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SCHEDA TECNICA

Vs. riferimento: LOTTO N. 50

PRODOTTO			
NUCLEUS		N. REPERTORIO 24555/R	
CODICE PRODOTTO	126/PVN229...PVN235		
CODICE GMDN	17453	CODICE CND	C019014

DESTINAZIONE D'USO (Intended use)	Per dilatazione valvola mitrale e aortica	
CARATTERISTICHE	Catetere da dilatazione a due lumi coassiali, con palloncino distale termoplastico, elastomerico, non compliante per la dilatazione delle stenosi valvolari (aortica e mitralica). Il fatto di essere un catetere con due lumi coassiali permette dei tempi di gonfiaggio e sgonfiaggio del palloncino veramente rapidi. Inoltre, al momento della sterilizzazione, è conferita al palloncino una memoria termica di ripiegamento, quindi una volta sgonfiato, è possibile nuovamente avvolgere il pallone attorno al catetere mediante rotazione dello shaft in senso antiorario. Tutto ciò permette di eliminare il fastidioso effetto ali del pallone. Il catetere è in nylon e si caratterizza per l'eccezionale capacità di spinta, resistenza al kinking, controllo di torsione, nonché per l'ottima trackability. La parte distale dello shaft che porta il pallone, si presenta rastremata, dunque atraumatica ed in grado di navigare nelle tortuosità vasali più pronunciate, grazie al basso profilo. Il pallone, infine, una volta gonfiato, è in grado di rispettare l'anatomia vasale senza diminuire la propria pressione di lavoro, eseguendo in tal modo la dilatazione della stenosi senza però alcun danno per la parete vasale. Il catetere presenta tre reperi in platino a livello del pallone, due di essi si trovano nei punti di massimo diametro, mentre il terzo si trova al centro del pallone a livello dell'incisura che si forma al momento dei primi gonfiaggi del pallone. Tale incisura, si ottiene già a 1.5 atm di pressione e caratterizza la particolare forma assunta dal Nucleus. Tale proprietà vale solo per i primi gonfiaggi del pallone e va sparendo, a mano a mano che si ripete l'operazione; con il passare del tempo, il pallone assumerà poi la geometria tipica. Il catetere ha una lunghezza utile di 85 cm, 110 cm ed accetta guide da 0.035". Il diametro del pallone va da un minimo di 10 mm, ad un massimo di 30 mm; mentre le lunghezze sono di 30 e 40 mm.	
CONTROINDICAZIONI	Nessuna, nei limiti della destinazione d'uso del prodotto.	
MATERIALE	Poliammide (Pebax) e marker in platino	LATTICE ASSENTE (LATEX)
CONTROLLI DI QUALITA'	I controlli di qualità del materiale vengono effettuati all'origine dal Fabbricante e rispondono alle normative vigenti. L'intero ciclo produttivo è realizzato nel rispetto delle procedure GMP (Good Manufacturing Practice).	

lotto 58

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segue " Nucleus"

STERILIZZAZIONE	I prodotti Numed sono sterilizzati ad ossido di etilene Gas residuo nel rispetto delle vigenti normative. Sono rispettate tutte le prescrizioni tecniche e legislative previste in materia. Prodotto non nocivo. **DURATA STERILIZZAZIONE: 5 ANNI** Le informazioni inerenti data di sterilizzazione e relativa scadenza, numero di lotto, sono riportati chiaramente in etichetta.	
METODO DI RISTERILIZZAZIONE	Il prodotto è sterile MONOUSO. Vietata la risterilizzazione.	**MONOUSO**
VALIDITA' PRODOTTO	5 ANNI	
MODALITA' DI CONSERVAZIONE	Conservare a temperatura ambiente in luogo fresco ed asciutto. Fare comunque riferimento alle indicazioni specifiche riportate sulla confezione e sul foglietto illustrativo	
CONFEZIONAMENTO	La confezione del prodotto è stata studiata per consentirne la buona conservazione, il facile immagazzinamento per sovrapposizione e riporta in modo chiaro e ben leggibile la descrizione quali/quantitativa del contenuto, il nome del produttore ed ogni altra informazione utile all'immediato riconoscimento del prodotto stesso. Le singole confezioni sono di facile apertura, tali da non permettere che il materiale aderisca alla confezione e facilitano il prelievo del prodotto senza inquinamento.	**QUANTITA' PER CONFEZIONE** 1
ETICHETTATURA	In accordo al D.Lgs 46/97 e s.m.i., allegato 1 articolo 13.3 e Direttiva 93/42/CE.	**CODICE A BARRE** PRESENTE
MODALITA' DI SMALTIMENTO	Conformemente alle vigenti normative in materia. Fare comunque riferimento ai vigenti protocolli ospedalieri.	
ISTRUZIONI PER L'USO	Conforme all'all.1 art. 13.6 e 13.1 D.Lgs 46/97 e s.m.i. in recepimento della Direttiva 93/42/CE	

Lotto 50

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SCHEDA TECNICA

segue " Nucleus"

MARCATURA CE	Dispositivo medico in **CLASSE III** in accordo alla **Direttiva 93/42/CEE**	
CERTIFICATO CE	Ente Notificato SGS 0120	Certificato n. US98/14631 US99/50368
CERTIFICATO ISO FABBRICANTE	Certificato ISO 13485:2003	Ente di certificazione SGS
FABBRICANTE	**NuMED Inc.** 2880 Main Street P.O. Box 129 Hopkinton, NY12965 U.S.A.	
MANDATARIO EUROPEO	**G. van Wageningen B.V** Hallenweg 40 5683 CT Best The Netherlands	
IMPORTATORE E DISTRIBUTORE	**ab medica s.p.a.** Via Nerviano, 31 - 20020 Lainate (MI) tel. 02-93305.1 fax 02-93305.400 distributore esclusivo in tutta Italia	

GAMMA PRODOTTI

CODICE	DESCRIZIONE
126/PVN 229	CATETERE VALVULOP. MITR.18X40 MM. 110 CM
126/PVN 230	CATETERE VALVULOP. MITR.20X40 MM. 110 CM
126/PVN 231	CATETERE VALVULOP. MITR.22X40 MM. 110 CM
126/PVN 232	CATETERE VALVULOP. MITR.25X40 MM. 110 CM
126/PVN 233	CATETERE VALVULOP. MITR.28X40 MM. 110 CM
126/PVN 235	CATETERE VALVULOP. MITR.30X40 MM. 100 CM

Lo 77050

Certificate US99/50368

NuMED, Inc.

2880 Main Street,
Hopkinton, NY, 12965, United States

Device Identification:
TYSHAK, TYSHAK II, TYSHAK X, TYSHAK II X, Tyshak Mini, Z-MED, Z-MED II, Z-MED X, Z-MED II X, Nucleus-X, COEfficient.

Medical Purpose of Device:
Percutaneous transluminal valvuloplasty.

has been assessed and certified as meeting the requirements of

EC Directive 93/42/EEC

On Medical Devices Annex II Section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to regular compliance visits.

This certificate is valid from 25 February 2009 until 24 February 2014
Issue 22

Certification is based on report number(s) WW/PCI 202095 dated 30 January 2009

Addenda to that report have been issued on the following dates:

Addendum Date	Reason for Addendum

Notified Body Number 0120

Authorised by

CE
0120

SGS United Kingdom Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS EC 01 1007

6TT050

Certificate US98/14631

The management system of

NuMED, Inc.

2880 Main Street,
Hopkinton, NY, 12965, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

Annex II (excluding Section 4) and Annex V (Sterility Aspects Only)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 14 August 2009 until 16 July 2011 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 11 June 2011
Issue 11. Certified since 5 November 1998

Notified Body Number 0120

Authorised by

SGS United Kingdom Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

CE
0120

SGS CE 01 0308 M2

NuMED, Inc.

Directive 93/42/EEC

Annex II (excluding Section 4) and Annex V (sterility aspects only)

Issue 11

Detailed scope

Annex II (excluding section 4)

Atrioseptostomy catheters; Percutaneous transluminal valvuloplasty (PTV) catheters; Percutaneous transluminal angioplasty (PTA) catheters; Angiographic diagnostic catheters, Percutaneous transluminal sizing (PTS) catheters; Mitral dilatation kit, Balloon in Balloon (BIB) catheter, CP stent, Dialysis catheters, NuMED TIRO Catheter.

Annex V (sterility aspects only)

Tear Duct Catheter.

Additional facilities

CE 0120

L6TTQ50

NuMED, Inc.
PO Box 129
Hicksville, NY 11565
Phone: 315-328-4401
Fax: 315-328-4941

DECLARATION OF CONFORMITY

This is to confirm that the following NuMED, Inc. products bearing the CE Mark Label meet the Essential Requirements of European council Directive 93/42/EEC Annex I and the EC Declaration of Conformity in Annex II, as certified by SGS United Kingdom Ltd., Unit 202B, Worle Parkway, Weston-Super-Mare, North Somerset, BS22 6WA, Notified Body Number 0120.

CE MARKED PRODUCTS

Class III devices according to Rule 6 (subclause 1) of Annex IX of the MDD:

Indication:	Devices:
Atrioseptostomy:	Z-5 Atrioseptostomy™
PTV:	Tyshak®, Tyshak-X™, Tyshak II®, Tyshak II-X™, Z-MED™, Z-MED-X™, Z-MED II™, Z-MED II-X™, NuCLEUS-X™, Tyshak Mini®, COEfficient™
Angiographic:	Multi-Track™, Multi-Track™ End Hole, Mitral Dilatation Kit™
Sizing:	PTS®, PTS-X™
Stent Placement:	Balloon in Balloon Catheter (BIB®)

Class III devices according to Rule 8 (subclause 2) of Annex IX of the MDD:

Indication:	Devices:
Coaretation of the Aorta:	CP Stent™, Covered CP Stent™, Mounted CP Stent™, Covered Mounted CP Stent™

Class IIa devices according to Rule 6 of Annex IX of the MDD:

Indication:	Devices:
PTA:	Balloon in Balloon Catheter (BIB®), Mullins™, Mullins-X™, Ghost II™, Mini Ghost™, PTA Ghost™, High Five™
Dialysis:	DS™, DSC™
Occlusion:	TiRO™

Class I devices according to Rule 5 of Annex IX of the MDD:

Indication:	Devices:
Dacryocystoplasty:	Tearduct™

NuMED, Inc.
PO Box 329
Hopkinton, NY 12965
Phone: 315-328-4401
Fax: 315-328-4441

DECLARATION OF CONFORMITY

Manufacturer:	Manufacturer's European Representative:
NuMED, Inc. 2880 Main Street Hopkinton, N.Y. 12965 Email: info@numedusa.com	G. van Wageningen B.V. Hallenweg 40 5683 CT Best The Netherlands Email: info@heartmedical.nl

Signature: _____ Date: 8/04/09

Allen J. Tower, Sr., CEO
NuMED, Inc.

