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SCHOOL OF MEDICINE

Abstract # 199: THE RECIPROCATING PROCEDURE DEVICE FOR FINE NEEDLE ASPIRATION BIOPSY OF THE THYROID

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Disclosures

- o Dr. Randy Sibbitt and Dr. Wilmer Sibbitt are the inventors of the reciprocating procedure device (RPD) and its derivative devices.
- o The patents for the RPD are owned by the University of New Mexico.
- o There was no industry support for this presentation.



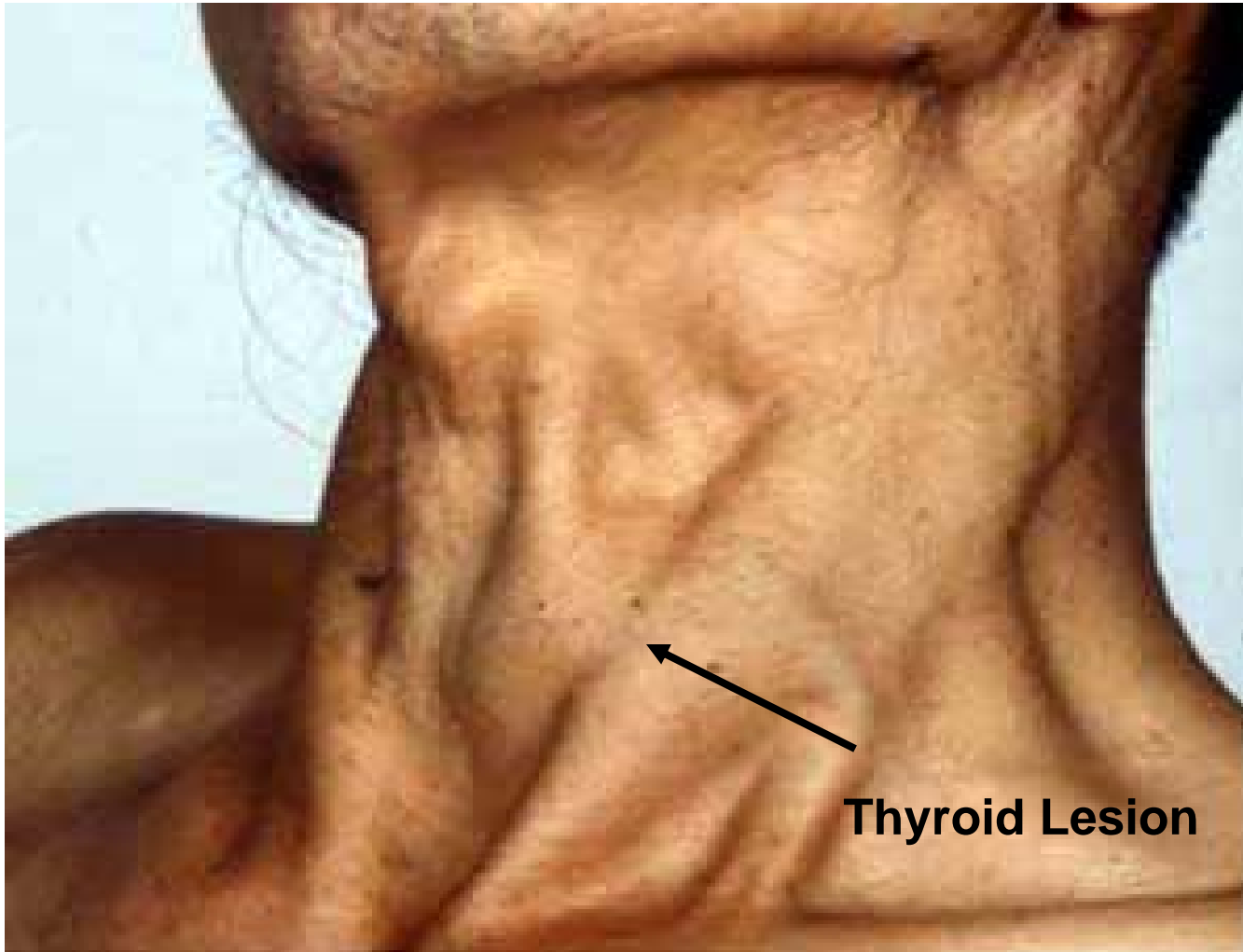
Background: Thyroid Nodules and Thyroid Cancer

- 40% of the population has thyroid nodules by ultrasound.
- Cystic lesions and solid lesions less than 1 cm in diameter are unlikely to be carcinoma and can be observed or biopsied.
- Isolated hypoechogenic lesions, lesions with indistinct margins, or lesions with punctate calcifications have increased carcinoma risk and should be biopsied.





