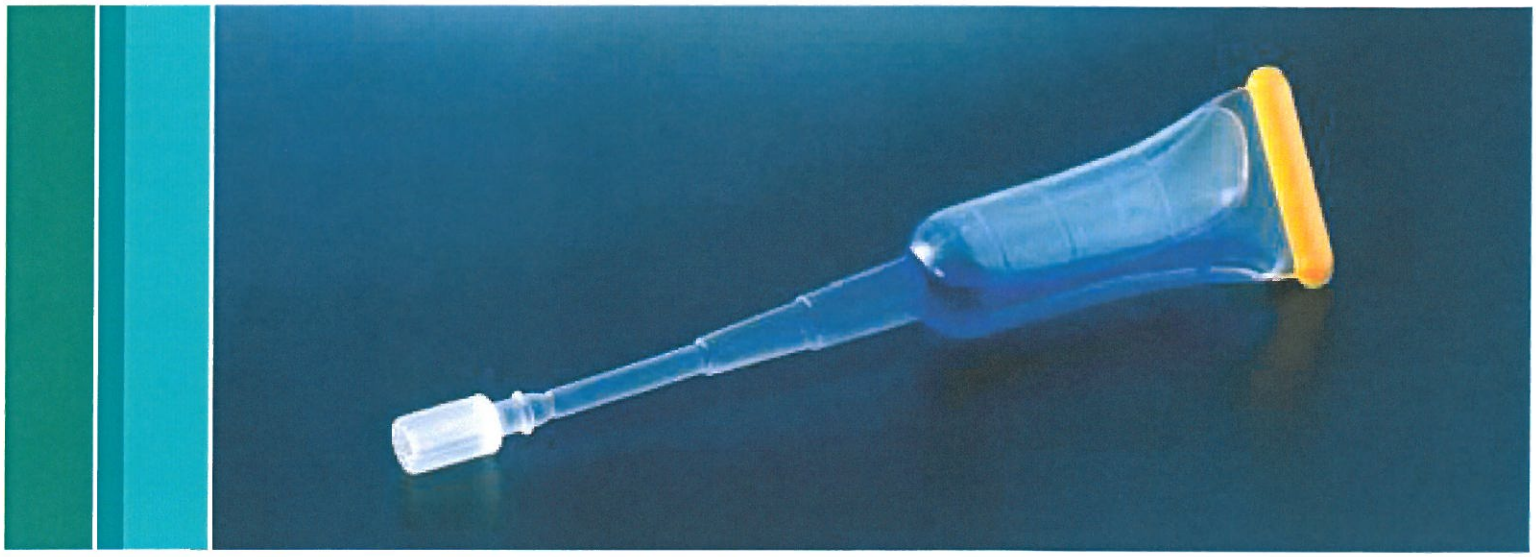
Histoacryl®

The real thing
Tissue adhesive



Biosurgicals

Digitally signed by Roibu Tatiana
Date: 2023.04.07 12:03:47 EEST
Reason: MoldSign Signature
Location: Moldova

B|BRAUN
SHARING EXPERTISE

Histoacryl®

The real thing – now even simpler and faster

For decades medical professionals around the world have put their trust in Histoacryl®, the first surgical tissue adhesive based on cyanoacrylate. The successful application of Histoacryl® is described in more than 1,200 publications.

Now the classic product for the closure of skin wounds is available

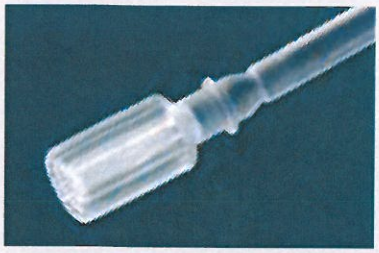
- in a new ampoule with a twist-off tip.
- with increased content of n-butyl-2-cyanoacrylate.
- with the indication for closure of skin wounds and for sclerosation therapy of esophageal and fundal varices.

New twist-off tip

Histoacryl®

now even simpler and faster

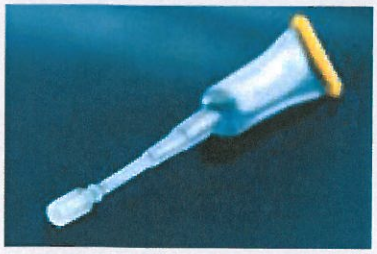
- Simply twist off the ribbed tip of the ampoule
- Then, as usual, Histoacryl® can be applied precisely with the slim cannula



Translucent Histoacryl® L

for facial applications

To be on the safe side, it is recommended to use Histoacryl® L, a version which does not contain dye, for facial applications.



www.histoacryl.com

Classic advantages

Well-known advantages of Histoacryl®:

- fast wound closure
- superior strength
- simple and precise dosage due to slim cannula and blue dye
- applying just one layer is enough
- choice between blue and translucent version
- showering possible

Why tissue adhesive?

- no suturing – no pain
- saves time and costs (no local anaesthetics, no suture removal, no second consultation)
- antibacterial film protects the wound
- no wound dressing necessary

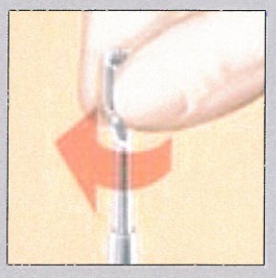
Product Range

Ordering Information

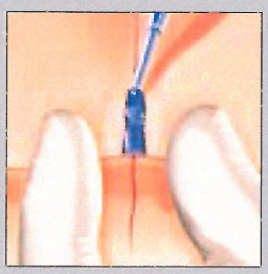
Description	Color	Article No.
5 x 0.5 ml Histoacryl®	blue	105 0052
10 x 0.5 ml Histoacryl®	blue	105 0044
5 x 0.2 ml Histoacryl®	blue	105 0036
10 x 0.2 ml Histoacryl®	blue	105 0028
5 x 0.5 ml Histoacryl® L	translucent	105 0060

- Literature is available upon request.

