THE UNIVERSITY OF NEW MEXICO ◆ HEALTH SCIENCES CENTER
SCHOOL OF MEDICINE

THYROID BIOPSY WITH THE RECIPROCATING PROCEDURE DEVICE (RPD) © 2006,2007

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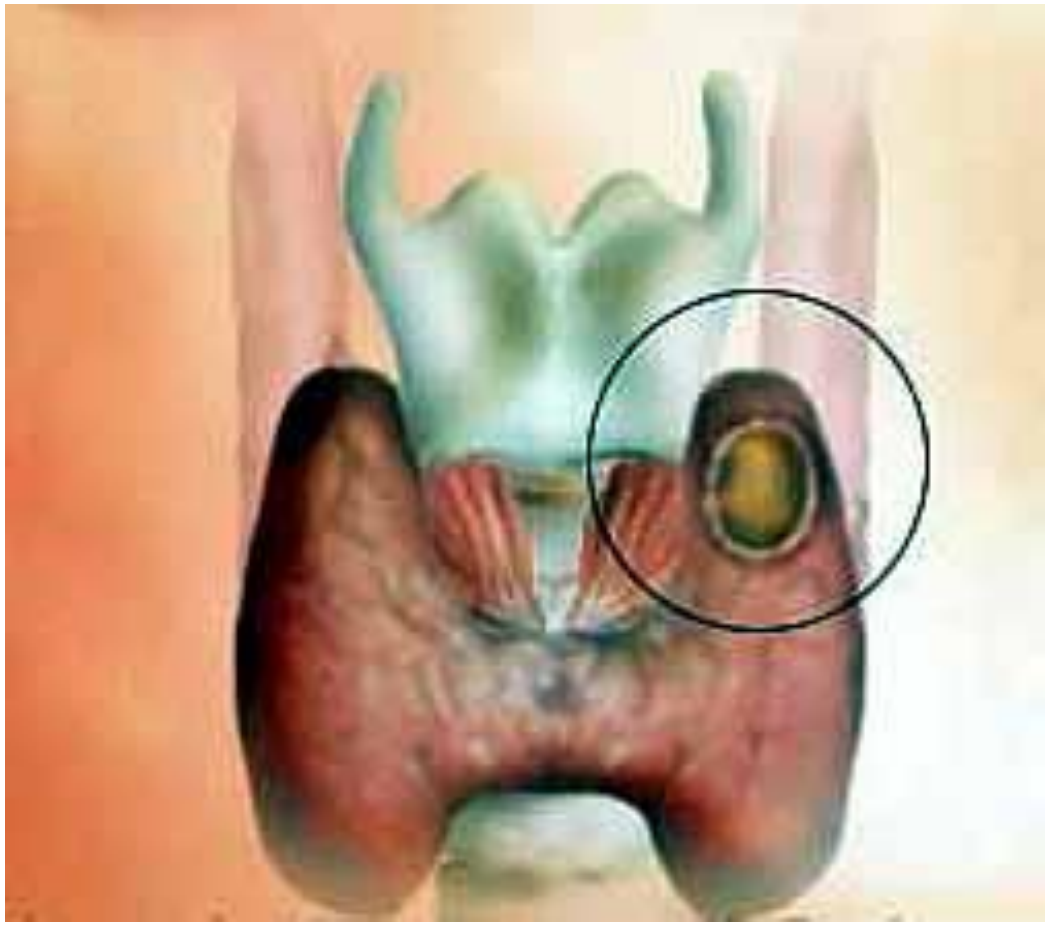
Educational Objectives

- To review the indications for thyroid biopsy and thyroid cyst aspiration.
- To understand the different forms of thyroid biopsy and their indications.
- To understand the advances in technology in fine needle aspiration and cyst aspiration of the thyroid.
- To understand and apply ultrasound-guided FNA and cyst aspiration using the RPD to the thyroid patient.

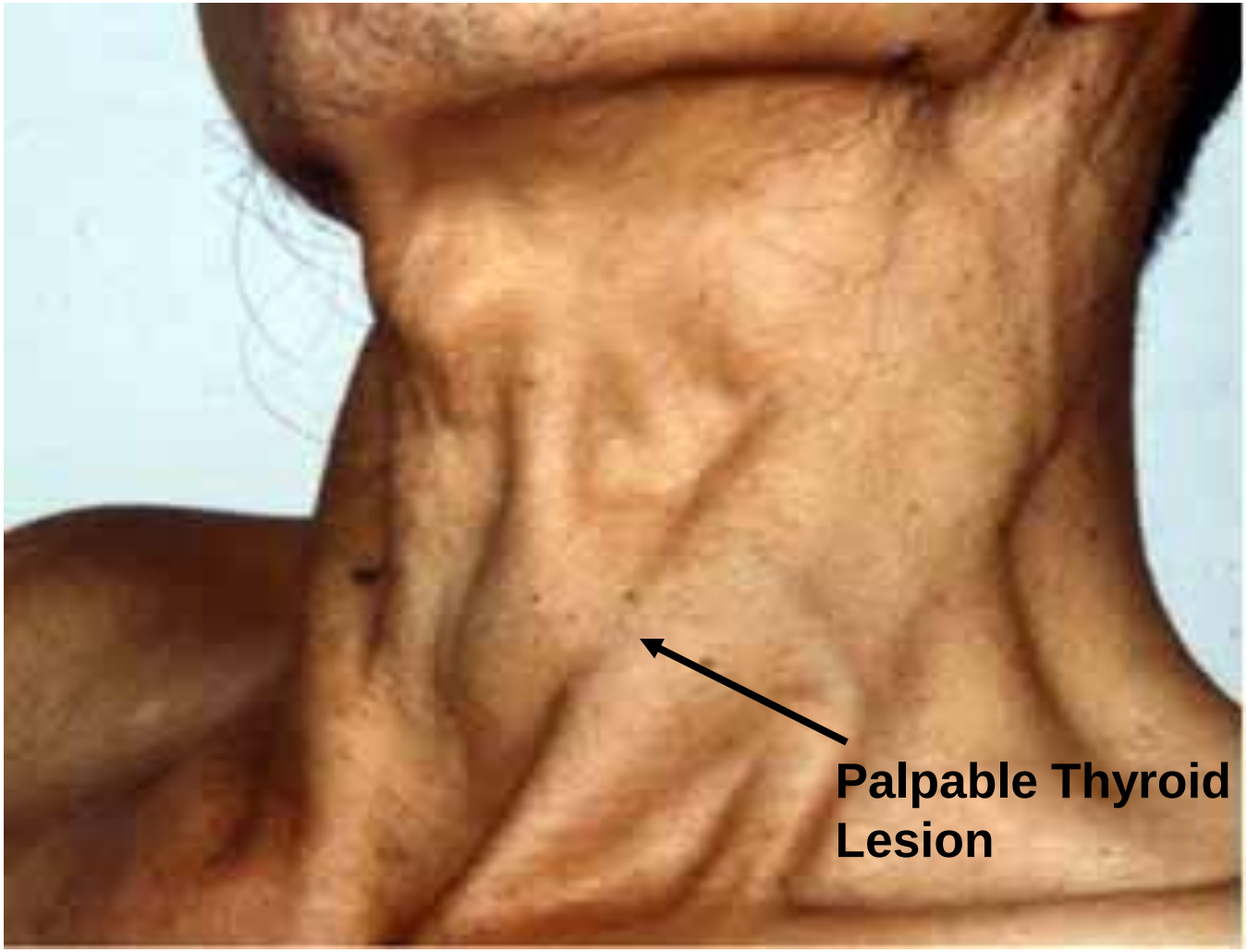
Evaluation and Biopsy of the Thyroid Lesion



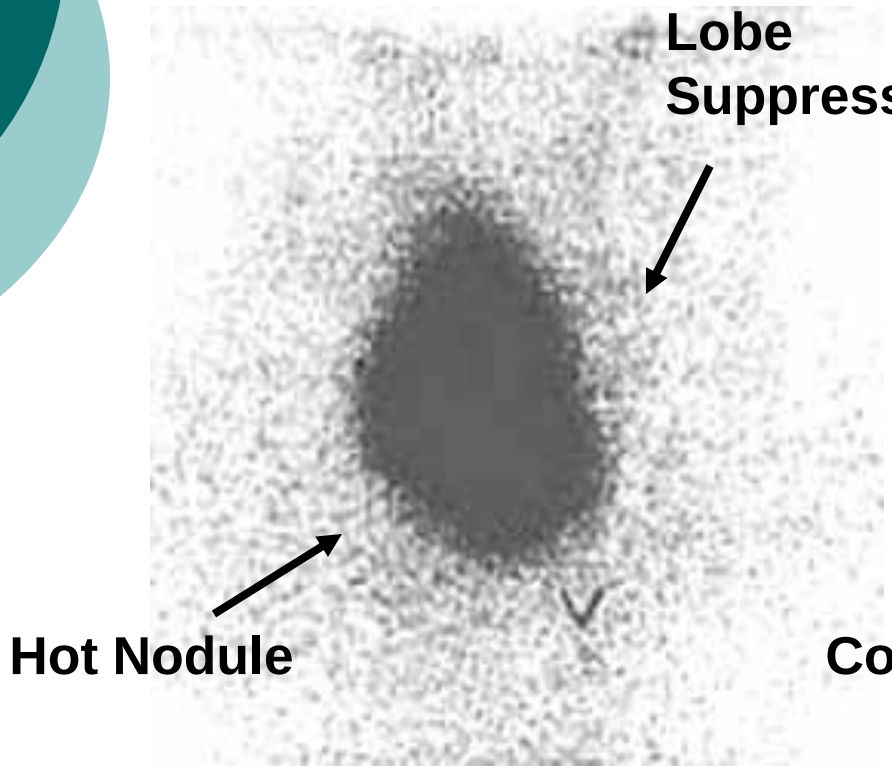
Types of Clinical Thyroid Lesions

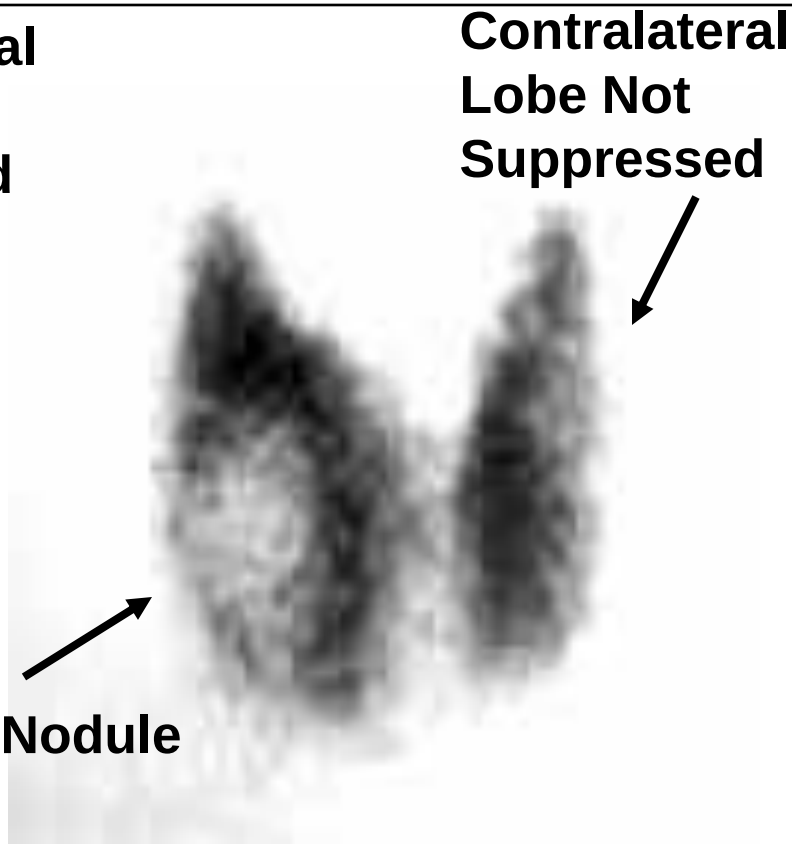
- **Palpable nodule or cyst.**
- **Nodule or cyst on Ultrasound.**
- **Euthyroid lesion.**
- **Hyperthyroid lesion.**
- **Hypothyroid lesion.**
- **Cold euthyroid nodule on I^{131}**
- **Hot hyperthyroid nodule on I^{131}**
- **Hyperthyroid and Hypothyroid lesions may be managed medically first before biopsy.**

Palpable Thyroid Lesion



Hot vs.Cold Thyroid Lesions I^{131}





Hot Nodule

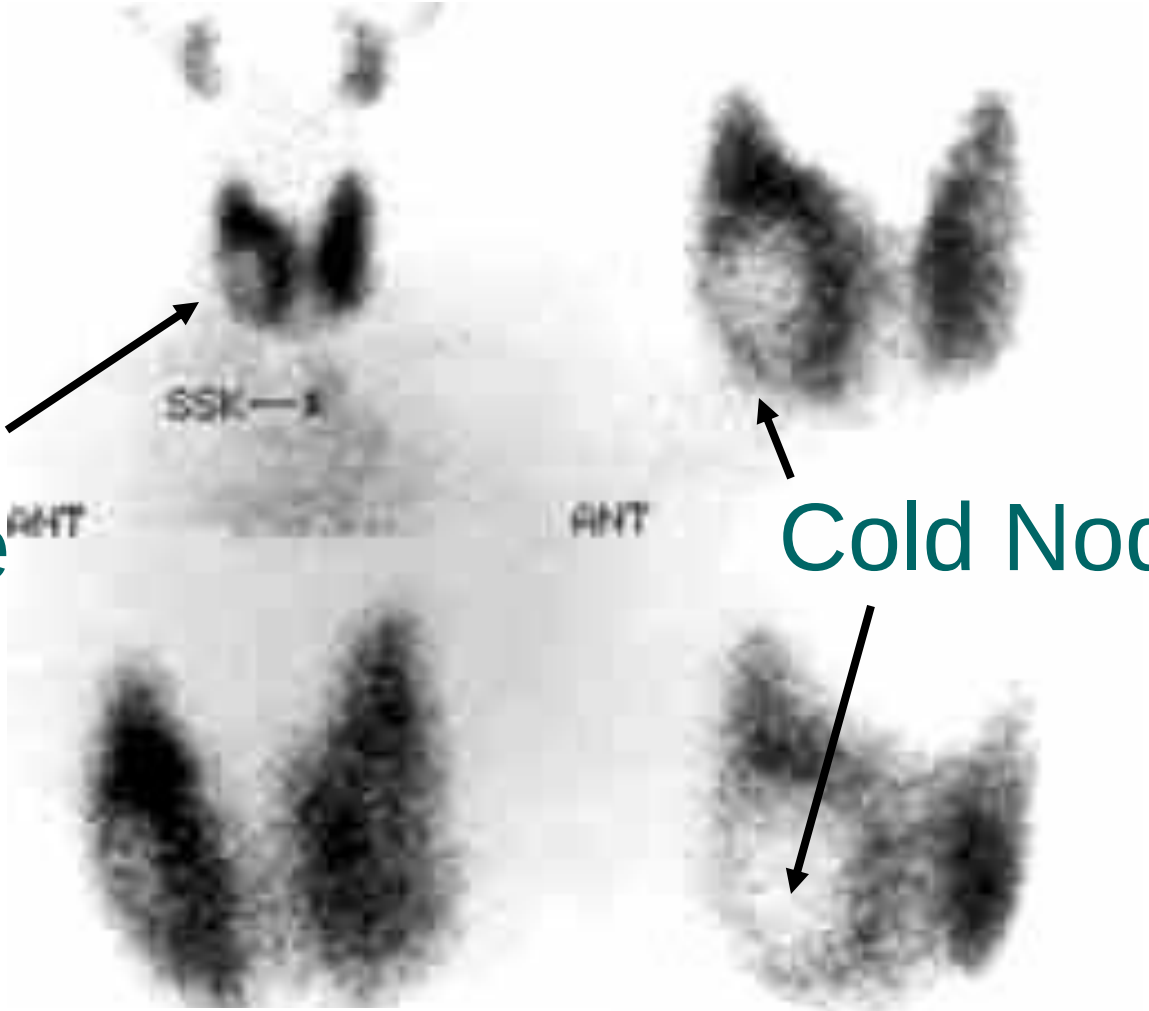
Cold Nodule

Adapted from *Lange et al Geneeskunde 2001;43 (2) and G Henneman, Chapter 13, Thyroid Disease Manager.*

Hyperthyroid Lesions

- Hyperthyroid lesions often require complex medical management.
- Cold hyperthyroid lesions usually not biopsied until patient is euthyroid.
- Hot hyperthyroid lesions are usually not biopsied but rather treated first with I^{131} ablation.
- Hot hyperthyroid lesions or nodules are not usually appropriate for biopsy as an initial management step.

Cold Euthyroid Nodules on I^{131} may be Cancer or Benign



Cold Nodule

Cold Nodule

Adapted from *Lange et al Geneeskunde 2001;43 (2).*

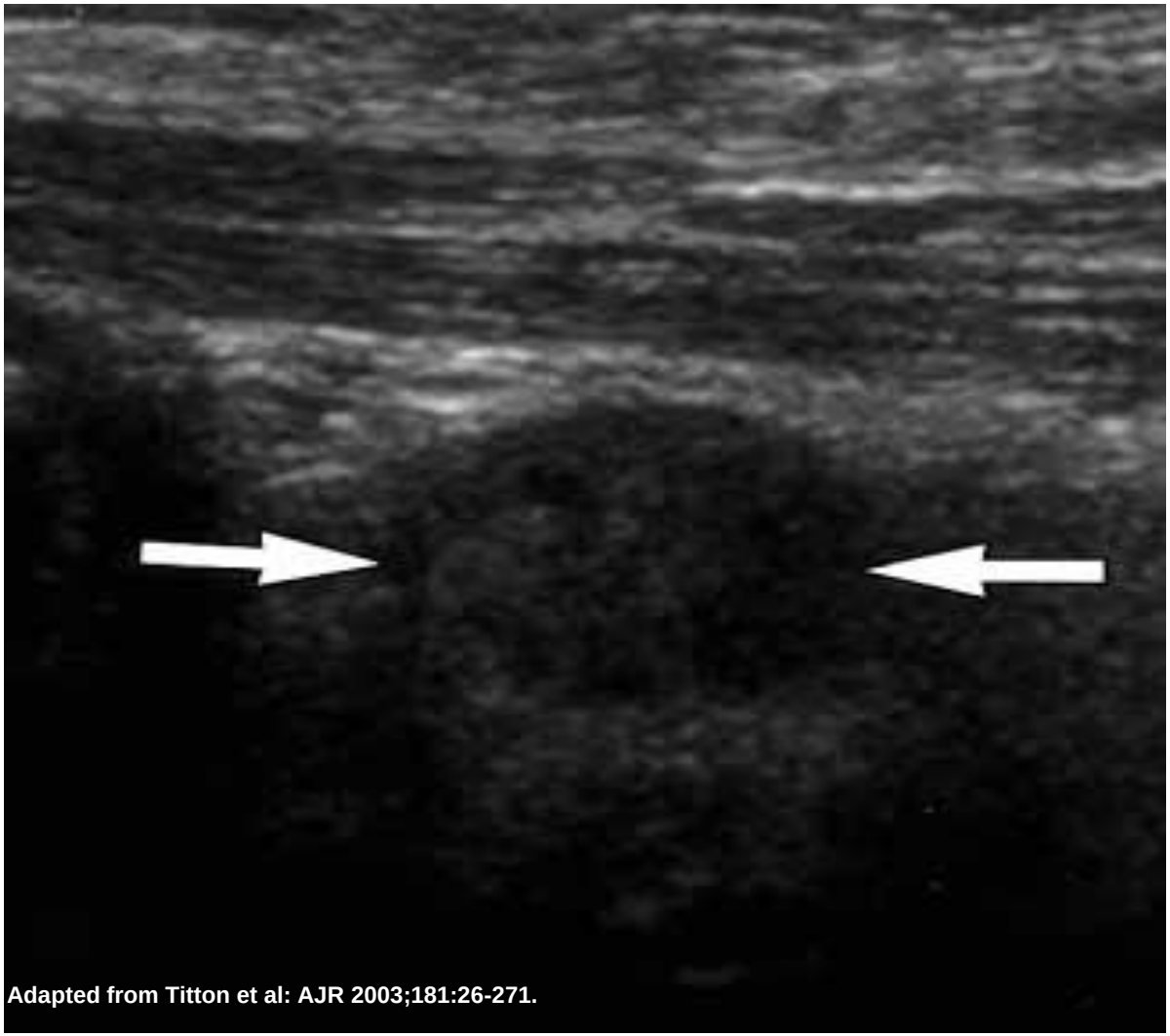
Euthyroid Lesions

- Euthyroid lesions can be cancer, benign neoplasms, cysts, or inflammatory.
- Palpable euthyroid lesions can be biopsied with the palpation method or can be studied further with ultrasound.
- Ultrasound visible simple cysts are only aspirated with they are symptomatic.
- Ultrasound complex cysts and solid euthyroid lesions are often appropriately biopsied.