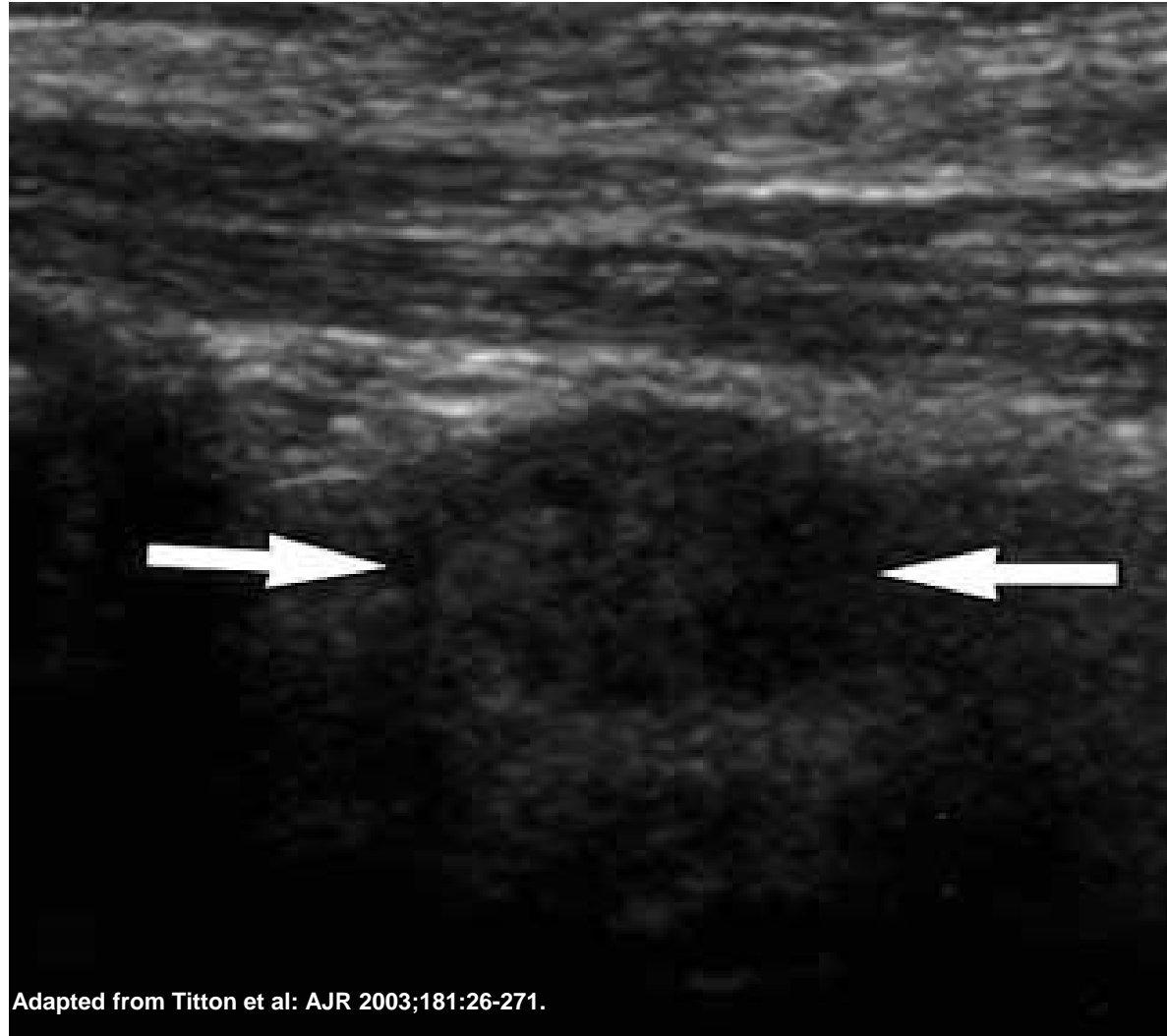
Thyroid Nodule





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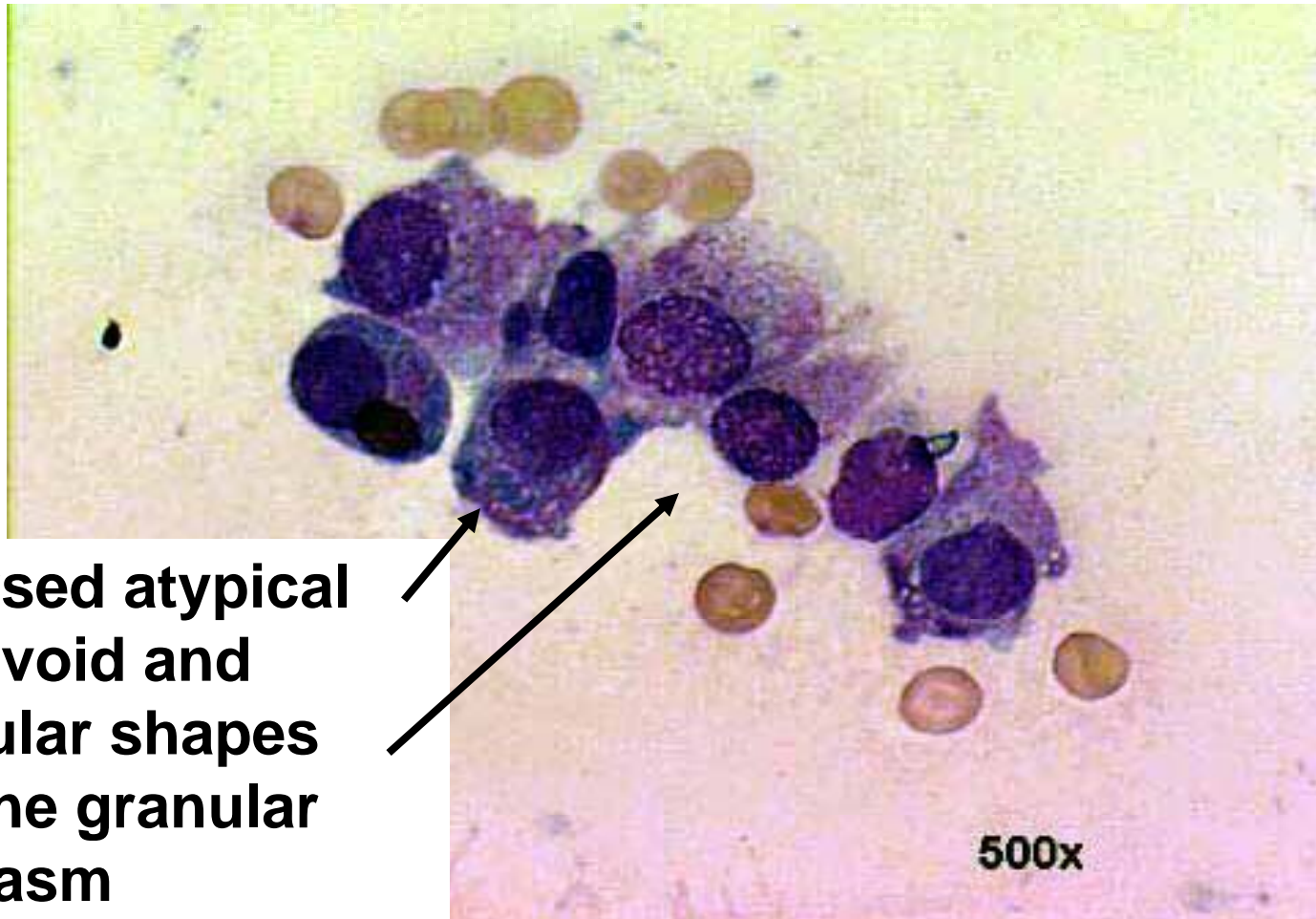
Solid Lesion on Ultrasound in a Patient with Previous Thyroid Carcinoma



Adapted from Titton et al: AJR 2003;181:26-271.



FNA: Thyroid Medullary Carcinoma



Dispersed atypical cells ovoid and triangular shapes with fine granular cytoplasm

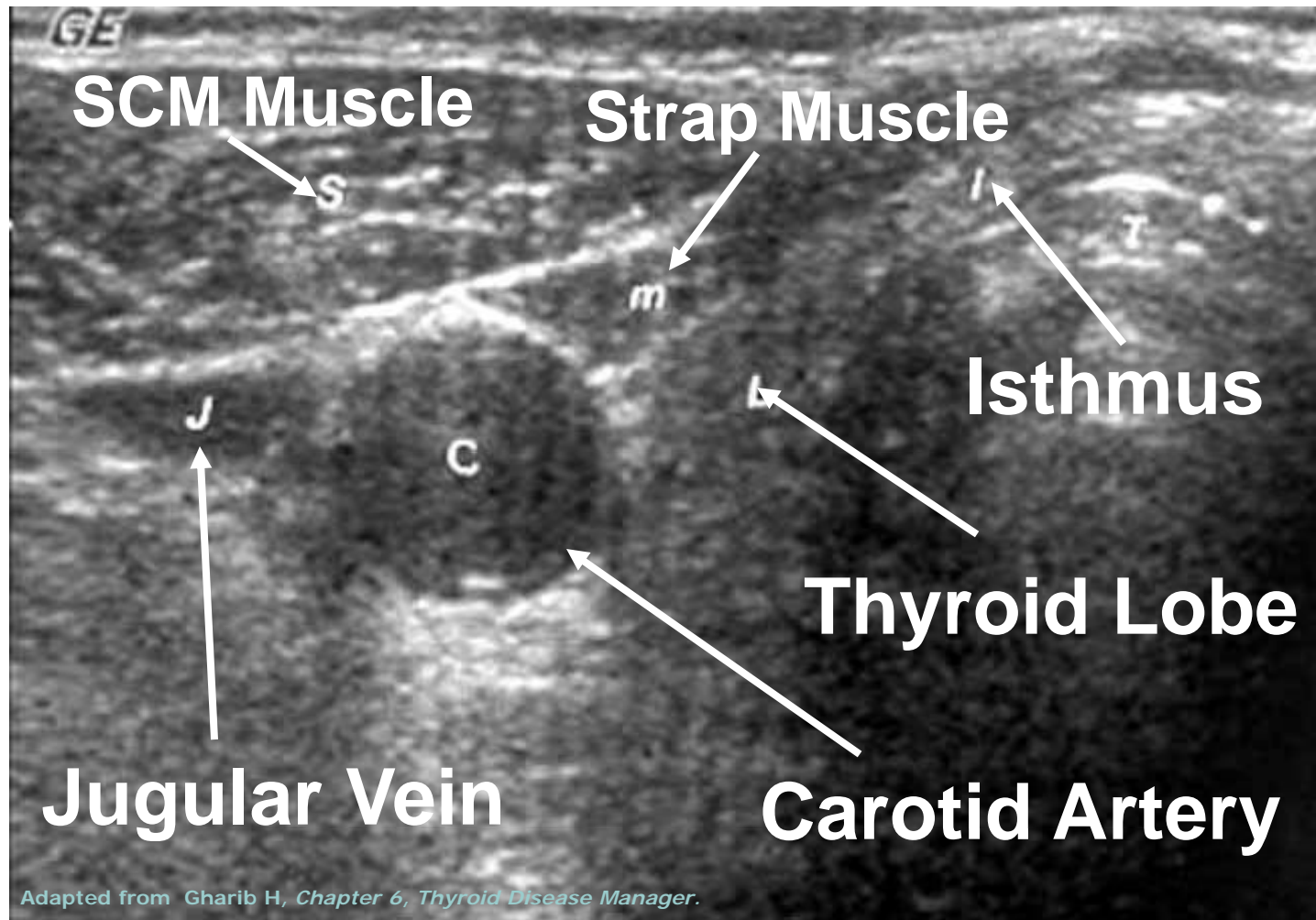


Thyroid Biopsy Techniques for Initial Evaluation

- **Open biopsy** - not indicated for initial evaluation.
- **Cutting needle aspiration biopsy** - no better than FNA, not necessary in thyroid.
- **Fine-needle nonaspiration biopsy (FNNA)** - For thyroid malignancy as good as FNA, but provides inadequate sample in benign lesions.
- **Core needle biopsy** - provides larger sample than FNA and is a competitor to FNA.
- **Fine-needle aspiration biopsy (FNA)** - benign.



Hazardous Anatomy for FNA



Adapted from Gharib H, Chapter 6, *Thyroid Disease Manager*.



Complications of Thyroid FNA

- Complications of Thyroid FNA are generally minimal, but include:
 - Hematoma, Pain, Bruising, Inflammation (common 5-10%, benign).
 - Puncture of carotids (rare, life-threatening).
 - Progressive hematoma with respiratory compromise (rare, life-threatening; requires surgical intervention).
 - Vascular proliferation of the thyroid (rare, dangerous).
 - Pneumothorax and pneumomediastinum (rare, occasionally dangerous).
 - Abscess (rare, life-threatening).
 - Needle track seeding of tumor (rare, life-threatening).
 - Tumor and thyroid necrosis (rare, interferes diagnostically).
 - Vocal cord paralysis (rare, usually reversible).



Hypotheses

- **Hypothesis 1:** FNA of the thyroid with the RPD may yield higher rates of adequate or diagnostic samples.
- **Hypothesis 2:** FNA Biopsy of the thyroid with the RPD may be safer or less painful as the control seems better.