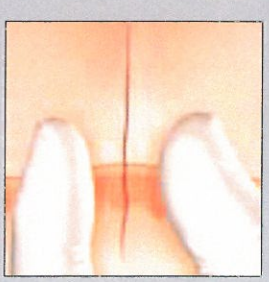
Wound closure in a minute:



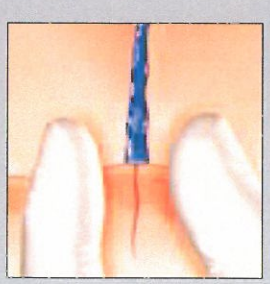
Clean the wound and turn open the ampoule



Apply Histoacryl® sparingly, do not allow tissue adhesive to flow into the wound



Adapt wound edges (wounds under tension and wounds longer than 3 cm require additional suturing)



Keep wound edges aligned for about one minute – that's all!

Histoacryl®

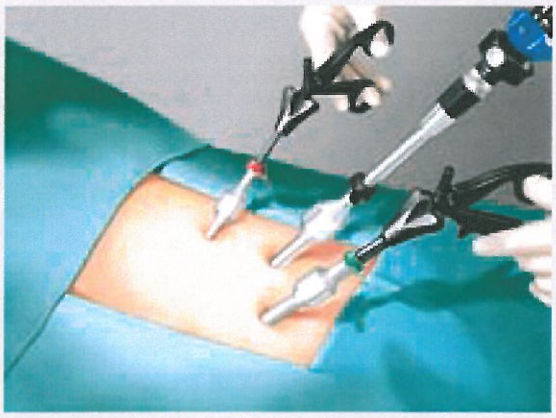
Histoacryl®

The real thing – now even simpler and faster

Histoacryl® for closure of endoscopic incisions

The Histoacryl® ampoule is supplied in sterile condition; therefore, Histoacryl® is the ideal tissue adhesive for use in the OR.
For example, it may be used for the closure of endoscopic incisions, as described in:

Rosin D et al. Closure of laparoscopic trocar site wounds with cyanoacrylate tissue glue: a simple technical solution. J Laparoendosc Adv Surg Tech 2001; 11(3):157-9.

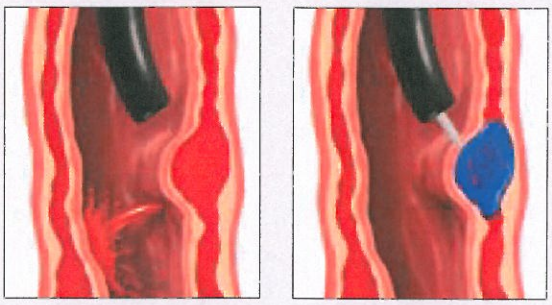


Sclerosation of esophageal and fundal varices with Histoacryl®

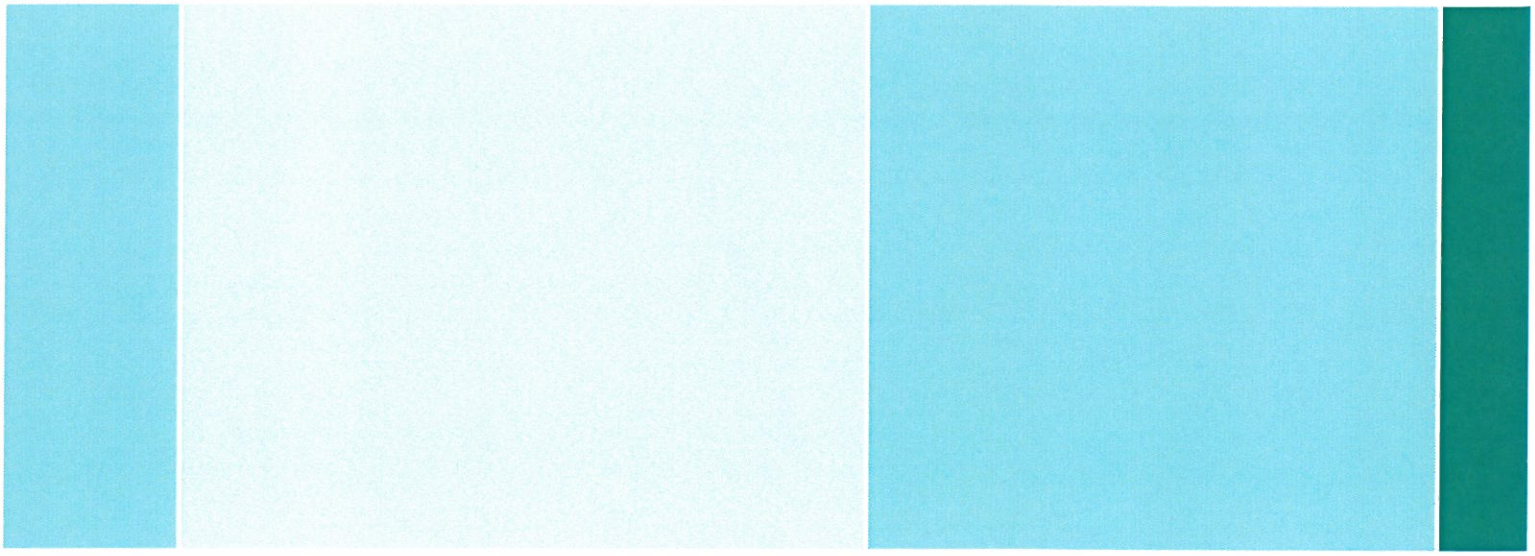
The formation of esophageal and fundal varices is a common and dangerous consequence of portal hypertension. Effective sclerosation of these varices is possible with Histoacryl®.

Varically injected Histoacryl® polymerizes intravasally to form a plastic cylinder and effects immediate obturation or thrombosing of the vessel. The procedure is described in detail in the relevant literature, for instance in the following article:

Caldwell SH et al. Enbucrilate for gastric varices: extended experience in 92 patients. Aliment Pharmacol Ther 2007; 26:49-59.



