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ORDIN DE PLATA NR.: 900                                TIP.DOC. 1 :
                                DATA EMITERII:9 septembrie 2021 :
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PLATITI: 19000-00                                LEI: Nouasprezece Mii lei 00 bani :
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=====:
PLATITOR: (R) "BIOSISTEM                                CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L.                                MD95ML000000002251429243 :
                                CODUL FISCAL :1010600028048 / :
:
:
=====:
PRESTATORUL PLATITOR                                CODUL BANCII:
BC"Moldindconbank"S.A. fil."Invest" Chisinau                                :MOLDMD2X329:
=====:
BENEFICIAR (R) Centrul pen                                CONTUL DE PLATI/CODUL IBAN :
tru achizitii publice central MD23TRPCCC518430B01859AA :
izate in sanatate                                CODUL FISCAL :1016601000212 / :
:
:
=====:
PRESTATORUL BENEFICIAR                                CODUL BANCII:
Ministerul Finantelor - Trezoreria de Stat                                :TREZMD2X :
=====:
DESTINATIA PLATII:/P102/19000,00 Pentru : TIPUL TRANSFERULUI :
garantia pentru oferta la procedura de a: NORMAL/URGENT :N:
chizi?ie publica nr. ocds-b3wdp1-MD-1628: :
158934564 din 10.09.2021 :
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:
=====:
                                CODUL TRANZACTIEI:101: :
DATA PRIMIRII:09/09/2021 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
:-----:
CONDUCTATOR:Web Poiata Vitalie :
MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB:
DQEHAaCCBGwggRoMIIDUKADAgECAhNHAACjbilrgFksQ0G4AAAAAKNuMA0GCSq:
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4:
DTIxMDEyODExMzgwNVoxDTIOMDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRA:
gYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml :
:
(semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBHAWggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzkwOFoxDTIOMDEyODExNDkwOFowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
:
L.S. (semnatura electronica) :
CONDUCTATOR: :
(semnatura manuala) :
CONTABIL-SEF: :
(semnatura manuala) :
SEMNATURA PRESTATORUL L.S. :
:-----:
MOTIVUL REFUZULUI : L.S. :
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BC "MOLDINDCONBANK" S.A.

Filiala "Invest"

Republica Moldova, MD-2068
mun. Chișinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 - 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московской, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent în moneda națională al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML000000002251429243**.

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"
— ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT —

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

Svirepova Ludmila, registrator

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

L. Svirepova
semnătura

MD 0101250





I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. 8506 din 28.04.2021

Denumirea completă: **Societatea cu Răspundere Limitată «BIOSISTEM MLD».**

Denumirea prescurtată: **«BIOSISTEM MLD» S.R.L.**

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

Sediul: **MD-2001, str. Albișoara, 16/1, ap.(of.) 7, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1 Activitatea farmaceutică;**
- 2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;**
- 4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;**
- 5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;**
- 6 Consultații în domeniul sistemelor de calcul.**

Capitalul social: **5400 lei.**

Administrator: POIATA VITALIE,

Asociați:

- 1. POIATA VITALIE 33,40 %**
- 2. NASEDCHIN ALEXANDR 33,30 %**
- 3. KOJEVNIKOV DMITRII 33,30 %.**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 28.04.2021.

Specialist coordonator
tel. 022-207-840



Lazari Aliona



EB 0358735

Lista fondatorilor Biosistem-mld SRL

Nr.	Nume, Prenume	IDNP
1.	Vitalie Poiata	0983103892591
2.	Alexandr Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ **A2115192**

din
от **08.09.2021**

1. Destinația / Назначение

Pentru participarea la proceduri de achizitii publice

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea Наименование	Codul fiscal / Numărul de identificare Фискальный код / Идентификационный номер
BIOSISTEM MLD S.R.L.	1010600028048
Adresa sediului de bază (strada, numărul) Адрес основного месторасположения (улица, номер)	Codul - Denumirea localității Код - Наименование населенного пункта
Albisoara nr.16 bl.1 of.7	0150-SEC.RISCANI

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat /
Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет:
0,00 lei/лей.

4. Valabil pînă la / Действителен до 23.09.2021

5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы



Semnătura/Подпись

Viorica CĂUȘ

Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 08.09.2021 ora 14:25:51
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (3,52)

Дата предоставления 11.05.2021 10:00:47

Anexe la SNC
 "Prezentarea situatiilor financiare"
 Aprobat de Ministerul Finantelor
 al Republicii Moldova

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2020 - 31.12.2020

Entitatea: BIOSISTEM MLD S.R.L.
 Cod CUIIO: 40717392
 Cod IDNO: 1010600028048

Sediuul:
 MD:
 Raionul(municipiul): 106, DOF, RISCANI
 Cod CUATM: 0150, SEC, RISCANI
 Strada: SECTORUL RISCANI STR.Albisoara nr.16 bl.1 of.7

Activitatea principală: 08646, Comerț cu ridicata al produselor farmaceutice
 Forma de proprietate: 16, Proprietate colectivă
 Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:
 Telefon: +3732808719
 WEB:
 E-mail: zmil13@gmail.ru
 Numele și coordonatele al contabilului-șef: DI (dna) Tel.

Numărul mediu al salariaților în perioada de gestiune: 3 persoane.

Persoanele responsabile de semnarea situațiilor financiare* Nasedchin Alexandr

Unitatea de măsură: leu

BILANȚUL

la

Anexa 1

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrșitul perioadei de gestiune
1	2	3	4	5
	A C T I V			
	ACTIVE IMOBILIZATE			
	I. Imobilizări necorporale			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020	487	
	din care:			
	2.1. concesiuni, licențe și mărci	021	487	
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023		
	2.4. alte imobilizări necorporale	024		
	3. Fond comercial	030		
	4. Avansuri acordate pentru imobilizări necorporale	040		
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050	487	
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060		
	2. Terenuri	070		
	3. Mijloace fixe, total	080	2208593	2793637
	din care:			
	3.1. clădiri	081		
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	2204135	2791637
	3.4. mijloace de transport	084		

A.	3.5. inventar și mobilier	085		
	3.6. alte mijloace fixe	086	4458	2000
	4. Resurse minerale	090		
	5. Active biologice imobilizate	100		
	6. Investiții imobiliare	110		
	7. Avansuri acordate pentru imobilizări corporale	120		
	Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	2208593	2793637
	III. Investiții financiare pe termen lung			
	1. Investiții financiare pe termen lung în părți neafiliate	140		
	2. Investiții financiare pe termen lung în părți afiliate, total	150		
	din care:	151		
	2.1. acțiuni și cote de participație deținute în părțile afiliate			
	2.2. Împrumuturi acordate părților afiliate	152		
	2.3 Împrumuturi acordate aferente intereselor de participare	153		
	2.4 alte investiții financiare	154		
	Total investiții financiare pe termen lung (rd.140 + rd.150)	160		
	IV. Creanțe pe termen lung și alte active imobilizate			
	1. Creanțe comerciale pe termen lung	170		
	2. Creanțe ale părților afiliate pe termen lung	180		
	Inclusiv: creanțe aferente intereselor de participare	181		
	3. Alte creanțe pe termen lung	190		
	4. Cheltuieli anticipate pe termen lung	200		
	5. Alte active imobilizate	210		
	Total creanțe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220		
	TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220)	230	2209080	2793637
B.	ACTIVE CIRCULANTE			
	I. Stocuri			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	54051	51978
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	5710647	7221203
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	5764698	7273181
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	4337729	3912218
	2. Creanțe ale părților afiliate curente	310		
	Inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	166486	74631
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350	4	2
	7. Alte active circulante	360	1647908	5756117
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	6152127	9742968
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți neafiliate	380		
	2. Investiții financiare curente în părți afiliate, total	390		
	din care:	391		
	2.1. acțiuni și cote de participație deținute în părțile afiliate			
	2.2. Împrumuturi acordate părților afiliate	392		
	2.3. Împrumuturi acordate aferente intereselor de participare	393		

	2.4. alte investiții financiare în părți afiliate	394		
	Total investiții financiare curente (rd.380 + rd.390)	400		
	IV. Numerar și documente bănești	410	8911899	3942779
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	20828724	20958928
	TOTAL ACTIVE (rd.230 + rd.420)	430	23037804	23752565
	P A S I V			
	CAPITAL PROPRIU			
	I. Capital social și neînregistrat			
	1. Capital social	440	5400	5400
C.	2. Capital nevărsat	450	()	()
	3. Capital neînregistrat	460		
	4. Capital retras	470	()	()
	5. Patrimoniul primit de la stat cu drept de proprietate	480		
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	5400	5400
	II. Prime de capital	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
	3. Alte rezerve	530		
	Total rezerve (rd.510 + rd.520 + rd.530)	540		
	IV. Profit (pierdere)			
	1. Corecții ale rezultatelor anilor precedenți	550	X	
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	21021465	12085295
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	7974831
	4. Profit utilizat al perioadei de gestiune	580	X	()
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	21021465	20060126
	V. Rezerve din reevaluare	600		
	VI. Alte elemente de capital propriu	610		
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	21026865	20065526
D.	DATORII PE TERMEN LUNG			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640		
	din care:			
	2.1. Împrumuturi din emisiunea de obligațiuni	641		
	Inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643		
	3. Datorii comerciale pe termen lung	650		
	4. Datorii față de părțile afiliate pe termen lung	660		
	Inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700		
	DATORII CURENTE			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720		

E.	din care:	721		
	2.1. Împrumuturi din emisiunea de obligațiuni			
	Inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	1331928	3252667
	4. Datorii față de părțile afiliate curente	740		
	Inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	159545	188105
	6. Datorii față de personal	760	2913	50
	7. Datorii privind asigurările sociale și medicale	770		
F.	8. Datorii față de buget	780	434590	187676
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	81963	58541
	TOTAL DATORII CURENTE (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	2010939	3687039
	PROVIZIOANE			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clientșilor	840		
	3. Provizioane pentru impozite	850		
	4. Alte provizioane	860		
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870		
	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	23037804	23752565

SITUAȚIA DE PROFIT ȘI PIERDERE

de la până la

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	27319617	25963175
din care:			
venituri din vânzarea produselor și mărfurilor	011	26856566	25044358
venituri din prestarea serviciilor și executarea lucrărilor	012	463051	918817
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016		
Costul vânzărilor, total	020	15672962	15186814
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	15672962	15186814
costul serviciilor prestate și lucrărilor executate terților	022		
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	11646655	10776361
Alte venituri din activitatea operațională	040	28586	247603
Cheltuieli de distribuie	050	16306	19740
Cheltuieli administrative	060	964136	1259776
Alte cheltuieli din activitatea operațională	070	417394	640169
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	10277405	9104279

Venituri financiare, total	090	490609	519239
din care:			
venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	093		25612
inclusiv: veniturile obținute de la părțile afiliate	094		
venituri din alte investiții financiare pe termen lung	095		
inclusiv: veniturile obținute de la părțile afiliate	096		
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097		
venituri din ieșirea investițiilor financiare	098		
venituri aferente diferențelor de curs valutar și de sumă	099	490609	493627
Cheltuieli financiare, total	100	686605	597528
din care:			
cheltuieli privind dobânzile	101		
inclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103		
cheltuieli aferente ieșirii investițiilor financiare	104		
cheltuieli aferente diferențelor de curs valutar și de sumă	105	686605	597528
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	-195996	-78289
Venituri cu active imobilizate și excepționale	120		
Cheltuieli cu active imobilizate și excepționale	130		
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	-195996	-78289
Profit (pierdere) până la impozitare (rd.080 + rd.150)	160	10081409	9025990
Cheltuieli privind impozitul pe venit	170	1178993	1051159
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	8902416	7974831

SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la până la

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfârșitul perioadei de gestiune
1	2	3	4	5	6	7
I.	Capital social și neînregistrat					
	1. Capital social	010				
	2. Capital nevărsat	020	()	()	()	()
	3. Capital neînregistrat	030				
	4. Capital retras	040	()	()	()	()
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
II.	Prime de capital	070				
III.	Rezerve					
	1. Capital de rezervă	080				
	2. Rezerve statutare	090				
	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
	Profit (pierdere)					
	1. Corecții ale rezultatelor anilor precedenți	120	X			

IV.	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130			
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X		
	4. Profit utilizat al perioadei de gestiune	150	X	()	()
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160			
V.	Rezerve din reevaluare	170			
VI.	Alte elemente de capital propriu	180			
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190			

SITUAȚIA FLUXURILOR DE NUMERAR

de la până la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vânzări	010		
Plăți pentru stocuri și servicii procurate	020		
Plăți către angajați și organe de asigurare socială și medicală	030		
Dobânzi plătite	040		
Plata impozitului pe venit	050		
Alte încasări	060		
Alte plăți	070		
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080		
Fluxuri de numerar din activitatea de investiții			
Încasări din vânzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobânzi încasate	110		
Dividende încasate	120		
Inclusiv: dividende încasate din străinătate	121		
Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150		
Plăți aferente rambursării creditelor și împrumuturilor	160		
Dividende plătite	170		
Inclusiv: dividende plătite nerezidenților	171		
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200		
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210		
Diferențe de curs valutar favorabile (nefavorabile)	220		
Sold de numerar la începutul perioadei de gestiune	230		
Sold de numerar la sfârșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Documente atașate - Notă explicativă (fișierul pdf)

Версия для печати

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Расписка 2

Респондент

Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.

