

Canon Communications LLC Publication

September 2000

Medical device & diagnostic industry.

22, no. 9 (Sept. 2000)

General Collection

W1 ME29661

Received: 09-21-2000

DEVELOPMENT & MANUFACTURING ELECTRONIC DEVICE & DIAGNOSTIC INDUSTRY

THE MAGAZINE OF MEDICAL PRODUCT DESIGN, MANUFACTURING, AND MARKETING

<http://www.devicelink.com/mddi>

Design Control Strategies

Updating traditional
methods to keep pace
with new technologies,
p. 76



PROPERTY OF THE
NATIONAL
LIBRARY OF
MEDICINE

**High-Pressure
Balloons for
Medical Devices,
p. 86**

**Workforce Quality:
A Site Selection
Priority, p. 98**

**COMPONENT
SUPPLIERS
DIRECTORY, p. 114**

MDDI 15106 55 99*****3-DIGIT 208
SERIAL RECORDS C 412
NATL LIBRARY OF MED
8600 ROCKVILLE PIKE
BETHESDA MD 20894-0002



Presenting...
HelixMark™
 By The Trusted Source
 for Silicone Products

Reinforced Silicone Tubing



Silicone Tubing



Silicone Sanitary Gaskets



Silicone Stoppers



Helix Medical is the world's
 only manufacturer to focus
 exclusively on silicone products
 for the medical & pharmaceutical
 community. We are a global
 leader in the development &
 manufacturing of BioMedical/
 Pharmaceutical Grade Platinum-
 Cured Silicone Products.

Choose only
 the best...
 Call for a free catalog today!

16 Years
 Experience
 Manufacturing Silicone
 Products

Standard Tubing Available

On The Shelf

The Industry's Widest Selection
 of Material Choices



GE Silicones

WACKER

DOW CORNING

HELIX
 MEDICAL, INC.

CALL TODAY for a free catalog or to order:
(800) 266-4421

1110 Mark Avenue
 Carpinteria, CA 93013, USA
 Email: sales@helixmed.com
 FAX: (805) 684-1934
 www.helixmed.com

FDA registered
 ISO 9001
 EN 46001

MEDICAL DEVICE & DIAGNOSTIC INDUSTRY

PUBLISHER

William F. Cobert

EDITORIAL DIRECTOR

John Bethune

ASSOCIATE EDITORIAL DIRECTOR

Steven Halasey

EDITOR

Jon Katz

EXECUTIVE EDITOR

Gregg Nighswonger

MANAGING EDITOR

Robert Drummond

ASSISTANT EDITORS

Ani Grigorian

Kira Prater

EUROPEAN EDITOR

Norbert Sparrow

PROOFREADERS

Debra Duff, Stephen Levy,

Annie Lubinsky

CONTRIBUTING EDITORS

James G. Dickinson

Greg Freiherr

Jonathan S. Kahan

Michael E. Wiklund

ART DIRECTOR

Tom Medsger

ASSOCIATE ART DIRECTOR

James Schlesinger

ASSISTANT ART DIRECTORS

Marco Aguilera, Taisha Payton

PRODUCTION DIRECTOR

David S. Sutton

PRODUCTION MANAGER

Roger Burg

ELECTRONIC PREPRESS MANAGER

Michael Ciardiello

ASSOCIATE PRODUCTION MANAGER

Martin Schneggenburger

ASSISTANT PRODUCTION MANAGER

Brian Wu

PRODUCTION COORDINATOR

Tanya Von Grumbkow

DIGITAL AD COORDINATOR

Carlos Flores

SENIOR PRODUCTION ARTIST

Jeff Polman

PRODUCTION ARTISTS

Ricardo Esparza, Juan Gonzalez,

Thomas Hultgren, Hagit Worona

CIRCULATION DIRECTOR

Willy Bruijns-Miller

CIRCULATION MANAGER

Camille Phillips

ADVERTISING INFORMATION

310/445-3700, Fax: 310/445-3799

DIRECTOR OF SALES

Ed Sexton

ASSOCIATE DIRECTOR OF SALES

Justine Miller

SALES MANAGER

Howard A. Revitch

(973/808-8942)

ACCOUNT EXECUTIVES

Southwest: Mandy V Harrison

(310/445-3710)

Northwest: Alaleh Konoudi

(310/445-3717)

Midwest: Neal Halter

(310/445-3716)

Eastern: Julie Steinkraus

(973/808-9445)

Northeast: Keith Parry

(973/808-6554)

North Central: Rick Rosenberg

(973/808-1221)

LIST RENTAL AND REPRINTS

SueEllen Belliveau

DIRECT MARKETING ACCOUNT EXECUTIVE

Rebecca Bermudez

CLASSIFIEDS ACCOUNT EXECUTIVES

Xavier Contaot, Donald Elliott,

Gina Martire

DIGITAL MEDIA SALES MANAGER

Lisa Bradley

DIGITAL MEDIA ACCOUNT EXECUTIVE

Tahirah Uqдах

INTERNATIONAL SALES

Colin Martin

European Sales Manager

Tel: +44 1233 624915

Fax: +44 1233 620945

Hermann Jordi, Charlotte Hasler,

Laura Polidori

Italy, Switzerland, Western Austria

Jordi Publipress

Utzenstorf, Switzerland

Tel: +41 32 6653186

Fax: +41 32 6655233

Other Regions

Tel: +1 310 4453700

Fax: +1 310 4453799

Medical Device & Diagnostic Industry (ISSN 0194844X) is published monthly by Canon Communications LLC, 11444 W. Olympic Blvd., Los Angeles, CA 90064; 310/445-4200; FAX 310/445-4299. Periodicals postage paid at Los Angeles, California, and at additional mailing offices. SUBSCRIPTIONS—Free to qualified subscribers as defined on the subscription card. Basic subscription price \$125 (one year). Delivery outside United States by air service. For telephone inquiries regarding subscriptions call 651/686-7824. Back issues: \$10 per copy, prepaid. CHANGE OF ADDRESS—Notices should be sent promptly to P.O. Box 21651, St. Paul, MN 55121. Please provide old mailing label as well as new address. Allow two months for change. EDITORIAL CONTRIBUTIONS—Unsolicited manuscripts should be submitted in triplicate and should be accompanied by stamped return envelopes. Copy will receive every reasonable care; however, the publishers assume no responsibility for safety of artwork, photographs, or manuscripts. NOTICE—Every precaution is taken to ensure accuracy of content; however, the publishers cannot accept responsibility for the correctness of the information supplied or advertised or for any opinion expressed herein. POSTMASTER—Send address changes to *Medical Device & Diagnostic Industry*, P.O. Box 21651, St. Paul, MN 55121. Canadian Post International Publications Mail Product (Canadian Distribution) Sales Agreement No. 0589527. Printed in U.S.A. ©2000 by Canon Communications LLC. All rights reserved. Reproduction in whole or part without written permission is prohibited.

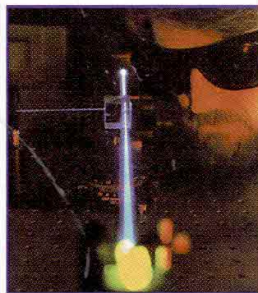


SPECIALIZING IN Low to Mid Volume CONTRACT MANUFACTURING

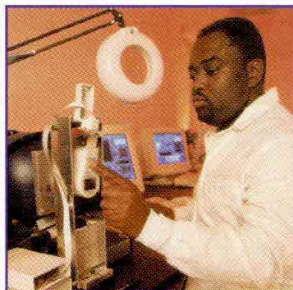
- ✓ Prototypes/Short Runs
- ✓ Class I/II Medical Devices
- ✓ FDA Registered Facility
- ✓ ISO 9001 Registered
- ✓ EN 46001 Registered
- ✓ Also Non-Medical Devices



- Electro-Mechanical Assembly
- Box Build
- Disposable Assembly



- Spectrophotometry
- Optics Assembly
- Lasers



- Functional Test
- Full Traceability

Packaging • Direct Distribution • Depot Repair

SPECTR_X

SpectRx, Inc.
Norcross, GA 30071
Tel: (770) 242-8723
Fax: (770) 242-8651
Contact: Scott Kellogg
Email: skellogg@spectrx.com