Methods

- **83 needle thyroid biopsies were performed at St. Peters Hospital and the Fort Harrison VAH of Helena , MT by a interventional radiology group.**
- **All biopsies were ultrasound-directed.**
- **27 were performed with standard syringe and needle**
- **56 were performed by FNA using the reciprocating procedure device (RPD).**
- **All samples were analyzed blindly by the cytopathologist and were rated as "adequate" or "inadequate".**



Methods

- FNA was performed with a 1.5 or 2 inch 25 gauge needle under ultrasound direction.
- Vacuum was provided by the Reciprocating procedure device (AVANCA Medical Devices, Inc, Albuquerque, NM, USA).
- The RPD was used because it was already the preferred device because it is disposable, more easily controlled and allowed variable amounts of suction.
- The RPD was operated with one or two hands as necessary.



RPD: FNA of the Thyroid

- Generation of Vacuum for FNA.
- Control of the Needle in FNA.
- Expelling sample for FNA.
- Administration of Local Anesthesia -The RPD is less painful than a traditional syringe as shown in other studies for similar uses.



Design Differences Between the RPD and Traditional Syringe

- The traditional syringe consists of one barrel and one plunger; in the aspiration phase the plunger-syringe complex becomes longer forcing the needle forward into patient tissues.
- The Biosuk syringe likewise has the tendency to advance the needle as the hand is squeezed to apply suction
- The RPD because of its unique design does not become longer and does not force the needle forward, protecting patient tissues.