6110 50

Certificate US98/14630

The management system of

NuMed, Inc.

2880 Main Street,
Hopkinton, NY, 12965, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2003

For the following activities

Design and manufacture of medical devices including dilatation and electrode catheters and angiographic devices and stents.

This certificate is valid from 17 July 2008 until 16 July 2011 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 11 June 2011
Issue 8. Certified since 5 November 1998

Authorised by

UKAS QUALITY MANAGEMENT
005

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 13485-2 0308

Lotto 50

NuMED, Inc.

2880 Main Street
Hopkinton, New York 12965
U.S.A.
Tel: (315) 328-4491
Fax: (315) 328-4941

May 25, 2006

AB Medica
Via Nerviano, 31
20020 Lainate (MI)
Italy

RE: Sterilization of Product

To Whom It May Concern:

The sterilization method is as follows. The method of packaging includes placing the finished catheter within a polyethylene loop which is then heat sealed within two Tyvek pouches. A label is applied to the outer pouch and this package is then put into an individual carton, which is also labeled, for distribution. Pyrogen testing is performed on samples which are included with each sterilization load.

All Catheters will be sterilized with 100% Ethylene Oxide. The sterility assurance level will be 10^{-6} or better. The clinical laboratory standard test procedure for determination of pyrogenicity, the Limulus Amebocyte Lysate (LAL) Method will be used for validation. The maximum ETO residuals are determined at 10 days post sterilization. They will not exceed the following limits:

Ethylene Oxide:	20 mg
Ethylene Chlorohydrin:	12 mg

This sterilization cycle is validated using the half-cycle approach as described in ANSI/AAMI/ISO 11135-1194: "Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization" and is re-validated annually.

NuMED, Inc. has contracted Ethox Corp in Buffalo, NY to perform the sterilization testing and Medical Manufacturing Corp in Erie, PA to perform the sterilization process. This sterilization validation has been approved by SGS, reference Job No: 09581.

If you need any other information, please let me know.

Sincerely,

Melissa Tracy
QS Manager

Visit us on the World Wide Web at:
http://www.numed.on.ca

Medtrials
INCORPORATED

CLINICAL LITERATURE REVIEW

Clinical Literature Review Protocol for the NuMED Family of products intended for Percutaneous Transluminal Valvuloplasty

May, 2005

2777 Stemmons Freeway * Suite 900 * Dallas, TX 75207 * 214.630.0288 * www.medtrials.com

1. INTRODUCTION

The objective of this literature review is to provide a method for the systematic identification, selection, collation and review of relevant studies to support the marketed use of the following NuMED family of Percutaneous Transluminal Valvuloplasty (PTV) catheters:

1. NuMED COEfficient™ PTV Catheter – Pediatric
2. NuMED Nucleus™ PTV Catheter
3. NuMED TYSHAK® PTV Catheter
4. NuMED TYSHAK Mini® PTV Catheter – Pediatric
5. NuMED TYSHAK II® PTV Catheter
6. NuMED TYSHAK-X™ PTV Catheter
7. NuMED TYSHAK II-X™ PTV Catheter
8. NuMED Z-MED™ PTV Catheter
9. NuMED Z-MED-X™ PTV Catheter
10. NuMED Z-MED II™ PTV Catheter
11. NuMED Z-MED II-X™ PTV Catheter

Indications: Recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve

- A patient with isolated pulmonary stenosis
- A patient with valvular pulmonary stenosis with minor congenital heart disease that does not require surgical intervention

The PTV Catheters are made of the following materials:

Name	Indication	Balloon	Outer Shaft	Inner Shaft	Image Bands
COEfficient	Pediatric PTV	[redacted]	[redacted]	[redacted]	2
Nucleus	PTV	[redacted]	[redacted]	[redacted]	3
TYSHAK	PTV	[redacted]	[redacted]	[redacted]	2
TYSHAK Mini	Pediatric PTV	[redacted]	[redacted]	[redacted]	2
TYSHAK II	PTV	[redacted]	[redacted]	[redacted]	2
TYSHAK-X	PTV	[redacted]	[redacted]	[redacted]	2
TYSHAK II-X	PTV	[redacted]	[redacted]	[redacted]	2
Z-MED	PTV	[redacted]	[redacted]	[redacted]	2
Z-MED-X	PTV	[redacted]	[redacted]	[redacted]	2

Name	Indication	Balloon	Outer Shaft	Inner Shaft	Image Bands
Z-MED II	PTV	[redacted]	[redacted]	[redacted]	2
Z-MED II-X	PTV	[redacted]	[redacted]	[redacted]	2

Materials:

[redacted]

1.1. Comprehensive Cumulative History

This is the first version of the Literature Review Protocol. A cumulative History is not applicable.

2. LITERATURE REVIEW METHODOLOGY

The literature search will be conducted through the auspices of MedTrials, Inc of Dallas, Texas, USA as described below.

2.1. Sources

The literature source review will be primarily conducted through an online strategy that will utilize large databases that are applicable to, and are likely to contain, information related to the safe use and specific hazards associated with PTV catheters. These databases include, but are not necessarily limited to:

• Medline	• PubMed
• Medscape	• Toxline

The resources of the University of Texas Southwestern Medical School Library, located in Dallas, Texas were also accessed. These combined sources allowed access to a high volume of journals and periodicals. Listing these is beyond the scope of this document

2.2. Inclusion Criteria

Inclusion Criteria for this Literature review is based upon the following criteria:

- Articles of relevance to the safe use of Percutaneous Transluminal Valvuloplasty catheters.
- Articles with the following keywords: *Percutaneous Transluminal Valvuloplasty Catheter, PTV Catheter, Percutaneous Transluminal Commissurotomy, PTC Catheter, catheter, catheter materials, Catheter adverse events, catheter materials, catheter infection, NuMED PTV, NuMED PTC*
- Articles containing specific NuMED product names (listed above).

- Articles referencing products similar to the NuMED family of PTV catheters (listed above).
- Articles with a direct linkage between the catheter cited and the identified hazard. These hazards fall into the following categories:
    - Physical Hazards – either through product failure or operator error
    - Chemical Hazards – from the leeching of undesirable components from the materials making up the product, from a product coating or from drugs used in conjunction with the catheter that may have produced unforeseen events.
    - Biological Hazards - This primarily targets the sterility of the catheter and any iatrogenic sources of contamination of the catheterized site.

2.3. Exclusion Criteria

The Exclusion Criteria consists of the following:

- Articles that could not be readily obtained (i.e., articles in a language other than English).
- Articles that do not bear a direct link to the use and safety of catheters (i.e., articles whose keywords met inclusion criteria but were not directly related to the intrinsic safety of catheters).
- Isolated case reports, random experience and reports lacking insufficient detail with which to make a sound scientific evaluation and/or do not bear a direct relationship to the subject matter.

2.4. Published Data

One reference was found regarding the use of a NuMED PTV catheter:

Balloon dilatation of congenital mitral stenosis in a critically ill infant
Bilkis Abdul Aziz, Mazeni Alwi
Catheterization and Cardiovascular Interventions
Volume 48, Issue 2, 1999. Pages 191-193

Note that this article cites the use of the NuMED catheter during treatment of an infant with severe congenital mitral stenosis. There were no adverse effects associated with the use of the catheter identified by the authors.

Using the above referenced strategy for searching the following list of relevant papers was encountered:

1. Aldenhoff, Yvette B.J. *et al.* **Coils and tubes releasing heparin: Studies on a new vascular draft prototype.** Biomaterials 25 (2004): 3125-3133.

2. Anon. **Expert Advisory Panel on DEHP in Medical Devices Report** Health Canada Final Report January 11, 2002 http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/eap-dehp-final-report-2002-jan-11_e.html

3. Anon. **Valvuloplasty** Amersham Health Medcyclopaedia; www.amershamhealth.com/medcyclopaedia

4. Buller, Christopher E., and Carere, Ronald G. **New advances in the management of acute coronary syndromes 3. The role of catheter based procedures** CMAJ 2002; 166(1): 51-61.

5. Chandrasekar, Baskaren, MD; **Complications of Cardiac Catheterization in the Current Era: A Single-Center Experience** Catheter Cardiovasc Interv 2001 Mar 52 (3): 289-95.

6. Chikwe, Joanna *et al.* **The Surgical Management of Aortic Valve Disease** Br J Cardiol 10(6): 453-461, 2003.

7. Chikwe, Joanna *et al.* **The Surgical Management of Mitral Valve Disease** Br J Cardiol 11(1): 42-48, 2004.

8. Cho, Leslie, MD; *et al.* **Superficial Femoral Artery Occlusion: Nitinol Stents Achieve Flow and Reduce the Need for Medications Better than Angioplasty** J Invasiv Cardiol 15(4): 198-200, 2003.

9. Cochran, Kevin, MD; *et al.* **Use of Lepirudin During Percutaneous Vascular Interventions in Patients with Heparin-Induced Thrombocytopenia** J Invasive Cardiol 15(11): 617-621, 2003.

10. Dalby, Miles *et al.* **Non-Surgical Aortic Valve Replacement.** Br J Cardiol 10(6): 450-452, 2003.

11. Dauterman, Kent W. *et al.* **Is There Any Indication for Aortic Valvuloplasty in the Elderly?** Am J Geriatr Cardiol 12(2): 190-196, 2003.

12. Donlan, Rodney M; **Biofilms and Device-Associated Infections** Emerg Infect Dis 7(2), 2001.

13. Douglas, L. Julia; **Medical Importance of Biofilms in *Candida* Infections** Rev Iberoam Micol 2002; 19:139-143.

14. Genser, Dieter, MD, PhD; **Homocysteine, Vitamins, and Restenosis After Percutaneous Coronary Interventions** Cardivasc Rev Rep 24(5):253-258, 2003.

15. Gilon, Dan, MD; *et al.* **Right Atrial Thrombi Are Related to Indwelling Central Venous Catheter Position: Insights into Time Course and Possible Mechanism of Formation** Am Heart J 135(3): 457-462, 1998.

16. Gurrea, A.; *et al.* **Arterial percutaneous angioplasty in upper limbs with vascular access devices for Haemodialysis** Nephrol Dial Transplant (2002) 17:842-851.

17. Heuser, Richard, MD; *et al.* **A retrospective Study of 6,671 Patients Comparing Coronary Stenting to Balloon Angioplasty** J Invasive Cardiol 12(7): 354-362.

18. Hung, Jui-Sung, MD; *et al.* **Complications of Inoue Balloon Mitral Commissurotomy: Impact of Operator Experience and Evolving Technique** Am Heart J 138(1): 114-121, 1999.