Risks for Thyroid Cancer

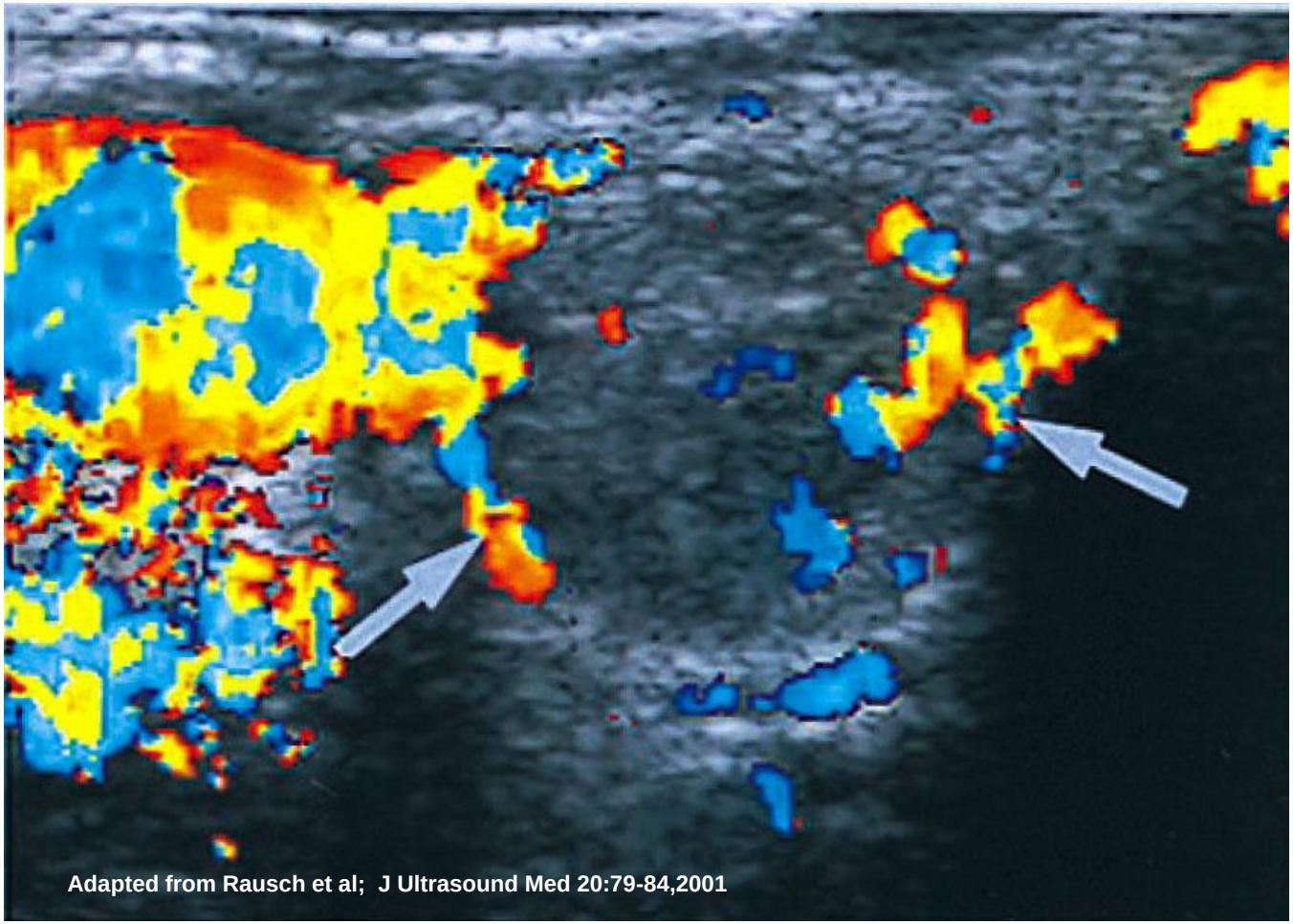
- Enlarging painless lesion.
- Multiple endocrine neoplasia II syndrome.
- Cervical lymph node biopsy results consistent with thyroid cancer.
- Prior head and neck radiation.
- Past thyroid lobectomy for carcinoma now appearing as a nodule in the contralateral lobe.

Solid Lesion on Ultrasound in a Patient with Previous Thyroid Carcinoma



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

Color Doppler - Lesion with Reduced Perfusion

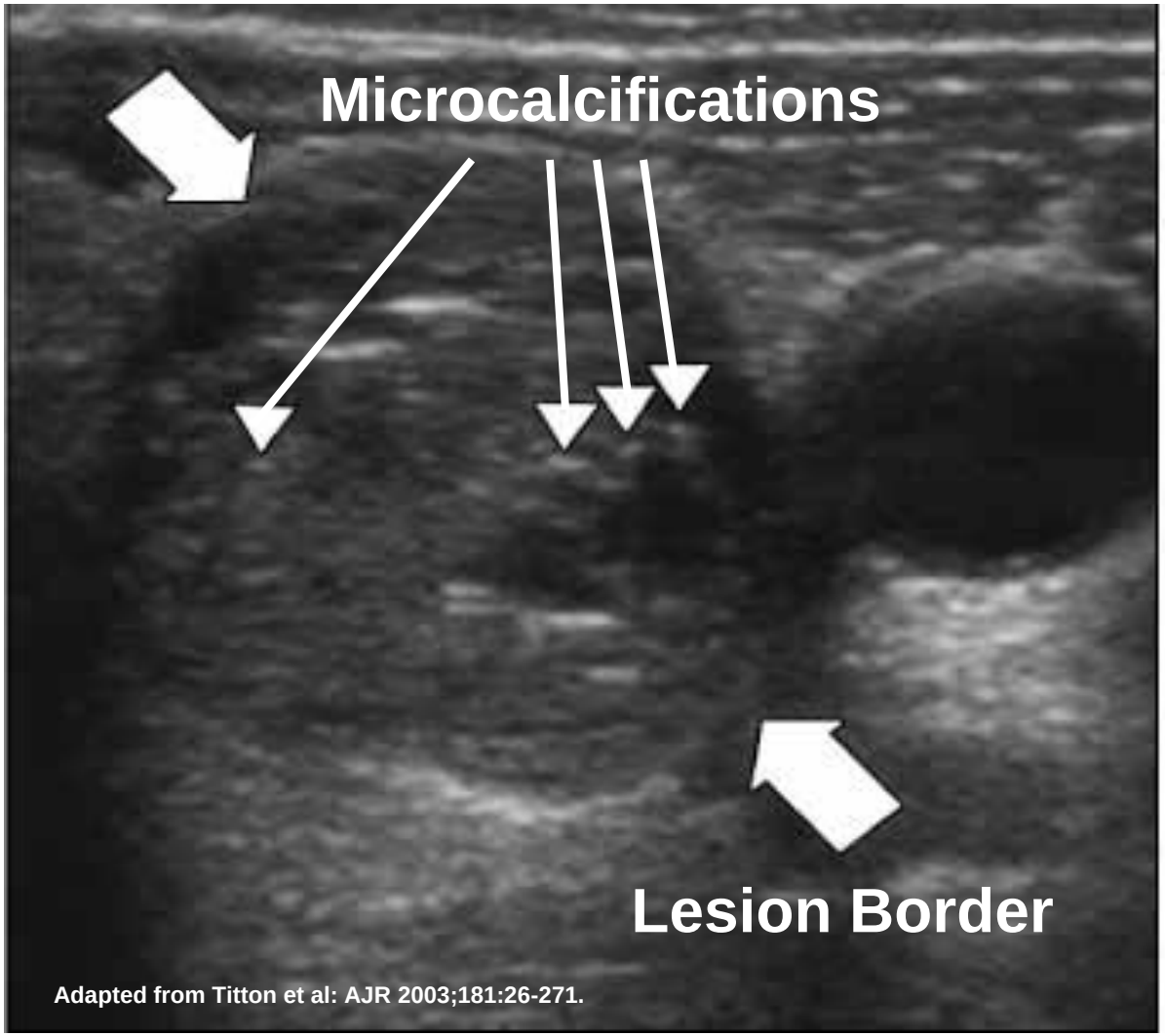


Adapted from Rausch et al; J Ultrasound Med 20:79-84,2001

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.

Mixed Solid Cystic Lesion on Ultrasound



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

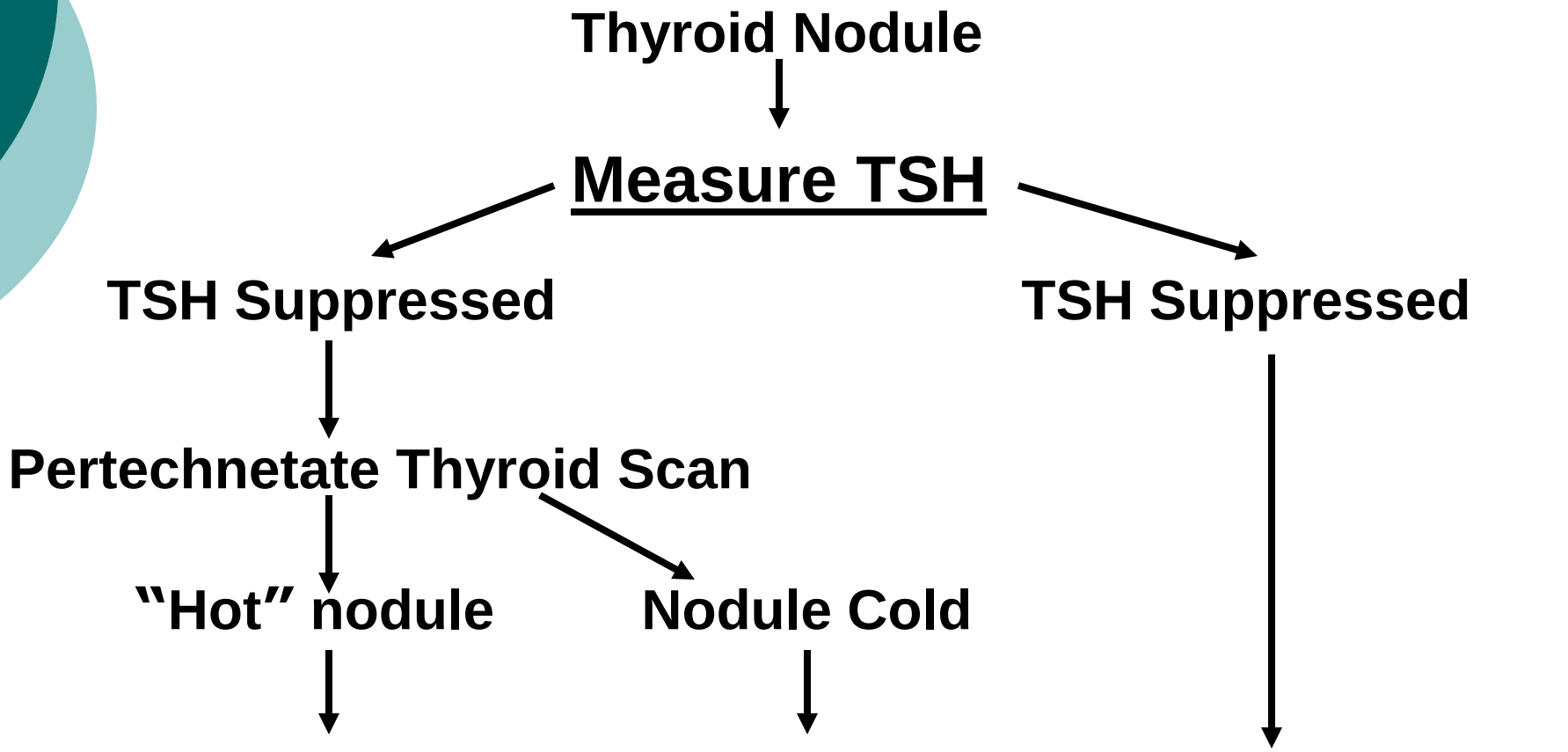
Characteristics of Benign Thyroid Lesions

- Typically isoechoic or echogenic.
- Hypoechoic peripheral "halo" is characteristic but not an invariable or a specific finding.
- Most benign nodules are either adenomas or colloid cysts.
- Adenomas are often mixed solid and cystic lesions that may undergo internal hemorrhage to varying degrees.
- Calcifications within benign nodules tend to be either of 2 types: (1) peripheral "eggshell" calcifications or (2) large, coarse calcifications.

Characteristics of Malignant Thyroid Lesions

- A single hypoechoic lesion with indistinct margins,
- With or without small punctate calcifications.
- Gray scale US imaging differentiates benign from malignant nodules with sensitivities ranging from 75% to 87% and specificities ranging from 61% to 95%.
- Vascularity is variable, and it is not possible to reliably differentiate benign from malignant nodules with color Doppler or US alone.
- Thus, thyroid biopsy is frequently necessary.

Evaluation of a Thyroid Nodule

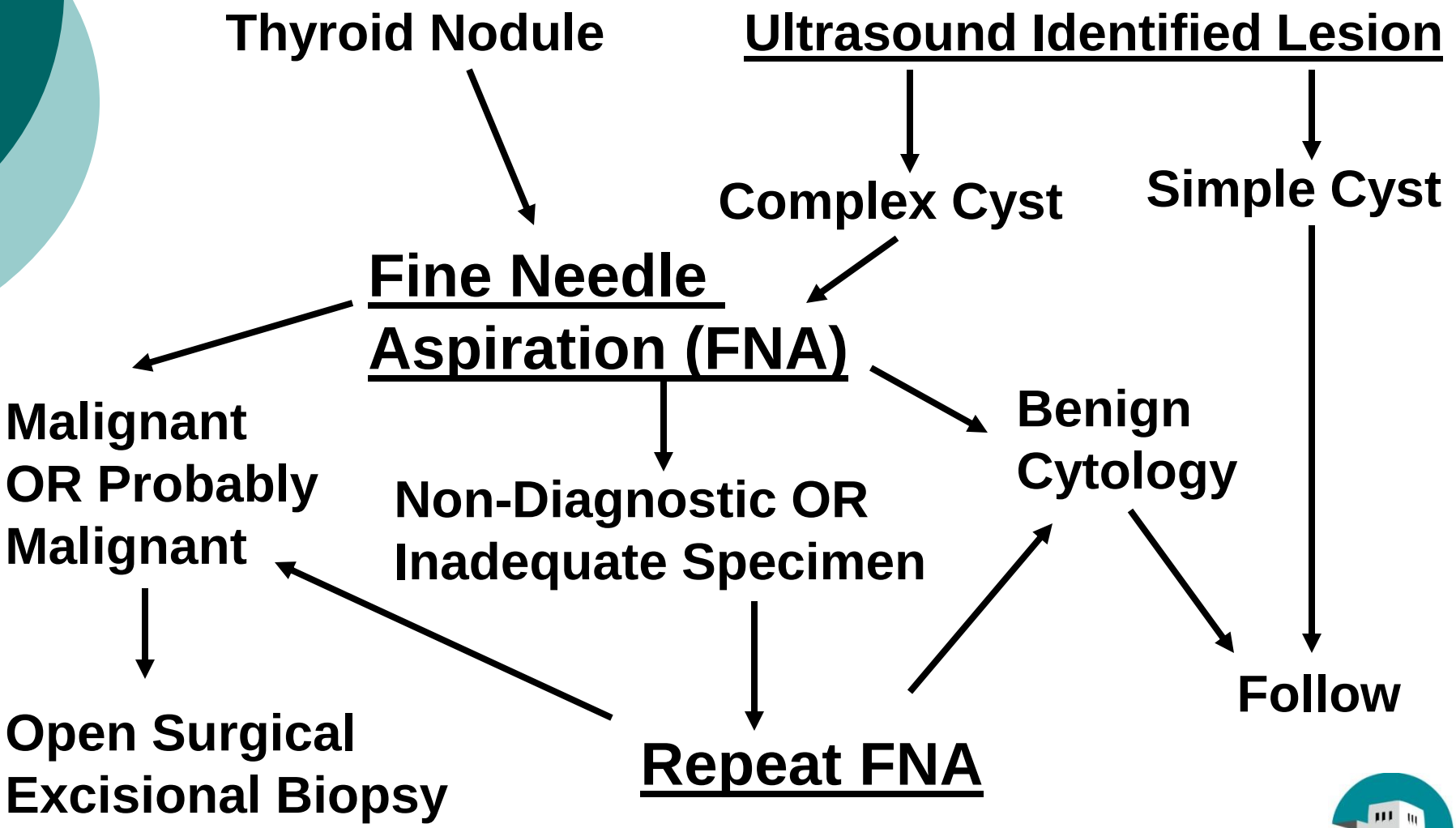


Adapted from *Mackenzie EJ et al: Chapter 6, MJA Practice Essentials*

National Institutes of Health: Evaluation of the Euthyroid Lesion

- Recommend biopsing suspicious palpable or US-visible euthyroid lesions 1 cm diameter or larger.
- Recommend US as the imaging modality of choice for euthyroid lesions.
- Recommend fine needle aspiration (FNA) biopsy as the thyroid biopsy procedure of choice.
- Recommend repeat FNA for non-diagnostic specimens or inadequate specimens.
- Recommend open biopsy only for malignant or suspiciously malignant cytology on FNA.

National Institutes of Health
Evaluation of Euthyroid Thyroid Lesions

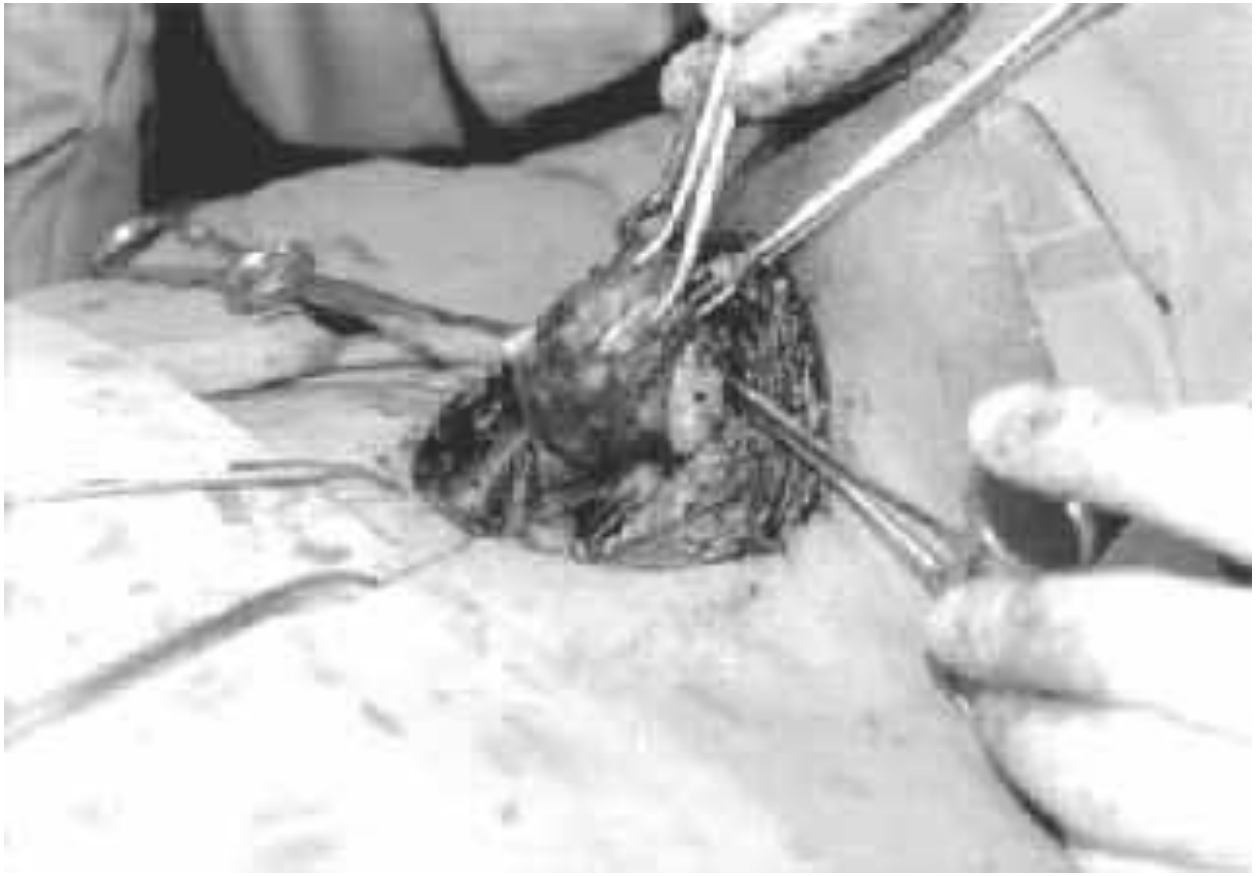


Adapted from *the National Institutes of Health*

Thyroid Biopsy Techniques

- **Open biopsy** with complete or partial lobectomy - moderately dangerous.
- **Core needle biopsy** - minimally dangerous.
- **Cutting needle aspiration biopsy** - minimally dangerous.
- **Fine-needle nonaspiration biopsy (FNNA)** - benign.
- **Fine-needle aspiration biopsy (FNA)** - benign.

Open Thyroid Biopsy



Adapted from *Majlis et al Rev. méd. Chile v.127 n.8 Santiago ago. 1999*

Open Biopsy

- Gold Standard
- Can be curative.
- Hazards include: general anesthesia, injury to recurrent laryngeal nerves, carotids, trachea,or parathyroid glands; hemorrhage, infection, cosmetic injury, death.
- For most patients, a needle-based diagnostic technique is advantageous before open biopsy is planned.

Core Needle Biopsy of the Thyroid

Spring-Loaded

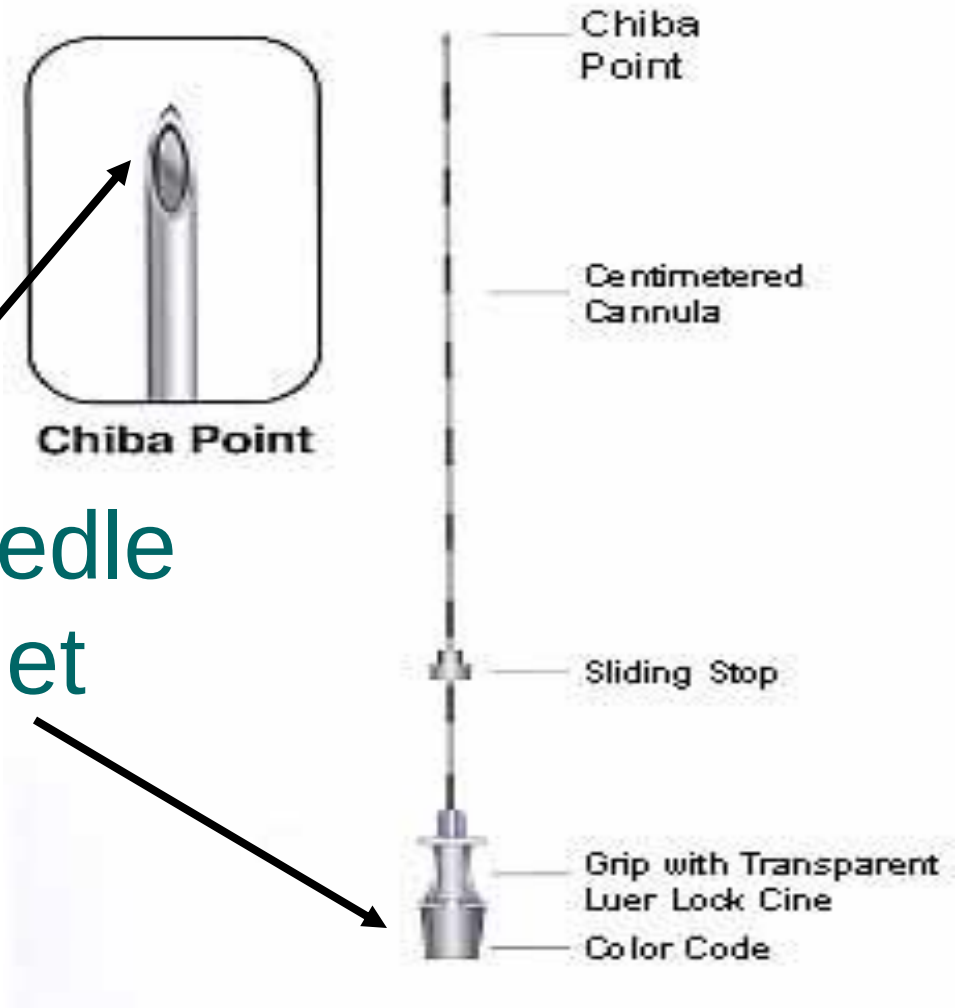
US-Guided

Core Needle Biopsy of the Thyroid

- **Core biopsy is performed with a spring-loaded gun. Often a small incision is required.**
- The biopsy needle "springs" forward, cutting a "core" of tissue.
- Core biopsy provides a larger piece of tissue, but also leaves a larger hole.
- However, core biopsy has no greater sensitivity or specificity than FNA techniques.
- Core biopsy results in a greater risk to surrounding structures and of hemorrhage. Thus, core biopsy is not the technique of choice for the thyroid.

