosis plaque, thus forming the starting point for crack propagation.

The main body of the OTW type cutting balloon dilatation catheter is of dual-lumen design, the outer lumen being the balloon inflation lumen, and the inner lumen delivering the cutting balloon to the lesion portion to be expanded via the wire. At the end of the atherotome blades are radiopaque marker bands, providing a reference point after the placement of the balloon inside the blood vessels.

RX-type cutting balloon dilatation catheter contains two lumens. The proximal catheter handle is made of hypotube containing balloon inflation lumen. The distal handle is made of flexible material. The balloon tip and wire lumen are coated green, facilitating the observation and fast balloon exchange. Wire exit is located 24 cm from the catheter tip.

3.4.1.2 Features and Models

The balloon dilatation catheter is indicated for endovascular treatment of seriously calcified plaque, hard plaque, in-stent restenosis, and other vascular stenoses. At 6 atm pressure, the balloon will inflate to a specified diameter and length at a rated burst pressure of 10–12 atm. The balloon dilatation catheter can be divided into two types: OTW and RX.

- Cutting balloon with 5–8 mm diameter is OTW type balloon, suitable for matching with 0.46 mm (0.018in) wire; the balloon (including blade) is 20 mm in length, with four blades and 50 cm, 90 cm, and 135 cm in delivery shaft length.
- Cutting balloon with 2–4 mm diameter is RX type balloon, suitable for matching with 0.36 mm (0.014in) wire; the balloon (including balde) is 15 mm in length, with 3–4 blades and 140 cm in delivery shaft length.

3.4.2 VascuTrak Dual-Wire Balloon Dilatation Catheter

3.4.2.1 Product Structure

The VascuTrak Dual-Wire balloon dilatation catheter is the US Bard-produced RX-type semi-compliant balloon (Fig. 3.6). A steel wire is attached outside the balloon portion of the catheter. When the balloon inflates, the steel wire and the balloon attach with the vascular wall, playing a role of cutting the inner membrane inside the vascular lumen.

3.4.2.2 Features and Models

The balloon dilatation catheter is characterized by a small outer diameter, high lesion crossability, and ability of cutting the plaque, suitable for endovascular dilatation treatment for calcified vessels or in-stent restenosis. The burst pressure of the balloon is 12 atm, with 80 cm and 140 cm in delivery shaft length, and it can be divided into two types: VascuTrak 14 and

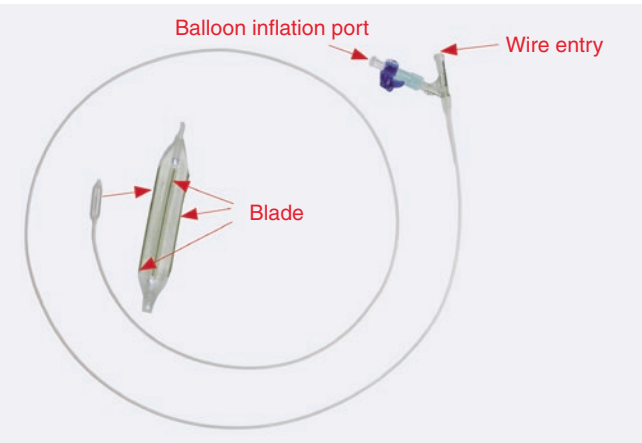

Fig. 3.5 Peripheral Cutting balloon dilatation catheter (Boston Scientific)

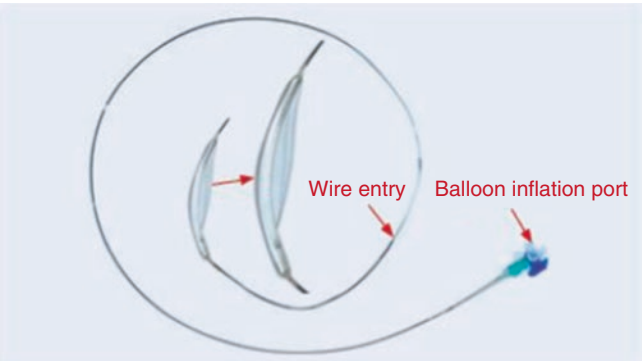

Fig. 3.6 VascuTrak dual-wire balloon dilatation catheter (Bard)

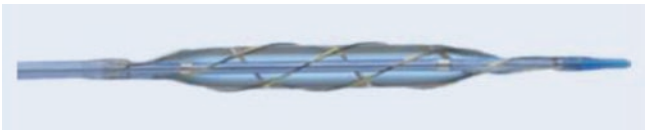

Fig. 3.7 AngioSculpt scoring balloon (Spectranetics)

VascuTrak 18 balloons. VascuTrak 14 is suitable for matching with 0.36 mm (0.014in) wire and 5–7F vascular sheath, with 2–3.5 mm in diameter and 20–300 mm in length. VascuTrak 18 balloon matches with 0.46 mm (0.018in) wire and 5F vascular sheath, available with 4–7 mm diameter and 20–30 mm length.

3.4.3 AngioSculpt Scoring Balloon

3.4.3.1 Product Structure

The AngioSculpt scoring balloon, the US Spectranetics-produced OTW semi-compliant balloon, consists of a balloon catheter with a triple-helical hollow tube laser engraved from Ni-Ti alloy (Fig. 3.7). When the balloon opens, an expansion force of 15–25 times larger than the balloon itself produces via the three helical Ni-Ti steel wires mounted outside the balloon, where the diameter of the steel wire is 0.18 mm. The expansion force, like a scoring, changes the tension of lesion tissue so that it can expand under very low balloon pressure.