RPD™

Injection
Plunger

Functional Barrel

Reciprocating
Mechanism

Aspiration
Plunger

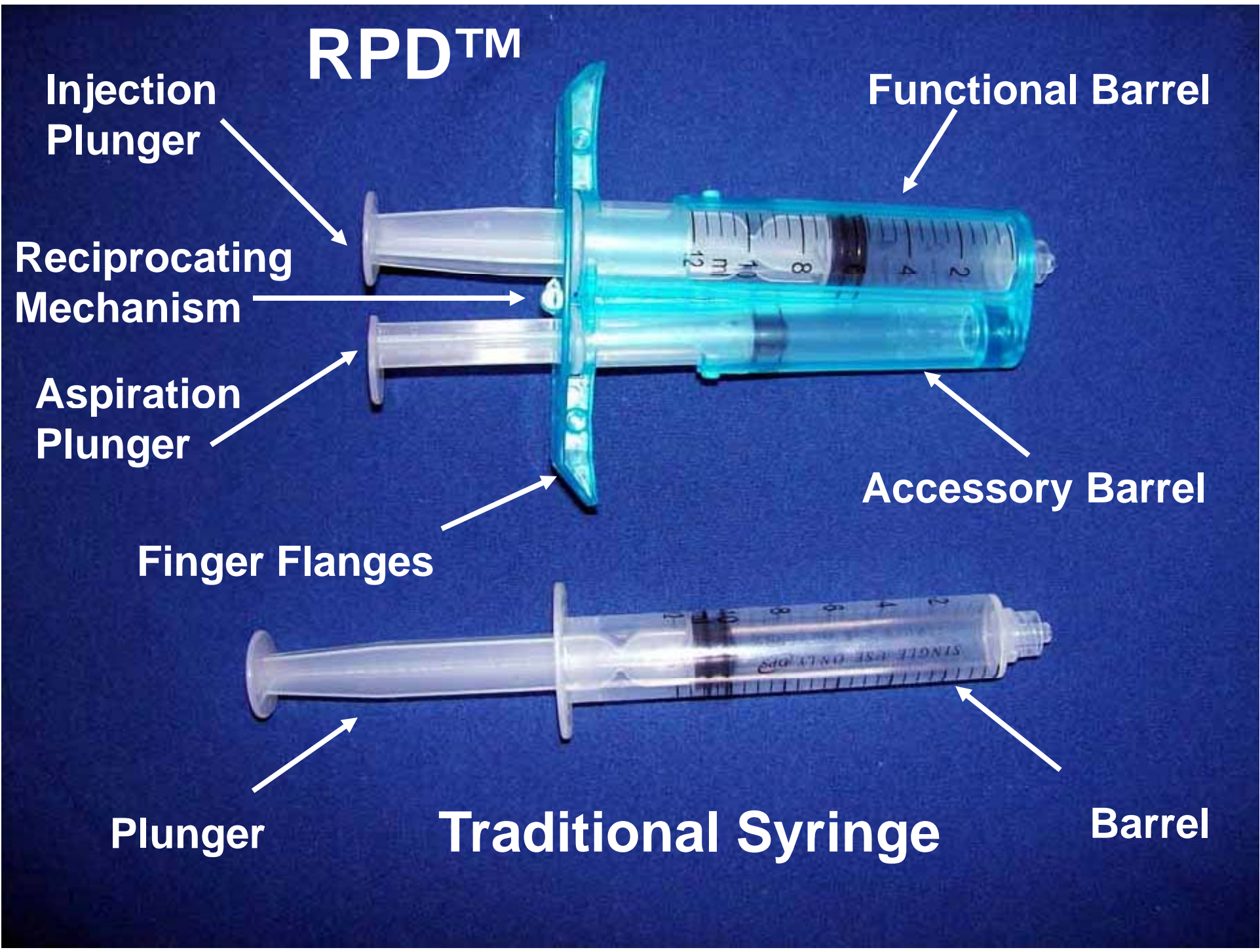
Accessory Barrel

Finger Flanges

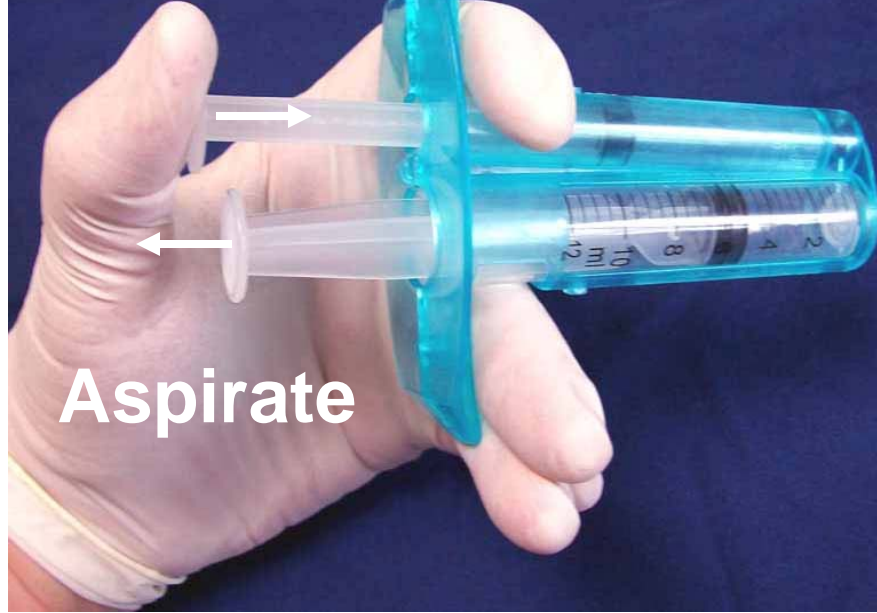
Plunger

Traditional Syringe

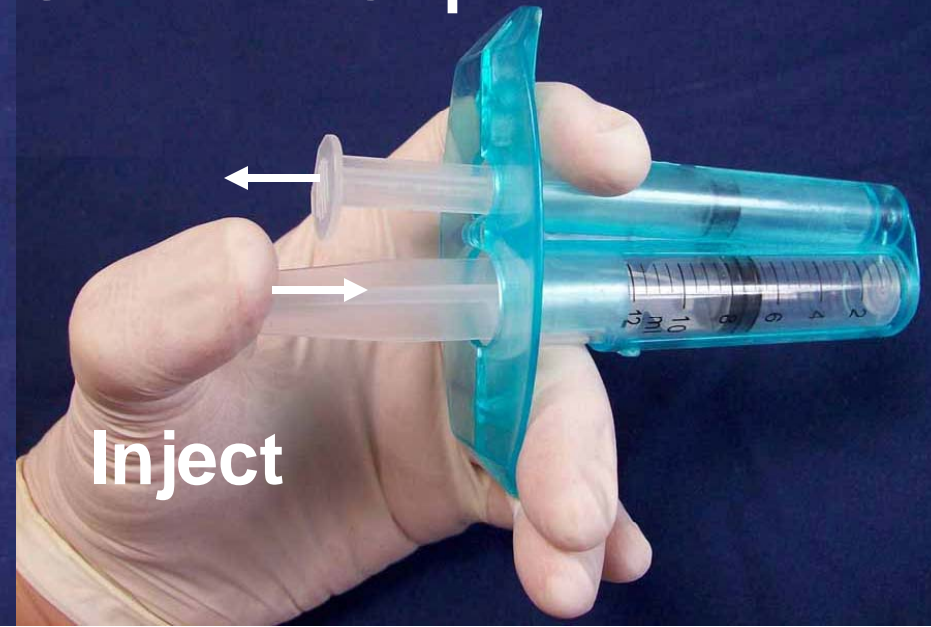
Barrel



One-Handed Standard Grip



Aspirate



Inject

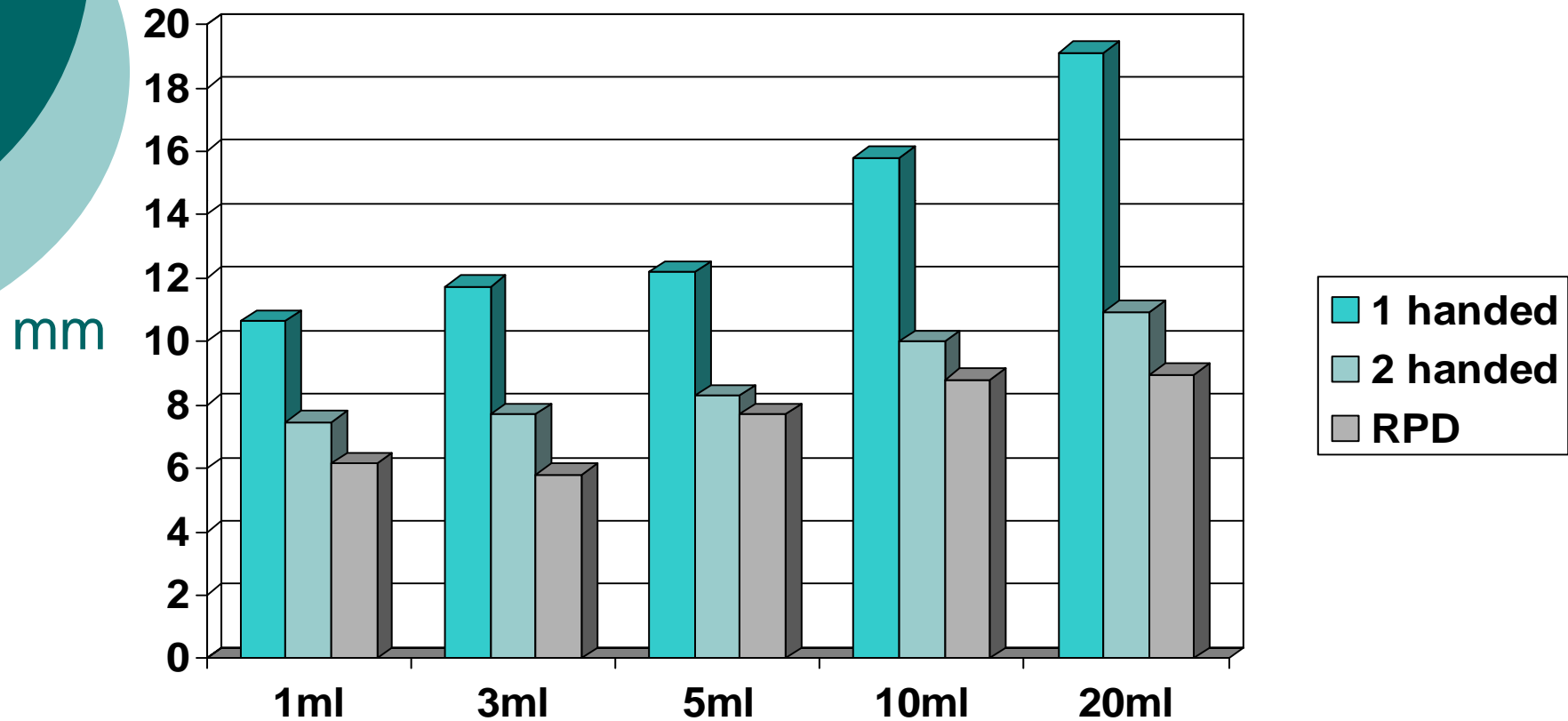
Aspirate with RPD

- the smaller plunger is depressed with the thumb
- index and middle fingers on the finger flanges

Inject with RPD

- the larger plunger is depressed with the thumb
- index and middle fingers on the finger flanges

Physician Control of Syringe and Needle Loss of Control in the Forward Direction

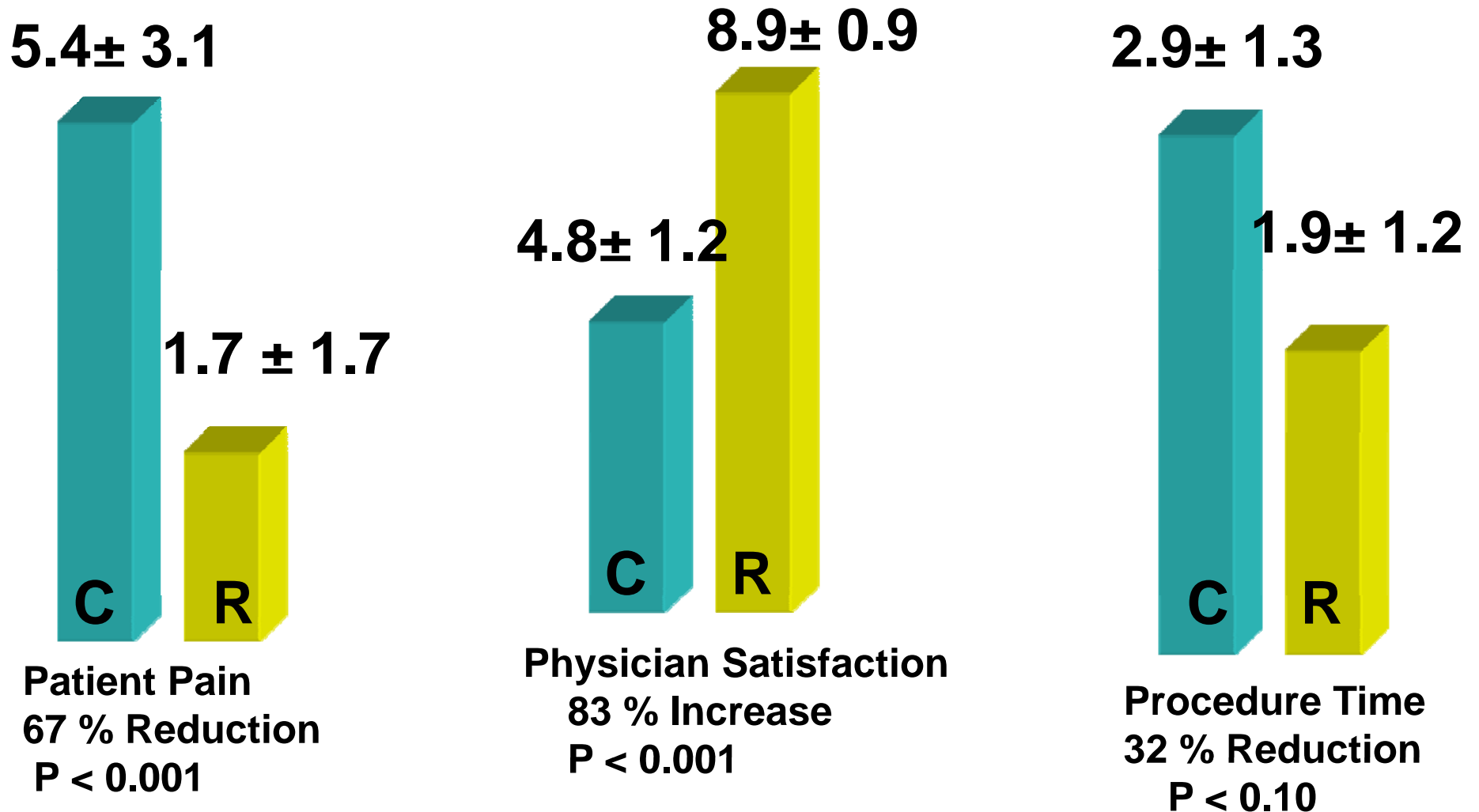


RPD with 1-hand is better controlled than the Traditional Syringe with 1 or 2 hands

From: *J Rheumatol.* 2006;33:771-8; *J Vas Inter Rad* 2007, Abstract 377;
J Vas Inter Rad 2005, Abstract 195