Visit our website: www.spectrx.com/mfg

MEDICAL DEVICE & DIAGNOSTIC INDUSTRY

Canon Communications LLC Corporate Staff

William F. Cobert
President & CEO

FINANCE

Daniel Koskovich
Chief Financial Officer
Christine Danzeisen
Accounting Manager
David Harris
Treasury Manager
Chau Do
Senior Accounts Payable Clerk
Christine Hang
Accounts Payable Clerk
Jason Allen
Credit & Collections
Anna Bodden
Senior Staff Accountant
Le Tran
Staff Accountant
Selemawit Asrat
Adriana Flores
Accounts Receivable Clerks

OFFICE ADMINISTRATION

Erie Feragne
Office Manager
Rick Cortez
Senior Mail Room Clerk
Diana Cortez
Office Clerk
Martyn Lewis
Office Administrative Assistant
Robert Kingsley
Mail Room Clerk
Sheila Rosenfeld
Administrative Assistant
Linda Richardson
Receptionist
Dawn Ortiz
Administrative Clerk

HUMAN RESOURCES

Charleen Bonney
Director of Human Resources
Le Dawn Dyson
Sheba Kane
Human Resources Assistants

INFORMATION SYSTEMS

Nick Nguyen
IT Manager
Dennis Reveche
Systems Analyst
Elmer Alcantara
Systems Administrator
Rollie Balao
Dean Bruni
Pedro Garcia
Elmer Tolentino
Help Desk Analysts

CIRCULATION/SUBSCRIPTIONS

Willy Bruijns-Miller
Circulation Director
Sandra Martin
Camille Phillips
Circulation Managers

Carol Hernandez
Carlota Valle
Circulation Assistants

Lynnel Resnick
Reader Service Coordinator

EDITORIAL SUPPORT

John Bethune
Editorial Director
Steve Halasey
Associate Editorial Director
Gabriel Spera
On-line Editor
David Bowen
Associate On-line Editor
Patricia Harada
Administrative Assistant

PRODUCTION

David Sutton
Production Director
Jeff Tade
Associate Production Manager
Norman Nathan
Tanya Von Grumbkow
Production Assistants
Jodi Rochford
Collateral Production Manager
Maria del Campo
Maria Jimenez
Collateral Production Coordinators
Kimberly Atwood
Design & Production Supervisor
Blaine Barkey
Sherry Spencer
Collateral Production Artists

PUBLICATIONS SALES

Ed Sexton
Director of Sales
Justine Miller
Associate Director of Sales
Colin Martin
European Sales Manager
Howard A. Revitch
Sales Manager

Danielle Matthews
Office Manager
Tram Tran
Sales Analyst
Tonna Anuligo
Digital Media Sales Support

Sochin Lee
Senior Sales Assistant
Salvador Aceves
Janine Mangino
Manny Pedraja
Keith Rhodes
Katie Sauter
Sales Assistants

PUBLICATIONS MARKETING

Tom Baker
Marketing Research Analyst
Lindee Levicke
Promotions Manager
Mary Hoegy
Promotions Coordinator
Phyllis Simpson
Marketing Services Coordinator

TRADE SHOW DIV.
310/445-4200

Diane O'Connor
Director of Trade Shows
David Holman
Financial Administrator
Kelvin Tran
Database Administrator
Cindy Tuzzolino
Administrative Assistant

Registration Department

Karen Zisko
Registration Manager

Trade Show Conference

Mary Gordon
Conference Manager

Trade Show Marketing

Daniel Cutrone
Marketing Manager
Suzanna Rosemont
Assistant Marketing Manager
Lisa Yoshida
Senior Marketing Coordinator
Chad Rutt
Annabella Vicente
Marketing Coordinators
Gretchen Hawley
Public Relations Coordinator
Erin Hakes
Public Relations Assistant
Margaret Chau
Sabrina Hwang
Assistant Marketing Coordinators

Trade Show Operations

Roger White
Operations Manager
Marni Barranco
Rhonda Williams
Senior Operations Coordinators
Anna Sussman
Operations Coordinator

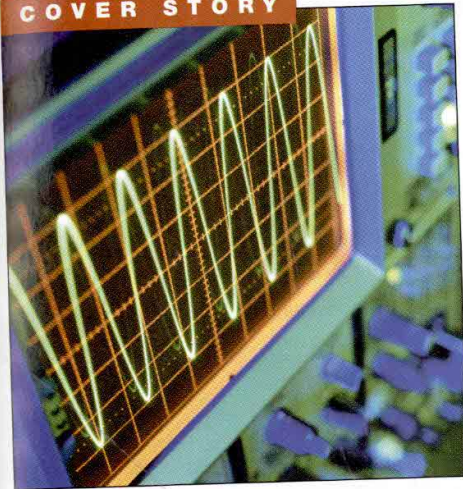
Trade Show Sales

Kevin O'Keefe
Sales Manager
Mark Temple-Smith
European Sales Manager, Exhibitions
Amy Lindstrom
Sales Operations Manager
Lisa Kerr
Daniel Montoya
Sales Secretaries
Marilyn Campanelli
Sharon Coyle
Cathy Engel
Charlie Engel
Erwin Laner
Ellen Locke
Nancy Niver
Joseph Privitera
Jane Sullivan
Tami Tirgrath
Account Executives
Kasey Gilmore
Assistant Account Executive

MEDICAL DEVICE & DIAGNOSTIC INDUSTRY

TABLE OF CONTENTS ▼ SEPTEMBER 2000

COVER STORY



DEVELOPING DESIGN CONTROL STRATEGIES TO MEET TECHNOLOGY ADVANCES

To take full advantage of emerging technologies, manufacturers need to update their design control model.

76

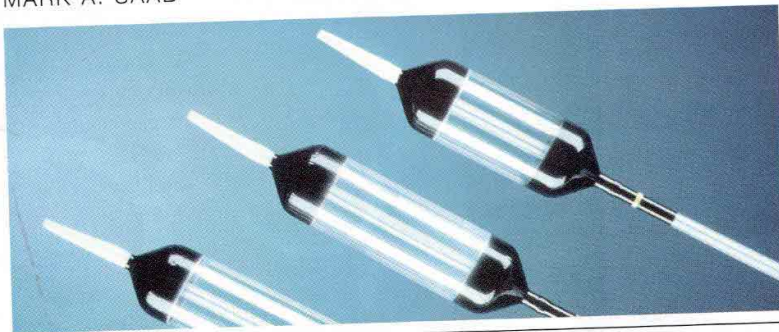
Cover photo by Andrew Brookes/The Stock Market

DAN OLIVIER

FEATURES

86 ▼ High-Pressure Medical Balloons: Expanding the Design Options

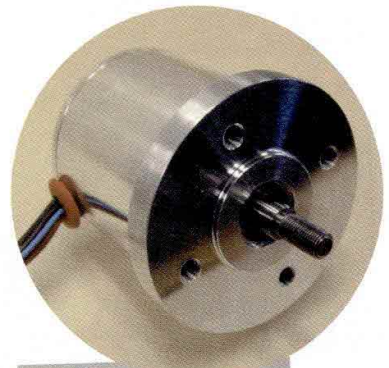
Increased device applications for balloons reflect technology advances and the growing prominence of minimally invasive procedures.
MARK A. SAAB



98 ▼ Workforce Quality: A Key Priority in Relocation and Expansion

How can medical device companies involved in site selection assess whether an area is likely to offer a well-trained and stable workforce?

MARK TURNER



106 ▼ Controlling Noise and Vibration in Brushless Motor-Driven Devices

Well-conceived designs for both internal and external motor system components can help reduce unacceptable noise and vibration.

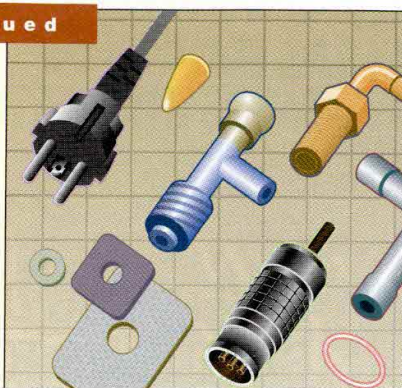
FRANK LEONG

FEATURES continued

Directory to COMPONENT SUPPLIERS

Company Listing 114

Components Categories . . 133



Medical Plastics and Biomaterials SPECIAL SECTION



Profiling: The Missing Link in Measurement Technology

64

With noncontact, laser-based technology, components that previously could only be measured via manual methods can now be inspected rapidly, automatically, and accurately.