Histoacryl®



B. Braun Surgical SA | Carretera de Terrassa, 121 | 08191 Rubí | Spain
Phone +34 93 5 86 62 00 | Fax +34 93 6 99 73 03 | www.bbraun.es

Aesculap AG | Am Aesculap-Platz | 78532 Tuttlingen | Germany
Phone +49 7461 95-0 | Fax +49 7461 95-26 00 | www.aesculap.com

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Brochure No. B01102 0211/0.5/13

B BRAUN
SHARING EXPERTISE

INTERVENTIONAL
VASCULAR
DIAGNOSTICS
AND THERAPY

SeQuent® Please NEO

CLINICALLY PROVEN DRUG COATED BALLOON CATHETER

SeQuent® Please NEO

CUTTING-EDGE DRUG COATED BALLOON CATHETER

THE SECOND GENERATION DCB

Outstanding performance:

- Advanced crossing properties
- Improved pushability
- Hydrophilic shaft coating
- Reduced balloon wall thickness

Clinically proven indications:

- In-stent restenosis
- De novo
- Small vessel disease
- Bifurcations

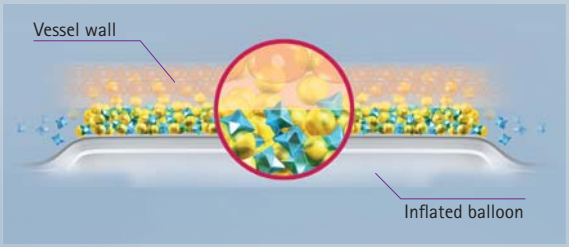
OVER 28 CLINICAL TRIALS WITH OVER 5,900 ENROLLED PATIENTS

IMPLANT-FREE WITH SeQuent® Please NEO

No stent-related complications and only **1-month DAPT** for the treatment with DCB-only

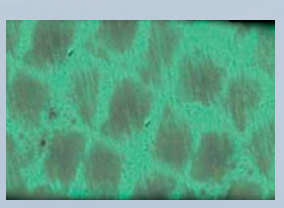
Clinically proven Paclitaxel and Iopromide coating

The matrix coating of Paclitaxel and Iopromide ensures the effective drug release into the vessel wall.



Homogenous drug delivery[1-4]

Only a "single shot" drug delivery with SeQuent® Please NEO is needed to ensure a sustained anti-proliferative effect. A short inflation time of only 30 seconds proved to be sufficient to inhibit cell proliferation.[2]



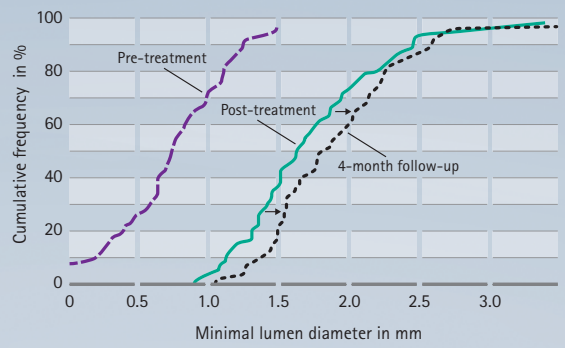
Stent struts of a DES lead to an inhomogenous drug distribution pattern. About 85 % of the vascular wall is not covered by the struts resulting in low drug tissue level.[1]

Homogenous drug distribution with SeQuent® Please NEO.[3]

PROVEN LATE LUMEN ENLARGEMENT

SeQuent® Please NEO supports the inherent mechanism of natural vessel restoration and leads to late lumen enlargement

Clinical trial to study late lumen enlargement of de novo lesions after DCB-only[5]



Angiographic Measure	Minimal Lumen Diameter in mm
Pre-treatment	0.81 ± 0.47
Post-treatment	1.75 ± 0.58
4-month follow-up	1.91 ± 0.55
p-value pre vs. post	< 0.001
p-value post vs. 4-month follow-up	< 0.001

Late lumen enlargement after 4 months

+ 0.16 mm

[1-4] Axel DI et al. Circulation 1997; 96: 636-45. | Hwang CW et al. Circulation 2004; 104: 600-5. | Scheller B et al. Circulation 2004; 110: 810-4. | Scheller B et al. Heart 2007; 93: 539-41.
[5] Kleber F et al. Clin Res Cardiol 2015; 104: 217-25.

SeQuent® Please NEO

DCB-ONLY TREATMENT

ADVANTAGES OF DCB-ONLY

No unnecessary stent implantation

- **No inflammation** due to a foreign body implant
- **No risk** of stent thrombosis
- **No stent-related limitations** for further treatment
- **No stent edge effect**

Efficacy of DCB

- **Enable positive remodeling**
- **Keep natural vessel vasomotion**
- **Only 1-month DAPT: Cost efficacy studies** ongoing

DCB-only provides the standard of care for all patients with high bleeding risks and atrial fibrillation[6]

METHODOLOGY[7]

LESION PREPARATION

Pre-dilation with

PTCA Balloon | Non-Compliant Balloon | Scoring Balloon

Ratio balloon-vessel-diameter 0.8 - 1.0, inflation pressure > nominal

Acceptable angiographic result:
No dissection or only type A or B;
TIMI III; residual stenosis ≤ 30 %

DCB-only with SeQuent® Please NEO

- DCB distal and proximal at least 2 - 3 mm longer than pre-dilated area
- Ratio balloon-vessel-diameter 0.8 - 1.0
- Inflation pressure 8 - 10 atm, time 30 seconds

DAPT DCB-only: 1 month
BMS-ISR: 1 month
DES-ISR: Duration defined by DES but at least 1 month

Unacceptable angiographic result:
Dissection type C – F; TIMI < III;
residual stenosis > 30 %

