

BIJECT

Feedback From The Field: Needle-free Injection Use in Large Scale Immunization Campaigns

Rockville, MD

18 December 2003

Roadmap



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- ✦ Bioject's Approach -- Overview of **needle-free injection (NFI)** technology used in immunization (**IZ**) therapy
- ✦ The Biojector® 2000 NFI System
 - Function and Components
 - Clinical Performance and Cost of Use
- ✦ Support for Medium and Hi- volume Immunization Opns.
 - Recent Applications
 - U.S. Military Highlights
 - Public Health and Private Practice Initiatives
- ✦ Healthcare Worker Safety
- ✦ Summary

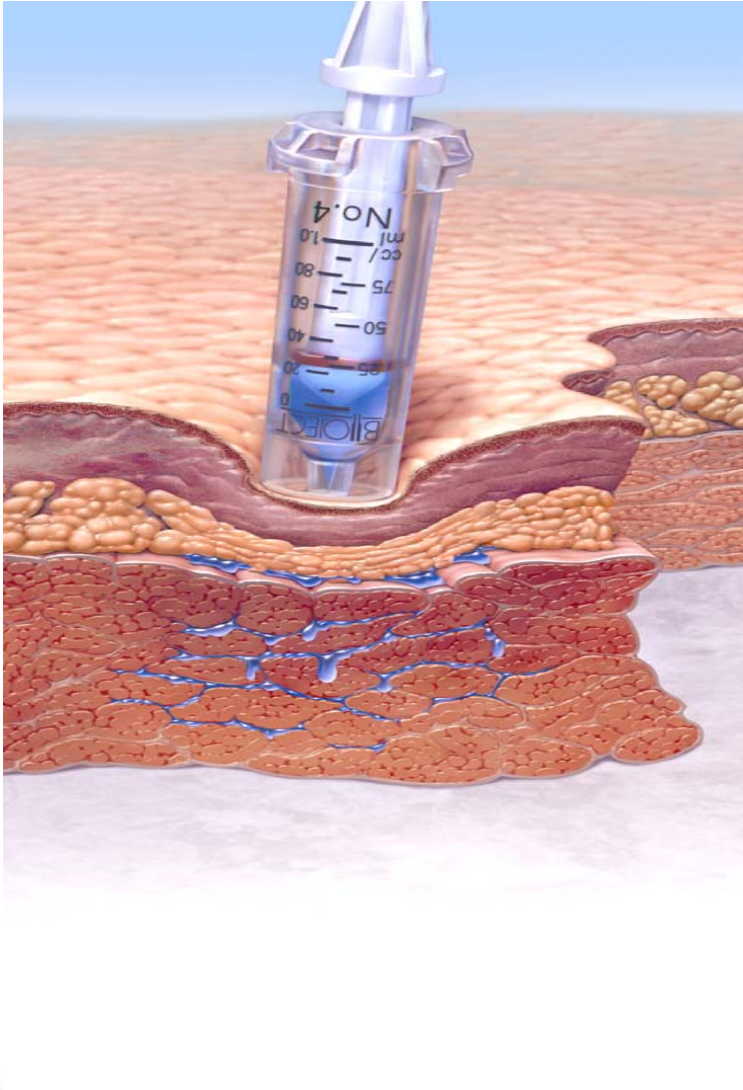
Needle-free Injection Technology

- ✦ Widely used since late 1940s
- ✦ Some systems w/ CO2 pressure tank
- ✦ High-volume systems were large, complex, bulky
- ✦ Some limited to SQ delivery
- ✦ Widely used for mass immunizations (Public Health, Military, WHO)
- ✦ Not patient friendly/ many injection site issues
- ✦ Older technology could spread cross contamination
- ✦ Older equipment time consuming to sterilize



