



U.S. Department
of Transportation
**Research and
Special Programs
Administration**

DEC 13 2000

400 Seventh St., S.W.
Washington, D.C. 20590

Ms. Marilyn Dirkx
Manager, Dangerous Goods Compliance
Alaska Airlines
Box 68900
Seattle, WA 98168-0900

Reference No.: 00-0206

Dear Ms. Dirkx:

This is in response to your July 24, 2000 letter concerning certain carbon dioxide cylinders that are used in a medical device to administer needle-free injections. Specifically, you asked if the cylinders may be carried on board a passenger aircraft in checked or carry-on luggage under the exception in § 175.10(a)(4)(i), 175.10(a)(18) or § 175.10(a)(25) of the Hazardous Materials Regulations (49 CFR Parts 171-180). I apologize for the delay and any inconvenience it may have caused.

Based on our review of information provided by a manufacturer of these medical devices, it is our opinion that the cylinders may be carried aboard passenger-carrying aircraft in checked or carry-on luggage under the provision in § 175.10(a)(4)(i). The devices do not qualify for the exceptions in §§ 175.10(a)(18) and 175.10(a)(25). The Federal Aviation Administration is in agreement with this position.

Should you have further questions, please contact this office.

Sincerely,

Edward T. Mazzullo
Director, Office of Hazardous Materials Standards

Alaska Airlines

Corbin

8 175.10

06-0206

U.S. Department of Transportation
Research and Special Programs Administration
Office of Hazardous Materials Standards
400 Seventh St SW
Washington, DC 20590
Attn: Mr. Ed Mazzullo

July 24, 2000

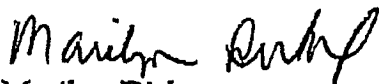
Dear Mr. Mazzullo:

Recently, a passenger attempted to carry in his checked luggage two small carbon dioxide cylinders used for administering medical injections. They were discovered during CTX screening. (The CTX is an explosive detection x-ray system that has been instrumental in detecting undeclared hazardous materials.) The screener advised the passenger that the cylinders could not be carried in luggage, and the passenger was forced to remove them from his luggage. The passenger, a physician, was very irritated, and stated that these small carbon dioxide cylinders are very common and that people are carrying them around all the time. According to the supervisor who responded to the call by the CTX operator, the cylinders were smaller than the type used in live vests that are approved for carriage by 49CFR 175.10(a)(25).

My question to you is this: May small carbon dioxide cylinders used for the administration of medical injections be carried onboard or transported in checked luggage as permitted in 175.10(a)(25), or 175.10(a)(18), or can they be considered medicinal and allowed per 175.10(a)(4)(i)?

Thank you for your response.

Sincerely,



Marilyn Dirkx
Manager, Dangerous Goods Compliance
Tel 206-431-7442
Fax 206-433-3225

To: Mr. Ed Mazzullo
U.S. Department of Transportation
Research and Special Programs Administration
Office of Hazardous Materials Standards
Fax number 202-366-3012

From: Marilyn Dirkx
Manager, Dangerous Goods Compliance
Alaska Airlines
Fax number 206-433-3225
Tel number 206-431-7442

Pages: 2 including this cover.

Hattie,

Considering the several exceptions in 475.10 for CO₂ devices, and the like, I do not see that this instrument poses a threat when transported in an air passenger's baggage (checked or stowed) or when carried on their person. Also, considering its end use I am satisfied that it is a medicinal article.

Tom A
Acting AA for HMS
10-18-00

MEMORANDUM**BIOJECT**

To: Gigi Corbin
U.S. Department of Transportation
RSPA/DHM-12/ Room 8422
400 Seventh Street, SW
Washington, DC 20590-0001

From: Jim Bonicatto

Date: 01 November 2000

Cc: Tom Brooks

Subject: Bioject Inc. Part No. 1C08010, 8 gram CO₂ Gas Cartridge(s)

BIOJECT INC.
7620 S.W. BRIDGEPORT ROAD
PORTLAND, OREGON 97224
TELEPHONE: (503) 639-7221
FAX: (503) 634-9002
WWW.BIOJECT.COM

This memorandum along with the attached data (2 pages) serves to address the above mentioned 8 gram CO₂ gas cartridge (cylinder) for use with the Biojector® Needle Free Injection Management System.

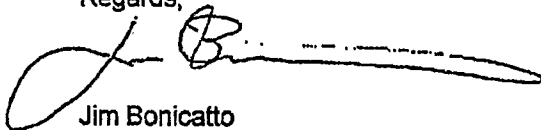
The cylinders are filled with 8 grams of CO₂ and sealed. Once sealed in an enclosed, constant volume, the gas pressure is related to the temperature of the environment. The following table and attachments show the relationship of temperature and pressure. It must also be noted that the minimum burst pressure of the cylinders is rated at over 6000 psi. This provides sufficient margin for product delivered and stored at normal temperatures.

Summary of Pressure vs. Temperature:

Temperature (F)	Pressure (psi)
32	506
68	831
88	1071
140	3190

If there any further questions please feel free to contact myself (503) 639-7221 x417 or Tom Brooks (x437).

Regards,



Jim Bonicatto
R&D Manager



INDUSTRIAL PRODUCTS

PRODUCT INFORMATION

Product Range				
STANDARDS	EN, DIN, TÜV, DOT, MOD, BS, MIL, FAA, TSO, ASTM, EMPA, DAN			
FILLING	Carbon Dioxide (CO ₂), Nitrogen (N ₂)			
SURFACE TREATMENT	Electroplated Zinc, Super (high corrosion resistant) Zinc			
MARKING	Ink Jet, Engraving or Printing to specification			
Select from table below. Other sizes, gases and fillings on request.				
Nominal Weight(s) of CO ₂ grams	Water Capacity ml	Body Diameter mm	Overall Length mm	Neck details
8	10	18	66.5	3/8" x 24 UNF 1A
10.5 & 12	15	18.6	82.5	8.7 mm Dia PLAIN
10 & 11.5	14	18.6	82.5	3/8" x 24 UNF 1A
12	14	18.6	82.5	7.3 mm Dia PLAIN
16	21	22	88.5	8.7 mm Dia PLAIN
16	21	22	88.5	8.9 mm Dia PLAIN
16	21	22	88.5	3/8" x 24 UNF 1A/2A
20, 23 & 24	32	25.4	105	1/2" x 20 UNF 1A
28	40	20.7	160	8.7 mm Dia PLAIN
28	40	20.7	160	3/8" x 24 UNF 1A
28, 30 & 33	45	25.4	139	1/2" x 20 UNF 1A
35 & 38	52	30	118	1/2" x 20 UNF 1A
45	62	30	138	1/2" x 20 UNF 1A
55 & 60	85	31.8	163	1/2" x 20 UNF 1A
75	103	31.8	189	1/2" x 20 UNF 1A
84	115	41.3	145	1/2" x 20 UNF 1A
86	120	35	198	1/2" x 20 UNF 1A
120* & 135*	210	50	176	1/2" x 20 UNF 1A
120, 135 & 150	210	50	171	1/2" x 20 UNF 1A
215	300	50	226	1/2" x 20 UNF 1A
230*	350	50	275	1/2" x 20 UNF 1A
290*	450	60	225	1/2" x 20 UNF 1A
295	400	60	213	1/2" x 20 UNF 1A
315	440	50	311	1/2" x 20 UNF 1A
330*	500	50	375	1/2" x 20 UNF 1A
345	525	60	265	1/2" x 20 UNF 1A
450	600	60	311	1/2" x 20 UNF 1A
460*	700	60	368	1/2" x 20 UNF 1A

* DOT Approved.

Product range may be updated. Please check with us.

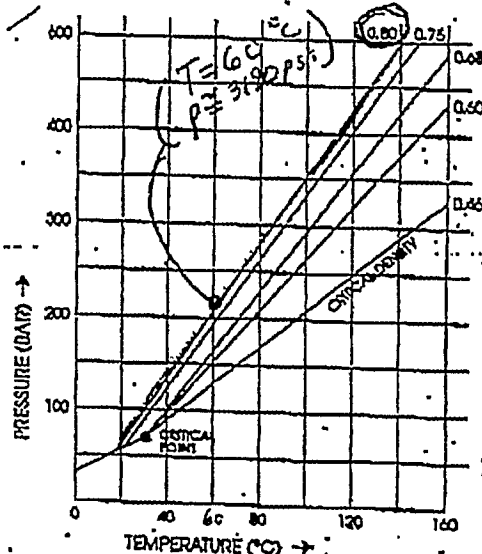
* DOT Approved.

Product range may be updated. Please check with us.

Conversion Factors		
Multiply	By	To obtain
mm	0.0394	in
cm ²	0.155	in ²
cm ³ (1 m)	0.061	in ³
Newton	0.225	lbf
lb	0.454	kg
kg/cm ²	14.22	lbf/in ²
bar	14.5	lbf/in ²
atmosphere	1.013	bar
N/mm ²	145	lbf/in ²
US gallon	3.785	litres
UK gallon	4.546	litres
US fluid ounce	29.57	ml

14.5 psi = conversion
Bar

PRESSURE - TEMPERATURE
FOR VARIOUS FILLING DENSITIES OF CO₂
Filling density = $\frac{\text{Wt of CO}_2 \text{ (g)}}{\text{Water capacity (ml)}}$



Physical Characteristics

	Carbon Dioxide (CO ₂)	Nitrogen (N ₂)
Odour	Slightly pungent	None
Taste	Acidic/Bitting	None
Fire hazard	Non-flammable	Non-flammable
Toxicity	Max. 0.5% v/v continuous	Non-toxic
Liquid density (20°C)	0.775 kg/l	
Gas density (15°C and 100 kPa)		

Carbon Dioxide

291

Temp F	Pressure		Volume cu ft/lb	Density lb/cu ft	Enthalpy** Btu/lb		Entropy** Btu/(lb) (°R)	
	psia	psig	Vapor	Solid or Liquid	Solid or Liquid	Vapor	Solid or Liquid	Vapor
-6	276.3	261.6	0.3233	64.62	193.0	316.01	0.6979	0.9691
-4	285.8	271.1	0.3119	64.29	193.9	315.99	0.7000	0.9678
-2	295.7	281.0	0.3010	63.96	194.9	315.95	0.7022	0.9666
+0	305.8	291.1	0.2906	63.63	195.8	315.92	0.7043	0.9654
2	316.3	301.6	0.2805	63.30	196.9	315.88	0.7064	0.9642
4	327.0	312.3	0.2707	62.97	198.0	315.83	0.7085	0.9629
6	337.9	323.2	0.2613	62.64	198.9	315.76	0.7106	0.9616
8	349.0	334.3	0.2523	62.30	200.0	315.68	0.7127	0.9603
10	360.5	345.8	0.2436	61.99	200.9	315.59	0.7148	0.9589
12	372.2	357.5	0.2353	61.69	202.0	315.50	0.7169	0.9575
14	384.3	369.6	0.2273	61.32	203.0	315.40	0.7190	0.9561
16	396.5	381.8	0.2196	61.02	204.1	315.27	0.7211	0.9547
18	409.0	394.3	0.2122	60.67	205.2	315.13	0.7232	0.9533
20	421.9	407.2	0.2050	60.32	206.3	314.96	0.7253	0.9520
22	435.1	420.4	0.1980	59.91	207.4	314.80	0.7275	0.9507
24	448.7	434.0	0.1911	59.57	208.4	314.62	0.7297	0.9493
26	462.5	417.8	0.1845	59.17	209.5	314.42	0.7319	0.9479
28	476.6	461.9	0.1783	58.78	210.6	314.19	0.7341	0.9465
30	490.8	476.1	0.1722	58.40	211.7	313.90	0.7363	0.9450
32	505.5	490.8	0.1663	58.02	212.8	313.58	0.7385	0.9434
34	520.5	505.8	0.1602	57.59	214.0	313.20	0.7407	0.9417
36	536.0	521.3	0.1542	57.12	215.1	312.77	0.7429	0.9399
38	551.7	537.0	0.1482	56.70	216.4	312.28	0.7452	0.9380
40	567.7	553.0	0.1425	56.29	217.4	311.76	0.7475	0.9360
42	584.0	569.3	0.1372	55.89	218.7	311.20	0.7598	0.9340
44	600.8	586.1	0.1321	55.44	220.0	310.63	0.7521	0.9321
46	617.8	603.1	0.1273	54.95	221.2	310.05	0.7544	0.9302
48	635.2	620.5	0.1226	54.43	222.5	309.47	0.7568	0.9283
50	652.9	638.2	0.1181	53.91	223.7	308.90	0.7593	0.9264
52	671.2	656.5	0.1138	53.45	225.0	308.32	0.7618	0.9246
54	689.7	675.0	0.1095	52.95	226.4	307.75	0.7643	0.9227
56	708.6	693.9	0.1054	52.37	227.7	307.13	0.7668	0.9207
58	727.9	713.2	0.1014	51.81	229.1	306.49	0.7694	0.9187
60	747.6	732.9	0.09752	51.17	230.6	305.78	0.7720	0.9166
62	767.7	753.0	0.09372	50.47	232.0	305.03	0.7746	0.9145
64	788.3	773.6	0.08999	49.78	233.5	304.22	0.7773	0.9123
66	809.3	794.6	0.08631	49.08	235.1	303.35	0.7801	0.9100
68	830.8	816.1	0.08261	48.39	236.7	302.45	0.7830	0.9077
70	852.7	838.0	0.07894	47.62	238.3	301.52	0.7861	0.9053
72	875.0	860.3	0.07535	46.80	240.3	300.51	0.7894	0.9030
74	897.8	883.1	0.07173	45.90	242.1	299.39	0.7930	0.9006
76	921.1	906.4	0.06811	44.94	244.3	298.10	0.7970	0.8982
78	945.1	930.4	0.06411	43.90	246.4	296.57	0.8013	0.8957
80	969.5	954.8	0.06013	42.67	248.9	294.75	0.8060	0.8924
82	994.5	979.8	0.05603	41.23	251.5	292.46	0.8112	0.8881
84	1020	1005	0.05171	39.59	254.7	289.67	0.8170	0.8821
86	1046	1031	0.04711	37.03	259.0	285.64	0.8249	0.8737
87.9	1071	1056	0.03423	29.21	272.7	272.70	0.8483	0.8483

**Based on 0 for the perfect crystal at absolute zero of temperature, -459.67° (-273.15°C)

TO: Tom Brooks

Date: Aug. 1, 2000

FAX: (503) 624-9002

RE: Product Specs for Biojector 2000 and similar devices

Send to:

Gigi Corbin
U.S. Department of Transportation
RSPA/DHM-12/ Room 8422
400 Seventh Street, SW
Washington, DC 20590-0001

(202) 366-4465

Thanks.

GIGI-

THANKS FOR YOUR CALL; THIS IS THE
INFO TO DEN @ THE FAA.

175.10.4.i, LOOKS GOOD, I ALSO
THOUGHT 175.10.4.IV WAS INTERESTING ALSO.

I'LL BE WAITING FOR OUR NEXT
DISCUSSION, AS THIS IS CRITICAL TO OUR
BUSINESS.

THKS AGAIN -

Tom

TO: Tom Brooks

Date: Aug. 1, 2000

FAX: (503) 624-9002

RE: Product Specs for Biojector 2000 and similar devices

Send to:

Gigi Corbin
U.S. Department of Transportation
RSPA/DHM-12/ Room 8422
400 Seventh Street, SW
Washington, DC 20590-0001

(202) 366-4465

Thanks.

***** -COMM. JOURNAL- ***** DATE AUG-01-2000 ***** TIME 15:24 *** P.01

MODE = MEMORY TRANSMISSION

START=AUG-01 15:23

END=AUG-01 15:24

FILE NO.= 091

STN NO.	COM	ABBR NO.	STATION NAME/TEL.NO.	PAGES	DURATION
001	OK	*	915036249002	001/001	00:00'20"

-HMIC

-

***** -2023663012

- ***** -

- *****

TO: Tom Brooks

Date: Aug. 1, 2000

FAX: (503) 624-9002

RE: Product Specs for Biojector 2000 and similar devices

Send to:

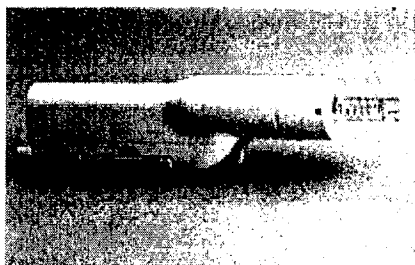
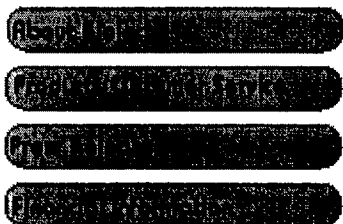
Gigi Corbin
U.S. Department of Transportation
RSPA/DHM-12/ Room 8422
400 Seventh Street, SW
Washington, DC 20590-0001

(202) 366-4465

Thanks.