Stenting

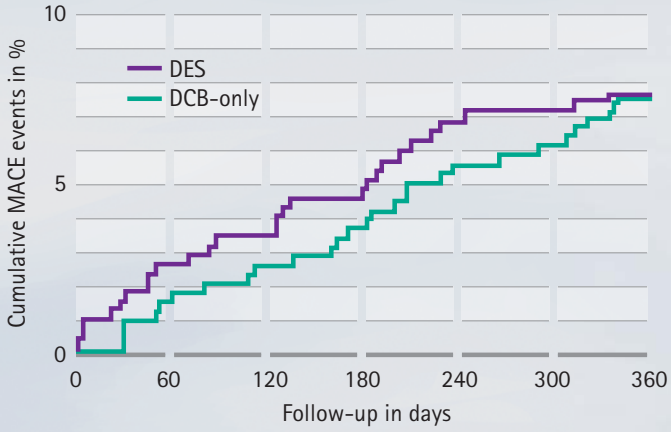
DES implantation Coroflex® ISAR NEO

DAPT according to current guideline

[6] Valgimigli M et al. European Heart Journal 2018; 39(3): 213-60.
[7] Kleber F et al. Clin Res Cardiol 2013; 102: 785-97.

GO IMPLANT-FREE

BASKET-SMALL 2: Randomized clinical trial for DCB-only vs. DES in de novo lesions (small vessel disease)[8]

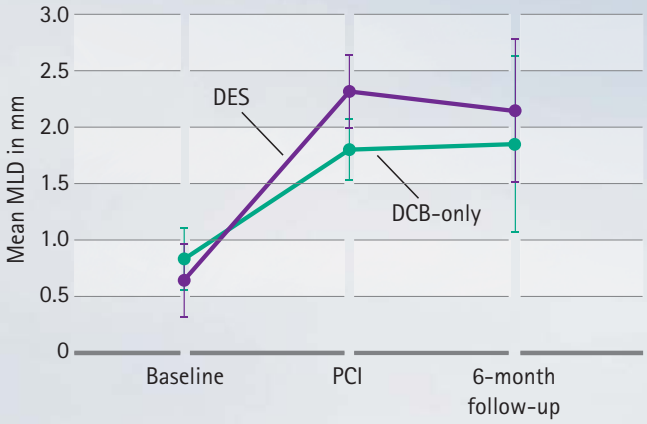


Primary endpoint: MACE at 12-month follow-up in %

DES (Xience/ Taxus® Element™)	7.54
DCB-only (SeQuent® Please NEO)	7.57
p-value	0.92

DCB-only is non-inferior to DES in de novo lesions up to 3 mm

OCTOPUS II: Clinical trial using OCT to evaluate the use of DCB without stenting in de novo lesions[9]



Primary endpoint: Late Lumen Loss at 6-month follow-up in mm

DES (Xience)[10]	0.16 ± 0.15
DCB-only (SeQuent® Please)	-0.13 ± 0.44
p-value	< 0.05

DCB-only achieves long-term late lumen gain contrary to DES

[8] Jeger R et al. The Lancet 2018; 392(10150): 849-56.
[9] Poerner T et al. Clin Res Cardiol 2017; 106: 18–27.
[10] Poerner T et al. CCI 2014; 7(6): 760-7.

SeQuent® Please NEO

CLINICALLY PROVEN INDICATIONS

IN-STENT RESTENOSIS

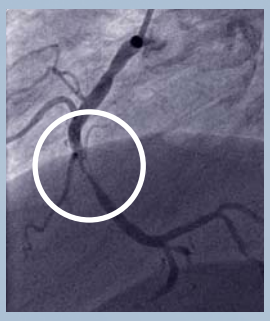
Patient: Male, 55 years

Indication: ISR of BMS (3.5 x 15 mm) implanted 2 years ago

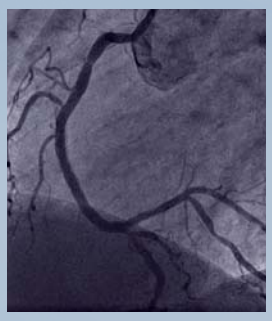
Procedure: Pre-dilation 3.5 x 15 mm PTCA balloon

DCB-only SeQuent® Please (3.5 x 20 mm) proximal lesion

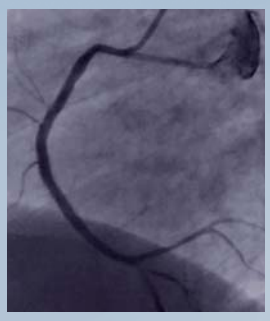
DCB-only SeQuent® Please (3.5 x 15 mm) distal lesion



Pre-treatment



Post-treatment



4-month follow-up

Drug coated balloons are recommended for the treatment of in-stent restenosis (BMS or DES) by the ESC Guidelines[11]	I	A	507-511,524

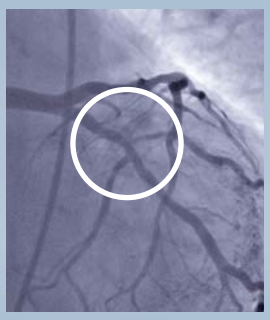
DE NOVO LESION

Patient: Female, 67 years

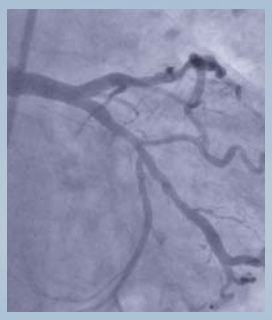
Indication: De novo stenosis of obtuse marginal branch

Procedure: Pre-dilation 2.5 x 15 mm PTCA balloon

DCB-only SeQuent® Please (2.5 x 20 mm)



Pre-treatment



Post-treatment

4-month follow-up

BIFURCATION

Patient: Male, 54 years

Indication: Stenoses of mid circumflex artery (CX) and its posterolateral branch (PL-CX)

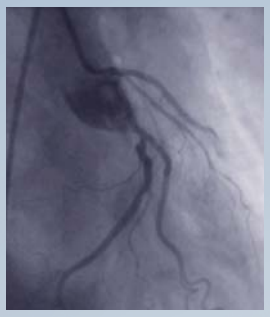
Procedure: Pre-dilation 2.5 x 20 mm PTCA balloon of CX

