

# DETACHABLE BALLOONS

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## Introduction

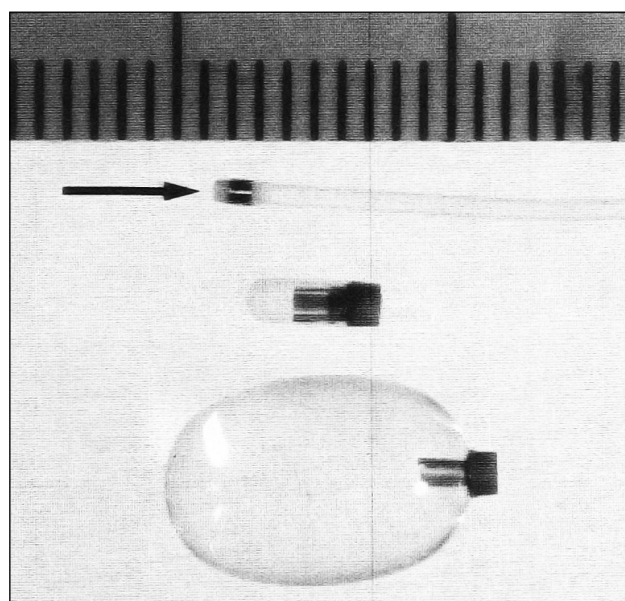
Embolic agents are devices used for the intentional occlusion or “embolization” of vascular structures. Detachable balloons are embolic agents which are tubular shape and a few millimeters in diameter before use. They are percutaneously introduced into the circulatory system mounted on a catheter about a millimeter in diameter and several centimeters in length. Once appropriately positioned, the balloons are inflated with about a milliliter of liquid into a sausage shape several millimeters in diameter. The catheter is then removed, leaving the balloon behind to occlude the desired vessel.

No detachable balloons are currently cleared for marketing in the United States by the Food and Drug Administration. They have been, however, in widespread compassionate use. One silicone (Detachable Silicone Balloon; DSB; Interventional Therapeutics Corporation; ITC (now Target Therapeutics Corporation); Fremont, California; Fig. 8.1) and one latex balloon (Debrun Tie-on; Nycomed, Paris, France; Fig. 8.2) are being used under Investigational Device Exemptions by a few centers (Table 1). These two balloons and four additional latex balloons (i.e., Gold Valve and Super Gold Valve, Nycomed, Paris, France; Fig. 8.3; Latex String Valve and Integral Valve, Balt, Montmorency, France) are currently in use throughout the world. One latex balloon is currently being used in

Ukraine (i.e., V.I. Shcheglov, Center for Endovascular Neurosurgery, Kiev, the Ukraine; Fig. 8.4). Another latex balloon is currently under development in the United States (i.e. G.M. Debrun, Medtronic-Micro Interventional Systems; Medtronic-MIS; Fremont, California).

## History

*Latex.* F. Serbinenko, a Russian, was the first to describe detachable balloons. He began using balloons made of latex in 1968 [1]. He presented his results at the First All-Union Congress of Neurosurgeons in Moscow and published his initial paper on the subject in 1971 [2]. He subsequently published several papers describing the use of detachable balloons [3, 4], most notably, “Balloon catheterization and occlusion of major cerebral vessels,” which appeared in the Journal of Neurosurgery in 1974 [5]. His group recently published a summary of their clinical experience with these devices



**Fig. 8.1.** Target Therapeutics “Apollo” DSB balloon deflated and inflated. The balloon may be attached to a Tracker-18 catheter (Target Therapeutics, arrow)

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**Table 8.1. Commonly used detachable balloons**