Needle-free Injection

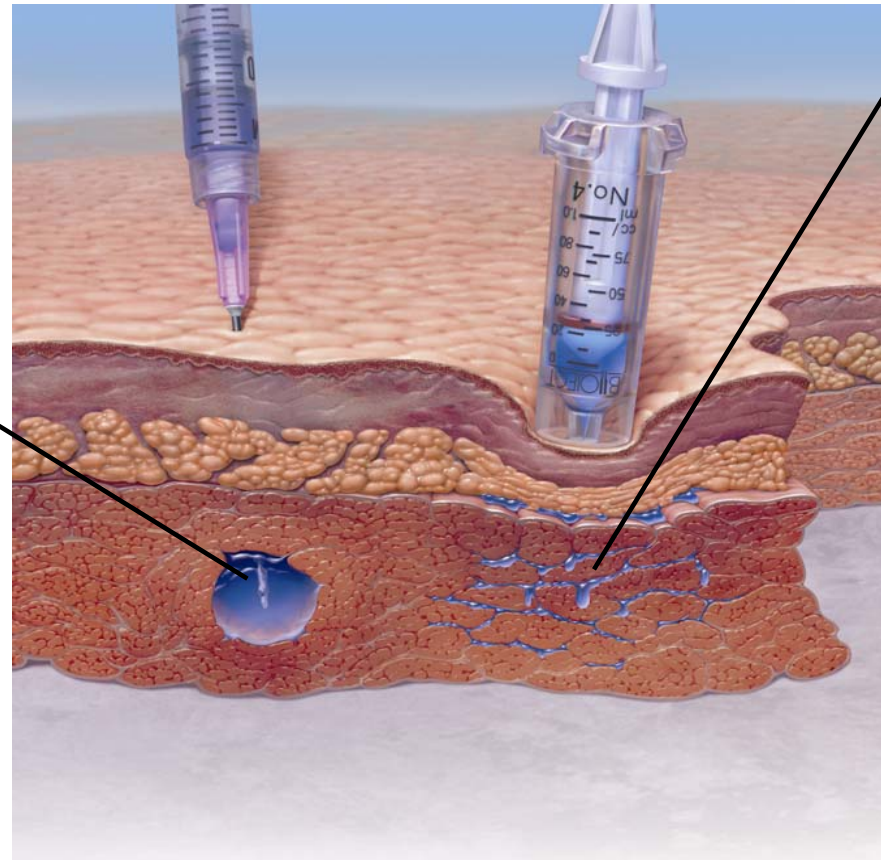
How does it work?



- ✦ Medication pushed at high speed through a tiny orifice ($< .015$ inches)
- ✦ Fine stream of medication penetrates the tissue
- ✦ The injection event takes 0.5 seconds, or less
- ✦ Depth of penetration controlled by type of needle-free syringe selected