JON GAMBLE AND JIM KIMMET

MPB Bulletin Board

Medical materials news.

74

COLUMNS

Washington Wrap-Up

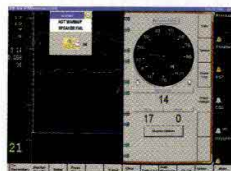
38

Product liability suits under
FDA law?

James G. Dickinson

R&D Horizons

46



Virtual instrumentation boosts
capabilities and reduces costs

William Loob

DeviceLink Digest

58

Web site keeps medical industry



connected
to FDA
Tuan Phan
and Gabriel
Spera

UP FRONT

Editor's Page

14

News & Analysis

18



Can wireless prescription systems
reduce medication errors? • Needle
design improves bone marrow
biopsies • Radiolucent composites
meet requirements for surgical tools
• Notice of intended rule making by
HCFA draws additional comments
• Expansion of CABG trials approved
• E-commerce redefines the supply
chain and distribution process

DEPARTMENTS

Web Mart

142

Products & Services

146



The latest in
components,
equipment,
materials,
services, and
supplies, with a
focus on extrusion.

Calendar

174

Classifieds

177

Advertisers Index

183

NEXT MONTH

- Salary Survey
- MD&M Minneapolis Preview
- Quality

NATIONAL LIBRARY OF MEDICINE



NLM 01889718 6

A Perfect Blend

M V T R



C O E F F I C I E N T

MEDIFILM® 437

Announcing MEDIFILM® 437, which blends a high MVTR with a very low coefficient of friction, giving you the benefits of both in one standard component film. This new Aliphatic, Polyether-based film is available in a variety of finishes, pigments, additives, carriers and hypoallergenic adhesives. Plus, you can order it in thicknesses of 1/2 mil to 10 mil and in roll widths of 1" to 61".

MEDIFILM® 437, a perfect alternative to custom manufacturing and an ideal standard component for wound care dressings.



Your One Source

MYLAN TECHNOLOGIES INC.

110 Lake Street • St. Albans, VT 05478

800-532-5226 • Fax: 802-527-8151

www.mylantech.com

Circle Reader Service 12

Front Line Med. Techs., Inc. Ex-1006-6

Applications of High-Pressure Balloons in the Medical Device Industry

Advances in balloon technology have opened up endless design possibilities, including both specialized and multifunctional devices.

Mark A. Saab

RECENT ADVANCES in the design and fabrication of high-pressure medical balloons have enhanced their performance capabilities and broadened their use into new applications in the device industry. Developed in the late 1970s, high-pressure balloons have traditionally been used in angioplasty, a procedure that opens a blood vessel clogged by a buildup of fatty plaque. The balloon, tightly wrapped around a catheter shaft to minimize its profile, is inserted through the skin and into the narrowed section of the vessel. Inflating the balloon—typically with saline or a radiopaque solution forced through a syringe—exerts high pressure, which compresses the plaque against the wall of the vessel and allows the blood to flow normally. For

retraction, a vacuum is pulled through the balloon to collapse it. The procedure was developed as a less-invasive and less-costly alternative to coronary bypass, a complex surgical procedure that skirts the blockage by grafting a section of vein, usually taken from the leg, to locations above and below the afflicted area.

Today's high-pressure medical balloons—with thinner walls, higher strength, and smaller profiles—are well suited for use in a broad range of minimally invasive procedures. They can be produced in a variety of lengths, diameters, and shapes, including complex custom shapes for specific applications, and sup-

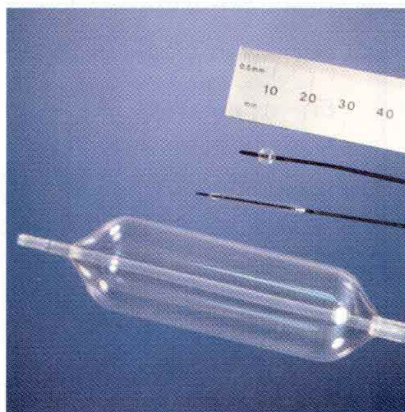
plied with specialty coatings for added performance. Innovations in balloon design and technology have provided increased flexibility to product designers, making the development of new and improved devices possible. As a result, high-pressure balloons are being employed in a growing number of diagnostic and therapeutic procedures. Applications include the following:

- Angioplasty catheters.
- Other dilatation catheters.
- Stent-delivery catheters.
- Heat-transfer catheters.
- Photodynamic therapy devices.
- Laser balloon catheters.
- Cryogenic catheters.
- Drug-delivery devices.
- Positioning catheters.
- Arthrectomy catheters.

It should be noted that many of the applications and procedures discussed in this article are experimental and have not yet been cleared for commercial use by FDA.

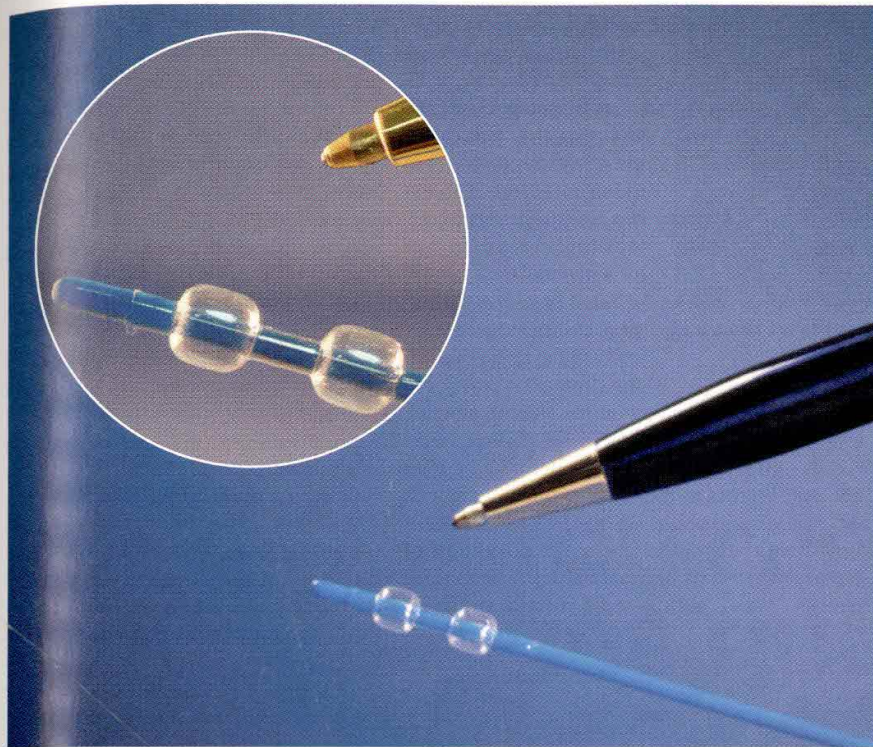
BASIC BALLOON TYPES

Two basic types of balloons are used in the medical industry. This article is primarily concerned with the first type: high-pressure, nonelastic dilatation- or angioplasty-type balloons used to apply force. The second type comprises low-pressure, elastomeric balloons, typically made of latex or silicone, that are used primarily in fixation and occlusion.



Angioplasty balloons come in a range of sizes, from coronary artery-sized versions to large-diameter models for peripheral vessels.

plied with specialty coatings for added performance. Innovations in balloon design and technology have provided increased flexibility to product designers, making the development of new and



they will not continue to expand and damage or rupture the artery after opening a blockage. *Balloon compliance* is the term used to describe the degree to which the diameter of a high-pressure balloon changes as a function of pressure. For example, a low-compliance, high-pressure balloon might expand only 5–10% when inflated to the rated pressure, whereas a high-compliance, high-pressure balloon might stretch 18–30%. Conversely, low-pressure elastomeric balloons—which are inflated by volume, not pressure—can stretch 100–600%; when the pressure is released, they recover close to their original size and shape. Such balloons generally cannot be used to exert high pressure in medical applications.

