

New Vaccine Delivery Technologies

15th Annual General Meeting—Developing Country Vaccine Manufacturers Network

Vaccines, Our Shared Responsibility
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New vaccine delivery technologies

Delivery devices



- Disposable-syringe jet injectors*
- Intradermal delivery devices*
- Microneedles*
- Intranasal delivery
- Aerosol/dry powder inhalation
- Electroporation

Packaging



- Prefilled syringes/compact prefilled autodisable devices*
- Blow-fill seal/multi-mono dose*
- Integrated reconstitution*

Formulation



- Fast-dissolving tablets and gels
- Solid-dose implants

* discussed in presentation

New and alternative delivery technologies

- Many new technologies are needle free.
- Some are compatible with existing vaccine formats (e.g., vials or ampoules).
- Others are integrated with formulation (e.g., combination products).
- Improved ease of vaccine delivery, efficacy, cost-effectiveness, and safety are areas of focus.
- Developers include industry, academic, and nonprofit research groups.



Photo: Georgia Tech



Photo: The Hindu



Photo: PATH

Potential public health benefits

- Increase vaccine access and coverage—enable community health workers to deliver vaccines.
- Improve immunogenicity.
- Reduce the need for and the number of injections.
- Reduce risk of infections/cross-contamination.
- Reduce potentially dangerous sharps waste.

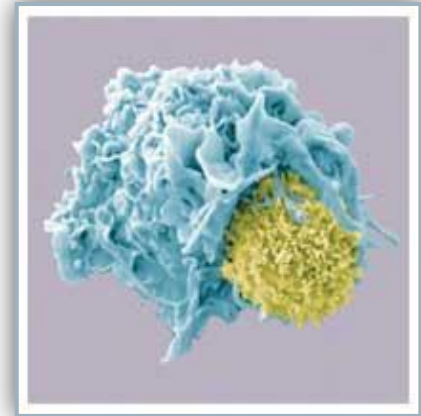


Photo: World Health Organization



Image: PATH

Potential public health benefits

- Relieve tensions and fears surrounding immunization.
- Reduce dropout by optimizing schedules.
- Reduce health worker workload—simplified administration and reconstitution (free up time for other tasks).
- Reduce cold chain dependency through improved thermostability (heat and freeze stability)—incorporation of enhanced formulation in presentation.



Photo: Ümit Kartoglu



Photo: PATH/Debra Kristensen



Photo: PATH/Debra Kristensen

Current challenges to vaccine delivery

- Training and availability for health care workers.
- Routine, supplementary immunization activity, and outbreak response.
- Appropriate vaccine management.
- Supply access (e.g., needles and syringes, safety boxes).
- Needlestick injuries to health care workers.
- Disposal of sharps waste—community needlestick injuries.