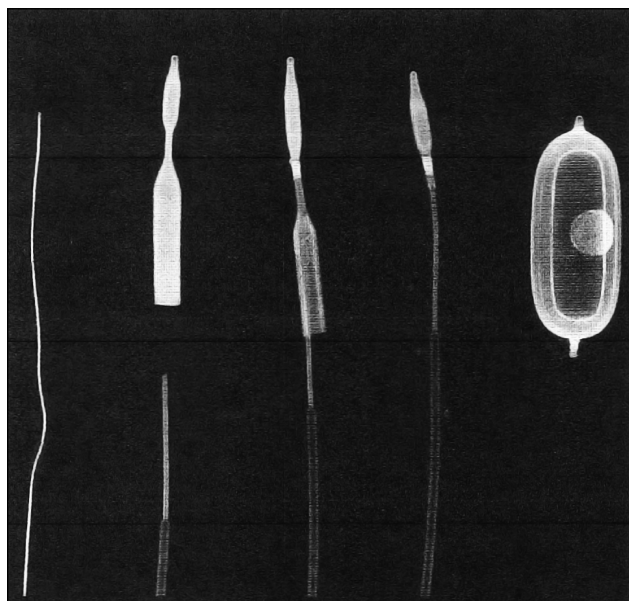
Company	Name & Catalogue #	Deflated Dimensions (Diameter × Length, mm)	Inflated Dimensions (Diameter × Length, mm)	Maximum Volume (ml)
ITC†	DSB 1509 L, M, H*	1.5 × 7.3	8.5 × 21.0	0.90
ITC†	DSB 1505 L, M, H*	1.5 × 5.1	7.5 × 13.5	0.50
ITC†	DSB 1815 L, M, H*	1.8 × 7.6	10.0 × 23.0	1.50
Nycomed	Debrun Tie-on GC #16	1.2 × 6.6	7.0 × 18.9	0.60
Nycomed	Gold Valve GVB #16	1.5 × 6.5	8.0 × 21.0	0.80
Nycomed	Debrun Tie-on GC #9	1.75 × 6.6	10.0 × 21.0	1.00
Nycomed	Gold Valve GVB #9	1.6 × 6.5	11.0 × 19.0	1.30
Nycomed	Debrun Tie-on GC #17	1.6 × 2.5	8.5 × 11.5	0.50
Nycomed	Gold Valve GVB #17	1.6 × 3.0	8.5 × 11.5	0.50

\* Refers to L – Low (20–30 gm), M – Median (30–40 gm), and H – High (40–55 gm) release-force range; † Now Target Therapeutics Corporation.

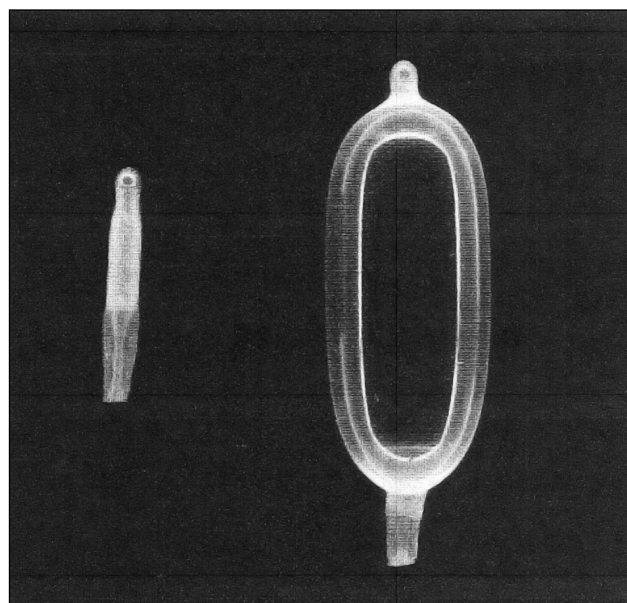
from 1974–1989 [6]. Although F. Serbinenko obtained a patent for his balloon in the United States, it has not been commercialized.