Dispersion Patterns

I.M. Injection



Spherical bolus

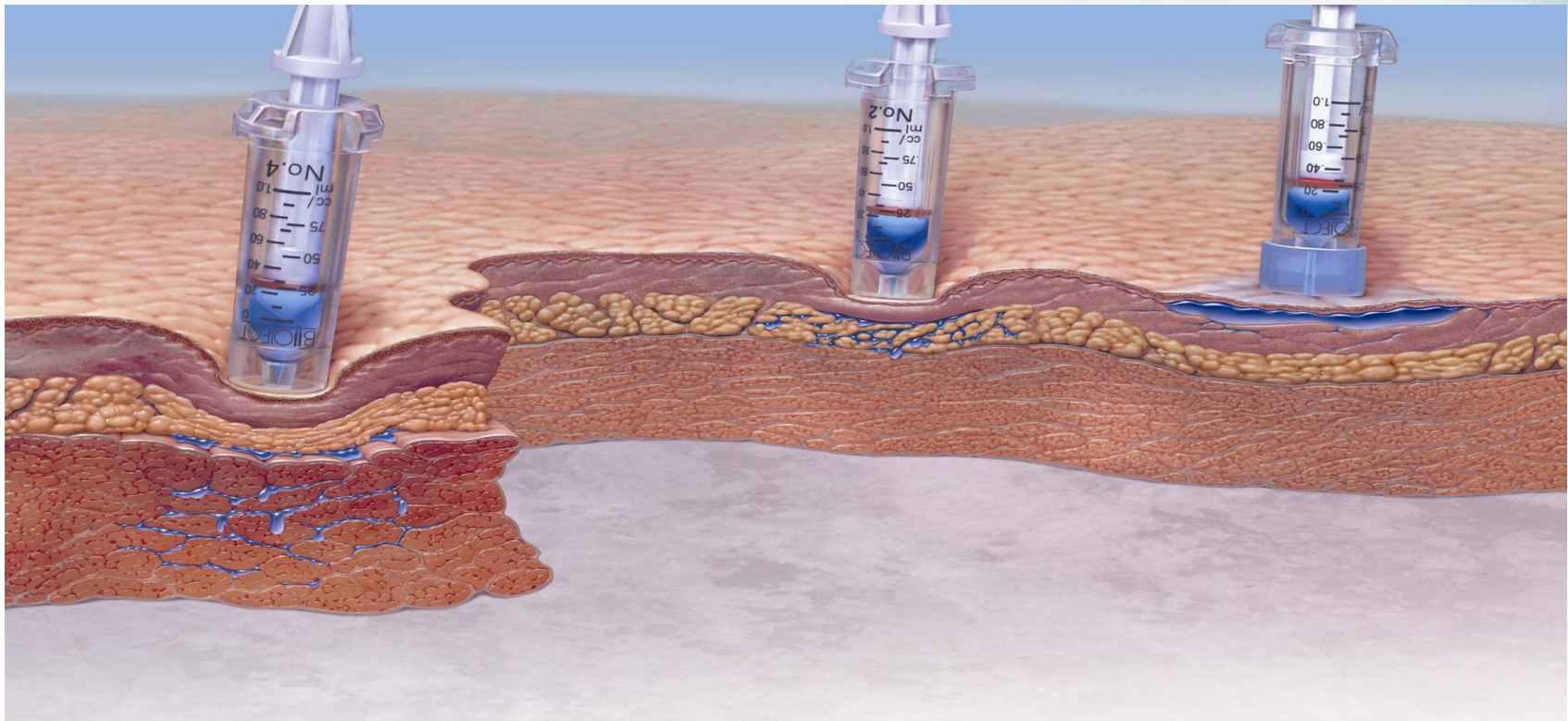
- lowest possible Surface Area- to- Volume ratio
- limited tissue exposed to medication

Wide dispersion pattern

- Amplified dispersion in tissue
- very high Surface Area- to- Volume ratio
- tissue exposure significantly enhanced
- medication follows path of least resistance

Biojector Capabilities

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Intramuscular

Subcutaneous

Intradermal
(future product)

Needle-free Injection Systems

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Biojector® 2000



**Vitajet® 3
Cool.click™
SeroJet™**



**lject™
(Now in
clinical trials)**

Research Collaborations

Over 30 active research collaborations



MSK – cancer trials



USNMRC –
malaria



Dale and Betty Bumpers
Vaccine Research Center
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Biojector® 2000 Components

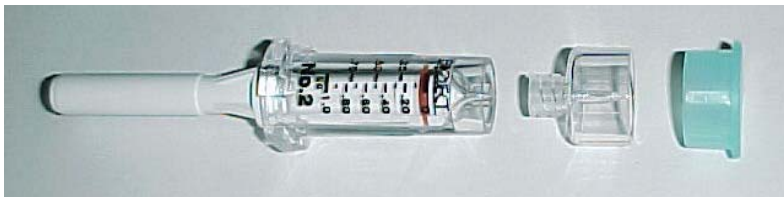
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- ✦ **Biojector® 2000, Class 2 Medical Device**
- ✦ **Life cycle of 120K+ injections**
- ✦ **FDA Market Release in 1994, 1989**