Предоставил отчет: RSF1_21

На фискальный период: A/2020

Дата предоставления: 11.05.2021

Временная метка отчёта зарегистрированного в Информационной Системе НБС : 11.05.2021 12:26:31

National Bureau of Statistics (NBS) received the electronic version of the report, sent by you. The data provided is verified by NBS.

Версия для печати

Сохранить

Расписка

Респондент

Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.

Предоставил отчет: RSF1_21

На фискальный период: A/2020

Дата предоставления: 11.05.2021

Временная метка отчёта зарегистрированного в Системе Электронной Отчётности и отправленного в Информационную Систему БНС : 11.05.2021 10:00:47



BIOSISTEM-MLD S.R.L.

c/f 1010600028048; adresa: str. Albișoara 16/1 of.7, or. Chișinău
tel.+373-22-808517, +373-22-808719, fax +373-22-808519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Către Grupul de lucru pentru evaluarea

Procedurii de achiziție nr. ocds-b3wdp1-MD-1628158934564

Din 18 aug 2021, 12:08 - 10 sept 2021, 12:08

din cadrul CAPCS

Declarație

Prin prezenta, SRL „Biosistem-mld”, declara ca :

- Termenul de valabilitate restant (la momentul livrării) va constitui 80% din termenul total al produsului, dar nu mai mic de 12 luni..
- Pentru produsele noi sau necunoscute pentru medici, vor fi prezentate mostre de către potențialii cîștigători în termen de 5 zile de la solicitare
- Va înregistra bunurile contractate la Agentia Medicamentului si a Dispozitivelor Medicale până la momentul livrării acestuia.

_____ Vitalie Poiata

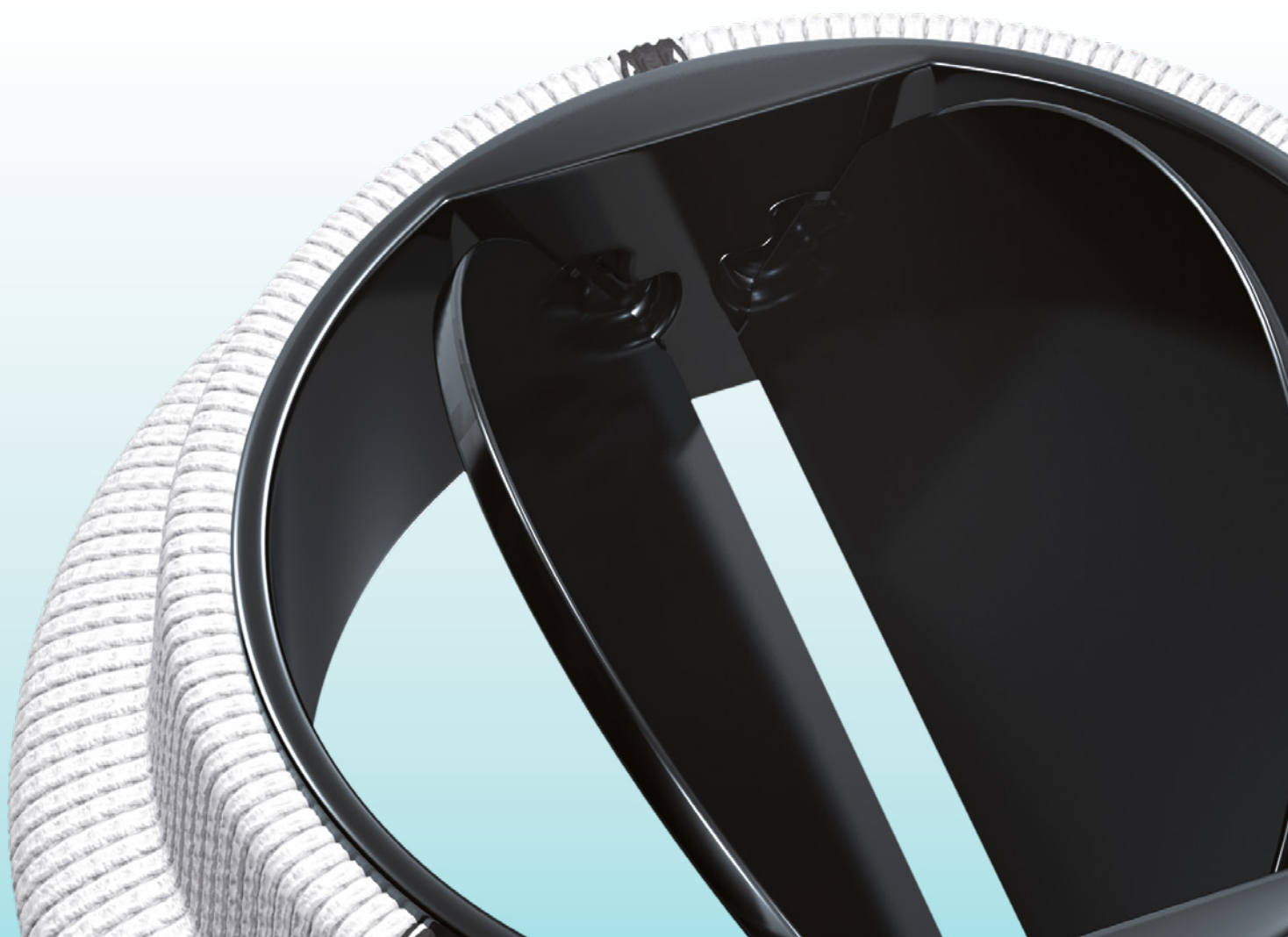
L.Ș.

LivaNova

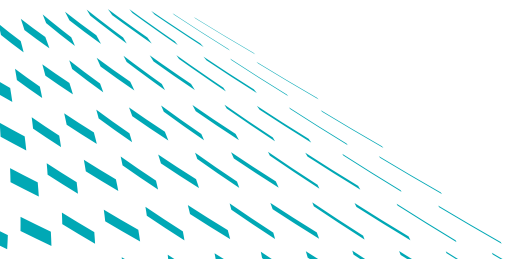
Health innovation that matters

CARBOMEDICS® FAMILY

Tailored reliability
for patients and surgeons



Adult and Pediatric bileaflet mechanical heart valves

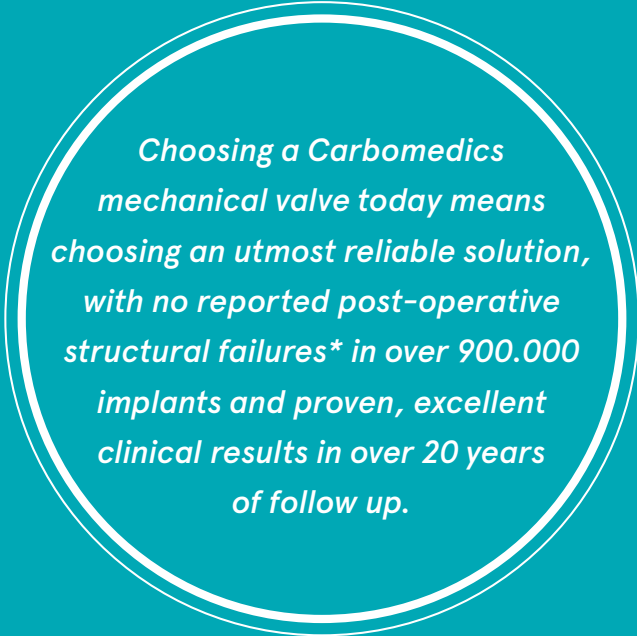


Tailored options for better patient outcomes

With its Carbomedics line of products LivaNova offers cardiac surgeons and patients a complete set of mechanical heart valve solutions to reliably treat even the most challenging cases.

The Carbomedics name is intrinsically linked to the historical development of mechanical heart valves. Carbomedics is well recognized for having pioneered and mastered pyrolytic Carbon technology for prosthetic devices in the late 1960's, supplying pyrolite components for over 2 million valves manufactured by 14 different companies worldwide. Carbomedics has also contributed to the design and manufacturing of 17 types of valves for a number of companies.

Based on this great expertise and with the clear mission of providing highly reliable and technologically advanced solutions, in 1986 Carbomedics introduced to the market the first mechanical bileaflet valve with a rotatable housing for optimal leaflet positioning. Since this first step, the Carbomedics portfolio has been enriched over time up to the current, complete and compelling set of solutions that offer surgeons the maximum flexibility while treating their patients.



*Choosing a Carbomedics
mechanical valve today means
choosing an utmost reliable solution,
with no reported post-operative
structural failures* in over 900.000
implants and proven, excellent
clinical results in over 20 years
of follow up.*

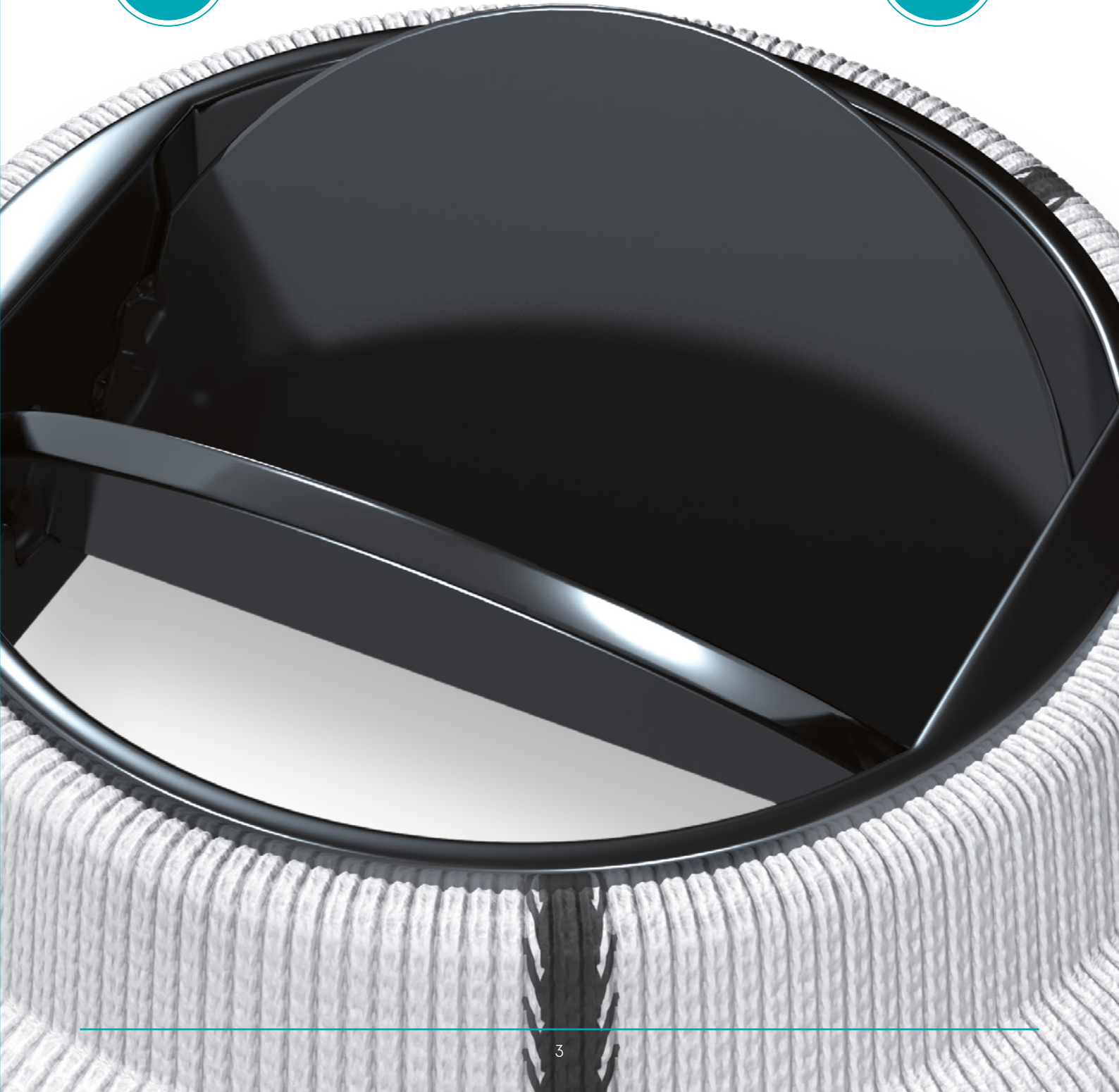
* No reported structural valve failure in the published scientific literature. None of the events reported to LivaNova Quality System has been classified as structural valve failure upon completion of the analysis.