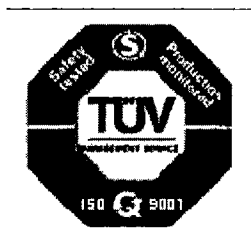
Welcome to the Future of Needle-free Technology



**Download the
1999 Annual
Report**

The 1999 Annual Report is in pdf format. If you are unable to read pdf files, then click on the Adobe Acrobat logo, and download Adobe Acrobat

Reader.



What's New

Bioject Closes \$10 Million in Equity Financing



Go !



Commitment to Performance

Through the commitment of each employee, the Bioject team will deliver quality products and responsive services which meet or exceed customer requirements and raise community awareness of safe, effective, needle-free injection technology.

Contaminated needlestick injuries take an enormous toll on today's healthcare industry threatening the well being of medical professionals and costing health care providers millions of dollars annually.

Now there is an effective needle-free drug delivery method for subcutaneous and intramuscular injections that prevents contaminated needlestick injuries and the subsequent spread of bloodborne pathogens. Because it is easy to use and patient preferred, it marks a new standard of care for administering injections.

The Biojector 2000 Needle-Free Injection Management System delivers medications parenterally without a needle. Instead, the Biojector uses compressed carbon dioxide (CO₂) as a safe power source to inject medication through a micro-orifice within a fraction of a second. This delivery action effectively penetrates the skin and delivers the medication into the patients's tissue.

The Biojector eliminates costly maintenance and the threat of cross-contamination with its unique, patented, disposable medication syringe. Once an injection is given, the needle-free syringe is discarded. Single-use Bioject syringes provide safe injections for patients and needle-free drug delivery for medical professionals, advancing the overall quality of healthcare.



Send Comments About The Web Site To:

Write:

Bioject Inc.
Customer Service
7620 SW Bridgeport Road
Portland OR 97224

Call: 800.683.7221

E-Mail:

customerservice@Bioject.Com

Biojector® is a registered trademark, and Bioject and Needle-Free Injection Management Systems are trademarks of Bioject Inc. Last updated: 28 July 2000



Biojector 2000 Description & Specifications

The System

The Biojector is a high speed delivery system designed to inject medication intramuscularly (IM) or subcutaneously (SC) without a needle. The Biojector employs compressed carbon dioxide (CO₂) as a power source to eject medication through a tiny orifice in a fraction of a second, effectively penetrating the skin.

Energy Source

The Biojector is energized by a standard CO₂ cartridge. Each CO₂ cartridge delivers an average of 10 injections with proper technique. Installing the CO₂ cartridge is a simple procedure, which is described in the Instruction Manual. The CO₂ does not interact with the medication.

Sterile, Single-Use Biojector Syringe

The Biojector is the first jet injector in history to delivery medications from a sterile single-use syringe. This plastic syringe is the only part of the system that comes in contact with the patient's skin. This unique feature virtually eliminates the risk of bloodborne pathogen cross-contamination to patients and healthcare providers.

Advances on Proven Technology

Pneumatically powered injectors have been used for many years. Millions of injections have been given, proving that this technology is efficacious. Jet injectors were most widely used to immunize large numbers of people quickly and economically. All of these early devices injected through a stationary nozzle, which required labor intensive rinsing, cleaning and sterilization for proper maintenance. Later, it was learned that the stationary nozzle, through which the medication was ejected, could pass bloodborne pathogens from one patient to another. This cross-contamination problem has been eliminated by the B2000.

Unique Design

Several important design elements distinguish the Biojector from other jet injection devices.

The Biojector removes the possibility of cross-contaminating patients through use of a disposable single-use syringe. After each injection, the old syringe is discarded and a new one is inserted for the next patient. Because of this design, sterilization and daily maintenance are not necessary.

Needle-Free Injections

The Biojector Syringe is packaged with a fill needle, which is only used to draw medication from a vial into the syringe. The needle is then discarded and the filled syringe is inserted into the device. A sterile, protective cap is provided to prevent touch contamination. This cap is placed over the filled syringe before the injection. After inserting the syringe into the injector, the protective cap is removed, the injector is placed firmly against the skin at a 90° angle, and the actuator is pressed and released to delivery the injection. Five different syringe sizes allow the clinician to achieve various penetration depths for an intramuscular or subcutaneous injection, depending on the patient's body size. The needle-free syringe eliminates "needlephobia" and reduces patient anxiety associated with injections. Many people seem to truly fear injections and may avoid seeking health care because of this phobia.

Patient Preferred

Delivery of medication through the skin creates some physical sensation in nearly every case. Varying degrees of pain have been experienced with injections administered by both needle/syringe and jet injection. Work with jet injectors shows that patient acceptance seems to be higher since the injection is delivered more rapidly. (1, , Patients have preferred the Biojector over needle/syringe for the following reasons: It decreases the fear of a traditional needle injection. It appears less intimidating than the traditional needle/syringe'. The injection occurs in a fraction of a second)

Local Site Reaction

Depending upon the characteristics of the injectate, most people report little to no pain with a Biojector injection. Some drug preparations contain components that cause stinging, burning, aching or other painful reactions and this does not change with the Biojector. Bioject recommends that the medication package insert be read carefully so each patient can be advised of a medication's side effects.

Product Specifications

- * Size: 8.5 inches (22 cm)
- * Weight: 20.5 ounces (580 grams)
- * Operation Temperature Range: < 60°-100°F (14°-38° C)
- * Power Source: CO2 Cartridge
- * Injections per CO2 Cartridge: 6 - 10
- * Pressure Indicator: Yes
- * Syringe/Actuator Interlock: Yes
- * Recommended Service and Calibration Interval (for the Biojector): 18 months
- * Warranty: One Year
- * Administration: Intramuscular and subcutaneous under the direction of a physician

To request product literature or to order products or training materials:



[Home Page](#)

Write:
Bioject Inc.
Customer Service
7620 SW Bridgeport Road
Portland, OR 97224

Call: 800/683-7221 Ext. 436

E-Mail:
customerservice@bioject.com

Biojector® is a registered trademark, and Bioject and Needle-Free Injection Management Systems are trademarks of Bioject Inc. Last updated: 5/4/99



Frequently Asked Questions about the Biojector

How does the Biojector work?

The Biojector uses compressed gas (carbon dioxide) and sterile, disposable medication syringes to deliver medication into the body's tissue without using a needle. The compressed gas simply provides the power to deliver your medication. It never comes in contact with the medication or your skin. The actual injection is over in a fraction of a second.

What does a Biojector injection feel like?

Some people say they don't feel any sensation with the Biojector. Others feel an aching or momentary "pricking" or stinging sensation. And, since there is no needle, most patients prefer receiving their "shots" with the Biojector. As with a needle injection, some medications will cause stinging, burning or aching when injected. These are normal sensations and should go away in a short time. The doctor or nurse can explain if you should expect any of these reactions from the medication you are receiving.

What kinds of injections can be administered with the Biojector 2000?

Intramuscular (IM) and subcutaneous (SC) injections can be administered with the Biojector 2000.

How does the device administer the different depths of penetration?

The size of the orifice, or hole, through which the medication is ejected varies by syringe size. The higher the number of syringe, the deeper the penetration of the injection.

Can I buy a Biojector 2000 for home use?

Yes, but you must have a prescription from your physician. Using the Biojector is fairly simple, however it is important to be trained by a medical professional on how to administer injections with the B2000.

Is the Biojector 2000 covered by my insurance?

You will need to contact your insurance company for information about medical device coverage. Some cover the entire cost, while others do not.

What other products are available from Bioject?

Besides the professional device, the B2000, Bioject also offers the disposable syringes and the compressed gas (CO2) cartridges.

Is Bioject ISO 9000 Certified?

Yes, Bioject received its ISO 9000 certification on January 28, 1999. Bioject is currently certified to ISO 9001 and EN 46001.

What is ISO 9000 and what does it mean to Bioject?

ISO certification is based on meeting a series of internationally accepted quality system standards developed by the International Organization for Standardization adopted in 1987 and revised in 1994. ISO, from the Greek term "isos" meaning "equal," has been extrapolated by the standards organization mean an equal standard for quality system management. ISO 9000 has become an international requirement and will help facilitate regulatory clearance requirements in Europe and other countries, thereby increasing sales. It is also a requirement of many US businesses that have come to recognize ISO 9000 certification as a benchmark for quality systems. It also provides a structure to increase both product and process quality and will help improve competitiveness, both in the United States and abroad.

Is the Biojector approved by the FDA?

Under FDA's regulations, the Biojector 2000 has been cleared for marketing in the USA. Which means that the Biojector can be sold in the USA.

How much does the Biojector, syringes, and CO2 cartridges cost?

Pricing is presented exclusively by our Regional Sales Managers. If you would like your Regional Sales Manager to contact you regarding pricing, please call 800/683-7221 Extension 436 or e-mail: customerservice@bioject.com

For additional information:



Write:

Bioject Inc.
Customer Service
7620 SW Bridgeport Road
Portland, OR 97224

Call: 800/683-7221 Ext. 416

E-Mail:

customerservice@bioject.com

Biojector® is a registered trademark, and Bioject and Needle-Free Injection Management Systems are trademarks of Bioject Inc. Last updated: 5/4/99

8/2/00

Hattie -

This came from the
manufacturer on the
Carbon dioxide cylinders
used to administer
medication.

Sorry I didn't catch you
before you left. Who
should look at this
and determine if this
comes under the
exception in 175.10(a)(4)(i)

Thanks - see you Tues.

Gigi

BIOJECT

FACSIMILE TRANSMISSION COVER SHEET

BIOJECT INC.
7620 S.W. BRIDGEPORT ROAD
PORTLAND, OREGON 97224
TELEPHONE: (503) 639-7221
FAX: (503) 624-9002

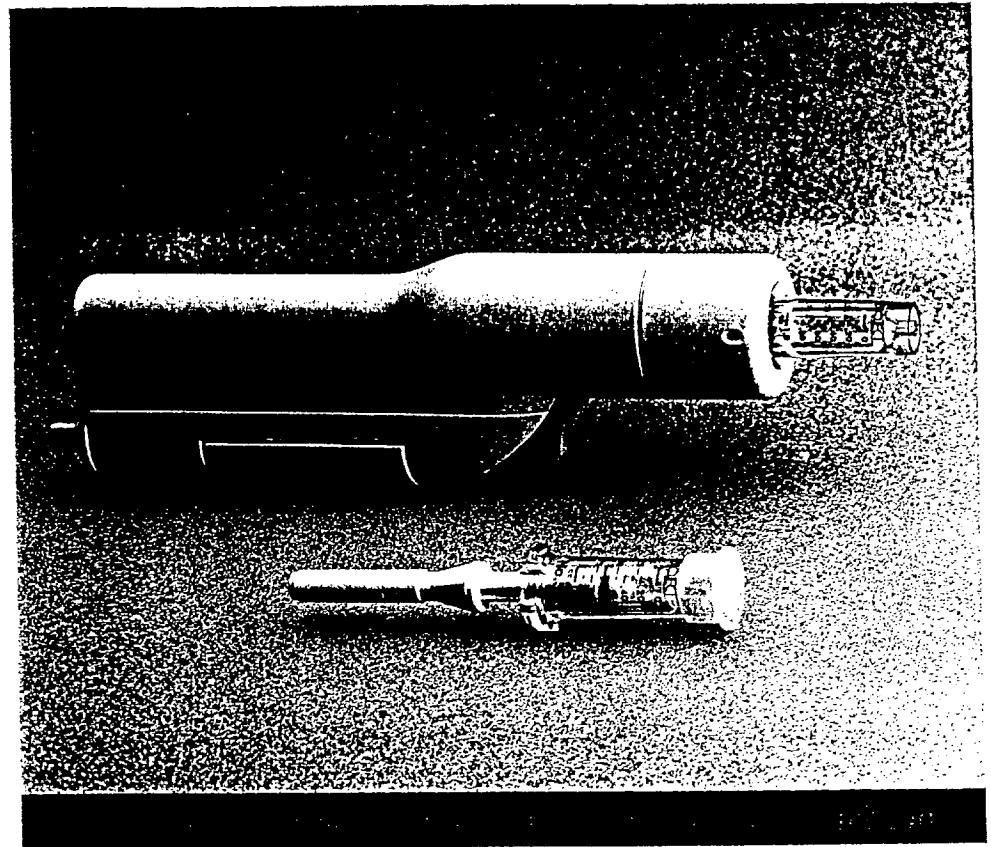
Transmitting Fax Number: (503) 624-9002

Troubleshooting Number: (503) 639-7221

Date: 7/2/00	Receiving Fax No: 326-2127
The following document consists of <u>12</u> page(s) including this cover sheet. (12) Please call the troubleshooting number above if pages are not received.	
PLEASE DELIVER THIS TRANSMISSION TO:	
Name: Don Stinger - #3	
Company: FAA	
Department: Haz-mat	
THIS DOCUMENT IS FROM:	
Name: Richard Storer MD	
Comments: Right	
Don,	
Here is the info we discussed.	
I also included our "CO2 SPEC'S". What	
Are the SPEC'S for your "Life Trainers"?	
Richard Storer	
THE ORIGINAL DOCUMENT BEING TRANSMITTED:	
<input checked="" type="checkbox"/> will not be sent to you	<input type="checkbox"/> will be sent by overnight mail
<input type="checkbox"/> will be sent by regular mail	<input type="checkbox"/> other: _____

CONFIDENTIALITY NOTICE: This facsimile [this page and any accompanying pages(s)] is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that the unauthorized dissemination, distribution, or copying of this communication, or the taking of any action in reliance on the contents of this information, is strictly prohibited. If you have received this facsimile in error, please notify us immediately by telephone (collect), and return the original message to us at the above address via the U.S. Postal Service. Thank you.

A NEW ERA OF PARENTERAL THERAPY IS AT HAND



- State-of-the-art injection technology
- Needle-free injections safer for healthcare workers and patients
- Portable and compact design
- Proven efficacy
- Unique, portable design
- Easy to learn, easy to use
- Safer, cost-effective disposal
- Maintenance-free
- Value added cost-in-use
- Eliminates fear associated with needle injections

BIOJECT

Safety. Innovation. Quality.

Contaminated needlestick injuries extract an enormous toll on today's healthcare industry threatening the well being of medical professionals and costing healthcare providers millions of dollars annually.

Now there is an effective needle-free drug delivery method for subcutaneous and intramuscular injections that prevents contaminated needlestick injuries and the subsequent spread of bloodborne pathogens. Because it is easy to use and patient preferred¹, it marks a new standard of care for administering injections.

The Biojector 2000 Needle-Free Injection Management System delivers medications parenterally without a needle. Instead, the Biojector uses compressed carbon dioxide (CO₂) as a safe power source to eject medication through a micro-orifice within a fraction of a second. This delivery action effectively penetrates the skin and delivers the medication into the patient's tissue.

The Biojector eliminates costly maintenance and the threat of cross-contamination with its unique, patented, disposable medication syringe. Once an injection is given, the needle-free syringe is discarded. Single-use Bioject syringes provide safe injections for patients and needle-free drug delivery for medical professionals, advancing the overall quality of healthcare.

The future of needle-free drug delivery is here.



PRODUCT INFORMATION

Syringe No. Order No.
Biojector 2000 Needle-Free Injector #1B02000

Biojector Syringes
(Box of 100, up to 1.0 cc variable-dose)

No. 2 Needle-Free Syringe #1S02100
No. 3 Needle-Free Syringe #1S03100
No. 4 Needle-Free Syringe #1S04100
No. 5 Needle-Free Syringe #1S05100
No. 7 Needle-Free Syringe #1S07100
CO₂ Power Cartridges (Box of 10) #1CO8010

CUSTOMER SERVICE AND ORDERING INFORMATION

Bioject is committed to providing the best possible service and support. Our customer service representatives are well qualified and readily available to answer any of your questions regarding the Biojector 2000.