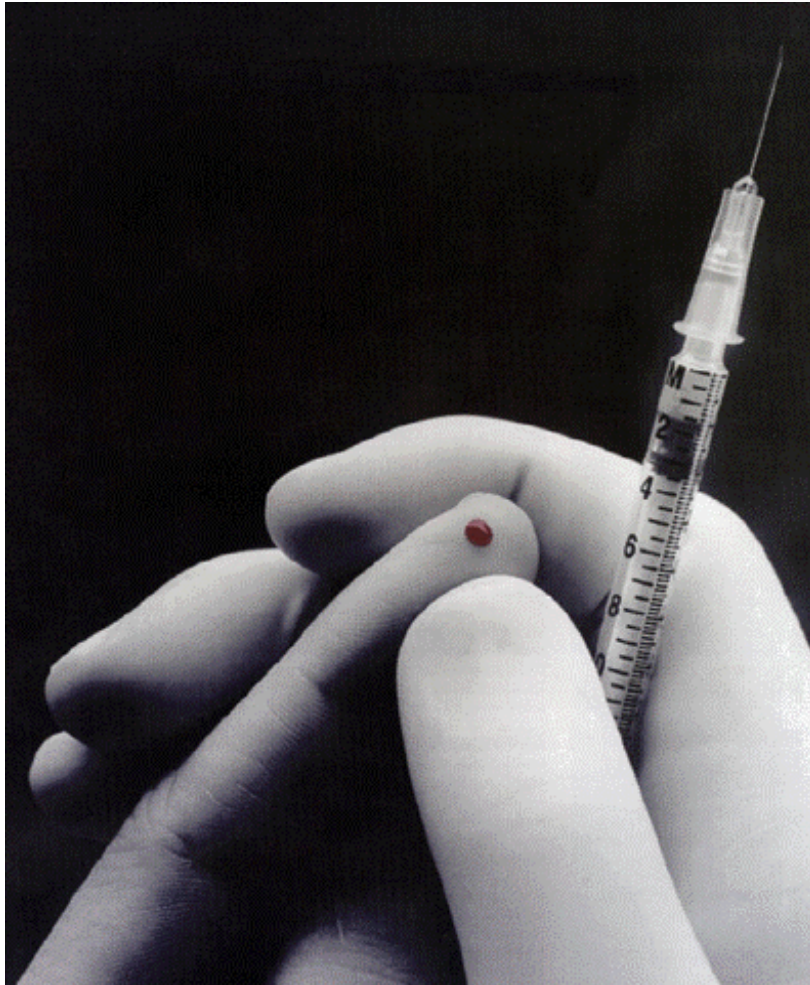


- ✦ **CO2 Power Cartridge**
- ✦ **10 - 15 injections**
- ✦ **Pressure tank adapter available for mass immunization programs**



- ✦ **Single use, sterile, disposable polycarbonate syringes**
- ✦ **Deliver SC or IM**
- ✦ **Various packaging formats**

Acceptable Risk ?



- ✦ Over 600,000 accidental needlestick injuries occur annually in the U.S.*
- ✦ Accidental needlesticks can transmit HIV, hepatitis, and other deadly diseases
- ✦ Average direct cost to investigate each needlestick injury is \$500-\$3000*

**Sources: GAO, CDC, OSHA, University of Virginia*

Using the “C” Word

Cost of Use, NFI vs. Safety Needle

- ✦ Does purchase price = cost of use ?
- ✦ Compare apples to apples
 - Include sharps disposal, post- exposure testing, treatment, investigation, reporting, lost work time, human cost, insurance risk
- ✦ Safety needles *may* prevent up to 76% needle-stick injuries (GAO Study)
- ✦ NFI technology offers highest degree of safety, no extra steps required to activate safety features
- ✦ Some healthcare workers fail to activate needle safety syringe
- ✦ Safety needles actually increase “sharps waste” volume

High Risk Environments

- ✦ NFI technology -- ideal solution for high risk patient care settings
 - Struggling or non-compliant patients (peds !!)
 - Patients w/ unknown medical history/ risk factors
 - Needle phobic patients
 - Prison and jail health clinics
 - STD Clinics
- ✦ Mass IZ campaigns often conducted at non-traditional sites: schools, retail centers, gyms
 - Medium to high volume settings, using pre-filled syringes, production line protocols

NFI Use

Mass IZ Operations

- ✦ Utilize production line protocols
- ✦ Throughput, patient controls and speed of processing are critical considerations
- ✦ Nurses and trained medical technicians administer injections at multiple stations
- ✦ Coordination essential between key players
 - public health, local transportation, media, healthcare networks, law enforcement
 - supporting state + federal agencies

NFI Use

Mass IZ Operations (Continued)