Tailored performance
for excellent clinical
outcomes

Tailored
ease of implant

Tailored
safety and durability

Tailored solutions
for patients and surgeons





Tailored safety and durability

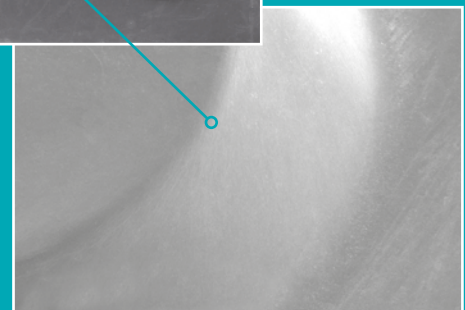
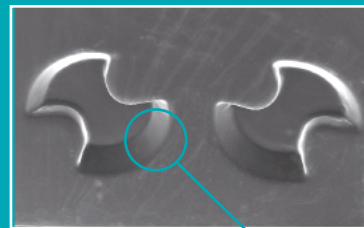
Leader in biocompatible materials

Due to its robust design, the Carbomedics bileaflet mechanical heart valve has no reported post-operative structural failures in over 900.000 implants worldwide.*

Carbomedics Pyrolite® Carbon is engineered to provide excellent thromboresistance combined with optimal strength.

This is achieved by co-depositing a small amount of Silicon during the manufacturing process, because the Silicon acts as a reinforcing element to the crystal structure of Pyrolytic Carbon.¹ The surface is then polished to remove the superficial roughness, thus achieving a mirror like finish.

Polished Silicon alloyed varieties of Pyrolytic Carbon exhibit an excellent degree of thromboresistance while improving resistance to wear,^{1,2} offering excellent and durable clinical results as proven in over 20 years of clinical follow up.



* No reported structural valve failure in the published scientific literature. None of the events reported to LivaNova Quality System has been classified as structural valve failure upon completion of the analysis.

A robust design for no structural failure

Pyrolytic carbon coated leaflets

The leaflets of the Carbomedics valves are made of a substrate of tungsten filled graphite coated with Pyrolite® Carbon. The presence of Tungsten provides better radiopacity allowing a non invasive diagnostic observation of the leaflets' motion through fluoroscopy or similar methodologies.

Pyrolytic carbon housing

Differently from the substrate processes used by other manufacturers, which results in a graphite core coated with pyrolytic carbon, Carbomedics valves employ an advanced mandrel process resulting in a low profile housing made entirely of Pyrolite® Carbon.

The mandrel process allows pivots to be located within the housing, minimizing pannus ingrowth and interference with leaflet motion that can occur around the protruding “pivot ear” design.^{3,4,5} Moreover, it permits a more sophisticated design of the pivot, the shape of which grants total washing of its entire surface, minimizing thromboembolic events.⁶



Structural components

To further enhance structural stability, the housing is reinforced by a titanium stiffening band which makes it up to 30 times stronger than a valve without a stiffening element, minimizing the risk of deformation and consequently, the risk of leaflet dislodgement or lockup.⁷

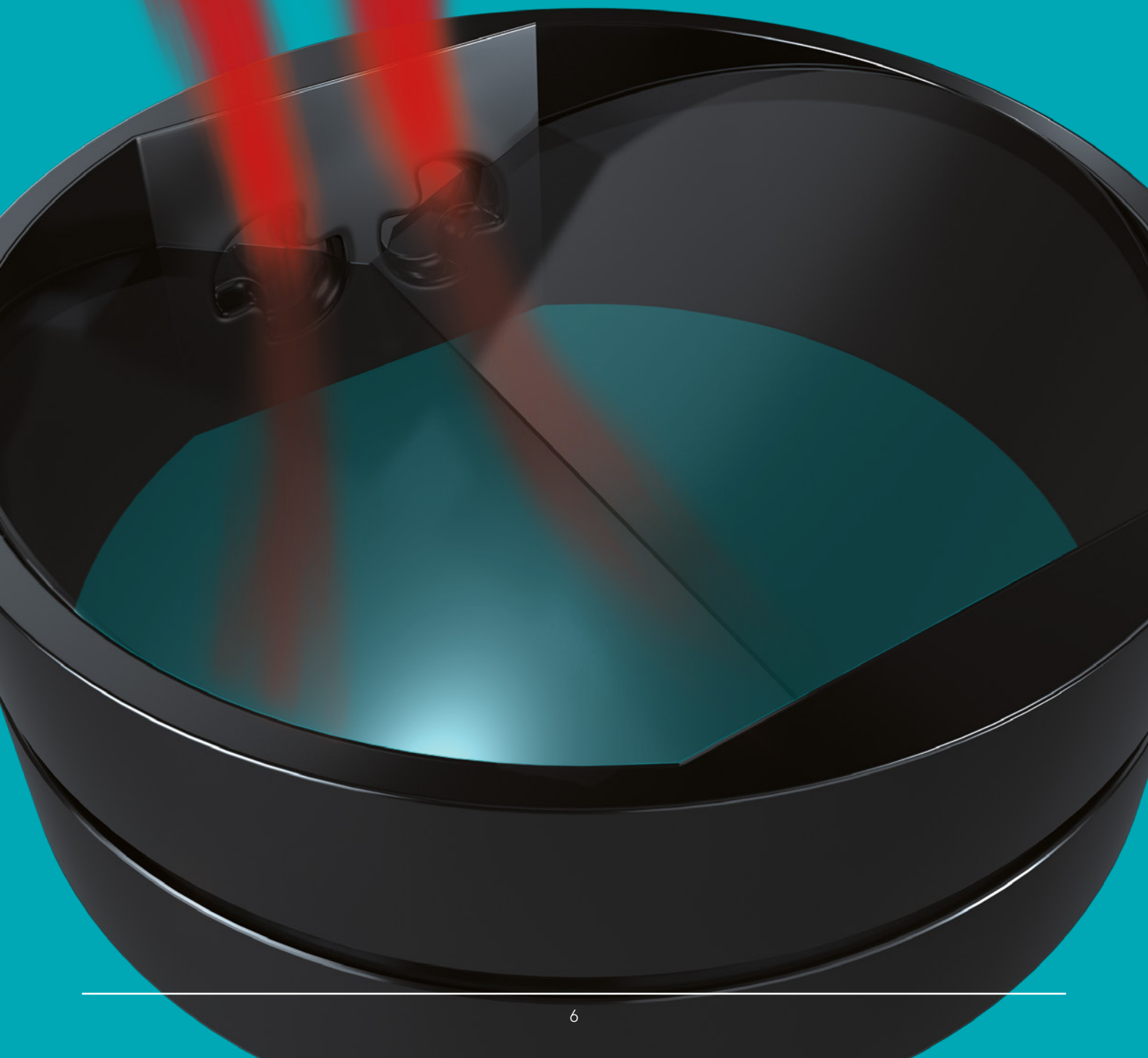
A lock wire forms a solid mechanical bond between the housing and the titanium reinforcement band while creating a track for rotation. Secure attachment of the sewing cuff to the housing is ensured by double lock wires.

1. Carbon Biomedical Devices. J.C. Bokros - Carbon, 1977;15:355-71.
2. Platelet responses to silicon-alloyed pyrolytic carbons. Goodman et al. - Wiley Periodicals, Inc. J Biomed Mater Res 83A: 64-69, 2007
3. Obstruction of St Jude medical valves in the aortic position: a consideration for pathogenic mechanism of prosthetic valve obstruction. Aoyagi et al. - Cardiovasc Surg. 2002 Aug;10(4):339-44
4. Entrapment of subvalvular mitral tissue causing intermittent failure of a St Jude mitral prosthesis. Dearani et Al. - J Am Soc Echocardiogr. 2000 Dec;13(12):1121-3
5. Entrapment of mitral chordal apparatus causing early postoperative dysfunction of a St. Jude mitral prosthesis. Greaves et Al. -J Am Soc Echocardiogr. 2002 Aug;15(8):843-4
6. Echocardiographic Description Of The Carbomedics Bileaflet Prosthetic Heart Valve. Chambers et al.- J Am Coll Cardiol 1993;21:398-405
7. Leaflet arrest in St Jude medical and Carbomedics valves: an experimental study. Grattan MT, Thulin LI, Eur J - Cardiothoracic Surg. 2004 Nov; 25 (6): 953-7



CARBOMEDICS® FAMILY

**Tailored performance for excellent
clinical outcomes**

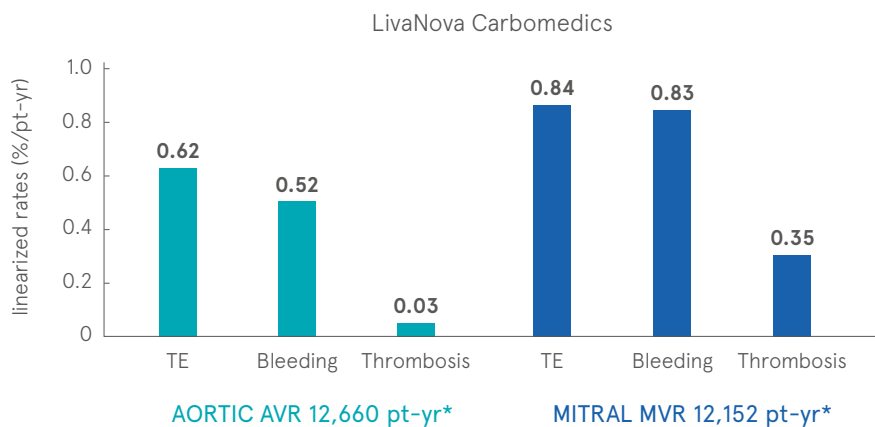


Carbomedics valves are engineered to achieve true clinical benefits for patients throughout their lifetime

In its long clinical history Carbomedics valve has demonstrated to be of utmost reliability and safety, with no post-operative structural failures and very low incidence of complications.

The enhanced orifice hinge design allows for low thrombogenicity, minimizing pannus overgrowth. The inner surfaces of the pivots are completely open to the flow for washing when the leaflets are closed.⁶

The effectiveness of the Carbomedics design is reflected in the low linearized rates (%/pt-yr) of thromboembolic events reported in published scientific literature.