Karstrup et al: Eur J Ultrasound. 2001;13:1-5.

Cutting Needle Aspiration Biopsy

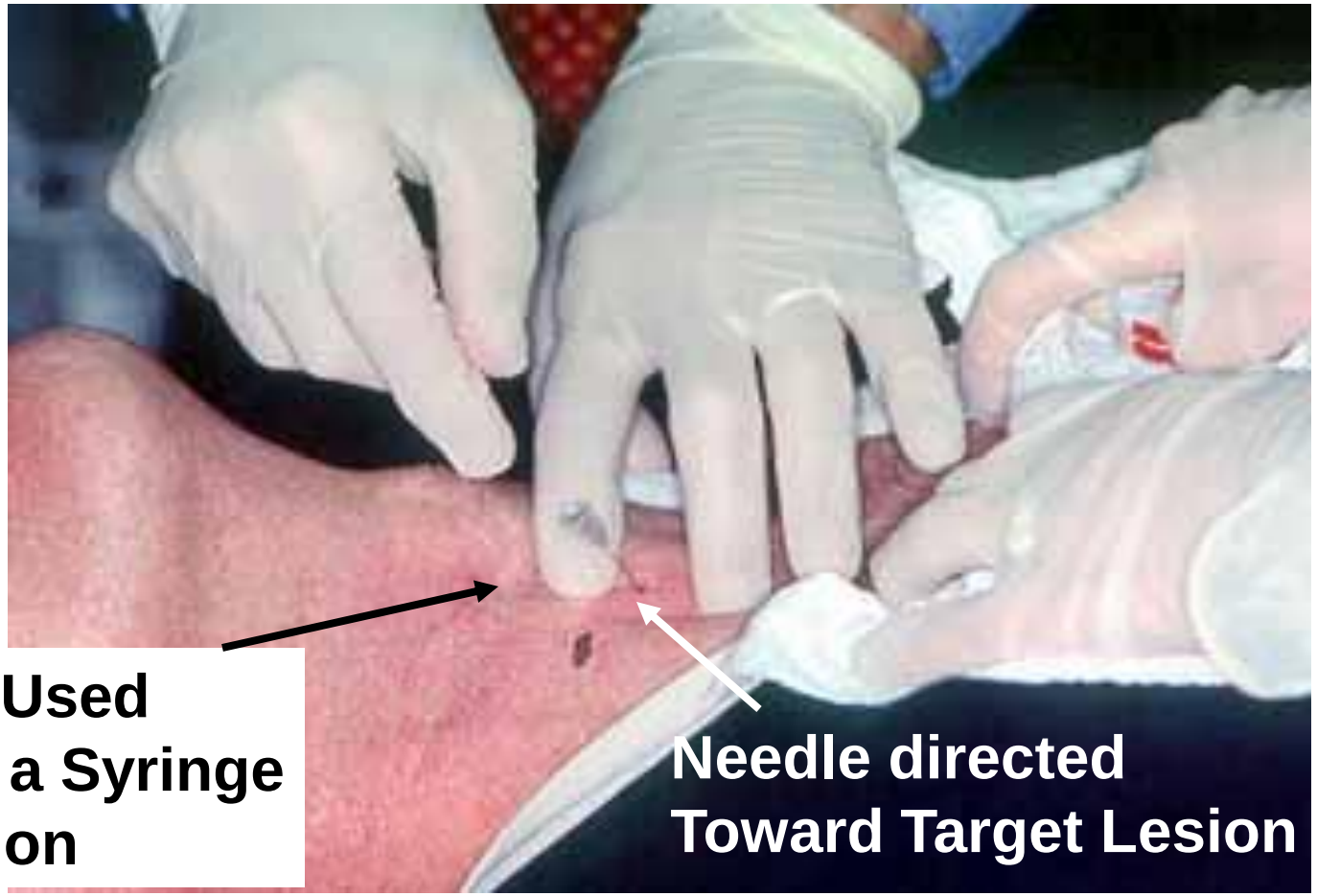


Cutting Needle Has a Stylet

Cutting Needle Aspiration
Biopsy of the Thyroid

- **Cutting needle biopsy is performed with a needle with a stylet.** A typical example is a Chiba cutting needle. When the stylet is removed, suction is applied with a syringe to biopsy.
- Cutting needle biopsy requires extra steps compared to FNA, and leaves a larger hole, resulting in greater hemorrhage.
- Cutting needle aspiration biopsy is not superior to FNA in the thyroid, and thus is not the technique of choice.

Fine Needle Non-Aspiration (FNNA) Biopsy of the Thyroid



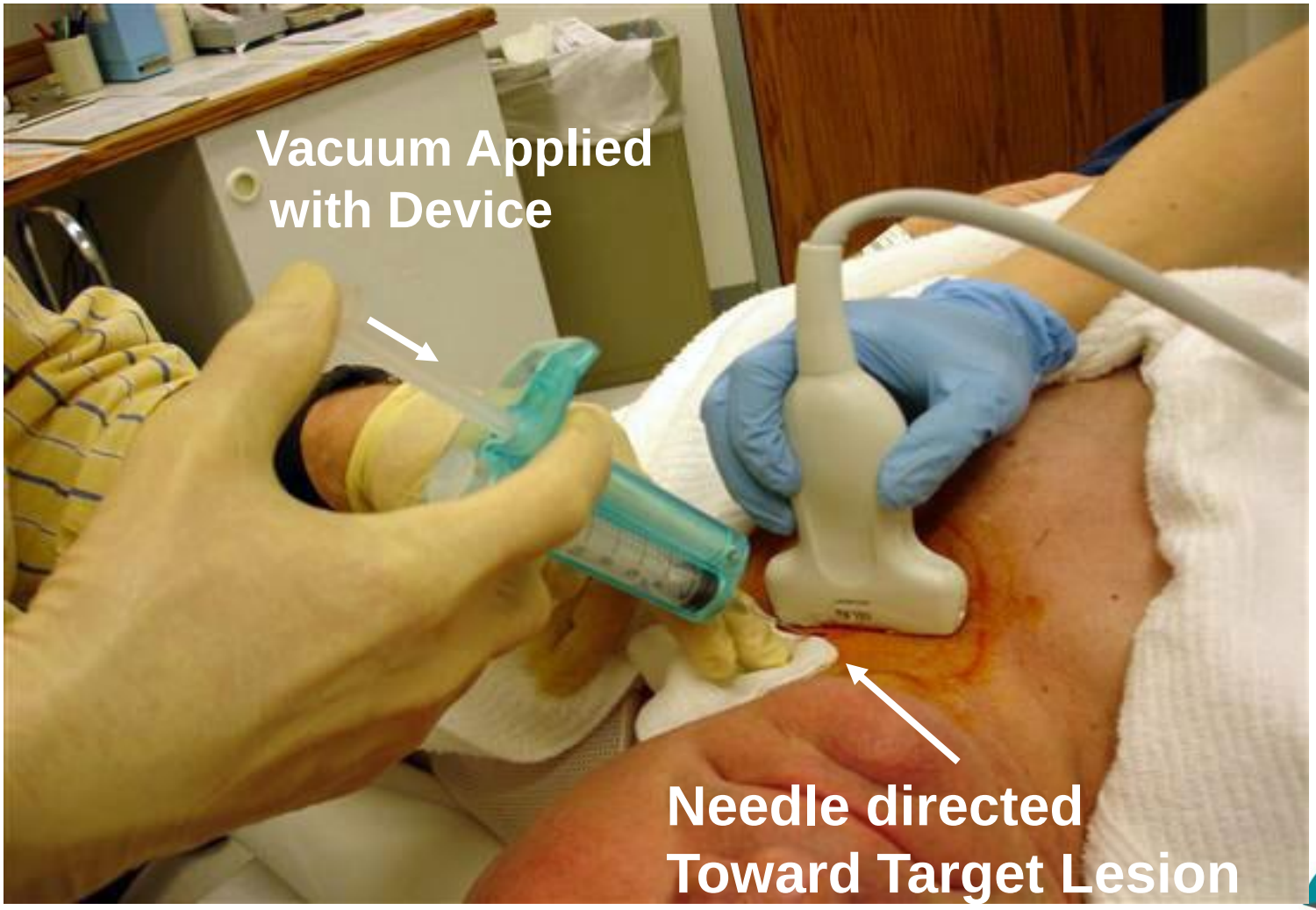
Needle Used Without a Syringe Or Suction

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

Fine Needle Non-Aspiration (FNNA) Biopsy of the Thyroid

- **FNNA is performed with a 25 gauge conventional needle.**
- The needle is held in the fingers or placed on a syringe without a plunger.
- The needle is directed at the lesion.
- Multiple passes through the lesion are performed, and the needle is removed from the lesion.
- The sample is attached to a syringe,expelled on a cytology slide, or into carrier/fixative solution, or sent to the pathology laboratory in the needle.

Fine Needle Aspiration of Thyroid



Fine Needle Aspiration (FNA)

- **FNA is performed with a 25 to 20 gauge conventional needle and a syringe.**
- The needle is placed on a syringe.
- The needle is directed at the lesion.
- Once the needle is in the lesion, suction is gently applied.
- Multiple passes through the lesion are performed, vacuum removed, and the needle removed from the lesion.
- The sample is expelled on a cytology slide, or into carrier/fixative solution, or sent to the pathology laboratory in the needle.

FNA vs. FNNA: Which is Better?

FNNA?

FNA?

FNA vs. FNNA: Which is Better?

- FNA and FNNA of the thyroid provide essentially the same sensitivity for malignant lesions. However, FNA is clearly superior to FNNA in all other tissues.
- FNNA samples of the thyroid are smaller with fewer cells and of lesser volume.
- FNNA is also insensitive to benign lesions of the thyroid and often does not provide adequate sample, thus more patients with FNNA have repeat FNA procedures and open procedures due to inadequate sample.
- Thus, FNA is to be recommended over FNNA.

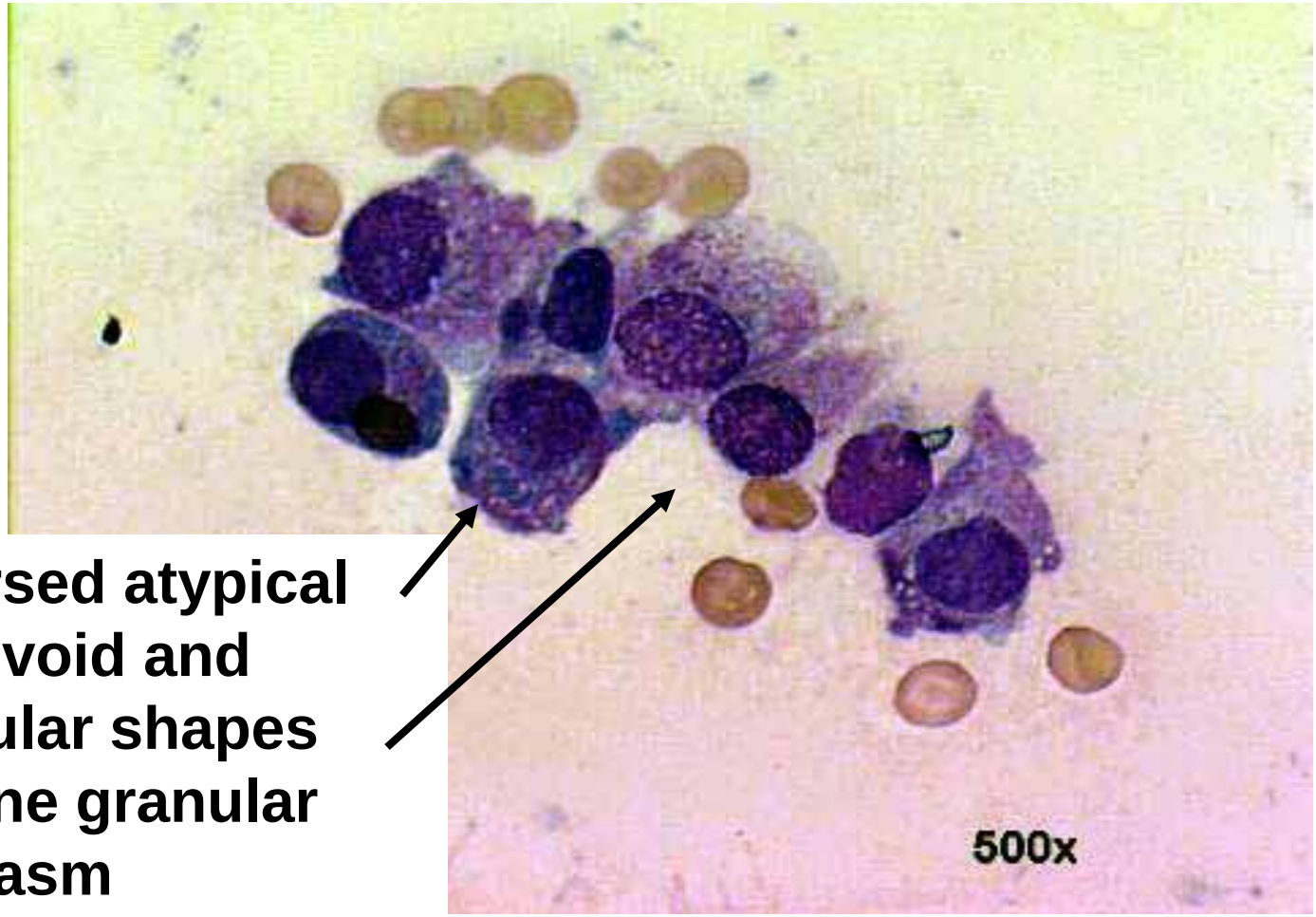
Findings on FNA: Neoplasm

- **Neoplasm 5% of the time.**
- **Papillary Thyroid Carcinoma (70-80%).**
- **Follicular Thyroid Carcinoma (5%).**
- **Huerthle Cell Carcinoma (5%).**
- **Medullary Carcinoma (5-10%).**
- **Anaplastic Thyroid Carcinoma (3%).**
- **Malignant Lymphoma (1-2%).**
- **Metastatic Carcinoma (2-4%).**

Findings on FNA: Benign

- **Lesions Benign 95% of the time.**
- **Multinodular Goiter.**
- **Hashimotos Thyroiditis.**
- **Simple or Hemorrhagic Cysts.**
- **Follicular Adenomas.**
- **Subacute Thyroiditis.**

FNA: Thyroid Medullary Carcinoma



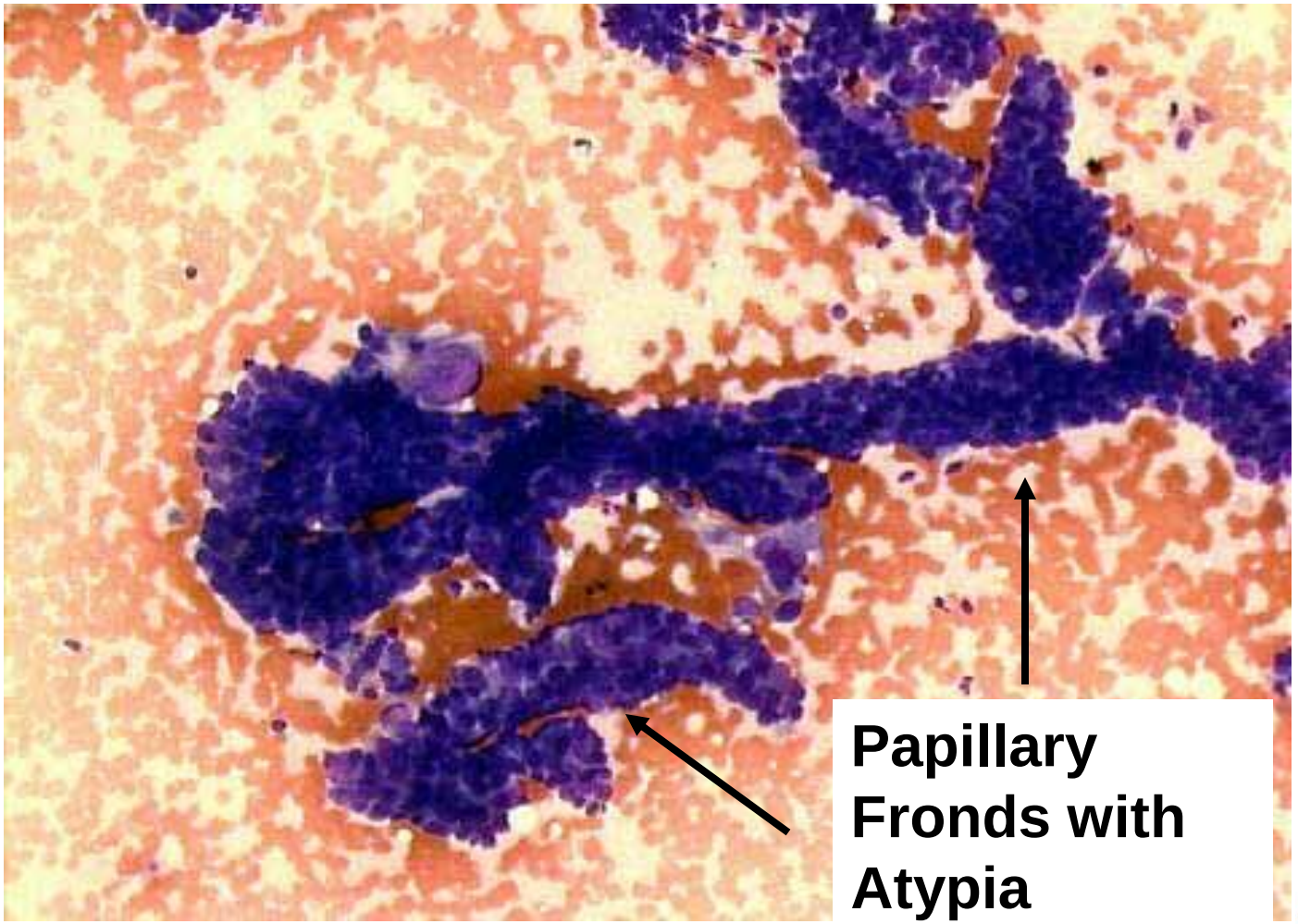
Dispersed atypical cells ovoid and triangular shapes with fine granular cytoplasm

FNA: Benign Colloid Nodule

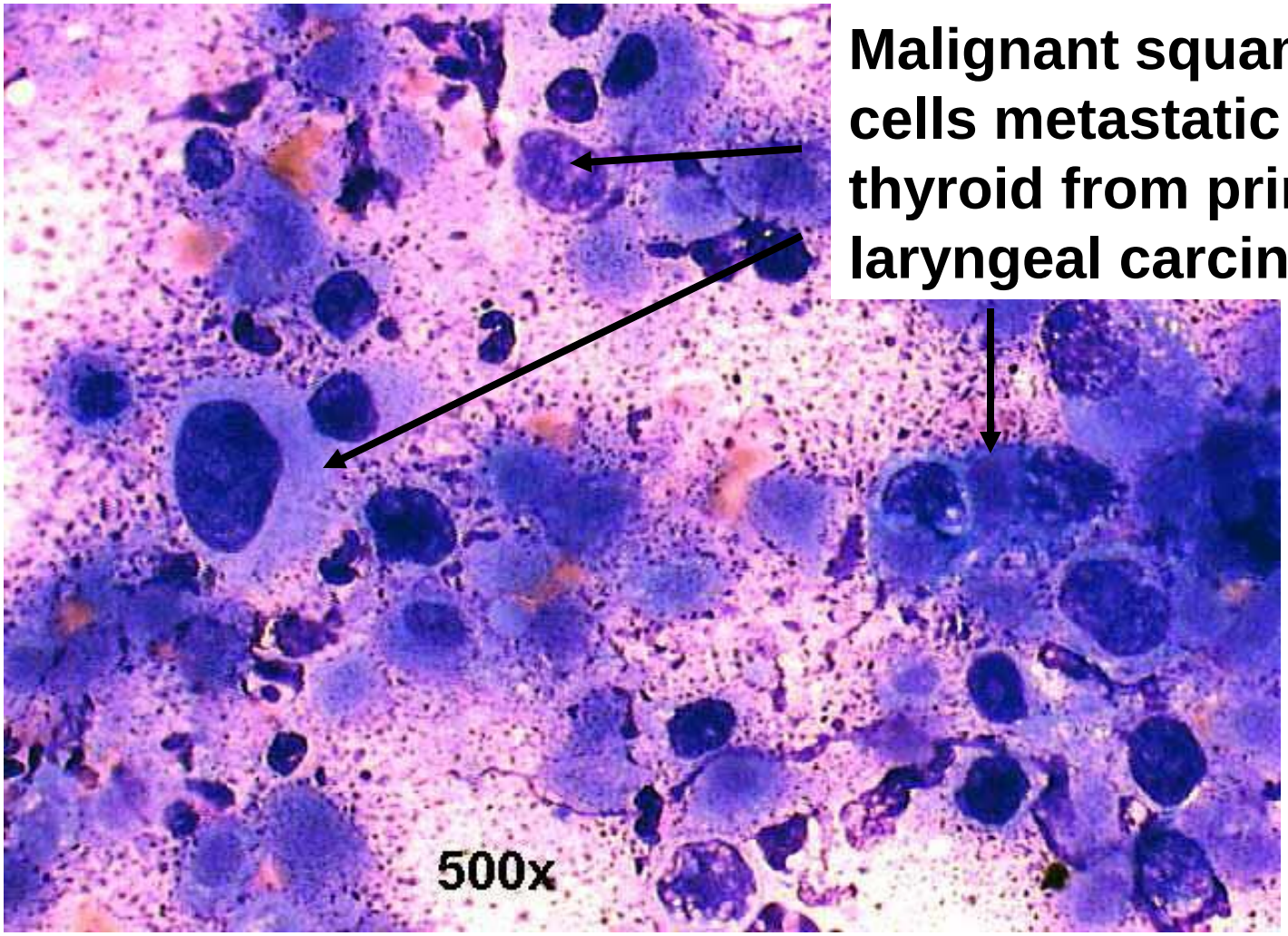
Adapted from Rausch et al; J Ultrasound Med 20:79-84,2001