HIGH-PRESSURE BALLOON MATERIALS

For drug delivery applications, two discrete balloons or a dog bone-shaped balloon can be used to seal off the precise area that requires treatment, thus sparing healthy surrounding tissue.

The two types have few similarities. High-pressure balloons are molded to their inflated geometry from noncompliant or low-compliant materials that retain their designed size and shape even under high pressure. They are thin walled and exhibit high tensile strength, with relatively low elongation. Low-pressure balloons are typically dip molded in a

tubular shape, and are then expanded to several times their original size during use. Thus, these balloons cannot be inflated to precise dimensions and cannot retain well-defined shapes, nor maintain high pressures.

For angioplasty, balloons must have a controllable or repeatable size (diameter versus pressure) in order to ensure that

The first angioplasty balloons were fabricated from flexible polyvinyl chloride (PVC). They were relatively thick walled and designed for low pressure, compared with today's high-pressure balloons. Cross-linked polyethylene came into use in the early to mid-1980s, about the same time that polyethylene terephthalate (PET) was adopted for high-pressure balloons; to a large degree, these

Materials	Tensile Strength	Compliance	Stiffness	Profile	Max. Rated Pressure for PTCA		Sterilization Methods
					ATM	PSI	
PET	High–Very High	Low–Medium	High	Low	20	294	EtO or radiation
Nylon	Medium–High	Medium	Medium	Low–Medium	16	235	EtO
PE (crosslinked) and other polyolefins	Low	High	Low	High	10	147	EtO or radiation
Polyurethane	Low–Medium	Medium–High	Low–Medium	Medium–High	10	147	EtO
PVC (flexible)	Low	High	Low	High	6–8	88–117	Radiation

Table 1. Comparison of high-pressure balloons made with various materials. (The maximum rated pressure is based on practical limitations and usefulness. Obviously, very thick walls can be formed with any material to increase the rated pressure; however, the resulting balloon would be useless in medical applications.)

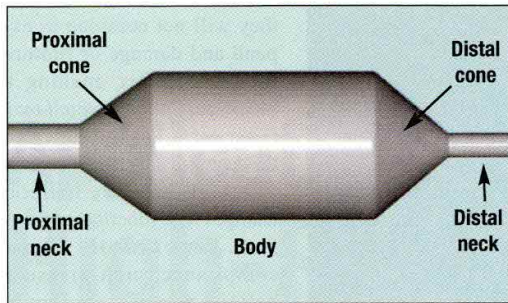


Figure 1. A standard balloon consists of a cylindrical body, two conical tapers, and two necks.

two materials replaced PVC. Nylon balloons were introduced in the late 1980s, and polyurethane balloons followed in the early 1990s. Nylon, though not as strong as PET or as compliant as polyethylene, was seen as a compromise because it is relatively strong and can be used in relatively thin designs. Currently,

the larger the diameter, the lower the rated pressure: as the diameter of a balloon increases, the stress in the balloon wall also increases when inflated to its nominal diameter. One major advantage of PET is its unusual ability to be molded into ultrathin walls from 5 to 50 μm

most high-pressure medical balloons are made from either PET or nylon. PET offers advantages in tensile strength and maximum pressure rating, whereas nylon is softer. Table I shows a comparison of various high-pressure balloon materials.

Rated pressures for angioplasty balloons are typically in the range of 2–20 atm (from 30 to nearly 300

psi), depending on the size. In general,

High-pressure PET balloons can be produced with diameters from 0.5 to 50 mm or more, in any working length, with very thin walls. They can be custom designed with varying diameters along the length of the balloon, and with tapered ends from 1° to 90°. Other benefits include excellent heat-transfer characteristics and optical clarity, making PET balloons suitable for energy delivery via Nd:YAG and other lasers or ultrasound and microwave equipment.

Compared with PET versions, nylon high-pressure balloons require a thicker wall for a given burst pressure. This generally means that a nylon balloon will have a larger profile than a comparable PET balloon upon insertion into the body and when crossing a lesion. However, because nylon is softer, it is more easily refolded and is easier to withdraw into the guiding catheter or introducer sheath.

A wide variety of coatings can be added to the surface of a balloon to enhance or alter its properties to meet new requirements. Balloon coatings include formulations designed to modify lubricity (both hydrophilic and hydrophobic coatings), abrasion and puncture resistance, conductivity, thrombogenicity, drug release, and reflectivity, among other characteristics.

BALLOON MECHANICS

Virtually all high-pressure balloons are fabricated by first extruding a tube or preform, cross-linking the extrusion (if required), then reheating and stretch-blow molding the extrusion into the desired geometry. A standard dilatation balloon consists of a cylindrical body; two conical tapers; and two necks, proximal and distal (Figure 1).

The stresses in a standard balloon are represented by the following equations:¹

$$\sigma_r = pd/2t, \sigma_l = pd/4t$$

where p = pressure, d = diameter, t = thickness, σ_r = hoop or radial stress, and σ_l = axial or longitudinal

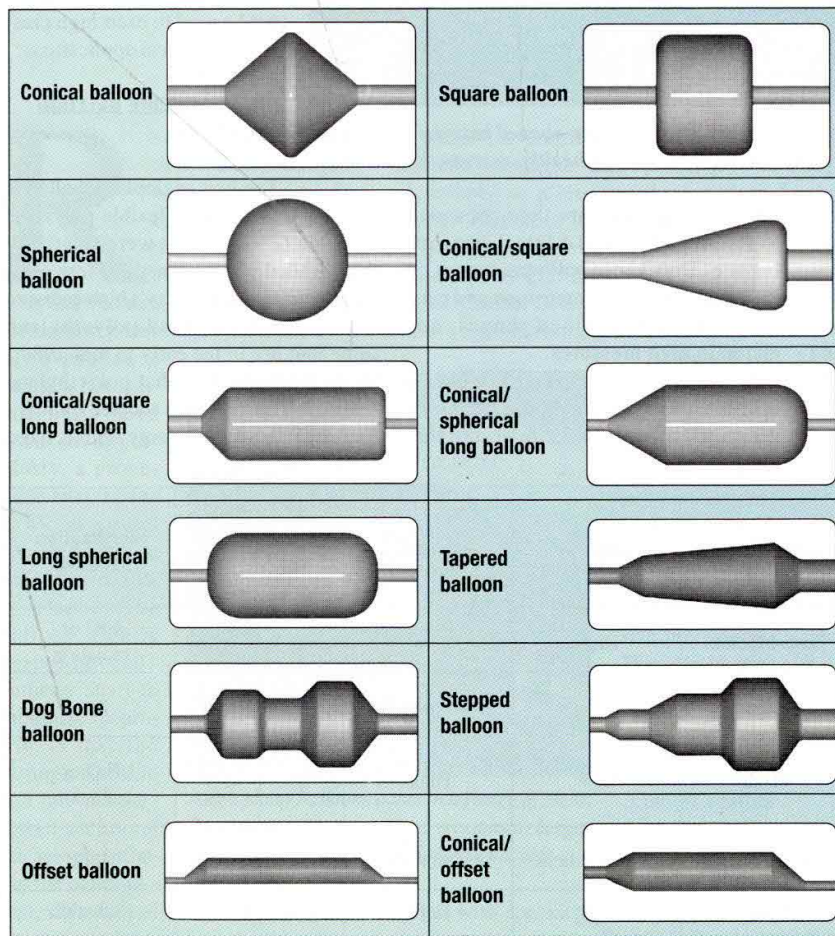


Figure 2. Examples of high-pressure balloon shapes. A specific shape may be demanded by the particularities of the anatomical site, the requirements of the treatment process, or both. (The designs shown here can be formed in different diameters and lengths.)

KEY DEFINITIONS

Balloon Diameter: Nominal inflated balloon diameter measured at a specified pressure.

Balloon Length: Typically refers to the working length or the length of the straight body section.

Burst Pressure: Average pressure required to rupture a balloon; usually measured at body temperature.

Rated Burst Pressure: Maximum statistically guaranteed pressure to which a balloon can be inflated without failing. For PTCA and PTA catheters, this is normally at a 95% confidence/99.9% guaranteed level.

Balloon Profile: Maximum diameter of the balloon when mounted on a catheter in its deflated and wrapped condition, or the smallest hole through which the deflated wrapped balloon catheter can pass.