DCB-only SeQuent® Please (3.0 x 15 mm) of PL-CX

DCB-only SeQuent® Please (3.0 x 20 mm) of CX

Pre-treatment

Post-treatment

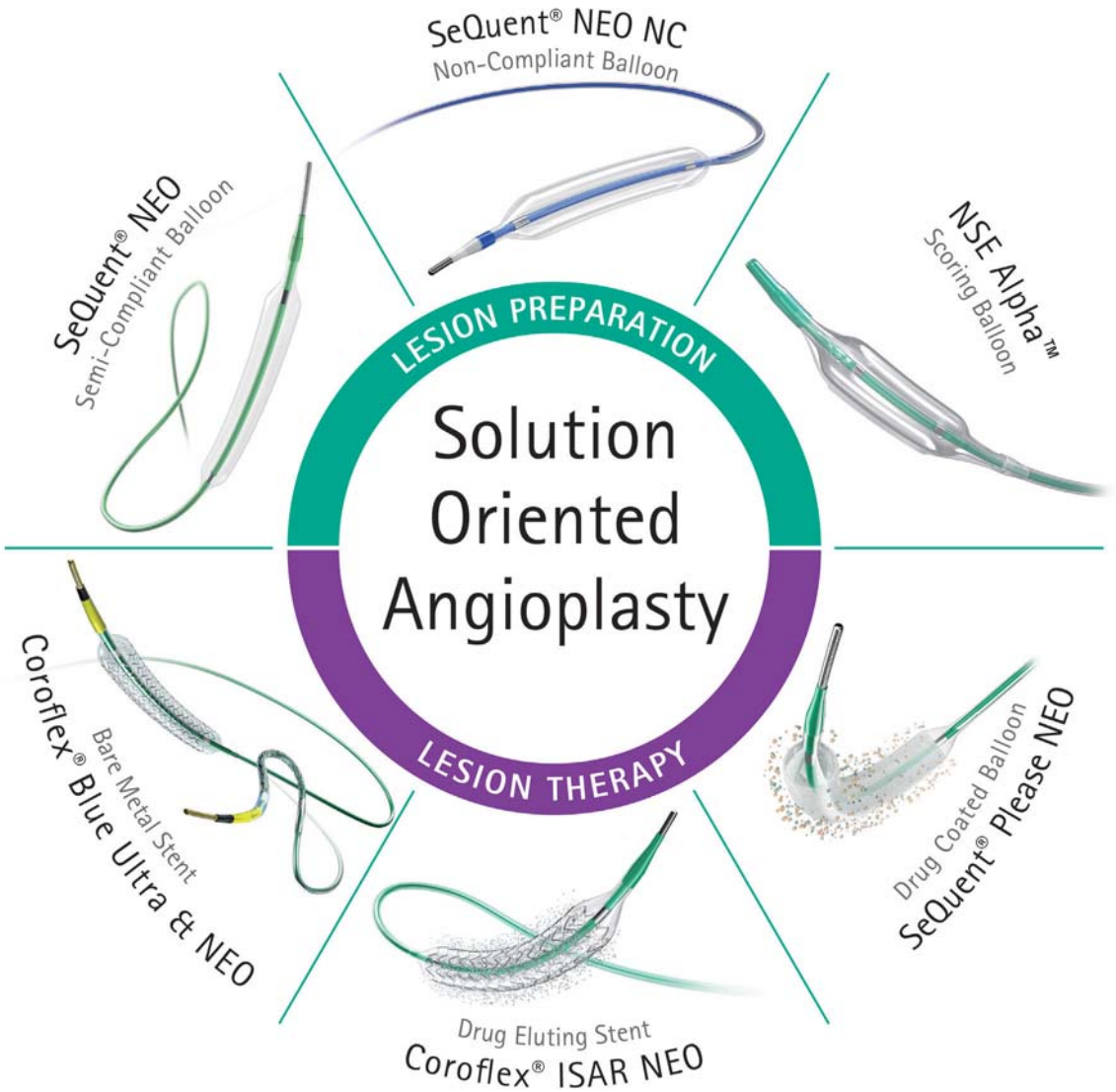


4-month follow-up

[11] Windecker S et al. European Heart Journal 2014; 35: 2541-619.

Balloon Diameter	Balloon Length							Nominal Pressure	Rated Burst Pressure
	10 mm	15 mm	20 mm	25 mm	30 mm	35 mm	40 mm		
2.0 mm	5023200	5023210	5023220	5023230	5023240	5023250	5023260	6 atm	14 atm
2.25 mm	5023201	5023211	5023221	5023231	5023241	5023251	5023261	6 atm	14 atm
2.5 mm	5023202	5023212	5023222	5023232	5023242	5023252	5023262	6 atm	14 atm
2.75 mm	5023203	5023213	5023223	5023233	5023243	5023253	5023263	6 atm	14 atm
3.0 mm	5023204	5023214	5023224	5023234	5023244	5023254	5023264	6 atm	14 atm
3.5 mm	5023206	5023216	5023226	5023236	5023246	5023256	5023266	6 atm	14 atm
4.0 mm	5023207	5023217	5023227	5023237	5023247	5023257	5023267	6 atm	14 atm

Technical Data	
Proximal shaft	1.9 F
Distal shaft	2.5 F
Usable length	145 cm
Balloon crossing profile	0.033" - 0.037"
Lesion entry profile	0.016"
Guiding catheter compatibility	5 F standard guiding catheter
Guidewire compatibility	0.014"
Rated burst pressure [RBP]	14 atm
Nominal pressure [NP]	6 atm



Distributor

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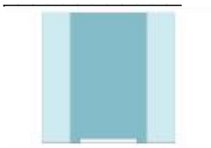
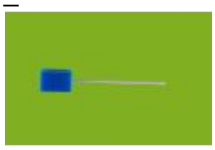
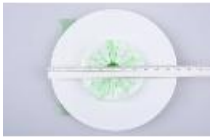
Phone +49 30 568207-300 | Fax +49 30 568207-210 | www.bbraun.com

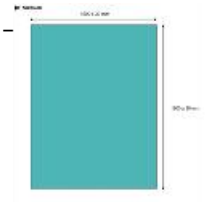
Manufacturer acc. to MDD 93/42/EEC of SeQuent® Please NEO is the B. Braun Melsungen AG, Carl-Braun-Str. 1, 34212 Melsungen, Germany.