Abdundant Colloid (diffuse purple) and Clusters of Epithelial Cells

FNA: Thyroid Papillary Carcinoma

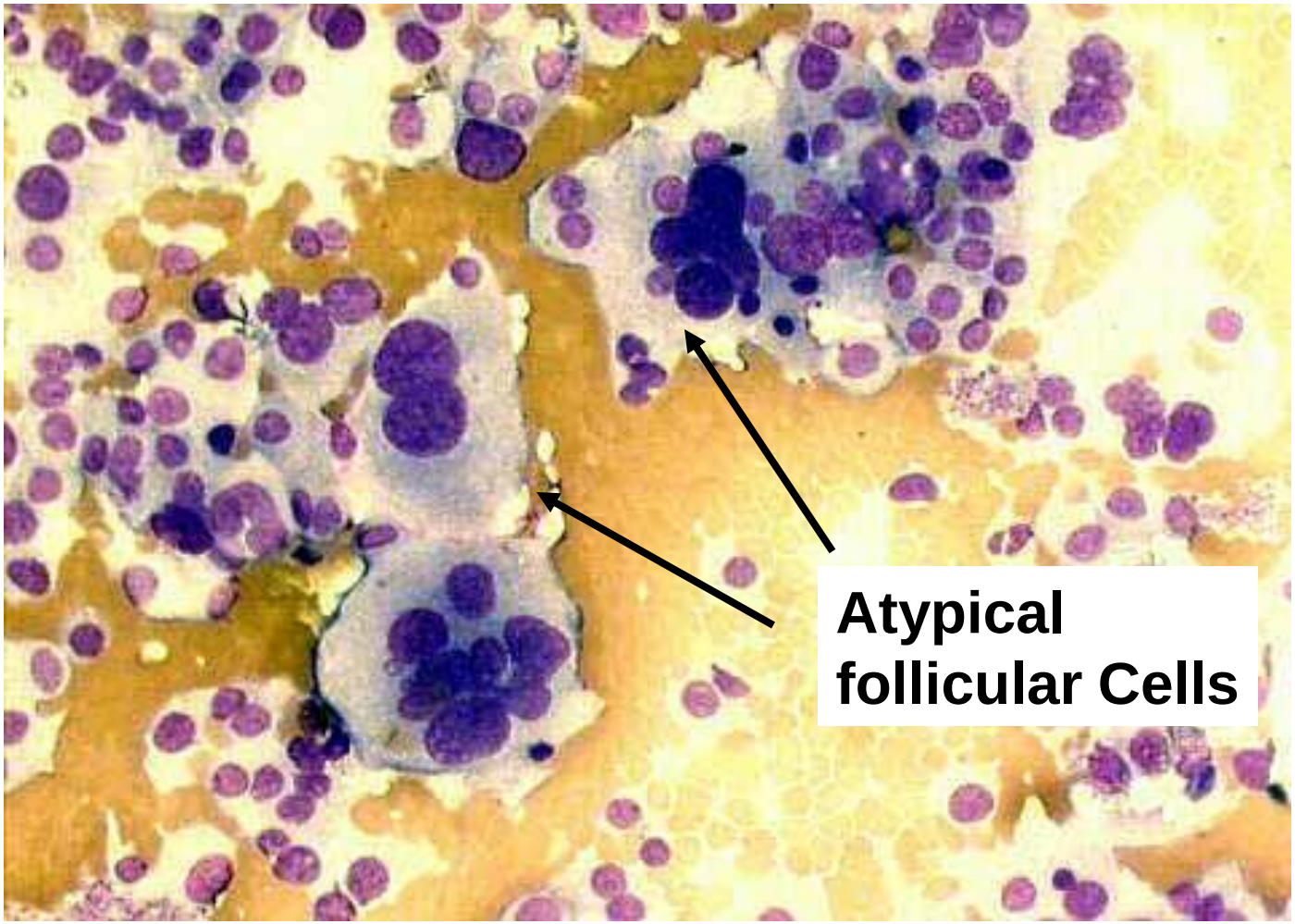


FNA: Squamous Cell Carcinoma



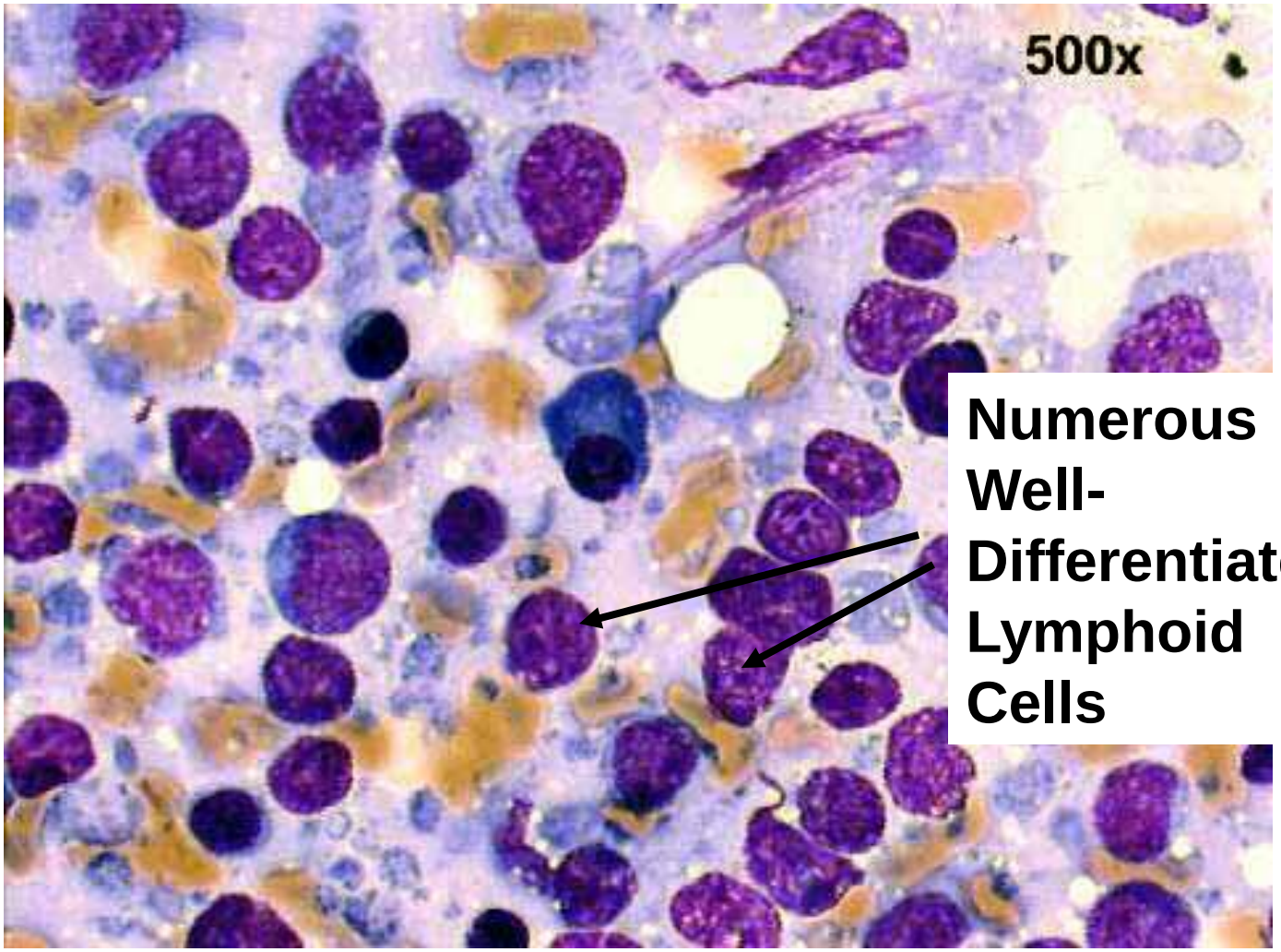
Malignant squamous cells metastatic to thyroid from primary laryngeal carcinoma

FNA: Thyroid Follicular Carcinoma



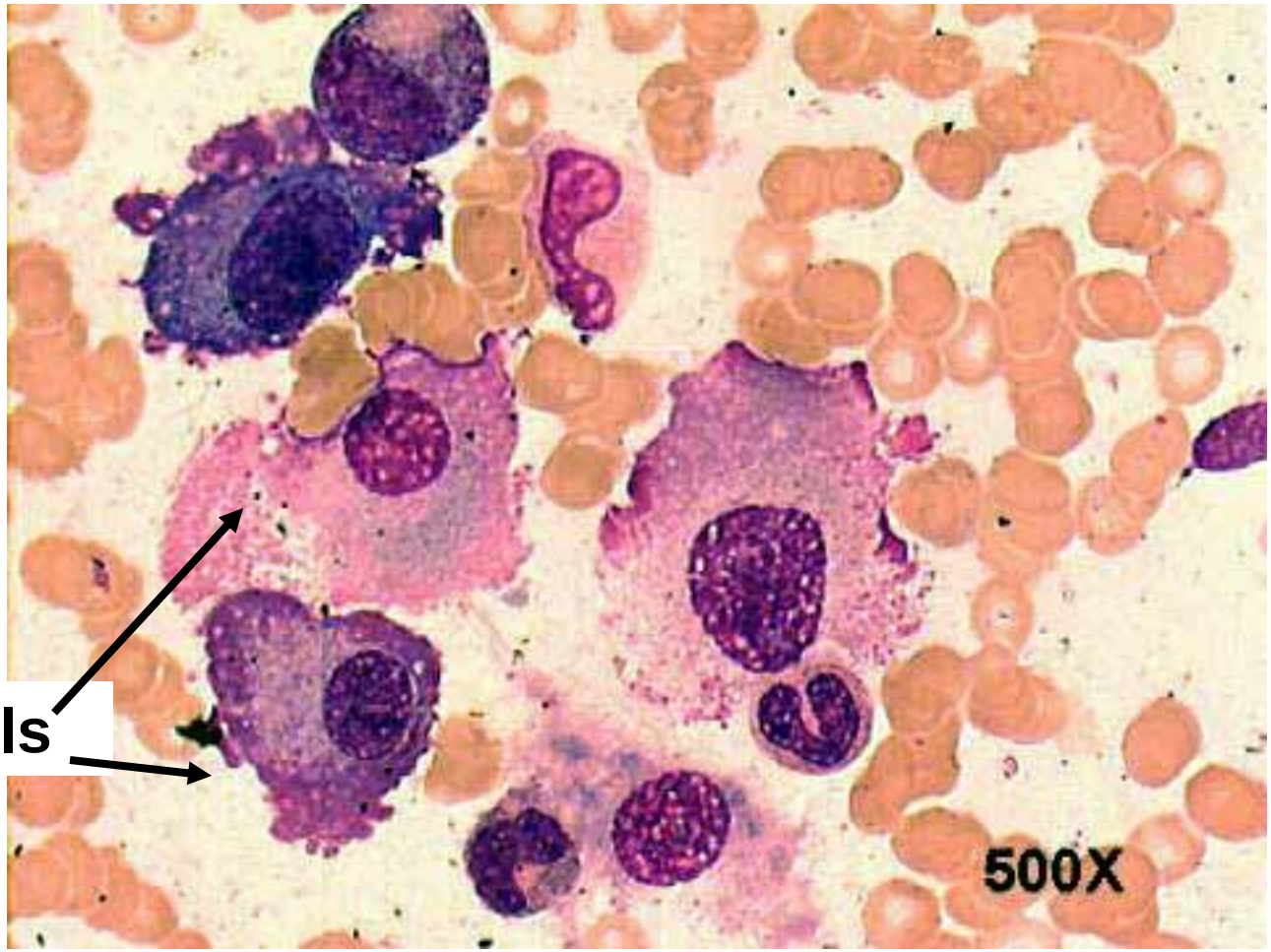
Adapted from Dr. JC Prolla and Dr. Ada R. S. Diehl: Atlas of Histopathology

FNA: Hashimoto's Thyroiditis

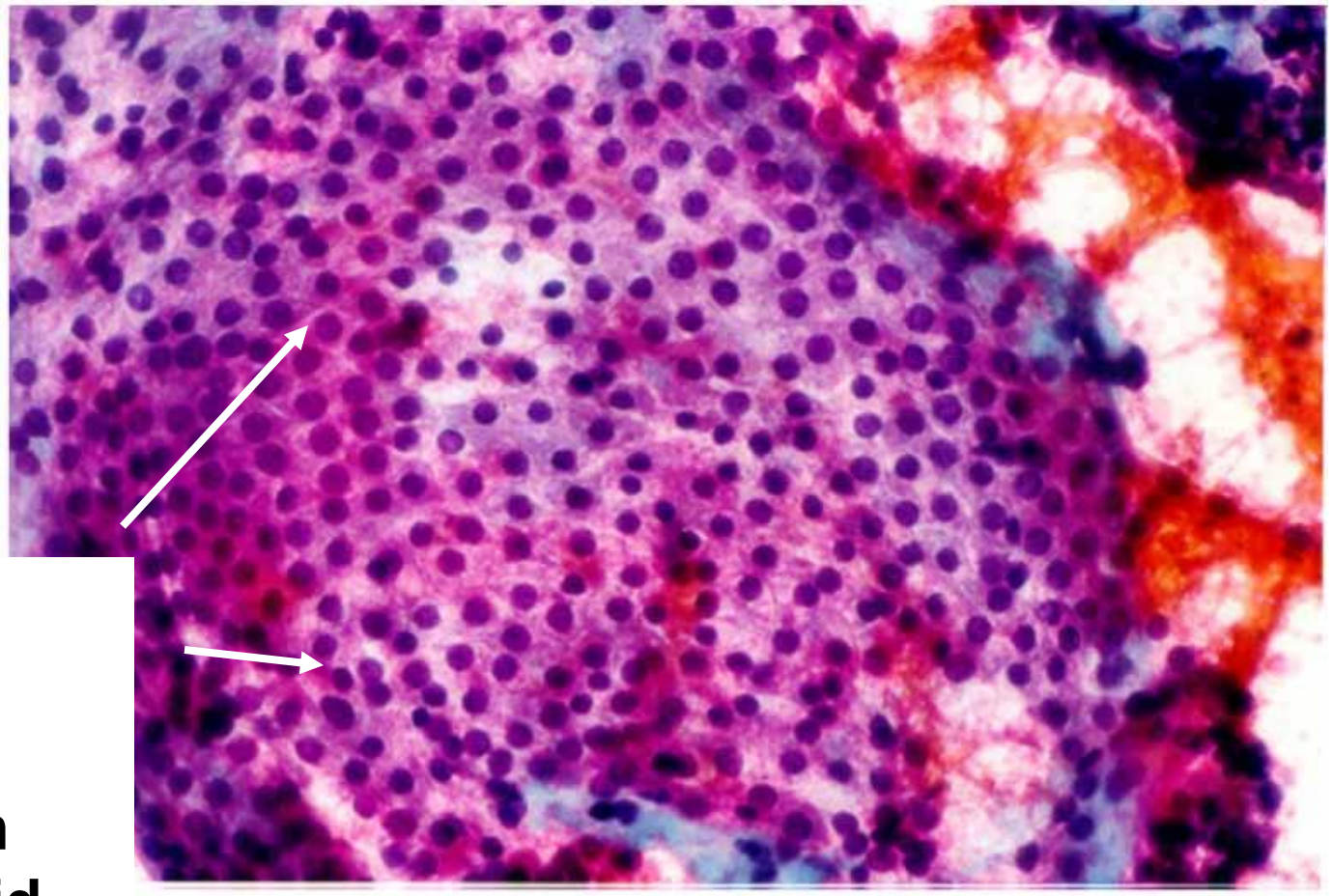


Adapted from Dr. JC Prolla and Dr. Ada R. S. Diehl: Atlas of Histopathology

FNA: Thyroid Primary Plasmacytoma

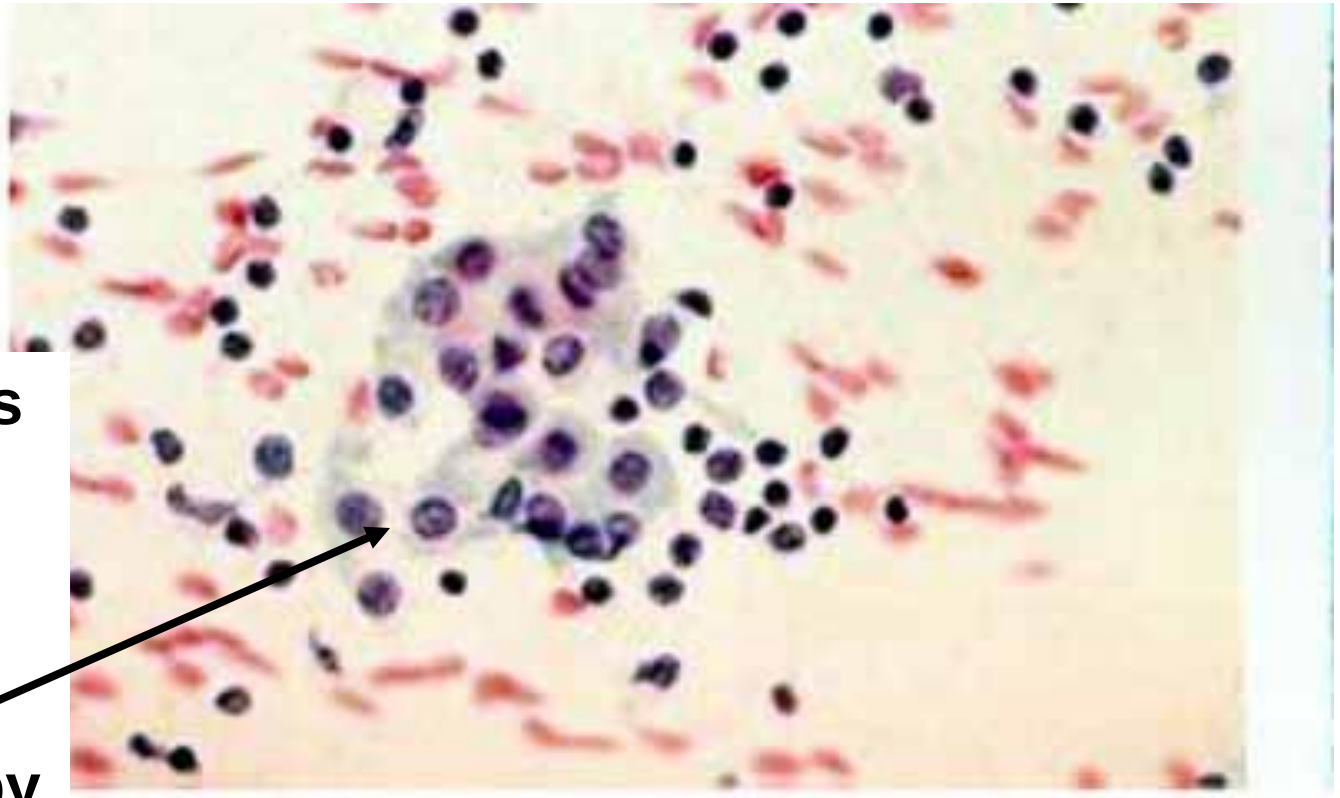


FNA: Benign Colloid Nodule



Sheets of Normal Thyroid Epithelium with Colloid

FNA: Huerthle Cell Carcinoma

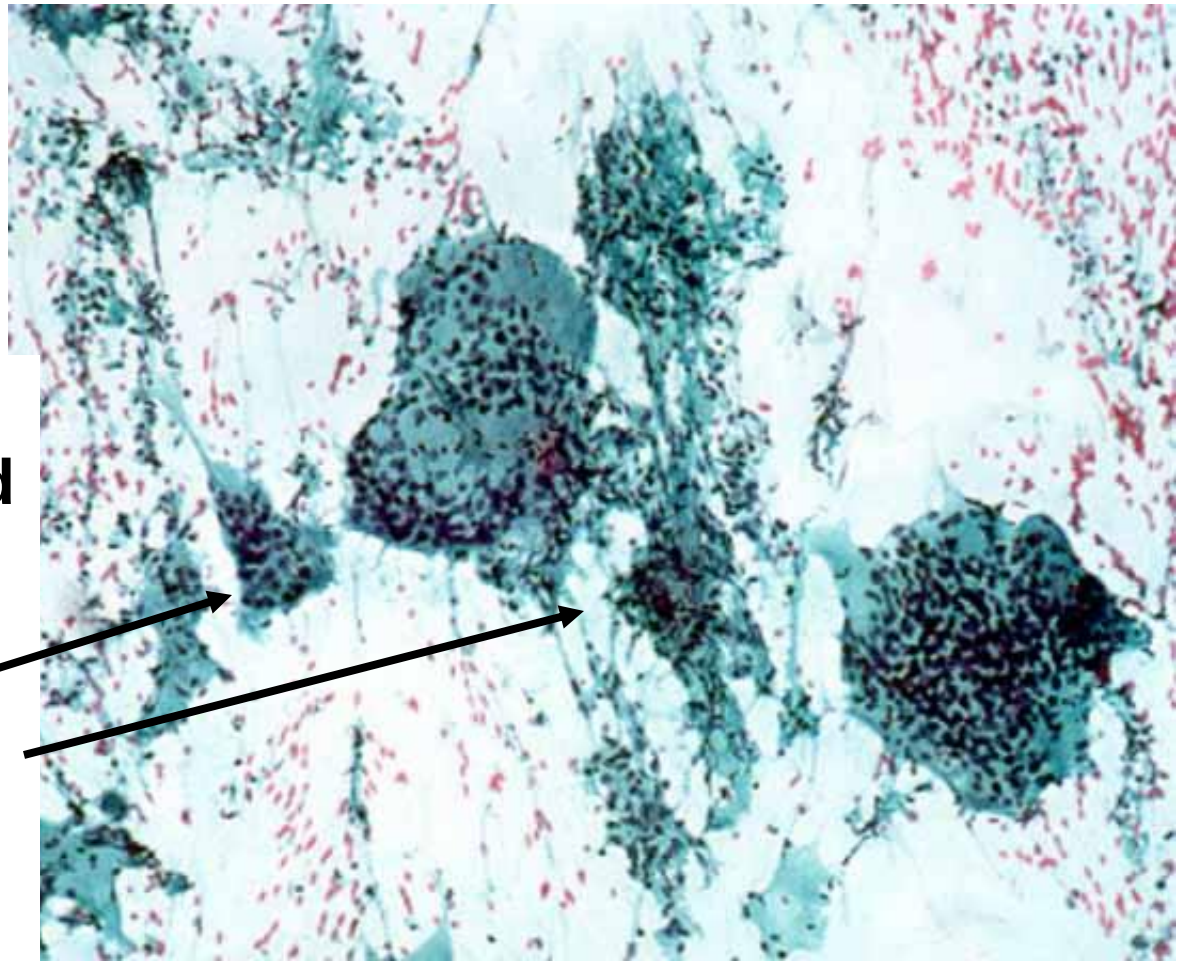


Huerthle Cells with large nuclei and prominent cytoplasm surrounded by lymphocytes

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

FNA: Subacute Thyroiditis

Large multinucleated giant cells on a background of lymphocytes and little colloid



How Effective Diagnostically is FNA?

- FNA is extremely effective diagnostically as follows:
  - 5% of biopsied thyroid nodules are malignant.
  - Approximately The diagnostic sensitivity for identifying a lesion is 80-93% and the diagnostic specificity is 54-92%
  - Positive predictive value of 50-90% and a negative predictive value of 92-95%.
  - 18% malignancy rate for indeterminate or suspicious findings on FNA.
  - More dangerous methods, including core biopsy, open biopsy, and cutting needle biopsy should only be used when FNA fails.