Balloon Compliance: Change in balloon diameter as a function of inflation pressure.

stress. From the above equation, the calculated radial tensile strength (TS) of a balloon can be easily calculated as follows:

$$TS = pd/2t$$

where p = burst pressure, d = diameter (as made), and t = thickness (as made). Fortunately, the radial (or hoop) stress is twice the longitudinal stress; therefore, when a balloon fails, it normally splits along its length rather than circumferentially. This is preferable in a clinical sense, since radial or circumferential balloon failures can cause complications in medical procedures.

BALLOON ENDS AND SHAPES

High-pressure balloon ends are available in a variety of forms: conical sharp corner, conical radius corner, square end, spherical end, and offset neck, with other more-complex forms also possible. The choice of an end form depends on the requirements of the end-use procedure.

The shape of the balloon body can also vary from the standard shape shown in Figure 1. It can be sectioned into different diameters and lengths (e.g., dog bone-shaped and stepped balloons) or

fashioned and shaped into a conical, square, or spherical shape (or a combination of these). If required by the application, different ends can also be used on the same balloon. Some examples of high-pressure balloon shapes are shown in Figure 2.

APPLICATIONS OF HIGH-PRESSURE BALLOONS

Dilatation. Angioplasty is the most common application of high-pressure

balloons. Percutaneous transluminal coronary angioplasty (PTCA) uses dilatation balloons to dilate and unblock arteries that feed the heart. Typical balloons for PTCA catheters range in size from 2 to 4 mm in diameter and 10 to 40 mm in length, with pressure-capability ratings of 10–20 atm. For noncoronary percutaneous transluminal angioplasty (PTA)—that is, dilatation of arteries other than the coronary arteries—balloon sizes typically range from 4 to 12 mm in diameter and 20 to

IF THEY SAID

**"You can't
get quality
prototypes!"**
parts!



THEN
VISIT
polymerdesign.com

AND WE CAN SHOW YOU HOW.

- Functional parts not just prototypes.
- Perfect for short production runs.
- 3-5 days

Polymer Design • Rockland, MA • Tel: 781.871.4606
Protoparts is a trademark of Polymer Design.

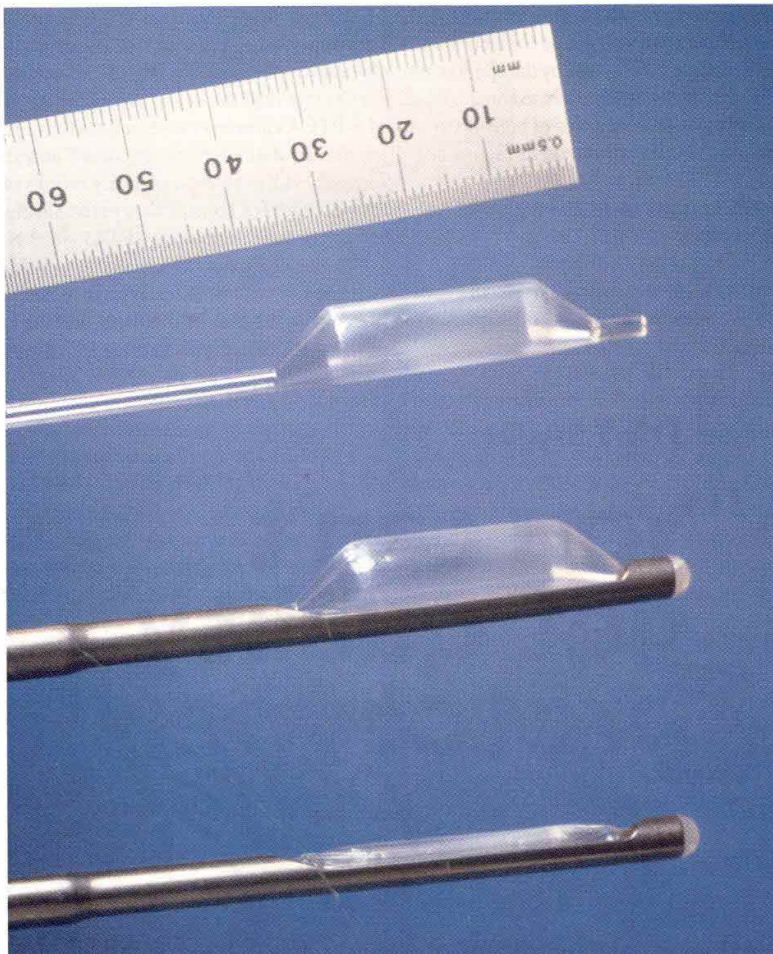


Photo courtesy of United States Surgical Corp.

Figure 3. Balloons for carpal tunnel dilatation: the balloon as formed (top); the inflated balloon in its assembled state (middle); the deflated balloon profile (bottom).



Photos courtesy of IntraTherapeutics

Figure 4. A coronary stent, at minimum diameter, is crimped over a balloon and ready to be inserted into an artery.

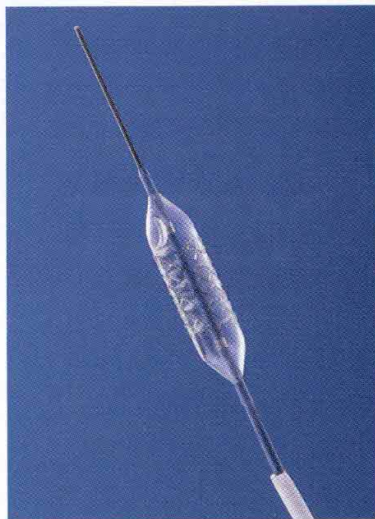


Figure 5. The coronary stent expanded by the balloon. The balloon presses the stent against and partially into the arterial wall.

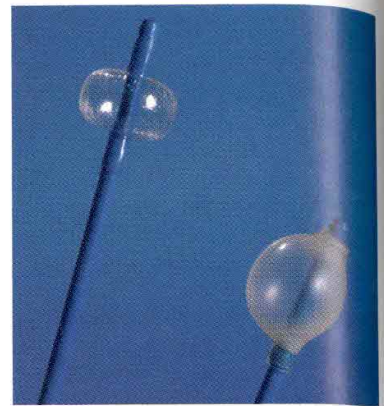


Figure 6. Offering less precision, an elastomeric balloon (right) will often expand asymmetrically compared with a high-pressure, thin-walled balloon (left).

100 mm in length. Rated pressures for PTA catheters range from 8 to 20 atm.

High-pressure balloons are also used or are being developed to dilate constrictions and blockages virtually anywhere in the body. These uses include esophageal, biliary-duct, urethral, fallopian-tube, heart-valve, tear-duct, and carpal-tunnel dilatation. Several of these procedures—like carpal-tunnel dilatation—are new and emerging (Figure 3), whereas others such as the dilatation of heart valves (valvuloplasty) have existed for many years. All of these applications benefit from high-pressure, low-compliance, low-profile balloons.

High-pressure balloons are commonly used to deploy and postdilate stents to reduce the rate of arterial restenosis or acute reclosure following angioplasty. Coronary stents—generally, machined tubes or wire mesh—are crimped over a balloon and inserted into the area of a blockage after angioplasty (Figure 4). Inflating the balloon opens the stent (Figure 5), which remains expanded to keep the vessel open after the balloon is deflated and removed from the body. The characteristics of high-pressure balloons enable the physician to fully expand a stent until it is in full contact with the arterial wall. The use of a low-compliance balloon imparts added confidence that the stent and the artery will not be overexpanded and that the balloon will not dog-bone and overexpand the artery on either end of the stent. Stents are being used with increasing frequency in association with angioplasty procedures, and currently represent the second-largest market for high-pressure balloons.



Figure 7. A directional coronary atherectomy catheter is shown with the balloon inflated, which pushes a cutter against arterial plaque.

Positioning. A new market for high-pressure balloons is their use to precisely position devices other than stents in a vessel or body cavity. Elastomeric balloons are often used for positioning; however, high-pressure balloons are preferred when a precise balloon shape or catheter position is required. An elastomeric balloon can stretch and roll, shifting back and forth, which is unacceptable in critical positioning applications. In addition, elastomeric balloons often inflate nonconcentrically and unpredictably, which precludes their use in applications demanding extreme accuracy (Figure 6).