- ✦ Trained volunteers set- up, orient/ direct patients, control flow, fill syringes, site prep, maintain records
- ✦ Often conducted at non- traditional sites
 - School gyms, malls, work sites, community and transit centers
 - Isolate suspected exposed patients from healthy patient population
- ✦ Multiple and repeat clinics will insure higher compliance rates
 - Take the IZ show on the road
 - Go to where the patients already are

Recent NFI Use

Military Healthcare

- ✦ Naval Hospital Great Lakes conversion, June '03
 - Most vaccinations provided by medical technicians
 - Volume: over 250k per year
 - Patients are all adults, 18 – 45 years of age
 - Separate mass IZ campaign for influenza October - December
- ✦ Large scale use for adult and pediatrics immunization
- ✦ Mass immunization opns. employ CO2 tank adapters
- ✦ Adopted and fielded aggressively by Naval healthcare providers
 - Over 25 hospitals and independent clinics



Recent NFI Use

Military Healthcare (Continued)

- ✦ Pilot programs evaluating NFI equipment in clinics aboard ships for routine IM and SC injections
 - Main application is adult IZ
 - Storage and treatment space extremely limited
 - Time away from duty stations must be strictly limited
- ✦ Minesweeper fleet based at Ingleside, TX
 - Very small ships, 1 advanced medical technician per crew



- ✦ Pacific NW fleet based at Everett, WA
 - Mix of large and small platforms

Recent NFI Use

Public Health Operations



- ✦ Anne Arundel County, MD
 - Flu season, 2002 and 2003
 - Over 20k doses administered, all needle-free
 - Largest daily operation = 1,900 patients (using 8 stations)

- ✦ Southington Township, CT
 - New user, very small staff
 - Largest daily operation = 1,100 patients (using 2 stations)

- ✦ Kern County, CA
 - 13 Nov., 2003 biodefense exercise in Bakersfield
 - Planned for 900 flu vaccinations as rehearsal

- ✦ Brownsville, TX
 - Non-profit community health center
 - Over 16k pediatric and adult immunizations given in CY 2003



Public Health Opns.

Southington, CT, Health Dept.

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- ★ Southington Township, CT (30 miles SW of Hartford)
- ★ Suburban health dept., director, 2 nurses + 3 contract nurses
 - Mission: provide general health protection services as part of community “safety net”
- ★ Community senior center used as IZ site
- ★ Control measures used to maximize patient flow
 - Volunteers, shuttle for non- drivers, police on site, large waiting area for intake
 - Pre- filled needle- free syringes, 2 IZ stations, relief for nurses





Public Health Opns. Southington, CT, (Continued)

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- ★ Most patients aged 55 or older
 - Small number of first responders and healthcare workers
- ★ Goal was to vaccinate about 1,200 patients in 2 sessions (flu vaccine)
 - 29 October, **1159 patients in 3 hours**
 - 5 November, **370 patients in 1.5 hours**
- ★ Public Health Director, Mr. Charles Motes
 - Contact: 860. 276. 6275 motes@southington.org





Public Health Opns. Kern County, CA, Health Dept.

- ✦ Kern County, CA (Bakersfield)
- ✦ Urban health dept. with 40 P.H. nurses and large rural geography (120 miles x 60 miles)
- ✦ **13 Nov., 2003** -- Simulated plague outbreak to test public health dept., emergency svcs., law enforcement, public relations, media, local hospital reporting
- ✦ Vaccination exercise conducted in community activities center



Public Health Opns. Kern County, CA (Continued)

- ✦ Goal was to vaccinate about 900 patients
 - Treated **400 patients in 4 hours** (using 5 stations)
 - Isolated treatment area for “exposed” patients
 - Local demand for flu vaccine was low
- ✦ Steven Chambers, Public Health Planner/ Coordinator
 - Contact: 661. 868. 0378 chambers@kern.ca.us
 - Rebecca Tucker, RN Nursing Manager



Public Health Opns. Kern County, CA, Health Dept.