Hosler et al Diagn Cytopathol. 2006;34:101-5; Raber et al: Thyroid. 2000;10:709-12; Hatipoglu et al: Thyroid. 2000;10:63-9; Gharib et al: Endocr Pract. 1995;1:410-7; Liu et al:.Am Surg. 1995;61:628-32. Gharib et al: Clin Lab Med. 1993;1:699-709.

Who Performs Thyroid FNA?

- Generally, physicians as follows:
  - Interventional and Ultrasound Radiologists (usually US-guided, occasionally CT-guided).
  - Endocrinologists (palpation and US-guided).
  - Otolaryngologists (usually palpation guided).
  - Family practice (usually palpation guided).

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).

Nishihara et al Thyroid. 2005;15:1183-7; Sun et al:Head Neck. 200224:84-6.; Pinto.et al: Acta Cytol. 1996;40:739-41. Gharib et al: Endocr Pract. 1995;1:410-7; Tomoda et al: Thyroid. 2006;16:697-9; Roh JL: Laryngoscope. 2006;116:154-6. Noordzij et al:Am J Otolaryngol. 2005;26:398-9; Tsang et al: Arch Pathol Lab Med. 1992;116:1040-2.


THE
RECIPROCATING
PROCEDURE
DEVICE (RPD™)

The Reciprocating Procedure Device (RPD) vs. Traditional Vacuum Sources for FNA

- **Reciprocating Procedure Device (RPD).**
- **The Conventional Syringe.**
- **The Conventional Syringe with Plunger Lock.**
- **The 3-ringed control syringe.**
- **The Bio-Suk-7**
- **Syringe Pistols**

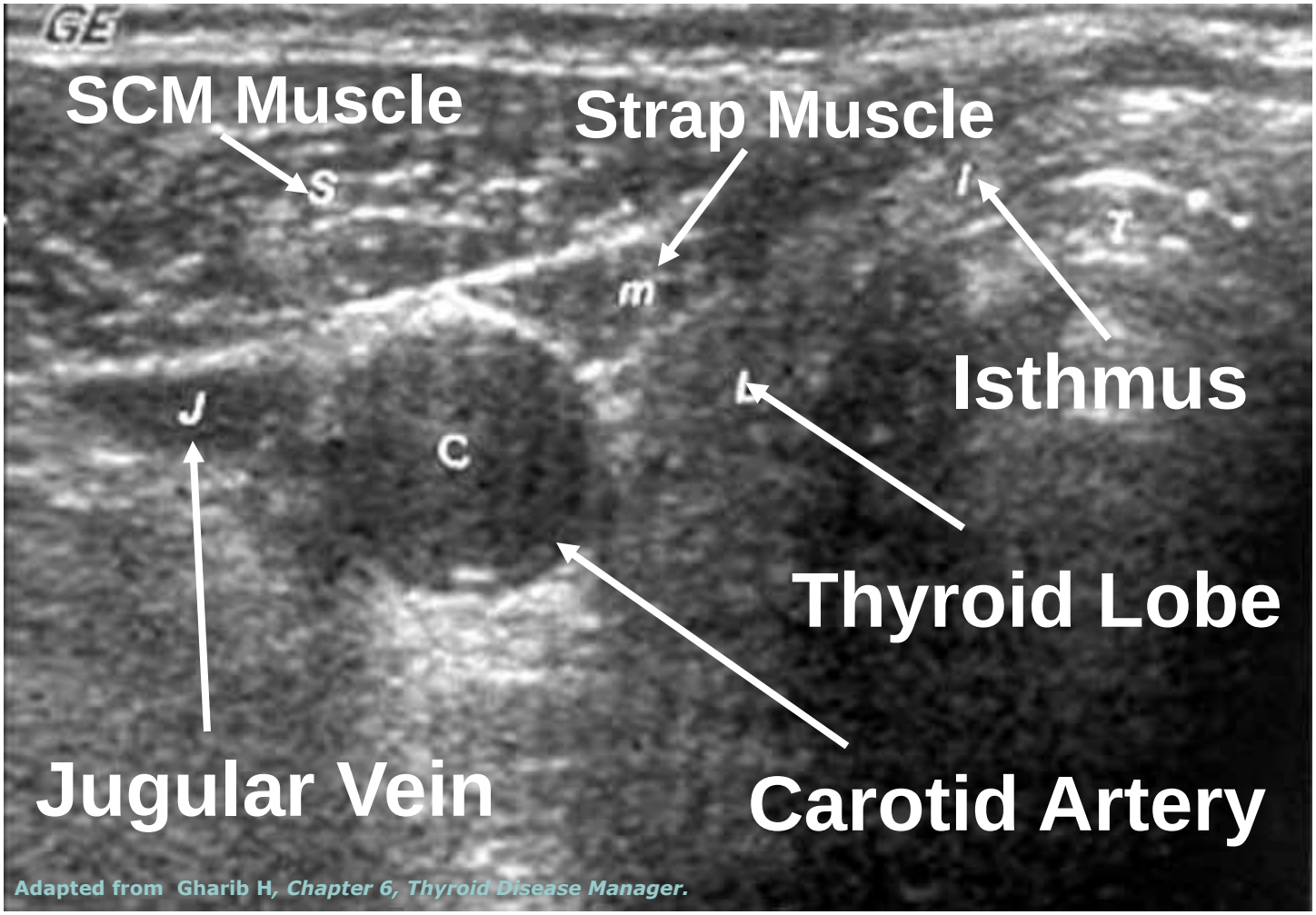
What is the RPD?

The RPD is a one-handed device that is functionally superior to and replaces the conventional syringe, control syringes, and syringe pistols for FNA. The RPD is better controlled and safer than previous devices.

Why Use the RPD for Thyroid FNA?

- 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.

Hazardous Anatomy for FNA



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

The RPD: Improved Outcomes for Syringe Procedures

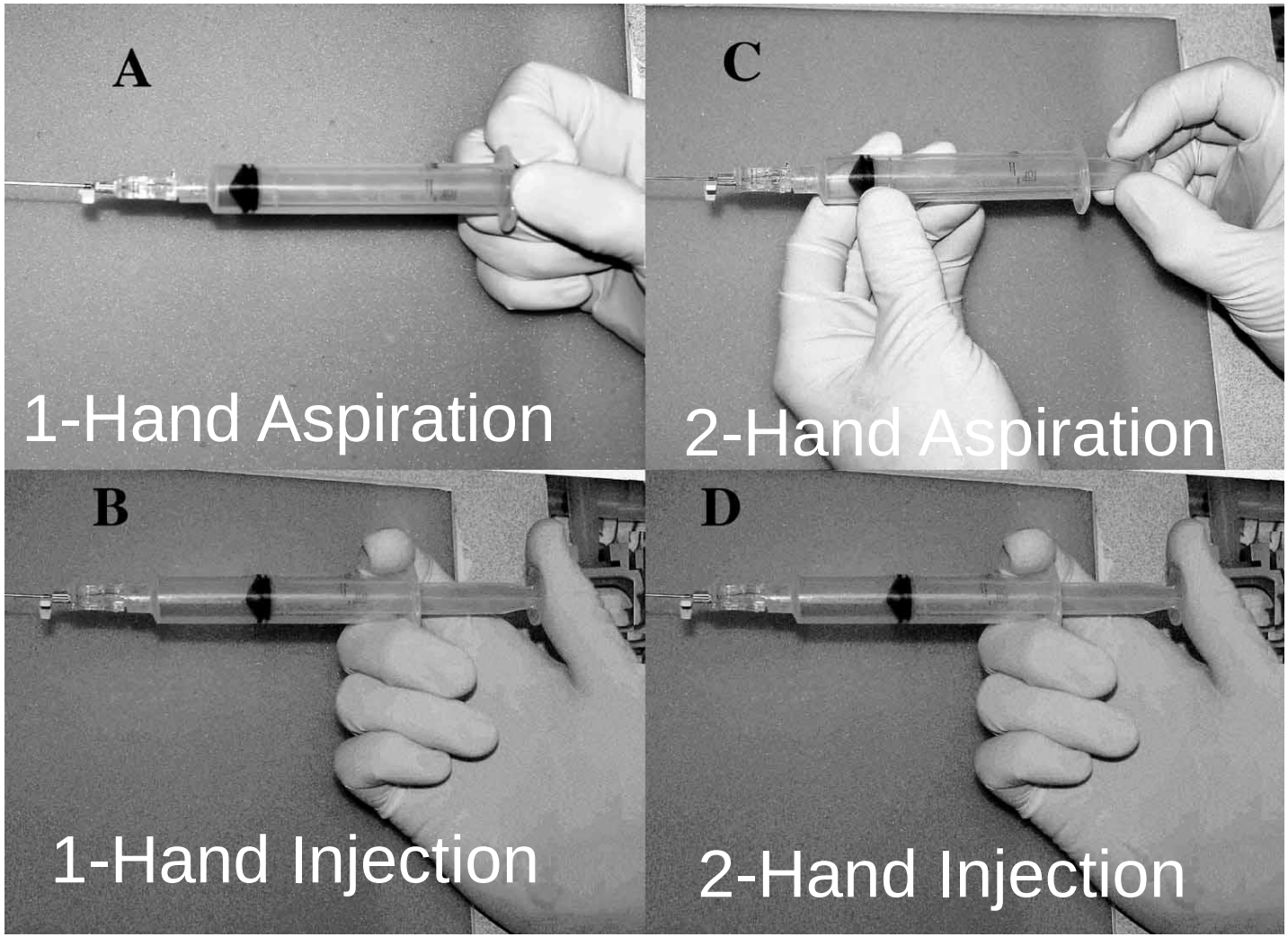
- In physician-performed syringe procedures, including FNA, the RPD results in:
  - Greater accuracy and needle control.
  - Reduced patient pain and tissue trauma.
  - Reduced procedure time.
  - Improved tissue and fluid samples.
  - Facilitates physician-administered local anesthetic.
  - Improved safety.
  - Superb vacuum control
  - Improved patient outcomes.

Expert Response:
The RPD is Safer for the Patient

Linda Williams, RN, MSI of the Veteran's Administration National Center for Patient Safety noted,

"The design is marvelous in its own right, but it is also a great example of the best kind of safety solution."

RPD vs. Conventional Syringe



RPD Clinical Trials

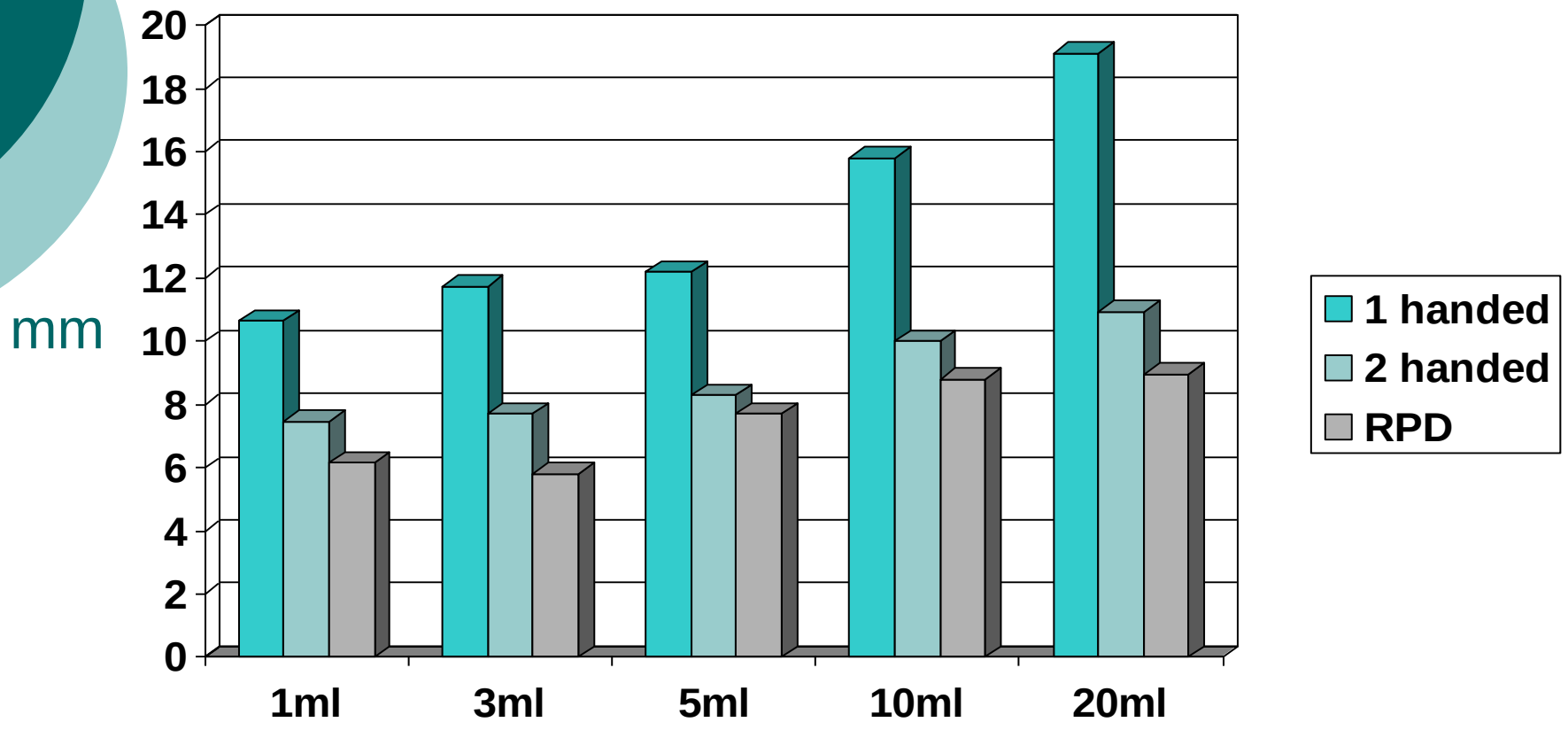
Clinical trials have demonstrated that the RPD is superior to the conventional syringe in terms of:

- physician control of syringe and needle
- aspiration of body fluids and tissues
- suction needle biopsy and thyroid biopsy
- arthrocentesis and intraarticular therapy
- administration of local anesthesia

The RPD consistently caused less patient pain and reduced procedure time.

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

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

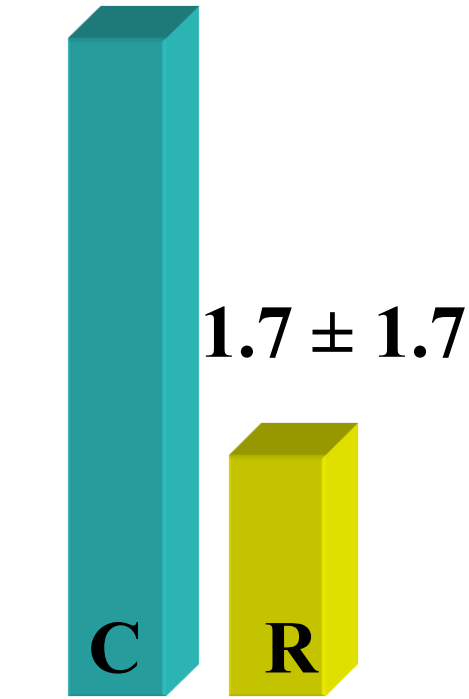
From: *J Rheumatol.* 2006;33:771-8; *J Vas Inter Rad* 2007, Abstract 377; *J Vas Inter Rad* 2005, Abstract 195

Physical Control of RPD: Conclusions

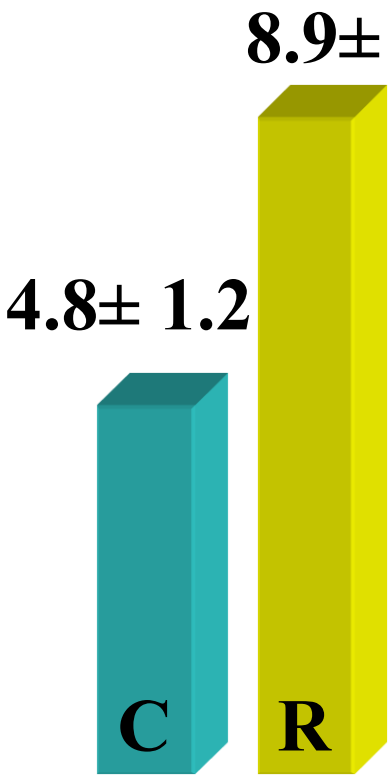
- The RPD markedly reduces unintended forward penetration (loss of control in the forward direction).
- The RPD markedly reduces unintended retraction (loss of control in the reverse direction).
- The RPD is superior to the conventional syringe at every size (1, 3, 5, 10, and 20 ml).
- The improved control of the RPD results in significantly reduced patient pain, reduced procedure time, reduced perforation rates, and improved outcomes.

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

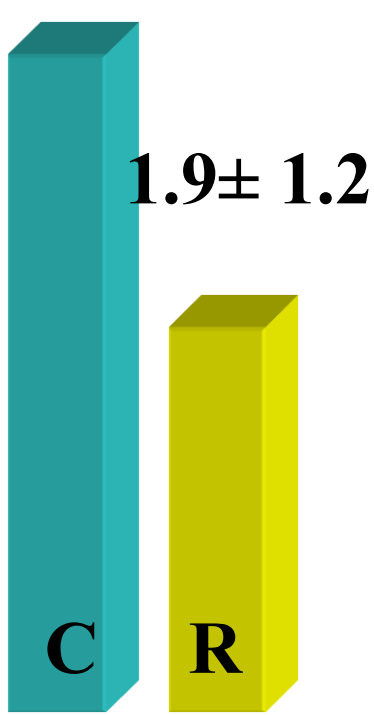
Aspiration of Body Fluids and Tissue: The RPD vs. the Conventional Syringe



Patient Pain
67 % Reduction
P < 0.001



Physician Satisfaction
83 % Increase
P < 0.001



Procedure Time
32 % Reduction
P < 0.10

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

Needle Procedures: Conclusions

- In needle procedures, the RPD with one hand is superior to the conventional syringe with two hands or one hand.
- Reduced patient pain and procedure time.
- The RPD improves operator satisfaction.
- The RPD provides greater sample yield with less trauma (hemorrhage).
- The RPD is superior to the conventional syringe for aspiration of body fluid and tissue.

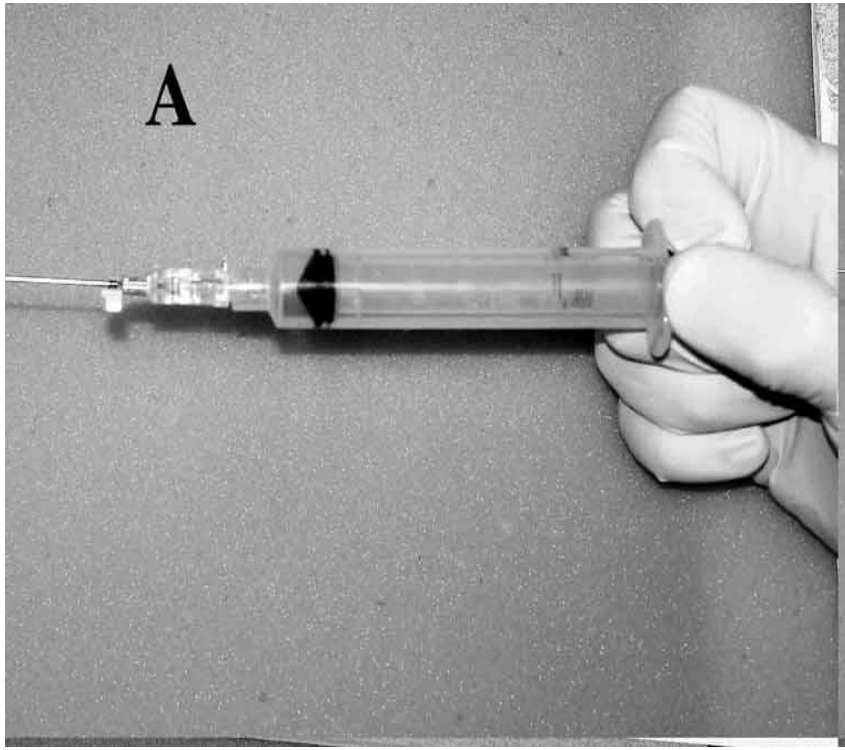
From: *J Rheumatol.* 2006;33:771-8; *Ann Rheum Dis.* 2006;65:1084-7
J Vas Inter Rad 2007, Abstract 199

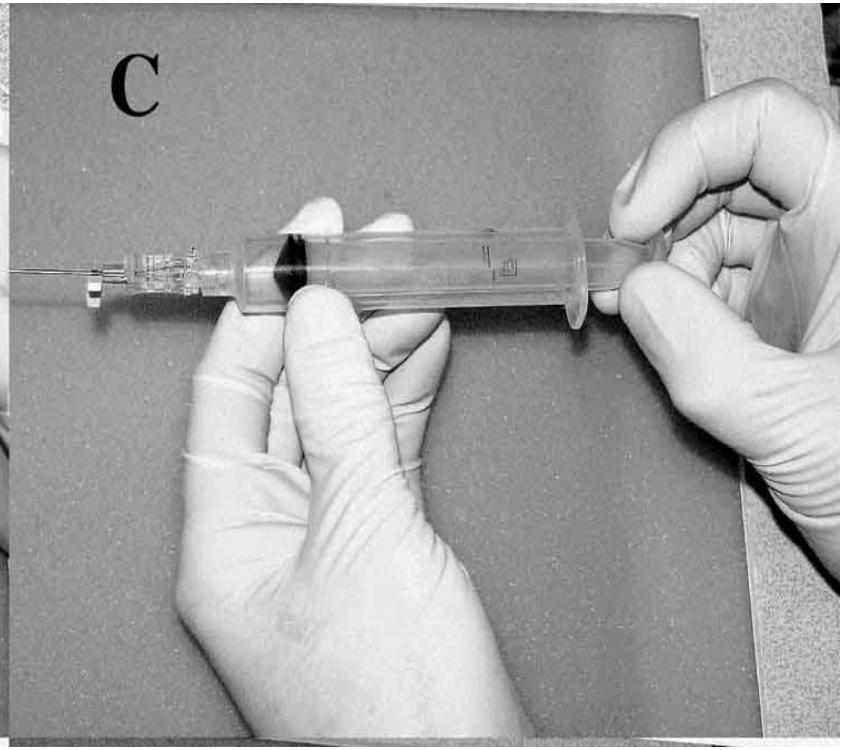
The RPD as a FNA Device

- RPD demonstrated markedly improved needle control compared to plunger locks, syringe pistols, three-ringed control syringes, and dedicated biopsy syringes.
- The RPD was able to control vacuum better than all these devices.
- The RPD was able to eject the sample more easily than the above devices.
- For FNA and cutting needle procedures the RPD was superior to other existing devices.