V. Shcheglov, a Ukrainian, first learned the principles of detachable balloons during visits with F. Serbinenko in Moscow in the early 1970's. After F. Serbinenko would complete a case, V. Shcheglov would collect the discarded detachable balloon materials and study them. He befriended a technologist of F. Serbinenko's who provided him with some of the raw materi-

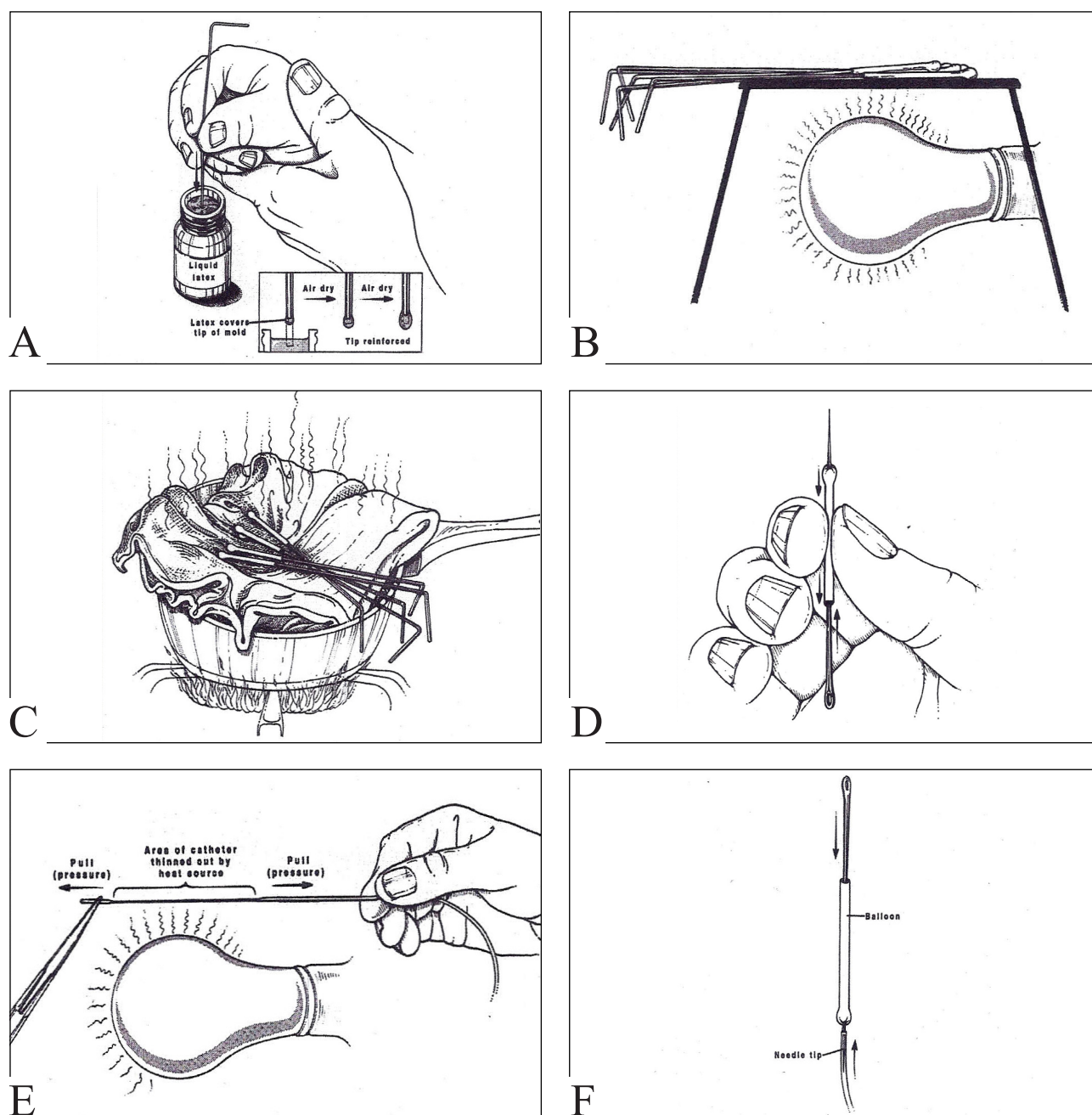
als required for constructing the balloons. Over the years, V. Shcheglov perfected his detachable latex balloon in his home using his kitchen stove. He used inexpensive materials he had manufactured in the Ukraine or obtained by favor and barter. V. Shcheglov has used this device to treat intracranial aneurysms in over a thousand patients since its original description 1976 [7–10]. Almost all treatments of intracranial aneurysms in the Ukraine today (population of 50 million) are done by V. Shcheglov with this detachable balloon. He constructs each balloon by hand prior to its use. Attempts to commercialize V. Shcheglov's balloon have been unsuccessful.