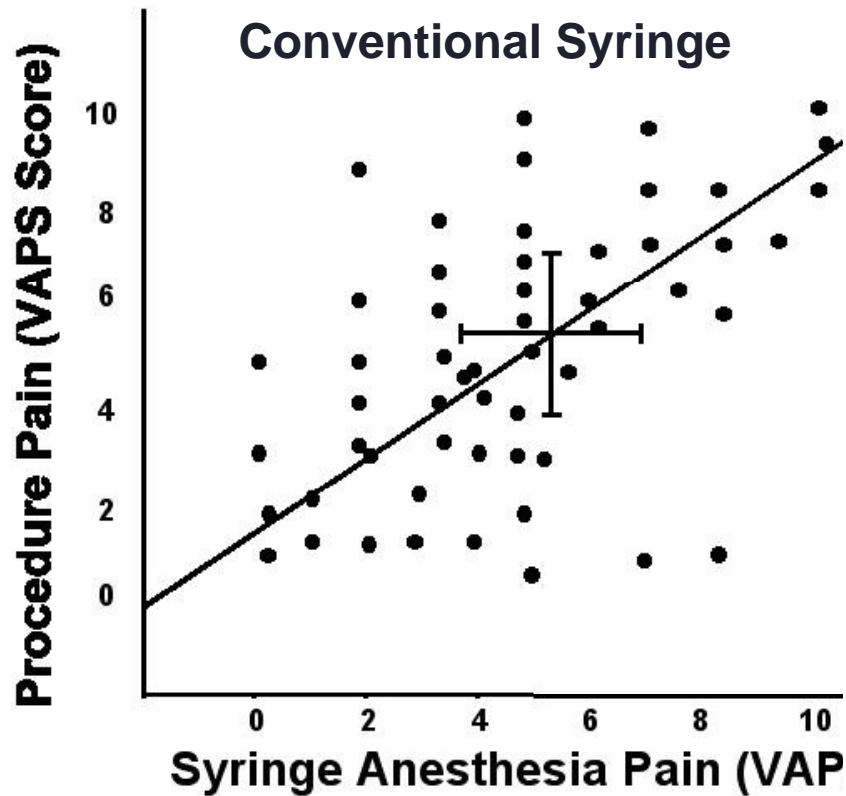


Aspiration of Body Fluids and Tissue: The RPD vs. the Conventional Syringe

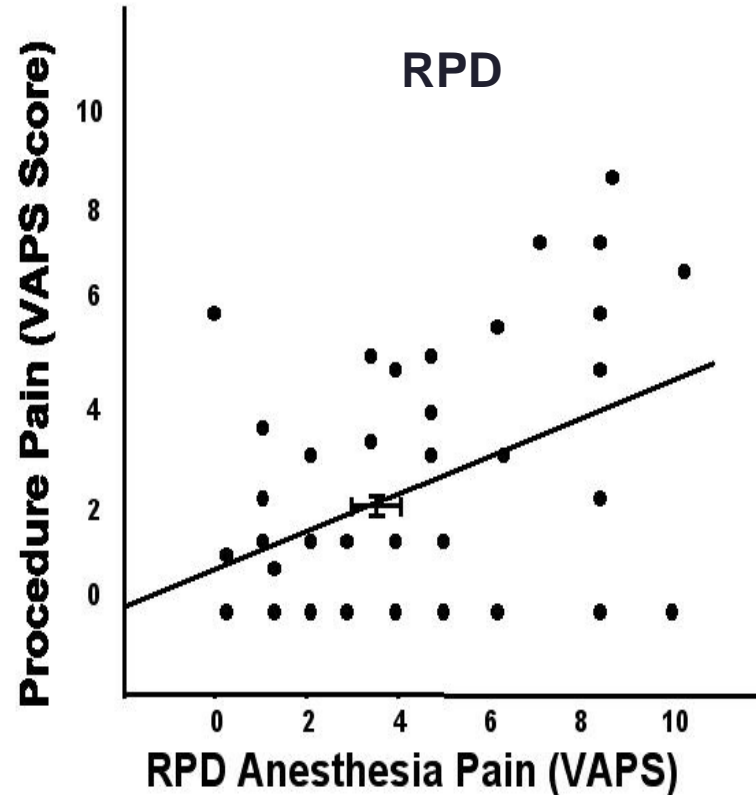


From: *J Rheumatol.* 2006;33:771-8;
Ann Rheum Dis. 2006;65:1084-7
J Vas Inter Rad 2007, Abstract 199

The RPD is Less Painful for Local Anesthesia And Deep Needle Procedures



**Conventional Syringe More Painful
and Less Effective for Local Anesthesia**

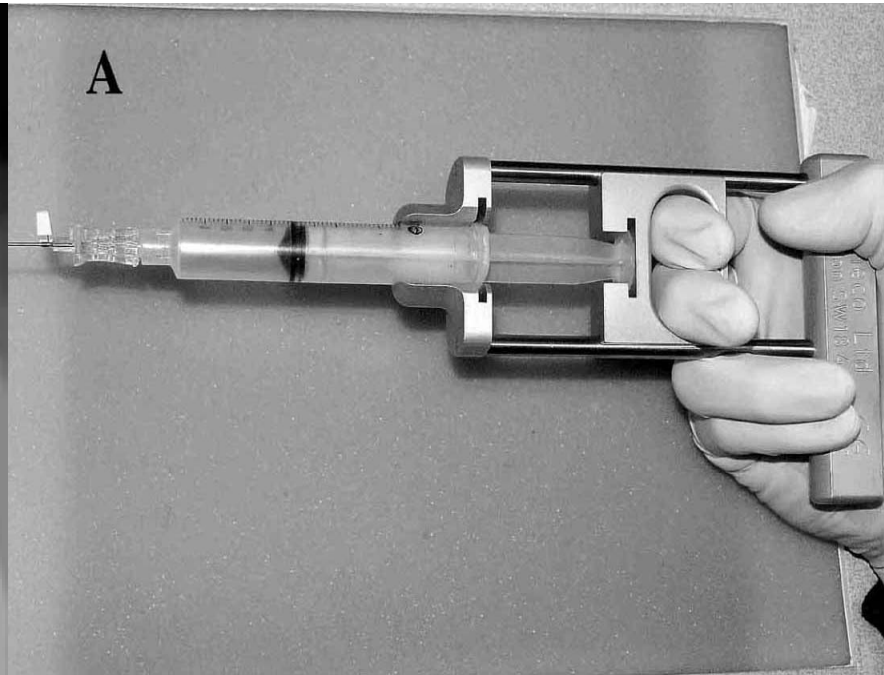


**RPD Less Painful and More
Effective for Local Anesthesia**

The RPD vs Syringe Pistols



Syringe Biopsy Gun

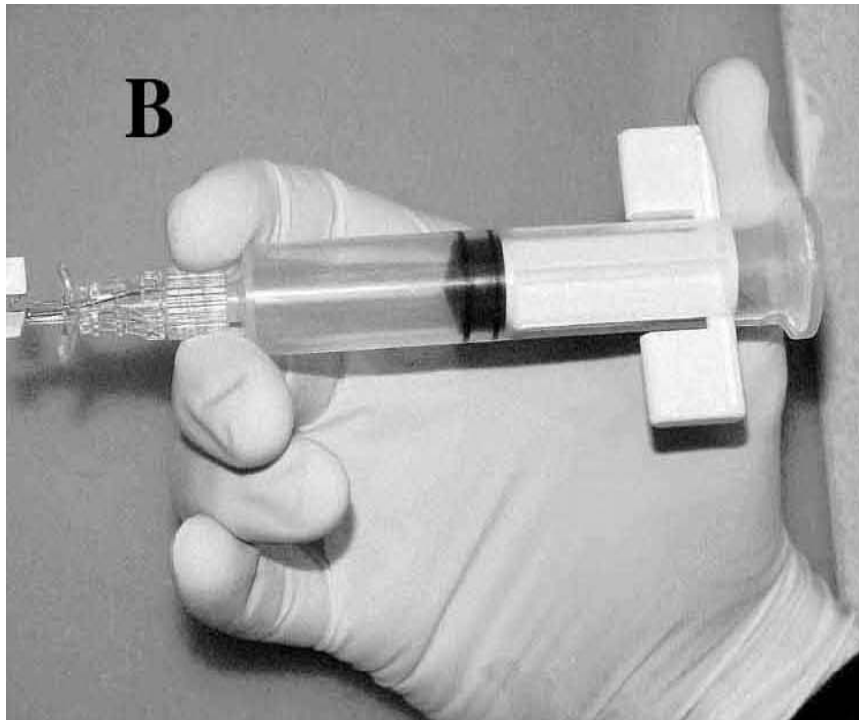


Syringe Pistol

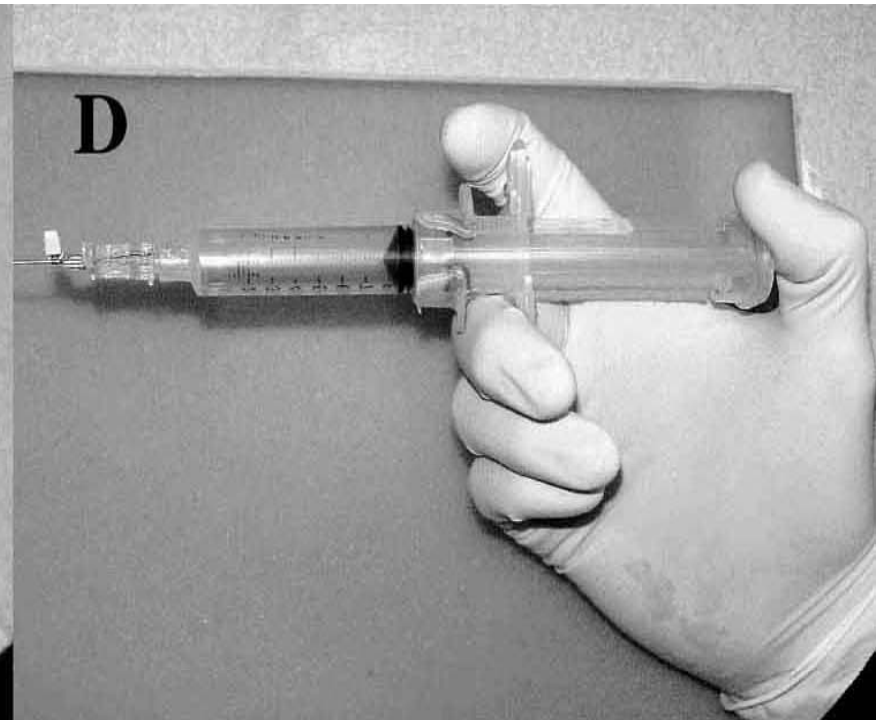
From: *J Vasc Interv Radiol.* 2006;17:1657-69.; *J Vas Inter Rad* 2007, Abstract 199;
Arthritis Rheum 2004:208 (209).