Photo: World Health Organization



Photo: World Health Organization

Disposable-syringe jet injectors



Photo: PharmaJet



Photo: PATH



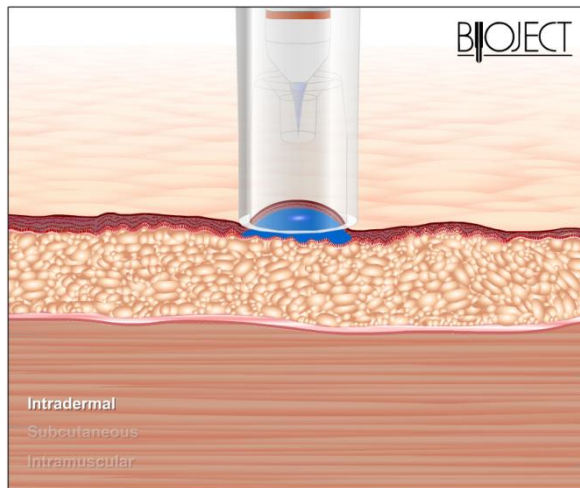
Photo: PATH

Delivery using jet injectors

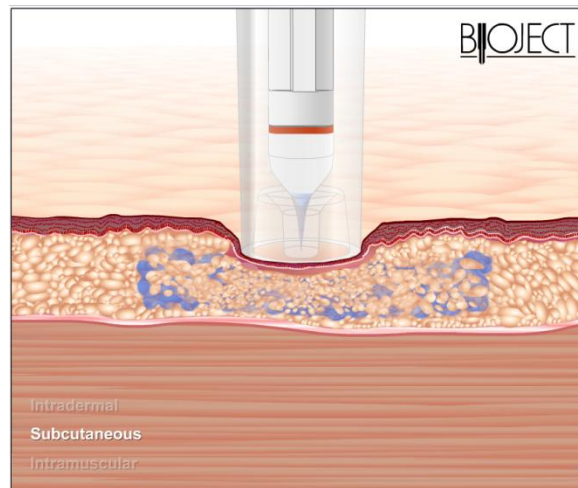
Jet injectors deliver vaccines and medicines without using needles; instead, jet injectors generate a pressurized liquid stream that pushes through the skin, penetrating it to deliver injections into the tissue.



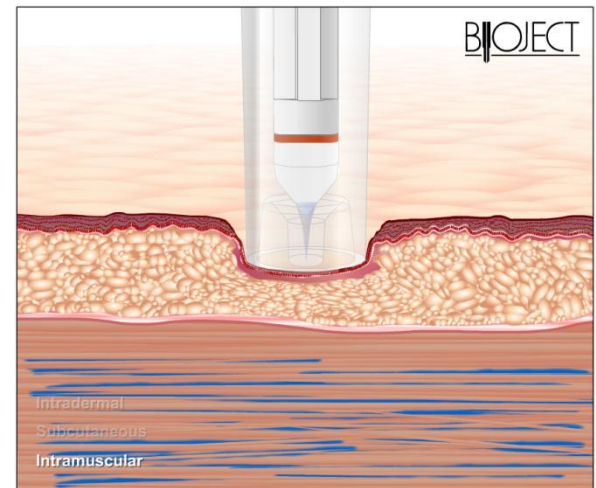
A PharmaJet DSJI injection in action.



ID injection with a DSJI.



SC injection with a DSJI.



IM injection with a DSJI.

All images: Bioject

DSJI WHO prequalification

- Prequalification requirements are based upon the International Organization for Standardization standard for jet injectors (ISO+).
- Requires device clearance through globally recognized national regulatory authority.
- PharmaJet Stratis® technology was the first DSJI to complete this process (January 2013).

INTERNATIONAL
STANDARD

ISO
21649

First edition
2006-06-01

Needle-free injectors for medical use —
Requirements and test methods

Injecteurs sans aiguille à usage médical — Exigences et méthodes
d'essai



PQS performance specification

WHO/PQS/E08/JI01.1

Original: English
Distribution: General

TITLE: Single-use auto-disable needle-free syringe injectors

Specification reference: E08/JI01.1
Product verification protocol: E08/JI01-VP.1
Issue date: 21.04.2010
Date of last revision: New specification

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PERFORMANCE QUALITY SAFETY



E008: Auto-disable syringe for fixed dose immunization

PQS code: E008/050
Description: single-use auto-disable needle-free jet injector
Manufacturer's reference: PharmaJet Stratis®
Manufactured in: United States
Company: PharmaJet, Inc.
Address: 400 Corporate Circle,
Suite N
Golden, Colorado 80401
USA
Telephone: +1 (6) 303 5264278
Email: michael.royals@pharmajet.com
Web address: <http://www.pharmajet.com/>

Specifications

Reset station	Injector	Needle free syringe	Filling adaptor
Reference manufacturer: C501-20	Reference manufacturer: C501-10	Reference manufacturer: C501-31	Reference manufacturer: C501-40
Activation: manual	Administration: IM or SC	Nominal capacity and graduation: 0.5ml	Material of adaptor: Polycarbonate
Force applied:	Energy source: spring	Main materials of syringe: Polycarbonate	Compatibility only with the Stratis needle-free syringe
Life time cycles: 20,000 min	Main material: ABS, stainless steel	Prevented from reuse by: Plunger break before injection	Intended for one vial use for field-filling of syringes
Carrying case IP: 55	Inadvertent actuation prevention feature	Primary packaging: paper blister packs	Primary packaging: paper blister packs
Warranty 2 years	Warranty 2 years	Number of syringes per pack: 250 units	Number of syringes per pack: 75 units

The PharmaJet Stratis™ needle-free injection system is intended to deliver various medications and vaccines either intramuscularly or subcutaneously by means of a narrow, high velocity fluid jet, which penetrates body tissues.