**Fig. 8.2.** Nycomed Debrun Tied-on balloon. From left to right latex thread; catheter and deflated balloon; deflated balloon tied on to catheter with latex thread and excess latex trimmed away; and inflated detached balloon



**Fig. 8.3.** Nycomed Gold Valve balloon deflated and inflated



**Fig. 8.4 (Part 1).** Materials required for construction of V. Shcheglov balloons polyethylene catheter (Center for Endovascular Surgery Kiev, Ukraine); liquid latex (Center for Endovascular Surgery Kiev, Ukraine); balloon mold (approximately 18 Gauge wire at least 3 inches long with a blunt tip); sewing needle; monofilament suture or thread silver market (approximately 21 Gauge wire); heat source (light bulb); steam source (stove pot with water); bowl of talcum powder; cheesecloth; hemostats; and forceps

A — the tip of the mold is dipped in the latex several times with complete air drying between each coat of latex. The off-white opaque latex dries to a yellow semi-clear color. It is important to keep the latex well stirred and to skim the surface intermittently. A magnifying glass is helpful. The mold is dipped further into the latex several times with complete air drying between each coat of latex. The mold is dipped in talcum powder; B — the mold is “baked” for 30 minutes by placing near a covered light bulb; C — the mold is held over a steam pot covered with cheesecloth for about 20 minutes. The balloon is removed from the mold and once again “baked” for about 30 minutes. It is then cut to usable length; D — a sewing needle is introduced into the open end of the balloon and passed through the closed end; E — the catheter is held over a light bulb while stretching in order to taper the end of the catheter. The thinned area of the catheter is cut with a sharp razor blade to yield a tapered segment of 1.5 to 2.5 cm in length; F — the thinned end of the catheter is pushed on to the tip of the needle which has been coated with a light synthetic oil



Debrun described and patented another detachable balloon system made of latex in 1975 [11, 12]. This was the basis for the Nycomed. “Debrun Tie-on” and Balt “Latex String Valve” balloons that are available today. Some have said that Debrun patterned his balloon after one previously developed by Y. Zubkov in Russia. O’Reilly described a detachable latex balloon in 1984 which was the basis for the Nycomed “Gold-Valve” balloon commonly used today [13].

D. Rufenacht [14] and F. Brassel, independent of one another designed a similar detachable latex balloon which is the basis for the Balt “Integral Valve” balloon that is currently available. The balloon is similar to the “Debrun Tie-on” balloon, however, it uses a different type of delivery catheter and attachment mechanism. Instead of a coaxial catheter, it uses a double lumen catheter. Instead of attaching the balloon on the catheter with a latex thread, variable size washers are placed on the end of the delivery catheter and the balloon is stretched over these. It was widely used for treating intracranial aneurysms; however, since the description of various detachable coil systems for treating aneurysms, its use has declined. Other detachable latex balloons have been described in Russian [15, 16].

*Silicone.* In 1976, M. DiTullio et al. [17, 18] described a detachable balloon made of silicone which was made by the Dow Corning Company (Midland, Michigan). G. Hieshima et al described a similar balloon in 1980 which was made by the Heyer-Shulte Company (Goleta, California) [19]. This balloon was the basis for the ITC/Target “DSB” balloon commonly used today [20].

J. Pevsner also described and patented a detachable balloon made of silicone in 1977 [21, 22]. It was manufactured under license by the Becton-Dickinson Company (Rutherford, New Jersey). J. White et al. reported the results of several animal and human studies performed with this balloon [23–29]. The balloon was withdrawn from the market in the late 1980s.

Two innovations in detachable balloon design came from investigators in Japan. M. Taki et al. described a detachable balloon system which had two microelectrodes in the wall of the delivery catheter. When the balloon was appropriately positioned it was detached by applying a current that melted the tip of the delivery catheter [30].

