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PharmaJet[®]

Helping You Protect Every Last Child



Tropis[®] Needle-Free Injection
and Polio Eradication

Did You Know?

The World Health Organization's (WHO) Polio Eradication and Endgame Strategic Plan 2013-2018¹ calls on countries to to:

- **Introduce at least 1 dose of inactivated polio vaccine (IPV)** into routine immunization schedules
- **Strengthen routine immunization**
- **Phase out oral polio vaccine (OPV)** starting with OPV type 2, which has caused more than 24 outbreaks with approximately 1000 cases of vaccine derived polio around the world in recent years.²



OPV

Vision:
100% IPV



IPV

Current Challenges

- **Vaccine supply shortage – supply is less than half the demand**
 - Higher dosage requirement with traditional intramuscular/subcutaneous delivery
 - Most countries are faced with a lack of supply or severe shortage of the vaccine needed to protect their population
 - Continued shortage anticipated for years to come
- **Increased Cost** - IPV is up to 15x more expensive than OPV³

Clinical researchers identified ways to stretch the limited supply of injectable polio vaccine

- Clinical studies performed by the WHO, CDC and Gates Foundation have shown that **two fractional doses of intradermal IPV (fIPV) (2 x 0.1mL) are superior to one full dose (0.5mL) administered intramuscularly.**⁴
- fIPV uses **60% less vaccine** and has no safety concerns⁵.

For More Information

- Planning for IPV Introduction, FAQs, http://www.who.int/immunization/diseases/poliomyelitis/inactivated_polio_vaccine/ipv_general_faq_04mar2014.pdf?ua=1
- Scientific rationale for IPV introduction and OPV withdrawal, http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/rationale/en/
- SAGE discussion statement in relation with the IPV supply situation; 10 March, 2016; http://www.who.int/immunization/sage/meetings/2016/april/SAGE_statement_IPV_situation.pdf?ua=1

Sources

1. About the polio endgame strategic plan, http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/about/en/
2. Position paper on Polio vaccine, The World Health Organization - Weekly epidemiological record - 25 MARCH 2016, 91th YEAR - No 12, 2016, 91, 145-168; <http://www.who.int/wer/2016/wer9112.pdf?ua=1>
3. Polio Eradication initiative, <http://polioeradication.org/news-post/innovation-series-the-last-millimetre/>
4. Immunogenicity to poliovirus type 2 following two doses of fractional intradermal inactivated poliovirus vaccine: A novel dose sparing immunization schedule. Anand A., et al. Vaccine, 2017 May 19;35(22):2993-2998; <https://www.ncbi.nlm.nih.gov/pubmed/28434691>
5. Early priming with inactivated poliovirus vaccine (IPV) and intradermal fractional dose IPV administered by a microneedle

device: A randomized controlled trial, Anand A., et al., Vaccine.

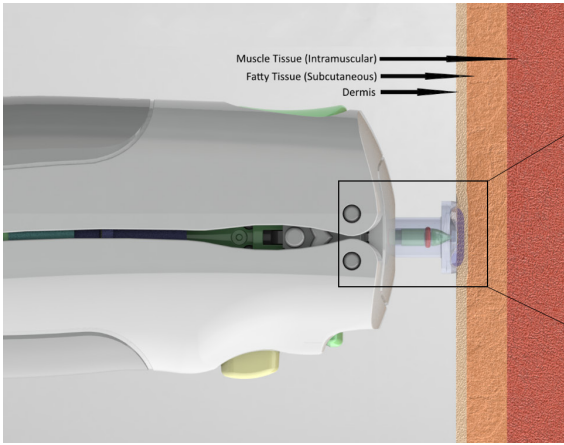
2017 May 19;35(22):2993-2998. doi: 10.1016/j.vaccine.2017.03.008.