19. Ikeda, Shunya, MD; *et al.* **Economic Outcomes Analysis of Stenting Versus Percutaneous Transluminal Coronary Angioplasty for Patients with Coronary Artery Disease in Japan** J Invasive Cardiol 12(4): 194-199, 2000.

20. Iung, Brenard *et al.* **Immediate Results of Percutaneous Mitral Commissurotomy** Circulation 94: 2124-2130.

21. Iung, B *et al.* **Immediate and mid-term results of repeat percutaneous mitral commissurotomy for restenosis following earlier percutaneous mitral commissurotomy** European Heart Journal 21: 1683-1689, 2000.

22. Jarrar, Mourad *et al.* **Long-Term Invasive and Noninvasive Results of Percutaneous Balloon Pulmonary Valvuloplasty in Children, Adolescents, and Adults** Am Heart J 138(5): 950-954, 1999.

23. Katz, Stanley, MD; *et al.* **Nonrandomized Comparison Between Stent Deployment and Percutaneous Transluminal Coronary Angioplasty in Acute Myocardial Infarction** Am Heart J 139(1): 44-51, 2000.

24. Minai, Kazuo, MD; *et al.* **Long-Term Outcome of Primary Percutaneous Transluminal Coronary Angioplasty (PTCA) for Low-Risk Acute Myocardial Infarction (AMI) in Patients Older Than 80 Years: A Single-Center, Open, Randomized Trial** Am Heart J 143(3): 497-505, 2002.

25. Miner, Steven E.S., MD *et al.* **Homocysteine, Lipoprotein (a), and Restenosis After Percutaneous Transluminal Angioplasty: A Prospective Study** Am Heart J 140(2): 272-278.

26. Pukin, L., MD; **Devices and Techniques for Endovascular Surgery: Catheters, Stents, and Stented Grafts** Mt Sinai J Med 70 (6), November 2003.

27. Richey, T., *et al.* **Surface Modification of Polyethylene Balloon Catheters for Local Drug Delivery** Biomaterials 21:1057-1065, 2000.

28. Saab, Mark A. **Applications of High-Pressure Balloons in the Medical Device Industry** Advanced Polymers, Inc. 1999.

29. Salvioni, A., MD; *et al.* **Thrombin Activation and Late Restenosis After Percutaneous Transluminal Coronary Angioplasty** AM Heart J 135(3): 503-509, 1998.

30. Sharif, F.; *et al.* **Current status of catheter and stent-based gene therapy** Cardiovascular Rees 64 (2004): 208-216.

31. Song, Jong-Min *et al.* **Valvular and Congenital Heart Disease: Outcome of Significant Functional Tricuspid Regurgitation After Percutaneous Mitral Valvuloplasty** Am Heart J 145(2): 371-376, 2003.

32. Unverdorben, M., MD PhD; *et al.* **Change of the Mechanical Properties of Two Different Balloon Catheters with Increasing Numbers of Cycles of Destabilization** Catheterization and Cardiovascular Interventions 58:29-33 (2003).

33. Uretsky, B.F., MD; *et al.* **A Prospective Evaluation of Angiography-Guided Coronary Stent Implementation with High Versus Very High Balloon Inflation Pressure** Am Heart J 140(5): 804-812, 2000.

34. Wang, Andrew *et al.* **Assessing the Severity of Mitral Stenosis: Variability Between Noninvasive and Invasive Measnrements in Patients with Symptomatic Mitral Valve Stenosis** Am Heart J 138(4): 777-784.

35. Wennberg, D.E., MD, MPH; *et al.* **Percutaneous Transluminal Coronary Angioplasty in the Elderly: Epidemiology, Clinical Risk Factors, and In-Hospital Outcomes** Am Heart J 137(4): 639-645, 1999.

36. Wiggins, B.S., Pharm.D.; *et al.* **Bivalirudin: A Direct Thrombiu Inhibitor for Percutaneous Transluminal Coronary Angioplasty.** Pharmacotherapy 22(8): 1007-1018, 2002.

37. Wilensky, R.L., MD: *et al.* **Iucreased Thrombin Activity Correlates With Increased Ischemic Event Rate After Percutaneous Transluminal Coronary Angioplasty: Lack of Efficacy of Locally Delivered Urokinase.** Am Heart J 138(2): 319-325, 1999.

2.5. Uupublished Data

Package inserts, Physician brochures, Descriptive product profiles and some web material from NuMED, Inc were also considered in this review.

2.6. Market Experience

The catheters and balloons included in the NuMED family of valvuloplasty products are sometimes termed Balloon catheters and were first introduced in the late 1970's. These Balloon Catheters have been used in valvuloplasty, a procedure that opens heart valves after the process of stenosis. The balloon is tightly wrapped around a catheter so as to minimize its profile and is then inserted into the section of the heart valve that is narrowed or restricted. The balloon is then inflated with saline or a radiopaque solution, forced through a syringe that exerts a high hydraulic pressure. This causes the leaflets of the heart valve to be stretched apart and separated and allows the blood to flow more freely. To retract the balloon and catheter, a vacuum is then applied to collapse the balloon and the catheter removed. Balloon catheter procedures were developed originally as a less invasive/less costly alternative to more invasive procedures.[4, 26, and 28]

Over the past 25 years balloon catheters have become more sophisticated, becoming available in a wide range of shapes and sizes as well as materials. Advances in material technology has permitted higher strength, thinner walled balloons that have a greatly reduced profile. The modifications made to shape and length permit highly specific and detailed applications and some catheters employ special coating to enhance performance. This expanding technology has permitted a great deal of diversity in the therapeutic application of these medical devices.

Balloons come in two basic conformations: One is the high pressure, non-elastic dilatation or angioplasty type balloon. The second is the low-pressure elastomeric balloon, usually made from silicone or latex. Angioplasty requires balloons that have a controlled or repeatable size in order to ensure that the balloon will not continue to expand and rupture a blood vessel after the blockage has been removed. A low compliance (less stretchy) high pressure will expand only 5-10% over its rated pressure. A highly compliant (very stretchy) low pressure balloons can expand 100-600% of original size if over-inflated. Low-pressure elastomeric balloons are not generally used due to their propensity to inflate asymmetrically. This discussion will be limited to high-pressure balloons as these are most relevant to NuMED's family of PTV catheters.[26, 28]

2.6.1. Materials used in High Pressure Balloons

Originally, angioplasty balloons were fabricated from Polyvinyl Chloride (PVC). They had a low tensile strength but had relatively thick walls to compensate and were pressurized at a much lower rate than today's high-pressure balloons. During the 1980's cross-linked polyethylene (PE) and polyester (PET) polyethylene terephthalate was employed in the manufacture of high-pressure balloons and replaced PVC to a large degree. Nylon balloons were introduced by the late 1980's and by the 90's polyurethane balloons soon followed. Nylon is not as strong as PET or as compliant as PE

but was introduced because it was softer than PET, while remaining thin and relatively strong. Today, most high-pressure balloons are fabricated either from either nylon or PET. PET offers greater advantages in tensile strength, hence a higher maximum pressure, while nylon is softer (Table 1). [28]

Materials	Tensile Strength	Compliance	Stiffness	Profile	Maximum Pressure (ATM)	(PSI)	Sterilization Method
PET	High-Very High	Low-medium	High	Low	20	294	Ethylene Oxide (EtO) or radiation
Nylons	Medium-High	Medium	Medium	Low-Medium	16	235	EtO
PE (cross-linked and other Polyolefins	Low	High	Low	High	10	147	Ethylene Oxide (EtO) or radiation
Polyurethanes	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 materials used in high-pressure balloons [28]

Rated pressures for balloons are typically in the range of 1-20 atmospheres (30-300 psi), depending on size. This is because the greater the diameter balloon size, the lower the rated pressure as the stress on the balloon wall becomes greater when inflated to its nominal diameter.

One major advantage of PET is its unusual ability to be molded into ultra thin walls and very precise shapes. This allows for the manufacture of balloons with very low profiles that are of use in smaller blood vessels.

High Pressure PET Balloons can have a diameter ranging from 0.5mm-50mm or more and can be of any working length, at the same time maintaining very thin walls. Nylon balloons are softer than PET balloons and require thicker walls to compensate. This gives the balloon a greater profile when entering into the body and crossing a lesion, however because it is softer, it is more easily refolded making it easier to withdraw into the guiding catheter.

2.6.2. Major Applications of High-Pressure Balloons

Dilatation

Dilatation is a term used to describe the use of a balloon catheter to dilate a blood vessel and Angioplasty is the most widely used application of high-pressure balloons in medicine.[28] Dilatation balloons are employed to dilate and clear arteries in Percutaneous Transluminal Angioplasty (PTA) and specifically the coronary arteries in Percutaneous Transluminal Coronary Artery Angioplasty (PTCA). PTA balloon sizes range from 2-12 mm in diameter and 20-100 mm in length. The pressure range is generally 8-20 ATM. PTCA balloon sizes run from 2-4 mm in diameter and 20-20 mm in length. They are rated for pressure in the 10-20 ATM range. [26, 28, 33]

Dilatation balloons are being used to dilate blockages and free passageways almost anywhere in the body including the esophagus, urethra, and fallopian tubes, tear ducts and heart valves (valvuloplasty). [18]

Stent delivery

Balloon catheters are also used in the placement and dilatation of stents. Stents are woven mesh or solid metal tubes that are placed to support the walls of blood vessels and other body cavities. For example Coronary stents are placed over a wrapped balloon and inserted in the coronary artery where a blockage or restriction has occurred. Inflating the balloon opens the stent, which remains expanded to provide support for the blood vessel. The balloon is then deflated and removed leaving the stent in place. The use of balloon catheters with stents is secondary only to the use of balloon catheters in dilatation. [1, 8, 17, 19, 23, 26, 28, 30]

Positioning

Balloon Catheters can be used to accurately position a device (other than a stent) in a blood vessel or other body cavity and is a relatively new market for specialty applications. Elastomeric balloons are sometimes used but high-pressure balloons are preferred when critical positioning is involved. One example of this technology is the delivery of a radioactive particle in an effort to prevent a blood vessel from undergoing restenosis. Centering the

particle means a symmetrical dosage is being applied on the vessel wall. Still other procedures are aimed at offset placement such as positioning a cutter to one side of an arterial wall in order that deposits of plaque can be removed (arthectomy).[28]

Occlusion

Often low-pressure, elastomeric balloons are used for occlusion/sealing. In some cases, however, it is more desirable to use a high-pressure balloon if a precise size and/or shape is required. High-pressure balloons also have an advantage over elastomeric balloons in that the length of the balloon can be determined as well as the end-shape of the balloon. Elastomeric balloons tend to be bulbous in nature and of a spherical shape.[28]