T. Makita et al. described wire-directed detachable balloons [31]. They successfully placed them in the intended vessels of dogs. These devices did not become widely available outside Japan.

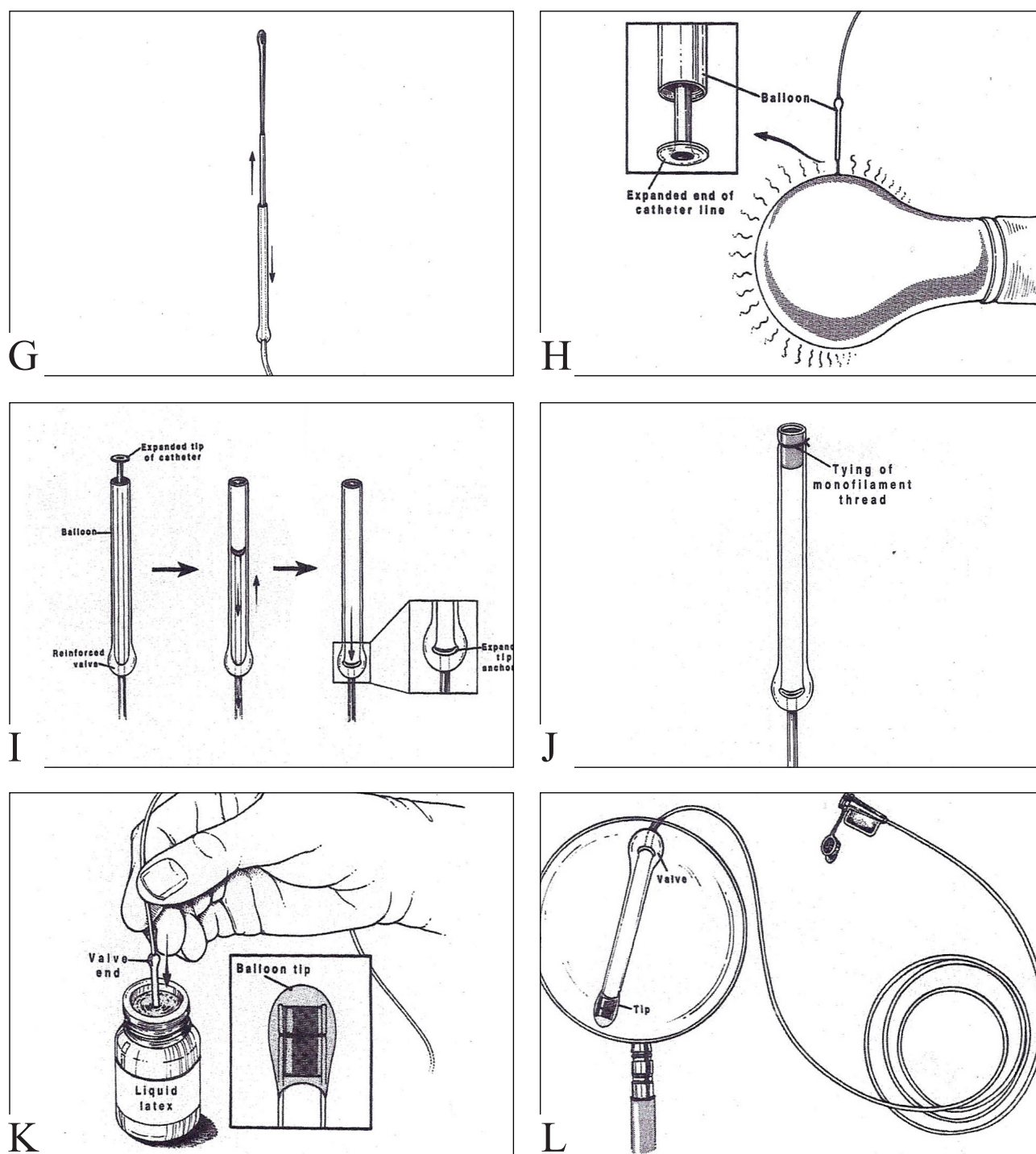
## Description

*Nycomed Latex Detachable Balloons.* The Nycomed balloons are made from latex and have a radiopaque gold marker. A number of sizes and shapes are available. They come with (Gold Valve and Super Gold Valve) and without (Debrun Tie-on) an integral valve. The Super Gold Valve balloon is similar to the Gold Valve except that the valve does not protrude from the base of the balloon. Those without an integral valve must be secured to the delivery catheter with a latex thread. The two most commonly used are the number 9 and 16 balloons. The numbers refer to the chronological numbers of the original molds used to construct the balloons.