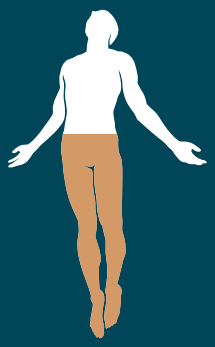
6050333 0918/2.0/2

Tray ID	97039056
Tray name	SET INTERVENTII CARDIO STIMULATOARE
Speciality filter	CARDIOVASCULAR
Intervention filter	Cardiovascular Other
Hospital filter	Tehnomedica SRL

	Description	Qty
	Adh. op sheet Light 175x175cm	1
	BNS Angiography Drape 240x330 cm	1
	Adh. op towel Light 90x75cm SA edge 5cm	1
	Surgical gown Primary Standard Perfomance XL 127cm	2
	Hand towel 18x25cm	2
	Op tape 9x49cm	1
	Banded bag 140cm Circ. Elast. Transp.	1
	Bowl 500ml Graduated (transparent)	2

	Bowl 250ml Graduated red	2
	Medicine/Specimen cup 120ml Polyethylene Transp. Lid	1
	Forceps tweezer plastic green	1
	Scalpel SS N°22	1
	Sponge appl. 15cm 3,5x3,5cm Blue	5
	Forceps 12cm plastic green	4
	Paper bag 25x38x10cm White	1
	Light handle cover large Light green/white collar	1
	Nonwoven swab 7,5x7,5cm 30g 4P White	200
	Paper bag 25x38x10cm White	1

	Surg.glove latex 7.0 PF 2/1 Biogel Surgeons	2
	Surg.glove latex 8.0 PF 2/1 Biogel Surgeons	2
	Surgical gown Primary Standard Perfomance XL 127cm	1
	Hand towel 18x25cm	1
	Mayo stand cover 79x145cm Abs.65x85cm	1
	Reinforced Table Cover 150 x 190 wrapping	1



optimed

sinus-SuperFlex-535

Self-expanding nitinol stent system

ARTERIAL | 5 F Ø device | .035i guide wire | NiTi nitinol stent

5F application device adapted to .035 inch guide wire

ABOVE THE KNEE ATK & BTK BELOW THE KNEE

sinus-

535

sinus-SuperFlex-535

Superflexibel durch sinus-Struktur zur Anpassung an den Gefäßverlauf

Hohe Radialkraft

Selbstexpandierender Nitinol Stent erhältlich bis zu einem Durchmesser von Ø 10 mm

Atraumatische Systemspitze „Tipless System"

Geeignet für Cross-Over-Technik

La flexibilité issue du design sinus-sinusoïdal permet une adaptation à la forme

du vaisseauGrande force radiale

Stent autoexpansible en Nitinol disponible jusqu'à Ø 10 mm

Embout atraumatique « Tipless System »

Adapté aux procedures en controlatéral

sinus-structure with super-flexibility mirrors the contours of the vessel

High radial force

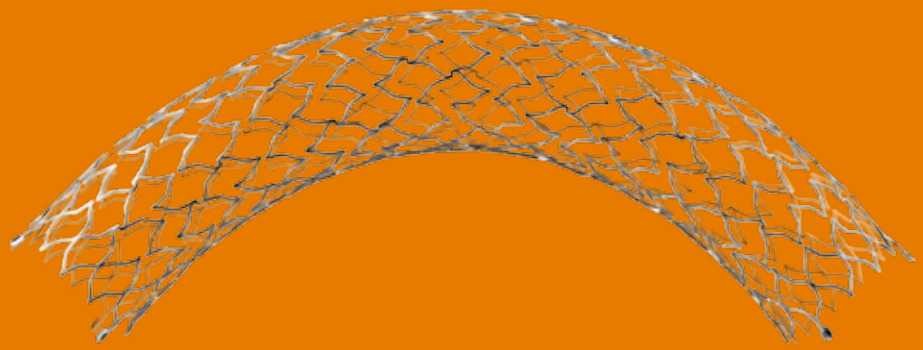
Self-expanding nitinol stent available up to Ø 10 mm

Atraumatic "Tipless System"