Contact Bioject Customer Service at:
(800) 683-7221 ext. 436, or
(503) 639-7221 ext. 436

Or write:
Bioject Inc.
Customer Service
7620 SW Bridgeport Road
Portland, OR 97224

Inservice video tapes and educational materials are also available upon request from Bioject's Customer Service Department.



All sales are subject to Bioject's standard terms and conditions.
Prices are subject to change without notice.

1. Leads from the MMWR. Hepatitis B associated with jet gun injection—California. JAMA. 256(4): 446-447; July 1986.

Biojector is a registered trademark, and Bioject and Needle-Free Injection Management System(s) are trademarks of Bioject Medical Technologies Inc. and its subsidiary, Bioject Inc.

©Copyright 1994 Bioject Inc. All rights reserved. 171-0117-04, Rev. B, 3/96

PRODUCT SPECIFICATIONS

- **Message Capacity:**
100 messages
- **Audio/Visual System:**
100 messages, 1000 words
100 messages, 1000 words
100 messages, 1000 words
- **Operation Temperature Range:**
60°–140°F (15°–38°C)
- **Weight:**
25 oz. (640 grams)
- **Size:**
8 1/2 in. (22 cm) long
- **Pressure Indicator:**
Yes
- **Syringe-Secured Indicator:**
Yes
- **Syringe/Actuator Interlock:**
Yes
- **Recommended Service and Calibration Interval (Biojector):**
18 months
- **Warranty:**
One year

BIOJECT

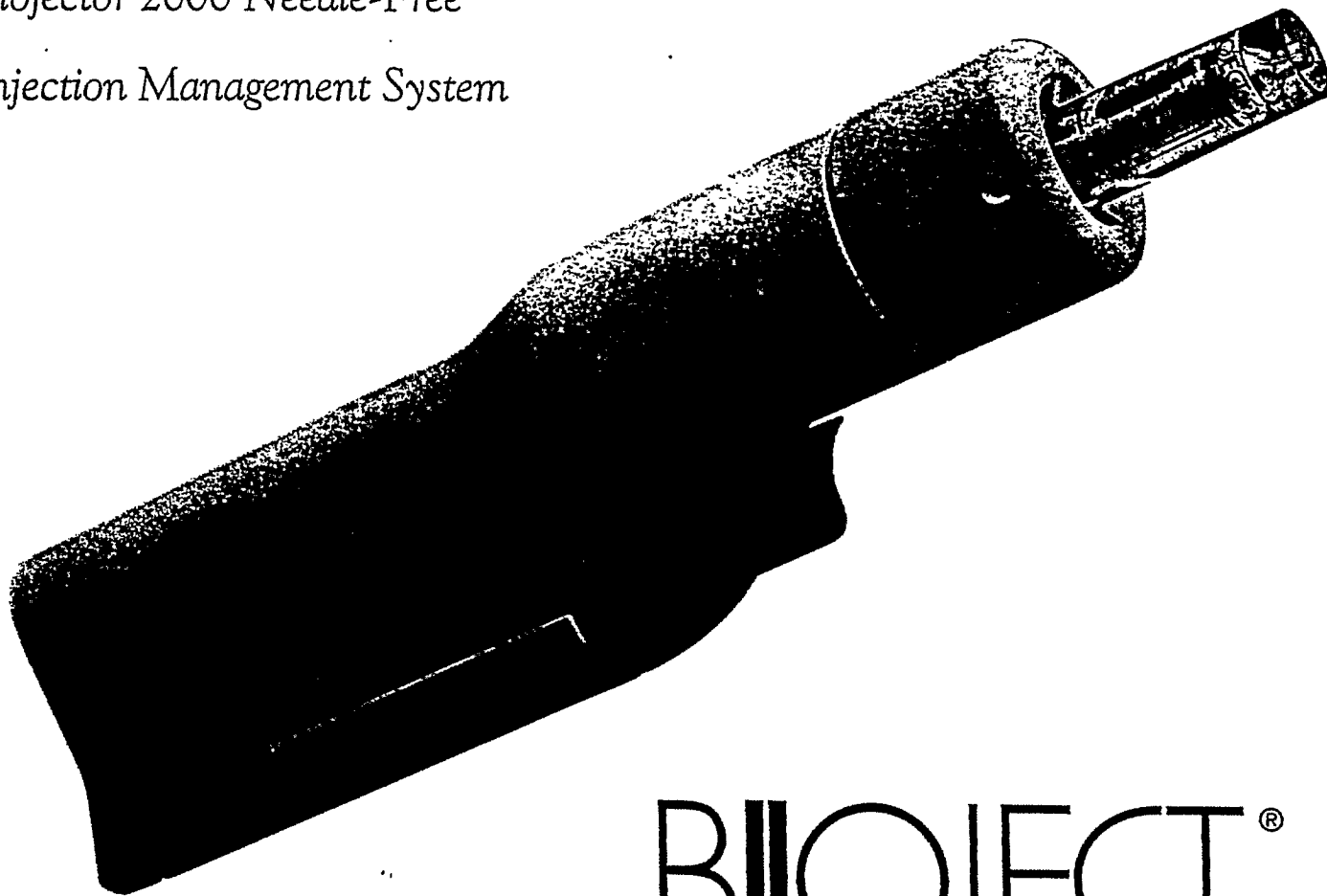
Safety. Innovation. Quality.

BIOJECTOR® 2000

Product information and benefits of the

Biojector 2000 Needle-Free

Injection Management System



BIOJECT®

*Needle-Free Injection
Management Systems*

1 CONTENTS

DESCRIPTION

<i>The System</i>	2
<i>Energy Source</i>	2
<i>Sterile, Single-Use Biojector Syringe</i>	2
<i>Advances on Proven Technology</i>	3
<i>Unique Design</i>	3
<i>Needle-Free Injections</i>	3
<i>Patient Preferred</i>	4
<i>Local Reactions</i>	4
<i>Customer Service</i>	4
<i>Product Specifications</i>	4

BENEFITS OF THE BIOJECTOR

<i>Healthcare Worker Benefits</i>	5
<i>No Contaminated Needle:</i>	
<i>Safer for the Healthcare Worker</i>	5
<i>Proven Efficacy</i>	5
<i>Easier Disposal</i>	5
<i>Maintenance Free</i>	5
<i>Cost Effective</i>	5
<i>Patient Benefits</i>	6
<i>No Needle: Safer for the Patient</i>	6
<i>No Needle: Patient Preferred</i>	6
<i>Faster and Easier Delivery</i>	6
<i>Less Tissue Trauma</i>	6

REFERENCES	6
-------------------------	---

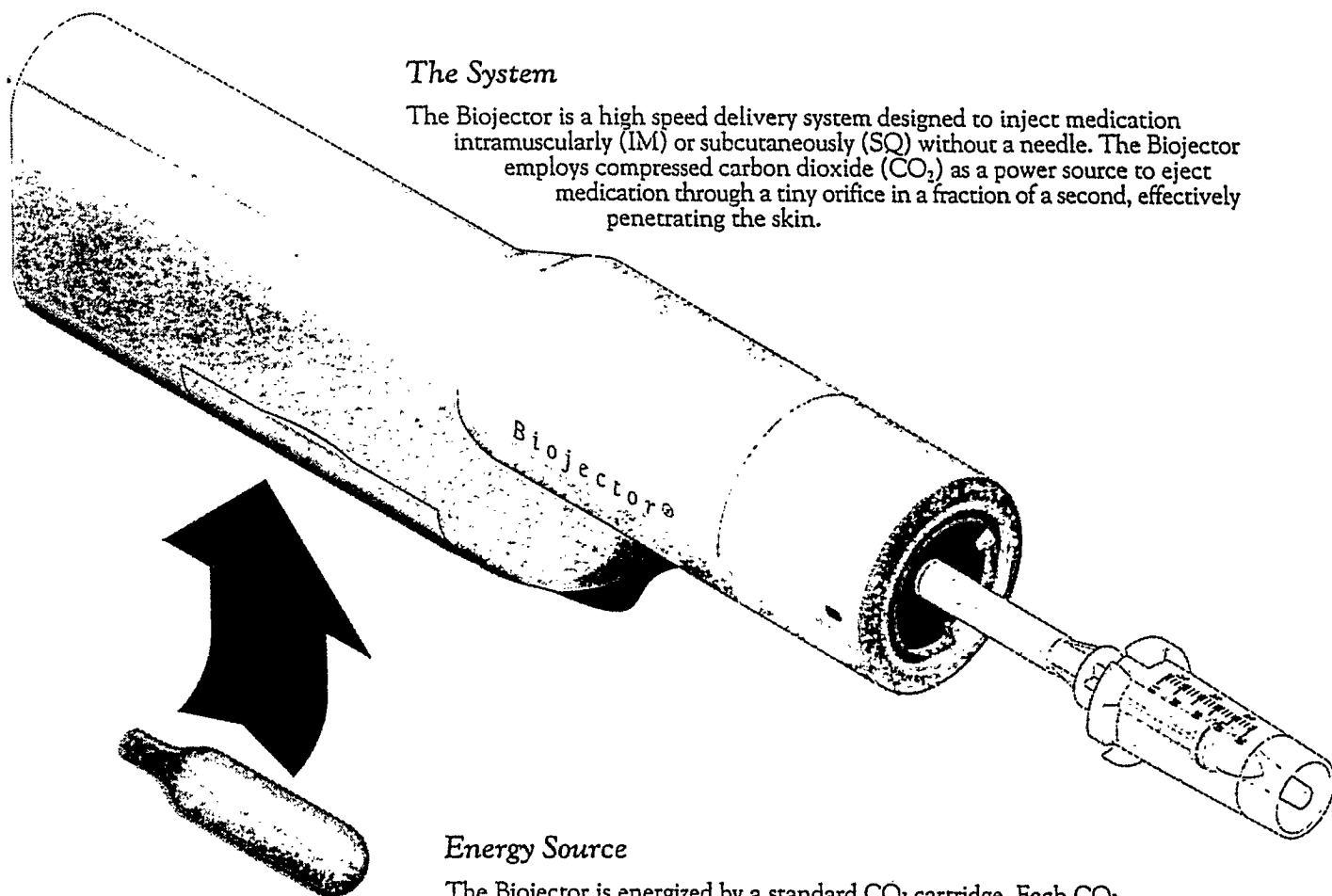
Biojector® is a registered trademark, and Bioject®
and Needle-Free Injection Management
Systems are trademarks of Bioject Inc.

DESCRIPTION

2

The System

The Biojector is a high speed delivery system designed to inject medication intramuscularly (IM) or subcutaneously (SQ) without a needle. The Biojector employs compressed carbon dioxide (CO₂) as a power source to eject medication through a tiny orifice in a fraction of a second, effectively penetrating the skin.

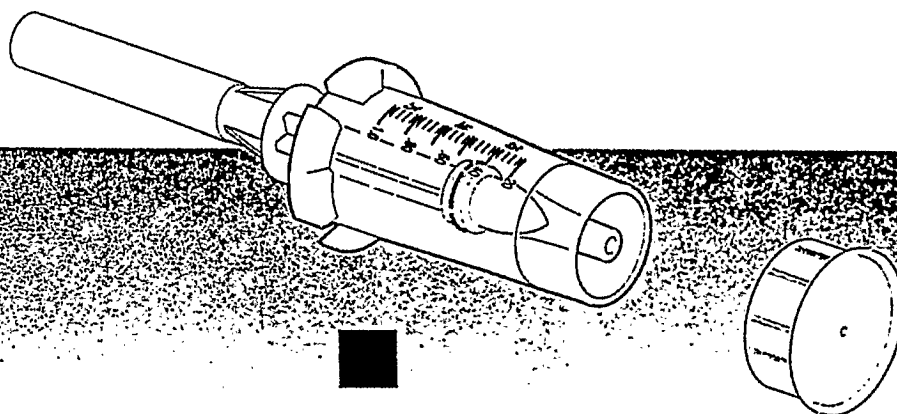


Energy Source

The Biojector is energized by a standard CO₂ cartridge. Each CO₂ cartridge delivers from 6-10 injections with proper technique. Installing the CO₂ cartridge is a simple procedure, which is described in the Instruction Manual. The CO₂ never interacts with the medication.

Sterile, Single-Use Biojector Syringe

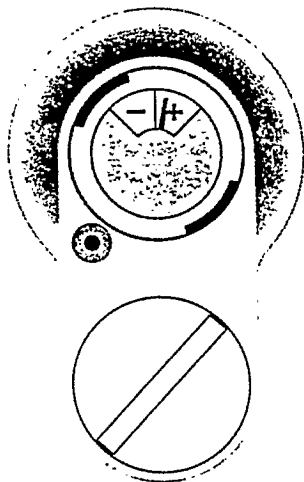
The Biojector is the first jet injector in history to deliver medications from a sterile single-use syringe. This plastic syringe is the only part of the system that comes in contact with the patient's skin. This unique feature virtually eliminates the risk of bloodborne pathogen cross-contamination to patients and healthcare providers.



3 DESCRIPTION

Advances on Proven Technology

Pneumatically powered injectors have been used for many years.¹ Millions of injections have been given, proving that this technology is efficacious. Jet injectors were most widely used to immunize large numbers of people quickly and economically. All of these early devices injected through a stationary nozzle, which required labor intensive rinsing, cleaning and sterilization for proper maintenance.² Later, it was learned that the stationary nozzle, through which the medication was ejected, could pass bloodborne pathogens from one patient to another. This cross-contamination problem has been eliminated by the B2000.



Unique Design

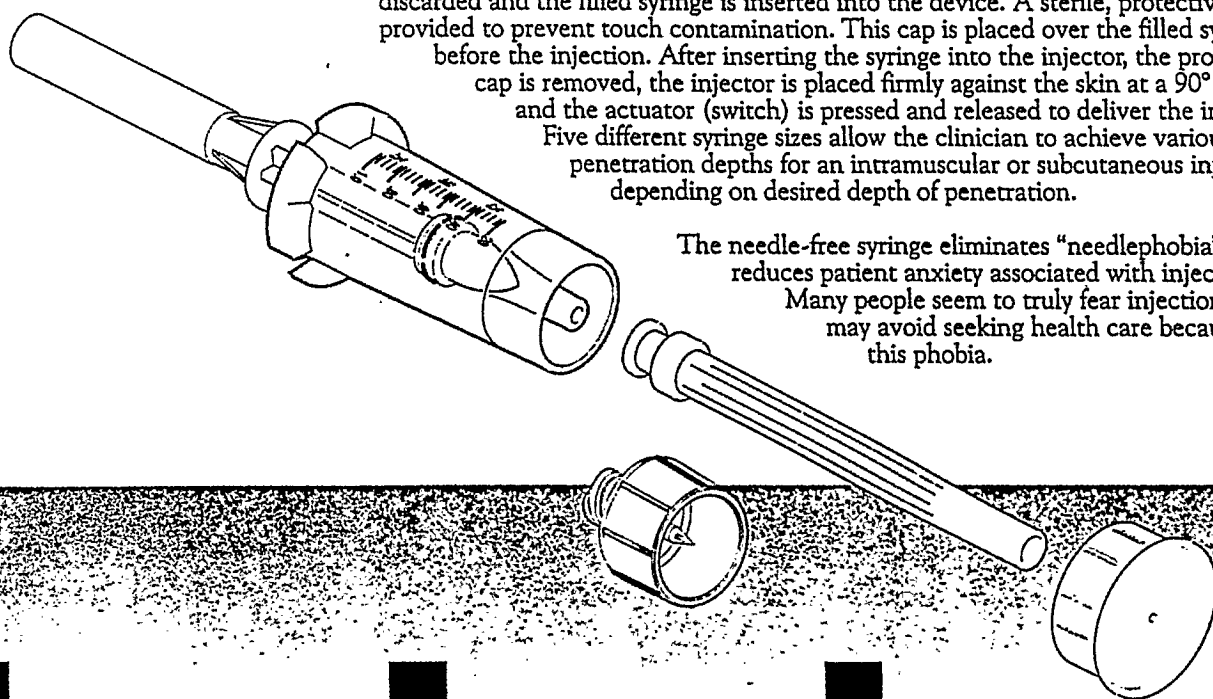
Several important design elements distinguish the Biojector from other jet injection devices.