The Debrun Tie-on balloons are usually delivered with a coaxial catheter consisting of a red inner 2F Teflon catheter, intended to carry the latex balloon, and a black outer 3F Teflon catheter which is used to “push” the balloon off the 2F catheter when appropriate (#CCOXLS). The Gold Valve balloons can be delivered with the same coaxial catheter or with a Teflon tipped catheter manufactured by other companies.

Some believe latex is superior to silicone for construction of detachable balloons because of its greater elasticity. The coefficient of elasticity of latex is approximately eight compared to four silicone [32]. This means that deflated balloons measuring 2 mm in diameter can be inflated to 16 mm if made of latex and only 8 mm if made of silicone. Latex balloons should also therefore be more durable when inflated to the same degree as silicone balloons.

Latex balloons are not semipermeable like silicone balloons. For this reason, the osmolarity of the contrast that is used to inflate them is not as crucial as with silicone balloons [33]. Latex is thought to incite more of an inflammatory response than silicone which should therefore yield more permanent vessel closure. Other major advantages of the Debrun Tie-on latex balloons over silicone balloons are their much more secure attachment to the delivery catheters and their reduced cost.



**Fig. 8.4 (Part 2).** Materials required for construction of V. Shcheglov balloons polyethylene catheter (Center for Endovascular Surgery Kiev, Ukraine); liquid latex (Center for Endovascular Surgery Kiev, Ukraine); balloon mold (approximately 18 Gauge wire at least 3 inches long with a blunt tip); sewing needle; monofilament suture or thread silver market (approximately 21 Gauge wire); heat source (light bulb); steam source (stove pot with water); bowl of talcum powder; cheesecloth; hemostats; and forceps

*G* — the thinned tip of the catheter which is mounted on the needle, is pulled back through the closed end of the balloon end out the open end of the balloon; *H* — the thinned tip of the catheter is flared by touching it to a light bulb; *I* — the flared tip of the catheter is pulled back into the balloon and seated against the closed end; *J* — a silver marker is inserted into the open end of the balloon and secured by tying a monofilament around the end of the balloon which holds the silver marker; *K* — the open end of the balloon is dipped in latex and air dried; *L* — completed catheter-balloon system

*Interventional Therapeutics Corporation / Target Therapeutics Silicone Detachable Balloons*. Interventional Therapeutics Corporation DSB detachable balloons are made from "... uniquely blended, biocompatible, non-biodegradable silicone elastomers." It has been claimed that this material is superior to latex for construction of balloons because it is softer and it expands in a more gradual fashion, thereby causing less vessel trauma during delivery. They come in a variety of sizes. The two most commonly used are the #1509 and #1815. The first two numbers refer to the deflated diameter (i.e., 1.5 mm and 1.8 mm) and the second two numbers refer to the maximum inflated volume (i.e., 0.9 ml and 1.5 ml). The balloons have an integral valve which comes in three different detachment strengths (L, M, H; low, medium, and high). They are usually delivered on a 2 French polyethylene catheter (#CS30002). They can also be delivered on polyethylene tipped catheters manufactured by other companies.

Unlike the Nycomed Debrun Tie-on latex balloons, ITC/Target DSB balloons come pre-assembled for use. Although Nycomed Gold Valve balloons come preassembled, they do not have a choice of different detachment strengths like the ITC /Target DSB balloons. In contrast to Nycomed and Balt, Target has applied for Investigational Device Exemptions and marketing approval of its balloons in the United States and tests every balloon prior to shipping.