A balloon can be used to center a device in a vessel, such as a radioactive seed, to deliver radiation intended to prevent restenosis. Centering the device ensures symmetrical dosage around the vessel wall. Some procedures concentrate on only one side of a vessel or cavity, such as directional atherectomy, which cuts away plaque from the wall of a vessel using a cutter that spins at high speed inside a housing. A balloon is mounted to the back of the housing and inflated, pushing the cutter against the vessel wall (Figure 7).

Another example is the treatment of benign prostate hyperplasia (BPH), an enlargement of the prostate gland. In this application, an offset balloon can be used



A variety of complex balloon shapes can be fabricated from PET to completely fill various body cavities.

to position a device off to the side, directly against a lobe of the gland, to deliver microwave or laser energy only where it is needed (Figure 8). Conversely, a standard balloon can be used to ensure that the device remains centered.

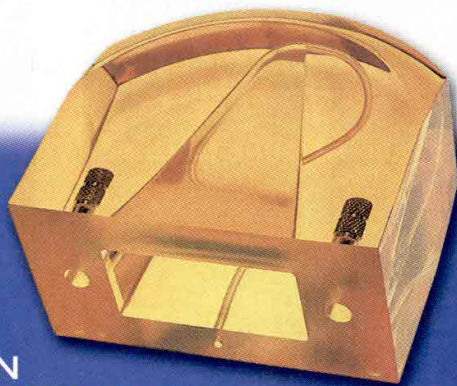
High-pressure balloons are also used to position diagnostic devices inside vessels or body cavities for ultrasound imaging and other techniques. Rather than having a complicated steering or positioning mechanism on the end of a catheter, a

high-pressure balloon can be used to either center or offset the device, precisely positioning it as required.

Occlusion. Normally, low-pressure, elastomeric balloons are used for occlusion or sealing, but in some cases, when precise sizes or shapes are required, it is desirable to use a high-pressure balloon. High-pressure occlusion balloons can be made shorter or longer than elastomeric balloons, thus either reducing or increasing the surface area covered in the vessel

IF THEY SAID

"You can't get quality cast parts!"



THEN VISIT polymerdesign.com

AND WE CAN SHOW YOU HOW.

- Liquid Resin Casting (LRC) yields high precision castings.
- Perfect for complex, low volume part runs.
- 2-5 weeks

Polymer Design • Rockland, MA • Tel: 781.871.4606

or cavity. Because high-pressure balloons can be precisely shaped, particularly in the transition area, they offer advantages over elastomeric balloons, whose ends are always spherically shaped. Conical, square, or spherical high-pressure balloons are those typically used for various occlusion applications.

Endovascular Graft Delivery.

A new market for high-pressure balloons is being used in a procedure to repair aneurysms without open surgery. A balloon-mounted, woven artificial graft with a stentlike structure built in on each end or over the entire length is wrapped tightly onto the balloon to minimize its profile. The graft, which is longer than the aneurysm, is deployed and attached to the artery wall by inflating the balloon within the artery. The graft bypasses the weakened area of the artery and remains in place permanently anchored to the vessel

wall, restoring normal circulatory flow after the balloon is deflated and removed.² A wide variety of balloon diameters and

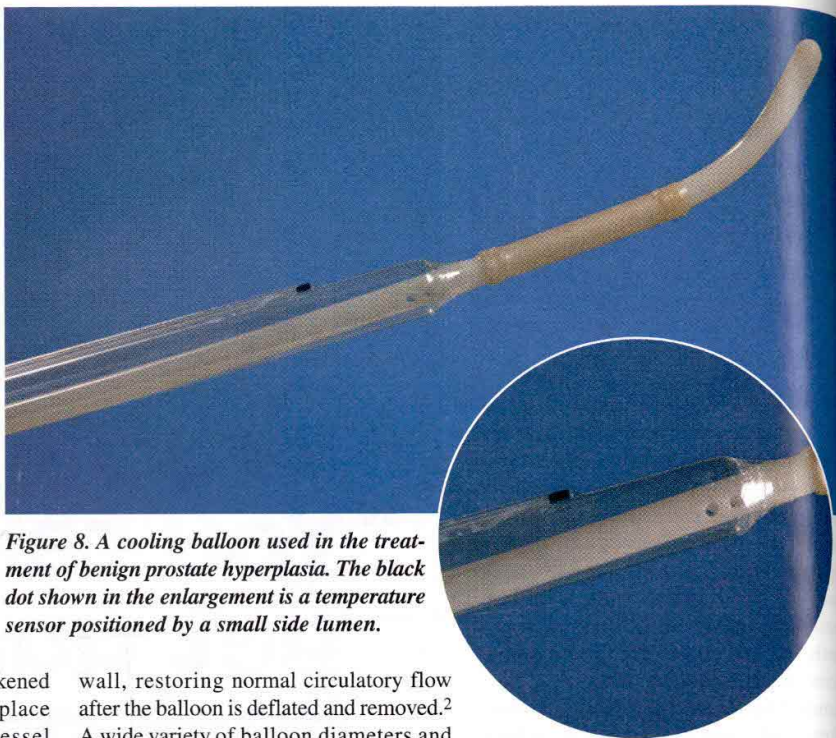


Figure 8. A cooling balloon used in the treatment of benign prostate hyperplasia. The black dot shown in the enlargement is a temperature sensor positioned by a small side lumen.

Limtech, Inc.
A Leader in Silicone Molding Technology for the Twenty-first Century
A Division of QUADRA, INC.

Complete LIQUID SILICONE MOLDING and On-Site Tool Manufacturing

Rapid Prototyping
Production Tooling with Short Lead Times
Tool Design Engineering
Silicone Materials with Class VI Testing
Controlled Molding Environment

1810 Renaissance Blvd.
Sturtevant, WI 53177
phone (262) 417-1307
fax (262) 417-1315
email: nbrust@limtechinc.com

The World's Leading Manufacturer of Plastic Netting

- Finest Quality Materials
- Multiple Configurations
- Many Engineered Polymers
- Superior Customer Service & Support
- Cooperative Research & Development

Zicot®
A low-cost, biplanar permeate carrier that provides edgeflow & promotes cleanliness

Naltex®
www.naltex.com • 800.531.5112



Photo courtesy of Richard Spears, MD

Figure 9. A laser balloon angioplasty device used in coronary angioplasty. The laser is mounted inside the balloon and transmits light through the balloon walls.

lengths are required in this procedure, with tapered and otherwise custom-shaped balloons sometimes specified as well.

Light Therapy. PET balloons are optically clear and permit the transmission of light over a broad spectrum, making them well suited for laser balloon angioplasty and photodynamic therapy (PDT) with light-activated drugs (Figure 9). The simultaneous application of heat and pressure during laser balloon angioplasty of coronary arteries reduces arterial recoil, remodels thrombi into a nonobstructive film, eliminates vasospasm, and may seal minute dissections induced during conventional PTCA.³ Devices mounted inside the balloon can emit light through the balloon wall.

PDT is currently used in the treatment of Barrett's esophagus, a precancerous condition that is being experimentally treated by a light-activated drug. In this procedure, the patient is given an intravenous drug treatment one to two days before light therapy. A laser delivery device is mounted inside a specially designed balloon catheter and introduced into the patient's esophagus (Figure 10). When the balloon is inflated in the treatment area and the laser turned on, the laser light emitted through the clear "window" portion of the balloon activates the drug designed to destroy the precancerous cells. The inflated PDT balloon opens the esophagus, which

is normally collapsed, and centers the laser delivery device. An opaque coating on the ends of the balloon prevents the light from treating other healthy areas of the organ, so that only the cells exposed to the light are destroyed.

Drug Delivery. Another prominent application area for high-pressure balloons is drug delivery. Use of the balloons enables physicians to localize the medication and avoid systemic intravenous administration. One method

that can be used to deliver a toxic drug to a blockage or lesion is to use two discrete balloons mounted on a catheter shaft to seal off the afflicted area, while the medication is infused through a port in the catheter between the two balloons. Once the treatment is complete, the fluid is drained, the area flushed, and the balloons deflated and retracted.

A dog bone-shaped balloon can also be used to deliver drugs in a similar manner. The ends of the balloon can be of

IF THEY SAID

"You can't get quality molded parts fast!"