3.4.3.2 Features and Models

The balloon is indicated for endovascular treatment for such lesions as calcified peripheral arteries and in-stent restenosis. The triple helical design of the AngioScuplt scoring balloon takes into account the balloon crossability, scoring function, and consistency in lumen diameter after expansion. The balloon is suitable for matching with 0.36 mm (0.014 in) and 0.46 mm (0.018 in) wires and 5–6F vascular sheath. The balloon is 2–8 mm in diameter and 20–200 mm in length, available with 12–20 atm burst pressure and 50 cm, 90 cm, 137 cm, and 155 cm in delivery length.

3.4.4 Drug-Coated Balloon

Drug-coated balloon mainly consists of drugs (paclitaxel, etc., requiring high lipid solubility), a matrix coating, and a balloon system carrier. Drug-coated balloon is designed based on the principle that the drug against vascular intimal hyperplasia is applied on the surface of the balloon via the matrix coating. When the balloon reaches the diseased vascular wall and is inflated so that it contacts with the inner membrane of the vascular wall, the drugs are released quickly and transferred into partial vascular wall, thus partially inhibiting vascular intimal hyperplasia and preventing occurrence of restenosis following the intimal hyperplasia. Drug-coated balloon does not simply mean to apply drugs on the balloon drug, but rather, it differs in various aspects, such as types of catheter drugs, the coating technique, and the release technique, from conventional balloon technology. For the drug-coated balloon, it is necessary to prevent as much as possible the drug from being flushed away by the blood flow during expansion, and the drug can be quickly released to vascular wall tissues shortly after the expansion (usually less than 60 s), rather than slowly eluted, where the role of the matrix coating technique is mainly reflected and where the difference with the drug-eluting stent lies. Therefore, many experts propose to change the name of the drug-coated balloon from its original drug-eluting balloon (DEB) to the present drug-coated balloon (DCB).

The drug-coated balloon acts primarily as a drug-loading system to resist intimal hyperplasia and prevent restenosis. In order to better retain the drug from eluting from the balloon before dilatation, it is necessary to carry out conventional balloon pre-expansion before the deployment of the drug-coated balloon. Drug-coated balloon has no continuous resistance against elastic retraction, which is mainly achieved by the stent. Therefore, the concept of using drug-coated ball and metal bare stents and drug-eluting stent is not contradictory, but rather a good complementary treatment program. At the same time, if serious dissection occurs after DCB dilatation, stent is stilled necessary for covering the dissection without exceeding the both ends of the drug-coated balloon. Currently, drug-coated balloons have extensive indications, including in-stent restenosis, bifurcation lesions, small blood vessels lesions, or positions unsuitable for or unable of placement of stents. Meanwhile, even if the drug-eluting stent is used, there will still be occurrence of restenosis, where the drug-coated balloon can well distinguish itself.

The drug-coated balloon is mainly characterized by:

- Advantages: Drugs are evenly distributed on the specific vascular wall areas (while for the drug-eluting stent, drugs are distributed on the stent beam structure). No metal remnants remain, retaining the original anatomical morphology of the blood vessels; the time of antiplatelet therapy shortens (1–2 years required for antiplatelet therapy after operation with the drug-eluting stent, but only 3–6 months for the drug-coated balloon).
- Disadvantages: Unavailable for preventing acute elastic retraction and treating acute dissection.

Currently, foreign DCB brands include Boston Scientific, Bard, Medtronic, Biotronik, etc., and Chinese brands include ACOMED and others.

Acotec Drug Balloon Dilatation Catheter

1. Product Structure
   Acotec drug balloon dilatation catheter, the China ACOMED-produced drug-eluting peripheral balloon

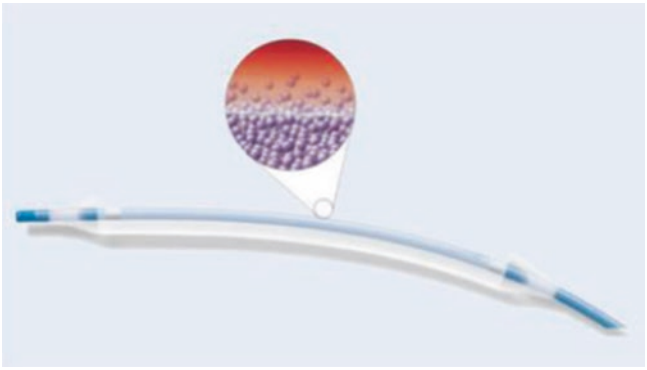

Fig. 3.8 Acotec drug balloon dilatation catheter (ACOMED)

(Fig. 3.8), consists of a balloon, a catheter tip, a dual-lumen shaft, Y connector, and radiopaque marker bands. The balloon is made of polyamide 12, surfaced with drug coating by way of solvent bonding. The coating contains paclitaxel at a dose of 3.3 μg per square millimeter, and the drug-loading matrix is magnesium stearate. This OTW-type balloon dilatation catheter can be classified as orchid type and dahlia type according to its matching wire.

2. Features and Models

This drug balloon dilatation catheter is indicated for percutaneous transluminal angioplasty of femoral artery and arteries. Orchid-type drug balloon adapts to 0.89 mm (0.035in) wire and 5–6F vascular sheath, available with 3–12 mm in balloon diameter and 20–300 mm in length. Dahlia-type drug balloon adapts to 0.46 mm (0.018in) wire and 5–6F vascular sheath, available with 3–12 mm in balloon diameter and 20–300 mm in length. The burst pressure of the balloon is 6–17 bar, with 80 cm and 120 cm in delivery shaft length.