### Investigations

Numerous *in vitro* and *in vivo* animal investigations of latex and silicone detachable balloons have been reported in the literature since the early 70s [11, 12, 18, 19, 24, 25, 29, 31, 33–53].

*In vitro*. The effectiveness of detachable balloons is dependent on their safe delivery to the vessel of interest, their atraumatic inflation, and their ability to remain inflated for an appropriate length of time.

One of the feared complications of detachable balloon therapy is spontaneous or premature detachment of the balloon during placement with resultant occlusion of undesired vascular territories [41, 54–63]. I. Pollak et al. compared the forces of detachment and the durability of inflation of three different balloons [41] and concluded

that any of these devices should adequately block most or all vessels. L. Monsein et al. have demonstrated that currently available latex balloons can be more firmly attached to delivery catheters than currently available silicone balloons and therefore should offer significantly less risk of premature detachment [64].

B. Schueler and D. Rufenacht studied the relationship between balloon inflation pressure, cerebral artery dilatation, and balloon rupture [40]. Pressures within inflated balloons vary with balloon type, material, degree of inflation and constraint. Constrained (within a vessel) balloons have markedly higher internal pressures, which may lead to vessel rupture if balloons are much larger than the vessel diameter.

The length of time a balloon remains inflated can be due to the material it is made out of, its construction or the liquid used to inflate it. Studies have been done to evaluate the permeability of balloons, causes of deflation, and various inflation materials. T. Tomsick studied the effect of osmotic content on long-term inflation of latex balloons [33]. He concluded that osmotic influence had little effect on short-term latex balloon inflation *in vitro*. Balloon inflation *in vivo* does not parallel inflation *in vitro*.

This was later confirmed by T. Hawkins and K. Szaz [36] who studied the permeability of latex balloons by filling the balloons with varying concentrations of metrizamide (a water soluble contrast agent) in tritiated water (HTO). They showed that the wall of the balloon is permeable to tritiated water, but not to a significant quantity of metrizamide. The passage of HTO through the wall of the balloon was unrelated to the concentration of metrizamide within the balloon, and therefore unrelated to the osmotic gradient between the balloon contents and the surrounding plasma. Therefore, deflation of a balloon *in vivo* is not due to an osmotic gradient between the contents of the balloon and the surrounding plasma. It is more likely due to damage of the balloons during manipulation, use of time-expired balloons, or escape of contrast from poorly tied balloons.

K. Goto et al. described the use of homopolymers of 2-hydroxyethyl methacrylate (HEMA) as a permanent inflation agent [37]. In their study, they used metrizamide and HEMA to permanently inflate silicone balloons. They found that at least

a 429 % solution of HEMA was required for the balloon to completely solidify. L. Monsein et al. [39] and subsequently others [38] (ApSimon, HT and Hodes, JE by personal communication) studied the compatibility of latex balloons with different compositions of silicone and HEMA. They found that HEMA can cause degradation of latex balloons and therefore it should not be used with them.

*In vivo.* A variety of animal models have been used to demonstrate the feasibility and histological nature of using detachable balloons for the treatment of various vascular disorders. In 1975, Debrun demonstrated the possibility of using latex balloons to treat arteriovenous fistulas utilizing a dog model of fistulas. Twelve out of 12 carotid-jugular fistulas were successfully treated.

Several other investigators have used various animal models to develop methods for the treatment of cerebral malformations [18, 34, 35, 43, 44]. B. Liliequist et al. [44] occluded the carotid artery of pigs successfully with a latex balloon.

T. Tomsick et al. and M. DiTullio et al. also successfully used detachable balloon to occlude experimental carotid-jugular fistulas in a canine model [18, 35].

G. Geremia et al. used a canine model of artificially induced aneurysms to facilitate training in using latex balloons [43]. The model was suitable for practicing detachable balloons techniques and for studying the pathologic consequences of this mode of treatment in an animal model. The catheters and balloon systems used are nearly identical to those used in the treatment of human cerebral conditions via the femoral approach.