Suited for cross-over technique

5F & .035

working channel for contrast injection



anti-jump technique

braided sheath

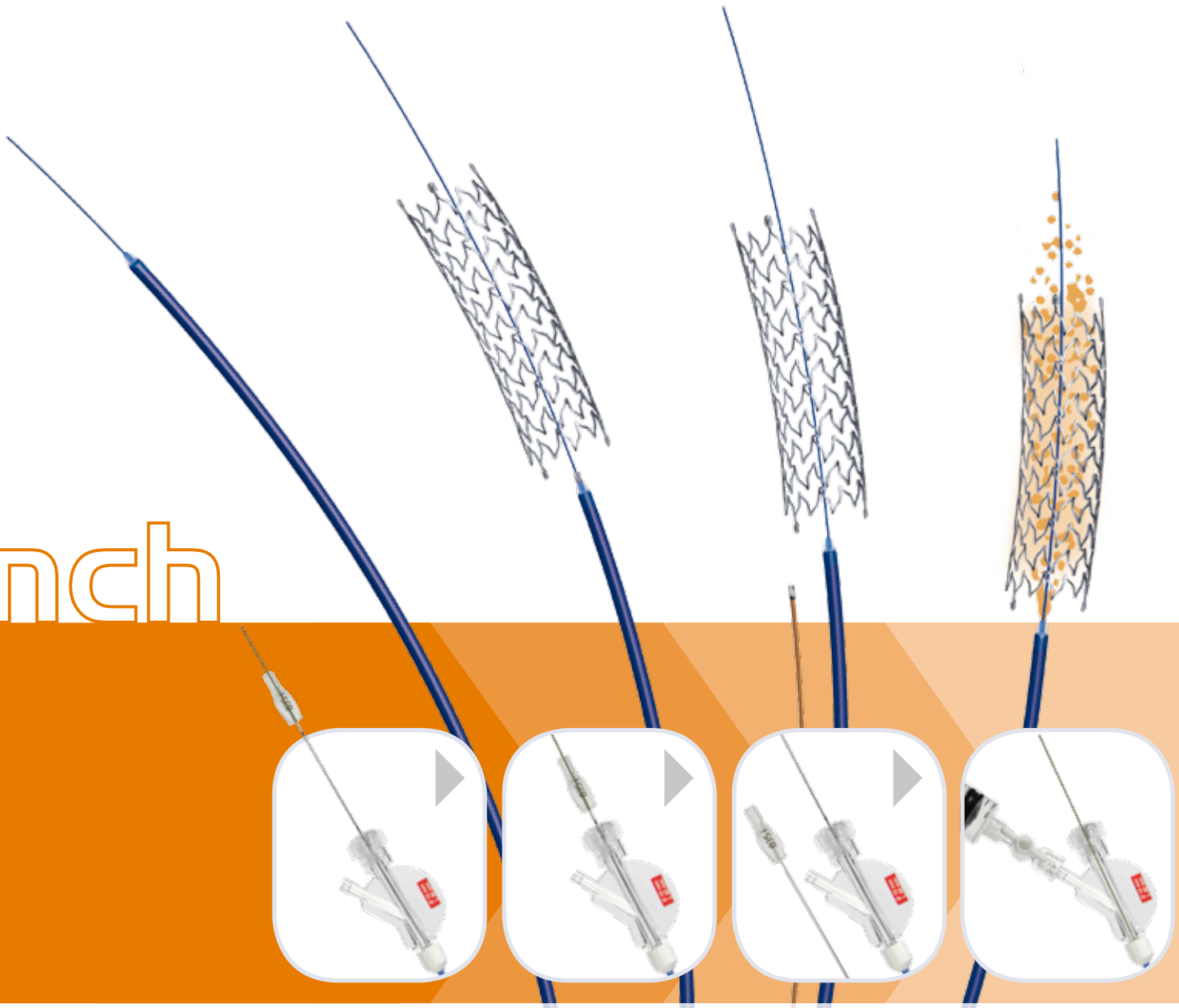
Entfernbarer Innenkatheter

Die Systemspitze ist aus dem Schleusenende geformt - es entfällt die sonst übliche Spitze am Innenkatheter.
Dadurch lässt sich der Innenkatheter nach Stentablage komplett entfernen - es entsteht ein bereits liegender Arbeitskanal zur Kontrastmittelgabe.

Cathéter interne amovible

L'extrémité du système de largage est une extension de la gaine extérieure. Elle remplace la pointe normale qui est en fait une partie du cathéter interne. Après libération du stent, il est possible d'enlever le cathéter interne. La gaine extérieure peut alors être utilisée comme voie d'accès pour injecter le produit de contraste.

inch



stent placement *stent release* *remove inner catheter* *contrast media injection*

Removable inner catheter

The tip of the delivery system is an extension of the outer sheath - it replaces the normal tip which is part of the inner catheter. After stent release it is possible to remove the entire inner catheter - now the outer sheath can be used as a working channel for contrast injection.

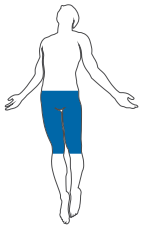
open-cell design

radiopaque markers

electro-polishing

sinus-SuperFlex-535

sinus-SuperFlex-535 -ATK-



ATK

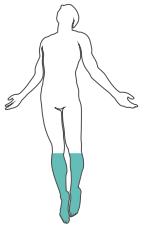
Bestell-Nr. – Länge des Einführbestecks *référence – longueur système de pose* *order code – length of application device*		Stent	Stent Länge / *longueur / length*
75 cm	120 cm	Ø / mm	mm
6106-6020*	6106-7020*	6	20
6106-6030	6106-7030	6	30
6106-6040	6106-7040	6	40
6106-6060	6106-7060	6	60
6106-6080	6106-7080	6	80
6107-6020*	6107-7020*	7	20
6107-6030	6107-7030	7	30
6107-6040	6107-7040	7	40
6107-6060	6107-7060	7	60
6107-6080	6107-7080	7	80
6108-6020*	6108-7020	8	20
6108-6030	6108-7030	8	30
6108-6040	6108-7040	8	40
6108-6060	6108-7060	8	60
6108-6080	6108-7080	8	80
6109-6020*	6109-7020*	9	20
6109-6030	6109-7030*	9	30
6109-6040	6109-7040*	9	40
6109-6060	6109-7060*	9	60
6109-6080	6109-7080*	9	80
6110-6020*	6110-7020*	10	20
6110-6030	6110-7030*	10	30
6110-6040	6110-7040*	10	40
6110-6060	6110-7060*	10	60
6110-6080	6110-7080*	10	80

* Mindestbestellmenge / Lieferzeit auf Anfrage
* *quantité minimum de commande / délai de livraison sur demande*
* *minimum order quantity / delivery time upon request*

Adaptiert auf .035 inch Führungsdraht
adapté au fil-guide de .035 inch
adapted to .035 inch guide wire

Verpackungseinheit: 1 Stück
conditionnement : 1 unité
box: 1 unit

sinus-SuperFlex-535 -BTK-



BTK

Bestell-Nr. – Länge des Einführbestecks *référence – longueur système de pose* *order code – length of application device*		Stent	Stent Länge / *longueur / length*
75 cm	120 cm	Ø / mm	mm
6104-6030*	6104-7030	4	30
6104-6040	6104-7040	4	40
6104-6060	6104-7060	4	60
6104-6080*	6104-7080	4	80
6105-6030*	6105-7030	5	30
6105-6040	6105-7040	5	40
6105-6060	6105-7060	5	60
6105-6080	6105-7080	5	80