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- ✦ Video clip from biodefense exercise, 13 Nov.
- ✦ Shown in Twinbrook Room at break- out meeting

NFI Technology Advantages

- ✦ **Field Proved** -- safer, faster, less invasive
- ✦ **Cost Savings** -- reduces expense from needle-stick injuries and sharps waste disposal
- ✦ **Workforce Protection** -- prevents dangerous needle-stick injuries; meets OSHA safety requirements
- ✦ **Clinical Results** -- improves some vaccines' efficacy, faster onset of desired immune response
- ✦ **Flexibility** -- safely and quickly administers IM and SC injections, even for off- site operations
- ✦ **Patient Compliance** – eliminates needles as a barrier to patient receiving required treatment

Biojector® 2000 Is

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- ✦ Proven NFI technology – over 12 million injections since 1995
- ✦ Cost effective and affordable
- ✦ Quick to train, easy to use
- ✦ Adaptable for mass immunization operations
- ✦ Used at over 25 military healthcare facilities and 100+ U.S. public health departments
- ✦ Comfortable, effective, needle-free, SC or IM
- ✦ Durable, lightweight and portable
- ✦ FDA released to market -- 1989 and 1994



Summary

Thanks for your time and interest

- ✦ Bioject actively developing high workload injector to meet global mass immunization needs
- ✦ NFI needs support of policy makers and clinical users
- ✦ Bioject's Goal -- support healthcare professionals in selected market segments as they become leaders NFI
- ✦ Current and emerging NFI products must exceed OSHA requirements -- zero risk of cross contamination
- ✦ High quality customer service and clinical support post-sale
- ✦ NFI products must demonstrate safety and efficacy -- respected clinical study partners are critical
- ✦ Optional meeting today, **6:00 PM**, in **Twinbrook Room**



Contact Information

BIOJECT



For Product and Clinical Questions: 800. 683. 7221

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Kurt Lynam, Field Applications/ Sales

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Web Site

www.bioject.com

Technical Data - Q&A

I'm

Glad

You

Asked

That

Question !!!



Orifice Size Needle-free Syringe



BIOJECT ORIFICE SIZE AND COMPARATIVE DATA FOR NEEDLE DIAMETERS AND PARTICLE SIZE

Syringe Number	Inch Size	Millimeter Size	Micron Size	Needle Gauge OD	Needle Gauge ID
#2	.0045	.114	114	32	*36
#3	.0062	.157	157	30	*34
#4	.0085	.216	216	27	33
#5	.0104	.264	264	25	31
#7	.0147	.373	373	22	28

* not commercially available

Filling the Needle-free Syringe

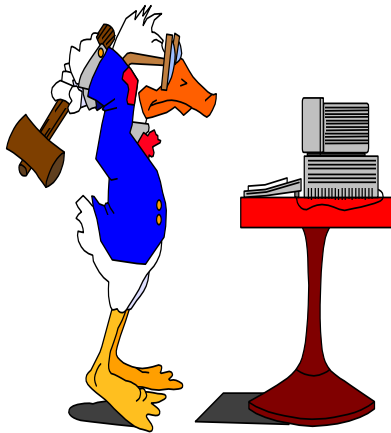
Helpful Hints



- ✦ Attach vial adapter before accessing medication vial
- ✦ Read volume at top edge of red pressure ring
- ✦ Carefully purge air bubbles using “Pull - Push” method, or tapping the plunger
- ✦ Create small meniscus at tip of orifice
- ✦ Don't touch the tip of the syringe
- ✦ Attach blue safety cap immediately after filling
- ✦ Handle filled syringes according to instructions for that med.

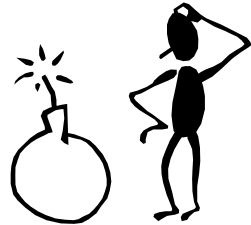
Troubleshooting

What should I do if?



- ✦ **Press actuator, no injection** -- check CO2 pressure gauge, replace if needle is in white zone
- ✦ **Actuator won't operate** -- check syringe locking collar for green indicator
- ✦ **Less than 8 injections** per CO2 cartridge -- check adjusting knob on rear of device; also, check for CO2 cartridges from Austria
- ✦ **Syringe won't insert properly** into B-2000 -- check syringe locking collar; it may have rotated into the locked "green" position

Hidden Cost of Needle-stick Injuries



Hmm... This may not be a good thing ...