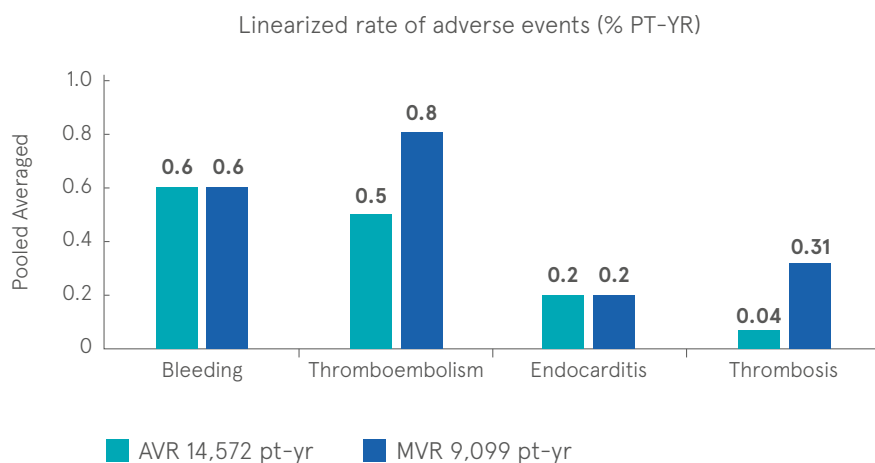


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Carrier. J Heart V Dis 2006 Jan;15(1): 67-72
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 Tominaga. Ann Thorac Surg 2005 Mar;79(3): 784-9
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 Wu. J Heart V Dis 2006 15: 414-420
 Onoda. Artificial Organs 2002 26(5): 479-82

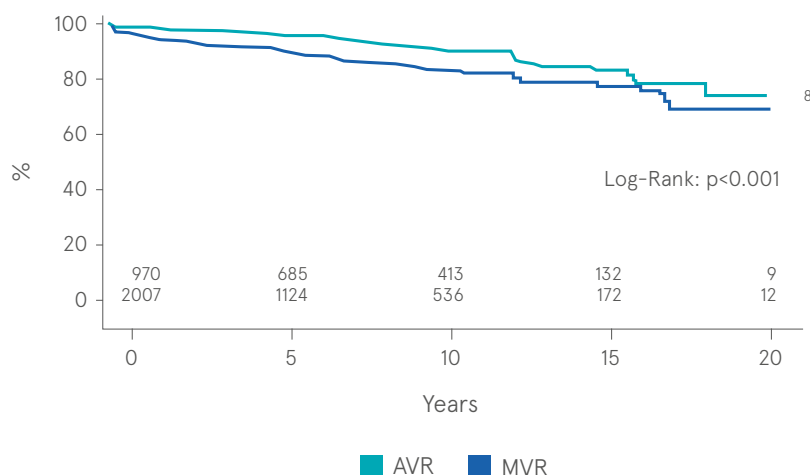
Twenty-Year Experience With the CarboMedics Mechanical Valve Prosthesis

These outstanding clinical results are confirmed by over **twenty years** of published follow up.⁸



* Pooled analysis of cited references. If follow-up years for subgroups (AVR, MVR) was not reported in the paper, their value was calculated from event rates values and graphs data, and the most conservative value inferred was performed.

Freedom from valve-related mortality after mitral and aortic valve replacement*



Utmost reliability with low thrombogenicity

Thrombogenicity remains to date one of the major concerns related to the implantation of mechanical heart valves. The safety of the Carbomedics valve with respect to thrombogenicity has been extensively proved in published scientific literature and is well recognized by the current European guidelines for heart valve disease management which classify Carbomedics as a Low thrombogenic prosthesis.¹⁰

Carbomedics valves have proven to be safe even at INR ranges well below the recommended target.^{11,12,13}

*All sudden or unknown causes of death were considered valve related in accordance to the Guidelines for reporting morbidity and mortality after cardiac valvular operations.⁹

8. Twenty-Year Experience With the CarboMedics Mechanical Valve Prosthesis. Bouchard et al. – Ann Thorac Surg 2014;97:816–23

9. Guidelines for reporting morbidity and mortality after cardiac valvular operations. Edmunds et al., Ad Hoc Liaison Committee for Standardizing Definitions of Prosthetic Heart Valve Morbidity of the American Association for Thoracic Surgery and the Society of Thoracic Surgeons. – J Thorac Cardiovasc Surg 1996;112:708–11.

10. Guidelines on the management of valvular heart disease (version 2012). The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)– European Heart Journal (2012) 33, 2451–2496

11. Low dose warfarin in patients with Carbomedics heart valves prostheses. P.V. Andersen, J. Aagard– Asian Cardiovasc Thorac Ann 2000; 8:11–4

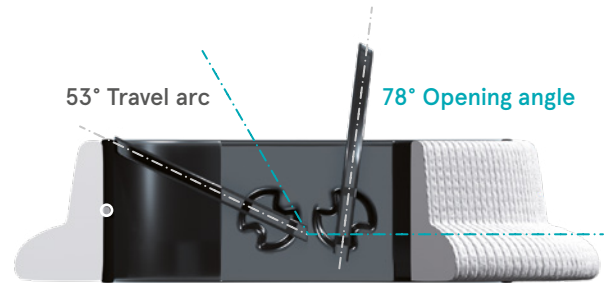
12. Is low anticoagulation intensity more beneficial for patients with bileaflet mechanical mitral valves? A meta-analysis. Zhe Xu et al., The Journal of Cardiovascular Surgery 2016 February; 57 (1):90–9

13. Clinical Observation of Postoperative Warfarin Anticoagulation in 300 Patients Undergoing Mitral Valve Replacement with a Carbomedics Mechanical Valve. Wu et al. The Heart Surgery Forum 2015; 18 (2): E063–E066

A unique platform with excellent hemodynamics

One of the key factors influencing the clinical success of a mechanical heart valve prosthesis is its hemodynamic efficiency.

The opening angle and travel arc of the leaflets of the Carbomedics valve have been established by hydrodynamic testing in order to achieve low pressure gradients and an optimal balance between forward flow and regurgitant volume, thus minimizing total energy loss while promoting quiet operation.

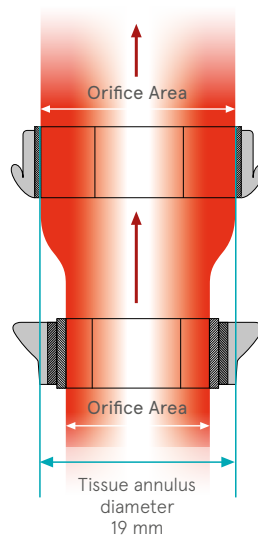


Top Hat, top hemodynamic performance

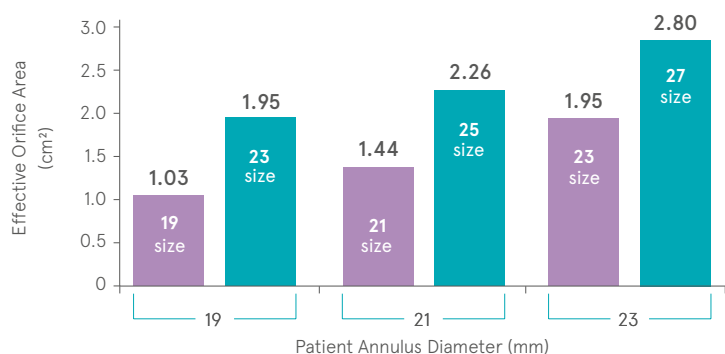
To further optimize hemodynamics, especially in small aortic annuli, LivaNova features in its Carbomedics portfolio the Top Hat prosthesis, a truly totally supra-annular model¹⁴ which provides an advantage of 1 to 2 sizes over intra-annular valves.^{15,16} Top Hat improves effective valve orifice area thanks to a 100% orifice to annulus match, thus contributing to reduce the risk of PPM.¹⁷

“The Top Hat valve minimizes the risk of patient-prosthesis mismatch, improves hemodynamic performance, and thereby reduces morbidity and mortality.”¹⁶

100% ORIFICE TO ANNULUS MATCH

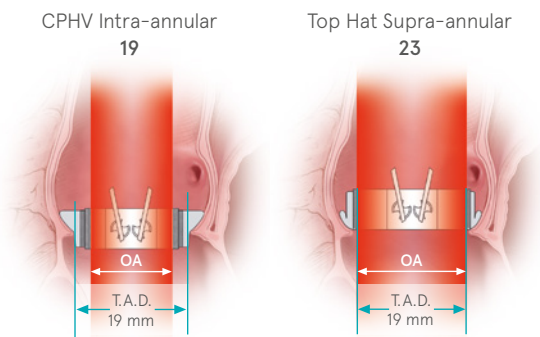


Carbomedics *in vitro* data*

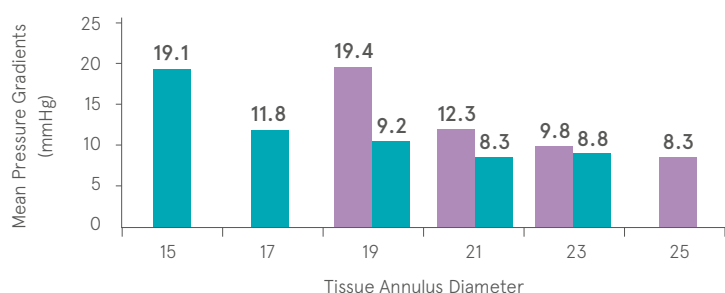


■ CPHV Intra-annular ■ Carbomedics Top Hat

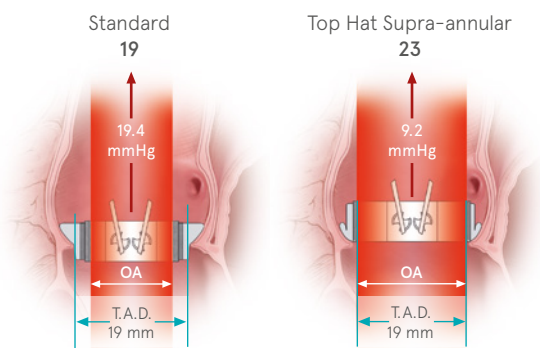
*In vitro test - 5l/min 70 bpm (Data on file at Livanova)



Carbomedics *in vivo* data^{18,19}



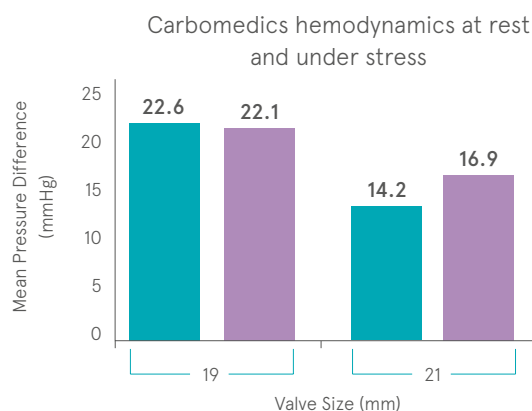
■ Standard ■ Carbomedics Top Hat



Differently from other competitive valves, Carbomedics has also shown an improved Effective Orifice Area under stress.

"The result is an optimization of the discharge coefficient with exercise, indicating a good design of the moving part of the valve."²⁰

■ Under stress ■ At rest



14. Supra annular model as defined by International Standard for Cardiovascular implants - Cardiac valve Prostheses-Part 2. ISO 5840-2:2015(E)

15. The Carbomedics Supraannular Top hat Valve improves prosthesis size in the Aortic Root. Lundblad R et al. - J Heart Valve Dis 2001;10:196-201

16. Maximizing prosthetic valve size with the Top Hat® supraannular aortic valve. Aagard et al. - The Journal of Heart Valve Disease 2007;16:84-90

17. Hemodynamic and Clinical Impact of Prosthesis-Patient Mismatch in the Aortic Valve Position and its Prevention. Pibarot P, Dumesnil JG. - J Am Coll Cardiol 2000;36:1131- 41

18. The Carbomedics "Top Hat" Supra-annular prosthesis. Bernal et al. - Ann Thorac Surg. 1999;67:1299-303

19. Echocardiographic description of the Carbomedics bileaflet prosthetic heart valve. Chambers et al. - JACC 1993; 21(2): 398-405

20. Hemodynamic performance of small diameter Carbomedics and St. Jude valves. De Paulis et al. - J Heart Valve Dis 1996;5 (Suppl III):S339-43



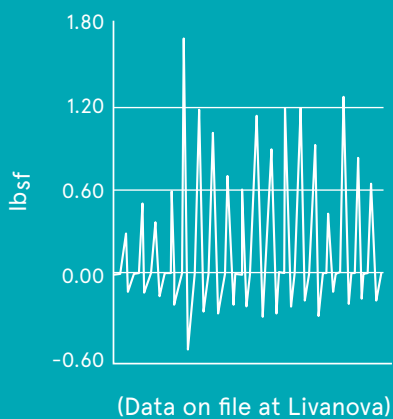
Tailored ease of implant

Carbomedics valves are designed for a smooth implant experience

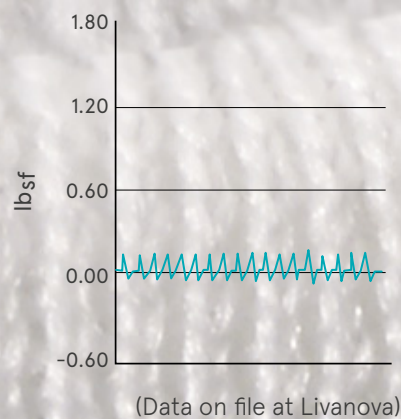
This is why they are considered by many leading cardiac centers the 'most accommodating' valve in the world.