Drug Delivery/Gene Therapy

High-pressure balloons can be used when it is desirable to deliver a drug or gene product to a specific area of the body. For example, to deliver a toxic drug to a localized blockage or lesion a catheter will be crafted with two balloons, one behind the other with a gap in between them. When the balloons are inflated they take on what is termed a 'dog bone' shape with two large ends and a narrow middle. When the two end balloons are inflated this creates a small chamber in the blood vessel where a drug may be introduced to act locally. This is particularly useful where is undesirable to introduce a toxic drug or a gene product intravenously.[1, 9, 30, 36, 37]

Another method of localized drug delivery is through the use of porous membrane balloons. In this method the balloon is filled with the drug or compound to be delivered. When the balloon is inflated the porous skin of the balloon then begins to 'weep' attaining delivery of the drug or compound.[26]

2.6.3. Hazards Associated with PTV Catheters

Chemical Hazards

Chemical Hazards are those hazards derived from the intrinsic chemistry of the materials used in the balloon/catheter. A review of the materials used in the manufacture of balloon catheters (above) holds no surprises. Virtually all materials listed (ex. PVC.PET. Nylon) are all materials that have not demonstrated any overt short or long term toxicity. The possible exception to this may be the use of certain Phthalates. Phthalates are generally referred to as plasticizers and are used to make plastics more compliant. The most

commonly used for this purpose is Di-2-ethylhexyl Phthalate (DEHP). This compound gained notoriety in the 1980's when there were questions about carcinogenicity. The initial focus then on possible carcinogenic effects of products containing DEHP has turned out not to be the most important issue. Instead, other potential effects seen largely in animal studies and particularly related to possible reproductive problems now appear of more concern. The possibility that such effects might occur in susceptible humans requires rigorous study.

There are essentially no data to confirm toxicity of DEHP or its metabolites in humans; indeed DEHP has been used in the plastic used in the manufacture of blood bags for several decades without reports of disease or unexplained "ahnormalitics" in humans. The limited studies that exist are not adequate in design and outcomes to demonstrate the cause-effect relationships between DEHP exposure and toxicity. Therefore evaluation of risk to humans can only be extrapolated from animal data. Such extrapolations are questionable (without the incorporation of quantitative data on interspecies differences or human variability in toxicokinetics and toxicodynamics into the toxicity assessment) since there are significant species differences in metabolism that may completely alter the effect of a substance between experimental animal models and the human. This means that confirmed toxicity in an animal species may not occur at all in the human; or conversely a substance that appears safe in animals may nltimately demonstrate significant toxicity in humans. Only good quality and extensive human data can reliably confirm or refute a concern about toxicity.

This is particularly important for DEHP in the case of carcinogenicity. DEHP induces liver tumors in rats and mice when administered at high doses in their diet. The International Agency for Research on Cancer, however, has concluded that the mechanism by which this occurs in rodents is NOT relevant to humans.

Conversely, although there are also no data on the reproductive and developmental toxicity of DEHP or its metabolites in the human, the mechanism by which developmental and testicular toxicity in particular occur in rodents appears relevant to humans. It is not possible to assess the degree of risk based on rodent data because a) dose and, in most cases, the route of exposure (oral in the animal experiments) are different from in the human, and b) although qualitatively similar, there are several major differences between the metabolism of DEHP in rats and primates. Therefore it is not possible to even estimate the NOAEL (no-observable-adverse-effect level) of DEHP in humans from the animal data or even to be certain that such toxicity can occur.

It has been concluded in several reviews that that the risk of developmental and reproductive problems in the general adult population is small; but the

risk to infants, toddlers, critically ill children and during pregnancy and lactation may be more significant. However, for the purposes of this discussion the concentration of DEHP in the device and the length of time the person is exposed to the device/DEHP would seem to dictate that the dose would be insufficient to manifest any toxicological effects, even in children. [2]

Physical Hazards

Physical hazards are considered those hazards that are caused by operator error or some intrinsic physical property of the balloon catheter device.

General hazards associated with PTV catheters:

Cardiac complications: When considering injury from operational or device-related one must realize the high high-risk clinical profiles of the individual patients. Q-wave Myocardial infarction (Q-MI) has been noted to be higher in patients that have undergone therapeutic catheterizations. Non-Q-MI, however, is seen in a higher number of patients and tends to be the most common complication amongst patients undergoing balloon catheterization. In one study [5] the author cited this rate as 3.4% of all patients on study.

Emergency Coronary Artery Bypass (CABG) has also been noted as a complication of catheterization. In the no-flow phenomenon catheterization may be done effectively, but upon removal the artery exhibits no flow as the angioplasty has dislodged plaques from the wall of the vessel. Acute closure, wherein the artery collapses will also require CABG. Another condition arising and requiring CABG is the advent of guiding catheter-induced left main coronary artery dissection, wherein the artery undergoes significant damage as a result of catheter insertion. To a much lesser degree, pulmonary edema has been observed in patients.

Non-coronary interventions would appear to form a significantly smaller proportion of procedures related to catheterization. These include percutaneous transseptal mitral valvuloplasty (sometimes called Percutaneous transseptal commissurotomy or PTMC) and pulmonary valvuloplasty. Other less occurring complications include episodes of ventricular tachycardia or ventricular fibrillation, vasovagus episodes requiring atropine and occasionally vasopressors, no-reflow phenomenon, air embolism and cardiac tamponade noted during diagnostic procedures requiring transseptal catheterization.[5, 14, 15, 18, 24, 25, 29, 35]

Local complications: Complications at the femoral access site have been noted and are derived from both diagnostic and therapeutic procedures. The most common complication among diagnostic interventions appears to be

pseudoaneurysm formation. Amongst therapeutic interventions the need for a blood transfusion was the most prominent. Other local complications include hematoma, arterio-venous fistula and bleeding.[5]

Miscellaneous Complications: These are complications that do not fall into the categories of cardiac or local complications. The most common are acute renal insufficiency requiring hemodialysis and cerebrovascular accidents consisting of focal neurological deficits of varying degrees of severity. Other less common complications include allergic reactions to iodine, transient ischemic attacks, and episodes of confusion without demonstrable focal neurological deficit, neutropenia and thrombocytopenia.[5]

Biological Hazards

Nosocomial infections are perhaps the most common biological hazard to catheterization. As stated in Table1 (above) all catheters are markcted as sterile, usually through the use of Ethylene Oxide. It is because of this that contamination can only arise if the packaging of the device is compromised or if pathogens are present at the time of device use. Such problems are readily mitigated if there is effective and efficient cleaning of the procedure area or if devices with compromised packaging are returned to the manufaeturer or discarded.

More relevant to this discussion is the development of biofilm on cathcters that, for a variety of reasons, may be left indwelling for a (relatively) extended period of time. Microorganisms commonly attach to living and nonliving surfaces, including those of indwelling medical devices, and form biofilms made up of extracellular polymers. In this state, microorganisms are highly resistant to antimicrobial treatment and are tenaciously bound to the surface.

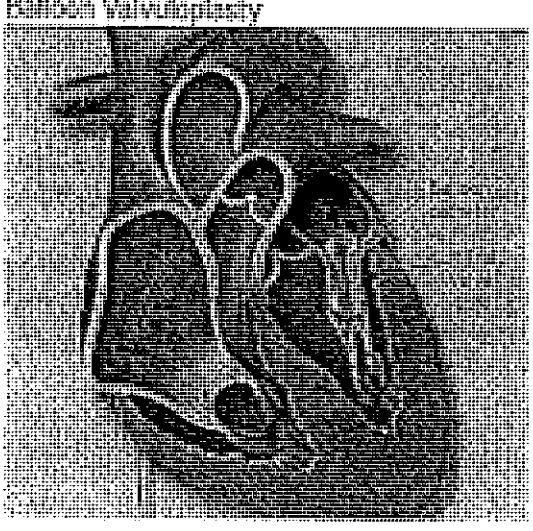
Biofilms on indwelling medical devices may be composed of gram-positive or gram-negative bacteria or yeasts. Bacteria commonly isolated from these devices include the gram-positive *Enterococcus faecalis,Staphylococcus aureus, Staphylococcus epidermidis*, and *Streptococcus* viridans; and the gram-negative *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis*, and *Pseudomonas aeruginosa*. These organisms may originate from the skin of patients or health-care workers, tap water to which entry ports are exposed, or other sources in the environment. Biofilms may be composed of a single species or multiple species, depending on the device and its duration of use in the patient. A distinguishing characteristic of biofilms is the presence of extracellular polymeric substances, primarily polysaccharides, surrounding and encasing the cells. This biofilm matrix may act as a filter, entrapping minerals or host-produced serum components. Biofilms are both tenacious and highly resistant to antimicrobial treatment. [5, 12, 13]

When an indwelling medical device is contaminated with microorganisms, several variables determine whether a biofilm develops. First the microorganisms must adhere to the exposed surfaces of the device long enough to become irreversibly attached. Once these cells irreversibly attach and produce extracellular polysaccharides to develop a biofilm, rate of growth is influenced by flow rate, nutrient composition of the medium, antimicrobial-drug concentration, and ambient temperature.

The microorganisms in biofilms are difficult or impossible to treat with antimicrobial agents and detachment from the device may result in infection. Although medical devices may differ widely in design and use characteristics, as stated above, specific factors determine susceptibility of a device to microbial contamination and biofilm formation. For example, duration of use, number and type of organisms to which the device is exposed, flow rate and composition of the medium in or on the device, device material construction, and conditioning films on the device all may influence biofilm formation. More effective biofilm control strategies should result as researchers develop more reliable techniques for measuring biofilms and better model systems for evaluating control strategies. A clearer picture of the importance of biofilms in public health should also result as the role of biofilms in antimicrobial-drug resistance is investigated and the link is established between biofilm contamination and patient infection.