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

The RPD: Superior for FNA to Syringe





RPD Superior To Syringe with 1-Hand

RPD Superior To Syringe with 2-Hands

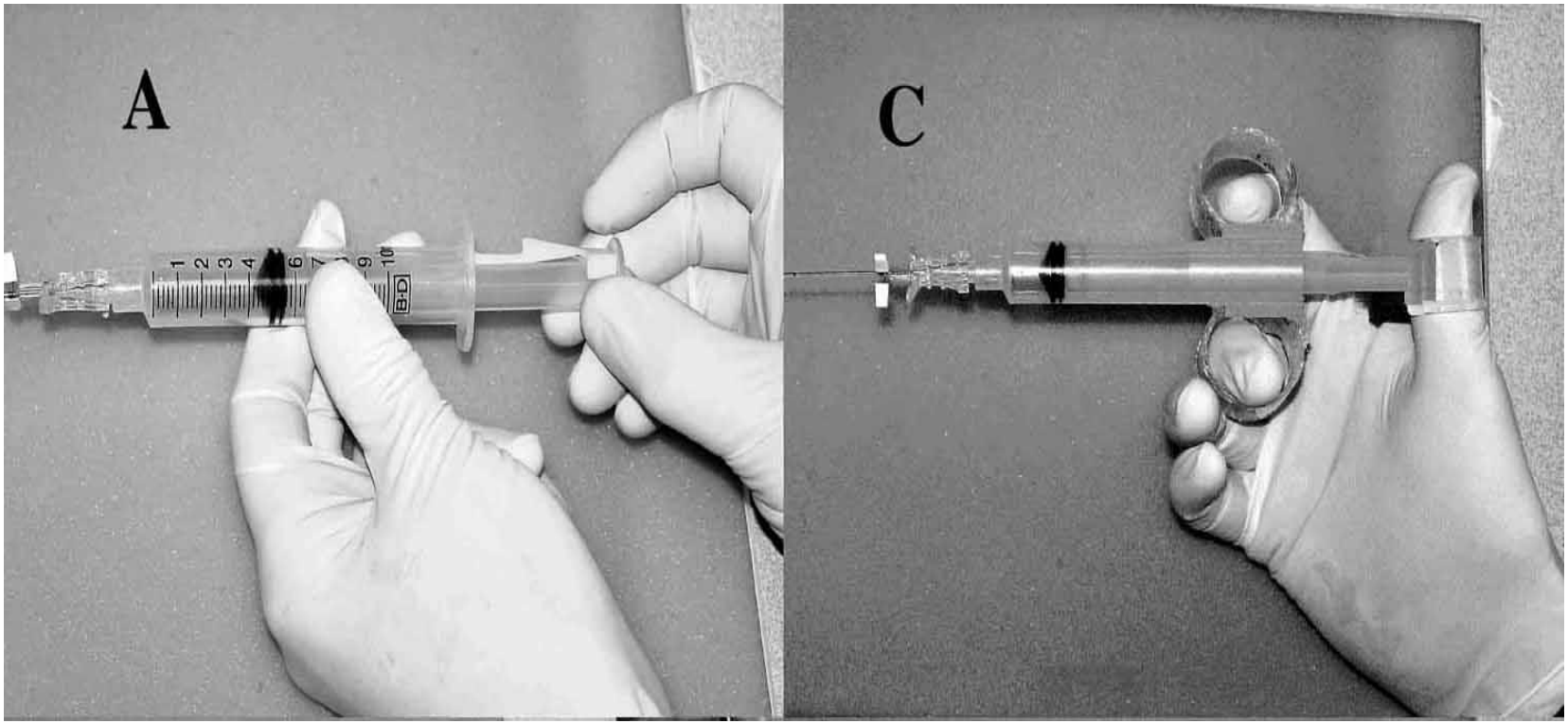
From: ***J*** *Vasc Interv Radiol*. 2006;17:1657-69.; *J Vas Inter Rad* 2007, Abstract 199; *Arthritis Rheum* 2004:208 (209).

Disadvantages to Traditional Syringes

- The traditional syringe becomes longer with aspiration forcing needle forward. Limited control with 2-hands.
- Poor control with 1-hand or two hands.
- RPD demonstrates better control, less pain, and improved procedure outcome.
- RPD shown to be superior in syringe procedures.

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

The RPD: Superior for FNA to Control Syringes



RPD Superior To Plunger Locks

RPD Superior To 3-Ring Control Syringe

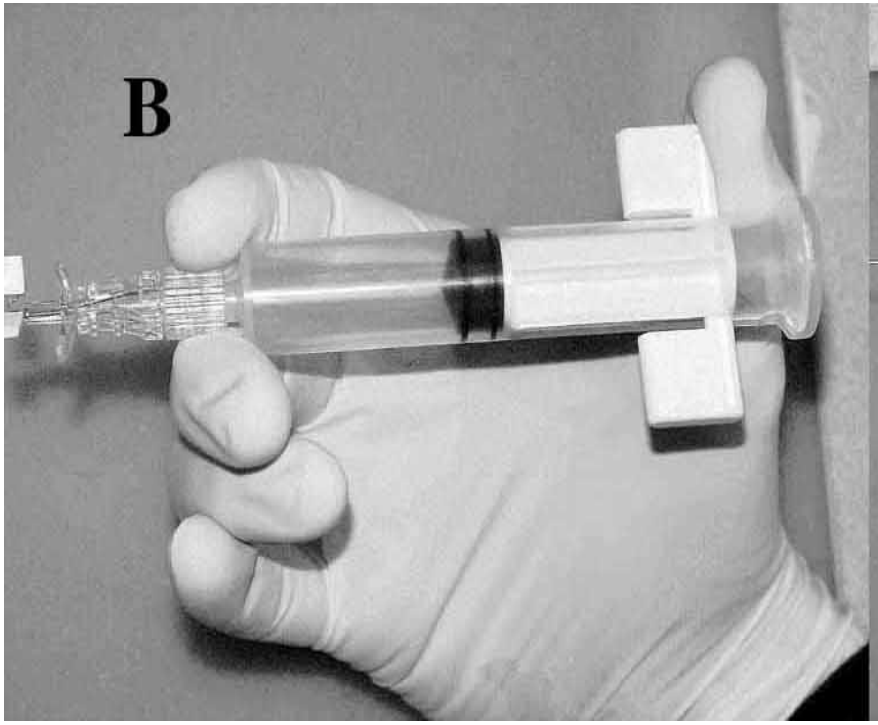
From: ***J*** *Vasc Interv Radiol*. 2006;17:1657-69.; *J Vas Inter Rad* 2007, Abstract 199; *Arthritis Rheum* 2004:208 (209).

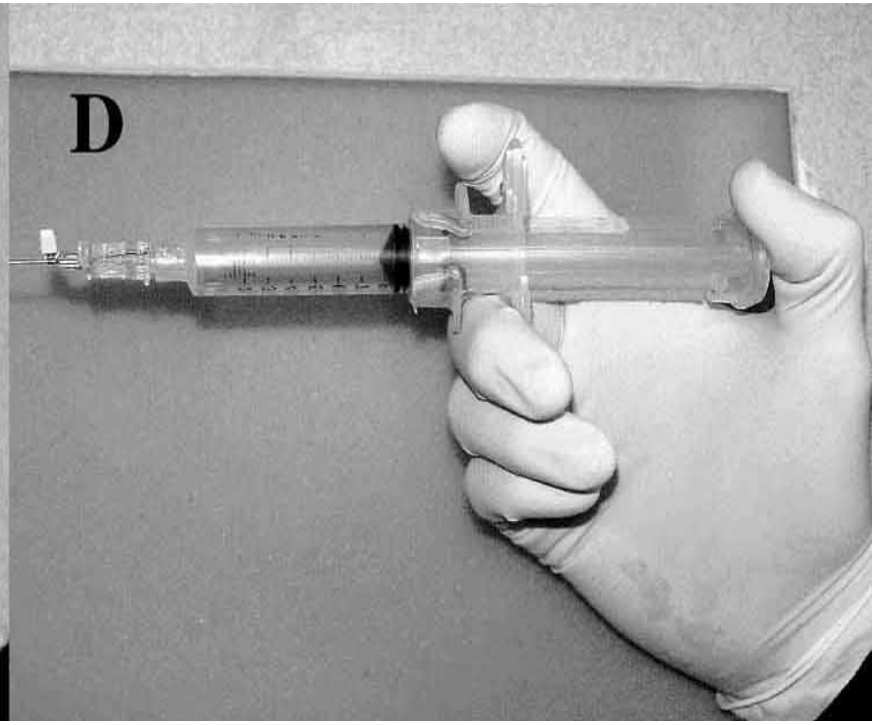
Disadvantages to Control Syringes

- Syringes becomes longer with aspiration forcing needle forward.
- Plunger lock difficult to release vacuum.
- Difficult to generate vacuum in 3-ring syringe.
- RPD demonstrates better control than plunger locks and 3-ring control syringes during typical FNA procedures.
- RPD is superior to plunger locks and control syringes.

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

The RPD: Superior to Biopsy Syringes





RPD Superior To Bio-Suk

RPD Superior To Reverse Syringes

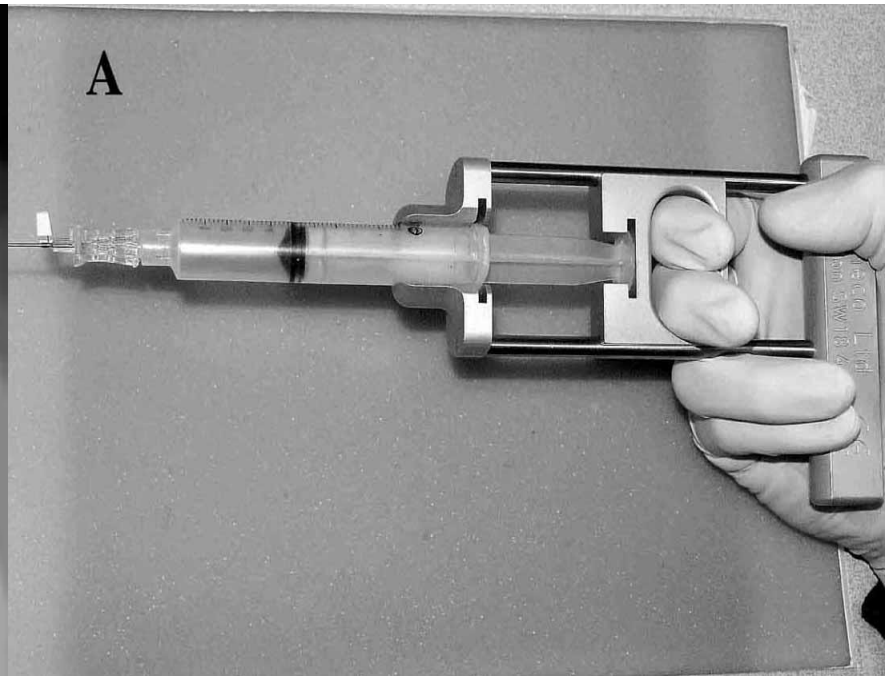
From: ***J*** *Vasc Interv Radiol*. 2006;17:1657-69.; *J Vas Inter Rad* 2007, Abstract 199; *Arthritis Rheum* 2004:208 (209).

Disadvantages to Biopsy Syringes

- Biopsy syringes becomes longer with aspiration forcing needle forward.
- Requires major change in hand positioning when transitioning from aspiration to injection.
- RPD demonstrates better control than the Bio-Suk-7 and reverse aspiration biopsy syringes.
- RPD is superior to plunger locks and control syringes.

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

The RPD: Superior to Syringe Pistols



INRAD Biopsy Gun

Cameco Syringe Pistol

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

Disadvantages to Biopsy Guns and Pistols

- Major hand movement is required to generate vacuum.
- Control is not with the fingers, but rather the base of the hand and arm.
- Difficult to insert and remove syringe.
- Syringe pistols violate OSHA Blood Bourne Infection Standards and promote spread of patient-to-patient and patient-to-physician viral, pyogenic, and prion infections.
- RPD is better controlled than and superior to syringe pistols.

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

Biopsy: Conclusions

- In suction biopsy, the RPD was superior in control, generating vacuum, one-handed use, and clearing the sample from the biopsy needle.
- The RPD was superior to the syringe pistol, dedicated biopsy syringes, three-ringed syringe, and conventional syringe.
- The RPD was also superior for image guided thyroid biopsy and non-thyroid biopsy.

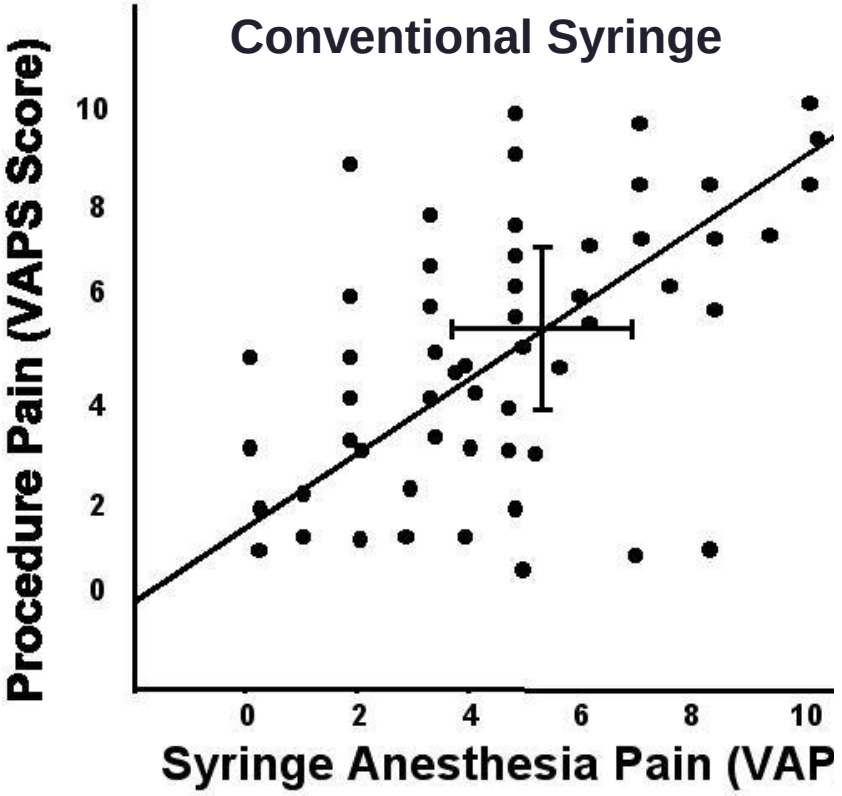
From: ***J*** *Vasc Interv Radiol*. 2006;17:1657-69.; *J Vas Inter Rad* 2007, Abstract 199; *Arthritis Rheum* 2004:208 (209).

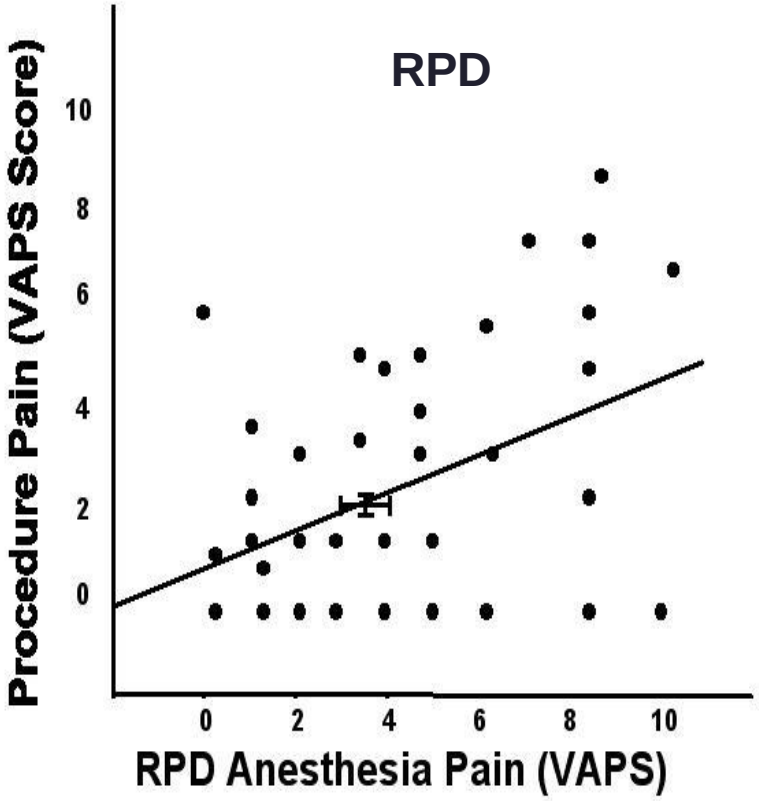
RPD: FNA of the Thyroid

- Generation of Vacuum for FNA.
- Control of the Needle in FNA.
- Expelling sample for FNA.
- Administration of Local Anesthesia -The RPD is less painful the a traditional syringe.

From: *J Rheumatol*. 2006;33:771-8; *Ann Rheum Dis*. 2006;65:1084-7; *J Rheum* 2007;34:187-92; *Journal Clinical Rheumatology* 2007 (in Press)

The RPD was Compared to the Conventional Syringe for Local Lidocaine Anesthesia in 150 Deep Needle Procedures





Conventional Syringe More Painful and Less Effective for Local Anesthesia

RPD Less Painful and More Effective for Local Anesthesia

From: J Vasc Interv Rad 2007, Abstract 377

Local Anesthesia: Conclusions

- Administration of local lidocaine anesthesia is 30-40% less painful with the RPD as compared to the conventional syringe.
- Anesthesia administration time is significantly reduced.
- Local lidocaine anesthesia administered by the RPD is more effective than with a conventional syringe, presumably due to better anatomic placement and less trauma.
- The RPD is superior to the conventional syringe for the administration of local anesthesia.

From: J Vasc Interv Rad 2007, Abstract 377

How is the RPD Different than a Traditional Syringe?

- **The RPD is designed to provide better control of the needle than any existing syringe device.**
- **The RPD is designed to provide superb vacuum control.**
- **The RPD can be used to both aspirate and inject with effortless transition.**
- **The RPD is designed to be operated with one hand so that the other hand can be used for other tasks during the procedure.**

The RPD - Designed for Control

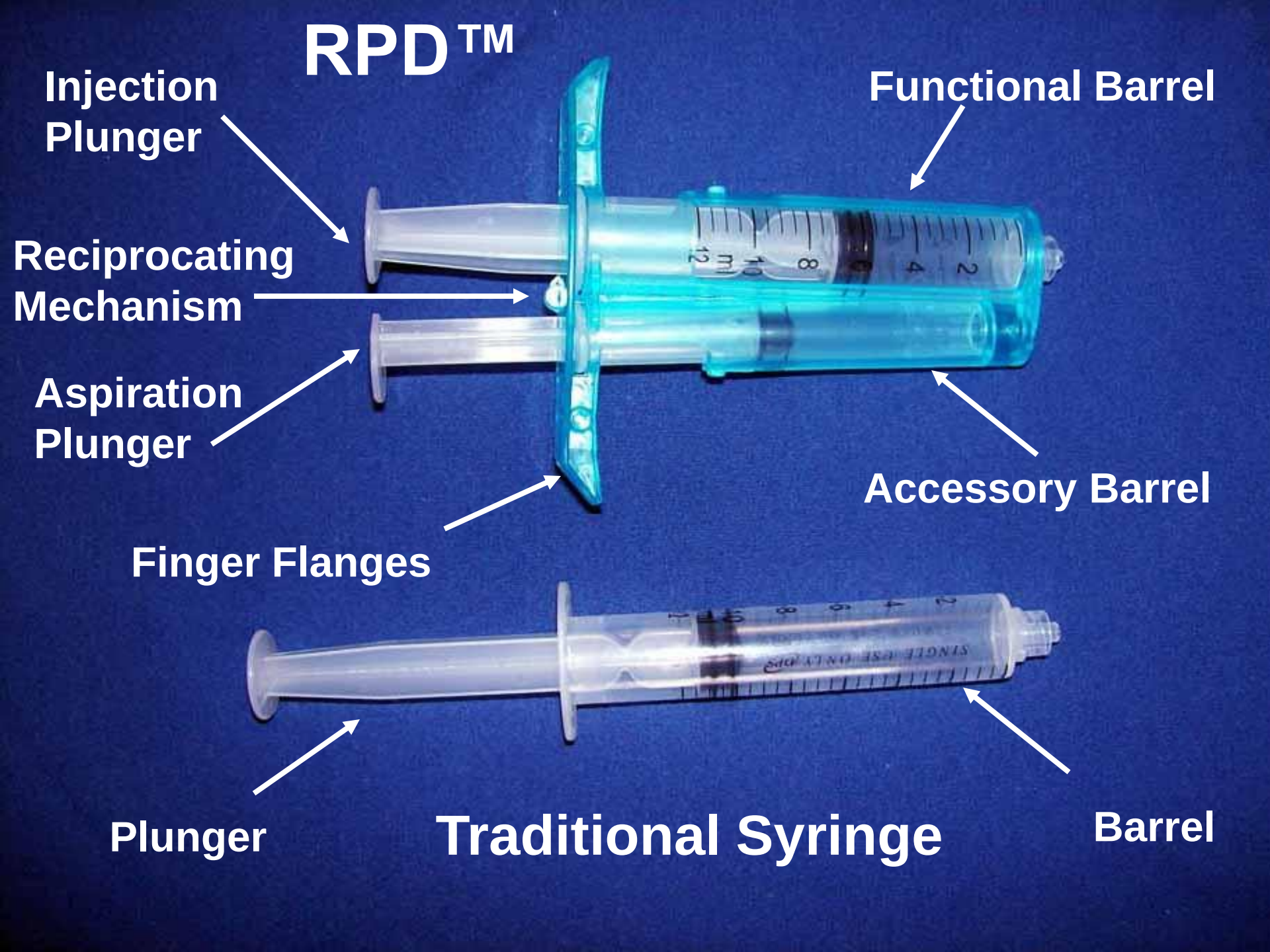
- **The RPD is designed so aspiration and injection use the same finger motions and the strongest muscles of the hand - the flexors.**

- **The RPD is designed so that the stabilizing digits, the index and middle fingers, <u>do not change position</u> when transitioning from aspiration to injection.**

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 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