Quality system Standard: ISO 9001, ISO 13485, Product standard: ISO 7886-3, FDA 510(k), CE 556625

Single-use auto-disable needle-free jet injector
Note: Jet injectors (single-use auto-disable needle-free syringe injectors) as medical devices (Class II) are regulated by National Regulatory Authorities. A jet injector prequalified by the WHO PQS programme to deliver medications and vaccines is to be used according to label to deliver ONLY those medications and vaccines that have been approved by the relevant Authorities.

Current PQS status: pre-qualified; 31 Jan 2013

Valid until: Apr 2014

Note: If current PQS status is 'Suspended' or 'Withdrawn', this product is NOT to be purchased
NEW Product AS AT 31.01.2013

10/29/2014



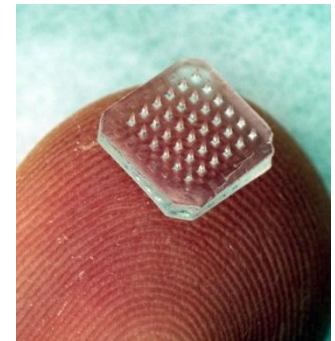
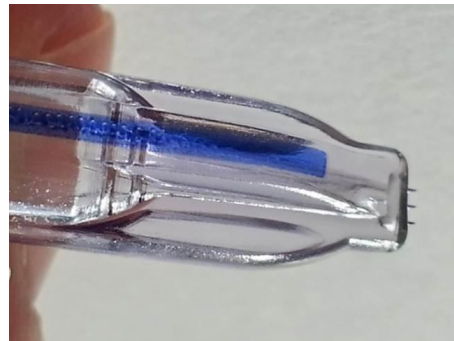
ID delivery device categories

Needle-based devices (standard needle and syringe, hollow microneedles, mini-needles, ID adapters)

Disposable-syringe jet injectors

Microneedle patches (solid coated or dissolvable)

Field filled or
prefilled with
liquid vaccine



All photos: PATH except where noted

Photo: Georgia Institute of Technology

ID delivery devices: Needle based

Manufacturer	Device	Development Status	Image
<u>West Pharmaceutical Services, Inc. (West)</u>	<u>ID Adapter</u>	Commercialized	A
<u>BD</u>	<u>Soluvia™</u>	Commercialized (influenza vaccine)	B
<u>Star Syringe, Ltd.</u>	<u>Star ID</u>	Preclinical	C
<u>NanoPass</u>	<u>MicronJet 600</u>	Commercialized	D



All photos: PATH except where noted

10/29/2014

ID delivery devices: Disposable-syringe jet injectors

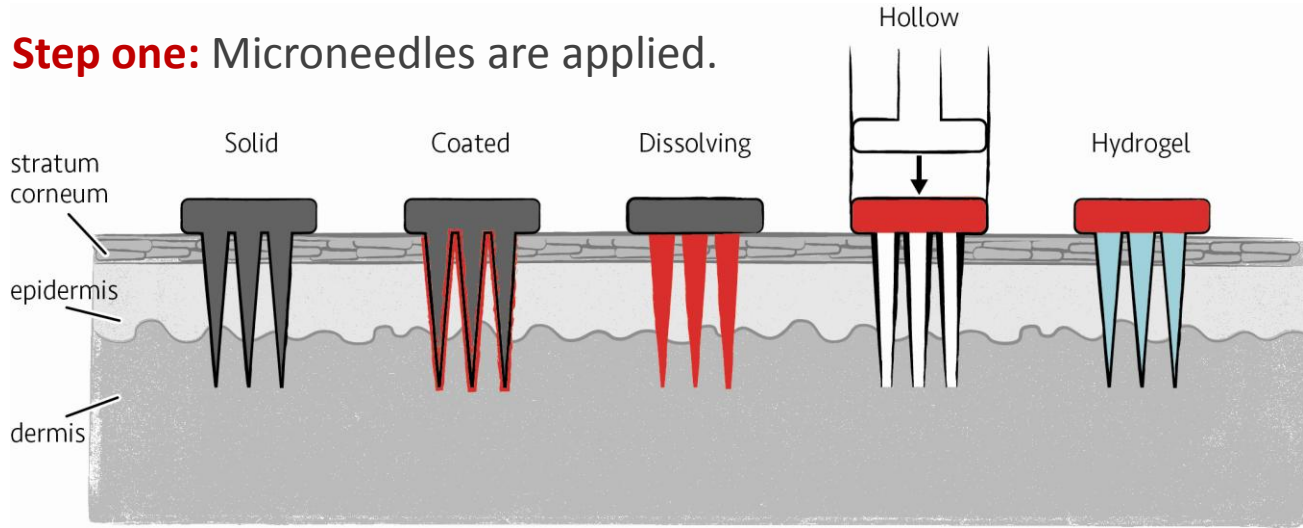
Manufacturer	Device	Development Status (for ID delivery)	Image
PharmaJet®	Tropis	Clinical	A
Bioject	ID Pen	Clinical	B
	Zetajet®	Clinical	—
	Biojector® 2000	Device clearance	D
Medical International Technologies	Dart	Preclinical	C
	H4	Preclinical	—