Hazards specific to Percutaneous Transluminal Valvuloplasty Catheters

Percutaneous Transluminal Valvuloplasty is a minimally invasive technique using a balloon-tipped catheter to dilate and separate fused stenotic valve leaflets (Figure 1). Valvuloplasty of the mitral valve involves transseptal puncture and passage of one or two balloon catheters across the septum and into the mitral orifice. Inflation of the balloon(s) produces commissural separation and fracture of valvular calcification. Complications include systemic embolization, cardiac rupture and mitral regurgitation. The mitral valves that are the most favorable for valvuloplasty have some residual mobility, little or no calcification and little or no fusion of the subvalvular apparatus. Valvuloplasty of the aortic valve consists of retrograde passage of one or two balloon dilatation catheters across the aortic orifice. Most favourable results occur in children with congenital aortic stenosis. The benefit is limited in calcific aortic stenosis in adults due to restenosis. In adults, the procedure is usually applied in patients who are poor surgical candidates. The complications include systemic embolization, cardiac perforation and myocardial infarction. Valvuloplasty of the pulmonary valve is now the preferred method for treatment of



congenital pulmonary stenosis. The balloon catheter is passed antegrade from the right ventricle into the pulmonary orifice. The results of pulmonary valvuloplasty are generally excellent with a relatively low restenosis rate. [3] There are four primary hazards associated with PTV Catheterization:

1) Increased regurgitation from the valve on which the PTC procedure was carried out (Mitral or Aortic). [6, 7, 22]

2) Restenosis of the valve upon which the procedure was carried out (Mitral or Aortic). [6, 7, 10, 11, 21]

3) Impact of Operator experience.[18]

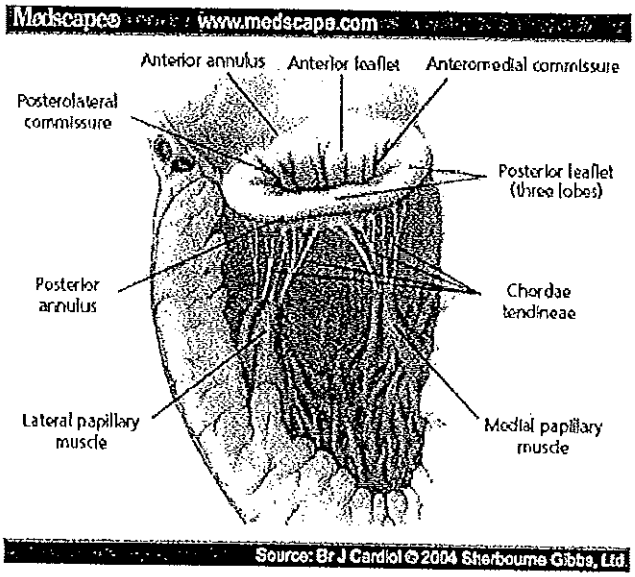
4) Stroke or heart attack due to dislodging of a plaque into the blood circulation during the procedure (rare occurrence). [3, 21]

Figure 1

Mitral Valve Regurgitation

For the purposes of this discussion, the focus will be generally on the mitral valve as there is a more significant database on the mitral valve than exists for the aortic valve.

The most common causes of mitral regurgitation are mitral valve prolapse syndrome, rheumatic heart disease, ischaemic heart disease, infective endocarditis and collagen vascular disease. Mitral valve prolapse refers to the systolic billowing of one or both mitral leaflets into the left atrium with or without mitral regurgitation, and is the most common form of valvular heart disease, with a prevalence of 2-6%. [6, 7, 22]



The mitral valve apparatus is a complex structure composed of the mitral annulus; valve leaflets, chordae tendineae, papillary muscles, and the supporting left ventricular wall, left atrial and aortic walls (figure 2). Disease processes involving any of these components may result in dysfunction of the valve apparatus, prolapse and regurgitation. Mitral regurgitation can be classified into three patho-anatomic types: (I) normal leaflet (chordal) motion, (II) leaflet prolapse (excessive chordal motion), and (III) restricted leaflet or chordal motion.

Figure 2

Whatever the etiology of mitral insufficiency, the pathophysiological changes can be thought of as progressing through one or more of three stages: acute mitral regurgitation, chronic compensated mitral regurgitation, and chronic decompensated mitral regurgitation. Mitral regurgitation results in volume overload of the left ventricle at the end of diastole, i.e. increased preload, as well as a reduction in afterload due to the regurgitant pathway back into the left atrium. The combination of increased preload and reduced afterload means that a larger volume of blood is ejected from the left ventricle. Because a large proportion of ejected blood enters the left atrium rather than the aorta, the forward stroke volume and hence the cardiac output, decreases.[7]

The American Heart Association (AHA) guidelines state that patients with severe chronic mitral regurgitation should be referred for surgery if they have New York Heart Association (NYHA) functional class II or above symptoms, if they have an ejection fraction < 0.60 or if they have an endsystolic dimension greater than 45 mm. The introduction of more effective management strategies for congestive cardiac failure and endocarditis, and the prevention of recurrent rheumatic fever and thromboembolic events have resulted in patients with chronic mild to moderate mitral regurgitation. They are then unlikely to require surgery and therapy is aimed at treating the symptoms and preventing complications.[6, 7, 10, 11, and 22]

Stenosis/Restenosis

Mitral Stenosis: The most common cause of mitral stenosis is rheumatic fever. A disease process that causes leaflet thickening and calcification, commissural and chordal fusion. Isolated mitral stenosis occurs in 40% of all patients presenting with rheumatic heart disease, and 60% of patients with mitral stenosis give a history of rheumatic fever. The ratio of female to male patients with this pathology is 2:1. Congenital malformation of the mitral valve occurs rarely.[7]

Aortic Stenosis: Aortic stenosis is the most common acquired valvular lesion with a prevalence of 1-2% in patients over 65. A bicuspid aortic valve is a risk factor for aortic stenosis and is present in up to 2% of the UK population.[6] Calcific aortic stenosis, the commonest cause of aortic stenosis, shares the pre-disposing factors of coronary artery disease: age, male sex and hypercholesterolaemia.[7, 10, 11]

Major hemodynamic compromise does not occur until the aortic valve size is reduced to less than half the normal aortic valve area of 3-4 cm^2 but beyond this, left ventricular outlet obstruction rapidly increases. Pressure overload of the left ventricle gradually leads to concentric hypertrophy of the ventricular wall. While this compensatory mechanism results in generation of the high

interventricular pressures required in maintaining cardiac output through the stenosis, there are a number of associated maladaptive features. Thickening of the ventricular wall and increased collagen content lead to diastolic dysfunction, with systolic dysfunction occurring eventually as a result of excess afterload and decreased contractility.[7, 11]

DESCRIPTION OF GRAPHICAL SYMBOLS:
DESCRIPTION DES SYMBOLES GRAPHIQUES :
DESCRIZIONE DEI SIMBOLI GRAFICI:
ERKLÄRUNG DER ZEICHEN:
DESCRIPCION DE LOS SIMBOLOS GRAFICOS:

BESKRIVNING AV GRAFISKA SYMBOLER:
BESKRIVELSE AF DE GRAFISKE SYMBOLER:
BESCHRIJVING VAN DE GRAFISCHE SYMBOLEN:
DESCRIÇÃO DOS SÍMBOLOS GRÁFICOS:

TEMPERATURE LIMITATION
LIMITE DE TEMPÉRATURE
LIMITE DELLA TEMPERATURA
TEMPERATURGRENZE
LIMITE DE TEMPERATURA
TEMPERATUURBEGRANSNING
TEMPERATURBEGRÆNSNING
TEMPERATUURLIMIET
LIMITE DE TEMPERATURA

MANUFACTURER
FABRICANT
PRODUTTORE
HERSTELLER
FABRICANTE
TILLVERKARE
PRODUCENT
FABRIKANT
FABRICANTE

EC REP

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REPRESENTANT AGRÉÉ DANS LA COMMUNAUTÉ EUROPÉENNE
RAPPRESENTANTE AUTORIZZATO DELLA COMUNITÀ EUROPEA
BEVOLLMÄCHTIGTER VERTRETER IN DER EUROPÄISCHEN GEMEINSCHAFT
REPRESENTANTE AUTORIZADO EN LA UNIÓN EUROPEA
AUKTORISERAD EU-REPRESENTANT
AUTORISERET REPRÆSENTANT I DET EUROPÆISKE FÆLLESSKAB
GEAUTORISEERDE VERTEGENWOORDIGER IN DE EUROPESE GEMEENSCHAP
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CE
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NuCLEUS™

Percutaneous Transluminal Valvuloplasty Catheter

Contents of unopened, undamaged package are:

STERILE • NONPYROGENIC

Sterile in unopened and undamaged package if the word "gas-chex" on the sterility indicator strip has changed from red to green.

Non-sterile if the package has been opened or damaged or the word "gas-chex" on the sterility indicator strip is not green.

Disposable This device intended for one use only.
Do not reuse or resterilize.
Sterilized with Ethylene Oxide.

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician.

Read all instructions prior to use.

NuMED

Le contenu de l'emballage n'ayant été ni ouvert ni endommagé est le suivant :

STÉRILE • NON-PYROGÈNE

Stérile si l'emballage n'a été ni ouvert, ni endommagé et si l'expression "gas-chex" de la bande indicatrice de stérilité est passée du **rouge au vert**.

Non-stérile si l'emballage a été ouvert ou endommagé ou encore si l'expression "gas-chex" de la bande indicatrice de stérilité n'est **pas verte**.

Jetable - Ce dispositif est à usage unique.
Ne le retraitez pas et ne le restérilisez pas.
Stérilisez-le avec de l'oxyde d'éthylène.

Lisez toutes les instructions avant d'utiliser le dispositif.

Contenuto della confezione chiusa, non danneggiata:

STERILE • APIROGENO

Sterile in confezione chiusa e non danneggiata se la parola "gas-chex" sulla striscia dell'indicatore di sterilità da **rossa** è diventata **verde**.

Non-sterile se la confezione è stata aperta o danneggiata o se la parola "gas-chex" sulla striscia dell'indicatore di sterilità **non** è **verde**.

Monouso - Questo dispositivo è inteso per un solo uso.
Non riutilizzare o risterilizzare.
Sterilizzato con ossido di etilene.

Prima dell'utilizzo, leggere attentamente tutte le istruzioni.

Der Inhalt der ungeöffneten unbeschädigten Verpackung ist:

STERIL • NICHT PYROGEN

Steril in ungeöffneter und unbeschädigter Verpackung, wenn sich die Farbe des Worts "gas-chex" auf dem Sterilitätsanzeigestreifen von **rot in grün** geändert hat.

Nicht steril, wenn die Verpackung geöffnet oder beschädigt wurde oder das Wort "gas-chex" auf dem Sterilitätsanzeigestreifen **nicht grün** ist.

Einwegartikel - Dieses Gerät ist nur zur einmaligen Verwendung vorgesehen.
Nicht wieder verwenden oder erneut sterilisieren.
Mit Ethylenoxid sterilisiert.

Lesen Sie vor der Verwendung sämtliche Anweisungen.

El contenido del paquete sin abrir y sin alterar es el siguiente:

ESTÉRIL • NO PIROGÉNICO

Estéril en paquetes no abiertos y no alterados, si la palabra "gas-chex" en la franja indicadora de esterilidad ha cambiado de **rojo a verde**.

No estéril si el paquete fue abierto o alterado o si la palabra "gas-chex" en la franja indicadora de esterilidad **no es verde**.