Components of the RPD vs. the Traditional Syringe

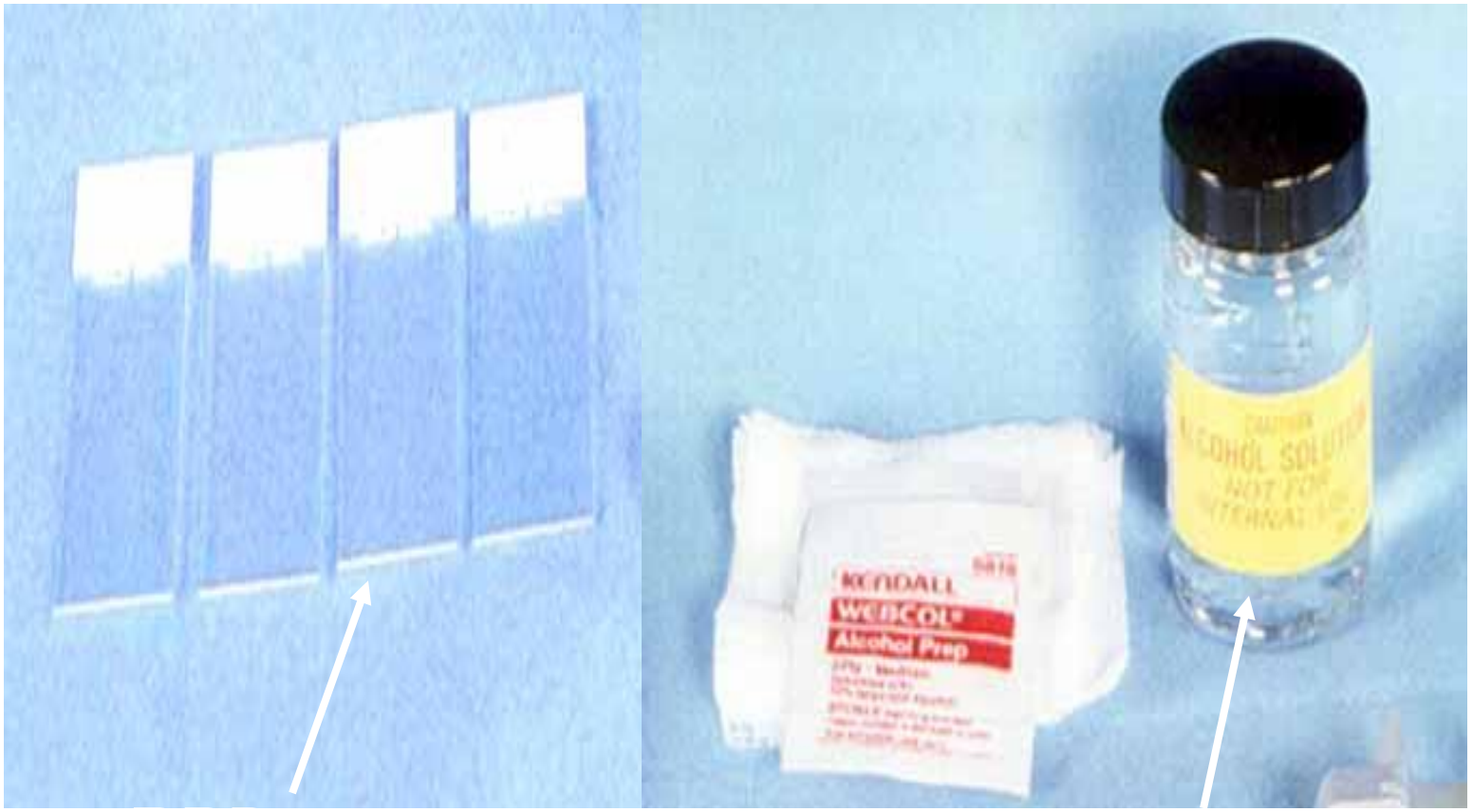
- The traditional syringe has no reciprocating mechanism.
- The RPD has a **reciprocating mechanism** connecting the two plungers. When the injection plunger is depressed the RPD injects; when the aspiration plunger is depressed, the RPD aspirates.
- **The mechanical linkage of the RPD causes the aspiration and injection plungers to reversibly "reciprocate" with each other.**

Equipment for Thyroid FNA

- 1.5 inch 25 or 27 gauge needles.
- Glass slides, frosted one end, 1mm thickness
- Alcohol prep sponges.
- Alcohol bottles for immediate fixing of slides.
- Gloves
- Containers for cystic fluid collection
- Cytology lab slips with patient name, origin of sample, type of sample, date, tests to be performed.
- Lidocaine 1% or 2%, very important.
- Reciprocating procedure device (RPD) 5 ml or 10 ml for vacuum source.

Equipment for Thyroid FNA

Equipment for Thyroid FNA



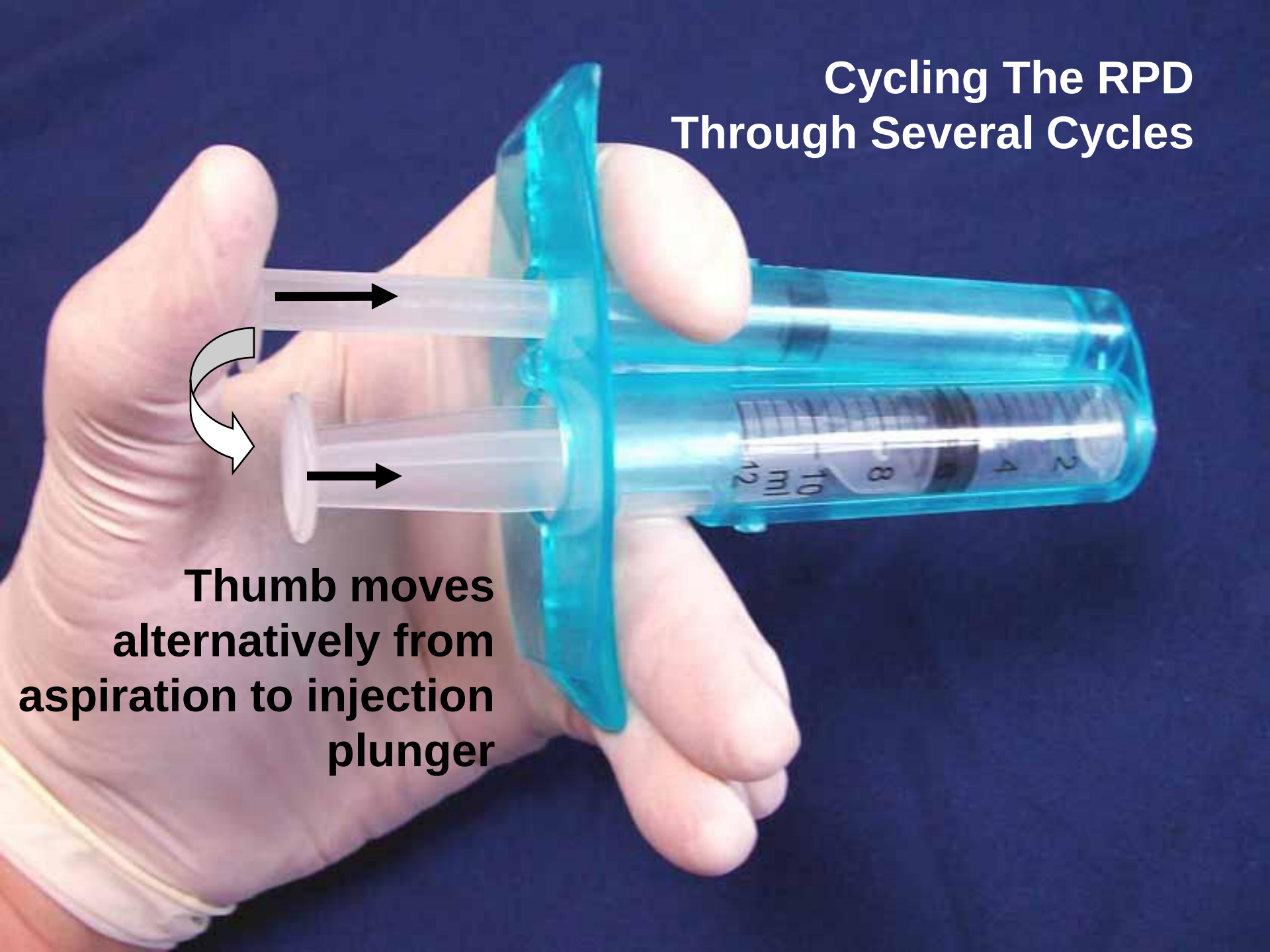
Histology Slides **Alcohol Fixative**

Prepare and Cycle RPD

Preparation for a Procedure with the RPD

- Remove the RPD from the sterile packaging.
- Press the plungers, one at a time, and cycle the RPD through several reciprocation cycles to assure smooth functioning.
- ***DO NOT PRESS BOTH PLUNGERS AT THE SAME TIME - EXCESSIVE FORCE MAY DAMAGE THE PULLEY MECHANISM.***
- ***DO NOT PULL PLUNGERS, ONLY PRESS.***


Remove RPD from Sterile Packaging


Cycling The RPD
Through Several Cycles
Thumb moves alternatively from aspiration to injection plunger

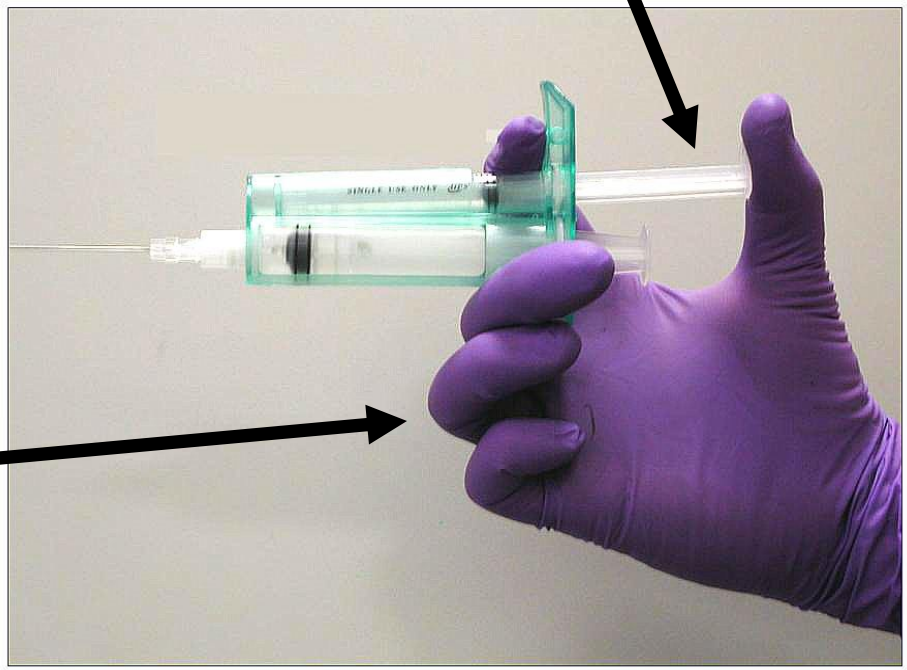
2. Attach Needle to RPD and Use Appropriate Grip

- **Attach needle or other device to needle fitting of RPD.**
- **Hold the RPD in 1-handed, 2-handed or trumpet grip.**
- **Press the larger plunger to inject.**
- **Press the smaller plunger to aspirate.**
- **Use the RPD in any procedure where a traditional syringe would be used.**

3. Press Reciprocating Plungers to Aspirate or Inject

1. Attach Needle to Needle Fitting

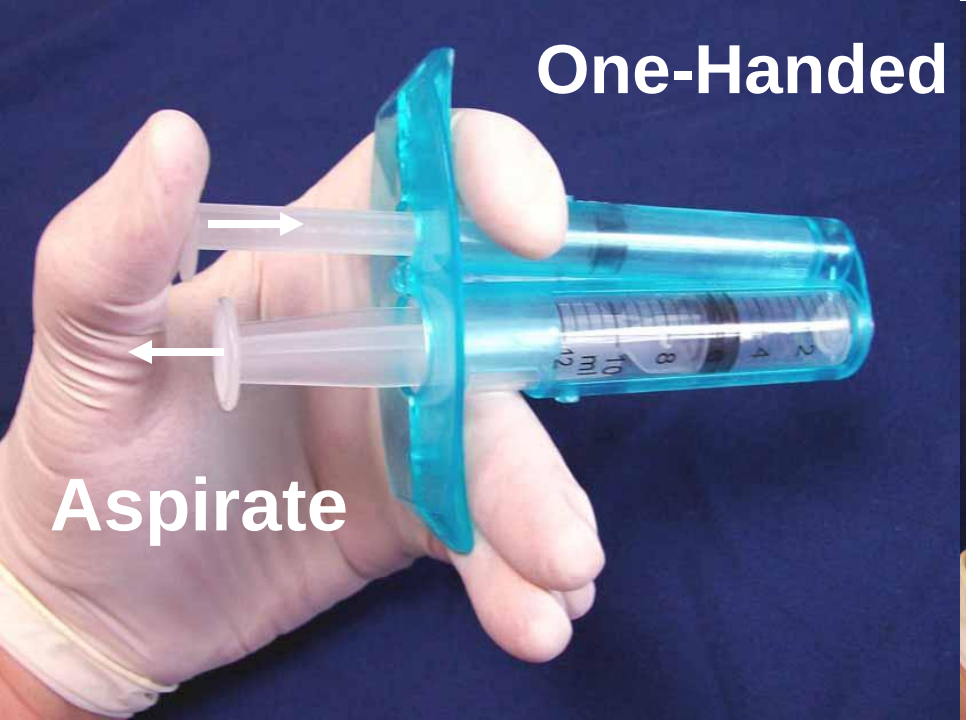
2. Hold RPD like a traditional syringe

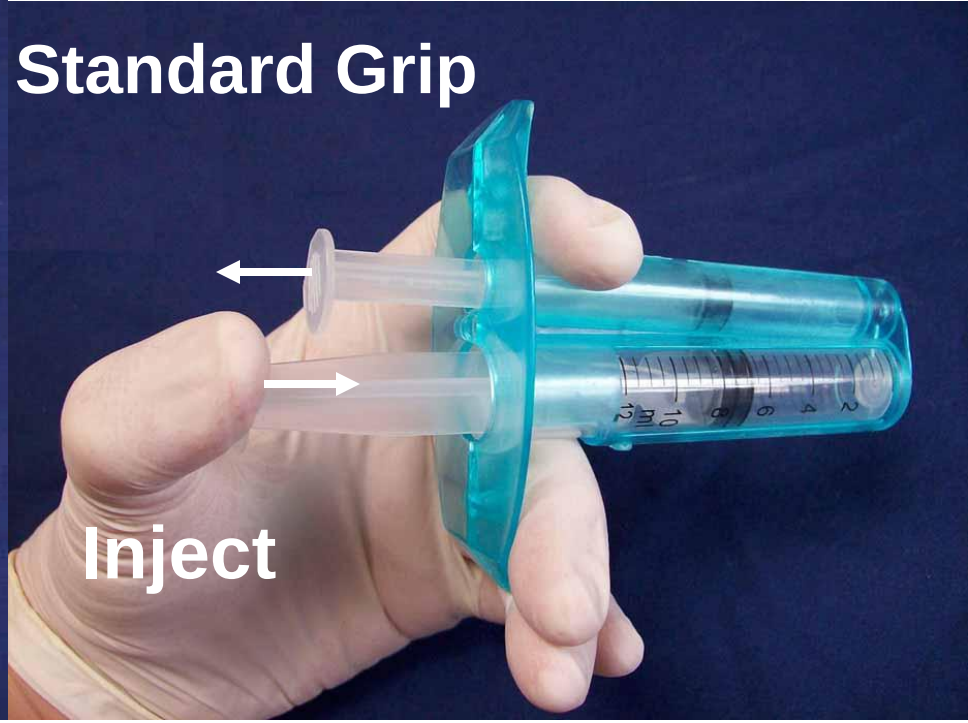


2. Holding the RPD

- **One-Handed Standard Grip** with RPD held between the index and middle fingers, and thumb operates the aspiration-injection plungers. The free hand is used for other tasks.
- **Two-Handed Standard Grip**. Like the One-Handed Standard Grip, but the free hand is used to further stabilize the RPD or direct needle.
- **Trumpet Grip-One-handed.** RPD held upside down, and index and middle fingers operate the aspiration-injection plungers like the keys of a trumpet. The free hand is used for other tasks.
- **Trumpet Grip-Two-handed.** Like the One-Handed Trumpet Grip, but the free hand is used to further stabilize the RPD or direct needle.

One-Handed Standard Grip





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

Trumpet Grip with the RPD

- **<u>To inject</u>**
the large plunger is depressed with the index finger

- **<u>To aspirate</u>**
the smaller plunger is depressed with the middle finger

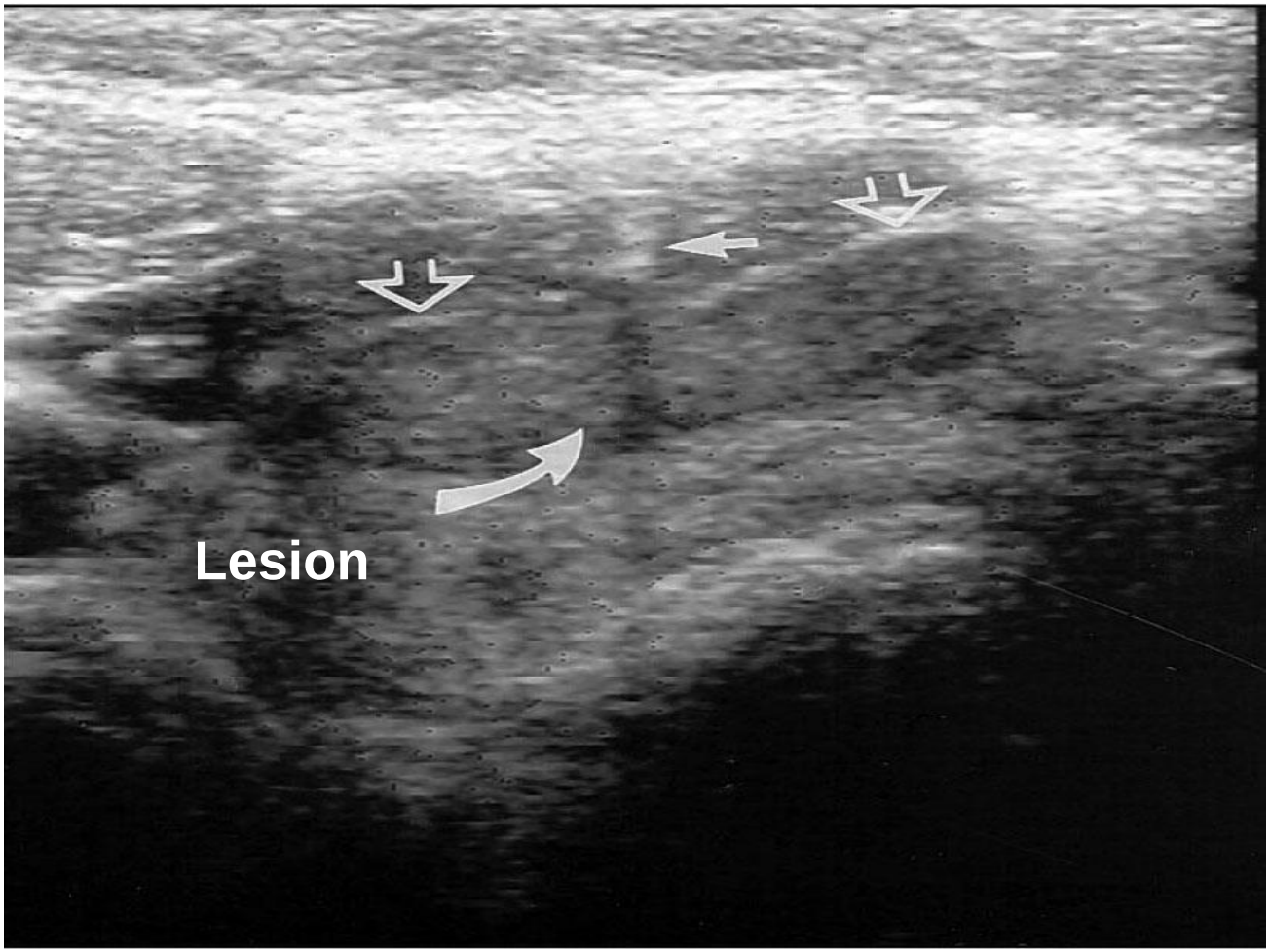
- **<u>Used in certain anatomic situations.</u>**

Thyroid FNA with the RPD

- Position patient with operator on side of patient.
- Cover ultrasound transducer with sterile dressing.
- Wear Gloves.
- Ultrasound transducer transverse to lesion.
- Local anesthetic with RPD on thyroid capsule.

Localize Lesion with Ultrasound

Localize Lesion with Ultrasound



Anesthetize Thyroid Capsule

Local Anesthesia with the RPD

- We recommend a 1 or 1.5 inch 22 gauge needle for aspirating drugs such as lidocaine.
- Hold lidocaine vial with one hand, and RPD with other.
- Pressing aspirating plunger, aspirate lidocaine into RPD.
- Needle is dulled going through stopper and becomes more painful for patient. We recommend discarding aspiration needle, and switching to a fresh 25 gauge or 27 gauge needle of length appropriate for procedure.

3. Local Anesthesia with the RPD (cont).

- Insert anesthesia needle mounted on RPD into target tissue.
- Depress aspiration plunger of RPD and be certain there is no blood return into the needle hub, assuring extravascular positioning of needle tip.
- If there is no blood return, slowly and cautiously inject lidocaine by pressing the RPD injection plunger. Repeat.