The Biojector removes the possibility of cross-contaminating patients through use of a disposable single-use syringe. After each injection, the old syringe is discarded and a new one is inserted for the next patient. Because of this design, sterilization and daily maintenance are not necessary.

Needle-Free Injections

The Biojector Syringe is packaged with a fill needle or vial adapter which is only used to draw medication from a vial into the syringe. The needle or vial adapter is then discarded and the filled syringe is inserted into the device. A sterile, protective cap is provided to prevent touch contamination. This cap is placed over the filled syringe before the injection. After inserting the syringe into the injector, the protective cap is removed, the injector is placed firmly against the skin at a 90° angle, and the actuator (switch) is pressed and released to deliver the injection. Five different syringe sizes allow the clinician to achieve various penetration depths for an intramuscular or subcutaneous injection, depending on desired depth of penetration.

The needle-free syringe eliminates "needlephobia" and reduces patient anxiety associated with injections. Many people seem to truly fear injections and may avoid seeking health care because of this phobia.



Patient Preferred

Delivery of medication through the skin creates some physical sensation in nearly every case. Varying degrees of pain have been experienced with injections administered by both needle/syringe and jet injection. Work with jet injectors shows that patient acceptance seems to be higher since the injection is delivered more rapidly.^{1,3,4}

Patients have preferred the Biojector over needle/syringe for the following reasons:

- It decreases the fear of a traditional needle injection
- It appears less intimidating than the traditional needle/syringe injection
- The injection occurs in a fraction of a second

Local Reactions

Depending upon the characteristics of the injectate, most people report little to no pain with a Biojector injection. Some drug preparations contain components that cause stinging, burning, aching or other painful reactions and this does not change with the Biojector. Bioject recommends that the medication package insert be read carefully so each patient can be advised of a medication's side effects.

Customer Service

Bioject is committed to providing you with quality products and responsive service. Our clinical staff is well qualified and readily available to provide education and consultation on the use of the Biojector Needle-Free Injection Management System.

In-service video tapes and educational materials are also available upon request from Bioject Customer Service, 800-683-7221 or 503-639-7221, Ext. 1.

Product Specifications

Size:	8-1/2 inches (22cm)
Weight:	20.5 ounces (580 grams)
Operation Temperature Range:	60°-100°F (14°-38°C)
Power Source:	CO ₂ Cartridge
Injections per CO ₂ Cartridge:	6-10
Pressure Indicator:	Yes
Syringe/Actuator Interlock:	Yes
Recommended Service and Calibration Interval (for the Biojector):	18 months
Warranty:	12 months
Administration:	Intramuscular and subcutaneous injections under the direction of a physician

BENEFITS OF THE BIOJECTOR

Healthcare Worker Benefits

No Contaminated Needle: Safer for the Healthcare Worker

The Biojector uses a fill needle or vial adapter to draw up medication from a standard vial. Once the disposable syringe is filled, the fill needle or vial adapter is discarded prior to administering an injection. Only the blunt-end plastic syringe comes in contact with the patient's skin. The concern over transmitting bloodborne pathogens through a needlestick injury is eliminated, since there is no contaminated needle.

Proven Efficacy

Jet injection has been proven to be an efficacious method of delivering medications.¹ Clinical studies demonstrate that the Biojector delivers medication into intramuscular or subcutaneous tissue when used according to the Syringe Selection Guide.

Easier Disposal

Used Biojector syringes can be disposed of as standard medical waste (i.e. in a red bag); no "sharps" container or special handling is required.

Maintenance Free

The Biojector System is the only pneumatic device which employs a sterile, single-use syringe. Unlike other jet injectors, the Biojector does not require sterilization or cleaning after each use.

Cost Effective

The cost to investigate and treat needlestick injuries has soared. A portion of these costs includes those with employee time loss, replacement, or medical treatment should the healthcare worker develop a positive test for hepatitis B or HIV virus.

The Biojector eliminates the contaminated needle and removes the risk of bloodborne pathogen transmission through accidental needlesticks. The savings associated with this benefit are measurable not only in direct costs, but also in improved employee morale and productivity.

Patient Benefits

No Needle: Safer for the Patient

The liquid stream of medication takes the path of least resistance and flows around nerves and blood vessels rather than through them. The Biojector Needle-Free Injection Management System eliminates the risk of accidentally puncturing a nerve or injecting the medication directly into a blood vessel; thus it is inherently safer for the patient.

No Needle: Patient Preferred

Patients who become apprehensive or unduly fearful at the thought of receiving an injection are described as "needlephobic." These patients, and most everyone else, prefer to receive their injections without a needle.

Faster and Easier Delivery

The Biojector delivers a variable dose up to 1.0 cc in a fraction of a second.

Less Tissue Trauma

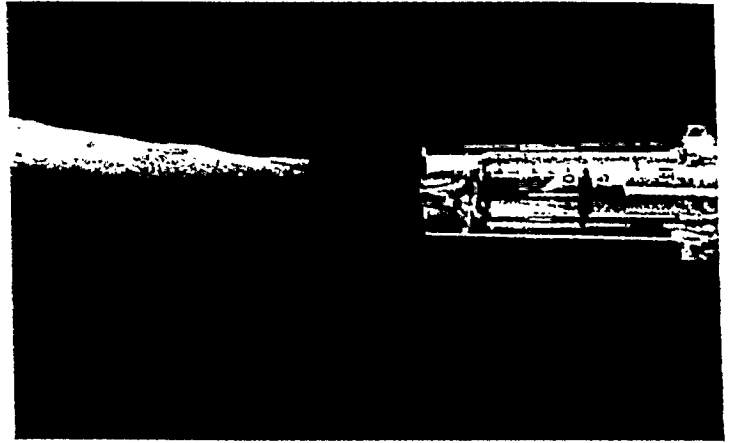
Published clinical studies report that there is less scarring, tissue trauma and atrophy when medication (such as insulin) is delivered via jet injection as opposed to a traditional needle/syringe.¹

REFERENCES

1. McKenzie R. Clinical applications of jet injection. *NZMJ*. 720:815-817; Nov. 1982.
2. Hingson R, et al. The historical development of jet injection and envisioned uses in mass immunization and mass therapy based upon two decades' experience. *Military Med*. 516-524; June 1963.
3. Neufeld P, Katz L. Comparative evaluation of three jet injectors for mass immunization. *Can J Pub Hlth*. 68:513-516; 1977.
4. Weller C, Linder M. Jet injection of insulin vs. the syringe and needle method. *JAMA*. 195:156-159; 1966.



Needle-Free Injection Management Systems



7620 SW Bridgeport Road

Portland, Oregon 97224

503/639-7221

800/683-7221

www.bioject.com

*Copyright© 1998 Bioject Inc.
All Rights Reserved
171-0119-01 Rev. B (9/98)*

 *** TX REPORT ***

TRANSMISSION OK

TX/RX NO 4105
 CONNECTION TEL 18567517289p40
 CONNECTION ID
 ST. TIME 07/21 11:29
 USAGE T 16'06
 PGS. SENT 24
 RESULT OK

BIOJECT

July 21, 2000

BIOJECT INC.
 7620 S.W. BRIDGEPORT ROAD
 PORTLAND, OREGON 97224
 TELEPHONE: (503) 639-7221
 FAX: (503) 624-9002
 WWW.BIOJECT.COM

RE: Bioject Product Information

Thanks for your inquiry regarding the Bioject Needle-Free Injection System. The Biojector® 2000 uses compressed carbon dioxide (CO₂) to deliver medication through a disposable, single-use syringe without the use of a needle. It is a safe, effective delivery method for subcutaneous and intramuscular injections.

The features which differentiate our Biojector® 2000 system from other needle-free injection devices are:

- Administers up to 1 ml. of injectate
- Delivers either subcutaneous or intramuscular injections, as indicated by the medication/ vaccine labeling
- Eliminates completely the risk of cross contamination between patients, and the risk of accidental needle- stick injuries for healthcare professionals
- Administers different types of medication with the same device, using single use, disposable syringes
- Reduces the volume and expense of hazardous medical waste (sharps) disposal
- Ease of training and use for medical technicians and health care professionals
- Extremely portable
- High level of patient acceptance
- Addresses the sharps-safe issues raised by recent OSHA legislation.

◆ Each Biojector 2000 Injector	\$675.00
◆ Each box of single use, sterile, disposable needle-free syringes (100 SC or IM syringes per box)	\$67.00
◆ Each box of CO ₂ power cartridges (10 CO ₂ cartridges per box)	\$5.00

For additional information regarding ordering and pricing, please contact either myself (Ext. 436), or our National Sales Manager, Mr. Kurt Lynam, at 503/639-7221 extension 501. If you would like to contact one of our nurses for additional clinical information please contact Tricia Diamond at extension 578.

Thanks again for your interest in Bioject's products and technology. Please contact us at the number below if you need any additional information.

BIOJECT INC.

FAXDate: 10-18-200Number of pages including cover sheet: 19

To:

GIGI CORPIN

Phone:

Fax phone: 202-366-3012

CC:

From:

Tom Brooks

Phone:

(503) 639-7221

Fax phone:

(503) 624-9002

REMARKS:

☐ Urgent☐ For your review☐ Reply ASAP☐ Please comment**BIOJECT**7620 S.W. BRIDGEPORT ROAD
PORTLAND, OREGON 97224

INDUSTRIAL PRODUCTS

PRODUCT INFORMATION

Product Range				
STANDARDS	EN, DIN, TÜV, DOT, MOD, BS, MIL, FAA, TSO, ASTM, EMPA, DAN			
FILLING	Carbon Dioxide (CO ₂), Nitrogen (N ₂)			
SURFACE TREATMENT	Electroplated Zinc, Super (high corrosion resistant) Zinc			
MARKING	Ink Jet, Engraving or Printing to specification			
Select from table below. Other sizes, gases and fillings on request.				
Nominal Weight(s) of CO ₂ grams	Water Capacity ml	Body Diameter mm	Overall Length mm	Neck details
8	10	18	66.5	3/8" x 24 UNF 1A
10.5 & 12	15	18.6	82.5	8.7 mm Dia PLAIN
10 & 11.5	14	18.6	82.5	3/8" x 24 UNF 1A
12	14	18.6	82.5	7.3 mm Dia PLAIN
16	21	22	88.5	8.7 mm Dia PLAIN
16	21	22	88.5	8.9 mm Dia PLAIN
16	21	22	88.5	3/8" x 24 UNF 1A/2A
20, 23 & 24	32	25.4	105	1/2" x 20 UNF 1A
28	40	20.7	160	8.7 mm Dia PLAIN
28	40	20.7	160	3/8" x 24 UNF 1A
28, 30 & 33	45	25.4	139	1/2" x 20 UNF 1A
35 & 38	52	30	118	1/2" x 20 UNF 1A
45	62	30	138	1/2" x 20 UNF 1A
55 & 60	85	31.8	163	1/2" x 20 UNF 1A
75	103	31.8	189	1/2" x 20 UNF 1A
84	115	41.3	145	1/2" x 20 UNF 1A
86	120	35	198	1/2" x 20 UNF 1A
120* & 135*	210	50	176	1/2" x 20 UNF 1A
120, 135 & 150	210	50	171	1/2" x 20 UNF 1A
215	300	50	226	1/2" x 20 UNF 1A
230*	350	50	275	1/2" x 20 UNF 1A
290*	450	60	225	1/2" x 20 UNF 1A
295	400	60	213	1/2" x 20 UNF 1A
315	440	50	311	1/2" x 20 UNF 1A
330*	500	50	375	1/2" x 20 UNF 1A
345	525	60	265	1/2" x 20 UNF 1A
450	600	60	311	1/2" x 20 UNF 1A
460*	700	60	368	1/2" x 20 UNF 1A

DOT Approved.

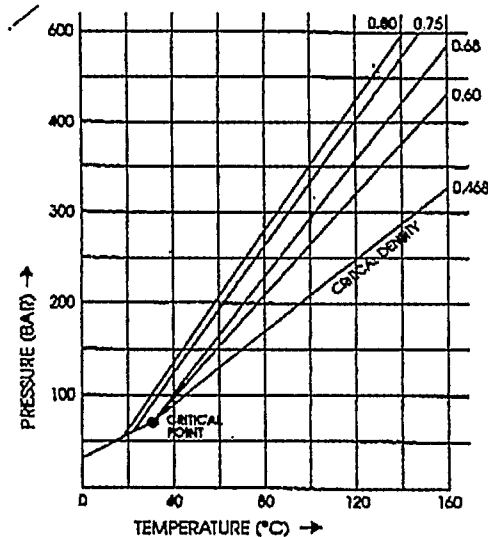
Product range may be updated. Please check with us.

* DOT Approved.

Product range may be updated. Please check with us.

Conversion Factors		
Multiply	By	To obtain
mm	0.0394	in
cm ²	0.155	in ²
cm ³ (1 ml)	0.061	in ³
Newton	0.225	lbf
lb	0.454	kg
kg/cm ²	14.22	lbf/in ²
bar	14.5	lbf/in ²
atmosphere	1.013	bar
N/mm ²	145	lbf/in ²
US gallon	3.785	litres
UK gallon	4.546	litres
US fluid ounce	29.57	ml

PRESSURE - TEMPERATURE
FOR VARIOUS FILLING DENSITIES OF CO₂
Filling density = $\frac{\text{Wt of CO}_2 \text{ (g)}}{\text{Water capacity (ml)}}$

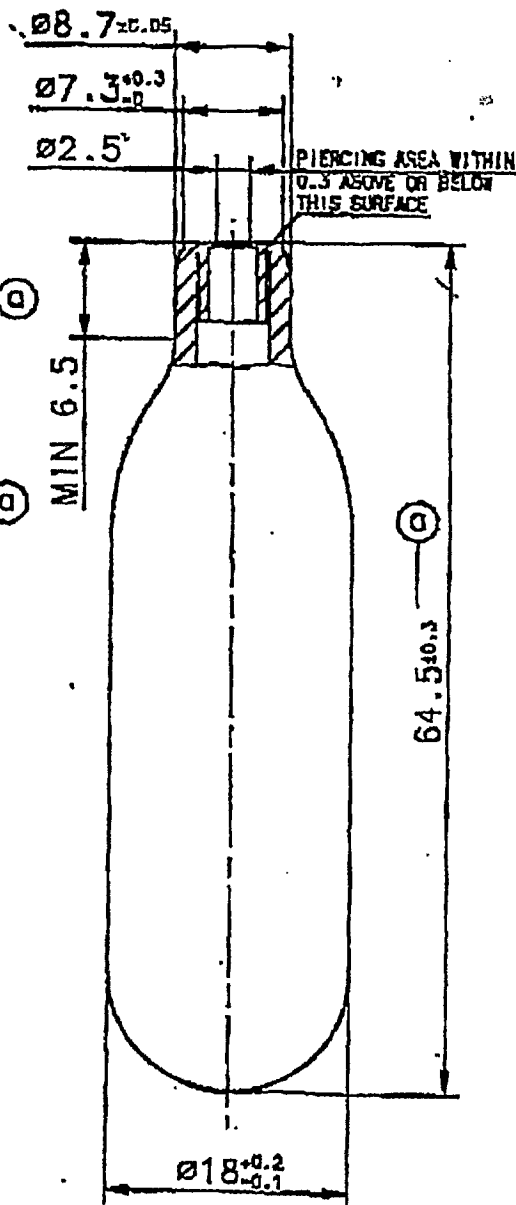


Physical Characteristics		
	Carbon Dioxide (CO ₂)	Nitrogen (N ₂)
Odour	Slightly pungent	None
Taste	Acidic/Biting	None
Fire hazard	Non-flammable	Non-flammable
Toxicity	Max. 0.5% v/v continuous	Non-toxic
Liquid density (20°C)	0.775 kg/l	-
Gas density (15°C and 100 KPa)	1.85 kg/m ³ (g/l)	1.17 kg/m ³ (g/l)