Carbomedics sewing cuffs are optimized for ease of implant and good seating. Compared to other valves in the market, the Carbomedics sewing cuff requires much less force for needle penetration facilitating the suturing phase.

Typical valve
Sewing Cuff Penetration Force



Carbomedics standard
Sewing Cuff Penetration Force



Most importantly, the Carbomedics sewing cuff conforms to the tissue rather than forcing the tissue to conform to its shape, thus minimizing the tension on sutures and consequently the risk of dehiscence. This is particularly relevant in fragile or heavily calcified annuli.

A variety of configurations ensures an optimal fit in any anatomical situation.



**Tailored solutions for every patient and
surgeon's need**



Unique options that make the difference

CARBOMEDICS TOP HAT

A truly, totally supra-annular aortic prosthesis for improved hemodynamics.

Top Hat contributes to reduce the risk of PPM especially in small or severely calcified aortic annuli.

It is of particular advantage also in double valve replacement, where a total supra-annular seating helps minimise the risk of interference with the mitral prosthesis.



CARBOMEDICS OPTIFORM

A unique mitral prosthesis with versatile positioning to approach even the most challenging situations.

Thanks to its flexible, generous symmetrical sewing cuff Optiform valve can optimally conform to almost any annulus. Valve placement can be adjusted simply by varying suture entry and exit sites.



Everted Suture Technique



For atrial positioning (supra-annular),
needle enters at bottom of cuff
and exits at midline



For intra-annular positioning,
needle enters at bottom of cuff
and exits at top of cuff



For sub-annular positioning,
needle enters at midline of cuff
and exits at top of cuff

The most complete set of mechanical heart valve solutions in the market

Four different aortic models

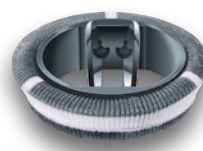
Carbomedics Top Hat



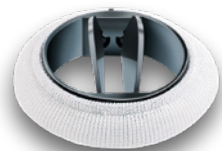
Carbomedics Standard



Carbomedics Reduced

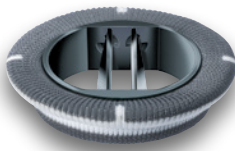


Carbomedics Orbis

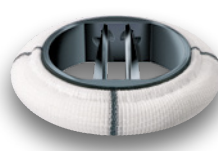


Three different mitral models

Carbomedics Standard



Carbomedics Optiform



Carbomedics Orbis



Pediatric aortic and mitral valves

Carbomedics Standard Pediatric



Two different conduit models

Carbomedics Carbo-Seal



Carbomedics Carbo-Seal Valsalva



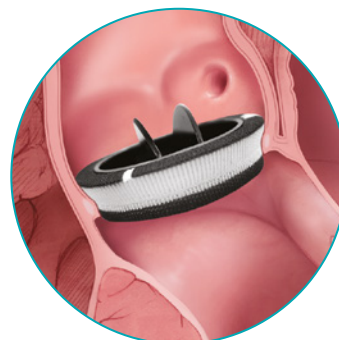
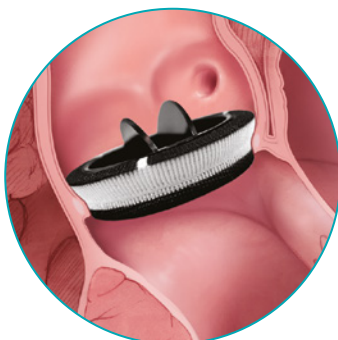
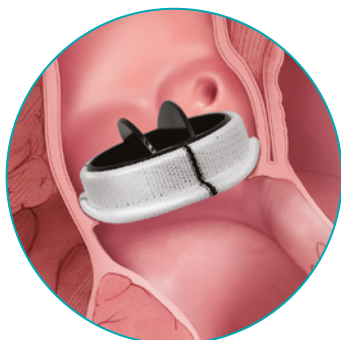
The voice of experience

"We observed that the Carbomedics mechanical prosthesis had excellent durability with no structural failures, good hemodynamics, and a low incidence of TE."

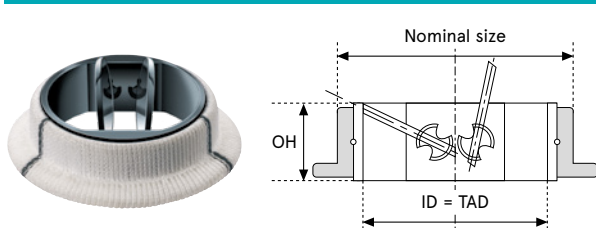
"Our experience demonstrates excellent functional result of the Carbomedics valve in both mitral and aortic positions. Valve-related events were low and often caused by patient-related factors as opposed to the presence of the prosthesis."

"In our experience, structural valve failure with this device is inexistent. The Carbomedics mechanical valve is a solid choice for long-term valvular replacement."

CARBOMEDICS TOP HAT	CARBOMEDICS REDUCED	CARBOMEDICS ORBIS	CARBOMEDICS STANDARD
TOTALLY SUPRA-ANNULAR AORTIC VALVE Sizes 19–27 mm	AORTIC VALVE Sizes 19–29 mm	AORTIC VALVE Sizes 19–31 mm	AORTIC VALVE Sizes 19–31 mm
			
Application			
• Aortic procedures • Normal sinus area • Small aortic annulus • Severely calcified aortic annulus • Double valve replacement	• Aortic procedures • Low coronary ostia • Narrow, rigid aortic annulus • Small, inflexible aorta (Sinus of Valsalva)	• Aortic procedures • Low coronary ostia • Narrow, rigid aortic sinus • Large annulus • Redo AVR	
Implantation Consideration			
• Totally supra-annular placement – allows for largest valve possible – increases ease and safety of DVR procedure • Titanium stiffening ring allows for rotatability in-situ • Three orientation markers for suture spacing • Special sizers allow surgeon to assess position of valve within sinus area and clearance of coronaries before implantation	• Titanium stiffening ring allows rotatability in-situ • Orientation markers provide easy visual suture positioning • Smaller, pliable (Carbomedics Reduced only) sewing cuff allows for improved seating in a smaller annulus or small root	• Titanium stiffening ring allows rotatability in-situ • Orientation markers provide easy visual suture positioning • Generous sewing cuff conforms to annulus, minimizing perivalvular leaks	
Clinical Considerations			
• Size upgrades provide improved valve hemodynamics • Totally supra-annular design allows the largest possible orifice available to blood flow • Alternative to aortic root enlargement • Titanium stiffening ring minimizes the possibility of leaflet lockup or escape • Utmost reliable structural stability • Excellent clinical record for valve-related events	• Alternative to aortic root enlargement where supra-annular valve will not fit in sinus • Titanium stiffening ring minimizes the possibility of leaflet lockup or escape • Utmost reliable structural stability • Excellent clinical record for valve-related events	• Low implant profile minimizes housing interference with the coronary ostia • Titanium stiffening ring minimizes the possibility of leaflet lockup or escape • Utmost reliable structural stability • Excellent clinical record for valve-related events	
Valve placement <i>in-situ</i>			

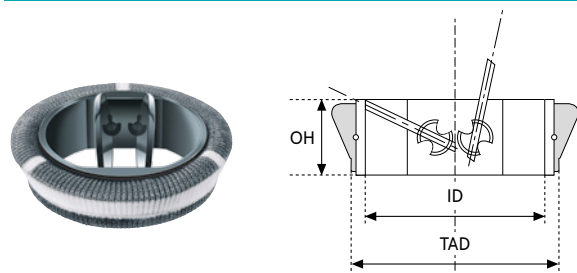


CARBOMEDICS TOP HAT



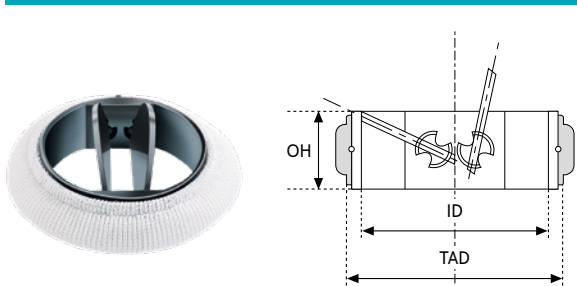
Nominal size	TAD	ID	OH	GOA	EOA	Catalog N.
19	14.7	14.7	6.2	1.59	1.0 ¹	S5-019
21	16.7	16.7	6.6	2.07	1.4 ²	S5-021
23	18.5	18.5	7.3	2.56	1.9 ²	S5-023
25	20.5	20.5	7.7	3.16	2.2 ²	S5-025
27	22.5	22.5	8.4	3.84	2.9 ²	S5-027

CARBOMEDICS REDUCED



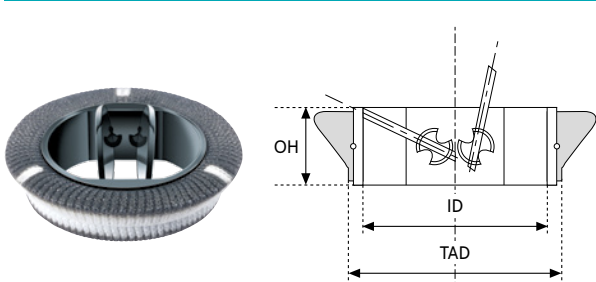
Nominal size	TAD	ID	OH	GOA	EOA ¹	Catalog N.
19	18.8	14.7	6.2	1.59	1.0	R5-019
21	20.8	16.7	6.6	2.07	1.5	R5-021
23	22.6	18.5	7.3	2.56	1.6	R5-023
25	25.0	20.5	7.7	3.16	2.0	R5-025
27	27.0	22.5	8.4	3.84	2.4	R5-027
29	29.0	24.2	8.7	4.44	2.6	R5-029

CARBOMEDICS ORBIS



Nominal size	TAD	ID	OH	GOA	EOA ¹	Catalog N.
19	18.8	14.7	6.2	1.59	1.0	A1-019
21	20.8	16.7	6.6	2.07	1.5	A1-021
23	22.6	18.5	7.3	2.56	1.6	A1-023
25	25.0	20.5	7.7	3.16	2.0	A1-025
27	27.0	22.5	8.4	3.84	2.4	A1-027
29	29.0	24.2	8.7	4.44	2.6	A1-029
31	31.0	24.2	8.7	4.44	2.6	A1-031

CARBOMEDICS STANDARD



Nominal size	TAD	ID	OH	GOA	EOA ¹	Catalog N.
19	19.8	14.7	6.2	1.59	1.0	A5-019
21	21.8	16.7	6.6	2.07	1.5	A5-021
23	23.8	18.5	7.3	2.56	1.6	A5-023
25	25.8	20.5	7.7	3.16	2.0	A5-025
27	27.8	22.5	8.4	3.84	2.4	A5-027
29	29.8	24.2	8.7	4.44	2.6	A5-029
31	31.8	24.2	8.7	4.44	2.6	A5-031

Legend

TAD = Tissue Annulus Diameter (mm)

OH = Orifice Height (mm)

ID = Internal Diameter (mm)

GOA = Geometric Orifice Area (cm²)

EOA = In vivo Effective Orifice Area (cm²)