R. Quisling et al. also demonstrated the feasibility of using latex balloons to treat arteriovenous fistulas utilizing a rat model of high-flow fistulas [45, 46]. Twelve out of 12 aortocaval fistulas were successfully treated. Two fistulas recurred due to premature balloon deflation. They also examined the associated histological changes, which could be divided into three phases. The acute phase occurred during the first two weeks, and was associated with acute thrombosis of the vena cava and occlusion of the fistula. This was followed by an intermediate or subacute phase, where the acute inflammatory reaction and acute thrombosis were replaced by fibrosis of the thrombus. Finally, the chronic stage was marked by decreased inflammation and progressively in-

creased fibrosis of the fistula site. The latex balloon became encapsulated by the fibrotic reaction, but remained nonadherent and was easily removed at all study intervals. No abscess formation or vasculitis was reported.

S. Miyachi et al. [47] compared the histopathology of silicone and latex detachable balloons used to embolize bilateral, symmetrical, experimental aneurysms produced with an anastomosed vein flap in the carotid arteries of 24 mongrel dogs. There was delayed endothelialization around the silicone balloons as compared to the latex balloons. This could account for movement of the silicone balloon within the aneurysm leading to trauma to the aneurysm wall, and contribute to rupture of the aneurysm. The great number of parent artery occlusions with the latex balloons could be attributed to the increased thrombus formation around latex balloons as compared to the silicone balloons. If the tail of the latex balloon protruded into the parent artery thrombus formation, then parent artery occlusion was more likely to occur. S. Miyachi et al. proposed that silicone balloons are more dangerous than latex balloons.

C. Heilman et al. did a similar study, comparing the histological changes occurring after embolization with silicone and latex balloons in a rabbit model of aneurysms [48]. Results were similar to the S. Miyachi et al. study. Latex balloons exhibited more of a fibrotic response than silicone. This study also demonstrated the need for follow-up angiography to check for aneurysm recurrence.

R. White et al. have studied embolization techniques using silicone balloons in swine [24, 29, 49]. They studied the long-term effects of balloon embolization in maintaining vascular occlusion, and the effects on occluded arteries and tissues [29]. They also studied various radiopaque fillings for silicone balloon embolization [49]. They demonstrated that the duration of silicone balloon inflation was related to the concentration of contrast used to inflate the balloon. The silicone acts as a semipermeable membrane. They demonstrated that silicone balloons offer an effective method of performing selective vascular occlusions. The balloon was incorporated into the vessel walls by organized thrombus at the level of the occlusion. There was minimal inflammatory reaction at the site of the organized thrombus around the balloon.



V. Graves et al. studied the flow dynamics of lateral carotid artery aneurysms and their effects on coils and balloons in a canine model [50]. The effect of intra-aneurysmal flow on balloons was significant and capable of modifying the position of the balloon. The balloon was in a stable position if it completely blocked the aneurysm with no inflow zone.

### Clinical Use

Detachable balloons have primarily been used for the treatment of cerebral aneurysms [10, 65, 66], carotid-cavernous fistulas [67, 68], pulmonary arteriovenous malformations [28, 69], and varicoceles [27, 69].

Potential complications of balloon embolotherapy include intra-arterial balloon rupture [57], spontaneous or premature detachment [41, 54–63], shrinkage [67, 70], migration [57, 58, 70], vessel rupture or occlusion [54, 57, 67], normal pressure perfusion breakthrough [71],

pseudoaneurysm formation [63, 70, 72], cranial nerve deficits [32, 57, 67, 73], and death [56].

### Conclusion

Detachable balloons are an excellent embolic agent for the occlusion of large arteries and veins. They are safe, effective, easy-to-use, and inexpensive. They come in a variety of sizes and shapes which can be dynamically altered by different degrees of inflation.

Latex and silicone detachable balloons have been extensively compared regarding a number of properties including their permeability, compatibility, geometry, sterility, quality control, packaging, histological reaction, inflation, deflation, and detachment characteristics. In the United States, the choice of a detachable balloon has largely been determined by availability and training. Whichever system is chosen, one should be well informed and skilled in its use before using it clinically.

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