- ★ Average lifetime costs of seroconversion
 - \$94,726 HIV infection (Gable, J Acquir Immune Defic Sydr Hum Retoviol 1996; 14(4):380-2)
 - \$115,000 Hep B infection (Mauskopf, J Occ Med 1991;33:691-9)
 - \$37,263 Hep C infection (Younossi, Hepatology 1999; 30(5):1318-24)
- ★ \$484,671,869 estimated annual cost burden U.S.
- ★ Adds cost: \$0.30 per needle- syringe injection
- ★ 1.7 B clinical needle injections per year
(Becton Dickinson, Annual Report 1997)

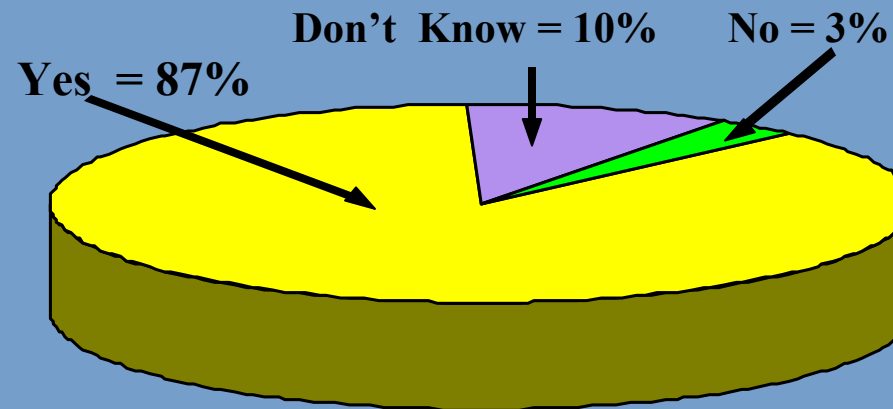
Hidden Cost of Needle-stick Injuries (cont'd)

- ✦ 600,000 accidental needle-stick injuries per year
(Jagger, J. Advances in Exposure Prevention, 1998;4:1)
- ✦ Needle-stick consequences
 - \$500 per incident in follow-up and investigation
(Jagger, Infec Cont Hosp Epid, 1990;11:584-8)
 - 26.5 average new HIV infections per year
(Jagger, J. Advances in Exposure Prevention, 1998;4:1)
 - 400 new Hepatitis B infections in 1995
(Arch Intern Med 1997;157:2601-3)
 - 3010 average new Hepatitis C infections per year
(Jagger, J. Advances in Exposure Prevention, 1998;4:1,
Dr. R. Garvin, Hepatitis Branch, CDC)

Oklahoma Preference Survey

Public Health Clinics

**Graph 2: Clients receiving multiple injection only.
Were you satisfied with your needle-free injection method?**



Results from those clients receiving multiple injections with the Biojector were tabulated, showing an 87% satisfaction rating for the needle-free system.

Strategic Partners



- ✦ Serono S.A.
 - Global license for Vitajet™ 3
 - Saizen® recombinant human growth hormone for treatment of pediatric growth hormone deficiency
 - Serostim® recombinant human growth hormone for treatment of AIDS wasting

Case Study

Saizen® cool.click

cool.click™
Needle-Free GH Delivery



- ✦ Six-month FDA release to market
- ✦ First partnered needle-free product to market
- ✦ European product launch Fall 2002
- ✦ New SeroJet™ Model for Serostim® (AIDS wasting therapy)