THEN
VISIT
polymerdesign.com

AND WE CAN SHOW YOU HOW.

- Low and high volume part runs.
- Clean room facilities
- Highly engineered parts in 4 to 8 weeks.

Polymer Design • Rockland, MA • Tel: 781.871.4606

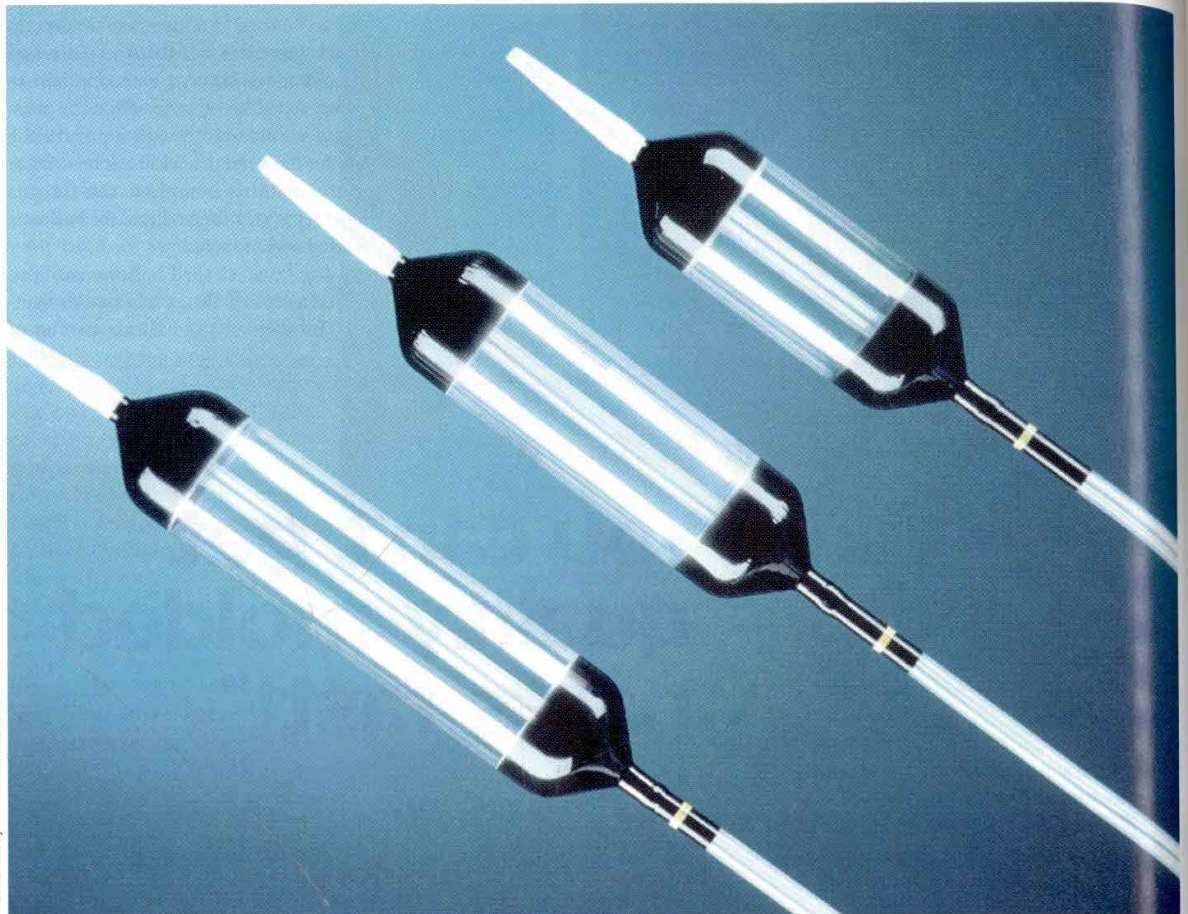


Photo courtesy of Wilson-Cook Medical Inc.

Figure 10. Balloon catheters with different-sized, optically clear "windows" used to deliver laser light energy that activates a drug for the treatment of Barrett's esophagus. The balloon ends have an opaque coating to protect adjacent tissue.

equal or different sizes, depending on the shape of the cavity or vessel. When inflated, the ends seal off the area to be treated, and the medication is infused through a hole or series of holes in the narrower center section of the balloon. The holes can be made in the surface of the balloon with a laser, hot wire, or drilling device, creating a sort of sponge. Such processing can be accomplished with virtually any balloon.

Alternatively, an ultrathin-walled PET balloon can be converted to a microporous membrane, with hole sizes ranging from less than 1 μm to several microns in diameter. Hundreds of thousands or even millions of holes of this size can be placed in a single balloon. Such a design permits pore size to be precisely controlled, enabling very small amounts of a drug to be infused over an accurately defined area—a critical advantage with drugs that are both expensive and toxic (Figures 11 and 12).

Although such balloons contain millions of micropores they are, surprisingly, very strong due to the material's unique structure. In fact, they can still be used for angioplasty: while the inflated balloon dilates the afflicted area, it can also infuse medication, perhaps delivering an anticoagulant onto the wall of the vessel. Drug absorption and penetration into the vessel wall can be controlled by the rate of fluid flow across the membrane and by the pressure at which the fluid is delivered. Through control of hole size and pattern, fluid flow can be governed and directed.

Drugs can also be coated onto the surface of a balloon for delivery to a specific site in the body. Transfer of the drug from a balloon's surface to the cavity wall can be accomplished with pressure, heat, or laser light. For example, laser and thermal energy have been used experimentally to enhance the binding of heparin to an injured arterial wall. In the experiment, lesions were treated immediately after

PTCA with a laser balloon that had been coated with heparin. The results suggest that heparin therapy is a safe treatment that yields favorable acute angiographic results.³

Heat Transfer. High-pressure balloons can be used to transfer heat or cold, either into or out of a vessel or body cavity. Balloons serve as a very good medium because their ultrathin walls provide a relatively high rate of heat transfer. They also provide intimate contact with the area being treated, conforming to curves and irregularities in the surface of a vessel.

For example, in cryosurgery of the prostate, a specially designed fluid-circulating high-pressure balloon catheter is inserted in the urethra.⁴ The long, thin-walled balloon covers the length of the urethra up into the bladder to protect the urethra and urethral sphincter muscles from being damaged by the extreme cold produced by cryoprobes inserted in to the prostate gland. Flexibility,



We Speak one language... Yours.

As a leading global provider to the medical device industry, TÜV Product Service is proud to announce it has been designated a **Notified Body for the European Union In Vitro Diagnostic Directive.**

TÜV also provides global conformity assessment services for:

- EU Notified Body for:
 - In Vitro Diagnostic Directive
 - Medical Devices Directive
 - Active Implantable Medical Devices Directive
- Software Evaluations
 - EN/IEC 60601-1-4
- CB Scheme Certificates
- FDA 510(k) Third Party Reviewer
- Quality Certification
 - ISO 9000 / 14001
 - ISO 13485 / 13488
 - EN 46000
- Japanese In-Country Caretaker
- EMC Testing
 - EN/IEC 60601-1-2
- Electrical Safety
 - EN/IEC 60601-1
 - EN/IEC 61010-1
- USA-EU Conformity Assessment Body
- Healthcare Certification

So, get the support you deserve from the professionals who understand your business - and speak your language. **TÜV.***

www.tuvglobal.com

1-800-TUV-0123

TÜV

MANAGEMENT SERVICE
PRODUCT SERVICE

*TÜV Product Service and TÜV Management Service are divisions of TÜV America Inc., a subsidiary of TÜV SÜddeutschland AG.

Circle Reader Service #119



bridge

medical product development



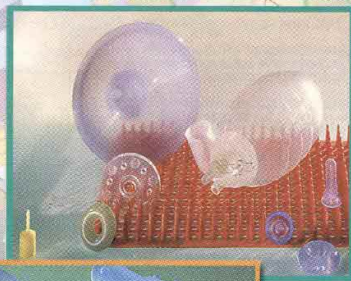
ISO 9001 certified

industrial design | product development | pilot manufacturing
san francisco | www.bridgedesign.com

Circle Reader Service #120

**SPECIALTYTM
SILICONE
FABRICATORS**

**Precision Liquid
Injection Molding**



Specialty Silicone Fabricators Has Proven To Be The Leader
In Liquid Injection Molding For Medical Applications.