* Mindestbestellmenge / Lieferzeit auf Anfrage
* *quantité minimum de commande / délai de livraison sur demande*
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Adaptiert auf .035 inch Führungsdraht
adapté au fil-guide de .035 inch
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Verpackungseinheit: 1 Stück
conditionnement : 1 unité
box: 1 unit

optimed
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Order Code 9999-0205 Rev (05/2014)

Latex
Biogel® Surgeons

The Biogel® Surgeons is a sterile, latex surgical glove with excellent barrier protection. The unique Biogel® coating provides great fit, feel and comfort and makes the glove easy to don, even with damp hands.

ACTUAL COLOUR REF 822

Biogel® key features and benefits

- 9/10 surgeons prefer Biogel for fit, feel and comfort[1]
- Reduced chance of a hole with an industry-leading AQL* result of 0.65[1]
- Every glove (100%) is air inflation tested and visually inspected for quality and safety[1]
- Improved efficiency as less gloves are wasted[2]
- Non-pyrogenic, potentially reducing the risk of post-operative complications[3]

Recommended use

Recommended for all surgical procedures.

Material information

- Natural rubber latex
- Micro-roughened surface
- Biogel hydrogel polymer coating
- Beaded cuff
- Powder-free
- Non-pyrogenic

Biogel quality

Biogel has an industry leading freedom from holes AQL* of 0.65. The industry standard requirement for AQL* is 1.5. The lower the number, the fewer the holes and the higher the quality of glove. Biogel is proven to have the lowest glove failure rate among major competitors. Non-Biogel gloves are at least 3.5 times as likely to fail than Biogel gloves[2].

Re-order REF 822

REF	Size	Pairs
82255	5½	50/Box
82260	6	50/Box
82265	6½	50/Box
82270	7	50/Box
82275	7½	50/Box
82280	8	50/Box
82285	8½	50/Box
82290	9	40/Box

4 boxes per case

MÖLNLYCKE HEALTH CARE

Product specifications Biogel® Surgeons gloves REF 822

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
82255	5.5	283	71
82260	6.0	285	77
82265	6.5	285	85
82270	7.0	288	91
82275	7.5	298	96
82280	8.0	299	103
82285	8.5	301	109
82290	9.0	301	115

Pairs per box: 50/40 for size 9

Typical thickness profile – single wall		
Cuff	8.1 mils	0.21 mm
Palm	10.0 mils	0.26 mm
Finger	10.6 mils	0.27 mm

Physical glove properties	Standard requirement	Biogel
Force at break (N) (EN455)		
Initial	≥9	19
Aged	≥9	17
Typical accelerator analysis % w/w		
Dithiocarbamate (DTC)	n/a	<0.02
Diphenyl thiourea (DPTU)	n/a	none
Diphenyl guanidine (DPG)	n/a	none
Zinc mercaptobenzothiazole (ZMBT)	n/a	none
Thiurams	n/a	none
Typical extractable protein (using Modified Lowry EN455/ ASTM D5712)	<50µg/g	<20µg/g
AQL* freedom from holes (1000 ml water leak test)	1.5	0.65
Post packing and irradiation Process average typically		<0.20%
Grip (Measure of the surface grip. Scale of 1-5, the higher the value, the greater the level of drag)	n/a	1.0

General information

Contra-indications: This product contains natural rubber latex which may cause allergic reactions including anaphylactic responses.

Allergenicity: Biogel gloves are produced to have low levels of aqueous extractable protein and have been shown to have a low potential for inducing allergic contact dermatitis or 'Type IV allergy'.

Pyrogenicity: Each batch of Biogel gloves is tested to have a low endotoxin level (<20 EU/pair).

Product standards: Biogel gloves are tested and manufactured to the following standards:

- **Quality/Environmental:** ISO 9001, ISO 13485, ISO 14001
- **Product:** ASTM D3577, EN455-1, EN455-2, EN455-3, EN455-4
- **Sterilisation:** Gamma irradiation
- **Viral Penetration:** Bacteriophage test, ASTM F1671
- **Allergenicity/Pyrogenicity:** ISO 10993 (PART 5 and 10)

Registering authority: In Europe the gloves are CE marked (notified body BSi, number 0086) indicating compliance with Council Directive 93/42/EEC. In US the gloves are FDA registered. Biogel Surgical gloves are a Class IIa Product.

Storage: Store in a cool, dry place away from sources of heat or direct sunlight.

Packaging: One pair per pack, in a high quality inner wrap, packed into a film pack (constructed of a laminate of polyester and low-density polyethylene). 50 pairs per collation case for sizes 5.5–8.5; 40 pairs for size 9.0; 200 pairs per transit case for sizes 5.5–8.5; 160 pairs for size 9.0.

Disposal: Gloves & outer wrap dispose of as clinical waste. Paper inner wrap, collation case & transit case can be recycled as paper or disposed of as clinical waste.

Shelf life: Five (5) years from date of manufacture.

Manufacturer: Made and packed in Malaysia by Mölnlycke Health Care Sdn Bhd.

Country of origin: Malaysia.

E-mail address: biogel@molnlycke.com

Date of issue: May 2012.

References: 1. Why Choose Biogel. MKT004. 2009. Data on file. 2. In Use Surgical Glove Failure Rate Comparison. Study G009-005. 2009. Data on file. 3. Biogel Endotoxin Report, Non-Pyrogenic Surgical Gloves. REPRHJV004. 2010. Data on file.

*AQL=Acceptable Quality Level refers to the maximum number of defective products that could be considered acceptable during the random sampling of an inspection, in this case freedom from holes in gloves.

Find out more at www.molnlycke.com

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MÖLNLYCKE HEALTH CARE

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