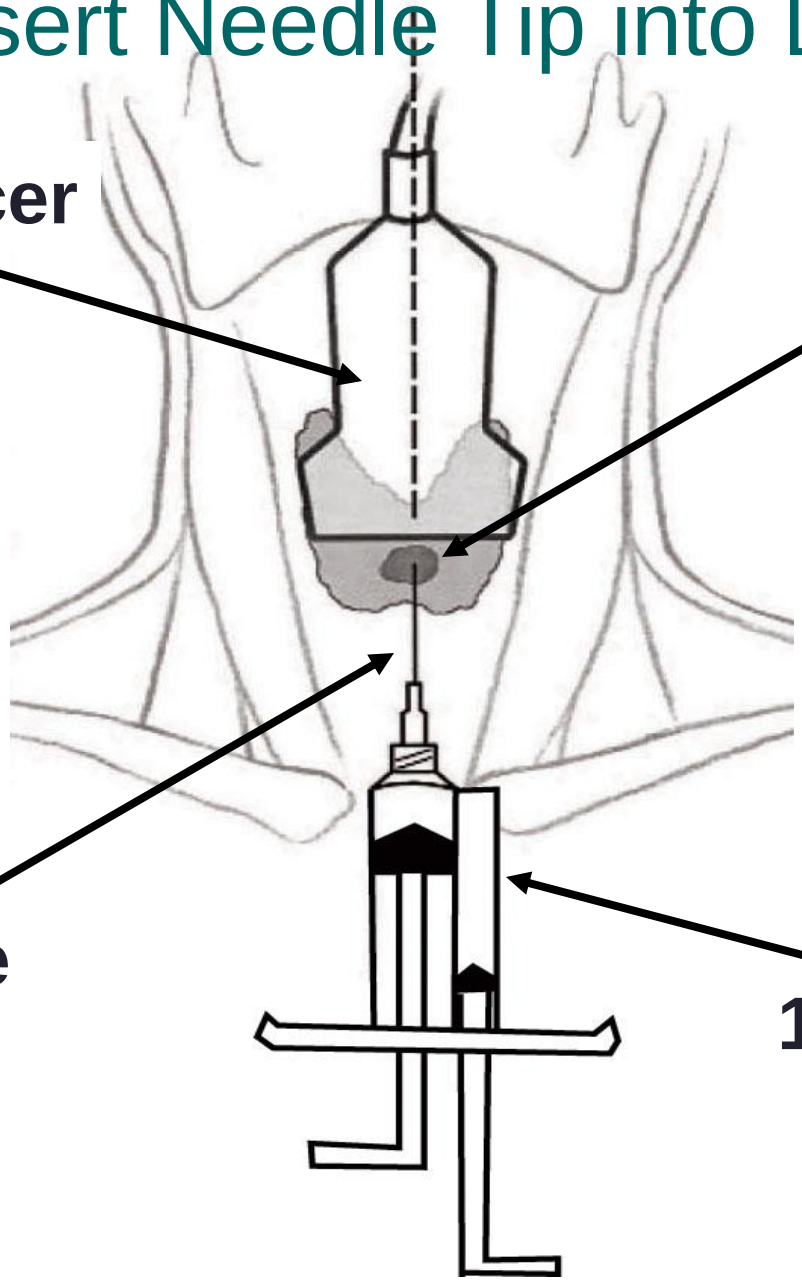
1. Aspirate Lidocaine

2. Insert Needle

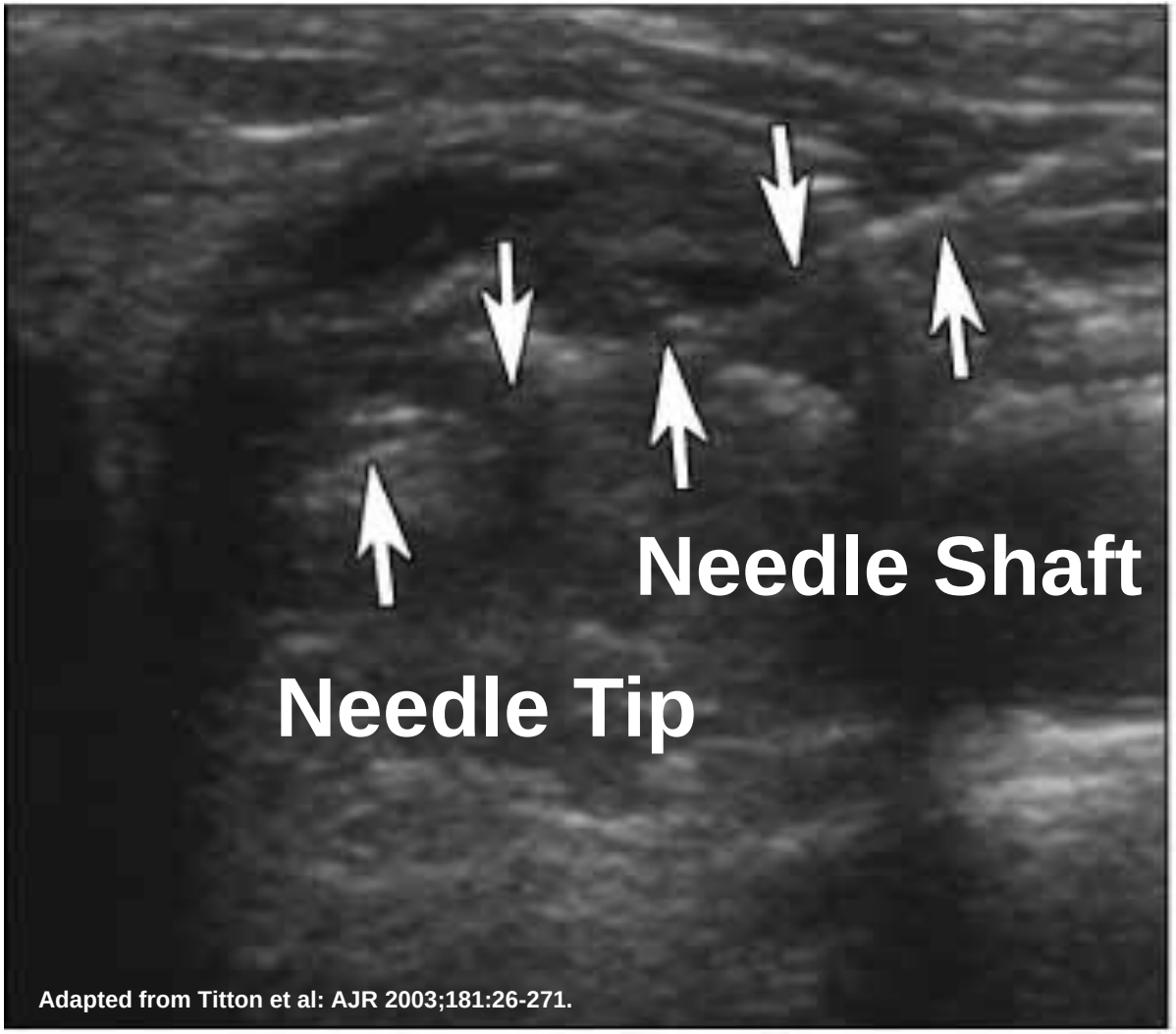
3. Aspirate for Blood Return before Injecting

4. If No Blood Returns, Inject Lidocaine

Insert Needle Tip into Lesion



Insert Needle Tip into Lesion



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

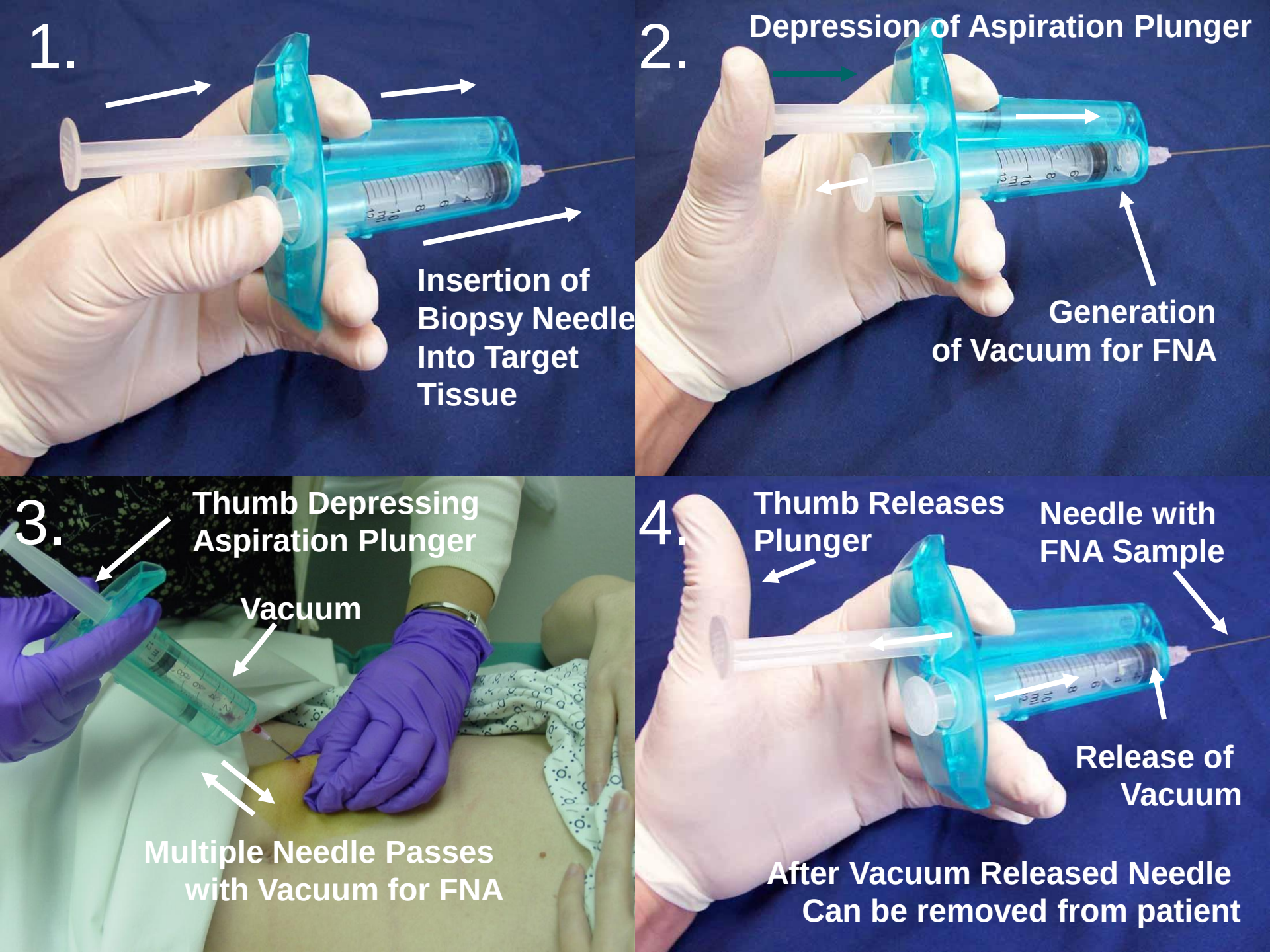
Apply Vacuum with Needle in Lesion

The RPD for FNA

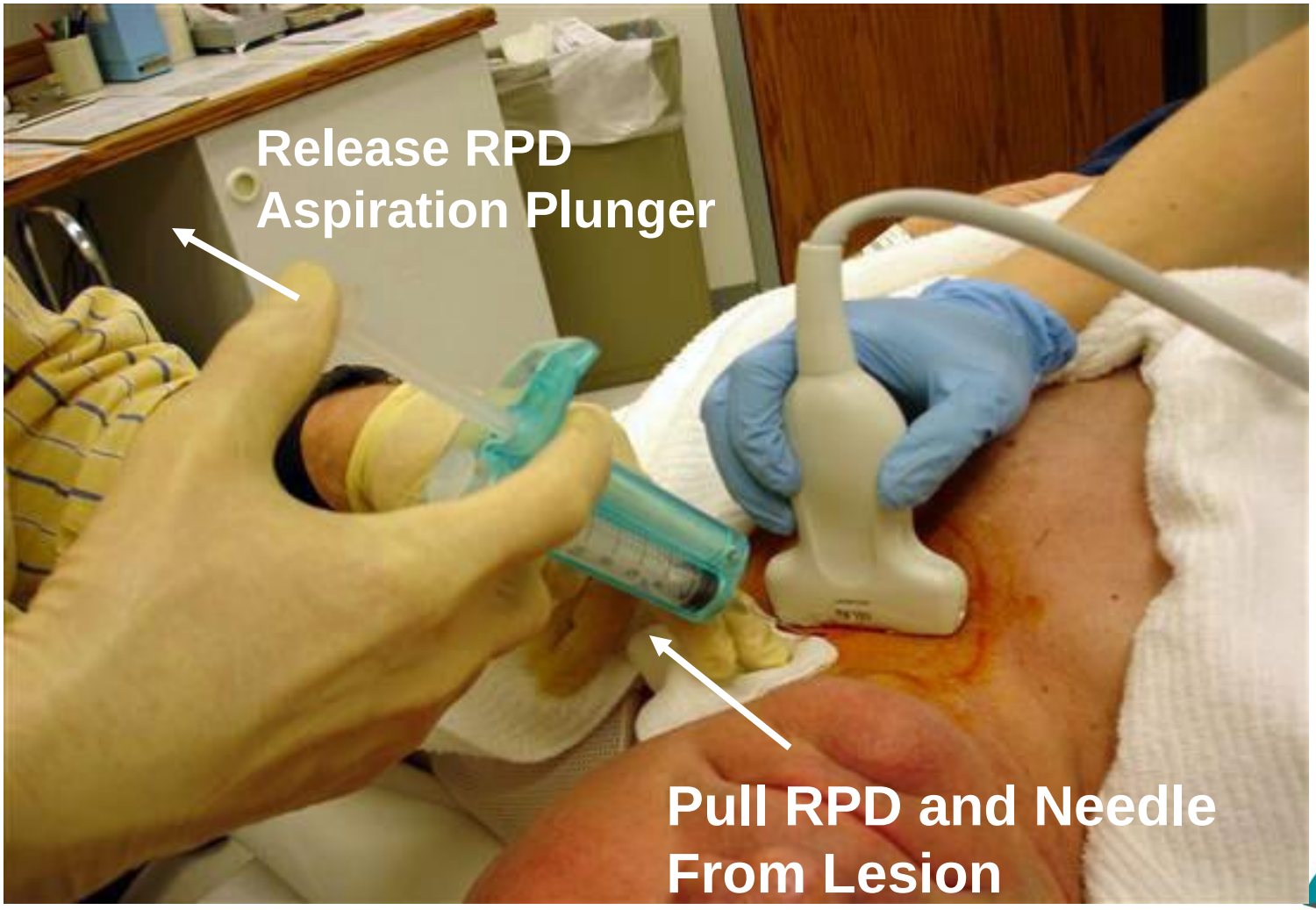
- Generation of vacuum is important for FNA.
- After the biopsy needle on the RPD is inserted into the target tissue, vacuum is generated by depressing the aspiration (smaller) plunger.
- The vacuum is maintained by keeping the aspiration plunger depressed as multiple needle passes through tissue are obtained.

4. General Instructions:
The RPD for FNA

- Prior to extracting the needle from the patient, the aspiration plunger is released, eliminating the vacuum and preventing the sample from being sucked into the barrel and trapped there.


1.
Insertion of Biopsy Needle Into Target Tissue
2.
Depression of Aspiration Plunger
Generation of Vacuum for FNA
3.
Thumb Depressing Aspiration Plunger
Vacuum
Multiple Needle Passes with Vacuum for FNA
4.
Thumb Releases Plunger
Needle with FNA Sample
Release of Vacuum
After Vacuum Released Needle Can be removed from patient

Release Vacuum and Lesion



5. Expelling FNA Sample Using the RPD

- After the FNA, the tissue sample may need to be expelled to a cytological slide or container.
- To accomplish this, the biopsy needle is removed.
- The aspiration plunger is depressed, putting air into the RPD barrel.
- The biopsy needle is reattached.
- The injection plunger is depressed, expelling the tissue sample for cytological analysis.

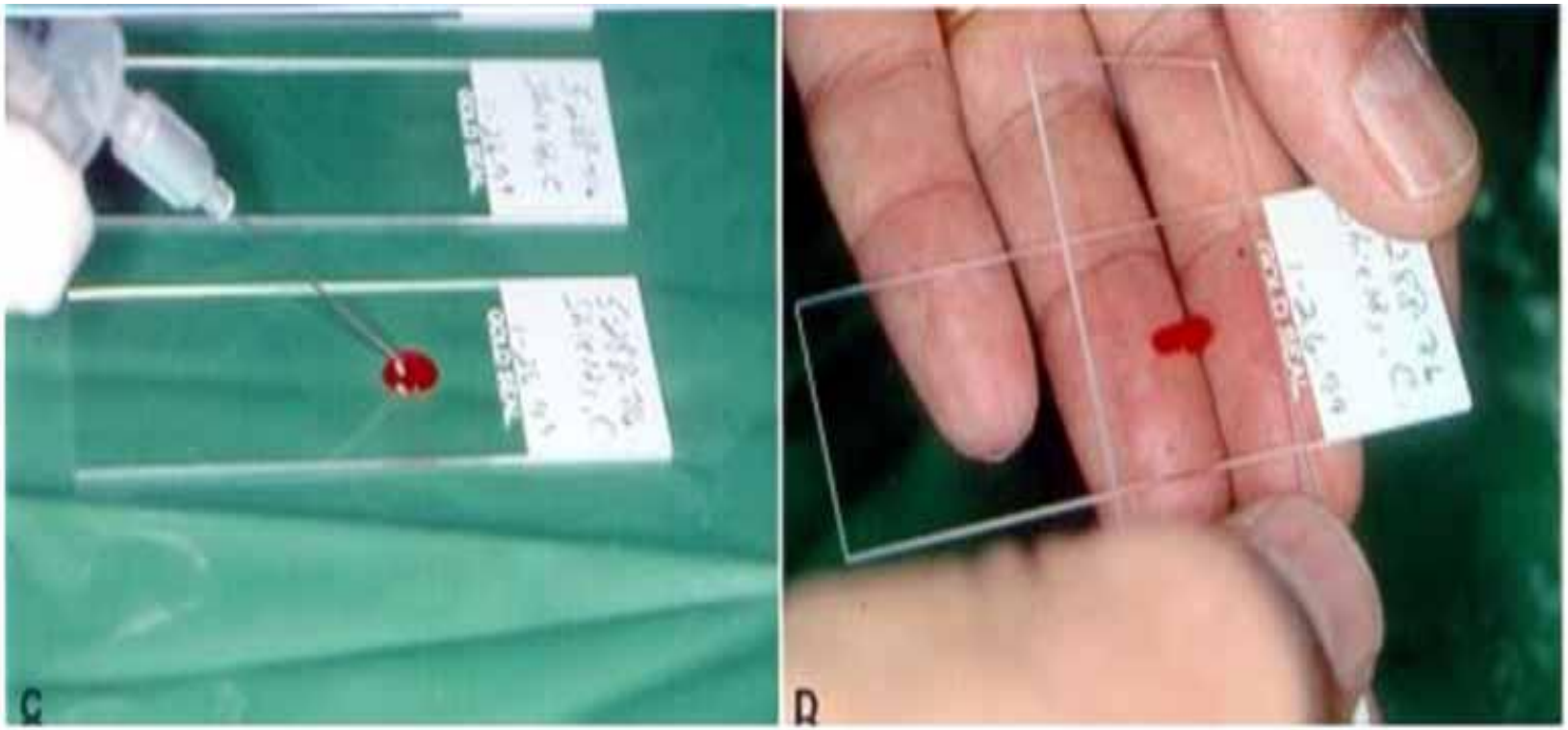

1. Remove Needle
With FNA Sample


Depression of
Aspiration Plunger
Needle With
Sample
2. Fill RPD
with Air
Air Enters
Functional Barrel


3. Reattach FNA Needle to RPD
Functional Barrel
Filled with Air


4. With Needle Attached, Expel
FNA Sample
FNA Sample
Expelled
From Needle
Depression of
Injection Plunger

Preparation of Cytologic Slides



1. Expel sample on Slide **2. Smear between slides**

3. Immediately fix slides in alcohol

After Biopsy Completed

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

How Effective is FNA with the RPD?

- 83 patients with a thyroid nodule underwent either FNA with the RPD or a core biopsy.
- 51 patients under FNA with the RPD.
- 32 patients underwent core biopsy with a spring loaded core device.
- All samples were analyzed blindly by the cytopathologist.

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

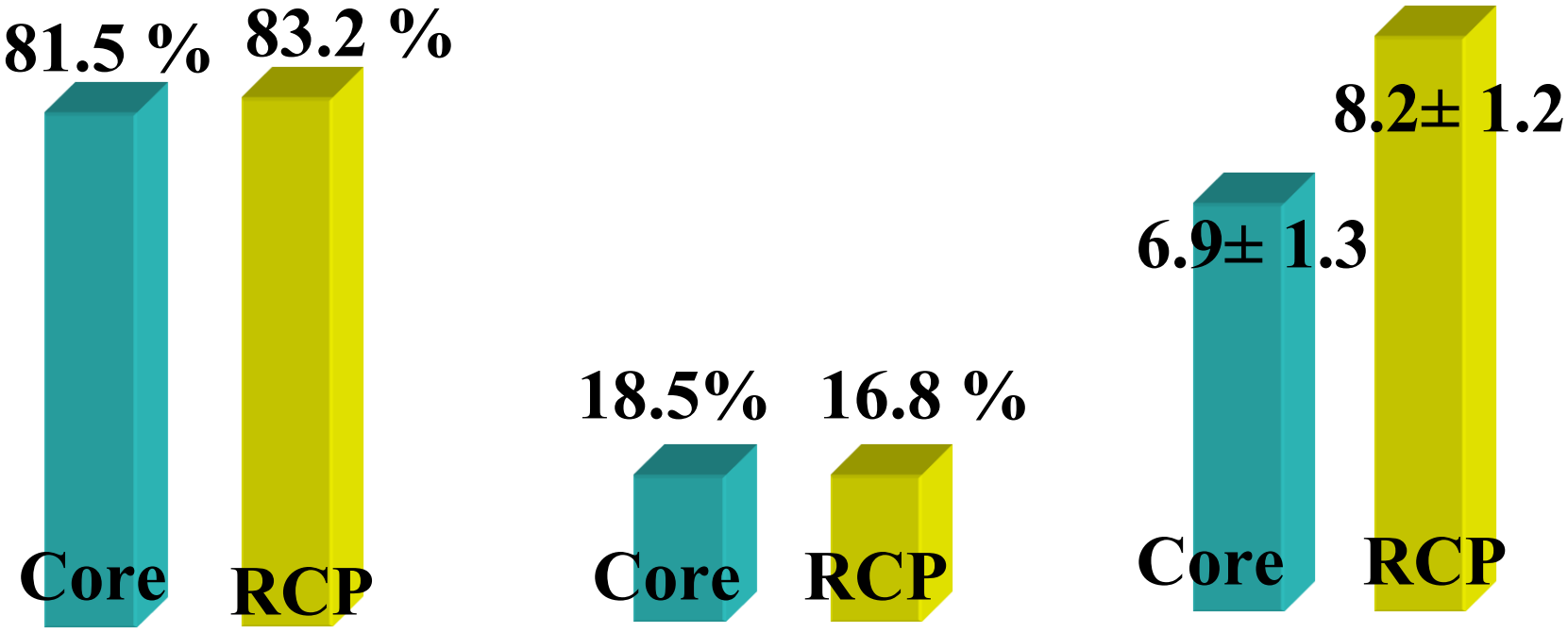
How Effective is FNA with the RPD?

- The samples were classified as either diagnostic or inadequate-non-diagnostic, requiring an additional procedure.
- All suspicious or definitely malignant aspirates resulted in open surgery.
- Operating physicians rated ease of use, satisfaction, and effectiveness of the RPD for FNA.

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

RESULTS:

RPD FNA vs. Core Biopsy of Thyroid



Diagnostic Biopsies
P > 0.1

Inadequate or Non-Diagnostic Sample
P > 0.1

Physician Satisfaction
P < 0.02

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

CONCLUSIONS:

RPD FNA vs. Core Biopsy of Thyroid

- FNA with the RPD is as effective as core biopsy for diagnosis of thyroid lesions.
- FNA with the RPD is easier to perform and safer than core biopsy of the thyroid.
- Operating physicians physicians rated the RPD was superior for FNA of the thyroid.
- Based on this data, the practice group stopped using core biopsies of the thyroid and completely converted to FNA using the RPD.

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

Patents

- The patents for the RPD are owned by the University of New Mexico. The RPD is protected by patents in both the USA and other countries.

- The RPD is manufactured by
  AVANCA Medical Devices, Inc.,
  600 Central Ave SE, Suite 232
  Albuquerque, NM, 87102 USA
  www.AVANCAMedical.com
  Tele: 505 243-4600
  Fax: 505 243-4601