Call Us To Get The Best Results On Your Projects
From Design To Prototype To Production.

Innovation • Technology • Excellence

3077 Rolfe Gates Drive
Paso Robles, CA 93446
805. 239. 4284
fax 805. 239. 0523

222 Industrial Park Drive
Elk Rapids, MI 49629
231. 264. 0087
fax 231. 264. 0187

800. 394. 4284
www.ssfab.com



Circle Reader Service #121

Front Line Med. Techs., Inc. Ex-1006-16

conformability, and high heat-transfer rates are critical to protect tissue and muscles in the application.

MULTIFUNCTIONAL BALLOONS

High-pressure balloons can be designed to perform several tasks at once—for instance, occlusion in conjunction with device positioning. An example would be a treatment for BPH that involves the application of thermal energy to the prostate with a microwave antenna inside a balloon (Figure 8). Microwave energy is emitted through the walls of the balloon, heating the prostate from the inside out as the microwaves penetrate the tissue. The antenna must be cooled during the procedure to keep it from overheating, which is achieved through administration of a cooling fluid that also cools the lining of the urethra to protect it from thermal damage. As an added function, a small side lumen is added to the cooling balloon that precisely positions a thermal sensor relative to the curve of the catheter and holds it against the tissue

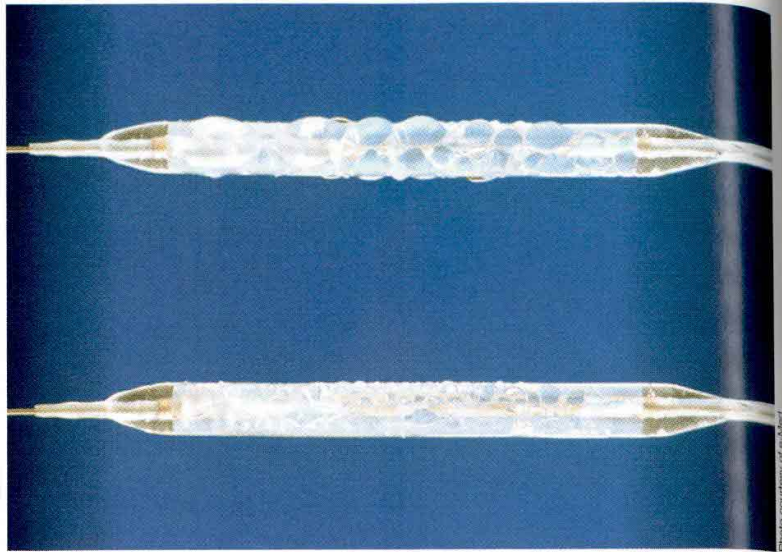


Figure 11. A balloon fabricated as a microporous membrane can be designed to "weep" medication, which spreads in a thin film between the balloon and surrounding tissue.

being treated. The sensor can be used to control the energy level of the microwave antenna and cut off power if the temperature gets too high.

MULTILUMEN BALLOONS

Balloons can be created with several lumens or channels so as to allow them to

How to specify the right miniature pump.

Start with the right design—and cost-effective features to extend system life while ensuring optimum performance...

Innovative pump head designs with exclusive valve action and choice of inert materials of construction.

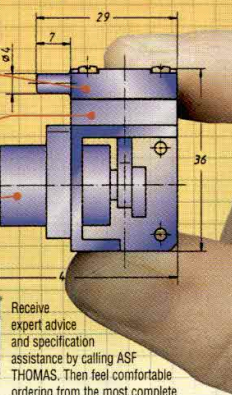
Proprietary diaphragm and pump chamber can be modified for special OEM requirements.

Long lasting, brushless motor options.

Low EMI/RFI interference designs.

Choice of pump technologies for diverse applications.

Dual Diaphragm Rotary Vane Diaphragm Wob-1 Piston



Receive expert advice and specification assistance by calling ASF THOMAS. Then feel comfortable ordering from the most complete source of miniature vacuum pumps and compressors. With over 50 years experience, chances are good that we've already solved your vacuum or compression challenge. Make ASF THOMAS your first choice for reliable miniature diaphragm, piston, rotary vane and vibrating armature pumps and compressors.

Tel. (920) 457-4891 • FAX (920) 451-4276



ASF THOMAS
COMPRESSORS
& VACUUM PUMPS

First Name in Innovation

1419 Illinois Ave. • Sheboygan, WI 53082
www.thomaspumps.com

SelfCHARGE™
Unlimited Power Solutions

Your OEM resource for Portable Power



**Custom Battery Chargers,
Integrated Battery Packs, and
Portable Device Accessories**



Intelligent Chargers & Battery Packs

Tel 425.881.9199

www.selfcharge.com

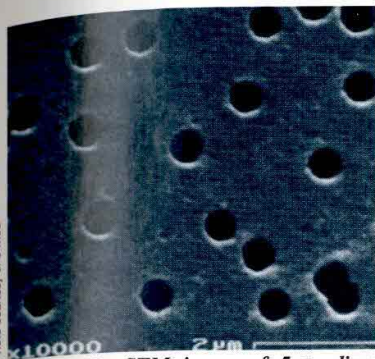


Figure 12. SEM image of 5- μ m-diam pores in a PET membrane. A single balloon can incorporate millions of pores.

perform multiple functions in both the inflated and deflated state.⁵ For example, a balloon can be fabricated in such a way as to enable blood to flow through one or multiple lumens while the other lumens inflate to perform angioplasty. In another design, one or more of the lumens could be used to contain a diagnostic or therapeutic device (or multiple devices) for precise positioning.

CONCLUSION

High-pressure balloons, traditionally used only in angioplasty, are now being employed in a wide range of diagnostic and therapeutic devices due to improvements in materials, balloon design, and fabrication technology. These improvements include increased diameters, additional lengths, ultrathin walls (for minimal invasiveness and a smaller profile), varying diameters throughout the balloon, custom shapes, tapered ends and angles, and specialty coatings, among others. The developments in high-pressure balloon technology have resulted in multifunctional balloons that provide endless product design possibilities for the medical device design engineer. A single balloon or device can now have many functions. All of these enhancements are enabling designers to develop new and improved medical devices.

ACKNOWLEDGMENTS

The author would like to thank Michael Barbere and Ilidia Porto, both of Advanced Polymers Inc., and Victor Porto of Porto Computer Solutions for their contributions to this article. Appreciation is also extended to the companies that provided products or photographs.

REFERENCES

1. Beer and Johnston, eds., *Mechanics of Materials* (New York: McGraw-Hill, 1981), 325-327.
2. Baxter Healthcare, PR Newswire, August 11, 1999.
3. James J Glazier et al., "Laser Balloon Angioplasty Combined with Local Intracoronary Heparin Therapy: Immediate and Short-term Follow-up Results," *American Heart Journal* 134, no. 2 (1997): 266-273.
4. Mark Saab, Heat-transfer catheters and

methods of making and using same, U.S. Pat. 5,624,392, April 29, 1997.

5. Mark Saab, Multilumen balloons and catheters made therewith, U.S. Pat. 5,342,301, August 30, 1994.

Mark A. Saab is president of Advanced Polymers Inc. (Salem, NH). The company manufactures ultrathin-walled heat-shrink tubing and high-pressure balloons, specializing in the design, development, and fabrication of PET angioplasty balloons and custom balloon catheters. ■



WE CAN

Soft FLEXIBLE Medical Grade Tubing

- Natural rubber latex • TPE compounds (including latex replacement) • Polyurethane and PVC • Durometers from 25-80 Shore A

HANDLE

The PERFORMANCE You Need

- High resilience • Great elongation • Color matching • Dimensional stability • Sterilizable

YOUR

The SERVICE You Demand

- Prompt quotations • Knowledgeable technical support • Expert material and application evaluations • On-time delivery • Short lead times

TUBING

Call For Complete Literature: 800.331.4762

NEEDS!



1500 St. Clair Ave. Kent, Ohio 44240 ■ Fax: 330.673.1351
E-mail: info@kentelastomer.com ■ Web: www.kentelastomer.com

©2000, Kent Elastomer Products 300-26