Desechable - Este dispositivo está previsto para ser utilizado una sola vez.
No reutilizar ni reesterilizar.
Esterilizado con óxido de etileno.

Lea todas las instrucciones antes de utilizar el producto.

Innehållet i en oöppnad och oskadad förpackning är:

STERILT • ICKE-PYROGENT

Steril i oöppnad och oskadad förpackning om ordet "gas-chex" på sterilitetsindikeringsremsan har ändrat färg från **rött till grönt**.

Icke-sterilt om förpackningen är öppnad eller skadad, eller om ordet "gas-chex" på sterilitetsindikeringsremsan **inte är grönt**.

För engångsbruk - Denna enhet är endast avsedd för ett användningstillfälle.
Återanvänd inte och sterilisera inte om.
Steriliserad med etylenoxid.

Läs anvisningarna före användning.

Indholdet af uåbnet og ubeskadiget pakning er:

STERILT • PYROGENFRIT

Sterilt i uåbnet og ubeskadiget pakning, hvis ordet "gas-chex" på indikatorstrippen for sterilitet har ændret farve fra **rødt til grønt**.

Usterilt hvis pakningen har været åbnet eller er beskadiget, eller ordet "gas-chex" på indikatorstrippen **ikke er grønt**.

Engangsbrug - Denne enhed er kun til engangsbrug.
Må ikke genbruges eller resteriliseres.
Steriliseret med ethylenoxid.

Læs alle anvisninger før brug.

De inhoud van de ongeopende, onbeschadigde verpakking is:

STERIEL • PYROGEENVRIJ

Steriel in de ongeopende en onbeschadigde verpakking als het woord "gas-chex" op de steriliteitsindicatorstrook van **rood** naar **groen** veranderd is.

Niet-steriel als de verpakking geopend of beschadigd is, of als het woord "gas-chex" op de steriliteitsindicatorstrook **niet groen** is.

Disposable - Dit hulpmiddel is uitsluitend voor eenmalig gebruik bestemd.
Niet opnieuw gebruiken of opnieuw steriliseren.
Gesteriliseerd met ethyleenoxide.

Neem alle aanwijzingen vóór gebruik goed door.

O conteúdo da embalagem fechada e não danificada é:

ESTÉRIL • APIROGÉNICO

Estéril em embalagem fechada e não danificada se a palavra "gas-chex" na faixa indicadora de esterilidade tiver passado de **vermelho a verde**.

Não estéril se a embalagem tiver sido aberta ou danificada ou se a palavra "gas-chex" na faixa indicadora de esterilidade **não estiver verde**.

Descartável - Este aparelho destina-se a uma única utilização.
Não voltar a utilizar ou a esterilizar.
Esterilizado por Óxido de Etileno.

Antes de utilizar, leia todas as instruções.

Istruzioni per l'uso

INDICAZIONI

Consigliato per valvuloplastica percutanea transluminale (PTV) per la posizione mitrale e aortica e per applicazioni di angioplastica centrata. L'uso di questo catetere è indicato in particolar modo nelle stenosi laddove possa risultare difficile il posizionamento del palloncino durante il gonfiaggio.

DESCRIZIONE

Il catetere NuMED NuCLEUS PTV prevede un singolo palloncino di gonfiaggio sullo stelo del catetere coassiale. Il palloncino presenta una sezione centrale più piccola per facilitarne il blocco nella valvola o nell'area da gonfiare. All'iniezione del volume di gonfiaggio, questa sezione centrale si espande al 90% del diametro nominale del palloncino. L'estensione riportata con la misura del palloncino e con il numero di lotto del prodotto si riferisce al gonfiaggio/sgonfiaggio del palloncino. L'altra apertura per connettore 'Y' viene usata per far passare la guida.

La punta interna del catetere è realizzata in tubo in termoplastica ed è contrassegnata con tre marker radiopachi situati sulla sezione centrale e dietro le spalle del palloncino, per definirne la posizione.

Ogni palloncino si gonfia a una determinata pressione, fino a raggiungere il diametro e la lunghezza prefissati. Le dimensioni raggiunte dal palloncino sono pari al ± 10% della pressione nominale di rottura (RBP), che dipende dalle dimensioni del palloncino stesso. Controllare il valore di RBP sull'etichetta della confezione. Durante il gonfiaggio, è importante non superare questo valore.

CONTROINDICAZIONI

Oltre ai rischi standard associati all'inserimento di un catetere cardiovascolare, non vi sono controindicazioni note per la valvuloplastica. Le condizioni mediche del paziente potrebbe compromettere l'utilizzo di questo catetere.

AVVERTENZE

- ATTENZIONE: non superare il valore di RBP. Per monitorare la pressione, si consiglia l'uso di un dispositivo di gonfiaggio dotato di indicatore della pressione. Una pressione superiore a RBP può causare la rottura del palloncino, impedendo potenzialmente la retrazione del catetere lungo la guaina di introduzione.
- Durante la selezione di una misura adeguata per il paziente, considerare con attenzione il diametro di gonfiaggio del palloncino del catetere. Il diametro del palloncino gonfiato non deve essere di molto superiore al diametro della valvola. La selezione della misura di palloncino da usare per la stenosi valvolare è definita nel Registro VACA come pari a 1,2 - 1,4 volte l'anulo della valvola. È importante eseguire un angiogramma prima della valvuloplastica, al fine di misurare la valvola nella proiezione laterale.
- I palloncini ≥ 4 cm di lunghezza potrebbero collidere sulla valvola tricuspide e danneggiarla. Si sconsigliano palloncini con lunghezza superiore ai 4 cm per i bambini ≤ 10 anni.
- Usare solo un mezzo di gonfiaggio del palloncino appropriato. Non usare aria o mezzi gassosi. Per in gonfiaggio e lo sgonfiaggio del palloncino si consiglia di utilizzare una siringa di almeno 20 cc.
- Si sconsiglia di usare questo catetere per misurare la pressione o per iniettare liquidi.
- Durante la procedura, non rimuovere mai la guida dal catetere.
- Questo dispositivo è esclusivamente monouso. Non risterilizzarlo né riutilizzarlo.
- Utilizzare il catetere prima della data di scadenza 'Usare prima del' riportata sull'etichetta della confezione.
- Con palloncini di dimensioni una volta e mezza la grandezza dell'anulo della valvola si sono verificati danni al tratto di deflusso ventricolare destro.
- Il catetere è adatto solo per applicazioni di valvuloplastica, non per interventi di angioplastica.
- Non usare il catetere per la ridilatazione di stent.

PRECAUZIONI

- Condurre la dilatazione sotto guida fluoroscopica con apparecchi di raggi X adatti.
- Le guide sono strumenti delicati: maneggiarle con prudenza per evitare la loro possibile rottura.
- Prima dell'apertura, ispezionare il contenitore sigillato del catetere. Se il sigillo è rotto oppure il contenitore è danneggiato o bagnato, la sterilità non è assicurata.
- Per evitare l'introduzione di aria nel sistema, prima di procedere, verificare con cura la tenuta delle connessioni del catetere e l'aspirazione.
- Non forzare mai l'avanzamento di alcun componente del catetere. Identificare la causa della resistenza in fluoroscopia e adottare le procedure più indicate per risolvere il problema.
- Se si incontra resistenza al momento della rimozione, estrarre il palloncino, la guida e la guaina come unica unità (soprattutto in caso di rottura o perdita dal palloncino, sospetta o accertata). Afferrare saldamente il catetere con palloncino e la guaina come unica unità e retrarli associando alla trazione un delicato movimento di rotazione.
- Prima di rimuovere il catetere dalla guaina, accertarsi che il palloncino sia completamente sgonfio.
- Il funzionamento corretto del catetere dipende dalla sua integrità, quindi dovrebbe essere maneggiato con cautela: attorcigliamenti, stiramenti o strofinamenti vigorosi possono danneggiarlo.

ISTRUZIONI PER L'USO

Prima di procedere con la valvuloplastica, controllare con attenzione tutti gli strumenti da usare durante la procedura, incluso il catetere, per accertarne il corretto funzionamento. Verificare che il catetere e la confezione sterile non abbiano subito danni durante la spedizione e il catetere sia della misura adatta.

NOTA: RIMUOVERE LA PROTEZIONE DEL PALLONCINO SOLO A COMPLETAMENTO DELLA PROCEDURA DI SPURGO.

1.0 Fissare un rubinetto a 3 vie all'estensione di gonfiaggio del palloncino del catetere.

2.0 Riempire il dispositivo di gonfiaggio con manometro (vedi tabella) con circa 6 cc di soluzione salina normale. Fissare questa siringa all'apertura diritta del rubinetto e girarne la manopola per chiudere l'apertura vuota.

3.0 Tenere il catetere dalla punta distale ed il palloncino rivolto in basso. Iniettare nel catetere circa metà dei 6 cc di fluido. Tirare indietro la siringa per creare un vuoto. Ripetere questa procedura 2 o 3 volte per eliminare completamente l'aria.

4.0 Staccare il dispositivo di gonfiaggio con manometro dal rubinetto e riempire con mezzo di contrasto (vedi tabella) diluito (30%) in quantità leggermente superiore al volume consigliato. Riattaccare questa siringa al rubinetto a 3 vie.

5.0 Spurgare il rubinetto e dopo aver spurgato la siringa accertarsi di lasciare esattamente il volume consigliato per il contrasto.

6.0 Attaccare inoltre una siringa da 20 cc alla restante apertura del rubinetto. Girare la manopola del rubinetto verso questa siringa e bloccare la siringa in posizione di vuoto.

7.0 Tirare il vuoto sul dispositivo di gonfiaggio con manometro per eliminare tutta l'aria ancora presente nel rubinetto.

8.0 Girare la manopole del rubinetto in modo da esporre l'apertura del catetere sulla siringa del vuoto da 20 cc. In questo modo si tirano circa 2 cc di fluido nella siringa.

ITALIANO

LOTTO

9.0 Togliere la protezione del palloncino ed inserire il catetere sulla guida seguendo una tecnica percutanea con guaina di introduzione.

10.0 Dopo aver controllato la corretta posizione, girare il rubinetto per chiudere l'apertura delle siringa del vuoto.

11.0 Iniettare il volume di fluido nel palloncino (vedi tabella). Questa iniezione gonfia le estremità del palloncino con sezione centrale, assestandolo in posizione.