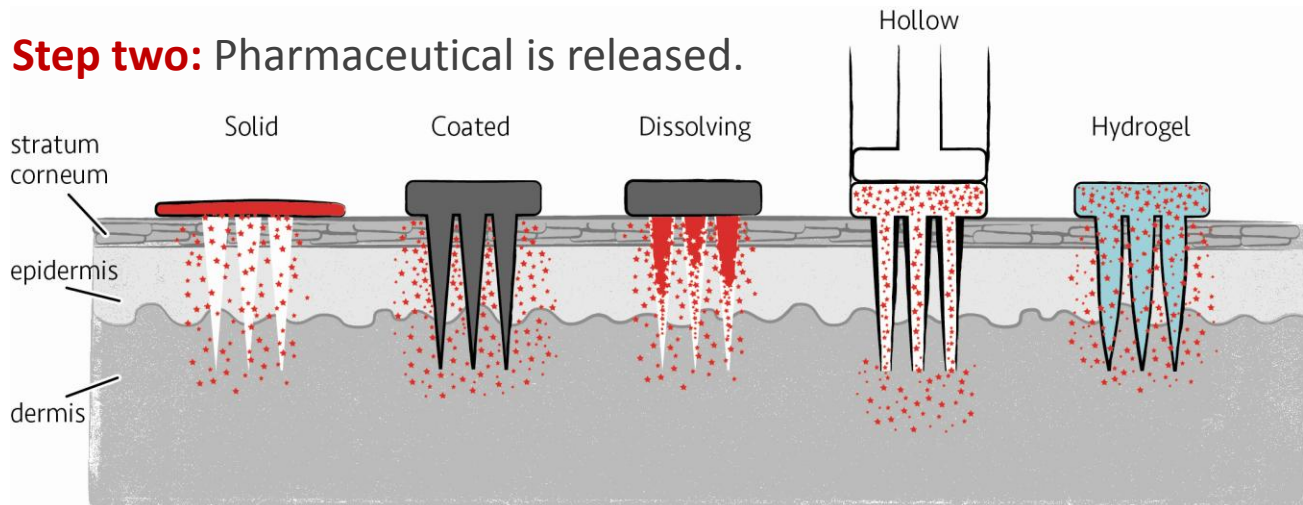
Comparison of microneedle types

Solid, coated, dissolving, hollow, and hydrogel.

Step one: Microneedles are applied.



Step two: Pharmaceutical is released.



Images: PATH

ID delivery devices: Microneedle patches

Developer	Device	Development Status	Patch type	Components	Image
<u>Georgia Institute of Technology</u>	—	Preclinical	Dissolvable	Patch (potentially no applicator needed)	A
<u>Corium</u>	<u>MicroCor®</u>	Preclinical	Dissolvable	Patch and integrated applicator	B
<u>Vaxxas</u> / University of Queensland	<u>Nanopatch™</u>	Preclinical	Solid coated	Patch and applicator	C