8 GRAM CO₂ (E)
8.7mm PLAIN NECK

ARTICLE No: YH1 J

NET WEIGHT	CO ₂	8±0.3G-
FULLGEWICHT	CO ₂	
POIDS DE REMPLISSAGE EN	CO ₂	
WATER CAPACITY		10.2 ml MIN
VOLUMEN		
CAPACITE EN EAU		
FILLING DENSITY		81% - MAX
FÜLLFAKTOR		
FACTEUR DE REMPLISSAGE		
TEST PRESSURE		250 BAR
PRÜFDRUCK		
PRESSION D'ESSAI		
BURST PRESSURE OF CYLINDER		>500 BAR
BERSTDRUCK DES ZYLINDERS		
PRESSION D'ECLATEMENTE DU CYLINDER		
CAP PIERCING FORCE		≤300 N
KAPPEN ANSTECKKRAFT		
FORCE DE PERCUSSION		
CO ₂ (E290) - ISI SPEC 0192 - 99.95% PURITY		
MARKING PROCESS: INK JET		
MARKING:		
BESCHRIFTUNG: MIN.GR.WT XX.XG		
INSCRIPTION: ISI/xxxxJ AUSTRIA M/Y		
PRINTING REPEATED THREE TIMES AROUND THE CYLINDER		
PACKING: LOOSE, IN CARTONS OF 430 PCS		
WT OF CARTON: 12.5 KG		
CARTON MARKING: CARBON DIOXIDE; 2.2; UN1013		



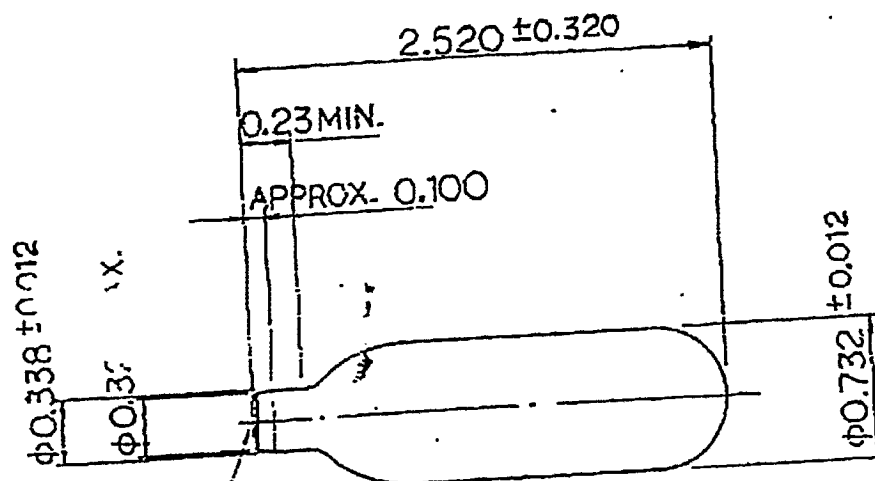
2	98-07-26	o	RS
1	88-05-26	title	RS
Iss.No.	Date	change	Name
	Date		Name
drawn	98-04-08		RS
dimensions in mm			

ISI © COPYRIGHT
ISI GmbH
A-1210 Wien,
Kärntnergasse 4

These products are the subject of patent
protection in AUSTRIA, GERMANY and principal
countries of the world. This drawing and all
information or descriptive matter set out
therein are confidential and copyright and
must not be disclosed, loaned, copied or used
for manufacturing, rendering or other purposes
without the prior and written consent of
the owner.

TITLE: 8G CO ₂ PLAIN NECK CYLINDER		
8G CO ₂ ZYLINDER OHNE HALSGEWINDE		
BOUTEILLE DE 8G CO ₂ SANS FILETAGE		
Mat: W-NR.1.0338 DIN 1624		
SPECIAL DEEP DRAWING STEEL		
DrqNo: YH1 J 2	Surface Finish DIN 50951 Fe/Zn5Cd	Scale 2:1 ..
Art.No: YH1 J		
this DrqNo incl. DrqNo YH1 J 1		

SYM.	REVISION	DA.
△		
△		
△		



SAFETY SEALING CAP
ELECTRICALLY WELDED

GAS RELEASE CRITERIA
SEALING CAP MUST REMAIN INTACT
AT GAS TEMPERATURES LESS THAN
158°F & MUST RUPTURE AT A GAS
PRESSURE OF 6827 lbf/in² MAX.



CO. WEIGHT 8.0 ± 0.4 g
MATERIAL JIS G3141 SPCE
FINISH JIS H8610 MFZnII-C
BURST PRESSURE MIN. 7250 lbf/in²

NAME P-1009-EW-Cn1R				DATE JUN-26-'86	
DRAWN	DESIGN	CHECKED	APPROVED	SCALE 1 : 1	
Y. Endo			M. Kaise	DRAWING NUMBER CP-1667-1	
NIPPON TANSAN GAS CO., LTD.					
TOKYO JAPAN					

All dimensions are in decimal inches.

2681-2

TOKYO JAPAN

GAS CYLINDER APPLICATIONS.

Portable pressurised gas is a remarkably versatile working fluid. ISI gas filled pressure vessels provide a pressurised gas delivery facility of exceptional integrity. ISI INDUSTRIAL, with their expertise in the design, manufacture and characteristics of these products, have assisted many customers to exploit this versatility in their products, some of which are listed here:

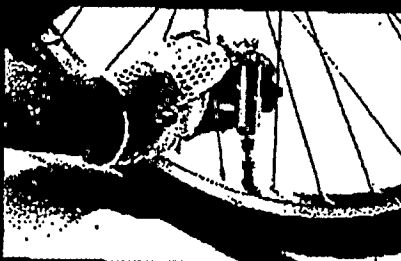
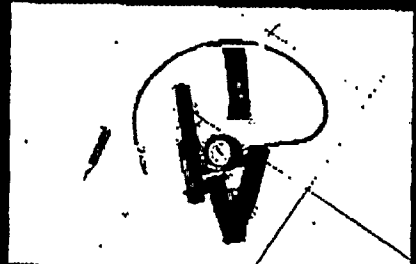
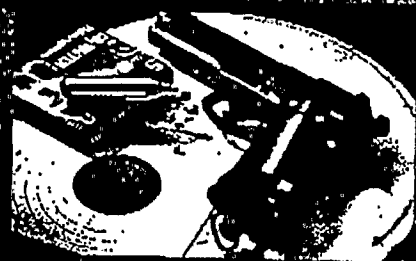
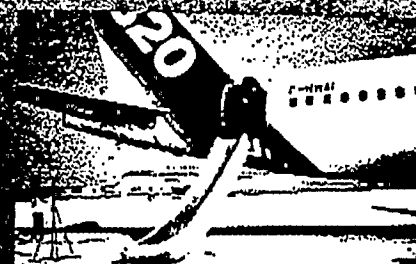
The safe, effective and economic use of the portable gas cylinder involves many considerations. Areas requiring particular attention are the piercing and sealing mechanisms, the desired rate of gas availability, the gas condition required by the appliance and the operating temperature range.

In addition, special provisions are necessary to ensure conformance with regulations and standards.

ISI INDUSTRIAL will readily help designers to select gas cylinders and will collaborate in the design and development of appliances and gas cylinders (including ISI refillable cylinders) to suit customer requirements.

- LIFE JACKETS, RAFTS AND DINGHIES
- FIRE EXTINGUISHERS
- INFLATABLE SEALS
- CO₂ SPORTING GUNS
- INFLATABLE SPORTING GOODS
- CAR SAFETY (AIRBAGS)
- MEDICAL EQUIPMENT
- SMOKE AND HEAT RELEASE SYSTEMS
- TYRE FILLING DEVICES
- RE-USABLE SPRAY CANS
- SONAR BOUYS
- pH CONTROL SYSTEMS
- EMERGENCY SHUT-DOWN SYSTEMS

ORMD?
MEM 30

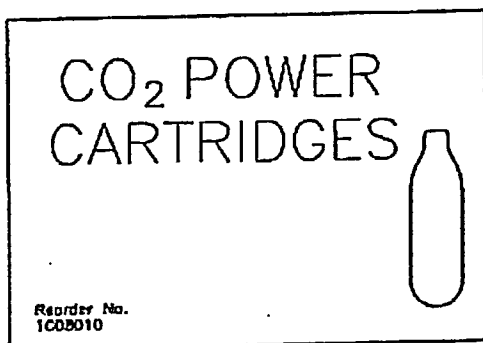
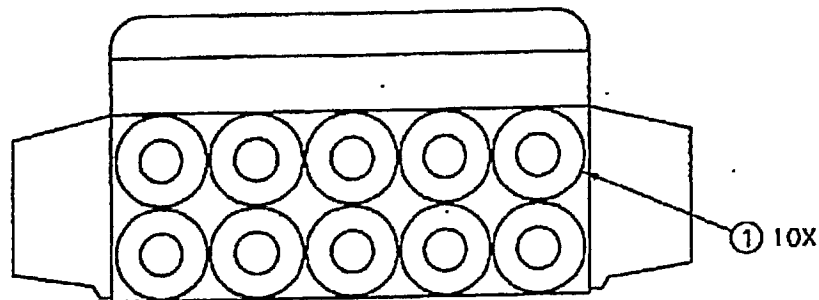


VOLUME: 10.33 mL

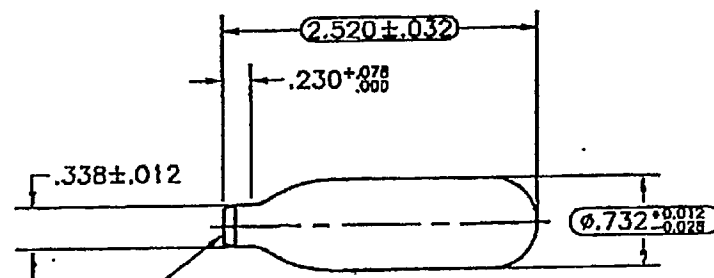
MASS: 10.29 grams

DO NOT COPY

CONFIDENTIAL



REVISIONS					
REV.	DESCRIPTION	PRINTED NAME	SIGNATURE	DATE	OCR #
A	INITIAL PRODUCTION RELEASE	J.BONICATTO		09/17/97	
B	ADDED ALTERNATE MATERIAL AND INCREASE OD TOLERANCE	J.BONICATTO		01/21/00	990073



SEALING CAP, ELECTRICALLY WELDED, Ø.323 MAX.

ITEM 1 DIMENSIONS

NOTES: (UNLESS OTHERWISE SPECIFIED)

- 1) DO NOT SCALE.
- 2) PACKAGE SHOWN WITHOUT DETAIL FOR CLARITY.
- 3) CO2 WEIGHT PER CARTRIDGE: 8.0 ± 0.6 gm.
- 4) CARTRIDGE MATERIAL/FINISH, STEEL:
 - a. SOURCE: NITTAN/ JIS G3141 SPEN/ JIS H 8610 MFZn1=C.
 - b. SOURCE: ISI N.A./ W-NR.1.0338 DIN 1624/ DIN 50961 Fe/Zn5Cd
- 5) BURST PRESSURE, MIN.: 6400 psi (450 kg/cm²).
- 6) INSPECTION FEATURES DENOTED BY:

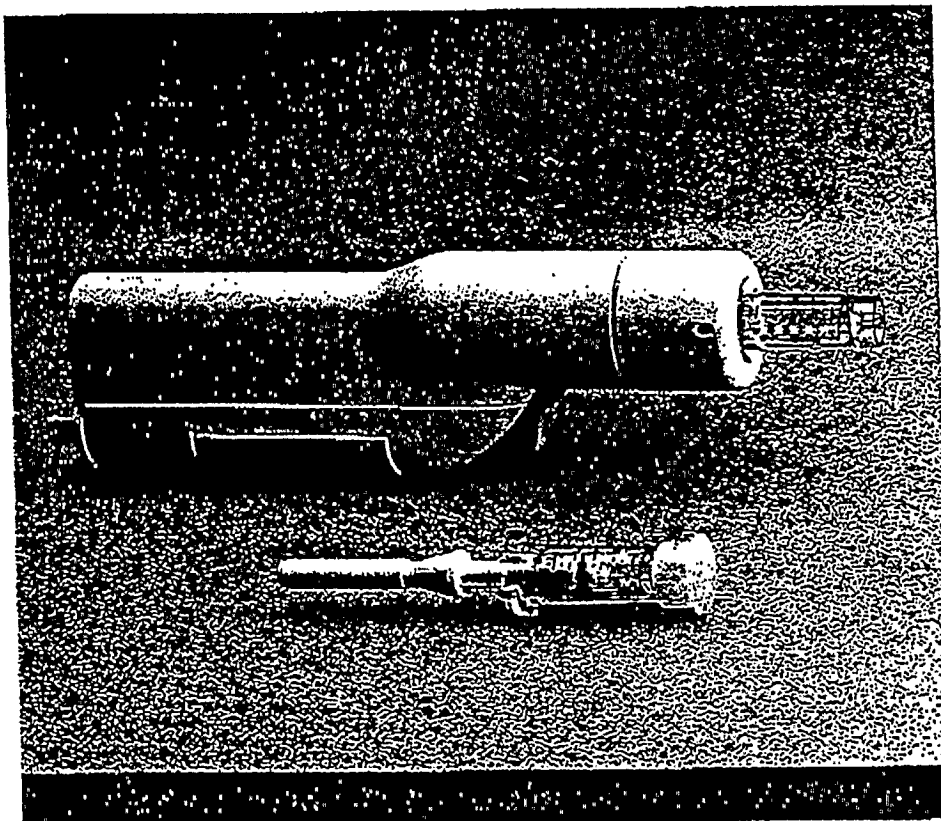
ITEM:	DESCRIPTION:	PART #:	QUANTITY/CASE:
1	CO2 CARTRIDGE	-	10
2	CARTON, PRINTED, 10PK CO2	183-D102-001	1

PROPRIETARY	UNLESS OTHERWISE SPECIFIED	DESIGNED BY: J.BONICATTO	DATE: 09/16/97	BIOJECT	BIOJECT INC. 7239 S.W. BRIDGEPORT RD. PORTLAND, OREGON 97224	
	TOLERANCES	REVIEWED BY: J.BONICATTO	DATE: 11/30/99			
INFORMATION CONTAINED IN THIS DOCUMENT IS THE EXCLUSIVE PROPERTY OF BIOJECT AND MAY NOT BE COPIED OR USED FOR ANY PURPOSE WITHOUT THE WRITTEN CONSENT OF BIOJECT.	MATERIAL: SEE NOTE 4	TITLE: CO2 GAS CARTRIDGES, 10/BOX		SCALE: NONE	SHEET: 1 of 1	ATTACHED FILE: 1C08010B.DWG
	FINISH: SEE NOTE 4	SHRINK: PART NO.: 1C08010				
DIMENSIONAL UNITS IN: INCH		THIRD ANGLE PROJECTION:		REV: 8		

QAF-140(B) REV. A 8/95

A NEW ERA OF PARENTERAL THERAPY IS AT HAND

- Safe, efficient, infection-free
- Needle-free injection, safe for healthcare workers and patients
- Fast, efficient drug delivery
- Proven efficacy
- Unique portable design
- Easy to learn, easy to use
- Safer, cost-effective disposal
- Maintenance-free
- Value added, cost-in-use
- Eliminates fear associated with needle injections



Contaminated needlestick injuries extract an enormous toll on today's healthcare industry threatening the well being of medical professionals and costing healthcare providers millions of dollars annually.

Now there is an effective needle-free drug delivery method for subcutaneous and intramuscular injections that prevents contaminated needlestick injuries and the subsequent spread of bloodborne pathogens. Because it is easy to use and patient preferred¹, it marks a new standard of care for administering injections.

The Biojector 2000 Needle-Free Injection Management System delivers medications parenterally without a needle. Instead, the Biojector uses compressed carbon dioxide (CO₂) as a safe power source to eject medication through a micro-orifice within a fraction of a second. This delivery action effectively penetrates the skin and delivers the medication into the patient's tissue.

The Biojector eliminates costly maintenance and the threat of cross-contamination with its unique, patented, disposable medication syringe. Once an injection is given, the needle-free syringe is discarded. Single-use Bioject syringes provide safe injections for patients and needle-free drug delivery for medical professionals, advancing the overall quality of healthcare.

The future of needle-free drug delivery is here.



BIOJECT

Safety. Innovation. Quality.