12.0 Dopo aver confermato la corretta posizione, gonfiare il palloncino con il resto del volume di gonfiaggio.

13.0 Sgonfiare il palloncino tirando il vuoto sulla siringa. Nota: maggiore è l'aspirazione applicata durante l'estrazione, minore sarà il profilo del palloncino sgonfio. Estrarre il catetere con delicatezza. Nel momento in cui il palloncino fuoriesce dal vaso, procedere con movimenti lineari, delicati e continui, in senso antiorario. Se si osserva resistenza al momento della rimozione, togliere il palloncino, la guida e la guaina come unica unità, particolarmente se si sospetta o si è osservata una lesione o una perdita del palloncino. A questo scopo afferrare il catetere del palloncino e la guaina come unica unità e farli fuoriuscire insieme, con un movimento delicato e ruotante abbinato a trazione.

14.0 Esercitare pressione al sito di penetrazione seguendo la pratica standard o il protocollo ospedaliero relativo alle procedure vascolari percutanee.

Complicazioni/Effetti avversi potenziali

Potenziale separazione del palloncino in seguito a rottura o abuso e conseguente necessità di usare un cappio o altre tecniche di intervento medico per recuperare le parti.

NOTA: sono stati segnalati casi saltuari di palloncini con diametro superiore che sono scoppiati in circonferenza, probabilmente a causa di una combinazione di restringimenti focali in vasi di grosso calibro. In qualsiasi situazione in cui si noti la rottura di un palloncino durante l'uso, prima di estrarlo dal sito di penetrazione, si consiglia di applicare una guaina sopra al palloncino rotto. A tale scopo, tagliare l'estremità prossimale del catetere o far scivolare una guaina delle dimensioni appropriate sopra al catetere nel sito di inserzione. Per dettagli sulla tecnica, fare riferimento a: Tegtmeyer, Charles J., M.D. & Bezirdjian Diran R., M.D. "Removing the Stuck, Ruptured Angioplasty Balloon Catheter." Radiology, Volume 139, 231-232, April 1981.

Tra le potenziali complicazioni e gli effetti avversi relativi associati al catetere per valvuloplastica vi sono:

- Perforazione
- Lesione del sistema di conduzione
- Eventi tromboembolici
- Ematoma
- Lesione cardiovascolare e infundibolo
- Sviluppo di aritmia
- Strappo valvolare o trauma
- Sviluppo di restenosi
- Infiammazione
- Infezione

Avvertenza:

I cateteri NuMED vengono usati in parti del corpo umano che sono estremamente ostili, per cui potrebbero non funzionare a causa di diversi motivi, tra cui possibili complicazioni mediche o il mancato funzionamento dei cateteri a causa di una rottura. Inoltre, nonostante il design dettagliato, la selezione accurata dei componenti e della produzione e il collaudo prima della vendita, i cateteri potrebbero facilmente subire danni prima, durante o dopo l'inserimento a causa di un uso scorretto o della presenza di altri fattori. Di conseguenza, non viene fornita alcuna rappresentanza o garanzia dell'assenza di eventuali guasti o di interruzioni di funzionamento o che il corpo non reagirà in modo indesiderato all'inserimento dei cateteri o che infine non vi saranno complicazioni dovute all'uso dei cateteri.

NuMED non garantisce gli accessori NumED, poiché la loro struttura potrebbe essere stata danneggiata da manipolazione scorretta prima o durante l'uso. Di conseguenza, non viene fornita alcuna rappresentanza o garanzia al riguardo.

Garanzia e limitazioni

I cateteri e i relativi accessori vengono venduti come sono. I rischi riguardanti la qualità e le prestazioni del catetere sono esclusivamente a carico dell'acquirente. NuMED non offre alcuna garanzia, espressa o implicita, per quanto riguarda i cateteri e gli accessori, comprese eventuali garanzie implicite di commerciabilità o adeguatezza per un certo scopo. NuMED non si assume alcuna responsabilità nei confronti di alcuna persona o di eventuali spese mediche o danni diretti o indiretti conseguenti all'uso di un catetere o accessorio o causati da difetti, guasto o mancato funzionamento del catetere o dell'accessorio, sia che il reclamo si basi su garanzia, contratto, illecito o altra forma. Nessuno possiede l'autorità di vincolare NuMED a rappresentare o garantire i cateteri e gli accessori.

ITALIANO

Caratteristiche di gonfiaggio NuCLEUS™

Lunghezza palloncino di 3 cm

Misura palloncino (mm x cm)	Misura stelo (Fr)	Introduttore (Fr)	Disp. gonf./ siringa a vuoto (cc)	Totale volume gonfiaggio dopo lo spurgo (cc) *	Volume a diametro cc = Diam pall / sezione centrale in mm	Diam sezione centrale gonfiata (mm)	Pressione nom di rottura (atm)
10 x 3	6	7	20/20	5	2cc = 9,0mm / 5,0mm 4cc = 9,7mm / 7,0mm 5cc = 10,0mm / 9,6mm	9,6	9,0
12 x 3	6	8	20/20	6,5	3cc = 11,0mm / 6,0mm 6cc = 11,7mm / 9,0mm 6,5cc = 12,2mm / 11,5mm	11,5	7,0
14 x 3	7	9	20/20	8	4cc = 13,0mm / 6,0mm 6cc = 13,7mm / 12,5mm 8cc = 14,2mm / 13,7mm	13,7	6,0
16 x 3	7	9	20/20	10	5cc = 13,5mm / 7,0mm 7cc = 14,5mm / 9,0mm 9cc = 15,2mm / 13,8mm 10cc = 16,0mm / 15,5mm	15,5	5,0
18 x 3	8	10	20/20	13	6cc = 16,0mm / 7,0mm 8cc = 17,0mm / 11,0mm 10cc = 17,5mm / 13,0mm 12cc = 18,0mm / 16,5mm 13cc = 18,5mm / 17,5mm	17,5	4,0

Lunghezza palloncino di 4 cm

Misura palloncino (mm x cm)	Misura stelo (Fr)	Introduttore (Fr)	Disp. gonf./ siringa a vuoto (cc)	Totale volume gonfiaggio dopo lo spurgo (cc) *	Volume a diametro cc = Diam pall / sezione centrale in mm	Diam sezione centrale gonfiata (mm)	Pressione nom di rottura (atm)
10 x 4	6	7	20/20	6	4cc = 9,2mm / 5,0mm 6cc = 10,0mm / 9,6mm	9,6	9,0
12 x 4	6	8	20/20	8	4cc = 11,0mm / 6,0mm 6cc = 11,5mm / 10,0mm 8cc = 12,2mm / 11,5mm	11,5	7,0
14 x 4	7	9	20/20	10	5cc = 12,5mm / 6,0mm 7cc = 13,5mm / 9,5mm 9cc = 14,0mm / 12,5mm 10cc = 14,2mm / 13,7mm	13,7	6,0
16 x 4	7	9	20/20	13	7cc = 15,0mm / 7,0mm 9cc = 15,0mm / 12,5mm 11cc = 15,8mm / 14,0mm 13cc = 16,0mm / 15,5mm	15,5	5,0

Misura palloncino (mm x cm)	Misura stelo (Fr)	Introduttore (Fr)	Disp. gonf./ siringa a vuoto (cc)	Totale volume gonfiaggio dopo lo spurgo (cc) *	Volume a diametro cc = Diam pall / sezione centrale in mm	Diam sezione centrale gonfiata (mm)	Pressione nom di rottura (atm)
18 x 4	8	10	20/20	16	8cc = 16,0mm / 7,0mm 10cc = 17,0mm / 11,0mm 12cc = 17,2mm / 12,0mm 14cc = 18,0mm / 16,5mm 16cc = 18,5mm / 17,5mm	17,5	4,0
20 x 4	8	12	30/20	17,5	8cc = 18,0mm / 8,0mm 10cc = 18,5mm / 9,0mm 12cc = 18,5mm / 13,5mm 14cc = 19,0mm / 15,0mm 16cc = 19,5mm / 16,5mm 17,5cc = 20,1mm / 18,5mm	18,5	4,0
22 x 4	9	12	30/20	24	12cc = 19,5mm / 9,0mm 14cc = 19,5mm / 14,0mm 16cc = 20,0mm / 16,0mm 18cc = 20,0mm / 16,0mm 20cc =20,5mm / 19,0mm 22cc = 21,0mm / 19,5mm 24cc = 22,0mm / 20,5mm	20,5	4,0
25 x 4	9	12	30/20	29	17cc = 22,0mm / 10,0mm 19cc = 22,0mm / 13,0mm 21cc = 22,0mm / 15,0mm 23cc = 22,0mm / 16,0mm 25cc = 22,5mm / 17,0mm 27cc = 24,0mm / 21,0mm 29cc = 24,0mm / 23,5mm	23,5	4,0
28 x 4	9	14	40/20	35	18cc = 25,0mm / 13,0mm 20cc = 25,5mm / 15,0mm 22cc = 25,5mm / 18,0mm 24cc = 26,0mm / 20,0mm 26cc = 26,5mm / 22,0mm 28cc = 26,5mm / 23,0mm 30cc = 27,0mm / 25,0mm 32cc = 27,5mm / 26,5mm 35cc = 28,0mm / 27,0mm	27,0	2,0
30 x 4	9	14	40/20	38	19cc = 26,0mm / 12,0mm 21cc = 26,5mm / 14,0mm 23cc = 27,0mm / 16,0mm 25cc = 27,5mm / 16,5mm 27cc = 28,0mm / 18,0mm 29cc = 28,5mm / 20,0mm 31cc = 28,5mm / 22,0mm 33cc = 29,0mm / 24,0mm 35cc = 29,0mm / 26,0mm 38cc = 29,5mm / 28,0mm	28,0	2,0

* Se gonfiato per circa il 50% del volume di gonfiaggio totale, il palloncino presenta la forma NuCLEUS.

CON I CATETERI NUMED, USARE UN DISPOSITIVO DI GONFIAGGIO DOTATO DI INDICATORE DELLA PRESSIONE.

Gebrauchsanweisung:

INDIKATION:

Für perkutane transluminale Valvuloplastie (PTV) in Mitral- und Aortenposition sowie für Angioplastie in zentraler Position empfohlen. Dieser Katheter eignet sich insbesondere bei Stenose, wenn sich die Positionierung des Ballons beim Aufblasen als schwierig erweist.

BESCHREIBUNG:

Beim PTV-Katheter NuCLEUS von NuMED handelt es sich um einen Dilatationsballon auf einem koaxialen Katheterschaft. Dieser Ballon hat in der Mitte einen kleineren „Taillenumfang", um die Anbringung in der Klappe oder in einem anderen Bereich, der aufgedehnt werden soll, zu erleichtern. Die „Taille" wird beim Einspritzen der Inflationslösung auf 90 % des Nenndurchmessers des Ballons aufgeweitet. Die Verlängerung mit der angegebenen Ballongröße und Produktlosnummer dient zur Balloninflation/-deflation. Der andere „Y"-Anschluss dient zum Einführen des Führungsdrahts.