1. Echocardiographic description of the Carbomedics bileaflet prosthetic heart valve. Chambers et al. - JACC 1993; 21(2): 398-405

2. Midterm Evaluation of Hemodynamics of the Top Hat Supraannular Aortic Valve. Aagard et al. - Asian Cardiovasc Thorac Ann 2010;18:1-5

CARBOMEDICS STANDARD SMALL SIZES

AORTIC VALVES

Sizes 16 and 18 mm



Size 16



Size 18

CARBOMEDICS STANDARD SMALL SIZES

MITRAL VALVES

Sizes 16, 18 and 21 mm



Size 16



Size 18



Size 21

Application

- Aortic procedures
- Extremely small aortic annulus
- Design allows for intra (size 18) or partially supra-annular (size 16) placement

- Extremely small annulus
- Design allows for intra-annular placement

Implantation Consideration

- Excellent orifice-to-annulus ratio without sacrificing safety or efficacy
- Sewing cuff assembly reduces cuff size for maximum orifice area

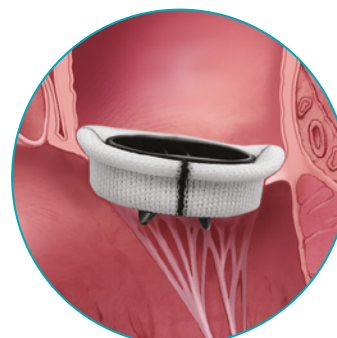
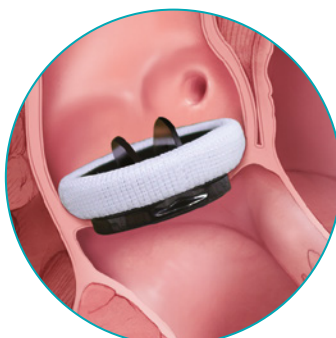
- Sewing cuff assembly reduces cuff size for maximum orifice area
- Titanium stiffening ring allows rotatability in-situ
- Orientation markers provide easy visual suture positioning
- Excellent orifice-to-annulus ratio without sacrificing safety or efficacy

Clinical Considerations

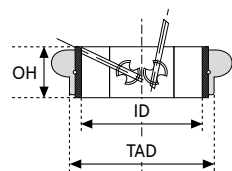
- Minimizes repeated replacements in the growing heart
- Fits where other bileaflet valves will not
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Utmost reliable structural stability

- Minimizes replacements in the growing heart
- Fits where other bileaflet valves will not
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Utmost reliable structural stability

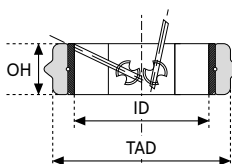
Valve placement *in-situ*



CARBOMEDICS STANDARD SMALL SIZES – AORTIC VALVES

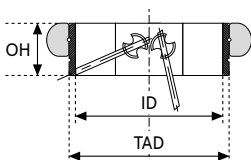


Nominal size	TAD	ID	OH	GOA	EOA ¹	Catalog N.
16	16.2	14.7	6.2	1.59	1	A5-016

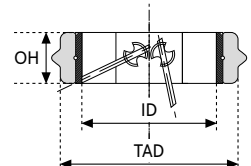


18	18.8	14.7	6.2	1.59	1	A5-018
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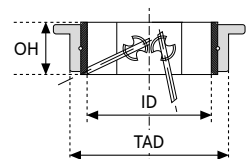
CARBOMEDICS STANDARD SMALL SIZES – MITRAL VALVES



Nominal size	TAD	ID	OH	GOA	Catalog N.
16	16.2	14.7	6.2	1.59	M7-016



18	18.8	14.7	6.2	1.59	M7-018
----	------	------	-----	------	--------



21	21.8	16.7	6.6	2.07	M7-021
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Legend

TAD = Tissue Annulus Diameter (mm)

OH = Orifice Height (mm)

ID = Internal Diameter (mm)

GOA = Geometric Orifice Area (cm²)

EOA = In vivo Effective Orifice Area (cm²)

1. Echocardiographic description of the Carbomedics bileaflet prosthetic heart valve. Chambers et al. - JACC 1993; 21(2); 398-405

CARBOMEDICS CARBO-SEAL VALSALVA

ASCENDING AORTIC PROSTHESIS (AAP)

Sizes 21-29 mm



CARBOMEDICS CARBO-SEAL

ASCENDING AORTIC PROSTHESIS (AAP)

Sizes 21-33 mm



Application

- Disease conditions of the aorta combined with disease or degeneration of the aortic valve
 - Ascending aortic aneurys
 - Ascending aorta dissection
 - Infective aortitis
 - Marfan's Syndrome
- Disease conditions of the aorta combined with disease or degeneration of the aortic valve
 - Ascending aortic aneurys
 - Ascending aorta dissection
 - Infective aortitis
 - Marfan's Syndrome

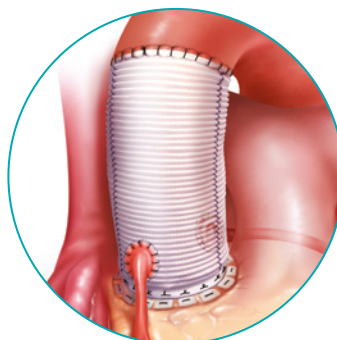
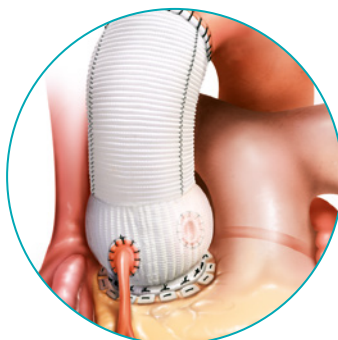
Implantation Consideration

- Vertical orientation of sinus pleats facilitates coronary anastomosis
- Graft material resists fraying and quickly seals suture holes, minimizing bleeding
- Easier handling and suturing in comparison to bulkier velour materials
- Ultra-low porosity fabric results in less leakage, weeping and blushing
- Pliable, cork-shaped sewing cuff conforms to annulus, minimizing potential perivalvular leaks
- Titanium stiffening ring allows valve rotatability in-situ
- Orientation markers provide easy visual suture positioning
- Pliable, cork-shaped sewing cuff conforms to annulus, minimizing potential perivalvular leaks
- Graft material resists fraying and quickly seals suture holes, minimizing bleeding
- Easier handling and suturing in comparison to bulkier velour materials
- Ultra-low porosity fabric results in less leakage, weeping and blushing
- Titanium stiffening ring allows rotatability in-situ
- Orientation markers provide easy visual suture positioning

Clinical Considerations

- Graft is infused with minimally crosslinked gelatin for faster healing, encouraging a secure neo-intimal attachment with reduced inflammatory response
- Collagen gel hydrolyzes within 14 days
- Sinus of Valsalva replicates the native sinus, reducing required dissection of and stress on the coronary anastomoses
- Sinus design encourages natural formation of systolic vortex
- Full-sized standard aortic valve provides excellent hemodynamics
- Excellent thromboembolic performance
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Graft is infused with minimally cross-linked gelatin for faster healing, encouraging a secure neo-intimal attachment with reduced inflammatory response
- Collagen gel hydrolyzes within 14 days
- Full-sized standard aortic valve provides excellent hemodynamics
- Excellent thromboembolic performance
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape

Valve placement *in-situ*

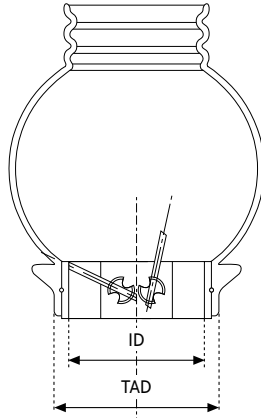


Product specifications

CARBOMEDICS® AORTIC MECHANICAL CONDUITS

CARBOMEDICS CARBO-SEAL VALSALVA

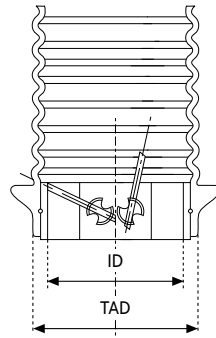
Length of graft: 10 cm · Sinus diameter: Graft ID + 8 mm



Nominal size	TAD	ID	GOA	Graft ID	Catalog N.
21	21.8	16.7	2.07	24	CP-021
23	23.8	18.5	2.56	26	CP-023
25	25.8	20.5	3.16	28	CP-025
27	27.8	22.5	3.84	30	CP-027
29	29.8	24.2	4.44	32	CP-029

CARBOMEDICS CARBO-SEAL

Length of graft: 10 cm



Nominal size	TAD	ID	GOA	Graft ID	Catalog N.
21	21.8	16.7	2.07	24	AP-021
23	23.8	18.5	2.56	26	AP-023
25	25.8	20.5	3.16	28	AP-025
27	27.8	22.5	3.84	30	AP-027
29	29.8	24.2	4.44	32	AP-029
31	31.8	24.2	4.44	34	AP-031
33	33.8	24.2	4.44	34	AP-033

Legend

TAD = Tissue Annulus Diameter (mm)

GOA = Geometric Orifice Area (cm²)

ID = Internal Diameter (mm)



CARBOMEDICS STANDARD

MITRAL VALVE

Sizes 23–33 mm



CARBOMEDICS OPTIFORM

MITRAL VALVE

Sizes 23–33 mm



CARBOMEDICS ORBIS

MITRAL VALVE

Sizes 21–33 mm



Application

- Mitral valve replacement with or without using mitral leaflet preservation procedures
- Double valve replacement
- Mitral valve replacement with or without using mitral leaflet preservation procedures
- Heavily calcified annulus
- Mitral redo surgery
- Double valve replacement
- Endocarditis

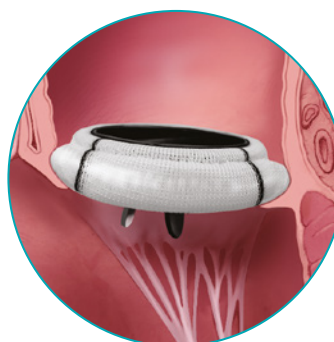
Implantation Consideration

- Large, flexible sewing cuff promotes coaptation to annulus
- Extra large sewing cuff displaces tissue up and away from orifice and leaflets when seating, minimizing the potential for perivalvular leaks
- Titanium stiffening ring allows rotatability in-situ
- Orientation markers provide easy visual suture positioning
- Symmetrical cuff design allows valve to be placed in a supraannular, intra-annular or subannular position simply by varying suture entry and exit sites
- Flexible, generous cuff easily conforms to difficult patient annular anatomy
- Titanium stiffening ring allows rotatability in-situ
- Orientation markers provide easy visual suture positioning (Carbomedics Optiform only)

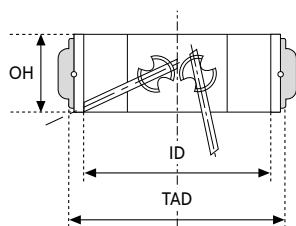
Clinical Considerations

- Low-profile pivot design minimizes protrusion into low-flow atrial area, reducing potential for thrombus formation
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Utmost reliable structural stability
- Excellent clinical record for valve-related events
- Variable valve placement allows surgeon to choose best valve position for each patient
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Utmost reliable structural stability
- Excellent clinical record for valve-related events

Valve placement *in-situ*

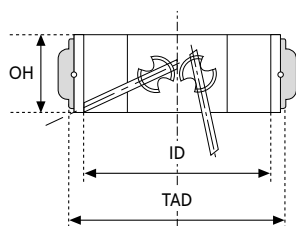


CARBOMEDICS OPTIFORM



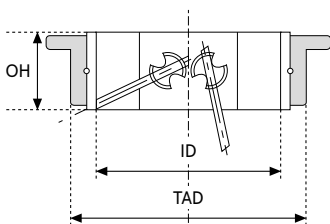
Nominal size	TAD	ID	OH	GOA	Catalog N.
23	22.6	18.5	7.3	2.56	F7-023
25	25.0	20.5	7.7	3.16	F7-025
27	27.0	22.5	8.4	3.84	F7-027
29	29.0	24.2	8.7	4.44	F7-029
31	31.0	24.2	8.7	4.44	F7-031
33	33.0	24.2	8.7	4.44	F7-033