PRODUCT INFORMATION

Syringe No. Order No.
 Biojector 2000 Needle-Free Injector #1B02000

Biojector Syringes
 (Box of 100, up to 1.0 cc variable-dose)

No. 2 Needle-Free Syringe #1S02100
 No. 3 Needle-Free Syringe #1S03100
 No. 4 Needle-Free Syringe #1S04100
 No. 5 Needle-Free Syringe #1S05100
 No. 7 Needle-Free Syringe #1S07100
 CO₂ Power Cartridges (Box of 10) #1CO8010

CUSTOMER SERVICE AND ORDERING INFORMATION

Bioject is committed to providing the best possible service and support. Our customer service representatives are well qualified and readily available to answer any of your questions regarding the Biojector 2000.

Contact Bioject Customer Service at:
 (800) 683-7221 ext. 436, or
 (503) 639-7221 ext. 436

Or write:

Bioject Inc.
 Customer Service
 7620 SW Bridgeport Road
 Portland, OR 97224

Inservice video tapes and educational materials are also available upon request from Bioject's Customer Service Department.



All sales are subject to Bioject's standard terms and conditions.
 Prices are subject to change without notice.

1. Leads from the MMWR. Hepatitis B associated with jet gun injection—California. JAMA. 256(4): 446-447; July 1986.

Biojector is a registered trademark, and Bioject and Needle-Free Injection Management System(s) are trademarks of Bioject Medical Technologies Inc. and its subsidiary, Bioject Inc.

©Copyright 1994 Bioject Inc. All rights reserved. 171-0117-04, Rev. B, 3/96

PRODUCT SPECIFICATIONS

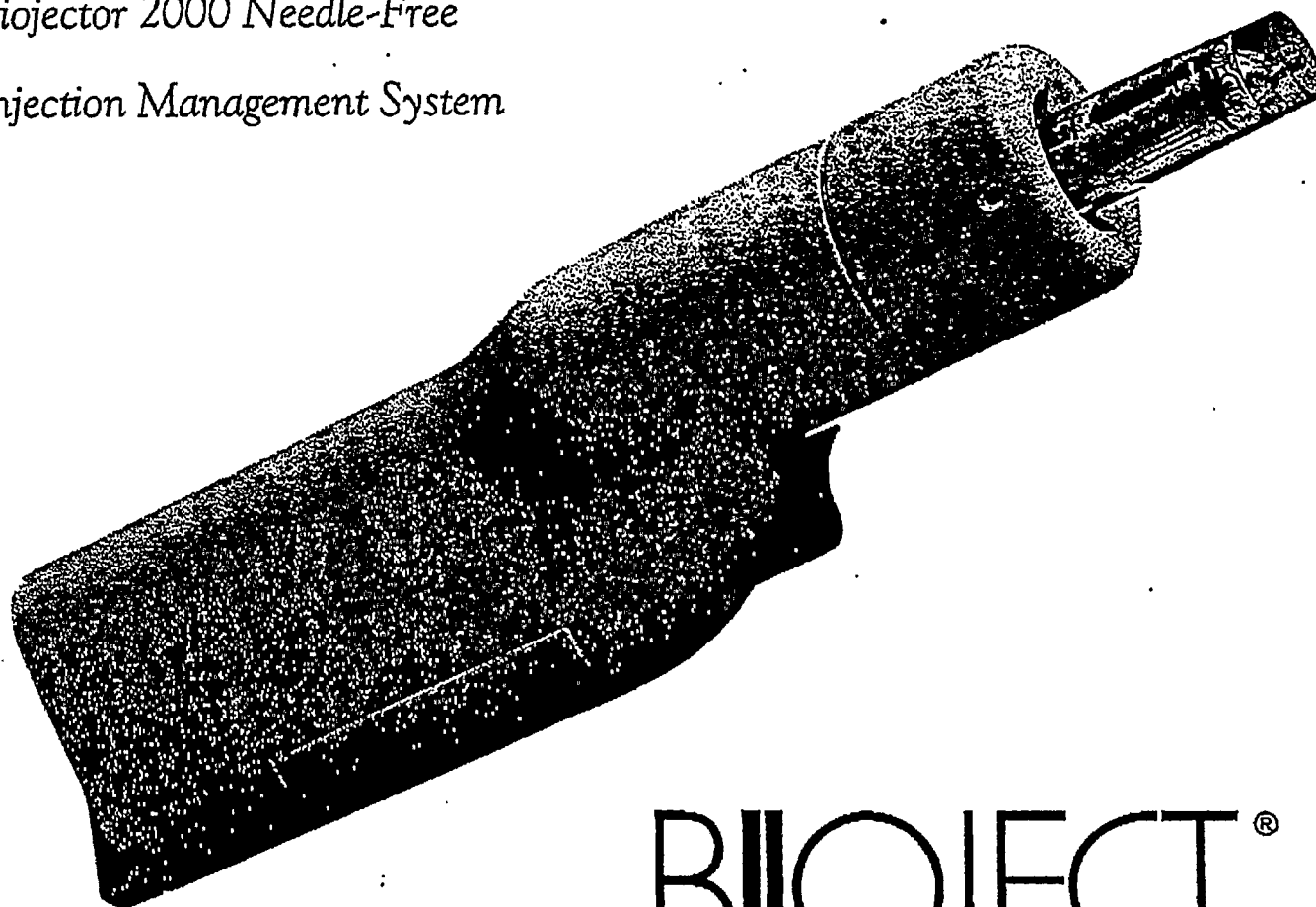
- **Booster:** 100% CO₂ cartridges (Box of 10)
- **Actuator:** 100% CO₂ cartridges (Box of 10)
- **Operation:** 100% CO₂ cartridges (Box of 10)
- **Operation Temperature Range:** 60°F to 104°F (15°C to 40°C)
- **Weight:** 2.5 oz. (64g)
- **Size:** 8 1/2 in. (22 cm) long
- **Pressure Indicator:** Yes
- **Syringe-Secured Indicator:** Yes
- **Syringe/Actuator Interlock:** Yes
- **Recommended Service and Calibration Interval (Biojector):** 18 months
- **Warranty:** One year

BIOJECT

Safety. Innovation. Quality.

BIOJECT® 2000

*Product information and benefits of the
Biojector 2000 Needle-Free
Injection Management System*



BIOJECT®

*Needle-Free Injection
Management Systems*

1 CONTENTS

DESCRIPTION

<i>The System</i>	2
<i>Energy Source</i>	2
<i>Sterile, Single-Use Biojector Syringe</i>	2
<i>Advances on Proven Technology</i>	3
<i>Unique Design</i>	3
<i>Needle-Free Injections</i>	3
<i>Patient Preferred</i>	4
<i>Local Reactions</i>	4
<i>Customer Service</i>	4
<i>Product Specifications</i>	4

BENEFITS OF THE BIOJECTOR

<i>Healthcare Worker Benefits</i>	5
<i>No Contaminated Needle:</i>	
<i>Safer for the Healthcare Worker</i>	5
<i>Proven Efficacy</i>	5
<i>Easier Disposal</i>	5
<i>Maintenance Free</i>	5
<i>Cost Effective</i>	5
<i>Patient Benefits</i>	6
<i>No Needle: Safer for the Patient</i>	6
<i>No Needle: Patient Preferred</i>	6
<i>Faster and Easier Delivery</i>	6
<i>Less Tissue Trauma</i>	6

REFERENCES	6
-------------------------	---

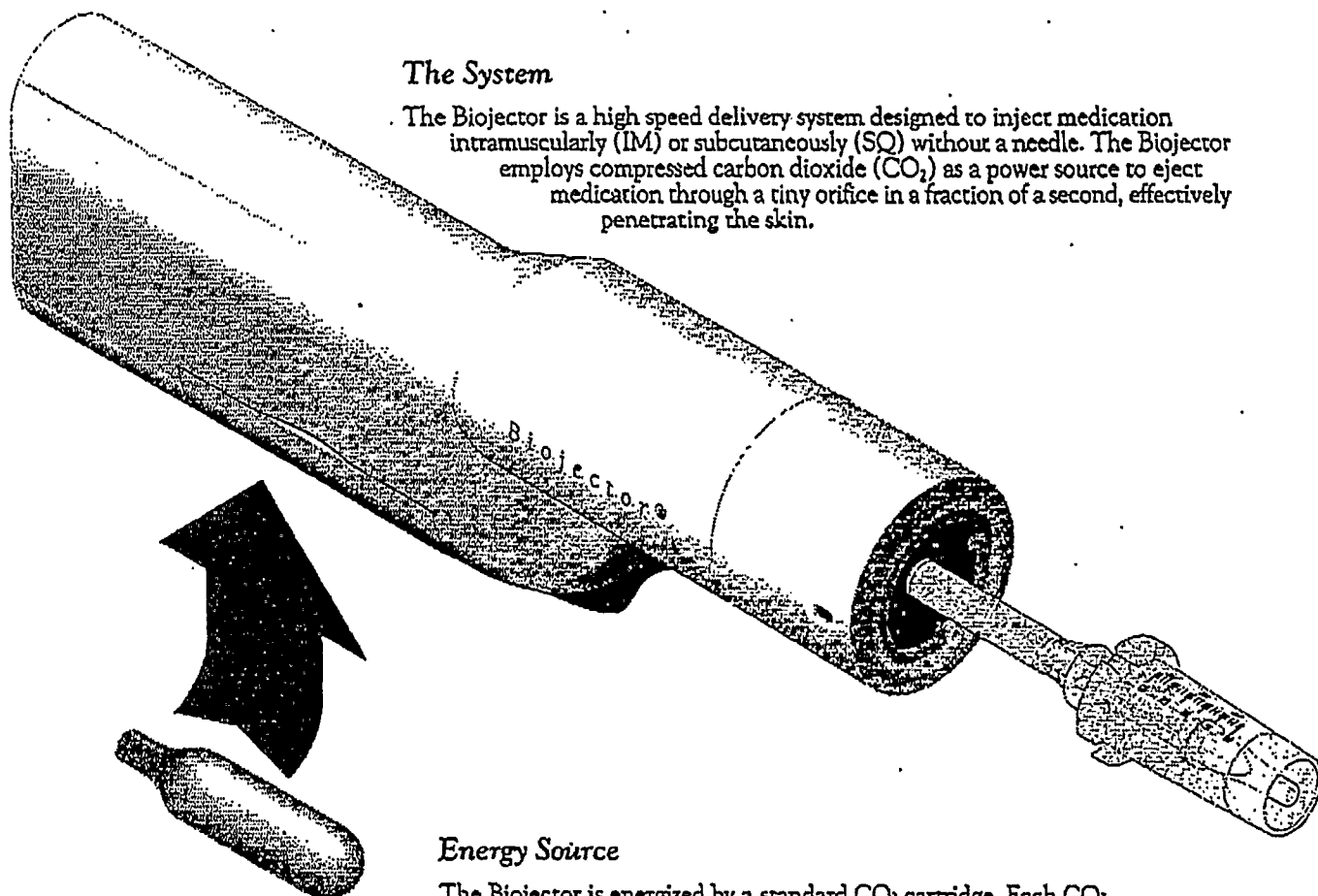
Biojector® is a registered trademark, and Bioject®
and Needle-Free Injection Management
Systems are trademarks of Bioject Inc.

DESCRIPTION

2

The System

The Biojector is a high speed delivery system designed to inject medication intramuscularly (IM) or subcutaneously (SQ) without a needle. The Biojector employs compressed carbon dioxide (CO₂) as a power source to eject medication through a tiny orifice in a fraction of a second, effectively penetrating the skin.

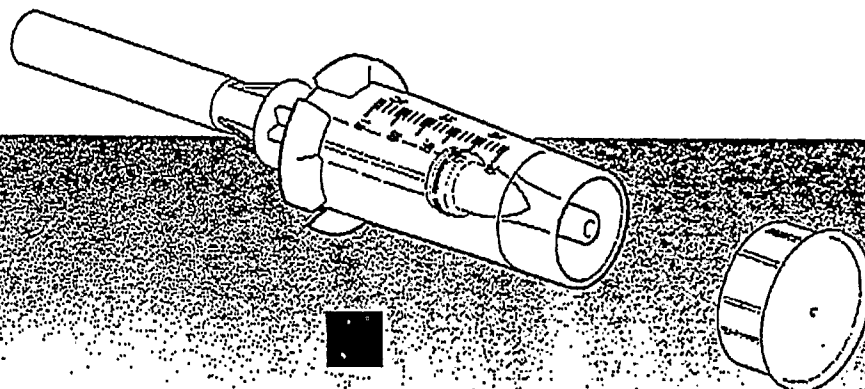


Energy Source

The Biojector is energized by a standard CO₂ cartridge. Each CO₂ cartridge delivers from 6-10 injections with proper technique. Installing the CO₂ cartridge is a simple procedure, which is described in the Instruction Manual. The CO₂ never interacts with the medication.

Sterile, Single-Use Biojector Syringe

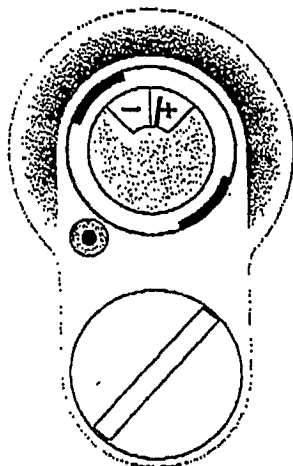
The Biojector is the first jet injector in history to deliver medications from a sterile single-use syringe. This plastic syringe is the only part of the system that comes in contact with the patient's skin. This unique feature virtually eliminates the risk of bloodborne pathogen cross-contamination to patients and healthcare providers.



3 DESCRIPTION

Advances on Proven Technology

Pneumatically powered injectors have been used for many years.¹ Millions of injections have been given, proving that this technology is efficacious. Jet injectors were most widely used to immunize large numbers of people quickly and economically. All of these early devices injected through a stationary nozzle, which required labor intensive rinsing, cleaning and sterilization for proper maintenance.² Later, it was learned that the stationary nozzle, through which the medication was ejected, could pass bloodborne pathogens from one patient to another. This cross-contamination problem has been eliminated by the B2000.



Unique Design

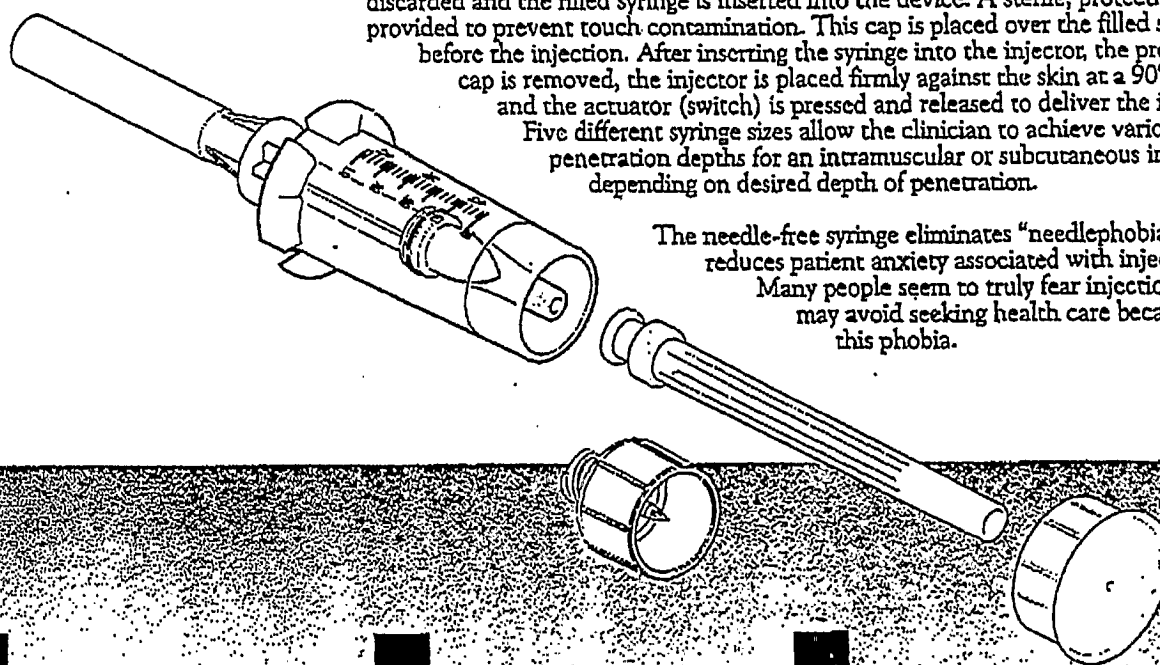
Several important design elements distinguish the Biojector from other jet injection devices.