The RPD vs Biopsy Syringes



**RPD Superior
To Bio-Suk**

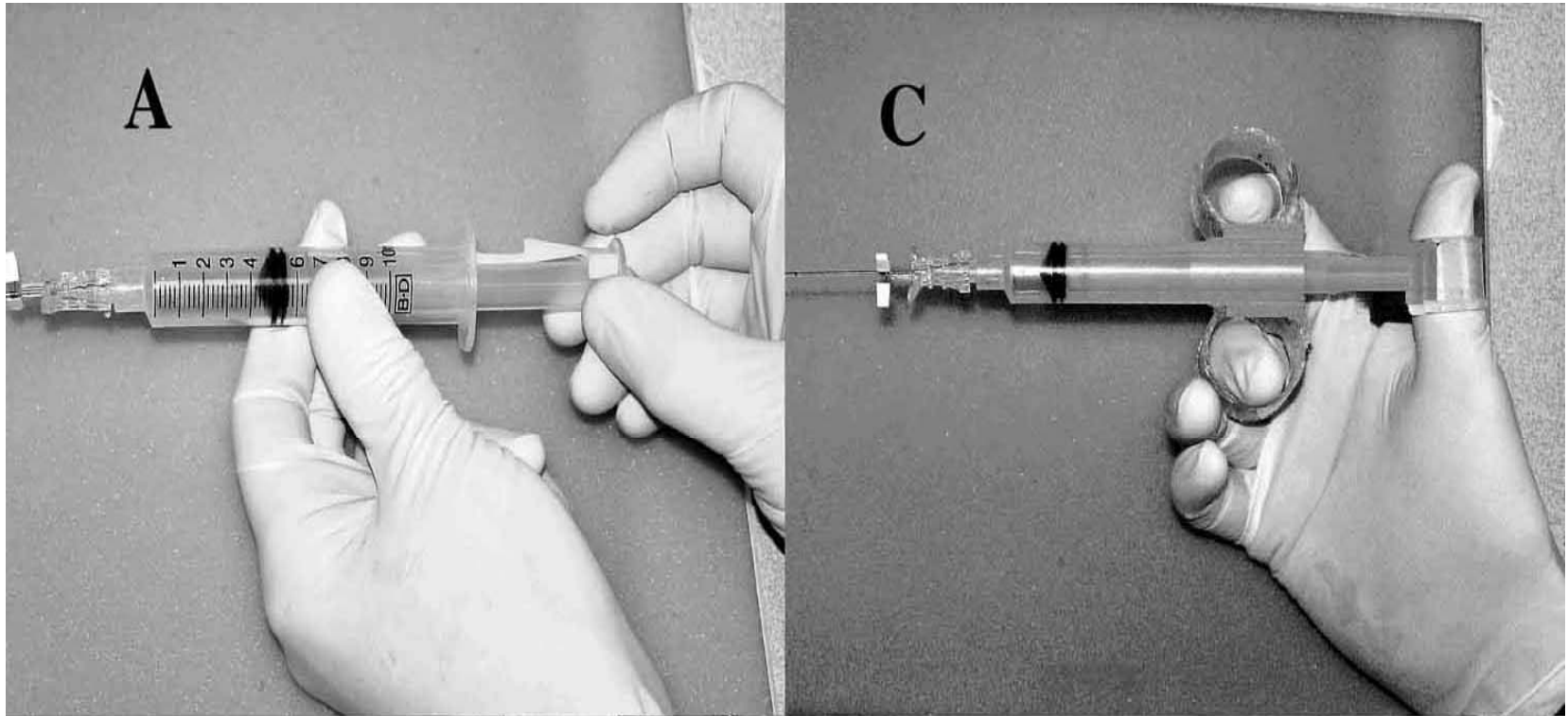


**RPD Superior
To Reverse Syringes**

From: *J Vasc Interv Radiol.* 2006;17:1657-69.; *J Vas Inter Rad* 2007, Abstract 199;
Arthritis Rheum 2004:208 (209).



The RPD vs Control Syringes



**RPD Superior
To Plunger Locks**

**RPD Superior
To 3-Ring Control Syringe**

*From: J Vasc Interv Radiol. 2006;17:1657-69.; J Vas Inter Rad 2007, Abstract 199;
Arthritis Rheum 2004:208 (209).*



Equipment for Thyroid FNA



**OR ThinPrep or
other Pap-type
CYTOLOGIC
PREPARATION FLUID**

Histology Slides and Alcohol Fixative

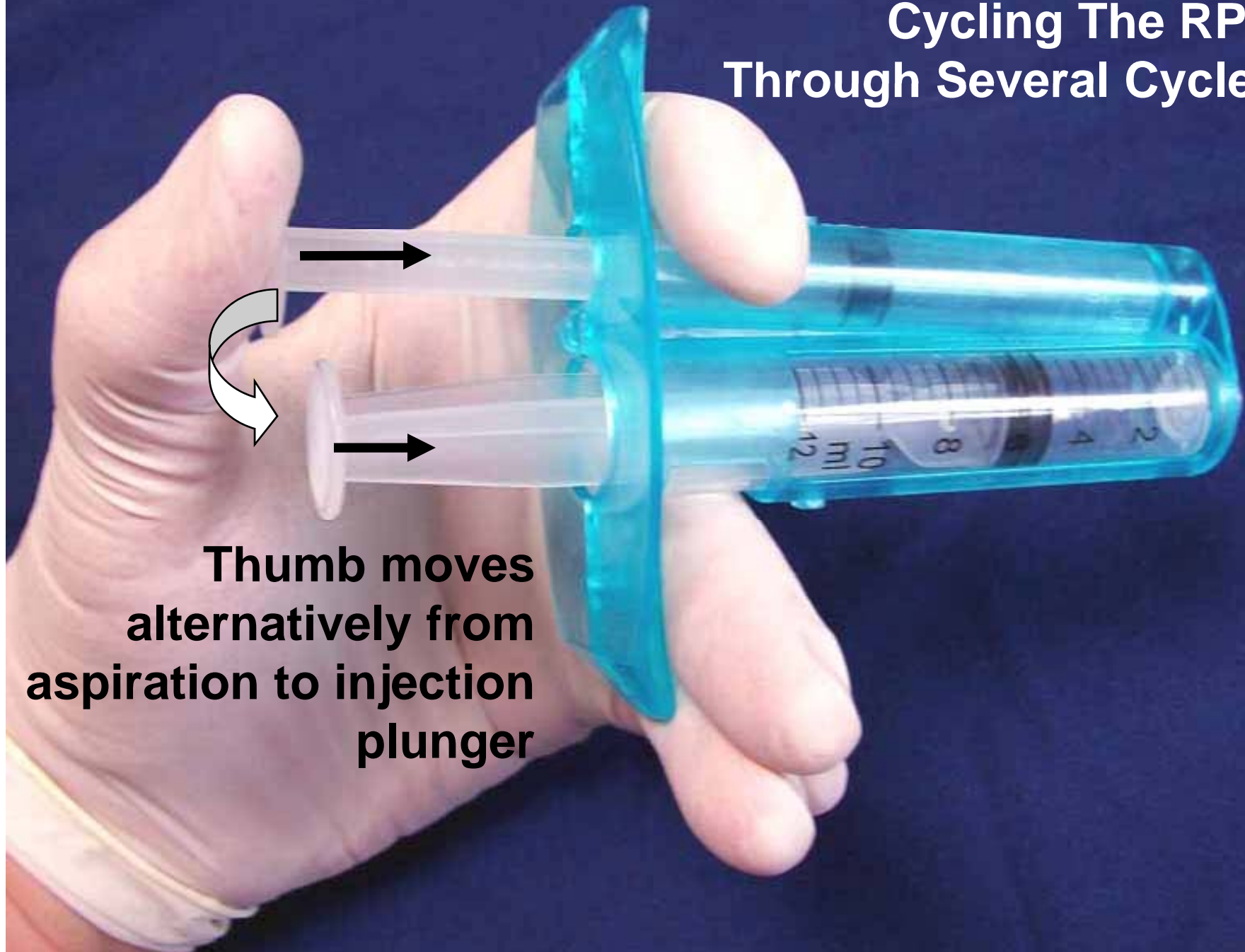




Prepare and Cycle RPD



Cycling The RPD Through Several Cycles



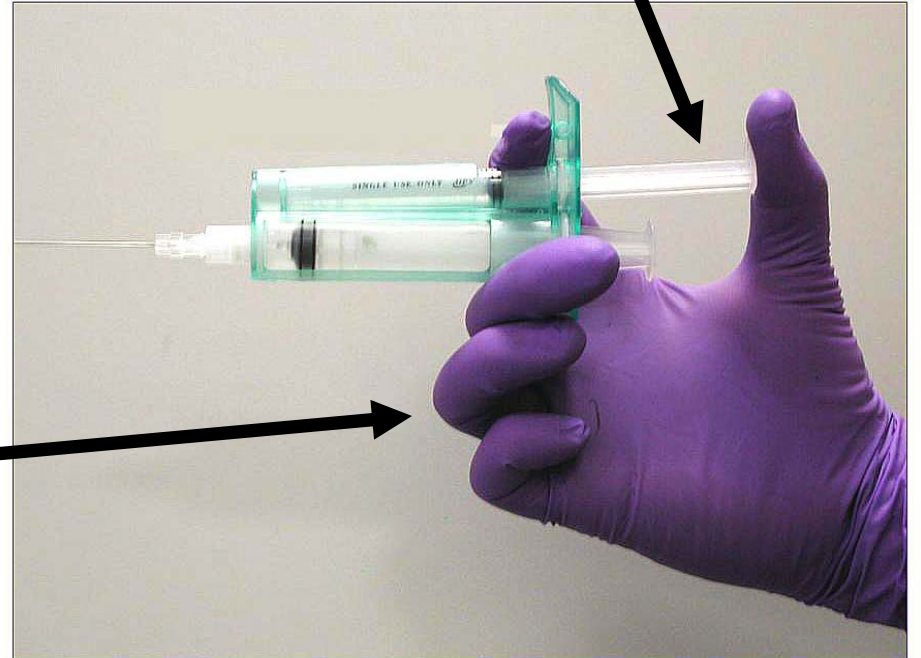
**Thumb moves
alternatively from
aspiration to injection
plunger**