CARBOMEDICS ORBIS



Nominal size	TAD	ID	OH	GOA	Catalog N.
21	20.8	16.7	6.6	2.07	M2-021
23	22.6	18.5	7.3	2.56	M2-023
25	25.0	20.5	7.7	3.16	M2-025
27	27.0	22.5	8.4	3.84	M2-027
29	29.0	24.2	8.7	4.44	M2-029
31	31.0	24.2	8.7	4.44	M2-031
33	33.0	24.2	8.7	4.44	M2-033

CARBOMEDICS STANDARD



Nominal size	TAD	ID	OH	GOA	Catalog N.
23	23.8	18.5	7.3	2.56	M7-023
25	25.8	20.5	7.7	3.16	M7-025
27	27.8	22.5	8.4	3.84	M7-027
29	29.8	24.2	8.7	4.44	M7-029
31	31.8	24.2	8.7	4.44	M7-031
33	33.8	24.2	8.7	4.44	M7-033

Legend

TAD = Tissue Annulus Diameter (mm)

OH = Orifice Height (mm)

ID = Internal Diameter (mm)

GOA = Geometric Orifice Area (cm²)



Aortic Mechanical Valves

CARBOMEDICS TOP HAT

Aortic Mechanical Bileaflet Valve

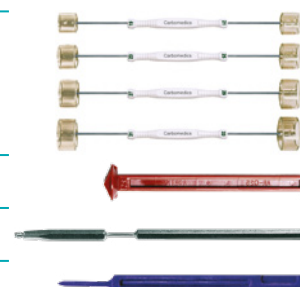
Article	Code	Description
Empty tray	TR-101	1 empty tray
Sizer set	SAS-200	3 sizers 19mm, 21-23mm, 25-27mm
Rotators set	AR-150	6 aortic rotators
Valve handle	VH-100	1 universal bendable handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)



CARBOMEDICS REDUCED, ORBIS, STANDARD

Aortic Mechanical Bileaflet Valve

Article	Code	Description
Empty tray	TR-101	1 empty tray
Sizer set	VS-200	4 sizers 19-21mm, 23-25mm 27-29mm, 31-33mm
Rotators set	AR-150	6 aortic rotators
Valve handle	VH-100	1 universal bendable handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)



Aortic Mechanical Conduits

CARBOMEDICS CARBO-SEAL VALSALVA, CARBO-SEAL

Aortic Mechanical Conduit

Article	Code	Description
Empty tray	TR-101	1 empty tray
Sizer set	VS-200	4 sizers 19-21mm, 23-25mm 27-29mm, 31-33mm
Rotators set	AR-150	6 aortic rotators
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)



Mitral Mechanical Valve

CARBOMEDICS® ACCESSORIES

CARBOMEDICS OPTIFORM, ORBIS, STANDARD

Mitral Mechanical Bileaflet Valve



Article	Code	Description
Empty tray	TR-101	1 empty tray
Sizer set	VS-200	4 sizers 19-21mm, 23-25mm 27-29mm, 31-33mm
Rotators set	RM-399	6 mitral rotators: 16-18mm, 21mm, 23mm, 25mm, 27mm, 29-31-33mm + 1 bendable handle
Bendable handle	RH-100	1 bendable handle to use with mitral valve rotators
Valve handle	VH-100	1 universal bendable handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)



Pediatric Mechanical Valves

CARBOMEDICS STANDARD PEDIATRIC

Aortic Mechanical Bileaflet Valve



Article	Code	Description
Empty tray	TR-101	1 empty tray
Sizer	VS2-1618	1 sizer (16-18mm)
Rotators set	AR-150	6 aortic rotators
Valve handle	VH-100	1 universal bendable handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)



CARBOMEDICS STANDARD PEDIATRIC

Mitral Mechanical Bileaflet Valve



Article	Code	Description
Empty tray	TR-101	1 empty tray
Sizer	VS2-1618	1 sizer (16-18mm)
Sizer set	VS-200	4 sizers 19-21mm, 23-25mm 27-29mm, 31-33mm
Rotators set	RM-399	6 mitral rotators: 16-18mm, 21mm, 23mm, 25mm, 27mm, 29-31-33mm + 1 bendable handle
Bendable handle	RH-100	1 bendable handle to use with mitral valve rotators
Valve handle	VH-100	1 universal bendable handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)





www.livanova.com



Manufactured by:

Sorin Group Italia Srl

A wholly-owned subsidiary of LivaNova PLC
Via Crescentino - 13040 Saluggia (VC) Italy
Tel: +39 0161 487472 - Fax: +39 0161 487316
info.cardiacsurgery@livanova.com

Federal law (USA) restricts this device to sale by or on the order of a physician.
Please always refer to the Instructions For Use (IFU) manual provided with each product for detailed information, warnings, precautions and possible adverse side effects.

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Product Service

EC Certificate

EC Type-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex III
(Devices in class IIb or III)

No. G5 17 09 01664 011

Manufacturer:**SORIN GROUP ITALIA S.r.l.**

Via Crescentino sn
13040 Saluggia (VC)
ITALY

**Product:**

Heart Valves
Sorin Mechanical Heart Valves

The Certification Body of TÜV SÜD Product Service GmbH declares that a type examination has been carried out on the respective device type in accordance with MDD Annex III (4). This representative sample for the envisaged production conforms to the requirements of this Directive. For marketing of class III devices an additional Annex IV or V certificate is mandatory. For marketing of class IIb devices an additional Annex IV, V or VI certificate is mandatory. See also notes overleaf.

Report no.:

713114103

Valid from:

2017-10-17

Valid until:

2021-12-19

**Date,** 2017-10-16

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



Product Service

EC Certificate**EC Type-Examination Certificate**Directive 93/42/EEC on Medical Devices (MDD), Annex III
(Devices in class IIb or III)**No. G5 17 09 01664 011****Model(s):****Bicarbon Fitline
Bicarbon Slimline
Bicarbon Overline****Parameters:****Model Name**
Bicarbon Fitline
LFA Aortic**Product codes**ICV0917/ART19LFA
ICV0918/ART21LFA
ICV0919/ART23LFA
ICV0920/ART25LFA
ICV0921/ART27LFA
ICV0922/ART29LFA
ICV0923/ART31LFABicarbon Fitline
LFM MitralICV0924/MTR19LFM
ICV0925/MTR21LFM
ICV0926/MTR23LFM
ICV0927/MTR25LFM
ICV0928/MTR27LFM
ICV0929/MTR29LFM
ICV0930/MTR31LFM
ICV0931/MTR33LFMBicarbon Slimline
LSA AorticICV0934/ART17LSA
ICV0935/ART19LSA
ICV0936/ART21LSA
ICV0937/ART23LSA
ICV0938/ART25LSA
ICV0939/ART27LSABicarbon Overline
AorticICV0870/ART16LOV
ICV0871/ART18LOV
ICV0872/ART20LOV
ICV0873/ART22LOV
ICV0874/ART24LOV**Facility(ies):**SORIN GROUP ITALIA S.r.l.
Via Crescentino sn, 13040 Saluggia (VC), ITALY



Product Service

Certificate

No. Q5 057574 0067 Rev. 03

Holder of Certificate: **Sorin Group Italia S.r.l.**

Via Statale 12 Nord, 86
41037 Mirandola MO
ITALY

Certification Mark:



Scope of Certificate:

Design and development, production and distribution of non active blood recovery, cell separation, blood monitoring disposables as well as oxygenators, cannulae, catheters, filters, reservoirs, cardioplegia, centrifugal pumps and customized tubing sets for cardiac surgery, autotransfusion and extracorporeal life support applications.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 057574 0067 Rev. 03

Report No.: ITA1672710

Valid from: 2021-05-15

Valid until: 2024-05-14

Date, 2021-04-29

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 057574 0067 Rev. 03

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Sorin Group Italia S.r.l.
Via Statale 12 Nord, 86, 41037 Mirandola MO, ITALY

Design and development, production, sterilization and distribution of non active blood recovery, cell separation, blood monitoring disposables as well as oxygenators, cannulae, catheters, filters, reservoirs, cardioplegia, centrifugal pumps and customized tubing sets for cardiac surgery, autotransfusion and extracorporeal life support applications.

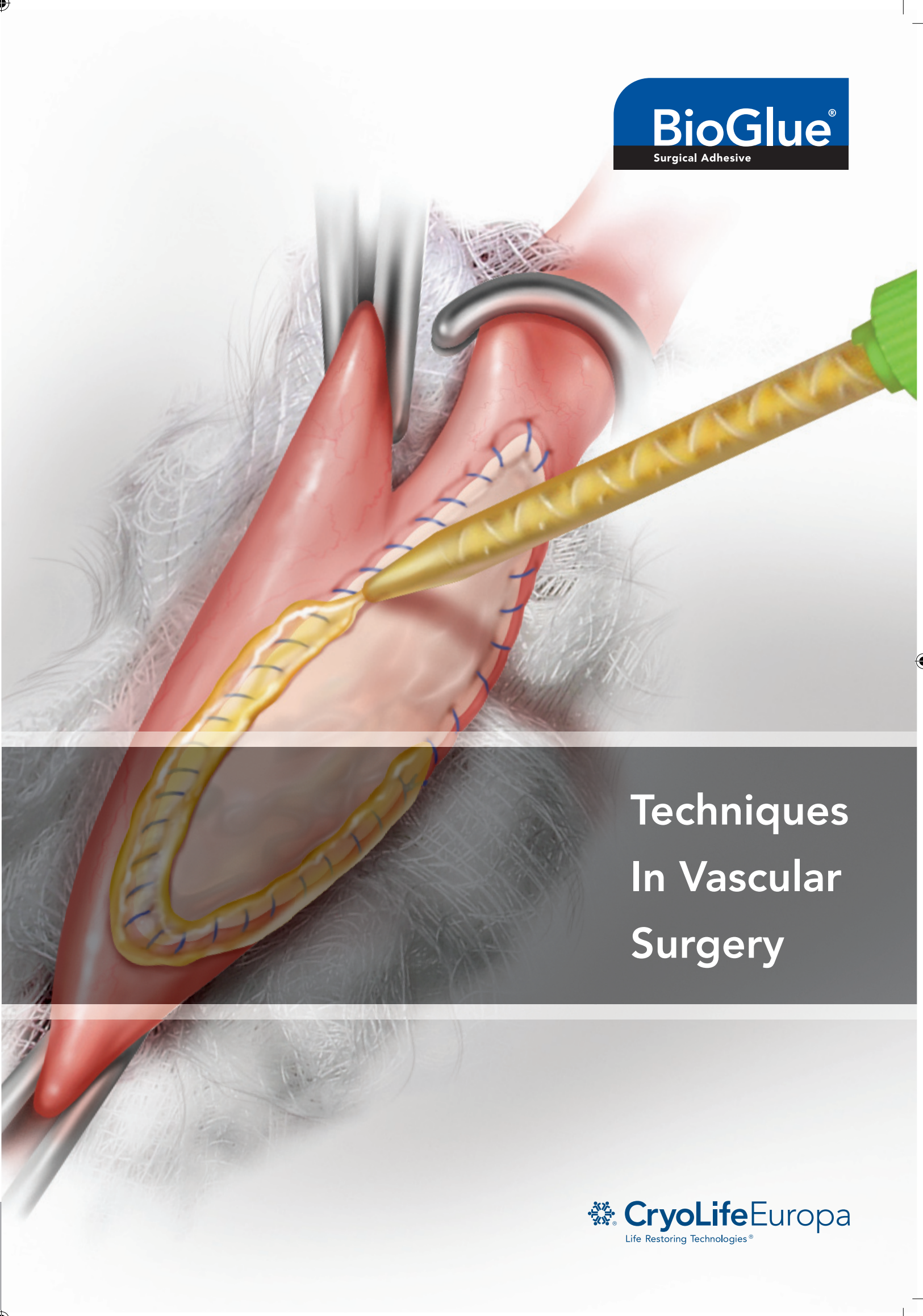
Sorin Group Italia S.r.l.
Via Leonardo da Vinci 12, 41036 Medolla MO, ITALY

Production of disposables for cardiac surgery and extracorporeal life support applications.