The Biojector removes the possibility of cross-contaminating patients through use of a disposable single-use syringe. After each injection, the old syringe is discarded and a new one is inserted for the next patient. Because of this design, sterilization and daily maintenance are not necessary.

Needle-Free Injections

The Biojector Syringe is packaged with a fill needle or vial adapter which is only used to draw medication from a vial into the syringe. The needle or vial adapter is then discarded and the filled syringe is inserted into the device. A sterile, protective cap is provided to prevent touch contamination. This cap is placed over the filled syringe before the injection. After inserting the syringe into the injector, the protective cap is removed, the injector is placed firmly against the skin at a 90° angle, and the actuator (switch) is pressed and released to deliver the injection. Five different syringe sizes allow the clinician to achieve various penetration depths for an intramuscular or subcutaneous injection, depending on desired depth of penetration.

The needle-free syringe eliminates "needlephobia" and reduces patient anxiety associated with injections. Many people seem to truly fear injections and may avoid seeking health care because of this phobia.



DESCRIPTION

4

Patient Preferred

Delivery of medication through the skin creates some physical sensation in nearly every case. Varying degrees of pain have been experienced with injections administered by both needle/syringe and jet injection. Work with jet injectors shows that patient acceptance seems to be higher since the injection is delivered more rapidly.^{1,3,4}

Patients have preferred the Biojector over needle/syringe for the following reasons:

- It decreases the fear of a traditional needle injection
- It appears less intimidating than the traditional needle/syringe injection
- The injection occurs in a fraction of a second

Local Reactions

Depending upon the characteristics of the injectate, most people report little to no pain with a Biojector injection. Some drug preparations contain components that cause stinging, burning, aching or other painful reactions and this does not change with the Biojector. Bioject recommends that the medication package insert be read carefully so each patient can be advised of a medication's side effects.

Customer Service

Bioject is committed to providing you with quality products and responsive service. Our clinical staff is well qualified and readily available to provide education and consultation on the use of the Biojector Needle-Free Injection Management System.

In-service video tapes and educational materials are also available upon request from Bioject Customer Service, 800-683-7221 or 503-639-7221, Ext. 1.

Product Specifications

Size:	8-1/2 inches (22cm)
Weight:	20.5 ounces (580 grams)
Operation Temperature Range:	60°-100°F (14°-38°C)
Power Source:	CO ₂ Cartridge
Injections per CO ₂ Cartridge:	6-10
Pressure Indicator:	Yes
Syringe/Actuator Interlock:	Yes
Recommended Service and Calibration Interval (for the Biojector):	18 months
Warranty:	12 months
Administration:	Intramuscular and subcutaneous injections under the direction of a physician

5 BENEFITS OF THE BIOJECTOR

Healthcare Worker Benefits

No Contaminated Needle: Safer for the Healthcare Worker

The Biojector uses a fill needle or vial adapter to draw up medication from a standard vial. Once the disposable syringe is filled, the fill needle or vial adapter is discarded prior to administering an injection. Only the blunt-end plastic syringe comes in contact with the patient's skin. The concern over transmitting bloodborne pathogens through a needlestick injury is eliminated, since there is no contaminated needle.

Proven Efficacy

Jet injection has been proven to be an efficacious method of delivering medications.¹ Clinical studies demonstrate that the Biojector delivers medication into intramuscular or subcutaneous tissue when used according to the Syringe Selection Guide.

Easier Disposal

Used Biojector syringes can be disposed of as standard medical waste (i.e. in a red bag); no "sharps" container or special handling is required.

Maintenance Free

The Biojector System is the only pneumatic device which employs a sterile, single-use syringe. Unlike other jet injectors, the Biojector does not require sterilization or cleaning after each use.

Cost Effective

The cost to investigate and treat needlestick injuries has soared. A portion of these costs includes those with employee time loss, replacement, or medical treatment should the healthcare worker develop a positive test for hepatitis B or HIV virus.

The Biojector eliminates the contaminated needle and removes the risk of bloodborne pathogen transmission through accidental needlesticks. The savings associated with this benefit are measurable not only in direct costs, but also in improved employee morale and productivity.

BENEFITS OF THE BIOJECTOR

6

Patient Benefits

No Needle: Safer for the Patient

The liquid stream of medication takes the path of least resistance and flows around nerves and blood vessels rather than through them. The Biojector Needle-Free Injection Management System eliminates the risk of accidentally puncturing a nerve or injecting the medication directly into a blood vessel; thus it is inherently safer for the patient.

No Needle: Patient Preferred

Patients who become apprehensive or unduly fearful at the thought of receiving an injection are described as "needlephobic." These patients, and most everyone else, prefer to receive their injections without a needle.

Faster and Easier Delivery

The Biojector delivers a variable dose up to 1.0 cc in a fraction of a second.

Less Tissue Trauma

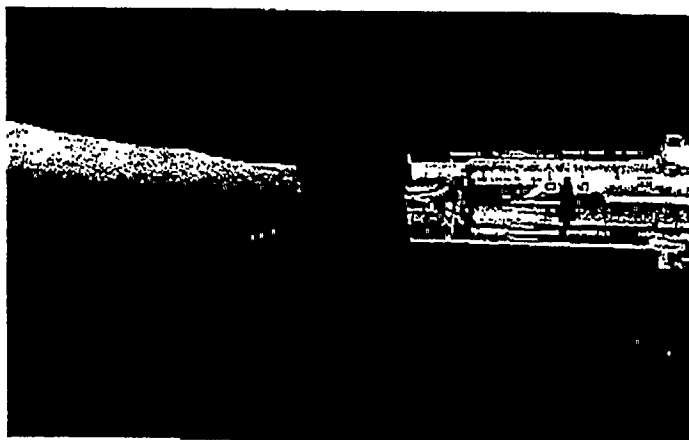
Published clinical studies report that there is less scarring, tissue trauma and atrophy when medication (such as insulin) is delivered via jet injection as opposed to a traditional needle/syringe.¹

REFERENCES

1. McKenzie R. Clinical applications of jet injection. *NZMJ*. 720:815-817; Nov. 1982.
2. Hingson R, et al. The historical development of jet injection and envisioned uses in mass immunization and mass therapy based upon two decades' experience. *Military Med*. 516-524; June 1963.
3. Neufeld P, Katz L. Comparative evaluation of three jet injectors for mass immunization. *Can J Pub Hlth*. 68:513-516; 1977.
4. Weller C, Linder M. Jet injection of insulin vs. the syringe and needle method. *JAMA*. 195:156-159; 1966.



Needle-Free Injection Management Systems



7620 SW Bridgeport Road

Portland, Oregon 97224

503/639-7221

800/683-7221

www.bioject.com

Copyright© 1998 Bioject Inc.
All Rights Reserved
171-0119-01 Rev. B (9/98)

*** TX REPORT ***

TRANSMISSION OK

TX/RX NO	4105
CONNECTION TEL	18587517289p40
CONNECTION ID	
ST. TIME	07/21 11:29
USAGE T	16'06
PGS. SENT	24
RESULT	OK

BIOJECT

July 21, 2000

BIOJECT INC.
7600 S.W. BRIDGEPORT ROAD
PORTLAND, OREGON 97224
TELEPHONE: (503) 639-7221
FAX: (503) 624-9002
WWW.BIOJECT.COM

RE: Bioject Product Information

Thanks for your inquiry regarding the Bioject Needle-Free Injection System. The Biojector® 2000 uses compressed carbon dioxide (CO₂) to deliver medication through a disposable, single-use syringe without the use of a needle. It is a safe, effective delivery method for subcutaneous and intramuscular injections.

The features which differentiate our Biojector® 2000 system from other needle-free injection devices are:

- Administers up to 1 ml. of injectate
- Delivers either subcutaneous or intramuscular injections, as indicated by the medication/ vaccine labeling
- Eliminates completely the risk of cross contamination between patients, and the risk of accidental needle- stick injuries for healthcare professionals
- Administers different types of medication with the same device, using single use, disposable syringes
- Reduces the volume and expense of hazardous medical waste (sharps) disposal
- Ease of training and use for medical technicians and health care professionals
- Extremely portable
- High level of patient acceptance
- Addresses the sharps-safe issues raised by recent OSHA legislation.

- | | |
|---|----------|
| • Each Biojector 2000 Injector | \$675.00 |
| • Each box of single use, sterile, disposable needle-free syringes
(100 SC or IM syringes per box) | \$67.00 |
| • Each box of CO ₂ power cartridges
(10 CO ₂ cartridges per box) | \$5.00 |

For additional information regarding ordering and pricing, please contact either myself (Ext. 436), or our National Sales Manager, Mr. Kurt Lynam, at 503/639-7221 extension 501. If you would like to contact one of our nurses for additional clinical information please contact Tricia Diamond at extension 578.

Thanks again for your interest in Bioject's products and technology. Please contact us at the number below if you need any additional information.

91-20-1995 12:23

619-272-8545

NITTAN U. S. A.

P. 82

Material Safety Data Sheet

to be used to comply with
OSHA's Hazard Communication Standard,
29 CFR 1910.1200. Standard must be
consulted for specific requirements.

U.S. Department of Labor

Occupational Safety and Health Administration

(Non-Mandatory Form)

Form Approved

OMB No. 1218-0072



IDENTITY (As Used on Label and List)

PART #168-0100-00 CO2 CARTRIDGE

Note: Blank spaces are not permitted. If any item is not applicable, or no information is available, the space must be marked to indicate that.

Section I

Manufacturer's Name

NIPPON TANSAN GAS CO., LTD.

Emergency Telephone Number

1-800-535-5052

Address (Number, Street, City, State, and ZIP Code)

32-26, 3-Chome, Aoi, Adachi-Ku, Tokyo, Japan

Telephone Number for Information

Tokyo 03 (849) 1571

Date Prepared

Signature of Preparer (optional)

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
---	----------	-----------	--------------------------	--------------

DNA

Section III — Physical/Chemical Characteristics

Bolling Point (at 1atm °C)	-78.48	Specific Gravity (H ₂ O = 1) (at 0°C 1atm kg/m ³)	1.977
Vapor Pressure (mm Hg) (at 0°C kgf/cm ² abs)	35.54	Melting Point	
Vapor Density (AIR = 1)	1.52	Evaporation Rate (Butyl Acetate = 1)	
Solubility in Water (at 0°C 1atm m ³ /water m ³)	1.713		
Appearance and Odor	Colorless Gas, None		

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Nonflammable Gas	Flammable Limits	LEL	UEL
Extinguishing Media				

Fire Fighting Procedures

Unusual Fire and Explosion Hazards

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid	Keep out of heat
	Stable			At normal temperature

Incompatibility (Materials to Avoid)

DNA

Hazardous Decomposition or Byproducts

DNA

Hazardous Polymerization

May Occur

Conditions to Avoid

DNA

Will Not Occur

DNA

Section VI — Health Hazard Data

Route(s) of Entry:

Inhalation?

Skin?

Ingestion?

Health Hazards (Acute and Chronic)

Carcinogenicity:

NTP?

IARC Monographs?

OSHA Regulated?

Signs and Symptoms of Exposure

Medical Conditions

Generally Aggravated by Exposure

Emergency and First Aid Procedures

Breathe Oxygen and Air to ventilate lungs

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material is Released or Spilled

Keep room well - ventilated

Waste Disposal Method

Keep room well - ventilated

Precautions to Be Taken in Handling and Storing

Keep out of heat

Other Precautions

Keep out of fire and any shock

Section VIII — Control Measures

Respiratory Protection (Specify Type)

DNA

Ventilation

Local Exhaust

Special

Mechanical (General)

Other

Protective Gloves

DNA

Eye Protection

DNA

Other Protective Clothing or Equipment

DNA

Work/Hygienic Practices

DNA

B|JECT

FACSIMILE TRANSMISSION COVER SHEET

B|JECT INC.
7623 S.W. 31002PCRT 10A0
PORTLAND, OREGON 97224
TELEPHONE: (503) 639-7221
FAX: (503) 624-9002

Transmitting Fax Number: (503) 624-9002



Troubleshooting Number: (503) 639-7221

Date: 7/25/00	Receiving Fax No: 326-2127
The following document consists of <u>4</u> page(s) including this cover sheet. Please call the troubleshooting number above if pages are not received.	
PLEASE DELIVER THIS TRANSMISSION TO:	
Name: <u>Don Stiger</u>	
Company: <u>FAA</u>	
Department:	
THIS DOCUMENT IS FROM:	
Name: <u>Tom Brooks</u>	
Comments: <u>ADDITIONAL SPECS ON OUR 8gm.</u> <u>CYLINDERS - TALK WITH YOU</u> <u>LATER</u>	
<u>Tom Brooks</u> <u>x437</u>	
THE ORIGINAL DOCUMENT BEING TRANSMITTED:	
<input type="checkbox"/> will not be sent to you	<input type="checkbox"/> will be sent by overnight mail
<input type="checkbox"/> will be sent by regular mail	<input type="checkbox"/> other: _____

CONFIDENTIALITY NOTICE: This facsimile [this page and any accompanying pages(s)] is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that the unauthorized dissemination, distribution, or copying of this communication, or the taking of any action in reliance on the contents of this information, is strictly prohibited. If you have received this facsimile in error, please notify us immediately by telephone (collect), and return the original message to us at the above address via the U.S. Postal Service. Thank you.

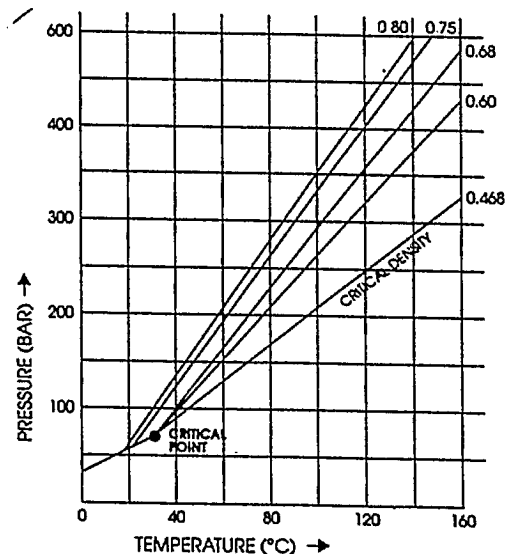
INDUSTRIAL PRODUCTS

PRODUCT INFORMATION

Product Range 				
STANDARDS EN, DIN, TÜV, DOT, MOD, BS, MIL, FAA, TSO, ASTM, EMPA, DAN				
FILLING Carbon Dioxide (CO ₂), Nitrogen (N ₂)				
SURFACE TREATMENT Electroplated Zinc, Super (high corrosion resistant) Zinc				
MARKING Ink Jet, Engraving or Printing to specification				
Select from table below. Other sizes, gases and fillings on request.				
Nominal Weight(s) of CO ₂ grams	Water Capacity ml	Body Diameter mm	Overall Length mm	Neck details
 8	10	18	66.5	3/8" x 24 UNF 1A
10.5 & 12	15	18.6	82.5	8.7 mm Dia PLAIN
10 & 11.5	14	18.6	82.5	3/8" x 24 UNF 1A
12	14	18.6	82.5	7.3 mm Dia PLAIN
16	21	22	88.5	8.7 mm Dia PLAIN
16	21	22	88.5	8.9 mm Dia PLAIN
16	21	22	88.5	3/8" x 24 UNF 1A/2A
20, 23 & 24	32	25.4	105	1/2" x 20 UNF 1A
28	40	20.7	160	8.7 mm Dia PLAIN
28	40	20.7	160	3/8" x 24 UNF 1A
28, 30 & 33	45	25.4	139	1/2" x 20 UNF 1A
35 & 38	52	30	118	1/2" x 20 UNF 1A
45	62	30	138	1/2" x 20 UNF 1A
55 & 60	85	31.8	163	1/2" x 20 UNF 1A
75	103	31.8	189	1/2" x 20 UNF 1A
84	115	41.3	145	1/2" x 20 UNF 1A
86	120	35	198	1/2" x 20 UNF 1A
120* & 135*	210	50	176	1/2" x 20 UNF 1A
120, 135 & 150	210	50	171	1/2" x 20 UNF 1A
215	300	50	226	1/2" x 20 UNF 1A
230*	350	50	275	1/2" x 20 UNF 1A
290*	450	60	225	1/2" x 20 UNF 1A
295	400	60	213	1/2" x 20 UNF 1A
315	440	50	311	1/2" x 20 UNF 1A
330*	500	50	375	1/2" x 20 UNF 1A
345	525	60	265	1/2" x 20 UNF 1A
450	600	60	311	1/2" x 20 UNF 1A
460*	700	60	368	1/2" x 20 UNF 1A
* DOT Approved. Product range may be updated. Please check with us.				