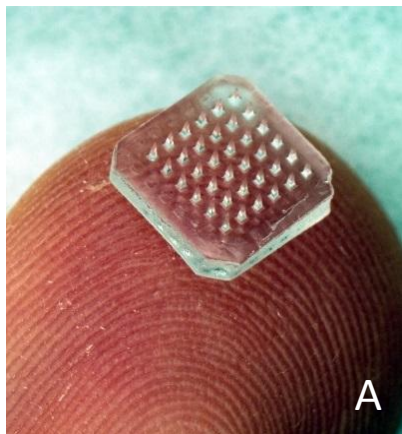


Photo: Georgia Tech

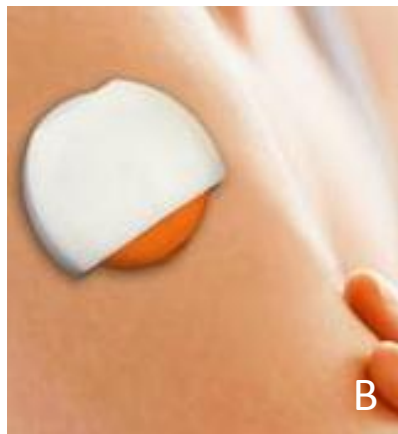


Photo: Corium

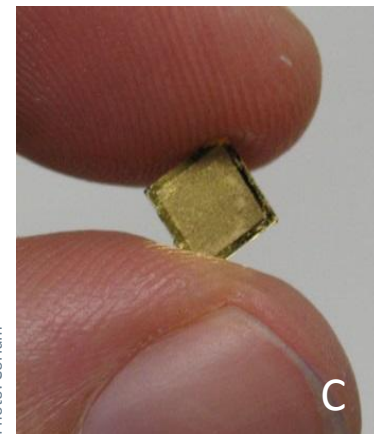


Photo: Vaxxas

Oral Prefill Technologies

Manufacturer	Device	Development Status	Image
<u>BD®</u>	<u>Uniject</u> DP	Market available	A
<u>Rommelag</u>	<u>BFS</u>	Market available	B
	BFS MMD	In development	C
<u>Lameplast</u>	<u>Tube</u>	Market available	D



A



D



B

Photos: PATH/Patrick Mckern



C

Photo: PATH/Greg Kachmarik

PATH 3D-printed prototype.

Technology example: Multi-mono dose

Multi-mono dose:

- A conjoined strip of single-dose containers with a single label and vaccine vial monitor.
- Separating a single container from the strip opens the container.
- Formed using BFS or other plastic container technologies.

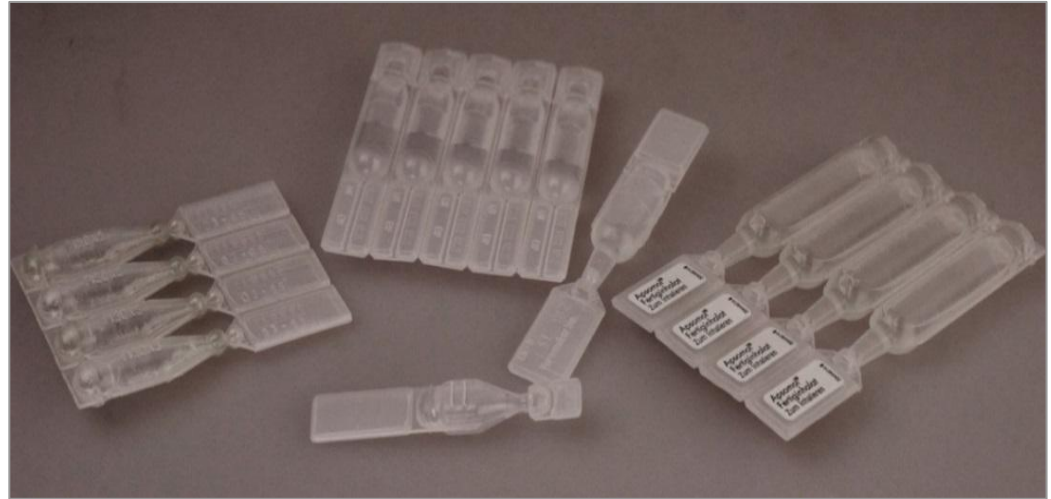
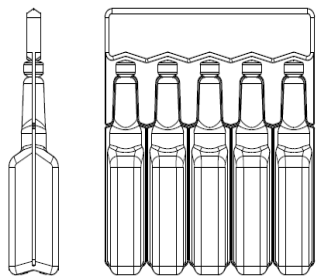


Photo: PATH

Conjoined BFS packaging.