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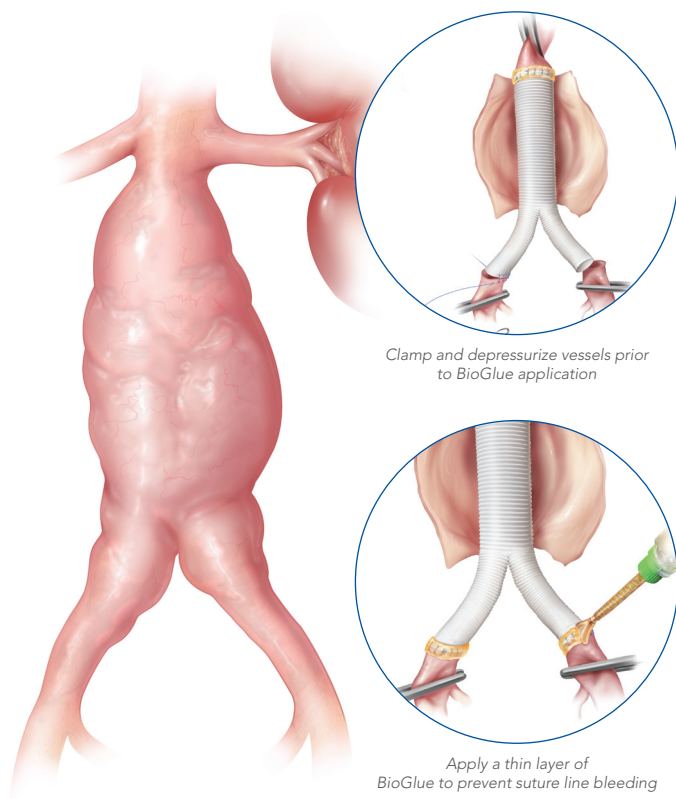
BioGlue®
Surgical Adhesive



The illustration depicts a surgical site on a patient's arm. A large, red, elongated incision is visible, with a yellow, gel-like substance (BioGlue) applied along its length. A green-handled applicator is shown dispensing the adhesive. The surrounding skin is light-colored with some hair. A metal surgical clip is visible at the top of the incision.

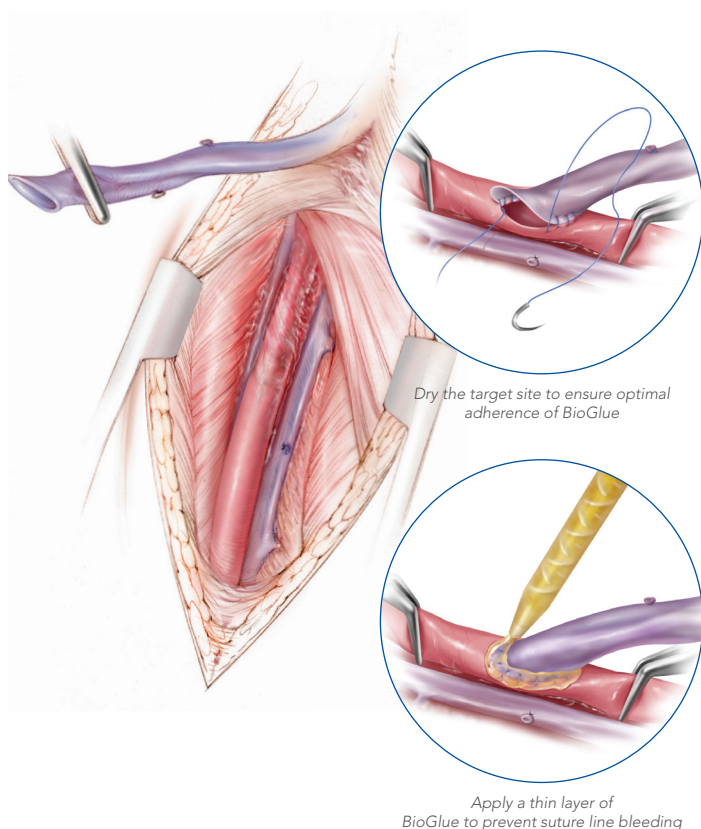
Techniques In Vascular Surgery

Application Technique



Abdominal Aortic Aneurysm

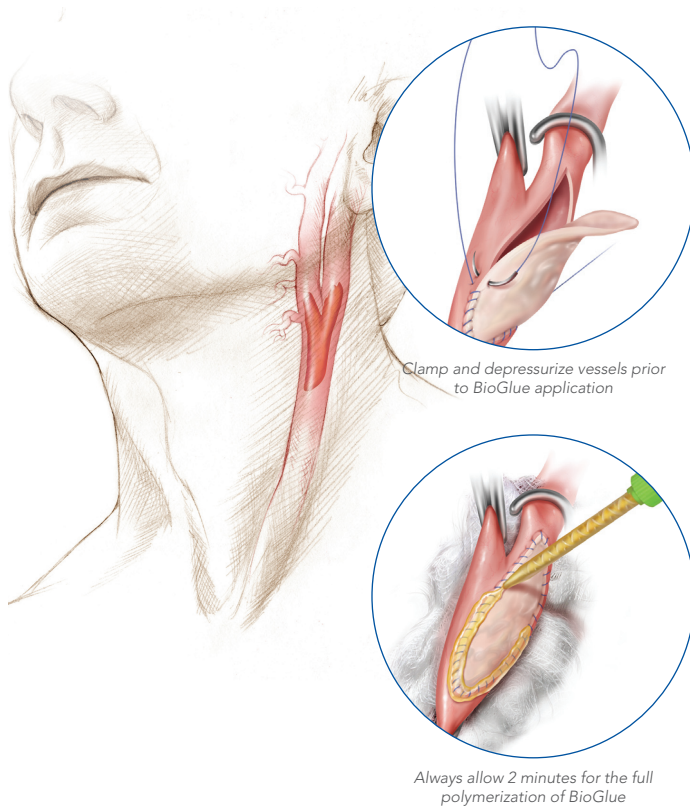
- Clamp and depressurize vessels prior to BioGlue application
- Dry the target site to ensure optimal adherence of BioGlue to the target tissue
- Prime the applicator tip and apply a thin layer of BioGlue that extends 1cm in either direction of the suture line
- Wait 2 minutes for BioGlue to completely polymerize before pressurizing the anastomosis
- Complete all remaining anastomoses, and again apply a thin layer of BioGlue to prevent suture line bleeding
- Wait 2 minutes before re-establishing systemic blood flow



Peripheral Bypass / AV Access

- Clamp and depressurize vessels prior to BioGlue application
- Dry the target site to ensure optimal adherence of BioGlue to the target tissue
- Prime the applicator tip and apply a thin layer of BioGlue directly onto the suture line
- Wait 2 minutes for BioGlue to completely polymerize before pressurizing the anastomosis
- Complete the final anastomosis, and again apply a thin layer of BioGlue to prevent suture line bleeding
- Wait 2 minutes before re-establishing systemic blood flow

es in Vascular Surgery



Carotid Endarterectomy

- Once the graft has been sewn into place, carefully pack gauze around the target area to prevent BioGlue from running into unwanted areas
- Clamp and depressurize vessels prior to BioGlue application
- Dry the target site to ensure optimal adherence of BioGlue to the target tissue
- Prime the applicator tip and apply a thin layer of BioGlue directly onto the suture line around the patch
- Wait 2 minutes for BioGlue to completely polymerize before re-establishing systemic blood flow

Key Application Techniques

1. Dry the target site to ensure optimal adherence of BioGlue to target tissue
2. Clamp and depressurize vessels prior to applying BioGlue to targeted anastomoses
3. Prime the applicator tip to ensure proper mixing of the components
4. Switch from Cell Saver® to wall suction to prevent BioGlue from entering the pump system
5. Apply a thin layer of BioGlue directly onto the suture line to prevent suture line bleeding
6. Wait 2 minutes before pressurizing the anastomoses to allow for full BioGlue polymerization

BioGlue Surgical Adhesive... Ideal for Vascular Surgery

- Reinforces Friable Tissue
- Seals Needle Holes
- Clinically Proven in more than 500,000 procedures worldwide



BioGlue Syringe Delivery System

Catalogue Number	Product	Contains
BG3510-5-G	Syringe 10mL 5-Pack Kit	Five single packs – Each contains one 10mL syringe and syringe plunger, four standard syringe tips, and three 12mm spreader tips
BG3515-5-G	Syringe 5mL 5-Pack Kit	Five single packs – Each contains one 5mL syringe and syringe plunger, and four standard syringe tips
BG3502-5-G	Syringe 2mL 5-Pack Kit	Five single packs – Each contains one 2mL syringe and syringe plunger, and four standard syringe tips
BG3500N	Syringe Delivery Device	One single pack – Contains one non-sterile reusable syringe delivery device
BGAT-SY	Syringe Applicator Tip	Ten single packs – Each contains four standard syringe tips
BGAT-10-SY	Syringe 10cm Applicator Tip	Ten single packs – Each contains four 10cm syringe tips
BGAT-27-SY	Syringe 27cm Applicator Tip	Ten single packs – Each contains four 27cm syringe tips
BGST-12	Syringe 12mm Spreader Tip	Ten single packs – Each contains three 12mm spreader tips
BGST-16	Syringe 16mm Spreader Tip	Ten single packs – Each contains three 16mm spreader tips



BioGlue® Surgical Adhesive
CE MARKED

INDICATIONS FOR USE: BioGlue Surgical Adhesive is indicated for use as an adjunct to standard methods of surgical repair (such as sutures, staples, electrocautery, and/or patches) to bond, seal, and/or reinforce soft tissue. BioGlue may also be applied alone to seal and/or reinforce damaged parenchyma when other ligature or conventional procedures are ineffective or impractical. Indicated soft tissues are cardiac, vascular, pulmonary, genitourinary, dural, alimentary (esophageal, gastrointestinal, and colorectal), and other abdominal (pancreatic, splenic, hepatic and biliary). Additionally, BioGlue is used in the fixation of surgical meshes in hernia repair.

EC DESIGN EXAMINATION CERTIFICATE

This is to certify that Lloyd's Register Quality Assurance, a Notified Body under the terms of:
the Medical Devices Directive 93/42/EEC;
the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618;
did (in accordance with Annex II clause 4 of the Directive) undertake an EC Design Examination on the stated products to ensure their conformity with the requirements of the Directive which apply to them. The products identified below were shown to comply.

This certificate is issued to:

MANUFACTURER:

CryoLife, Inc.

1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144, United States

PRODUCT NAME:

BioGlue© Surgical Adhesive

PRODUCT DESCRIPTION:

BioGlue Surgical Adhesive is indicated for use as an adjunct to standard methods of surgical repair (such as sutures, staples, electrocautery, and/or patches) to bond, seal, and/or reinforce soft tissue.

DESIGN DOSSIER REFERENCE: document #TF00007.003, revision 003, dated 31 May 2017

This Certificate is not valid for products, the design or characteristics of which have been varied from those examined. The manufacturer shall notify LRQA of any modification or changes to the products in order to maintain a valid certificate.

Certificate No: 0088/094334/00050

Current Certificate: 1 December 2017

Expiry Date: 30 November 2022

Certificate Identity Number: 10039484

LRQA Notified Body Number: 0088

Original Approvals: 25 November 1997

Approval Certificate Number: MDD – 0015237



Chris Koci

Issued By: Lloyd's Register Quality Assurance Ltd



Lloyd's
Register

EC DESIGN EXAMINATION CERTIFICATE CERTIFICATE 0949334 SUPPLEMENT

Certificate Identity Number: 10039484

CryoLife, Inc.

1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144, United States

LRQA hereby confirms that the change(s) detailed below have been reviewed in conjunction with the approved Design Dossier and the EC Design Examination remains valid.

This supplement is only valid in association with the EC Design Examination certificate detailed above.

Supplement Number:	Supplement Date:	Details of amendment:
0	21 November 2017	Renewal under jobs 1222716 & 1223002

Certificate No: 0088/094334/00050

Current Certificate: 1 December 2017

Expiry Date: 30 November 2022

Certificate Identity Number: 10039484

LRQA Notified Body Number: 0088

Original Approvals: 25 November 1997

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