Conversion Factors		
Multiply	By	To obtain
mm	0.0394	in
cm ²	0.155	in ²
cm ³ (1 ml)	0.061	in ³
Newton	0.225	lbf
lb	0.454	kg
kg/cm ²	14.22	lbf/in ²
bar	14.5	lbf/in ²
atmosphere	1.013	bar
N/mm ²	145	lbf/in ²
US gallon	3.785	litres
UK gallon	4.546	litres
US fluid ounce	29.57	ml

PRESSURE - TEMPERATURE
FOR VARIOUS FILLING DENSITIES OF CO₂
Filling density = $\frac{\text{Wt of CO}_2 \text{ (g)}}{\text{Water capacity (ml)}}$

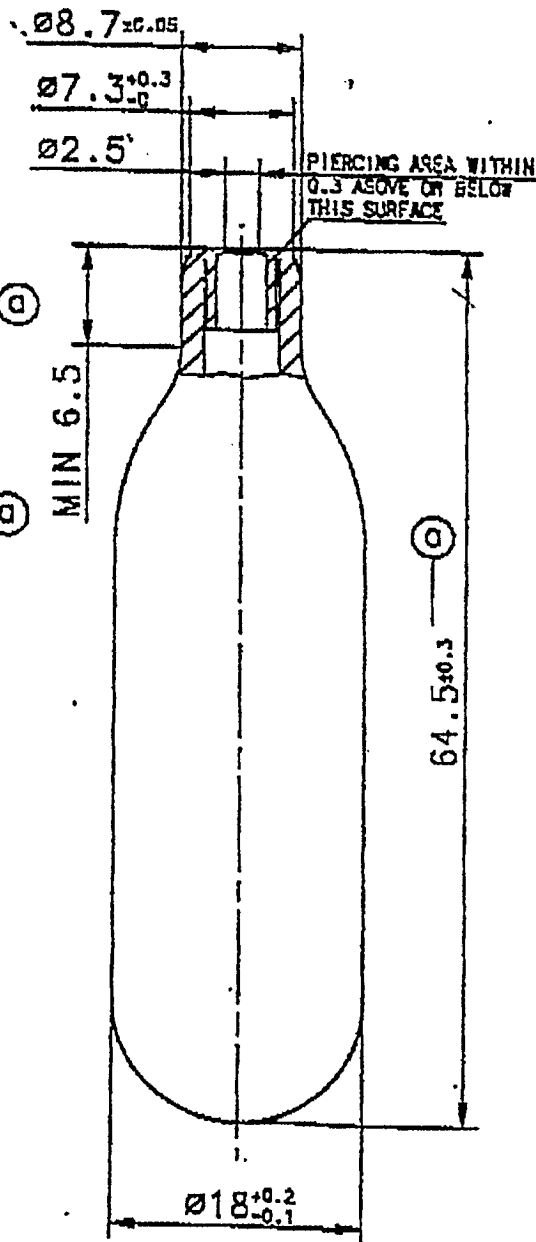



Physical Characteristics		
	Carbon Dioxide (CO ₂)	Nitrogen (N ₂)
Odour	Slightly pungent	None
Taste	Acidic/Biting	None
Fire hazard	Non-flammable	Non-flammable
Toxicity	Max. 0.5% v/v continuous	Non-toxic
Liquid density (20°C)	0.775 kg/l	-
Gas density (15°C and 100 KPa)	1.85 kg/m ³ (g/l)	1.17 kg/m ³ (g/l)

8 GRAM CO₂ (E)
8.7mm PLAIN NECK

ARTICLE No: YH1 J

NET WEIGHT FÜLLGEWICHT POIDS DE REMPLISSAGE EN CO ₂	CO ₂ CO ₂ CO ₂	8±0.3G-
WATER CAPACITY VOLUMEN CAPACITE EN EAU		10.2 ml MIN
FILLING DENSITY FÜLLFAKTOR FACTEUR DE REMPLISSAGE		81% - MAX
TEST PRESSURE PRÜFDRUCK PRESSION D'ESSAI		250 BAR
BURST PRESSURE OF CYLINDER BERSTDRUCK DES ZYLINDERS PRESSION D'ECLATEMENT DU CYLINDER		>500 BAR
CAP PIERCING FORCE KAPPEN ANSTECKKRAFT FORCE DE PERCUSSION		≤300 N
CO ₂ (E290) - ISI SPEC 0192 - 99.95% PURITY		
MARKING PROCESS: INK JET		
MARKING: BESCHRIFTUNG: MIN.GR.WT XX.XG INSCRIPTION: ISI/xxxxJ AUSTRIA M/Y		
PRINTING REPEATED THREE TIMES AROUND THE CYLINDER		
PACKING: LOOSE, IN CARTONS OF 430 PCS WT OF CARTON: 12.5 KG CARTON MARKING: CARBON DIOXIDE; 2.2; UN1013		



 © COPYRIGHT ISI GmbH A-1210 Wien, Kärntnerstrasse 4				TITLE: 8G CO ₂ PLAIN NECK CYLINDER 8G CO ₂ ZYLINDER OHNE HALSGEWINDE BOUTEILLE DE 8G CO ₂ SANS FILETAGE			
2	98-07-26	o	RS	Mat: W-NR.1.0338 DIN 1624 SPECIAL DEEP DRAWING STEEL			
1	98-05-25	title	RS	DrgNo: YH1 J 2 Art.No: YH1 J			
iss.No.	Date	change	Name	this DrgNo repl.DrgNo YH1 J 1		Surface finish DIN 50961 Fe/Zn5Cd	Scale 2:1
drawn	98-04-08		RS	dimensions in mm			

These products are the subject of patent protection in AUSTRIA, EUROPE and principal countries of the world. This drawing and all information or descriptive matter set out therein are confidential and copyright and must not be disclosed loaned copied or used for manufacturing tendering or other purposes without the prior and written consent of the owners.

GAS CYLINDER APPLICATIONS.

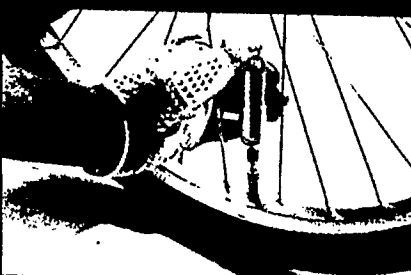
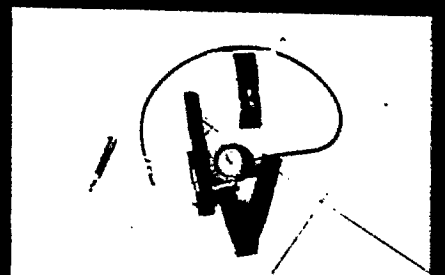
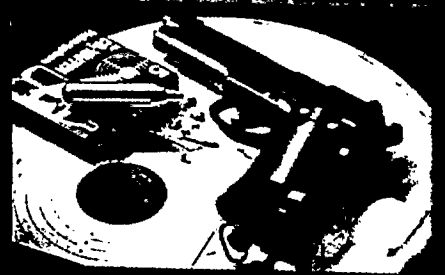
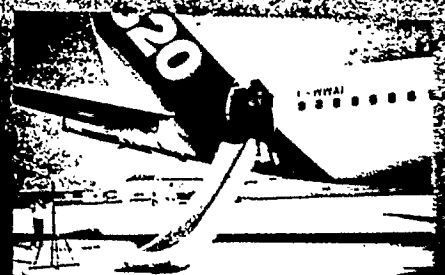
Portable pressurised gas is a remarkably versatile working fluid. ISI gas filled pressure vessels provide a pressurised gas delivery facility of exceptional integrity. ISI INDUSTRIAL, with their expertise in the design, manufacture and characteristics of these products, have assisted many customers to exploit this versatility in their products, some of which are listed here.

The safe, effective and economic use of the portable gas cylinder involves many considerations. Areas requiring particular attention are the piercing and sealing mechanisms, the desired rate of gas availability, the gas condition required by the appliance, and the operating temperature range.

In addition, special provisions are necessary to ensure conformance with regulations and standards.

ISI INDUSTRIAL will readily help designers to select gas cylinders and will collaborate in the design and development of appliances and gas cylinders (including ISI refillable cylinders) to suit customer requirements.

- LIFE JACKETS, RAFTS AND DINGHIES
- FIRE EXTINGUISHERS
- INFLATABLE SEALS
- CO₂ SPORTING GUNS
- INFLATABLE SPORTING GOODS
- CAR SAFETY (AIRBAGS)
- MEDICAL EQUIPMENT
- SMOKE AND HEAT RELEASE SYSTEMS
- TYRE FILLING DEVICES
- RE-USABLE SPRAY CANS
- SONAR BOUYS
- pH CONTROL SYSTEMS
- EMERGENCY SHUT-DOWN SYSTEMS



A NEW ERA OF PARENTERAL THERAPY IS AT HAND

Contaminated needlestick injuries extract an enormous toll on today's healthcare industry, threatening the well-being of healthcare professionals and costing healthcare providers millions of dollars annually.

Now there is an effective, needle-free delivery method for intramuscular and subcutaneous injections that prevents needlestick injuries and the spread of bloodborne pathogens. Because it is easy to use and patient-preferred, it marks a new standard of care for administering injections.

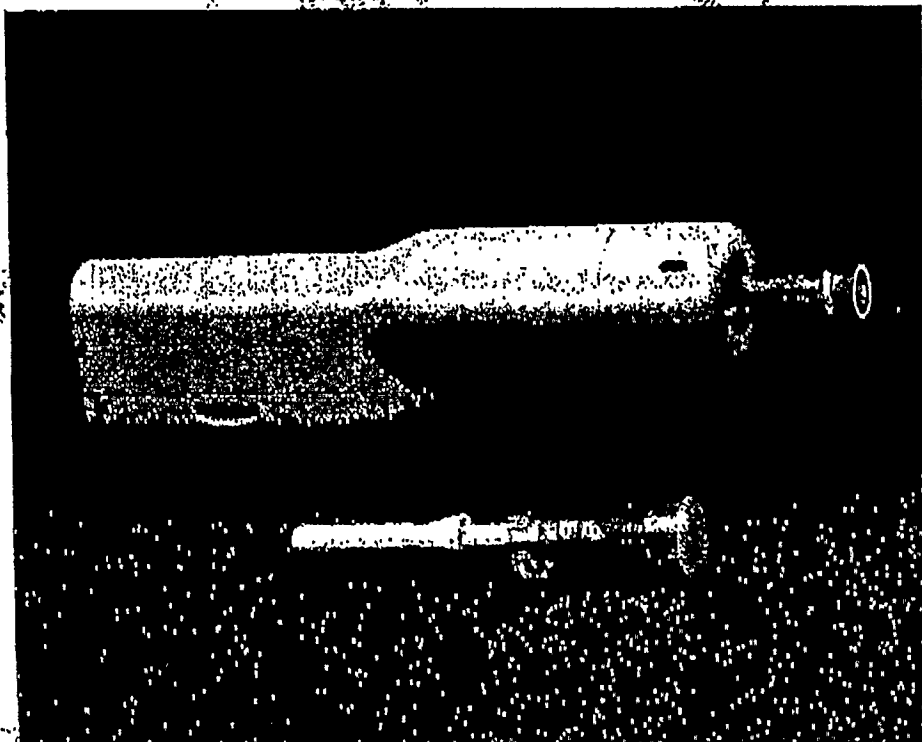
The Biojector® 2000 Needle-Free Injection Management System delivers medication parenterally *without a needle*. Instead, the Biojector uses compressed carbon dioxide (CO₂) as a safe power source to eject medication through a micro orifice within a fraction of a second. This jet action effectively penetrates the skin and delivers the medication into patient tissue.

THE FUTURE IS HERE. Other jet injectors have been used in a variety of applications for many years and millions of injections have been given to prove their safety and efficacy. However, yesterday's devices injected from a steel chamber and stationary nozzle, requiring extensive rinsing, cleaning and sterilization. They were bulky devices that called for labor-intensive and costly maintenance. Moreover, the old injectors could infect patients with bloodborne pathogens such as hepatitis B.

Today, the Biojector eliminates costly maintenance and the threat of cross-contamination with its unique, patented, disposable medication syringe. Once an injection is given, the needle-free syringe is discarded. So simple, so smart. Single-use Bioject syringes provide safer injections for patients and needle-free injection delivery for healthcare professionals, advancing the overall quality of healthcare.

BIOJECT

Safety. Innovation. Quality.



Bioject has advanced the science of jet injection for modern medicine. Professional design and precision engineering make the Biojector easy to use in all healthcare environments.

■ Bioject's needle-free injection management system prevents cross-contamination of bloodborne pathogens such as HIV and hepatitis B caused by needlestick injury. ■ The Biojector 2000 eliminates "needlephobia" and helps reduce patient apprehension of injections. ■ Different orifice sizes allow clinicians to select the proper syringe for either subcutaneous or intramuscular injections. ■ The Biojector's blend of ergonomic design and operating features is based upon recommendations from physicians and nurses.

THE BIOJECTOR 2000*Patient Preference*

The Biojector has been the injection method preferred by many patients for the following reasons:

- It eliminates the fear of injection associated with needles.
- It is less intimidating than traditional needle-syringes.
- The injection occurs within a fraction of the time required for the needle-syringe method and is often more comfortable.⁽²⁾

PRODUCT INFORMATION

Biojector 2000 Needle-Free Injector #1B02000

Bioject Syringes

(Box of 100, up to 1.0 cc variable-dose)

No. 2 Biojector Syringe for needle-free injections #1S02100

No. 3 Biojector Syringe for needle-free injections #1S03100

No. 4 Biojector Syringe for needle-free injections #1S04100

No. 5 Biojector Syringe for needle-free injections #1S05100

No. 6 Biojector Syringe for needle-free injections #1S06100

No. 7 Biojector Syringe for needle-free injections #1S07100

CO₂ Power Cartridges (Box of 10) #1C08010

PRODUCT SPECIFICATIONS

Size: 8½ in. (22cm)

Weight: 23 oz. (640 grams)

Operation Temperature Range:

60°–100°F (15°–38°C)

Dosage Capacity: 0.1–1.0 cc variable-dose

Administration: Intramuscular and subcutaneous under the direction of a physician.

Power Source: CO₂ cartridge

Injections per CO₂ Cartridge:

Approximately 10

Pressure Indicator: Yes

Syringe-Secured Indicator: Yes

Syringe/Actuator Interlock: Yes

Recommended Service and Calibration

Interval (Biojector): 18 Months

Warranty: One year

Customer Service

Bioject is committed to providing you with the best possible service and support. Our medical personnel are well qualified and readily available to provide in-service training and on-site consultation on the use of the Biojector 2000 Needle-Free Injection Management System.

In-service video tapes and educational materials are available upon request from Bioject's Customer Service Department.

1. Leads from the MMWR. Hepatitis B associated with jet gun injection — California.

JAMA. 256(4):446–447, July 1986.

2. Data on file. Available upon request from Bioject Inc.

Biojector® is a registered trademark of Bioject Inc.

©1993 Bioject Inc.

171-0117-02, 2/93

BIOJECT

(800) 683-7221

(503) 639-7221

Bioject Inc.
7620 SW Bridgeport Road
Portland, Oregon 97224

FAX**Duke University Occupational and
Environmental Safety Office****Division of Biological Safety****Date:** 7/28/00**Number of pages including cover sheet** 3**TO:**Eileen Edmonson**Phone****Fax Phone** 1-202-366-3012**CC:****FROM:**Dr. Debra HuntOccupational &
Environmental Safety
OfficeBox 3149Durham, NC 27710**Phone** (919) 684-8822**Fax Phone** (919) 681-7509**REMARKS:**☐Urgent☐For your review☐Reply ASAP☐Please Comment