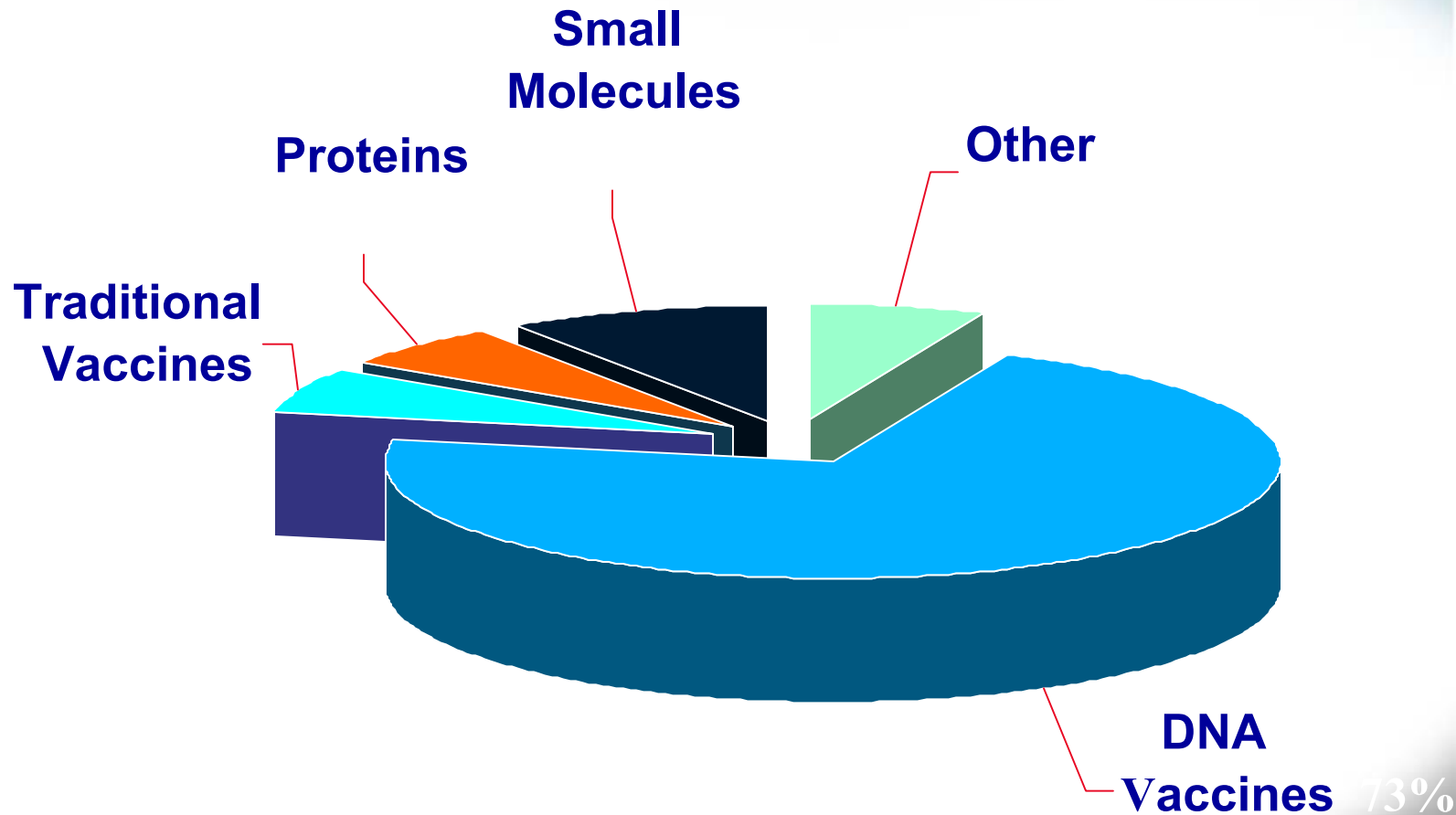
Iject

(under development)



- ✦ IM or SC
- ✦ Gas powered
- ✦ Disposable
- ✦ Pre- filled or U- fill format
- ✦ Professional use or self- injection

Clinical Research by Category



On-going and Pending Studies

- ✦ DNA-based vaccines for HIV/AIDS (NIH), Fall 03
- ✦ Safety and Efficacy w/ rabies vaccine (CSU), Spring 03
- ✦ DNA-based vaccine for Ebola (NIH), Winter 03 - 04
- ✦ DNA vaccine for lymphoma (Stanford)
- ✦ DNA vaccine for melanoma (Memorial Sloan Kettering)
- ✦ DNA vaccines for malaria (Navy Med. Research Center)
- ✦ Cardiovascular Applications (Epicardial, Endocardial)
- ✦ Microspheres: (In-vitro and In-vivo testing)
- ✦ High workload NFI for production animal vaccination