1. Attach Needle to Needle Fitting

2. Hold RPD like a traditional syringe

3. Press Reciprocating Plungers to Aspirate or Inject





Localize Lesion with Ultrasound or Palpation





Anesthetize Thyroid Capsule



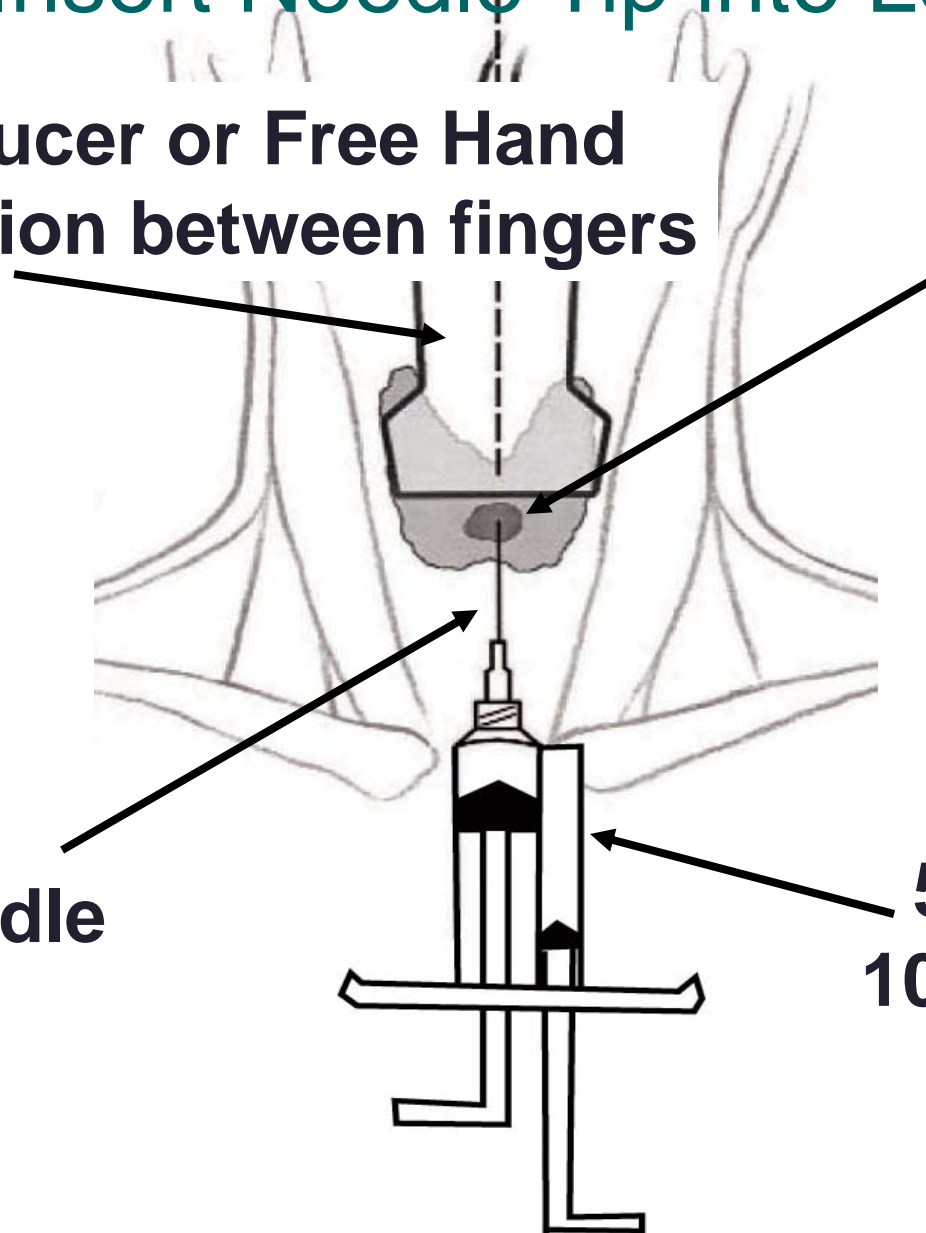
Insert Needle Tip into Lesion

**US Transducer or Free Hand
Holding Lesion between fingers**

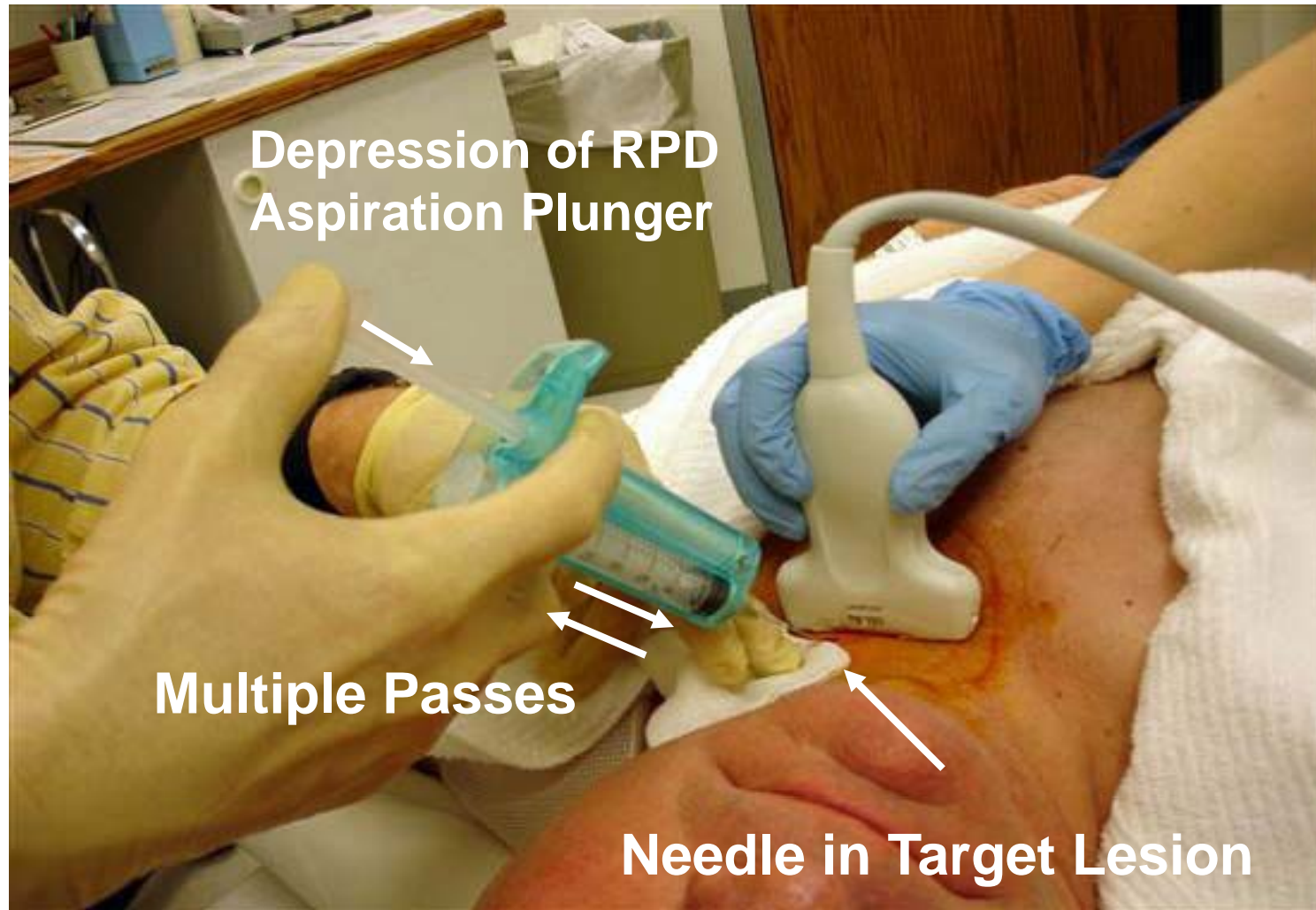
**Thyroid
Lesion**

**25 or 27
gauge needle**

**5 ml or
10 ml RPD**

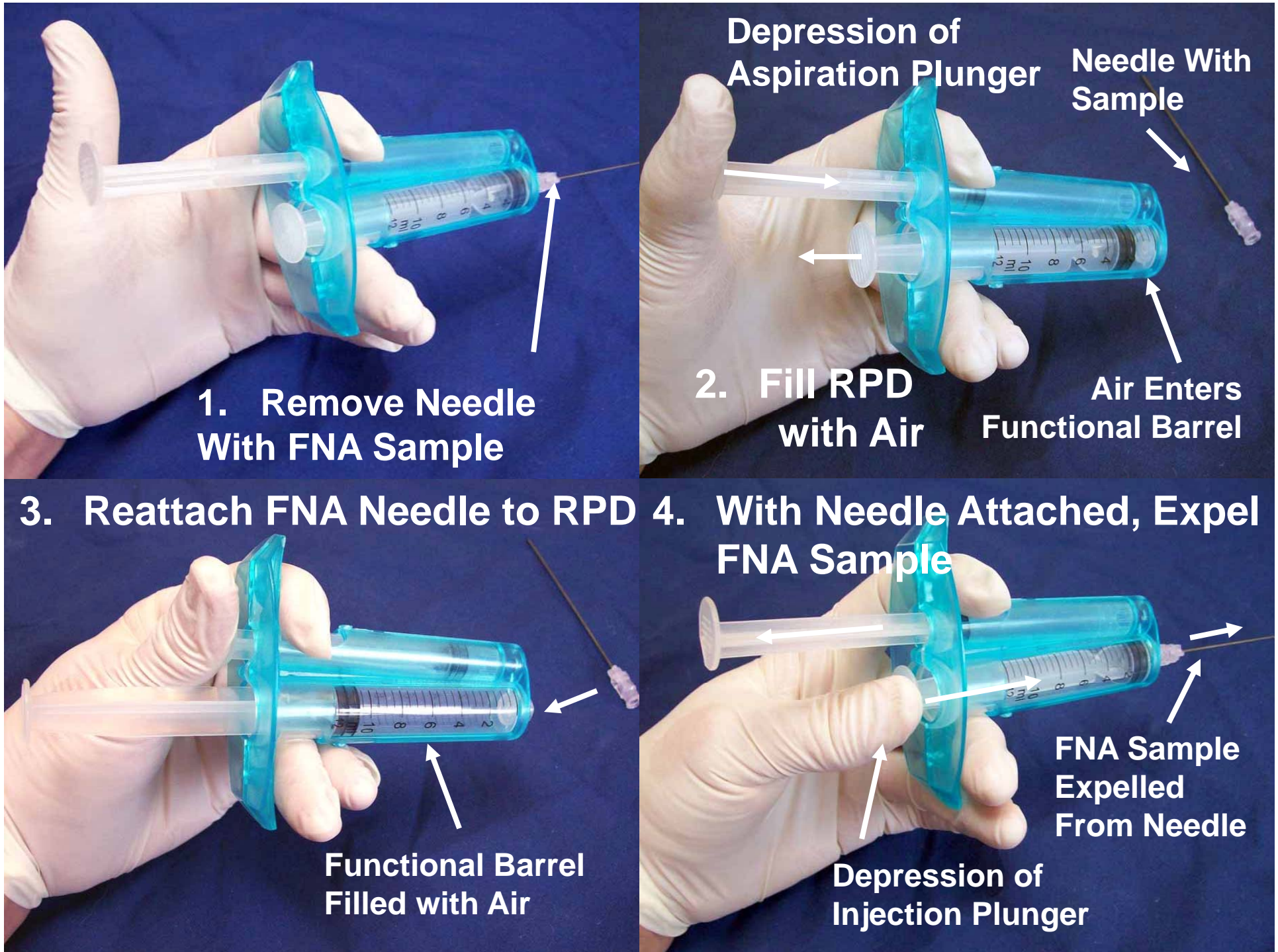


Apply Vacuum with Needle in Lesion

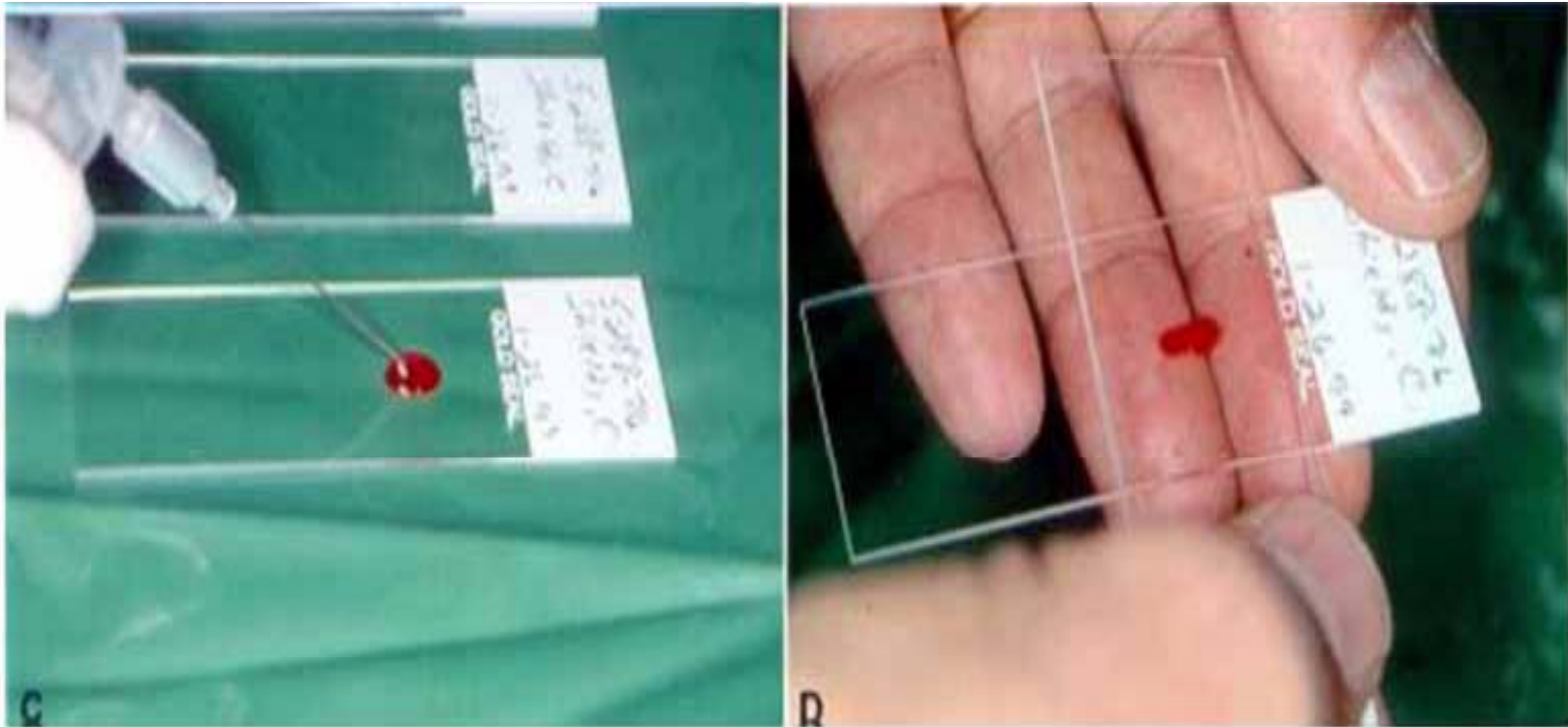


To Prevent Sample from being sucked to Syringe, Release Vacuum **BEFORE** Exiting Skin





Preparation of Cytologic Slides



- 1. Expel sample on Slide**
- 2. Smear between slides**
- 3. Immediately fix slides in alcohol**



**ALTERNATIVELY EXPEL SAMPLE INTO ThinPrep OR other
PAP-like CYTOLOGIC PREPARATION FLUID and SEND TO
PATHOLOGY LABORATORY**



**Once sample is expelled, re-biopsy lesion
multiple times using various levels vacuum
and expel multiple samples into fluid**



After Biopsy Completed

- Apply pressure to biopsy site
- Apply plastic adhesive strip.



CONCLUSIONS:

RPD FNA vs. Core Biopsy of Thyroid

- FNA with the RPD is easier to perform and different levels of vacuum can be achieved
- Use RPD with various levels of vacuum (none, mild, or maximum) to obtain best biopsy specimens in both malignant and benign lesions.
- Operating physicians physicians rated the RPD as superior for FNA of the thyroid.

Sibbitt RR et al: *J Vas Inter Rad* 2007, Abstract 199.



Concluding remarks on Thyroid FNA with the RPD

- Most serious complications of thyroid biopsy are related to poor direction of the needle, resulting unintended puncture of a vital structure.
- The RPD with one hand is better controlled than the traditional syringe, control syringes, syringe pistols and guns used with 1 or 2 hands.
- Unlike syringe pistols and gun, the RPD is disposable, reducing infection risk.
- Since the RPD is a one-handed device, the free hand can be used for other necessary tasks.