Epub 2017 Apr 20. http://www.who.int/immunization/sage/meetings/2016/april/7_Anand_et_al.pdf

6. Use of fractional dose IPV in routine immunization programmes: Considerations for decision-making, WHO Polio Global Eradication Initiative, March 2017; http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/inactivated_polio_vaccine/fIPV_considerations_for_decision-making_March2017.pdf?ua=1
7. IPV introduction and RI strengthening, WHO; http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/inactivated_polio_vaccine/en/
8. Ad hoc Virtual TAG Meeting 20176, 10, March 2017, Washington D.C., USA, p. 7; http://www.who.int/immunization/sage/meetings/2017/april/6_2017_TAG_Ad-hoc_Meeting_Report_EN.pdf
9. A pragmatic trial to quantitatively and qualitatively assess different techniques for the ID administration of fractional dose IPV in a campaign setting in The Gambia, Campaign-based ID fIPV administration trial, Bashorun Adedapo, Polio Research Committee Meeting, Geneva, Switzerland, 11th April, 2017, p. 23; clinicaltrials.gov/NCT02967783
10. Intradermal Administration of Fractional Dose of Inactivated Poliovirus Vaccine (fIPV) Using Tropis® Intradermal Needle Free Injection System, Karachi Pakistan, Community Based Polio Vaccination Campaign, December 2016; Ali Faisal Saleem, Mach Ondrej, Muhammad Tahir Yousafzai, Attaullah Baig, Roland Sutter, Anita KM Zaidi, Aga Khan University, Karachi Pakistan, WHO, Geneva, Switzerland

Refer to Instructions for Use to ensure safe injections and to review risks.

How it Works



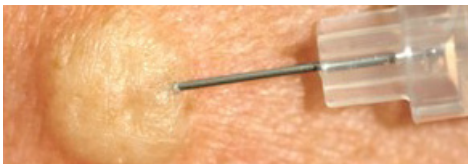
Delivers vaccine into the skin by a narrow, precise fluid stream. No needle.

Compare Needles to Needle-free¹⁰

Mantoux Technique (needle)



- Slow
- Inconsistent/painful
- Technically difficult



Needle-free Technique



- Fast – about 1/10th second
- Precise/consistent
- Easy



CE
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Two fIPV doses are more immunogenic than one full dose

Author	Year Published	Country	Schedule	% Immunogenicity	
				One Full-Dose IPV	Two Fractional Doses IPV
Resik ⁶	2013	Cuba	IPV	63% (4 mos)	98% (4+8mos)
Anand A ⁶	2015	Bangladesh	IPV	39% (6wks)	81% (6+14 wks)

Endorsements

WHO Strategic Advisory Group of Experts (SAGE): *“Given the ongoing IPV shortage and available data on ID IPV, the WHO recommended that countries adopt a two fractional dose IPV schedule in the routine immunization and outbreak response.”*⁷

Technical Advisory Group on Vaccine-preventable Diseases (TAG) – Pan American Health Organization (PAHO): *“Countries that administer more than 100,000 doses of IPV each year and have the capacity to adequately train health care workers and supervise implementation should immediately begin to prepare to implement a fractional dose IPV schedule. These countries include: Argentina, Bolivia, Brazil, Chile, Colombia, Cuba, Ecuador, El Salvador, Honduras, Nicaragua, Paraguay, Peru, Uruguay and Venezuela.”*⁸

PharmaJet Tropis®

Vaccinate more children consistently and safely



Stretches limited resources

- Fractional dose can vaccinate 2-3x more children with the same amount of vaccine
- Get 25% more doses out of a vial⁹
- Injector tested to 20,000 uses



Avg. Doses/ Vial*

Needle/syringe	50
Tropis Needle-free	63

*Doses extracted from a 5mL IPV multi-dose vial

Safe

- Auto-disabling, single use Syringe
- Eliminates needlestick injuries
- Reduces needle disposal and sharps management costs

Easy

- Minimal training required
- Consistent and accurate point and click intradermal vaccination
- 50-70% less preparation and administration time¹⁰

Comparison of Intradermal Devices Field Experience⁷

Average time to prepare and administration (seconds)

Tropis
48

WestPharm
152

Star Syringe
102

BCG Syringe
112

Simple 4-Step Process

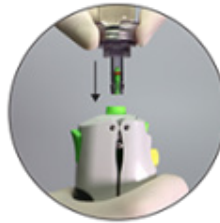
1 Prepare the Injector



2 Fill the Syringe



3 Load Injector



4 Give Injection (Deltoid or Lateral Thigh)