Die innere Spitze des Katheters besteht aus einer thermoplastischen Zuleitung und ist zur Kennzeichnung der Ballonposition an der „Taille" und unter den Ansätzen des Ballons mit drei Kontrastbändern versehen.

Jeder Ballon wird bei einem bestimmten Druck auf den angegebenen Durchmesser und die angegebene Länge aufgeblasen. Bei maximalem Arbeitsdruck (RBP) beträgt die Ballongröße ± 10 %. Der maximale Arbeitsdruck variiert je nach Größe. Der maximale Arbeitsdruck ist auf der Verpackung angegeben. Der Ballon darf auf keinen Fall über den maximalen Arbeitsdruck hinaus aufgeblasen werden.

KONTRAINDIKATION:

Abgesehen von den herkömmlichen Risiken im Zusammenhang mit dem Einführen eines Kardiovaskulär-Katheters gibt es für eine Valvuloplastie keine bekannten Kontraindikationen. Der Gesundheitszustand des Patienten könnte Auswirkungen auf die Verwendung dieses Katheters haben.

WARNUNG:

- ACHTUNG: Der maximale Arbeitsdruck darf nicht überschritten werden. Es empfiehlt sich die Verwendung eines Inflators mit Druckmesser zur Druckkontrolle. Wird der maximale Arbeitsdruck überschritten, kann im Ballon ein Riss entstehen. Dies kann zur Folge haben, dass sich der Katheter nicht mehr durch die Einführschleuse herausziehen lässt.
- Der Durchmesser des aufgeblasenen Katheterballons muss bei der Auswahl einer bestimmten Größe für einen Patienten genau berücksichtigt werden. Der Durchmesser des aufgeblasenen Ballons sollte nicht wesentlich größer sein als der Klappendurchmesser. Laut VACA-Register soll der für eine Klappenstenose verwendete Ballon etwa 1,2 bis 1,4 mal so groß sein wie der Klappenanulus. Vor einer Valvuloplastie muss ein Angiogramm erstellt werden, um die Klappengröße in einer lateralen Aufnahme festzustellen.
- Ballone, die ≥ 4 cm lang sind, können an die Trikuspidalklappe anstoßen und eine Verletzung verursachen. Ballone, die mehr als 4 cm lang sind, sollten für Kinder ≤ 10 Jahre nicht verwendet werden.
- Verwenden Sie nur eine geeignete Ballonfüllung. Verwenden Sie zum Aufblasen des Ballons weder Luft noch ein gasförmiges Mittel. Es wird empfohlen, für die Balloninflation und -deflation eine Spritze mit einem Volumen von mindestens 20 cc zu verwenden.

DEUTSCH

6/1050

NUCLEUS™

Percutaneous Transluminal Valvuloplasty Catheter / cathéter de valvuloplastie transluminale percutanée / Catetere per valvuloplastica percutanea transluminale / percutane transluminale valvuloplastiekkatheter / Catéter de valvuloplastia transluminal percutánea / Perkutan transluminal valvuloplastikkateter / Percutant transluminalt valvuloplastikkateter / Katheter für perkutane tansluminale Valvuloplastie / Cateter de Valvuloplastia Transluminal Percutânea

REF PVN

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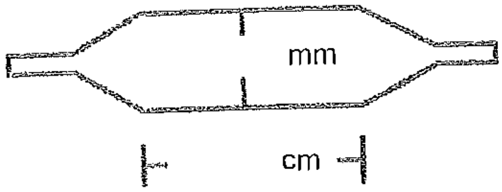
+5 °C +41 °F — +45 °C +113 °F

CE 0120



Introducer (Fr) / Introducteur / Introduttore vasale / Introducer / Introductor / Introducer / Introducer / Einführschleuse / Introdutor	Shaft Size (Fr) / Taille de la tige / Diametro del catetere / Schachtmaat / Tamaño de la vaina / Skaftstorlek / Skaftstørrelse / Schaftgröße / Dimensões do corpo	Usable Length (cm) / Longueur utilisable / Lunghezza utilizzabile / Bruikbare lengte / Longitud Útil / Användbar längd / Anvendelig længde / Nutzbare Länge / Comprimento útil

Guidewire (inch) / Guide métallique / Guida angiografica / Voerdraad / Guía / Ledare / guidewire / Führungsdraht / Fio-guia	Rated Burst Pressure (ATM) / Pression maximale avant éclatement / Pressione nominale di rottura / Nominale barstdruk / Presión nominal de rotura / Nominellt brisningstryck / Nominelt sprængningstryk / Maximaler Arbeitsdruck / Pressão Nominal de ruptura	Nominal Pressure (ATM) / Pression nominale / Pressione nominale / Nominale druk / Presión nominal / Nominellt tryck / Nominelt tryk / Nenndruck / Pressão nominal
		N/A

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Rx ONLY

IF PACKAGE IS DAMAGED OR OPEN DO NOT USE / N'UTILISEZ PAS SI L'EMBALLAGE A ÉTÉ OUVERT OU ENDOMMAGÉ / NON USARE SE LA CONFEZIONE È STATA APERTA O DANNEGGIATA / NIET GEBRUIKEN ALS DE VERPAKKING GEOPEND OF BESCHADIGD IS / NO UTILICE SI EL PAQUETE FUE ABIERTO O ALTERADO / FÅR INTE ANVÄNDAS OM FÖRPACKNINGEN HAR ÖPPNATS ELLER ÄR SKADAD / MÅ IKKE BRUGES HVIS PAKKEN HAR VÆRET ÅBNET ELLER ER BESKADIGET / NICHT VERWENDEN, WENN DIE VERPACKUNG GEÖFFNET ODER BESCHÄDIGT WURDE / NÃO UTILIZE SE A EMBALAGEM TIVER SIDO ABERTA OU DANIFICADA

Do not remove the guidewire from the catheter at any time during the procedure. / Ne retirez le guide métallique du cathéter à aucun moment de la procédure. / Durante la procedura, non rimuovere la guida angiografica in nessun momento. / Entfernen Sie den Führungsdraht während des Eingriffs nicht vom Katheter. / No extraiga la guía del catéter en ningún momento durante el procedimiento. / Ta aldrig bort ledaren från katetern under förfarandet. / Aftag ikke på noget tidspunkt guidewiren fra katetret under proceduren. / Verwijder nooit de voerdraad uit de katheter tijdens de operatie. / Nunca remova o fio-guia do cateter durante o procedimento.

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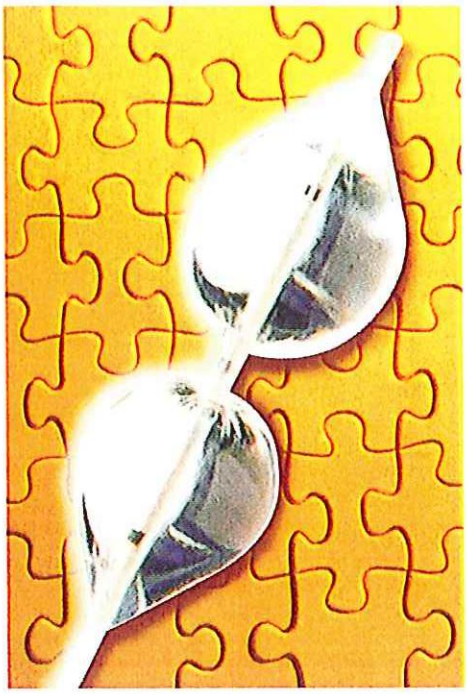
C-P-230CE-00

NUCLEUS™

Percutaneous Transluminal Valvuloplasty Catheter

(Patent # 5,352,199)



Catheter Characteristics

The NuMED **NuCLEUS™** PTV catheter is engineered for maximum steering and tracking. The coaxial shaft design provides enhanced column strength and pushability combined with a flexible distal tip for optimum steerability. The innovative single balloon design facilitates positive positioning while holding the balloon in the correct location prior to and during inflation.

Radiopaque Marker

Platinum marker bands facilitate reliable positioning of the balloon and are located at the 'waist' center and beneath the shoulders of the balloon for clear identification under fluoroscopy.

Maximum Trackability

The distal shaft through the balloon is highly flexible for exceptional maneuverability. This, combined with the pushability of the coaxial shaft, provides outstanding tracking performance.

Micro-Thin Non-Compliant Balloon

The NuMED **NuCLEUS™** PTV patented design allows for accurate balloon placement. Initial inflation will hold balloon in the desired position, further inflation expands the center of the balloon to effect satisfactory dilatation.

The NuMED **NuCLEUS™** PTV balloon is micro-thin for a low deflated profile that maintains tip flexibility. The exceptionally low profile balloon requires the smallest introducer possible. Nominal dimensions are maintained over the entire length of the non-compliant balloon.

Feature:

Low profile

Coaxial catheter

Maximum steering and trackability

For information regarding inflation graduations at various pressures and fluid volumes, refer to NuMED **NuCLEUS™** inflation characteristics within the instructions for use booklet.

Nucleus™ Specifications

Balloon Diameter (MM)	Balloon Length (CM)	Introducer Size (FR)	Shaft Size (FR)	Guide Wire (Inches)	Rated Burst (ATM)	Catalog No. Usable Lengths (Shaft Length)	
						85CM	110CM
10.0	3.0	7	6	0.035	9	PVN200	PVN218
10.0	4.0	7	6	0.035	9	PVN201	PVN219
12.0	3.0	7	6	0.035	7	PVN202	PVN220
12.0	3.0	8	6	0.035	7	PVN203	PVN221
12.0	4.0	7	6	0.035	7	PVN204	PVN222
12.0	4.0	8	6	0.035	7	PVN205	PVN223
14.0	3.0	9	7	0.035	6	PVN206	PVN224
14.0	4.0	9	7	0.035	6	PVN207	PVN225
16.0	3.0	9	7	0.035	5	PVN208	PVN226
16.0	4.0	9	7	0.035	5	PVN209	PVN227
18.0	3.0	10	8	0.035	4	PVN210	PVN228
18.0	4.0	10	8	0.035	4	PVN211	PVN229
20.0	4.0	12	8	0.035	4	PVN212	PVN230
22.0	4.0	12	9	0.035	4	PVN213	PVN231
25.0	4.0	12	9	0.035	4	PVN214	PVN232
28.0	4.0	12	9	0.035	2	PVN215	PVN233
28.0	4.0	14	9	0.035	2	PVN216	PVN234
30.0	4.0	14	9	0.035	2	PVN217	PVN235

Materials

Catheter Body: Polymeric.
Balloon: Non-Compliant Thermoplastic Elastomer.
Image Band: Platinum Iridium.

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NuMED offers Physicians speedy response to catheter design a
manufacturing service. The enhanced catheter technology offe
Physicians a technically superior option in dealing with clinical