CAD models of multi-mono-dose design.



Images: PATH



Photo: PATH/Greg Kachmarik

PATH 3D-printed prototype.

Parenteral prefill technologies

Manufacturer	Device	Development Status	Image
<u>BD®</u>	<u>Uniject</u>	Market available	A
<u>BD®</u>	<u>Hypak</u>	Market available	B
<u>Gerresheimer</u>	<u>Gx RTF®</u>	Market available	C
<u>Taisei Kako Co., Ltd</u>	<u>ClearJect™ (COC polymer)</u>	Market available	D
<u>Rommelag</u>	<u>BFS for injection</u>	In development	E
<u>Angela Brevetti</u>	<u>Secureject®</u>	Market available	F



Reconstitution Technologies

Manufacturer	Device	Development Status	Image
Vetter	Lyo-Ject	Market available	A
Eulysis	SVS	In development	B
LyoGo	LyoGo	In development	C
LyoTip	LyoTip	In development	D



Photo: Vetter

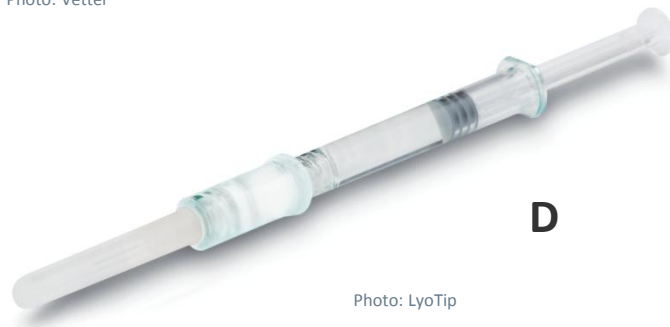


Photo: LyoTip



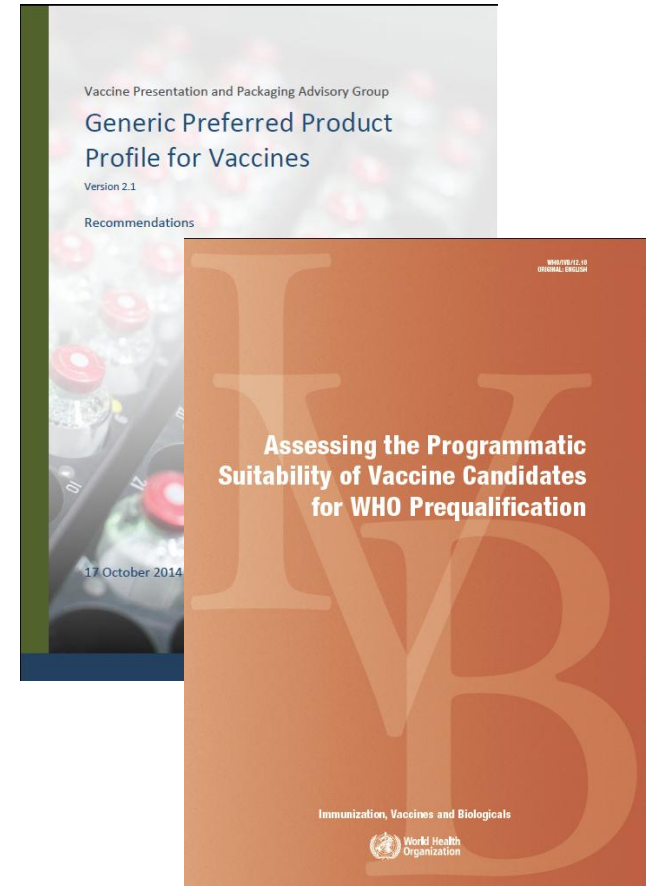
Photo: Eulysis



Photo: Lyogo

Key considerations—vaccine delivery technologies

- Integrate new technology early in vaccine development process.
- Ensure alignment with generic preferred product profile for vaccines—pursue consultation with VPPAG.
- Confirm programmatic suitability for WHO prequalification.
- Estimate device costs (cost of goods, cost per delivered dose).
- Assess potential cold chain impact.
- Confirm human factors/health care worker usability.



Thank you



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